Appendix F. MAUDE and Medical Device Recall Reports

Table F1. Reports on Stereotactic Body Radiation Therapy Devices From the FDA MAUDE Database

Report Number	Event Date	Event Type	Manufacturer	Date Received	Product Code	Brand Name	Device Problem	Patient Problem	Event text
9612186-2022-00003	12/12/2022	Malfunction	ELEKTA INSTRUMENT AB	23/12/2022	HAW	LEKSELL VANTAGE STEREOTACTIC SYSTEM	Calibration Problem; Compatibility Problem	No Clinical Signs, Symptoms or Conditions	
9612186-2022-00004	21/11/2022	Malfunction	ELEKTA INSTRUMENT AB	23/12/2022	HAW	LEKSELL VANTAGE STEREOTACTIC SYSTEM	Calibration Problem; Compatibility Problem	No Clinical Signs, Symptoms or Conditions	The customer reported accuracy deviations with leksell vantage during surgery with a systematic error of about 2 mm. The customer was using the non-compatible microdrive from the manufacturer alpha-omega. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has been completed.
3023194190-2022-70001	21/09/2022	Malfunction	NAVINETICS	08/11/2022	HAW	NAVINETICS REUSABLE STEREOTACTIC SYSTEM	Use of Device Problem; Device Dislodged or Dislocated	No Clinical Signs, Symptoms or Conditions	
8043933-2022-00056	07/09/2022	Injury	BRAINLAB AG	05/10/2022	OLO	SPINE & TRAUMA 3D NAVIGATION SOFTWARE (VERSION 1.5)	Use of Device Problem	No Clinical Signs, Symptoms or Conditions	A minimally invasive surgery on the thoracic and lumbar spine on vertebrae t9 - l1, with intended placement of 10 vertebra screws, was performed with the aid of the display by the brainlab navigation software spine&trauma 3d 1.5. During the procedure the surgeon: with the patient in prone position, attached the navigation reference array on the spinous process of vertebra t12. Acquired an intra-operative c-arm scan of the patient's region of interest with automatic image registration of the current patient anatomy to the navigation. Verified the registration and accepted the accuracy to proceed. Calibrated non-brainlab instruments (burr and screw driver) to the navigation for instrument position display. Placed vertebra screws with the aid of navigation (5 screws on the left side, 5 screws on the right). Acquired a verification intra-operative c-arm scan, and determined

									that the screws placed at the right side of the vertebras deviated from its intended position. Decided to remove the screws and to re-place them without the aid of navigation. Completed the surgery successfully as intended and closed the patient. According to the surgeons (treating clinicians): the deviation of the spine screws placed with the aid of navigation was detected by the surgeon with an intra-operative c-arm scan before finalizing the surgery, and this placement was addressed at the very same surgery. The final outcome of this surgery was successful as intended, with the placements correct at the end of the surgery. There was no harm nor negative effect to the patient due to the deviating initial placements, also not due to the surgery/anesthesia prolong of ca. 1 hour. There were further no remedial actions for the patient done, necessary or planned. Hospitalization was not prolonged either. Manufacturer narrative: a risk to the patient's health could not be excluded for these specific circumstances, since screws were placed in the patient's spine in a different position than desired with navigation involved, although according to the surgeon (treating clinician): the deviation of the spine screws placed with the aid of navigation was detected by the surgeon with an intra-operative c-arm scan before finalizing the surgery, and this placement was addressed at the very same surgery. The final outcome of this surgery was successful as intended, with the placements correct at the end of the surgery. There was no harm nor negative effect to the patient due to the deviating initial placements, also not due to the surgery/anesthesia prolong of ca. 1 hour. There were further no remedial actions for the patient done, necessary or planned. Hospitalization was not prolonged either. According to the results of this technical investigation and information provided by the hospital, it can be concluded that the root cause of the misplacement of the right

									screws is: relative movement of the anatomy between t12 (patient reference array fixation) and the other vertebrae (i.e. L1, t9, t10, t11) (operated region of interest) due to a non-rigid connection and/or forces applied on the anatomy. Apparently, the resulting deviation of the anatomy location displayed by the navigation was not recognized by the user with the necessary navigation accuracy verification throughout the procedure, before and during preparing and performing the screw placements in the spine. A misplacement of the right t12 screw could not be explained by relative movement, as the patient reference was attached to this vertebra. However it could not be finally confirmed, whether this screw was also misplaced or not. In case this screw was also misplaced, the root cause could be a missing re-calibration of the screwdriver with the new screw mounted. A possible not inline mounted screw could have caused a deviation. There is no indication of a systematic error or malfunction of the brainlab device (navigation). Corresponding brainlab measures to minimize this anticipated risk as low as reasonably practicable are already in place. Brainlab intends to re-iterate the relevant topics regarding the use of the device to this customer.
8043933-2022-00055	31/08/2022	Injury	BRAINLAB AG	04/10/2022	OLO	SPINE & TRAUMA 3D NAVIGATION SOFTWARE (VERSION 1.5)	Use of Device Problem	No Clinical Signs, Symptoms or Conditions	A minimally invasive surgery on the thoracic and lumbar spine for fusion of vertebrae t9 - l1, with intended placement of 8 vertebra screws, was performed with the aid of the display by the brainlab navigation software spine&trauma 3d 1.5. During the procedure the surgeon: with the patient in prone position, attached the navigation reference array on the spinous process of vertebra t12. Acquired an intra-operative c-arm scan of the patient's region of interest with automatic image registration of the current patient anatomy to the navigation. Verified the registration and accepted the accuracy to proceed. Used the navigated pedicle access needle to open the cortical bone and to create the pilot holes, followed by

									placements of 8 k-wires into the vertebrae. Calibrated a non-brainlab screwdriver to the navigation for instrument position display. Placed the 8 spine screws with the navigated non-brainlab screwdriver. Acquired a verification intra-operative c-arm scan, and determined that one of the screws placed (at right t12) deviated from its intended position. Decided to remove the screw and to re-place it with the aid of navigation confirmed its correct position with an another verification intra-operative c-arm scan. Completed the surgery successfully as intended and closed the patient. According to the surgeon (treating clinician): the deviation of the spine screw placed with the aid of navigation was detected by the surgeon with an intra-operative 3d scan before finalizing the surgery, and this placement was addressed at the very same surgery. The final outcome of this surgery was successful as intended, with the placements correct at the end of the surgery. There was no harm nor negative effect to the patient due to the deviating initial placements, also not due to the surgery/anesthesia prolong of ca. 25min. There were further no remedial actions for the patient done, necessary or planned. Hospitalization was not prolonged either. Manufacturer narrative: a risk to the patient's health could not be excluded for these specific circumstances, since a screw was placed in the patient's spine in a different position than desired with navigation involved, although according to the surgeon (treating clinician): the deviation of the spine screw placed with the aid of navigation was detected by the surgeons with an intra-operative 3d scan before finalizing the surgery, and this placement was addressed at the very same surgery. The final outcome of this surgery was successful as intended, with the placements correct at the end of the surgery. There was no harm nor negative effect to the patient due to the deviating initial placements, also not due to the

									surgery/anesthesia prolong of ca. 25min. There were further no remedial actions for the patient done, necessary or planned. Hospitalization was not prolonged either. According to the results of technical investigation and the information provided by the hospital, the investigation results could neither confirm nor disprove an actual inaccuracy of the information provided by brainlab navigation. For the right t12 screw placement having deviated by ca. 4-5mm from its intended position, a likely root cause can be attributed to the screw planning at a less than ideal location, i.e. On top of a bony part that caused a skiving of the instruments. Apparently, the resulting deviation of the anatomy location displayed by the navigation was not recognized by the user with the necessary navigation accuracy verification of the scan registration and throughout the procedure, before and during preparing and performing the screw placements in the spine. Further contributing factors are a missing re-calibration of the screwdriver with the new screw mounted and/or a possible not inline mounted screw that could have caused a deviation. There is no indication of a systematic error or malfunction of the brainlab navigation device. Corresponding brainlab measures to reduce this already anticipated risk to be as low as reasonably practicable are in place. Brainlab intends to re-iterate the relevant topics regarding the use of the device to this customer.
8043933-2022-00052	08/08/2022	Injury	BRAINLAB AG	08/09/2022	OLO	SPINE & TRAUMA 3D NAVIGATION SOFTWARE (VERSION 1.5)	Adverse Event Without Identified Device or Use Problem; Insufficient Information	No Clinical Signs, Symptoms or Conditions	A surgery on the spine, with intended placement of vertebra screws, was performed with the aid of the display by the brainlab navigation software spine&trauma 3d 1.5. During the procedure the surgeon: placed screws with the aid of brainlab navigation. Acquired an intra-operative verification x-ray image, and determined that one screw, that had been placed with the aid of navigation, deviated from its intended position. Decided to remove and replace the screw. According to the surgeon (treating clinician): the deviation of the

									spine screw placed with the aid of navigation, was detected by the surgeon with an intra-operative x-ray image before finalizing the surgery, and these placements were addressed at the very same surgery. There was no negative clinical effect to the patient reported by the hospital, nor any medical/surgical remedial action that would have been necessary, done or planned for this patient due to this issue (besides replacement of the misplaced screw). Manufacturer narrative: a risk to the patient's health could not be excluded for these specific circumstances, since a pedicle screw was positioned in the patient's spine in a different position than desired with brainlab navigation involved, although according to the hospital/surgeon: the deviation of the spine screw placed with the aid of navigation, was detected by the surgeon with an intra-operative x-ray image before finalizing the surgery, and these placements were addressed at the very same surgery. There was no negative clinical effect to the patient reported by the hospital, nor any medical/surgical remedial action that would have been necessary, done or planned for this patient due to this issue (besides replacement of the misplaced screw). A comprehensive investigation by brainlab regarding this specific event is currently ongoing and final conclusions are pending. Brainlab plans to issue a follow-up report to the fda upon completion of investigation.
8043933-2022-00054	07/08/2022	Injury	BRAINLAB AG	28/09/2022	HAW	CRANIAL NAVIGATION SYSTEM - NAVIGATION 4.0	Use of Device Problem; Insufficient Information	No Clinical Signs, Symptoms or Conditions	A planned cranial surgery for a posterior fossa tumor resection has been performed with the aid of the brainlab cranial navigation software version 4.0. A pre-operative mri scan that was acquired 3 days before the surgery was used to register the patient anatomy to the navigation. During the procedure the surgeon: positioned the patient in prone position in a non-brainlab head holder, and attached the reference array for navigation to the head holder. Used the softouch for surface matching to acquire skin points on the patient's head to

									register the current patient anatomy to the navigation. Verified the registration to navigation, and accepted the accuracy to proceed. Planned the incision and the craniotomy (burr hole) location with the navigated pointer. Performed the incision and created the craniotomy in the skull. Determined that the tentorium had been inadvertently traversed. Rechecked landmarks with the navigation and determined a shift of the navigation display of instrument positions relative to the actual patient anatomy. Completed the surgery without the aid of navigation. Scheduled a follow up surgery performed with the aid of a non-brainlab navigation system. According to the surgeon (treating clinician): the deviation of the craniotomy planned with the aid of navigation was detected after the craniotomy before any surgical actions were performed in the brain (such as resection of brain tissue). There was an increased risk of venous sinus thrombosis for this patient due to the unintended exposure of the transverse sinus and torcula. There was no harm or negative effect to the patient reported to brainlab. There was also no report of any further remedial medical/surgical actions that would have been necessary, done, or planned for this patient. There was neither any report of prolonged hospitalization. Manufacturer narrative: a risk to the patient's health could not be excluded for these specific circumstances, since a craniotomy deviated from the desired location, according to the surgeon resulting in an increased risk of venous sinus thrombosis for this patient due to the unintended exposure of the transverse sinus and torcula, with the brainlab device involved, despite according to the surgeon: the deviation of the craniotomy planned with the aid of navigation was detected after the craniotomy before any surgical actions were performed in the brain (such as resection of brain tissue). There was no harm or negative effect to the patient

									reported to brainlab. There was also no report of any further remedial medical/surgical actions that would have been necessary, done, or planned for this patient. There was neither any report of prolonged hospitalization. A comprehensive investigation by brainlab regarding this specific event is currently ongoing and final conclusions are pending. Brainlab plans to issue a follow-up report to the fda upon completion of investigation.
3002250546-2022-00002	16/06/2022	Injury	FHC, INC.	13/07/2022	HAW	WAYPOINT STEREOTACTIC PLATFORM	Image Orientation Incorrect; Malposition of Device	Failure of Implant; Muscle Weakness; Dysphasia; Ambulation Difficulties; Confusion/ Disorientation	During depth electrode (mer) placement, mer was not conclusive on the first pass and the microelectrode was found in imaging (in brainlab) to be roughly 2mm anterior and 3mm lateral from its expected location. Image registration was difficult due to the o-arm spin scan being flipped top to bottom. Physician was able to complete the registration and determined an offset move to target. While i was attempting to register the o-arm scan in navigator, he had removed the drive, positioner and hub to begin setup for the second pass. Equipment setup was checked. Mer was also not conclusive on the second pass. The second pass o-arm scan showed the microelectrode on the opposite side of target from the first pass. The doctors conferred and concluded the initial center track should have placed them at target and decided to try that again, with an electrode also in the posterior track to add additional mer data, hoping to not need a fourth pass. Mer on both center and posterior tracks of the third pass was good enough for the doctors to place a lead in the posterior track. An o-arm spin was not done, as post op ct had been scheduled and they didn't want to expose the patient to excessive radiation. No equipment was noted as damaged or not working properly. During this surgery there was no known patient injury or delay other than multiple track mer that might be expected during dbs procedures. On (b)(6) 2022 physician notified of several symptoms observed in patient - "several symptoms likely from passing into her caudate from the off target

									electrodes" and the patient being "weak, has word finding difficulties, confusion, and imbalance." on (b)(6) 2022 field rep followed up with physician and noted: "recovering. I think she'll be fine. Thanks for checking." manufacturer narrative: fhc is submitting this report to comply with 21 c.f.r. Part 803, the medical device reporting regulation. This report is basedupon information obtained by fhc, which the company may not have been able to fully investigate or verify prior to the date thereport was required by the fda. Fhc has made reasonable efforts to obtain more complete information in the time allotted andhas provided as much information as is available to the company as of the submission date this report. This report does notconstitute an admission or a conclusion by fda, fhc, or its employees that the device, fhc or its employees caused orcontributed to the event described in the report. In particular, this report does not constitute an admission by anyone that theproduct described in this report has any "defects" or has "malfunctioned". These words are included in the fda 3500a form andare fixed items for selection created by the fda, to categorize the type of event solely for the purpose of reporting pursuant topart 803. Fhc objects to the use of these words and others like it because of the lack of definition and the connotations impliedby these terms. This statement should be included with any information or report disclosed to the public under the freedom ofinformation act.
1526439-2022-00728	22/04/2022	Malfunction	DEPUY SPINE INC.	21/05/2022	OLO	5.5 VIPER UNIV POLY DRIVER	Break	No Clinical Signs, Symptoms or Conditions	Device report from depuy synthes reports an event in switzerland as follows: it was reported by the sales rep in switzerland that during a spinal fusion procedure on (b)(6) 2022, it was observed that the tip of the poly driver device broke upon insertion. It was unknown how the procedure was completed with a delay of 10 minutes. There were no adverse patient consequences nor surgical delay reported. No additional information was provided.

									Manufacturer narrative: depuy synthes is submitting this report pursuant to the provisions of 21 cfr, part 803. This report may be based on information which depuy synthes has not been able to investigate or verify prior to the required reporting date. This report does not reflect a conclusion by fda, depuy synthes or its employees that the report constitutes an admission that the device, depuy synthes, or its employees caused or contributed to the potential event described in this report. If the information is unknown, not available or does not apply, the section/field of the form is left blank. Device was used for treatment, not diagnosis. If information is obtained that was not available for the initial medwatch, a follow-up medwatch will be filed as appropriate. Complainant part is expected to be returned for manufacturer review/investigation, but has yet to be received. Reporter is a j&j sales representative. The investigation could not be completed; no conclusion could be drawn, as no product was received. Based on the information available, it has been determined that no corrective and/or preventative action is proposed. This complaint will be accounted for and monitored via post market surveillance activities. If additional information is made available, the investigation will be updated as applicable.
3008492462-2022-00008	14/04/2022	Malfunction	DEVICOR MEDICAL PRODUCTS, INC	27/05/2022	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE	Device Markings/Labelling Problem	Foreign Body In Patient	It was reported by the affiliate that during a patient having a breast clips, we used a t4 lot f12147319d, but could see this was not correct and looked to be the same as the t3 placed - lot f12147317d. The patient was ok and no further clips were placed. We have removed all stock of this t4 so have x19 to return and be replaced. Manufacturer narrative: the hydromark biopsy site identifier is a sterile, single use device intended for use after an open surgical or percutaneous breast biopsy procedure to mark the biopsy site. The instruction for use and deployment guide, provided with the device, must be followed

									to avoid the applicator from shearing. In accordance with iso 13485:2016 and iso 10993-1 requirements, the mammomark¿ biopsy site identifier devices have been tested for biocompatibility for their intended use and patient contact duration per iso 10993-1. The collagen marker and titanium clip are the only mammomark components classified as having "permanent patient contact." components of the applicator are classified as "limited patient contact" and qualified for the intended use during the procedure. Applicator materials are considered medical-grade but have not been evaluated for permanent implantation. As with any implanted device, the implant site should be monitored for any signs of irritation or reaction following the surgical procedure. It was reported that there was a labeling issue, a t4 was labeled as a t3. There was no harm to the patient and no further clips were placed. The customer returned 19 devices and all were investigated. All were found to be correct and no labeling issues were found. We have informed production line of the event and no issues have been found. There have been no similar complaints that have come in from the field. If new information comes available the incident will be reassessed accordingly.
1526439-2022-00642	04/04/2022	Injury	DEPUY SPINE INC.	29/04/2022	OLO	5MM TAP, DUAL LEAD CANN	Break	No Clinical Signs, Symptoms or Conditions	This is report 1 of 2 for (b)(4). It was reported that by the sales rep that during a spinal fusion procedure on (b)(6) 2022, while tapping for a pedical screw, it was observed that the 6mm tap snapped by 1 cm from the tip while removing it from the bone. According to the report, while tapping another pedical with a 5mm tap, it was observed that the tap snapped 1 cm from the tip while removing it. All the fragments were removed. There was a surgical delay of two hours. There were no adverse patient consequences reported. No additional information was provided. This report is for one (1) 5mm tap, dual lead cann device. This complaint involves two (2)

									devices. Manufacturer narrative: additional narrative: device was used for treatment, not diagnosis. If information is obtained that was not available for the initial medwatch, a follow-up medwatch will be filed as appropriate. The lot number was unknown. Therefore, the expiration date and device manufacture date were unknown. Without a lot number the device history records review could not be completed. Product was not returned. Based on the information available, it has been determined that no corrective and/or preventative action is proposed. This complaint will be accounted for and monitored via post market surveillance activities. If additional information is made available, the investigation will be updated as applicable.
1526439-2022-00643	04/04/2022	Injury	DEPUY SPINE INC.	29/04/2022	OLO	MOD CANNULATED 6MM TAP	Break	No Clinical Signs, Symptoms or Conditions	This is report 2 of 2 for (b)(4). It was reported that by the sales rep that during a spinal fusion procedure on (b)(6) 2022, while tapping for a pedical screw, it was observed that the 6mm tap snapped by 1 cm from the tip while removing it from the bone. According to the report, while tapping another pedical with a 5mm tap, it was observed that the tap snapped 1 cm from the tip while removing it. All the fragments were removed. There was a surgical delay of two hours. There were no adverse patient consequences reported. No additional information was provided. This report is for one mod cannulated 6mm tap device. This complaint involves two (2) devices. Manufacturer narrative: additional narrative: device was used for treatment, not diagnosis. If information is obtained that was not available for the initial medwatch, a follow-up medwatch will be filed as appropriate. The lot number was unknown. Therefore, the expiration date and device manufacture date were unknown. Without a lot number the device history records review could not be completed. Product was not returned. Based on the information available, it has been determined that no corrective and/or preventative action is proposed. This complaint will be accounted

									for and monitored via post market surveillance activities. If additional information is made available, the investigation will be updated as applicable.
9612186-2022-00001	24/02/2022	Malfunction	ELEKTA INSTRUMENT AB	28/03/2022	HAW	LEKSELL VANTAGE STEREOTACTIC SYSTEM - FIRMFIX	Break	Foreign Body In Patient; No Clinical Signs, Symptoms or Conditions	The customer reported that a tip of a firmfix screw found to be broken after surgery. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed.
MW5107800	10/02/2022	Malfunction	HOLOGIC INC.	01/03/2022	KNW	EVIVA STEREOTACTIC GUIDED BREAST BIOPSY SYSTEM BIOPSY DEVICE	Break	Insufficient Information	Tubing that connects for sampling popped and did not allow for proper sampling. Fda safety report id# (b)(4).
MW5105581	02/11/2021	Injury	CARDINAL HEALTH 200, LLC	24/11/2021	LRO	STEREOTACTIC BIOPSY PACK	Break; Entrapment of Device	Device Embedded In Tissue or Plaque	During a stereotactic biopsy, the doctor was injecting lidocaine to numb the breast of the patient and when she removed the syringe, the 25g x1 12 needle remained embedded in the patient's breast. The needle had broken off from the hub and remained in the breast. Fda safety report id# (b)(4).
MW5105639	02/11/2021	Malfunction	C. R. BARD / BARD PERIPHERAL VASCULAR, INC.	26/11/2021	KNW	ENCOR PROBE STEREOTACTIC ULTRASOUND BIOPSY	Suction Problem; Output Problem	Insufficient Information	Stereotactic breast biopsy on a (b)(6) f done in the vertical approach using bard 7g biopsy probe. Due to the ongoing issues concerning bard probes and the encor biopsy system, the encor unit was replaced. This procedure was done using a brand new bard encor biopsy system and the bard rep was on site during the procedure. During the sampling process, we noticed that the specimen container on the probe was filling up with fluid and not draining. The bard rep asking the radiologist to perform several additional vacuum procedures to aid in fluid drainage. The fluid would not drain from the container. The bard rep suggested that we increase the suction on the encor unit, which we did. It did not make any appreciable difference. It was noted that there was fluid dripping from the several parts of the probe and the fluid was accumulating in the compression paddle that was holding the patient in position.

									During sampling, it was noted that there was very little specimen in the container and what was in the container was floating around in the saline. The bard rep attempted to remove the specimen container to drain the fluid however that caused more fluid to leak out onto the patient. There was very little specimen in the container even after 9 samples. The bard rep was attempting to instruct the technologist on ways to remove the specimen from the container without losing it in the saline and when she began removing the basket, it detached from the rest of the probe and specimen flew out of the container and onto the patient, bard rep and the technologist. The bard rep used forceps to remove specimen from the patient's shoulder. Once the specimen was imaged and was found not to contain the abnormality, another set of samples were taken. There was still very little tissue in the samples. At this time, it was decided to stop and place a clip at the site of the biopsy. No tissue was found at the insertion site on the patient. The patient will have to undergo another biopsy due to the fact that the abnormality was not acquired. Per emails and conversations with bard, we were assured that the 7g probes could be used for both vertical and horizontal approach. The saline flow and suction were adjusted at the direction of the bard rep. Patients were done in both vertical and horizontal approach with similar issues. Fda safety report id # (b)(4).
3002250546-2021-00004	20/10/2021	Injury	FHC	16/11/2021	HAW	WAYPOINT STEREOTACTIC PLATFORM	Malposition of Device; Positioning Problem; Appropriate Term/Code Not Available	No Clinical Signs, Symptoms or Conditions	After dbs bilateral lead placement surgery using starfix bilateral platform, it was noted that the post op ct revealed that on the left side the lead was placed appropriately, however the right side revealed in post op scans that the lead was 2.8 cm deeper than expected. This did not cause a delay in dbs surgery, when the lead was placed. No harm to the patient was caused during the surgery. A revision surgery was completed the following day and released.

9612186-2021-00003	20/10/2021	Malfunction	ELEKTA INSTRUMENT AB	15/11/2021	HAW	LEKSELL VANTAGE STEREOTACTIC SYSTEM	Output Problem; Inadequate Lubrication	Insufficient Information; No Clinical Signs, Symptoms or Conditions	The customer reported that they have experienced that the vantage arc grib on the right side seems compromised. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has been completed.
MW5104935	19/10/2021	Injury	HOLOGIC, INC.	25/10/2021	KNW	EVIVA STEREOTECTIC GUIDED BREAST BIOPSY SYSTEM BIOPSY DEVICE	Material Puncture/Hole; Physical Resistance/Sticking	Insufficient Information	During a diagnostic stereotactic breast biopsy, the physician was excising breast tissue using a guided breast biopsy device. Upon withdrawing the device from the breast tissue, the physician noted resistance, and upon complete removal discovered two holes in the sheath covering the device. Fda safety report id# (b)(4).
MW5105637	07/10/2021	Malfunction	CR BARD / BARD PERIPHERAL VASCULAR, INC.	26/11/2021	KNW	ENCOR PROBE STEREOTACTIC	Suction Failure	Calcium Deposits/Calcification	Stereotactic breast biopsy on a (b)(6) f done in the vertical approach using bard 7g biopsy probe. During the sampling process, we noticed that the specimen container on the probe was not draining. The radiologist attempted to manually drain the excess fluid from the specimen container to aid in tissue removal. The biopsy probe was removed and the nurse began holding pressure at the biopsy site. The nurse noticed tissue coming from the insertion site and was able to remove a large piece of specimen from the breast. This piece of specimen was larger than any piece retrieved from the specimen container. The specimen was imaged and was found to contain the largest amount of calcifications. Very few calcifications were seen in the specimen that was acquired by the probe. Fda safety report id # (b)(4).
1723170-2021-02569	30/08/2021	Malfunction	MEDTRONIC NAVIGATION, INC	26/10/2021	OLO	CANNULATED SOLERA DRIVER	Material Integrity Problem	No Clinical Signs, Symptoms or Conditions	Medtronic received information regarding a navigation system used during a sacroiliac and thoracolumbar procedure. It was reported that during wide bilateral decompressive laminectomies at l1-2, 2-3, 3-4, 5-s1, and bilateral fusion with autograft onlay facet arthrodesis fusion with stereotactic neuro navigation, the tip of the screwdriver broke off. The tip was retrieved and verified. There was no reported delay to the procedure. There were no patient symptoms or complications reported as a result of this event. Manufacturer narrative:

									no products have been returned to medtronic for analysis. If information is provided in the future, a supplemental report will be issued.
MW5104982	26/08/2021	Malfunction	VARIAN MEDICAL SYSTEMS, INC	27/10/2021	IYE	VARIAN TRUEBEAM LINEAR ACCELERATOR	Communication or Transmission Problem; Protective Measures Problem	Insufficient Information	Patient under radiation therapy treatment to the brain over 10 treatments using varian aria record and verify and varian truebeam linac. Patient plan has 2 treatment fields. Both were loaded at linac console on (b)(6) 2021 and were treated by radiation therapists. Aria recorded only 1 field treated, calculating that only half of the prescribed dose was delivered. The treatment displayed as a partial treatment in the treatment summary workspace in aria emr. Aria safety mechanisms for partial treatment deliveries include prohibiting any subsequent treatment delivery until the chart is reviewed by staff and one of the following is selected: resume the partial treatment to complete the partial fraction or ignore the partial treatment and go onto the next fraction. This did not deploy, despite being listed as a partial treatment. This meant that the incorrect recording of the plan was not found until weekly chart review was performed by the physicist a few days later. The fraction was handled as a completed appointment on the aria emr schedule with a green check, whereas partial treatments are given a gold check by the system. Varian was contacted by the physicist to determine if both treatment fields were delivered on (b)(6). Based upon the mlc log files, both varian and the physicist independently determined that both fields were delivered. Varian opened an investigation as to why the field did not record back and the results of the investigation are as follows: "the version reported was 2.7 mr4. The log files were reviewed. The investigation determined the varian truebeam treatment console did not work as intended. Review of logs show that all treatment fields were fully treated (on (b)(6) 2021) 13:29:10 field treated: beam name:rao, specified meterset:108.4440, delivered meter set:108.4440 13:30:11

									field treated: beam name: lao, specified meter set:107.5990, delivered meters et:107.5990 at 13:35:05, the user then tried to save back the patient plan. The logs show that when the user attempted to save back they got "dicom error missing_attribute" and "value is invalid: [invalid]contains illegal character" errors. This appears to be a known design discrepancy. When there is an error which causes the truebeam treatment console to interrupt saving back of patient treatment. The treatment console should mitigate that interruption. In this case mitigation did not work as designed; a design discrepancy has been entered for this issue. The issue is considered a malfunction in the truebeam treatment console. The issue is not covered in our customer/service facing documentation. See the truebeam instruction for use (p1011692-007-g): when you finish the patient's treatment, the system prepares a record of the entire treatment and sends it to the patient's treatment history, so that the patient's records are kept up-to-date. In certain circumstances, this automatic process may be interrupted or impaired in some way. When this happens, an error message, recording failed, appears with additional information. Make a physical record of the mu delivered, which is displayed on the backup counter on the control console." customer documentation should be available and attempts should be made to correct this issue. If the emr were relied upon to be correct, which a "record and verify" would often be, the patient could have received additional treatment field radiation dose to make up for missing fields that were in fact not missing. This could have led to overtreatment of organs, which for this patient would have overdosed the lenses. In this particular case the malfunction was caught and the dose was found to be given not missing, therefore no additional dose was given. Incorrect records of radiation treatments could have a variety

									of effects depending on which site is being treated, coupled with the dose per fraction. The potential severity of this malfunction would be magnified in the case of stereotactic radiosurgery. Fda safety report id # (b)(4).
MW5104982	26/08/2021	Malfunction	VARIAN MEDICAL SYSTEMS, INC	27/10/2021	IYE	VARIAN ARIA RECORD AND VERIFY	Communication or Transmission Problem; Protective Measures Problem	Insufficient Information	Patient under radiation therapy treatment to the brain over 10 treatments using varian aria record and verify and varian truebeam linac. Patient plan has 2 treatment fields. Both were loaded at linac console on (b)(6) 2021 and were treated by radiation therapists. Aria recorded only 1 field treated, calculating that only half of the prescribed dose was delivered. The treatment displayed as a partial treatment in the treatment summary workspace in aria emr. Aria safety mechanisms for partial treatment deliveries include prohibiting any subsequent treatment delivery until the chart is reviewed by staff and one of the following is selected: resume the partial treatment to complete the partial fraction or ignore the partial treatment and go onto the next fraction. This did not deploy, despite being listed as a partial treatment. This meant that the incorrect recording of the plan was not found until weekly chart review was performed by the physicist a few days later. The fraction was handled as a completed appointment on the aria emr schedule with a green check, whereas partial treatments are given a gold check by the system. Varian was contacted by the physicist to determine if both treatment fields were delivered on (b)(6). Based upon the mlc log files, both varian and the physicist independently determined that both fields were delivered. Varian opened an investigation as to why the field did not record back and the results of the investigation are as follows: "the version reported was 2.7 mr4. The log files were reviewed. The investigation determined the varian truebeam treatment console did not work as intended. Review of logs show that all treatment fields were fully treated (on (b)(6) 2021) 13:29:10 field treated: beam

									name:rao, specified meterset:108.4440, delivered meter set:108.4440 13:30:11 field treated: beam name: lao, specified meter set:107.5990, delivered meters et:107.5990 at 13:35:05, the user then tried to save back the patient plan. The logs show that when the user attempted to save back they got "dicom error missing_attribute" and "value is invalid: [invalid]contains illegal character" errors. This appears to be a known design discrepancy. When there is an error which causes the truebeam treatment console to interrupt saving back of patient treatment. The treatment console should mitigate that interruption. In this case mitigation did not work as designed; a design discrepancy has been entered for this issue. The issue is considered a malfunction in the truebeam treatment console. The issue is not covered in our customer/service facing documentation. See the truebeam instruction for use (p1011692-007-g): when you finish the patient's treatment, the system prepares a record of the entire treatment and sends it to the patient's treatment history, so that the patient's records are kept up-to-date. In certain circumstances, this automatic process may be interrupted or impaired in some way. When this happens, an error message, recording failed, appears with additional information. Make a physical record of the mu delivered, which is displayed on the backup counter on the control console." customer documentation should be available and attempts should be made to correct this issue. If the emr were relied upon to be correct, which a "record and verify" would often be, the patient could have received additional treatment field radiation dose to make up for missing fields that were in fact not missing. This could have led to overtreatment of organs, which for this patient would have overdosed the lenses. In this particular case the malfunction was caught and the dose was found to be given not missing, therefore no

									additional dose was given. Incorrect records of radiation treatments could have a variety of effects depending on which site is being treated, coupled with the dose per fraction. The potential severity of this malfunction would be magnified in the case of stereotactic radiosurgery. Fda safety report id # (b)(4).
1723170-2021-02499	03/08/2021	Injury	MEDTRONIC NAVIGATION, INC	13/10/2021	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Hematoma; Hemorrhage/Bleeding; Intracranial Hemorrhage; High Blood Pressure/ Hypertension; Hydrocephalus	Runge, j., ascencao, l.c., blahak, c., kinfe, t.m., schrader, c., wolf, m.e., saryyeva, a., krauss, j.k. Deep brain stimulation in patients on chronic antiplatelet or anticoagulation treatment. Acta neurochirurgica 2021. Https://doi.org/10.1007/s00701-021-04931 background: in the aging society, many patients with movement disorders, pain syndromes, or psychiatric disorders who are candidates for deep brain stimulation (dbs) surgery sufer also from cardiovascular co-morbidities that require chronic antiplatelet or anticoagulation treatment. Because of a presumed increased risk of intracranial hemorrhage during or after surgery and limited knowledge about perioperative management, chronic antiplatelet or anticoagulation treatment often has been considered a relative contraindication for dbs. Here, we evaluate whether or not there is an increased risk for intracranial hemorrhage or thromboembolic complications in patients on chronic treatment (paused for surgery or bridged with subcutaneous heparin) as compared to those without. Methods: out of a series of 465 patients undergoing functional stereotactic neurosurgery, 34 patients were identified who were on chronic treatment before and after receiving dbs. In patients with antiplatelet treatment, medication was stopped in the perioperative period. In patients with vitamin k antagonists or novel oral anticoagulants (noacs), heparin was used for bridging. All patients had postoperative stereotactic ct scans, and were followed up for 1 year after surgery. Results: in patients on chronic antiplatelet

									or anticoagulation treatment, intracranial hemorrhage occurred in 2/34 (5.9%) dbs surgeries, whereas the rate of intracranial hemorrhage was 15/431 (3.5%) in those without, which was statistically not significant. Implantable pulse generator pocket hematomas were seen in 2/34 (5.9%) surgeries in patients on chronic treatment and in 4/426 (0.9%) without. There were only 2 instances of thromboembolic complications which both occurred in patients without chronic treatment. There were no hemorrhagic complications during follow-up for 1 year. Conclusions: dbs surgery in patients on chronic antiplatelet or anticoagulation treatment is feasible. Also, there was no increased risk of hemorrhage in the first year of follow-up after dbs surgery. Appropriate patient selection and standardized perioperative management are necessary to reduce the risk of intracranial hemorrhage and thromboembolic complications. Reportable events: there was one patient who suffered from mild intraoperative air embolism with coughing, but without dyspnea or hemodynamic instability. A (b)(6) year-old man had an intraventricular hemorrhage associated with a transventricular electrode in the postoperative ct. After four asymptomatic days, his condition worsened due to hydrocephalus, requiring an external ventricular drainage for 5 days. A (b)(6) year-old woman had a small, asymptomatic intracerebral bleeding along the electrode trajectory in the postoperative ct scan. There were no longterm consequences. 16 patients had arterial hypertension. 2 patients had ipg pocket hematomas see literature article attached manufacturer narrative: patient age is the mean value of patients in the study. Patient gender is the majority value of patients in the study. Patient weight not available from the site. Event date is the online publishing date of the literature article. Device lot number, or serial number, unavailable. 510(k) is

									dependent upon the device model number and is therefore, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacture date is dependent on the device lot/serial number, therefore is unavailable. If information is provided in the future, a supplemental report will be issued.
MW5102887	27/07/2021	Injury	HOLOGIC, INC.	29/07/2021	IZH	HOLOGIC	Defective Device	Insufficient Information	Stereotactic device malfunction; during stereotactic breast procedure, the equipment malfunctioned. Ca testing was performed prior to the commencement of the procedure, which passed. As procedure was being performed (after needle was inserted into pt's breast), the equipment failed to take any further exposures. Error codes occurred: "error code 10, 2, 1." the reset button also failed to work. The procedure was aborted; no biopsy or "clip placement" was performed and the needle had to be manually removed from the pt. No significant pt injury occurred due to this event. The pt will require this procedure to be repeated.
2182207-2021-01809	21/07/2021	Injury	MEDTRONIC NEUROMODULATION	15/10/2021	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Wound Dehiscence; Bacterial Infection; Purulent Discharge; Erythema; Unspecified Infection; Burning Sensation; Discomfort; Swelling/ Edema	Summary: deep brain stimulation (dbs) hardware complications have been traditionally managed by removal of the entire system. Explantation of the system results in prolonged interruption to the patient¿s care and potential challenges when considering reimplantation of the cranial leads. The purpose of this study was to understand whether complete explantation can be avoided for patients initially presenting with wound dehiscence and/or infection of hardware. The authors performed a retrospective study that included 30 cases of wound dehiscence or infection involving the dbs system. Patients underwent reoperation without explantation of the dbs system, with partial explanation, or with complete explantation as initial management of the complication. Results: a total of 17/30 cases were managed with hardware-sparing wound revisions. The majority presented with wound dehiscence (94%), with the scalp (n = 9) as the most common location. This was

									successful in 76.5% of patients (n = 13). Over 11/30 patients were managed with partial explantation. The complication was located at the generator (91%) or at the scalp (9%). Partial explantation was successful in 64% of patients (n = 7). In cases that underwent a lead-sparing approach, 33% of patients ultimately required removal of the intracranial lead, and 2/30 cases of hardware infection were managed initially with total explantation. Wound dehiscence can be successfully managed without complete removal of the dbs systemin most cases. In cases of infection, removing the involved component(s) and sparing the intracranial leads may be considered. Wound revision without removal of the entire dbs system is safe and can improve quality of life by preventing or shortening the withdrawal of dbs treatment. Reported events: 12 patients experienced 16 complications of wound dehiscence and infection which were initially managed with wound revision and debridement. Two cases of wound dehiscence at the site of generator presented after replacement from depletion and not directly following initial placement. Wound dehiscence without signs of infection was observed in 11 cases. Five patients had both wound dehiscence and signs of infection (including erythema, tenderness, swelling and/or warmth) without frank purulent material in the wound. Location of complication was at scalp in 9 patients, behind the ear in 5, and at the chest in 2. In 4 cases, the patient reported a direct trauma to the site of dehiscence. In 3 cases, a temporalis muscle flap was created and then rotated over the hardware. The area was thoroughly irrigated, with any purulence washed out in cases of infection. Vancomycin powder was used in all cases. Median hospital stay was 1 day (1-3 days), with all patients receiving postoperative antibiotics regardless of infection. Wound revision/debridement was successful in 12 cases. Six cases

									required second revision, and one case a third revision which was ultimately successful. Three cases ultimately led to removal of part of system (ins and/or extension) without removal of leads (due to infection in 1 and dehiscence in 2). The lead was explanted due to infection in one case. These patients were implanted for parkinson's disease, essential tremor, dystonia, and obsessive compulsive disorder (ocd), but specific patient therapies could not be identified. Comorbidities included diabetes mellitus (n=5), hypertension (n=5), and current smoker (n=6). Average bmi was 26.4. 2. There were 11 cases of wound dehiscence and/or infection which resulted in partial explant of the system. In 9 cases, reason for partial explant was infection located in chest. In 2 cases, reason for partial explant was wound dehiscence, one in chest incision and one scalp incision. In one case, there was no obvious purulent material on examination, but intraoperative wound exploration revealed pus surrounding the generator. Purulent material was identified in 9 cases and cultures were sent for analysis. Any infectious tissue was removed and the wound was thoroughly irrigated. In 6 cases, the generator and extension were explanted. In 3 cases, the generator was the only device explanted. In 1 case, only one lead was explanted. In 1 case, the generator, extension and unilateral lead were removed. The extensions were irrigated and sutured into a pocket created away from the infection in cases where they were not explanted. Median hospital stay was 3 days all patients received postoperative antibiotics and were discharged with antibiotics based on culture. Staphylococcus was identified in 8 cases. In 8 cases, the explanted component was reimplanted at a later date (me dian: 4 months). Partial explant was successful in 7 cases. The remaining 3 patients required explant of the lead due to persistent infection. These patients were implanted

									for parkinson's disease and essential tremor, although specific patients could not be identified. Patient comorbidities included diabetes mellitus (n=1), hypertension (n=4), and current smoker (n=1). Average bmi was 26.9. Literature article. No device information could be identified in the article. Manufacturer narrative: ginalis ee, hargreaves el, caputo dl, danish sf. Is it possible to save the deep brain stimulation hardware when presenting with wound dehiscence or hardware infection? Stereotact funct neurosurg. 2021:1-10.10.1159/000517299. Age or date of birth: this value is the average age of the patients reported in the article as specific patients could not be identified. Sex: this value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Other relevant device(s) are: product id: neu_unknown_ext, serial/lot #: unknown, udi#: asku ; product id: neu_unknown_lead, serial/lot #: unknown, udi#: asku ; product id: neu_ins_stimulator, serial/lot #: unknown, udi#: asku ; product id: neu_unknown_ext, serial/lot #: unknown, udi#: asku ; product id: neu_unknown_lead, serial/lot #: unknown, udi#: asku. If information is provided in the future, a supplemental report will be issued.
2182207-2021-01810	21/07/2021	Injury	MEDTRONIC NEUROMODULATION	15/10/2021	MFR	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Abscess; Unspecified Infection; Convulsion/Seizure	Summary: deep brain stimulation (dbs) hardware complications have been traditionally managed by removal of the entire system. Explantation of the system results in prolonged interruption to the patient¿s care and potential challenges

									when considering reimplantation of the cranial leads. The purpose of this study was to understand whether complete explantation can be avoided for patients initially presenting with wound dehiscence and/or infection of hardware. The authors performed a retrospective study that included 30 cases of wound dehiscence or infection involving the dbs system. Patients underwent reoperation without explantation of the dbs system, with partial explanation, or with complete explantation as initial management of the complication. Results: a total of 17/30 cases were managed with hardware-sparing wound revisions. The majority presented with wound dehiscence (94%), with the scalp (n = 9) as the most common location. This was successful in 76.5% of patients (n = 13). Over 11/30 patients were managed with partial explantation. The complication was located at the generator (91%) or at the scalp (9%). Partial explantation was successful in 64% of patients (n = 7). In cases that underwent a lead-sparing approach, 33% of patients ultimately required removal of the intracranial lead, and 2/30 cases of hardware infection were managed initially with total explantation. Wound dehiscence can be successfully managed without complete removal of the dbs systemin most cases. In cases of infection, removing the involved component(s) and sparing the intracranial leads may be considered. Wound revision without removal of the entire dbs system is safe and can improve quality of life by preventing or shortening the withdrawal of dbs treatment. Reported events: one patient implanted for obsessive compulsive disorder (ocd) experienced infection (cerebral abscess) without dehiscence, resulting in seizures. The patient was treated with wound debridement and revision, was monitored in icu for 48 hours, was in close contact with surgeon after discharge, and was treated with 8 weeks of iv ceftriaxone as intraoperative cultures

									grew back. Monitoring included ct and mri scans for 3 months after discharge. The patient was successfully managed without device removal. See attached literature article. No device information could be identified in the article. Manufacturer narrative: ginalis ee, hargreaves el, caputo dl, danish sf. Is it possible to save the deep brain stimulation hardware when presenting with wound dehiscence or hardware infection? Stereotact funct neurosurg. 2021:1-10.10.1159/000517299. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Other relevant device(s) are: product id: neu_unknown_lead, serial/lot #: unknown, ubd: , udi#: (b)(4). If information is provided in the future, a supplemental report will be issued.
12293697	15/07/2021	Malfunction	HOLOGIC, INC.	09/08/2021	KNW	EVIVA STEREOTACTIC BREAST BIOPSY DEVICE	Activation Failure; Physical Resistance/Sticking	Device Embedded In Tissue or Plaque	Radiologist had difficulty deploying biopsy clip. The sheath that the clip slides thru became stuck in breast and biopsy clip did not deploy. Manufacturer response for eviva stereotactic biopsy device, eviva stereotatic biopsy device (per site reporter).
2182207-2021-01678	02/07/2021	Malfunction	MEDTRONIC NEUROMODULATION	29/09/2021	MHY	ACTIVA	Insufficient Information	Insufficient Information	Lin z, dai l, zhang c, li d, sun b. Rescue anterior capsulotomy after failure of nucleus accumbens deep brain stimulation in anorexia nervosa: a case report. Stereotact funct neurosurg. 2021:1-5.10.1159/000517105. Summary: anorexia nervosa (an) is a highly disabling mental disorder with high rates of morbidity and mortality. Few psychological treatments and pharmacotherapy are proven to be effective for adult an. Two invasive stereotactic neurosurgical interventions, deep brain stimulation (dbs) and anterior capsulotomy, are now commonly used as

									investigational approaches for the treatment of an. Here, we report the long-term safety and efficacy of rescue bilateral anterior capsulotomy after the failure of bilateral nucleus accumbens (nacc)-dbs in an 18-year-old female patient with life-threatening and treatment-resistant restricting subtype an. Improvements in the neuropsychiatric assessment were not documented 6 months after the nacc-dbs. Rescue bilateral anterior capsulotomy was proposed and performed, resulting in a long-lasting restoration of body weight and a significant and sustained remission in an core symptoms. The dbs pulse generator was exhausted 2 years after capsulotomy and removed 3 years postoperatively. No relapse was reported at the last follow-up (7 years after the first intervention). From this case, we suggest that capsulotomy could be a rescue treatment for patients with treatment-resistant an after nacc-dbs failure. Further well-controlled studies are warranted to validate our findings. Identified events: the implantable neurostimulator (ins) was exhausted two years after capsulotomy and removed three years post-operatively. It was indicated the dbs ins had a failure which led to the capsulotomy. It was also indicated the patient still suffered from an extremely low bmi with the persistence of anorexia nervosa symptoms (eat-26 and ede-! Score of 42 and 4.3 respectively. In addition, the comorbidities including persistent depression, anxiety, and ocd were resistant to the postoperative complementary pharmacotherapy. Manufacturer narrative: lin z, dai l, zhang c, li d, sun b. Rescue anterior capsulotomy after failure of nucleus accumbens deep brain stimulation in anorexia nervosa: a case report. Stereotact funct neurosurg. 2021:1-5.10.1159/000517105. Please note that this device was used in an off-label manner as it was implanted for anorexia nervosa. This value is the average age of the patients reported in the article as specific patients

									could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. If information is provided in the future, a supplemental report will be issued.
2182207-2021-01679	02/07/2021	Malfunction	MEDTRONIC NEUROMODULATION	29/09/2021	MHY	ACTIVA	Insufficient Information	Insufficient Information	Lin z, dai l, zhang c, li d, sun b. Rescue anterior capsulotomy after failure of nucleus accumbens deep brain stimulation in anorexia nervosa: a case report. Stereotact funct neurosurg. 2021:1-5.10.1159/000517105 summary: anorexia nervosa (an) is a highly disabling mental disorder with high rates of morbidity and mortality. Few psychological treatments and pharmacotherapy are proven to be effective for adult an. Two invasive stereotactic neurosurgical interventions, deep brain stimulation (dbs) and anterior capsulotomy, are now commonly used as investigational approaches for the treatment of an. Here, we report the long-term safety and efficacy of rescue bilateral anterior capsulotomy after the failure of bilateral nucleus accumbens (nacc)-dbs in an (b)(6) female patient with life-threatening and treatment-resistant restricting subtype an. Improvements in the neuropsychiatric assessment were not documented 6 months after the nacc-dbs. Rescue bilateral anterior capsulotomy was proposed and performed, resulting in a long-lasting restoration of body weight and a significant and sustained remission in an core symptoms. The dbs pulse generator was exhausted 2 years after capsulotomy and removed 3 years postoperatively. No

									relapse was reported at the last follow-up (7 years after the first intervention). From this case, we suggest that capsulotomy could be a rescue treatment for patients with treatment-resistant an after nacc-dbs failure. Further well-controlled studies are warranted to validate our findings. Identified events: 1. The implantable neurostimulator (ins) was exhausted two years after capsulotomy and removed three years post-operatively. It was indicated the dbs ins had a failure which led to the capsulotomy. It was also indicated the patient still suffered from an extremely low bmi with the persistence of anorexia nervosa symptoms (eat-26 and ede-! Score of 42 and 4.3 respectively. In addition, the comorbidities including persistent depression, anxiety, and ocd were resistant to the postoperative complementary pharmacotherapy. Manufacturer narrative: lin z, dai l, zhang c, li d, sun b. Rescue anterior capsulotomy after failure of nucleus accumbens deep brain stimulation in anorexia nervosa: a case report. Stereotact funct neurosurg. 2021:1-5.10.1159/000517105. Please note that this device was used in an off-label manner as it was implanted for anorexia nervosa. This value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. If information is provided in the future, a supplemental report will be issued.

3005099803-2021-03825	28/06/2021	Malfunction	BOSTON SCIENTIFIC CORPORATION	27/07/2021	OVB	SPACEOAR VUE SYSTEM	Positioning Problem	No Clinical Signs, Symptoms or Conditions	It was reported to boston scientific corporation that spaceoar vue was implanted during a spaceoar placement procedure performed on (b)(6) 2021. It was reported that the physician removed the needle after hydrodissection and had to reinsert the needle for placement of hydrogel with spaceoar vue. Upon review of the images, it appeared on the sagittal view there was a very thick dark line within the gel which was potentially dissected anterior rectal wall, suggesting anterior rectal wall infiltration. 5mm of spaceoar was noted between the dissected anterior rectal wall and the posterior edge of the prostate. The physician decided to cut back from stereotactic body radiation therapy (sbrt) and switched over to hypofractionation. Boston scientific has been unable to obtain additional information regarding the event to date, despite good faith efforts. Manufacturer narrative: the complainant was unable to provide the suspect device lot number. Therefore, the expiration and device manufacture dates are unknown. (b)(4). The complainant indicated that the device remains implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental mdr will be filed.
2182207-2021-01531	25/06/2021	Injury	MEDTRONIC NEUROMODULATION	06/09/2021	MHY	IMPLANTABLE NEUROSTIMULATOR	Break; Energy Output Problem; Adverse Event Without Identified Device or Use Problem; Insufficient Information	Adhesion(s); Unspecified Infection; Discomfort; Insufficient Information; No Clinical Signs, Symptoms or Conditions	Abdallat m, saryyeva a, blahak c, et al. Centromedian-parafascicular and somatosensory thalamic deep brain stimulation for treatment of chronic neuropathic pain: a contemporary series of 40 patients. Biomedicines. 2021; 9(7).10.3390/biomedicines9070731. Summary: introduction: the treatment of neuropathic and central pain still remains a major challenge. Thalamic deep brain stimulation (dbs) involving various target structures is a therapeutic option which has received increased re-interest. Beneficial results have been reported in several more recent smaller studies, however, there is a lack of prospective studies on larger series

									providing long term outcomes. Methods: forty patients with refractory neuropathic and central pain syndromes underwent stereotactic bifocal implantation of dbs electrodes in the centromedian¿parafascicular (cm¿pf) and the ventroposterolateral (vpl) or ventroposteromedial (vpm) nucleus contralateral to the side of pain. Electrodes were externalized for test stimulation for several days. Outcome was assessed with five specific vas pain scores (maximum, minimum, average pain, pain at presentation, allodynia). Results: the mean age at surgery was 53.5 years, and the mean duration of pain was 8.2 years. During test stimulation significant reductions of all five pain scores was achieved with either cm¿pf or vpl/vpm stimulation. Pacemakers were implanted in 33/40 patients for chronic stimulation for whom a mean follow-up of 62.8 months (range 3¿180 months) was available. Of these, 18 patients had a follow-up beyond four years. Hardware related complications requiring secondary surgeries occurred in 11/33 patients. The vas maximum pain score was improved by 50% in 8/18, and by 30% in 11/18 on long term follow-up beyond four years, and the vas average pain score by 50% in 10/18, and by 30% in 16/18. On a group level, changes in pain scores remained statistically significant over time, however, there was no difference when comparing the efficacy of cm¿pf versus vpl/vpm stimulation. The best results were achieved in patients with facial pain, poststroke/central pain (except thalamic pain), or brachial plexus injury, while patients with thalamic lesions had the least benefit. Conclusion: thalamic dbs is a useful treatment option in selected patients with severe and medically refractory pain. Identified events: five patients had their implantable neurostimulator (ins) system explanted because of chronic infections, including three which were after the ins replacement. All of these patients did not

									undergo re-implant after the infection. Eight patients had ins replacements due to hardware-related complications. Three patients had ins replacements/second implanted electrode because of decline in efficacy with stimulation of the target. Three patients had lead revisions because of electrodeFracture or discomfort because of bowstringing. Manufacturer narrative: abdallat m, saryyeva a, blahak c, et al. Centromedian-parafascicular and somatosensory thalamic deep brain stimulation for treatment of chronic neuropathic pain: a contemporary series of 40 patients. Biomedicines. 2021; 9(7).10.3390/biomedicines9070731. Information references the main component of the system. Other relevant device(s) are: product id: neu_ins_stimulator, serial/lot #: unknown, ubd: , udi#: ; product id: neu_ins_stimulator, serial/lot #: unknown, ubd: , udi#: ; product id: 3387, serial/lot #: unknown, ubd: , udi#:. Age: this value is the average age of the patients reported in the article as specific patients could not be identified. Sex: this value had the same number of males and females in the study. Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. If information is provided in the future, a supplemental report will be issued.
12173178	16/06/2021	Malfunction	MEDTRONIC NAVIGATION, INC.	15/07/2021	OLO	PIN, 9733236, 150MM, STERILE, PERC REF	Break	Foreign Body In Patient	During a spinal fusion, a piece of one of the percutaneous pins being used in a stereotactic frame broke off in the posterior iliac crest. The pin originally measured 150mm on insertion but was 127mm when removed. The piece was left in the posterior

									iliac crest because it was considered to be in a benign position.
1222780-2021-00193	15/06/2021	Malfunction	HOLOGIC, INC.	02/07/2021	KNW	EVIVA STEREOTACTIC GUIDED BREAST BIOPSY SYSTEM	Material Fragmentation	No Clinical Signs, Symptoms or Conditions	It was reported that the plastic sheath that covers the needle broke off and became lodged in the patient during a biopsy procedure. No injury reported. Additional information was obtained from the customer that the plastic piece was removed by using a second biopsy needle with no additional medical or surgical intervention required and the biopsy was completed successfully. Manufacturer narrative: the device is not being returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
3002250546-2021-00001	04/06/2021	Malfunction	FHC	29/06/2021	HAW	WAYPOINT STEREOTACTIC PLATFORM	Use of Device Problem; Output Problem	Insufficient Information; No Clinical Signs, Symptoms or Conditions	Incident occurred on (b)(6) 2021, during a bilateral platform case using fhc waypoint stereotactic platform (mp-kit-p-bi). While fitting the platform to the patient, it did not fit. The case had to be cancelled and rescheduled for (b)(6) 2021. After the case was canceled, new scans were complete and the platform was rebuilt using the new scans. The follow up case was completed on (b)(6) 2021 successfully.
1723170-2021-02155	01/06/2021	Injury	MEDTRONIC NAVIGATION, INC	30/08/2021	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Muscle Weakness	Citation: katherine c. Pehlivan, paritosh c. Khanna, jennifer d. Elster, megan rose paul, michael l. Levy, john r. Crawford, david d. Gonda. Clinical and neuroimaging features of magnetic resonance guided stereotactic laser ablation for newly diagnosed and recurrent pediatric brain tumors: a single institutional series. World neurosurg. (2021) 150:e378-e387. Https://doi.org/10.1016/j.wneu.2021.03.027. Summary: objective: we describe our single-institutional experience with magnetic resonance-guided stereotactic laser ablation (sla) for the treatment of newly diagnosed and recurrent pediatric brain tumors. Methods: eighteen consecutive ablation procedures were performed in 17 patients from march 2016-april 2020. Patient demographics, indications, procedures, neuroimaging

									features, and outcomes were reviewed retrospectively. Results: seventeen patients (mean age of 11.4 years, 11 boys, 6 girls) underwent sla with a mean follow-up of 24 months (range: 3-45 months). Tumor histologies included pilocytic astrocytoma (n=5), ganglioglioma (n=3), low grade glioma not otherwise specified (n=4), glioblastoma (n=2), meningioma (n=1), medulloblastoma (n=1), and metastatic malignant peripheral nerve sheath tumor (n=1). Sla was first-line therapy in 10 patients. Mean procedure duration including anesthesia time was 328 minutes (range: 244-529 minutes), and mean postoperative length of stay was 1.5 days (range 1-5 days). The complication rate was 29%, which included 3 patients who experienced postoperative motor changes, which resolved within several weeks of surgery, 1 patient with self-limited intraoperative bradycardia and hypotension, and 1 patient who died postoperatively due to intracranial hemorrhage from a distant lesion. Twelve of 17 patients had a neuroimaging response after sla (4 complete responses, 8 partial responses, 1 stable disease). Percentage of tumor shrinkage from baseline ranged from 33%-100% (mean 75%). Patients with low-grade glioma exhibited the best responses to sla (range 3%-100% decrease; mean 90%; 36% complete response rate). Conclusions: sla is a minimally invasive modality for the treatment of newly diagnosed and recurrent low-grade pediatric brain tumors. Low-grade gliomaexhibited the best responses. Identification of ideal candidates for sla, mitigation of perioperative complications, and demonstration of long-term outcomes need to be better defined in a clinical trial setting. Reported event: one twelve-year-old female patient diagnosed with neurofibromatosis type 1 (nf1) ganglioglioma experienced transient left-sided weakness. It was reported that the patient had a large optic pathway glioma with thalamic involvement which had progress despite numerous chemotherapy

									regimens causing increasing weakness even before intervention and underwent sequential ablation. The patient experienced left-sided weakness immediately after the first ablation which improve to baseline 4-6 weeks later. Due to the success of the ablation, the patient underwent a second procedure and experienced worsening left-sided weakness which improved again with physical and occupational therapy. See attached article. Manufacturer narrative: patient information was not included in the journal article. Date of event) please note that this date is based off of the date the article was published as the event date was not provided in the published literature. Article citation is included. System product number and serial number not provided in journal article. Udi not available for this system. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
12040236	21/05/2021	Malfunction	HOLOGIC, INC	22/06/2021	OTE	SELENIA DIMENSIONS MAMMOGRAPHY SYSTEMS, 3D	Unintended Movement	Bruise/Contusion; Discomfort	During stereotactic guided left breast biopsy, while the needle was inserted and compression engaged, the gantry unexpectedly started to rotate. The unit could not be rotated back to the 90 degree position until compression was released. A post-biopsy marker could not be placed due to the incident. The patient reported discomfort, and later, bruising. Manufacturer response for 3d mammography, dimensions (per site reporter): manufacturer evaluated the device logs of the proper operation of the device, additionally they preventively replaced the rotation switches.
3005099803-2021-04606	19/05/2021	Malfunction	BOSTON SCIENTIFIC CORPORATION	03/09/2021	OVB	SPACEOAR VUE SYSTEM	Positioning Problem	Pain; Perforation	It was reported to boston scientific corporation that spaceoar vue was implanted during a spaceoar vue placement procedure performed on (b)(6) 2021. Fiducials were administered transperineally and the procedure was done under local anesthesia. The patient experienced rectal pain, magnetic resonance imaging (mri) showed early radiation proctatitis and

									infiltration of spaceoar into the rectal wall and possibly rectal lumen. On (b)(6) 2021, the physician stopped his treatment after three stereotactic body radiation therapy (sbrt) the patient received 7.25gy x 3. The patient pain was treated with ibuprofen, tylenol, and rectal lidocaine. On (b)(6) 2021, the patient had magnetic resonance imaging (mri) which showed perforation of the anterior rectal wall with hydrogel extending into the rectosigmoid. The patient was advised to wait for 6 months until the gel dissolved he already received 60% of a course of radiation and leaning towards finishing with about 40gy of conventional fractionation intensity-modulated radiation therapy (imrt). Manufacturer narrative: the complainant was unable to provide the suspect device lot number. Therefore, the expiration and device manufacture dates are unknown. (b)(4). The complainant indicated that the device remains implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental mdr will be filed.
1222780-2021-00163	11/05/2021	Malfunction	HOLOGIC, INC.	21/06/2021	KNW	EVIVA STEREOTACTIC GUIDED BREAST BIOPSY SYSTEM	Suction Problem	Hemorrhage/Bleeding; Syncope/Fainting	It was reported on (b)(6) 2021 that during a biopsy procedure a second device needed to be used to complete the biopsy. Additional information was received on 05/25/2021 that reported the initial device failed to suction tissue/cores and no samples were retrieved. The patient experienced "copious bleeding and ultimately fainting." attempts to obtain additional information on the patient impact have been unsuccessful as of today. Manufacturer narrative: the device is not being returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
3015967359-2021-01738	10/05/2021	Malfunction	STRYKER INSTRUMENTS-A	05/08/2021	HBE	2.3MM TAPERED ROUTER	Fracture	No Clinical Signs,	It was reported via medwatch report 5101846 that during a stereotactic right craniotomy surgical procedure, the router

			DIVISION OF STRYKER CORP					Symptoms or Conditions	broke. It was further reported that the broken pieces were recovered. It was also reported there were no delays and no adverse consequences as a result of this event. It was further reported that the procedure was completed successfully. Manufacturer narrative: a follow up report will be filed once the quality investigation is complete.
1723170-2021-02210	08/05/2021	Injury	MEDTRONIC NAVIGATION, INC	07/09/2021	GEX	MEDTRONIC NAVIGATION	Material Fragmentation; Biocompatibility	Intracranial Hemorrhage; Paresis; Loss of Vision; Paresthesia; Unspecified Nervous System Problem	Malcolm, j.g., miller douglas, j., greven, a., rich, c., dawoud, r.a., hu, r., reisner, a., barrow, d.l., gross, r.e., willie, j.t. Feasibility and morbidity of magnetic resonance imaging-guided stereotactic laser ablation of deep cerebral cavernous malformations: a report of 4 cases. Neurosurgery 0:1¿10, 2021 https://doi.org/10.1093/neuros/nyab241 background: magnetic resonance imaging (mri)-guided laser interstitial thermal therapy (mrglitt) has been used successfully to treat epileptogenic cortical cerebral cavernous malformations (ccm). It is unclear whether mrglitt would be as feasible or safe for deep ccms objective: to describe our experience with mrglitt for symptomatic deep ccms methods: patients¿ records were reviewed retrospectively. Mrglitt was carried out using a commercially available system in an interventional mri suite with efforts to protect adjacent brain structures. Immediate postoperative imaging was used to judge ablation adequacy. Delayed postoperative mri was used to measure lesion volume changes during follow-up. Results: four patients with ccm in the thalamus, putamen, midbrain, or subthalamus presented with persistent and disabling neurological symptoms. A total of 2 patients presented with disabling headaches and sensory disturbances and 2 with recurrent symptomatic hemorrhages, of which 1 had familial ccm. Patients were considered by vascular neurosurgeons to be poor candidates for open surgery or had refused it. Multiple trajectories were used in most cases. Adverse events included device malfunction with leakage of saline causing

									transient mass effect in one patient, and asymptomatic tract hemorrhage in another. One patient suffered an expected mild but persistent exacerbation of baseline deficits. All patients showed improvement from a previously aggressive clinical course with lesion volume decreased by 20% to 73% in follow-up. Conclusion: mrglitt is feasible in the treatment of symptomatic deep ccm but may carry a high risk of complications without the benefit of definitive resection. We recommend cautious patient selection, low laser power settings, and conservative temperature monitoring in surrounding brain parenchyma. Reportable events: 1 patient who was 27 years old had a perioperative mild parasthesia. During 1 patients procedure, who was 41 years old, had the device malfunction causing a saline leakage into the brain. Which caused an incomplete ablation, transient upper extremity apraxia and transient left hemiparesis. Also the device top melted due to high laser energy. 1 patient who was 14 years old had 2 persistent exacerbation of hemiparesis and hemianopia 1 patient who was 62 years old had a small asymptomatic tract hemorrhage see attached literature article manufacturer narrative: this value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date the article was accepted for publication as the event dates were not provided in the published literature. No parts have been received by the manufacturer for evaluation. If information is provided in the future, a supplemental report will be issued.
3005099803-2021-02458	04/05/2021	Malfunction	BOSTON SCIENTIFIC CORPORATION	28/05/2021	OVB	SPACEOAR SYSTEM	Positioning Problem	No Clinical Signs, Symptoms or Conditions	It was reported to boston scientific corporation that spaceoar was implanted during a spaceoar placement procedure performed on (b)(6) 2021. Fiducials were administered prior to the patient's first course of radiation and the procedure was

									done under general anesthesia. Imaging was taken post procedure and it showed a rectal wall infiltration. 2cc of hydrogel was noted to be in the rectal wall. There were no patient complications reported as a result of this event. The physician was planning re-irradiation stereotactic body radiation therapy (sbrt), 34 gy/5 fractions. Manufacturer narrative: the complainant was unable to provide the suspect device lot number. Therefore, the manufacture date and expiration date are unknown. (b)(4). The complainant indicated that the device remains implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental mdr will be filed.
3005099803-2021-02749	01/05/2021	Injury	BOSTON SCIENTIFIC CORPORATION	09/06/2021	OVB	SPACEOAR SYSTEM	Positioning Problem	Abscess; Fistula; Hemorrhage/Bleeding; Unspecified Infection; Inflammation; Pain; Ulcer; Discomfort; Fluid Discharge; Unspecified Kidney or Urinary Problem	Boston scientific corporation became aware of an event through the article "hydrogel spacer rectal wall infiltration associated with severe rectal injury and related complications following dose intensified prostate cancer stereotactic ablative radiotherapy" written by mark f. Mclaughlin md, phd, et al. The patient underwent transrectal ultrasound (trus) guided transperineal placement of a commercial hydrogel spacer (spaceoar, boston scientific) and gold fiducials under moderate sedation. Visualization of needle placement was performed under both sagittal/axial views in a "dual" view mode. A computerized tomography (ct) scan and magnetic resonance imaging (mri) was used to delineate the prostate, the standard organs at risk and spacer gel distribution. Mri included t1- and t2-weighted sequences with fast spoiled gradient sequence particularly for fiducial recognition to aid fusion to ct. There were no abnormalities noted during plan quality assurance or intra-fraction imaging at the time and in repeated later review. The patient tolerated treatment well without gastrointestinal complaints and return to baseline urinary function by 6 weeks on the selective alpha-

									blocker, tamsulosin. Prior to the procedure, simulation procedures included enema for rectal emptying, bladder filling, vacuum mold from arms, up to the patient's mid thigh, and indexed stereotactic frame. The patient's prostate volume was expanded 3mm to create the planning tumor volume (ptv). The mri appeared to indicate adequate displacement of the rectum from prostate, ranging from 1.2 to 1.5 cm along the craniocaudal axis of the prostate. Significant anterior rectal wall infiltration was present. An area of deeper infiltration with "delamination" or discontinuity of the muscularis propria was identified. Stereotactic ablative radiotherapy (sabr) was prescribed to an escalated dose of 45 gy in 5 fractions, delivered on non-consecutive days over 3 weeks using volumetric modulated arc therapy, following treatment. 5 months after sabr completion, the patient reported worsening urinary symptoms, perineal fullness and occasional blood on wiping after bowel movements. Cystoscopic exam was negative for signs of urethral or bladder neck injury. Over the next month, the patient developed anal pain and mucous discharge with some bowel movements, unresponsive to hydrocortisone suppository and methylprednisolone dose pack for suspected radiation proctitis. Digital rectal examination noted anterior rectal wall tenderness with nodularity in expected area of prostate, without blood. Before endoscopic assessment could be pursued electively, the patient experienced acute worsening of rectal bleeding, prompting hospital admission outside our institution. Sigmoidoscopy revealed a large anterior wall ulceration. 6 months after sabr the previously seen area of spacer infiltration, and diverting colostomy was pursued by endoscopy. Notably the endoscopy did not show diffuse radiation changes of the adjacent rectum. The patient underwent hyperbaric oxygen treatments (50 dives) over the next 2 months, with resolution of

									rectal bleeding and pain. 9 months after sabr completion, the patient developed urine per rectum, related to a large recto-urethral fistula, as shown on retrograde urethrogam. Despite receiving suprapubic tube in attempt to temporize for flap repair, he developed osteomyelitis and soft tissue abscess, eventually requiring abdomino-perineal resection, cystoprostatectomy, and ileal conduit urinary diversion, now at 15 months from sabr. Due to these complications and corrective procedures, the patient has required routine physical therapy and had to take leave from work for several months, with associated substantial effects on his quality of life. Manufacturer narrative: the date of event is unknown. The provided event date of (b)(6) 2021, was chosen as a best estimate based on the date that the manufacturer became aware of the event, (b)(6) 2021. The complainant was unable to provide the device lot number. Therefore, the manufacture and expiration dates are unknown. Literature source: mark f. Mclaughlin md, phd, et al. "hydrogel spacer rectal wall infiltration associated with severe rectal injury and related complications following dose intensified prostate cancer stereotactic ablative radiotherapy, advances in radiation oncology (2021), doi: https://doi.org/10.1016/j.adro.2021.100713 (b)(4). The device was implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental medwatch will be filed.
1723170-2021-02457	21/04/2021	Injury	MEDTRONIC NAVIGATION, INC	07/10/2021	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage	Citation: tao jx, satzer d, issa np, et al. Stereotactic laser anterior corpus callosotomy for lennox-gastaut syndrome. Epilepsia. 2020; 61:1190¿1200. Https://doi.org/10.1111/epi.16535 summary: objective: corpus callosotomy is an effective palliative treatment for drug-resistant lennox-gastaut syndrome (lgs). Laser interstitial thermal therapy has been

									increasingly used in the treatment of epilepsy. Here, we assess the safety and effectiveness of minimally invasive stereotactic laser anterior corpus callosotomy (slacc) for drop attacks in lgs. Methods: we reviewed sequential cases of patients with medically intractable lgs who underwent slacc using a two-cannula technique between november 2014 and july 2019. Pre- and postoperative magnetic resonance imaging was used to measure the anteroposterior length of callosal ablation (contrast-enhancing lesion) and estimated disconnection (gap in tract projections on diffusion tensor imaging). Patients were followed longitudinally to assess clinical outcomes. Results: ten patients were included in this study. The median age was 33 (range = 11-52) years, median duration of epilepsy was 26 (range = 10-49) years, and median duration of postoperative follow-up was 19 (range = 6-40) months. In the anteroposterior direction, 53 ± 7% (mean ± sd) of the corpus callosum was ablated and 62 ± 19% of the corpus callosum was estimated to be disconnected. Six (60%) of 10 patients achieved >80% seizure reduction, two (20%) of whom became seizure-free. Eight (80%) patients had >80% reduction in drop attacks, five (50%) of whom became free of drop attacks. Three patients subsequently underwent laser posterior callosotomy with further improvement in drop attacks and/or overall seizure frequency. One patient had an asymptomatic intracerebral hemorrhage along the cannula tract. One patient developed significant aggression after becoming seizure-free. Significance: seizure outcomes following slacc were comparable to previously reported outcomes of open callosotomy, with reasonable safety profile. Slacc appears to be an effective alternative to open anterior corpus callosotomy with minimal postoperative discomfort and a short recovery period. Reported events: 1. One patient had a 13-ml parietal intracerebral hemorrhage near a cannula

									entry site. The hemorrhage was clinical asymptomatic with no focal deficit or reported functional impairment. See attached article. Manufacturer narrative: patient information was not included in the journal article. This value reflects the median age of the patients in the article as specific patients could not be identified. Please note that this date is based off of the date the article was published as the event dates were not provided in the published literature. Article citation is included. System serial number not provided in journal article. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
MW5100974	21/04/2021	Malfunction	DEVICOR MEDICAL PRODUCTS	23/04/2021	KNW	MAMMOTOME STEREOTACTIC PROBE	Break	Insufficient Information	Suction connection on the mammotome stereotactic probe cracked/broke during procedure. The setup did pass initial testing. Fda safety report id # (b)(4).
2182207-2021-01437	20/04/2021	Malfunction	MEDTRONIC NEUROMODULATION	18/08/2021	MRU	ACTIVA	Energy Output Problem; Malposition of Device	Paresthesia; No Clinical Signs, Symptoms or Conditions	Evidente vgh, rokhlin p, evidente mh, lambert m, garrett r, ponce fa. Thalamic deep brain stimulation is effective in alleviating cr aniocervical dystonia. Movement disorders clinical practice. 2021.10.1002/mdc3.13233. Summary: meige syndrome (ms) is an idiopathic adult-onset segmental dystonia characterized initially by blepharospasm, followed by dystonia of the mid-facial and lower facial muscles, mouth, jaw, tongue, or pharyngeal muscles. 1¿3 patients with ms may have further spread of dystonia to the cervical muscles, leading to craniocervical dystonia (cd). Severe meige or cd is often refractory to oral medications. Botulinum toxin (btx) injections remain the cornerstone of the management of ms or cd, although many patients experience a diminished response over time attributed to either progression of the disease or development of neutralizing antibodies. 2,3 we and other groups have reported the effectiveness of deep brain stimulation (dbs) of either the globus pallidus internus or subthalamic nucleus for medically refractory ms or cd.

									4¿7 we report on a patient with medically refractory cd who underwent bilateral asleep dbs surgery of the ventralis intermedius nucleus (vim) with dramatic response. Reported events: a (b)(6)-year-old female patient with dystonia was implanted with a lead that showed a stereotactic radial error of 1.1 mm posteromedial on the left and 0.8 mm posteromedial on the right. The left vim electrode settings were case (+), 0, 0.7v, 60 microseconds, and 185 hz, the right vim electrode settings were 11 (+), 8, 0.7v, 60 microseconds, and 185 hz. At these settings, the patient had immediate improvement of their hand tremors, but only mild improvement of their facial dyskinesias and neck movements. The amplitude was increased 3 days later to 1.5 volts in each side, and their eyelid spasms, facial dyskinesias, and retrocollis were markedly improved. The patient did note they have transient paresthesia in their hands or perioral region with programming adjustments. Manufacturer narrative: evidente vgh, rokhlin p, evidente mh, lambert m, garrett r, ponce fa. Thalamic deep brain stimulation is effective in alleviating cr aniocervical dystonia. Movement disorders clinical practice. 2021.10.1002/mdc3.13233. Other relevant device(s) are: product id: 3387, serial/lot #: unknown, ubd: , udi#:. If information is provided in the future, a supplemental report will be issued.
1222780-2021-00119	20/04/2021	Malfunction	HOLOGIC, INC.	20/05/2021	KNW	EVIVA STEREOTACTIC GUIDED BREAST BIOPSY SYSTEM	Material Deformation	No Clinical Signs, Symptoms or Conditions	It was reported that during a biopsy the probe would not move in the breast and was difficult to remove after the biopsy was completed. Once the probe was removed it was noted that the "plastic sheath had crenulated around the probe" and a hole could be seen in the plastic. No injury reported. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.

1222780-2021-00112	19/04/2021	Malfunction	HOLOGIC, INC.	17/05/2021	KNW	EVIVA STEREOTACTIC GUIDED BREAST BIOPSY SYSTEM	Material Twisted/Bent	Breast Discomfort/Pain	It was reported that during a biopsy procedure when removing the probe to insert the site marker it was difficult to remove. The probe and introducer had to be removed together and a site marker was not able to be placed. Once removed it was noted the probe had been bent. The patient experienced pain during removal, but no medical or surgical intervention was required. Manufacturer narrative: the device is not being returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
2182207-2021-01085	16/04/2021	Injury	MEDTRONIC NEUROMODULATION	21/06/2021	MRU	ACTIVA	Migration or Expulsion of Device; Adverse Event Without Identified Device or Use Problem	Unspecified Infection; No Clinical Signs, Symptoms or Conditions	Luciano furlanetti, jonathan ellenbogen, hortensia gimeno, laura ainaga, vijay narbad, harutomo hasegawa, jean-pierre lin, keyoumars ashkan and richard selway objective deep brain stimulation (dbs) is an established treatment for pediatric dystonia. The accuracy of electrode implantation is multifactorial and remains a challenge in this age group, mainly due to smaller anatomical targets in very young patients compared to adults, and also due to anatomical abnormalities frequently associated with some etiologies of dystonia. Data on the accuracy of robot-assisted dbs surgery in children are limited. The aim of the current paper was to assess the accuracy of robot-assisted implantation of dbs leads in a series of patients with childhood-onset dystonia. Methods forty-five children with dystonia undergoing implantation of dbs leads under general anesthesia between 2017 and 2019 were included. Robot-assisted stereotactic implantation of the dbs leads was performed. The final position of the electrodes was verified with an intraoperative 3d scanner (o-arm). Coordinates of the planned electrode target and actual electrode position were obtained and compared, looking at the radial error, depth error, absolute error, and directional error, as well as the euclidean distance.

									Functional assessment data prospectively collected by a multidisciplinary pediatric complex motor disorders team were analyzed with regard to motor skills, individualized goal achievement, and patients¿ and caregivers¿ expectations. Results a total of 90 dbs electrodes were implanted and 48.5% of the patients were female. The mean age was 11.0 ± 0.6 years (range 3¿18 years). All patients received bilateral dbs electrodes into the globus pallidus internus. The median absolute errors in x-, y-, and z-axes were 0.85 mm (range 0.00¿3.25 mm), 0.75 mm (range 0.05¿2.45 mm), and 0.75 mm (range 0.00¿3.50 mm), respectively. The median euclidean distance from the target to the actual electrode position was 1.69 ± 0.92 mm, and the median radial error was 1.21 ± 0.79. The robot-assisted technique was easily integrated into the authors¿ surgical practice, improving accuracy and efficiency, and reducing surgical time significantly along the learning curve. No major perioperative complications occurred. Conclusions robot-assisted stereotactic implantation of dbs electrodes in the pediatric age group is a safe and accurate surgical method. Greater accuracy was present in this cohort in comparison to previous studies in which conventional stereotactic frame-based techniques were used. Robotic dbs surgery and neuroradiological advances may result in further improvement in surgical targeting and, consequently, in better clinical outcome in the pediatric population. Reported events: it was reported that 2 patient's presented wound site infections and the implants were temporarily removed. It was reported that 3 patients experienced migration with one of their leads, which were revised accordingly. Manufacturer narrative: information references the main component of the system and other applicable components are: product id 37612 lot# serial# unknown implanted: explanted: product type

									implantable neurostimulator product id 3389 lot# unknown serial# implanted: explanted: product type lead information references the main component of the system. Other relevant device(s) are: product id: 3389, serial/lot #: unknown, ubd: , udi#: this value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. If information is provided in the future, a supplemental report will be issued.
3005099803-2021-02073	13/04/2021	Malfunction	BOSTON SCIENTIFIC CORPORATION	07/05/2021	OVB	SPACEOAR VUE SYSTEM	Positioning Problem	Hemorrhage/Bleeding; Burning Sensation	It was reported to boston scientific corporation that spaceoar vue was implanted during a spaceoar vue placement procedure performed on (b)(6) 2021. Additionally, the needle was difficult to position and the procedure was done under local anesthesia. During procedure, the anatomy was particularly difficult to clearly identify and the case quickly became more complicated with 12cc of saline clouding the ultrasound image. The placement was finally confirmed but during aspiration, blood was detected and the physician repositioned the needle twice. The aspiration was clear and the decision to place spaceoar was made. As soon as the injection began, the patient felt a burning sensation and artifact appeared to highlight the prostate posteriorly. The case was immediately stopped with only 1cc of product injected. The decision was made to cancel the case out of an abundance of caution. Additionally, there was a potential partial gel injection into the prostate. The burning sensation was transient, lasting only 1 second. No pain treatment was needed. The patient will receive stereotactic body radiation therapy (sbrt). Manufacturer narrative: (b)(4). The complainant indicated that the device remains implanted and will

									not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental mdr will be filed.
3005099803-2021-02081	01/04/2021	Malfunction	BOSTON SCIENTIFIC CORPORATION	06/05/2021	OVB	SPACEOAR VUE SYSTEM	Positioning Problem	Micturition Urgency; Discomfort	It was reported to boston scientific corporation that spaceoar vue was implanted during a spaceoar vue placement procedure performed on (b)(6) 2021. The procedure was done under general anesthesia. Images were taken post procedure and it showed possible rectal wall infiltration. Patient also complained of feeling urgency, fullness and discomfort post implant. The physician will hold off the stereotactic body radiation therapy (sbrt) and will do androgen deprivation therapy (adt). Patient was schedluled for magnetic resonance imaging (mri). Manufacturer narrative: the complainant was unable to provide the suspect device lot number. Therefore, the manufacture date and expiration date are unknown. (b)(4). The complainant indicated that the device remains implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental mdr will be filed.
3004785967-2021-01019	31/03/2021	Malfunction	MEDTRONIC NAVIGATION, INC (LITTLETON)	18/08/2021	OXO	O-ARM IMAGING SYSTEM	Image Display Error/Artifact;Imprecision	No Clinical Signs, Symptoms or Conditions	Citation: atsumi h, matsumae m. Fusing of preoperative magnetic resonance and intraoperative o-arm images in deep brain stimulation enhance intuitive surgical planning and increase accuracy of lead placement. Neurol med chir (tokyo). 2021 may 15; 61(5):341-346. Doi: 10.2176/nmc.tn.2020-0317. Epub 2021 mar 31. Pmid: 33790132; pmcid: pmc8120096. Summary: intraoperative fluoroscopy and microelectrode recording (mer) are useful techniques for guiding lead placement in deep brain stimulation (dbs). Recent advances in magnetic resonance imaging (mri) have enabled information on the location of the basal ganglia, as the target of dbs, to be obtained preoperatively. However, intraoperative images with few

									artifacts are required to enable accurate fusion of preoperative imaging data with intraoperative lead position data. With our method, we first fuse preoperative mri and pre-frame fixed computed tomography (ct) images, then fuse the ct images exactly after mounting the frame, using this fusion image as a platform image. Compared with before and after frame fixation, the pre-frame fixed ct has less artifacts, facilitating the identification of soft tissues such as the ventricles and cortical surface on pre-frame fixed ct images. By fusing the structural information for these soft tissues between pre-frame fixed ct and mr images, this fusion process can provide improved accuracy that is intuitively understood by the surgeon. Using platform images, surgical planning and intraoperative lead positioning can then be evaluated on the same coordinate axis. Positional data on the lead acquired as three-dimensional (3d) data are then added to the platform image. The proposed surgical steps permit the acquisition of accurate lead position data reported events: euclidean distances between the electrode coordinates of the 3dct images taken intraoperatively and the electrode coordinates from the preoperative surgical plan were measured, ranging from 1.32 to 2.56 mm. It was noted that many sources of error are conceivable, including scanning-related artifacts, but those errors arising when a stereotactic brain surgery frame is used are considered to remain within acceptable limits. Manufacturer narrative: patient information was not included in the journal article. Date of event: please note that this date is based off of the date the article was published as the event dates were not provided in the published literature. Article citation is included. System product number and serial number not provided in journal article. Udi not available for this system. No 510k provided as system is unknown. No evaluation was performed as this event was reported in literature. Device manufacturing

									date is unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2021-02101	31/03/2021	Malfunction	MEDTRONIC NAVIGATION, INC	18/08/2021	HAW	MEDTRONIC NAVIGATION	Imprecision	No Clinical Signs, Symptoms or Conditions	Citation: atsumi h, matsumae m. Fusing of preoperative magnetic resonance and intraoperative o-arm images in deep brain stimulation enhance intuitive surgical planning and increase accuracy of lead placement. Neurol med chir (tokyo). 2021 may 15; 61(5):341-346. Doi: 10.2176/nmc.tn.2020-0317. Epub 2021 mar 31. Pmid: 33790132; pmcid: pmc8120096. Summary: intraoperative fluoroscopy and microelectrode recording (mer) are useful techniques for guiding lead placement in deep brain stimulation (dbs). Recent advances in magnetic resonance imaging (mri) have enabled information on the location of the basal ganglia, as the target of dbs, to be obtained preoperatively. However, intraoperative images with few artifacts are required to enable accurate fusion of preoperative imaging data with intraoperative lead position data. With our method, we first fuse preoperative mri and pre-frame fixed computed tomography (ct) images, then fuse the ct images exactly after mounting the frame, using this fusion image as a platform image. Compared with beforeand after frame fixation, the pre-frame fixed ct has less artifacts, facilitating the identification of soft tissues such as the ventricles and cortical surface on pre-frame fixed ct images. By fusing the structural information for these soft tissues between pre-frame fixed ct and mr images, this fusion process can provide improved accuracy that is intuitively understood by the surgeon. Using platform images, surgical planning and intraoperative lead positioning can then be evaluated on th e same coordinate axis. Positional data on the lead acquired as three-dimensional (3d) data are then added to the platform image. The proposed surgical steps permit the acquisition of accurate lead position data reported events: euclidean distances between the electrode coordinates of the

									3dct images taken intraoperatively and the electrode coordinates from the preoperative surgical plan were measured, ranging from 1.32 to 2.56 mm. It was noted that many sources of error are conceivable, including errors arising during the fusion of the images used, but those errors arising when a stereotactic brain surgery frame is used are considered to remain within acceptable limits. Manufacturer narrative: patient information was not included in the journal article. Date of event) please note that this date is based off of the date the article was published as the event dates were not provided in the published literature. Article citation is included. See 3004785967-2021-01019 for imaging system allegation. System product number and serial number not provided in journal article. Udi not available for this system. No 510k provided as system is unknown. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
3005099803-2021-03649	26/03/2021	Injury	BOSTON SCIENTIFIC CORPORATION	22/07/2021	OVB	SPACEOAR SYSTEM	Positioning Problem	Inflammation; Pain; Fluid Discharge	It was reported to boston scientific corporation that spaceoar was implanted during a spaceoar placement procedure performed on (b)(6) 2021. The procedure was done under local anesthesia. It was reported that there was a suspected fistula in the rectum however, the definitive diagnosis is inflammation. The patient also experienced rectal pain. After spaceoar insertion, stereotactic body radiation therapy (sbrt) ((b)(6) irradiation with 40gy/5fr was performed, after that, yellow mucus was constantly discharged for two months it was attributed to the inflammation. Blood test showed two c-reactive proteins (crp), elevated neutrophils, and the inflammatory response persisted, but not enough to suggest an abscess. The subsequent magnetic resonance imaging (mri) showed that only a small part of gel was leaking into the rectal wall of the needle path. The patient was treated with

									an antibiotic. Manufacturer narrative: the complainant was unable to provide the suspect device lot number. Therefore, the expiration and device manufacture dates are unknown. (b)(4). The complainant indicated that the device remains implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental mdr will be filed.
2182207-2021-00907	23/03/2021	Injury	MEDTRONIC NEUROMODULATION	26/05/2021	MBX	IMPLANTABLE NEUROSTIMULATOR	Break	No Clinical Signs, Symptoms or Conditions	Summary: deep brain stimulation (dbs) is an established treatment for patients with medical refractory movement disorders with continuously increasing use also in other neurological and psychiatric diseases. Early and late complications can lead to revision surgeries with partial or complete dbs-system removal. In this study, the authors aimed to report on their experience with a frameless x-ray-based lead re-implantation technique after partial hardware removal or dysfunction of dbs-system, allowing the preservation of intracerebral trajectories. The authors describe a surgical procedure with complete implant removal due to infection except for the intracranial part of the electrode and with non-stereotactic electrode re-implantation. A retrospective analysis of a patient series treated using this technique was performed and the surgical outcome was evaluated including radiological and clinical parameters. A total of 8 dbs-patients with lead re-implantation using the frameless x-ray-based method were enrolled in the study. A revision of 14 leads was performed, whereof a successful lead re-implantation could be achieved without any problems in 10 leads (71%). In two patients (one patient with dystonia and one patient with tremor), the procedure was not successful, so the authors placed both leads frame-based stereotactically. The described x-ray-based technique allows a reliable frameless electrode re-implantation after infection and electrode dysfunction and might represent an efficient alternative to

									frame-based procedures for lead revision making the preservation of intracerebral trajectories possible. Reported events: a (b)(6) male patient implanted for epilepsy experienced lead rupture leading to explant and replacement. No specific device information could be identified in the article. See attached literature article. Manufacturer narrative: malinova v, jaskolski dj, wojcik r, mielke d, rohde v. Frameless x-ray-based lead re-implantation after partial hardware removal of deep brain stimulation system with preservation of intracerebral trajectories. Acta neurochirurgica. 2021. 10.1007/s00701-021-04807-1. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Other applicable components are: product id: neu_unknown_lead, serial/lot #: unknown, ubd: , udi#: (b)(4). If information is provided in the future, a supplemental report will be issued.
2182207-2021-00906	23/03/2021	Injury	MEDTRONIC NEUROMODULATION	26/05/2021	MHY	IMPLANTABLE NEUROSTIMULATOR	Break; Insufficient Information	Unspecified Infection; No Clinical Signs, Symptoms or Conditions	Summary: deep brain stimulation (dbs) is an established treatment for patients with medical refractory movement disorders with continuously increasing use also in other neurological and psychiatric diseases. Early and late complications can lead to revision surgeries with partial or complete dbs-system removal. In this study, the authors aimed to report on their experience with a frameless x-ray-based lead re-implantation technique after partial hardware removal or dysfunction of dbs-system, allowing the preservation of intracerebral trajectories. The authors describe a surgical procedure with complete implant removal due to infection except for

									the intracranial part of the electrode and with non-stereotactic electrode re-implantation. A retrospective analysis of a patient series treated using this technique was performed and the surgical outcome was evaluated including radiological and clinical parameters. A total of 8 dbs-patients with lead re-implantation using the frameless x-ray-based method were enrolled in the study. A revision of 14 leads was performed, whereof a successful lead re-implantation could be achieved without any problems in 10 leads (71%). In two patients (one patient with dystonia and one patient with tremor), the procedure was not successful, so the authors placed both leads frame-based stereotactically. The described x-ray-based technique allows a reliable frameless electrode re-implantation after infection and electrode dysfunction and might represent an efficient alternative to frame-based procedures for lead revision making the preservation of intracerebral trajectories possible. Reported events: a (b)(6) year old male patient implanted for parkinson's disease experienced infection of the ins and extension site resulting in explant of the entire system. The ins and extensions were removed and leads were cut in one procedure. The leads were replaced later following minimum 6-week antibiotic therapy and uneventful wound healing. A (b)(6) year old male patient implanted for parkinson's disease experienced infection of the extension site resulting in explant of the entire system. The ins and extensions were removed and leads were cut in one procedure. The leads were replaced later following minimum 6-week antibiotic therapy and uneventful wound healing. A (b)(6) year old female patient implanted for parkinson's disease experienced lead rupture leading to explant. The patient was later re-implanted. A (b)(6) year old male patient implanted for parkinson's disease experienced lead dysfunction (loss of stimulation or cableFracture) leading to explant. The

									patient was later re-implanted. No specific device information could be identified in the literature article. Manufacturer narrative: malinova v, jaskolski dj, wojcik r, mielke d, rohde v. Frameless x-ray-based lead re-implantation after partial hardware removal of deep brain stimulation system with preservation of intracerebral trajectories. Acta neurochirurgica. 2021. 10.1007/s00701-021-04807-1. Age or date of birth/sex: date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Other relevant device(s) are: product id: neu_unknown_ext, serial/lot #: unknown, udi#: asku ; product id: neu_unknown_lead, serial/lot #: unknown, udi#: asku ; product id: neu_ins_stimulator, serial/lot #: unknown, udi#: asku ; product id: neu_unknown_ext, serial/lot #: unknown, udi#: asku ; product id: neu_unknown_lead, serial/lot #: unknown, udi#: asku ; product id: neu_unknown_lead, serial/lot #: unknown, udi#: asku ; product id: neu_unknown_lead, serial/lot #: unknown, udi#: asku. If information is provided in the future, a supplemental report will be issued.
2182207-2021-00908	23/03/2021	Injury	MEDTRONIC NEUROMODULATION	26/05/2021	MRU	IMPLANTABLE NEUROSTIMULATOR	Malposition of Device; Adverse Event Without Identified Device or Use Problem	Unspecified Infection; No Clinical Signs, Symptoms or Conditions	Summary: deep brain stimulation (dbs) is an established treatment for patients with medical refractory movement disorders with continuously increasing use also in other neurological and psychiatric diseases. Early and late complications can lead to revision surgeries with partial or complete dbs-system removal. In this study, the authors aimed to report on their experience with a frameless x-ray-based lead re-implantation technique after partial

									hardware removal or dysfunction of dbs-system, allowing the preservation of intracerebral trajectories. The authors describe a surgical procedure with complete implant removal due to infection except for the intracranial part of the electrode and with non-stereotactic electrode re-implantation. A retrospective analysis of a patient series treated using this technique was performed and the surgical outcome was evaluated including radiological and clinical parameters. A total of 8 dbs-patients with lead re-implantation using the frameless x-ray-based method were enrolled in the study. A revision of 14 leads was performed, whereof a successful lead re-implantation could be achieved without any problems in 10 leads (71%). In two patients (one patient with dystonia and one patient with tremor), the procedure was not successful, so the authors placed both leads frame-based stereotactically. The described x-ray-based technique allows a reliable frameless electrode re-implantation after infection and electrode dysfunction and might represent an efficient alternative to frame-based procedures for lead revision making the preservation of intracerebral trajectories possible. Reported events: a (b)(6) female patient implanted for dystonia experienced infection of the extension site resulting in explant of the entire system. The ins and extensions were removed and leads were cut in one procedure. The leads were replaced later following minimum 6-week antibiotic therapy and uneventful wound healing. A (b)(6) female patient implanted for dystonia underwent lead re-implant due to failure to place the lead along the same trajectory using frameless x-ray-based lead implant approach. A new lead was placed using frame-based stereotaxy. No specific device information could be identified in the article. Manufacturer narrative: malinova v, jaskolski dj, wojcik r, mielke d, rohde v. Frameless x-ray-based lead re-implantation after partial hardware removal of deep

									brain stimulation system with preservation of intracerebral trajectories. Acta neurochirurgica. 2021. 10.1007/s00701-021-04807-1. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Other applicable components are: product id: neu_unknown_ext, serial/lot #: unknown, udi#: asku; product id: neu_unknown_lead, serial/lot #: unknown, udi#: asku; product id: neu_unknown_lead, serial/lot #: unknown, udi#: asku. If information is provided in the future, a supplemental report will be issued.
2182207-2021-00901	23/03/2021	Injury	MEDTRONIC NEUROMODULATION	26/05/2021	PJS	IMPLANTABLE NEUROSTIMULATOR	Malposition of Device; Insufficient Information	Unspecified Infection; No Clinical Signs, Symptoms or Conditions	Summary: deep brain stimulation (dbs) is an established treatment for patients with medical refractory movement disorders with continuously increasing use also in other neurological and psychiatric diseases. Early and late complications can lead to revision surgeries with partial or complete dbs-system removal. In this study, the authors aimed to report on their experience with a frameless x-ray-based lead re-implantation technique after partial hardware removal or dysfunction of dbs-system, allowing the preservation of intracerebral trajectories. The authors describe a surgical procedure with complete implant removal due to infection except for the intracranial part of the electrode and with non-stereotactic electrode re-implantation. A retrospective analysis of a patient series treated using this technique was performed and the surgical outcome was evaluated including radiological and clinical parameters. A total of 8 dbs-patients with lead re-implantation using the frameless x-ray-based method were

									enrolled in the study. A revision of 14 leads was performed, whereof a successful lead re-implantation could be achieved without any problems in 10 leads (71%). In two patients (one patient with dystonia and one patient with tremor), the procedure was not successful, so the authors placed both leads frame-based stereotactically. The described x-ray-based technique allows a reliable frameless electrode re-implantation after infection and electrode dysfunction and might represent an efficient alternative to frame-based procedures for lead revision making the preservation of intracerebral trajectories possible. Reported events: a (b)(6) male patient implanted for tremor experienced infection of the ins and extension site resulting in explant of the entire system. The ins and extensions were removed and leads were cut in one procedure. The leads were replaced later following minimum 6-week antibiotic therapy and uneventful wound healing. A (b)(6) male patient implanted for tremor experienced lead dysfunction (loss of stimulation or cableFracture) leading to explant. The patient was later re-implanted. One patient implanted for tremor underwent lead re-implant due to failure to place the lead along the same trajectory using frameless x-ray-based lead implant approach. A new lead was placed using frame-based stereotaxy. No specific device information could be identified in the literature article. Manufacturer narrative: malinova v, jaskolski dj, wojcik r, mielke d, rohde v. Frameless x-ray-based lead re-implantation after partial hardware removal of deep brain stimulation system with preservation of intracerebral trajectories. Acta neurochirurgica. 2021. 10.1007/s00701-021-04807-1. Event 3 is either involving patient from event 1 or event 2, but it could not be determined from the article. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not

									possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Other relevant device(s) are: product id: neu_unknown_ext, serial/lot #: unknown, ubd: , udi#: asku ; product id: neu_unknown_lead, serial/lot #: unknown, ubd: , udi#: asku ; product id: neu_unknown_lead, serial/lot #: unknown, ubd: , udi#: asku ; product id: neu_unknown_lead, serial/lot #: unknown, ubd: , udi#: asku. If information is provided in the future, a supplemental report will be issued.
1222780-2021-00091	22/03/2021	Malfunction	HOLOGIC, INC.	23/04/2021	KNW	EVIVA STEREOTACTIC GUIDED BREAST BIOPSY SYSTEM	Material Deformation	No Clinical Signs, Symptoms or Conditions	It was reported that during a biopsy procedure, when trying to remove the needle to put in the clip the introducer seemed to be stuck to the needle and the patient. When the introducer was removed it was noted to be "scrunched up." no injury reported. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
3004785967-2021-01164	02/03/2021	Injury	MEDTRONIC NAVIGATION, INC (LITTLETON)	30/09/2021	OXO	O-ARM IMAGING SYSTEM	Adverse Event Without Identified Device or Use Problem	Cardiac Arrest; Hematoma; Hemorrhage/Bleeding; Intracranial Hemorrhage; Unspecified Infection; Depression	Ribault, s., simon, e., berthiller, j., polo, g., nunes, a., brinzeu, a., mertens, p., danaila, t., thobois, s., laurencin, c. Comparison of clinical outcomes and accuracy of electrode placement between robot-assisted and conventional deep brain stimulation of the subthalamic nucleus: a single-center study. Acta neurochirurgica 2021 163:1327¿1333https://doi.org/10.1007/s00701-021-04790-7 background several surgical methods are used for deep brain stimulation (dbs) of the subthalamic nucleus (stn) in parkinson¿s disease (pd). This study aimed to compare clinical outcomes and electrode placement accuracy after robot assisted (ras) versus frame-based stereotactic (fss) stn dbs in parkinson¿s

									disease. Methods in this single-center open-label study, we prospectively collected data from 48 consecutive pd patients who underwent ras (n euromate®; n = 20) or fss (n = 28) stn dbs with the same mri-based stn targeting between october 2016 and december 2018 in the university neurological hospital of lyon, france. Clinical variables were assessed before and 1 year after surgery. The number of electrode contacts within the stn was determined by merging post-operative ct and pre-operative mri using brainlab® guide¿xt software. Results one year after surgery, the improvement of motor manifestations (p = 0.18), motor complications (p = 0.80), and quality of life (p= 0.30) and the reduction of dopaminergic treatment (p = 0.94) and the rate of complications (p = 0.99) were similar in the two groups. Surgery duration was longer in the ras group (p = 0.0001). There was no difference in the number of electrode contacts within the stn. Conclusion: this study demonstrates that ras and fss stn dbs for pd provide similar clinical outcomes and accuracy of electrode placement. Reported incidents 1 severe psychiatric case where the patient had severe depression 1 subarachnoid hemorrhage accompanied by an intraparenchymal hemorrhage with persistent motor and cognitive disabling 1 subdural hematoma with ad integrum recovery and spontaneous resorption 1 asymptomatic intraparenchymal hemorrhage. 1 infection requiring ablation and repositioning of leads and ipg 1 subarachnoid hemorrhage with intraparenchymal hemorrhage without any sequelae 1 junctional cardio-embolic stroke within days after the surgery. Manufacturer narrative: patient age is the mean value of patients in the study. Patient gender is the majority value of patients in the study. Patient weight not available from the site. Event date is the online publishing date of the literature article. Device lot number, or serial number, unavailable. 510(k) is

									dependent upon the device model number and is therefore, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacture date is dependent on the device lot/serial number, therefore is unavailable. If information is provided in the future, a supplemental report will be issued.
2182207-2021-00726	02/03/2021	Injury	MEDTRONIC NEUROMODULATION	29/04/2021	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Stroke/CVA; Intracranial Hemorrhage; Unspecified Infection	Ribault s, simon e, berthiller j, et al. Comparison of clinical outcomes and accuracy of electrode placement between robot-assisted and conventional deep brain stimulation of the subthalamic nucleus: a single-center study. Acta neurochir (wien). 2021. 10.1007/s0 0701-021-04790-7. Several surgical methods are used for deep brain stimulation (dbs) of the subthalamic nucleus (stn) in parkinson¿s disease (pd). This study aimed to compare clinical outcomes and electrode placement accuracy after robot assisted (ras) versus frame-based stereotactic (fss) stn dbs in parkinson¿s disease. It was stated that 22 of the patient's involved were implanted with a device from this manufacturer, and 26 of the devices were a different manufacturer. Reported events: 4 patients experienced intracranial bleedings described as subarachnoid hemorrhage, intraparenchymal hemorrhage. One patient experienced infection requiring ablation and repositioning of the system. 1 patient experienced cardio-embolic stroke within days of surgery. 1 patient experienced severe depression. 1 patient experienced severe psychiatric decompensation. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: information references the main component of the system. Other relevant device(s) are: product id: neu_ins_stimulator, serial/lot #: unknown, ubd:, udi#:. Product id: neu_ins_stimulator, serial/lot #: unknown, ubd:, udi#:. Age or date of birth. This value is the average age of the patients reported in the article as specific patients could not

									be identified. Sex. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. If information is provided in the future, a supplemental report will be issued.
3004785967-2021-00524	23/02/2021	Injury	MEDTRONIC NAVIGATION, INC (LITTLETON)	23/04/2021	OXO	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage; Unspecified Infection; Depression; Cognitive Changes	Citation: shams ribault, emile simon, julien berthiller, gustavo polo, adélaïde nunes, andrei brinzeu, patrick mertens, teodor danaila, stéphane thobois, chloé laurencin. Comparison of clinical outcomes and accuracy of electrode placement between robot-assisted and conventional deep brain stimulation of the subthalamic nucleus: a single-center study. Acta neurochirurgica. 2021. Https://doi.org/10.1007/s00701-021-04790-7 abstract: background several surgical methods are used for deep brain stimulation (dbs) of the subthalamic nucleus (stn) in parkinson¿s disease (pd). This study aimed to compare clinical outcomes and electrode placement accuracy after robot assisted (ras) versus frame-based stereotactic (fss) stn dbs in parkinson¿s disease. Methods in this single-center open-label study, we prospectively collected data from 48 consecutive pd patients who underwent ras (neuromate®; n = 20) or fss (n = 28) stn dbs with the same mri-based stn targeting between october 2016 and december 2018 in the university neurological hospital of lyon, france. Clinical variables were assessed before and 1 year after surgery. The number of electrode contacts within the stn was determined by merging post-operative ct and pre-operative mri using brainlab® guide¿xt software. Results one year after surgery, the improvement of motor manifestations (p = 0.18), motor complications (p = 0.80), and quality of life (p= 0.30) and the reduction of dopaminergic treatment (p = 0.94) and the rate of complications (p = 0.99) were similar in the two groups.

									Surgery duration was longer in the ras group (p = 0.0001). There was no difference in the number of electrode contacts within the stn. Conclusion this study demonstrates that ras and fss stn dbs for pd provide similar clinical outcomes and accuracy of electrode placement. Reported events: fss group. One severe psychiatric decompensation. Three intracranial bleedings. One subarachnoid hemorrhage accompanied by an intraparenchymal hemorrhage with persistent motor and cognitive disabling. One subdural hematoma with ad integrum recovery. One symptomatic intraparenchymal hemorrhage. Ras group. One case of severe depression. One infection requiring ablation and repositioning of leads and ipg. One subarachnoid hemorrhage with intraparenchymal hemorrhage without sequelae. One junctional cardio-embolic stroke within days after the surgery manufacturer narrative: patient age is the mean value of patients in the study. Patient gender is the majority value of patients in the study. Patient weight not available from the site. Event date is the accepted date of the publication. Device lot number, or serial number, unavailable. 510(k) is dependent upon, therefore unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
2182207-2021-00687	22/02/2021	Injury	MEDTRONIC NEUROMODULATION	23/04/2021	MHY	IMPLANTABLE NEUROSTIMULATOR	Malposition of Device; Adverse Event Without Identified Device or Use Problem	Unspecified Infection; Cognitive Changes; No Clinical Signs, Symptoms or Conditions	Almahariq f, sedmak g, vuletic v, et al. The accuracy of direct targeting using fusion of mr and ct imaging for deep brain stimulation of the subthalamic nucleus in patients with parkinson's disease. J neurol surg a cent eur neurosurg. 2021. 10.1055/s-0040-1715826 summary: in 33 consecutive patients with parkinson¿s disease (pd) undergoing awake deep brain stimulation (dbs) without microelectrode recording (mer), we assessed and validated the precision and accuracy of direct targeting of

									the subthalamic nucleus (stn) using preoperative magnetic resonance imaging (mri) and stereotactic computed tomography (ct) image fusion combined with immediate postoperative stereotactic ct and postoperative mri, and we report on the side effects and clinical results up to 6 months¿ follow-up. Identified events: 33 patients had slight inaccuracies in their lead placement. The observed differences between the planned electrode position and the final lead position were similar in values reported in previous studies and were considered satisfactory to provide good clinical outcomes. 1 patient experienced postoperative infection in the pectoral subcutaneous pocket, requiring a removal of the system. Of note, the patient has had a history of various infections indicating they have a susceptibility towards infections. Some patients had the electrode moved after two years due to psychiatric issues. The patients' state was described as a mood disorder and could not be associated with the known adverse side effects of dbs. The subjective issues were noted as improvement in independency and acceptance of lack of motor symptoms, accompanied by constant scratching of the wound. The issue was treated by adjusting the stimulation protocol and no additional medication was necessary. Manufacturer narrative: other relevant device(s) are: product id: neu_unknown_lead, serial/lot #: unknown; product id: neu_unknown_lead, serial/lot #: unknown.
1222780-2021-00040	05/02/2021	Malfunction	HOLOGIC, INC.	04/03/2021	KNW	EVIVA STEREOTACTIC GUIDED BREAST BIOPSY SYSTEM	Material Deformation	Pain	It was reported that during a biopsy procedure, a sample wasn't able to be collected and the needle was stuck in the patient breast. When the needle was removed from the breast it was noted that the sheath was completely wrinkled. The patient had pain while removing the needle, no injury reported. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. Device history

									record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
3005099803-2021-01137	01/02/2021	Malfunction	BOSTON SCIENTIFIC CORPORATION	22/03/2021	OVB	SPACEOAR SYSTEM	Adverse Event Without Identified Device or Use Problem; Positioning Problem	No Clinical Signs, Symptoms or Conditions	It was reported to boston scientific corporation that spaceoar was implanted during a spaceoar placement procedure performed on an unknown date. Reportedly, fiducials were administered transperineally and the procedure was done under local anesthesia. During the procedure, the spaceoar gel was injected into the patient vein. There were no patient complications reported as a result of this event. The patient planned to receive stereotactic body radiation therapy (sbrt). Manufacturer narrative: the exact date of the event is unknown. The provided event date, (b)(6) 2021, was chosen as a best estimate based on the date that the manufacturer became aware of the event, (b)(6) 2021. The complainant was unable to provide the suspect device lot number. Therefore, the manufacture date and expiration date are unknown. (b)(6). (b)(4). The complainant indicated that the device remains implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental mdr will be filed.
1222780-2021-00068	01/02/2021	Malfunction	HOLOGIC, INC.	02/04/2021	KNW	EVIVA STEREOTACTIC GUIDED BREAST BIOPSY SYSTEM	Material Twisted/Bent	Intraoperative Pain; Breast Discomfort/Pain	It was reported that during a biopsy procedure, after taking several specimen, the patient complained of pain in the breast and the samples being cut were smaller than before. After drawing the needle back and out of the breast, the tip of the needle was noted to be "bent or even twisted." no serious injury reported and no medical intervention was required. This event occurred in (b)(6) 2021, but was not reported by the customer to hologic until (b)(6) 2021. Manufacturer narrative: the device is not being returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the

									reported identification number. The lot was released meeting all qa specifications.
11313116	01/02/2021	Malfunction	MEDTRONIC NAVIGATION, INC.	11/02/2021	HAW	STEALTH ARM 9734252	Mechanical Problem; Device Slipped; Use of Device Problem	Insufficient Information	Stealth arm failed to stay in locked position resulting in failure to use stereotactic navigation for the rest of the case.
3005099803-2021-00748	25/01/2021	Injury	BOSTON SCIENTIFIC CORPORATION	04/03/2021	OVB	SPACEOAR SYSTEM	Adverse Event Without Identified Device or Use Problem	Abscess; Micturition Urgency; Pain; Discomfort; Dysuria	It was reported to boston scientific corporation that spaceoar was implanted during a spaceoar placement procedure performed on (b)(6) 2020. Reportedly, the procedure was done under general anesthesia. It was reported, on (b)(6) 2021, the patient complained of dysuria, urgency, pain and discomfort. On (b)(6) 2021, the patient was re-admitted. Urine culture was performed and it showed white cells in it. The abdomen of the patient was very tense in the lower part and he was dull to percussion. The physician performed computerized tomography (ct) scan and it showed an abscess. The physician concluded that the abscess was caused by the spaceoar while dysuria, pain and discomfort were caused by the abscess. The urologist drained the abscess with interventional radiology (ir) transrectally, draining 21cc. The patient was put on vancomycin and intravenous(iv). He was also treated with cefotetan intraop and ceftonir (omnicef) for 5 days. Another computerized tomography (ct) scan was performed and it showed that abscess was markedly decreased. Reportedly, the patient has fully recovered. The patient completed stereotactic body radiation therapy (sbrt) cyberknife on the first week of (b)(6) 2020. Manufacturer narrative: the complainant was unable to provide the suspect device lot number. Therefore, the manufacture date and expiration date are unknown. (b)(4). The complainant indicated that the device remains implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further

									relevant information is identified, a supplemental mdr will be filed.
MW5098948	19/01/2021	Malfunction	DEVICOR MEDICAL PRODUCTS INC.	21/01/2021	FZP	MAMMOTOME BIOPSY SITE IDENTIFIER	Break	Foreign Body In Patient	During stereotactic breast biopsy, piece of insertion device for biopsy clip identifier broke off leaving plastic embedded at biopsy site. Abnabno. Fda safety report id# (b)(4).
2020394-2021-00373	15/01/2021	Malfunction	BARD PERIPHERAL VASCULAR, INC.	01/03/2021	KNW	ENCOR BIOPSY PROBE	Unintended Movement	No Clinical Signs, Symptoms or Conditions	It was reported that during a stereotactic vacuum breast biopsy through calcified tissue, the device allegedly had an unintended movement. There was no reported patient injury. Manufacturer narrative: as the lot number for the device was not provided, a review of the device history records could not be performed. The sample was not returned to the manufacturer for inspection/evaluation. Therefore, the investigation of the reported event is inconclusive. Based upon the available information, the definitive root cause for this event is unknown. The instructions for use (ifu) is adequate for the reported device/patient code(s) and provides general instructions for use, as well as warnings, precautions and potential complications associated with the device. Upon receipt of new or additional information, a follow-up report will be submitted as applicable.
1723170-2021-02380	14/01/2021	Injury	MEDTRONIC NAVIGATION, INC	27/09/2021	HAW	STEALTHSTATION S7	Adverse Event Without Identified Device or Use Problem	Headache; Intracranial Hemorrhage	Citation: carlos e. Restrepo, david b. Clarke, p. Daniel mcneely, matthew d. Cooper, murray hong, ron hill, lutz m. Weise. Validation of 3d fl uoroscopy for image-guidance registration in depth electrode implantation for medically refractory epilepsy. Acta neurochirurgica (2021) 163:1347-1354. Https://doi.org/10.1007/s00701-021-04706-5 abstract: background: frame registration is a critical step to ensure accurate electrode placement in stereotactic procedures such as stereoel ectroencephalography (seeg) and is routinely done by merging a computed tomography (ct) scan with the preoperative magnetic resonance (mr) examination. Three-dimensional fluoroscopy (xt) has emerged as a method for intraoperative

									electrode verification following electrode implantation and more recently has been proposed as a registration method with several advantages. Methods: we compared the accuracy of seeg electrode placement byframe registration with ct and xt imaging by analyzing the euclidean distance between planned and post-implantation trajectories of the seeg electrodes to calculate the error in both the entry (ep) and target (tp) points. Other variables included radiation dose, efficiency, and complications. Results: twenty-seven patients (13 ct and 14 xt) underwent placement of seeg electrodes (319 in total). The mean ep and tp errors for the ct group were 2.3 mm and 3.3 mm, respectively, and 1.9 mm and 2.9 mm for the xt group, with no statistical difference (p = 0.75 and p = 0.246). The time to first electrode placement was similar (xt, 82 ± 10 min; ct, 84 ± 22 min; p = 0.858) and the average radiation exposure with xt (234 ± 55 mgy*cm) was significantly lower than ct (1245 ± 123 mgy*cm) (p <(> <<)> 0.0001). Four complications were documented with equal incidence in both groups. Conclusions: the use of xt as a method for registration resulted in similar implantation accuracy compared with ct. Advantages of xt are the substantial reduction in radiation dose and the elimination of the need to transfer the patient out of the room which may have an impact on patient safety and or efficiency. Reported events: 1) two patients experienced intracranial hemorrhages in post-operative computed tomography (ct) scans. A. One hemorrhage was noted to be symptomatic with a transient mild headache and no neurological deficit. Manufacturer narrative: patient age is the mean value of patients in the xt group. Patient gender is the majority value of patients in the xt group. Patient weight not available from the site. Event date is the online publishing date of the literature article. Device lot number, or serial number, unavailable. No parts have been received by

									the manufacturer for evaluation. Device manufacture date is dependent on the device lot/serial number, therefore is unavailable. If information is provided in the future, a supplemental report will be issued.
3004785967-2021-01150	14/01/2021	Injury	MEDTRONIC NAVIGATION, INC (LITTLETON)	27/09/2021	OWB	O-ARM O2 IMAGING SYSTEM	Adverse Event Without Identified Device or Use Problem	Headache; Intracranial Hemorrhage	Citation: carlos e. Restrepo, david b. Clarke, p. Daniel mcneely, matthew d. Cooper, murray hong, ron hill, lutz m. Weise. Validation of 3d fluoroscopy for image-guidance registration in depth electrode implantation for medically refractory epilepsy. Acta neurochirurgica (2021) 163:1347-1354. Https://doi.org/10.1007/s00701-021-04706-5. Abstract: background: frame registration is a critical step to ensure accurate electrode placement in stereotactic procedures such as stereo electroencephalography (seeg) and is routinely done by merging a computed tomography (ct) scan with the preoperative magnetic resonance (mr) examination. Three-dimensional fluoroscopy (xt) has emerged as a method for intraoperative electrode verification following electrode implantation and more recently has been proposed as a registration method with several advantages. Methods: we compared the accuracy of seeg electrode placement by frame registration with ct and xt imaging by analyzing the euclidean distance between planned and post-implantation trajectories of the seeg electrodes to calculate the error in both the entry (ep) and target (tp) points. Other variables included radiation dose, efficiency, and complications. Results: twenty-seven patients (13 ct and 14 xt) underwent placement of seeg electrodes (319 in total). The mean ep and tp errors for the ct group were 2.3 mm and 3.3 mm, respectively, and 1.9 mm and 2.9 mm for the xt group, with no statistical difference (p = 0.75 and p = 0.246). The time to first electrode placement was similar (xt, 82 ¿ 10 min; ct, 84 ¿ 22 min; p = 0.858) and the average radiation exposure with xt (234 ¿ 55 mgy*cm) was significantly lower than ct

									(1245 ¿ 123 mgy*cm) (p < 0.0001). Four complications were documented with equal incidence in both groups. Conclusions: the use of xt as a method for registration resulted in similar implantation accuracy compared with ct. Advantages of xt are the substantial reduction in radiation dose and the elimination of the need to transfer the patient out of the room which may have an impact on patient safety and or efficiency. Reported events: two patients experienced intracranial hemorrhages in post-operative computed tomography (ct) scans. A. One hemorrhage was noted to be symptomatic with a transient mild headache and no neurological deficit. Manufacturer narrative: age or date of birth: patient age is the mean value of patients in the xt group. Sex) patient gender is the majority value of patients in the xt group. Weight: patient weight not available from the site. Event date is the online publishing date of the literature article. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacture date is dependent on the device lot/serial number, therefore is unavailable. Mdr 1723170-2021-02380 documents the medtronic navigation system used in the literature article. If information is provided in the future, a supplemental report will be issued.
1222780-2021-00027	13/01/2021	Malfunction	HOLOGIC, INC.	05/02/2021	KNW	EVIVA STEREOTACTIC GUIDED BREAST BIOPSY SYSTEM	Material Twisted/Bent	Pain	It was reported that during a biopsy procedure, following lavage the probe was rotated to help collapse the cavity and the patient complained of pain. The needle was seen to be bent on subsequent images. Manufacturer narrative: device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
1222780-2021-00026	11/01/2021	Malfunction	HOLOGIC, INC.	05/02/2021	KNW	EVIVA STEREOTACTIC GUIDED BREAST BIOPSY SYSTEM	Inability to Irrigate	Hematoma; Pain	It was reported that during a biopsy the chamber holding the local anaesthetic would not hold in place and the saline did not flush through the system during the procedure. These issues resulted in the patient not receiving adequate local anaesthetic and may have caused a larger

									amount of hematoma at the biopsy site. The biopsy site was not able to be flushed with saline during lavage which caused the biopsy marker to move from the biopsy site. Attempts to obtain additional information were unsuccessful. Manufacturer narrative: device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
MW5098866	08/01/2021	Malfunction	HOLOGIC, INC.	15/01/2021	NEU	HOLOGIC LOCALIZER	Break; Malposition of Device	Failure of Implant	Patient undergoing stereotactic guided tag localizer on left breast. When the tag was deployed, the provider said it felt unusual. When post-procedure imaging was done, the tag was several centimeters away from target. Provider could see tag was broken after deployment. Patient will need to return for another procedure due to defective product. Fda safety report id # (b)(4).
3008492462-2021-00001	05/01/2021	Malfunction	DEVICOR MEDICAL PRODUCTS INC	03/02/2021	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE	Break	Foreign Body In Patient	It was reported by sales rep during procedure, fragments left in breast after firing and biopsy. This incident has been documented as complaint # (b)(4). Manufacturer narrative: the mammotome revolve dual vacuum assisted biopsy system is intended to obtain tissue samples from the breast or axillary nodes for diagnosic analysis of breast abnormalities. Images provided did not contain information that could confirm what caused the alledged failure. The device has not been returned for evaluation, which prevents a full investigation and analysis of the root cause at this time. Patient did not undergo any additional surgery, however, due to the allegation of foreign material we are submitting this medwatch report pursuant to 21 cfr 803.
3005099803-2021-00350	01/01/2021	Injury	BOSTON SCIENTIFIC CORPORATION	10/02/2021	OVB	SPACEOAR SYSTEM	Adverse Event Without Identified Device or Use Problem	Abscess; Unspecified Infection; Perforation	It was reported to boston scientific corporation that spaceoar was implanted during a spaceoar placement procedure performed on an unknown date. According to the complainant, the physician noted the spaceoar placement looked ideal on computerized tomography (ct) scan and magnetic resonance imaging (mri). Two months after stereotactic body radiation

									therapy (sbrt) treatment, the patient has developed an abscess between the prostate and rectum, and subsequently had rectal perforation. Patient was treated with oral antibiotics. Reportedly, magnetic resonance imaging (mri) was performed again and it showed a walled off gel material or possibly gel mixed with abscess walled off and communicating with the rectum through a perforation. Boston scientific has been unable to obtain additional information regarding the event to date, despite good faith efforts. Manufacturer narrative: the exact date of the event is unknown. The provided event date, (b)(6) 2021, was chosen as a best estimate based on the date that the manufacturer became aware of the event, (b)(6) 2021. (b)(4). The complainant indicated that the device remains implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental mdr will be filed.
11123078	22/12/2020	Malfunction	HOLOGIC, INC.	06/01/2021	KNW	INSTRUMENT, BIOPSY	Application Program Problem: Dose Calculation Error	Insufficient Information	Patient was positioned for stereotactic biopsy, cleaned off and numbed and small incision made for biopsy device. The radiologist began to wind the biopsy device to target but noticed that something did not seem right with the target numbers. The calculation was showing to be at the target already without any manipulation from the radiologist, but the device was still outside of the breast. The staff re-targeted for a new calculation and the same scenario happened. The patient was moved to a backup biopsy room and the exam was able to be completed.
11116283	18/12/2020	Malfunction	SIEMENS HEALTHCARE GMBH	05/01/2021	MUE	MAMMOMAT REVELATION	Failure to Power Up; Device Displays Incorrect Message	Insufficient Information	When attempting a stereotactic biopsy, the biopsy needle was attached. When the tube head was moved back into position after attaching the needle, the machine stopped responding and kept showing error messages. Could not move tube head out of the way again to remove the biopsy needle. Had to use the compression paddle emergency release button to remove patient from the machine. After reboot and

									shut down the machine would not come back up. Patient had to be rescheduled to another day and siemens was called for an emergency service call.
2182207-2021-00286	16/12/2020	Injury	MEDTRONIC NEUROMODULATION	19/02/2021	MHY	IMPLANTABLE NEUROSTIMULATOR	Migration or Expulsion of Device; Adverse Event Without Identified Device or Use Problem	Unspecified Infection; Swelling/ Edema; No Clinical Signs, Symptoms or Conditions	Goransson n, johansson jd, wardell k, zsigmond p. Postoperative lead movement after deep brain stimulation surgery and the change of stimulation volume. Stereotact funct neurosurg. 2020:1-9. 10.1159/000511406 summary: lead movement after deep brain stimulation may occur and influence the affected volume of stimulation. The aim of the study was to investigate differences in lead position between the day after surgery and approximately 1 month postoperatively and also simulate the electric field (ef) around the active contacts in order to investigate the impact of displacement on affected volume. Methods: twenty-three patients with movement disorders underwent deep brain stimulation surgery (37 leads). Computed tomography at the 2 time points were co-fused respectively with the stereotactic images in surgiplan. The coordinates (x, y, and z) of the lead tips were compared between the 2 dates. Eleven of these patients were selected for the ef simulation in comsol multiphysics. Postoperative changes of ef spread in the tissue due to conductivity changes in perielectrode space and due to displacement were evaluated by calculating the coverage coefficient and the sørensen-dice coefficient identified events: 37 total leads had movement/migration and were displaced. In addition, there was edema noticed around the leads. One patient suffered from an early infection and the dbs system was removed. The following device specifics were provided: lead model 3389, ins models 37601 and 37603. Manufacturer narrative: goransson n, johansson jd, wardell k, zsigmond p. Postoperative lead movement after deep brain stimulation surgery and the change of stimulation volume. Stereotact funct neurosurg. 2020:1-9. 10.1159/000511406.

									Other relevant device(s) are: product id: 3389, serial/lot #: unknown. This value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. If information is provided in the future, a supplemental report will be issued.
1723170-2021-02165	11/12/2020	Injury	MEDTRONIC NAVIGATION, INC	30/08/2021	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Unspecified Nervous System Problem; Unspecified Tissue Injury	Citation: dhiego c. A. Bastos, rafael a. Vega, jeffrey i. Traylor, amol j. Ghia, jing li, md,2 marilou oro, andrew j. Bishop, debra n. Yeboa, behrang amini, vinodh a. Kumar, ganesh rao, laurence d. Rhines, and claudio e. Tatsui. Spinal laser interstitial thermal therapy: single-center experience and outcomes in the first 120 cases. J neurosurg spine 34:354-363, 2021. Https://thejns.org/doi/abs/10.3171/2020.7.spine20661 abstract: objective the objective of this study was to present the results of a consecutive series of 120 cases treated with spinal laser interstitial thermal therapy (slitt) to manage epidural spinal cord compression (escc) from metastatic tumors. Methods the electronic records of patients treated from 2013 to 2019 were analyzed retrospectively. Data collected included demographic, pathology, clinical, operative, and imaging findings; degree of epidural compression before and after slitt; length of hospital stay; complications; and duration before subsequent oncological treatment. Independent-sample t-tests were used to compare means between pre- and post-slitt treatments. Survival was

									estimated by the kaplan-meier method. Multivariate logistic regression was used to analyze predictive factors for local recurrence and neurological complications. Results there were 110 patients who underwent 120 slitt procedures. Spinal levels treated included 5 cervical, 8 lumbar, and 107 thoracic. The pre-slitt frankel grades were e (91.7%), d (6.7%), and c (1.7%). The preoperative escc grade was 1c or higher in 92% of cases. Metastases were most common from renal cell carcinoma (39%), followed by non¿small cell lung carcinoma (10.8%) and other tumors (35%). The most common location of escc was in the vertebral body (88.3%), followed by paraspinal/foraminal (7.5%) and posterior elements (4.2%). Adjuvant radiotherapy (spinal stereotactic radiosurgery or conventional external beam radiation therapy) was performed in 87 cases (72.5%), whereas 33 procedures (27.5%) were performed as salvage after radiotherapy options were exhausted. Slitt was performed without need for spinal stabilization in 87 cases (72.5%). Post-slitt frankel grades were e (85%), d (10%), c (4.2%), and b (0.8%); treatment was associated with a median decrease of 2 escc grades. The local control rate at 1 year was 81.7%. Local control failure occurred in 25 cases (20.8%). The median progression-free survival was not reached, and overall survival was 14 months. Tumor location in the paraspinal region and salvage treatment were independent predictors of local recurrence, with hazard ratios of 6.3 and 3.3, respectively (p = 0.01). Complications were observed in 22 cases (18.3%). Slitt procedures performed in the lumbar and cervical spine had hazardratios for neurological complications of 15.4 and 17.1 (p <(><<)> 0.01), respectively, relative to the thoracic spine. Conclusions slitt is safe and provides effective local control for high-grade escc from vertebral metastases in the thoracic spine, particularly when combined with adjuvant radiotherapy. The

									authors propose considering slitt as an alternative to open surgery in selected patients with spinal metastases. Complications: 9 patients experienced neurological complications a. 2 patients were in the cervical spine level group b. 4 patients were in the thoracic spine level group c. 3 patients were in the lumbar spinal level group. 6 patients experienced medical complications. 7 patients experiencedFracture complications that required spinal stabilization procedures. Manufacturer narrative: patient age is the mean value of patients in the study. Patient gender is the majority value of patients in the study. Patient weight not available from the site. Event date is the online published date of the literature article. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacture date is dependent on the device lot/serial number, therefore is unavailable. If information is provided in the future, a supplemental report will be issued.
2020394-2021-00091	09/12/2020	Malfunction	BARD PERIPHERAL VASCULAR, INC.	01/02/2021	KNW	ENCOR BIOPSY PROBE	Device Misassembled During Manufacturing/Shipping; Device Contamination with Chemical or Other Material	No Clinical Signs, Symptoms or Conditions	It was reported that prior to a stereotactic guided breast biopsy procedure, the device allegedly received in unexpected configuration. The procedure was completed using another device. There was no patient contact. Manufacturer narrative: as the lot number for the device was provided, a review of the device history record is currently being performed. The device has been returned to the manufacturer for evaluation. The investigation of the reported event is currently underway. (expiry date: 09/2021).
1222780-2021-00070	01/12/2020	Malfunction	HOLOGIC, INC.	02/04/2021	KNW	EVIVA STEREOTACTIC GUIDED BREAST BIOPSY SYSTEM	Material Twisted/Bent	IntraoperativePain; Breast Discomfort/Pain	It was reported that during a biopsy, after taking 3-5 specimens, the patient complained of pain. When attempting additional samples the patient continued to have pain and the specimen passing the tube seemed to be smaller than usual. A control picture showed the deformed needle and a decision was made to stop the procedure. Difficulties in drawing the needle out of the breast. No serious injury

									reported and no medical intervention required. This event occured in (b)(6) 2020, but was not reported by the customer to hologic until (b)(6) 2021. Manufacturer narrative: the device is not being returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
2182207-2021-00242	30/11/2020	Injury	MEDTRONIC NEUROMODULATION	11/02/2021	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem; Insufficient Information	Hematoma; Unspecified Infection; Ambulation Difficulties; Suicidal Ideation	Summary: asleep deep brain stimulation (dbs) for parkinson¿s disease (pd) is being performed more frequently; however, motor outcomes and safety of asleep dbs have never been assessed in a prospective randomized trial. The authors conducted a prospective, randomized, noncomparative trial to assess the motor outcomes of asleep dbs. Leads were implanted in the subthalamic nucleus (stn) according to probabilistic stereotactic coordinates with a surgical robot under o-arm imaging guidance under either general anesthesia without microelectrode recordings (mer) (20 patients, asleep group) or local anesthesia with mer and clinical testing (9 patients, awake group). The mean motor improvement rates on the unified parkinson¿s disease rating scale part iii (updrs-3) between off and on stimulation without medication were 52.3% (95% ci: 45.4¿59.2%) in the asleep group and 47.0% (95% ci: 23.8¿70.2%) in the awake group, 6 months after surgery. Except for a subcutaneous hematoma, the authors did not observe any complications related to the surgery. Three patients (33%) in the awake group and 8 in the asleep group (40%) had at least one side effect potentially linked with neurostimulation. Owing to its randomized design, the authors' study supports the hypothesis that motor outcomes after asleep stn-dbs in pd may be nonin ferior to the standard awake procedure. Reported events: one patient experienced suicidal ideation. Six patients were re-operated for previous complications (infection and dysfunction).

									One patient experienced subcutaneous abdominal hematoma under the implantable neurostimulator (ins) which required puncture of the collection. One patient experienced postoperative freezing and walking disorders despite decrease in dyskinesia. The patient was re-operated on, but without any benefit from the second intervention. The patients were implanted for parkinson's disease. The following device information was identified in the article: lead model 3389-40. Manufacturer narrative: engelhardt j, caire f, damon-perriere n, et al. A phase 2 randomized trial of asleep versus awake subthalamic nucleus deep brain stimulation for parkinson's disease. Stereotact funct neurosurg. 2020:1-11. 10.1159/000511424. This value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Other relevant device(s) are: product id: neu_ins_stimulator, serial/lot #: unknown, udi#: (b)(4), product id: neu_ins_stimulator, serial/lot #: unknown, udi#: (b)(4), product id: neu_ins_stimulator, serial/lot #: unknown, udi#: (b)(4). If information is provided in the future, a supplemental report will be issued.
2182207-2021-00243	30/11/2020	Malfunction	MEDTRONIC NEUROMODULATION	11/02/2021	MHY	IMPLANTABLE NEUROSTIMULATOR	Insufficient Information	No Clinical Signs, Symptoms or Conditions	Summary: asleep deep brain stimulation (dbs) for parkinson¿s disease (pd) is being performed more frequently; however, motor outcomes and safety of asleep dbs have never been assessed in a prospective randomized trial. The authors conducted a

									prospective, randomized, noncomparative trial to assess the motor outcomes of asleep dbs. Leads were implanted in the subthalamic nucleus (stn) according to probabilistic stereotactic coordinates with a surgical robot under o-arm imaging guidance under either general anesthesia without microelectrode recordings (mer) (20 patients, asleep group) or local anesthesia with mer and clinical testing (9 patients, awake group). The mean motor improvement rates on the unified parkinson¿s disease rating scale part iii (updrs-3) between off and on stimulation without medication were 52.3% (95% ci: 45.4¿59.2%) in the asleep group and 47.0% (95% ci: 23.8¿70.2%) in the awake group, 6 months after surgery. Except for a subcutaneous hematoma, the authors did not observe any complications related to the surgery. Three patients (33%) in the awake group and 8 in the asleep group (40%) had at least one side effect potentially linked with neurostimulation. Owing to its randomized design, the authors' study supports the hypothesis that motor outcomes after asleep stn-dbs in pd may be noninferior to the standard awake procedure. Reported events: one patient experiencedFailure of Implant on one side due to a technical incident. The patients were implanted for parkinson's disease. The following device information was identified in the article: lead model 3389-40. Manufacturer narrative: engelhardt j, caire f, damon-perriere n, et al. A phase 2 randomized trial of asleep versus awake subthalamic nucleus deep brain stimulation for parkinson's disease. Stereotact funct neurosurg. 2020:1-11. 10.1159/000511424. This value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the

									article [or the date that the article was accepted for publication] as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. If information is provided in the future, a supplemental report will be issued.
1723170-2021-01005	27/11/2020	Injury	MEDTRONIC NAVIGATION, INC	15/04/2021	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Headache; Muscle Weakness; Visual Impairment; Sleep Dysfunction; Partial Hearing Loss	Citation: gupta k, dickey as, hu r, faught e and willie jt (2020) robot assisted mri-guided litt of the anterior, lateral, and medial temporal lobe for temporal lobe epilepsy. Front. Neurol. 11:572334. Doi: 10.3389/fneur.2020.572334 summary: robotic systems have fundamentally altered the landscape of functional neurosurgery. These allow automated stereotaxy with high accuracy and reliability, and are rapidly becoming a mainstay in stereotactic surgeries such as deep brain stimulation (dbs), stereoelec troencephalography (seeg), and stereotactic laser ablation/mri guided laser interstitial thermal therapy (mrglitt). Robotic systems have been effectively applied to create a minimally invasive approach for diagnostics and therapeutics in the treatment of epilepsy, utilizing robots for expeditious and accurate stereotaxy for seeg and mrglitt. Mrglitt has been shown to approach open surgical techniques in efficacy of seizure control while minimizing collateral injury. We describe the use of robot assisted mrglitt for a minimally invasive laser anterior temporal lobotomy, describing the approach and potential pitfalls. Goals of mrglitt are complete ablation of the epileptogenic zone and avoiding injury to uninvolved structures. In the middle fossa these include structures such as cranial nerves in the skull base and cavernous sinus and the thalamus. These can be mitigated with careful trajectory

									planning and control of laser ablation intensity. Reported events: a (b)(6)-year-old right handed female presented with a 2-year history of medically refractory right temporal lobe epilepsy. Her seizures comprised 2 semiologies; the first consisted of focal seizures with d¿j¿ vu, out of body sensation and dreamlike state, shortness of breath, nausea, diaphoresis, and bilateral hand paresthesia. These sometimes progress to behavioral arrest and loss of awareness. She reported post-ictal tiredness, fear and confusion. These initially occurred 220 times per day, however the frequency reduced to 13 times per month with lacosamide treatment, and followed a catamenial pattern. Her second seizure semiology consisted of generalized tonic seizures, characterized by arm extension and stiffening, lasting a few minutes, with 2 h of post-ictal confusion. These were infrequent, having occurred twice since the onset of her seizures. She has an existing diagnosis of depression and took citalopram for this. She denied specific risk factors, precipitating events, or other psychiatric comorbidities. She reported, however, that she was hospitalized with fever of unknown origin at age (b)(6) years-old and again at (b)(6) years-old (1011 years prior to seizure on set). Her other medical history was unremarkable and she had not had prior epilepsy surgery or evaluation. She had failed trials of levetiracetam, oxcarbazepine, and lamotrigine. Cerebrospinal fluid and blood serology were negative for auto-antibodies. She was neurologically non-focal on examination. Stereoelectroencephalography (seeg) was performed targeting the right temporal lobe and related networks. Sampled locations included mesial structures (entorhinal cortex, parahippocampal gyrus, amygdala, hippocampus), basal structures (fusiform gyrus), lateral structures (superior, middle, and inferior temporal gyrus), and limbic lobe associated structures (insula, frontal and temporal opercula, orbitofrontal cortex,

									retrosplenial cingulate cortex). Twelve electrode arrays were placed in total, utilizing non-medtronic robot, and the patient was monitored for 4-weeks. She had one typical clinical seizure (characterized by behavioral arrest and oral automatism noticed by patients spouse) which was first detected in the contacts located in the fusiform gyrus with spread to the superior, middle, and inferior temporal gyrus. She also had subclinical seizures with a similar onset, as well as two independent seizure onset zones in the lateral superior temporal gyrus or the lateral inferior temporal gyrus (figures 1d,f). In each of these three locations, however, low voltage fast activity was not detected, suggesting that the true epileptogenic zone had not been captured. Given the widespread and multifocal right temporal involvement for the electrographic seizures, it was determined that the patient woul d benefit from anterior temporal lobectomy. Options of surgical therapy by conventional open anterior lobectomy vs. Mri-guided laser interstitial thermal therapy (mrglitt) were presented, and she ultimately expressed a preference for a minimally invasive approach. Mrglitt was performed utilizing the non-medtronic stereotactic robot, at 6 trajectories encompassing the right temporal lobe. The patients head was secured within a stereotactic frame base ring and then affixed to the robot. Stereotactic registration was performed and the robotic articulated arm was navigated to each trajectory. In each location a twist-drill hole was made and laser bolts were placed. Once the bolts had been placed, alignment stylets were inserted to target and a 3-dimensional image was obtained to ensure that the trajectories were accurate. The distance to target from the top of each bolt was recorded for laser fiber insertion. The alignment stylets were removed and the bolts and surrounding scalp were covered with a sterile impermeable adhesive barrier. The patient was

									transferred to the interventional mri suite, positioned supine on the mri table with the right shoulder bumped and the head turned laterally. A head coil was positioned to allow access to all the bolts and the adhesive barrier was prepped with betadine. The area was then draped with sterile towels and the sterile impermeable adhesive barrier was removed for each trajectory, exposing the underlying sterile field. For each trajectory, and the laser fiber was inserted to the appropriate depth), using the distance from the bolt to the target that had been recorded earlier. A 980 nm/15w diode laser was used to ablate all six trajectories, with the intention of confluent ablation of the medial temporal structures (extending posteriorly to the landmark of the lateral mesencephalic sulcus), as well as temporal pole, basal temporal lobe, and lateral temporal lobe extending 5 cm from the temporal tip. Two trajectories began in the parietal-occipital region to cannulate the long axes of the hippocampus/uncus and the rhinal cortices and medial temporal pole, two oblique lateral trajectories began in the posterolateral temporal region and terminated in the superior and inferior lateral temporal pole, and two lateral trajectories completed the lateral neocortical ablation at the level of the uncus and the hippocampal body. A final volumetric mri confirmed the extent of the ablation, and demonstrates the complete ablation of the targeted structures. The final ablation volume was 49.9 cm3. At the end of the case, the bolts were removed and a single interrupted suture was placed at each bolt site. Immediately after sur gery the patient had no gross neurological deficits. By post-operative day 1, however, she was noted to have the onset of right facial weakness. This gradually progressed by post-operative day 3 to an inability to close her right eye (house brackman grade 4). Direct thermal injury during the ablation was considered unlikely to have occurred as

									the laser fiber was intentionally placed 8mm away from the middle fossa skull base, and deficit took time to develop. She underwent repeat ct that demonstrated stable post-ablation changes. She remained admitted for 3 days to ensure that radiographic imaging and clinical symptoms were stable prior to discharge. She was advised to tape the right eye closed to prevent exposure keratopathy. She was evaluated by ophthalmology as an out-patient: a left superior quadrantanopsia was noted on formal goldman visual field testing; 3rd, 4th and 6th cranial nerves were functioning normally; and she was advised on continued eye-care to prevent exposure keratopathy. She and her husband reported cluster of 11 focal impaired-awareness seizures immediately after discharge however no further seizures by 6-weeks after surgery. At 6-weeks post-op she was noted to have worsening hemifacial weakness (now house brackman grade 5). A brain mri was obtained as an out-patient to evaluate her ablation and determine an etiology for her symptoms. Immediately after surgery there was evidence of mild enhancement of the distal canalicular, labyrinthine, geniculate and tympanic segments of the facial nerve compared to pre-operative imaging). At 3-month follow-up there was intense perineural enhancement of the greater-superficial petrosal nerve, geniculate ganglion and tympanic segment of facial nerve. At 6-months after surgery, her hemifacial weakness had improved considerably to house brackman grade 2, not visible at rest and she was able to close her right eye completely, and some residual reduced acuity of hearing with the right ear. She reported subjective headaches and insomnia but she did not find these symptoms bothersome enough to warrant further investigation. Her husband also reported multiple episodes of brief staring and unresponsiveness, and the patient denied recollection of these events, and given history of non-epileptic events, the

									episodes remained unconfirmed. These events occurred several times per week, without conversion to generalized seizure. Given the history of non-epileptic events, these episodes could not be discriminated from possible focal impaired awareness seizures, and lacosamide dosing was increased by her treating neurologist. At 12-months after surgery, she reported complete resolution of her hemifacial weakness, however she acknowledged subjectively reduced acuity of right-sided hearing. She was referred to otorhinolaryngology, but chose not to pursue this. She denied new memory complaints and did not submit to post-operative neuropsychological assessment. Notably, follow up history and physical examinations did not detect visual defects or complaints, although we did not pursue formal ophthalmological evaluations. She and her husband denied any further episodes of impaired awareness since the increase in lacosamide dosing and no generalized seizures since surgery. See attached article. Manufacturer narrative: patient information was not included in the journal article. Please note that this date is based off of the date the article was published as the event dates were not provided in the published literature. Article citation is included. System product number and serial number not provided in journal article. Udi not available for this system. No 510k provided as the system is unknown. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable.
2182207-2021-00360	25/11/2020	Injury	MEDTRONIC NEUROMODULATION	03/03/2021	OLM	ACTIVA	Adverse Event Without Identified Device or Use Problem	Unspecified Infection; Ambulation Difficulties	Summary: obsessive-compulsive disorder (ocd) is among the most disabling chronic psychiatric disorders and has a significant negative impact on multiple domains of quality of life. Deep brain stimulation (dbs) is a treatment option for severe therapy-resistant ocd. The primary outcome measure (the yale-brown obsessive compulsive scale [y-bocs]) and secondary outcomes depressive symptoms, anxiety,

									and quality of life were retrospectively analyzed. Dbs leads were warped into standard stereotactic space. A normative connection was used to identify the neural network associated with clinical outcome. With a median stimulation duration of 26 months, patients exhibited a mean y-bocs reduction of 10.5 resulting in a response rate of 63%. Modulation of a fiber bundle traversing the anterior limb of the internal capsule (alic) was associated with y-bocs reduction. This fiber bundle connected the frontal regions to the subthalamic nucleus (stn) and was functionally identified as the hyper direct pathway of the basal ganglia circuitry. The authors' findings show that in vc/vs stimulation, the neural network associated with clinical outcome shows overlap with that of previously described for other targets namely the anterior limb of the internal capsula, the nucleus accumbens, or the stn, which supports the evolvement from the concept of an optimal gray matter target to conceiving the target as part of a symptom modulating network. Reported events: one patient implanted with subthalamic nucleus (stn) deep brain stimulation (dbs) for obsessive compulsive disorder (ocd) experienced severe wound infection. According to the authors, the infection was probably due to compulsive cleaning of the surgical area, for which the implantable neurostimulator (ins) had to be removed. One patient implanted with dbs for ocd experienced severe motor-side effects (i.e. Coordination and balance deficits) after which it was decided to switch to vc/vs stimulation. The event was classified as major stimulation-related neurological complication. Two patients implanted with dbs for ocd experienced minor infection. The following device information was identified in the published literature: ins model 37601 and lead model 3387. Manufacturer narrative: van der vlis t, ackermans l, mulders aep, et al. Ventral capsule/ventral striatum stimulation in obsessive-compulsive disorder: toward a

									unified connectomic target for deep brain stimulation? Neuromodulation. (b)(4). This value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date that the article was accepted for publication as the event dates and publication date were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Other relevant device(s) are: product id: 37601, serial/lot #: unknown, ubd: , udi#: asku ; product id: 37601, serial/lot #: unknown, ubd: , udi#: (b)(4). If information is provided in the future, a supplemental report will be issued.
2182207-2021-00241	23/11/2020	Malfunction	MEDTRONIC NEUROMODULATION	11/02/2021	MHY	ACTIVA	Energy Output Problem; Low impedance; Impedance Problem; Patient Device Interaction Problem	Visual Impairment; Visual Disturbances	Summary: deep brain stimulation (dbs) is an effective surgical treatment for movement disorders. Early versions of implantable systems delivered stimulation with constant voltage (cv); however, advances in available and newer platforms have permitted programming in constant current (cc).from a treatment management perspective, there are theoretical advantages of cc stimulation. In this case series, the authors present clinical evidence supporting the maintenance of current regardless of changes to impedance. This case series included 3 patients with parkinson¿s disease status post-bilateral subthalamic nucleus dbs. Patients in this series self-reported intermittent diplopia pressure applied to the scalp. Patients were subsequently examined and converted from cv to cc and re-examined. Impedances were checked prior to and after conversion from cv to cc as well as while applying pressure to the scalp that induced the adverse

									effects. Across patients, the authors observed that compression of the scalp overlying the connector, while patients were maintained in cv, consistently and objectively induced unilateral adduction of an eye. In addition, during scalp compression, while in cv, impedance was reduced, which would increase current delivery. Converting the patients to cc stimulation without changing other stimulation parameters eliminated diplopia and objective findings of eye deviation with compression of the scalp overlying the hardware despite changes in impedance. In this case series, the authors provide clinical support for the principal differences between cv and cc stimulation. Reported events: a (b)(6) male patient implanted with bilateral subthalamic nucleus (stn) deep brain stimulation (dbs) for parkinson's disease (pd) experienced blurry vision with stimulation from two most ventral contacts of the right lead. The left lead induced diplopia at thresholds of stimulation of 1.5v, 60 usec and 130 hz in the most ventral contact. At one year post-op, the patient reported that palpating the scalp overlying the connector of the lead wires to the extension wire resulted in right eye transient adduction. With stimulation-on, but without palpation of the affected region, the right eye was marginally injected and had a slight decreased palpebral fissure, and both eyes had normal extraocular movements. While maintaining pressure on the scalp overlying the connection, the right eye adducted and was sustained in fixed medial position, resolving immediately upon release, while there was minimal adduction of the left eye. No change in pupil size was observed in either eye. Reducing stimulation on the right lead resolved the findings while increasing stimulation exacerbated the symptoms. Turning off the ins resolved the issue. X-ray demonstrated normal connection between lead and extension. The stimulation was switched from constant voltage (cv) to constant

									current (cc), with other parameters held consistent. The oculomotor findings via compression of the connector could not be reproduced in ccmode, and the patient's symptoms were well controlled. The physicians theorized a short circuit was created when the connector was palpated, delivering stimulation to the most ventral contacts that were more medially positioned. A (b)(6) male patient implanted with bilateral stn dbs for pd experienced diplopia with stimulation of the left lead, primarily most severe with the ventral most contact. Thirteen months post-op, the patient reported palpating the scalp caused diplopia. Eye exam was normal with stimulation on and without palpating scalp, but left eye adducted with stimulation on and palpation overlying the connector. Eye adduction was sustained until pressure was released. Through testing it was determined that the left lead was primarily contributing to the oculomotor findings. Stimulation was changed from cv to cc without adjusting other parameters, which eliminated the ability to induce unilateral eye deviation with compression of the connector. The physicians theorized a short circuit was created when the connector was palpated, delivering stimulation to the most ventral contacts that were more medially positioned. A (b)(6) male patient implanted with bilateral stn dbs for pd experienced diplopia during initial programing with the most ventral contact of the right lead. Two years later, the patient reported diplopia with compression of the skin overlying the right lead connector. Eye exam was normal with stimulation on and without palpation of the scalp. Palpating scalp overlying connector resulted in adduction of the right eye without pupillary changes that was sustained until pressure was released. Turning off the ins resolved the findings as well as stimulating in more dorsal contacts. Cv was changed to cc without adjustment of other parameters, which eliminated the ability to induce unilateral eye adduction.

									Impedances were checked in various conditions. In cv, therapeutic impedance was 1104 ohms and 2.5 ma, but reduced to 884 ohms, and current increased to 3.1 ma while palpating the connector. Impedance reduction with compression compared to without compression was greatest for ventral contacts: 227 and 190 ohms for contacts 0 and 1, r espectively and the least for dorsal contacts: 82 and 74 ohms for contacts 2 and 3, respectively. Anatomical and dbs lead constructions were created and segmentations derived. The lead was positioned medial with the most ventral contacts within the substantia nigra pars reticulata. The physicians theorized a short circuit was created when the connector was palpated, delivering stimulation to the most ventral contacts that were more medially positioned. The following device information was identified in the article: ins models 37601 and 37603; lead models 3387 and 3389 see attached literature article. Manufacturer narrative: kern ds, fasano a, thompson ja, abosch a, ojemann s, munhoz rp. Constant current versus constant voltage: clinical evidence supporting a fundamental difference in the modalities. Stereotact funct neurosurg.2020:1-5. 10.1159/000510803. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Other relevant device(s) are: product id: 3387, serial/lot #: unknown, udi#: (b)(4) ; product id: 37601, serial/lot #: unknown, ubd: , udi#: asku ; product id: 3387, serial/lot #: unknown, (b)(4) ; product id: 37603, serial/lot #: unknown, (b)(4) ; product id: 3389, serial/lot #: unknown,

									udi#: ask. If information is provided in the future, a supplemental report will be issued.
1222780-2021-00046	23/11/2020	Malfunction	HOLOGIC, INC.	10/03/2021	KNW	EVIVA STEREOTACTIC GUIDED BREAST BIOPSY SYSTEM	Material Deformation	No Clinical Signs, Symptoms or Conditions	It was reported on (b)(6) 2020 that the biopsy sheath would not pull away from the probe and the entire probe had to be removed. A biopsy clip was not able to be placed after the procedure. Additional information received from the customer confirmed that the biopsy area was still visualized on post biopsy mammogram images and the pathology results were benign fibrocystic changes with no removal necessary. The reported device was returned for investigation on 02/10/2021 and at that time it was determined that the introducer sheath was crumpled and still mounted on the device. Manufacturer narrative: device received and inspected for reported complaint. Device arrived with quad tube set cut by customer. Visual assessment only. Introducer sheath is crumpled and still mounted on device. Complaint verified. Root cause unknown. This observation will be monitored and trended.
2182207-2021-00095	18/11/2020	Injury	MEDTRONIC NEUROMODULATION	19/01/2021	MHY	IMPLANTABLE NEUROSTIMULATOR	Energy Output Problem; Battery Problem; Adverse Event Without Identified Device or Use Problem	Unspecified Infection; No Clinical Signs, Symptoms or Conditions	Xu w, zhang x, wang y, et al. Sustained relief after pallidal stimulation interruption in tourette's syndrome treated with simultaneous capsulotomy. Stereotact funct neurosurg. 2020:1-10. 10.1159/000510946. Summary: tourette¿s syndrome (ts) is a common childhood-onset neuropsychiatric disorder, with an estimated 86% of cases having comorbid physical or psychiatric conditions, such as obsessive-compulsive disorder (ocd), attention deficit hyperactivity disorder (adhd), and anxiety and depressive disorders [1, 2]. Tics can be highly variable and can commonly resolve or become less severe in adolescence or young adulthood [3]. However, 22% of the patients examined still suffered from moderate-to-severe tics with a moderate level of impairment of global functioning by the age of 20 years [2, 4]. Moreover, severe ts along with comorbid ocd and certain other psychiatric symptoms, including self-injurious

									behaviors, uncontrollable anger, and aggression, can result in serious physical self-harm (e.g., myelopathies, retinal detachment, and body injuries), a life-threatening condition, which occurs in approximately 4¿5% of cases [5]. The presence of these comorbidities can add to the difficulty in developing a treatment strategy that addresses not only the tics but also the comorbid disorders [6¿9]. Identified events: 6 patients experienced unintentional or accidental stimulation interruption due to battery exhaustion. 2 patients experienced an infection at the ins site, which led to the removal of the ins. 1 patient experienced two infections and had am ins replacement. The following device specifics were provided: lead 3387. Patients were implanted for tourette¿s syndrome (ts) with psychiatric comorbidities. Manufacturer narrative: xu w, zhang x, wang y, et al. Sustained relief after pallidal stimulation interruption in tourette's syndrome treated with simultaneous capsulotomy. Stereotact funct neurosurg. 2020:1-10. 10.1159/000510946. Other relevant device(s) are: product id: neu_ins_stimulator, serial/lot #: unknown. Product id: neu_ins_stimulator, serial/lot #: unknown. Age: this value is the average age of the patients reported in the article as specific patients could not be identified. Sex: this value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Common device name: the

									device was used for an off label indication. If information is provided in the future, a supplemental report will be issued.
3008769756-2021-00022	02/11/2020	Injury	NEUWAVE MEDICAL, INC.	23/06/2021	NEY	UNK_MICROWAVE ABLATION SYSTEM CHINA	Appropriate Term/Code Not Available	Insufficient Information	It was reported via journal article title: primary efficacy of percutaneous microwave ablation of malignant liver tumors: comparison of stereotactic and conventional manual guidance. Author : jan schaible, lukas lürken , philipp wiggermann, niklas verloh , ingo einspieler, florian zeman, andreas g. Schreyer, reto bale, christian stroszczynski & lukas beyer. Citation: scientific reports | (2020) 10:18835 https://doi.org/10.1038/s41598-020-75925-6. This study aims to evaluate the primary efficacy of stereotactic ablation for malignant liver tumors and compare the findings with those for conventional manual ablation in a retrospective cohort. A total of of 221 patients (179 male, 42 female) with median age of 64 years (range 30¿85) were included in the study. A total of 423 tumors spread across all liver segments were treated using microwave ablation (mwa) with either stereotactic (s-group) or manual guidance (m-group).some lesions are in subphrenic location in 43 patients in m group and 64 patients in s group with proximity to vessel 30 in m group and 88 for s group. For mwa, depending on tumor configuration and relationship to the surrounding tissue, either the acculismicrowave tissue ablation (mta) system (angiodynamics, (b)(4), usa), the emprint¿ ablation system (medtronic, (b)(4), usa) and subsequently, the neuwave ablation system (ethicon, johnson & johnson, (b)(4)) were used. Reported complications included : grade i complications (any deviation from the normal postinterventional course, e.g. Fever or pain medication) occurred in 16 patients for s group and 4 patients in the m group (n=20). Grade ii complications (any deviation from the normal postinterventional course, e.g. Fever or pain medication) occurred in 3 patients in the s group and 4 patients in the m group (n=7).

									Grade iii complications in 5 patients in the s group and 1 in the m group (n=6). Grade iv complications occurred in 3 patients in the m group (n=3). Incomplete efficacy in 34 patients in s group and 45 in m group (n=79). One patient died after mwa due to an accidental puncture of the pericardium with hemopericardium in the s group (n=1). It was concluded, that the use of stereotactic navigation improved primary efficacy compared to conventional manual guidance. Manufacturer narrative: (b)(4). As the device was not returned, an analysis investigation could not be performed. A conclusion could not be reached as to what may have caused or contributed to the event. We did not receive a batch or lot number for the product involved in this complaint. Therefore, we were unable to check manufacturing records for any related non-conformance.
3008769756-2021-00023	02/11/2020	Death	NEUWAVE MEDICAL, INC.	23/06/2021	NEY	UNK_MICROWAVE ABLATION SYSTEM CHINA	Appropriate Term/Code Not Available	Insufficient Information	It was reported via journal article title: primary efficacy of percutaneous microwave ablation of malignant liver tumors: comparison of stereotactic and conventional manual guidance. Author: jan schaible, lukas lürken , philipp wiggermann, niklas verloh , ingo einspieler, florian zeman, andreas g. Schreyer, reto bale, christian stroszczynski & lukas beyer. Citation: scientific reports | (2020) 10:18835. Https://doi.org/10.1038/s41598-020-75925-6. This study aims to evaluate the primary efficacy of stereotactic ablation for malignant liver tumors and compare the findings with those for conventional manual ablation in a retrospective cohort. A total of 221 patients (179 male, 42 female) with median age of 64 years (range 30¿85) were included in the study. A total of 423 tumors spread across all liver segments were treated using microwave ablation (mwa) with either stereotactic (s-group) or manual guidance (m-group).some lesions are in subphrenic location in 43 patients in m group and 64 patients in s group with proximity to vessel 30 in m group and 88 for s group. For mwa, depending on tumor

									configuration and relationship to the surrounding tissue, either the acculismicrowave tissue ablation (mta) system (angiodynamics, latham, ny, usa), the emprint¿ ablation system (medtronic, minneapolis, usa) and subsequently, the neuwave ablation system (ethicon, johnson & johnson, bridgewater new jersey and cincinnati, ohio) were used. Reported complications included: grade i complications (any deviation from the normal postinterventional course, e.g. Fever or pain medication) occurred in 16 patients for s group and 4 patients in the m group (n=20). Grade ii complications (any deviation from the normal postinterventional course, e.g. Fever or pain medication) occurred in 3 patients in the s group and 4 patients in the m group (n=7). Grade iii complications in 5 patients in the s group and 1 in the m group (n=6). Grade iv complications occurred in 3 patients in the m group (n=3). Incomplete efficacy in 34 patients in s group and 45 in m group (n=79). One patient died after mwa due to an accidental puncture of the pericardium with hemopericardium in the s group (n=1). It was concluded, that the use of stereotactic navigation improved primary efficacy compared to conventional manual guidance. Manufacturer narrative: (b)(4). As the device was not returned, an analysis investigation could not be performed. A conclusion could not be reached as to what may have caused or contributed to the event. We did not receive a batch or lot number for the product involved in this complaint. Therefore, we were unable to check manufacturing records for any related non-conformance.
2182207-2021-00008	28/10/2020	Injury	MEDTRONIC NEUROMODULATION	04/01/2021	MHY	IMPLANTABLE NEUROSTIMULATOR	Break; Adverse Event Without Identified Device or Use Problem	Convulsion/Seizure; No Clinical Signs, Symptoms or Conditions	Summary: evidence has been provided that the subiculum may play an important role in the generation of seizures. Electrical stimulation at this target has been reported to have anticonvulsive effects in kindling and pilocarpine rat models, while in a clinical study of hippocampal deep brain stimulation (dbs), contacts closest to the

									subiculum were associated with a better anticonvulsive effect. Six patients with refractory mtle and hs, who had focal impaired awareness seizures (fias) and focal to bilateral tonic-clonic seizures (fbtcs), had dbs electrodes implanted in the subiculum. During the first month after implantation, all patients were off stimulation, then they all completed an open-label follow-up of 24 months on stimulation. Dbs parameters were setat 3 v, 450 s, 130 hz, cycling stimulation 1 min on, 4 min off. There was a mean reduction of 49.16% (±sd 41.65) in total seizure number (fias + fbtcs) and a mean reduction of 67.93% (±sd 33.33) in fbtcs at 24 months. Fbtcs decreased significantly with respect to baseline, starting from month 2 on stimulation. Subiculum stimulation is effective for fbtcs reduction in patients with mtle and hs, suggesting that the subiculum mediates the generalization rather than the genesis of mesial temporal lobe seizures. Better results were observed at longer follow-up times. Reported events: a (b)(6) year old male patient implanted for epilepsy experienced increased total seizures (20%) at 24 month follow-up, but had 50% reduction of focal to bilateral tonic-clonic seizures (fbtcs). The patient had focal impaired awareness seizures (fias) and fbtcs at baseline. Total seizure increase was observed only during 3 non-continuous months, and he was fbtcs free for 17 months. The remain ing seizures were exclusively nocturnal. A (b)(6) year old male patient implanted for epilepsy experienced increased total seizure count during most of follow-up, which was related to fias increase. Fbtcs were decreased during all of the study, and was 100% reduced by the end of the study. A (b)(6) year old male patient implanted for epilepsy experienced a leadFracture during a seizure in the first month after implant. The patient was re-implanted successfully and continued the study. The following device information was identified in the article: activa sc ins (it could not be determined if

									model 37602 and/or 37603 was/were used), lead model 3387. Manufacturer narrative: vazquez-barron d, cuellar-herrera m, velasco f, velasco al. Electrical stimulation of subiculum for the treatment of refractory mesial temporal lobe epilepsy with hippocampal sclerosis: a 2-year follow-up study. Stereotactic and functional neurosurgery. 2020:1-8. 10.1159/000510295. Age/sex: see for patient demographic details. Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Information references the main component of the system. Other relevant device(s) are: product id: neu_ins_stimulator, serial/lot #: unknown, ubd: asku, implanted: unknown, explanted: unknown, udi#: asku. Product id: 3387, serial/lot #: unknown, ubd: asku, implanted: unknown, explanted: unknown, udi#: asku ; (b)(6). If information is provided in the future, a supplemental report will be issued.
1121308-2021-00042	27/10/2020	Injury	INTEGRA NEUROSCIENCES PR	10/10/2021	GXQ	DURAGEN SUTURABLE DURAL REGENERATION TEMPLATE 3	Adverse Event Without Identified Device or Use Problem	Post Operative Wound Infection	An adverse event (ae) was reported under (b)(6) clinical study ((b)(6)) with the following information: it was reported that a patient participating in this study suffered a deep surgical infection. Patient complained of drainage from incision site at post operational visit. Patient was taken to operating room on (b)(6) 2020 for wound wash out. On (b)(6) 2020, patient still had infected surgical site. Patient returned to operating room for removal of hardware and closure of wound. Patient received antibiotic treatment. See additional details of the adverse event as follows: device information: cat#/product code# (durs3391). Surgery date: on (b)(6) 2020.

									Date of discharge: on (b)(6) 2020. Patient diagnosis: epilepsy. Surgical region: supratentorial. Surgical procedure: 10-stereotactic craniotomy. Adverse event: ae term: surgical site infection ¿ deep. Adverse event onset or start date: on (b)(6) 2020. Did the ae result in an initial or prolonged hospitalization: yes (admission date: on (b)(6) 2020, discharge date: on (b)(6) 2020). Did the ae require intervention to prevent permanent impairment or damage?: yes. Details of intervention: patient underwent surgery twice to clean wound, resulted in eventual hardware removal. Patient received antibiotic treatment. Outcome: resolved without sequelae. Adverse event resolution/end date: on (b)(6) 2020. Manufacturer narrative: an investigation has been initiated based on the reported information. Upon completion of the investigation, a follow-up report will be submitted.
3008492462-2022-00011	26/10/2020	Injury	DEVICOR MEDICAL PRODUCTS INC	29/09/2022	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE	Use of Device Problem	Hemorrhage/Bleeding	Notification from canda vigilance program was received on 9/6/2022. It was reported by the affiliate that during procedure the biopsy was delayed due to significant bleeding. The mechanism broke in the needle, it became impossible to turn to retrieve a sample. Patient was punctured twice, but due to the abundant bleeding the biopsy had to be rescheduled. Manufacturer narrative: the mammotome revolve dual vacuum assisted biopsy system is intended to obtain tissue samples from the breast or axillary nodes for diagnostic analysis of breast abnormalities. On 9/6/22 mammotome was notified of an event that occurred on (b)(6) 2020. Based on the allegation of injury resulting from the patient having to undergo a secondary puncture and needing to have their biopsy rescheduled delaying diagnosis. Given the date of the event the device was not available for analysis however, review of the details has been conducted. Based on the information available and our product knowledge the event was most likely caused by one of the scenarios below. The

									rotation knob could not be rotated due to a defect with the probe; the rotation knob could not be rotated due to damage in the holster; the user potentially induced damage as the event has happened 15x with this user.
2020394-2020-20869	23/10/2020	Malfunction	BARD PERIPHERAL VASCULAR, INC.	17/12/2020	KNW	ENCOR BIOPSY PROBE	Suction Problem; Device Contamination with Chemical or Other Material	No Clinical Signs, Symptoms or Conditions	It was reported that during a stereotactic guided breast biopsy through fibroadenoma tissue, the device allegedly had suction issue. The procedure was completed using another device. There was no reported patient injury. Manufacturer narrative: as the lot number for the device was provided, a review of the device history record is currently being performed. The device has been returned to the manufacturer for evaluation. The investigation of the reported event is currently underway. (expiry date: 11/2021).
2182207-2020-01544	20/10/2020	Injury	MEDTRONIC NEUROMODULATION	22/12/2020	MRU	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Unspecified Infection	Summary: deep brain stimulation (dbs) of the globus pallidus internus has become an accepted treatment for severe isolated idiopathic and inherited dystonia. Patients who had other forms of surgery earlier, such as radiofrequency lesioning or selective peripheral denervation, however, usually are not considered candidates for dbs. The aim of this study was to evaluate the long-term outcome of pallidal dbs in a rare subgroup of patients who had undergone both pallidotomy and selective peripheral denervation previously with a waning effect over the years. Pallidal dbs was performed according to a prospective study protocol in 2 patients with isolated idiopathic dystonia, and patients were followed for a period of at least 6 years. Both patients benefitted from long-lasting amelioration of dystonia after pallidal dbs, which was comparable to that of patients who did not have previous surgeries. In a (b)(6) year-old female with cervical dystonia both the burke-fahn-marsden (bfm) and the toronto western spasmodic torticollis rating scale (twstrs) motor scores were improved at follow-up 8 years after surgery (50 and 39%). In a (b)(6) year-old male with generalized dystonia, the bfm motor and

									disability scores showed marked improvement at 6.5 years of follow-up (82 and 66%). Pallidal dbs can yield marked and long-lasting improvement in patients who underwent both pallidotomy and selective peripheral denervation earlier. Therefore, such patients, in general, should not be excluded from dbs. Reported events: patient 2: a (b)(6) year old male patient experienced infection after replacement of the ins. Treatment included surgical revision and long term antibiotics. Manufacturer narrative: saryyeva a, capelle hh, kinfe tm, schrader c, krauss jk. Pallidal deep brain stimulation in patients with prior bilateral pallidotomy and selective peripheral denervation for treatment of dystonia. Stereotactic and functional neurosurgery. 2020:1-5. 10.1159/000509822. Please note that this date is based off of the date of publication of the article or the date that the article was accepted for publication as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. If information is provided in the future, a supplemental report will be issued.
3006630150-2020-05530	15/10/2020	Injury	BOSTON SCIENTIFIC NEUROMODULATION	12/11/2020	NHL	VERCISE	Adverse Event Without Identified Device or Use Problem	Hemorrhage/Bleeding; Confusion/ Disorientation	It was reported that a hemorrhage was observed during microelectrode recording during the implant procedure. This was assessed to be due to wrong stereotactic coordinates and was moderate in severity. Hospitalization was prolonged, but no further action was taken. The physician assessed that the event had a causal relationship to the procedure, and is not related to the device hardware or stimulation. The issues is resolving and the patient is recovering.
1222780-2020-00143	15/10/2020	Injury	HOLOGIC, INC.	27/10/2020	KNW	EVIVA STEREOTACT	Adverse Event	Appropriate Clinical Signs,	This is the second of two reports related to one event. The second report is filed under

						IC BREAST BIOPSY SYSTEM	Without Identified Device or Use Problem	Symptoms, Conditions Term/Code Not Available	1222780-2020-00142. It was reported that during the biopsy, air was pushed into the breast and it traveled up toward the patient neck. The procedure was aborted. An x-ray was performed but came back unremarkable. The biopsy was not completed. No additional details available. Manufacturer narrative: device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications. The device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. If the device is returned and evaluation completed, a supplemental medwatch will be filed. Appropriate term: air injection (soft tissue).
10784794	15/10/2020	Malfunction	HOLOGIC, INC.	04/11/2020	KNW	ATEC SAPPHIRE 100	Defective Device; Suction Failure	Insufficient Information	During stereotactic biopsy, the atec malfunctioned and instead of suctioning, it reversed and blew air into the breast filling the breast and neck with subcutaneous air. Procedure was halted and a soft tissue neck x-ray was performed. The atec was pulled from use.
1723170-2021-02496	13/10/2020	Injury	MEDTRONIC NAVIGATION, INC	13/10/2021	HAW	MEDTRONIC NAVIGATION	Imprecision	Unspecified Tissue Injury	Citation: philipp krauss, markus florian oertel, heide baumann-vogel, lukas imbach, christian rainer baumann, johannes sarnthein, luca regli, lennart henning stieglitz. Intraoperative neurophysiologic assessment in deep brain stimulation surgery and its impact on lead placement. J. Neurol surg. Doi: 10.1055/s-0040-1716329 abstract: objectives while the efficacy of deep brain stimulation (dbs) to treat various neurological disorders is undisputed, the surgical methods differ widely and the importance of intraoperative microelectrode recording (mer) or macrostimulation (ms) remains controversially debated. The objective of this study is to evaluate the impact of mer and ms on intraoperative lead placement. Patients and methods: we included 101 patients who underwent awake bilateral implantation of electrodes in the subthalamic nucleus with mer and ms for parkinson¿s disease from 2009 to 2017 in a retrospective observational study. We

									analyzed intraoperative motor outcomes between anatomically planned stimulation point (psp) and definite stimulation point (dsp), lead adjustments and unified parkinson¿s disease rating scale item iii (updrs-iii), levodopa equivalent daily dose (ledd), and adverse events (ae) after 6 months. Results: we adjusted 65/202 leads in 47/101 patients. In adjusted leads, ms results improved significantly when comparing psp and dsp (p <(><<)> 0.001), resulting in a number needed to treat of 9.6. After dbs, updrs-iii and ledd improved significantly after 6 months in adjusted and nonadjusted patients (p <(><<)> 0.001). In 87% of leads, the active contact at 6months still covered the optimal stimulation point during surgery. In total, 15 ae occurred. Conclusion: mer and ms have a relevant impact on the intraoperative decision of final lead placement and prevent from a substantial rate of poor stimulation outcome. The optimal stimulation points during surgery and chronic stimulation strongly overlap. Follow-up updrs-iii results, ledd reductions, and dbs-related ae correspond well to previously published data. Reported events: five leads required adjustment due to stereotactic inaccuracy >2mm. Manufacturer narrative: patient age is the mean value of patients in the study. Patient gender is the majority value of patients in the study. Patient weight not available from the site. Event date is the publish date of the literature. Device lot number, or serial number, unavailable. 510(k) is dependent upon the device model number, therefore is unavailable. No parts have been received by the manufacturer for evaluation. Device manufacture date is dependent on the device lot/serial number, therefore is unavailable. If information is provided in the future, a supplemental report will be issued.
1717344-2021-01245	12/10/2020	Death	COVIDIEN MFG DC BOULDER	09/09/2021	GEI	UNKNOWN RF ELECTRODE	Adverse Event Without Identified	Abscess; Hypovolemic Shock; Renal	According to the literature, a retrospective study assessed the frequency of major complications following the treatment of liver tumors with multiprobe stereotactic

							Device or Use Problem	Failure; Septic Shock	radiofrequency ablation (srfa) between july 2003 and december 2018. It is noted that a maximum of three 17g cool-tip radiofrequency (rf) electrodes were introduced through coaxial needles for serial tumor ablation, which was further carried out using the unipolar cool-tip rf generator and cool-tip rf switching controller. There were 793 patients treated in 1235 srfa sessions and it was noted that there was a thirty-day mortality rate of 0.5% with a total of 6 deaths including: 4 hemorrhagic shock initially treated with angiographic coiling, 1 septic shock due to liver abscess which initially required surgical intervention with drainage and 1 acute-on-chronic renal failure. All of which was admitted to the intensive care unit. Manufacturer narrative: title: frequency and risk factors for major complications after stereotactic radiofrequency ablation of liver tumors in 1235 ablation sessions: a 15-year experience source: european radiology (2021) 31:3042¿3052 https://doi.org/10.1007/s00330-020-07409-0. If information is provided in the future, a supplemental report will be issued.
1717344-2021-01246	12/10/2020	Injury	COVIDIEN MFG DC BOULDER	09/09/2021	GEI	UNKNOWN RF ELECTRODE	Adverse Event Without Identified Device or Use Problem	Abscess; Burn(s); Fistula; Hemorrhage/Bleeding; Pleural Effusion; Pneumothorax	According to the literature, a retrospective study assessed the frequency of major complications following the treatment of liver tumors with multiprobe stereotactic radiofrequency ablation (srfa) between july 2003 and december 2018. It is noted that a maximum of three 17g cool-tip radiofrequency (rf) electrodes were introduced through coaxial needles for serial tumor ablation, which was further carried out using the unipolar cool-tip rf generator and cool-tip rf switching controller. There were 793 patients treated in 1235 srfa sessions and complications included: thermal damage to hollow viscera, skin, and central bile ducts, which required additional surgery and/or endoscopic retrograde cholangiopancreatography (ercp) with ultrasound (us)-guided drainage, pleuro-cutaneous fistula secondary to thermal injury, treated with a series of us-

									guided drainages, liver abscesses treated with surgical intervention or us-guided drainage,<(>,<)> arterio-portal fistula treated with angiographic coiling, peri-intrahepatic hemorrhage treated with angiographic coiling, major pleural effusion treated with thoracocentesis, and pneumothorax treated with chest tube insertion. Manufacturer narrative: title: frequency and risk factors for major complications after stereotactic radiofrequency ablation of liver tumors in 1235 ablation sessions: a 15-year experience source: european radiology (2021) 31:3042¿3052 https://doi.org/10.1007/s00330-020-07409-0. If information is provided in the future, a supplemental report will be issued.
3004785967-2021-00834	06/10/2020	Injury	MEDTRONIC NAVIGATION, INC (LITTLETON)	28/06/2021	OXO	O-ARM IMAGING SYSTEM	Imprecision	Unspecified Tissue Injury	Citation: luciano furlanetti, jonathan ellenbogen, hortensia gimeno, laura ainaga, vijay narbad, harutomo hasegawa, jean-pierre lin, keyoumars ashkan, and richard selway. Targeting accuracy of robot-assisted deep brain stimulation surgery in childhood-onset dystonia: a single-center prospective cohort analysis of 45 consecutive cases. Jns pediatrics april 2021. Doi: 10.3171/2020.10.peds20633. Abstract: objective: deep brain stimulation (dbs) is an established treatment for pediatric dystonia. The accuracy of electrode implantation is multifactorial and remains a challenge in this age group, mainly due to smaller anatomical targets in very young patients compared to adults, and also due to anatomical abnormalities frequently associated with some etiologies of dystonia. Data on the accuracy of robot-assisted dbs surgery in children are limited. The aim of the current paper was to assess the accuracy of robot-assisted implantation of dbs leads in a series of patients with childhood-onset dystonia. Methods: forty-five children with dystonia undergoing implantation of dbs leads under general anesthesia between 2017 and 2019 were included. Robot-assisted stereotactic implantation of the dbs leads was

									performed. The final position of the electrodes was verified with an intraoperative 3d scanner (o-arm). Coordinates of the planned electrode target and actual electrode position were obtained and compared, looking at the radial error, depth error, absolute error, and directional error, as well as the euclidean distance. Functional assessment data prospectively collected by a multidisciplinary pediatric complex motor disorders team were analyzed with regard to motor skills, individualized goal achievement, and patients¿ and caregivers¿ expectations. Results: a total of 90 dbs electrodes were implanted and 48.5% of the patients were female. The mean age was 11.0 ± 0.6 years (range 3¿18 years). All patients received bilateral dbs electrodes into the globus pallidus internus. The median absolute errors in x-, y-, and z-axes were 0.85 mm (range 0.00¿3.25 mm), 0.75 mm (range 0.05¿2.45 mm), and 0.75 mm (range 0.00¿3.50 mm), respectively. The median euclidean distance from the target to the actual electrode position was 1.69 ± 0.92 mm, and the median radial error was 1.21 ± 0.79. The robot-assisted technique was easily integrated into the authors¿ surgical practice, improving accuracy and efficiency, and reducing surgical time significantly along the learning curve. No major perioperative complications occurred. Conclusions: robot-assisted stereotactic implantation of dbs electrodes in the pediatric age group is a safe and accurate surgical method. Greater accuracy was present in this cohort in comparison to previous studies in which conventional stereotactic frame-based techniques were used. Robotic dbs surgery and neuroradiological advances may result in further improvement in surgical targeting and, consequently, in better clinical outcome in the pediatric population. Reported events: a total of 7 (7.7%) of the 90 electrodes were readjusted following the intraoperative scan, based on an ed greater

									than 2 mm (mean 3.0 ± 0.6 mm). The median absolute errors in the x-, y-, and z-axes were 0.85 mm (range 0.00¿3.25 mm), 0.75 mm (range 0.05¿2.45 mm), and 0.75 mm (range 0.00¿3.50 mm), respectively. The median ed was 1.69 ± 0.92 mm (range 0.46¿4.42 mm), and the median re was 1.21 ± 0.79 mm (range 0.17¿3.49 mm). Manufacturer narrative: patient age is the mean value of patients in the study. Patient gender is the majority value of patients in the study. Patient weight not available from the site. Event date is the accepted date of the publication. Device lot number, or serial number, unavailable. 510(k) is dependent upon field device lot number, or serial . Therefore the value is unavailable. No parts have been received by the manufacturer for evaluation. Device manufacture date is dependent on the device lot/serial number, therefore is unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2020-02763	01/10/2020	Malfunction	MEDTRONIC NAVIGATION, INC	21/10/2020	HAW	S8 STEALTHSTATION NAVIGATION SYSTEM	Human-Device Interface Problem	No Known Impact Or Consequence To Patient	Citation: j m kwak, j h lee, j kim, j m choo, s. W. Cho. Stereotactic pelvic navigation surgery for recurrent rectal cancer. Int j cars (2020) 15 (suppl 1):s1-s214 purpose stereotactic navigation is useful for localizing, targeting, and guiding surgical procedures when a target cannot be seen directly [1]. It has been an established technology in several surgical and interventional radiological fields. Like neuronavigation surgery, stereotactic navigation for pelvic surgery is feasible since the soft tissue organs are confined to the bony pelvis, and other important anatomical structures are relatively fixed to, where well defined landmarks, and a rigid registration are available [1, 2]. On the other hand, pelvic surgery is technically difficult, and there is a high risk of unexpected complications such as major vessel injury and ureter injury, especially during minimally invasive surgery, which has lack of tactile feedback. The aim of this study was to apply stereotactic navigation for recurrent rectal cancer cases and

									evaluate clinical feasibility and usefulness by the concept of enhancing surgeon¿s spatial awareness and eliminating much of guesswork. Methods: preoperative computer tomography scans were used for image data. Before image acquisition, 6¿8 skin fiducials were attached along the inguinal ligament and the pubic bone. A stealth station s8 optical navigation system (medtronic, minneapolis, mn) was used with cranial software for the study. Patient lied on the bean bag to minimize sliding movement during position change, and a patient tracker was mounted on the operating table. After preoperative ct scan images were loaded into the system, and verified to meet the minimum system requirement, each point of skin fiducials were localized in image space with a registration pointer to complete patient-to-image paired point registration. The instrument tracker was mounted on the distal shaft of laparoscopic instrument and calibrated for instrument tracking. Results from december 2018 to november 2019, we experienced three cases of pelvic recurrence after rectal cancer surgery and performed minimally invasive surgery under the real time 3 dimensional image guidance. The numbers of used skin fiducials were 8, 8, and 6 in each case, and the registration error were 3.4 mm, 3.2 mm, and 4.2 mm, respectively (fig. 1). Total setup time for navigation surgery was less than 30 min in all cases. Stereotactic navigation guidance contributed to better localization of the tumor. It enabled surgeon to perform his procedure with better spatial awareness, and minimize guessing of surrounding anatomy (fig. 2). No intraoperative major complication was noted. Conclusion application of currently available stereotactic navigation system seems to be feasible with satisfactory accuracy in recurrent rectal cancer in a pelvic cavity by targeting pelvic and retroperitoneal structures. Patient-tailored image-guided navigation surgery especially for challenging

									cases will enhance surgical quality and patient safety. Reported events: three procedures were noted to have inaccurate patient registration as the registration error was >2mm. Manufacturer narrative: patient age not available from the site. Patient sex not available from the site. Patient weight not available from the site. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1222780-2021-00069	01/10/2020	Malfunction	HOLOGIC, INC.	02/04/2021	KNW	EVIVA STEREOTACTIC GUIDED BREAST BIOPSY SYSTEM	Material Twisted/Bent	IntraoperativePain; Breast Discomfort/Pain	During a biopsy procedure, after taking several specimens, the patient complained of pain in her breast. After drawing the needle back and out of the breast it was noted the tip of the needle was "bent or event twisted." no serious injury reported and no medical intervention was required. This event occurred in (b)(6) 2020, but was not reported by the customer to hologic until 3/8/2021. Manufacturer narrative: the device is not being returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
MW5097960	01/10/2020	Injury	UNK	17/11/2020	NEU	TITANIUM BREAST MARKER	Migration or Expulsion of Device	Pain; Weight Changes; Appropriate Clinical Signs, Symptoms, Conditions Term/Code Not Available	Not sure how involved there. During stereotactic needle biopsy of l breast in (b)(6) 2018, a titanium marker was implanted. Modest pain did not resolve for several months. I asked about migration, but staff knew of no such phenomena. After weight loss (20/25#) the following year, modest pain recurred sporadically with some strenuous arm muscle activity. This fall (2020), the pain changed to a sharp cut-like pain whose locus feels closer to nipple than previously. Much more frequent, painful and disruptive than previous episodes. A routine screening mammogram 2 weeks ago failed to reveal any tissue anomalies. My sense is that the marker has been migrating and has now

									moved into a much more nerve-dense area, triggering the sharper and more frequent pain. I don't think i can tolerate this level of recurrent pain over the long haul, so will seek removal of the device. I was given no warning about the risk of migrating, and was met with denial of any known problem with migration when i reported the problem to the provider within three months of the procedure. Fda safety report id # (b)(4).
1723170-2020-02755	30/09/2020	Malfunction	MEDTRONIC NAVIGATION, INC	20/10/2020	HAW	STEALTHSTATION S7 NAVIGATION	Imprecision	No Known Impact Or Consequence To Patient; No Clinical Signs, Symptoms or Conditions	Medtronic received information regarding a navigation system used during an electrode and probe placement procedure. It was reported that an responsive neurostimulation (rns) lead was placed inaccurately. It was reported that they were using a stereotactic frame biopsy procedure. They were placing the rns leads on the left and right side of the patient. They found that the lead was placed inaccurately by looking at the post op scan and saw that the rns lead was in the incorrect place on the left side of the patient. It was superior about 2.5 inches. They checked the coordinates on the system and say that the vertical coordinate was displayed as negative 11, but the surgeon did positive 11 on the frame, which would cause the inaccuracy. They left the rns lead in. No surgery was scheduled to remove the lead at the time. There was no delay to the procedure. It was noted that the patient was impacted. Additional information was received. It was clarified that there was no affect to the patient, just that the leads were placed inaccurately. The leads being placed inaccurately did not have any adverse consequences. It was unknown if a second procedure would be scheduled, but if one is, the local representative would be notified at that time. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued.
3002250546-2020-00005	28/09/2020	Malfunction	FHC, INC.	29/10/2020	HAW	FHC WAYPOINT STEREOTACTIC SYSTEM	Inadequate or Insufficient Training	No Clinical Signs, Symptoms or Conditions	Physician stated that he had a safety concern regarding the fhc multi oblique dual trajectory platform targeting guides: "in our or the other day, despite having done many of these cases, the wrong number was read-

									out (biopsy depth rather than target depth), resulting in a placement that was 1cm too deep. Fortunately, no injury resulted (the tip was in a csf space), but there was the real possibility of disaster. I would recommend that you either 1) remove the biopsy depth column and simply note separately that biopsy depth is 10mm further (something that should be obvious to anyone, anyway), or else 2) simply write in that column "+10mm". This issue was due to user error, the depth sheet was correct and displayed as it was intended to.
3002250546-2020-00006	28/09/2020	Malfunction	FHC, INC.	29/10/2020	HAW	FHC WAYPOINT STEREOTACTIC SYSTEM	Manufacturing, Packaging or Shipping Problem	No Clinical Signs, Symptoms or Conditions	Physician informed fhc that there was an issue with a starfix case. Physician reports that a platform height of 130 was chosen for the plan for this bilateral platform for patient. In the case physician observed a value of t=30 on the platform embossing. Being new to starfix, she followed this label and implanted the lead at 30 without questioning it. In post-operative scans, it was observed that the lead is 10 mm short of her target. The patient impact is that he/she will require a revision which bick plans to do using rosa. Physician informed fhc that they decided to bring the patient back in for a revision on10/1 with the same platform. They re-processed the platform and reattached without issue. Patient did very well during the revision surgery and in post-op.
2182207-2020-01467	21/09/2020	Injury	MEDTRONIC NEUROMODULATION	13/12/2020	MRU	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Awareness during Anaesthesia; Atrial Fibrillation; Intracranial Hemorrhage; Low Blood Pressure/ Hypotension	Authors: elsa m. Ronde, marja silvasti-lundell, johanna pekkola, minna tallgren, riku kivisaari. Title: preoperative magnetic resonance image quality in motion disorder patients scheduled for deep brain stimulation surgery. Stereotactic and functional neurosurgery. Doi: 10.1159/000506998. Abstract background: to obtain magnetic resonance (mr) images of good quality for accurate target localization in deep brain stimulation (dbs) surgery, sedation or anesthesia may be used, although their usefulness has not been proven. Objective: to assess whether sedation or general anesthesia (ga) improve the quality of mr imaging (mri). Methods:

									the records of dbs procedures for parkinson¿s disease (pd), dystonia, and essential tremor in our tertiary neurosurgical unit between january 2011 and june 2016 were reviewed. Adult patients with preoperative mr images were included. Patient records concerning mri, surgery, adverse events, and clinical outcome were retrospectively scrutinized and analyzed. Mr image quality was assessed by two independent radiologists. Results: a total of 215 preoperative mr images for 177 dbs procedures were analyzed. The mri sequences performed under ga were superior to those performed wit hout anesthesia or under sedation (p <(><<)> 0.01). Virtually all images captured under ga were of good quality, while the proportions among those captured with sedation or without anesthesia were <(><<)> 65%. Good image quality was not associated with better clin ical outcome (> 50% improvement in the unified parkinson¿s disease rating scale iii score) among patients with pd. Conclusion: ga was associated with better mri sequences than intravenous sedation or no anesthesia. Reported events: pli 10: it was reported that there were 3 patient's with intracranial hemorrhage. Pli 20: it was reported that 1 patient developed atrial fibrillation during their mri session and an immediate and successful cardioversion was performed. Pli 30: it was reported that there were 3 patients who were admitted to the hospital overnight due to anesthesia. Pli 40: it was reported that there were 9 patients who had hypotension which required medication. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: concomitant medical products: product id: neu_ins_stimulator, serial# :unknown, product type: implantable neurostimulator. Product id: neu_ins_stimulator, serial#: unknown, product type: implantable neurostimulator.

									Product id: neu_ins_stimulator, serial#: unknown, product type: implantable neurostimulator. Other relevant device(s) are: product id: neu_ins_stimulator, serial/lot #: unknown; product id: neu_ins_stimulator, serial/lot #: unknown; product id: neu_ins_stimulator, serial/lot #: unknown. This value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. If information is provided in the future, a supplemental report will be issued.
2182207-2020-01468	21/09/2020	Injury	MEDTRONIC NEUROMODULATION	13/12/2020	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Awareness during Anaesthesia; Atrial Fibrillation; Intracranial Hemorrhage; Low Blood Pressure/ Hypotension	Authors: elsa m. Ronde, marja silvasti-lundell, johanna pekkola, minna tallgren, riku kivisaari. Title: preoperative magnetic resonance image quality in motion disorder patients scheduled for deep brain stimulation surgery. Stereotactic and functional neurosurgery. Doi: 10.1159/000506998. Abstract background: to obtain magnetic resonance (mr) images of good quality for accurate target localization in deep brain stimulation (dbs) surgery, sedation or anesthesia may be used, although their usefulness has not been proven. Objective: to assess whether sedation or general anesthesia (ga) improve the quality of mr imaging (mri). Methods: the records of dbs procedures for parkinson¿s disease (pd), dystonia, and essential tremor in our tertiary neurosurgical unit between january 2011 and june 2016 were reviewed. Adult patients with preoperative mr images were included. Patient records concerning mri, surgery, adverse events, and clinical outcome were retrospectively scrutinized and analyzed. Mr image quality was assessed by two independent radiologists. Results: a total of 215 preoperative mr images for 177 dbs procedures were

									analyzed. The mri sequences performed under ga were superior to those performed wit hout anesthesia or under sedation (p < 0.01). Virtually all images captured under ga were of good quality, while the proportions among those captured with sedation or without anesthesia were < 65%. Good image quality was not associated with better clinical outcome (> 50% improvement in the unified parkinson¿s disease rating scale iii score) among patients with pd. Conclusion: ga was associated with better mri sequences than intravenous sedation or no anesthesia. Reported events: pli 10: it was reported that there were 3 patient's with intracranial hemorrhage. Pli 20: it was reported that 1 patient developed atrial fibrillation during their mri session and an immediate and successful cardioversion was performed. Pli 30: it was reported that there were 3 patients who were admitted to the hospital overnight due to anesthesia. Pli 40: it was reported that there were 9 patients who had hypotension which required medication. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: concomitant medical products: product id: neu_ins_stimulator, serial#: unknown, product type: implantable neurostimulator. Product id: neu_ins_stimulator, serial#: unknown, product type: implantable neurostimulator. Product id: neu_ins_stimulator, serial#: unknown, product type: implantable neurostimulator. Product id: neu_ins_stimulator, serial/lot #: unknown. Product id: neu_ins_stimulator, serial/lot #: unknown. Product id: neu_ins_stimulator, serial/lot #: unknown. Age: this value is the average age of the patients reported in the article as specific patients could not be identified. Sex: this value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event: please note that this date is

									based off of the date of publication of the article as the event dates were not provided in the published literature. If information is provided in the future, a supplemental report will be issued.
2182207-2020-01419	21/09/2020	Injury	MEDTRONIC NEUROMODULATION	08/12/2020	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Awareness during Anaesthesia; Atrial Fibrillation; Intracranial Hemorrhage; Low Blood Pressure/ Hypotension	Authors: elsa m. Ronde, marja silvasti-lundell, johanna pekkola, minna tallgren, riku kivisaari. Title: preoperative magnetic resonance image quality in motion disorder patients scheduled for deep brain stimulation surgery. Stereotactic and functional neurosurgery. Doi: 10.1159/000506998. Abstract background: to obtain magnetic resonance (mr) images of good quality for accurate target localization in deep brain stimulation (dbs) surgery, sedation or anesthesia may be used, although their usefulness has not been proven. Objective: to assess whether sedation or general anesthesia (ga) improve the quality of mr imaging (mri). Methods: the records of dbs procedures for parkinson¿s disease (pd), dystonia, and essential tremor in our tertiary neurosurgical unit between january 2011 and june 2016 were reviewed. Adult patients with preoperative mr images were included. Patient records concerning mri, surgery, adverse events, and clinical outcome were retrospectively scrutinized and analyzed. Mr image quality was assessed by two independent radiologists. Results: a total of 215 preoperative mr images for 177 dbs procedures were analyzed. The mri sequences performed under ga were superior to those performed wit hout anesthesia or under sedation (p < 0.01). Virtually all images captured under ga were of good quality, while the proportions among those captured with sedation or without anesthesia were < 65%. Good image quality was not associated with better clin ical outcome (> 50% improvement in the unified parkinson¿s disease rating scale iii score) among patients with pd. Conclusion: ga was associated with better mri sequences than intravenous sedation or no anesthesia. Reported events:

									pli 10: it was reported that there were 3 patient's with intracranial hemorrhage. Pli 20: it was reported that 1 patient developed atrial fibrillation during their mri session and an immediate and successful cardioversion was performed. Pli 30: it was reported that there were 3 patients who were admitted to the hospital overnight due to anesthesia. Pli 40: it was reported that there were 9 patients who had hypotension which required medication. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: concomitant medical products: product id: neu_ins_stimulator, serial#: unknown, product type: implantable neurostimulator. Product id: neu_ins_stimulator, serial#: unknown, product type: implantable neurostimulator. Product id: neu_ins_stimulator, serial#: unknown, product type: implantable neurostimulator. Product id: neu_ins_stimulator, serial/lot #: unknown. Product id: neu_ins_stimulator, serial/lot #: unknown. Product id: neu_ins_stimulator, serial/lot #: unknown. Age: this value is the average age of the patients reported in the article as specific patients could not be identified. Gender: this value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. If information is provided in the future, a supplemental report will be issued.
3005099803-2020-04429	21/09/2020	Malfunction	BOSTON SCIENTIFIC CORPORATION	19/10/2020	OVB	SPACEOAR SYSTEM	Positioning Problem	No Consequences Or Impact To Patient	It was reported to boston scientific corporation that spaceoar was implanted during a spaceoar placement procedure performed on (b)(6) 2020. Reportedly, fiducials were administered transperineally prior to spaceoar implantation. Additionally, the procedure was done under general anesthesia. According to the complainant, magnetic resonance imaging (mri) was

									performed post procedure and it showed that the gel infiltrated the rectal wall. Reportedly, saline was injected in the rectal wall during hydrodissection. There were no patient complications reported as a result of this event. The patient has received stereotactic body radiation therapy (sbrt). Manufacturer narrative: patient's exact age is unknown; however, it was reported that the patient was over the age of 18. The complainant was unable to provide the upn and suspect device lot number. Therefore, the expiration and device manufacture dates are unknown. (b)(4). The complainant indicated that the device remains implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental mdr will be filed.
MW5096674	14/09/2020	Malfunction	DEVICOR MEDICAL PRODUCTS INC.	15/09/2020	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE	Therapeutic or Diagnostic Output Failure	No Known Impact Or Consequence To Patient	Mammotome revolve probe unable to be "initialized" prior to beginning procedure. A subsequent "like" probe was used without issue. Fda safety report id# (b)(4).
10670191	09/09/2020	Malfunction	HOLOGIC, INC.	13/10/2020	KNW	EVIVA_0913-20	No Flow	No Clinical Signs, Symptoms or Conditions	During stereotactic breast biopsy the eviva handpiece did not allow saline to flow through tubing. Attempted to use another handpiece and the same result occurred. Manufacturer response for instrument, biopsy, eviva_0913-20 (per site reporter). Manufacturer is requesting return of the equipment. Hospital policy is to retain the equipment. I am confirming hospital policy at this time.
3005099803-2020-04309	01/09/2020	Injury	BOSTON SCIENTIFIC CORK LIMITED	30/09/2020	OVB	SPACEOAR SYSTEM	Adverse Event Without Identified Device or Use Problem	Fistula	It was reported to boston scientific corporation that spaceoar was implanted during a spaceoar placement procedure performed on an unknown date. According to the complainant, the patient requested spaceoar with stereotactic body radiation therapy (sbrt). Reportedly, there was no issue with spaceoar placement. The patient developed a fistula approximately 14 to 15 months after the procedure. The fistula was confirmed with a colonoscopy. The patient was referred to undergo a loop ileostomy with suprapubic tube placement to divert urine and stool. The patient is planned to

									undergo a delayed repair with gracilus muscle interposition. Manufacturer narrative: the exact age of the patient is unknown; however, it was reported that the patient was under the age of 60. Date of event: the exact date of the event is unknown. The provided event date, (b)(6) 2020, was chosen as a best estimate based on the date that the manufacturer became aware of the event, (b)(6) 2020. The complainant was unable to provide the device lot number. Therefore, the expiration and device manufacture dates are unknown. (implant date): the exact implant date is unknown. The provided implant date, (b)(6) 2019, was chosen as the best estimate based on the information that spaceoar was implanted 14-15 months prior to the fistula occurrence. (b)(4). The complainant indicated that the device remains implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental mdr will be filed.
1723170-2020-02484	01/09/2020	Malfunction	MEDTRONIC NAVIGATION, INC	21/09/2020	HAW	STEALTHSTATION S8 SYSTEM	Communication or Transmission Problem; Human-Device Interface Problem	No Patient Involvement; No Clinical Signs, Symptoms or Conditions	Medtronic received information regarding a navigation system being used outside of a procedure. It was reported that the århus did have issues, mostly related to pacs import, but also nav to nav transfer had issues. One of the doctors tried 12 times to move exams from pacs, but also from stealth plan to stealth their own system. A separate but maybe related issue was on a scan that was not accepted by the s8, the rep had this one anonymized on a usb stick. This was a stereotactic exam from århus ct with the standard leksell andframe ct box. The exam itself was accepted by the s8 but the frame failed auto registration, looking at it on the planning station it looked fine so there were no obvious reasons for it not to work, so it was important to get it analyzed. No patient was present. Manufacturer narrative: onsite functional and visual examination was performed by a manufacturer representative. The system

									passed a system checkout and was determined to be operational. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: no patient information provided as no patient was present. No parts have been received by the manufacturer for evaluation. Other relevant device(s) are: pn: 9736113, ln/sn: unk. If information is provided in the future, a supplemental report will be issued.
1045254-2020-00419	26/08/2020	Injury	MEDTRONIC XOMED INC.	22/09/2020	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage	Medtronic received information regarding a thermal therapy system being used for a neuro soft tissue ablation procedure. It was reported that intra-operatively, when they got down to magnetic resonance imaging (mri) to do a volumetric scan, they noticed a small hemorrhage in the patient's brain. Additional information was received regarding the placement of the catheter. It was reported that the site placed two catheters. The hemorrhage occurred on the first catheter placement, the more posterior catheter of the two. There were no issues placing either catheters, and both were placed accurately. A non-medtronic robot was used to stereotactically place the catheters. The surgeon suspected that the hemorrhage may have occurred while inserting the catheter; the catheter was accurately placed and secure throughout the procedure, it was suspected that it may have hit a small blood vessel when it was initially inserted. The surgeon was not concerned and continued the case. The procedure was completed without delay. The patient left same day without issues. There was no reported impact to patient outcome. Manufacturer narrative: no parts have been received by the manufacturer for evaluation. If information is provided in the future, a supplemental report will be issued.
3013649990-2020-00003	18/08/2020	Malfunction	HEALTH BEACONS, INC.	18/09/2020	NEU	LOCALIZER	Material Split, Cut or Torn	Breast Discomfort/Pain	On (b)(6) 2020, health beacons became aware of an incident at (b)(6). Patient was having a health beacons tag placed with a 10cm tag applicator. According to the rn, the applicator was difficult to push through the breast, as the patient's breast was very

									dense. After evaluating placement of the needle with images, the tag deployed and at some point, the tag appears on imaging to have split in two pieces. The tag did not give a signal after implantation, but the signal and tag id# had been confirmed during intial scanning of the packaging prior to implantation. Patient became vasovagal due to the fact she was sitting up for the upright stereotactic placement of the tag. The physician determined there was enough evidence for orientation to remove the area of interest without difficulty, and the patient's surgery was scheduled for the following week as originally intended. Date of the surgery was not moved. On (b)(6) 2020, health beacons spoke with the clinical specialist, who confirmed the removal of the tissue, and the tag were successful, and that the recovered tag had been sent with the tissue to pathology. Clinical specialist expressed confidence that the cause of the tagBreakage was delivering the tag against resistance. They have encountered this before, and in another case had determined to use an introducer to aid placement. On 11-sep-2020, the field representative shared images of the explanted tag, which clearly show the tag broken in two. Manufacturer narrative: justification for the submission of the mdr past the required 30 days: day 30: on (b)(6) 2020, emdr was packaged for submission. When connected to webtrader to submit report, the system rejected the report submission due to an expired certificate. It was not possible to renew the certificate on 17-sep-2020. Day 31: on (b)(6) 2020, an alternate way to submit the report through parent company (hologic inc.) Was decided upon. Report is being submitted one day late.
2020394-2020-20759	05/08/2020	Malfunction	BARD PERIPHERAL VASCULAR, INC.	07/12/2020	KNW	ENCOR BIOPSY PROBE	Difficult to Remove	No Clinical Signs, Symptoms or Conditions	It was reported during the stereotactic breast biopsy, the device allegedly difficult to remove. There was no reported patient injury. Manufacturer narrative: as the lot number for the device was not provided, a review of the device history record could

									not be performed. The return of the sample is pending. However, a photo was provided for review. The investigation of the reported event is currently underway.
1723170-2021-02443	04/08/2020	Injury	MEDTRONIC NAVIGATION, INC	06/10/2021	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Hematoma	Bertuccio, a., elia, a., robba, c., scaglione, g., longo, g.p., sgubin, d., vitali, m., barbanera, a. Frameless stereotactic biopsy with dti-based tractography integration: how to adjust the trajectory¿a case series. World neurosurgery 2020 143: 346-352 https://doi.org/10.1016/j.wneu.2020.08.0 background: frameless stereotactic biopsy represents a minimally invasive procedure used for the histopathological diagnosis of brain tumors or to safely approach deep-seated lesions near eloquent areas not amenable for classical neurosurgical procedures. Traditionally, biopsy is performed relying on anatomical landmarks, but it can lead itself to intra- and postoperative complications, such as hemorrhage and fiber disruption. Diffusion tensor imaging (dti) tractography represents a useful tool that can analyze the individual fiber tract conformation in cases of brain tumor and consequently identify the best biopsy trajectory, preserving white matter pathways. In our study, we present a novel technique that is based on the use of preoperative dti for biopsy. Methods: between january 2018 and january 2020, data about patients who underwent frameless biopsy using dti tractography were retrospectively reviewed. The inclusion criterion was adult patients eligible for elective surgery for a single or multiple deep-seated lesions with contraindications to complete surgical resection. Results: we included 12 patients (mean age of 67.9 [9.6] years). A single cranial lesion was detected in 7 cases, and multiple lesions in 5 cases. The use of dti enabled the identification of white matter pathways in all cases and adjustment of the biopsy trajectory based on anatomical landmarks in 7 cases. Postoperative hematoma was reported in 1 case, and histological diagnosis was obtained in 11

									cases. Conclusion: according to our results, tractography is a useful tool that can enhance the safety of cerebral lesions biopsy sparing any fiber tract damages. Reportable events: in 1 case, a postoperative hematoma was reported and was conservatively managed. Manufacturer narrative: patient age is the mean value of patients in the study. Patient gender is the majority value of patients in the study. Patient weight not available from the site. Event date is the date the article was accepted for publication. Device lot number, or serial number, unavailable. 510(k) is dependent upon the device model number and is therefore, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacture date is dependent on the device lot/serial number, therefore is unavailable. If information is provided in the future, a supplemental report will be issued.
3002250546-2020-00003	03/08/2020	Injury	FHC, INC.	19/08/2020	HAW	WAYPOINT IMPLANT KIT	Adverse Event Without Identified Device or Use Problem	Post Operative Wound Infection	Physician was in surgery and discovered that one of the waypoint anchor screw sites was infected and purulent. It was the anterior-right anchor. The burr hole had not yet been drilled, so only the fiducial site skin incisions had been made. Physician was going to remove the anchor and postpone the dbs implantation to another date. Physician planned to re-implant new fiducials and redesign the platform for the rescheduled case. There was no indication of larger harm to the patient, and physician intends to reschedule to implant the same way soon. There was no indication of any failure or defect of the anchor screw.
3004608878-2020-00514	27/07/2020	Injury	INTEGRA LIFESCIENCES CORPORATION OH/USA	10/09/2020	HBL	MAYFIELD MODIFIED SKULL CLAMP	Insufficient Information	Laceration(s)	This is 1 or 4 reports. A medwatch form with uf/ importer report (b)(4) was received on 13aug2020 with the following information: a (b)(6) male patient suffered a scalp laceration as a result of the a1059 mayfield modified skull clamp. Additional information received on 14aug2020 indicated that the patient undergone a stereotactic brain biopsy on (b)(6) 2020. The patient was initially positioned supine and was not repositioned during surgery.

									The patient suffered scalp laceration (unspecified); compression was applied. The patient was doing fine after the procedure. Manufacturer narrative: the device was not yet received by the manufacturer for evaluation. The plant investigation is in progress and a supplemental medwatch report will be submitted upon completion of the investigation. Linked to mfg report numbers 3004608878-2020-00515, 3004608878-2020-00516, and 3004608878-2020-00517.
2134265-2021-08849	17/07/2020	Death	BOSTON SCIENTIFIC CORPORATION	13/07/2021	NAJ	EMBOZENE MICROSPHERES	Adverse Event Without Identified Device or Use Problem	AbdominalPain; Fatigue; Hemorrhage/Bleeding; Nausea	It was reported a subject passed away following transarterial chemoembolization (tace) via a journal article. Sixteen patients were enrolled the study. 13 patients received single-fraction stereotactic body radiation therapy (sbrt) followed by tace within 24 hours. Median follow-up was 15.3 months. The most common toxicities were fatigue (46.2%), abdominal pain (38.5%), and nausea (38.5%). Crude rates of grade 1 or higher and grade 2 or higher toxicity were 85% and 38%, respectively. There were no grade 3 or 4 toxicities. One patient in cohort 2 died of intraperitoneal hemorrhage 4 days after tace (grade 5 toxicity), which was probably related to protocol therapy. Manufacturer narrative: date of event: event date not provided and publication date of journal article was used. Sebastian, nikhil t., et al. "a pilot trial evaluating stereotactic body radiation therapy to induce hyperemia in combination with transarterial chemoembolization for hepatocellular carcinoma." international journal of radiation oncology* biology* physics 108.5 (2020): 1276-1283.
8043933-2020-00043	17/07/2020	Malfunction	BRAINLAB AG	28/08/2020	IYE	EXACTRAC (VERSION 6.2)	Use of Device Problem; Insufficient Information	Radiation Overdose; Unintended Radiation Exposure; No Clinical Signs, Symptoms or Conditions	A patient was intended to be positioned for a fractionated 4 arc stereotactic rt treatment for a vestibular schwannoma with brainlab exactrac patient positioning system (version (b)(4)) and varian truebeam radiotherapy system (version (b)(4)) using the auxiliary device interface (adi). Adi is utilized to send couch move requests from exactrac to the treatment application and to authorize beam requests of the treatment

									application by exactrac. When a patient is loaded by exactrac, exactrac verifies the position of the patient and only authorizes beam requests if the patient is correctly positioned (i.e. Ok icon visible on exactrac screen). For this specific treatment, the patient plan was selected from the varian truebeam queue and opened, the associated plan was available in exactrac and this was also opened. After prepositioning of the patient, the correction shifts for exact patient positioning have been calculated by exactrac with the x-ray correction step. A translation shift was required, but the calculated pitch and roll shifts were within tolerance for this site and did not need correction. The brainlab robotics (pitch and roll) movements were canceled, the translation was applied for the couch, and the shift was verified by the acquisition of another orthogonal x-ray image pair (x-ray verification step). All parameters were within tolerance and no additional corrections were necessary, and the user finished all tasks in the fusion workspace in the exactrac software. A message to apply robotic movements (pitch and roll shifts) was displayed on exactrac, but despite the robotics were within tolerance, the message was not canceled by the user, and the robotic shifts were sent to varian truebeam in error. When the hospital's staff proceeded to treatment and the user pressed the motion enable button, the gantry was moved to the starting position for arc 1, and afterwards the brainlab robotics applied the pitch and roll shifts from exactrac. The root cause for this movement is not yet confirmed and is undergoing further investigation. The user did not notice the application of the robotic couch movement and despite the exactrac was now displaying the "low accuracy" icon and did not show the "ok" icon, the truebeam was authorized to treat and the treatment was started by the user. After 37 mu from arc 1 were delivered, the user noticed the low accuracy message on

									exactrac and stopped the treatment. The patient was repositioned and the correct positioning was verified. The treatment was completed as intended. According to the hospital there were no negative clinical effects for this patient due to this issue, despite the patient has been irradiated in a slightly deviated position than intended (with 0.7% of the total mu to be delivered). Manufacturer narrative: although according to the hospital, there are no negative clinical effects for this patient due to this issue. A risk to the patient's health could not be excluded for these specific circumstances, since the patient has been irradiated in a slightly deviated position than intended, with the brainlab device involved. A comprehensive investigation by brainlab regarding this specific event is currently ongoing and final conclusions are pending. Brainlab plans to issue a follow-up report to the fda upon completion of investigation.
MW5095843	14/07/2020	Injury	DEVICOR MEDICAL PRODUCTS, INC.	31/07/2020	KNW	MAMMOTOME REVOLVE STEREOACTIVE PROBE NEEDLE	Break	Calcium Deposits/Calcification; Foreign Body In Patient	Stereotactic left bread biopsy was performed. A 12 cm, 10-gauge mammotome revolve needle was inadvertently loaded in mammotome instead of a 9cm, 10-gauge needle. Biopsy of left breast lesion was performed. Postbiopsy images showed a 4mm v shaped retained metallic fragment in left breast. Inspection of the needle showed a damaged cannula at the tip. Patient was immediately referred to breast clinic and seen by breast surgeon. Patient scheduled for elective surgery for removal of breast lesion/calcifications and retained metallic fragment/foreign body. The 12 cm long needle may have had contact with the table mount where upon the tip of the biopsy needle was damaged and resulted in avulsion of a 4 mm retained foreign body. The original packaging for the probe in question was not kept, nor was the probe.
3008492462-2020-00008	14/07/2020	Injury	DEVICOR MEDICAL PRODUCTS, INC	29/09/2020	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE	Material Fragmentation	Foreign Body In Patient	It was reported via medwatch voluntary event report that during a stereotactic left breast biopsy procedure, a 12 cm, 10 gauge mammotome revolve needle was

									inadvertently loaded in mammotome instead of a 9 cm, 10 gauge needle. Biopsy of left breast lesion was performed. Post biopsy images showed a 4 mm v shaped retained metallic fragment in left breast. Inspection of the needle showed a damaged cannula at the tip. Patient was immediately referred to breast clinic and seen by breast surgeon. Patient scheduled for elective surgery for removal of breast lesion/calcifications and retained metallic fragment/foreign body. The original packaging for the probe in question was not kept, nor was the probe. Device was traced back to (b)(6) hospital-(b)(6)(1383998) based off the lot number. Manufacturer narrative: mst1012 probes are sterile, single use devices, indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis of breast abnormalities. It was reported via medwatch voluntary event report that stereotactic left breast biopsy was performed. A 12 cm, 10 gauge mammotome revolve needle was inadvertently loaded in mammotome instead of a 9 cm, 10 gauge needle. Post biopsy images showed a 4 mm v shaped retained metallic fragment in left breast. Inspection of the needle showed a damaged cannula at the tip. Patient was immediately referred to breast clinic and seen by breast surgeon. Patient scheduled for elective surgery for removal of breast lesion/calcifications and retained metallic fragment/foreign body. Based on the description of the event provided in fda report mw5095843, it is believed that the customer entered the incorrect product code information in to the stereotactic targeting dimensions. Upon firing of device, because the user thought they had a 9cm needle (and the actually had a 12cm needle), the extra 3sm length unaccounted for in the targeting software, the needle was able to be fired past the zero point and into the bucky of the stereotactic brest imaging table. Firing into the bucky is sufficient force toBreak off the tip of the

									needle of the stereotactic biopsy device, embedding it into the soft tissue of the patients breast.
1222780-2020-00106	10/07/2020	Injury	HOLOGIC, INC.	24/07/2020	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Failure to Fire; Suction Failure	No Code Available	It was reported that during the procedure, needle was not passing test during a biopsy, while a patient was on the table. Second needle passed test, was working, but still had issues with taking multiple core samples and a non diagnostic sample was taken. The patient exam has to be repeated. No additional details available. Manufacturer narrative: potential harm to patient due to delay in biopsy results. Lot and serial number of the disposable device not provided by the complainant, therefore the expiration date is not known. The device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. If the device is returned and evaluation completed, a supplemental medwatch will be filed. Lot number of the disposable device not provided by the complainant, therefore the manufacture date is not known. Device history record (dhr) review was unable to be conducted for the disposable device as the identification numbers were not provided by the complainant.
1222780-2020-00105	10/07/2020	Injury	HOLOGIC, INC.	22/07/2020	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Failure to Fire; Suction Failure	No Code Available	It was reported that during the procedure, "the needle was not passing test during a biopsy, while a patient was on the table. Second needle passed test, was working, but still had issues with taking multiple core samples and a non diagnostic sample was taken. The patient exam has to be repeated." no additional details available. Manufacturer narrative: potential harm to patient due to delay in biopsy results. Lot and serial number of the disposable device not provided by the complainant, therefore the expiration date is not known. The device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. If the device is returned and evaluation completed, a supplemental medwatch will be filed. Lot number of the disposable device not provided by the complainant, therefore the

									manufacture date is not known. Device history record (dhr) review was unable to be conducted for the disposable device as the identification numbers were not provided by the complainant.
2649622-2020-13294	08/07/2020	Injury	MPRI	10/07/2020	MHY	ACTIVA	Break	No Known Impact Or Consequence To Patient	It was reported that when pulling the lead out of the skin between the skull and scalp the most distal contact of the electrode came loose and the cable with the electrode hung out. The defective electrode was no longer usable so it was then cut off. A new stereotactic frame was attached, and a new ct was run. Then they went back to the operating room where they removed the defective electrode and re-implanted a new electrode. The issue was resolved. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued.
2182207-2020-00756	07/07/2020	Injury	MEDTRONIC NEUROMODULATION	24/08/2020	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Seizures	Summary: in most centers, the surgery of deep brain stimulation (dbs) is performed using a stereotactic frame. Compared with frame-based technique, frameless stereotaxy reduces the duration of surgical procedure and patient¿s discomfort, with lead placing accuracy equivalent after the learning curve. Although several studies have investigated the targeting accuracy of this technique, only a few studies reported clinical outcomes, with data of short-term follow-up. To assess clinical efficacy and safety of frameless bilateral subthalamic nucleus (stn) dbs in parkinson¿s disease (pd) patients at 1- and 3-year follow-up. Consecutive pd patients who underwent bilateral stn-dbs with a manual adjustable frameless system were included in the study. The data were collected retrospectively. Eighteen pd patients underwent bilateral stn-dbs implant and were included in the study. All patients completed 1-year observation and ten of them completed 3-year observation. At 1-year follow-up, motor efficacy of stn stimulation in off-med condition was of 30.1% (p = 0 .003) and at 3-year follow-up was of 36.3%, compared with off-stim condition at 3-year follow-up (p = 0.005).

									Dopaminergic drugs were significantly reduced by 31.2% 1 year after the intervention (p = 0.003) and 31.7% 3 years after the intervention (p = 0.04). No serious adverse events occurred during surgery. Frameless stereotaxy is an effective and safe technique for dbs surgery at 1- and 3-year follow-up, with great advantages for patients¿ discomfort during surgery. Reported events: one patient experienced a single seizure after the implantable neurostimulator (ins) was turned on. The following device information was identified in the article: lead model 3389. Manufacturer narrative: piano c, bove f, mulas d, bentivoglio ar, cioni b, tufo t. Frameless stereotaxy in subthalamic deep brain stimulation: 3-year clinical outcome. Neurol sci. 2020. 10.1007/s10072-020-04561-9. Age at time of event: this value is the average age of the patients reported in the article as specific patients could not be identified. Sex: this value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. If information is provided in the future, a supplemental report will be issued.
2182207-2020-00755	07/07/2020	Malfunction	MEDTRONIC NEUROMODULATION	24/08/2020	MHY	IMPLANTABLE NEUROSTIMULATOR	Insufficient Information	No Known Impact Or Consequence To Patient	Summary: in most centers, the surgery of deep brain stimulation (dbs) is performed using a stereotactic frame. Compared with frame-based technique, frameless stereotaxy reduces the duration of surgical procedure and patient¿s discomfort, with lead placing accuracy equivalent after the learning curve. Although several studies

									have investigated the targeting accuracy of this technique, only a few studies reported clinical outcomes, with data of short-term follow-up. To assess clinical efficacy and safety of frameless bilateral subthalamic nucleus (stn) dbs in parkinson¿s disease (pd) patients at 1- and 3-year follow-up. Consecutive pd patients who underwent bilateral stn-dbs with a manual adjustable frameless system were included in the study. The data were collected retrospectively. Eighteen pd patients underwent bilateral stn-dbs implant and were included in the study. All patients completed 1-year observation and ten of them completed 3-year observation. At 1-year follow-up, motor efficacy of stn stimulation in off-med condition was of 30.1% (p = 0 .003) and at 3-year follow-up was of 36.3%, compared with off-stim condition at 3-year follow-up (p = 0.005). Dopaminergic drugs were significantly reduced by 31.2% 1 year after the intervention (p = 0.003) and 31.7% 3 years after the intervention (p = 0.04). No serious adverse events occurred during surgery. Frameless stereotaxy is an effective and safe technique for dbs surgery at 1- and 3-year follow-up, with great advantages for patients¿ discomfort during surgery. Reported events: one patient experienced malfunction of one lead contact. The following device information was identified in the article: lead model 3389. Manufacturer narrative: piano c, bove f, mulas d, bentivoglio ar, cioni b, tufo t. Frameless stereotaxy in subthalamic deep brain stimulation: 3-year clinical outcome. Neurol sci. 2020. 10.1007/s10072-020-04561-9. Age: this value is the average age of the patients reported in the article as specific patients could not be identified. Sex: this value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event: please note that this date is based off of the date of publication of the article as the event dates

									were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Information references the main component of the system. Other relevant device(s) are: product id: 3389, serial/lot #: unknown, implant date: asku , udi#: asku. If information is provided in the future, a supplemental report will be issued.
1723170-2020-01895	06/07/2020	Injury	MEDTRONIC NAVIGATION, INC	10/07/2020	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Pulmonary Embolism; Arrhythmia; Atrial Fibrillation; BoneFracture(s); Hemorrhage, Cerebral; Muscle Weakness; Nerve Damage; Pneumonia	Citation: dhiego c. A. Bastos, md, rafael a. Vega, md, phd, jeffrey i. Traylor, bs, amol ghia, md, jing li, md, marilou oro, dnp, andrew j. Bishop, md, debra yeboa, md, behrang amini, md, vinodh a. Kumar, md; ganesh rao, md, laurence d. Rhines, md, claudio e. Tatsui, md. Spinal laser interstitial thermal therapy: single-center experience and outcomes in the first 120 cases. Abstract objective: presenting results of a consecutive series of 120 patients treated with spinal laser interstitial thermal therapy (slitt) to manage epidural spinal cord compression (escc) from metastatic tumors. Methods: electronic records of patients treated from 2013 to 2019 were analyzed retrospectively. Data collected included: demographics, pathology, clinical, operative, and imaging findings; degree of epidural compression before and after slitt; length of hospital stay; complications, and time before subsequent oncologic treatment. Independent sample t tests were used to compare means between pre-slitt and post-slitt treatments. Survival was estimated by the kaplan-meier method. Multivariate logistic regression was used to analyze predictive factors for local recurrence and neurological complications. Results: there were 110 patients undergoing 120 slitt procedures. Spinal levels treated included: 5 cervical, 8 lumbar, and 107 thoracic. Pre-slitt frankel scores were e (91.7%), d (6.7%),

									and c (1.7%). Preoperative escc was 1c or higher in 92% of cases. Metastases were most common from renal cell carcinoma (39%), followed by non-small cell lung carcinoma (12%), and other tumors (49%). The most common location of escc was in the vertebral body (88.3%), followed by paraspinal/foraminal (7.5%), and posterior elements (4.2%). Adjuvant radiotherapy (spinal stereotactic radiosurgery or cebrt) was performed in 87 cases (72.5%), whereas 33 (27.5%) procedures were performed as salvage after radiotherapy options were exhausted. Slitt was performed without need for spinal stabilization in 87 cases (72.5%). Postslitt frankel scores were e (85%), d (10%), c (4.2%), and b (0.8%); treatment was associated with a median decrease of 2 escc grades. Local control rate at one year was 81.7%. Local control failure occurred in 25 (20.8%) cases. The median progression-free survival was not reached, and overall survival was 14 months. Tumor location in the paraspinal region and salvage treat ment were independent predictors of local recurrence, with odds ratios (ors) of 6.3 and 3.3, respectively (p=0.01). Complications were observed in 22 cases (18.3%). Slitt procedures performed in the lumbar and cervical spine had ors for neurological complications of 15.4 and 17.1 (p < 0.01), respectively, relative to thoracic spine. Conclusions: slitt is safe and provides effective local control for high-grade escc from vertebral metastases in the thoracic spine, particularly when combined with adjuvant radiotherapy. We propose considering slitt as an alternative to open surgery in selected patients with spinal metastases. Reported events: (b)(6) yr lumbar patient experienced aFracture 85 days post-operative (b)(6) yr cervical patient experienced spinothalamic dysfunction (b)(6) yr thoracic patient experienced wound dehiscence (b)(6) yr lumbar patient experienced a l1/2 nerve root palsy (b)(6) yr thoracic patient experienced aFracture 17

									days post-operative (b)(6) yr lumbar patient experienced a l1/2 nerve root palsy (b)(6) yr thoracic patient experienced a spinothalamic dysfunction (b)(6) yr lumbar patient experienced aFracture 172 days post-operative (b)(6) yr lumbar patient experienced an instance of cauda equina syndrome (b)(6) yr cervical patient experienced a cerebellar stroke (b)(6) yr thoracic patient experienced aFracture 165 days post-operative (b)(6) yr thoracic patient experienced a cardiac arrhythmia (b)(6)yr thoracic patient experienced lle-weakness-hospice (b)(6) yr thoracic patient experienced pneumonia (b)(6) yr thoracic patient experienced aFracture 105 days post-operative (b)(6) yr thoracic patient experienced pneumonia (b)(6) yr thoracic patient experienced lle weakness/open decompression (b)(6) yr thoracic patient experienced lle weakness/open decompression (b)(6) yr thoracic patient experienced aFracture 20 days post-operative (b)(6) yr thoracic patient experienced aFracture 145 days post-operative (b)(6) yr thoracic patient experienced an atrial fibrillation (b)(6) yr thoracic patient experienced a pulmonary embolism. Manufacturer narrative: patient age is the mean value of patients in the study. Patient gender is the majority value of patients in the study. Patient weight not available from the site. Event date is the receipt date of the manuscript. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. (b)(4). If information is provided in the future, a supplemental report will be issued.
1723170-2020-03237	05/07/2020	Injury	MEDTRONIC NAVIGATION, INC	10/12/2020	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage; Unspecified Nervous System Problem	Citation: monica lara-almunia & javier hernandez-vicente. Symptomatic intracranial hemorrhages and frame based stereotactic brain biopsy. Surgical neurology international. 2020, 11(218). Doi : 10.25259/sni_102_2020. Abstract:

									background: stereotactic biopsy is a well-established procedure in neurosurgery. Our objective is to define the clinical, radiological, and technical factors that can condition the emergence of postbiopsy symptomatic intracranial hemorrhage. Based on our findings, we suggest recommendations to improve its usual clinical practice. Methods: we made a retrospective study of 429 cases with stereotactic biopsies performed in the past 37 years. The surgical procedure-was adapted in terms of the stereotactic frames (todd-wells, crw, leksell), neuroimaging tests, and planning programs available in the hospital. Fifty-three variables were analyzed for each patient (spss.23). Results: the diagnostic yield was 90.7%. Forty-one patients (9.5%) suffered a symptomatic postbiopsy hemorrhage; only 17 (3.9%) had permanent morbidity. The mortality was 0.93% (n = 4). A postsurgical ct scan was requested only in 99 patients (23%) of our series. Lesion mass effect, cystic component, contrast enhancement, histological nature, or number of targets were not associated with a greater risk of symptomatic postbiopsy hemorrhage (p > 0.05). On the other hand, the biopsies made by nonexpert neurosurgeons (p = 0.01) or under general anesthesia (p = 0.02) resulted in a greater risk of symptomatic postbiopsy hemorrhage. Anesthetic type was the clearest predictive factor of bleeding with this technique (or: 0.24). Conclusion: stereotactic biopsy is a very valuable tool. To optimize its safety and minimize the risk of intracranial bleeding, it requires both a knowledge of stereotactic techniques and very careful surgical planning. While the patient¿s stay in intensive vigilance units after the procedure is a useful strategy, the request for control ct scans should be conditioned by the clinical evolution of each patient. Reported event(s): -14 patients experienced hemorrhages in post-operative ct scans. 6 cases were found to have neurological deterioration and 8 were noted

									to be small and asymptomatic. Manufacturer narrative: patient age is the mean value of patients in the study. Patient sex is the majority value of patients in the study. Patient weight not available from the site. Event date is the accepted date of the publication. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
10642554	01/07/2020	Injury	TRISALUS LIFE SCIENCES	28/09/2020	DQO	TRINAV INFUSION SYSTEM	Therapy Delivered to Incorrect Body Area	Radiation Exposure, Unintended	Stereostatic body radiation therapy utilizing y-90 to the liver with a suture-fire (one-way) catheter. Radiation found in stomach / esophagus. Subsequently the pt developed severe gastritis / esophagitis leading stereotactic body radiation therapy utilizing y-90 to the liver with a sure-fire (one-way) catheter. Radiation found in stomach / esophagus. Subsequently the pt developed severe gastritis/esophagitis leading to radiation gastritis and radiation ulcerations. Pt needed a laparoscopic jejunostomy feeding tube placement for caloric intake on (b)(6) 2020.
1723170-2021-02215	24/06/2020	Injury	MEDTRONIC NAVIGATION, INC	07/09/2021	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Abscess; Encephalopathy; Headache; Hematoma; Intracranial Hemorrhage; Unspecified Infection; Muscle Weakness; Dysphasia; Convulsion/Seizure; Unspecified Nervous System Problem; Thrombosis/Thrombus;	Citation: gupta k, cabaniss b, kheder a, et al. Stereotactic mri-guided laser interstitial thermal therapy for extratemporal lobe epilepsy. Epilepsia. 2020; 61:1723¿1734. Https://doi.org/10.1111/epi.16614 summary: objective: magnetic resonance imaging (mri)¿guided laser interstitial thermal therapy (mrg-litt) is an alternative to open epilepsy surgery. We assess safety and effectiveness of mrg-litt for extratemporal lobe epilepsy (etle) in patients who are considered less favorable for open resection. Methods: we retrospectively reviewed sequential cases of patients with focal etle who underwent mrg-litt between 2012 and 2019. Epileptogenic zones were determined from standard clinical and imaging data ± stereoelectroencephalography (seeg). Standard stereotactic techniques, mri

								Insufficient Information	thermometry, and a commercial laser thermal therapy system were used for ablations. Anatomic mri was used to calculate ablation volumes. Clinical outcomes were determined longitudinally. Results: thirty-five patients with mean epilepsy duration of 21.3 ± 12.2 years underwent mrg-litt for focal etle at a mean age 36.4 ± 12.7 years. A mean 2.59 ± 1.45 trajectories per patient were used to obtain ablation volumes of 8.8 ± 7.5 cm3. Mean follow-up was 27.3 ± 19.5 months. Of 32 patients with >12 months of follow-up, 17 (53%) achieved good outcomes (engel class i + ii) of whom 14 (44%) were engel class i. Subgroup analysis revealed better outcomes for patients with lesional etle than for those who were nonlesional, multifocal, or who had failed prior interventions (p = .02). Of 13 patients showing favorable seizure-onset patterns (localized low voltage fast activity or rhythmic spiking on seeg) prior to ablation, 9 (69%) achieved good outcomes, whereas only 3 of 11 (27%) who show other slower onset patterns achieved good outcomes. Minor adverse events included six patients with transient sensorimotor neurologic deficits and four patients with asymptomatic hemorrhages along the fiber tract. Major adverse events included one patient with a brain abscess that required stereotactic drainage and one patient with persistent hypothalamic obesity. Three deaths¿two seizure-associated and one suicide¿were unrelated to surgical procedures. Reported events: four patients experienced asymptomatic tract hemorrhage on imaging during the course of the surgery that did not require any intervention or impact hospital length of stay. The total rate of procedure-related intracranial hemorrhages was 4 of 35 (11%); none caused deficits or required surgical intervention. One male patient experienced surgical readmission for an intracranial abscess at the site of ablation. He had already undergone three right craniotomies

									for sde grid-based evaluation and right temporal lobectomy. He did not maintain long-term seizure freedom and 3 years later underwent seeg reinvestigation, which revealed an ez involving right retrosplenial cingulate, posterior cingulate, and posterior parahippocampal cortices. Six months later he underwent laser ablation of the right retrospenial/posterior cingulate and posterior parahippocampal cortices with three de novo laser bolt trajectories placed by stereotactic robot. Notably, one such bolt was placed through a prior craniotomy scar near the vertex. He presented 4 weeks later with altered mental status and superficial drainage from this specific site. Diffusion and contrasted mri suggested a brain abscess involving the ablation site and stereotactic tract with surrounding vasogenic edema. Incision through vascularly compromised scalp and poor healing was felt to be a risk factor for infection. He underwent stereotactic needle aspiration and a course of intravenous antibiotics, recovered without long-term sequelae, and had excellent seizure control. Five patients experienced medical readmission. One patient who was ablated in the context of palliative treatment of status epilepticus, had an extended postoperative hospitalization for medical management of hyponatremia. Six patients (17%) were readmitted perioperatively for various reasons including infection, seizures, postoperative headaches, medication encephalopathy and transient vague complaints, and initiation of anticoagulation for new diagnosis of deep vein thrombosis. One patient who had a prior history of deep vein thrombosis and chronic anticoagulation, was readmitted briefly for a delayed anticoagulation associated symptomatic subdural hematoma at a previous operative site that was successfully managed nonoperatively. One patient experienced persistent deficit of hypothalamic obesity see attached article. Manufacturer narrative: patient

									information was not included in the journal article. This value reflects the mean age of patients in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients in the article as specific patients could not be identified. Please note that this date is based off of the date the article was accepted as the event dates were not provided in the published literature. Article citation is included. System product number and serial number not provided in journal article. Udi not available for this system. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2020-02953	19/06/2020	Injury	MEDTRONIC NAVIGATION, INC	11/11/2020	HAW	MEDTRONIC NAVIGATION	Imprecision	Unspecified Infection; No Code Available	Citation: joseph s. Domino, md, mph, kyle a. Smith, md, and paul m. Arnold, md, facs, clinical and radiologic outcomes of thoracolumbar fusions using intraoperative ct guidance and stereotactic navigation in a spinal trauma population, clin spine surg, 2020. Summary: study design: retrospective review of prospectively collected single-institution database. Objective: to analyze the clinical and radiographic outcomes of posterior thoracolumbar fusions using intraoperative computed tomography (ct)-guidance and stereotactic navigation in thoracolumbar spinal trauma. Summary of background data: pedicle screw instrumentation is utilized for stabilization in thoracolumbar fusions. Suboptimal placement may lead to neurovascular complications, pseudarthrosis, postoperative pain, and the need for revision surgery. Image- guided spinal surgery is commonly used to improve accuracy, particularly for complex anatomy such as encountered with traumaticFractures. Methods: we retrospectively identified 58 patients undergoing posterior thoracolumbar fusions using intraoperative ct and stereotactic navigation for traumaticFractures from 2010 to 2017 at a single institution. Pedicle

									screw accuracy, realignment, clinical outcomes, and ease of use were retrospectively reviewed. Accuracy was assessed on post-placement or postoperative ct. Breach grades included: grade 1 (< 2 mm), grade 2 (2¿4 mm), and grade 3 (> 4 mm). Results: a total of 58 patients were identified having undergone 58 operations, which involved placement of 519 pedicle screws. TraumaticFracture patterns and levels of injury were varied. Accurate pedicle screw placement was found in 95.8% and was stable over time. Breach included: grade 1 in 19 screws, grade 2 in 2 screws, and grade 3 in 1 screw. No neurovascular complications were noted. No revision surgery was performed for misplacement. A subgroup of 6 ankylosing spondylitis patients were identified having undergone 6 operations with 63 pedicle screws. Accurate pedicle screw placement was found in 93.7%. Conclusion: intraoperative ct-guidance and stereotactic navigation can overcome the difficulty associated with thoracolumbar trauma resulting in complex anatomy with malalignment and unpredictable trajectories. Intraoperative ct can be used with stereotactic guidance or for intraoperative verification of free-hand screw placement with repositioning as needed. Ct-guidance maintains the benefit of reduced fluoroscopic exposure while improving accuracy of instrumentation and reducing reoperation for screw malposition. Reported event: 1. Two screws were grade ii and one screw was grade iii. Due to the availability to obtain immediate post-placement ct, all three of the screws with grade ii or iii breaches were identified intraoperatively, and the screws were repositioned, thereby avoiding potential revision surgery. 2. No neurovascular complications occurred in the 59 operations. Alignment was restored in all patients based on assessment of post operative ct imaging. No immediate revision surgery was performed for misplacement of

									screws. Complication rates were low, with infection occurring in two patients (3.4%) and pseudarthrosis in four patients (6.9% of cases). The cases of pseudarthrosis were identified during routine follow-up as the facility's standard practice was to obtain plain radiographs at follow-up appointments until evidence of advanced fusion was observed. Imaging evidence of pseudarthrosis was seen on plain radiograph in three patients and on ct in a fourth patient who was having recurrent back pain. The median length of follow-up was 12 months. Manufacturer narrative: patient information was not included in the journal article. This value is the mean age of the patients in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients in the article as specific patients could not be identified. Please note that this date is based off of the date the article was accepted as the event dates were not provided in the published literature. Article citation is included. System product number and serial number not provided in journal article. Udi not available for this system. No 510k provided as system is unknown. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2020-02955	19/06/2020	Malfunction	MEDTRONIC NAVIGATION, INC	11/11/2020	HAW	MEDTRONIC NAVIGATION	Imprecision	No Known Impact Or Consequence To Patient	Citation: joseph s. Domino, md, mph, kyle a. Smith, md, and paul m. Arnold, md, facs, clinical and radiologic outcomes of thoracolumbar fusions using intraoperative ct guidance and stereotactic navigation in a spinal trauma population, clin spine surg, 2020. Summary: study design: retrospective review of prospectively collected single-institution database. Objective: to analyze the clinical and radiographic outcomes of posterior thoracolumbar fusions using intraoperative computed tomography (ct)-guidance and stereotactic navigation in thoracolumbar spinal trauma. Summary of background data: pedicle screw

									instrumentation is utilized for stabilization in thoracolumbar fusions. Suboptimal placement may lead to neurovascular complications, pseudarthrosis, postoperative pain, and the need for revision surgery. Image- guided spinal surgery is commonly used to improve accuracy, particularly for complex anatomy such as encountered with traumaticFractures. Methods: we retrospectively identified 58 patients undergoing posterior thoracolumbar fusions using intraoperative ct and stereotactic navigation for traumaticFractures from 2010 to 2017 at a single institution. Pedicle screw accuracy, realignment, clinical outcomes, and ease of use were retrospectively reviewed. Accuracy was assessed on postplacement or postoperative ct. Breach grades included: grade 1 (< 2 mm), grade 2 (2¿4 mm), and grade 3 (> 4 mm). Results: a total of 58 patients were identified having undergone 58 operations, which involved placement of 519 pedicle screws. TraumaticFracture patterns and levels of injury were varied. Accurate pedicle screw placement was found in 95.8% and was stable over time. Breach included: grade 1 in 19 screws, grade 2 in 2 screws, and grade 3 in 1 screw. No neurovascular complications were noted. No revision surgery was performed for misplacement. A subgroup of 6 ankylosing spondylitis patients were identified having undergone 6 operations with 63 pedicle screws. Accurate pedicle screw placement was found in 93.7%. Conclusion: intraoperative ct-guidance and stereotactic navigation can overcome the difficulty associated with thoracolumbar trauma resulting in complex anatomy with malalignment and unpredictable trajectories. Intraoperative ct can be used with stereotactic guidance or for intraoperative verification of free-hand screw placement with repositioning as needed. Ct-guidance maintains the benefit of reduced fluoroscopic exposure while

									improving accuracy of instrumentation and reducing reoperation for screw malposition. Reported event: 1. Nineteen screws were grade i. 2. A subgroup of six patients with ankylosing spondylitis (as) were identified having undergone six operations (63 pedicle screws). There were varied injury patterns encountered, including chanceFracture andFracture-dislocation. Accurate pedicle screw placement was found in 93.7% (59/63 pedicle screws). See attached article. Manufacturer narrative: patient information was not included in the journal article. This value is the mean age of the patients in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients in the article as specific patients could not be identified. Please note that this date is based off of the date the article was accepted as the event dates were not provided in the published literature. Article citation is included. System product number and serial number not provided in journal article. Udi not available for this system. No 510k provided as system is unknown. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2020-02424	09/06/2020	Malfunction	MEDTRONIC NAVIGATION, INC	11/09/2020	HAW	STEALTHSTATION S8 PLANNING STATION	Imprecision	No Known Impact Or Consequence To Patient	Citation: jordan m. Spatz, adam k. Conner, jacob s. Young, philip a. Starr. Intraoperative stereotactic frame registration using a three-dimensional imaging system with and without preoperative computed tomography for image fusion. Stereotactic and functional neurosurgery. 2020. Doi: 10.1159/000509312 abstract: background: the o-arm o2 imaging system (oao2) is an intraoperative cone beam 3d tomogram imaging tool with a wide enough field of view to perform intraoperative fiducial registration with standard stereotactic frames. However, the oao2 3d images (cone beam ct) provide limited tissue contrast, which may reduce the accuracy of fusion to a preoperative targeting mri for planning awake deep brain stimulation (dbs)

									surgeries. Therefore, most users obtain a preoperative ct scan to use as the reference exam for computational fusion with the preoperative targeting mri and the intraoperative oao2 cone beam ct. Objective: in this study, we retrospectively analyzed the discrepancy between stereotactic coordinates of deep brain targetson mri derived from intraoperative oao2 fiducial registration with and without the use of preoperative ct as the reference for image fusion. Methods: preoperative stereotactic ct/mri and intraoperative oao2 cone beam ct were retrospectively evaluated for 27 consecutive dbs patients, using two commercial surgical planning software packages (brainlab elements and medtronic stealth 8). The anterior commissure, posterior commissure, and left subthalamic nucleus were identified on preoperative mri. Each patient had intraoperative fiducial registration using the oao2 with a leksell headframe. For each subject, the reference scan for image fusion was set as either the preoperative ct or the preoperative mri (volumetric t1 with contrast). Computed stereotactic coordinates for each target were then compared. Results: for 8 of 27 subjects, a discrepancy greater than 1.0 mm for at least one designated target was observed utilizing the medtronic stealth s8 planning station when a preoperative ct scan was not used. An additional 5 (5/27) had a discrepancy greater than 2 mm. The most common discrepancy was in the z axis. No coordinate discrepancies greater than 1 mm were observed utilizing brainlab elements. Conclusions: caution is advised in fusing intraoperative oao2 images directly to preoperative mri without a preoperative ct as the reference exam for image fusion, as the specific fusion algorithm employed may unpredictably affect targeting accuracy. Reported events: eight subjects had a discrepancy of greater than 1.0mm observed from acceptable stereotaxic accuracy without the use of a pre-operative

									computed tomography (ct). Five subjects had a discrepancy of greater than 2.0mm observed from acceptable stereotaxic accuracy without the use of a pre-operative computed tomography (ct). Manufacturer narrative: patient age is the mean value of patients in the study. Patient gender is the majority value of patients in the study. Patient weight not available from the site. Event date is the accepted date of the publication. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2021-00346	08/06/2020	Injury	MEDTRONIC NAVIGATION, INC	10/02/2021	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Convulsion/Seizure	Spennato, p., mirone, g., mazio, f., ruggiero, c., cicala, d., de santi, ms., imperato, a., cinalli, g., magnetic resonance-guided laser interstitial thermal therapy: preliminary experience in children. Childs nervous system. 2020 36:2180. Https://doi.org/10.1007/s00381-020-04544-3 introduction: magnetic resonance-guided laser interstitial thermal therapy (mrglitt) is a minimally invasive procedure that can be used to treat intracranial tumors, epilepsy, and chronic pain syndromes. We report our preliminary experience with two pediatric patients. Methods: two patients with pediatric brain tumors were treated with mrglitt since july 2019. At the time of preparing the abstract another 4 patients are scheduled for surgery. The visualase thermal laser system (medtronic) was used. Laser catheter was placed with a frameless stereotactic approach (medtronic stealth station). Results: the first patient was a (b)(6) baby girl affected by onco-predisposing syndrome, who developed a recurrence of glioblastoma (gbm) in the right peritrigonal region. The second patient was a (b)(6) girl, affected by nf1, who presented a contrast enhanced right frontal lesion during the follow up. Both patients underwent

									frameless stereotactic biopsy during the same procedure, that confirmed glioblastoma (in the first case) and revealed a low-grade glial tumor (in the second case). The procedures were uneventful. Gbm patient developed seizures in the first post-operative days that required medications and prolongation of the hospital stay. The second patient was discharged from the hospital 48 hours following the procedure. On post-operative mri both tumors presented internal necrosis. Tumor volume decreased in the first 3 months after surgery. Follow up was 5 months for both patients, with no recurrence/progression. Conclusions: our experience appears to confirm that mrglitt is an effective first- or second-line treatment for select pediatric brain tumors. It can be joined with frameless stereotaxy to obtain tissue for diagnosis. Reported events: patient developed seizures in the first post-operative days that required medications and prolongation of the hospital stay. Manufacturer narrative: patient weight not available from the site. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. The unique identification was not available at the time of reporting. No parts have been received by the manufacturer for evaluation. The manufacture date was not available at the time of reporting. If information is provided in the future, a supplemental report will be issued.
1723170-2021-00347	08/06/2020	Injury	MEDTRONIC NAVIGATION, INC	10/02/2021	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Convulsion/Seizure	Spennato, p., mirone, g., mazio, f., ruggiero, c., cicala, d., de santi, ms., imperato, a., cinalli, g., magnetic resonance-guided laser interstitial thermal therapy: preliminary experience in children. Childs nervous system. 2020 36:2180. Https://doi.org/10.1007/s00381-020-04544-3 introduction: magnetic resonance-guided laser interstitial thermal therapy (mrglitt) is a minimally invasive procedure that can be used to treat intracranial tumors, epilepsy, and chronic pain

									syndromes. We report our preliminary experience with two pediatric patients. Methods: two patients with pediatric brain tumors were treated with mrglitt since july 2019. At the time of preparing the abstract another 4 patients are scheduled for surgery. The visualase thermal laser system (medtronic) was used. Laser catheter was placed with a frameless stereotactic approach (medtronic stealth station). Results: the first patient was a 9-year old baby girl affected by onco-predisposing syndrome, who developed a recurrence of glioblastoma (gbm) in the right peritrigonal region. The second patient was a 9-year old girl, affected by nf1, who presented a contrast enhanced right frontal lesion during the follow up. Both patients underwent frameless stereotactic biopsy during the same procedure, that confirmed glioblastoma (in the first case) and revealed a low-grade glial tumor (in the second case). The procedures were uneventful. Gbm patient developed seizures in the first post-operative days that required medications and prolongation of the hospital stay. The second patient was discharged from the hospital 48 hours following the procedure. On post-operative mri both tumors presented internal necrosis. Tumor volume decreased in the first 3 months after surgery. Follow up was 5 months for both patients, with no recurrence/progression. Conclusions: our experience appears to confirm that mrglitt is an effective first- or second-line treatment for select pediatric brain tumors. It can be joined with frameless stereotaxy to obtain tissue for diagnosis. Reported events: patient developed seizures in the first post-operative days that required medications and prolongation of the hospital stay. Manufacturer narrative: weight: patient weight not available from the site. Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Udi #: the unique

									identification was not available at the time of reporting. Device evaluated by mfr: no parts have been received by the manufacturer for evaluation. Device manufacture date: the manufacture date was not available at the time of reporting. If information is provided in the future, a supplemental report will be issued.
1723170-2020-01648	05/06/2020	Injury	MEDTRONIC NAVIGATION, INC	11/06/2020	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Hypothermia; Muscle Weakness; Paresis	Citation: levin, david neville; mcclain, craig d.; stone, scellig s.d.; madsen, joseph r.; soriano, sulpicio. Anesthetic management and outcomes for mri-guided laser interstitial thermal therapy (litt) for seizure focus in pediatrics: a single centre experience with 10 consecutive patients. Doi: 10.1111/pan.13929 introduction: mri-guided laser interstitial thermal therapy (litt) is a stereotactically guided percutaneous minimally invasive procedure, which delivers light energy to tissue via a fiberoptic catheter, resulting in selective thermal ablation. Its use in drug-resistant epilepsy has increased because safety and efficacy have been well-established in adult and pediatric populations 1-4. The anesthetic management of this procedure in children has not been previously reported. Reported events: one patient was left intubated prior to transfer to the intensive care unit (icu) due to residual neuromuscular blockage and hypothermia. One patient had severe edema with hemiparesis and aphasia, which was managed medically for 7 days in the icu, and ultimately resolved completely. Manufacturer narrative: patient age is the mean value of patients in the study. Patient gender is the majority value of patients in the study. Patient weight is the mean value of patients in the study. Event date populated as aware date as the accepted date of the publication was not provided. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore,

									unavailable. If information is provided in the future, a supplemental report will be issued.
1222780-2020-00092	04/06/2020	Injury	HOLOGIC, INC	29/06/2020	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Adverse Event Without Identified Device or Use Problem	Hematoma	This is report one of two related to a case that occurred at the (b)(6) clinic on (b)(6) 2020. The second report will be submitted under manufacturer report number 1222780-2020-00094. It was reported that at the end of the biopsy, the device wouldn't lavage which caused a hematoma and severe bleeding at the biopsy site. At this time, there have been no additional issues reported with patient recovery. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. If the device is returned and evaluation completed, a supplemental medwatch will be filed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications. This is report one of two related to a case that occurred at the (b)(6) clinic on (b)(6) 2020. The second report will be submitted under manufacturer report number 1222780-2020-00094.
1222780-2020-00091	04/06/2020	Malfunction	HOLOGIC, INC	24/06/2020	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Leak/Splash	No Known Impact Or Consequence To Patient	It was reported that during the procedure, during sampling, "the mesh with the filter fell down on the ground." no known impact to patient. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. If the device is returned and evaluation completed, a supplemental medwatch will be filed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
1723170-2021-02417	26/05/2020	Malfunction	MEDTRONIC NAVIGATION, INC	04/10/2021	HAW	STEALTHSTATION S7	Imprecision	No Clinical Signs, Symptoms or Conditions	Citation: fady girgis, eric ovruchesky, jeffrey kennedy, masud seyal, kiarash shahlaie, ignacio saez. Superior accuracy and precision of seeg electrode insertion with frame-based vs. Frameless stereotaxy methods. Acta neurochirurgica (2020) 162:2537-2532. Https://doi.org/10.1007/s00701-020-04427-1 abstract: background: stereotactic

									electroencephalography has largely become the preferred method for intracranial seizure localization in epileptic patients due to its low morbidity and minimally invasive approach. While robotic placement is gaining popularity, many centers continue to use manual frame-based and frameless methods for electrode insertion. However, it is unclear how these methods compare in regard to accuracy, precision, and safety. Here, we aim to compare frame-based insertion using a crw frame (integra®) and frameless insertion using the stealthstation¿ s7 (medtronic®) navigation system for common temporal seeg targets. Methods: we retrospectively examined electrode targets in seeg patients that were implanted with either frame-based or frameless methods at a level 4 epilepsy center. We focused on two commonly used targets: amygdala and hippocampal head. Stealth station software was used to merge pre-operative mr with post-operative ct images for each patient, and coordinates for each electrode tip were calculated in relation to the midcommissural point. These were compared to predetermined ideal coordinates in regard to error and directional bias. Results: a total of 81 seeg electrodes were identified in 23 patients (40 amygdala and 41 hippocampal head). Eight of 45 electrodes (18%) placed with the frameless technique and 0 of 36 electrodes (0%) placed with the frame-based technique missed their target and were not clinically useful. The average euclidean distance comparing actual to ideal electrode tip coordinates for frameless vs. Frame-based techniques was 11.0mmvs. 7.1 mm(p <(><<)> 0.001) for the amygdala and 12.4mmvs. 8.5mm(p <(><<)> 0.001) for the hippocampal head, respectively. There were no hemorrhages or clinical complications in either group. Conclusions: based on this series, frame-based seeg insertion is significantly more accurate and precise and results in more clinically useful electrode contacts, compared to frameless

									insertion using a navigation guidance system. This has important implications for centers not currently using robotic insertion. Reported event: eight of 45 electrodes placed using the frameless technique missed their target and were not clinically useful. Manufacturer narrative: patient age is the mean value of patients in the frameless group. Patient gender is the majority value of patients in the frameless group. Patient weight not available from the site. Event date is the online publication date of the literature article. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacture date is dependent on the device lot/serial number, therefore is unavailable. If information is provided in the future, a supplemental report will be issued.
9612186-2020-00008	25/05/2020	Malfunction	ELEKTA INSTRUMENT AB	24/09/2020	HAW	LEKSELL STEREOTACTIC SYSTEM	Flaked; Material Fragmentation	No Clinical Signs, Symptoms or Conditions	The customer reported that the paint on the leksell vantage arc was flaking. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has been completed.
2182207-2020-01469	20/05/2020	Injury	MEDTRONIC NEUROMODULATION	13/12/2020	MHY	UNKNOWN EXTENSION	Adverse Event Without Identified Device or Use Problem	Unspecified Infection	Mackel ce, papavassiliou e, alterman rl. Risk factors for wireFracture or tethering in deep brain stimulation: a 15-year experience. Oper neurosurg (hagerstown). 2020. 10.1093/ons/opaa215 summary: deep brain stimulation (dbs) reversibly modulates brain function through stimulatory electrodes placed stereotactically within specific subcortical nuclei and connected to an implantable pulse generator via subcutaneously tunneled extension cables. It may be employed as an adjunct to medical therapy for specific movement disorders and a variety of other functional brain disorders.1-3 because dbs is an elective procedure aimed at improving quality of life, minimizing complications related to surgery and the implanted hardware is essential. Identified events: 1. 12 extensions were removed and replaced due to infection. Manufacturer narrative:

									mackel ce, papavassiliou e, alterman rl. Risk factors for wireFracture or tethering in deep brain stimulation: a 15-year experience. Oper neurosurg (hagerstown). 2020. 10.1093/ons/opaa215. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the accepted date of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Related regulatory reports: 257541398, 257541412, 257541399, and 257541424. If information is provided in the future, a supplemental report will be issued.
1723170-2021-00983	15/05/2020	Injury	MEDTRONIC NAVIGATION, INC	13/04/2021	HAW	STEALTHSTATION S7	Adverse Event Without Identified Device or Use Problem	Hemorrhage/Bleeding	Minchev, g., kronreif, g., ptacek, w., kettenbach, j., micko, a., wurzer, a., maschke, s., wolfsberger, s. Frameless stereotactic brain biopsies: comparison of minimally invasive robot-guided and manual arm-based technique. Operative neurosurgery. 19 (292¿301) doi: 10.1093/ons/opaa123 background: most brain biopsies are still performed with the aid of a navigation-guided mechanical arm. Due to the manual trajectory alignment without rigid skull contact, frameless aiming devices are prone to considerably lower accuracy. Objective: to compare a novel minimally invasive robot-guided biopsy technique with rigid skull fixation to a standard frameless manual arm biopsy procedure. Methods: accuracy, procedural duration, diagnostic yield, complication rate, and cosmetic result were retrospectively assessed in 40 consecutive cases of frameless stereotactic biopsies and compared between a minimally invasive robotic technique using the isys1 guidance device (isys medizintechnik gmbh) (robot-

									guided group [rob], n = 20) and a manual arm-based technique (group man, n = 20). Results: application of the robotic technique resulted in significantly higher accuracy at entry point (group rob median 1.5 mm [0.4-3.2 mm] vs manual arm-based group (man) 2.2 mm [0.2-5.2 mm], p = .019) and at target point (group rob 1.5 mm [0.4-2.8 mm] vs group man 2.8 mm [1.4-4.9 mm], p = .001), without increasing incision to suture time (group rob 30.0 min [20-45 min vs group man 32.5 min [range 20-60 min], p = .09) and significantly shorter skin incision length (group rob 16.3 mm [12.7-23.4 mm] vs group man 24.2 mm [18.0-37.0 mm], p = .008). Conclusion :according to our data, the proposed technique of minimally invasive robot guided brain biopsies can improve accuracy without increasing operating time while being equally safe and effective compared to a standard frameless arm-based manual biopsy technique. Reported events: 2 patients one from each group had a hemorrhage at the target site postoperative ct see attached literature article manufacturer narrative: patient information was unavailable from the site. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. The unique identifier was not known at the time of reporting concomitant medical products: information references the main component of the system. Other relevant device(s) are: product id: unk_nav_comp, serial/lot #: unknown, ubd: , udi#: no parts have been received by the manufacturer for evaluation. The manufacture date was not known at the time of reporting.
1222780-2020-00080	05/05/2020	Malfunction	HOLOGIC, INC.	22/05/2020	KNW	EVIVA STEREOTACTIC GUIDED BREAST BIOPSY SYSTEM	Material Twisted/Bent	No Known Impact Or Consequence To Patient	It was reported that during a biopsy procedure utilizing the eviva stereotactic guided breast biopsy system on (b)(6) 2020 the needle guide sheath became deformed making it hard to remove the sheath and needle from the patient. The biopsy was successful with adequate samples. There was no harm or injury reported to the

									patient or end user. Manufacturer narrative: information provided by the user indicated that there was no injury to the patient or the user however this failure mode has previously resulted in an injury to the patient requiring medical intervention. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications. The device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. If the device is returned and evaluation completed, a supplemental medwatch will be filed.
2182207-2020-00960	03/05/2020	Injury	MEDTRONIC NEUROMODULATION	27/09/2020	MHY	UNKNOWN EXTENSION	Break	No Known Impact Or Consequence To Patient	Mackel ce, papavassiliou e, alterman rl. Risk factors for wireFracture or tethering in deep brain stimulation: a 15-year experience. Oper neurosurg (hagerstown). 2020. 10.1093/ons/opaa215 summary: deep brain stimulation (dbs) reversibly modulates brain function through stimulatory electrodes placed stereotactically within specific subcortical nuclei and connected to an implantable pulse generator via subcutaneously tunneled extension cables. It may be employed as an adjunct to medical therapy for specific movement disorders and a variety of other functional brain disorders.1-3 because dbs is an elective procedure aimed at improving quality of life, minimizing complications related to surgery and the implanted hardware is essential. Identified events: 16 patients experienced aFractured extension that led to an explant. 2 patients experienced a tethered extension that led to an explant. Patients were implanted for parkinson's disease. Manufacturer narrative: mackel ce, papavassiliou e, alterman rl. Risk factors for wireFracture or tethering in deep brain stimulation: a 15-year experience. Oper neurosurg (hagerstown). 2020. 10.1093/ons/opaa215. Other relevant device(s) are: product id: neu_unknown_ext, serial/lot #: unknown. This value reflects the gender of the majority of the patients

									reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Related regulatory reports: 257541399, 257541412, and 257541424. If information is provided in the future, a supplemental report will be issued.
2182207-2020-00961	03/05/2020	Injury	MEDTRONIC NEUROMODULATION	27/09/2020	MHY	UNKNOWN EXTENSION	Break	No Known Impact Or Consequence To Patient	Mackel ce, papavassiliou e, alterman rl. Risk factors for wireFracture or tethering in deep brain stimulation: a 15-year experience. Oper neurosurg (hagerstown). 2020. 10.1093/ons/opaa215 summary: deep brain stimulation (dbs) reversibly modulates brain function through stimulatory electrodes placed stereotactically within specific subcortical nuclei and connected to an implantable pulse generator via subcutaneously tunneled extension cables. It may be employed as an adjunct to medical therapy for specific movement disorders and a variety of other functional brain disorders.1-3 because dbs is an elective procedure aimed at improving quality of life, minimizing complications related to surgery and the implanted hardware is essential. Identified events: 1. 5 patients experienced aFractured extension that led to an explant. Patients were implanted for essential tremor. Manufacturer narrative: mackel ce, papavassiliou e, alterman rl. Risk factors for wireFracture or tethering in deep brain stimulation: a 15-year experience. Oper neurosurg (hagerstown). 2020. 10.1093/ons/opaa215. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of

									publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Related regulatory reports: (b)(6). If information is provided in the future, a supplemental report will be issued.
2182207-2020-00963	03/05/2020	Injury	MEDTRONIC NEUROMODULATION	27/09/2020	MHY	UNKNOWN EXTENSION	Break	No Known Impact Or Consequence To Patient; No Clinical Signs, Symptoms or Conditions	Mackel ce, papavassiliou e, alterman rl. Risk factors for wireFracture or tethering in deep brain stimulation: a 15-year experience. Oper neurosurg ((b)(6)). 2020. 10.1093/ons/opaa215 summary: deep brain stimulation (dbs) reversibly modulates brain function through stimulatory electrodes placed stereotactically within specific subcortical nuclei and connected to an implantable pulse generator via subcutaneously tunneled extension cables. It may be employed as an adjunct to medical therapy for specific movement disorders and a variety of other functional brain disorders.1-3 because dbs is an elective procedure aimed at improving quality of life, minimizing complications related to surgery and the implanted hardware is essential. Identified events: 1 patients experienced aFractured extension that led to an explant. Patient was implanted for obsessive-compulsive disorder. See literature article. Manufacturer narrative: mackel ce, papavassiliou e, alterman rl. Risk factors for wireFracture or tethering in deep brain stimulation: a 15-year experience. Oper neurosurg ((b)(6)). 2020. 10.1093/ons/opaa215. Sex. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the

									published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Related regulatory reports: (b)(4). If information is provided in the future, a supplemental report will be issued.
2182207-2020-00962	03/05/2020	Injury	MEDTRONIC NEUROMODULATION	27/09/2020	MHY	UNKNOWN EXTENSION	Break; Adverse Event Without Identified Device or Use Problem	Adhesion(s); No Known Impact Or Consequence To Patient	Mackel ce, papavassiliou e, alterman rl. Risk factors for wireFracture or tethering in deep brain stimulation: a 15-year experience. Oper neurosurg ((b)(6)). 2020. 10.1093/ons/opaa215 summary: deep brain stimulation (dbs) reversibly modulates brain function through stimulatory electrodes placed stereotactically within specific subcortical nuclei and connected to an implantable pulse generator via subcutaneously tunneled extension cables. It may be employed as an adjunct to medical therapy for specific movement disorders and a variety of other functional brain disorders.1-3 because dbs is an elective procedure aimed at improving quality of life, minimizing complications related to surgery and the implanted hardware is essential. Identified events: 4 patients experienced aFractured extension that led to an explant. 4 patients experienced a tethered extension that led to an explant. Patients were implanted for dystonia. See literature article. Manufacturer narrative: mackel ce, papavassiliou e, alterman rl. Risk factors for wireFracture or tethering in deep brain stimulation: a 15-year experience. Oper neurosurg ((b)(6)). 2020. 10.1093/ons/opaa215. Concomitant medical products: product id: neu_unknown_ext, serial/lot #: unknown. Sex. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event. Please note that this date is based off of the date of

									publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Related regulatory reports: (b)(4). If information is provided in the future, a supplemental report will be issued.
2182207-2020-00428	30/04/2020	Injury	MEDTRONIC NEUROMODULATION	26/06/2020	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Edema; Unspecified Infection; Therapeutic Effects, Unexpected; Seizures, Grand-Mal; Therapeutic Response, Decreased; Shaking/Tremors; Confusion/ Disorientation	Summary: deep brain stimulation of the ventral intermediate nucleus (vim) or caudal zona incerta (czi) is effective for refractory essential tremor (et). To refine stereotactic planning for lead placement, the authors developed a unique individualized anatomy-based planning protocol that targets both the vim and the czi in patients with et. 33 patients with et underwent vim-czi lead implantation with targeting based on the authors' protocol. Indirect targeting was adjusted based on anatomic landmarks as reference lines bisecting the red nuclei and ipsilateral subthalamus. Outcomes were evaluated through the follow-up of 31.1 +/- 18.4 months. Active contact coordinates were obtained from reconstructed electrodes in the montreal neurological institute space using the matlab lead-dbs toolbox. Mean tremor improvement was 79.7% +/- 22.4% and remained stable throughout the follow-up period. Active contacts at last postoperative visit had mean montreal neurological institute coordinates of 15.5 +/- 1.6 mm lateral to the intercommissural line, 15.3 +/- 1.8 mm posterior to the anterior commissure, and 1.4 +/- 2.9 mm below the intercommissural plane. No hemorrhagic complications were observed in the analyzed group. Reported events: one patient implanted with deep brain stimulation (dbs) for essential tremor (et) experienced tonic-clonic seizure in the immediate postoperative period. There were no permanent complications

									associated with the event. One patient implanted with dbs for et experienced infection at the implantable neurostimulator (ins) implant site. There were no permanent complications associated with the event. Two patients implanted with dbs for et experienced waning stimulation effect, which required right lead repositioning (replacement and revision). One patient experienced this effect at 3 months, and the other at 2 years after initial implant. A significant reduction in tremor control together with intolerable stimulation-induced side effects was seen. After revision, both patients had short lived improvements in stimulation dependent tremor control that waned within 2-3 months. The following device information was identified in the literature article: lead model 3387. Manufacturer narrative: diaz a, cajigas i, cordeiro jg, et al. Individualized anatomy-based targeting for vim-czi dbs in essential tremor. World neurosurg. 2020. 10.1016/j.wneu.2020.04.240. This value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event: please note that this date is based off of the date that the article was accepted for publication as the publication date and event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Information references the main component of the system. Other relevant device(s) are: product id: 3387, serial/lot #: unknown, udi#: asku. Product id: neu_ins_stimulator, serial/lot #: unknown, udi#: asku. Product id: 3387, serial/lot #: unknown, udi#: asku. If

									information is provided in the future, a supplemental report will be issued.
1723170-2020-01363	30/04/2020	Malfunction	MEDTRONIC NAVIGATION, INC	04/05/2020	HAW	S8 PREMIUM STEALTHSTATION NAVIGATION SYSTEM	Human-Device Interface Problem	No Patient Involvement	Medtronic received information that, while outside of a procedure, the site could not pass auto registration. It was reported that the stereotactic frame on a magnetic resonance imaging (mri) scan was not detected. The scan was loaded onto a second navigation system without resolution. There was no patient present when this issue was identified. Manufacturer narrative: a medtronic representative went to the site to test the equipment. Testing revealed that the navigation system functioned as designed and the reported issue could not be replicated. The system then passed the system checkout and was found to be fully functional. Related codes: fdm, fdr; software files from the navigation system have been returned to the manufacturer for evaluation. However, analysis findings are not available at time of filing. Related codes: fdc. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: no patient information provided as no patient was involved in this concern. No parts have been received by the manufacturer for evaluation. Other relevant device(s) are: product id: 9735740, serial/lot #: unk, ubd: , udi#: if information is provided in the future, a supplemental report will be issued.
2184149-2020-00061	22/04/2020	Injury	ST. JUDE MEDICAL, INC.	14/05/2020	GXD	4 LESION NT2000 PAIN MANAGEMENT RF GENERATOR	Adverse Event Without Identified Device or Use Problem	Partial thickness (Second Degree) Burn	Related manufacturer reference number: 2182269-2020-00043. Following a stereotactic radiofrequency ablation of c2 and c3, a patient burn was noted. Prior to the procedure the patient's skin had been prepared and the grounding pad was placed on dry skin with no overlapping or wrinkled parts. The procedure was completed without any issues or alarms, but when the grounding pad was removed from the left shoulder area, a burn with blistering was noted. The wound was treated with flamazine cream. There were no performance issues with any abbott device. Manufacturer narrative: the results, method

									and conclusion codes along with investigation results will be provided in the final report.
2182269-2020-00043	22/04/2020	Injury	ST. JUDE MEDICAL, INC.	14/05/2020	GEI	DISPOSABLE GROUNDING PAD W/CABLE	Adverse Event Without Identified Device or Use Problem	Partial thickness (Second Degree) Burn	Related manufacturer reference number: 2184149-2020-00061. Following a stereotactic radiofrequency ablation of c2 and c3, a patient burn was noted. Prior to the procedure the patient's skin had been prepared and the grounding pad was placed on dry skin with no overlapping or wrinkled parts. The procedure was completed without any issues or alarms, but when the grounding pad was removed from the left shoulder area, a burn with blistering was noted. The wound was treated with flamazine cream. There were no performance issues with any abbott device. Manufacturer narrative: the results, method and conclusion codes along with investigation results will be provided in the final report.
2182207-2020-00697	13/04/2020	Injury	MEDTRONIC NEUROMODULATION	12/08/2020	MHY	ACTIVA	Migration or Expulsion of Device; Unintended Collision	Bacterial Infection; Pain; Seizures; Therapeutic Effects, Unexpected	Alon kashanian, jasmine a. T. Dicesare, pratik rohatgi, luigi albano, scott e. Krahl, ausaf bari, antonio de salles, nader pouratian case series: deep brain stimulation for facial pain doi: 10.1093/ons/opaa170 background: deep brain stimulation (dbs) has been used for chronic pain for decades, but its use is limited due to a lack of reliable data about its efficacy for specific indications. Objective: to report on 9 patients who underwent dbs for facial pain, with a focus on differences in outcomes between distinct etiologies. Methods: we retrospectively reviewed 9 patients with facial pain who were treated with dbs of the ventral posteromedial nucleus of the thalamus and periventricular gray. We report on characteristics including facial pain etiology, complications, changes in pain scores using the visual analog scale (vas), and willingness to undergo dbs again. Results: nine patients underwent dbs for either post stroke, post-traumatic, postherpetic, or atypical facial pain. Eight patients (89%) were permanently implanted. Seven patients had sufficient

									follow-up (mean 40.3 mo). Of these 7 patients, average vas scores decreased from 9.4 to 6.1 after dbs. The average decrease in vas was 55% for post-traumatic facial pain (2 patients), 45% for post stroke (2 patients), 15% for postherpetic neuralgia (2 patients), and 0%for atypical facial pain (1 patient). Three of the 8 implanted patients (38%) had complications which required removal of hardware. Only 2 of 7 (29%) patients met classical criteria for responders (50% decrease in pain scores). However, among 4 patients who were asked about willingness to undergo dbs again, all expressed that they would repeat the procedure. Conclusion: there is a trend towards improvement in pain scores following dbs for facial pain, most prominently with post-traumatic pain. Pli 10: it was reported that the patient was diagnosed with pseudomonas infection at the site of the scalp, approximately 1.5 months after the operation. Subsequently they were treated with antibiotics and surgical debridement; however, their therapy was complicated by numerous allergies and intolerances to various antibiotics. Ultimately the patient required complete removal of their dbs hardware, but then was re-implanted after a successful course of antibiotics. Pli 20: it was reported that there was transient cycling with a visual analog scale (vas) of 3 for a week then 8 as the results weren¿t sustained for more than a few days to a week. It was also reported that the patient had a stereotactic radiosurgery and radiofrequency ablation surgeries for further management months after surgery. Pli 30 and 40: it was reported that the patient experienced a scalp infection, positive for staphylococcus aureus, approximately 4 years after their dbs surgery. The patient underwent the removal of their entire system and had successful course of antibiotics. Prior to this though the patient had seizures, fall and lead migration, pain at site of extension wires. Pli

									50: it was reported that the patient had a fall, pain at their extension site and ultimately necessitated the removal of their dbs system. Manufacturer narrative: other applicable components are: product id: 3387, serial#: unknown, product type: lead. Product id: 3387, serial#: unknown, product type: lead. Product id: neu_unknown_ext, serial#: unknown, product type: extension. Product id: neu_unknown_ext, serial#: unknown, product type: extension. Information references the main component of the system. Other relevant device(s) are: product id: 3387, serial/lot #: unknown; product id: 3387, serial/lot #: unknown; product id: neu_unknown_ext, serial/lot #: unknown; product id: neu_unknown_ext, serial/lot #: unknown. Date of event: please note that this date is based off of the date of publication of the article [or the date that the article was accepted for publication] as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. The device was used for an off label indication. If information is provided in the future, a supplemental report will be issued.
1723170-2020-01544	12/04/2020	Injury	MEDTRONIC NAVIGATION, INC	29/05/2020	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Edema; Complaint, Ill-Defined	Citation: gamboa, n.t., karsy, m., iyer, r.r. Et al. Stereotactic laser interstitial thermal therapy for brainstem cavernous malformations: two preliminary cases. Acta neurochir (2020). Https://doi.org/10.1007/s00701-020-04316-7. Summary: brainstem cavernous malformations (cms) often have high hemorrhage rates and significant post hemorrhage morbidity. The authors present two cases in which magnetic resonance thermography-guided laser interstitial therapy was used for treatment of pontine

									cms after recurrent hemorrhage. Both patients showed significant symptomatic improvement and were hemorrhage-free at 12- and 6-month follow-up, respectively. Each had radiographic evidence of lesion involution on serial follow-up imaging. These early results demonstrate this treatment modality may be technically safe; however, larger case numbers and longer follow up are needed to demonstrate efficacy. Reported event: a (b)(6) year-old woman with a history of multiple cerebral cms and one prior resection of a left occipital lobe cm presented after a new 1.1-cm right pontine cm hemorrhage resulted in worsening horizontal diplopia (right cranial nerve vi palsy), left facial numbness, and paresthesias. The patient underwent a right frontal transcapsular approach, typically used for pediatric brain stem biopsies, for litt treatment. Postoperatively, she showed some worsened left-sided facial numbness, left-sided weakness, and dysarthria that gradually improved. Early postoperative imaging disclosed a small zone of injury in the posterior internal capsule and cerebral peduncle related to the fiber trajectory and some circumferential edema around the cm. Her postoperative convalescence required inpatient medical rehabilitation. She has been monitored for 18 months and has showed substantial improvement in her neurological examination¿notably, resolved diplopia and left facial numbness with some residual left-sided weakness and ataxia. Manufacturer narrative: patient identifier and weight not provided in journal article. Please note that this date is based off of the date the date the article was published online as the event dates were not provided in the published literature. Article citation is included. System product number and serial number not provided in journal article. Udi not available for this system. No 510k provided as system is unknown. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is

									provided in the future, a supplemental report will be issued.
1226348-2020-00210	09/04/2020	Malfunction	RAYNHAM	15/07/2020	HBF	CODMAN DISPOS PERFORATOR	Mechanical Problem	No Known Impact Or Consequence To Patient	A facility reported the codman disposable perforator 14mm seized up and stopped drilling bone half way through skull while performing a stereotactic biopsy. Manufacturer narrative: attempts are being made to obtain additional information. Upon completion of the investigation, a follow-up report will be submitted.
2182207-2020-00290	02/04/2020	Death	MEDTRONIC NEUROMODULATION	03/06/2020	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Bacterial Infection; Dementia; Hemorrhage, Cerebral; Memory Loss/Impairment; Pneumonia; Cognitive Changes; Confusion/ Disorientation	Matthew d. Cooper & carlos restrepo & ron hill & murray hong & ryan greene & lutz m. Weise abstract: background stereotactic registration is the most critical step ensuring accuracy in deep brain stimulation (dbs) surgery. 3d fluoroscopy (xt) is emerging as an alternative to ct. Xt has been shown to be safe and effective for intraoperative confirmation of lead position following implantation. However, there is a lack of studies evaluating the suitability of xt to be used for the more crucial step of registration and its capability of being merged to a preoperative mri. This is the first study comparing accuracy, efficiency, and radiation exposure of xt- vs ct-based stereotactic registration and xt/mri merging in deep brain stimulation. Methods mean absolute differences and euclidean distance between planned (adjusted for intraoperative testing) and actual lead trajectories were calculated for accuracy of implantation. The radiation dose from each scan was recorded as the dose length product (dlp). Efficiency was measured as the time between the patient entering the operating room and the initial skin incision. A one-way anova compared these parameters between patients that had either ct- or xt-based registration. Results forty-one patients underwent dbs surgery¿25 in the ct group and 16 in the xt group. The mean absolute difference between ct and xtwas not statistically significant in the x (p = 0.331), y (p = 0.951), or z (p = 0.807) directions. The euclidean distance between patient groups did not differ significantly (p = 0.874). The average

									radiation exposure with xt (220.0 ± 0.1 mgy*cm) was significantly lower than ct (1269.3 ± 112.9 mgy*cm) (p <(><<)> 0.001). There was no significant difference in registration time between ct (107.8 ± 23.1 min) and xt (106.0 ± 18.2 min) (p = 0.518). Conclusion xt-based frame registration was shown to result in similar implantation accuracy and significantly less radiation exposure compared with ct. Our results surprisingly showed no significant difference in registration time, but this may be due to a learning curve effect. Reported events: it was reported that one patient had a very prolonged hospital stay and a complicated course following the surgery. They acquired significant disorientation and memory issues post operatively, and a hematoma was found only on their third postoperative ct scan 12 days after the dbs surgery. Their cognitive impairment progressed to mild dementia and they started to have recurrent bouts of pneumonia and eventually passed away. It was not possible to ascertain any additional specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: this value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that the actual date of death was not provided in the literature article; this date is based on the date of article publication. Please note that this date is based off the date that the article was accepted for publication as the event dates were not provided in the published literature. If information is provided in the future, a supplemental report will be issued.
1723170-2020-02660	30/03/2020	Malfunction	MEDTRONIC NAVIGATION, INC	08/10/2020	HAW	MEDTRONIC NAVIGATION	Imprecision	No Known Impact Or Consequence To Patient	Citation: cho, steve s., et al. ¿surface-registration frameless stereotactic navigation is less accurate during prone surgeries: intraoperative near-infrared visualization using second window

									indocyanine green offers an adjunct.¿ mol imaging biol (2020), 30 mar. 2020, doi:h ttps://doi.org/10.1007/s11307-020-01495-8 abstract: background: frameless neuronavigation allows neurosurgeons to visualize and relate the position of surgical instruments to intracranial pathologies based on preoperative tomographic imaging. However, neuronavigation can often be inaccurate. Multiple factors have been proposed as potential causes, and new technologies are needed to overcome these challenges. Objective: to evaluate the accuracy of neuronavigation systems compared to near-infrared (nir) fluorescence imaging using second window indocyanine green, a novel technique, and to determine factors that lead to neuronavigation errors. Methods: a retrospective analysis was conducted on 56 patients who underwent primary resections of intracranial tumors. Patients received 5 mg/kg icg approximately 24 h preoperatively. Intraoperatively, neuronavigation was used to plan craniotomies to place the tumors in the center. After craniotomy, nir imaging visualized tumor-specific nir signals. The accuracy of neuronavigation and nir fluorescence imaging for delineating the tumor boundary prior to durotomy was compared. Results: the neuronavigation centers and nir centers were 23.0 ± 7.7 % and 2.6 ± 1.1 % deviated from the tumor centers, respectively, relative to the craniotomy sizes. In 12 cases, significant changes were made to the planned durotomy based on nir imaging. Patient position was a significant predictor of neuronavigation inaccuracy on both univariate and multivariate analysis, with the prone position having significantly higher inaccuracy (29.2 ± 8.1 %) compared to the supine (16.2 ± 8.1 %, p value g 0.001) or the lateral (17.9 ± 5.1 %, p value = 0.003) positions. Conclusion: patient position significantly affects neuronavigation accuracy. Intraoperative nir fluorescence

									imaging before durotomy offers an opportunity to readjust the neuronavigation image space to better align with the patient space. Medtronic stealth was used in 4 of the cases captured in the reported events below, and other commercially available neuronavigation systems were used in the other cases. In cases when neuronavigation and nir imaging differed in tumor localization, nir imaging was used to plan the dura opening. Reported events: 1. Neuronavigation was often inconsistent with the location of the nir fluorescence and the margin of error seemed to be exacerbated when the patients were prone. Compared to the tumor center, the neuronavigation center was, on average, 23.0 ± 7.7 % (range 4.3¿47.6 %) deviated relative to the size of the craniotomy. It was noted that the prone position was associated with significantly higher inaccuracies (29.2 ± 8.1 %) compared to the supine (16.2 ± 8.1 %, p value < 0.001) or the lateral (17.9 ± 5.1 %, p value = 0.003) positions. Furthermore, using 15% deviation as the cutoff for clinically significant deviation, 12/13 (92.3%) of prone cases were significantly deviated, versus 16/31 (52 %) for supine and 4/8 (50 %) for lateral cases. It was noted that the inaccuracies associated with the prone position likely stemmed from multiple factors. The neuronavigation systems used relied on surface registration to align the image space to the patient space. When this registration was performed on the anterior surface of the face for prone cases, poor access to facial surface features could have limited accurate registration. In addition, small errors from anterior registrations may have propagated into larger errors over the increased distance between the registration surface and the posterior operative surface. Furthermore, preoperative images were performed with the patient supine, but when patients were placed prone, the skin and overall head shape changed due to gravity, which exacerbated the discrepancy

									between the image space and patient space. Finally, because the brain is relatively mobile compared to the skull, the prone position likely affected the degree and direction of brain shift differently than in the supine position. Additionally, it was noted that even if perfect registration was achieved, neuronavigation could have lost accuracy intraoperatively. Opening the dura, draining cerebrospinal fluid, removing tissue, and retracting the brain were all unavoidable steps in surgery that changed the intraoperative patient space that would not have been reflected in the pre-acquired image space. Manufacturer narrative: patient age is average age of patients in the article. Patient gender is the majority gender of patients in the article. Patient weight was not included in the journal article. Please note that this date is based off of the date the article was published online as the event dates were not provided in the published literature. Article citation is included. System product number and serial number not provided in journal article. Udi not available for this system. No 510k provided as system is unknown. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2020-01432	27/03/2020	Death	MEDTRONIC NAVIGATION, INC	14/05/2020	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Hemorrhage, Cerebral; Hydrocephalus	Citation: arocho-quinones, e. V., lew, s. M., handler, m. H., tovar-spinoza, z., smyth, m., bollo, r., donahue, d., perry, m., levy, m. L., gonda, d., mangano, f. T., storm, p. B., price, a. V., couture, d. E., oluigbo, c., duhaime, a., barnett, g. H., muh, c. R., sather, m. D., fallah, a., wang, a. C., bhatia, s., patel, k., tarima, s., graber, s., huckins, s., hafez, d. M., rumalla, k., bailey, l., shandley, s., roach, a., alexander, e., jenkins, w., tsering, d., price, g., meola, a., evanoff, w., thompson, e. M., brandmeir, n. (2020). Magnetic resonance¿guided stereotactic laser ablation therapy for the treatment of pediatric brain tumors: a multiinstitutional retrospective study, journal of

									neurosurgery: pediatrics ped, , 1-9. Published online march 27, 2020; doi: 10.3171/2020.1.peds19496. Summary: objective this study aimed to assess the safety and efficacy of mr-guided stereotactic laser ablation (sla) therapy in the treatment of pediatric brain tumors. Methods data from 17 north american centers were retrospectively reviewed. Clinical, technical, and radiographic data for pediatric patients treated with sla for a diagnosis of brain tumor from 2008 to 2016 were collected and analyzed. Results a total of 86 patients (mean age 12.2 ± 4.5 years) with 76 low-grade (i or ii) and 10 high-grade (iii or iv) tumors were included. Tumor location included lobar (38.4%), deep (45.3%), and cerebellar (16.3%) compartments. The mean follow-up time was 24 months (median 18 months, range 3¿72 months). At the last follow-up, the volume of sla-treated tumors had decreased in 80.6% of patients with follow-up data. Patients with high-grade tumors were more likely to have an unchanged or larger tumor size after sla treatment than those with low-grade tumors (or 7.49, p = 0.0364). Subsequent surgery and adjuvant treatment were not required after sla treatment in 90.4% and 86.7% of patients, respectively. Patients with high-grade tumors were more likely to receive subsequent surgery (or 2.25, p =0.4957) and adjuvant treatment (or 3.77, p = 0.1711) after sla therapy, without reaching significance. A total of 29 acute complications in 23 patients were reported and included malpositioned catheters (n = 3), intracranial hemorrhages (n = 2), transient neurological deficits (n = 11), permanent neurological deficits (n = 5), symptomatic perilesional edema (n =2), hydrocephalus (n = 4), and death (n = 2). On long-term follow-up, 3 patients were reported to have worsened neuropsychological test results. Pre-sla tumor volume, tumor location, number of laser trajectories, and number of lesions created did not result in a significantly

									increased risk of complications; however, the odds of complications increased by 14% (or 1.14, p = 0.0159) with every 1-cm3 increase in the volume of the lesion created. Conclusions sla is an effective, minimally invasive treatment option for pediatric brain tumors, although it is not without risks. Limiting the volume of the generated thermal lesion may help decrease the incidence of complications. Reported event: one patient death was directly related to the procedure, where targeting of a posterior fossa tumor resulted in a cerebellar hemorrhage with acute hydrocephalus and death despite a decompressive craniectomy and external ventricular drain placement. Manufacturer narrative: patient information was not included in the journal article. This value is the mean age of the patients in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients in the article as specific patients could not be identified. Date of death was not provided in journal article. Date provided is the date the article was published online. Please note that this date is based off of the date the article was published online as the event dates were not provided in the published literature. Article citation is included. System product number and serial number not provided in journal article. Udi not available for this system. No 510k provided as system is unknown. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2020-01433	27/03/2020	Injury	MEDTRONIC NAVIGATION, INC	14/05/2020	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Edema; Intracranial Hemorrhage; Neurological Deficit/Dysfunction; Hydrocephalus	Citation: arocho-quinones, e. V., lew, s. M., handler, m. H., tovar-spinoza, z., smyth, m., bollo, r., donahue, d., perry, m., levy, m. L., gonda, d., mangano, f. T., storm, p. B., price, a. V., couture, d. E., oluigbo, c., duhaime, a., barnett, g. H., muh, c. R., sather, m. D., fallah, a., wang, a. C., bhatia, s., patel, k., tarima, s., graber, s., huckins, s., hafez, d. M., rumalla, k., bailey, l., shandley, s., roach, a.,

									alexander, e., jenkins, w., tsering, d., price, g., meola, a., evanoff, w., thompson, e. M., brandmeir, n., & . (2020). Magnetic resonance¿guided stereotactic laser ablation therapy for the treatment of pediatric brain tumors: a multiinstitutional retrospective study, journal of neurosurgery: pediatrics ped, , 1-9. Published online march 27, 2020; doi: 10.3171/2020.1.peds19496. Summary: objective this study aimed to assess the safety and efficacy of mr-guided stereotactic laser ablation (sla) therapy in the treatment of pediatric brain tumors. Methods data from 17 north american centers were retrospectively reviewed. Clinical, technical, and radiographic data for pediatric patients treated with sla for a diagnosis of brain tumor from 2008 to 2016 were collected and analyzed. Results a total of 86 patients (mean age 12.2 ± 4.5 years) with 76 low-grade (i or ii) and 10 high-grade (iii or iv) tumors were included. Tumor location included lobar (38.4%), deep (45.3%), and cerebellar (16.3%) compartments. The mean follow-up time was 24 months (median 18 months, range 3¿72 months). At the last follow-up, the volume of sla-treated tumors had decreased in 80.6% of patients with follow-up data. Patients with high-grade tumors were more likely to have an unchanged or larger tumor size after sla treatment than those with low-grade tumors (or 7.49, p = 0.0364). Subsequent surgery and adjuvant treatment were not required after sla treatment in 90.4% and 86.7% of patients, respectively. Patients with high-grade tumors were more likely to receive subsequent surgery (or 2.25, p =0.4957) and adjuvant treatment (or 3.77, p = 0.1711) after sla therapy, without reaching significance. A total of 29 acute complications in 23 patients were reported and included malpositioned catheters (n = 3), intracranial hemorrhages (n = 2), transient neurological deficits (n = 11), permanent neurological deficits (n = 5), symptomatic perilesional edema (n =2),

									hydrocephalus (n = 4), and death (n = 2). On long-term follow-up, 3 patients were reported to have worsened neuropsychological test results. Pre-sla tumor volume, tumor location, number of laser trajectories, and number of lesions created did not result in a significantly increased risk of complications; however, the odds of complications increased by 14% (or 1.14, p = 0.0159) with every 1-cm3 increase in the volume of the lesion created. Conclusions sla is an effective, minimally invasive treatment option for pediatric brain tumors, although it is not without risks. Limiting the volume of the generated thermal lesion may help decrease the incidence of complications. Reported event: two patients had intracranial hemorrhages. Five patients had permanent neurological deficits. Eleven patients had transient neurological deficits. Two patients had symptomatic perilesional edema. Four patients had hydrocephalus. On long-term follow-up, three patients were reported to have worsened neuro-psychological test results. Manufacturer narrative: patient information was not included in the journal article. This value is the mean age of the patients in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients in the article as specific patients could not be identified. Please note that this date is based off of the date the article was published online as the event dates were not provided in the published literature. Article citation is included. System product number and serial number not provided in journal article. Udi not available for this system. No 510k provided as system is unknown. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
2182207-2020-00213	25/03/2020	Injury	MEDTRONIC NEUROMODULATION	14/05/2020	MHY	IMPLANTABLE	Adverse Event Without	Purulent Discharge; Staphylococcus	Razmkon a, yousefi o, vaidyanathan j. Using pre-implanted deep brain stimulation electrodes for rescue thalamotomy in a case

						NEUROSTIMULATOR	Identified Device or Use Problem	Aureus; Therapeutic Response, Decreased	of holmes tremor: a case report and review of the literature. Stereotact funct neurosurg. 2020:1-6. 10.1159/000506083. Chronic stimulation of the thalamus is a surgical option in the management of intractable holmes tremor. Patients with deep brain stimulation (dbs) can encounter infection as a postoperative complication, necessitating explantation of the hardware. We report the case of a patient with holmes tremor who had stable control of symptoms with dbs of the nucleus ventralis intermedius of the thalamus (vim) but developed localized infection over the extension at the neck, followed by gradual loss of a therapeutic effect as the neurostimulator reached the end of its service life. Three courses of systemic antibiotic therapy failed to control the infection. After careful consideration, we decided to make a rescue lesion through the implanted lead in the right vim before explanting the complete dbs hardware. The tremor was well controlled after the rescue lesion procedure, and the effect was sustained during a 2-year follow-up period. Reported events: one patient developed a pustular eruption over the extension connector, roughly under the mastoid eminence. The pustule gradually lead to persistent purulent discharge from the wound. A culture showed (b)(6) bacteria. Multiple attempts of outpatient and inpatient systemic antibiotic therapy and local debridement of the wound were made to control the infection. These efforts were mostly transiently effective, and discharge commenced again. Due to ins depletion, gradual loss of tremor suppression was observed. Manufacturer narrative: concomitant medical products: product id: 3389, lot#: unknown, product type: lead. Product id: neu_unknown_ext, lot#: serial#: unknown, product type: extension. Product id: 3389, serial/lot #: unknown. Product id: neu_unknown_ext, serial/lot #: unknown. Date of event: please note that this date is based off of the date of publication of the

									article as the event dates were not provided in the published literature. The device was used for an off label indication; see literature article. If information is provided in the future, a supplemental report will be issued. (b)(4).
2182207-2020-00198	25/03/2020	Injury	MEDTRONIC NEUROMODULATION	12/05/2020	OLM	ACTIVA	Adverse Event Without Identified Device or Use Problem	Post Operative Wound Infection	Summary: gilles de la tourette syndrome (gts) is a neurobehavioral disorder comprising motor and vocal tics. In most cases it is associated with other disorders such as obsessive-compulsive disorder (ocd). In refractory cases deep brain stimulation (dbs) is a valid treatment option. This paper describes the case of a (b)(6)-year-old adolescent with an extremely refractory gts with associated ocd. The patient developed catatonia associated with ocd, which partially remitted after electroconvulsive therapy. At the peak of the disease the yale global tic severity scale (ygtss) was 100 and the patient required sedation and intubation. All medical treatment options were unsuccessful. Bilateral dbs of the anterior limb of internal capsule (alic)/bed nucleus of stria terminalis (bst) region was performed, using a target below the bst and a trajectory through the alic, with stimulation of contacts 0 and 3. Two weeks after surgery sedatives were suspended and the patient was successfully extubated. One year after surgery the patient reached a ygtss of 19, representing an 81% improvement. Ocd completely resolved. Adverse events were a superficial infection and weight gain. In conclusion, this alic/bst stimulation appears to have been an effective and safe treatment for gts with ocd in this case. Young age should not be an exclusion criterion for dbs in severe gts and ocd. Further studies should be pursued for this target. Reported events: a (b)(6) year old male patient implanted with deep brain stimulation (dbs) for gilles de la tourette syndrome (gts) and obsessive compulsive disorder (ocd) experienced superficial scalp wound infection one month after implant, which was related to compulsive picking of the scalp wound. It

									was noted that at this time, the patient's symptoms were not controlled. Interventions included wound revision and administration of antibiotics. See literature article. The following device information was identified in the article: lead model 3387, ins model 37601. Manufacturer narrative: duarte-batista p, coelho m, quintas s, et al. Anterior limb of internal capsule and bed nucleus of stria terminalis stimulation for gilles de la tourette syndrome with obsessive-compulsive disorder in adolescence: a case of success. Stereotact funct neurosurg. 2020:1-9. 10.1159/000505702. Date of event: please note that this date is based off of the date of publication of the article [or the date that the article was accepted for publication] as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Information references the main component of the system. Other relevant device(s) are: product id: 3387, serial/lot #: unknown. If information is provided in the future, a supplemental report will be issued. (b)(4).
8043933-2020-00020	10/03/2020	Injury	BRAINLAB AG	03/04/2020	HAW	CRANIAL NAVIGATION SOFTWARE (VERSION 3.1)	Use of Device Problem	No Consequences Or Impact To Patient	A cranial surgery for a biopsy for retrieval of a diagnostic sample of an assumed glioblastoma, located ca. 47mm deep in the right side of the brain, with a diameter of ca. 15mm, has been performed with the aid of the brainlab navigation version 3.1. The pre-operative t1 mri scan used with navigation was acquired 5 days before the surgery. The trajectory was planned on this scan. During the procedure the surgeon: positioned the patient in a lateral orientation in a non-brainlab head holder, and attached the unsterile navigation reference array to the head holder. Performed the image registration with

									surface matching, acquiring registration points using the softouch on the patient's skin surface to match the display of the navigation to the current patient anatomy, verified the accuracy and accepted the registration to proceed. Determined the entry point with the navigated pointer, marked it on the patient skin, removed the unsterile navigation reference array and draped the patient. Attached a sterile reference array, re-marked the entry point, performed the incision, used again the pointer to determine the location of the burr hole in the skull for the desired entry point and approach with navigation, and created the burr hole. Aligned the varioguide to the planned trajectory and performed the biopsy with a navigated biopsy needle through the navigated varioguide. 1 pass for 1 sample was intended, the specimen were provided to pathology. Since the desired pathological tissue was not retrieved, 3 further sample passes were attempted at different depth and different trajectories other than planned. The further samples provided to pathology were also non-diagnostic. Checked the navigation accuracy at the entry point, and determined a ca. 6mm deviation of the instrument position display by navigation on the skull, compared to the actual patient anatomy. Completed the surgery and closed the patient. A post-surgery ct scan was taken, a revision biopsy surgery was planned for this patient and took place 3 days later on (b)(6) 2020. The revision biopsy surgery was performed using the same already existing burr hole (craniotomy), with a stereotactic frame instead of navigation, and the desired diagnostic sample was retrieved. According to the surgeon: the surgeries were only to retrieve diagnostic samples, not to remove or treat the lesion. The final outcome after revision surgery was successful as intended, with no change of the already existing craniotomy. There was no harm or negative effect to the patient due to the initial

									surgery or its biopsy attempts, neither due to prolong of the initial surgery/anesthesia (of ca.30-60min), nor due to the repeat of surgery/anesthesia (of ca. 60min) for the revision. There are further no remedial actions necessary, done or planned for this patient. There was no prolong of hospitalization either. Manufacturer narrative: a risk to the patient's health could not be excluded for these specific circumstances, since biopsies were applied in a different location in the brain than anticipated and desired with the brainlab navigation involved, and the desired diagnostic sample was not retrieved at this surgery, despite according to the surgeon: the surgeries were only to retrieve diagnostic samples, not to remove or treat the lesion. The final outcome after revision surgery was successful as intended, with no change of the already existing craniotomy. There was no harm or negative effect to the patient due to the initial surgery or its biopsy attempts, neither due to prolong of the initial surgery/anesthesia (of ca.30-60min), nor due to the repeat of surgery/anesthesia (of ca. 60min) for the revision. There are further no remedial actions necessary, done or planned for this patient. There was no prolong of hospitalization either. According to the results of the brainlab investigation and the information provided by the hospital, it can be concluded that the root cause for the deviation of the actual trajectories applied, compared to the intended trajectories displayed by the navigation, by ca. 6mm observed at the entry point, is that a shift of the navigation reference array occurred during the surgery after registration, due to a not sufficiently rigid fixation of the array's connection arm to the head holder by the user. The movement of the array occurred most likely before creating the burr hole when applying forces e.g. During draping. This led to a deviation of displayed instrument positions on the pre-operative mri, different than originally registered to

									the scan. A further potential contributing factor is a combination of using an mri scan not fulfilling the requirements as per the brainlab scan protocol for registration to navigation, not providing a sufficient smooth surface reconstruction due to noise artefacts and skin shift/changes, and an acquisition of registration points by the user not as required by the navigation, with the points not sufficiently distributed on both sides of the head and nose, and acquired on areas with scan artefacts. This might have led to a less accurate than desired match of the actual patient anatomy to the image set used with navigation. Apparently the resulting deviation of the navigation display was not detected by the user before the craniotomy and applying the biopsies, with the necessary continued user verification of navigation accuracy after registration, after draping and throughout the surgery. There is no indication of a systematic error or malfunction of the brainlab device (navigation). Corresponding brainlab measures to minimize this anticipated risk as low as reasonably practicable are already in place. Brainlab intends to reiterate the relevant topics regarding the use of the device to this customer.
6000030-2020-00161	06/03/2020	Injury	MEDTRONIC NEUROMODULATION	08/04/2020	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Erosion; Cellulitis; Hemorrhage, Subdural; Unspecified Infection; Thrombosis	Yarema b. Bezchlibnyk, vibhash d. Sharma, kushal b. Naik, faical isbaine, john t. Gale, jennifer cheng, shirley d. Triche, svjetlana miocinovic, cathrin m. Buetefisch, jon t. Willie, nicholas m. Boulis, stewart a. Factor, thomas wichmann, mahlon r. Delong, robert e. Gross j neurosurg doi: 10.3171/2019.12.jns192010. Objective deep brain stimulation (dbs) lead placement is increasingly performed with the patient under general anesthesia by surgeons using intraoperative mri (imri) guidance without microelectrode recording (mer) or microstimulation. The authors assessed the accuracy of lead placement, safety, and motor outcomes in patients with parkinson disease (pd) undergoing dbs lead placement into the globus pallidus internus (gpi) using imri or mer guidance. Methods the authors

									identified all patients with pd who underwent either mer- or imri-guided gpi-dbs lead placement at emory university between july 2007 and august 2016. Lead placement accuracy and adverse events were determined for all patients. Clinical outcomes were assessed using the unified parkinsonâ¿¿s disease rating scale (updrs) part iii motor scores for patients completing 12 months of follow-up. The authors also assessed the levodopa-equivalent daily dose (ledd) and stimulation parameters. Results seventy-seven patients were identified (mer, n = 28; imri, n = 49), in whom 131 leads were placed. The stereotactic accuracy of the surgical procedure with respect to the planned lead location was 1.94 â± 0.21 mm (mean â± sem) (95% ci 1.54â¿¿2.34) with frame-based mer and 0.84 â± 0.007 mm (95% ci 0.69â¿¿0.98) with imri. The rate of serious complications was similar, at 6.9% for mer-guided dbs lead placement and 9.4% for imri-guided dbs lead placement (rr 0.71 [95% ci 0.13%â¿¿3.9%]; p = 0.695). Fifty-seven patients were included in clinical outcome analyses (mer, n = 16; imri, n = 41). Both groups had similar characteristics at baseline, although patients undergoing mer-guided dbs had a lower response on their baseline levodopa challenge (44.8% â± 5.4% [95% ci 33.2%â¿¿56.4%] vs 61.6% â± 2.1% [95% ci 57.4%â¿¿65.8%]; t = 3.558, p = 0.001). Greater improvement was seen following imri-guided lead placement (43.2% â± 3.5% [95% ci 36.2%â¿¿50.3%]) versus mer-guided lead placement (25.5% â± 6.7% [95% ci 11.1%â¿¿39.8%]; f = 5.835, p = 0.019). When updrs iii motor scores were assessed only in the contralateral hemibody (per-lead analyses), the improvements remained significantly different (37.1% â± 7.2% [95% ci 22.2%â¿¿51.9%] and 50.0% â± 3.5% [95% ci 43.1%â¿¿56.9%] for mer- and imri-guided dbs lead placement, respectively). Both groups exhibited similar reductions in ledds (21.2% and 20.9%, respectively; f = 0.221, p

									= 0.640). The locations of all active contacts and the 2d radial distance from these to consensus coordinates for gpi-dbs lead placement (x, â±20; y, +2; and z, -4) did not differ statistically by type of surgery. Conclusions imri-guided gpi-dbs lead placement in pd patients was associated with significant improvement in clinical outcomes, comparable to those observed following mer-guided dbs lead placement. Furthermore, imri-guided dbs implantation produced a similar safety profile to that of the mer-guided procedure. As such, imri guidance is an alternative to mer guidance for patients undergoing gpi-dbs implantation for pd. Pli 10: it was reported that 1 patient aged (b)(6) had an infection and required explantation of unilateral dbs lead, extension, and ipg. Pli 20: it was reported that 1 patient aged (b)(6) had an infection and required explantation of unilateral dbs lead, extension, and ipg. Pli 30: it was reported 1 patient aged (b)(6) had deep vein thrombosis/pulmonary embolism. Pli 40: it was reported that a patient aged (b)(6) had the patient had multiple erosions requiring revisions of bilateral leads, leading to lead explantation and pallidotomy. Pli 50: it was reported 1 patient aged (b)(6) had their ipg and extension wire infected required explantation pli 60: it was reported that 1 patient aged (b)(6) had erosion over their lead requiring i & d and z-plasty pli 70: it was reported 1 patient aged (b)(6) had their ipg and extension wire infected required explantation. Pli 80: it was reported that 1 patient aged (b)(6) had a small right subdural hematoma. Pli 90: it was reported that 1 patient aged (b)(6) had a small right subdural hematoma. Pli 100: it was reported that 1 patient aged (b)(6) had a left subdural hematoma. Pli 110: it was reported that a patient aged (b)(6) had cranial cellulitis that was treated with iv antibiotics. Pli 120: it was reported that a patient aged (b)(6) had a revision of their unilateral lead with imri-dbs. Pli 130: it was reported that a patient aged (b)(6) had a

									revision of their unilateral lead with imri-dbs. Pli 140: it was reported that a patient aged (b)(6) had a revision of their unilateral lead with imri-dbs. Pli 150: it was reported that a patient aged (b)(6) had a bilateral lead revision with bilateral stn-dbs. Pli 160: it was reported that a patient aged (b)(6) had a unilateral lead revision with mer-dbs. The following device specifics were provided: lead model 3389. Manufacturer narrative: age. This value is the average age of the patients reported in the article as specific patients could not be identified. Sex. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event. Please note that this date is based off of the date of publication of the article [or the date that the article was accepted for publication] as the event dates were not provided in the published literature. Yarema b. Bezchlibnyk, vibhash d. Sharma, kushal b. Naik, faical isbaine, john t. Gale, jennifer cheng, shirley d. Triche, svjetlana miocinovic, cathrin m. Buetefisch, jon t. Willie, nicholas m. Boulis, stewart a. Factor, thomas wichmann, mahlon r. Delong, robert e. Gross. Information references the main component of the system and other applicable components are: product id: neu_unknown, serial#: unknown, product type: unknown. Product id: neu_unknown, serial#: unknown, product type: unknown. Product id: 3389, lot#: unknown, product type: lead. Product id: neu_unknown, serial#: unknown, product type: unknown. Product id: 3389, lot#: unknown, product type: lead. Product id: neu_unknown, serial#: unknown, product type: unknown. Product id: 3389, lot#: unknown, product type: lead. Product id: 3389, lot#: unknown, product type: lead. Product id: 3389, lot#: unknown, product type: lead. Product id: 3389, lot#: unknown, product type: lead. Product id: 3389, lot#: unknown, product type: lead. Product id: 3389, lot#: unknown, product

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2182207-2020-00140	04/03/2020	Injury	MEDTRONIC NEUROMODULATION	16/04/2020	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Hemorrhage, Cerebral; Intracranial Hemorrhage; Cognitive Changes	On (b)(6) 2020 frequin hl, bot m, dilai j, et al. Relative contribution of magnetic resonance imaging, microelectrode recordings, and awake test stimulation in final lead placement during deep brain stimulation surgery of the subthalamic nucleus in parkinson's disease. Stereotact funct neurosurg. 2020:1-11. 10.1159/000505710. Data on seventy-six patients that underwent implantation of 146 dbs leads. Pd patients undergoing mri targeted stn dbs surgery with three-channel mer and awake test stimulation between february 2010 and january 2014 were analyzed to determine in which mer trajectory final leads were implanted and why this tract was chosen. Reported events: one patient had a symptomatic subcortical hemorrhage manifesting in delirium. The patient recovered fully. In 3 patients a postoperative ct scan showed an asymptomatic postoperative intracerebral hemorrhage. Manufacturer narrative: information references the main component of the system. Other relevant device(s) are: product id: 3389, serial/lot #: unknown. Product id: 3389, serial/lot #: unknown.

									Age. This value is the average age of the patients reported in the article as specific patients could not be identified. Date of event. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. If information is provided in the future, a supplemental report will be issued. (b)(4).
9612186-2020-00004	03/03/2020	Injury	ELEKTA INSTRUMENT AB	07/04/2020	HAW	LEKSELL STEREOTACTIC SYSTEM	Use of Device Problem; Malposition of Device	Patient Problem/Medical Problem; No Known Impact Or Consequence To Patient	The customer reported that the headframe shifted during treatment. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed.
2182207-2020-00162	25/02/2020	Injury	MEDTRONIC NEUROMODULATION	24/04/2020	LGW	IMPLANTABLE NEUROSTIMULATOR	Migration or Expulsion of Device	Therapeutic Response, Decreased	Lai, y., pan, y., wang, l., zhang, c., sun, b., li, d. Spinal cord stimulation with surgical lead improves pain and gait in parkinson's disease after a dislocation of percutaneous lead: a case report. Stereotact funct neurosurg. 2020, 1-6. Doi: 10.1159/000505707. Summary: spinal cord stimulation (scs) is receiving increasing interests for treating pain and gait disorders in patients with parkinson¿s disease (pd). In an scs study, it is hard to apply a double-blind approach, especially at low frequencies, as the stimulation normally induces paresthesia which can be perceived by the patient. We herein demonstrate a case treated with scs in which a blinding design was accomplished by an accidental dislocation of a stimulation lead. A (b)(6)-year-old man with pd was admitted to our hospital because of relapsed low back pain. This was due to the dislocation of a previously implanted scs lead, which caused a decrease in its effectiveness in alleviating pain (from 81 to 43% measured by king¿s parkinson¿s disease pain scale) and improving gait (from 35 to 28% measured by the timed up and go test). A second scs surgery using a paddle lead solved this problem, with improvements in pain and gait rebounded to 81 and 45%. In this case, the paresthesia induced by scs (us using either a paddle lead or percutaneous leads)

									was below the threshold of perception when the patient was sitting and standing, and a dislocation of one previously implanted percutaneous lead did not cause evident changes in his sensation of paresthesia. At last follow-up, the patient¿s quality of life had improved by 40% as measured by the 8-item parkinson¿s disease questionnaire (pdq-8). This study could serve partly as a proof that low-frequency scs is effective in improving pain as well as gait problems in pd patients, which was unlikely a result of a placebo effect. Reported event: a (b)(6)-year-old male patient complained of a relapse lbp and fog 2 months after scs surgery. X-ray photography demonstrated dislocation of one of the two cylindrical percutaneous electrodes. Notably, though vas scores were the worst 2 months after the first scs, no major changes occurred in the tug, the items ¿arising from chair¿ or ¿turn in bed¿ in updrs iii. This time, a paddle lead with three columns of contacts (5¿6¿5 model 39565; medtronic) was implanted in the epidural space of the thoracic spine (t8¿9) by partial laminectomy. Two months after this second scs surgery, his vas score decreased from 7 to 3, kpps decreased from 12 to 4, tug decreased from 29 s to 22 s, and updrs iii changed from 45 to 42. At the time of his follow-up, with cycling stimulation 30 min on and 15 min off (8 s soft start), the settings for scs were a1: 0¿1¿6¿8+/4.0 v/390 us/60 hz; a2: 1 + 5¿6¿12+/4.0 v/360 us/60 hz; a3: 11¿12¿ 13+/3.6 v/270 us/60 hz). The patient¿s quality of life demonstrated a huge improvement, with 40% (10 to 6) improvement found in the 8-item parkinson¿s disease questionnaire (pdq-8) and also marked improvements in 4 items in the 36-item short form questionnaire (sf-36). Also, his mood improved as a decrease from 18 to 6 was found in the beck depression inventory ii (bdiii) scoring. No specific device information provided. Manufacturer narrative: date of event. Please note that

									this date is based off of the date that the article was accepted for publication as the event dates were not provided in the published literature. Concomitant medical products: product id: 3777, lot#: unknown, product type: lead. Product id: 3777, serial/lot #: unknown. If information is provided in the future, a supplemental report will be issued.
9612186-2020-00003	24/02/2020	Malfunction	ELEKTA INSTRUMENT AB	24/03/2020	HAW	LEKSELL VANTAGE ARC SYSTEM	Manufacturing, Packaging or Shipping Problem	No Patient Involvement	During an internal inspection of two vantage arc systems, it was found that the arc carrier was unable to lock securely. Manufacturer narrative: during an internal check of a leksell vantage stereotactic arc system it was discovered that a faulty locking piece of the instrument carrier did not meet the requirement of locking force to the arc. In systems with the faulty locking piece there is a risk that the instrument carrier is insufficiently locked even after tightening the knob firmly. The instrument carrier may in some instances be moved along the arc when forces below the specified requirement are applied, which may lead to an instrument introduced into the brain moving out of the planned trajectory and may cause injury. The root cause has been found to be a manufacturing error on an inner radius of the locking piece. The part has been manufactured out of specification. An important field safety notice (b)(4) will be sent to all affected customers on (b)(6) 2020. Replacement of faulty carriers is estimated to be released (b)(6) 2020.
3004785967-2020-00328	20/02/2020	Malfunction	MEDTRONIC NAVIGATION, INC (LITTLETON)	06/03/2020	OWB	O2	Poor Quality Image	No Patient Involvement	Medtronic received information regarding an imaging system. It was reported outside of a procedure that when scanning crw stereotactic frame (in dry run), using 40cm field of view in stereotaxy mode, the images are poor and cannot be registered to the dbs application. No patient was present at the time of the event. Manufacturer narrative: no patient information provided as no patient was involved in this concern. The initial reporter was not known at the time of reporting. (b)(4). The manufacturer representative went to the site to test the

									imaging system. The reported issue was not confirmed and they performed the image quality tests and the results were good (including 40cm field of view). In addition, the crw stereotaxy frame on the hd mode, anatomy-head large gave good images and registration was possible. No parts were replaced. If information is provided in the future, a supplemental report will be issued.
6000030-2020-00137	04/02/2020	Injury	RICE CREEK MFG	13/03/2020	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Fatigue; Muscle Weakness; Nausea; Paresis; No Code Available	Reported event a (b)(6) year old female patient implanted with bilateral internal globus pallidus (gpi) deep brain stimulation (dbs) for parkinson's disease experienced post-operative symptomatic pneumocephalus. Patient's post-operative neurological examination was stable. Post-operative brain ct showed intraparenchymal air surrounding the superior portion of the right lead and significant bilateral subdural frontal pneumocephalus. The intraparenchymal air volume around the lead was 4.3 cc and subdural air volume was 49.8 cc. The patient was doing well the morning of the first post-op day, and was discharger home. Later that day, she had persistent fatigue and nausea, per family. On post-op day 5, the patient had left sided weakness. On examination, the patient was alert and oriented with a 3/5 left hemiparesis. A head ct demonstrated increase of pneumocephalus volume around right lead (19 cc) with compression of cortical brain parenchyma. The patient was taken to the or for pneumocephalus evacuation, irrigation, and wound revision. The burr hole cover was removed while manually holding the lead in position. The cavity surrounding the lead was washed out with sterile saline. The burr hole cover was re-secured and the cap replaced. The wound was closed in layers "in the usual fashion." the operation was well tolerated by the patient and she was weaned from non-rebreather oxygen mask over 5 days. The brain ct scan before discharge showed pneumocephalus resorption, with volume of air around the lead at 7.22 cc and no subdural air. Examination on discharge

									showed recovery with symmetric strength. At 6 month follow-up, more on-time and decreased dyskinesias with activation of dbs system was demonstrated. The following device specifics were identified in the literature article: lead model 3387. Manufacturer narrative: albano l, rohatgi p, kashanian a, bari a, pouratian n. Symptomatic pneumocephalus after deep brain stimulation surgery: report of 2 cases. Stereotact funct neurosurg. 2020:1-7. 10.1159/000505078. Date of event: please note that this date is based off of the date that the article was accepted for publication as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Medical device information references the main component of the system. Other relevant device(s) are: product id: 3387, serial/lot #: unknown, implanted: unknown. If information is provided in the future, a supplemental report will be issued.
6000030-2020-00138	04/02/2020	Injury	RICE CREEK MFG	13/03/2020	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Edema; Paresis; Dysphasia; No Code Available	Reported event: a (b)(6) year old female patient implanted with unilateral ventralis intermediate nucleus (vim) of the thalamus deep brain stimulation (dbs) for essential tremor experienced symptomatic pneumocephalus. Of note, the patient had a 1x8 strip electrode placed over the motor cortex during the procedure as part of a research protocol. The patient was transported to post-anesthesia care unit in stable condition without neurological deficit. Routine post-operative brain ct revealed small volume of left subdural frontal pneumocephalus without mass effect measuring 11.8 cc without an intraparenchymal component. On first post-op day, she developed progressive right-sided hemiparesis and expressive dysphasia.

									A repeat head ct demonstrated pneumocephalus had redistributed along the lead, with surrounding edema noted. Dexamethasone was started and the patient's sodium was verified to be normal. The symptoms didn't improve throughout the day, so surgical exploration took place with removal of burr hole cover and with the lead held in place. The wound was irrigated, the burr hole cover was re-secured and the scalp was closed in normal fashion. Head ct demonstrated resolution of pneumocephalus without shift in lead location. Dexamethasone was slowly tapered off, and the patient was discharged on post-op day 4 with resolution of both language impairment and right hemiparesis. The patient underwent uneventful implantable neurostimulator (ins) placement several weeks later. It was noted that a fibrin burr hole sealant was used to minimize risk of pneumocephalus. The authors noted it was possible that positioning the patient in a semi-recumbent position, with head-of-bed elevated at approximately 20-30 degrees may have contributed to the development of pneumocephalus, but it was difficult to determine the exact cause of the issue. The following device specifics were identified in the literature article: lead model 3387. Manufacturer narrative: albano l, rohatgi p, kashanian a, bari a, pouratian n. Symptomatic pneumocephalus after deep brain stimulation surgery: report of 2 cases. Stereotact funct neurosurg. 2020:1-7. 10.1159/000505078. Date of event: please note that this date is based off of the date that the article was accepted for publication as the event dates were not provided in the published literature: it was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the

									reported events. Other relevant device(s) are: product id: 3387, serial/lot #: unknown, implanted: unknown, udi#: (b)(4). If information is provided in the future, a supplemental report will be issued. [(b)(4)].
2182207-2020-00015	03/02/2020	Injury	MEDTRONIC NEUROMODULATION	17/03/2020	MHY	UNKNOWN IMPLANTABLE EXTENSION	Low impedance	Dysphasia; Complaint, Ill-Defined; Ambulation Difficulties	Dayal v, akram h, zrinzo l, limousin p, foltynie t. Subthalamic nucleus deep brain stimulation in parkinson's disease: valuable programming insights from anecdotal observations. Stereotact funct neurosurg. 2020:1-3. 10.1159/000505701. In this article, the authors use a case to illustrate and discuss some practically important learning points about programming subthalamic nucleus deep brain stimulation for parkinson¿s disease patients and highlight clinically relevant issues resulting from anatomical and device-related anomalies. Reported events: pli 10: it was reported that the patient had effective therapy relief. The patient's ins battery depleted normally, and was replaced with a new manufacturers device, but the extension remained. The patient had significant deterioration over the course of hours featuring severe bradykinesia affecting dexterity, gait and speech. Impedance measurements found low impedance on the right side. Reprogramming did not resolve the issue. The low impedance was resolved with replacing the extension. Manufacturer narrative: this report references the extension of the system created by the manufacturer. The extension was implanted with a different manufacture's ins, which is considered off-label use of the device. Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. See attached literature article. If information is provided in the future, a supplemental report will be issued.
1222780-2020-00035	24/01/2020	Malfunction	HOLOGIC, INC.	18/02/2020	KNW	BREVERA BIOPSY SYSTEM WITH CORLUMINA	Separation Failure; Failure to Eject	No Known Impact Or Consequence To Patient	It was reported that during a stereotactic biopsy, the brevera device driver got stuck on the biopsy device adapter. The end user reported that they "attached the device driver onto the device adapter until it made

						IMAGING TECHNOLOGY			the clicking noise as instructed. The device driver was secured onto the adapter, but once the physician fired the needle the driver shot back and hooked itself from the device adapter." the physician locked the driver back onto the adapter and proceeded with taking the biopsy samples. After the samples were collected, it was not possible to lift the tab on the back of the driver. The physician had to back the entire needle including the introducer out of the patient. Since the introducer was removed with the needle, the physician was unable to place a marker to identify the biopsy region. Attempts to gather additional information have been unsuccessful. No additional details at this time. Manufacturer narrative: the udi number of this specific device is unknown at this time. Device history record (dhr) review was conducted for the identified serial number. No abnormalities were found related to the reported information. This device passed final testing prior to release. The brevera biopsy console was evaluated by a field service engineer. The engineer replaced the locking tab on the device driver and verified the unit was working as intended. Unit meets specification.
6000030-2020-00096	14/01/2020	Injury	MEDTRONIC NEUROMODULATION	05/03/2020	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Hemorrhage, Cerebral; Seizures	Eleopra r, rinaldo s, devigili g, et al. Frameless deep brain stimulation surgery: a single-center experience and retrospective analysis of placement accuracy of 220 electrodes in a series of 110 patients. Stereotact funct neurosurg. 2020:1-10. 10.1159/000503335. Summary: proper lead placement is considered one of the key factors in achieving a good clinical outcome in deep brain stimulation (dbs), but there is still considerable controversy surrounding the accuracy of the frameless in comparison to the frame-based technique. Identified events: 3 patients were seen to have asymptomic, or transient symptomatic, small cortical hemorrhages close to the cortex and far from the distal lead. 1 patient complained of an isolated seizure at the end of surgery. Manufacturer narrative: other

									relevant device(s) are: product id: neu_ins_stimulator, serial/lot #: unknown. This value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. If information is provided in the future, a supplemental report will be issued.
1220984-2020-00012	09/01/2020	Malfunction	HOLOGIC, INC	29/01/2020	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was reported that the table is moving up and down on its own and when the button is touched it jumps. No injury reported. A field engineer was dispatched to the site and determined the membrane keypad needed to be replaced. Once this was completed the system was working as intended.
1723170-2020-01657	03/01/2020	Injury	MEDTRONIC NAVIGATION, INC	15/06/2020	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Abscess; Erosion; Post Operative Wound Infection	Citation: de almeida bastos, d., everson, r., de oliveira santos, b., habib, a., vega, r. A., oro, m., rao, g., li, j., ghia, a. J., bishop, a. J., yeboa, d., amini, b., rhines, l. D., <(>&<)> tatsui, c. (2020). A comparison of spinal laser interstitial thermotherapy with open surgery for metastatic thoracic epidural spinal cord compression, journal of neurosurgery: spine spi, 32(5), 667-675. Published online january 3, 2020; doi: 10.3171/2019.10.spine19998. Summary: objective the proximity of the spinal cord to compressive metastatic lesions limits radiosurgical dosing. Open surgery is used to create safe margins around the spinal cord prior to spinal stereotactic radiosurgery (ssrs) but carries the risk of potential surgical morbidity and interruption of systemic oncological treatment. Spinal

									laser interstitial thermotherapy (slitt) in conjunction with ssrs provides local control with less morbidity and a shorter interval to resume systemic treatment. The authors present a comparison between slitt and open surgery in patients with metastatic thoracic epidural spinal cord compression to determine the advantages and disadvantages of each method. Methods this is a matched-group design study comprising patients from a single institution with metastatic thoracic epidural spinal cord compression that was treated either with slitt or open surgery. The two cohorts defined by the surgical treatment comprised patients with epidural spinal cord compression (escc) scores of 1c or higher and were deemed suitable for either treatment. Demographics, pre- and postoperative escc scores, histology, morbidity, hospital length of stay (los), complications, time to radiotherapy, time to resume systemic therapy, progression-free survival (pfs), and overall survival (os) were compared between groups. Results eighty patients were included in this analysis, 40 in each group. Patients were treated between january 2010 and december 2016. There was no significant difference in demographics or clinical characteristics between the cohorts. The slitt cohort had a smaller postoperative decrease in the extent of escc but a lower estimated blood loss (117 vs 1331 ml, p <(> <<)> 0.001), shorter los (3.4 vs 9 days, p <(><<)> 0.001), lower overall complication rate (5% vs 35%, p = 0.003), fewer days until radiotherapy or ssrs (7.8 vs 35.9, p <(><<)> 0.001), and systemic treatment (24.7 vs 59 days, p = 0.015). Pfs and os were similar between groups (p = 0.510 and p = 0.868, respectively). Conclusions the authors¿ results have shown that slitt plus xrt is not inferior to open decompression surgery plus xrt in regard to local control, with a lower rate of complications and faster resumption of oncological treatment. A prospective randomized controlled study is needed to

									compare slitt with open decompressive surgery for escc. Complications were defined as any adverse event within 30 days related to the procedure. Major complications were defined as medical or surgical complications that required a prolonged hospital stay or new surgical procedure. Reported events: one patient with a histology of non-small cell lung cancer (nsclc) underwent slitt and post-operatively had an epidural abscess which was categorized as a major complication. One patient with a histology of renal cell carcinoma (rcc) underwent slitt and post-operatively had woundBreakdown and infection which was categorized as a minor complication. Manufacturer narrative: patient information was not included in the journal article. Average age was unable to be determined based on data provided in article. This value reflects the gender of the majority of the patients in the article who underwent slitt as specific patients could not be identified. Please note that this date is based off of the date the article was published online, as the event dates were not provided in the published literature. Article citation is included. System product number and serial number not provided in journal article. Udi not available for this system. No 510k provided as system is unknown. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
2182207-2020-00343	01/01/2020	Injury	MEDTRONIC NEUROMODULATION	12/06/2020	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Hemorrhage, Cerebral; Unspecified Infection	Bucurenciu i, staack am, gharabaghi a, steinhoff bj. High-frequency electrical stimulation of the anterior thalamic nuclei increases vigilance in epilepsy patients during relaxed and drowsy wakefulness. Epilepsia. 2020. 10.1111/epi.16514. Abstract: the objective of this study was to evaluate the clinical results of asleep vim dbs using indirect coordinates and real-time interventional magnetic resonance imaging guidance. Retrospective review of a prospectively collected database was

									performed to identify patients with essential tremor undergoing asleep vim dbs using interventional magnetic resonance imaging guidance. Stereotactic and clinical outcomes were abstracted and analyzed using descriptive statistics reported events: a 6 mm, asymptomatic left-sided cortical intraparenchymal hemorrhage occurred in 1 patient. 2 patients developed superficial surgical site infections (1 cranial,1 infraclavicular), both resolving with short courses of oral antibiotics. Manufacturer narrative: this value is the average age of the patients reported in the article as specific patients could not be identified. A. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. If information is provided in the future, a supplemental report will be issued. (b)(4).
3008769756-2021-00020	01/01/2020	Injury	NEUWAVE MEDICAL, INC.	23/06/2021	NEY	UNKNOWN_NEUWAVE	Appropriate Term/Code Not Available	Insufficient Information	It was reported via journal article title: thermal ablation versus stereotactic body radiotherapy following transarterial chemoembolization for inoperable hepatocellular carcinoma: a propensity score weighted analysis authors: nima nabavizadeh, md, younes jahangiri, md, ramtin rahmani, ba, yuki tomozawa, md, phd, yindee geeratikun, md, yiyi chen, phd, arthur hung, md, catherine degnin, phd, khashayar farsad, md, phd citation: ajr (2020), doi:10.2214/ajr.20.24117. The aim of this retrospective study is to compare outcomes for inoperable hcc between tace with percutaneous thermal ablation (t-ta) and tace with stereotactic body radiotherapy (t-sbrt) using propensity-score-weighted cohorts. Between 2007 to 2018, a total of 190 patients with a single inoperable hcc were treated with either t-sbrt in 90 patients (74 male and 16 female; median age = 60 years) or t-ta in 100 patients (68 male and 32 female; median

									age = 61 years) after prior tace. In the t-ta group, ablation was performed using microwave (neuwave medical, ethicon). The median follow-up time was 48.2 months. Reported complications included death (n=?), and treatment-related hepatotoxicity (n=9%). In conclusion, our analyses show that compared to t-sbrt, t-ta is associated with improved os and pfs after propensity-score weighting. Hepatotoxicity was worse in the t-sbrt group, possibly explaining the inferior os despite similar local control. However, subset analyses of the patients with the earliest-stage hcc and most preserved liver function identified similar os and pfs. Prospective randomized studies evaluating these two combined modality strategies are warranted. Manufacturer narrative: (b)(4). Date of event: only event year known: 2020; captured as citation date. As the device was not returned, an analysis investigation could not be performed. A conclusion could not be reached as to what may have caused or contributed to the event. If information is obtained that was not available for the initial report, a follow-up report will be filed as appropriate.
3008769756-2021-00021	01/01/2020	Death	NEUWAVE MEDICAL, INC.	23/06/2021	NEY	UNKNOWN_NEUWAVE	Appropriate Term/Code Not Available	Insufficient Information	It was reported via journal article title: thermal ablation versus stereotactic body radiotherapy following transarterial chemoembolization for inoperable hepatocellular carcinoma: a propensity score weighted analysis authors: nima nabavizadeh, md, younes jahangiri, md, ramtin rahmani, ba, yuki tomozawa, md, phd, yindee geeratikun, md, yiyi chen, phd, arthur hung, md, catherine degnin, phd, khashayar farsad, md, phd citation: ajr (2020), doi:10.2214/ajr.20.24117. The aim of this retrospective study is to compare outcomes for inoperable hcc between tace with percutaneous thermal ablation (t-ta) and tace with stereotactic body radiotherapy (t-sbrt) using propensity-score-weighted cohorts. Between 2007 to 2018, a total of 190 patients with a single inoperable hcc were treated with either t-

									sbrt in 90 patients (74 male and 16 female; median age = 60 years) or t-ta in 100 patients (68 male and 32 female; median age = 61 years) after prior tace. In the t-ta group, ablation was performed using microwave (neuwave medical, ethicon). The median follow-up time was 48.2 months. Reported complications included death (n=?), and treatment-related hepatotoxicity (n=9%). In conclusion, our analyses show that compared to t-sbrt, t-ta is associated with improved os and pfs after propensity-score weighting. Hepatotoxicity was worse in the t-sbrt group, possibly explaining the inferior os despite similar local control. However, subset analyses of the patients with the earliest-stage hcc and most preserved liver function identified similar os and pfs. Prospective randomized studies evaluating these two combined modality strategies are warranted. Manufacturer narrative: (b)(4). Date sent: 6/23/2021. Event date: only event year known: 2020; captured as citation date. As the device was not returned, an analysis investigation could not be performed. A conclusion could not be reached as to what may have caused or contributed to the event. We did not receive a batch or lot number for the product involved in this complaint. Therefore, we were unable to check manufacturing records for any related non-conformance.
1723170-2020-01647	31/12/2019	Injury	MEDTRONIC NAVIGATION, INC	11/06/2020	HAW	S7 STEALTHSTATION NAVIGATION SYSTEM	Adverse Event Without Identified Device or Use Problem	Hemorrhage/Bleeding	Citation: yan chen, tieshuan huang, yang sun, jianxiang liao, dezhi cao, lin li, kui xiang, chun lin, cong li, qian chen. Surface-based registration of mr scan versus refined anatomy-based registration of ct scan: effect on the accuracy of seeg electrodes implantation performed in prone position under frameless neuronavigation. Stereotact funct neurosurg 2020; 98:73¿79. Doi: 10.1159/000505713 abstract introduction: stereoelectroencephalography (seeg) refers to a commonly used diagnostic procedure to localise and define the epileptogenic zone of refractory focal epilepsies, by means of minimally invasive

									operation techniques without large craniotomies. Objective: this study aimed to investigate the influence of different registration methods on the accuracy of seeg electrode implantation under neuronavigation for paediatric patients with refractory epilepsy. Methods: the clinical data of 18 paediatric patients with refractory epilepsy were retrospectively analysed. The seeg electrodes were implanted under optical neuronavigation while the patients were in the prone position. Patients were divided into two groups on the basis of the surface-based registration of mr scan method and refined anatomy-based registration of ct scan. Registration time, accuracy, and the differences between electrode placement and preoperative planned position were analysed. Results: thirty-six electrodes in 7 patients were placed under surface-based registration of mr scan, and 45 electrodes in 11 patients were placed under refined anatomy-based registration of ct scan. The registration time of surface-based registration of mr scan and refined anatomy-based registration of ct scan was 45 ± 12 min and 10 ± 4 min. In addition, the mean registration error, the error of insertion point, and target error were 3.6 ± 0.7 mm, 2.7 ± 0.7 mm, and 3.1 ± 0.5 mm in the surfacebased registration of mr scan group, and 1.1 ± 0.3 mm, 1.5 ± 0.5 mm, and 2.2 ± 0.6 mm in the refined anatomy-based registration of ct scan group. The differences between the two registration methods were statistically significant. Conclusions: the refined anatomy-based registration of ct scan method can improve the registration efficiency and electrode placement accuracy, and thereby can be considered as the preferred registration method in the application of seeg electrode implantation under neuronavigation for treatment of paediatric intractable epilepsy. Reported events: two patients experienced hemorrhages. Manufacturer narrative: patient age is the mean value of patients in

									the study. Patient gender is the majority value of patients in the study. Patient weight not available from the site. Event date is the accepted date of the publication. Brand name included as the system type was included in the publication. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1222780-2020-00017	31/12/2019	Malfunction	HOLOGIC, INC	24/01/2020	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Failure to Obtain Sample	No Known Impact Or Consequence To Patient	It was reported that at the end of the procedure, "tissue samples were to be removed from probe only to find no samples were collected. Post biopsy images demonstrate a biopsy cavity and biopsy clip posterolateral to the targeted asymmetry within the left breast. The patient has multiple small similar densities , likely cysts or lymph nodes and one of these were sampled inadvertently given the proximity. Discussion about additional biopsy verses follow up mammogram of the area was discussed." patient will return in 6 months for follow up left mammogram to ensure stability. No additional details available. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. If the device is returned and evaluation completed, a supplemental medwatch will be filed device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
1723170-2020-01653	30/12/2019	Injury	MEDTRONIC NAVIGATION, INC	12/06/2020	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Unspecified Infection; Tissue Damage	Citation: yarema b. Bezchlibnyk, vibhash d. Sharma, kushal b. Naik, faical isbaine, john t. Gale, jennifer cheng, shirley d. Triche, nicholas m. Boulis, stewart a. Factor, thomas wichmann, mahlon r. Delong, and robert e. Gross. Clinical outcomes of globus pallidus deep brain stimulation for parkinson disease: a comparison of intraoperative mri- and mer-guided lead placement. J neurosurg march 6, 2020 doi: 10.3171/2019.12.jns192010 objective:

									deep brain stimulation (dbs) lead placement is increasingly performed with the patient under general anesthesia by surgeons using in reoperative mri (imri) guidance without microelectrode recording (mer) or microstimulation. The authors assessed the accuracy of lead placement, safety, and motor outcomes in patients with parkinson disease (pd) undergoing dbs lead placement into the globus pallidus internus (gpi) using imri and mer guidance. Methods: the authors identified all patients with pd who underwent either mer or imri guided gpi-dbs lead placement at emory university between july 2007 and august 2016. Lead placement accuracy and adverse events were determined for all patients. Clinical outcomes were assessed using the unified parkinson's disease rating scale (updrs) part iii motor scores for patients completing 12 months of follow-up. The authors also assessed the levodopa-equivalent daily dose (ledd) and stimulation parameters. Results: seventy-seven patients were identified (mer, n = 28; imri, n = 49), in whom 131 leads were placed. The stereotactic accuracy of the surgical procedure with respect to the planned lead location was 1.94 + 0.21mm (mean + sem) (85% cl 1.54-2.34) with frame-based mer and 0.84 _ 0.0007 mm (95% cl 0.69-0.98) with imri. The rate of serious complications were similar at 6.9% for mer-guided dbs lead placement with 9.4% for imri-guided dbs lead placement (rr 0.71 [95% cl 0.13-3.9%]; p = 0.695). Fifty-seven patients were included in clinical outcome analyses (mer, n = 16; imri, n = 41). Both groups had similar characteristics at baseline, although patient undergoing mer-guided lead placement (25.5% + 6.7% [95% cl, 33.2%-56.4%] versus 61.6% + 2.1% [85% cl 57.4%-65.8%]; t = 3.558, p = 0.001). Greater improvement was seen following imri-guided lead placement (43.2% + 3.5% [95% cl 36.2%-50.3%]) versus mer-guided lead placement (25.5% + 6.7% [95% cl 11.1%-39.8%]; f = 5.835, p = 0.019). When updrs

									iii motor scores were assessed only in the contralateral hemibody (per-lead) analyses), the improvements remained significantly different (37.1% + 7.2% [95% cl 22.2%-51.9%] and 50.0% + 3.5% [95% cl 43.1% - 56.9%] for mer and imri guided dbs lead placement, respectively). Both groups exhibited similar reductions in ledds (21.2% and 20.9% respectively; f = 0.221, p = 0.640). The locations of all active contacts and the 2d radial distance from these to consensus coordinates for gpi-dbs lead placement (x, +20; y, +2; and z, -4) did not differ statistically by type of surgery. Conclusion: imri-guided gpi-dbs lead placement in pd patients was associated with significant improvement in clinical outcomes, comparable to those observed following mer-guided dbs lead placement. Furthermore, imri-guided dbs implantation produced a similar safety profile to that of the mer-guided procedure. As such, imri guidance is an alternative to mer guidance for patients undergoing gpi-dbs implantation for pd. Reported events: (b)(6) yr male experienced an infection requiring explantation of unilat dbs lead, extension and ipg. (b)(6) yr female experienced an infection requiring explantation of unilat dbs lead, extension and ipg. (b)(6) yr male experienced revision of unilat lead with imri-dbs. (b)(6) yr male experienced revision of unilat lead with imri-dbs. (b)(6) yr male experienced revision of unilat lead with imri-dbs. Manufacturer narrative: patient age is the mean value of patients in the cohort. Patient gender is the majority value of patients in the cohort. Patient weight not available from the site. Event date is the accepted date of the publication. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. 510(k) is dependent on the model number of the product. Therefore, 510(k) is unavailable. If information is

									provided in the future, a supplemental report will be issued.
2182207-2020-00248	30/12/2019	Injury	MEDTRONIC NEUROMODULATION	25/05/2020	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage	Helmers ak, kubelt c, birkenfeld f, et al. Screening for platelet dysfunction and use of prophylactic tranexamic acid in patients undergoing deep brain stimulation: a retrospective analysis of incidence and outcome of intracranial hemorrhage. Stereotact funct neurosurg. 2020:1-6. 10.1159/000505714. Summary: the rate of intracranial hemorrhage (ich) after deep brain stimulation (dbs) is between 1.5 and 6.1%, with prolonged deficits occurring in 0.4¿2.5% of the patients. This retrospective study investigates whether the prophylactic administration of tranexamic acid (ta) to patients with abnormal platelet function detected preoperatively by platelet function analyzer (pfa) lowered the risk for an ich event. Identified events: 11 patients experienced intracranial hemorrhage without prolonged deficits. 5 patients experienced intracranial hemorrhage with prolonged deficits. Manufacturer narrative: concomitant medical products: product id: neu_ins_stimulator, serial#: unknown, product type: implantable neurostimulator. Product id: neu_ins_stimulator, serial/lot #: unknown. Helmers ak, kubelt c, birkenfeld f, et al. Screening for platelet dysfunction and use of prophylactic tranexamic acid in patients undergoing deep brain stimulation: a retrospective analysis of incidence and outcome of intracranial hemorrhage. Stereotact funct neurosurg. 2020:1-6. 10.1159/000505714. This value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with

									previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. If information is provided in the future, a supplemental report will be issued. (b)(4).
2182207-2020-00249	30/12/2019	Injury	MEDTRONIC NEUROMODULATION	25/05/2020	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage; Paresis; Dysphasia; Ambulation Difficulties; Confusion/ Disorientation	Helmers ak, kubelt c, birkenfeld f, et al. Screening for platelet dysfunction and use of prophylactic tranexamic acid in patients un dergoing deep brain stimulation: a retrospective analysis of incidence and outcome of intracranial hemorrhage. Stereotact funct neurosurg. 2020:1-6. 10.1159/000505714 summary: the rate of intracranial hemorrhage (ich) after deep brain stimulation (dbs) is between 1.5 and 6.1%, with prolonged deficits occurring in 0.4¿2.5% of the patients. This retrospective study investigates whether the prophylactic administration of tranexamic acid (ta) to patients with abnormal platelet function detected preoperatively by platelet function analyzer (pfa) lowered the risk for an ich event. Identified events: 1 patient who suffered from intracranial hemorrhage also experienced postural instability. The postural instability was a persisting deficit for four years. 1 patient who suffered from intracranial hemorrhage also experienced hemiparesis. The hemiparesis was a persisting deficit for six years. 1 patient who suffered from intracranial hemorrhage also experienced hemiparesis. The hemiparesis persisted for three years. 1 patient who suffered from intracranial hemorrhage had no additional symptoms. 1 patient who suffered from intracranial hemorrhage also experienced confusion which persisted for days. 1 patient who suffered from intracranial hemorrhage had no additional symptoms. 1 patient who suffered from intracranial hemorrhage had no additional symptoms. 1 patient who suffered from intracranial hemorrhage also experienced dysarthria which persisted for less than three months. 1 patient who

									suffered from intracranial hemorrhage also experienced postural instability which persisted for four weeks. Manufacturer narrative: other relevant device(s) are: product id: neu_ins_stimulator, serial/lot #: unknown; product id: neu_ins_stimulator, serial/lot #: unknown; product id: neu_ins_stimulator, serial/lot #: unknown; product id: neu_ins_stimulator, serial/lot #: unknown; product id: neu_ins_stimulator, serial/lot #: unknown; product id: neu_ins_stimulator, serial/lot #: unknown; product id: neu_ins_stimulator, serial/lot #: unknown; product id: neu_ins_stimulator, serial/lot #: unknown .helmers ak, kubelt c, birkenfeld f, et al. Screening for platelet dysfunction and use of prophylactic tranexamic acid in patients un dergoing deep brain stimulation: a retrospective analysis of incidence and outcome of intracranial hemorrhage. Stereotact funct neurosurg. 2020:1-6. 10.1159/000505714. This value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. If information is provided in the future, a supplemental report will be issued. [(b)(4)].
2182207-2020-00250	30/12/2019	Injury	MEDTRONIC NEUROMODULATION	25/05/2020	MRU	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Facial Nerve Paralysis; Intracranial Hemorrhage; Nausea; Paralysis	Helmers ak, kubelt c, birkenfeld f, et al. Screening for platelet dysfunction and use of prophylactic tranexamic acid in patients undergoing deep brain stimulation: a retrospective analysis of incidence and outcome of intracranial hemorrhage. Stereotact funct neurosurg. 2020:1-6.

									10.1159/000505714. Summary: the rate of intracranial hemorrhage (ich) after deep brain stimulation (dbs) is between 1.5 and 6.1%, with prolonged deficits occurring in 0.4¿2.5% of the patients. This retrospective study investigates whether the prophylactic administration of tranexamic acid (ta) to patients with abnormal platelet function detected preoperatively by platelet function analyzer (pfa) lowered the risk for an ich event. Identified events: a patient suffered from an intracranial hemorrhage and additionally experienced nausea which lasted for days. A patient suffered from an intracranial hemorrhage and additionally experienced hemiplegia which was a persistent deficit for three years. A patient suffered from an intracranial hemorrhage and had no additional symptoms. A patient suffered from an intracranial hemorrhage and additionally experienced facial paralysis with no additional follow up necessary. Manufacturer narrative: information references the main component of the system. Other relevant device(s) are: product id: neu_ins_stimulator, serial/lot #: unknown. Product id: neu_ins_stimulator, serial/lot #: unknown. Product id: neu_ins_stimulator, serial/lot #: unknown. Helmers ak, kubelt c, birkenfeld f, et al. Screening for platelet dysfunction and use of prophylactic tranexamic acid in patients undergoing deep brain stimulation: a retrospective analysis of incidence and outcome of intracranial hemorrhage. Stereotact funct neurosurg. 2020:1-6. 10.1159/000505714. This value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article

									or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. If information is provided in the future, a supplemental report will be issued. (b)(4).
1222780-2020-00007	20/12/2019	Malfunction	HOLOGIC, INC	09/01/2020	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Fluid/Blood Leak	No Known Impact Or Consequence To Patient	It was reported that when the biopsy was done and as the tubing was moved, "the specimen container opened freely (as if it had not been re-closed / locked) and of course any remaining fluid - saline & blood was spilled to clothing, floor, vacuum equipment. This is the 3rd time it has happened with the petite needle." no additional details available. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. If the device is returned and evaluation completed, a supplemental medwatch will be filed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
3005099803-2020-00083	20/12/2019	Malfunction	AUGMENIX, INC.	17/01/2020	OVB	SPACEOAR SYSTEM	Positioning Problem	No Consequences Or Impact To Patient	It was reported to boston scientific corporation on december 24, 2019 that spaceoar was implanted during a spaceoar placement procedure performed on (b)(6) 2019. Reportedly, antibiotics were administered and an enema was performed prior to the procedure. The procedure was done under general anesthesia. Reportedly, hydro dissection was performed prior to reaching the perirectal fat. According to the complainant, during a magnetic resonance imaging (mri) scan, the physician noted that the spaceoar gel was present in the rectal serosa. Per mri review, the rectal wall infiltration (rwi) was observed to be just under 25% of the rectal wall circumference. Interventional radiology (ir) pain relief was used post procedure. There were no patient complications reported as a result of this event. The patient's condition post procedure was reported to be stable. As of

									(b)(6) 2020, the patient continued to receive stereotactic body radiation therapy. Manufacturer narrative: the complainant was unable to provide the suspect device lot number. Therefore, the manufacture date and expiration date are unknown. (b)(4). The device was implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental medwatch will be filed.
1222780-2020-00015	18/12/2019	Malfunction	HOLOGIC, INC	17/01/2020	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Material Deformation	No Known Impact Or Consequence To Patient	It was reported that during the procedure, the product sheath compressed into an accordion and the device was unable to be removed. The procedure was completed successfully with a second device with no impact to patient. No additional details available. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. If the device is returned and evaluation completed, a supplemental medwatch will be filed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
9805044	16/12/2019	Malfunction	MONTERIS MEDICAL CORP	09/03/2020	GEX	MONTERIS NEUROBLATE	Defective Device	No Consequences Or Impact To Patient	During an attempted left stereotactic brain biopsy with left laser interstitial thermal ablation, the laser was not operational despite multiple attempts to fix by our monteris representative. After investigation, the failure occurred due to cim pcm (protection circuit module) assembly was not supplying 24 volts to the laser device, signal conditioner and other devices. The procedure was aborted. There was no harm to the patient. The patient will be rescheduled for surgery after laser repairs are completed.
1723170-2020-01637	15/12/2019	Death	MEDTRONIC NAVIGATION, INC	11/06/2020	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Atrial Fibrillation; Complaint, Ill-Defined	Citation: ali h palejwala, md, kyle p o¿connor, bs, camille k milton, bs, panayiotis e pelargos, md, chad a glenn, md, bradley n bohnstedt, md, ozer algan, md, michael e sughrue, md, laser interstitial thermal therapy for metastatic melanoma after failed radiation therapy: a case series,

									operative neurosurgery, https://doi.org/10.1093/ons/opaa012. Summary: background: laser interstitial thermal therapy (litt) is a growing technology to treat a variety of brain lesions. It offers an alternative to treatment options, such as open craniotomy and stereotactic radiosurgery. Objective: to analyze our experience using litt for metastatic melanoma. Methods: this is a retrospective chart review of the patients from our institution. Our case series involves 5 patients who had previously failed radiation treatment. Results: our patients have low complication rates and short hospital stays. Both are considerably lower when compared to the literature for metastatic melanoma. Conclusion: litt is a safe therapy, with few complications and short hospital stays. Reported events: one (b)(6)-year-old male with a history of history of melanoma who was found to have a right frontal and cerebellar intracranial lesions underwent complete ablation to a lesion volume of 0.296 cc with 1-fiber litt. The patient spent 5 days in the hospital and was discharged with a 10-day steroid taper. The patient was kept for 5 days because he had an isolated episode of atrial fibrillation. No perioperative complications were encountered. The patient died 21 months post-litt from complication form extracranial disease. Manufacturer narrative: patient information was not included in the journal article. This value is the average age of the patients in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients in the article as specific patients could not be identified. Date of death not provided in article. This date is based off of the date the article was accepted. Please note that this date is based off of the date the article was accepted as the event dates were not provided in the published literature. Article citation is included. System product number and serial number not provided in journal

									article. Udi not available for this system. No 510k provided as system is unknown. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2020-01638	15/12/2019	Injury	MEDTRONIC NAVIGATION, INC	11/06/2020	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Atrial Fibrillation; Edema	Citation: ali h palejwala, md, kyle p o¿connor, bs, camille k milton, bs, panayiotis e pelargos, md, chad a glenn, md, bradley n bohnstedt, md, ozer algan, md, michael e sughrue, md, laser interstitial thermal therapy for metastatic melanoma after failed radiation therapy: a case series, operative neurosurgery, https://doi.org/10.1093/ons/opaa012. Summary: background: laser interstitial thermal therapy (litt) is a growing technology to treat a variety of brain lesions. It offers an alternative to treatment options, such as open craniotomy and stereotactic radiosurgery. Objective: to analyze our experience using litt for metastatic melanoma. Methods: this is a retrospective chart review of the patients from our institution. Our case series involves 5 patients who had previously failed radiation treatment. Results: our patients have low complication rates and short hospital stays. Both are considerably lower when compared to the literature for metastatic melanoma. Conclusion: litt is a safe therapy, with few complications and short hospital stays. Reported events: one (b)(6)-year-old male with a history of melanoma who was found to have a left-sided lesion underwent 2-fiber litt, with a complete ablation of a tumor volume of 5.864 cc. The patient remained inpatient 4 days and was discharged home on an 11-day steroid taper. The patient was kept for 4 days because of an asymptomatic episode of atrial fibrillation. His strength remained the same post-procedure. One (b)(6)-year-old male with a history of melanoma who was found to have multiple intracranial lesions underwent complete ablation of a 7.84-cc volume tumor with 2-fiber litt. The

									patient had an inpatient stay of 1 day and discharged with a 7-day steroid taper. Preoperative strength was 4/5 in right lower extremity, and the patient reported a headache. No perioperative complications were encountered; however, the patient remained 4/5 strength in the right lower extremity. The patient reported improvement in his headache. Re-imaging at 4 months demonstrated edema without recurrence at the litt site with metastatic disease progression at other intracranial sites. Manufacturer narrative: patient information was not included in the journal article. This value is the average age of the patients in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients in the article as specific patients could not be identified. Date of event please note that this date is based off of the date the article was accepted as the event dates were not provided in the published literature. Article citation is included. System product number and serial number not provided in journal article. Udi not available for this system. No 510k provided as system is unknown. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2020-00669	13/12/2019	Malfunction	MEDTRONIC NAVIGATION, INC	28/02/2020	HAW	MEDTRONIC NAVIGATION	Imprecision	No Known Impact Or Consequence To Patient	Citation: craven, claudia l., et al. ¿approach to slitlike ventricles: parietal-occipital versus frontal burr catheter entry sites.¿ world neurosurgery, 13 dec. 2019, pp. Doi:10.1016/j.wneu.2019.12.030. Abstract: background: slit ventricles can be a challenging target during shunt catheter insertion. Traditionally, the frontal approach has been considered optimal for small ventricles. At this center, routine use of electromagnetic (em) stereotactic guidance (stealth, medtronic, dublin, ireland) has enabled a parietooccipital (p-o) burr hole approach to the frontal horns. We compare shunt placement and revisions required for patients with slit ventricles who had shunts

									inserted via a p-o approach versus frontal shunt. Methods: we studied a retrospective cohort of patients with slit ventricles and a ventricular shunt inserted using em guidance between 2012 and 2018. Slitlike ventricles were defined as the widest point of the lateral ventricle <3 mm. Outcome measures included placement accuracy and survival using the kaplan-meier curve. Optimal final catheter tip location was considered to be the frontal horn of the ipsilateral lateral ventricle. Results: eighty-two patients (77 female, 5 male) aged 34.9 ± 10.8 years (mean ± standard deviation) had ventricular shunts inserted for idiopathic intracranial hypertension (n = 63), chiari/syrinx (n = 8), congenital (n = 10), and pseudomeningocele (n = 1). Of those identified, 35 had primary p-o shunts and 46 had frontal shunts. Overall, 94% of cases had the catheter tip sitting in the frontal horn. The p-o approach was just as accurate as the frontal approach. Eight p-o shunts and 9 frontal shunts required revision over a 60-month period. There was no significant different in shunt survival between the 2 approaches (p = 0.37). Conclusions: em-guided placement has enabled the p-o approach to be as safe and with equivalent survival to frontal approach. The accuracy of shunt placement between the 2 approaches was similar. Reported events: 1) there were four total cases where the final catheter tip position/placement was inaccurate (deviated from the intended location o f the ipsilateral frontal horn). Specifically in the p-o group, one tip was positioned in the occipital horn and one tip was positioned in the cisternal. In the frontal group, one tip was positioned in the body and one tip was positioned in the parenchymal. Manufacturer narrative: patient age is average age of patients in the article. Patient gender is the majority gender of patients in article. Patient weight was not included in the journal article. Please note that this date is based off of the date the article was published as the event

									dates were not provided in the published literature. Article citation is included. System product number and serial number not provided in journal article. Udi not available for this system. No 510k provided as system is unknown. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
3005099803-2020-00021	12/12/2019	Injury	AUGMENIX, INC.	14/01/2020	OVB	SPACEOAR SYSTEM	Adverse Event Without Identified Device or Use Problem	Abscess; Unspecified Infection; Necrosis; Urinary Retention; Obstruction/Occlusion; Abdominal Distention; No Code Available	It was reported to boston scientific corporation on december 17, 2019 that spaceoar was implanted between the prostate and anterior rectal wall during a spaceoar placement procedure performed on (b)(6) 2019. Reportedly, the procedure was done under local anesthesia and there were no issues noted during spaceoar placement. However, it was reported that the procedure took a long time and they needed a few extra sticks in order to correctly place the gold markers. According to the complainant, after the procedure, the patient tried to urinate before leaving the hospital but was unable to do so. The patient also declined to take cipro, an antibiotic administered by the hospital. Reportedly, the night of (b)(6) 2019, the patient went to the emergency room (er) for retention per the recommendation of the physician's assistant. At the er, the patient's white blood cell (wbc) count was elevated. The wbc count dropped back to a normal level after a few days of treatment. The patient's platelet count was normal. On (b)(6) 2019, a computerized tomography (ct) scan was performed in the er. A linear tract of extraluminal air between the rectum and prostate gland and additional fluid density was observed, which was reported to be expected after hydrogel implantation. On (b)(6) 2019, another ct scan was performed. The ct scan revealed no evidence of active bleeding. The ct scan showed that the internal mesenteric artery (ima) was occluded. There was a small bowel obstruction with dilation of the proximal jejunum. Increased fat stranding near

									sigmoid colon, which may represent colitis, was also observed. On (b)(6) 2019, a magnetic resonance imaging (mri) scan was also performed. A small amount of ill-defined fluid between the anterior wall of rectum and posterior prostate was observed. No rim-enhancing drainable collections were observed in the pelvis. There were signs of devitalization along the right lateral wall of the rectum and posterior prostate as well as in the intervening soft tissues. Continued small bowel obstruction and mild distention of the sigmoid colon were observed. Per the mri report, the spaceoar was placed correctly. On (b)(6) 2019, it was reported that the patient had urinary issues. A colonoscopy was performed and did not show any bowel issues. As of (b)(6) 2019, the patient had a diverting ostomy and it is unknown if the patient is still hospitalized. The patient has not received his stereotactic body radiation treatment yet. Manufacturer narrative: the complainant was unable to provide the suspect device lot number. Therefore, the expiration and device manufacture dates are unknown. (b)(4). The device was implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental medwatch will be filed.
MW5092022	12/12/2019	Injury	BOSTON SCIENTIFIC LIMITED	03/01/2020	OVB	SPACEOAR	Adverse Event Without Identified Device or Use Problem	Hemorrhage/Bleeding; Pain; Ulcer; Injury	Summary: grade 4 rectal ulceration approx 6 months after stereotactic body radiotherapy with space oar gel of unexpected nature. Difficult to discern reason; reporting given unexpected rectal dosimetry / use of gel. Pt is a relatively healthy gentleman diagnosed with prostate cancer who underwent radiotherapy (rt) to prostate 5-6/2019, tolerating well, with use of rectal hydrogel spacer (space oar, boston scientific). At 3-4 months from therapy, initiated grade 1-2 proctitis / tenesmus symptoms unusual for this therapy when get in place and without precursor symptoms. Despite conservative measures

									(steroid suppositories / creams, dietary change, systemic steroid pulse), worsened to involve frank pain with bowel movements, rectal bleeding and generalized pelvic floor symptoms (showing of urination when straining with negative cystoscopy for cystitis from radiation). By 6 months, admitted to hosp for urgent work up frankly worsening bleeding / pain, with sigmoidoscopy showing a large ulcer in anterior rectum essentially exposing posterior prostate. While bleeding not life-threatening and no infection, the pain and risk of worsening required diverting colostomy with hope to allow rectum to heal conservatively. Analysis of radiation plan, delivery (including portal cone beam images/ shifts), contours was conducted, yielding no aberrant rectal dose, with the dose being far below our institutional constraints based upon approx 10 yrs of prospective trials. In particular, rectal dose was lowered by our routine use of rectal hydrogel spacer since 2015, to address a 6.6% rate of grade >=3 rectal injury like this with much higher doses to return in early phase i-ii trials. Thus, this grade 4 rectal injury is the first rectal injury >grade 2 in hundreds of pts since introduction of new measures and followed an unusual course. Given anecdotal reports of rectal hydrogel spacer in cases with high grade rectal injury where speculation was made about potential direct rectal wall injury by the gel (ie: the et al bmj case report 2014 https://www.ncbi.nlm.nih.gov/pmc/articles/pmc4275689, schorghofer et al pro 2019 https://www.ncbi.nlm.nih.gov/pmc/articles/pmc6419822/), we thus considered the potential for the rectal spacer gel to have contributed and make this report here. We note of course that substantial volumes of data have been published including by our institution on a lack of such events, even when rectal hydrogel spacer infiltrates the rectal wall (fischer-valuck et al radiat oncol 2019 https://www.ncbi.nlm.nih.gov/pubmed/280

									89528). With that said, i felt he need to report this event due to: a) the highly unusual nature and severity of the rectal injury despite low radiation dose to rectal wall/lack of pt co-morbidities; b) somewhat odd timing with lack of symptoms for months before a swift worsening, starting at a time point (approx 4-5 months from spacer insertion) where the gel would be predicted to start dissolving); c) post-hoc review of the pt's radiation planning mri showing an area of anterior rectal wall infiltration by the gel, with potential sign of delamination. Again this has been commonly seen in our and multiple other institutional experiences without clinical correlation in past, and so this was not at the time felt to preclude therapy; d) lack of imaging / bladder cystitis / acute symptoms to suggest a major failure in radiation targeting. In terms of the gel placement, records and post-hoc review with the pt indicate that there was nothing particularly unusual, and again other than subtle pressure feeling most men have, he reported no pain or major change in life after 30 mins to recover from procedure. Overall, we are considering this a high grade rt proctitis with potential contribution of the spacer, unable to discern what dosimetry or change in technique would have changed outcome. Fda safety report id# (b)(4).
3005985723-2019-00919	29/11/2019	Malfunction	MAKO SURGICAL CORP.	23/12/2019	OLO	3.0 RIO ROBOTIC ARM - MICS	Inappropriate Tactile Prompt/Feedback	No Known Impact Or Consequence To Patient	Mako left tka - unable to complete distal femur & posterior chamfer cuts due to flexion angle showing "red" on screen in all flexion angles, unable to engage into stereotactic boundary. Full presurgery checks were completed and passed prior to surgery. Initial registrations of landmarks and bone were completed successfully. Pose captures were completed and implants were adjusted. Robot was pushed into recommended position. Tibia cut was completed successfully. Anterior femur, posterior femur & anterior chamfer cuts were also completed successfully. At distal femur cut, femur checkpoint & sawblade

									checkpoint passed and entered into distal cutting page. Surgeon successfully engaged into stereotactic boundary and was able to complete sawing at the distal lateral condyle, and as he was sawing the distal medial condyle, stereotactics got disengaged. Surgeon tried to re-engage but failed, and screen showed "red" on flexion angle @ 108deg, and prompting to rotate joint away from robot. Surgeon rotated joint away from robot till the prompting disappeared, and flexion of joint was changed, however flexion angle on screen was still red despite trying all angles (30deg to 130deg). Mps then moved the robot in order to try to accommodate to the angle of the arm, but despite that, the flexion angle continued to be "red" throughout various flexion angles, and surgeon could not engage into stereotactics. This was attempted for 20mins on both distal and posterior chamfer cuts before surgeon decided to abort mako and completed the rest of surgery with manual instrumentation. Post surgery, fse did a check on robot and there was no problem with the hardware. Case type: tka. Surgical delay : > 30 minutes. Manufacturer narrative: use this comment: as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available.
1723170-2020-01669	12/11/2019	Injury	MEDTRONIC NAVIGATION, INC	16/06/2020	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage	Background: deep brain stimulation (dbs) is considered standard of care for the treatment of medically refractory parkinson disease (pd). The placement of brain electrodes is performed using contrast imaging to enhance blood vessel identification during stereotactic planning. We present our experience with a series of patients implanted using noncontrast imaging. - methods: all cases of dbs surgery for pd performed between 2012 and 2018 with noncontrast imaging were retrospectively reviewed. Clinical features, postoperative imaging, and complications

									were analyzed. - results: a total of 287 deep-seated electrodes were implanted in 152 patients. Leads were placed at the subthalamic nucleus and globus pallidus internus in 258 and 29 hemispheres, respectively. We identified 2 cases of intracranial hemorrhage (0.7%). - conclusions: dbs lead placement can be performed without the use of intravenous contrast with a postoperative intracranial hemorrhage rate comparable with other reported series. Adverse events: two patients with intra-cranial hemorrhage. Manufacturer narrative: no further patient information was provided in the article. No system/product information was provided in the article. E) corresponding author for the article listed, no further information was provided in the article. If information is provided in the future, a supplemental report will be issued.
1723170-2020-01670	12/11/2019	Injury	MEDTRONIC NAVIGATION, INC	16/06/2020	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage	Background: deep brain stimulation (dbs) is considered standard of care for the treatment of medically refractory parkinson disease (pd). The placement of brain electrodes is performed using contrast imaging to enhance blood vessel identification during stereotactic planning. We present our experience with a series of patients implanted using noncontrast imaging. - methods: all cases of dbs surgery for pd performed between 2012 and 2018 with noncontrast imaging were retrospectively reviewed. Clinical features, postoperative imaging, and complications were analyzed. - results: a total of 287 deep-seated electrodes were implanted in 152 patients. Leads were placed at the subthalamic nucleus and globus pallidus internus in 258 and 29 hemispheres, respectively. We identified 2 cases of intracranial hemorrhage (0.7%). - conclusions: dbs lead placement can be performed without the use of intravenous contrast with a postoperative intracranial hemorrhage rate comparable with other reported series. Adverse events: two patients with intra-cranial hemorrhage.

									Manufacturer narrative: see 1723170-2020-01669 for the other patient in the article with intra-cranial hemmorhage a) no further patient information was provided in the article. No system/product information was provided in the article. E) corresponding author for the article listed, no further information was provided in the article. If information is provided in the future, a supplemental report will be issued.
3006630150-2020-05184	12/11/2019	Injury	BOSTON SCIENTIFIC NEUROMODULATION	27/10/2020	GXI	PROBE, RADIOFREQUENCY LESION	Use of Device Problem	Paralysis	It was reported that during a intracerebral thermocoagulation surgery to treat a patient with serious focal pharmacoresistant epilepsy, it was realized that a small part of the insolated sheath of the electrode was missing after surgery. It was suspected that part of the insulated sheath of the reusable stereotactic electrode had been removed perhaps during the sterilization process, so the lesion or burning had been bigger than expected. The procedure was unsuccessful and when the surgeon put electrode off the brain, he realized isolated sheath was missing, therefore he decided to stop the intervention. When the patient woke up post-operatively, his left foot was paralyzed. A few days later the patient recovered and was no longer experiencing paralysis. The patient has fully recovered. Manufacturer narrative: model number and description: stereotactic tc electrode model (1.6) (3) (250).
3012165443-2019-00023	08/11/2019	Malfunction	QUALITY TECH SERVICES LLC	03/12/2019	HAW	PASSIVE BIOPSY NEEDLE	Output Problem	No Known Impact Or Consequence To Patient	Medtronic received information that, while in a stereotactic biopsy of the left cerebral peduncular, the biopsy needle was found to be defective. It was reported that the depth stop "puck" of the unit would not engage on the needle when tightened. It was noted that the issue was discovered prior to use and that a second needle was used to complete the procedure. There was a reported delay to the procedure of fifteen minutes due to this issue. There was no reported impact on patient outcome. Manufacturer narrative: patient weight not available from the site. No devices were returned to the manufacturer for analysis. If

									information is provided in the future, a supplemental report will be issued.
1723170-2019-05760	07/11/2019	Malfunction	MEDTRONIC NAVIGATION, INC	25/11/2019	HAW	S8 PREMIUM	Imprecision	No Known Impact Or Consequence To Patient	Medtronic received information regarding a navigation system being used in a electrode and probe placement procedure. It was reported that after the 1st imaging 3d acquisition, the patient orientation was not set properly on the imaging system, therefore, the image had been flipped on the navigation system (upside down and right-left). However, the coordinates of the entry points on the patient anatomy didn't match. Troubleshooting included doing a 2nd imaging 3d acquisition performed with the right orientation, the stereotactic coordinates did match with patient anatomy. There was less than an hour delay in the procedure. No impact on patient outcome. Manufacturer narrative: the software analysis was completed and found that when the imaging system 3d acquisition were performed with the right orientation, the stereotactic coordinates did match with patient anatomy. The software seems to be working as designed. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: other relevant device(s) are: product id: 9735699, version #: (b)(4). Report source: foreign country: (b)(6). The manufacturer representative went to the site to test the navigation system. The reported issue was confirmed and they removed the stereotatic frame and 2nd 3d acquisition performed. If information is provided in the future, a supplemental report will be issued.
1222780-2019-00268	07/11/2019	Malfunction	HOLOGIC, INC	25/11/2019	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Material Deformation	No Known Impact Or Consequence To Patient	It was reported that during the procedure, the sleeve on the introducer crumpled as the doctor was trying to insert it into the patient breast. A second device was used to complete the procedure. There was no harm to the patient. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. If the device is returned and evaluation completed, a supplemental medwatch will

									be filed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
2020394-2019-05219	07/11/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	04/12/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, the device allegedly made a hissing sound and failed to obtain adequate sized samples. It was further alleged that upon removal of the probe, blood was found to have leaked into the driver. The procedure was rescheduled for completion. There was no reported patient injury. Manufacturer narrative: a customer notification was issued for the encor breast biopsy probe for specific product code/lot number combinations. The affected product code/lot number combinations may be at risk of experiencing a leak between the probe and the tissue collection chamber, which could result in minimal suction, leakage, minimal or no tissue sample obtained, or an egress of fluids from the device. A root cause investigation and field action determination was conducted as a result of an increase in complaints for leaks, suction issues, and failure to obtain samples. The investigation included an extensive manufacturing review, risk documentation review for the three reported malfunctions, and evaluations performed on the returned devices. The investigation identified that one of the features on the trap chamber was under specified and during the implementation of a new trap chamber (dc2448) mold, one of the dimensions changed and went undetected, creating a difference between the amount of space that the seal has between the trap chamber and the front seal cap. This gap between the trap chamber and front seal cap resulted in conditions that led to a higher likelihood of leaks, suction issues, and failure to obtain samples. All reported complaints from the affected product code/lot number combinations that are possibly related to the gap between the trap chamber and front seal cap have been classified as leak,

									suction issues), or failure to obtain samples. This reported complaint is from an affected lot number that was reported for one of these trap chamber issues. (b)(4), (expiry date 10/2020).
1220984-2019-00137	05/11/2019	Malfunction	HOLOGIC, INC	04/12/2019	IZH	MULTICARE PLATINUM	Imprecision	No Consequences Or Impact To Patient	It was reported that the needle hit the breast platform shield and cracked it. No injury reported. Additional information received from the customer noted that during the procedure the targeting looked correct, but when the needle was fired it hit the cover. The customer reported that a similar issue occurred in august, also no injury. There have been biopsies completed since this event with no problems reported. A field engineer was dispatched to the site and the breast platform shield was replaced. Clinical applications was made aware of the intermittent targeting issues. Manufacturer narrative: as of today the investigation is still in progress.
1226348-2021-00075	01/11/2019	Injury	CODMAN AND SHURTLEFF, INC	04/10/2021	KGG	UNK LIQUID EMBOLIC	Adverse Event Without Identified Device or Use Problem	Stroke/CVA; Hematoma; Hemorrhage/Bleeding; Ruptured Aneurysm	"Literature article ¿multimodal cerebral arteriovenous malformation treatment: a 12-year experience and comparison of key outcomes to aruba¿ reviewed. Pulli b, chapman ph, ogilvy cs, patel ab, stapleton cj, leslie-mazwi tm, hirsch ja, carter bs, rabinov jd. J neurosurg. 2019 nov 1:1-10. Doi: 10.3171/2019.8.jns19998. Epub ahead of print. Pmid: 31675689. Objective: curative treatment of unruptured brain arteriovenous malformations (avms) remains controversial after the only randomized controlled trial, a randomized trial of unruptured brain arteriovenous malformations (aruba), was halted prematurely because interim analysis revealed superiority of the medical management group. In contrast, meta-analyses of retrospective cohorts suggest that intervention is much safer than was found in aruba. Methods the authors retrospectively analyzed 318 consecutive adult patients with brain avms treated at their institution with embolization, surgery, and/or proton beam radiosurgery. Analysis was performed in 142 aruba-eligible patients (baseline modified rankin scale

									[mrs] score 0¿1, no history of hemorrhage), and results were compared to primary and secondary outcomes from aruba, as well as to natural history cohorts. Lot, model and catalog number are not available, but the suspected cerenovus device possibly associated with reported adverse events: trufill n-butyl cyanoacrylate (codman) other cerenovus devices that were also used in this study: n/a non-cerenovus devices that were also used in this study: onyx (medtronic), stereotactic bragg peak, proton beam therapy adverse event(s) and provided interventions: (1) intraprocedural cavm rupture (1) postoperative hemorrhage requiring repeat craniotomy and hematoma evacuation (2) stroke (either ischemic or hemorrhagic) (1) death was attributed to embolization (intraprocedural avm rupture that required emergency craniotomy for clot evacuation). Manufacturer narrative: (b)(4). "literature article ¿multimodal cerebral arteriovenous malformation treatment: a 12-year experience and comparison of key outcomes to aruba¿ reviewed. Pulli b, chapman ph, ogilvy cs, patel ab, stapleton cj, leslie-mazwi tm, hirsch ja, carter bs, rabinov jd. J neurosurg. 2019 nov 1:1-10. Doi: 10.3171/2019.8.jns19998. Epub ahead of print. Pmid: 31675689. Device history record (dhr) review cannot be conducted because the lot number was provided by the customer. If information is obtained that was not available for the initial report, a follow-up report will be filed as appropriate.
1226348-2021-00076	01/11/2019	Death	CODMAN AND SHURTLEFF, INC	04/10/2021	KGG	UNK LIQUID EMBOLIC	Adverse Event Without Identified Device or Use Problem	Ruptured Aneurysm	Literature article ¿multimodal cerebral arteriovenous malformation treatment: a 12-year experience and comparison of key outcomes to aruba¿ reviewed. Pulli b, chapman ph, ogilvy cs, patel ab, stapleton cj, leslie-mazwi tm, hirsch ja, carter bs, rabinov jd. J neurosurg. 2019 nov 1:1-10. Doi: 10.3171/2019.8.jns19998. Epub ahead of print. Pmid: 31675689. Objective: curative treatment of unruptured brain arteriovenous malformations (avms)

									remains controversial after the only randomized controlled trial, a randomized trial of unruptured brain arteriovenous malformations (aruba), was halted prematurely because interim analysis revealed superiority of the medical management group. In contrast, meta-analyses of retrospective cohorts suggest that intervention is much safer than was found in aruba. Methods the authors retrospectively analyzed 318 consecutive adult patients with brain avms treated at their institution with embolization, surgery, and/or proton beam radiosurgery. Analysis was performed in 142 aruba-eligible patients (baseline modified rankin scale [mrs] score 0¿1, no history of hemorrhage), and results were compared to primary and secondary outcomes from aruba, as well as to natural history cohorts. Lot, model and catalog number are not available, but the suspected cerenovus device possibly associated with reported adverse events: trufill n-butyl cyanoacrylate (codman) other cerenovus devices that were also used in this study: n/a. Non-cerenovus devices that were also used in this study: onyx (medtronic), stereotactic bragg peak, proton beam therapy. Adverse event(s) and provided interventions: intraprocedural cavm rupture. Postoperative hemorrhage requiring repeat craniotomy and hematoma evacuation. Stroke (either ischemic or hemorrhagic). Death was attributed to embolization (intraprocedural avm rupture that required emergency craniotomy for clot evacuation). Manufacturer narrative: manufacturer's ref. No: (b)(4). Literature article ¿multimodal cerebral arteriovenous malformation treatment: a 12-year experience and comparison of key outcomes to aruba¿ reviewed. Pulli b, chapman ph, ogilvy cs, patel ab, stapleton cj, leslie-mazwi tm, hirsch ja, carter bs, rabinov jd. J neurosurg. 2019 nov 1:1-10. Doi: 10.3171/2019.8.jns19998. Epub ahead of print. Pmid: 31675689. Device history record (dhr) review cannot be conducted

									because the lot number was provided by the customer. If information is obtained that was not available for the initial report, a follow-up report will be filed as appropriate.
1222780-2019-00251	23/10/2019	Malfunction	HOLOGIC, INC	11/11/2019	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Difficult to Remove	No Consequences Or Impact To Patient	It was reported that during the procedure, the aperture would not close during biopsy mode. The tissue that was obtained was "too little and too thin." the procedure was completed with the little obtained tissue. The handpiece seems to have "low power suction" as commented by radiologist. Radiologist had to take the needle out of the patient breast while the aperture still open. A second device was not used. No additional details available. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. If the device is returned and evaluation completed, a supplemental medwatch will be filed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
9259674	22/10/2019	Malfunction	MEDTRONIC NAVIGATION, INC.	31/10/2019	HAW	NEUROLOGICAL STEREOTAXIC INSTRUMENT	Defective Component	No Known Impact Or Consequence To Patient	Prior to use in stereotactic biopsy of the left cerebral peduncular, a biopsy needle was discovered before it was used on the patient to have a defect. This needle has a puck with a set screw that serves as a depth gauge. The set screw when fully tightened did not engage the needle so there was no way to lock the puck in place. There was a delay of about 15 minutes as the nurse attempted to get a replacement from case carts. The biopsy needle was given to the supply specialist who has arranged for the medtronic representative to pick the needle up today for return to medtronic for inspection.
1220984-2019-00120	18/10/2019	Malfunction	HOLOGIC, INC	05/11/2019	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was reported that the table goes up on its own. No injury reported. A field engineer was dispatched to the site and determined that the control panel switches needed to be replaced. Once this was completed the system was working as intended.

3007566237-2019-02475	11/10/2019	Injury	MEDTRONIC NEUROMODULATION	05/12/2019	MRU	IMPLANTABLE NEUROSTIMULATOR	Break; Malposition of Device; Positioning Problem	Cellulitis; Hematoma; Intracranial Hemorrhage; Unspecified Infection; Muscle Weakness; Paresis; Pneumonia; Therapeutic Effects, Unexpected	Summary: lead placement for deep brain stimulation (dbs) using intraoperative mri (imri) relies solely on real-time intraoperative neuroimaging to guide electrode placement, without microelectrode recording (mer) or electrical stimulation. There is limited information, however, on outcomes after imri-guided dbs for dystonia. The authors evaluated clinical outcomes and targeting accuracy in patients with dystonia who underwent lead placement using an imri targeting platform. Patients with dystonia undergoing imri-guided lead placement in the globus pallidus pars internus (gpi) were identified. Patients with a prior ablative or mer-guided procedure were excluded from clinical outcomes analysis. Burke-fahn-marsden dystonia rating scale (bfmdrs) scores and toronto western spasmodic torticollis rating scale (twstrs) scores were assessed preoperatively and at 6 and 12 months postoperatively. Other measures analyzed include lead accuracy, complications/adverse events, and stimulation parameters. A total of 60 leads were implanted in 30 patients. Stereotactic lead accuracy in the axial plane was 0.93 ± 0.12 mm from the intended target. Nineteen patients (idiopathic focal, n = 7; idiopathic segmental, n = 5; dyt1, n = 1; tardive, n = 2; other secondary, n = 4) were included in clinical outcomes analysis. The mean improvement in bfmdrs score was 51.9% ± 9.7% at 6 months and 63.4% ± 8.0% at 1 year. Twstrs scores in patients with predominant cervical dystonia (n = 13) improved by 53.3% ± 10.5% at 6 months and 67.6% ± 9.0% at 1 year. Serious complications occurred in 6 patients (20%), involving 8 of 60 implanted leads (13.3%). The rate of serious complications across all patients undergoing imri-guided dbs at the authors¿ institution was further reviewed, including an additional 53 patients undergoing gpi-dbs for parkinson disease. In this expanded cohort, serious complications occurred in 11 patients (13.3%) involving 15

									leads (10.1%). Intraoperative mri¿guided lead placement in patients with dystonia showed improvement in clinical outcomes comparable to previously reported results using awake mer-guided lead placement. The accuracy of lead placement was high, and the procedure was well tolerated in the majority of patients. However, a number of patients experienced serious adverse events that were attributable to the introduction of a novel technique into a busy neurosurgical practice, and which led to the revision of protocols, product inserts, and on-site training. Reported events: 1. A (b)(6) year old male patient implanted in gpi for idiopathic generalized dystonia experienced asymptomatic acute intraprenchymal hematoma noted intraoperatively that remained stable on follow-up imaging and did not extend hospital stay. 2. Case 13: a (b)(6) year old female patient implanted in gpi for idiopathic segmental dystonia experienced an insular intracerebral hemorrhage (insula) resulting in mild, transient upper extremity paresis and weakness that resolved quickly and also did not extend hospitalization. 3. Case 15: a (b)(6) year old male patient implanted in gpi for idiopathic segmental dystonia experienced ins and extension wire infection which required explant. 4. Case 15: a (b)(6) year old male patient implanted in gpi for idiopathic segmental dystonia patient experienced ipsilateral leadFracture, which required explant. 5. Case 19: a (b)(6) year old female patient implanted in gpi for metabolic generalized dystonia had system infection which required explantation of all hardware: bilateral leads, extensions and ins. 6. One patient implant in gpi for dystonia experienced unilateral lead infection requiring explantation (the patient had many previous surgeries). 7. Case 11: a (b)(6) year old female patient implanted in gpi for tardive cd experienced cranial cellulitis, which required removal of the burr hole device. The patient went on to develop

									pneumonia. 8. Two patients implanted in gpi for dystonia had suboptimal efficacy due to leads place in suboptimal locations within the internal globus pallidus (gpi). Both patients underwent repositioning in the gpi: one with imri guidance after 2 years and the other with mer guidance after approximately 9 months. 9. Case 9: an (b)(6) year old male patient implanted in gpi for acquired hemidystonia had a second gpi lead placed ipsilateral to the first during the same surgery as the stylet was believed to be suboptimally positioned intraoperatively and efforts to realign it to a more satisfactory trajectory led to it falling into the same tract. Thus, leads were placed both along the initial tract and along the revised trajectory. Both leads were left in situ in order to ensure that either lead could be tested clinically. The authors noted they found that repositioning of leads that have been mistargeted by 1¿2 mm from the optimal site often lead to improvements in clinical outcome. The following device specifics were identified in the literature article: 3389 lead model, activa ins (specific ins model not provided), stimloc burr hole cover. Manufacturer narrative: sharma, v.d., bezchlibnyk, y.b., isbaine, f., naik, k.b., cheng, j., gale, j.t., miocinovic, s., buetefisch, c., factor, s.a, willie, j.t., boulis, n.m., wichmann, t., delong, m.r., gross, r.e. Clinical outcomes of pallidal deep brain stimulation for dystonia implanted using intraoperative mri. Journal of neurosurgery. 2019. Doi: 10.3171/2019.6.jns19548. Patient age: this value is the average age of the patients reported in the article. Patient sex: this value reflects the gender of the majority of the patients reported in the article. Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the

									author of the article inquiring about individual patient information and additional information regarding the reported events. Other relevant device(s) are: product id: 3389, serial/lot #: unknown, udi#: asku ; product id: 3389, serial/lot #: unknown, udi#: asku ; product id: neu_unknown_ext, serial/lot #: unknown, udi#: asku ; product id: 3389, serial/lot #: unknown, udi#: asku ; product id: 3389, serial/lot #: unknown, udi#: asku ; product id: neu_unknown_ext, serial/lot #: unknown, udi#: asku ; product id: neu_ins_stimulator, serial/lot #: unknown, udi#: asku ; product id: 3389, serial/lot #: unknown, udi#: asku ; product id: neu_stimloc_acc, serial/lot #: unknown, udi#: asku ; product id: 3389, serial/lot #: unknown, udi#: asku ; product id: 3389, serial/lot #: unknown, udi#: asku. If information is provided in the future, a supplemental report will be issued.
3007566237-2019-02476	11/10/2019	Injury	MEDTRONIC NEUROMODULATION	05/12/2019	MHY	IMPLANTABLE NEUROSTIMULATOR	Malposition of Device	Pulmonary Embolism; Erosion; Cellulitis; Hematoma; Hemorrhage, Subdural; Unspecified Infection; Therapeutic Effects, Unexpected; Thrombosis	Summary: lead placement for deep brain stimulation (dbs) using intraoperative mri (imri) relies solely on real-time intraoperative neuroimaging to guide electrode placement, without microelectrode recording (mer) or electrical stimulation. There is limited information, however, on outcomes after imri-guided dbs for dystonia. The authors evaluated clinical outcomes and targeting accuracy in patients with dystonia who underwent lead placement using an imri targeting platform. Patients with dystonia undergoing imri-guided lead placement in the globus pallidus pars internus (gpi) were identified. Patients with a prior ablative or mer-guided procedure were excluded from clinical outcomes analysis. Burke-fahn-marsden dystonia rating scale (bfmdrs) scores and toronto western spasmodic torticollis rating scale (twstrs) scores were assessed preoperatively and at 6 and 12 months postoperatively. Other measures analyzed include lead accuracy, complications/adverse events, and stimulation parameters. A total of 60 leads

									were implanted in 30 patients. Stereotactic lead accuracy in the axial plane was 0.93 ± 0.12 mm from the intended target. Nineteen patients (idiopathic focal, n = 7; idiopathic segmental, n = 5; dyt1, n = 1; tardive, n = 2; other secondary, n = 4) were included in clinical outcomes analysis. The mean improvement in bfmdrs score was 51.9% ± 9.7% at 6 months and 63.4% ± 8.0% at 1 year. Twstrs scores in patients with predominant cervical dystonia (n = 13) improved by 53.3% ± 10.5% at 6 months and 67.6% ± 9.0% at 1 year. Serious complications occurred in 6 patients (20%), involving 8 of 60 implanted leads (13.3%). The rate of serious complications across all patients undergoing imri-guided dbs at the authors¿ institution was further reviewed, including an additional 53 patients undergoing gpi-dbs for parkinson disease. In this expanded cohort, serious complications occurred in 11 patients (13.3%) involving 15 leads (10.1%). Intraoperative mri¿guided lead placement in patients with dystonia showed improvement in clinical outcomes comparable to previously reported results using awake mer-guided lead placement. The accuracy of lead placement was high, and the procedure was well tolerated in the majority of patients. However, a number of patients experienced serious adverse events that were attributable to the introduction of a novel technique into a busy neurosurgical practice, and which led to the revision of protocols, product inserts, and on-site training. Reported events: a (b)(6) female patient implanted in the internal globus pallidus (gpi) for parkinson's disease (pd) experienced deep vein thrombosis/pulmonary embolism. The leads and ins were explanted at one surgery. A (b)(6) male patient implanted in gpi for pd experienced multiple erosions and infection requiring revision of bilateral leads, leading to left lead explant and pallidotomy. A 70 year old male patient implanted in gpi for pd experienced lead erosion requiring incision and drainage <(>&<)> z-plasty. It

									was reported the patient had infection which required explant of some hardware. A (b)(6) female patient implanted in gpi for pd experienced ins and extension infection which required explant. A (b)(6) female patient implanted in gpi for pd experienced ins and extension infection which required explant. A (b)(6) female patient implanted in gpi for pd experienced small right subdural hematoma. The leads and ins were explanted at one surgery. A (b)(6) male patient implanted in gpi for pd experienced small right subdural hematoma. A (b)(6) male patient implanted in gpi for pd experienced small left subdural hematoma. A (b)(6) male patient implanted in gpi for pd experienced cranial cellulitis treated with intravenous antibiotics. Two patients implanted in gpi for pd underwent lead revisions due to suboptimal outcomes: one a bilateral revision targeting the subthalamic nucleus (stn) and another to reposition the lead in a subsequent mer-guided procedure. The authors noted they found that repositioning of leads that have been mistargeted by 1¿2 mm from the optimal site often lead to improvements in clinical outcome. The following device specifics were identified in the literature article: 3389 lead model, activa ins (specific ins model not provided), stimloc burr hole cover. See attached literature article. Manufacturer narrative: sharma, v.d., bezchlibnyk, y.b., isbaine, f., naik, k.b., cheng, j., gale, j.t., miocinovic, s., buetefisch, c., factor, s.a, willie, j.t., boulis, n.m., wichmann, t., delong, m.r., gross, r.e. Clinical outcomes of pallidal deep brain stimulation for dystonia implanted using intraoperative mri. Journal of neurosurgery. 2019. Doi: 10.3171/2019.6.jns19548. This value is the average age of the patients reported in the article, please see b5 for specific patient age where it could be identified. This value reflects the gender of the majority of the patients reported in the article. Please note that this date is based off of the date of publication of the article as the event dates

									were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Section d information references the main component of the system. Other relevant device(s) are: product id: neu_ins_stimulator, serial/lot #: unknown, ubd: , udi#: (b)(4); product id: 3389, serial/lot #: unknown, udi#: (b)(4) ; product id: 3389, serial/lot #: unknown, udi#: (b)(4) ; product id: 3389, serial/lot #: unknown, udi#: (b)(4) ; product id: neu_ins_stimulator, serial/lot #: unknown, udi#: (b)(4) ; product id: neu_unknown_ext, serial/lot #: unknown, udi#: (b)(4); product id: neu_ins_stimulator, serial/lot #: unknown, udi#: (b)(4) ; product id: neu_unknown_ext, serial/lot #: unknown, udi#: (b)(4) ; product id: 3389, serial/lot #: unknown, udi#: (b)(4) ; product id: 3389, serial/lot #: unknown, udi#: (b)(4) ; product id: 3389, serial/lot #: unknown, udi#: (b)(4) ; product id: 3389, serial/lot #: unknown, udi#: (b)(4) ; product id: neu_ins_stimulator, serial/lot #: unknown, udi#: (b)(4). If information is provided in the future, a supplemental report will be issued.
3007566237-2020-00026	10/10/2019	Injury	MEDTRONIC NEUROMODULATION	07/01/2020	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Battery Problem	Therapeutic Response, Decreased; Shaking/Tremors	Isobe t, sato h, goto t, yako t, yoshida k, hashimoto t. Long-term suppression of disabling tremor by thalamic stimulation in a patient with spinocerebellar ataxia type 2. Stereotact funct neurosurg. 2019:1-3. 10.1159/000504062 summary: the beneficial effect of thalamic deep brain stimulation (dbs) on action tremor has been reported in a few cases of spinocerebellar ataxia (sca); however, several factors should be taken into account regarding the indication for dbs in advanced cases. We performed dbs of the ventral intermediate nucleus (vim) of the thalamus for treatment of coarse action tremor in a patient with

									sca2 (spinocerebellar ataxia type 2) in the wheelchair-bound stage. Although improvement of the tremor of the proximal part was incomplete, the patient regained substantial parts of daily functioning. The effect lasted for more than 6 years, and the suppression of tremor significantly contributed to maintaining the level of the patient¿s expression into the bedridden stage. Vim dbs can be a treatment option for tremor in sca patients, even in the advanced stage, as long as the tremor is depriving the patient of behavioral expression. As residual proximal tremor may hamper functional recovery, dbs of other targets or multi-targets should be further explored to attain a better outcome. Reported events: a woman presented with coarse tremor of the head and limbs, and a few years later, gait and limb ataxia and dysarthria appeared. A bilateral vim dbs was performed on the patient. The tremor showed improvement. The patient's voice became less tremulous, however their ataxic speech remained. At age (b)(6), the tremor acutely deteriorated and they were admitted to the hospital for treatment. It was confirmed the battery was depleting, so the ins was replaced. After the replacement, the tremors were suppressed. Both speech and hand movements became easier than before. The following device specifics were provided: ins:7426 or 37602/37603 lead: (b)(4). Manufacturer narrative: please note that this date is based off of the date that the article was accepted for publication as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence was sent to the author of the article inquiring about individual patient information and additional information regarding the reported events and any device information received was noted. If information is

									provided in the future, a supplemental report will be issued. (b)(4).
1220984-2019-00122	09/10/2019	Malfunction	HOLOGIC, INC	05/11/2019	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was initially reported soon we switch the stage light, the carm is going up alone. No injury reported. A field engineer was dispatched to the site and determined the control panel needed to be replaced. Once this was completed the system was working as intended. The customer called back on (b)(6) 2019, to say the table up/down didn't work. The field engineer replaced a fuse and the system was again working as intended.
3008492462-2019-00048	08/10/2019	Malfunction	DEVICOR MEDICAL PRODUCTS INC	02/11/2019	KNW	8G MAMMOTOME REVOLVE STEREOTACTIC PROBE	Fluid/Blood Leak	No Known Impact Or Consequence To Patient	It was reported by rep during procedure during biopsy, rad went into inject additional lido and the lido shot out of the back of the specimen collection chamber. As a result, a tissue sample as hanging out of the back of the collection chamber and both the rad and tech had gotten sprayed with fluid. They were able to complete the biopsy but wanted to make note of this occurrence. The procedure was completed with the original device. No patient complications. Manufacturer narrative: the mammotome revolve dual vacuum assisted biopsy system is intended to obtain tissue samples from the breast or axillary nodes for diagnostic analysis of breast abnormalities. The device has not been returned for evaluation, which prevents a full investigation and analysis of the root cause at this time. However, this failure mode has been reviewed by our medical advisor and identified in the risk management file for performance expectations. The device is intended to be used by a trained professional who is familiar with precautions related to blood borne pathogen exposure when completing a biopsy procedure. However, ejection with velocity is not expected by the user and has greater chance to harm than fluid egression including, but not limited to, the fluid entering mucous membranes. The device is not meeting its intended performance specification and claims and is considered to have malfunctioned. The patient or user

									may be exposed to biological hazards resulting in infection or cross-contamination. Although no serious injuries have occured, this failure mode has been evaluated by our medical advisor and based on potential for cross contamination or infection due to possible exposure to body fluids, it has been determined to be a reportable malfunction. Thus, pursuant to 21 cfr 803, we are submitted this medwatch report.
3005099803-2019-05573	03/10/2019	Malfunction	AUGMENIX, INC.	14/11/2019	OVB	SPACEOAR SYSTEM	Positioning Problem	Urinary Retention	It was reported to boston scientific corporation on october 21, 2019 that spaceoar was implanted in the perirectal space between the prostate and rectum by a urologist during a spaceoar placement procedure performed on (b)(6) 2019. There were no issues noted during the procedure. Reportedly, the patient underwent stereotactic body radiation therapy (sbrt) on (b)(6) 2019 for five fractions. According to the complainant, during a magnetic resonance imaging (mri) the spaceoar gel was noted to be present in the denonvilliers fascia. The patient experienced mild urinary retention post procedure and rapaflo was used to treat the retention. As of (b)(6) 2019, the patients condition was reported to be fine with no complaints. Manufacturer narrative: the complainant was unable to provide the device lot number. Therefore, the manufacture and expiration dates are unknown. (b)(4). The device was implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental medwatch will be filed.
3005099803-2019-05574	02/10/2019	Malfunction	AUGMENIX, INC.	14/11/2019	OVB	SPACEOAR SYSTEM	Positioning Problem	Urinary Retention	It was reported to boston scientific corporation on october 21, 2019 that spaceoar was implanted by a urologist during a spaceoar placement procedure performed on (b)(6) 2019. Reportedly, the perirectal space was very tight and the physician needed to reposition the needle multiple times before a good hydrodissection was obtained. The patient underwent stereotactic body radiation

									therapy (sbrt) on (b)(6) 2019 for five fractions. According to the complainant, during a magnetic resonance imaging (mri) the spaceoar gel was noted to be present in the denonvilliers fascia and the patient experienced urinary retention post procedure. A foley catheter was placed and rapaflo was prescribed by the physician to treat the patient's urinary retention. As of (b)(6) 2019, the patients condition was reported to be fine and his radiation treatment has been on schedule without delay. Manufacturer narrative: the complainant was unable to provide the device lot number. Therefore, the manufacture and expiration dates are unknown. (b)(4). The device was implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental medwatch will be filed.
3004426659-2019-00049	27/09/2019	Injury	NEUROPACE, INC.	29/10/2019	PFN	NEUROPACE RNS SYSTEM	Adverse Event Without Identified Device or Use Problem; Migration	No Known Impact Or Consequence To Patient	The patient underwent rns system placement on (b)(6) 2019. It was communicated to neuropace that the cortical strip placement was impeded during the procedure due to the stereotactic frame placement. Two ct scans were performed post-procedure and comparison of the scans indicated that the unconnected strip lead had migrated. The patient was brought back to the or for lead repositioning. No further information was provided by the treating center. Manufacturer narrative: (b)(4). Lead migration is a potential risk as indicated in the rns® system physician manual. As indicated in the approved labeling, "the implanted lead(s) may migrate from their desired implant location. Lead migration can result in changes in detections and stimulation effectiveness, and may require additional surgical procedures to modify the lead location."
3009185973-2019-00373	27/09/2019	Malfunction	MEDTECH SA	25/10/2019	HAW	ROSA BRAIN	Imprecision	No Known Impact Or Consequence To Patient	The arm of the robot has failed to drive to the exact location of the planned trajectories and appears to be translated ~2mm off center and remaining parallel. Friday¿s case ((b)(6)) was puzzling, we began

									by achieving a very good registration (rms = 0.29) and subsequent verification. Surgeon began by placing the ground first, and chose to do an o-arm spin to verify it¿s location. After merging the spin, we measured the trajectory as being translated 2mm off center (though it appeared parallel to the decided trajectory). Our first thought was to create a trajectory from the fiducial and drive to that target to check registration. We did so and it was also ~2mm off and appeared to be parallel. We had not observed a change in fixation/position, so we thought it was possible that the pointer probe might not have been seated flush with the interface. We repeated registration sterilely and got an rms value of 0.22. We then drove to the fiducial trajectory again and were off ~2mm and in the same direction as before. What¿s interesting is that when the robot drove to a trajectory, the highlighted "live feed" trajectory line did not match up to the chosen trajectory on screen but the screen matched what we were seeing actually at the patient. We then put the robot in free/slow mode and put it directly on the fiducial and the screen again showed the pointer as placed perfectly in the fiducial, thus eliminating our concern that the merge had failed. We repeated this with a fiducial on the other side of the head, getting the same result. By this time, we had seen the ~2mm translation at 2 fiducials, 1 ground, and while using both of their instrument holders and their pointer probe. Dr. (b)(6) adjusted the plan to build in plenty of padding for a 2mm translation in any direction and we finished the rest of the case without incident. Now for the puzzling part (to me at least). On (b)(6) the company field service engineer performed an in-depth applicative test (even checking accuracy of the entry points and also verifying depth with a stereotactic ruler) and observed none of the translation we saw during the case. For a sanity check, he used his phantom immediately after the case, even using the

									same room and not unplugging/restarting the robot, and did not see this inaccuracy: rosa was driving the 3mm ball of the pointer exactly to the center of the 4mm hole in my phantom head: so far as he can tell the only differences are that the arm was no longer being draped, the phantom head provided less weight on the mayfield than a patient, and that his phantom head had only one ct verses 2-3 mri and 2-3 ct scans. Very confusing¿but he am certain that our results during the case are not a result of user error at any step and that we have an urgent technical problem on our hands. Manufacturer narrative: the device has not been evaluated yet for investigation purpose. Once the evaluation is performed, a follow-up medwatch report will be submitted. (b)(4).
2029214-2020-01312	26/09/2019	Death	MICRO THERAPEUTICS, INC. DBA EV3	16/12/2020	OUT	PIPELINE	Adverse Event Without Identified Device or Use Problem	Brain Injury	Cherian, j., srinivasan, v., froehler, m. T., grossberg, j. A., cawley, c. M., hanel, r. A., puri, a., dumont, t., ducruet, a. F., albuquerque, f., arthur, a., cheema, a., spiotta, a., anadani, m., lopes, d., saied, a., kim, l., kelly, c. M., chen, p. R., mocco, j. (2020). Flow diversion for treatment of intracranial aneurysms in pediatric patients: multicenter case series. Neurosurgery, 87(1), 53¿62. Doi:10.1093/neuros/nyz380 medtronic received a literature article aiming to report technical, angiographic, and clinical outcomes in patients aged 21 or below undergoing flow-diversion treatment for intracranial aneurysms. The article included 39 patients undergoing 46 treatment sessions with pipeline embolization device placement between 2012 and 2018. A total of 50 intracranial aneurysms were treated. The study included a majority male patients. Nonsaccular morphology was seen in half of identified aneurysms. Six aneurysms were giant, and five patients were treated acutely after ruptured presentation. Complete aneurysm occlusion was seen in 74% of treated aneurysms. In the first case related death a (b)(6) yr-old boy presented with severe traumatic brain injury and

									polytrauma. Workup revealed diffuse subarachnoid hemorrhage with intraventricular extension and hydrocephalus. Noninvasive imaging identified a basilar artery dissect ion with an associated 2.4mm distal basilar artery aneurysm. The patient underwent uncomplicated placement of a single ped with shield technology spanning the midbasilar to left p2. Despite initial recovery, the patient acutely declined on postprocedure day 19. Imaging revealed rerupture of the dissecting aneurysm with extensive subarachnoid and brainstem hemorrhage. The patient died shortly t hereafter. A in the second case related death a (b)(6) yr-old girl with a history of recurrent pituitary blastoma treated previously with resection, stereotactic radiosurgery, and chemotherapy, presented with headache, seizure, and left hemiparesis. Emergent imaging revealed subarachnoid hemorrhage and a 5mm right internal carotid artery terminus aneurysm. Interval imaging 2 weeks post procedure showed new intraventricular hemorrhage and aneurysmal recurrence. This recurrence was treated with additional coil embolization and pipeline placement. The operation was uncomplicated, and the patient woke at neurologic baseline. However, the patient declined suddenly the following day. Repeat head ct revealed extensive subarachnoid, intraparenchymal, and subdural hemorrhages. The patient ultimately died several days later. A third death occurred in a patient with microcephalic osteodysplastic primordial dwarfism type ii with multiple intracranial aneurysms. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued.
1222780-2019-00236	23/09/2019	Malfunction	HOLOGIC, INC	15/10/2019	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Loose or Intermittent Connection	Radiation Exposure, Unintended	It was reported that during the breast biopsy procedure, when the needle fired it "bounced" inside the patient breast. It was noted that the clip on the stage of the needle was not sturdy and it was loosely attached. They attempted to move forward

									with the biopsy, but were not getting any suction. The technologist noticed there was a large kink in the tubing. The technologist does not recall anything happening during set up that would have caused this. The needle was taken out of the breast and a new needle was opened. The biopsy was successfully completed with the new needle. Additional x-ray exposures were required to complete the procedure. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. If the device is returned and evaluation completed, a supplemental medwatch will be filed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
1222780-2019-00232	19/09/2019	Malfunction	HOLOGIC, INC	08/10/2019	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Material Deformation	No Known Impact Or Consequence To Patient	It was reported that during the biopsy, the breast tissue was dense and the calcifications moved away from the incoming needle. As a result the doctor decided to retarget and was able to fire the device three times. After sampling and lavage, it was difficult to remove the needle from the patient breast. Ultimately, the device was removed and the marker was then inserted. Marker insertion was "not as easy as usual," but the marker placement was successful and accurate. Removing the needle introducer sheeth was difficult and looked "knurled" when the device was removed from the breast. Manufacturer narrative: device evaluated by mfr: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. If the device is returned and evaluation completed, a supplemental medwatch will be filed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
1723170-2020-00854	13/09/2019	Injury	MEDTRONIC NAVIGATION, INC	12/03/2020	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified	Hemorrhage/Bleeding; Seizures	Citation: roberto eleopra, sara rinaldo, grazia devigili, massimo mondani, stanislao d'auria, christian lettieri, tamara ius, miran skrap. Framless deep brain stimulation

							Device or Use Problem		surgery: a single-center experience and retrospective analysis of placement accuracy of 220 electrodes in a series of 110 patients. Stereotactic and functional neurosurgery, 2020. Doi: 10.1159/000503335 background: proper lead placement is considered one of the key factors in achieving a good clinical outcome in deep brain stimulation (dbs), but there is still considerable controversy surrounding the accuracy of the frameless in comparison to the frame-based technique. Objective: we report our single-center experience with dbs electrode placement to evaluate the accuracy of the frameless stereotactic system. Methods: we prospectively analyzed the data of 110 patients who underwent dbs surgery for parkinson disease, dystonia, essential tremor, or refractory epilepsy. The final targets (fts) of the 220 leads were: subthalamic nucleus, globus pallidus pars interna, ventralis intermedius nucleus, and anterior nuclei of thalamus in thalamus. A bilateral stereotactic approach using a combined identification of target based on preoperative images (mri and ct scan fusion) and intraoperative micro-electrode recording (mer) were done. We collected and compared the coordinates of planned target (pt), the definitive expected target (et) during mer, and the effective final location (ft) of the lead using the postoperative ct. Accuracy was assessed by both vector error (ve) and deviation from the pt. Results: the mean and sd from pts was 0.78 ± 0.43 mm in the x direction, 0.68 ± 0.41 mm in the y direction, and 0.76 ± 0.41 mm in the z direction. Global ve was 1.43 ± 0.37. Conclusion: frameless systems appear to be a reliable and accurate technique. Reported events: 1. Three patients experienced asymptomatic, or transient symptomatic, small cortical hemorrhages close to the cortex and far from distal leads. 2. One patient complained of an isolated seizure at the end of the surgery. Manufacturer narrative: patient

									age is the mean value of the patients in the study. Patient gender is the majority value of patients in the study. Patient weight not available from the site. Event date is the accepted date of the publication. Device lot number, or serial number, unavailable. 510(k) not provided as the model number is dependent on lot number/serial number. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1222780-2019-00258	12/09/2019	Injury	HOLOGIC, INC	15/11/2019	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Adverse Event Without Identified Device or Use Problem	Reaction	It was reported that the vacuum assisted breast biopsy and marker placement procedure were uncomplicated. A few days after the procedure, the patient returned saying she had hypersensitivity to metals. Further allergy testing revealed nickel delayed hypersensitivity and disposal delayed hypersensitivity. Attempts to obtain additional information were unsuccessful. Manufacturer narrative: lot and serial number of the disposable device not provided by the complainant, therefore the expiration date is not known. The device is not being returned therefore, a failure analysis of the complaint device cannot be completed. If additional relevant information is received or device evaluation completed, a supplemental medwatch will be filed. Lot number of the disposable device not provided by the complainant, therefore the manufacture date is not known. Device history record (dhr) review was unable to be conducted for the disposable device as the identification numbers were not provided by the complainant.
1222780-2019-00227	09/09/2019	Injury	HOLOGIC, INC	30/09/2019	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Adverse Event Without Identified Device or Use Problem	Hematoma	It was reported that during the procedure the device passed set up testing but would not lavage the biopsy site which resulted in a hematoma in the patient breast. No medical intervention was required for the hematoma. The biopsy was successfully completed with this device. Manufacturer narrative: the device is not being returned

									therefore, a failure analysis of the complaint device cannot be completed. If additional relevant information is received or device evaluation completed, a supplemental medwatch will be filed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications. Internal reference #: (b)(4).
1222780-2019-00226	09/09/2019	Injury	HOLOGIC, INC	27/09/2019	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Adverse Event Without Identified Device or Use Problem	Hematoma	It was reported that during the procedure the device passed set up testing but would not lavage the biopsy site which resulted in a hematoma in the patient breast. No medical intervention was required for the hematoma. The biopsy was successfully completed with this device. Manufacturer narrative: the device is not being returned therefore, a failure analysis of the complaint device cannot be completed. If additional relevant information is received or device evaluation completed, a supplemental medwatch will be filed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications. Internal reference #: (b)(4).
2020394-2019-03883	02/09/2019	Injury	BARD PERIPHERAL VASCULAR, INC.	11/10/2019	KNW	UNKNOWN ENCORE BIOPSY PROBE	Adverse Event Without Identified Device or Use Problem	Injury	It was reported that during an upright stereotactic procedure, the device allegedly nicked a blood vessel and the sample chamber overfilled with blood. It was further reported that 45 minutes of compression was applied to stop the bleeding and eventually a stitch was placed. Finally the stitch was removed and compression was re-applied, and a large hematoma formed. The procedure was not completed. Manufacturer narrative: as the lot number for the device was not provided, a manufacturing review could not be performed. The sample was not returned to the manufacturer for inspection/evaluation. Therefore, the investigation of the reported event is inconclusive. Based upon the available information, the definitive root cause for this event is unknown. The instructions for use (ifu) is adequate for the reported device/patient code(s) and provides general instructions for use, as

									well as warnings, precautions and potential complications associated with the device. Upon receipt of new or additional information, a follow-up report will be submitted as applicable.
1723170-2020-03405	01/09/2019	Injury	MEDTRONIC NAVIGATION, INC	23/12/2020	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage; Paresis	Mri-guided stereotactic laser ablation of deep-seated cerebral cavernous malformations douglas j.a.m.; greven a.c.m.; rich c.w.; malcolm j.g.; gross r.e.; willie j.t. Clinical neurosurgery (2019) 66 supplement 1 (116). Date of publication: 1 sep 2019 embase link https://www.embase.com/search/results?subaction=viewrecord <(>&<)>id=l630630425<(>&<)>from=export introduction: magnetic resonance imaging (mri)-guided stereotactic laser ablation (sla) is a minimally invasive alternative to open surgery for symptomatic cerebral cavernous malformations (ccms). While sla of neocortical and medial temporal lesions is described, we examined the safety and effectiveness of sla of deep-seated symptomatic ccms in patients considered to be poor candidates for open resection. Methods: we analyzed 4 patients who presented with neurological symptoms associated with a ccm in deep brain structures. Each patient underwent ccm sla with an effort to exclude adjacent brain parenchyma followed by standard clinical and imaging follow-up. Results: three patients presented with chronic medically refractory headache and small lesions (0.1-2.6 cm3) consistent with ccm in thalamus (2) or putamen (1). A fourth patient presented with recurrent bleeding and hemiparesis associated with a large ccm (4.3 cm3) of the subthalamus/midbrain. Symptoms durations were 0.5 to 7 yr. Sla was performed using visualase (medtronic, inc.); perilesional brain was monitored to avoid thermal injury. Out of 4 patients, all demonstrated a decrease in ccm volume and improvement of neurological symptoms at 5 to 23 mo follow-up. Two patients (one thalamus, one putamen), experienced evidence of hemorrhage during ablation

									(apparent with intraoperative mri), limiting the extent of ablation in one case. Both patients were stabilized and made full recoveries. The ablation in subthalamus/ midbrain was not associated with bleeding but did exacerbate hemiparesis, requiring rehabilitation. Hospital stays ranged from 2 to 5 d. Conclusion: in a retrospective series, mr thermography guided sla of symptomatic deep brain ccm was technically feasible. Unlike a prior series of more superficial epileptogenic ccm in which no hemorrhages were observed, sla of deep ccm may carry higherrisk of bleeding and neurological deficits. Larger, longer-term studies are required. Reported events: 1. Two patients (one thalamus, one putamen), experienced evidence of hemorrhage during ablation, limiting extent of ablation in one case. 2. One patient with ablation in the subthalamus/midbrain experienced exacerbated hemiparesis requiring rehabilitation. Manufacturer narrative: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Includes the article citation. The literature article is attached. If information is provided in the future, a supplemental report will be issued.
3007566237 -2019- 02073	21/08/2019	Injury	MEDTRONIC NEUROMODULAT ION	04/10/2019	MHY	IMPLANTABL E NEUROSTIM ULATOR	Malposition of Device	Erosion	Abstract: both subthalamic nucleus (stn) and caudal zona incerta (czi) have been implicated as the optimal locus for deep brain stimulation (dbs) in parkinson¿s disease (pd). We present a retrospective clinico-anatomical analysis of outcomes from dbs targeting both stn and czi. Forty patients underwent bilateral dbs using an image-verified implantable guide tube/stylette technique. Contacts on the same quadripolar lead were placed in both stn and czi. After pulse generator programming, contacts yielding the best clinical effect were selected for chronic stimulation. Off medication unified pd rating scale (updrs) part iii scores pre-operatively and on stimulation at 1¿2 year follow up were compared. Active contacts

									at follow-up were anatomically localised from peri-operative imaging. Overall, mean updrs part iii score improvement was 55 ± 9% (95% confidence interval), with improvement in subscores for rigidity (59 ± 13%), bradykinesia (58 ± 13%), tremor (71 ± 24%) and axial features (36 ± 19%). Active contacts were distributed in the following locations: (1) within posterior/dorsal stn (50%); (2) dorsal to stn (24%); (3) in czi (21%); and (4) lateral to stn (5%). When contacts were grouped by location, no significant differences between groups were seen in baseline or post-operative improvement in contralateral updrs part iii subscores. We conclude that when both stn and czi are targeted, active contacts are distributed most commonly with in and immediately dorsal to stn. In a subgroup of cases, czi contacts were selected for chronic stimulation in preference. Dual targeting of stn and czi is feasible and may provide extra benefit compared with conventional stn dbs is some patients. Reported events: 2 patients underwent skin erosion at the pectoral ins site requiring ins removal. 1 patient experienced skin erosion managed surgically and with prolonged intravenous antibiotics without ins removal. 1 patient had a second procedure to re-implant the guide tubes that were inaccurately placed due to intra-operative displacement of the stereotactic frame. The following device specifics were mentioned: ins models 37601 and 7428, and lead model 3389. Manufacturer narrative: this value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported

									events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Section d information references the main component of the system. Other relevant device(s) are: product id: neu_ins_stimulator, serial/lot #: unknown, implant/explant: unknown; product id: 3389, serial/lot #: unknown, implant/explant: unknown. Mostofi a, evans jm, partington-smith l, yu k, chen c, silverdale ma. Outcomes from deep brain stimulation targeting subthalamic nucleus and caudal zona incerta for parkinson's disease. Npj parkinsons dis. 2019; 5:17. 10.1038/s41531-019-0089-1. If information is provided in the future, a supplemental report will be issued.
1220984-2019-00099	14/08/2019	Malfunction	HOLOGIC, INC	12/09/2019	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was reported that the carm is intermittently not staying locked during exposure. No injury reported. A field engineer was dispatched to the site and determined that the membrane switch needed to be replaced. Once this was completed the system was working as intended.
2020394-2019-03167	12/08/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	09/09/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy a hissing sound could allegedly be heard from the device. It was further reported that no sample was obtained and there was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. As the lot number for the device was provided, a review of the device history records is currently being performed. The device has not yet been returned to the manufacturer for evaluation. The investigation of the reported event is currently underway. (expiry date: 09/2020), (b)(4).
1723170-2019-06072	09/08/2019	Injury	MEDTRONIC NAVIGATION, INC	18/12/2019	GEX	VISUALASE	Adverse Event	Visual Impairment	Citation: natalie l. Voets, ivan alvarez, deqiang qiu, christopher leatherday, jon t.

							Without Identified Device or Use Problem		Willie, stamatios sotiropoulos, ezequiel gleichgerrcht, leonardo bonilha, nigel p. Pedersen, nadja kadom, amit m. Saindane, robert e. Gross, daniel l. Drane. Mechanisms and risk factors contributing to visual field deficits following stereotactic laser amygdalohippocampotomy. Stereotactic and functional neurosurgery 2 019; 97:255-265. Doi: 10.1159/000502701 abstract selective laser amygdalohippocampotomy (slah) is a minimally invasive surgical treatment for medial temporal lobe epilepsy. Visual field deficits (vfds) are a significant potential complication. The objective of this study was to determine the relationship between vfds and potential mechanisms of injury to the optic radiations and lateral geniculate nucleus. We performed a retrospective cross-sectional analysis of 3 patients (5.2%) who developed persistent vfds after slah within our larger series (n = 58), 15 healthy individuals and 10 slah patients without visual complications. Diffusion tractography was used to evaluate laser catheter penetration of the optic radiations. Using a complementary approach, we evaluated evidence for focal microstructural tissue damage within the optic radiations and lateral geniculate nucleus. Overablation and potential heat radiation were assessed by quantifying ablation and choroidal fissure csf volumes as well as energy deposited during slah. Slah treatment parameters did not distinguish vfd patients. Atypically high overlap between the laser catheter and optic radiations was found in 1/3 vfd patients and was accompanied by focal reductions in fractional anisotropy where the catheter entered the lateral occipital white matter. Surprisingly, lateral geniculate tissue diffusivity was abnormal following, but also preceding, slah in patients who subsequently developed a vfd (all p = 0.005). In our series, vision related complications following slah, which appear to occur less frequently than following open temporal lobe surgery, were not directly

									explained by slah treatment parameters. Instead, our data suggest that variations in lateral geniculate structure may influence susceptibility to indirect heat injury from transoccipital slah. Reported events: 1) 43 year old male experienced a right superior quadrantanopsia following a singular left slah. It was noted that the issue persisted at one year follow-up though it had improved. No clear-cut cause for the event was identified. 2) 65 year old female experienced a right superior quadrantanopsia following a singular left slah. The condition was noted to have been constricted and persisted at one year follow-up. No clear-cut cause for the event was identified. Manufacturer narrative: patient age is the mean value of the two patients in the reported events. Patient gender included 1 male and 1 female in the reported events. Patient weight not available from the site. The event date is the accepted date of the publication. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
2020394-2019-03166	09/08/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	09/09/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem; Failure to Obtain Sample	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, the probe allegedly was unable to complete the sampling cycle. It was further alleged that the device was reattached and the sampling cycle restarted resulting with the same issue. Reportedly, there was enough samples obtained to complete the procedure. It was also reported that the suction was weak. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. As the lot number for the device was provided, a manufacturing review will be

									performed. The sample was not returned to the manufacturer for inspection/evaluation. Therefore, the investigation of the reported event is inconclusive. Based upon the available information, the definitive root cause for this event is unknown. The instructions for use (ifu) is adequate for the reported device/patient code(s) and provides general instructions for use, as well as warnings, precautions and potential complications associated with the device. Upon receipt of new or additional information, a follow-up report will be submitted as applicable. (expiry date: 11/2020), (b)(4).
1723170-2019-06076	09/08/2019	Injury	MEDTRONIC NAVIGATION, INC	18/12/2019	GEX	VISUALASE	Use of Device Problem	Visual Impairment	Citation: natalie l. Voets, ivan alvarez, deqiang qiu, christopher leatherday, jon t. Willie, stamatios sotiropoulos, ezequiel gleichgerrcht, leonardo bonilha, nigel p. Pedersen, nadja kadom, amit m. Saindane, robert e. Gross, daniel l. Drane. Mechanisms and risk factors contributing to visual field deficits following stereotactic laser amygdalohippocampotomy. Stereotactic and functional neurosurgery 2 019; 97:255-265. Doi: 10.1159/000502701 abstract selective laser amygdalohippocampotomy (slah) is a minimally invasive surgical treatment for medial temporal lobe epilepsy. Visual field deficits (vfds) are a significant potential complication. The objective of this study was to determine the relationship between vfds and potential mechanisms of injury to the optic radiations and lateral geniculate nucleus. We performed a retrospective cross-sectional analysis of 3 patients (5.2%) who developed persistent vfds after slah within our larger series (n = 58), 15 healthy individuals and 10 slah patients without visual complications. Diffusion tractography was used to evaluate laser catheter penetration of the optic radiations. Using a complementary approach, we evaluated evidence for focal microstructural tissue damage within the optic radiations and lateral geniculate nucleus. Overablation and potential heat radiation were assessed by

									quantifying ablation and choroidal fissure csf volumes as well as energy deposited during slah. Slah treatment parameters did not distinguish vfd patients. Atypically high overlap between the laser catheter and optic radiations was found in 1/3 vfd patients and was accompanied by focal reductions in fractional anisotropy where the catheter entered the lateral occipital white matter. Surprisingly, lateral geniculate tissue diffusivity was abnormal following, but also preceding, slah in patients who subsequently developed a vfd (all p = 0.005). In our series, vision related complications following slah, which appear to occur less frequently than following open temporal lobe surgery, were not directly explained by slah treatment parameters. Instead, our data suggest that variations in lateral geniculate structure may influence susceptibility to indirect heat injury from transoccipital slah. Reported events: 1) 44 year old female experienced a near complete persistent left homonymous hemianopsia where it was suspected that the catheter pe netrated the lateral geniculate nucleas (lgn). However, pre-operative imaging was not available for the patient so a determination could not be determined in regards to post-operative abnormal lgn diffusion reflect a change. Manufacturer narrative: patient weight not available from the site. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
3007521480-2019-00021	08/08/2019	Malfunction	ORTHALIGN, INC.	13/09/2019	OLO	ORTHALIGN PLUS	Patient Data Problem	No Known Impact Or Consequence To Patient	As described by the initial reporter: "dr. (b)(6) had a case in which the summary screen displayed a 0.0 for the app anteversion value, which did not seem to match what he previously navigated to. (b)(6) provided notes to actual value recorded during procedure." manufacturer narrative: a software bug was discovered on

									navigation units with software version (b)(4). After a verbal communication of this complaint was reported to orthalign staff. Swift action was taken to understand the impact of this software bug and the risks that needed to be considered. It was discovered that in the supine pathway only, if the user navigates to summary screen (navigation to this screen is optional), the app anteversion number will be displayed as zero degrees. The software bug does not impact the values shown during the navigation process - the software functions as designed during navigation. The orthalign navigation system is intended to assist the surgeon in determining reference alignment axes in relation to anatomical and instrumentation structures during stereotactic orthopedic surgical procedures. The system facilitates the accurate position of implants, relative to these alignment axes. These is no risk during the routine, indicated navigation process with the orthalign navigation units as the display of information during the navigation steps is accurate and is not affected by the software bug under review. When considering the risks that this bug poses in the surgical setting two were identified: an increased procedure time and the incorrect information of the information display. A review of the orthalign complaint database was conducted for the lots of navigation units manufactured with this software bug. This complaint is currently the only complaint orthalign has received and at this point the complaint rate is calculated as (b)(4). Based on the analysis that orthalign has completed the current complaint rate is within expected ranges as documented with in orthalign's product risk management file. A surgeon may question the orthalign software results when viewing the summary data which may cause action to revert to common navigational techniques of using x-ray navigation. Alternatively, a surgeon may choose to repeat the cup navigation steps to reaffirm navigated values. Either of these

									may lead to an increase in procedure but will still likely fall within an acceptable range based on orthalign risk analysis documents. The risks associated with that alternative are no different and no greater than the risk of the orthalign procedure. Orthalign is filing this mdr with an abundance of caution with the understanding that displaying incorrect information may cause an increased procedure time that may cause potential harm to the patient.
1220984-2019-00094	05/08/2019	Malfunction	HOLOGIC, INC	23/08/2019	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was reported that when the needle is being fired it is bouncing. No injury reported. A field engineer was dispatched to the site and determined that the x potentiometer and x motor needed to be replaced. Once this was completed the system is working as intended.
1222780-2019-00197	02/08/2019	Malfunction	HOLOGIC, INC	25/08/2019	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Material Twisted/Bent	No Known Impact Or Consequence To Patient	It was reported that during the procedure, the introducer sheath collapsed like an accordion once the radiologist placed the biopsy marker in position to deploy the marker. A second device completed the procedure. No harm to the patient. No additional details available. Manufacturer narrative: the device is not being returned therefore, a failure analysis of the complaint device cannot be completed. If additional relevant information is received or device evaluation completed, a supplemental medwatch will be filed. Internal reference #: (b)(4).
2020394-2019-02925	30/07/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	26/08/2019	KNW	ENCOR BIOPSY PROBE	Failure to Obtain Sample	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, the device allegedly failed to obtain samples after performing six sample passes. The procedure was completed after replacing the probe. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. As the lot number for the device was provided, a manufacturing review will be performed. The sample was not returned to the manufacturer for inspection/evaluation.

									Therefore, the investigation of the reported event is inconclusive. Based upon the available information, the definitive root cause for this event is unknown. The instructions for use (ifu) is adequate for the reported device/patient code(s) and provides general instructions for use, as well as warnings, precautions and potential complications associated with the device. Upon receipt of new or additional information, a follow-up report will be submitted as applicable. (b)(4), (expiry date: 12/2020).
2020394-2019-02926	30/07/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	26/08/2019	KNW	ENCOR BIOPSY PROBE	Filling Problem; Failure to Obtain Sample	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, it was allegedly difficult to obtain samples and the saline flow was low. The procedure was completed successfully with the probe. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. As the lot number for the device was provided, a manufacturing review will be performed. The sample was not returned to the manufacturer for inspection/evaluation. Therefore, the investigation of the reported event is inconclusive. Based upon the available information, the definitive root cause for this event is unknown. The instructions for use (ifu) is adequate for the reported device/patient code(s) and provides general instructions for use, as well as warnings, precautions and potential complications associated with the device. Upon receipt of new or additional information, a follow-up report will be submitted as applicable. (b)(4), (expiry date: 12/2020).
1723170-2021-02517	29/07/2019	Injury	MEDTRONIC NAVIGATION, INC	15/10/2021	HAW	MEDTRONIC NAVIGATION	Imprecision	Cerebrospinal Fluid Leakage; Unspecified Infection; Unspecified Tissue Injury	Citation: federico frio, domenico solari, luigi maria cavallo, paolo cappabianca, gérald raverot, emmaluel jouanneau. Ommaya resevoir system for the treatment of cystic craniopharyngiomas: surgical results in a series of 11 adult patients and review of the

									literature. World neurosurgery. Https://doi.org/10.1016/j.wneu.2019.07.217 abstract: objectives: treatment of cystic craniopharyngiomas can be challenging and recurrences are frequent, even after total resection. In selected cases, less aggressive surgery with the sole drainage of the cyst reliefs symptoms caused by mass effect and represents a valid alternative option, notably in pediatric population. We herein analyze a series of adult cystic craniopharyngiomas, managed with ommaya reservoir implant, focusing on local tumor control and eventual complications. Methods: 11 non-consecutive adult cystic craniopharyngiomas (7 recurrent lesions) have been treated with ommaya reservoir system (ors), in two neurosurgical centers. Ors was placed in nine cases using minimally invasive procedures: six burr hole endoscopic insertion and three navigated electromagnetic placement; in the remaining two patients, the ommaya reservoir was used as a shunt to prevent cyst recollection during a transcranial approach. Results: the main presenting symptoms were visual impairment (75%), cognitive and behavioral disorders (66.7%), hypopituitarism (38%), headache (30.8%) and hypothalamic obesity (8%). The median follow-up period was 41.4 months. In all patients the visual function and intracranial hypertension improved after decompression. Local tumor control was accomplished in eight patients (72.7%), without the need of adjuvant treatments. The endoscopic vision carried similar rates of tumor control than stereotaxy (75% vs 66.7%). Conclusions: in selected patients, tailored procedures are required to achieve long-term tumor control and as well limit surgery-related morbidity. Ors could represent a safe and effective treatment option for cystic craniopharyngiomas, providing also reduced surgical related morbidity especially in recurrent lesions and in patients non suitable for radical surgery. Reported events: one patient experienced

									an ommaya infection two weeks after the neuroendoscopic placement which required system removal. One instance of stereotactic catheter malpositioning, which required a stereotactic replacement. One patient experienced a cerebrospinal fluid (csf) leakage around the subcutaneous reservoir that was derived with a meningo-peritoneal shunt. Manufacturer narrative: patient information was unavailable from the site. Event date is the accepted date of the publication. Device lot number, or serial number, unavailable. 510(k) is dependent upon the device model/part number, therefore unavailable. No parts have been received by the manufacturer for evaluation. Device manufacture date is dependent on the device lot/serial number, therefore is unavailable. If information is provided in the future, a supplemental report will be issued.
3007566237-2019-01775	26/07/2019	Injury	MEDTRONIC NEUROMODULATION	15/08/2019	MBX	ACTIVA	Break	No Known Impact Or Consequence To Patient	Information was received from a health care provider (hcp) and a manufacturer representative (rep) regarding a patient who was being implanted with deep brain stimulation (dbs) leads and implantable neurostimulator (ins) for epilepsy and dbs therapy indications. It was reported that the right lead was damaged during stage two following the case. The physician damaged the lead when they pulled in the lead end cap to expose it. The lead end cap was attached, but the rubber boot that provides some strain relief was not attached. The surgeon had to pull on the lead cap to expose the lead, but the incision may have been a little small, which caused the physician to need more force than usual. The lead was explanted, stereotactic equipment was set up again, a new registration scan to align to target, new lead was placed, and a final scan was taken to check the location. No patient symptoms/complications were reported. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued.

3002250546-2019-00006	24/07/2019	Malfunction	FHC, INC,	23/08/2019	HAW	WAYPOINT STEREOTACTIC PLATFORM	Material Deformation	No Known Impact Or Consequence To Patient	Physician had difficulty attaching the starfix platform to the implanted fiducials at the start of the case. He checked multiple times the peek standoffs from the sks kits and was still having difficulty attaching the final posterior left foot the standoff. It showed a 3mm posterior shift that physician did not feel comfortable proceeding with the surgery with 3 legs without knowing why the 4th leg was shifted so much. The surgery was cancelled and the impact to the patient was opening the fiducial sites and closing again and having the patient get another ct to double check everything. The case concluded successfully with the use of the platform created from the 2nd set of ct scans. Manufacturer narrative: device evaluation: the platform used in the surgery was returned and evaluated. The investigation shows that no issues were found during receiving, processing, manufacturing and qc'ing of the original platform. The returned platform was inspected and found to have non-conforming measurements that are well over the specified tolerances. This is indicative that the geometry of the platform was altered after leaving fhc. The follow-up case was successful. Since the second platform was processed, manufactured and qc'd just as the original, this lends to the conclusion that the problem with the first platform happened outside of fhc control. A root cause could not be determined at this time.
9109028	22/07/2019	Malfunction	HOLOGIC, INC.	24/09/2019	KNW	EVIVA 0913-20	Gas/Air Leak	No Consequences Or Impact To Patient	While performing a stereotactic biopsy it was noticed that there was a significant amount of air infiltrating the saline line. The eviva needle also did not take any core specimens. A new eviva needle was opened and used and it did obtain core specimens. No apparent patient harm.
1220984-2019-00085	16/07/2019	Malfunction	HOLOGIC, INC	05/08/2019	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was reported that the table lowers on its own. No injury reported. A field engineer was dispatched to the site and determined that the table control membrane switch needed to be replaced. Once this was

									completed, the system was working as intended.
MW5088230	11/07/2019	Malfunction	SUN NUCLEAR CORPORATION	18/07/2019	IYE	DOSECHECK (PART OF SUNCHECK)	Application Program Problem	No Known Impact Or Consequence To Patient	Dosecheck software is used as an external beam radiation therapy second calculation check of a pt's treatment plan. The software includes database of peer reviewed published organ dose limits that can be used to verify that organ doses in pt's treatment plan are within safe limits. American association of medicine task group report 101 (aapm tg-101) gives tolerance doses for organs at risk for stereotactic radiosurgery (srs) and stereotactic radiotherapy (srt) treatment techniques. Aapm tg-101 is the u.s. Industry standard organ tolerance for srs and srt uses high doses per fraction in a short course of therapy of one to five fractions. The tolerances doses in aapm tg 101 are grouped by serial and parallel organs, as both have responses to radiation therapy that are quantified differently. In aapm tg-101, serial tissues have minimum point dose tolerances along with volume tolerance. The volume tolerance is set to the maximum volume to which a certain dose can be tolerated by the organ. For example, 4cc of tracheal/large bronchus can receive no more that 16.5 gy in 5 fractions. The parallel tissues listed in aapm tg-101 are given with a minimum volume threshold, instead of a maximum volume threshold. This is to ensure that enough of the parallel organ remains for function of the organ. For example, for the renal cortex 200cc must not receive 8.4gy in one fraction. This means the system should look up the volume receiving 8.4gy and subtract that volume from the total volume of the renal cortex to find a minimum critical volume. This volume should then be at least 200cc t maintain basic renal function. In the dose check software, the software is incorrectly handling serial tissues, despite stating that it aapm tg-101 limits. This incorrect handling means that instead of the minimum volume spared, the software reports the maximum volume to a certain dose, like aa serial

									tissue. The system gives a pass / fail result against a criterion for parallel tissues that is not correct. Incorrect organ limits used in this software may cause pts to be treated with external beam radiation therapy plans that are not safe for delivery for the lungs, liver and renal cortex. According to aapm tg-101, the dose tolerance for not meeting the parallel organ tolerances include grade 3 or greater of loss of basic lung function, loss of basic liver function, basic renal function or pneumonitis. The organ tolerance feature for aapm tg-101 was not used at our facility as a definitive check of the plan (this was performed manually in the treatment planning software). No pts at our facility were affected by this software error. Fda safety report id# (b)(4).
2020394-2019-02262	09/07/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	05/08/2019	KNW	ENCOR BIOPSY PROBE	Leak/Splash	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, blood allegedly leaked from between the sample tray and the probe, contaminating the driver. The procedure was completed by exchanging the probe. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. As the lot number for the device was provided, a manufacturing review will be performed. The sample was not returned to the manufacturer for inspection/evaluation. Therefore, the investigation of the reported event is inconclusive. Based upon the available information, the definitive root cause for this event is unknown. The instructions for use (ifu) is adequate for the reported device/patient code(s) and provides general instructions for use, as well as warnings, precautions and potential complications associated with the device. Upon receipt of new or additional information, a follow-up report will be submitted as applicable. (b)(4), expiry date: 07/2020.

1220984-2019-00082	09/07/2019	Malfunction	HOLOGIC, INC	29/07/2019	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was reported that the table is lowering on its own without pressing anything. No injury reported. A field engineer was dispatched to the site and determined that the motor control board needed to be replaced. Once this was completed the system was working as intended.
3007566237-2019-01882	05/07/2019	Injury	MEDTRONIC NEUROMODULATION	03/09/2019	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Break	Bacterial Infection; Unspecified Infection; Ulceration	Summary: internal pulse generator (ipg) replacement is considered a relatively minor surgery but exposes the deep brain stimulation system to the risk of infectious and mechanical adverse events. The authors retrospectively reviewed complications associated with ipg replacement surgery in the authors' center and reviewed the most relevant publications on the issue. A retrospective analysis of all the ipg replacements performed in the authors' center from january 2003 until march 2018 was performed. A logistic regression model was used to analyze the risk factors associated with ipg infections at the authors' center. A total of 171 ipg replacements in 93 patients were analyzed. The overall rate of replacement complications was 8.8%, whereas the rate of infection was 5.8%. Ipg removal was required in 8 out of 10 infected cases. An increased risk of infection was found in patients with subcutaneous thoracic placement of the ipg (or 5.3, p = 0.016). The most commonly isolated germ was staphylococcus coagulase negative (60%). The authors found a non-significant trend towards increased risk of infection in patients with more than 3 replacements (p = 0.07). Infection is the most frequent complication related to ipg replacement. Staphylococcus coagulase negative is the most commonly isolated bacteria causing the infection. According to the authors' results, the subcutaneous thoracic placement represents a greater risk of infection compared to subcutaneous abdominal placement. Reported events: ten patients experienced infection related to ins replacement. Nine of these ten tested

									positive for staphylococcus (staphylococcus aureus: 3 cases, staphylococcus coagulase negative: 6 cases). Three of the ten developed infection secondary to skin ulceration, even though the battery was relocated on the contralateral side and they received antibiotic therapy for 2 weeks. One of these ten required whole dbs system removal because infection extended along the extension wires. Two patients experienced leadFracture that presented in the same surgery as ins replacement and required the implantation of new extension wires. The article indicates that patients with reported complications were implanted for dystonia and parkinson's disease although specific patients couldn't be identified in the article. The following device specifics were identified in the literature article: ins models 7428, 7426, 37601, 37612. Manufacturer narrative: narvaez-martinez, y., roldan ramos, p., alexander hoyos, j., culebras, d., compta, y., camara, a., munoz, e., marti, m.j., valldeoriola, f., rumia, j. Single-center complication analysis associated with surgical replacement of implantable pulse generators in deep brain stimulation. Stereotactic and functional neurosurgery. 2019. Doi: 10.1159/000500210. This value is the median age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. (pma): p960009 (mhy) and h020007 (mru) both apply as patients were implanted with parkinson's and dystonia, although it was not possible to determine which patients experienced which events. Concomitant medical products: product id: neu_unknown_ext, serial# unknown, product type: extension. Product id: neu_unknown_ext, serial# unknown, product type: extension. Other

									relevant device(s) are: product id: neu_unknown_ext, serial/lot #: unknown, udi#: asku; product id: neu_unknown_ext, serial/lot #: unknown, udi#: asku. If information is provided in the future, a supplemental report will be issued.
3005985723-2019-00510	05/07/2019	Malfunction	MAKO SURGICAL CORP.	15/07/2019	OLO	ANSPACH® EMAX2 PLUS MOTOR	Output Problem; Non Reproducible Results	No Known Impact Or Consequence To Patient	It was reported by the distributor that mps and surgeon were in the case, after completed the registration and balancing and begin to resect the bone. Before completing the cut the motor starts to fail, tried setting cutter and reengage the stereotactic boundaries a few times but not resolved. The distributor check the assembly of the motor to make sure its properly attach and run a burr status check, and the result was failed. Finally, another anspach motor as replacement and the case completed without any further issue. Surgery was delayed for about 45 mins because we need time to transport another sterile set of anspach motor urgently to the hospital. Manufacturer narrative: as part of the normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available.
2020394-2019-02089	04/07/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	01/08/2019	KNW	ENCOR BIOPSY PROBE	Leak/Splash	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy on a upright table, blood allegedly leaked out from the sample basket chamber onto the driver. The procedure was completed successfully. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. As the lot number for the device was provided, a manufacturing review will be performed. The sample was not returned to the manufacturer for inspection/evaluation. Therefore, the investigation of the reported event is inconclusive. Based upon the available information, the definitive root cause for this event is unknown. The

									instructions for use (ifu) is adequate for the reported device/patient code(s) and provides general instructions for use, as well as warnings, precautions and potential complications associated with the device. Upon receipt of new or additional information, a follow-up report will be submitted as applicable. (b)(4), (expiry date 12/2020).
8840720	28/06/2019	Malfunction	STRYKER INSTRUMENTS	30/07/2019	HBB	STRYKER MAESTRO SYSTEM	Device Damaged by Another Device	No Known Impact Or Consequence To Patient	Neurosurgery resident was performing stereotactic brain biopsy with attending. While creating burr hole, drill malfunctioned and tore resident's glove. Drill immediately removed from service. Perforator bit held, complete with lot number intact. Neither patient nor resident injured. Reported incident to drill company rep.
2020394-2019-01701	25/06/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	22/07/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy performed on a ge table through a microcalcification and a mass of asymmetrical density, hissing could allegedly be heard coming from the probe. It was further reported that the procedure was completed with another device. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. As the lot number for the device was provided, a review of the device history records is currently being performed. The device has not yet been returned to the manufacturer for evaluation. The investigation of the reported event is currently underway. (expiry date: 12/2020), (manufacturing date: 01/2019), (b)(4).
2020394-2019-01700	25/06/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	22/07/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy performed on a ge table through a microcalcification and a mass of asymmetrical density, hissing could allegedly be heard coming from the probe. It was further reported that the procedure was completed with another device. There was no reported patient injury. Manufacturer narrative: this event is being

									reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. As the lot number for the device was provided, a review of the device history records is currently being performed. The device has not yet been returned to the manufacturer for evaluation. The investigation of the reported event is currently underway. (expiry date: 12/2020), (manufacturing date: 01/2019), (b)(4).
1220984-2019-00076	25/06/2019	Malfunction	HOLOGIC, INC	16/07/2019	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was reported that when moving the c-arm the table is lowering. No injury reported. A field engineer was dispatched to the site and it was determined that the table control keypad needed to be replaced. Once this was completed the system was working as intended.
2020394-2019-01969	20/06/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	25/07/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem; Failure to Obtain Sample	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, the device allegedly failed to obtain adequate sized samples. It was further alleged that the vacuum was cycling frequently. The issue was unable to be resolved after exchanging the needle. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. As the lot number for the device was provided, a manufacturing review will be performed. The sample was not returned to the manufacturer for inspection/evaluation. Therefore, the investigation of the reported event is inconclusive. Based upon the available information, the definitive root cause for this event is unknown. The instructions for use (ifu) is adequate for the reported device/patient code(s) and provides general instructions for use, as well as warnings, precautions and potential complications associated with the device. Upon receipt of new or additional information, a follow-up report will be

									submitted as applicable. (b)(4), expiry date 09/2020.
2020394-2019-01968	20/06/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	25/07/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem; Failure to Obtain Sample	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, the device allegedly failed to obtain adequate sized samples. It was further alleged that the vacuum was cycling frequently. The issue was unable to be resolved after exchanging the needle. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. As the lot number for the device was provided, a manufacturing review will be performed. The sample was not returned to the manufacturer for inspection/evaluation. Therefore, the investigation of the reported event is inconclusive. Based upon the available information, the definitive root cause for this event is unknown. The instructions for use (ifu) is adequate for the reported device/patient code(s) and provides general instructions for use, as well as warnings, precautions and potential complications associated with the device. Upon receipt of new or additional information, a follow-up report will be submitted as applicable. (b)(4), expiry date-09/2020.
3005985723-2019-00490	18/06/2019	Malfunction	MAKO SURGICAL CORP.	03/07/2019	OLO	HANDPIECE MICS	Mechanical Problem; Non Reproducible Results	No Known Impact Or Consequence To Patient	Mics handpiece trigger broken, the motor seems to be faulty. Mics status check failed and unable to perform rio setup and registration. Surgical delay: 20 minutes. Case type: tka. Update: "the mics hand piece did not run outside the haptic boundary ¿ the trigger did not work from the beginning of the case and we couldn¿t enter rio setup or perform rio registration prior to commencing any bone cuts, so were unable to align to any stereotactic boundaries. We had to get a completely new mics handpiece, as it was completely non-functional". Manufacturer narrative: as part of the normal complaint follow-up, an evaluation of the event has been initiated

									by mako surgical. A supplemental report will be submitted when additional information becomes available.
1723170-2019-03717	17/06/2019	Malfunction	MEDTRONIC NAVIGATION, INC	21/06/2019	HAW	STEALTHSTATION S7 SYSTEM	Imprecision	No Known Impact Or Consequence To Patient	Medtronic received information regarding a navigation system being used for a stereotactic frame deep brain stimulation (dbs) case. It was reported that intraoperatively, the surgeon took an auto-registered spin with the imaging system and identified that it was not accurate. The surgeon took another spin which was accurate and continued with the case. There was a ten minute delay to the procedure. The surgeon suspected that the patient might have moved during the first spin. The procedure was completed successfully and there was no reported impact to patient outcome.medtronic received additional information that the inaccuracy noted after the first registration was approximately 5 millimeters. Manufacturer narrative: correction: software version for product id: 9735585 is software version: 3.0.2. An additional software analysis was initiated. However, the software evaluation found that a probable cause was unable to be determined from review of the exam. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: patient information and additional information received. A medtronic representative went to the site to test the equipment. Testing revealed that the system was performing as intended. The system passed the system checkout and was found to be fully functional. A software analysis was initiated. However, the software evaluation found that a probable cause was unable to be determined. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: patient information was unavailable. Other relevant device(s) are: product id: 9735585, serial/lot #: unknown. No parts have been received by the manufacturer for

									evaluation. If information is provided in the future, a supplemental report will be issued.
3008492462-2019-00030	12/06/2019	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	02/07/2019	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE	Failure to Obtain Sample	No Consequences Or Impact To Patient	Devicor medical products, inc. Received a report from a user facility stating, the probe took three attempts to latch to the holster. Latched after turning the thumb wheel and holding it down. During the procedure it did not collect tissue in the chamber but ended up putting the tissue into the canister. This has been documented in our system as record #: (b)(4). Manufacturer narrative: mst1009 probes are sterile, single use devices, indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis of breast abnormalities. The device was not returned to devicor medical products, inc. For evaluation. Therefore we are unable to determine a root cause for the reported incident. If the tissue is found within the canister rather than in the sample management system, a misdiagnosis is possible due to lost tissue. Following consultation with our medical director, due to the potential to cause or contribute to death or serious injury as a result of potential missed or lost tissue samples, pursuant to 21 cfr §803, this failure mode was determined to be a reportable malfunction.
3007566237-2019-01736	12/06/2019	Malfunction	MEDTRONIC NEUROMODULATION	12/08/2019	MRU	UNKNOWN STEREOTACTIC FRAME	Human-Device Interface Problem; Insufficient Information	Neurological Deficit/Dysfunction; Anxiety; Shaking/Tremors	Information was received from a consumer regarding a patient with dystonia. It was reported that during surgery a stereotactic frame was used and the surgery was aborted because it moved 5 cm in both directions which made it too dangerous to continue. The caller said they did not know the unit of measure for the units. Some interns tried to get it locked and couldn't. One tried and then another tried and the other said they think it was ok, but they never gave a real reason on why the frame shifted. They found a manual online that said the only reason it would shift was if it was not applied properly. On the call, multiple reasons as to why the frame shifted were reviewed, but it was stated to be speculation. The caller was redirected to their healthcare provider (hcp). Additional

									information received from a consumer indicated the hcp told her the frame had shifted due to her dystonia. No further complications were reported or anticipated with this event. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued.
1723170-2020-03359	09/06/2019	Injury	MEDTRONIC NAVIGATION, INC	21/12/2020	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Headache; Muscle Weakness; Unspecified Tissue Injury	Citation: jonathan parish, matthew mcpheeters, scott d. Wait. Endoscopic management of benign cystic lesions of the thalamus with fenestrated stent placement. Journal of clinical neuroscience 67 (2019) 226-230. Https://doi.org/10.1016/j.jocn.2019.06.028 abstract: benign intracranial cystic lesions of the thalamus are an uncommon clinical entity rarely requiring operative decompression. In combination with cyst fenestration, cerebrospinal fluid (csf) flow diversion or fenestrated stent placement may be performed at the time of surgery. We describe a method of treatment of these cysts using endoscopic cyst fenestration with fenestrated transventricular stent placement. Three patients with benign cystic lesions were treated with stereotactic-guided, endoscopic fenestration and fenestrated stent placement. All 3 had radiographic and clinical improvement. There were no complications. Endoscopic fenestration and transventricular fenestrated stent placement is a minimally invasive, effective, and safe method to decompress benign, symptomatic cystic lesions of the thalamus. Reported events: (b)(6) male experienced a mild headache and progressive left sided weaknessat four months post-operative. The patient subsequently underwent an additional fenestration and fenestrated stent placement which resolved the symptoms. (b)(6) male experienced displacement of their stent. The patient underwent a redo cyst fenestration and third ventriculostomy. Manufacturer narrative: patient age is the mean value of the patients who experienced adverse events in the study. Patient gender was the

									majority value of patients in the study who experienced adverse events in the study. Patient weight not available from the site. Event date is the accepted date of the publication. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
MW5087313	07/06/2019	Injury	SIEMENS AG/SIEMENS HEALTHCARE GMBH	12/06/2019	MUE	SIEMENS REVELATION BIOPSY DEVICE	Physical Resistance/Sticking	No Known Impact Or Consequence To Patient	Pt was having a stereotactic biopsy. The mammography machine did not allow the needle to be removed from the breast. This generally requires the tube head to be moved, it wouldn't move. Also, the paddle wouldn't release. The work around was toBreak the paddle in order to get the biopsy needle out of the pt. The problem with the tube head not moving has happened multiple times, and reported to the vendor - siemens - without resolution. Under the best of circumstances, the tube head is finicky to move and often requires the technologist to leave the pt to go to the console. This is a general pt safety issue as pts have vaso vagal reactions and need the needle removed immediately to avoid breast injury. This issue has been reported to the vendor also. Fda safety report id# (b)(4).
2020394-2019-01379	04/06/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	03/07/2019	KNW	ENCOR BIOPSY PROBE	Leak/Splash; Suction Problem	No Consequences Or Impact To Patient	It was reported that during an upright stereotactic breast biopsy, fluid allegedly leaked from seal between the sample basket and the probe, contaminating the driver. It was further alleged that the vacuum was cycling frequently. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. No medical records and no medical images were provided to the manufacturer. The lot number for the device was provided. The

									device history records are currently under review. The device has been returned for evaluation. The investigation is currently underway. (b)(4), expiry date-12/2020.
2020394-2019-01974	30/05/2019	Injury	BARD PERIPHERAL VASCULAR, INC.	26/07/2019	KNW	ENCOR BIOPSY PROBE	Adverse Event Without Identified Device or Use Problem	Injury	It was reported that during a stereotactic breast biopsy, the patient allegedly experienced an arterial bleed. The patient status is unknown. Manufacturer narrative: the device was not returned for evaluation to the manufacturer. The lot number was provided and a lot history review will be performed. The investigation is ongoing.
2020394-2019-01213	30/05/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	26/06/2019	KNW	ENCOR BIOPSY PROBE	Leak/Splash	No Consequences Or Impact To Patient	It was reported that during a stereotactic guided breast biopsy, after the six sample pass, the probe allegedly leaked, which led to arterial bleeding in the patient. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on (b)(6) 2019. As the lot number for the device was provided, a manufacturing review will be performed. The sample was not returned to the manufacturer for inspection/evaluation. Therefore, the investigation of the reported event is inconclusive. Based upon the available information, the definitive root cause for this event is unknown. The instructions for use (ifu) is adequate for the reported device/patient code(s) and provides general instructions for use, as well as warnings, precautions and potential complications associated with the device. Upon receipt of new or additional information, a follow-up report will be submitted as applicable. (expiry date: 12/2020), (b)(4).
2020394-2019-01200	29/05/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	25/06/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, the device allegedly had a suction issue. It was further reported that the procedure was completed with another probe. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these

									product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. The lot number for the device was provided. The device history records are currently under review. The device has been returned for evaluation. The investigation of the reported event is currently underway. (expiry date: 11/2020), (b)(4).
2020394-2020-02042	28/05/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	25/03/2020	KNW	ENCOR BIOPSY PROBE	Suction Problem	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, the device allegedly had a suction issue. The procedure was completed using another device. There was no reported patient injury. Manufacturer narrative: a customer notification was issued for the encor breast biopsy probe for specific product code/lot number combinations. The affected product code/lot number combinations may be at risk of experiencing a leak between the probe and the tissue collection chamber, which could result in minimal suction, leakage, minimal or no tissue sample obtained, or an egress of fluids from the device. A root cause investigation and field action determination was conducted as a result of an increase in complaints for leaks, suction issues, and failure to obtain samples. The investigation included an extensive manufacturing review, risk documentation review for the three reported malfunctions, and evaluations performed on the returned devices. The investigation identified that one of the features on the trap chamber was under specified and during the implementation of a new trap chamber ((b)(4)) mold, one of the dimensions changed and went undetected, creating a difference between the amount of space that the seal has between the trap chamber and the front seal cap. This gap between the trap chamber and front seal cap resulted in conditions that led to a higher likelihood of leaks, suction issues, and failure to obtain samples. All reported complaints from the affected product code/lot number combinations that are

									possibly related to the gap between the trap chamber and front seal cap have been classified as leak, suction issues), or failure to obtain samples. This reported complaint is from an affected lot number that was reported for one of these trap chamber issues. (expiry date 12/2020), (b)(4).
2020394-2019-00734	28/05/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	31/05/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, the device allegedly had a suction issue. The procedure was completed using another device. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. As the lot number for the device was provided, a manufacturing review will be performed. The sample was not returned to the manufacturer for inspection/evaluation. Therefore, the investigation of the reported event is inconclusive. Based upon the available information, the definitive root cause for this event is unknown. The instructions for use (ifu) is adequate for the reported device/patient code(s) and provides general instructions for use, as well as warnings, precautions and potential complications associated with the device. Upon receipt of new or additional information, a follow-up report will be submitted as applicable. (expiry date: 11/2020). (b)(4).
2020394-2019-00964	17/05/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	11/06/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem	No Consequences Or Impact To Patient	It was reported that during a stereotactic-guided breast biopsy, the device allegedly had a suction issue. It was further reported that the procedure was completed with another device. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. The lot number of the device was provided. The

									device history records are currently under review. The device has been returned for evaluation. The investigation is currently underway. (expiry date: 12/2020), (b)(4).
3005099803-2019-03005	16/05/2019	Injury	AUGMENIX, INC.	14/06/2019	OVB	SPACEOAR SYSTEM	Inadequacy of Device Shape and/or Size; Positioning Problem	Discomfort; Obstruction/Occlusion; Bowel Perforation	It was reported to boston scientific corporation on (b)(6) 2019 that spaceoar was implanted during a spaceoar implant procedure performed on (b)(6) 2019. Reportedly, there were no issues during the spaceoar placement. The procedure was performed under general anesthesia, fiducial markers were placed at the start of the procedure, and there were no brachytherapy seeds placed. The patient received five fractions of stereotactic body radiation therapy (sbrt) and was scheduled for a brachytherapy boost on (b)(6) 2019; however, the brachytherapy boost was aborted due to pubic arch interference. Reportedly, during this brachytherapy boost procedure, the patient experienced a blood pressure drop and heart rate increase when the transrectal ultrasound (trus) probe was being positioned. As a result of this sudden change in vital signs, the nurse anesthetist momentarily interrupted the procedure. The anesthetist expressed concern that what was being done in the rectum was distressing the patient even while under anesthesia. According to the complainant, nine weeks post procedure, the patient began complaining of discomfort and rectal fullness. Reportedly, magnetic resonance imaging (mri) showed that there was 2cm of spaceoar in some places in the perirectal area, and it looked like there was some gel injected into the rectal wall. The patient's discomfort was treated with anusol suppository. The patient was in continued discomfort and presented to a colorectal physician. Sometime during the weekend of (b)(6) 2019, a colonoscopy was performed and found that the spaceoar gel had perforated the colon posterior to the hydrogel placement. Reportedly, the spaceoar looked like "an upside down mushroom protruding into the lumen and obstructing bowel movement." the gel was

									shaved down flat, and the physician was "cautiously optimistic" that the perforation would heal on its own. In the physician's assessment, the cause of the perforation was impossible to pinpoint, but the gel in the rectal wall combined with the patient bearing down during a bowel movement or pressure from the trus probe during the aborted brachytherapy procedure may have contributed. According to the complainant, the patient reported discomfort after the spaceoar placement but did not have any significant problems until after the failed brachytherapy procedure. The patient's additional radiation therapy has been delayed. The patient is currently still admitted inpatient in the hospital. Manufacturer narrative: patient's exact age is unknown; however, it was reported that the patient was over the age of 18. The exact date of the event is unknown. The provided event date, (b)(6) 2019, was chosen as a best estimate based on the reported "nine week post procedure.". The lot number is not known per the complainant; therefore, the device manufacture and expiration dates cannot be determined. (b)(4). According to the complainant, the device is implanted in the patient and is not available for return. If any further relevant information is received, a supplemental mdr will be filed.
2020394-2019-01220	14/05/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	25/06/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem; Failure to Obtain Sample	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, in normal tissue, the device allegedly experienced a suction issue and allegedly failed to obtain tissue samples. Reportedly, under imaging a hematoma was visible, therefore, pressure was held. It was further reported that the patient developed a large hematoma and no further treatment was required. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. The lot

									number of the device was provided. The device history records are currently under review. The photo review is currently underway review. (expiry date: 07/2020), (b)(4).
2020394-2019-00908	14/05/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	10/06/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem; Failure to Obtain Sample	No Consequences Or Impact To Patient	It was reported that during a stereotactic biopsy of microcalcifications of the breast on a lorad table, the device was allegedly unable to vacuum fluids and the tissue samples retrieved were allegedly smaller than usual. It was further reported that the procedure was not completed and had to be rescheduled. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. As the lot number for the device was provided, a manufacturing review will be performed. The sample was not returned to the manufacturer for inspection/evaluation. Therefore, the investigation of the reported event is inconclusive. Based upon the available information, the definitive root cause for this event is unknown. The instructions for use (ifu) is adequate for the reported device/patient code(s) and provides general instructions for use, as well as warnings, precautions and potential complications associated with the device. Upon receipt of new or additional information, a follow-up report will be submitted as applicable. (expiry date: 09/2020), (manufacturing date: 10/2018), (b)(4).
1220984-2019-00059	14/05/2019	Malfunction	HOLOGIC, INC	03/06/2019	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was reported that the table drives down on its own. No injury reported. A field engineer was dispatched to the site and determined the table control board and table control switch needed to be replaced. Once this was completed the system was working as intended.
2020394-2019-00948	10/05/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	11/06/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem; Failure to	No Consequences	It was reported that during a stereotactic breast biopsy, the device allegedly had low suction even after exchanging the sample

							Obtain Sample	Or Impact To Patient	basket two times. The procedure was completed by exchanging the probe. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. No medical records and no medical images were provided to the manufacturer. The lot number for the device was provided. The device history records are currently under review. The return of the device is pending. The investigation is currently underway. (b)(4), expiry date-11/2020.
2020394-2019-00852	09/05/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	06/06/2019	KNW	ENCOR BIOPSY PROBE	Leak/Splash	No Consequences Or Impact To Patient	It was reported that after completion of a stereotactic breast biopsy through dense tissue density, the device allegedly leaked blood onto the driver upon removal. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019. As the lot number for the device was provided, a manufacturing review will be performed. The sample was not returned to the manufacturer for inspection/evaluation, however, a photo was provided and is currently under review. The investigation of the reported event is currently underway. (expiry date: 12/2020), (b)(4).
2020394-2019-00728	09/05/2019	Malfunction	BARD PERIPHERAL VASCULAR, INC.	30/05/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem	No Consequences Or Impact To Patient	It was reported that during a stereotactic guided breast biopsy, the device allegedly had a suction issue. The procedure was completed using another device. There was no reported patient injury. Manufacturer narrative: this event is being reported as a reportable malfunction for the special cause related to these product catalog/lot number combinations which is the subject of report of corrections and removal letter (806 notification) on may 2, 2019 as the lot number for the device was provided, a

									manufacturing review will be performed. The sample was not returned to the manufacturer for inspection/evaluation. Therefore, the investigation of the reported event is inconclusive. Based upon the available information, the definitive root cause for this event is unknown. The instructions for use (ifu) is adequate for the reported device/patient code(s) and provides general instructions for use, as well as warnings, precautions and potential complications associated with the device. Upon receipt of new or additional information, a follow-up report will be submitted as applicable. (b)(4).
3007566237-2019-01868	08/05/2019	Injury	MEDTRONIC NEUROMODULATION	01/09/2019	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Failure to Deliver Energy; Battery Problem	Therapeutic Response, Decreased; Complaint, Ill-Defined	Mitchell kt, volz m, lee a, et al. Patient experience with rechargeable implantable pulse generator deep brain stimulation for movement disorders. Stereotact funct neurosurg. 2019:1-7. 10.1159/000500993 summary: nonrechargeable deep brain stimulation implantable pulse generators (ipgs) for movement disorders require surgical replacement every few years due to battery depletion. Rechargeable ipgs reduce frequency of replacement surgeries and inherent risks of complications but require frequent recharging. Here, we evaluate patient experience with rechargeable ipgs and define predictive characteristics for higher satisfaction. Reported events: one subject had ipg depletion prompted an emergency department visit due to return of severe motor symptoms and multiple days of hospitalization due to delayed discovery that stimulation was off at an outside center. Two hardware infections occurred, both of which prompted removal of rc ipg and intracerebral lead. Both of these infections were in patients with known infections in prior nonrechargeable ipg systems that had been treated with a full course of intravenous antibiotics after hardware removal and prior to implantation with a rc ipg. The rc ipg was placed in these cases with the goal of limiting future replacement surgeries and corresponding infection risk. Manufacturer narrative:

									mitchell kt, volz m, lee a, et al. Patient experience with rechargeable implantable pulse generator deep brain stimulation for movement disorders. Stereotact funct neurosurg. 2019:1-7. 10.1159/000500993. This value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article [or the date that the article was accepted for publication] as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Concomitant medical products: product id: neu_ins_stimulator, serial/lot #: unknown. Product id: neu_ins_stimulator, serial/lot #: unknown. If information is provided in the future, a supplemental report will be issued. (b)(4).
3007566237-2019-01869	08/05/2019	Malfunction	MEDTRONIC NEUROMODULATION	01/09/2019	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Unstable; Charging Problem	No Known Impact Or Consequence To Patient	Mitchell kt, volz m, lee a, et al. Patient experience with rechargeable implantable pulse generator deep brain stimulation for movement disorders. Stereotact funct neurosurg. 2019:1-7. 10.1159/000500993 summary: non-rechargeable deep brain stimulation implantable pulse generators (ipgs) for movement disorders require surgical replacement every few years due to battery depletion. Rechargeable ipgs reduce frequency of replacement surgeries and inherent risks of complications but require frequent recharging. Here, we evaluate patient experience with rechargeable ipgs and define predictive characteristics for higher satisfaction. Reported events: 4. In one subject who reported inadequate charging, the rc ipg was found to be flipped on x-ray and was corrected by manual

									external manipulation in the clinic. 6. Six patients issues with impedances (excessively high or low) were reported. 7. One patient had partial intracerebral lead migration but had continued symptom control after reprogramming. 8. Seven patients reported malfunction of external recharging equipment and need for replacement by the vendor. 9. Twenty patients reported issues with pairing the recharger/finding the ¿right spot¿. 10. Eight patients had a feeling ¿tethered¿/length of time to charge. 12. Six patients reported issues with having a short-lasting charge. Manufacturer narrative: mitchell kt, volz m, lee a, et al. Patient experience with rechargeable implantable pulse generator deep brain stimulation for movement disorders. Stereotactic funct neurosurgery. 2019:1-7. 10.1159/000500993. This value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article [or the date that the article was accepted for publication] as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Other relevant device(s) are: product id: neuro-stimulator; serial/lot #: unknown; product id: neuro-stimulator. If information is provided in the future, a supplemental report will be issued.
3008492462-2019-00031	03/05/2019	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	02/07/2019	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE - 10G	Failure to Obtain Sample	No Consequences Or Impact To Patient	Devicor medical products, inc. Received a report from a user facility stating, during the procedure the 10g probe didn't get any samples. No patient complications. This has been documented in our system as report

									#(b)(4). Manufacturer narrative: mst1009 probes are sterile, single use devices, indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis of breast abnormalities. The probe was returned to devicor for evaluation. The device was received with blood in the cup and on chamber four. Initial attempt to take samples of chicken breast test medium was unsuccessful. The device was biopsied in water to clear the dried blood. A small piece of breast tissue was found. Following the clearing of the dried blood and tissue, the probe successfully obtained samples of the chicken breast test medium. The device was disassembled and no abnormalities were found. Probable root cause for the device not obtaining samples was the clogged probe. Due to the discovery of the tissue, this event was assessed against the result of the investigation. Following consultation with our medical director, due to the potential to cause or contribute to death or serious injury as a result of potential missed or lost tissue samples, pursuant to 21 cfr §803, this failure mode was determined to be a reportable malfunction.
1723170-2021-02391	02/05/2019	Death	MEDTRONIC NAVIGATION, INC	29/09/2021	HAW	STEALTHSTATION S7	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage	Millesi, m., kiesel, b., wöhrer, a., mercea, p.a, bissolo, m., roetzer, t., wolfsberger, s., furtner, j., knosp, e., widhalm, g. Is intraoperative pathology needed if 5-aminolevulinic-acid-induced tissue fluorescence is found in stereotactic brain tumor biopsy? Neurosurgery 2020 86:366¿373 doi:10.1093/neuros/nyz086 background: intraoperative histopathology and acquisition of multiple tissue samples in stereotactic biopsies results in a prolonged length of surgery and potentially increased complication rate. Objective: to investigate the clinical benefits of a novel strategy for stereotactic brain tumor biopsies with the assistance of 5-a minolevulinic acid (5-ala) induced fluorescence. Methods: patients that received 5-ala prior to stereotactic biopsy of a suspected brain tumor were included. According to our strategy, the procedure was terminated in the case of

									strong fluorescence of the biopsy samples. In contrast, intraoperative histology was demanded in the case of vague/no fluorescence. Length of surgery, number of biopsy samples, diagnostic rate, and periprocedural complications were compared between these 2 groups. Results: altogether, 79 patients were included, and strong fluorescence was present in 62 cases (79%), vague fluorescence was in 4 cases (5%), and no fluorescence was in 13 cases (16%). The diagnostic rate was comparable in biopsies with strong fluorescence without intraoperative histopathology and cases with vague/no fluorescence with intraoperative histopathology (98% vs 100%; p = 1.000). A significantly shorter length of surgery (41 vs 77 min; p <(><<)> .001) and reduced average number of biopsy samples (3.6 vs 4.9; p = .011) was found in patients with strong compared to vague/no fluorescence. However, no statically significant difference in periprocedural complications between cases with strong and vague/no fluorescence was found (7% vs 18%; p = .166). Conclusion: our data demonstrate the clinical benefits of a novel strategy for stereotactic brain tumor biopsies with assistance of 5-ala. Thus, this biopsy strategy will increase the efficiency of this standard neurosurgical procedure in the future. Reportable incidents there was 1 mortality (1%) that occurred. This patient died because of postoperative pulmonary embolism after prolonged hospitalization as consequence to a postoperative significant (symptomatic) intracerebral hemorrhage. Manufacturer narrative: patient information was unavailable from the site. Event date is the online publishing date of the literature article. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacture date is dependent on the device lot/serial number, therefore is unavailable. If information is provided in the future, a supplemental report will be issued.

1723170-2021-02392	02/05/2019	Injury	MEDTRONIC NAVIGATION, INC	29/09/2021	HAW	STEALTHSTATION S7	Adverse Event Without Identified Device or Use Problem	Hemorrhage/Bleeding; Dysphasia	Millesi, m., kiesel, b., w¿hrer, a., mercea, p.a, bissolo, m., roetzer, t., wolfsberger, s., furtner, j., knosp, e., widhalm, g. Is intraoperative pathology needed if 5-aminolevulinic-acid-induced tissue fluorescence is found in stereotactic brain tumor biopsy? Neurosurgery 2020 86:366373 doi:10.1093/neuros/nyz086 background: intraoperative histopathology and acquisition of multiple tissue samples in stereotactic biopsies results in a prolonged length of surgery and potentially increased complication rate. Objective: to investigate the clinical benefits of a novel strategy for stereotactic brain tumor biopsies with the assistance of 5-a minolevulinic acid (5-ala) induced fluorescence. Methods: patients that received 5-ala prior to stereotactic biopsy of a suspected brain tumor were included. According to our strategy, the procedure was terminated in the case of strong fluorescence of the biopsy samples. In contrast, intraoperative histology was demanded in the case of vague/no fluorescence. Length of surgery, number of biopsy samples, diagnostic rate, and periprocedural complications were compared between these 2 groups. Results: altogether, 79 patients were included, and strong fluorescence was present in 62 cases (79%), vague fluorescence was in 4 cases (5%), and no fluorescence was in 13 cases (16%). The diagnostic rate was comparable in biopsies with strong fluorescence without intraoperative histopathology and cases with vague/no fluorescence with intraoperative histopathology (98% vs 100%; p = 1.000). A significantly shorter length of surgery (41 vs 77 min; p <(><<)> .001) and reduced average number of biopsy samples (3.6 vs 4.9; p = .011) was found in patients with strong compared to vague/no fluorescence. However, no statically significant difference in periprocedural complications between cases with strong and vague/no fluorescence was found (7% vs 18%; p = .166). Conclusion: our data demonstrate the

									clinical benefits of a novel strategy for stereotactic brain tumor biopsies with assistance of 5-ala. Thus, this biopsy strategy will increase the efficiency of this standard neurosurgical procedure in the future. Reportable incidents for one patient a second biopsy procedure was performed with tissue acquisition. 6 patients had significant hemorrhages. 1 patient postoperatively speech was worsened and it was unrelated to hemorrhage. Manufacturer narrative: patient age is the mean value of patients in the study. Patient gender is the majority value of patients in the study. Patient weight not available from the site. Event date is the online publishing date of the literature article. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacture date is dependent on the device lot/serial number, therefore is unavailable. If information is provided in the future, a supplemental report will be issued.
3005099803-2019-03031	01/05/2019	Malfunction	AUGMENIX, INC.	18/06/2019	OVB	SPACEOAR SYSTEM	Positioning Problem	Pain; Discomfort	Boston scientific corporation became aware of events through early results of an investigator-sponsored clinical trial yet to be published. According to the preliminary information provided, spaceoar was implanted in 30 patients to demonstrate the feasibility of performing a randomised trial comparing prostate-only sabr to the addition of pelvic eni sabr in men with high-risk localised prostate cancer. In all procedures, spaceoar was implanted at the same time as three gold fiducials and six research biopsies were taken. All procedures were performed transperineally under local anesthetic and patients were given five days of ciprofloxacin antibiotics post-procedure. Reportedly, no study interventions were given in the month following insertion other than magnetic resonance imaging (mri) and a computed tomography (ct) scan. One patient complained of transient pain and tenesmus during spaceoar injection. The patient was asymptomatic following the procedure.

									Seven days later, mri showed rectal wall infiltration of spaceoar. The patient was taken off the trial. The patient received standard radiotherapy treatment with spaceoar in situ and experienced no unexpected or severe side effects. A grade 2 gastrointestinal (gi) adverse event of rectal wall infiltration was also noted. Reportedly, the patient was asymptomatic from day 1. Attempts to obtain additional information regarding these events have been unsuccessful to date. Should additional relevant details become available, a supplemental report will be submitted. Manufacturer narrative: the median age of the patients was 67 years, with the interquartile range (iqr) being 61.5-70 years. The exact date of the event is unknown. Date of event was approximated to (b)(6) 2019 based on the month the manufacturer became aware of the event. The lot number were not reported; therefore, the manufacture date and expiration date are unknown. Presentation slide deck details yet-to-be-published data from trial named "a randomised feasibility study evaluating stereotactic prostate radiotherapy (sabr) in high-risk localised prostate cancer with or without elective nodal irradiation". (b)(4). The devices have not been received for analysis; therefore, failure analysis of the complaint devices could not be completed. If any further relevant information is identified, a supplemental medwatch will be filed.
1723170-2019-05475	27/04/2019	Injury	MEDTRONIC NAVIGATION, INC	05/11/2019	GEX	VISUALASE	Insufficient Heating	Dysphagia/ Odynophagia; Neurological Deficit/Dysfunction; Pain; Complaint, Ill-Defined	Citation: gross, r. E. And stern, m. A. (2018), magnetic resonance¿guided stereotactic laser pallidotomy for dystonia. Mov disord., 33: 1502-1503. Doi:10.1002/mds.27400 summary: the attached article presented the use of mr-guided laser interstitial thermal therapy (mrglitt) pallidotomy in two patients with medically refractory generalized dystonia who were not considered deep brain stimulation (dbs) candidates, with mixed results. Reported event: 1. One 12-year-old male with dyt1+ primary dystonia affecting all extremities,

									trunk, neck, and cranial region, was unable to walk with acute bilateral hip dislocations. Mrglitt pallidotomy was performed using bilateral thermal therapy system cooled laser catheters. The catheters were introduced into the global pallidus interna using a non-medtronic platform. A right pallidotomy was performed using direct targeting and proprietary digital atlas software. A smaller left pallidotomy was then performed because off-target temperature limits were exceeded at low power. Post-operatively, gait and coordination issues persisted and the patient remained wheelchair bound and needing assistance with all activities of daily living. It was reported that the hypertonicity of the left upper extremity was noticeably worse and often associated withPain; it was noted that this was likely related to the larger right-sided lesion encroaching the capsule. It was reported that the patient developed jaw-opening dystonia postoperatively, leading to anarthria and dysphagia. See attached article. Manufacturer narrative: a software investigation analysis was initiated to determine the probable cause of the issue through review of the article. Software analysis found that there was no indication of the thermal therapy system having an issue. Analysis found that the software functioned as designed. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: patient identifier not provided in article. Patient weight not provided in article. Please note that this date is based off of the date the article was published online as the event date was not provided in the published literature. Article citation is included. No evaluation was performed as this event was reported in literature. If information is provided in the future, a supplemental report will be issued.
3008492462-2019-00023	23/04/2019	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	24/05/2019	KNW	MAMMOTOME REVOLVE	Failure to Obtain Sample	No Consequences	Devicor medical products, inc. Received a report from our affiliate, devicor medical (b)(4), stating the user acquired 6 tissue

						STEREOTACTIC PROBE		Or Impact To Patient	samples, but there were only 5 samples in the sms (sample management system) and then they found a tissue sample in the canister. This sample has many calcifications and the user believes that it is first sample. This has been documented in our system as record # (b)(4). Manufacturer narrative: mst1009 probes are sterile, single use devices, indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis of breast abnormalities. One mst1009 probe was received for investigation. Upon evaluation of the device, the sms cup is between chamber 10 and 11. It is likely that the sms cup was aligned on the marker chamber during the first sample, and therefore, the first sample went to the cannister. If the tissue is found within the canister rather than in the sample management system, a misdiagnosis is possible due to lost tissue. Following consultation with our medical director, due to the potential to cause or contribute to death or serious injury as a result of potential missed or lost tissue samples, pursuant to 21 cfr §803, this failure mode was determined to be a reportable malfunction.
3005099803-2020-00210	23/04/2019	Injury	AUGMENIX, INC.	30/01/2020	OVB	SPACEOAR SYSTEM	Positioning Problem	Pain; Ulcer; Fluid Discharge; No Code Available	It was reported to boston scientific corporation on january 6, 2020 that spaceoar was implanted during a spaceoar placement procedure performed on (b)(6) 2019. Reportedly, the patient underwent stereotactic body radiation therapy (sbrt) for 45 gray (gy) in 5 fractions of 9 gy each. The patent also had an adjacent indeterminate r anterior pubic bone lesion incorporated in the 35 gy isodose line. According to the complainant, during magnetic resonance imaging (mri) post procedure, mild infiltration of the gel into the rectal wall was noted. On (b)(6) 2019, around five months post spaceoar placement, the patient complained of rectal pain. A sigmoidoscopy was performed on (b)(6) 2019, during which a large ulceration was noted in the area right behind the prostate in the rectum. On (b)(6) 2019, the

									patient underwent a diverting colostomy procedure. On (b)(6) 2020, the patient started hyperbaric oxygen therapy. As of (b)(6) 2020, the patient continues to have some blood and mucous discharge from the rectum. The patient's pain, rectal symptoms, and urinary symptoms continue to improve with the colostomy in place. Manufacturer narrative: the complainant was unable to report the lot number; therefore, the manufacture date and expiration date are unknown. (b)(4). The device was implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental medwatch will be filed.
1222780-2019-00089	28/03/2019	Injury	HOLOGIC, INC.	18/04/2019	NEU	SECURMARK	Adverse Event Without Identified Device or Use Problem	Skin Irritation; Swelling; Burning Sensation	It was reported that two technologists were setting up a tray for a stereotactic biopsy, the last thing they opened was the package to the securmark marker and seconds after they noted buring and white marks on their fingers. Additional information received from the customer later that same day noted the white coloring was fading, but some swelling and tingling sensation remained. The technologists had applied ice to the affected area and used rubbing alcohol and hydrogen peroxide on the white markings. They were evaluated by employee health, but no medical intervention was given. It was noted that the technologists were not wearing gloves while handling the packaging. A second customer follow-up was made on (b)(6) 2019 and it was reported that the white marks had disappeared and the swelling went down. Manufacturer narrative: the returned product investigation is still in-process as of today, a follow-up will be filed as needed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications. Internal complaint reference: (b)(4).
3007566237-2019-01408	26/03/2019	Injury	MEDTRONIC NEUROMODULATION	27/06/2019	OLM	UNKNOWN IMPLANTABLE	Adverse Event Without	Emotional Changes; Fall; Anxiety;	Summary: obsessive-compulsive disorder (ocd) is characterized by intrusive, anxious thoughts with repetitive, ritualized

						NEUROSTIMULATOR	Identified Device or Use Problem	Depression; Joint Dislocation; Cognitive Changes	behaviors, and has negative impacts on family relationships and social life. Its lifetime prevalence is estimated to be 2e3% [1]. Cognitive and behavioral therapy and selective serotonin reuptake inhibitors are the standard treatments for ocd; nevertheless, despite these treatments, between 25 and 40% of patients display persistent symptoms leading to severe functional disability [2]. Neurosurgical treatment targeting different parts of the orbito-fronto-striatothalamo-cortical circuit has been proposed for the most severe and refractory forms, including both gamma knife non-invasive stereotactic lesions and invasive deep brain stimulation (dbs) [3] (supplementary information). However, the long-term efficacy (>3 years) and safety of dbs for ocd is not fully reported. We prospectively followed 14 ocd patients treated with subthalamic dbs (stn-dbs, stoc study) for 46 months. Reported events: 3 patients with deep brain stimulation (dbs) for obsessive compulsive disorder (ocd) attempted suicide in long term follow-up. 3 patients with dbs for ocd experienced 5 cases of increased ocd that was considered a serious adverse event. An adverse event was considered as serious if the patient required hospitalization, if sequelae were present, if the event induced vital distress, or if the clinician considered the event to be serious. 2 patients with dbs for ocd experienced increased anxiety that was considered a serious adverse event. An adverse event was considered as serious if the patient required hospitalization, if sequelae were present, if the event induced vital distress, or if the clinician considered the event to be serious. 5 patients with dbs for ocd experienced 6 cases of depression that was considered a serious adverse event. An adverse event was considered as serious if the patient required hospitalization, if sequelae were present, if the event induced vital distress, or if the clinician considered the event to be serious. 2 patients with dbs for ocd experienced 3

									cases of transient stimulation-related hypomania that was considered a serious adverse event. An adverse event was considered as serious if the patient required hospitalization, if sequelae were present, if the event induced vital distress, or if the clinician considered the event to be serious. A patient with dbs for ocd experienced a ¿transient¿ stimulation-related fall with shoulder luxation that was considered a serious adverse event. An adverse event was considered as serious if the patient required hospitalization, if sequelae were present, if the event induced vital distress, or if the clinician considered the event to be serious. A patient with dbs for ocd experienced transient stimulation-related impulsivity that was considered a serious adverse event. An adverse event was considered as serious if the patient required hospitalization, if sequelae were present, if the event induced vital distress, or if the clinician considered the event to be serious. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: age or date of birth: this value is the average age of the patients reported in the article as specific patients could not be identified. Sex: this value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Other relevant device(s) are: product id: neu_ins_stimulator, serial/lot #: unknown. Product id: neu_ins_stimulator, serial/lot #: unknown. Product id: neu_ins_stimulator, serial/lot #: unknown. Product id: neu_ins_stimulator, serial/lot #: unknown. Product id: neu_ins_stimulator, serial/lot #: unknown. Product id: neu_ins_stimulator, serial/lot #: unknown. Mallet l, du montcel st, clair ah, arbus, c., bardinet, e., baup, n.,

									chabardes, s., chereau, i., czernecki, v., fontaine, d., harik a-germaneau, g., haynes, wi., houeto, jl., jaafari, n., krack, p., millet, b., navarro, s., polosan, m., pelissolo, a., welter, ml. Long-term effects of subthalamic stimulation in obsessive-compulsive disorder: follow-up of a randomized controlled trial. Brain stimul. 2019. Doi: 10.1016/j.brs.2019.04.004. If information is provided in the future, a supplemental report will be issued.
1220984-2019-00034	25/03/2019	Malfunction	HOLOGIC, INC	08/04/2019	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was reported that the table was going up and sometimes down on its own. No injury reported. A field engineer was dispatched to the site and it was determined that the control panel keyboard switches were sticking and the control panel needed to be replaced. Once this was completed the system was working as intended.
3007566237-2019-01172	21/03/2019	Malfunction	MEDTRONIC NEUROMODULATION	28/05/2019	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Malposition of Device	No Known Impact Or Consequence To Patient	Sheehy jp, chen t, bohl ma, mooney ma, mirzadeh z, ponce fa. Accuracy in deep brain stimulation electrode placement: a single-surgeon retrospective analysis of stereotactic error in overlapping and non-overlapping surgical cases. Doi: 10.1159/000497150 summary: many surgeons utilize assistants to perform procedures in more than one operating room at a given time using a practice known as overlapping surgery. Debate has continued as to whether overlapping surgery improves the efficiency and access to care or risks patient safety and outcomes. Reported events: 324 patients implanted with 535 leads had an average radial error of 0.87 +/- 0.07 mm and an average euclidean error of 1.25 +/- 0.10 mm. Manufacturer narrative: other relevant device(s) are: product id: neu_unknown_lead, serial/lot #: unknown. Sheehy jp, chen t, bohl ma, mooney ma, mirzadeh z, ponce fa. Accuracy in deep brain stimulation electrode placement: a single-surgeon retrospective analysis of stereotactic error in overlapping and non-overlapping surgical cases. Doi: 10.1159/000497150. This value is the average age of the patients reported in the

									article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article [or the date that the article was accepted for publication] as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. If information is provided in the future, a supplemental report will be issued. (b)(4).
3007566237-2019-01173	21/03/2019	Injury	MEDTRONIC NEUROMODULATION	28/05/2019	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Malposition of Device; Adverse Event Without Identified Device or Use Problem	Wound Dehiscence; Complaint, Ill-Defined; No Known Impact Or Consequence To Patient	Sheehy jp, chen t, bohl ma, mooney ma, mirzadeh z, ponce fa. Accuracy in deep brain stimulation electrode placement: a single-surgeon retrospective analysis of stereotactic error in overlapping and non-overlapping surgical cases. Doi: 10.1159/000497150 summary: many surgeons utilize assistants to perform procedures in more than one operating room at a given time using a practice known as overlapping surgery. Debate has continued as to whether overlapping surgery improves the efficiency and access to care or risks patient safety and outcomes. Reported events: patient with stn target had hardware-related complications requiring revision had capsular side effects and high impedance affecting contacts 8, 9, 10 and had their right lead replaced. Interval time was 8 days. 1 patient with stn target had hardware-related complications requiring revision had high impedance on contacts 1 and 3. The extension was replaced. Interval time was 1 month. 1 patient with stn target had hardware-related complications requiring revision had high impedance on contact 10. Their extension was replaced

									with 0 day interval. 1 patient with vim target had hardware-related complications requiring revision had high impedance on contact 8, this was noted during the ipg placement and was localized to the lead. The right lead was replaced. There was a 0 day interval. 1 patient with stn target had hardware related complications requiring revision had ipg discomfort. The ipg was repositioned from the chest to the abdomen. The interval time was 10 months. 1 patient with vim target had hardware-related complications requiring revision had high impedance affecting both sides. Both extensions were replaced. There was a 5 month interval. 1 patient with vim target had hardware-related complications requiring revision had high impedance on the right side and the right lead was replaced. There was a 10 month interval. 4 patients experienced wound-related complications that required surgery. Manufacturer narrative: other relevant device(s) are: product id: neu_unknown_ext, serial/lot #: unknown; product id: neu_unknown_lead, serial/lot #: unknown; product id: neu_ins_stimulator, serial/lot #: unknown; product id: neu_unknown_lead, serial/lot #: unknown. This value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article [or the date that the article was accepted for publication] as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. If information is provided

									in the future, a supplemental report will be issued. (b)(4).
1222780-2019-00073	14/03/2019	Injury	HOLOGIC, INC.	02/04/2019	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Adverse Event Without Identified Device or Use Problem	No Information	It was reported that during a biopsy "the knife was not cutting completely the tissue." additional information was received on 03/18/2019 which noted that a vessel was struck during the biopsy. The biopsy was stopped and the needle was removed. No information was provided on patient impact or medical intervention. Manufacturer narrative: device evaluated by mfr: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications. Internal complaint reference: (b)(4).
3007566237-2019-01208	14/03/2019	Injury	MEDTRONIC NEUROMODULATION	31/05/2019	MRU	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Break	Therapeutic Effects, Unexpected	Summary: the authors present their operative experience of patients with movement disorders who developed intracerebral hemorrhage (ich), which was identified on intraprocedural stereotactic computed tomography (ct) imaging performed immediately after deep brain stimulation (dbs) lead placement and prior to the implantation of further components of the dbs hardware. Patients who underwent dbs lead implantation from january 2009 through december 2017 were included in the present study. Most of the surgeries were performed in a staged fashion. All patients were operated using identical surgical and intraprocedural imaging techniques, and no microelectrode recordings were done. Leksell stereotactic g frame and neuronavigation software was utilized for all surgeries. Intraprocedural stereotactic ct was performed to confirm the precise position of the implanted dbs lead and to rule out any hemorrhagic complications. Overall, 222 patients underwent 322 dbs lead implantations during 316 stereotactic procedures. Six patients exhibited early ich recognized on intraprocedural stereotactic ct performed immediately after dbs lead placement; in

									addition, two patients developed delayed ich due to large venous infarction. Four patients with ich were asymptomatic. The ich rate was 2.5% per electrode and 3.6% per patient; the permanent deficit rate was 1.2% per electrode and 1.8% per patient. The death rate due to ich in the cohort was 0.6% per electrode and 0.9% per patient. Intraprocedural stereotactic ct can not only visualize the implanted dbs lead in the stereotactic space but also rule out early ich. Identified predisposing factors for development of ich include patient's age, hypertension, and previous antiplatelet therapy. Careful planning of stereotactic trajectories plays a paramount role in reducing the rate of ich in dbs surgery. Reported events: two patients implanted with dbs for dystonia had electrodes re-implanted over follow-up due toBreakage of the extracranial lead. Two patients implanted with dbs for dystonia had electrodes re-implanted over follow-up due to the suboptimal clinical benefit. The following device information was identified in the article: lead model 3389; ins models 37602, 37603, 7426. Manufacturer narrative: sobstyl, m., alksandrowicz, m., zabek, m., pasterski, t. Hemorrhagic complications seen on immediate intraprocedural stereotactic computed tomography imaging during deep brain stimulation implantation. Journal of the neurological sciences (2019): 400; 97-103. Doi: 10.1016/j.jns.2019.01.033. Age: this value is the average age of the patients reported in the article as specific patients could not be identified. Sex: patient sex was not identified in the article. Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Concomitant medical products: product id: 3389, lot #: unknown product type: lead. Product id: 3389, lot #: unknown product type: lead. Other relevant device(s) are: product id: 3389, serial/lot #: unknown. Product id: 3389, serial/lot #:

									unknown. If information is provided in the future, a supplemental report will be issued.
3007566237-2019-01211	14/03/2019	Injury	MEDTRONIC NEUROMODULATION	31/05/2019	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Break; Malposition of Device; Patient Device Interaction Problem	Infarction, Cerebral; Fatigue; Hematoma; Intracranial Hemorrhage; Hemorrhage, Subarachnoid; Paresis; Therapeutic Effects, Unexpected; Dysphasia	Summary: the authors present their operative experience of patients with movement disorders who developed intracerebral hemorrhage (ich), which was identified on intraprocedural stereotactic computed tomography (ct) imaging performed immediately after deep brain stimulation (dbs) lead placement and prior to the implantation of further components of the dbs hardware. Patients who underwent dbs lead implantation from january 2009 through december 2017 were included in the present study. Most of the surgeries were performed in a staged fashion. All patients were operated using identical surgical and intraprocedural imaging techniques, and no microelectrode recordings were done. Leksell stereotactic g frame and neuronavigation software was utilized for all surgeries. Intraprocedural stereotactic ct was performed to confirm the precise position of the implanted dbs lead and to rule out any hemorrhagic complications. Overall, 222 patients underwent 322 dbs lead implantations during 316 stereotactic procedures. Six patients exhibited early ich recognized on intraprocedural stereotactic ct performed immediately after dbs lead placement; in addition, two patients developed delayed ich due to large venous infarction. Four patients with ich were asymptomatic. The ich rate was 2.5% per electrode and 3.6% per patient; the permanent deficit rate was 1.2% per electrode and 1.8% per patient. The death rate due to ich in the cohort was 0.6% per electrode and 0.9% per patient. Intraprocedural stereotactic ct can not only visualize the implanted dbs lead in the stereotactic space but also rule out early ich. Identified predisposing factors for development of ich include patient's age, hypertension, and previous antiplatelet therapy. Careful planning of stereotactic trajectories plays a paramount role in reducing the rate of ich in dbs surgery.

									Reported events: a (b)(6) male patient implanted with dbs in the left subthalamic nucleus (stn) for pd experienced a hypertensive event during the surgery with peak blood pressure at 190/110 mmhg, despite well controlled pre-existing hypertension and continual blood pressure monitoring by anesthesiology team. Intraprocedural ct revealed a large left frontal subcortical hemorrhage and bleeding along the lead with hematoma at the left stn. The patient also experienced permanent right-sided hemiparesis and dysarthria related to the hemorrhage. The dysarthria improved, but the patient was wheelchair-bound over the next 4 years. Right-sided hemiparesis improved, and 4 years after hemorrhage, the patient could ambulate using a stick to ambulate small distances. All ichs resulted in significant prolongation of hospitalization, with mean hospital stay for symptomatic ich being 44.7 days. The patient required extensive rehabilitation during their prolonged hospital stay at the department of neurosurgery and, subsequently, in rehabilitation units. Relevant medical history included hypertension and advanced parkinson's disease. A (b)(6) male patient implanted with dbs in the right internal globus pallidus (gpi) for parkinson's disease (pd) experienced somnolence 26 hours after surgery. After pia coagulation and introduction of a guiding cannula to the target, venous bleeding from the subdural space anterior to the burr hole was observed. Introduction of surgicel anteriorly completely stopped the bleeding. Intraprocedural stereotactic ct visualized the lead in the proper place without any hemorrhage. Ct was performed after occurrence of somnolence which showed a large hemorrhagic venous infarction in the right frontal region. The patient experienced left mild hemiparesis as a result, and underwent right frontal craniotomy for hematoma evacuation. After two months, the patient was discharge. All

									ichs resulted in significant prolongation of hospitalization, with mean hospital stay for symptomatic ich being 44.7 days. The patient required extensive rehabilitation during their prolonged hospital stay at the department of neurosurgery and, subsequently, in rehabilitation units. Relevant medical history included hypertension, advanced parkinson's and antiplatelet medication. A (b)(6) female patient implanted with dbs in the left gpi for pd experienced mild venous bleeding which was stopped with surgicel and resulted in large left frontal, subcortically located hemorrhage due to cerebral venous infarction with transient dysarthria 8 hours after implant. The patient had word finding difficulties. Implant of the ins and extension were postponed until the next day. The dysarthria resolved completely over six weeks. The patient underwent successful contralateral gpi dbs four years after initial surgery, and two years after bilateral gpi dbs, the patient remains independent in daily living activities and without severe and disabling bilateral dyskinesia. All ichs resulted in significant prolongation of hospitalization, with mean hospital stay for symptomatic ich being 44.7 days. The patient required extensive rehabilitation during their prolonged hospital stay at the department of neurosurgery and, subsequently, in rehabilitation units. Relevant medical history included hypertension and advanced parkinson's. A (b)(6) female patient implanted with dbs in the right stn for pd experienced small paraventricular bleeding with no neurological deficits. Intracerebral hemorrhage (ich) was identified on intraprocedural stereotactic ct. The ich resulted in postponing the implantation of dbs hardware. All ichs resulted in significant prolongation of hospitalization, with mean hospital stay for asymptomatic ich being 8.5 days. Relevant medical history included hypertension, antiplatelet medication, and advanced parkinson's disease. A (b)(6)

									female patient implanted with dbs in the left stn for pd experienced large subarachnoid hemorrhage around the dbs lead and in the left sylvian fissure. There were no neurological deficits associated with the issue. The ich resulted in postponing the implantation of dbs hardware. All ichs resulted in significant prolongation of hospitalization, with mean hospital stay for asymptomatic ich being 8.5 days. Relevant medical history included hypertension and advanced parkinson's disease. A (b)(6) female patient implanted with dbs in the right stn for pd experienced small right subcortical hematoma. There were no neurological deficits associated with the issue. The ich resulted in postponing the implantation of dbs hardware. All ichs resulted in significant prolongation of hospitalization, with mean hospital stay for asymptomatic ich being 8.5 days. Relevant medical history included advanced parkinson's disease. A (b)(6) male patient implanted with dbs in the left stn for pd experienced hematoma along the entire stereotactic trajectory. The patient experienced hypertensive event with rise of blood pressure to approximately 180/120 mmhg during targeting. The patient developed poorly controlled hypertension in the subsequent months, so further stereotactic procedures were stopped. There were no neurological deficits associated with the issue. All ichs resulted in significant prolongation of hospitalization, with mean hospital stay for asymptomatic ich being 8.5 days. Relevant medical history included hypertension, antiplatelet medication, and advanced parkinson's disease. One patient implanted with dbs for pd had revision of intracranial electrode for suboptimal clinical effect related to leadBreakage. This patient suffered an injury to the left parietal region with subsequent damage to the lead just above the connector. No revisions led to any neurological sequel and in all revisions a new entry point and a new stereotactic

									trajectory were created. Three patients implanted with dbs for pd had revision of intracranial electrode for suboptimal clinical effect related to leadBreakage. The leads had to be replaced due toBreakage of the extracranial part of the lead. No revisions led to any neurological sequel and in all revisions a new entry point and a new stereotactic trajectory were created. Two patients implanted with dbs for advanced pd had revisions of intracranial electrodes due to suboptimal clinical benefit over the follow-up period. One lead was found to be placed more medial and was repositioned 2 mm lateral while in the other the lead was found to be anterior, lateral, and superficial to the intended target of the stn. No revisions led to any neurological sequel and in all revisions a new entry point and a new stereotactic trajectory were created. The following device information was identified in the article: lead model 3389; ins models 37602, 37603, 7426. Manufacturer narrative: sobstyl, m., alksandrowicz, m., zabek, m., pasterski, t. Hemorrhagic complications seen on immediate intraprocedural stereotactic computed tomography imaging during deep brain stimulation implantation. Journal of the neurological sciences (2019): 400; 97-103. Doi: 10.1016/j.jns.2019.01.033. Age, sex : patient age and sex were not identified in the article. Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Concomitant medical products: product id: 3389, lot #: unknown, product type: lead. Product id: 3389, lot #: unknown, product type: lead. Product id: 3389, lot #: unknown, product type: lead. Product id: 3389, lot #: unknown, product type: lead. Product id: 3389, lot #: unknown, product type: lead. Product id: 3389, lot #: unknown, product type: lead. Product id: 3389, lot #: unknown, product type: lead. Product id: 3389, lot #: unknown, product type: lead. Product id: 3389, lot #: unknown, product type: lead. Product id:

									3389, lot #: unknown, product type: lead. Product id: 3389, lot #: unknown, product type: lead. Other relevant device(s) are: product id: 3389, serial/lot #: unknown, udi #: asku. Product id: 3389, serial/lot #: unknown, udi #: asku. Product id: 3389, serial/lot #: unknown, udi #: asku. Product id: 3389, serial/lot #: unknown, udi #: asku. Product id: 3389, serial/lot #: unknown, udi #: asku. Product id: 3389, serial/lot #: unknown, udi #: asku. Product id: 3389, serial/lot #: unknown, udi #: asku. Product id: 3389, serial/lot #: unknown, udi #: asku. Product id: 3389, serial/lot #: unknown, udi #: asku. Product id: 3389, serial/lot #: unknown, udi #: asku. If information is provided in the future, a supplemental report will be issued.
3007566237-2019-01206	14/03/2019	Injury	MEDTRONIC NEUROMODULATION	31/05/2019	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Malposition of Device	Intracranial Hemorrhage; Paresis; Therapeutic Effects, Unexpected; Dysphasia; Shaking/Tremors; Sleep Dysfunction	Summary: the authors present their operative experience of patients with movement disorders who developed intracerebral hemorrhage (ich), which was identified on intraprocedural stereotactic computed tomography (ct) imaging performed immediately after deep brain stimulation (dbs) lead placement and prior to the implantation of further components of the dbs hardware. Patients who underwent dbs lead implantation from january 2009 through december 2017 were included in the present study. Most of the surgeries were performed in a staged fashion. All patients were operated using identical surgical and intraprocedural imaging techniques, and no microelectrode recordings were done. Leksell stereotactic g frame and neuronavigation software was utilized for all surgeries. Intraprocedural stereotactic ct was performed to confirm the precise position of the implanted dbs lead and to rule out any hemorrhagic complications. Overall, 222 patients underwent 322 dbs lead implantations during 316 stereotactic procedures. Six patients exhibited early ich recognized on intraprocedural stereotactic ct performed immediately after dbs lead placement; in addition, two patients developed delayed

									ich due to large venous infarction. Four patients with ich were asymptomatic. The ich rate was 2.5% per electrode and 3.6% per patient; the permanent deficit rate was 1.2% per electrode and 1.8% per patient. The death rate due to ich in the cohort was 0.6% per electrode and 0.9% per patient. Intraprocedural stereotactic ct can not only visualize the implanted dbs lead in the stereotactic space but also rule out early ich. Identified predisposing factors for development of ich include patient's age, hypertension, and previous antiplatelet therapy. Careful planning of stereotactic trajectories plays a paramount role in reducing the rate of ich in dbs surgery. Reported events: (b)(6) year old female patient implanted with deep brain stimulation (dbs) in the left posterior subthalamic area (psa) for essential tremor (et) experienced large left frontal subcortical hemorrhage and bleeding along the dbs lead as evidenced by intraprocedural stereotactic ct. It was noted the same burr hole previously drilled for left-sided thalamotomy was used for lead implant. The patient experienced restlessness, right hemiparesis and dysarthria related to the issue. All ichs resulted in significant prolongation of hospitalization, with mean hospital stay for symptomatic ich being 44.7 days. The patient required extensive rehabilitation during their prolonged hospital stay at the department of neurosurgery and, subsequently, in rehabilitation units. Relevant medical history included hypertension and antiplated medications. One patient implanted with dbs for et was re-implanted due to suboptimal anti-tremor in the early postoperative period. One patient implanted with dbs for holmes's tremor was re-implanted due to suboptimal anti-tremor in the early postoperative period. Two patients implanted with dbs for et had leads found located medial to the stereotactic target and lateral repositioning of the leads by 2 mm resulted in good

									tremor control. The following device information was identified in the article: lead model 3389; ins models 37602, 37603, 7426. Manufacturer narrative: device brand name and common device name: these fields were not populated in the initial report. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: sobstyl, m., alksandrowicz, m., zabek, m., pasterski, t. Hemorrhagic complications seen on immediate intraprocedural stereotactic computed tomography imaging during deep brain stimulation implantation. Journal of the neurological sciences (2019): 400; 97-103. Doi: 10.1016/j.jns.2019.01.033. Specific patient age and sex are noted for events in which these fields could be determined. Average age and cohort sex distribution were not reported in the literature article. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Concomitant medical products: product id: 3389, lot# unknown, product type lead. Other relevant device(s) are: product id: 3389, serial/lot #: unknown, udi#: asku. If information is provided in the future, a supplemental report will be issued. (b)(4).
3007566237-2019-01209	14/03/2019	Injury	MEDTRONIC NEUROMODULATION	31/05/2019	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Malposition of Device	No Known Impact Or Consequence To Patient	Summary: the authors present their operative experience of patients with movement disorders who developed intracerebral hemorrhage (ich), which was identified on intraprocedural stereotactic computed tomography (ct) imaging performed immediately after deep brain stimulation (dbs) lead placement and prior to the implantation of further components of the dbs hardware. Patients who underwent dbs lead implantation from january 2009 through december 2017 were included in the present study. Most of the surgeries were performed in a staged fashion. All patients were operated using identical surgical and intraprocedural imaging techniques, and no microelectrode recordings were done. Leksell stereotactic g

									frame and neuronavigation software was utilized for all surgeries. Intraprocedural stereotactic ct was performed to confirm the precise position of the implanted dbs lead and to rule out any hemorrhagic complications. Overall, 222 patients underwent 322 dbs lead implantations during 316 stereotactic procedures. Six patients exhibited early ich recognized on intraprocedural stereotactic ct performed immediately after dbs lead placement; in addition, two patients developed delayed ich due to large venous infarction. Four patients with ich were asymptomatic. The ich rate was 2.5% per electrode and 3.6% per patient; the permanent deficit rate was 1.2% per electrode and 1.8% per patient. The death rate due to ich in the cohort was 0.6% per electrode and 0.9% per patient. Intraprocedural stereotactic ct can not only visualize the implanted dbs lead in the stereotactic space but also rule out early ich. Identified predisposing factors for development of ich include patient's age, hypertension, and previous antiplatelet therapy. Careful planning of stereotactic trajectories plays a paramount role in reducing the rate of ich in dbs surgery. Reported events: three patients implanted with dbs had immediate lead revision after intraprocedural ct revealed suboptimal locations. In all three cases, the electrodes targeting the left stn were located just anterior and medial to the stereotactic target. The following device information was identified in the article: lead model 3389; ins models 37602, 37603, 7426. Manufacturer narrative: sobstyl, m., alksandrowicz, m., zabek, m., pasterski, t. Hemorrhagic complications seen on immediate intraprocedural stereotactic computed tomography imaging during deep brain stimulation implantation. Journal of the neurological sciences (2019): 400; 97-103. Doi: 10.1016/j.jns.2019.01.033. Age or date of birth, sex: patient age and sex were not reported in the article. Date of event: please note that this date is based

									off of the date of publication of the article as the event dates were not provided in the published literature. Concomitant medical products: product id: 3389, lot #: unknown, product type: lead. Other relevant device(s) are: product id: 3389, serial/lot #: unknown, udi #: asku. If information is provided in the future, a supplemental report will be issued.
9259743	28/02/2019	Malfunction	PAJUNK GMBH MEDIZINTECHNOLOGIE	31/10/2019	HAW	DISPOSABLE BIOPSY NEEDLE	Difficult to Open or Close	No Known Impact Or Consequence To Patient	Dr. Performed a stereotactic biopsy on this pt where he uses the disposable biopsy needle kit. Ref#41778c. Biopsy needle malfunctioned. The tip was not opening and closing as instructed on port. Drs did troubleshoot the issue and noted it was not functioning properly. Did not use this biopsy needle once noted.
1723170-2020-00743	27/02/2019	Malfunction	MEDTRONIC NAVIGATION, INC	03/03/2020	HAW	PLANNING STATION	Mechanical Problem	No Known Impact Or Consequence To Patient	Medtronic received information regarding a navigation system being used for a stereotactic deep brain stimulation (dbs) procedure. It was reported that pre-operative planning based on magnetic resonance imaging (mri) sequences was done the day before; on the day of the event, stereotactic computed tomography (ct) scans were performed and saved in the local electronic picture archiving and communication systems (pacs) system. Download of one ct scans with about 500 slices as successful. After clicking on the ct scan, and defining it as reference sequence, the error message "warning: low system memory" occurred. The merge could be done. The surgeon deleted the ct scan and 1-2 mri sequences and rebooted the system. After restarting the system and choosing another second ct scan, the planning could be done. The procedure was completed using navigation and there was no reported impact to patient outcome. There was a reported delay to the procedure of less than one hour due to this issue. Manufacturer narrative: patient information was unavailable from the site. Other relevant device(s) are: product id: 9735737, version #: (b)(4). Report source foreign country: (b)(6). The software investigation found that the reported event was related to a software issue. This issue

									was documented in a medtronic navigation software anomaly tracking database. If information is provided in the future, a supplemental report will be issued.
1723170-2019-02700	21/02/2019	Injury	MEDTRONIC NAVIGATION, INC	28/05/2019	HAW	S7 STEALTHSTATION NAVIGATION SYSTEM	Adverse Event Without Identified Device or Use Problem	Neurological Deficit/Dysfunction	Citation: krishnapundha bunyaratavej & piyanat wangsawatwong (2019): catheter guided cerebral glioma resection combined with awake craniotomy: its usefulness and surgical outcome, british journal of neurosurgery, doi: 10.1080/02688697.2019.1587380. Summary: purpose: a challenging aspect of glioma surgery is to distinguish tumour tissue from surrounding eloquent structures and perform resection with accuracy. Various technologies have been used to address this issue including neuronavigator, intraoperative magnetic resonant imaging, intraoperative ultrasound, and fluorescence, each of which has certain drawbacks and limitations. In this study, authors demonstrate the technique of using stereotactically placed catheters as guidance during cerebral glioma resection and report the surgical outcomes. Materials and methods: this study included patients with intrinsic cerebral tumour adjacent to the eloquent structures. Catheter trajectories were planned using three-dimensional cerebral reconstruction on navigation software and catheters were stereotactically placed to mark the intended extent of resection. All craniotomies were performed in awake fashion under neurophysiologic mapping and continuous physical examination for safe maximal resection. Clinical outcome and intended versus actual extent of resection were analysed. Results: between january 2015 and december 2016, 15 consecutive patients (8 males and 7 females) with intrinsic cerebral tumour underwent craniotomy with this technique. Median age was 43 years. Seven patients (46.7%) had worsening neurological status within 24 h postoperatively. Of these 7 patients, 6 patients (85.7%) regained preoperative neurological status by 6 months. The

									intended extent of resections were total, subtotal and partial in 3 (20%), 9 (60%), and 3 (20%) patients, respectively. The actual extent of resections were total, subtotal and partial in 3 (20%), 8(53.3%), and 4 (26.7%) patients, respectively. There were no catheter related complications. There was no 30-day postoperative mortality. Conclusions: catheter guided resection along with awake surgery and neurophysiologic monitoring is a valid technique for infiltrative tumour, especially for ones locating near eloquent structures where the margin of error is low. This is a simple and economical. Reported events: (b)(6) female expired four months post operation from tumour progression. The patient was noted to have no immediate post-operative decline. (b)(6) female had worsening neurological status within 24 hours postoperative where pre-operative neurological status by six months. (b)(6) female had worsening neurological status within 24 hours postoperative where pre-operative neurological status by six months. (b)(6) male had worsening neurological status within 24 hours postoperative where pre-operative neurological status by six months. (b)(6) male had worsening neurological status within 24 hours postoperative where pre-operative neurological status by six months. (b)(6) male had worsening neurological status within 24 hours postoperative where pre-operative neurological status by six months. (b)(6) male had worsening neurological status within 24 hours postoperative where patient was lost to follow-up after 2-month visit. (b)(6) male had worsening neurological status within 24 hours postoperative where pre-operative neurological status by six months. Manufacturer narrative: age or date of birth: patient age is the mean value of patients involved in the study. Sex: patient sex is the majority value between male/female in the study. Weight: patient weight not available from the site. Date of event: event date reported is the accepted

									date of the article. Procedures were conducted between (b)(6) 2015 and (b)(6) 2016. Device evaluated by mfr: no parts have been received by the manufacturer for evaluation. Manufacture date: device manufacture date is unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2019-02702	21/02/2019	Death	MEDTRONIC NAVIGATION, INC	28/05/2019	HAW	S7 STEALTHSTATION NAVIGATION SYSTEM	Adverse Event Without Identified Device or Use Problem	Death	Citation: krishnapundha bunyaratavej & piyanat wangsawatwong (2019): catheter guided cerebral glioma resection combined with awake crani otomy: its usefulness and surgical outcome, british journal of neurosurgery, doi: 10.1080/02688697.2019.1587380. Summary: purpose: a challenging aspect of glioma surgery is to distinguish tumour tissue from surrounding eloquent structures and perform resection with accuracy. Various technologies have been used to address this issue including neuronavigator, intraoperative magnetic resonant imaging, intraoperative ultrasound, and fluorescence, each of which has certain drawbacks and limitations. In this study, authors demonstrate the technique of using stereotactically placed catheters as guidance during cerebral glioma resection and report the surgical outcomes. Materials and methods: this study included patients with intrinsic cerebral tumour adjacent to the eloquent structures. Catheter trajectories were planned using three-dimensional cerebral reconstruction on navigation software and catheters were stereotactically placed to mark the intended extent of resection. All craniotomies were performed in awake fashion under neurophysiologic mapping and continuous physical examination for safe maximal resection. Clinical outcome and intended versus actual extent of resection were analysed. Results: between january 2015 and december 2016, 15 consecutive patients (8 males and 7 females) with intrinsic cerebral tumour underwent craniotomy with this technique. Median age was 43 years. Seven patients (46.7%) had

									worsening neurological status within 24 h postoperatively. Of these 7 patients, 6 patients (85.7%) regained preoperative neurological status by 6 months. The intended extent of resections were total, subtotal and partial in 3 (20%), 9 (60%), and 3 (20%) patients, respectively. The actual extent of resections were total, subtotal and partial in 3 (20%), 8(53.3%), and 4 (26.7%) patients, respectively. There were no catheter related complications. There was no 30-day postoperative mortality. Conclusions: catheter guided resection along with awake surgery and neurophysiologic monitoring is a valid technique for infiltrative tumour, especially for ones locating near eloquent structures where the margin of error is low. This is a simple and economical reported events: (b)(6) female expired four months post operation from tumour progression. The patient was noted to have no immediate post-operative decline. (b)(6) female had worsening neurological status within 24 hours postoperative where pre-operative neurological status by six months. (b)(6) female had worsening neurological status within 24 hours postoperative where pre-operative neurological status by six months. (b)(6) male had worsening neurological status within 24 hours postoperative where pre-operative neurological status by six months. (b)(6) male had worsening neurological status within 24 hours postoperative where pre-operative neurological status by six months. (b)(6) male had worsening neurological status within 24 hours postoperative where pre-operative neurological status by six months. (b)(6) male had worsening neurological status within 24 hours postoperative where patient was lost to follow-up after 2-month visit. (b)(6) male had worsening neurological status within 24 hours postoperative where pre-operative neurological status by six months. Manufacturer narrative: patient weight not available from the site. Date of death not provided. Event date of reported

									issue used as date of death. Value was noted to be 4 months after their procedure was conducted. Event date is the accepted date by the publication. No parts have been received by the manufacturer for evaluation. Device manufacture date is unavailable. If information is provided in the future, a supplemental report will be issued.
1220984-2019-00019	21/02/2019	Malfunction	HOLOGIC, INC	13/03/2019	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was reported that the c-arm continued to move after letting go of the drive button. No injury reported. A field engineer was dispatched to the site and it was determined that the linear actuator needs to be replaced.
1220984-2019-00018	21/02/2019	Malfunction	HOLOGIC, INC	13/03/2019	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was reported that the table intermittently moves by itself. No injury reported. A field engineer was dispatched to the site and determined that the membrane switch needs to be replaced.
9611612-2019-00036	15/02/2019	Malfunction	PAJUNK GMBH MEDIZINTECHNOLOGIE	15/11/2019	HAW	DISPOSABLE BIOPSY NEEDLE WITH MARKER PLATES	Difficult to Open or Close	No Known Impact Or Consequence To Patient	Irn#: (b)(4). User facility report number: (b)(4). Describe the event or problem: or . Performed a stereotactic biopsy on this pt where he uses the disposable biopsy needle kit. Ref# (b)(4). Biopsy needle malfunctioned . The tip was not opening and closing as instructed on port. Drs did troubleshoot the issue and noted it was not functioning properly. Did not use this biopsy needle once noted. What was the original intended procedure?: stereotactic biopsy. Vlhat problem did the user have (check all that apply): device malfunction - that is, the device did not do what it was supposed to do; the device is manufactured by (b)(4) gmbh medizintechnologie exclusively for brainlab ag and distributed through brainlab in the united states of america. Manufacturer narrative: device is manufactured exclusively for brainlab ag to be used with the stereotactic and navigation instruments. Currently the data is quite poor and investigations are ongoing. Mfr (b)(4) gmbh medizintechnologie is in contact with the initially reporting hospital as well as with distributor/ customer brainlab in order to find out more details.

									Trend analysis as well as batch record do not indicate any adverse result nor abnormality. This is the first reported incident of this kind with the reported device malfunction. The device urgently needs to be analyzed. As soon as more information is available an updated report will be sent in to the food and drug administration.
8358887	14/02/2019	Malfunction	HOLOGIC, INC.	21/02/2019	IZH	AFFIRM BREAST BIOPSY GUIDANCE SYSTEM	Positioning Failure	Fainting	The stereotactic biopsy attempt failed to target the area of interest of calcifications. An attempt was made in the lateral approach to the breast tissue. As the biopsy device was being dialed into the target area. Staff noticed the numbers for the target were not what was expected, and the patient commented at the same time that she felt some pressure on the other side of her breast which is not normal. At that time the patient became vasovagal and we stopped the procedure to tend to her. The nurse navigator was called to treat the patient with smelling salts, cold compresses and ginger ale. No injuries occurred. Service was called. The quality control for the stereotactic was performed the morning of the procedure per protocol passed with no issues. The patient's biopsy was completed in the back up procedure room once the patient was feeling better.
3007566237-2019-01215	13/02/2019	Injury	MEDTRONIC NEUROMODULATION	31/05/2019	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	High impedance; Malposition of Device; Battery Problem	Erosion; Headache; Hemorrhage, Intraventricular; Therapeutic Response, Decreased	Summary: the authors present long-term follow-up results and analysis of stimulation sites of a prospective cohort study of six patients with chronic cluster headaches undergoing deep brain stimulation of the ipsilateral posterior hypothalamic region. The primary endpoint was the postoperative change in the composite headache severity score ¿¿headache load¿¿ after 12 months of chronic stimulation. Secondary endpoints were the changes in headache attack frequency, headache attack duration and headache intensity, quality of life measures at 12, 24, and 48 months following surgery. Stimulating contact positions were analysed and projected onto the stereotactic atlas of schaltenbrand and wahren. There was a

									significant reduction of headache load of over 93% on average at 12 months postoperatively that persisted over the follow-up period of 48 months (p=0.0041) and that was accompanied by a significant increase of reported quality of life measures (p=0.03). Anatomical analysis revealed that individual stimulating electrodes were located in the red nucleus, posterior hypothalamic region, mesencephalic pretectal area and centromedian nucleus of the thalamus. The authors' findings con firming long-term effectiveness of deep brain stimulation for chronic cluster headaches suggest that the neuroanatomical substrate of deep brain stimulation-induced headache relief is probably not restricted to the posterior hypothalamic area but encompasses a more widespread area. Reported events: patient 1: a (b)(6) year old male patient implanted with deep brain stimulation (dbs) for cluster headaches (ch) had parts of the system removed due to lead erosion through the skin. The system had been turned off/non-functioning for two years before the last follow-up at 140 months. Patient 3: a (b)(6) year old male patient implanted with left-sided dbs for ch presented with recurrence of cluster headaches after more than 9 years. Investigations of the system revealed a low battery status and impedance checks revealed high values out of range across all contacts. After successful complete revision and exchange of the system he returned to a headache free state at last follow-up at 138 months. Patient 4: a (b)(6) year old male patient implanted with right-sided dbs for ch experienced a return of severe headache load level of daily attacks. In a revision surgery after 14 months post-operation, the lead was retracted 3 mm. The patient was again pain-free for 4 months after this revision until headaches returned at lower frequency. The parameters were adjusted several times and the patient returned back to an almost pain free state at 3 years and remained almost pain free until last follow-

									up at 114 months post initial surgery. The patient reported mild headache attacks twice a year, which was not comparable to his situation pre-dbs. There were three instanced of ventricular haemorrhage. It was noted on the background of the third instance and the delicate are of dbs implant in the patient cohort, it was decided not to revise the leads immediately but to wait to see how the patients would respond clinically to the stimulation. The following device information was identified in the literature article: lead model 3389. Manufacturer narrative: report source: (b)(6). If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: nowacki, a., moir, l., owen, s.l.f., fitzgerald, j.j., green, a.l, aziz, t.z. Deep brain stimulation of chronic cluster headaches: posterior hypothalamus, ventral tegmentum and beyond. Cephalagia (2019). Doi: 10.1177/0333102419839992. Age: this value is the average age of the patients reported in the article and specific age is noted in when it could be determined. Sex: this value reflects the gender of the majority of the patients reported in the article and specific patient sex is noted in when it could be determined. Date of event: please note that this date is based off of the date that the article was accepted for publication as the event dates and publication date were not provided in the published literature. Procode/pma: patients were implanted for chronic cluster headaches, which is an off-label indication. Concomitant medical products: product id: 3389, lot# unknown, product type: lead. Product id: 3389, lot# unknown, product type: lead. Product id: neu_ins_stimulator, lot# unknown, product type: implantable neurostimulator. Product id: neu_unknown_ext, lot# unknown, product type: extension. Product id: 3389, lot# unknown, product type: lead. Product id: 3389, lot# unknown, product type: lead. Other relevant device(s) are: product id: 3389, serial/lot #: unknown. Product id:

									3389, serial/lot #: unknown. Product id: neu_unknown_ext, serial/lot #: unknown. Product id: neu_ins_stimulator, serial/lot #: unknown. Product id: 3389, serial/lot #: unknown. Product id: 3389, serial/lot #: unknown. If information is provided in the future, a supplemental report will be issued.
3007566237-2019-01216	13/02/2019	Malfunction	MEDTRONIC NEUROMODULATION	31/05/2019	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Malposition of Device	No Known Impact Or Consequence To Patient	Nowacki, a., moir, l., owen, s.l.f., fitzgerald, j.j., green, a.l, aziz, t.z. Deep brain stimulation of chronic cluster headaches: posterior hypothalamus, ventral tegmentum and beyond. Cephalagia (2019). Doi: 10.1177/0333102419839992 summary: the authors present long-term follow-up results and analysis of stimulation sites of a prospective cohort study of six patients with chronic cluster headaches undergoing deep brain stimulation of the ipsilateral posterior hypothalamic region. The primary endpoint was the postoperative change in the composite headache severity score ¿¿headache load¿¿ after 12 months of chronic stimulation. Secondary endpoints were the changes in headache attack frequency, headache attack duration and headache intensity, quality of life measures at 12, 24, and 48 months following surgery. Stimulating contact positions were analysed and projected onto the stereotactic atlas of schaltenbrand and wahren. There was a significant reduction of headache load of over 93% on average at 12 months postoperatively that persisted over the follow-up period of 48 months (p=0.0041) and that was accompanied by a significant increase of reported quality of life measures (p=0.03). Anatomical analysis revealed that individual stimulating electrodes were located in the red nucleus, posterior hypothalamic region, mesencephalic pretectal area and centromedian nucleus of the thalamus. The authors' findings con firming long-term effectiveness of deep brain stimulation for chronic cluster headaches suggest that the neuroanatomical substrate of deep brain stimulation-induced headache relief is probably not restricted to the posterior

									hypothalamic area but encompasses a more widespread area. Reported events: six patients implanted with dbs for ch experienced targeting error. The authors' targeting coordinates were reported to be 2mm lateral, 6mm posterior and 8mm below the midcommissural point (mcp); however, the actual position was on average more posterior (-7.8 mm) and superior (-1.9 mm) than intended and showed in general a considerable spread around the average contact position. Analysis of the targeting error showed that 3 leads had a targeting error of more than 3 mm with a predominantly posterior shift of the actual lead position compared to the intended target, which the authors were not able to explain. The mean vector of error was 2.90 mm. The following device information was identified in the literature article: lead model 3389. Manufacturer narrative: nowacki, a., moir, l., owen, s.l.f., fitzgerald, j.j., green, a.l, aziz, t.z. Deep brain stimulation of chronic cluster headaches: posterior hypothalamus, ventral tegmentum and beyond. Cephalagia (2019). Doi: 10.1177/0333102419839992. Age or date of birth: this value is the average age of the patients reported in the article as specific patients could not be identified. Sex: this value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event: please note that this date is based off of the date that the article was accepted for publication as the event dates and publication date were not provided in the published literature. Procode/pma: patients were implanted for chronic cluster headaches, which is an off-label indication. Concomitant medical products: product id: 3389, lot# unknown, product type: lead. Product id: 3389, serial/lot #: unknown. If information is provided in the future, a supplemental report will be issued. (b)(4).
8358891	11/02/2019	Malfunction	HOLOGIC, INC	21/02/2019	IZH	AFFIRM BREAST BIOPSY	Positioning Failure	No Known Impact Or	The stereotactic biopsy attempt failed to target the area of interest of calcifications with 2 attempts. An attempt was made in

						GUIDANCE SYSTEM		Consequence To Patient	the superior approach to the breast tissue. Tissue was extracted and x-rayed with no calcifications being seen in the samples. The patient was then repositioned in the lateral medial approach. Tissue was extracted and x-rayed with no calcifications seen in the sample again. The patient was then sent to ultrasound to attempt sampling of the area and was successful. The quality control for the stereotactic was performed the morning of the procedure per protocol passed with no issues.
1723170-2019-02632	01/02/2019	Injury	MEDTRONIC NAVIGATION, INC	24/05/2019	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Hemorrhage, Intraventricular ; Neurological Deficit/Dysfunction	Citation: world neurosurg. (2019) 122: e723-e728. Background: placement of intraventricular catheters in oncology patients is associated with high complication rates. Placing ommaya reservoirs with the zero-error precision protocol (zepp), a combination of neuronavigation (axiem stereotactic navigation) and direct verification of catheter tip placement with a flexible neuroendoscope,is associated with decreased complication rates as a result of increased catheter placement accuracy. However, the zepp costs more than traditional methods of catheter placement, and the question of whether this increased accuracy with the zepp is cost-effective is unknown. Methods: we performed a single-center retrospective chart review of 50 consecutive ommaya reservoir patient placements between 2010 and 2017. Twenty-five ventricular catheters were placed using the zepp protocol, and 25 ventricular catheters were placed using only axiem stealth navigation. Postoperative catheter accuracy and complication rates were assessed. A cost-benefit analysis was then conducted to determine if the overall cost for placing ommaya reservoirs with the zepp was effective compared with the alternative method of using neuronavigation alone. Results: in the non-zepp cohort, 10 of 25 catheters were placed within the optimal location compared with 25 of 25 catheters placed in the zepp cohort. Three complications

									occurred in the non-zepp cohort: 2 malpositioned catheters required surgical revision and 1 catheter-related hemorrhage resulted in a prolonged stay in the intensive care unit. No complications occurred in the zepp cohort. A cost-benefit analysis showed $4784 savings per patient with zepp utilization because of the high complication associated costs. Conclusions: implementation of the zepp for verifying ventricular catheter placement in ommaya reservoirs improved catheter tip accuracy, resulted in lower complication rates, and was more cost-effective when compared with the non-zepp cohort, which used only neuronavigation. The zepp can be used for ventricular shunt catheter placement to decrease complications and verify catheter tip accuracy in ommaya or standard ventriculoperitoneal shunts. Adverse events: the non-zepp group had a 40% success rate for optimal catheter localization (10/25). The non-zepp group also had a 12% complication rate (3/25). One patient suffered an intraventricular hemorrhage with neurologic deficit from multiple ventricular catheter passes that were done without neuroendoscopy before finally encountering csf. 2 other patients had parenchymal catheter tip location, necessitating a return to the operating room for surgical revision. Manufacturer narrative: additional review of the reported issue found that the reported literature file was previously reported under mdr 17 23170-2019-02262. Please refer to 1723170-2019-02262 in regards to the reported event. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: age or date of birth: the patient age is the average age of the 25 patients. Sex: there were 11 male patients and 14 female patients. Weight: patient weight not available from the site. Date of event: event date is approximated as it was reported that the surgeries were completed between (b)(6) 2010 and (b)(6) 2015. Lot #, serial #: device lot number, or

									serial number, unavailable. Udi #: udi not available for this system at time of filing. Device evaluated by mfr: the device was not returned, so no analysis was conducted. If information is provided in the future, a supplemental report will be issued.
3008492462-2019-00013	01/02/2019	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	01/03/2019	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE	Failure to Obtain Sample	No Consequences Or Impact To Patient	Devicor medical products, inc. Received a report stating, "probe sucked tissue into the canister instead of the individual chambers". No patient consequences reported. This has been documented in our system as record # (b)(4). Manufacturer narrative: mst1009 probes are sterile, single use devices, indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis of breast abnormalities. The device was not returned to devicor medical products, inc. For evaluation. Therefore we are unable to determine a root cause for the reported incident. If the tissue is found within the canister rather than in the sample management system, a misdiagnosis is possible due to lost tissue. Following consultation with our medical director, due to the potential to cause or contribute to death or serious injury as a result of potential missed or lost tissue samples, pursuant to 21 cfr §803, this failure mode was determined to be a reportable malfunction.
3008492462-2019-00010	01/02/2019	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	28/02/2019	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROB	Unsealed Device Packaging	No Consequences Or Impact To Patient	Devicor medical products, inc. Received a report from our affiliate devicor medical france, stating before the procedure the disposable box was already open and the device not sterile. No patient involvement. This has been documented in our system as record # (b)(4). Manufacturer narrative: the revolve stereotactic probe is a sterile, single-patient use device that may be used with imaging guidance to excise a tissue sample for diagnosis. The device has not been returned for investigation. No adverse event occurred with the usage of this product. Due to the open package that can potentially affect sterility, we consider this event to be a product malfunction that if it were to recur, has the potential to cause or contribute to a serious injury.

3008492462-2019-00012	28/01/2019	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	28/02/2019	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE - 10G	Failure to Obtain Sample	No Consequences Or Impact To Patient	Devicor medical products, inc. Received a report from affiliate, devicor medical japan stating, the samples obtained during the procedure were small, upon checking the canister there were tissue samples in the canister. No patient complications. This has been documented in our complaint system as record # (b)(4). Manufacturer narrative: mst1009 probes are sterile, single use devices, indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis of breast abnormalities. The device was not returned to devicor medical products, inc. For evaluation. Therefore we are unable to determine a root cause for the reported incident. If the tissue is found within the canister rather than in the sample management system, a misdiagnosis is possible due to lost tissue. Following consultation with our medical director, due to the potential to cause or contribute to death or serious injury as a result of potential missed or lost tissue samples, pursuant to 21 cfr §803, this failure mode was determined to be a reportable malfunction.
1220984-2019-00036	24/01/2019	Malfunction	HOLOGIC, INC	12/04/2019	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was initially reported on (b)(6) 2019 that the table was stuck in top position. No injury reported. Additional information received on 01/31/2019 noted that after moving the table down it drives up by itself. A field engineer was dispatched to the site and determined the power control board needed to be replaced. Once this was completed the system was working as intended.
1222780-2019-00036	23/01/2019	Malfunction	HOLOGIC, INC.	20/02/2019	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Deformation Due to Compressive Stress	No Consequences Or Impact To Patient	It was initially reported that during a biopsy procedure, the "introducer plastic sheath was broken when trying to remove probe needle from the breast, prior to deploying clip." additional information was obtained that the introducer sheath came out of the breast with the removal of the needle and was noted to be crumpled. A second needle and introducer were obtained and the biopsy was completed successfully and a marker clip was placed. No injury or misdiagnosis reported. Manufacturer

									narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. If the device is returned and evaluation completed, a supplemental medwatch will be filed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications. Internal complaint reference: (b)(4).
1222780-2019-00040	22/01/2019	Malfunction	HOLOGIC, INC.	26/02/2019	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Leak/Splash; Failure to Obtain Sample	No Consequences Or Impact To Patient	It was reported that during a biopsy procedure "saline was spraying out where the numbers are displayed and no tissue samples were able to be taken". No patient or user harm was reported. A second device completed the procedure successfully. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. If the device is returned and evaluation completed, a supplemental medwatch will be filed. Device history record (dhr) review was conducted for the identified lot number and serial number of the disposable device. No abnormalities were found related to the reported information. This device passed final testing prior to release. Internal complaint reference: (b)(4).
1723170-2019-02729	21/01/2019	Injury	MEDTRONIC NAVIGATION, INC	28/05/2019	HAW	STEALTHSTATION® S7	Adverse Event Without Identified Device or Use Problem	Hemorrhage, Cerebral; Paresis; Dysphasia	Citation: sobstyl, m., aleksandrowicz, m., zabek, m., & pasterski, t. (2019). Hemorrhagic complications seen on immediate intraprocedural stereotactic computed tomography imaging during deep brain stimulation implantation. Journal of the neurological sciences, 400, 97-103. Doi:10.1016/j.jns.2019.01.033. Background: we present our operative experience of patients with movement disorders who developed intracerebral hemorrhage (ich), which was identified on intraprocedural stereotactic computed tomography (ct) imaging performed immediately after deep brain stimulation (dbs) lead placement and prior to the implantation of further components of the dbs hardware. Methods: patients who underwent dbs lead implantation from

									january 2009 through december 2017 were included in the present study. Most of the surgeries were performed in a staged fashion. All patients were operated using identical surgical and intraprocedural imaging techniques, and no microelectrode recordings were done. Leksell stereotactic g frame and neuronavigation software was utilized for all surgeries. Intraprocedural stereotactic ct was performed to confirm the precise position of the implanted dbs lead and to rule out any hemorrhagic complications. Results: overall, 222 patients underwent 322 dbs lead implantations during 316 stereotactic procedures. Six patients exhibited early ich recognized on intraprocedural stereotactic ct performed immediately after dbs lead placement; in addition, two patients developed delayed ich due to large venous infarction. Four patients with ich were asymptomatic. The ich rate was 2.5% per electrode and 3.6% per patient; the permanent deficit rate was 1.2% per electrode and 1.8% per patient. The death rate due to ich in our cohort was 0.6% per electrode and 0.9% per patient. Conclusions: intraprocedural stereotactic ct can not only visualize the implanted dbs lead in the stereotactic space but also rule out early ich. Identified predisposing factors for development of ich include patient's age, hypertension, and previous antiplatelet therapy. Careful planning of stereotactic trajectories plays a paramount role in reducing the rate of ich in dbs surgery. Adverse events 8 patients had intracranial hemorrhages (4 asymptomatic and 4 were symptomatic). A (b)(6) male patient with hypertension and advanced parkinson's disease had permanent right sided paresis still present 4 years after the surgery. The patient was wheelchair bound and ambulates with a stick small distances. A (b)(6) female with hypertension and advanced parkinson's disease had transient dysarthria which completely resolved over a 6 week period. A (b)(6) female with hypertension, antiplated medication and

									advanced parkinson's disease had no neurological deficits. A (b)(6) female with hypertension and advanced parkinson's disease had no neurological deficits. A (b)(6) female with advanced parkinson's disease had no neurological deficits. A (b)(6) male with hypertension, antiplated medication and advanced parkinson's disease had no neurological deficits. There was no alleged malfunction of the navigation device. Manufacturer narrative: patient information: patient information is provided in event description. Date of event: event date is approximated as it was reported to have occurred between (b)(6) 2009 and (b)(6) 2017. Lot #, serial #: device lot number, or serial number, unavailable. Device evaluated by mfr: the device was not returned, so no analysis was conducted. Manufacture date: device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2019-02731	21/01/2019	Death	MEDTRONIC NAVIGATION, INC	28/05/2019	HAW	STEALTHSTATION® S7	Adverse Event Without Identified Device or Use Problem	Bradycardia; Hemorrhage, Cerebral	Citation: sobstyl, m., aleksandrowicz, m., zabek, m., <(>&<)> pasterski, t. (2019). Hemorrhagic complications seen on immediate intraprocedural stereotactic computed tomography imaging during deep brain stimulation implantation. Journal of the neurological sciences, 400, 97-103. Doi:10.1016/j.jns.2019.01.033 background: we present our operative experience of patients with movement disorders who developed intracerebral hemorrhage (ich), which was identified on intraprocedural stereotactic computed tomography (ct) imaging performed immediately after deep brain stimulation (dbs) lead placement and prior to the implantation of further components of the dbs hardware. Methods: patients who underwent dbs lead implantation from january 2009 through december 2017 were included in the present study. Most of the surgeries were performed in a staged fashion. All patients were operated using identical surgical and intraprocedural imaging techniques, and no

									microelectrode recordings were done. Leksell stereotactic g frame and neuronavigation software was utilized for all surgeries. Intraprocedural stereotactic ct was performed to confirm the precise position of the implanted dbs lead and to rule out any hemorrhagic complications. Results: overall, 222 patients underwent 322 dbs lead implantations during 316 stereotactic procedures. Six patients exhibited early ich recognized on intraprocedural stereotactic ct performed immediately after dbs lead placement; in addition, two patients developed delayed ich due to large venous infarction. Four patients with ich were asymptomatic. The ich rate was 2.5% per electrode and 3.6% per patient; the permanent deficit rate was 1.2% per electrode and 1.8% per patient. The death rate due to ich in our cohort was 0.6% per electrode and 0.9% per patient. Conclusions: intraprocedural stereotactic ct can not only visualize the implanted dbs lead in the stereotactic space but also rule out early ich. Identified predisposing factors for development of ich include patient's age, hypertension, and previous antiplatelet therapy. Careful planning of stereotactic trajectories plays a paramount role in reducing the rate of ich in dbs surgery. Adverse events 8 patients had intracranial hemorrhages (4 asymptomatic and 4 were symptomatic). (b)(6) year old female patient with hypertension, antiplated medication and essential tremor died 2 months after a dbs lead placement due to heart insufficiency. (b)(6) year old male patient with hypertension, antiplated medication and advanced parkinson's disease died 5 months after a dbs ead placement due to aspiration pneumonia. There was no alleged malfunction of the navigation device. Manufacturer narrative: patient information is provided. The dates the patient died are unavailable. Event date is approximated as it was reported to have occurred between (b)(6) 2009 and (b)(6) 2017. See mdr 1723170-2019-02729 for the report on the

									adverse events. Device lot number, or serial number, unavailable. The device was not returned, so no analysis was conducted. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued. (b)(4).
1222780-2019-00026	20/01/2019	Malfunction	HOLOGIC, INC.	12/02/2019	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Detachment of Device or Device Component; Difficult to Open or Close	No Consequences Or Impact To Patient	It was reported that the eviva needle was prepared and checked ready for a stereotactic biopsy. The needle was inserted into the patients breast and when the radiologist fired the needle there was a loud sound from the device which was louder than normal. The vab machine then flashed red and there was no suction to the needle or saline washing through. We then checked all the tubing and connection and found that one of the larger tubes had popped out of the biopsy device. We could not engage the biopsy option to close the notch and we had to remove the needle from the patient's breast with the notch open. Patient discomfort, but no injury reported. A second device was used to successfully complete the biopsy and the patient returned for her results appointment and did not report any issues. Manufacturer narrative: device evaluated by mfr? The device is not being returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications. Internal complaint reference: (b)(4).
3008492462-2019-00014	18/01/2019	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	21/03/2019	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE	Failure to Obtain Sample	Patient Problem/Medical Problem	Devicor medical products inc. Received a report from sales, stating, during procedure no tissue was acquired. This is documented in our system as record # (b)(4). Manufacturer narrative: the revolve stereotactic probe is a sterile, single-patient use device that may be used with imaging guidance to excise a tissue sample for diagnosis. One mst0809 probe was received february 11, 2019 and evaluated february 22, 2019. The device was found to have cup alignment on the marker port

									during first sample by user; therefore, tissue did not transport into chamber one. Breast tissue was found in the cutter of the probe. Due to the discovery of the tissue, this event was assessed against the result of the investigation. Following consultation with our medical director, due to the potential to cause or contribute to death or serious injury as a result of potential missed or lost tissue samples, pursuant to 21 cfr §803, this failure mode was determined to be a reportable malfunction.
1220984-2019-00014	18/01/2019	Malfunction	HOLOGIC, INC	15/02/2019	IZH	MULTICARE PLATINUM	Unintended Movement	No Consequences Or Impact To Patient	It was reported that the table will motor down on it's own intermittently. No injury reported. A field engineer was dispatched to the site. It was determined that the power control and lockout relay boards needed to be replaced and shielding was added to the through table cabling. Once this was completed the system was working as intended.
1222780-2019-00023	08/01/2019	Malfunction	HOLOGIC, INC.	05/02/2019	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Break	No Consequences Or Impact To Patient	It was reported that during a tomo biopsy, when trying to remove the needle, the radiologist had a lot of resistance. When the needle was removed it was noted that the sheath had pieces of plastic missing. No patient injury reported and no intervention was needed. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications. Internal complaint reference: (b)(4).
9172223	08/01/2019	Malfunction	HOLOGIC, INC.	09/10/2019	KNW	EVIVA	Component Missing; Material Deformation; Physical Resistance/Sticking	No Known Impact Or Consequence To Patient	Tomo biopsy performed. At end of procedure, while removing the needle to place the biopsy clip, sheath was missing plastic on it. The patient was scheduled for a three site stereotactic breast biopsy. After they completed the 2nd site, the radiologist felt resistance when she tried removing the needle to place a biopsy clip. When it was finally pulled out, it was noted that the plastic hologic eviva sheath had crimped. There was concern that pieces of the plastic could have broken off in the patient's breast. The radiologist had the

									mammographer take a breast tomosynthesis images of the breast. The radiologist reviewed the images and couldn't see any foreign body (plastic) in the breast. In addition, the radiologist had the mammographer take images of the sheath and no plastic was noted. The chief technologist called hologic to open an investigation. Hologic is going to send a hazardous kit for the contaminated hologic eviva sheath to be returned. Hologic with conduct a full investigation and send a report with the results. In addition, hologic will credit the supplies with the same lot number. The radiologist also called hologic and was notified that they have had other reportable incidents. The radiologist will call the patient and physician to report the incident. Please note the following: sterile needle and sheath were used. No known injury was noted. Product: eviva stereotactic guided breast biopsy system. Reference # (b)(4). Lot # 18jo3rt. Expiration date 9-02-2020.
1723170-2019-00391	03/01/2019	Malfunction	MEDTRONIC NAVIGATION, INC	24/01/2019	HAW	MAIN CART 9735669 STEALTH S8 EM ENT	Human-Device Interface Problem	No Patient Involvement	Medtronic received information regarding a navigation device being used outside a procedure. It was reported that when attempting to do a check-out on the system, the medtronic representative (mr) was unable to load demo exams through the file system or load with a disc. Each exam he tried to load from the file system stated transfer failed. The system also wasn't recognizing his disc with the demo exams on it. The mr went into stealth admin to attempt to mount the disc there, but the system was stating it was unable to access location each time he tried to click on the cd/dvd drive. The system was also no longer recognizing discs for patient exams that were previously loaded. There was no patient present when this issue was identified. Manufacturer narrative: the ssd 9735999 with s8 os s8 svc (lot# s3z6nbrk601934y) was returned for analysis. Analysis found a software functionality failure. The ssd was tested on a bench station and initially was unable to

									download exams from the computer and would get transfer errors. When trying to download other exams, demo lee, stereotactic soft tissue was able to download as well as a few others temporarily, then would get more transfer errors. When deleting exams that were downloaded from the ssd, the system's screen was darkened and stayed on the loading circle until the system was hard rebooted. Evaluation codes that apply to this testing: if information is provided in the future, a supplemental report will be issued. Manufacturer narrative: no patient information provided as no patient was involved in this concern. A medtronic representative went to the site to test the equipment. Testing revealed that the system performed as intended and hardware parts were replaced. The system then passed the system checkout and was found to be fully functional. The hard drive was returned and is still under analysis. If information is provided in the future, a supplemental report will be issued.
1723170-2020-03354	01/01/2019	Injury	MEDTRONIC NAVIGATION, INC	21/12/2020	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Muscle Weakness	Citation: mri-guided laser interstitial thermal pallidotomy for medically-intractable parkinson's disease. Harris m.; james p.; john s.; wilden j. Stereotactic and functional neurosurgery (2019) 97 supplement 1 (72-73). Date of publication: 2019 objectives: to describe six cases of medically intractable parkinson's disease treated with unilateral laser interstitial thermal therapy (litt) pallidotomy performed under real-time mri guidance. Deep brain stimulation (dbs) decreases symptoms, but not all patients are candidates. Pallidotomy has been accomplished with multiple modalities. However, radiofrequency and ultrasound lesioning require intra-procedural testing, ultrasound requires specific skull/scalp depth, and radiosurgery requires frame placement coupled with a therapeutic delay. As the population ages, there is increasing demand for a procedure that meets the following criteria: no hardware, no titration, 3. Fast and long-lasting results, no patient

									participation in procedure, minimal incision, and minimal recovery. Methods: six appropriate patients were identified for the novel pallidotomy procedure. Reasons for lesioning over dbs included: a advanced age, social factors, and medical comorbidities. All patients strongly preferred general anesthesia even with the stated risk of uncertain symptom control/side effects. Each patient underwent a unilateral litt pallidotomy using visualase therapy under live mri guidance in combination with the clearpoint stereotactic system. Six critical safety points were set around the planned ablation, four arranged circumferentially around the axial target at the ac-pc plane and two at the capsular border on a coronal slice. Four ablations were performed sequentially, starting just dorsolateral to the optic tract until ~4 mm above the ac-pc plane. This treatment resulted in a ~4 x 10 mm longitudinal ablation of the globus pallidus internus (figure 1). Results: all patients had an acute decrease in symptoms immediately post-operatively, which has been sustained through the short-term of 3-6 months. Incisions were minimal. The decrease in resting tremor, slowness, and stiffness has resulted in improved daily function, including hygiene, eating, drinking, and sleeping in all patients. No patient had a permanent, disabling side effect of pallidotomy. One patient had mild transient right-sided weakness that was not disruptive and resolved over four weeks. Conclusions: although long-term results are pending, mri-guided laser pallidotomy may be a useful treatment for medically intractable parkinson's disease in patients otherwise unsuitable for dbs. Reported event(s): one patient had mild transient right-sided weakness that was not disruptive and resolved over four weeks. Manufacturer narrative: patient age not available from the site. Patient sex not available from the site. Patient weight not available from the site. Event date is the publication date of the abstract. Device lot

									number, or serial number, unavailable. Facility and address not populated as the facility was not provided in the abstract provided. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
2029046-2020-00712	01/01/2019	Injury	BIOSENSE WEBSTER INC	17/06/2020	LPB	UNK_THERMOCOOL SF NAV	Adverse Event Without Identified Device or Use Problem	Pulmonary Embolism	This complaint is from a literature source. As reported in the literature publication entitled, ¿electroanatomical mapping¿guided stereotactic radiotherapy for right ventricular tachycardia storm.¿ a (b)(6)-year-old woman with a neuroendocrine tumor of paranasal sinus suffering from ventricular tachycardia (vt) storm. For the first 2 days, the patient was in incessant vt on intravenous antiarrhythmics. Catheter vt ablation was performed on the second day. The incessant vt at 130¿180 bpm improved to frequent vt at 80¿150 bpm with the same morphology. Epicardial ablation was considered; however, her comorbidities and her wishes were not encouraging. Hence repeat invasive ablation was not performed. Stereotactic body radiotherapy (sbrt) was performed on the seventh day. 3 days post sbrt she suffered a segmental pulmonary embolism. Objective: the case presentation of a patient who presented in a dire situation with ventricular tachycardia (vt) storm. Method: the patient was brought to the cardiac electrophysiological laboratory for vt ablation using carto electroanatomical mapping and pentaray (biosense webster, diamond bar, ca) mapping catheter. The vt was persistent and was mapped to the rv apical free wall, where it was 22 ms ahead of surface qrs. Ablation was performed using a force-sensing surround flow df nav catheter (biosense webster) the article was published in 2019. Manufacturer narrative: product complaint # (b)(4). Since the product was not returned for analysis, no product failure analysis can be conducted and no determination of possible

									contributing factors could be made. Device history record (dhr) review cannot be conducted because the no lot number was provided by the customer. Information regarding patient weight, height, medical history, race, and ethnicity was not reported.
3007566237-2019-00630	01/01/2019	Injury	MEDTRONIC NEUROMODULATION	15/03/2019	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Wound Dehiscence; Intracranial Hemorrhage; Hemorrhage, Subdural; TissueBreakdown	Summary: background: modern robotic-assist surgical systems have revolutionized stereotaxy for a variety of procedures by increasing operative efficiency while preserving and even improving accuracy and safety. However, experience with robotic systems in deep brain stimulation (dbs) surgery is scarce. Objective: to present an initial series of dbs surgery performed utilizing a frameless robotic solution for image-guided stereotaxy, and report on operative efficiency, stereotactic accuracy, and complications. Methods: this study included the initial 20 consecutive patients undergoing bilateral robot-assisted dbs. The prior 20 nonrobotic, frameless cohort of dbs cases was sampled as a baseline historic control. For both cohorts, patient demographic and clinical data were collected including postoperative complications. Intraoperative duration and number of microelectrode recording (mer) and final lead passes were recorded. For the robot-assisted cohort, 2d radial errors were calculated. Results: mean case times (total operating room, anesthesia, and operative times) were all significantly decreased in the robot-assisted cohort (all p-values <(><<)> .02) compared to frameless dbs. When looking at trends in case times, operative efficiency improved over time in the robot-assisted cohort across all time assessment points. Mean radial error in the robot-assisted cohort was 1.40 ± 0.11 mm, and mean depth error was 1.05 ± 0.18 mm. There was a significant decrease in the average number of mer passes in the robot-assisted cohort (1.05) compared to the nonrobotic cohort (1.45, p <(><<)> .001). Conclusion: this is the first report of application of frameless robotic-assistance

									with the mazor renaissance platform (mazor robotics ltd, caesarea, israel) for dbs surgery, and our findings reveal that an initial experience is safe and can have a positive impact on operative efficiency, accuracy, and safety. Reported events: 1 patient experienced a superficial wound dehiscence that required wound revision, but no hardware explantation. An unknown number of patients were excluded from the study because they were undergoing a revision surgery for unspecified reasons. 1 patient experienced a superficial eschar near the right cranial incision site that required superficial debridement and a short course of perioperative antibiotics, but no hardware explantation. 1 patient experienced an asymptomatic postoperative small track intracranial hemorrhage that was discovered on a routine ct scan. 1 patient experienced a small asymptomatic postoperative intracranialHemorrhage/subdural hemorrhage that was discovered on routine ct scans. 2 patients experienced a small acute subdural hemorrhage following a fall more than a month post-implant. The authors reported that stimloc devices were used to fix the device at the burr hole. However, no additional specific device information could be determined from the article and the event could not be matched with any previously reported events. Manufacturer narrative: this value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Other relevant device(s) are: product id: neu_ins_stimulator, serial/lot #: unknown. Product id: neu_unknown_lead, serial/lot #: unknown. Product id: neu_unknown_lead, serial/lot #: unknown. Product id:

									neu_unknown_lead, serial/lot #: unknown. Product id: neu_unknown_lead, serial/lot #: unknown, ho, al., pendharkar, av., brewster, r., martinez, dl., jaffe, ra., xu, lw., miller, kj., halpern, chs. Frameless robot-assisted deep brain stimulation surgery: an initial experience. Oper neurosurg (hagerstown). 2019. Doi: 10.1093/ons/opy395/5281550. If information is provided in the future, a supplemental report will be issued.
3002466018-2018-63933	26/12/2018	Malfunction	SIEMENS HEALTHCARE GMBH	23/01/2019	IYE	ARTISTE MV	Break; Mechanical Problem	No Known Impact Or Consequence To Patient	It was reported to siemens that during operation of an artiste mv system, the roller cage in the collimator bearing got stuck (broke). The bearing balls migrated into the bearing. Although there was no patient injury or mistreatment, this event is being reported due to the potential for two potentially hazardous situations that could occur due this incident if it were to reoccur. In the first scenario, a dose to the wrong location because of mechanical misalignment (deviation of the treatment field of 4 to 5 mm at the iso-center) could potentially occur: the mechanical deviation would be recognized during daily qa. In the case of stereotactic treatments, the deviation would be detected even before the treatment during the specific qa for stereotactic treatments. Otherwise, patient mistreatment may occur for one fraction resulting in moderate patient injury. In the second scenario, the defect of the bearing is not recognized and repaired, resulting in a totalBreakdown of the bearing. In a worst case scenario, the collimator may fall down. As the weight of the collimator is approximately 400kg, serious injury or death could result if the collimator fell. Manufacturer narrative: (b)(4). Siemens has initiated a technical investigation of the reported event. The affected part has been replaced. A root cause has not yet been identified. A supplemental report will be filed upon the completion of the investigation. The reported event occurred in (b)(6).
1723170-2019-01914	21/12/2018	Injury	MEDTRONIC NAVIGATION, INC	23/04/2019	HAW	S7 STEALTHSTA	Adverse Event	Tissue Damage	Citation: saeed s. Sadrameli, md, ms, ryan jafrani, md, blake n. Staub, md, majdi

						TION NAVIGATION SYSTEM	Without Identified Device or Use Problem		radaideh, md, paul j. Holman, md. "minimally invasive, stereotactic, wireless, percutaneous pedicle screw placement in the lumbar spine: accuracy rates with 182 consecutive screws." international journal of spine surgery, vol. 12, no. 6, 2018, pp. 650-658. Summary: background: standard fluoroscopic navigation and stereotactic computed tomography¿guided lumbar pedicle screw instrumentation traditionally relied on the placement of kirshner wires (k-wires) to ensure accurate screw placement. The use of k-wires, however, is associated with a risk of morbidity due to potential ventral displacement into the retroperitoneum. We report our experience using a computer image¿guided, wireless method for pedicle screw placement. We hypothesize that minimally invasive, wireless pedicle screw placement is as accurate and safe as the traditional technique using k-wires while decreasing operative time and avoiding potential complications associated with k-wires. Methods: we conducted a retrospective review of 42 consecutive patients who underwent a stereotactic-guided, wireless lumbar pedicle screw placement. All screws were placed to provide fixation to a variety of interbody fusion constructs including anterior lumbar interbody fusion, lateral interbody fusion, and transforaminal lumbar interbody fusion. The procedures were performed using the o-arm intraoperative imaging system with stealthstation navigation and medtronic navigated instrumentation. After placing a percutaneous navigation frame into the posterior superior iliac spine or onto an adjacent spinous process, an intraoperative o-arm image was obtained to allow subsequent stealthstation navigation. Para-median incisions were selected to allow precise percutaneous access to the target pedicles. The pedicles were cannulated using either a stereotactic drill or a novel awl-tipped tap along with a low-speed/high-torque power driver. The initial

									trajectory into the pedicle was recorded on the medtronic stealthstation prior to removal of the drill or awl-tap, creating a ¿¿virtual¿¿ k-wire rather than inserting an actual k-wire to allow subsequent tapping and screw insertion. Accurate screw placement is achieved by following the virtual path as an exact computer-aided design model of the screw traversing the pedicle is projected onto the display and by using audible and tactile feedback. A second o-arm scan was obtained to confirm accuracy of screw placement. Results: a total of 20 women and 22 men (average age ¼ 56 years) underwent a total of 182 pedicle screw placements using the stereotactic, wireless technique. The total breach rate was 9.9%, with a clinically significant breach rate of 0% (defined as .2 mm medial breach or .4 mm lateral breach) and a clinical complication rate of 0%. Conclusions: wireless, percutaneous placement of lumbar pedicle screws using computed tomography¿guided stereotactic navigation is a safe, reproducible technique with very high accuracy rates. Reported events: 1 patient had 2 grade i screw breaches (<2 millimeters) with an inferior trajectory that were corrected intraoperatively. Manufacturer narrative: patient gender updated. Patient gender is the majority gender of the patient in the procedure. Event date of the reported issue reflects the publication date of the article as the event dates were not provided. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: age or date of birth: this value is the average age of the patients reported in the article as specific patients could not be identified. Sex: patient sex not available from the site. Weight: patient weight not available from the site. Lot #, serial #: device lot number, or serial number, unavailable. Device evaluated by mfr: no additional information has been provided/submitted to the manufacturer for an evaluation to be conducted.

									Manufacture date: device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1220984-2019-00009	21/12/2018	Malfunction	Unknown Manufacturer	18/01/2019	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was reported that the c-arm is "slightly moving downward after reach maximum height." no injury reported. A field engineer was dispatched to the site. A recommendation was made by technical support to check the power control board and c-arm actuator motor assembly. It was reported on (b)(6) 2019 that the field engineer "has not been able to get an appointment to complete the job."
1723170-2019-01965	17/12/2018	Injury	MEDTRONIC NAVIGATION, INC	24/04/2019	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Hematoma	Citation: arthur carminucci, matthew parr, mireille bitar, shabbar f. Danish, delayed-onset cyst formation after laser interstitial thermal therapy: unreported long-term complication, world neurosurgery, volume 124, 2019, pages 219-223, issn 1878-8750, https://doi.org/10.10 16/j.wneu.2018.12.148. Summary: background: the majority of complications following (litt) therapy occur in the early postoperative period, with few long-term complications being reported. Case description: here we present 2 cases of delayed-onset cyst formation occurring more than 1 year following ablation, a previously unreported complication. In the first case, a (b)(6) year-old female who previously underwent litt for a radiation-induced cavernoma developed a 2-cm cystic lesion 18 months after ablation, resulting in recurrent seizures. In the second case, a (b)(6) year-old female with a recurrent left frontal cerebral metastasis developed a large cystic lesion 30 months post ablation. Both patients required craniotomies and resection of their cystic lesions. In both cases pathology demonstrated reactive gliosis and blood vessel sclerosis. Conclusions: we hypothesize chronic gliosis following litt therapy results in blood vessel sclerosis leading to blood-brain barrierBreakdown and delayed cyst formation. These findings

									support the need for long-term surveillance of patients treated with litt. Events: a (b)(6) year-old female with medical history significant for a right temporal arteriovenous malformation (avm), which had previously been treated by embolization and stereotactic radiosurgery (srs) 10 years prior. Ablation was performed using the thermal therapy system and trajectory was planned using the navigation system. The ablation was believed to be complete, and the catheter was removed at this time. Postoperatively, the patient did well with no significant complication. Post ablation mri demonstrated an evolving hematoma in the area of ablation. After ablation, the patient remained seizure free. Mri performed at 9 months postoperatively demonstrated a stable ablation cavity. Repeat mri at 18 months postoperatively once again demonstrated a stable ablation cavity, but now a small 1-cm cyst was evident adjacent to the ablation zone the cyst continued to slowly enlarge over the course of serial mris; however, the patient remained asymptomatic. Thirty months post ablation, the patient experienced aBreakthrough grand mal seizure. Mri showed the cyst to have grown to approximately 2 by 2 cm in size. Given the patient¿s new symptomatology, the decision was made for operative intervention to remove the cyst. The surgical pathology of the nodule revealed gliotic brain tissue and hemosiderin deposition. There was no indication of recurrent avm or radiation induced tumor. The patient recovered well from the procedure and has remained seizure free to date. A (b)(6) year-old female with a left frontal breast metastasis was treated with a craniotomy and tumor resection followed by adjuvant gamma knife treatment. One year later, she presented with an infield recurrence, which showed progressive growth on radiographic su rveillance. Due to increasing lesion growth and subsequent increasing steroid requirements, the patient

									was recommended for litt ablation. Laser placement into the lesion was performed as described earlier. The patient was transferred to mri to perform the ablation under real-time mri guidance. The ablation was believed to be complete, and the catheter was removed at this time. The patient tolerated the procedure well with no significant complication. Postoperative mri demonstrated complete ablation of the lesion. Thirty months post ablation, surveillance mri demonstrated a 3 centimeters cystic lesion extending from the ablation zone follow-up mri in 3 months demonstrated continued expansion of the cyst, now resulting in 1 cm of mass effect. The lesion was suspected to be an infield recurrence, and the decision was made to resect the cyst via a revision left frontal craniotomy. Postoperatively the patient was well, with no recurrent disease to date. Manufacturer narrative: patient information was not included in the journal article. This value is the mean age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date publication was accepted as the event dates were not provided in the published literature. Article citation is included. System serial number is not provided in journal article. Udi not available for this system. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
1220984-2019-00007	17/12/2018	Injury	HOLOGIC, INC	15/01/2019	IZH	MULTICARE PLATINUM	Adverse Event Without Identified Device or Use Problem	Hematoma	It was reported that during a biopsy the system never alarmed letting the technologist know that the stroke margin safety had been exceeded, and the needle went through the patient breast when fired. The technologist spoke with a clinical application specialist who reviewed multiple things with her to determine what could have caused the problem. All tests done

									showed the unit to be working properly. A field engineer evaluated the system and completed the quality control check alone and again with the technologist and no system malfunction was found. The plastic breast tray was replaced. Additional information received from the technologist noted that the patient had a small hematoma which resolved on its own and no medical intervention was needed. The biopsy was completed successfully and there have been other successful biopsies completed without issue since this event. She noted that the system had been "lagging" that day and the target had to be sent three times to be accepted. She was unsure if this issue was occurring with other systems that day or only this system.
1723170-2020-01767	10/12/2018	Injury	MEDTRONIC NAVIGATION, INC	02/07/2020	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Cerebrospinal Fluid Leakage; Hematoma; Hemorrhage/Bleeding; Unspecified Infection; Neurological Deficit/Dysfunction; Meningitis	Citation: robert e. Gross, md, phd; edward k. Sung, md, patrick mulligan, md; nealen g. Laxpati, md, phd; darlene a. Mayo, md; and john d. Rolston, md, phd. Accuracy of frameless image-guided implantation of depth electrodes for intracranial epilepsy monitoring.j neurosurg 132: 681-6901, 2020. Https://thejns.org/doi/abs/10.3171/2018.12.jns18749 objective: various techniques are available for stereotactic implantation of depth electrodes for intracranial epilepsy monitoring. The goal of this study was to evaluate the accuracy and effectiveness of frameless mri-guided depth electrode implantation. Methods: using a frameless mri-guided stereotactic approach (stealth), depth electrodes were implanted in patients via burr holes or craniotomy, mostly into the medial temporal lobe.in all cases in which it was possible, postoperative mr images were coregistered to planning mr images containing the marked targets for quantitative analysis of intended versus actual location of each electrode tip. In the subset of mr images done with sufficient resolution, qualitative assessment of anatomical accuracy was performed. Finally, the effectiveness of implanted electrodes for identifying seizure onset was

									retrospectively examined. Results: sixty-eight patients underwent frameless implantation of 413 depth electrodes (96% to medial temporal structures) via burr holes by one surgeon at 2 institutions. In 26 patients (203 electrodes) planning and postoperative mr images were available for quantitative analysis; an additional 8 procedures with 19 electrodes implanted via craniotomy for grid were also available for qualitative analysis. The median distance between intended target and actual tip location was 5.19mm (mean 6.19 + 4.13mm, ranged <(><<)>2mm-29.4mm). Inaccuracy for transtemporal depths was greater along the electrode (i.e., deep), and posterior, whereas electrodes inserted via an occipital entry deviated radially. Failure to localize seizure onset did not result from implantation inaccuracy, although 2 of 62 patients (3.2%) - both with electrodes inserted occipitally - required reoperation. Complications were mostly transient, but resulted in long-term deficit in 2 of 68 patients (3%) conclusions: despite modest accuracy, frameless depth electrode implantation was sufficient for seizure localization in the medial t emporal lobe when using orthogonal approach, but may not be adequate for occipital trajectories. Reported events: three patients experienced infections following burr hole depth electrode implantation surgeries one was noted to be an intracranial abscess, two were noted to be meningitis, one patient experienced a parenchymal hemorrhage of the left temporal lobe. The hemorrhage was suspected to contribute to a persistent verbal memory deficit. One patient experienced a significant subdural hematoma from depth electrode implantation through burr holes, requiring surgical evacuation without sequelae. Two patients experienced transient neurological deficits without specific etiology. Five patients experienced cerebrospinal fluid (csf) drainage or pseudomeningocele after depth electrode implantation. Two cases of

									postoperative wound infection were observed. Manufacturer narrative: patient information was unavailable from the site. Event date is the accepted date of the publication. Device lot number, or serial number, unavailable. Pma/510(k) is dependent upon the product number, therefore the value is unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. Additional fdp codes: c50672, c50579, c50487. If information is provided in the future, a supplemental report will be issued.
1723170-2020-01766	10/12/2018	Injury	MEDTRONIC NAVIGATION, INC	02/07/2020	HAW	MEDTRONIC NAVIGATION	Imprecision	Tissue Damage	Citation: robert e. Gross, md, phd; edward k. Sung, md, patrick mulligan, md; nealen g. Laxpati, md, phd; darlene a. Mayo, md; and john d. Rolston, md, phd. Accuracy of frameless image-guided implantation of depth electrodes for intracranial epilepsy monitoring.j neurosurg 132: 681-6901, 2020. Https://thejns.org/doi/abs/10.3171/2018.12.jns18749 objective: various techniques are available for stereotactic implantation of depth electrodes for intracranial epilepsy monitoring. The goal of this study was to evaluate the accuracy and effectiveness of frameless mri-guided depth electrode implantation. Methods: using a frameless mri-guided stereotactic approach (stealth), depth electrodes were implanted in patients via burr holes or craniotomy, mostly into the medial temporal lobe. In all cases in which it was possible, postoperative mr images were coregistered to planning mr images containing the marked targets for quantitative analysis of intended versus actual location of each electrode tip. In the subset of mr images done with sufficient resolution, qualitative assessment of anatomical accuracy was performed. Finally, the effectiveness of implanted electrodes for identifying seizure onset was retrospectively examined. Results: sixty-eight patients underwent frameless implantation of 413 depth electrodes (96%

									to medial temporal structures) via burr holes by one surgeon at 2 institutions. In 26 patients (203 electrodes) planning and postoperative mr images were available for quantitative analysis; an additional 8 procedures with 19 electrodes implanted via craniotomy for grid were also available for qualitative analysis. The median distance between intended target and actual tip location was 5.19mm (mean 6.19 + 4.13mm, ranged < 2mm-29.4mm). Inaccuracy for transtemporal depths was greater along the electrode (i.e., deep), and posterior, whereas electrodes inserted via an occipital entry deviated radially. Failure to localize seizure onset did not result from implantation inaccuracy, although 2 of 62 patients (3.2%) - both with electrodes inserted occipitally - required reoperation. Complications were mostly transient, but resulted in long-term deficit in 2 of 68 patients (3%) conclusions: despite modest accuracy, frameless depth electrode implantation was sufficient for seizure localization in the medial temporal lobe when using orthogonal approach, but may not be adequate for occipital trajectories. Reported events: 1) two of the initial procedures experienced inaccuracies resulting in failure to localize seizures. Manufacturer narrative: patient information was unavailable from the site. Event date is the accepted date of the publication. Device lot number, or serial number, unavailable. Pma/510(k): 510(k) is dependent upon the product number, therefore the value is unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1222780-2019-00004	10/12/2018	Malfunction	HOLOGIC, INC.	10/01/2019	KNW	EVIVA STEREOTACTIC BIOPSY SYSTEM	Leak/Splash	No Consequences Or Impact To Patient	It was reported that during a biopsy "after the 5th specimen the probe began to make a gurgling noise while acquiring a specimen. Tissue splattered from the probe onto the radiologist." no harm reported. Additional

									information received noted that "the tissue splatter hit the radiologist on her cheek. The radiologist did not need a medical evaluation." manufacturer narrative: evaluation of the returned sample could not confirm the reported condition, no abnormal noise was found. During functional testing , it was found that the inner cannula would not rotate which would not allow samples to be acquired. It is unknown if the inner cannula failure would have any relationship to the reported condition and/or event of the fluid leakage. A root cause is indeterminable at this time, hologic will continue to monitor and trend for safety. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications. Internal complaint reference: (b)(4).
3005985723-2018-00803	10/12/2018	Malfunction	MAKO SURGICAL CORP.	28/12/2018	OLO	HANDPIECE MICS	Mechanical Jam; Non Reproducible Results	No Known Impact Or Consequence To Patient	During reaming trigger on mics handpiece was getting stuck. Case type: tha. Mps stated is not sure if the mics continued to run while outside of the stereotactic boundary. "wwe" freed the arm to cut off power before the surgeon took it out of the stereotactic boundary. Manufacturer narrative: ¿as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available.¿
1723170-2020-00657	09/12/2018	Injury	MEDTRONIC NAVIGATION, INC	26/02/2020	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Muscle Weakness; Visual Impairment; Numbness	Citation: jon t. Willie, james g. Malcolm, matthew a. Stern, lindsay o. Lowder, stewart g. Neill, brian t. Cabaniss, daniel l. Drane, robert e. Gross. Safety and effectiveness of stereotactic laser ablation for epileptogenic cerebral cavernous malformations. Epilepsia 2019; 60; 220-232. Doi: 10.1111/epi.14634. Summary objective: magnetic resonance (mr) thermography¿guided laser interstitial thermal therapy, or stereotactic laser ablation (sla), is a minimally invasive alternative to open surgery for focal

									epilepsy caused by cerebral cavernous malformations (ccms). We examined the safety and effectiveness of sla of epileptogenic ccm. Methods: we retrospectively analyzed 19 consecutive patients who presented with focal seizures associated with a ccm. Each patient underwent sla of the ccm and adjacent cortex followed by standard clinical and imaging follow-up. Results: all but one patient had chronic medically refractory epilepsy (median duration 8 years, range 0.5-52 years). Lesions were located in the temporal (13), frontal (five), and parietal (one) lobes. Ccms induced magnetic susceptibility artifacts during thermometry, but perilesional cortex was easily visualized. Fourteen of 17 patients (82%) with >12 months of follow-up achieved engel class i outcomes, of which 10 (59%) were engel class ia. Two patients who were not seizure- free from sla alone became so following intracranial electrode-guided open resection. Delayed postsurgical imaging validated ccm involution (median 83% volume reduction) and ablation of surrounding cortex. Histopathologic examination of one previously ablated ccm following open surgery confirmed obliteration. Sla caused no detectable hemorrhages. Two symptomatic neurologic deficits (visual and motor) were predictable, and neither was permanently disabling. Significance: in a consecutive retrospective series, mr thermography¿guided sla was an effective alternative to open surgery for epileptogenic ccm. The approach was free of hemorrhagic complications, and clinically significant neurologic deficits were predictable. Sla presents no barrier to subsequent open surgery when needed. Reported events: (b)(6) yr male patient experienced a partial right superior quadrantanopia that was not disabling as the patient recovered subjectively. (b)(6) yr male patient developed intrinsic weakness of the nondominant hand during the ablation. Occupational therapy was

									administered and no functionality disability was observed at 12 month follow-up. (b)(6) yr female patient sustained an expected perioral sensory disturbance, which was noted to be persistent but non-disabling. Manufacturer narrative: patient age is the mean value of participants in the study. Patient gender is the majority value of the 19 participants in the study. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1220984-2019-00002	07/12/2018	Malfunction	HOLOGIC, INC	04/01/2019	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was reported that the table will lower on its own after they raise it up to the top of travel. No injury reported. A field engineer was dispatched to the site and determined that the table down switch on the control panel membrane switch bank was shorted out. The control panel membrane switch was replaced. Once this was completed the system was working as intended.
3005985723-2019-00001	06/12/2018	Malfunction	MAKO SURGICAL CORP.	02/01/2019	OLO	HANDPIECE MICS	Mechanical Problem	No Known Impact Or Consequence To Patient	When dr. (b)(6) squeezed the trigger on the mics, the reamer didn¿t spin. He let go of the trigger and tugged slightly on the arm, then the mics started spinning on its own. I clicked ¿free-mode¿ to shut the power off to the mics. Then when he went back into the acetabulum to try to ream again we couldn¿t engage the stereotactics. He pulled back out, i tried the ¿burr override¿ button and no power came to the mics. He decided he didn¿t want to wait for me to open another mics and finished the case manually. After the case i did a mics status check. Below is the error received. Also, attached is video of the mics spinning without me holding the trigger. Hand piece ran while outside of the stereotactic boundary. Surgical delay~5 minutes. The mics continued to run while outside of the stereotactic "haptic" boundary. Manufacturer narrative: ¿as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A

									supplemental report will be submitted when additional information becomes available.¿
1723170-2019-03053	23/11/2018	Injury	MEDTRONIC NAVIGATION, INC	07/06/2019	GEX	VISUALASE GUIDED LASER ABLATION SYSTEM	Adverse Event Without Identified Device or Use Problem	Hearing Impairment; Paresis	Citation: mr-guided laser interstitial thermal therapy in the treatment of recurrent intracranial meningiomas objective: recurrent meningiomas can prove problematic for treatment, especially if anaplastic, as options are limited primarily to surgery and radiation therapy. Laser interstitial thermal therapy (litt) is a minimally invasive technique for achieving immediate cytoreduction. This study seeks to determine the utility of litt in the setting of recurrent meningiomas. Materials and methods: patients undergoing litt for tumor treatment at our institution between november 2014 and february 2016 were identified. Those with biopsy-confirmed meningiomas were reviewed with attention to ablation volume, survival, demographic data, and complications. Data from imaging performed at set intervals post-operatively were available for all. Results: four patients were identified, three of whom had successful treatment with a total of four ablations. The one case that did not result in a successful ablation was due to problems with stereotactic placing of the laser catheter. One patient had a grade 1 meningioma, with the other two being grade 3. Immediate ablation volumes averaged 75% of preoperative tumor volume and increased to 97% at 2 weeks before dropping to 65% at 3 months. One patient had acute hemiparesis with speech difficulty, which resolved after 6 months. At date of last follow-up, two of three had progression at an average of nine weeks, and one had no progression at 28 weeks. Conclusion: litt appeared to be a potentially viable treatment for recurrent meningiomas. Ablation volumes increased over time, but not beyond the initial meningioma volume. Larger studies are needed to better determine complications and outcomes. Lasers surg.med. 51:245¿250, 2019. © 2018 wiley periodicals, inc. Reported events: patient

									experienced unsuccessful ablation due to problems with stereotactic placement of the laser catheter. (b)(6) female patient experienced acute hemiparesis with speech difficulty, which resolved after sixth months. Manufacturer narrative: weight: patient weight not available from the site. Date of event: event date is the accepted date of the article for publication. Udi #: unique device identifier (udi) is unavailable. Device evaluated by mfr: no parts have been received by the manufacturer for evaluation. Manufacture date: device manufacture date is unavailable. If information is provided in the future, a supplemental report will be issued.
3007566237-2019-00211	19/11/2018	Injury	MEDTRONIC NEUROMODULATION	24/01/2019	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	No Known Impact Or Consequence To Patient	Summary: background: thalamic ventral intermediate nucleus (vim) deep brain stimulation (dbs) is an effective therapy for medication- refractory essential tremor (et). However, 13¿40% of patients with an initially robust tremor efficacy lose this benefit over time despite reprogramming attempts. At our institution, a cohort of et patients with vim dbs underwent implantation of a second anterior (ventralis oralis anterior; voa) dbs lead to permit ¿confined stimulation.¿ we sought to assess whether confined stimulation conferred additional tremor capture compared to vim or voa stimulation alone. Methods: seven patients participated in a protocol-based programming session during which a video-recorded fahn- tolosa-marin part a (ftm-a) tremor rating scale was used in the following 4 dbs states: off stimulation, vim stimulation alone, voa stimulation alone, and dual lead (confined) stimulation. Results: the average (sd) baseline ftm-a off score was 17.6 (4.0). Vim stimulation alone lowered the average ftm-a total score to 6.9 (4.0). Confined stimulation further attenuated the tremor, reducing the total score to 5.7 (2.8). Conclusions: confined thalamic dbs can provide additional symptomatic benefits in patients with unsatisfactory tremor control from vim or voa stimulation alone. Reported events:

									patient 6: a (b)(6) year-old patient with bilateral ventral intermediate nucleus of the thalamus (vim) deep brain stimulation (dbs) for essential tremor (et) had their left lead revised once, and then again 3 years later. The cause for these revisions was not reported. The authors reported that they implanted scs models 377xx/977xx restore or 37702/97702 prime advanced models in this study. However, it was not possible to ascertain any additional specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: other relevant device(s) are: product id: neu_unknown_lead, serial/lot #: unknown. Isaacs, da., butler, j., sukul, v., rodriguez, w., pallavaram, s., tolleson, c., fang, jy., phibbs, ft., yu, h., konrad, pe., hedera, p. Confined thalamic deep brain stimulation in refractory essential tremor. Stereotact funct neurosurg. 2018; 96(5):296-304. Doi: 10.1159/000493546. If information is provided in the future, a supplemental report will be issued.
3008769756-2018-00015	19/11/2018	Death	NEUWAVE MEDICAL, INC.	21/12/2018	NEY	NEUWAVE FLEX PROBE 4	Adverse Event Without Identified Device or Use Problem	Death; Hemorrhage/Bleeding	It was reported via clinical trial patient (b)(6) that during a lung lesion flex ablation procedure, patient experienced bleeding during navigation. Following the procedure, the patient experienced ablation syndrome, hemoptysis, and hemorrhage- nos. Manufacturer narrative: (b)(4). Additional event information provided: event start date: (b)(6) 2018 pneumonitis. Event start date: (b)(6) 2018 shortness of breath. Event start date: (b)(6) 2018 pain. Event start date: (b)(6) 2018 chills. Event start date: (b)(6) 2018 anorexia. Event start date: (b)(6) 2018 fatigue. Event start date: (b)(6) 2018 low grade temperature. Relationship to study device for all events: unlikely. Relationship to procedure for all events: causal relationship. Data evaluation summary: call home was reviewed. A flex4, (b)(4), was connected and then reconnected. The probe tested successfully. An ablation was set to 10:00, 100w. The ablation completed successfully. The average active

									temperature was 85c with a max of about 90c. No errors were recorded. The system and its probes were performing to specifications. The probes were disposed of. The root cause is unknown. Manufacturer narrative: product complaint #: (b)(4). Review of work order (b)(4) (flex4), manufacturing lot 18043444: the probe used at the case ((b)(4)) was in-process serial number #(b)(4). It had no issues during manufacture. Everything was in spec and it passed all testing. Additional event information provided: event start date: (b)(6) 2018, bleeding during navigation. Event start date: (b)(6) 2018, blood in airway after ebus. Event start date: (b)(6) 2018, onset of more acute type of pain in the chest/pain and shortness of breath. Event start date: (b)(6) 2018, shortness of breath and back pain. Event start date: (b)(6) 2018, ablation syndrome. Event start date: (b)(6) 2018, hemoptysis. Event start date: (b)(6) 2018, cough. Event start date: (b)(6) 2018, "hemmorhage"- nos, outcome: fatal. Additional information provided by medical director: medical director was in the case and reported that as this was the first case; it took longer for anesthesia and for the case to get started. During the bronchoscopy, there was some mucosal bleeding that took several minutes to control which was not a significant event and is not uncommon. The procedure continued and there was a lengthy amount of time spent placing the probe. Abandoning the procedure was considered, but imaging at that point confirmed that the probe was exactly where it needed to be. The decision was made to proceed with the ablation, which was uneventful. The patient wanted to go home that day but was admitted overnight per the protocol and was doing well. On the day before the patient¿s demise, the patient reported to another hospital with posterior left chest pain. A ct scan was done and shared for review. The ct showed a generous ablation including involving the lining of the lung and

									pleura, which is typical of even the percutaneous ablation procedures; the ablation zone was sizeable but not atypical. Dead material was observed with no blood or fluid identified. It was determined to be symptomatic discomfort and the patient was sent home on steroids. The following day while at a gas station, the patient collapsed and, as reported by a witness, hit his face on concrete. The paramedics attempted treatment for cardiopulmonary arrest, including intubation. There was quite minimal bleeding in the nasal track. The patient was reported to be asystolic from the time found. It was reiterated that there had been minimal bleeding throughout patient care and it was added that the ablation zone was not near the pulmonary artery. There was discussion about potential causes which included the discussion of hemoptysis. Medical director explained that there would have been significant bleeding if the patient event was related to hemoptysis. The family refused an autopsy, but it is felt that this is unlikely a delayed event related to the ablation. The patient death was likely due to a sudden cardiovascular event but there is no proof as no autopsy was performed. During the discussion, it was also reported that the patient was on plavix. Narrative surrounding the events of (b)(6) ¿ serious adverse event (sae) provided by m.d. That performed the ablation procedure: history: patient is a (b)(6) male with known chronic lymphocytic leukemia and 2 nodules on the ct scan. The patient underwent bronchoscopic biopsy on (b)(6) and the lower lobe nodule was found to be biopsy proven squamous cell cancer. At the time of presentation, the patient had borderline pulmonary function testing and was thought to be very borderline operable. As such, he was counseled on stereotactic body radiation therapy (sbrt), surgery, percutaneous ablation, and a trial on bronchoscopic microwave ablation. After detailed discussions, the patient chose

									bronchoscopic microwave ablation. He was aware he would be the first patient to undergo this procedure at (b)(6) clinic and the 8th person nationally as part of the study. As part of study protocol, he had new pulmonary function tests (pfts) within 30 days, upon which time they had surprisingly improved. He was called prior to returning to (b)(6) for the ablation procedure and informed that surgery would now be a viable option. He chose to have the bronchoscopic microwave ablation procedure. Intraoperatively: standard endobronchial ultrasound guided lymph node biopsy (ebus) was performed without difficulty. We then attempted to navigate to the lesion with both augmented fluoroscopic guided and electromagnetic navigational guidance. This was a difficult navigation. At one point during the navigation we did encounter a modest amount of bleeding (about 100-150cc of blood). This stopped with cold saline and tamponade. We then proceeded with navigation and confirmed that we were within the nodule using cone beam ct. We reviewed the imaging prior to ablation with a (b)(6) expert in interventional radiology as well as the designated clinical proctors who were part of the sponsoring trial team. Ablation was then performed with collective agreement amongst both proceduralists and clinical proctors to complete a 10 minute ablation at 100 watts. We repeated a cone beam ct scan at 5 minutes and at 10 minutes to confirm out ablation zone. Post ablation cone beam ct was performed at 10 minutes post ablation and reviewed by all parties mentioned above and no obvious concerns were noted and felt the case was successful. Post-procedure: patient was observed for 24 hours with no adverse events. He was ambulatory within hours of the surgery. He was dismissed in good condition. He notified the service on post procedure 2 about chest pain and was sent to the emergency department to rule out

									pneumothorax. He was prescribed steroids for ablation syndrome. The patient did note that he has been having ongoing claudication with cessation of his plavix in preparation for the procedure. As such we advised that he wait 24 hours and then resume his plavix per his routine regimen. He then notified the service on (b)(6) and i called and spoke with him directly regarding his symptoms. He stated at that time that he had some mild fatigue and occasional exertional dyspnea but the pain medication and steroids did gradually improve his symptoms from the week prior. He was instructed to continue with the current regimen but call at the end of the week if no improvement. I received a message in my inbox on (b)(6) that the patient had presented to the emergency department on (b)(6). He had laboratory workup and ct scan and physical examination. The emergency department physician had noted thin bloody sputum without evidence of clots. The hemoglobin was 10.8 from 12.0 pre-procedurally and white blood cell count was 15. Of note the patient was on plavix for peripheral arterial disease with stents in place and was also on steroids for post ablation syndrome. The overall impression was ¿patient should be treated like traumatic lung injury in regards to ablation.¿ he was discharged with antibiotics and per report the on-call covering resident was notified at 10:54 p.m. Here in (b)(6). We have reached out to the resident to document their conversation with the emergency department. I received notification of the patient's ct scan on (b)(6) 2018. We plan to contact the patient on the morning of (b)(6) 2018. When i logged in to retrieve his information i noted that there was yet another adverse event in his chart. Per documentation from the outside emergency department at 1700 p.m. On (b)(6) 2018, the patient was found down at a local gas station and was in asystole and was rushed to the local emergency department. The initial report from

									ambulance is that they were having difficulty with suctioning and establishing airway. Upon arrival patient was profusely bleeding from the mouth and remained in asystole with cpr in progress. Per emergency department (ed) report: ¿iv access was established, patient was placed on cardiac monitoring and pulse oximetry. Pads from the crash cart replaced as well and the lucas device was placed on the patient's chest and turned on. I did attempt to intubate the patient, upon looking with the laryngoscope i was met with copious amounts of blood that seemed to be emanating from the airway. There were large clots throughout the mouth and in both nares. After extensive suctioning i was able to visualize the epiglottis and what i believe was the anterior portion of the vocal cords. The tube was inserted and cuff inflated. We did not have end-tidal co2 immediately available at that time. Patient initially bagged without difficulty; however, this did become more difficult with time. Patient's stomach did become more distended and we had some difficulty passing the ng tube. Patient received 2 rounds of epinephrine and chest compressions continuously with the lucas device. We did stop for pulse check before each epinephrine administration and after the 1st round of epinephrine we had pea on the monitor, after the 2nd epinephrine administration patient was in asystole. At this point given the patient's fixed and dilated pupils, the copious amount of bleeding from the airway and the time that we had run the code both in the emergency room and in the ambulance which totaled about 30 min we made the decision to cease life saving efforts. Time of death 1620. I then took some time to review the patient's charts and familiarize myself with who (b)(6) was as he was initially an unknown entity for about half of the code. I notified his brother at 1640. Coroner was also called¿. No autopsy is planned. Additional information was requested and

									the following was obtained: when was the plavix stopped prior to the ablation procedure (exact date)? Plavix was stopped 48 hours prior to the diagnostic bronchoscopy ((b)(6)). He was told not to resume his plavix between the (b)(6) bronchoscopy and (b)(6). When was the exact time/date the patient resumed plavix in relation to the procedure? The patient resumed plavix the day after the procedure (unknown exact time as he was dismissed) ¿ but he was complaining of claudication and had stents in his leg do you believe that an alleged deficiency with the neuwave device caused or contributed to the patient¿s death? No i do not believe this to be a deficiency with the probe ¿ i think it was likely poor patient selection and perhaps the bleed during the navigation should have caused us to abort ¿ where we had trouble was navigating to his lesion, once we did, the ablation part was very smooth and facile (with no additional bleeding whatsoever). In hindsight, we should have probably paused after the bleeding episode and thought about delaying the ablation until we made sure the bleeding was controlled with no sequelae. I do not believe this had anything to do with the neuwave probe. Also, about the discrepancy between the medical director's account and narrative from the m.d. That performed the ablation procedure: as i was obviously not notified of the patient¿s demise until after it happened, what i provided is a direct copy/paste of the emergency departments findings when he arrived there. However, in accordance with the medical director's narrative, when the patient was initially seen to collapse at the gas station, this was not preceded by a "hemetemesis" or hemoptysis event. Data safety monitoring board (dsmb) conclusion summary: the events of bleeding during navigation (ael) and death were both probably procedure related owing to the temporal sequence of events documented at the time of the procedure and

									subsequently upon review of available records through the time of the patient's death. The committee agrees the subject's death was probably caused by the hemorrhage described at the time of resuscitation which was contributed to by the initial sentinel bleeding event. The bleeding during navigation and death were both possibly device related as the stiffness of the device may have been more prone to puncture. However, the consensus is that technique and not the device is the more proximate cause of the initial complication.
1723170-2018-06307	19/11/2018	Malfunction	MEDTRONIC NAVIGATION, INC	17/12/2018	HAW	STEALTHSTATION S8 PREMIUM SYSTEM	Computer Software Problem	No Known Impact Or Consequence To Patient	Medtronic received information regarding a navigation system being used for a deep brain stimulation (dbs) case. It was reported that intra-operatively, while registering, the software was detecting the 10th rod, even though the site did not have one. It was showing points green where the 10th rod would be. The surgeon decided to re-spin. The procedure was completed using the navigation system and there was no reported impact to patient outcome.medtronic received additional information that technical services (ts) was unable to replicate the reported issue. No extra rod was detected when the exam archive was reviewed.medtronic received additional information that upon re-acquisition of a spin, the issue did not replicate. The issue has not reoccurred since. The surgeon and manufacturer representative suspected that there was an artifact within the leksell head frame that was detected by the navigation system in the spin which caused it to register as a 10th rod. There was surgical delay of about five minutes.it was noted that exams with a leksell ct frame, which has an optional 10th rod, would display the rod if it or a part of it was detected in the image. Neither the archive nor information about what type of stereotactic frame was used in this procedure was provided, thus there wasInsufficient Information to determine root cause. Manufacturer narrative: patient information was unavailable. Device serial

									number was unavailable. Udi not available for this system at time of filing. Name of initial reporter unknown at the time of filing. Facility name unknown at the time of filing. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: a medtronic representative went to the site to test the equipment. Testing revealed that the system was functioning normally. The system passed the system checkout and was found to be fully functional. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: patient age not available. Device serial number provided. Udi provided. Name of initial reporter provided. Facility name provided. Additional information: device manufacturing date provided. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: a software analysis was initiated. However, the software evaluation found that a probable cause was unable to be determined since the behavior could not be replicated. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: additional information: the archive was reviewed but providedInsufficient Information to determine the root cause of the reported behavior. If information is provided in the future, a supplemental report will be issued.
1723170-2019-01138	15/11/2018	Injury	MEDTRONIC NAVIGATION, INC	20/03/2019	HAW	MEDTRONIC NAVIGATION	Imprecision	Cerebrospinal Fluid Leakage; Hemorrhage/Bleeding	Citation: joshua d. Bernstock, zachary wright, asim k. Bag, florian gessler, george yancey gillespie, james m. Markert, gregory k. Friedman, james m. Johnston, stereotactic placement of intratumoral catheters for continuous infusion delivery of herpes simplex virus -1 g207 in pediatric malignant supratentorial brain tumors, world neurosurgery, volume 122, 2019, pages e1592-e1598, issn 1878-8750, https://doi.org/10.1016/j.wneu.2018.11.122. Summary: objective: the engineered herpes

									simplex virus-1 g207, is a promising therapeutic option for central nervous system tumors. The first-ever pediatric phase 1 trial of continuous-infusion delivery of g207 via intratumoral catheters for recurrent or progressive malignant brain tumors is ongoing. In this article, we describe surgical techniques for the accurate placement of catheters in multiple supratentorial locations and perioperative complications associated with such procedures. Methods: a prospective study of g207 in children with recurrent malignant supratentorial tumors is ongoing. Preoperative stereotactic protocol magnetic resonance imaging was performed, and catheter trajectories planned using stealthstation planning software. Children underwent placement of 3e4 silastic catheters using a small incision burr hole and the vertek system. Patients had a preinfusion computed tomography scan to confirm correct placement of catheters. Results: six children underwent implantation of 3e4 catheters. Locations of catheter placement included frontal, temporal, parietal, and occipital lobes, and the insula and thalamus. There were no clinically significant perioperative complications. Postoperative computed tomography scans coupled with preoperative mri scans demonstrated accurate placement of 21 of 22 catheters, with 1 misplaced catheter pulled back to an optimal location at the bedside. One patient had hemorrhage along the catheter tract that was clinically asymptomatic. Another patient had cerebrospinal fluid leak from a biopsy incision 9 days after surgery that was oversewn without complication. Conclusions: the placement of multiple intratumoral catheters in pediatric patients with supratentorial tumors via frameless stereotactic techniques is feasible and safe. Intratumoral catheters provide a potentially effective route for the delivery of g207 and may be employed in other trials utilizing oncolytic virotherapy for brain tumors.

									Reported events: one eleven-year-old male with glioblastoma in the left frontal required revision of one catheter that was in a tumor within the corpus callosum, but 2 mm from the ventricle. Given the proximity to the ventricle and cerebrospinal fluid (csf), the catheter was withdrawn 1.5 cm at the bedside into the main body of the tumor. The patient experienced a delayed csf leak from the initial biopsy and catheter placement site. He presented to the emergency department 9 days after the biopsy and placement of the catheters with clear fluid drainage from the surgical site, fever to 101 degrees fahrenheit, and no other complaints. His neurologic exam was unremarkable. The leak was overseen successfully at the bedside. His white blood cell count was elevated at 13.7 x 103/ml (normal range 3.8-9.8 x 103/ml) with a normal differential. A lumbar puncture was performed to rule out meningitis and the opening pressure was>50 cm h20, with 20 ml of csf removed to decrease pressures and for cytology. He was admitted for evaluation and had no additional fever, signs or symptoms of meningitis, or hsv encephalitis.csf bacterial cultures were negative and hsv viral polymerase chain reaction level was found to be 5480 copies/ml (3.7 log copies/ml), consistent with residual g207 virus from the infusion (1 x 108 plaqueforming units) 8 days prior. He was discharged after bacterial infection was ruled out with no further leak. Ophthalmologic evaluation demonstrated no papilledema. One thirteen-year-old male with glioblastoma in the mesial occipital, posterior temporal had a tract hemorrhage noted on postoperative ct scan. This hemorrhage did not include the catheter tip, did not cause neurologic sequelae, and was stable on follow-up mri scan. Manufacturer narrative: patient information was not included in the journal article. Age: this value is the average age of the patients reported in the article as specific patients could not be identified. Sex: this value

									reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Article citation is included. System name and serial number not provided in journal article. Journal article indicated use of stealthstation planning software. Udi not available for this system. Facility is not provided article. Corresponding author is listed at the university of alabama at birmingham, department of pediatrics, division of pediatric hematology-oncology and department of neurosurgery, division of pediatric neurosurgery. Procode provided is for most common navigation system. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
1220984-2018-00182	14/11/2018	Malfunction	HOLOGIC, INC	11/12/2018	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was reported that "table top will go back up by itself, as soon as it is driven down if the table is unlocked it will drive up on its own." no injury reported. A field engineer was dispatched to the site and it was determined that the touch keypad needed to be replaced. Once this was completed the system was working as intended.
3007566237-2019-00707	07/11/2018	Injury	MEDTRONIC NEUROMODULATION	25/03/2019	MHY	ACTIVA	Migration or Expulsion of Device	Infarction, Cerebral; Edema; Fatigue; Hematoma; Hemorrhage, Subdural	Summary: the true incidence of hemorrhagic venous infarctions in deep brain stimulation (dbs) procedures is very difficult to determine. These hemorrhagic venous complications are very rare and often grouped as all hemorrhagic complications. We report the clinical cases of 2 patients with parkinson¿s disease (pd) who received unilateral globus pallidus (gpi) dbs and developed hemorrhagic venous infarctions. In these 2 patients a small injury to a dural outflow venous structure or a superficial brain vein resulted in hemorrhagic venous infarctions. We present the management of these rare complication with detailed radiologic

									follow-up. The first patient made a full recovery but the second patient deceased 5 months after dbs surgery due to aspiratory pneumonia. We stress that careful planning of a stereotactic trajectory reduces significantly hemorrhagic complications in dbs surgery but not fully exclude some side effects like venous hemorrhagic infarctions which may result in prolong hospitalization or death. Reported event: a (b)(6) year-old man with a history of pd was scheduled for a right gpi dbs implant. Their pd symptoms were pronounced predominantly on their left side, and they exhibited tremor in their left upper extremity in the off-medication state. They also had incapacitating levodopa-induced dyskinesia only in their left extremities and painful early morning dystonia in their left foot. During preoperative assessment, their off-medication total updrs score was 50 and their on-medication total updrs score was 32. Their off-medication updrs motor score was 32 and their on-medication updrs motor score was 16. They underwent the procedure and after pia coagulation and introduction of the guiding cannula to the target, venous bleeding from the subdural space anterior to the burr hole was observed. Introduction of surgicel anteriorly completely stopped the venous bleeding. Intraoperative stereotactic ct showed the dbs lead in the appropriate place with no signs of intracranial bleeding. An ins was implanted and connected to the lead. 26 hours after surgery, the patient became somnolent. Ct revealed a large hemorrhagic venous infarct on the right frontal region with clearly visible displacement of the dbs lead. The small pial opening for insertion of guiding cannula caused the deflection of the brain with subsequent tearing of a bridging superficial vein that led to a large venous hemorrhagic infarct in the right frontal region. Urgent frontal craniotomy was performed to evacuate the hematoma. Post-operative ct showed less midline shift and a less displaced dbs lead as compared

									with that in preoperative ct. The dbs lead returned to its previous position after resolution of brain edema. The patient's status improved and they were able to perform their daily activities independently. They were transferred to a rehabilitation unit. They were eventually discharged home and received supportive care with help of daily activities. There was considerable amelioration of left-sided dyskinesia. The following device specifics were provided: ins model 37603. See attached literature article. Manufacturer narrative: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Other applicable components are: product id: neu_lead_unknown, lot# unknown, implanted: unknown, ubd: unknown, udi#: unknown, product type: lead, sobstyl, m., brzuszkiewicz-kuzmicka, g., aleksandrowicz, m., pasterski, t. Large hemorrhagic cerebral venous infarction due to deep brain stimulation leads placement. Report of 2 cases. Turkish neurosurgery. 2018. Doi: 10.5137/1019-5149.jtn.22281-17.3. If information is provided in the future, a supplemental report will be issued.
3007566237-2019-01416	01/11/2018	Injury	MEDTRONIC NEUROMODULATION	27/06/2019	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Break; High impedance	No Known Impact Or Consequence To Patient	Abstract: objective: implantation of deep brain stimulation (dbs) electrodes requires stereotactic imaging. Stereotactic magnetic resonance imaging (mri) for dbs surgery has become more popular and intraoperative mri scanners have become more available. We report on our cohort of movement disorder patients who underwent intraoperative stereotactic mri-only dbs electrode implantation. Methods: a review of our dbs database for eligible patients

									over a study period of 8 years was performed. Stereotactic accuracy was calculated as a directional error and the euclidean distance between planned and controlled electrode positions. Number and choice of microelectrodes, procedural times and complications were documented. Results: n = 86 surgeries in n = 81 patients with parkinson¿s disease (pd), essential tremor and dystonia were performed and n = 167 electrodes were implanted. Mean euclidean distance between planned and controlled target was 2.1mm (±0.6). The directional error showed that electrodes were implanted more medial (0.3mm ±0.9), posterior (0.5mm ±1.0) and inferior (0.6mm ±1.0) compared to plan. There were no significant differences for stereotactic accuracy between targets, hemispheres or order of implantation. No significant correlations between euclidean distance and number of microelectrode tracts or volume of intracranial air were observed. N = 539 microelectrodes were applied. In 28.7% non-center trajectories were chosen. Length of tremor (-61 minutes) and pd (-121 minutes) surgeries could be reduced significantly over the course of the study period. N = 1 (1.2%) intracranial hemorrhage occurred. N = 1 (0.6%) electrode had to be repositioned for lack of clinical effect. Conclusion: intraoperative stereotactic mri for dbs surgery is feasible with high stereotactic accuracy and low rates of complication. Reported events: 3 patients experienced hardware failure with high impedance due toFracture of extension leads and needed surgical replacement. Manufacturer narrative: age or date of birth: this value is the average age of the patients reported in the article as specific patients could not be identified. Sex: this value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event: date approximate. Please note that this date is based off of the date of publication of the article as the

									event dates were not provided in the published literature. Description of problem or event: it was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Other relevant device(s) are: product id: neu_unknown_ext, serial/lot #: unknown, implant/explant: unknown. Product id: neu_unknown_ext, serial/lot #: unknown, implant/explant: unknown. Product id: neu_unknown_ext, serial/lot #: unknown, implant/explant: unknown. Jakobs m, krasniqi e, kloss m, et al. Intraoperative stereotactic magnetic resonance imaging for deep brain stimulation electrode planning in patients with movement disorders. World neurosurg. 2018; 119: e801-e808. If information is provided in the future, a supplemental report will be issued.
3007566237-2019-01417	01/11/2018	Malfunction	MEDTRONIC NEUROMODULATION	27/06/2019	MHY	UNKNOWN LEAD	Malposition of Device	No Known Impact Or Consequence To Patient	Abstract: objective: implantation of deep brain stimulation (dbs) electrodes requires stereotactic imaging. Stereotactic magnetic resonance imaging (mri) for dbs surgery has become more popular and intraoperative mri scanners have become more available. We report on our cohort of movement disorder patients who underwent intraoperative stereotactic mri-only dbs electrode implantation. Methods: a review of our dbs database for eligible patients over a study period of 8 years was performed. Stereotactic accuracy was calculated as a directional error and the euclidean distance between planned and controlled electrode positions. Number and choice of microelectrodes, procedural times and complications were documented. Results: n = 86 surgeries in n = 81 patients with parkinson¿s disease (pd), essential tremor and dystonia were performed and n = 167 electrodes were implanted. Mean euclidean distance between planned and

									controlled target was 2.1 mm (±0.6). The directional error showed that electrodes were implanted more medial (0.3 mm ±0.9), posterior (0.5 mm ±1.0) and inferior (0.6 mm ±1.0) compared to plan. There were no significant differences for stereotactic accuracy between targets, hemispheres or order of implantation. No significant correlations between euclidean distance and number of microelectrode tracts or volume of intracranial air were observed. N = 539 microelectrodes were applied. In 28.7% non-center trajectories were chosen. Length of tremor (-61 minutes) and pd (-121 minutes) surgeries could be reduced significantly over the course of the study period. N = 1 (1.2%) intracranial hemorrhage occurred. N = 1 (0.6%) electrode had to be repositioned for lack of clinical effect. Conclusion: intraoperative stereotactic mri for dbs surgery is feasible with high stereotactic accuracy and low rates of complication. Reported events: the average directional error between planned and actual lead placement was 0.3 ±0.9 mm, 0.5 ± 1.0 mm, and 0.6 ± 1.0 mm in the x, y, and z axis respectively. The average euclidian distance between planned and actual electrode position was 2.1 ± 0.6 mm. Manufacturer narrative: this value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date approximate. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. Other relevant device(s)

									are: product id: neu_unknown_lead, qty: 167, serial/lot #: unknown, ubd: , udi#: ; implant/explant: unknown jakobs m, krasniqi e, kloss m, et al. Intraoperative stereotactic magnetic resonance imaging for deep brain stimulation electrode planning in patients with movement disorders. World neurosurg. 2018; 119:e801-e808. If information is provided in the future, a supplemental report will be issued.
3005099803-2019-04024	01/11/2018	Injury	AUGMENIX, INC.	09/08/2019	OVB	SPACEOAR SYSTEM	Material Integrity Problem; Positioning Problem	Capsular Contracture; Urinary Retention; Injury; No Code Available	It was reported to boston scientific corporation on july 17, 2019 that spaceoar was implanted during a spaceoar placement procedure performed in (b)(6) 2018. Reportedly, the implanting physician noted a high amount of pressure needed to apply the gel. Within 12 hours post-procedure, the patient complained of urinary retention. Magnetic resonance imaging (mri) showed spaceoar had been placed in the prostate, deviating the urethra, and measured approximately 1.5 cm in diameter. The patient needed a catheter for 48 hours but it was removed as urinary frequency returned to baseline. The patient underwent prostate salvage stereotactic body radiation therapy (sbrt), receiving 30 grays in 5 fractions. According to the complainant, approximately eight months after the procedure, the patient complained again of urinary retention. An mri taken six to seven months post-procedure showed that the hydrogel in the perirectal space was gone but a capsule, measuring 1.5 cm in diameter, remained in the prostate. The patients retention was being managed with self-catheterization. As of (b)(6) 2019, the physician planned to insert a needle in the capsule to drain the fluid. Attempts to obtain additional information regarding this event have been unsuccessful to date. Should additional relevant details become available; a supplement report will be submitted. Manufacturer narrative: date of event: date of event was approximated to (b)(6) 2018 as no event date was reported but it was reported that the procedure was

									performed in (b)(6) 2018. The complainant was unable to provide the suspect device lot number. Therefore, the expiration and device manufacture dates are unknown. Physician phone number: (b)(6). (b)(4). The device was implanted and will not be returned for evaluation; therefore a failure analysis of the complaint device could not be completed. If any further relevant information is identified, a supplemental medwatch will be filed.
8043933-2020-00007	30/10/2018	Death	BRAINLAB AG	31/01/2020	HAW	CRANIAL NAVIGATION SOFTWARE (VERSION 3.0)	Image Display Error/Artifact; Adverse Event Without Identified Device or Use Problem; Insufficient Information	Death	A right frontal burr hole and endoscopic (e.g. Direct visualization) resection of colloid cyst of 3rd ventricle with a stereotactic approach was performed with the aid of brainlab navigation system cranial 3.0. During the procedure the surgeon: performed an intraoperative ct scan using a non-brainlab ct scanner and accepted the automatic registration of the current patient anatomy to the navigation (to the intra-operative ct scan imported into and used by the navigation). Created a burr hole, and passed a sheath through the burr hole. Used the navigated brainlab pointer during the surgery with the sheath. Used a non-navigated non-brainlab endoscope through this sheath. At some point during the surgery, the surgeon detected a deviation of the display of navigation compared to the patient's anatomy. On (b)(6) 2020 brainlab was informed the patient died following complications, when brainlab received a request from the coroner for a report. Manufacturer narrative: with the currently available information, brainlab can neither exclude nor confirm that the brainlab device or its use caused or contributed to the death of the patient. Currently there is no indication of a systematic error or malfunction of the brainlab device, nor of insufficient measures to minimize this anticipated risk as low as reasonably practicable. A comprehensive investigation by brainlab regarding this specific event is currently ongoing and final conclusions are pending. Brainlab plans to

									issue a follow-up report upon completion of investigation.
1723170-2019-03329	24/10/2018	Injury	MEDTRONIC NAVIGATION, INC	14/06/2019	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	BoneFracture(s); Nerve Damage	Citation: jung-woo hur, md, jin-sung kim, md, phd, kyeong-sik ryu, md, phd, and myeong-hoon shin, md, phd. Accuracy and safety in screw placement in the high cervical spine: retrospective analysis of o-arm-based navigation-assisted c1 lateral mass and c2 pedicle screws. Clin spine surg 2019; 32:e193-e199) summary: objective: the purpose of present study was to evaluate accuracy, efficiency, and safety of intraoperative o-arm¿based navigation system for the placement of c1 lateral mass screw (c1lms) and c2 pedicle screws (c2pss) in high cervical spine operations. Summary of background data: high screw misplacement rates, various pedicle morphometry and vertebral body size variations have led to a search of image-guided systems to improve the surgical accuracy of screw insertion in high cervical spine. The use of o-arm has been proposed for more accurate and efficient spinal instrumentation. Materials and methods: between june 2009 and august 2016, a total of 48 patients with atlantoaxial instability were surgically treated using the image-guidance system. To reconstruct atlantoaxial instability, we have been using harm¿s technique of c1lms and c2ps fixations. A frameless, stereotactic o-arm¿based image-guidance system was used for correct screw placement. Postoperative computed tomographic scan with multiplanar reconstructions were used to determine the accuracy of the screw placement. Results: a total of 182 screws, including 90 c1lms and 92 c2pss were inserted using image-guidance system. In total, 4.4% (4/90) of c1lms and 7.6% (10/92) of c2ps had cortex violation over 2mm and considered as ¿significant.¿ among the significant cortex violations, ¿unexpected breech¿ was 3.3% of all the screws inserted. Two (2.1%) screws inserted had perforated the vertebral artery canal and iatrogenic vertebral artery stenosis was

									proved with postoperative computed tomography angiography. When divided into time periods, 60% of significant breech occurred during the beginning stage, 40% during adaptation stage and none during expert stage. Conclusions: in this study, the authors demonstrated that use of image-guidance system seems to be beneficial for high cervical instrumentation which requires much experience and steep learning curves. However, incidence of cortex violation does not disappear completely due to the close proximity to spinal canal and surrounding vessels. Reported events: two screws inserted had perforated the vertebral artery canal and iatrogenic vertebral artery stenosis was proved. No neurological complications were observed. One patient presented immediate neurological complications with a c2Fracture due to severe osteoporosis. In 10 procedures, patient not specified, perioperative screw revisions were performed due to wall perforation. Manufacturer narrative: patient weight not available from the site. Device lot number, or serial number, unavailable. 510(k) not provided as the serial number is unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2019-03325	24/10/2018	Injury	MEDTRONIC NAVIGATION, INC	14/06/2019	HAW	MEDTRONIC NAVIGATION	Human-Device Interface Problem	Tissue Damage	Citation: jung-woo hur, md, jin-sung kim, md, phd, kyeong-sik ryu, md, phd, and myeong-hoon shin, md, phd. Accuracy and safety in screw placement in the high cervical spine: retrospective analysis of o-arm-based navigation-assisted c1 lateral mass and c2 pedicle screws. Clin spine surg 2019; 32:e193-e199) summary: objective: the purpose of present study was to evaluate accuracy, efficiency, and safety of intraoperative o-arm¿based navigation system for the placement of c1 lateral mass screw (c1lms) and c2 pedicle screws (c2pss) in high cervical spine operations. Summary

									of background data: high screw misplacement rates, various pedicle morphometry and vertebral body size variations have led to a search of image-guided systems to improve the surgical accuracy of screw insertionin high cervical spine. The use of o-arm has been proposed for more accurate and efficient spinal instrumentation. Materials and methods: between june 2009 and august 2016, a total of 48 patients with atlantoaxial instability were surgically treated using the image-guidance system. To reconstruct atlantoaxial instability, we have been using harm¿s technique of c1lms and c2ps fixations. A frameless, stereotactic o-arm¿based image-guidance system was used for correct screw placement. Postoperative computed tomographic scan with multiplanar reconstructions were used to determine the accuracy of the screw placement. Results: a total of 182 screws, including 90 c1lms and 92 c2pss were inserted using image-guidance system. In total, 4.4% (4/90) of c1lms and 7.6% (10/92) of c2ps had cortex violation over 2mm and considered as ¿significant.¿ among the significant cortex violations, ¿unexpected breech¿ was 3.3% of all the screws inserted. Two (2.1%) screws inserted had perforated the vertebral artery canal and iatrogenic vertebral artery stenosis was proved with postoperative computed tomography angiography. When divided into time periods, 60% of significant breech occurred during the beginning stage, 40% during adaptation stage and none during expert stage. Conclusions: in this study, the authors demonstrated that use of image-guidance system seems to be beneficial for high cervical instrumentation which requires much experience and steep learning curves. However, incidence of cortex violation does not disappear completely due to the close proximity to spinal canal and surrounding vessels. Reported events: two screws inserted had perforated the vertebral artery canal and

									iatrogenic vertebral artery stenosis was proved. No neurological complications were observed. One patient presented immediate neurological complications with a c2Fracture due to severe osteoporosis. In 10 procedures, patient not specified, perioperative screw revisions were performed due to wall perforation. Manufacturer narrative: patient weight not available from the site. Device lot number, or serial number, unavailable. 510(k) not provided as the serial number of the product was not provided. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
3004785967-2019-00814	24/10/2018	Injury	MEDTRONIC NAVIGATION, INC	01/05/2019	OXO	O-ARM 1000 IMAGING SYSTEM	Imprecision	Tissue Damage	"Accuracy and safety in screw placement in the high cervical spine: retrospective analysis of o-arm¿based navigation-assisted c1 lateral mass and c2 pedicle screws." jung-woo hur, md, jin-sung kim, md, phd, kyeong-sik ryu, md, phd, and myeong-hoon shin, md, phd. Study design: this study was a retrospective analysis. Objective the purpose of present study was to evaluate accuracy, efficiency, and safety of intraoperative o-arm¿based navigation system for the placement of c1 lateral mass screw (c1lms) and c2 pedicle screws (c2pss) in high cervical spine operations. Summary of background data: high screw misplacement rates, various pedicle morphometry and vertebral body size variations have led to a search of image-guided systems to improve the surgical accuracy of screw insertion in high cervical spine. The use of o-arm has been proposed for more accurate and efficient spinal instrumentation. Materials and methods: between june 2009 and august 2016, a total of 48 patients with atlantoaxial instability were surgically treated using the image-guidance system. To reconstruct atlantoaxial instability, we have been using harm¿s technique of c1lms and c2ps

									fixations. A frameless, stereotactic o-arm¿based image-guidance system was used for correct screw placement. Postoperative computed tomographic scan with multiplanar reconstructions were used to determine the accuracy of the screw placement. Results: a total of 182 screws, including 90 c1lms and 92 c2pss were inserted using image-guidance system. In total, 4.4% (4/90) of c1lms and 7.6% (10/92) of c2ps had cortex violation over 2mm and considered as ¿significant.¿ among the significant cortex violations, ¿unexpected breech¿ was 3.3% of all the screws inserted. Two (2.1%) screws inserted had perforated the vertebral artery canal and iatrogenic vertebral artery stenosis was proved with postoperative computed tomography angiography. When divided into time periods, 60% of significant breech occurred during the beginning stage, 40% during adaptation stage and none during expert stage. Conclusions in this study, the authors demonstrated that use of image-guidance system seems to be beneficial for high cervical instrumentation which requires much experience and steep learning curves. However, incidence of cortex violation does not disappear completely due to the close proximity to spinal canal and surrounding vessels. Note: 140 screws of 182 total screws were placed as planned with no inaccuracies. Adverse events: the following inaccuracies were noted: 32 screws were placed with a less than 2 mm inaccuracy 10 screws were placed with an inaccuracy of 2-4 mm 4 screws were placed with an inaccuracy of more than 4 mm. Manufacturer narrative: patient information: 48 patients with mean age 58.8 years. 30 female patients, 18 male patients - gender female used as more females were in the study. Outcomes to adverse event: there was no information in the article that stated what the outcome of the adverse event was. Suspect medical device: exact system information unknown on the date of filing. Manufacture date:

									manufacture date unknown on the date of filing. Device evaluated by mfr: no parts have been received by the manufacturer for evaluation. If information is provided in the future, a supplemental report will be issued.
1723170-2019-02094	24/10/2018	Injury	MEDTRONIC NAVIGATION, INC	01/05/2019	HAW	STEALTHSTATION® S7	Imprecision	Tissue Damage	"Accuracy and safety in screw placement in the high cervical spine: retrospective analysis of o-arm¿based navigation-assisted c1 lateral mass and c2 pedicle screws." jung-woo hur, md, jin-sung kim, md, phd, kyeong-sik ryu, md, phd, and myeong-hoon shin, md, phd. Study design: this study was a retrospective analysis. Objective the purpose of present study was to evaluate accuracy, efficiency, and safety of intraoperative o-arm¿based navigation system for the placement of c1 lateral mass screw (c1lms) and c2 pedicle screws (c2pss) in high cervical spine operations. Summary of background data: high screw misplacement rates, various pedicle morphometry and vertebral body size variations have led to a search of image-guided systems to improve the surgical accuracy of screw insertion in high cervical spine. The use of o-arm has been proposed for more accurate and efficient spinal instrumentation. Materials and methods: between june 2009 and august 2016, a total of 48 patients with atlantoaxial instability were surgically treated using the image-guidance system. To reconstruct atlantoaxial instability, we have been using harm¿s technique of c1lms and c2ps fixations. A frameless, stereotactic o-arm¿based image-guidance system was used for correct screw placement. Postoperative computed tomographic scan with multiplanar reconstructions were used to determine the accuracy of the screw placement. Results: a total of 182 screws, including 90 c1lms and 92 c2pss were inserted using image-guidance system. In total, 4.4% (4/90) of c1lms and 7.6% (10/92) of c2ps had cortex violation over 2mm and considered as ¿significant.¿ among the significant cortex violations, ¿unexpected breech¿ was 3.3% of all the

									screws inserted. Two (2.1%) screws inserted had perforated the vertebral artery canal and iatrogenic vertebral artery stenosis was proved with postoperative computed tomography angiography. When divided into time periods, 60% of significant breech occurred during the beginning stage, 40% during adaptation stage and none during expert stage. Conclusions: in this study, the authors demonstrated that use of image-guidance system seems to be beneficial for high cervical instrumentation which requires much experience and steep learning curves. However, incidence of cortex violation does not disappear completely due to the close proximity to spinal canal and surrounding vessels. Note: 140 screws of 182 total screws were placed as planned with no inaccuracies. Adverse events: the following inaccuracies were noted: 32 screws were placed with a less than 2 mm inaccuracy 10 screws were placed with an inaccuracy of 2-4 mm 4 screws were placed with an inaccuracy of more than 4 mm. 10 screws were re-positioned. Manufacturer narrative: patient information: 48 patients with mean age 58.8 years. 30 female patients, 18 male patients - gender female used as more females were in the study. Outcomes to adverse event: there was no information in the article that stated what the outcome of the adverse event was. Suspect medical device: exact system information unknown on the date of filing. Manufacture date: manufacture date unknown on the date of filing. Device evaluated by mfr: no parts have been received by the manufacturer for evaluation. If information is provided in the future, a supplemental report will be issued.
1723170-2019-02261	20/10/2018	Injury	MEDTRONIC NAVIGATION, INC	10/05/2019	HAW	S7 STEALTHSTATION NAVIGATION SYSTEM	Adverse Event Without Identified Device or Use Problem	Tissue Damage	Citation: arthur wang, michael s. Tenner, meic h. Schmidt, christian bowers placement of ommaya reservoirs using electromagnetic neuronavigation and neuroendoscopy: a retrospective study with cost-benefit analysis. World neurosurgery volume 122, february 2019, pages e723-e728.

									Https://doi.org/10.1016/j.wneu.2018.10.127. Background: placement of intraventricular catheters in oncology patients is associated with high complication rates. Placing ommaya reservoirs with the zero-error precision protocol (zepp), a combination of neuronavigation (axiem stereotactic navigation) and direct verification of catheter tip placement with a flexible neuroendoscope, is associated with decreased complication rates as a result of increased catheter placement accuracy. However, the zepp costs more than traditional methods of catheter placement, and the question of whether this increased accuracy with the zepp is cost-effective is unknown. Methods we performed a single-center retrospective chart review of 50 consecutive ommaya reservoir patient placements between 2010 and 2017. Twenty-five ventricular catheters were placed using the zepp protocol, and 25 ventricular catheters were placed using only axiem stealth navigation. Postoperative catheter accuracy and complication rates were assessed. A cost-benefit analysis was then conducted to determine if the overall cost for placing ommaya reservoirs with the zepp was effective compared with the alternative method of using neuronavigation alone. Results in the non-zepp cohort, 10 of 25 catheters were placed within the optimal location compared with 25 of 25 catheters placed in the zepp cohort. Three complications occurred in the non-zepp cohort: 2 malpositioned catheters required surgical revision and 1 catheter- related hemorrhage resulted in a prolonged stay in the intensive care unit. No complications occurred in the zepp cohort. A cost-benefit analysis showed $4784 savings per patient with zepp utilization because of the high complication-associated costs. Conclusions implementation of the zepp for verifying ventricular catheter placement in ommaya reservoirs improved catheter tip accuracy,

									resulted in lower complication rates, and was more cost-effective when compared with the non-zepp cohort, which used only neuronavigation. The zepp can be used for ventricular shunt catheter placement to decrease complications and verify catheter tip accuracy in ommaya or standard ventriculoperitoneal shunts. Reported events: 1 patient experienced an extended icu stay due to a catheter related interventricular hemorrhage with neurologic deficit from multiple ventricular catheter passes. 2 patients had to undergo revision surgeries due to a parenchymal catheter tip location. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued. - manufacturer narrative: age or date of birth: patient age is mean value of patient age's from the study. Sex: patient sex not available from the site. Weight: patient weight not available from the site. Udi #: unique device identifier (udi) is unavailable. Device evaluated by mfr: no additional information has been provided/submitted to the manufacturer for an evaluation to be conducted. If information is provided in the future, a supplemental report will be issued.
1723170-2019-02262	20/10/2018	Injury	MEDTRONIC NAVIGATION, INC	10/05/2019	HAW	S7 STEALTHSTATION NAVIGATION SYSTEM	Adverse Event Without Identified Device or Use Problem	Hemorrhage/Bleeding	Citation: arthur wang, michael s. Tenner, meic h. Schmidt, christian bowers placement of ommaya resevoirs using electromagnetic neuronavigation and neuroendoscopy: a retrospective study with cost-benefit analysis. World neurosurgery volume 122, february 2019, pages e723-e728. Https://doi.org/10.1016/j.wneu.2018.10.127 background: placement of intraventricular catheters in oncology patients is associated with high complication rates. Placing ommaya reservoirs with the zero-error precision protocol (zepp), a combination of neuronavigation (axiem stereotactic navigation) and direct verification of catheter tip placement with a flexible

									neuroendoscope, is associated with decreased complication rates as a result of increased catheter placement accuracy. However, the zepp costs more than traditional methods of catheter placement, and the question of whether this increased accuracy with the zepp is cost-effective is unknown. Methods we performed a single-center retrospective chart review of 50 consecutive ommaya reservoir patient placements between 2010 and 2017. Twenty-five ventricular catheters were placed using the zepp protocol, and 25 ventricular catheters were placed using only axiem stealth navigation. Postoperative catheter accuracy and complication rates were assessed. A costbenefit analysis was then conducted to determine if the overall cost for placing ommaya reservoirs with the zepp was effective compared with the alternative method of using neuronavigation alone. Results in the non-zepp cohort, 10 of 25 catheters were placed within the optimal location compared with 25 of 25 catheters placed in the zepp cohort. Three complications occurred in the non-zepp cohort: 2 malpositioned catheters required surgical revision and 1 catheter- related hemorrhage resulted in a prolonged stay in the intensive care unit. No complications occurred in the zepp cohort. A cost-benefit analysis showed $4784 savings per patient with zepp utilization because of the high complication-associated costs. Conclusions implementation of the zepp for verifying ventricular catheter placement in ommaya reservoirs improved catheter tip accuracy, resulted in lower complication rates, and was more cost-effective when compared with the non-zepp cohort, which used only neuronavigation. The zepp can be used for ventricular shunt catheter placement to decrease complications and verify catheter tip accuracy in ommaya or standard ventriculoperitoneal shunts. Reported events: 1 patient experienced an extended icu stay due to a catheter related

									interventricular hemorrhage with neurologic deficit from multiple ventricular catheter passes. 2 patients had to undergo revision surgeries due to a parenchymal catheter tip location. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued. Manufacturer narrative: patient age is the mean of all patients in the study. Patient sex not available from the site. Patient weight not available from the site. Unique device identifier (udi) is unavailable. No additional information has been provided/submitted to the manufacturer for an evaluation to be conducted. If information is provided in the future, a supplemental report will be issued. (b)(4).
1222780-2018-00248	18/10/2018	Malfunction	HOLOGIC, INC.	11/12/2018	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Material Twisted/Bent	No Consequences Or Impact To Patient	It was reported that during a biopsy procedure, "the ended part of needle got damaged during firing process". Prior to the procedure no abnormalities were found, "they brought cocked device to target, they fired and started with biopsy cycle". No specimen was taken, the needle was removed and it was noted that "chamber area, the metal looks like turned". No injury was reported. A second device was used to successfully complete the biopsy. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications. Internal complaint reference: (b)(4).
1222780-2018-00244	18/10/2018	Injury	HOLOGIC, INC.	30/11/2018	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Suction Failure	Hematoma	It was reported that during a biopsy procedure, "it was only possible to take a sample of 3 pieces, because no vacuum built up." as reported, the procedure had to be stopped. The patient developed "an unexpected and big hematoma in the breast, taking place suddenly and remaining for more than one week. A clinical examination followed one week later. The physician reported that the samples had been sufficient and no additional procedure was needed. Manufacturer narrative: the

									device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications. Internal complaint reference: (b)(4).
3007566237-2018-03176	17/10/2018	Injury	MEDTRONIC NEUROMODULATION	30/10/2018	HAW	UNKNOWN BILATERAL NEXFRAME	Insufficient Information	No Known Impact Or Consequence To Patient	Information was received from a manufacturing representative about a patient with an implantable neurostimulator (ins) for unknown indications for use. It was reported that during the lead implant procedure one screw of stereotactic head frame required drilling of the base to remove the device. The first side was fixed with six screws, all of which were removed with a screwdriver. On the second side the frame was fixed with six screws and removed with a screwdriver, however one screw required drilling of the frame in order to remove the device. There were no difficulties to the patient and implant had good results. The procedure lasted an additional 30 minutes as a result. The issue was resolved at the time of the report. There were no symptoms reported. No further complications were reported or anticipated.it was reported that the cause of the issue was not determined. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued.
1220984-2018-00169	11/10/2018	Malfunction	HOLOGIC, INC	07/11/2018	IZH	MULTICARE PLATINUM	Positioning Problem	No Consequences Or Impact To Patient	It was reported that the x-axis is out of tolerance and tissue was missed on two patients. "both patients have to be treated again." no injury reported. A field engineer was dispatched to the site and determined the x-axis potentiometer needed to be replaced. Once this was completed the system was working as intended.
1723170-2019-05153	09/10/2018	Malfunction	MEDTRONIC NAVIGATION, INC	09/10/2019	HAW	MEDTRONIC NAVIGATION NAVIGATION SYSTEM	Output Problem	No Known Impact Or Consequence To Patient	Citation: julia d. Sharma, md, frcsc, kiran k. Seunarine, phd, muhammad zubair tahir, fcps, frcs(sn), and martin m. Tisdall, md, frcs(sn); accuracy of robot-assisted versus optical frameless navigated stereoelectroencephalography electrode

									placement in children. J neurosurg pediatr 23:297-302, 2019 objective the aim of this study was to compare the accuracy of optical frameless neuronavigation (on) and robotassisted (ra) stereoe lectroencephalography (seeg) electrode placement in children, and to identify factors that might increase the risk of misplacement. Methods the authors undertook a retrospective review of all children who underwent seeg at their institution. Twenty children were identified who underwent stereotactic placement of a total of 218 electrodes. Six procedures were performed using on and 14 were placed using a robotic assistant. Placement error was calculated at cortical entry and at the target by calculating the euclidean distance between the electrode and the planned cortical entry and target points. The mann-whitney u-test was used to compare the results for on and ra placement accuracy. For each electrode placed using robotic assistance, extracranial soft-tissue thickness, bone thickness, and intracranial length were measured. Entry angle of electrode to bone was calculated using stereotactic coordinates. A stepwise linear regression model was used to test for variables that significantly influenced placement error. Results between 8 and 17 electrodes (median 10 electrodes) were placed per patient. Median target point localization error was 4.5 mm (interquartile range [iqr] 2.8¿6.1 mm) for on and 1.07 mm (iqr 0.71¿1.59) for ra placement. Median entry point localization error was 5.5 mm (iqr 4.0¿6.4) for on and 0.71 mm (iqr 0.47¿1.03) for ra placement. The difference in accuracy between stealth-guided (on) and ra placement was highly significant for both cortical entry point and target (p <(><<)> 0.0001 for both). Increased soft-tissue thickness and intracranial length reduced accuracy at the target. Increased soft-tissue thickness, bone thickness, and younger age reduced accuracy at entry. There were no complications. Conclusions ra stereotactic

									electrode placement is highly accurate and is significantly more accurate than on. Larger safety margins away from vascular structures should be used when placing deep electrodes in young children and for trajectories that pass through thicker soft tissues such as the temporal region. Reported events: 1) mean accuracy of the electrodes placed with the navigation system was 4.5mm, higher than anticipated. Manufacturer narrative: patient age is the mean value of the patients in the study. Patient sex not available from the site. Patient weight not available from the site. Device lot number, or serial number, unavailable. 510(k) is dependent on the serial number and associated product number, which is therefore, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2019-05232	07/10/2018	Injury	MEDTRONIC NAVIGATION, INC	15/10/2019	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage	Citation: cristian de quintana-schmidt, andreas leidinger, joan molet teixido, gerardo conesa bertran. Application of a thrombin-gelatin matrix in the management of intractable hemorrhage during stereotactic biopsy. World neurosurgery 2019 121:180-185 - background: few studies have been published about percutaneous techniques for management of surgical bed hemorrhage during a stere otactic biopsy, a serious complication that may affect patient outcome. We describe the injection of a thrombin-gelatin matrix through the biopsy cannula as an effective method to arrest surgical bed bleeding that does not respond to conventional methods of hemostasis. - methods: we prospectively documented image-guided stereotactic brain biopsy procedures in 30 awake patients between july 2014 and july 2017 at our center. Among patients presenting with intractable surgical bed bleeding, a thrombin-gelatin matrix injection through the biopsy cannula was performed. Details

									of the injection technique, surgical outcome, and complications were recorded. - results: among 30 documented stereotactic brain biopsies, 3 (10%) had intractable surgical bed bleeding during the procedure. In all 3 cases, thrombin-gelatin matrix was injected, and an immediate arrest of hemorrhage was achieved. None of the patients required a craniotomy or further invasive measure to achieve hemostasis. No postoperative complications were recorded. - conclusions: our preliminary results suggest that thrombin-gelatin matrix injection is a simple, safe, and effective stereotactic practice to manage persistent surgical bed bleeding that cannot be arrested by standard, conventional hemostatic methods. Reported events: two patients experienced intra-operative surgical bed bleeding, assessed by exit of blood through the proximal end of the biopsy cannula during the procedure. Irrigation with temperate saline solution and controlled hypotension achieved hemostasis. Three patients experienced intra-operative surgical bed bleeding, presented with profuse arterial bleeding through the biopsy cannula. Defined by the surgeon as intractable, thrombin-gelatin matrix (tgm) injection was performed and immediate hemostasis was observed. Manufacturer narrative: patient age is the mean value of the 30 patients involved in the study. Patient gender is the majority value of the 30 patients involved in the study. Patient weight not available from the site. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. Other relevant device(s) are: product id: 9733986, serial/lot #: (b)(4). If information is provided in the future, a supplemental report will be issued.
2020394-2018-01998	28/09/2018	Malfunction	BARD PERIPHERAL VASCULAR, INC.	08/11/2018	KNW	ENCOR BIOPSY DEVICE	Device Contaminati on with	No Consequences	It was reported that after completing a stereotactic-guided biopsy, when needle was removed, allegedly a plastic piece was

							Chemical or Other Material	Or Impact To Patient	found in the needle guide. There was no reported patient injury. Manufacturer narrative: no medical records or no medical images have been made available to the manufacturer. As the lot number for the device was provided, a review of the device history records is currently being performed. The device has been returned to the manufacturer for evaluation. The investigation of the reported event is currently underway.
3005075696-2020-00017	26/09/2018	Malfunction	MAZOR ROBOTICS LTD	14/02/2020	HAW	RENAISSANCE SYSTEM	Use of Device Problem	No Known Impact Or Consequence To Patient	Medtronic received information regarding a guidance system being used during a cranial procedure. It was reported that planning was done a day prior to the case. The planning used t1, t1 with contrast, t2, the white matter was nulled, and mri's were taken. The base was mounted in the pre-op with the surgeon, and measurements were taken from nasion and both outer canthi. The ct scan was completed using low-dose children's stereotactic head protocol. The ct images downloaded from the pacs planning station, and the initial fusion was achieved with adjustments. The left gpi trajectory was accurate and the lead was placed. The stn trajectory was sent, but it seemed to be 2mm lateral and the surgeon elected to do another pass that was 3mm medial in the bengun. The o-arm spin was completed and fused, but the lead appeared to be 2mm posterior. The surgeon elected to adjust the plan 2mm anterior and pass through the medial hole in the bengun. The surgeon was pleased with the accuracy of the third pass and placed the lead. There was no patient harm and the procedure was not delayed over an hour. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued.
3008492462-2018-00066	24/09/2018	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	19/10/2018	IZH	MAMMOTEST, BIOPSY TABLE	Circuit Failure	No Patient Involvement	Devicor medical products received a report from affiliate stating, the generator is heated up and smells like something is burning. This has been documented in our complaint system as record (b)(4). Manufacturer narrative: the mammotome mammotest system is used for minimally invasive breast biopsy procedures. The

									system uses x-ray guidance for stereotactic localization, allows the physician to accurately place a biopsy needle for the retrieval of tissue samples in the area of concern. Devicor field service engineer evaluated the device and found the cause of the burning smell to be related to capacity on 24v power card. Excessive current draw from a short circuit; 24v to ground. It is not likely that this short circuit would have led to a fire in the device. Although there was no patient consequence, due to the remote potential of this malfunction to cause or contribute to death or serious injury as a result of a remote potential of device fire, this has been determined to be reportable pursuant to 21 cfr 803.
1723170-2018-05273	24/09/2018	Malfunction	MEDTRONIC NAVIGATION, INC	19/10/2018	HAW	STEALTHSTATION S7 SYSTEM	Computer Software Problem	No Patient Involvement	Medtronic received information regarding a navigation system being used during a stereotactic frame deep brain stimulation (dbs) case. It was report that intra-operatively, while navigating, the site had lined up in guidance view and locked down the stereotactic frame. The site then went back to the orthogonal views and their entry point was not where the probe was. They reset the entry but now going back into guidance, they were no longer lined up. The site then re-aligned the stereotactic frame and were able to proceed. The procedure was completed using the navigation system. There was no reported impact to patient outcome or surgical delay. Manufacturer narrative: a software analysis was conducted and it was determined that the event was a known anomaly. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: video has been received for analysis and is pending review. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
3002838670-2018-00003	24/09/2018	Injury	MRI INTERVENTIONS	15/10/2018	HAW	CLEARPOINT	Device Dislodged or Dislocated;U	Hemorrhage, Subdural; Seizures	During the procedure, the mri scanner table unexpectedly moved past iso center causing the drape to dislodge the smartframe stereotactic frame,Breaking the inserted

							nintended Movement		stylet. The stylet was removed without issue, a subsequent image was taken showing minor subdural bleeding. Cause of bleeding was not determined, patient was monitored for a period of time followed by the surgeon successfully completing the procedure. Shortly after the procedure the patient began to have seizures and was placed in medical induced state of unconsciousness. After approximately 1 week, the patient was awaken and is recovering well. Hospital engineering was made aware of the scanner table issue.
3008492462-2018-00083	21/09/2018	Malfunction	DEVICOR MEDICAL PRODUCTS INC.	19/10/2018	IZH	MAMMOTOME MAMMOTEST SYSTEM	Circuit Failure	No Consequences Or Impact To Patient	Devicor medical products inc. Received a report from affiliate, (b)(4), stating, during procedure of biopsy and first exposition of x-ray, screen of pc froze and it was not able to make any adjustments of picture. Software tools for adjustments and pictures don´t work. After that is reported that power supply of pc is down and motherboard smells of burning". This has been documented in our complaint system. Manufacturer narrative: the mammotome mammotest¿ system is used for minimally invasive breast biopsy procedures. The system uses x-ray guidance for stereotactic localization, allows the physician to accurately place a biopsy needle for the retrieval of tissue samples in the area of concern. The field service engineer confirmed the computer component of the device had a burning smell, however exhibited no signs of burning on the components. The likely cause of the failure was the capacitors on the motherboard. The cpu cooler was found to be working intermittently. Although there was no patient consequence, due to the remote potential of this malfunction to cause or contribute to death or serious injury as a result of a remote potential of device fire, this has been determined to be reportable pursuant to 21 cfr 803.
1220984-2018-00164	17/09/2018	Malfunction	HOLOGIC, INC	15/10/2018	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was reported that after raising the table it drifts back down and an electrical burning smell was also noted. No injury reported. A field engineer was dispatched to the site

									and it was determined that the power control board, the keypad, and lockout board needed to be replaced, and the microswitch needed to be adjusted. Once this was completed the system was working as intended.
1723170-2018-06488	12/09/2018	Injury	MEDTRONIC NAVIGATION, INC	28/12/2018	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Weakness	Citation: harris, m. , steele, j. , williams, r. , pinkston, j. , zweig, r. And wilden, j. A. (2018), mri-guided laser interstitial thermal thalamotomy for medically intractable tremor disorders. Movement disorders. Doi:10.1002/mds.27545 summary: abstract: introduction: medically intractable tremors are a common, difficult clinical situation. Deep brain stimulation decreases p arkinson¿s disease resting tremor and essential tremor, but not all patients are candidates from a diagnostic, medical, or social standpoint, prompting the need for alternative surgical strategies. Methods: we describe 13 patients with medically intractable tremor treated with laser interstitial thermal thalamotomy performed under general anesthesia using live mri-guidance and the clearpoint stereotactic system. Results: all patients had a dramatic decrease in tremor immediately postoperatively, which has been sustained through follow-up (3-17 months) in all but 1 patient (mean tremor score reduction of 62%; 10.33 ± 2.69 to 3.89 ± 3.1). Objective side effects were transient and included imbalance and paresthesia. Conclusion: medically intractable tremor treated with laser interstitial thermal thalamotomy may be a useful addition to the treatment armamentarium for medically intractable tremor disorders. Reported event: one male patient with essential tremor (et) had generalized weakness after the procedure that required inpatient rehabilitation. It was reported that his fragile state (leukemia) combined with anesthesia were likely contributing factors. Manufacturer narrative: age provided is the average age of male patients with essential tremor. Please note that this date is based off of the date that the article was accepted for

									publication as the event date was not provided in the published literature. Device serial number not provided. Udi not available for this system. No parts have been received by the manufacturer for evaluation. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
3005985723-2018-00564	07/09/2018	Malfunction	MAKO SURGICAL CORP.	02/10/2018	OLO	HANDPIECE MICS	Mechanical Problem; Non Reproducible Results	No Known Impact Or Consequence To Patient	The customer reported that the mics handpiece kept spinning even when the trigger was not depressed. The handpiece was used to complete the case as the reaming function was working correctly. If the handpiece continued to run on the stryker mako specialist switched it off using the override function on his computer. Hip case (tha). Mps stated- yes, handpiece continue to run while out of the stereotactic ¿haptic¿. Manufacturer narrative: as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available.
3005075696-2020-00028	04/09/2018	Malfunction	MAZOR ROBOTICS LTD	14/02/2020	HAW	RENAISSANCE SYSTEM	Insufficient Information	No Known Impact Or Consequence To Patient	Medtronic received information regarding a guidance system being used during a cranial procedure to place leads in bilateral gpi for deep brain stimulation. It was reported that the procedure was planned the day prior to surgery in the surgeon's clinical using t1, t1 with contrast, t2, white matter nulled and swan mris. The surgical base was mounted pre-operatively with the surgeon. Measurements were taken from nasion and both outer canthi. The ct was completed using stereotactic head protocol. The ct was downloaded from the pacs to the workstation. The initial fusion had to be adjusted to be acceptable but was verified to be accurate by the surgeon after adjustment. The left trajectory was sent to mark the skin for incision and this was repeated on the right. The left trajectory was sent for marking the burr hole, countersinking, and confirming the burr hole cover placement. The same was completed on the right. Remaining at the right side trajectory, the to-target guide

									cannula was placed with the stylet and a portable ct spin was done. The stylet appeared 2mm medial and the surgeon opted to do another pass 2mm lateral in a probe. Another portable ct spin was completed and the surgeon was pleased with the accuracy of the second pass. The right lead was placed. The same process was completed on the left side with the to-target guide cannula placed with the stylet and portable ct spin completed to verify location. The surgeon was please with the accuracy of the first pass and placed the lead. No patient harm was reported and surgery was delayed less than an hour. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued.
3005075696-2018-00021	02/09/2018	Injury	MAZOR ROBOTICS LTD.	27/09/2018	HAW	RENAISSANCE	Adverse Event Without Identified Device or Use Problem	Muscle Weakness; Nerve Damage; Neurological Deficit/Dysfunction; Paresis; Spinal Column Injury	After a surgical procedure using the renaissance system at (b)(6), on (b)(6) 2018 (reported to mazor on september 03, 2018) we received the following report from a senior surgeon (verbatim): "on (b)(6), during a trauma case at 21:00, the operating surgeon has had 1 lateral screw and 1 medial screw at t11. The reason, according to the senior surgeon, is that the operating surgeon used the hover-t platform, but chose the mdb icon on the operation mode, and on t11 when the sw suggested a solution with slider stations other than center, he did not realize that, and proceeded with slider station 21, while in fact he was using the hover-t meaning there is no option for moving the slider. This has resulted in 1 lateral and 1 medial deviation in t11. Afterwards the surgeon has noticed the error and chose center for all trajectories. The surgeon has chosen mdb and proceeded with the solution with slider stations, while in fact he mounted the hover-t platform. The surgeon has stated the patient is suffering from a severe neural deficit, the patient can barely move his legs." a follow up report from mazor clinical sales representative supporting the site a week later: "the patient was able to move his legs and to take a few steps." additional

									report on patient condition dated sep. 26, 2018: "there has been improvement in the patient condition. He will be rehabilitating the coming months. He is independently able to care for himself. He is able to walk longer distances with the aid of a walker-rollator."
1723170-2020-02930	28/08/2018	Injury	MEDTRONIC NAVIGATION, INC	09/11/2020	HAW	STEALTHSTATION S7	Adverse Event Without Identified Device or Use Problem	Hemorrhage/Bleeding	Citation: georgi minchev, gernot kronreif, wolfgang ptacek, christian dorfer, alexander micko, svenja maschke, federico g. Legnani, georg widhalm, engelbert knosp, and stefan wolfsberger. A novel robot-guided minimally invasive technique for brain tumor biopsies. J neurosurgery 132: 150-158, 2020. Https://thejns.org/doi/abs/10.3171/2018.8.jns182096 objective: as decisions regarding tumor diagnosis and subsequent treatment are increasingly based on molecular pathology, the frequency of brain biopsies is increasing. Robotic devices overcome limitations of frame-based and frameless techniques in terms of accuracy and usability. The aim of the present study was to present a novel, minimally invasive, robot-guided biopsy technique and compare the results with those of standard burr hole biopsy. Methods a tubular minimally invasive instrument set was custom-designed for the isys-1 robot-guided biopsies. Feasibility, accuracy, duration, and outcome were compared in a consecutive series of 66 cases of robot-guided stereotactic biopsies between the minimally invasive (32 patients) and standard (34 patients) procedures. Results application of the minimally invasive instrument set was feasible in all patients. Compared with the standard burr hole tech nique, accuracy was significantly higher both at entry (median 1.5 mm [range 0.2¿3.2 mm] vs 1.7 mm [range 0.8¿5.1 mm], p = 0.008) and at target (median 1.5 mm [range 0.4¿3.4 mm] vs 2.0 mm [range 0.8¿3.9 mm], p = 0.019). The incision-to-suture time was significantly shorter (median 30 minutes [range 15¿50 minutes] vs 37.5 minutes [range 25¿105 minutes], p

									<(><<)> 0.001). The skin incision was significantly shorter (median 16.3 mm [range 12.7¿23.4 mm] vs 28.4 mm [range 20¿42.2 mm], p = 0.002). A diagnostic tissue sample was obtained in all cases. Conclusions application of the novel instrument set was feasible in all patients. According to the authors¿ data, the minimally invasive robot-guidance procedure can significantly improve accuracy, reduce operating time, and improve the cosmetic result of stereotactic biopsies. Reported events: one patient from the standard burr hole group experienced an intralesional hemorrhage at the target position was observed on an early postoperative ct scanning. Manufacturer narrative: patient age is the mean value of patients in the study. Patient gender is the majority value of patients in the study. A4) patient weight not available from the site. Event date is the accepted date of the publication. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2018-04844	28/08/2018	Injury	MEDTRONIC NAVIGATION, INC. (LOUISVILLE)	19/09/2018	HAW	STEALTHSTATION S7 SYSTEM	Computer Software Problem; Imprecision	Tissue Damage	Medtronic received information that, while in a cranial biopsy, a mismatch was observed between the merges and plan for the procedure. It was noted there was a suspected shift in the brain. It was noted that the target coordinates shifted following the generation of the plan and trajectory. The reported issue occurred after placement of four screws and the stereotactic frame. The surgeon then opted to discontinue with the procedure.medtronic received information that, while in a cranial biopsy, a mismatch was observed between the merges and plan for the procedure. It was noted there was a suspected shift in the brain. It was noted that the target coordinates shifted following the generation of the plan and trajectory.

									The reported issue occurred after placement of four screws and the stereotactic frame. The surgeon then opted to discontinue with the procedure. Manufacturer narrative: a software analysis was initiated to determine the probable cause of the issue. Analysis was unable to determine probable cause without further information since the behavior cannot be replicated. This case may be reopened if additional information is received. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: no additional information has been provided/submitted to the manufacturer for an evaluation to be conducted. Device manufacture date is unavailable. Manufacturer narrative: correction: aware date of initial report inadvertently incorrect. Should have been (b)(6) 2018. Would have no affected timely reporting. Manufacturer narrative: additional information: unique device identification (udi) and device manufacture date provided. Manufacturer narrative: additional information: patient id. Patient weight asked but unknown. If information is provided in the future, a supplemental report will be issued.
1723170-2019-05016	24/08/2018	Injury	MEDTRONIC NAVIGATION, INC	26/09/2019	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Tissue Damage	Citation: zaman mirzadeh, md, phd, tinsue chen, md, kristina m. Chapple, phd, margaret lambert, rn, bsm, john p. Karis, md, rohit dhall, md, francisco a. Ponce, md. Procedural variables influencing stereotactic accuracy and efficiency in deep brain stimulation surgery. Operative neurosurgery volume 17, number 1, july 2019 background: deep brain stimulation (dbs) is well-established, evidence-based therapy for parkinson disease, essential tremor, and pri mary dystonia. Clinical outcome studies have recently shown that ¿asleep¿ dbs lead placement, performed using intraoperative imaging with stereotactic accuracy as the surgical endpoint, has motor outcomes comparable to traditional ¿awake¿ dbs using microelectrode recording (mer), but with

									shorter case times and improved speech fluency. Objective: to identify procedural variables in dbs surgery associated with improved surgical efficiency and stereotactic accuracy. Methods: retrospective review of 323 cases with 546 leads placed (august 2011-october 2014). In 52% (n = 168) of cases, patients were asleep under general anesthesia without mer. Multivariate regression identified independent predictors of reduced surgery time and improved stereotactic accuracy. Results: mer was an independent contributor to increased procedure time (+44 min; p= .03). Stereotactic accuracy was better in asleep patients. Accuracy was improved with frame-based stereotaxy at head of bed 0¿ vs frameless stereotaxy at head of bed 30¿. Improved accuracy was also associated with shorter procedures (r = 0.17; p= .049). Vector errors were evenly distributed around the planned target for the globus pallidus internus, but directionally skewed for the subthalamic (medial-posterior) and ventral intermediate nuclei (medial-anterior). Conclusion: distinct procedural variables in dbs surgery are associated with reduced case times and improved stereotactic accuracy. Reported events: 12 revisions surgeries were conducted out of 323 total procedures. Manufacturer narrative: patient age is the mean value of patient ages from the study. Patient sex not available from the site. Patient weight not available from the site. Device lot number, or serial number, unavailable. 510(k) is unavailable as the value is dependent on the serial number of the product. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
3007566237-2019-00065	24/08/2018	Injury	MEDTRONIC NEUROMODULATION	07/01/2019	MHY	UNKNOWN IMPLANTABLE	Adverse Event Without Identified	No Known Impact Or Consequence To Patient	Summary: background: deep brain stimulation (dbs) is well-established, evidence-based therapy for parkinson disease, essential tremor, and primary

						NEUROSTIMULATOR	Device or Use Problem		dystonia. Clinical outcome studies have recently shown that ¿asleep¿ dbs lead placement, performed using intraoperative imaging with stereotactic accuracy as the surgical endpoint, has motor outcomes comparable to traditional ¿awake¿ dbs using microelectrode recording (mer), but with shorter case times and improved speech fluency. Objective: to identify procedural variables in dbs surgery associated with improved surgical efficiency and stereotactic accuracy. Methods: retrospective review of 323 cases with 546 leads placed (august 2011-october 2014). In 52% (n = 168) of cases, patients were asleep under general anesthesia without mer. Multivariate regression identified independent predictors of reduced surgery time and improved stereotactic accuracy. Results: mer was an independent contributor to increased procedure time (+44 min; p= .03). Stereotactic accuracy was better in asleep patients. Accuracy was improved with frame-based stereotaxy at head of bed 0 vs frameless stereotaxy at head of bed 30. Improved accuracy was also associated with shorter procedures (r = 0.17; p= .049). Vector errors were evenly distributed around the planned target for the globus pallidus internus, but directionally skewed for the subthalamic (medial-posterior) and ventral intermediate nuclei (medial-a nterior). Conclusion: distinct procedural variables in dbs surgery are associated with reduced case times and improved stereotactic accuracy. Reported events: 12 patients with deep brain stimulation (dbs) included in the study were undergoing a revision surgery for unspecified reasons. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: age at time of event: this value is the average age of the patients reported in the article as specific patients could not be identified. Date of event: please note that this date is based

									off the date that the article was accepted for publication as the event dates were not provided in the published literature. Other relevant device(s) are: product id: neu_unknown_lead, serial/lot #: unknown, udi#: (b)(4). Z., chen, t., chapple, km., lambert, m., karis, jp., dhall, r., ponce, fa. Procedural variables influencing stereotactic accuracy and efficiency in deep brain stimulation surgery. Oper neurosurg (hagerstown). 2018. Doi: 10.1093/ons/opy291. If information is provided in the future, a supplemental report will be issued.
1820334-2018-02675	24/08/2018	Malfunction	COOK INC	10/09/2018	MIJ	KOPANS MODIFIED BREAST LESION LOCALIZATIO N NEEDLE	Material Separation	No Code Available	It was reported that a kopans modified breast lesion localization needle was inserted into the patient via stereotactic guidance prior to a procedure. Post wire mammograms were then performed without complication. The wire was secured to the patient after the mammogram. As the patient walked to another room, the wire broke in two, leaving one end still anchored in the patient's breast. The radiologist secured the small external piece of the wire with tape upon noticing the wire had broken. A second wire was required which was unrelated to the first wireBreaking, and upon insertion, the radiologist noticed that the first wire had broken at the proximal end near the hub. A second series of post wire mammogram showed both the intact and broken wires. Both wires were successfully removed during the procedure. Manufacturer narrative: (b)(6). Pma/510(k) #: exempt. This report includes information known at this time. A follow up report will be submitted should additional relevant information become available.
MW5080699	21/08/2018	Injury	DEVICOR MEDICAL PRODUCTS, INC.	18/10/2018	KNW	MAMMOTO ME REVALUE BIOPSY SITE IDENTIFIER	Break; Detachment of Device or Device Component	Foreign Body In Patient	On (b)(6) 2018 mammogram stereotactic right breast biopsy for indeterminate right breast microcalcifications. Multiple passes were made under ultrasound guidance using a vacuum assisted 10 gauge elite device. A titanium clip was placed at biopsy site. Specimen was sent to pathology for review. Microcalcifications were noted in the specimen radiograph. Post stereotactic

									biopsy right breast mammogram confirmed titanium clip was in the appropriate location. In addition, on the right mlo view, a 12 x 2.4 mm cylindrical structure, which likely corresponded to the radiopaque tip of the mammotome mark which sheared off during the procedure, located approx 7cm proximal to the titanium clip, superficially. The pt was informed of the sheared mammomark catheter tip and concurred with the surgeon's plan to leave the tip in place. The surgical pathology report revealed benign microcalcifications. The pt had no complaints of pain until (b)(6) 2018. On (b)(6) 2018, the pt underwent exploration and removal of foreign body in right breast under local anesthesia plus sedation. The tip of the mammotome was taken out and sent to pathology. On (b)(6) 2018, the pt was seen in the surgery clinic and was doing well with well healing wounds. Dates of use: (b)(6) 2018. Diagnosis or reason for use: stereotactic right breast biopsy. The product was not compounded; the product was not over-the-counter.
3008492462-2019-00011	21/08/2018	Injury	DEVICOR MEDICAL PRODUCTS, INC.	28/02/2019	NEU	MAMMOMARK BREAST BIOPSY SITE MARKER	Detachment of Device or Device Component	Device Embedded In Tissue or Plaque	Devicor medical products, inc. Received a user medwatch stating, "(b)(6) 2018 mammogram stereotactic right breast biopsy for indeterminate right breast microcalcifications, multiple passes were made under ultrasound guidance using a vacuum assisted 10-guage elite device. A titanium clip was placed at biopsy site. Specimen was sent to pathology for review. Microcalcifications were noted in the specimen radiograph. Post stereotactic biopsy right breast mammogram confirmed titanium clip was in the appropriate location. In addition, on the right mlo view, a 12x2.4 mm cylindrical structure, which likely corresponded to the radiopaque tip of the mammotome mark which sheared off during the procedure, located approx 7cm proximal to the titanium clip, superficially. The pt was informed of the sheared mammomark catheter tip and concurred with the surgeon's plan to leave the tip in

									place. The surgical pathology report revealed benign microcalcifications. The pt had no complaints of pain until (b)(6) 2018. On (b)(6) 2018, the pt underwent exploration and removal of foreign body in right breast under local anesthesia plus sedation. The tip of the mammotome was taken out and sent to pathology. On (b)(6) 2018 , the pt was seen in the surgery clinic and was doing well with well healing wounds. Dates of use: (b)(6) 2018. Diagnosis or reason for use: stereotactic right breast biopsy. The product was not compounded; the product was not over-the-counter". Report number mw5080699. This has been documented in our system as record # (b)(4). Manufacturer narrative: the mammomark biopsy site identifier is a sterile, single use device intended for use after an open surgical or percutaneous breast biopsy procedure to mark the biopsy site. The device is not available for analysis, which precludes a full investigation and analysis of the root cause. However, this failure mode is identified in the risk management file and will occur at the end of the procedure and involves the marker tip physicallyBreaking. The failure mode involves the tip of a side deploy marker shearing on the cutter of a disposable probe and separating from the body of the marker. Should this failure mode occur, there is a chance the broken marker tip may be left in the patient's breast. Medical intervention is required to remove the sheared tip. Based on patient consequences of unintended piece of the device of the device left in the biopsy site, and the additional surgical procedure to remove, and purusant to 21 cfr 803. We are submitting this medwatch report.
3008492462-2018-00070	15/08/2018	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	06/09/2018	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE - 10G	Failure to Obtain Sample	No Consequences Or Impact To Patient	Devicor medical products, inc. Has received a report from afiliate, devicor medical (b)(4) stating, "after the procedure there were tissue samples in the canister, not tray. The user investigated and found calcified sample. No patient complications". This has been documented in our complaint system

									as (b)(4). Manufacturer narrative: mst1009 probes are sterile, single use devices, indicated to obtain tissue samples from the breast or axillary lymph nodes for diagnostic analysis of breast abnormalities. The device was not returned to devicor medical products, inc. For evaluation. Therefore we are unable to determine a root cause for the reported incident. If the tissue is found within the canister rather than in the sample management system, a misdiagnosis is possible due to lost tissue. Following consultation with our medical director, due to the potential to cause or contribute to death or serious injury as a result of potential missed or lost tissue samples, pursuant to 21 cfr 803, this failure mode was determined to be a reportable malfunction.
1222780-2018-00213	14/08/2018	Malfunction	HOLOGIC, INC.	26/09/2018	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Break; Material Integrity Problem	No Consequences Or Impact To Patient	It was reported that during a biopsy procedure, a plastic introducer sheeth of the device was shredded. As indicated, the device test and the biopsy procedure were all successfully performed. However, when the physician wanted to remove the biopsy device at the end of the procedure, she felt resistance. Then by pulling it out with power, the plastic introducer sheeth was damaged and broken at its end. As reported, no patient harm, injury or impact did occur. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
3007566237-2018-02735	07/08/2018	Injury	MEDTRONIC NEUROMODULATION	12/09/2018	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Hemorrhage, Cerebral; Intracranial Hemorrhage; Paresis; Dysphasia	Summary:to evaluate deep brain stimulation (dbs) of the posterior subthalamic area (psa) in essential tremor (et) and compare it to the ventral intermediate nucleus of the thalamus (vim) in terms of stimulation efficacy, efficiency, and side effects. Methods dbs leads were implanted such that contacts were placed in the vim, on the intercommissural line, and in the psa. Thirteen patients with et entered a randomized, double-blind crossover phase

									and completed a 1-year follow-up. Results psa-dbs significantly reduced tremor severity and improved quality of life. There were no relevant differences in quality and frequency of stimulation side effects between vim and psa, with a tendency toward greater tremor improvement with psa stimulation. Clinical benefit was achieved at significantly lower stimulation amplitudes in the psa. The majority of patients remained with psa-dbs after 1 year. Conclusion in accordance with previous retrospective investigations, our prospective data suggest that psadbs is at least equally effective as but possibly more efficient than vim-dbs. Reported events: a patient who was receiving deep brain stimulation (dbs) of the posterior subthalamic area (psa) and the ventral intermediate nucleus of the thalamus (vim) for essential tremor (et) experienced an intraoperative intracerebral hemorrhage, resulting in cancellation of the lead implantation. The authors reported that it remained unclear whether the event was related to stereotactic targeting, but the study¿s safety monitor judged the hemorrhage to be attributable to individual factors such as brain atrophy and perioperative anticoagulation. A patient who received dbs of the psa and vim for et experienced a perioperative hemorrhage along the left lead that caused transient right hemiparesis and aphasia. The authors reported that it remained unclear whether the event was related to stereotactic targeting, but the study¿s safety monitor judged the hemorrhage to be attributable to individual factors such as brain atrophy and perioperative anticoagulation. 1 patient with dbs of the psa and vim for et experienced persistent and bothersome nausea that that began with the start of dbs treatment and necessitated a hospitalization. Neither extensive reprogramming or deactivation of stimulation produced symptom relief. 1 patient with dbs of the psa and vim for et

									experienced persistent and bothersome nausea that began with the start of dbs treatment and necessitated a hospitalization. Neither extensive reprogramming or deactivation of stimulation produced symptom relief. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: this value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Section d information references the main component of the system. Other relevant device(s) are: product id: neu_unknown_lead; product id: neu_unknown_lead; product id: neu_ins_stimulator. Barbe, mt., reker, p., hamacher, s., hamacher, s., franklin, j., kraus, d., dembek, ta., becker, j., steffen, jk., allert, n., wirths, j., dafsari, hs., voges, j., fink, gr., fink, gr., visser-vandewalle, v., timmermann, l. Dbs of the psa and the vim in essential tremor: a randomized, double-blind, crossover trial. Neurology. 2018; 91(6):e543-e550. Doi: 10.1212/wnl.0000000000005956. If information is provided in the future, a supplemental report will be issued. (b)(4).
1220984-2018-00143	07/08/2018	Malfunction	HOLOGIC, INC	05/09/2018	IZH	MULTICARE PLATINUM	Unintended System Motion	No Consequences Or Impact To Patient	It was reported that the table top moved upward without command. This did not occur during a patient exam and there was no injury reported. A field engineer was dispatched to the site and was unable to replicate the issue. The control pad was replaced and the system was working as intended. Attempts to obtain additional information were unsuccessful.
3005985723-2018-00523	06/08/2018	Malfunction	MAKO SURGICAL CORP.	05/09/2018	OLO	3.0 RIO® ROBOTIC ARM - MICS	Fitting Problem; Non	No Known Impact Or	The case was planned for a size 3 femur and a size 2 tibia and the patient¿s bone was resected accordingly. When the

							Reproducible Results	Consequence To Patient	surgeon went to trial the tibial baseplate he noticed that there were considerable gaps both lateral and medial and was not fitting both anterior and posterior, either. The pegs did not line up, as well. We went back to the implant planning page to confirm that the pre-planned size was a 2. Bone registration was done within recommended parameters. The surgeon then requested a size 3 baseplate trial to asses and found it to be a perfect fit per the resection that was made. The peg holes lined up and the only adjustment that had to be made was the normal posterior keel punch . The size 3 was trialed, confirmed and implanted into the patient. The surgeon liked the fit and feel of the size 3. Bottom line: the size 2 was selected and was resected but the size 2 trial did not fit. The size 3 fit and was implanted (no adjustments were ever made in the software to a size 3) pka-rom. Manufacturer narrative: as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available.
3007566237-2018-03086	31/07/2018	Injury	MEDTRONIC NEUROMODULATION	19/10/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Break; Failure to Deliver Energy; High impedance; Battery Problem	Headache; Neurological Deficit/Dysfunction; Therapeutic Response, Decreased; Pressure Sores	Summary: background: deep brain stimulation (dbs) and the proper target for chronic cluster headache (cch) are still subjects of controversy. Objectives: we present our long-term results of analysis of the target and its structural connectivity. Methods: fifteen patients with drug-resistant cch underwent dbs in coordinates 4 mm lateral to the iii ventricular wall and 2 mm behind and 5 mm below the intercommissural point. The clinical parameters recorded were the number of weekly attacks, pain intensity, and duration of the headache. Structural connectivity was studied using 3-t mr diffusion tensor imaging (dti). Results: all of our patients improved from a mean of 39 attacks/week to 2; pain intensity decreased from 9 to 3 out of 10, and the mean cephalalgia duration decreased from 53 to 8 min. The mean stereotactic coordinates of the effective contact location were 6.1 mm

									lateral to the midcommissural point and 1.2 mm behind and 4.0 mm below the intercommissural point. Dti analysis showed that this target was connected to tracts and nuclei of the posterior mesencephalic tegmentum, specifically the dorsal longitudinal and mammillotegmental fasciculi. Conclusions: our data showed dbs to be a safe and useful procedure for the treatment of drug-resistant cch; the rate of improvement was higher than those found in other series. Although these are promising results, larger series targeting those fasciculi with a longer follow-up are needed. Reported events: pli 10: patient 3: a (b)(6) patient with deep brain stimulation (dbs)for chronic cluster headache (cch) had the system explained due to a decubitus at the implantable neurostimulator (ins) location. The patient was reimplanted 4-months later and the patient was able to return to the prior improvement. Pli 20: patient 1: a (b)(6) patient with dbs for cch experienced an ¿excellent¿ response for 18 months, at which point they had a return of prior cch symptoms. A skull x-ray showedBreakage of the electrode. The lead was reportedly repositioned, resulting in a return to the patient¿s prior improvement. Pli 30: patient 2: a (b)(6) patient with dbs for cch necessitated removal of the entire system due to a decubitus scar at the l ead/electrode connection site. The patient was reportedly pain free without medication at the time of article publication. Pli 40: patient 4: a (b)(6) patient with dbs for cch experienced a sudden battery depletion resulting in a return of baseline pain. After replacement they had a return of prior therapeutic improvement. Pli 50: patient 5: a (b)(6) patient with dbs for cch experienced neck dystonia and an increase in the number of attacks. Impedances over 2,000 were measured on an active contact and radiogram showed a leadBreakage in the neck region. The electrode was replaced, and their dystonia and pain disappeared. Pli 60: patient 5: a (b)(6) patient with dbs for

									cch experienced a return of pain and another electrodeBreak was identified in (b)(6) 2016. Their pain subsided after electrode replacement. Pli 70: patient 8: a (b)(6) patient with dbs for cch experienced a sudden return of cch attacks after 4-years of stable improvement. Impedance testing and imaging were performed, and a leadBreakage was observed. A new electrode was implanted, and the patient experienced a return of prior therapeutic improvement. Pli 80: an unknown number of patients with dbs for cch experienced transient side-effects such as blurred vision, myosis, diplopia, dizziness, and euphoria. The authors reported that patients were implanted with itrel 3 model 7425 and activa sc model 37602/37603 neurostimulators, as well as 3389 model leads. It was not possible to ascertain any further specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: age/date of birth. This value is the average age of the patients reported in the article as specific patients could not be identified. Date of event. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Other relevant device(s) are: product id: 3389, serial/lot #: unknown; product id: neu_ins_stimulator, serial/lot #: unknown; seijo-fernandez, f., saiz, a., santamarta, e., nader, l., alvarez-vega, ma., lozano, b., seijo, e., barcia, ja. Long-term results of deep brain stimulation of the mammillotegmental fasciculus in chronic cluster headache. Stereotact funct neurosurg. 2018; 96(4):215-222. Doi: 10.1159/000489937. If information is provided in the future, a supplemental report will be issued.
1723170-2018-06192	28/07/2018	Death	MEDTRONIC NAVIGATION, INC	12/12/2018	GEX	VISUALASE	Adverse Event Without Identified	Death; Cognitive Changes; Confusion/ Disorientation	Citation: zervos tm, robin am, lee i. Bmj case rep published online first: [28 july 2018]. Doi:10.1136/bcr-2018-225473 summary: since there is no cure for glioblastoma multiforme (gbm), the goal of treatment

							Device or Use Problem		becomes prolonging the survival through cytoreduction while minimising neurological deficits. In this case report, laser interstitial thermal therapy (litt) was used once the tumour progressed into the isthmus of the cingulate gyrus. One year after temporal lobectomy, disorders of memory, emotion, personality and navigation, likely related to limbic system involvement along with hallucinations and fluctuating cognition occurred as the tumour progressed. After ablation of the posterior cingulum, worsening of topographical disorientation was observed. Per literature review, delirium has been noted in patients with strokes involving the right-sided temporo-parietooccipital junction, and topographical disorientation has been associated with lesions of the right posterior cingulum. Alternative causes of these deficits were ruled out, leaving structural changes as the primary explanation. This is the first report of the neurological deficits associated with tumour progression and vasogenic oedema in this region. Reported event: a (b)(6) male underwent elected litt over open craniotomy. Stereotactic biopsy was followed by laser interstitial thermal ablation using medtronic's thermal therapy system. The ablation was confirmed through intra-operative mri and the patient recovered uneventfully. One year later, progressive delusions and paranoia occurred requiring hospitalisation. The patient experienced fluctuating restlessness, confusion and visual hallucination along with paranoid delusions. Repeat mri showed progression of disease into the posterior border of the previous ablation zone of extending to the isthmus of the cingulate gyrus. Repeat litt was performed using a non-medtronic product. The patient was placed on 16 mg/day of dexamethasone in anticipation of postoperative oedema. The delirium was first treated through avoidance of benzodiazepines and anticholinergic medications and maintenance of an

									appropriate sleep¿wake cycle. Next, dexamethasone was tapered to 1 mg twice daily and levetiracetam was replaced with divalproex. While these medications can cause altered mental status, he was treated with these medication since his original diagnosis 2 years prior without significant side effects. Eeg and csf laboratories were unremarkable. He was treated with risperidone and divalproex and was discharged home. Ov er the following week, the delirium improved; however, he continued to have behavioural changes and topographical disorientation. He developed an insatiable appetite and was convinced that his blood glucose levels were low along with agitation. Despite not exhibiting focal weakness on neurological examination, he had difficulty with spatial tasks such as misjudging the distance to a chair and repeatedly falling when attempting to sit. He also experienced difficulty with the orientation of clothing such as putting a shirt on backwards. On examination, he was oriented with intact recall, strength, coordination, and on cranial nerve examination, however, he was unable to determine differentiated sidedness of hearing. He was eventually rehospitalised for worsening delirium and taken into the care of a hospice team. Two months after the last treatment with litt, he expired at home. This was approximately one year after medtronic litt and two years after initial diagnosis. The article reported that as the tumour progressed into the isthmus of the cingulate gyrus, profound changes in awareness occurred and it was conceivable that damage to this region could explain the psychological changes. The article reported that in this case, precise ablation of enhancing tissue located in the posterior cingulate gyrus was achieved; however, despite this, worsening of topographical disorientation was observed. This was coupled with delirium as tumour-associated oedema tracked into the right temporo-parieto-occipital junction in the setting of

									pre-existing atrophy from external beam radiation therapy (ebrt) and prior surgical temporal lobe resection. Manufacturer narrative: patient identifier not provided in article. Patient weight not provided in article. Date of death was not provided. Event date was not provided. Date publication was accepted is provided, system serial number used for procedure was not provided in article. Serial number provided is one of site's systems. No evaluation performed as this event was reported through literature. If information is provided in the future, a supplemental report will be issued.
2020394-2018-01739	27/07/2018	Malfunction	INFUS MEDICAL (THAILAND)	18/09/2018	NEU	SENOMARK ULTRA BREAST TISSUE MARKER	Positioning Failure; Difficult to Remove; Detachment of Device or Device Component	No Consequences Or Impact To Patient	It was reported that during preparation of a stereotactic breast biopsy, the device allegedly was observed to be bent. It was further reported that an attempt was made to deploy the device and it allegedly failed to deploy and was difficult to remove from the applicator. The procedure was concluded without any marker placed. There was no reported patient injury. Manufacturer narrative: no medical records or no medical images have been made available to the manufacturer. As the lot number for the device was provided, a review of the device history records is currently being performed. The device has been returned to the manufacturer for evaluation. The investigation of the reported event is currently underway. (b)(4). The information provided by bard represents all of the known information at this time. Despite good faith efforts to obtain additional information, the complainant / reporter was unable or unwilling to provide any further patient, product, or procedural details to bard.
8043933-2018-00024	24/07/2018	Malfunction	BRAINLAB AG	20/08/2018	IYE	EXACTRAC 5.5	Use of Device Problem; Improper or Incorrect Procedure or Method	Radiation Overdose; No Known Impact Or Consequence To Patient	Two separate treatment plans for stereotactic radiotherapy for two meningioma tumors for the same patient were imported into the brainlab exactrac 5.5 system, used for the positioning of the patient at the linear accelerator, and imported into the linear accelerator. Prescribed/intended were 3 treatment

									fractions for each tumor, with a radiation dose of 7.5 gy per fraction. The first tumor had a size of ca. 1.3 ccm, the second a size of ca. 2.6 ccm. When setting up the patient for the second treatment fraction of the second tumor, the physicist detected before irradiation of this fraction that the patient was positioned to the first tumor as per the display by exactrac. The plan currently open in the linear accelerator was the one for the second tumor. After detecting this mismatch of the plans selected, the hospital's review of this patient treatment so far revealed that the treatment fields and dose intended for the first fraction of the second tumor had been erroneously delivered to the first tumor. Since the second tumor was larger than the first, the multi-leaf-collimator treatment field aperture had been wider than the treatment target volume of the mistakenly irradiated first tumor at that former fraction. According to the hospital (physician): the clinically acceptable limits for normal tissue defined by this hospital radiotherapy department are not exceeded for this patient due to this issue as per the current hospital's estimation. The physician decided to re-deliver the treatment fraction that was erroneously given to the first target, to the intended second target volume. There were no negative clinical effects for this patient reported by the hospital. There are no other remedial actions for this patient reported by this hospital to be intended for this patient, except careful monitoring in the post-treatment period. Manufacturer narrative: a risk to the patient's health could not be excluded for these specific circumstances, since treatment fields and one of three planned fractions of therapeutic radiation dose intended for a different target volume - for a different plan for a different target location for the same patient - were applied to the positioned target volume, despite according to the hospital (physician): the clinically acceptable limits defined by this hospital radiotherapy

									department are not exceeded for this patient due to this issue as per the current hospital's estimation. The physician decided to re-deliver the treatment fraction that was erroneously given to the first target, to the intended second target volume. There were no negative clinical effects for this patient reported by the hospital. There are no other remedial actions for this patient reported by this hospital to be intended for this patient, except careful monitoring in the post-treatment period. According to the results of the brainlab investigation and the information provided by the hospital, it can be concluded that the root cause for the radiation treatment fraction applied to the other target volume than it was planned for, is an isolated case human error by selecting a different treatment plan for the same patient for positioning with exactrac than at the linear accelerator. There is no indication of an error or malfunction of the brainlab device (exactrac). The brainlab device works correctly as intended. Corresponding brainlab measures to minimize this anticipated risk as low as reasonably practicable are already in place. The customer has communicated that users at this hospital are already aware of the corresponding necessary user verification also with the functions available in the brainlab device (exactrac), to ensure matching treatment plans in both exactrac and the linear accelerator. The hospital has corresponding internal procedures already in place, only in this isolated specific case, these hospital procedures in place were apparently not correctly followed. (correspondingly, there are no re-iterations regarding the use of the device are applicable for this customer for this isolated case human error)
1222780-2018-00191	20/07/2018	Malfunction	HOLOGIC, INC.	20/08/2018	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Material Twisted/Bent	No Consequences Or Impact To Patient	It was reported that during a biopsy exam the needle bent and a portion of the tip dislodged. No injury reported. No additional information was provided. Manufacturer narrative: the device has not yet been returned therefore, a failure analysis of the

									complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications. Reference internal complaint: (b)(4).
MW5083191	20/07/2018	Injury	MONTERIS MEDICAL CORP.	16/01/2019	GEX	SIDEFIRE LASER PROBE	Nonstandard Device	Hemorrhage/Bleeding	Fda recall in relation to inadvertent probe heating. Pt treated with stereotactic laser for intractable epilepsy, to avoid a craniotomy. Pt developed complications post-op resulting in bleeding and neuro-deficits. Add'l info rec'd from reporter on 02/27/2019 for mw5083191: we worked with the mfr and it was determined that there was no evidence to show a malfunction in the sidefire laser probe that caused or contributed to the adverse event. This mdr is related to mw5083191 which was originally submitted to the fda on 17jan2019. This mdr is the supplemental to that report that includes the following updates: mfr list was previously incorrect. The correct mfr is captured within this report. The event report type was previously marked as product problem. The report type is serious injury as indicated in this report. The previous report stated no adverse events. The report should have stated yes, as indicated in this report. The event description was inaccurately captured in the previous report and is updated in this report. The previous report also did not call out concomitant medical products which are captured in this report.
3007566237-2018-03522	19/07/2018	Injury	MEDTRONIC NEUROMODULATION	05/12/2018	MHY	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Hematoma; Intracranial Hemorrhage; Unspecified Infection; Therapeutic Effects, Unexpected	The following events were reported in a literature publication: reported events: 1 male patient with ant dbs for treatment of epilepsy experienced an infection along his extension cables, which resulted in explant of the implantable neurostimulator (ins) and the extension cable lines with preservation of intracranial electrodes. 1 patient with ant dbs for treatment of epilepsy experienced a small asymptomatic subcortical hematoma/hemorrhage of the right frontal lobe along the electrode tract. The hematoma had a volume up to 3 cubic centimeters. It was noted that this was

									revealed on a postoperative mri. The authors stated that this could have occurred either during mer insertion or insertion of the stimulating electrode. 1 patient with ant dbs for treatment of epilepsy did not respond to stimulation well. It was noted that the patient had had positive mri and extensive brain lesions. The patient discontinued stimulation two years after the surgery due to the subjective unsatisfactory assessment of its effectiveness leading to subsequent explant of the dbs system. The following device information was provided in the article: lead model 3389. Manufacturer narrative: please note that this age is the average age of the patients reported in the article, as the actual age of patients involved was not provided. Please note that this is the gender of the majority of patients reported in the article. Please note that this date is based off the date of publication of the article as the actual event date was not provided. Other relevant components are: product id: neu_unknown_ext, serial# unknown, product type: extension. Product id: 3389, serial# unknown, product type: lead. Product id: neu_ins_stimulator, serial# unknown, product type: implantable neurostimulator. The reported events were from the following literature article: sitnikov ar, grigoryan ya, mishnyakova lp. Bilateral stereotactic lesions and chronic stimulation of the anterior thalamic nuclei for treatment of pharmacoresistant epilepsy. Surgical neurology international 2018; 9: 137 doi: 10.4103/sni.sni_25_18. If information is provided in the future, a supplemental report will be issued.
3007566237-2018-03523	19/07/2018	Malfunction	MEDTRONIC NEUROMODULATION	05/12/2018	MHY	IMPLANTABLE NEUROSTIMULATOR	Migration or Expulsion of Device; Pocket Stimulation; Malposition of Device	Undesired Nerve Stimulation; Therapeutic Effects, Unexpected	The following events were reported in literature: reported events: 1. Patient 3: one female patient with ant dbs for treatment of epilepsy experienced ¿current leak¿ at the implantable neurostimulator (ins) site with monopolar stimulation. The current leak was noted at the 6-month follow-up visit. This phenomenon disappeared after stimulation was changed

									to bipolar mode without reducing the amplitude/frequency and with the same efficacy in seizure reduction. 2. Patient 6: one male patient with ant dbs for treatment of epilepsy experienced ¿current leak¿ at the implantable neurostimulator (ins) site with monopolar stimulation. The current leak was noted at the 6-month follow-up visit.this phenomenon disappeared after stimulation was changed to bipolar mode without reducing the amplitude/frequency and with the same efficacy in seizure reduction. 3. 1 patient with ant dbs for treatment of epilepsy had a unilaterally displaced electrode and failed to achieve significant improvement in terms of seizures. However, the patient¿s quality of life improved as a result of objective improvement in cognitive and psychoemotional status. 4. 1 patient with ant dbs for treatment of epilepsy had one electrode that was found to be 2mm from the intended target. It was noted that this patient had been implanted without the aid of mer (microelectrode recording). The following device specifics were provided: lead model 3389. Manufacturer narrative: please note that this age is the average age of the patients reported in the article, as the actual age of patients involved was not provided. Please note that this is the gender of the majority of patients reported in the article. Please note that this date is based off the date of publication of the article as the actual event dates were not provided. Section d information references the main component of one of the systems involved in the reported events; other applicable components are: product id: 3389, serial# unknown, product type: lead; product id: 3389, serial# unknown, product type: lead; product id: 3389, serial# unknown, product type: lead. The reported events were from the following literature article: sitnikov ar, grigoryan ya, mishnyakova lp. Bilateral stereotactic lesions and chronic stimulation of the anterior thalamic nuclei for treatment of pharmacoresistant epilepsy. Surgical

									neurology international 2018; 9: 137 doi: 10.4103/sni.sni_25_18. If information is provided in the future, a supplemental report will be issued.
1220984-2018-00134	18/07/2018	Malfunction	HOLOGIC, INC	14/08/2018	IZH	MULTICARE PLATINUM	Unintended System Motion	No Known Impact Or Consequence To Patient	It was reported that the c-arm was continuously moving and making a clicking noise. No injury reported. An applications specialist spoke with the technologist and advised to reboot the system. A field engineer was dispatched to the site and it was determined that the table control panel and the c-arm rotational switches needed to be replaced. Once this was completed the system was working as intended. Attempts to obtain additional information were unsuccessful.
1220984-2018-00133	18/07/2018	Malfunction	HOLOGIC, INC	13/08/2018	IZH	MULTICARE PLATINUM	Unintended System Motion	No Known Impact Or Consequence To Patient	It was reported that the c-arm rotation would not lock and was moving uncommanded. No injury reported. A field engineer was dispatched to the site and it was determined that the power control board needed to be replaced. Once this was completed the system was working as intended.
3005985723-2018-00423	12/07/2018	Malfunction	MAKO SURGICAL CORP.	16/07/2018	OLO	HANDPIECE MICS	Mechanical Problem; Non Reproducible Results	No Known Impact Or Consequence To Patient	Information provided by: (b)(6) for mics 42060717 / (b)(4). Handpiece attached to robot during surgery as a replacement to the one that failed previously. However, this one failed as well. It did not past any checks. Additional information from (b)(6) for mics 42060917 / (b)(4). During bone prep, the mics was able to travel into the stereotactic boundary, but would not power the saw to make the necessary cuts. The cutter was reset multiple times and the mics was unplugged and plugged back in, but would not power the saw. Case type: tka. Yes - =15 minutes. Manufacturer narrative: as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available.
7725928	06/07/2018	Malfunction	NEUROPACE	27/07/2018	PFN	RNS NEUROSTIMULATOR KIT	Communication or Transmission Problem	No Known Impact Or Consequence To Patient	Patient with medically intractable complex partial epilepsy underwent stereotactic placement of bilateral mesial temporal responsive neurostimulation (rns) depth electrodes and placement of right parietal

									neuropace rns neurostimulator. The neurostimulator was positioned within the ferrule and secured by tightening the set screw with a torque limiting screwdriver. The electrodes were positioned and then connected to the neurostimulator. After tightening the screws, the team attempted an impedance check. They were unable to obtain an appropriate signal between the telemetry head as the neurostimulator. Multiple attempts were made and they changed the telemetry head and rehabilitated the programming computer. The neuropace representative called technical support and attempted several other maneuvers, all of which were unsuccessful in establishing communication between the programming system and the neurostimulator. The surgeon elected to remove the existing neurostimulator and replace it. A new neurostimulator was opened and brought onto the operative field. The connector assembly was transferred from the old stimulator to the new one and secured by tightening the set screw with a torque limiting screwdriver. An impedance check was performed on the new neurostimulator revealing good impedances and recordings were obtained from both mesial temporal electrodes. All contacts were working properly. The non-working neurostimulator was removed from the operative field and returned to the neuropace representative.
3008492462-2018-00052	04/07/2018	Malfunction	DEVICOR MEDICAL PRODUCTS INC	18/07/2018	KNW	10G X 9CM MAMMOTOME® REVOLVE STEREOTACTIC PROBE	Failure to Obtain Sample	Hematoma	Troubleshooting in vab, no core in the tray. Manufacturer narrative: the 10g x 9cm mammotome® revolve stereotactic probe is a sterile, single patient use instrument which may be used with imaging guidance, such as x-ray, to excise a diagnostic sample for diagnosis. The device is not available to be returned to the manufacturer for evaluation, which prevents a full investigation and analysis of the root cause at this time. However, the failure more has been identified in the risk management file and has been shown to occur if the tissue strip contained in the sample management

									systems are not fully aligned or seated properly as instructed within the ifu. Although no serious injuries occured, upon consultation with devicor's medical department, this failure mode has been determined to be a reportable malfunction as a result of potential loss of tissue for diagnostic purpose . Thus, pursuant to 21 cfr 803, we are submitting this medwatch report.
3008492462-2018-00053	02/07/2018	Malfunction	DEVICOR MEDICAL PRODUCTS INC	06/08/2018	KNW	8G X 12 MAMMOTOME STEREOTACTIC PROBE	Fluid/Blood Leak	No Known Impact Or Consequence To Patient	It was reported by the sales representative, the customer had 3 times lately where blood/fluid "shot/sprayed out" the back of the specimen chamber during a procedure. Procedure was completed with the original device. No patient complication. Manufacturer narrative: the mammotome revolve dual vacuum assisted biopsy system is intended to obtain tissue samples from the breast or axillary nodes for diagnostic analysis of breast abnormalities. The device has not been returned for evaluation, which prevents a full investigation and analysis of the root cause at this time. However, this failure mode has been reviewed by our medical advisor and identified in the risk management file for performance expectations. The device is intended to be used by a trained professional who is familiar with precautions related to blood borne pathogen exposure when completing a biopsy procedure. However, ejection with velocity is not expected by the user and has greater chance to harm than fluid egression including, but not limited to, the fluid entering mucous membranes. The device is not meeting its intended performance specification and claims and is considered to have malfunctioned. The patient or user may be exposed to biological hazards resulting in infection or cross-contamination. Although no serious injuries have occured, this failure mode has been evaluated by our medical advisor and based on potential for cross contamination or infection due to possible exposure to body fluids, it has been determined to be a reportable malfunction. Thus, pursuant to

									21 cfr 803, we are submitted this medwatch report.
3005075696-2018-00020	20/06/2018	Malfunction	MAZOR ROBOTICS LTD.	24/07/2018	HAW	MAZOR X	Loose or Intermittent Connection	No Known Impact Or Consequence To Patient	During a surgical procedure using the mazor x system at (b)(6) hospital, ((b)(6)), on (b)(6) 2018 (reported to mazor on june 25, 2018), while sending the surgical arm to ap scanning position the error 4059 "arm shift detected joint 6" was displayed on the screen. Device malfunction resulted in prolongation of the surgery by more than an hour, while the patient was already anesthetized. While the patient did not suffer any apparent direct harm, exposure of the patient to the effects of prolonged anesthesia might cause or contribute to a serious injury.
1220984-2018-00121	20/06/2018	Malfunction	HOLOGIC, INC	19/07/2018	IZH	MULTICARE PLATINUM	Unintended System Motion	Not Applicable	It was reported that the table randomly goes up itself, without touching anything on panel. No injury was reported. A field engineer was dispatched to the site and the investigation is still underway.the field engineer checked and measured the cables from keyboard to table. All was ok. The issue has not reoccurred. Manufacturer narrative: as of today the investigation regarding this issue is still in-process. A follow-up will be filed as needed.
3007566237-2018-02104	19/06/2018	Injury	MEDTRONIC NEUROMODULATION	16/07/2018	MHY	KINETRA	Battery Problem; Adverse Event Without Identified Device or Use Problem	Wound Dehiscence; Hematoma; Unspecified Infection; Discomfort; Complaint, Ill-Defined	Summary: deep brain stimulation for parkinson¿s disease (pd) utilises an implantable pulse generator (ipg) whose finite lifespan in non-rechargeable systems necessitates their periodic replacement. We wish to determine if there is any significant difference in longevity of 2 commonly used ipg systems; the medtronic kinetra, and the medtronic activa primary cell (pc), which has come to replace it. Methods: all patients with bilateral subthalamic nucleus stimulators for pd performed in our centre were included. Battery life was then assessed using a kaplan-meier approach and comparisons between the kinetra and activa pc batteries were performed using log-rank tests. Results: complete data was available for 183 patients. There was a significant difference in the average battery duration with an estimated median battery life in the kinetra cohort of 6.6 years (95% ci 6.4¿6.7),

									compared to 4.5 years (95% ci 4.4¿4.5) in the activa pc cohort (0.001). Conclusion: the activa pc ipg demonstrates a significantly reduced battery life of 2.1 years, with a median battery life of 4.5 years in comparison to 6.6 years in the kinetra ipg. Future technology developments should therefore be focused on improving the battery life of the newer ipg systems. Reported events: a patient with deep brain stimulation (dbs) for parkinson's disease (pd) developed an infection that required the eventual removal of the entire ins. Two patients with dbs for pd required repositioning of their implantable neurostimulator (ins) due to discomfort or cosmetic reasons. Four patients with dbs for pd developed wound dehiscence requiring revision surgery. A patient with dbs for pd experienced a post-operative hematoma that required surgical evacuation but did not lead to any further morbidity. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued. Manufacturer narrative: this value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Other relevant device(s) are: product id: 7428, serial/lot #: unknown. Product id: 7428, serial/lot #: unknown. Product id: 37601, serial/lot #: unknown. Fisher, b., kausar, j., garratt, h., hodson, j., white, a., ughratdar, i., mitchell, r. Battery longevity comparison of two commonly available dual channel implantable pulse generators used for subthalamic nucleus stimulation in parkinson's disease. Stereotact funct

									neurosurg. 2018:1-6. Doi: 10.1159/000488684. If information is provided in the future, a supplemental report will be issued.
3005985723-2018-00390	19/06/2018	Malfunction	MAKO SURGICAL CORP.	02/07/2018	OLO	UNKNOWN_JOINT REPLACEMENT_ROBOTICS_PRODUCT	Mechanical Problem	No Known Impact Or Consequence To Patient	(B)(6) reported arm locking up. Arm passed all checks. One hour case delay before case. When trying to do rio set up arm would lock. Pictures attached. After multiple resets finally was able to get arm to pass. During case 15-30 minute delay. First delay was on the second cut (posterior chamfer) arm showed the same warning as before. Had to manually release the arm behind the robot. Continued with cuts. Arm locked 8 times on tibia cut. Was able to release the arm on the computer screen with the unlock button. Surgeon decided to not continue with robot for the rest of day. Two cases lost on tuesday ((b)(6)) as well as 3 cases lost wednesday ((b)(6)) resolution: replaced j5 assembly. Patient was under anesthesia.gsp 165905: (b)(6) reported arm locking up. Arm passed all checks. One hour case delay before case. When trying to do rio set up arm would lock. Pictures attached. After multiple resets finally was able to get arm to pass. During case 15-30minute delay. First delay was on the second cut (posterior chamfer) arm showed the same warning as before. Had to manually release the arm behind the robot. Continued with cuts. Arm locked 8 times on tibia cut. Was able to release the arm on the computer screen with the unlock button. Surgeon decided to not continue with robot for the rest of day. 2 cases lost on tuesday (6/19) as well as 3 cases lost wednesday (6/20). Resolution: replaced j5 assembly. Patient was under anesthesia. Manufacturer narrative: as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available. Manufacturer narrative: "reported event: (b)(6) reported arm locking up. Arm passed all checks. Device evaluation and results: per gsp 165905: fse confirmed the issue

									and replaced the j5 assembly. Verified system is operating within mako tolerances and specifications. Product history review: a review of the dhr associated with rob297 found quality inspection procedures successfully passed. Complaint history review: a review of complaints in catsweb and trackwise related to p/n 204300, serial number rob297 shows no additional complaints related to the failure in this investigation. Conclusions: system ready for clinical use. Corrective action/preventive action: no action is required at this time as there is no indication to suggest a product non-conformity or unanticipated hazard."
1220984-2018-00119	18/06/2018	Malfunction	HOLOGIC, INC	18/07/2018	IZH	MULTICARE PLATINUM	Unintended System Motion	Not Applicable	It was reported that the table lowered uncommanded. No injury was reported. A field engineer was dispatched to the site and noted the control panel table down button was sticking. The control panel was replaced and the system was working as intended.
3007566237-2018-01825	14/06/2018	Injury	MEDTRONIC NEUROMODULATION	19/06/2018	MHY	UNKNOWN ELECTRICAL LEAD	Adverse Event Without Identified Device or Use Problem	Hypoxia; Neurological Deficit/Dysfunction; Seizures	Information was received from a healthcare provider (hcp) of a clinical study regarding a patient with an implantable neurostimulator (ins). It was reported that the patient was submitted to the fixation of the skull and halo implant. The patient was deprived of levodopa for more than 6 hours and developed intense off-dystonia that culminated in hypoxia and an intraoperative seizure. The event resulted in prolonged hospitalization, medications administered, and mechanical ventilation less than 60 minutes. The etiology of the event was related to the stereotactic location to implant procedure. The issue resolved on (b)(6) 2018. No further complications were reported as a result of this event.it was also noted there was a causal relationship to both study disease and underlying condition or disease.additional information received from a healthcare provider (hcp) of a clinical study indicated there was a causal relationship to the stereotaxic location to the implant. There was intervention, hospitalization starting 13 june, prolongation of hospitalization, medications

									administered, reprogramming, along with mechanical ventilation less than 60 minutes. The event resolved on (b)(6) 2018. The time from procedure was updated from "pre-procedure" to "during procedure". No further complications were reported as a result of this event.additional information was received from a manufacturer representative (rep) and confirmed by a hcp. It was reported that there was no status update on the lead as the site didn't provide information. The patient's name was not collected, however, their date of birth and sex was. The patient weight was not collected. The lot number of the lead was updated. No further complications were reported as a result of this event. Additional information was received from a healthcare provider (hcp) of a clinical study indicated that the patient was not previously reprogrammed. No further complications were reported as a result of this event. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued.
3005985723-2018-00389	14/06/2018	Malfunction	MAKO SURGICAL CORP.	02/07/2018	OLO	HANDPIECE MICS	Mechanical Problem; Non Reproducible Results	No Known Impact Or Consequence To Patient	As confirmed with the mps, this request involves 2 different mics that failed during the same tka case. Prior to the case the mics trigger was sticking and wouldn't return to its starting position. Replaced mics and proceeded on with the set up with no further issues. During cutting, the blade started to rattled. We checked the blade to ensure it was tight and it was. We proceeded to cut when the surgeon went to check the end of the handpiece, it literally fell apart. Bearings and all fell out. All parts were accounted for and no harm to the patient was done. Replaced the handpiece and proceeded with the case. Surgical delay =15 minutes. Manufacturer narrative: as

									part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available.
7677107	11/06/2018	Malfunction	HOLOGIC, INC., HEADQUARTERS	29/06/2018	KNW	HOLOGIC	Decrease in Suction; Suction Problem; Device Operational Issue	Syncope; Hematoma	During a stereotactic breast biopsy, the hologic atec vacuum assist machine did not function properly. This unit did not have the proper amount of suction and we were unable to get the proper amount of tissue resulting in a repeat biopsy for this pt. The pt went to er later that evening due to syncope. The pt developed a large 10 cm hematoma and her hemoglobin had dropped from the blood pooling in her breast. We did get this vac assist unit replaced with a replacement from hologic. When we went to do another stereotactic biopsy on a different pt, this replacement vac assist unit also lacked suction and this pt also had to have a repeat biopsy. Hologic clinical educator came in and suggested sending this unit back for another replacement. The second pt has not had any issues that we are aware of at this time.
1723170-2018-03170	07/06/2018	Malfunction	MEDTRONIC NAVIGATION, INC. (LITTLETON)	05/07/2018	OWB	O-ARM O2 IMAGING SYSTEM	Device Operates Differently Than Expected	No Patient Involvement	Medtronic received information regarding an imaging device being used outside of procedure. It was reported that there are some issues with acquisitions of stereotactic scans. It was reported by the site that the part was functioning normally. No patient present. Manufacturer narrative: no patient information provided as no patient was involved in this concern. Device manufacturing date is unavailable. A medtronic representative went to the site to test the equipment. Testing revealed that the enabled features were verified. System operation in 40 cm stereotaxic and 20 cm standard 3d were checked. The reported issue could not be verified. The imaging system then passed the system checkout and was found to be fully functional.
3005985723-2018-00388	05/06/2018	Malfunction	MAKO SURGICAL CORP.	29/06/2018	OLO	HANDPIECE MICS	Mechanical Problem	No Known Impact Or Consequence To Patient	Mics was making a bad noise and then ball bearings fell apart (see pictures). Tka case delayed 20 minutes.mics was making a bad noise and then ball bearings fell apart. Tka case delayed 20 minutes. Manufacturer

									narrative: follow-up #1 and final report submitted to update sections based on the results of investigation. "reported issue mics was making a bad noise and then ball bearings fell apart (see pictures). Tka case delayed 20 minutes. Device history records indicate 25 devices were manufactured under lot k080c and 23 including 4200901 were accepted into final stock on (b)(6) 2017. A review of qt17-03-0036 revealed that the issue is not related to the failure alleged in this compliant. A review of complaints related to p/n 209063, s/n (b)(4) in prodex lot k080c shows no additional complaint(s) related to the failure in this investigation. Visual inspection revealed no physical damage of unit. Two screws backed out of the unit and a third screw broke. See attached pictures. Dimensional inspection was not completed visual inspection clearly shows the failure of the device. The handpiece motor and electronics function as intended. Material analysis was not completed because functional inspection clearly showed failure. The screws hold the front end in place. If the screws back out then the front will come off. " manufacturer narrative: as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available.
3005985723-2018-00391	04/06/2018	Malfunction	MAKO SURGICAL CORP.	02/07/2018	OLO	HANDPIECE MICS	Electrical /Electronic Property Problem	No Known Impact Or Consequence To Patient	Mics handpiece was unresponsive and failed mics status check. Surgeon completed balancing, when we brought the robot in to make cuts, the surgeon pulled the trigger to auto align mics, there was no response. We performed troubleshooting steps, to include resetting the cutter, still no response from the mics. We swapped the mics for a new one; performed a mics status check - mics failed. We performed additional troubleshooting and attempted the status check again, still failed. We swapped the mics out again, this time the mics passed checks and worked properly. Tka case delayed 5 minutes. After the surgery was

									completed; i performed a mics status checks on all six mics handpieces - four failed (including the two used in the surgery). Manufacturer narrative: as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available.
3005985723-2018-00386	04/06/2018	Malfunction	MAKO SURGICAL CORP.	29/06/2018	OLO	HANDPIECE MICS	Electrical /Electronic Property Problem	No Known Impact Or Consequence To Patient	Mics handpiece was unresponsive and failed mics status check. Surgeon completed balancing, when we brought the robot in to make cuts, the surgeon pulled the trigger to auto align mics, there was no response. We performed troubleshooting steps, to include resetting the cutter, still no response from the mics. We swapped the mics for a new one; performed a mics status check - mics failed. We performed additional troubleshooting and attempted the status check again, still failed. We swapped the mics out again, this time the mics passed checks and worked properly. Tka case delayed 5 minutes. After the surgery was completed; i performed a mics status checks on all six mics handpieces - four failed (including the two used in the surgery). Manufacturer narrative: as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available.
3005985723-2018-00387	04/06/2018	Malfunction	MAKO SURGICAL CORP.	29/06/2018	OLO	HANDPIECE MICS	Electrical /Electronic Property Problem	No Known Impact Or Consequence To Patient	Mics handpiece was unresponsive and failed mics status check. Surgeon completed balancing, when we brought the robot in to make cuts, the surgeon pulled the trigger to auto align mics, there was no response. We performed troubleshooting steps, to include resetting the cutter, still no response from the mics. We swapped the mics for a new one; performed a mics status check - mics failed. We performed additional troubleshooting and attempted the status check again, still failed. We swapped the mics out again, this time the mics passed checks and worked properly. Tka case delayed 5 minutes. After the surgery was

									completed; i performed a mics status checks on all six mics handpieces - four failed (including the two used in the surgery). Manufacturer narrative: as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available.
3005985723-2018-00392	04/06/2018	Malfunction	MAKO SURGICAL CORP.	02/07/2018	OLO	HANDPIECE MICS	Electrical /Electronic Property Problem; Non Reproducible Results	No Known Impact Or Consequence To Patient	Mics handpiece was unresponsive and failed mics status check. Surgeon completed balancing, when we brought the robot in to make cuts, the surgeon pulled the trigger to auto align mics, there was no response. We performed troubleshooting steps, to include resetting the cutter, still no response from the mics. We swapped the mics for a new one; performed a mics status check - mics failed. We performed additional troubleshooting and attempted the status check again, still failed. We swapped the mics out again, this time the mics passed checks and worked properly. Tka case delayed 5 minutes. After the surgery was completed; i performed a mics status checks on all six mics handpieces - four failed (including the two used in the surgery). Manufacturer narrative: as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available.
3007566237-2018-02560	25/05/2018	Malfunction	MEDTRONIC NEUROMODULATION	28/08/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Malposition of Device	Emotional Changes; Dizziness; Dysphasia; Discomfort; Dyskinesia	Summary: subthalamic nucleus deep brain stimulation (stn-dbs) is a well-established treatment for the management of motor complications in parkinson¿s disease. Uncontrollable laughter has been reported as a rare side effect of stn stimulation. The precise mechanism responsible for this unique phenomenon remains unclear. We examined in detail the dbs electrode position and stimulation parameters in two patients with uncontrollable laughter during programming after stn-dbs surgery and illustrated the anatomical correlates of the acute mood changes with stn stimulation. Case report: unilateral stn-dbs induced

									uncontrollable laughter with activation of the most ventral contacts in both patients. However, the location of the electrodes responsible for this adverse effect differed between the patients. In the first patient, the dbs lead was placed more inferiorly and medially within the stn. In the second patient, the dbs lead was implanted more anteriorly and inferiorly than initially planned at the level of the substantia nigra reticulata (snr). Conclusion: unilateral stn-dbs can induce acute uncontrollable laughter with activation of electrodes located more anterior, medial, and inferior in relationship with the standard stereotactic stn target. We suggest that simulation of ventral and medial stn, surrounding limbic structures or the snr, is the most plausible anatomical substrate responsible for this acute mood and behavioral change. Our findings provide insight into the complex functional neuroanatomical relationship of the stn and adjacent structures important for mood and behavior. Dbs programming with more dorsal and lateral contacts within the stn should be entertained to minimize the emotional side effects. Reported events: 1. Case 1: a 52-year-old man with bilateral subthalamic nucleus (stn) deep brain stimulation (dbs) for parkinson's disease (pd) experienced dizziness and dysarthria related to high stimulation levels. During initial dbs monopolar review 1 month after surgery, he noticed a sudden onset of ¿giddiness and euphoria¿ best described as a need to laugh that was overwhelming and precluded him from talking when activating right stn contact 0. Symptoms appeared around 3.0 v [pulse width (pw) of 60 s and frequency of 140 hz] and became increasingly prominent as voltage was increased to 3.5 v. The patient reported a feeling of happiness and joy associated with involuntary laughing. Despite the jovial nature of his symptoms, he was uncomfortable and the sensation was not pleasant. He reported mild nausea and recurrence of euphoric, loose, and

									giddy feelings when activating adjacent contact 1 at 3.8 v. At 4.3 v, this feeling became persistent and more intense. Partial benefit in parkinsonism was observed with ventral contacts and the patient developed right foot dyskinesia, mild reduction in bradykinesia, and reduction in rigidity around 3.5 v. The rest of his monopolar review was unremarkable with improvement in parkinsonism with contacts 2 and 3 and dyskinesia at 2.5 v with contact 2. The uncontrollable laughter was reproducible after 6 months. The authors reported that the dbs lead was placed more inferiorly and medially within the stn than originally planned. 2. Case 2: a 39-year-old woman with bilateral stn-dbs for pd, during monopolar programming review 1 month postoperatively, noted sudden and uncontrollable laughter when activating contact 0 at 2.0 v (pw of 60 s and frequency of 140 hz) on the left side. Her symptoms were intermittent, with sudden laughter at higher voltages and episodes of normal mood. Uncontrollable laughter was reproducible with unilateral left stn stimulation but did not occur with right stn stimulation. Programming other contacts provided improvement in parkinsonism without acute mood effects. Her updrs-iii score off medications at 1 year improved from 51 to 26 points. The authors reported that the lead was implanted more anteriorly and inferiorly than initially planned at the level of the substantia nigra reticulata. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: this value is the average age of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Section d information references the main component of the system. Other relevant device(s) are: product id: 3389, serial/lot #:

									unknown, ubd: , udi#: ; product id: 3389, serial/lot #: unknown, ubd: , udi#: huang, y., aronson, jp., pilitsis, jg., gee, l., durphy, j., molho, es., ramirez-zamora, a. Anatomical correlates of uncontrollable laughter with unilateral subthalamic deep brain stimulation in parkinson¿s disease. Front. Neurol. 2018; 9:341. Doi: 10.3389/fneur.2018.00341. If information is provided in the future, a supplemental report will be issued. (b)(4).
1220984-2018-00105	25/05/2018	Malfunction	HOLOGIC, INC	22/06/2018	IZH	MULTICARE PLATINUM	Unintended System Motion	Not Applicable	It was reported that at the beginning of a procedure, the patient was positioned on the table and the tech was moving the table up to the height needed. She noticed that the table was moving back down slightly without command, and this would occur each time the position was changed. The patient was removed from the table and the procedure was cancelled. No injury related. A field engineer was dispatched to the site and it was determined that the control panel membrane switch needed to be replaced. Once this was completed the system was working as intended.
3005075696-2018-00017	23/05/2018	Malfunction	MAZOR ROBOTICS LTD.	21/06/2018	HAW	MAZOR X	Mechanical Problem; Device Displays Incorrect Message; Device Operational Issue	No Known Impact Or Consequence To Patient	During surgical procedure using the mazor x system at presbyterian hospital of plano (us) on (b)(6) 2018, shoulder shift requiring re-registration multiple times due to system hardware malfunction experienced at the site resulted in prolongation of surgery by more than an hour, while the patient was already anesthetized. Manufacturer narrative: (b)(4).
7681364	17/05/2018	Malfunction	MEDTEC, INC.	12/07/2018	IYE	VAC-LOK CUSHION	Deflation Problem	No Consequences Or Impact To Patient	The patient was being positioned and lined up for his fourth stereotactic body radiation therapy (sbrt) treatment. The patient was positioned on the couch using his vac-lok cushion and other positioning aids. When the radiation therapist attempted to confirm the patient's placement to his original ct simulation, the patient was not aligned. Upon re-entering the vault to make positioning adjustments, it was noted that the vac-lok cushion had deflated. There was no hole or leak point noted on the vac-lok. The patient had to be restimulated prior to moving forward with the fourth sbrt

									treatment. The vac-lok was disposed of by staff. There was no harm to the patient.
1723170-2018-02519	11/05/2018	Malfunction	MEDTRONIC NAVIGATION, INC. (LOUISVILLE)	05/06/2018	OLO	SPINOUS PROCESS CLAMP TALL	Break	No Patient Involvement	Medtronic received information regarding a navigation device being used outside a procedure. It was reported that an orthopedic stereotactic instrument was broken. There was no patient present when this issue was identified. Manufacturer narrative: no patient information provided as no patient was involved in this concern. Device lot number, or serial number, unavailable. No parts have been returned to the manufacturer for analysis. Device manufacture date is not available at time of filing.
1723170-2018-02630	11/05/2018	Malfunction	MEDTRONIC NAVIGATION, INC. (LOUISVILLE)	08/06/2018	HAW	STEALTHSTATION S7 SYSTEM	Imprecision; Device Operates Differently Than Expected	No Known Impact Or Consequence To Patient	Medtronic received information regarding a navigation device being used for an electrode and probe placement procedure. The event occurred intraoperatively during the navigate task and delayed surgery by less than one hour. It was reported that during a deep brain stimulation (dbs) case with the stereotactic frame, the site lined up the target guidance view and tightened the stereotactic frame device. The entry was then reset to the probe tip location and upon doing so, the target guidance view became off. The target guidance view was on the screen as a 1 up view and showed the target had moved by 2 inches (zoomed in view, not 2 anatomical inches, but 2 inches on the surgeon monitor). The surgery was completed with the navigation device and there was no impact on patient outcome. Manufacturer narrative: additional information: unique device identification (udi) and device manufacture date provided. Manufacturer narrative: udi and manufacture date not available for this instrument at time of filing. A medtronic representative went to the site to test the equipment. The hardware, software, and instruments passed the system checkout. The system was found to be fully functional. No parts were replaced in the system.
1222780-2018-00124	09/05/2018	Malfunction	HOLOGIC, INC.	08/06/2018	KNW	EVIVA STEREOTACT	Adverse Event	Not Applicable	It was reported that the technologist had trouble separating the eviva device from

						IC BREAST BIOPSY SYSTEM	Without Identified Device or Use Problem		the introducer sheath to place marker. The technologist noted that the needle aperture was bent/warped. Manufacturer narrative: the device is not being returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications. Currently unable to establish a relationship or impact to the reported observation. (b)(4).
1723170-2018-05468	28/04/2018	Injury	MEDTRONIC NAVIGATION, INC	02/11/2018	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Muscle Weakness; Paresis; Seizures; Visual Disturbances; Dysphasia	Citation: r nick hernandez, arthur carminucci, purvee patel, eric l hargreaves, shabbar f danish; magnetic resonance-guided laser-induced thermal therapy for the treatment of progressive enhancing inflammatory reactions following stereotactic radiosurgery, or peirs, for metastatic brain disease, neurosurgery, , nyy220, https://doi.org/10.1093/neuros/nyy220 summary: background: in patients who have previously undergone maximum radiation for metastatic brain tumors, a progressive enhancing inflammatory reaction (peir) that represents either tumor recurrence or radiation necrosis, or a combination of both, can occur. Magnetic resonance-guided laser-induced thermal therapy (litt) offers a minimally invasive treatment option for this problem. Objective: to report our single-center experience using litt to treat peirs after radiosurgery for brain metastases. Methods: patients with progressive, enhancing reactions at the site of prior radiosurgery for metastatic brain tumors and who had a karnofsky performance status of =70 were eligible for litt. The primary endpoint was local control. Secondary end points included dexamethasone use and procedure-related complications. Results: between 2010 and 2017, 59 patients who underwent 74 litt procedures for 74 peirs met inclusion criteria. The mean pre-litt peir size measured 3.4 ± 0.4 cm3. At a median

									follow-up of 44.6wk post-litt, the local control rate was 83.1%.most patients were weaned off steroids post-litt. Patients experiencing a post-litt complication were more likely to remain on steroids indefinitely. The rate of new permanent neurological deficit was 3.4%. Conclusion: litt is an effective treatment for local control of peirs after radiosurgery for metastatic brain disease. When possible, we recommend offering litt once peirs are identified and prior to the initiation of high-dose steroids for symptom relief. Reported events: 45 patients, ages 35 to 90 years of age, with 59 peirs who underwent 59 litt procedures were included in data analysis. 10 lesions recurred or progressed a. 4 treated with craniotomy b. 1 treated with craniotomy and gamma knife (stereotactic radiosurgery srs) c. 3 treated with repeated litt d. 2 elected not to pursue treatment 2. 11 patients experienced 14 complications; 7 with new or increased motor weakness; 6 with complete resolution, 3 with partial resolution, and 2 with persistent deficits at last follow-up. 1 patient with persistent post-procedure right arm weakness treated with 1 mg twice daily dexamethasone at last follow up. 1 patient with persistent post-procedure facial nerve palsy treated with a two week taper dose of dexamethasone. 1 patients with post-procedure left hemiparesis with partial resolution treated with a four week taper dose of dexamethasone. 1 patient with post-procedure left hemiparesis and slurred speech with partial resolution treated with 6 mg every 6 hours at last follow up. 1 patient with post-procedure left arm weakness with partial resolution treated with a two week taper dose of dexamethasone. 2 patients with post-procedure right arm weakness with complete resolution treated with a one week taper dose of dexamethasone. 1 patient with post-procedure expressive aphasia with complete resolution treated with a six week taper dose of

									dexamethasone. 1 patient with post-procedure expressive aphasia and right hemiparesis with complete resolution treated with an eight week taper dose of dexamethasone. 1 patient with post-procedure right eye visual hallucinations with complete resolution treated with a one week taper dose of dexamethasone. 1 patient with post-procedure increased left arm weakness and increased seizure frequency with complete resolution treated with t reated with a six month taper dose of dexamethasone. Patients with procedure related complications had longer post-litt hospital length of stay and were more likely to be on dexamethasone prior to and post-litt. It was reported that in this study no symptomatic complications were related to laser insertion. The authors hypothesized that ablated peirs adjacent to eloquent cortex can cause new neurological symptoms due to post ablation edema, with resolution of symptoms as they decrease in size during the follow-up period. Manufacturer narrative: patient information was unavailable. Please note that this date is based on the date of publication of the article as the event dates were not provided in the published literature. Article citation included. Please note that the system information was not included in the journal article and is unavailable. No parts have been received by the manufacturer for evaluation. H4: device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2018-05467	28/04/2018	Death	MEDTRONIC NAVIGATION, INC	02/11/2018	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Death; Paresis; Dysphasia	Citation: r nick hernandez, arthur carminucci, purvee patel, eric l hargreaves, shabbar f danish; magnetic resonance-guided laser-induced thermal therapy for the treatment of progressive enhancing inflammatory reactions following stereotactic radiosurgery, or peirs, for metastatic brain disease, neurosurgery, , nyy220, https://doi.org/10.1093/neuros/nyy220

									summary: background: in patients who have previously undergone maximum radiation for metastatic brain tumors, a progressive enhancing inflammatory reaction (peir) that represents either tumor recurrence or radiation necrosis, or a combination of both, can occur. Magnetic resonance-guided laser-induced thermal therapy (litt) offers a minimally invasive treatment option for this problem. Objective: to report our single-center experience using litt to treat peirs after radiosurgery for brain metastases. Methods: patients with progressive, enhancing reactions at the site of prior radiosurgery for metastatic brain tumors and who had a karnofsky performance status of =70 were eligible for litt. The primary endpoint was local control. Secondary end points included dexamethasone use and procedure-related complications. Results: between 2010 and 2017, 59 patients who underwent 74 litt procedures for 74 peirs met inclusion criteria. The mean pre-litt peir size measured 3.4 ± 0.4 cm3. At a median follow-up of 44.6wk post-litt, the local control rate was 83.1%.most patients were weaned off steroids post-litt. Patients experiencing a post-litt complication were more likely to remain on steroids indefinitely. The rate of new permanent neurological deficit was 3.4%. Conclusion: litt is an effective treatment for local control of peirs after radiosurgery for metastatic brain disease. When possible, we recommend offering litt once peirs are identified and prior to the initiation of high-dose steroids for symptom relief. 1 patient with post-procedure left hemiparesis treated with 4 mg twice weekly dexamethasone with partial resolution at last follow-up. Deceased, cause and how long after procedure unknown. 1 patient with post-procedure expressive aphasia treated with 4 mg twice daily dexamethasone with complete resolution at last follow-up. Deceased, cause and how long after procedure unknown.

									Manufacturer narrative: patient information was unavailable. Please note that the actual date of death was not provided in the literature article. Please note that this date is based on the date of publication of the article as the event dates were not provided in the published literature. Article citation included. Please note that the system information was not included in the journal article and is unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
2020394-2018-00658	16/04/2018	Malfunction	BARD PERIPHERAL VASCULAR, INC.	11/05/2018	KNW	VACORA COAXIAL	Bent; Material Twisted/Bent	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, the coaxial cannula was allegedly bent inside the patient. It was further reported that there were enough samples to complete the procedure. Reportedly, the coaxial was unable to be used to guide the marker placement. There was no reported patient injury. Manufacturer narrative: no medical records or no medical images have been made available to the manufacturer. The device has been returned to the manufacturer for evaluation. As the lot number for the device was provided, a review of the device history records is currently being performed. The investigation of the reported event is currently underway. The information provided by bard represents all of the known information at this time. Despite good faith efforts to obtain additional information, the complainant / reporter was unable or unwilling to provide any further patient, product, or procedural details to bard.
3005075696-2018-00013	12/04/2018	Injury	MAZOR ROBOTICS LTD.	22/05/2018	HAW	MAZOR X	Adverse Event Without Identified Device or Use Problem	No Known Impact Or Consequence To Patient	During a surgical procedure using the mazor x system at (b)(6) hospital center (us), on (b)(6) 2018, (reported to mazor on apr. 23, 2018), inaccurate screw placement resulted in a revision surgery. Manufacturer narrative: (b)(4).

3005075696-2018-00014	12/04/2018	Malfunction	MAZOR ROBOTICS LTD.	22/05/2018	HAW	MAZOR X	Computer Operating System Problem	No Known Impact Or Consequence To Patient	During a surgical procedure using the (b)(6) hospital center (us), on (b)(6) 2018, (reported to (b)(6) 2018), various malfunctions experienced at the site resulted in prolongation of surgery by more than an hour. The malfunctions were in both hardware and software, but all were minor (non-safety). While they were successfully resolved in the or, the troubleshooting collectively consumed over an hour while the patient was already anesthetized. While the patient did not suffer any apparent direct harm, exposure of the patient to the effects of prolonged anesthesia might cause or contribute to a serious injury. Manufacturer narrative: (b)(4).
3008492462-2018-00044	04/04/2018	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	10/05/2018	KNW	MAMMOTOME ST 11G PROBE	Device Contamination with Chemical or Other Material	No Consequences Or Impact To Patient	It was reported by the (b)(6) affiliate that prior to the procedure, there was foreign material in knockout tube. Manufacturer narrative: the mammotome st stereotactic probe is a sterile, single patient use instrument which may be used with imaging guidance, such as x-ray, to excise a diagnostic sample for diagnosis. The device has not been returned to the manufacturer for evaluation which prevents a full investigation and analysis of the root cause at this time. Although no serious injuries occurred, upon consultation with devicor's medical department, this failure mode has been determined to be evaluated as a reportable malfunction. Thus, pursuant to 21 cfr 803, we are submitting this medwatch report.
3007566237-2018-02707	03/04/2018	Injury	MEDTRONIC NEUROMODULATION	11/09/2018	LGW	NEU_INS_STIMULATOR	Adverse Event Without Identified Device or Use Problem	Unspecified Infection	Bartek j., jr., skyrman, s., nekludov, m., mathiesen, t., lind, f., schechtmann, g. Hyperbaric oxygen therapy as adjuvant treatment for hardware-related infections in neuromodulation. Stereotact funct neurosurg. 2018 96(2): 100-107. Doi: 10.1159/000486684. Summary: in neuromodulation therapies, hardware-related infections are a major challenge often leading to hardware removal. To investigate the role of adjuvant hyperbaric oxygen therapy (hbot) in hardware-related infections. Fourteen hardware-related

									infection events in 12 consecutive patients between 2002 and 2015 were treated with antibiotics and adjuvant hbot at (b)(6) hospital ((b)(6)). Two time-independent infection events related to hardware replacements occurred in 2 patients. Infection resolution and the need for hardware removal were assessed. Twelve out of 14 events of hardware-related infection were successfully treated without hardware removal (86%). The 2 patients treated twice with hbot on 2 time-independent occasions could retain their hardware in both cases. Hardware was removed following hbot failure in 2 infection events, with long-term infection control achieved in all patients. Further, an intrathecal pump malfunction caused by hbot at 2.8 bars was observed, leading to a change in the manufacturer¿s guidelines. This study indicates a potential benefit of adjuvant hbot in the treatment of hardware-related infections in neuromodulation, diminishing the need for hardware removal and treatment interruption. Prospective studies are warranted to establish the role of adjuvant hbot in the treatment of hardware-related infections in neuromodulation. Reported event: a (b)(6) female patient with neuropathic pain experienced and infection. The hardware-related infection event was treated with adjuvant hyperbaric oxygen the (hbot). The patient was on an antibiotic treatment for 10 weeks and their wound culture was determined to be negative. A wound debridement or crust removal was also performed. No specific device information was provided. See attached literature article. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued. Manufacturer narrative: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. If information is provided in the future, a supplemental report will be issued.

3007566237-2018-02709	03/04/2018	Injury	MEDTRONIC NEUROMODULATION	11/09/2018	LGW	NEU_INS_STIMULATOR	Adverse Event Without Identified Device or Use Problem	Unspecified Infection	Bartek j., jr., skyrman, s., nekludov, m., mathiesen, t., lind, f., schechtmann, g. Hyperbaric oxygen therapy as adjuvant treatment for hardware-related infections in neuromodulation. Stereotact funct neurosurg. 2018 96 (2): 100-107. Doi: 10.1159/000486684. Summary: in neuromodulation therapies, hardware-related infections are a major challenge often leading to hardware removal. To investigate the role of adjuvant hyperbaric oxygen therapy (hbot) in hardware-related infections, fourteen hardware-related infection events in 12 consecutive patients between 2002 and 2015 were treated with antibiotics and adjuvant hbot at (b)(6) hospital ((b)(6)). Two time-independent infection events related to hardware replacements occurred in 2 patients. Infection resolution and the need for hardware removal were assessed. Twelve out of 14 events of hardware-related infection were successfully treated without hardware removal (86%). The 2 patients treated twice with hbot on 2 time-independent occasions could retain their hardware in both cases. Hardware was removed following hbot failure in 2 infection events, with long-term infection control achieved in all patients. Further, an intrathecal pump malfunction caused by hbot at 2.8 bars was observed, leading to a change in the manufacturer¿s guidelines. This study indicates a potential benefit of adjuvant hbot in the treatment of hardware-related infections in neuromodulation, diminishing the need for hardware removal and treatment interruption. Prospective studies are warranted to establish the role of adjuvant hbot in the treatment of hardware-related infections in neuromodulation. Reported event: a (b)(6) female patient with neuropathic pain experienced and infection. The hardware-related infection event was treated with adjuvant hyperbaric oxygen the (hbot). The patient was on an antibiotic treatment for 10 weeks and no wound

									culture was taken at the time of the event. No specific device information reported. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued. Manufacturer narrative: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. If information is provided in the future, a supplemental report will be issued.
3007566237-2018-02710	03/04/2018	Injury	MEDTRONIC NEUROMODULATION	11/09/2018	LGW	NEU_INS_STIMULATOR	Adverse Event Without Identified Device or Use Problem	Unspecified Infection	Bartek j., jr., skyrman, s., nekludov, m., mathiesen, t., lind, f., schechtmann, g. Hyperbaric oxygen therapy as adjuvant treatment for hardware-related infections in neuromodulation. Stereotact funct neurosurg. 2018 96(2): 100-107. Doi: 10.1159/000486684. Summary: in neuromodulation therapies, hardware-related infections are a major challenge often leading to hardware removal. To investigate the role of adjuvant hyperbaric oxygen therapy (hbot) in hardware-related infections. Fourteen hardware-related infection events in 12 consecutive patients between 2002 and 2015 were treated with antibiotics and adjuvant hbot at the karolinska university hospital ((b)(4)). Two time-independent infection events related to hardware replacements oc¬curred in 2 patients. Infection resolution and the need for hardware removal were assessed. Twelve out of 14 events of hardware-related infection were successfully treat¬ed without hardware removal (86%). The 2 patients treated twice with hbot on 2 time-independent occasions could retain their hardware in both cases. Hardware was removed following hbot failure in 2 infection events, with long-term infection control achieved in all patients. Further, an intrathecal pump malfunction caused by hbot at 2.8 bars was observed, leading to a change in the manufacturer¿s guidelines. This study indicates a potential benefit of adjuvant hbot in the treatment of hardware-related infections in neuromodulation, diminishing the need for

									hardware removal and treatment interruption. Prospective studies are warranted to establish the role of adjuvant hbot in the treatment of hardware-related infections in neuromodulation. Reported event: a (b)(6) year-old female patient with epilepsy experienced and stimulation pocket infection 20 days after implantation. The hardware-related infection event was treated with adjuvant hyperbaric oxygen the (hbot). The patient was on an antibiotic treatment for 16 weeks and a wound culture no specific device information provided. Manufacturer narrative: the article mentioned in this reported has been previously. Please see regulatory report 3007566237-2018-01793. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. If information is provided in the future, a supplemental report will be issued.
3007566237-2018-02713	03/04/2018	Injury	MEDTRONIC NEUROMODULATION	11/09/2018	LGW	NEU_INS_STIMULATOR	Adverse Event Without Identified Device or Use Problem	Erosion; Unspecified Infection	Bartek j., jr., skyrman, s., nekludov, m., mathiesen, t., lind, f., schechtmann, g. Hyperbaric oxygen therapy as adjuvant treatment for hardware-related infections in neuromodulation. Stereotact funct neurosurg. 2018 96(2): 100-107. Doi: 10.1159/000486684 summary: in neuromodulation therapies, hardware-related infections are a major challenge often leading to hardware removal. To investigate the role of adjuvant hyperbaric oxygen therapy (hbot) in hardware-related infec¬tions. Fourteen hardware-related infection events in 12 consecutive patients between 2002 and 2015 were treated with antibiotics and adjuvant hbot at the karolinska university hospital (stockholm, sweden). Two time-independent infection events related to hardware replacements occurred in 2 patients. Infection resolution and the need for hardware removal were assessed. Twelve out of 14 events of hardware-related infection were

									successfully treated without hardware removal (86%). The 2 patients treated twice with hbot on 2 time-independent occasions could retain their hardware in both cases. Hardware was removed following hbot failure in 2 infection events, with long-term infection control achieved in all patients. Further, an intrathecal pump malfunction caused by hbot at 2.8 bars was observed, leading to a change in the manufacturer¿s guidelines. This study indicates a potential benefit of adjuvant hbot in the treatment of hardware-related infections in neuromodulation, diminishing the need for hardware removal and treatment interruption. Prospective studies are warranted to establish the role of adjuvant hbot in the treatment of hardware-related infections in neuromodulation. Reported event: 2 patients experienced a postoperative surgical site infection (ssi) which did not meet the centre for disease control (cdc) criteria or had a late infection in cases of chronic skin erosions and concomitant infection. (> 90 days after the last surgery). The combined therapy was successful without any hardware removal. No specific device information provided. . Manufacturer narrative: if information is provided in the future, a supplemental report will be issued. Manufacturer narrative: date of event. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. If information is provided in the future, a supplemental report will be issued.
3007566237-2018-01793	03/04/2018	Injury	MEDTRONIC NEUROMODULATION	15/06/2018	MHY	SOLETRA	Adverse Event Without Identified Device or Use Problem	Bacterial Infection; Erosion; Unspecified Infection; Pocket Erosion; Staphylococcus Aureus; Therapeutic Response, Decreased	Summary: in neuromodulation therapies, hardware-related infections are a major challenge often leading to hardware removal. Objective: to investigate the role of adjuvant hyperbaric oxygen therapy (hbot) in hardware-related infections. Methods: fourteen hardware-related infection events in 12 consecutive patients between 2002 and 2015 were treated with antibiotics and adjuvant hbot at the karolinska university hospital (stockholm,

									sweden). Two time-independent infection events related to hardware replacements occurred in 2 patients. Infection resolution and the need for hardware removal were assessed. Results: twelve out of 14 events of hardware-related infection were successfully treated without hardware removal (86%). The 2 patients treated twice with hbot on 2 time-independent occasions could retain their hardware in both cases. Hardware was removed following hbot failure in 2 infection events, with long-term infection control achieved in all patients. Further, an intrathecal pump malfunction caused by hbot at 2.8 bars was observed, leading to a change in the manufacturer¿s guidelines. Conclusions: this study indicates a potential benefit of adjuvant hbot in the treatment of hardware-related infections in neuromodulation, diminishing the need for hardware removal and treatment interruption. Prospective studies are warranted to establish the role of adjuvant hbot in the treatment of hardware-related infections in neuromodulation. Reported events: 1. Patient 5: a (b)(6) male patient with unilateral deep brain stimulation (dbs) for essential tremor (et) developed erosion and infection of the ins pocket 6 months after ins replacement. Staphylococcus aureus was cultured. The patient was treated with antibiotics for 10 weeks and all infections were also treated with hbot which involved placing the patient in hyperbaric chambers for a number of treatments sitting in 100% oxygen and pressurized to 2.0-2.8 bar. The patients breathed oxygen for three 25-minute periods which were interrupted by two 10-minute airBreaks. Removal of the ins was ultimately required, but the infection was resolved within 10 weeks. 2. Patient 1: a (b)(6) female patient with unilateral dbs for et developed an infection of the scalp incision above the burr hole 29 days after lead implantation. Staphylococcus aureus was cultured. The patient was treated with antibiotics for 16 weeks and all infections

									were also treated with hyperbaric oxygen therapy (hbot) which involved placing the patient in hyperbaric chambers for a number of treatments sitting in 100% oxygen and pressurized to 2.0-2.8 bar. The patients breathed oxygen for three 25-minute periods which were interrupted by two 10-minute airBreaks. A surgical site revision in the form of a wound debridement or crust removal procedure was performed, however no device removal was required. The infection was resolved by 16 weeks. 3. Patient 2: a (b)(6) male patient with unilateral dbs for et developed an infection of the scalp with exposed hardware and musculature 75 days after lead implantation. Propionibacterium acnes was cultured. The patient was treated with antibiotics for 12 weeks and all infections were also treated with hbot which involved placing the patient in hyperbaric chambers for a number of treatments sitting in 100% oxygen and pressurized to 2.0-2.8 bar. The patients breathed oxygen for three 25-minute periods which were interrupted by two 10-minute airBreaks. A surgical site revision in the form of a wound debridement or crust removal procedure was performed, however no device removal was required. The infection was resolved by 12 weeks. 4. Patient 3: an (b)(6) female patient with unilateral dbs for et developed an infection of the scalp with exposed hardware and musculature 43 days after implantable neurostimulator (ins) implantation. Staphylococcus aureus was cultured. The patient was treat ed with antibiotics for 60 weeks and all infections were also treated with hbot which involved placing the patient in hyperbaric chambers for a number of treatments sitting in 100% oxygen and pressurized to 2.0-2.8 bar. The patients breathed oxygen for three 25-minute periods which were interrupted by two 10-minute airBreaks. A surgical site revision in the form of a wound debridement or crust removal procedure was performed, however no device removal

									was required. The infection was resolved by 60 weeks. 5. Patient 3: an (b)(6) female patient with unilateral dbs for et developed an infection of the scalp with exposed hardware/erosion 24 months after ins implantation. Staphylococcus aureus was cultured. The patient was treated with antibiotics for 6 weeks and all infections were also treated with hbot which involved placing the patient in hyperbaric chambers for a number of treatments sitting in 100% oxygen and pressurized to 2.0-2.8 bar. The patients breathed oxygen for three 25-minute periods which were interrupted by two 10-minute airBreaks. A surgical site revision in the form of a wound debridement or crust removal procedure was performed, however no device removal was required. The infection was resolved within 6 weeks. 6. Patient 3: an (b)(6) female patient with unilateral dbs for et developed an infection with skin erosion 2 years after the previous procedure. All hardware was immediately removed because the neuromodulation therapy had reportedly lost its effect by that point. 7. Patient 4: a (b)(6) male patient with unilateral dbs for et developed an infection of the scalp with exposed hardware 13 days after lead implantation. Enterobacter aerogenes was cultured. The patient was treated with antibiotics for 6 weeks and all infections were also treated with hbot which involved placing the patient in hyperbaric chambers for a number of treatments sitting in 100% oxygen and pressurized to 2.0-2.8 bar. The patients breathed oxygen for three 25-minute periods which were interrupted by two 10-minute airBreaks. No device removal was required. The infection was resolved within 6 weeks. 8. Patient 6: a (b)(6) male patient with unilateral dbs for et developed erosion and infection of the scalp 30 months after lead implantation. Propionibacterium acnes was cultured. The patient was treated with antibiotics for 16 weeks and all infections were also treated with hbot which involved

									placing the patient in hyperbaric chambers for a number of treatments sitting in 100% oxygen and pressurized to 2.0-2.8 bar. The patients breathed oxygen for three 25-minute periods which were interrupted by two 10-minute airBreaks. A surgical site revision in the form of a wound debridement or crust removal procedure was performed, however no device removal was required. The infection was resolved by 16 weeks. 9. 2 patients with dbs developed a neuromodulation related infection that was treated with hbot. This involved placing the patient in hyperbaric chambers for a number of treatments sitting in 100% oxygen and pressurized to 2.0-2.8 bar. The patients breathed oxygen for three 25-minute periods which were interrupted by two 10-minute airBreaks. It was not possible to ascertain any additional specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued. Manufacturer narrative: age/date of birth. This value is the average age of the patients reported in the article as specific patients could not be identified. Sex. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. The main component of one of the systems involved in the reported events. Other relevant device(s) are: product id: neu_ins_stimulator, serial/lot #: unknown; product id: 3387, serial/lot #: unknown; product id: neu_unknown_lead, serial/lot #: unknown; product id: neu_ins_stimulator, serial/lot #: unknown; product id: 3389, serial/lot #: unknown; bartek, j, jr., skyrman, s., nekludov, m., mathiesen, t., lind, f., schechtmann, g. Hyperbaric oxygen therapy as adjuvant treatment for hardware-related

									infections in neuromodulation. Stereotact funct neurosurg. 2018. Doi: 10.1159/000486684. If information is provided in the future, a supplemental report will be issued.
3007566237-2018-01790	03/04/2018	Injury	MEDTRONIC NEUROMODULATION	14/06/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Staphylococcus Aureus	Summary: in neuromodulation therapies, hardware-related infections are a major challenge often leading to hardware removal. Objective: to investigate the role of adjuvant hyperbaric oxygen therapy (hbot) in hardware-related infections. Methods: fourteen hardware-related infection events in 12 consecutive patients between 2002 and 2015 were treated with antibiotics and adjuvant hbot at the (b)(6) hospital ((b)(6)). Two time-independent infection events related to hardware replacements occurred in 2 patients. Infection resolution and the need for hardware removal were assessed. Results: twelve out of 14 events of hardware-related infection were successfully treated without hardware removal ((b)(6)%). The 2 patients treated twice with hbot on 2 time-independent occasions could retain their hardware in both cases. Hardware was removed following hbot failure in 2 infection events, with long-term infection control achieved in all patients. Further, an intrathecal pump malfunction caused by hbot at 2.8 bars was observed, leading to a change in the manufacturer¿s guidelines. Conclusions: this study indicates a potential benefit of adjuvant hbot in the treatment of hardware-related infections in neuromodulation, diminishing the need for hardware removal and treatment interruption. Prospective studies are warranted to establish the role of adjuvant hbot in the treatment of hardware-related infections in neuromodulation. Reported events: patient 7: a (b)(6)-year-old male patient with bilateral dbs for lesch-nyhan syndrome required exchange of both electrodes and implantable neurostimulator (ins) for a new system implantation. The cause for this replacement was not provided. Patient 7: a (b)(6)-year-old male

									patient with bilateral dbs for lesch-nyhan syndrome developed a unilateral ins pocket infection 29 days after system replacement. (b)(6) was cultured. The patient was treated with antibiotics for 10 weeks and all infections were also treated with hbot which involved placing the patient in hyperbaric chambers for a number of treatments sitting in 100% oxygen and pressurized to 2.0-2.8 bar. The patients breathed oxygen for three 25-minute periods which were interrupted by two 10-minute airBreaks. A surgical site revision in the form of a wound debridement or crust removal procedure was performed, however no device removal was required. The infection was resolved within 10 weeks. Patient 7: a (b)(6)-year-old male patient with bilateral dbs for lesch-nyhan syndrome developed a unilateral ins pocket infection 10 days after ins exchange. (b)(6) was cultured. The patient was treated with antibiotics for 9 weeks and all infections were also treated with hbot which involved placing the patient in hyperbaric chambers for a number of treatments sitting in 100% oxygen and pressurized to 2.0-2.8 bar. The patients breathed oxygen for three 25-minute periods which were interrupted by two 10-minute airBreaks. No device removal was required. The infection was resolved within 9 weeks. Manufacturer narrative: this value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Information references the main component of the system. Other relevant device(s) are: product id: neu_ins_stimulator, serial/lot #: unknown, ubd: , udi#:. Bartek, j, jr., skyrman, s., nekludov, m., mathiesen, t., lind, f., schechtmann, g. Hyperbaric oxygen therapy

									as adjuvant treatment for hardware-related infections in neuromodulation. Stereotact funct neurosurg. 2018. Doi: 10.1159/000486684. If information is provided in the future, a supplemental report will be issued. (b)(4).
3007566237-2018-01799	03/04/2018	Injury	MEDTRONIC NEUROMODULATION	15/06/2018	LKK	SYNCHROMED II	Increase in Pressure; Device Operates Differently Than Expected; Activation Failure	Bacterial Infection; Post Operative Wound Infection	Summary: in neuromodulation therapies, hardware-related infections are a major challenge often leading to hardware removal. A (b)(6)-year-old male patient with a diagnosis of cerebral palsy experienced a battery pocket infection (superficial surgical site infection) 10 days after exchange of their intrathecal baclofen pump. The pump was implanted in the subcutaneous tissue of the abdomen. Material was collected aseptically for aerobic and anaerobic bacterial cultures. A wound culture revealed the infection to be (b)(6). There was no surgical site revision. There was no implant explantation. The patient was treated with antibiotics and adjuvant hyperbaric oxygen therapy (hbot). Hyperbaric treatment was administered at 2.0 to 2.8 bars. The patient received clindamycin, dicloxacillin, or flucloxacillin. The time to infection resolution was 12 weeks. Long term infection control was achieved. This was considered a post-operative hardware-related infection. No further complications were reported or anticipated. A (b)(6)-year-old male patient with a diagnosis of cerebral palsy experienced a lower back incision infection (superficial incisional surgical site infection) 13 days after revision of the catheter and exchange of the intrathecal pump (baclofen). The pump was implanted in the subcutaneous tissue of the abdomen. No wound culture was taken. There was no surgical site revision. There was no implant explantation. The patient was treated with antibiotics and adjuvant hbot. Hyperbaric treatment was administered at 2.0 to 2.8 bars. The patient received clindamycin, dicloxacillin, or flucloxacillin. The time to infection resolution was 10 weeks. Long term infection control was achieved. This was considered a post-operative hardware-

									related infection. No further complications were reported or anticipated. A (b)(6)-year-old female patient with a diagnosis of neuropathic pain experienced an intrathecal pump pocket infection (superficial surgical site infection) 14 days after the implant of the intrathecal pump (baclofen). Material was collected aseptically for aerobic and anaerobic bacterial cultures. The wound culture was (b)(6). It was stated 1 surgical site revision was performed, but there was no implant explantation. A wound debridement or crust removal was performed. The patient was treated with antibiotics and adjuvant hyperbaric oxygen therapy (hbot). Hyperbaric treatment was administered at 2.0 to 2.8 bars. The patient received clindamycin, dicloxacillin, or flucloxacillin. The time to infection resolution was 12 weeks. Long term infection control was achieved. This was considered a post-operative hardware-related infection. No further complications were reported or anticipated. A (b)(6)-year-old female patient with a diagnosis of neuropathic pain experienced an intrathecal pump pocket infection (deep incisional surgical site infection) 30 days after the implant of the intrathecal pump (clonidine). A wound culture was not taken. There was no surgical site revision. There was no implant explantation. The patient was treated with antibiotics and adjuvant hyperbaric oxygen therapy (hbot). Hyperbaric treatment was administered at 2.0 to 2.8 bars. The patient received clindamycin, dicloxacillin, or flucloxacillin. The time to infection resolution was 10 weeks. Long term infection control was achieved. This was considered a post-operative hardware-related infection. No further complications were reported or anticipated. A (b)(6)-year-old male patient with a diagnosis of cerebral palsy experienced a catheter revision. No further complications were reported or anticipated. A (b)(6)-year-old male patient with a diagnosis of cerebral palsy experienced an

									intrathecal pump malfunction caused by hbot at 2.8 bars. There was pump removal after the previously mentioned infection resolution. It was also stated this removal occurred 2 months after the end of hbot. The malfunction was caused by barotrauma resulting in an inadequate refilling capacity of the pump (14 ml instead of the normal 20 ml). It was not possible to fill the drug reservoir up to maximal capacity (20 ml). The healthcare provider (hcp) suspected that the air-filled reservoir had imploded or shrunk at the 2.8 bar treatment pressure level. No further complications were reported or anticipated. Manufacturer narrative: concomitant medical products: product id: 8637, serial# unknown, product type: pump. Product id: neu_unknown_cath, lot# unknown, product type: catheter. Product id: 8637-20, serial# unknown, product type: pump. Information references the main component of the system. Other relevant device(s) are: product id: 8637, serial/lot #: unknown, ubd: , udi#:; product id: neu_unknown_cath, serial/lot #: unknown, ubd: , udi#:; product id: 8637-20, serial/lot #: unknown, ubd: , udi#:. Bartek j, jr., skyrman s, nekludov m, mathiesen t, lind f, schechtmann g. Hyperbaric oxygen therapy as adjuvant treatment for hardware-related infections in neuromodulation. Stereotact funct neurosurg. 2018. Please note that this date is based off of the date of publication of the article, as the event dates were not provided in the published literature. If information is provided in the future, a supplemental report will be issued. [(b)(4)_lit.pdf].
3008492462-2018-00031	23/03/2018	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	09/04/2018	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE	Device Operates Differently Than Expected	No Consequences Or Impact To Patient	The sales rep reported that the tissue cup advanced from #2 to #7 and then bypassed the cup and went into the canister. No patient complications. Procedure was completed with original device. Manufacturer narrative: the revolve stereotactic probe is a sterile, single-patient use device that may be used with imaging guidance to excise a tissue sample for

									diagnosis. The device has not been returned to the manufacturer for evaluation which prevents a full investigation and analysis of the root cause at this time. However, this failure mode has been identified in the risk management file and has been shown to occur if the tissue strips contained in the sample management system are not fully aligned or seated properly as instructed within the ifu. Although no serious injuries occurred, upon consultation with devicor's medical department, this failure mode has been determined to be a reportable malfunction. Thus, pursuant to 21 cfr 803, we are submitting this medwatch report.
3005985723-2018-00227	21/03/2018	Malfunction	MAKO SURGICAL CORP.	09/04/2018	OLO	2.7 DEGREE ANGLED SAGITAL SAW	Detachment of Device or Device Component; Adverse Event Without Identified Device or Use Problem	No Known Impact Or Consequence To Patient	The blade disassociated from attachment upon start of cutting inside stereotactic boundary. Another blade was needed. Tka case delayed for 1 minute.the blade disassociated from attachment upon start of cutting inside stereotactic boundary. Another blade was needed. Tka case delayed for 1 minute. Manufacturer narrative: as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available. Manufacturer narrative: reported event: the blade disassociated from attachment upon start of cutting inside stereotactic boundary. Another blade was needed. Tka case delayed for 1 minute. Device evaluation and results: functional inspection shows that the knob locks and unlocks the blade clamp as intended. The attachment was connected to a mics handpiece and run for two 30 - second periods during which the blade remained securely clamped. The failure mode is not confirmed. Visual inspection: shows no damage to the part. See attached picture. The inspection also shows wear marks on the knob from where the knob wrench makes contact. Dimensional inspection: not performed as the item has been used and the dimensions and tolerances on the print are no longer accurately represented by the part. Material

									analysis: not performed as the failure mode is refuted by the visual and functional inspection. Product history review: a review of device history records shows that on 01/10/17 52 devices were inspected and 13 devices were placed on: (b)(4). A review of the data revealed that the non-conformances are not related to the failure alleged in this compliant. Complaint history review: a review of complaints in catsweb and trackwise related to p/n 212480, lot number 3500452 / 35021216 shows no additional complaints related to the failure in this investigation. Conclusions: the report of a saw attachment loosening during cutting was not confirmed. The issue was observed during the case and resulted in a 1 minute delay. There was no further effect on the successful completion of the case. Corrective action/preventive action: no action is required at this time as there is no indication to suggest a product non-conformity or unanticipated hazard.
3008492462-2018-00029	21/03/2018	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	09/04/2018	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE	Device Operates Differently Than Expected	No Consequences Or Impact To Patient	It was reported by our distributor in (b)(6) that during the procedure when the sample was taken by the customer it is supposed to go to cartridge but it didn't happen and sample went into the canister. No patient complications. Manufacturer narrative: the revolve stereotactic probe is a sterile, single-patient use device that may be used with imaging guidance to excise a tissue sample for diagnosis. The device has not been returned to the manufacturer for evaluation which prevents a full investigation and analysis of the root cause at this time. However, this failure mode has been identified in the risk management file and has been shown to occur if the tissue strips contained in the sample management system are not fully aligned or seated properly as instructed within the ifu. Although no serious injuries occurred, upon consultation with devicor's medical department, this failure mode has been determined to be a reportable malfunction. Thus, pursuant to 21 cfr 803, we are submitting this medwatch report.

3007566237-2018-01666	16/03/2018	Injury	MEDTRONIC NEUROMODULATION	01/06/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Discomfort; Complaint, Ill-Defined	Summary: objective recent studies have shown similar clinical outcomes between parkinson disease (pd) patients treated with deep brain stimulation (dbs) under general anesthesia without microelectrode recording (mer), so-called ¿asleep¿ dbs, and historical cohorts undergoing ¿awake¿ dbs with mer guidance. However, few studies include internal controls. This study aims to compare clinical outcomes after globus pallidus internus (gpi) and subthalamic nucleus (stn) dbs using awake and asleep techniques at a single institution. Methods pd patients undergoing awake or asleep bilateral gpi or stn dbs were prospectively monitored. The primary outcome measure was stimulation-induced change in motor function off medication 6 months postoperatively, measured using the unified parkinson¿s disease rating scale part iii (updrs-iii). Secondary outcomes included change in quality of life, measured by the 39-item parkinson¿s disease questionnaire (pdq-39), change in levodopa equivalent daily dosage (ledd), stereotactic accuracy, stimulation parameters, and adverse events. Results six-month outcome data were available for 133 patients treated over 45 months (78 gpi [16 awake, 62 asleep] and 55 stn [14 awake, 41 asleep]). Updrs-iii score improvement with stimulation did not differ between awake and asleep groups for gpi (awake, 20.8 points [38.5%]; asleep, 18.8 points [37.5%]; p = 0.45) or stn (awake, 21.6 points [40.3%]; asleep, 26.1 points [48.8%]; p = 0.20) targets. The percentage improvement in pdq-39 and ledd was similar for awake and asleep groups for both gpi (p = 0.80 and p = 0.54, respectively) and stn cohorts (p = 0.85 and p = 0.49, respectively). Conclusions in pd patients, bilateral gpi and stn dbs using the asleep method resulted in motor, quality-of-life, and medication reduction outcomes that were comparable to those of the awake method. Reported events: 1. 4 patients with bilateral deep brain stimulation (dbs) for parkinson's disease (pd)

									underwent implantable neurostimulator (ins) revision due to discomfort. 2. 1 patient with bilateral subthalamic nucleus (stn)-dbs for pd underwent unilateral lead repositioning because of unacceptably low motor thresholds discovered during initial programming. 3. 1 patient with dbs for pd presented to the study for revision surgery for an unspecified reason. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: this value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Information references the main component of the system. Other relevant device(s) are: product id: 3387, serial/lot #: unknown, ubd: , udi#: ; product id: neu_ins_stimulator, serial/lot #: unknown, ubd: , udi#: chen, t., mirzadeh, z., chapple, km., lambert, m., shill, ha., moguel-cobos, g., troster, ai., dhall, r., ponce, fa. Clinical outcomes following awake and asleep deep brain stimulation for parkinson disease. J neurosurg. 2018:1-12. Doi: 10.3171/2017.8.jns17883. If information is provided in the future, a supplemental report will be issued. (b)(4).
2916596-2020-03387	11/03/2018	Injury	THORATEC CORPORATION	13/07/2020	DSQ	HEARTMATE 3 LEFT VENTRICULAR ASSIST SYSTEM	Adverse Event Without Identified Device or Use Problem	Arrhythmia; Ventricular Tachycardia	It was reported the patient experienced cardiac arrhythmias. The patient underwent stereotactic ablation for recurrent ventricular tachycardia. No further information was reported. Manufacturer narrative: no further information was provided. A supplemental report will be submitted when the manufacturer¿s investigation is completed.
1723170-2018-02091	11/03/2018	Injury	MEDTRONIC NAVIGATION, INC. (LOUISVILLE)	16/05/2018	GEX	LASER 9735552	Adverse Event Without	Memory Loss/Impairment; Seizures;	The journal article was forwarded by medtronic representative. Article indicated the use of thermal therapy system.

						15W 980NM - VISUALASE	Identified Device or Use Problem	Polydipsia; No Code Available	Seventy-one (71) patients with the diagnosis of gelastic epilepsy related to hh were treated at a single center with stereotactic laser ablation from march 11, 2011 to february 9,2018. There were 46 males in the cohort, ages from 5 months to 20 years. Seventy-one (71) patients with the diagnosis of gelastic epilepsy related to hh were treated at a single center with stereotactic laser ablation from march 11, 2011 to february 9,2018. There were 46 males in the cohort, ages from 5 months to 20 years. Sixteen patients, 25%, had failed other surgical or radiosurgical interventions. After stereotactic laser ablation, 93% of the patients were free of their gelastic seizures at one year, and 78% of the patients with less than a year of follow-up are free of gelastic seizures. Twenty one of the patients in this series had secondary seizures that were lessened by ablation and controlled with medicines. Fourteen of the patients, 20%, required two ablations, and 2 patients required three ablations. Most patients experience a near instant improvement in their condition. 12% were seizure free and free of antiepileptic medicines on last follow-up. One case of diabetes insipidus was worsened to ddavp dependence by laser ablation. There was no instance in which laser ablation created or worsened hypothalamic obesity. One patient, who previously had undergone a right-sided temporal lobectomy, had a severe deficit in short-term memory postoperatively from left-sided mammillary body injury (discussed below). His deficit improved with techniques of accommodation but he remains disabled. Four patients had delayed wound healing and 3 patients had a single episode of hyponatremia requiring readmission for sodium supplementation without recurrence. Nine patients had a temporary increase in non-gelastic seizures that resolved at 4 months post surgery. Manufacturer narrative: patient identifier and weight were unavailable from the

									journal article or by the authors. Patient age and patient sex not made available the attached journal article or by the authors. The article reports that the oldest patient age was (b)(6) and the consisted of male patients in the study. Therefore (b)(6) year old and male were used. Event date is approximated. Date provided is when the journal article was accepted. Citation: daniel j. Currya, jeffery raskina, irfan alic, & angus a. Wilfong. Mr-guided laser ablation for the treatment of hypothalamic hamartomas (2018). Epilepsy research 142 (2018) 131¿134. Https://doi.org/10.1016/j.eplepsyres.2018.03.013. Brand name, common device name and procode not provided in the journal article. The article mentions a thermal therapy system (model not specified). Further information unavailable. Those selected are suspected to be for the device used. Further information unavailable. The exact system information could not be determined as it was not provided. However, the system listed on this form was at the address listed in the article during the time some of the surgeries were completed. Device udi not provided as actual product used for this study is unknown. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. Multiple attempts have been made to obtain additional information. No further information provided in the journal article or from the authors. The author could not provide any additional information or insight as he was not at the site when the surgeries were performed. No request for service have been received from the customer regarding these events. No parts have been replaced or returned to the manufacturer for evaluation. Per author, mr-guided stereotactic laser ablation is a safe and effective alternative in the treatment of gelastic seizures related to hh. The application of this technology to hh is increased the efficacy of the surgical

									treatment of the disease and lowered the complication profile. Although technically demanding, the procedure can be easily adopted by experienced stereotactic neurosurgical centers. It has minimal corridor related morbidity making it safely repeatable, allowing the technique to be used in an incremental fashion in situations of high-risk. Lastly, it is a nascent technology, the future iterations of which could improve the usability and safety profile. Medtronic navigation is filing this mdr to ensure visibility to a patient event as a result of a procedure that utilized medtronic navigation's thermal therapy system. There is no allegation to suggest that medtronic navigation's device caused or contributed to the reported event. Device not returned by customer.
3008492462-2018-00027	07/03/2018	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	28/03/2018	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE	Device Operates Differently Than Expected	No Consequences Or Impact To Patient	During an st procedure we couldn't find any calc on the xray of tissue and we knew we had biopsied the right area. After tidying up for the next patient we realized there were bits of tissue in the vacuum canister. We removed the tissue from the canister and x-rayed, and discovered the tissue recovered had calcs. Manufacturer narrative: the revolve stereotactic probe is a sterile, single-patient use device that may be used with imaging guidance to excise a tissue sample for diagnosis. The device has not been returned to the manufacturer for evaluation which prevents a full investigation and analysis of the root cause at this time. However, this failure mode has been identified in the risk management file and has been shown to occur if the tissue strips contained in the sample management system are not fully aligned or seated properly as instructed within the ifu. Although no serious injuries occurred, upon consultation with devicor's medical department, this failure mode has been determined to be a reportable malfunction. Thus, pursuant to 21 cfr 803, we are submitting this medwatch report.

3007566237-2018-01274	01/03/2018	Injury	MEDTRONIC NEUROMODULATION	27/04/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Pulmonary Embolism; Dyspnea; Fall; Hematoma; Hemorrhage, Subdural; Hypoxia; Irritation; Dizziness; Cognitive Changes; Thromboembolism	Summary: background/aims: interventional mri (imri) allows real-time confirmation of electrode and microcatheter location in anesthetized patients; however, mri-compatible pneumatic compression devices (pcd) to reduce the periprocedural venous thromboembolism (vte) risk are not commercially available. Given the paucity of literature on vte following imri surgery, better characterizing patients suffering this complication and the incidence of this event following imri procedures is pivotal for defining best surgical practices. We aim to investigate the incidence of postoperative vte in imri procedures without the use of pcd. Methods: medical records and operative times of patients were retrospectively reviewed. Patient demographics and mean surgical durations were reported with statistical comparisons via anova and the 2-tailed student t test, an ¿ of 0.05, and the bonferroni correction. Patients experiencing postoperative vte underwent an in-depth chart review. Results: two out of two hundred ten (0.95%) imri procedures resulted in postoperative vte events. There were statistically significant differences in procedure times between unilateral electrode (157.5 ± 5.7 min), bilateral electrode (193.6 ± 2.9 min), and bilateral gene therapy procedures (467.3 ± 26.5 min). Both patients had longer-than-average operative times for their respective procedures. Conclusions: the incidence of postoperative vte is low following imri procedures, even without the use of pcd during surgery. Reported events: 1 (b)(6) year old male with a bmi of 24.1 and a 13-year history of parkinson's disease had been well maintained on medical therapy for many years. However, in the year prior to his surgery (unknown date) he had experienced progressively worsening symptoms and wearing-off phenomenon, with significant motor symptom fluctuations including tremor and bradykinesia. He underwent an evaluation

									for bilateral deep brain stimulation (dbs) and was found to be a good surgical candidate. His past medical history was significant for depression, an episode of transient global amnesia, mild valvular heart disease, endocarditis, hypertension, and insomnia. His past surgical history included prostate, spine, and shoulder procedures. He had no history of thromboembolic events and his preoperative coagulation studies were normal. After an uncomplicated surgery lasting 225 min in which dbs electrodes were implanted in bilateral globus pallidus internus (gpi), he began ambulating the morning after surgery and was discharged to his home on the afternoon of postoperative day (pod) 1. It was noted that he patient had longer-than-average operative time, which was suspected to have contributed to the patient experiencing venous thromboembolism (vte). Over the following 3 days he developed progressive dizziness and cough which culminated in delirium and 6 mechanical falls, the last of which was down a flight of stairs on pod 4. He was brought to the emergency room and was found to have an acute, nonsurgical 8-mm right tentorial subdural hematoma. He was also noted to be short of breath and hypoxic. He was admitted for observation and, because of a persistent need for supplemental oxygen to maintain an oxygen saturation of 92% in the setting of no fever, a ct pulmonary angiogram was performed to rule out pulmonary embolism. The ct revealed an acute lingular segmental pulmonary embolism without radiographic evidence of increased right heart pressures. Subsequent doppler ultrasound measurements of the lower extremities were negative. Anticoagulation was contraindicated for this patient given the subdural hematoma he had sustained from his fall, so an inferior vena cava filter was placed by interventional radiology with plans to start full anticoagulation 2 weeks later. The patient made an uncomplicated

									recovery, his inferior vena cava filter was removed, and he was not on anticoagulation at the last follow-up, with normal pulmonary function. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: citation: kundishora, a., englot, d., starr, p., martin, a., larson, p. (2018). Venous thromboembolism during interventional mri-guided stereotactic surgery. Stereotactic and functional neurosurgery, 96(1), 40-45. Doi:10.1159/000486642. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. The source literature included that the procedure, equipment, and mri protocols can be found in their previous reports of adults and children. Upon review of these reports (citation below), the following device specifics were identified: implantable neurostimulator (ins) model 7428 - kinetra. However, it is unknown if this patient was also implanted with a 7428 kinetra ins. Adults: martin aj, larson ps, ostrem jl, keith sootsman w, talke p, weber om, et al: placement of deep brain stimulator electrodes using realtime high-field interventional magnetic resonance imaging. Magn reson med 2005; 54: 1107¿1114. Starr pa, martin aj, ostrem jl, talke p, levesque n, larson ps: subthalamic nucleus deep brain stimulator placement using highfield interventional magnetic resonance imaging and a skull-mounted aiming device: technique and application accuracy. J neurosurg 2010; 112: 479¿490. Children: starr pa, markun lc, larson ps, volz mm, martin aj, ostrem jl: interventional mri guided deep brain stimulation in pediatric dystonia: first experience with the clearpoint system. J neurosurg pediatr 2014; 14: 400¿ 408. If information is provided in the future, a supplemental report will be issued.

3007566237-2018-01276	01/03/2018	Injury	MEDTRONIC NEUROMODULATION	27/04/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Unspecified Infection	Summary: background/aims: interventional mri (imri) allows real-time confirmation of electrode and microcatheter location in anesthetized patients; however, mri-compatible pneumatic compression devices (pcd) to reduce the periprocedural venous thromboembolism (vte) risk are not commercially available. Given the paucity of literature on vte following imri surgery, better characterizing patients suffering this complication and the incidence of this event following imri procedures is pivotal for defining best surgical practices. We aim to investigate the incidence of postoperative vte in imri procedures without the use of pcd. Methods: medical records and operative times of patients were retrospectively reviewed. Patient demographics and mean surgical durations were reported with statistical comparisons via anova and the 2-tailed student t test, an ¿ of 0.05, and the bonferroni correction. Patients experiencing postoperative vte underwent an in-depth chart review. Results: two out of two hundred ten (0.95%) imri procedures resulted in postoperative vte events. There were statistically significant differences in procedure times between unilateral electrode (157.5 ± 5.7 min), bilateral electrode (193.6 ± 2.9 min), and bilateral gene therapy procedures (467.3 ± 26.5 min). Both patients had longer-than-average operative times for their respective procedures. Conclusions: the incidence of postoperative vte is low following imri procedures, even without the use of pcd during surgery. Reported events: 1 patient implanted with bilateral deep brain stimulation (dbs) in the centromedian nucleus of the thalamus for tourette syndrome developed a unilateral lead infection, which required removal. The electrode was replaced after the infection cleared. The patient underwent an initial staged implant procedure, however, the stage at which the infection developed is unclear (pre or post implantable

									neurostimulator [ins] implantation). It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: citation: kundishora, a., englot, d., starr, p., martin, a., larson, p. (2018). Venous thromboembolism during interventional mri-guided stereotactic surgery. Stereotactic and functional neurosurgery, 96(1), 40-45. Doi:10.1159/000486642. The reported age reflects the average age of the patients reported in the literature article. The reported sex reflects that of the majority of the patients reported in the literature article (120 male, 68 female). Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. The device was used for an off label indication; other relevant device(s) are: product id: neu_unknown_lead, serial/lot #: unknown. The source literature included that the procedure, equipment, and mri protocols can be found in their previous reports of adults and children. Upon review of these reports (citation below), the following device specifics were identified: lead model 3389, implantable neurostimulator (ins) model 7428 - kinetra. However, it is unknown if this patient was also implanted with these devices. Adults: martin aj, larson ps, ostrem jl, keith sootsman w, talke p, weber om, et al: placement of deep brain stimulator electrodes using realtime high-field interventional magnetic resonance imaging. Magn reson med 2005; 54: 1107¿1114. Starr pa, martin aj, ostrem jl, talke p, levesque n, larson ps: subthalamic nucleus deep brain stimulator placement using highfield interventional magnetic resonance imaging and a skull-mounted aiming device: technique and application accuracy. J neurosurg 2010; 112: 479¿490. Children: starr pa, markun lc, larson ps, volz mm, martin aj, ostrem jl: interventional mriguided deep brain stimulation in

									pediatric dystonia: first experience with the clearpoint system. J neurosurg pediatr 2014; 14: 400¿ 408. If information is provided in the future, a supplemental report will be issued.
2020394-2018-00298	27/02/2018	Malfunction	BARD PERIPHERAL VASCULAR, INC.	28/03/2018	KNW	BARD MONOPTY DISPOSABLE CORE BIOPSY INSTRUMENT	Failure to Prime; Detachment of Device or Device Component	No Consequences Or Impact To Patient	It was reported that during a stereotactic guided breast biopsy, after six sample passes, the device allegedly was unable to prime at first. However, once device was primed and fired, the inner stylet detached from the outer cannula. Reportedly, the procedure was completed with another device. There was no reported patient injury. Manufacturer narrative: no medical records or no medical images have been made available to the manufacturer. As the lot number for the device was provided, a review of the device history records is currently being performed. The device has been returned to the manufacturer for evaluation. The investigation of the reported event is currently underway. The information provided by bard represents all of the known information at this time. Despite good faith efforts to obtain additional information, the complainant / reporter was unable or unwilling to provide any further patient, product, or procedural details to bard.
2020394-2018-00258	20/02/2018	Malfunction	BARD PERIPHERAL VASCULAR, INC.	20/03/2018	KNW	ENCOR DRIVER	Break; Device Operates Differently Than Expected	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, the system monitor display was allegedly blacked out after completing almost a full around the clock sequence (sixth sample). It was further reported the probe aperture was closed and able to be removed without issue. Reportedly, there were enough samples to complete the biopsy. It was further reported that the system was able to restart and system error 0003 displayed. Another probe was used to place a breast tissue marker. There was no reported patient injury.
2020394-2018-00257	20/02/2018	Malfunction	BARD PERIPHERAL VASCULAR, INC.	20/03/2018	KNW	ENCOR ENSPIRE SYSTEM	Device Operates Differently Than Expected	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, the system monitor display was allegedly blacked out after completing almost a full around the clock sequence (sixth sample). It was further reported the probe aperture was closed and able to be

									removed without issue. Reportedly, there were enough samples to complete the biopsy. It was further reported that the system was able to restart and system error 0003 displayed. Another probe was used to place a breast tissue marker. There was no reported patient injury. Manufacturer narrative: no medical records or no medical images have been made available to the manufacturer. The device has been returned to the manufacturer for evaluation. As the serial number for the device was provided, a review of the device history records is currently being performed. The investigation of the reported event is currently underway. The information provided by bard represents all of the known information at this time. Despite good faith efforts to obtain additional information, the complainant / reporter was unable or unwilling to provide any further patient, product, or procedural details to bard.
1723170-2018-03746	16/02/2018	Injury	MEDTRONIC NAVIGATION, INC. (LOUISVILLE)	30/07/2018	GEX	SYSTEM 9735542 15W VISUALASE	Adverse Event Without Identified Device or Use Problem	Swelling; Tissue Damage; No Known Impact Or Consequence To Patient; Hydrocephalus	Summary: magnetic resonance imaging¿guided stereotactic laser ablation of intracranial targets, including brain tumors, has expanded dramatically over the past decade, but there have been few reports of complications, especially those occurring in a delayed fashion. Laser ablation of subependymal giant cell astrocytomas (segas) is an attractive alternative to maintenance immunotherapy in some children with tuberous sclerosis complex (tsc); however, the effect of treatment on disease progression and the nature and frequency of potential complications remains largely unknown. The authors report the case of a (b)(6)-year-old boy with tsc who underwent stereotactic laser ablation of a sega at the right foramen of monro on 2 separate occasions. After the second ablation, immediate posttreatment mri revealed gadolinium extravasation from the tumor into the lateral ventricle. Nine months later, the patient presented with papilledema and delayed obstructive hydrocephalus

									secondary to intraventricular adhesions causing a trapped right lateral ventricle. This was successfully treated with endoscopic septostomy. The authors discuss the potential cause and clinical management of a delayed complication not previously reported after a relatively novel surgical therapy. Reported events: (b)(6) year old boy with history of tsc, epilepsy, and autism with bilateral segas achieved subtotal ablation, without procedural complications, during stereotactic laser ablation. Eighteen months post ablation, significant interval growth of the residual tumor was noted. A second laser ablation was performed. Immediate posttreatment mri demonstrated near-complete ablation of the tumor but also hypersensitivity of the right lateral ventricle on postcontrast flair imaging, consistent with gadolinium extravasation into the ventricle. Noncontrast ct scanning the day after the procedure confirmed the absence of intraventricular hemorrhage and that the mri-demonstrated signal abnormality within the right ventricle was gadolinium. Nine months after the second ablation, the patient was evaluated by his ophthalmologist, who noted bilateral papilledema. Mri demonstrated a significantly decreased side of the right-sided sega but there was a trapped right lateral ventricle with obstructive hydrocephalus. The patient was treated with endoscopic septostomy. Manufacturer narrative: per author, the adverse event listed in article was not related to medtronic system. If this information was available prior to initial filing, this complaint would not be reported. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued. Manufacturer narrative: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Citation: karsy, michael; patel, daxa m.; bollo, robert j. ¿trapped ventricle after laser ablation of a subependymal giant

									cell astrocytoma complicated by intraventricular gadolinium extravasation: case report¿. Journal of neurosurgery: pediatrics, 21, 2018: 523-527. No further information provided in the journal article or from the authors. The author did not respond to a request for further information. No request for service have been received from the customer regarding these events. No parts have been replaced or returned to the manufacturer for evaluation. No parts returned.
2020394-2018-00259	15/02/2018	Malfunction	BARD PERIPHERAL VASCULAR, INC.	20/03/2018	KNW	ENCOR DRIVER	Break; Device Operates Differently Than Expected	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, the system monitor display was allegedly blacked out after completing almost a half an around the clock sequence (three samples). It was further reported the probe aperture was open and unable to be removed without issue. Reportedly, the system was able to restart and as soon as the aperture closed the probe was able to be removed from the patient. It was further reported that there were enough samples to complete the biopsy. Reportedly, the system error 0003 displayed with the probe and another probe was used to place a breast tissue marker. There was no reported patient injury.it was reported that during a stereotactic breast biopsy, the driver was connected to the system and the monitor display was allegedly blacked out after completing almost a half an around the clock sequence (three samples). It was further reported the driver controlling the probe was unable to close the probe aperture. Reportedly, the system was able to restart and as soon as the aperture closed the probe was able to be removed from the patient. It was further reported that there were enough samples to complete the biopsy. Reportedly, the system error 0003 displayed with the probe and driver. It was further reported that another probe with the initial driver was used to place a breast tissue marker. There was no reported patient injury. Manufacturer narrative: no medical records or no medical images have been made

									available to the manufacturer. The device has been returned to the manufacturer for evaluation. As the serial number for the device was provided, a review of the device history records is currently being performed. The investigation of the reported event is currently underway. The information provided by bard represents all of the known information at this time. Despite good faith efforts to obtain additional information, the complainant / reporter was unable or unwilling to provide any further patient, product, or procedural details to bard. Manufacturer narrative: manufacturing review: a lot history review was conducted and it was determined that a device history record (dhr) review was not required. Investigation summary: one encor driver was returned to the manufacturing site for service and repair. The returned driver successfully passed all functional testing; the driver was able to open and close the in-house probe aperture without issue, and no error codes displayed on the console the driver cable was replaced as it was noted to be discolored during the visual inspection of the returned driver. Therefore, the investigation is unconfirmed for the reported failure to cycle issue and confirmed forBreak, as the driver cable received was discolored/worn. Per the service and repair evaluation, it was noted that the returned encor driver was able to successfully pass all functional testing and the reported failure to cycle could not be reproduced. Additionally, other finding noted during service and repair were that the driver cable was found to be discolored. Although the discolored driver cable was replaced, the definitive root cause for the reported failure to cycle issue could not be determined based upon the provided information. It is unknown whether procedural issues contributed to the event. Labeling review: the review of the ifu (instructions for use), indications, warnings, precautions, cautions, possible complications, and contraindications

									showed that the product labeling is adequate.
2020394-2018-00260	15/02/2018	Malfunction	BARD PERIPHERAL VASCULAR, INC.	20/03/2018	KNW	ENCOR ENSPIRE BREAST BIOPSY SYSTEM	Device Operates Differently Than Expected	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, the system monitor display was allegedly blacked out after completing almost a half an around the clock sequence (three samples). It was further reported the probe aperture was open and unable to be removed without issue. Reportedly, the system was able to restart and as soon as the aperture closed the probe was able to be removed from the patient. It was further reported that there were enough samples to complete the biopsy. Reportedly, the system error 0003 displayed with the probe and another probe was used to place a breast tissue marker. There was no reported patient injury.it was reported that during a stereotactic breast biopsy, the system monitor display was allegedly blacked out after completing almost a half an around the clock sequence (three samples). It was further reported the probe aperture was open and unable to be removed without issue. Reportedly, the system was able to restart and as soon as the aperture closed the probe was able to be removed from the patient. It was further reported that there were enough samples to complete the biopsy. Reportedly, the system error 0003 displayed with the probe and another probe was used to place a breast tissue marker. There was no reported patient injury. Manufacturer narrative: manufacturing review: the device history records have been reviewed and this lot met all release criteria. There was nothing found to indicate there was a manufacturing related cause for this event. Investigation summary: one encor enspire system was returned to the manufacturing site for service and repair. The returned system successfully passed all functional testing and did not stop working or produce any error codes. Therefore, the investigation is unconfirmed for the reported blank screen, as the reported issue could not be reproduced. Per the service

									and repair evaluation, it was noted that the returned enspire system was able to successfully pass all functional testing and the reported blank screen could not be reproduced. Additionally, other findings noted during service and repair were that the pc power cable was catching inside the riser tube and a hard drive error appeared during the re-imaging of the software. Although the pc power cable and monitor were replaced, the definitive root cause for the reported blank screen could not be determined based upon the provided information. It is unknown whether procedural issues or continual use of the reusable equipment contributed to the event. Labeling review: the review of the ifu (instructions for use), indications, warnings, precautions, cautions, possible complications, and contraindications showed that the product labeling is adequate. Manufacturer narrative: no medical records or no medical images have been made available to the manufacturer. The device has been returned to the manufacturer for evaluation. As the serial number for the device was provided, a review of the device history records is currently being performed. The investigation of the reported event is currently underway. The information provided by bard represents all of the known information at this time. Despite good faith efforts to obtain additional information, the complainant / reporter was unable or unwilling to provide any further patient, product, or procedural details to bard.
2020394-2018-00254	15/02/2018	Malfunction	BARD PERIPHERAL VASCULAR, INC.	20/03/2018	KNW	ENCOR BIOPSY PROBE	Failure to Cycle; Difficult to Remove; Device Operates Differently Than Expected	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, the system monitor display was allegedly blacked out after completing almost a half an around the clock sequence (three samples). It was further reported the probe aperture was open and unable to be removed without issue. Reportedly, the system was able to restart and as soon as the aperture closed the probe was able to be removed from the patient. It was further

									reported that there were enough samples to complete the biopsy. Reportedly, the system error 0003 displayed with the probe and another probe was used to place a breast tissue marker. There was no reported patient injury.it was reported that during a stereotactic breast biopsy, the system monitor display was allegedly blacked out after completing almost a half an around the clock sequence (three samples). It was further reported the probe aperture was open and unable to be removed without issue. Reportedly, the system was able to restart and as soon as the aperture closed the probe was able to be removed from the patient. It was further reported that there were enough samples to complete the biopsy. Reportedly, the system error 0003 displayed with the probe and another probe was used to place a breast tissue marker. There was no reported patient injury. Manufacturer narrative: as the lot number for the device was not provided, a manufacturing review could not be performed. The sample was not returned to the manufacturer for inspection/evaluation. Therefore, the investigation of the reported event is inconclusive. Based upon the available information, the definitive root cause for this event is unknown. The instructions for use (ifu) is adequate for the reported device/patient code(s) and provides general instructions for use, as well as warnings, precautions and potential complications associated with the device. Upon receipt of new or additional information, a follow-up report will be submitted as applicable. Manufacturer narrative: as the lot number for the device was not provided, a manufacturing review could not be performed. The sample was not returned to the manufacturer for inspection/evaluation. Therefore, the investigation of the reported event is inconclusive. Based upon the available information, the definitive root cause for this event is unknown. The instructions for use (ifu) is adequate for the

									reported device/patient code(s) and provides general instructions for use, as well as warnings, precautions and potential complications associated with the device. Upon receipt of new or additional information, a follow-up report will be submitted as applicable. (b)(4).
2020394-2018-00231	15/02/2018	Malfunction	BARD PERIPHERAL VASCULAR, INC.	14/03/2018	KNW	ENCOR BIOPSY PROBE	Filling Problem; Difficult to Remove; Device-Device Incompatibility	No Consequences Or Impact To Patient	It was reported that during breast tissue marker placement under stereotactic guidance, the marker was protruding outside the sample notch and allegedly the probe was difficult to remove. It was further reported the marker was placed. There was no reported patient injury. Manufacturer narrative: no hospital/medical records or medical images have been made available to the manufacturer. As the lot number for the device was provided, a review of the device history records is currently being performed. The device has been returned to the manufacturer for evaluation. The investigation of the reported event is currently underway. The information provided by bard represents all of the known information at this time. Despite good faith efforts to obtain additional information, the complainant / reporter was unable or unwilling to provide any further patient, product, or procedural details to bard.
3008492462-2018-00024	13/02/2018	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	09/03/2018	KNW	MAMMOTOME REVOLVE BIOPSY PROBE	Failure to Obtain Sample	No Consequences Or Impact To Patient	The sales rep reported that during procedure the probe/ cutter would not take samples. Procedure was completed with another device. Manufacturer narrative: the revolve stereotactic probe is a sterile, single-patient use device that may be used with imaging guidance to excise a tissue sample for diagnosis. One mst0809 probe was received for investigation on (b)(6) and investigated on (b)(6). Device was in used condition. The device was connected to a holster for functional evaluation. The device initialized as designed. Using chicken as a medium, probe was unable to obtain samples. The device was then disassembled and the cutter was found to be clogged with tissue. The initial voice of customer

									was deemed not reportable as no patient consequence was noted. However, due to the discovery of the tissue, this event was reassessed for reportability against the result of the investigation. Following consultation with our medical director, due to the potential to cause or contribute to death or serious injury as a result of potential missed or lost tissue samples, pursuant to 21 cfr §803, this failure mode was determined to be a reportable malfunction. Thus, we are submitting this medwatch report.
1723170-2018-02075	06/02/2018	Injury	MEDTRONIC NAVIGATION, INC. (LOUISVILLE)	15/05/2018	GEX	LASER 9735552 15W 980NM - VISUALASE	Adverse Event Without Identified Device or Use Problem	Hematoma; Intracranial Hemorrhage; Nerve Damage; Neurological Deficit/Dysfunction; Visual Impairment	The attached journal article was forwarded by medtronic representative. Article indicated the use of laser ablation system. Surgical outcomes of a consecutive series of 58 patients with mesial temporal lobe epilepsy (mtle) who underwent the surgery at our institution with at least 12 months of follow-up were retrospectively evaluated, including 33 females and 25 males, ranging in age from 16 to 67 years (mean of 40 years) at the time of first slah. All patients who underwent stereotactic laser amygdalohippocampotomy (slah) for mtle between july 1, 2011 and june 30, 2016. Patients who were not free of disabling seizures following the procedure were considered for further surgical intervention, including open resection and, for patients in whom review of an interval postoperative mri scan showed a remnant region of the hippocampus and/or uncus thought to be responsible for ongoing seizures, repeat ablations. The latter were performed in a fashion similar to the initial ablation but from a more lateral entry, targeting the remnant medial temporal structures. Patients who failed a repeat ablation were again considered for open surgical procedures. A total of 67 laser ablation procedures were performed: 58 initial procedures and 9 repeat procedures in 9 patients. Two patients with recurrent seizures following slah elected to undergo atl as a secondary procedure, and 2 additional patients underwent anterior

									temporal lobectomy (atl) following unsuccessful repeat slah. Thirty-one of 58 patients (53.4%, 95% ci = 40.8¿65.7%) were free of disabling seizures (engel i) for 12 months following slah (fig 2a), including 3 patients who were initially not seizure-free but achieved engel i outcomes for 12 months following repeat ablation of remaining medial temporal tissue. Of patients with mts, 26 of 43 (60.5%, 95% ci = 45.6¿73.7%) were free of disabling seizures at 12 months, only 1 of whom underwent repeat ablation. Conversely, only 5 of 15 (33.3%, 95% ci = 15.0¿58.5%) patients without mts achieved engel i outcomes. Following repeat ablation, 7 of 9 patients experienced improved outcomes, with 3 of those achieving freedom from disabling seizures (engel ib; see fig 2b, c). Of the 31 patients who achieved freedom from disabling seizures, 22 were completely seizure-free (engel ia), 7 had nondisabling simple partial seizures (engel ib), 1 had a single generalized convulsive seizure with antiepileptic drug withdrawal (engel id), and 1 had generalized convulsive seizure associated with hyponatremia secondary to carbamazepine use (engel id). Four patients underwent atl following slah, 2 after a single slah procedure and 2 following repeat ablations. After 1 year, only 1 such patient achieved seizure freedom (a single simple partial seizure occurred at 6 weeks); the others experienced a reduction in seizure frequency (engel ii [n = 1] and engel iii [n = 2]). Notably, none of these 4 patients had mts on mri. Only 4 of 27 patients not free of disabling seizures underwent open resections. Reasons for not having subsequent open surgery varied, including (1) nearly seizure free or only nocturnal seizures (n = 11), (2) not interested in further surgery (n = 6), (3) moved or lost to follow-up (n = 3), (4) possible contralateral onsets (n = 1), (5) underwent callosotomy (n = 1), and (6) atl is scheduled to be performed. Five visual field deficits (vfds) occurred (5/58 = 8.6%), only 1 of which

									was persistent and symptomatic (1.7%; see supplementary table). This was a nearly complete homonymous hemianopia that followed a repeat ablation, and may be attributable to thermal spread to the ventral thalamus, in the region of the lateral geniculate nucleus. The second vfd was a superior quadrantanopia secondary to an intraparenchymal hematoma in the occipital region; although persistent on formal visual field and confrontation testing, it was asymptomatic on last follow-up. A third patient complained of vague visual difficulties and had a mild incongruous hemianopic central depression, thought to be at the level of the optic tract, but follow-up formal and confrontation visual field testing were normal. The other 2 vfds were mild superior quadrantanopias that were asymptomatic on followup confrontation testing; formal field testing was persistent in 1, and not obtained in the other. These mild quadrantanopias are believed to have resulted from the most posterior ablations having encroached upon the optic radiation in the external sagittal stratum. After this etiology had been recognized, it did not occur in the last 33 of 58 patients. In addition to the 1 intraparenchymal hematoma noted, there was 1 additional hemorrhage, an acute subdural hematoma that was operatively addressed immediately following ablation; it was not associated with a neurologic deficit. Four patients (4/58 5 6.9%) experienced transient nondisabling partial cranial nerve palsies (iii and iv), believed to have resulted from thermal injury spreading medially at the tentorium when ablating the uncus, subiculum, and/or entorhinal cortex. All 4 patients were treated with steroids and recovered completely. Four of 49 (8.2%) patients experienced a decline on 1 (n 5 3) or both (n 5 1) subscores of the ravlt (verbal memory) measure. Of the 3 language dominant slah patients to significantly decline on this memory measure, 2 declined on the learning trial only and the third

									declined on both the learning and delayed recall trials. Stereotactic laser ablation represents a paradigm shift in the surgical management of epilepsy. With careful consideration and technical execution, this generally low-risk, high-reward approach minimizes recovery time and cognitive risk while still providing a high chance of seizure control. As slah presents no barrier to subsequent ablation, open surgery, or other procedures, slah now fills an important gap between the ¿all or none¿ considerations of continued medical management and open resection. It provides a practical iterative approach to surgical epilepsy when patient need or desire dictates, and its availability improves utilization of potentially curative epilepsy surgery. Manufacturer narrative: patient identifier and weight were unavailable from the attached journal article or by the authors. Patient age and patient sex not made available the attached journal article or by the authors. The article reports that the mean patient age was 40 and the consisted of female patients in the study. Therefore 40 year old and female were used. Event date is approximated. Date provided is when the journal article was published. Citation: robert e. Gross, md, phd, matthew a. Stern, bs ,jon t. Willie, md, phd, rebecca e. Fasano, md, amit m. Saindane, md, bruno p. Soares, md, nigel p. Pedersen, mbbs, and daniel l. Drane, phd. Stereotactic laser amygdalohippocampotomy for mesial temporal lobe epilepsy (2018). Ann neurol 2018; 83:575-587. Doi: 10.1002/ana.25180. The exact system information could not be determined as it was not provided. However, the system listed on this form was at the address listed in the article during the time some of the surgeries were completed. Device udi not provided as actual product used for this study is unknown. Multiple attempts have been made to obtain additional information. No further information provided in the journal article or from the authors. The

									author could not provide any additional information or insight as he was not at the site when the surgeries were performed. No request for service have been received from the customer regarding these events. No parts have been replaced or returned to the manufacturer for evaluation. Medtronic navigation is filing this mdr to ensure visibility to a patient event as a result of a procedure that utilized medtronic navigation's laser ablation system. There is no allegation to suggest that medtronic navigation's device caused or contributed to the reported event. Not returned by customer.
2029046-2018-01274	06/02/2018	Injury	BIOSENSE WEBSTER INC	01/03/2018	LPB	THERMOCOOL® SMART TOUCH® SF BI-DIRECTIONAL NAVIGATION CATHETER	Adverse Event Without Identified Device or Use Problem	Cardiac Tamponade; No Code Available	It was reported that a male patient underwent an ablation procedure for atrial fibrillation with a thermocool® smart touch® sf bi-directional navigation catheter and suffered a cardiac tamponade requiring pericardiocentesis and surgical intervention. During ablation phase, the patient became slightly hypotensive and a pericardial effusion was confirmed via intracardiac echocardiography (ice). Pericardiocentesis was performed and yielded approximately 1500 ml of fluid. Although the patient was in stable condition, they were transferred to the operating room for surgical hemostasis. Patient recovered after surgical intervention. Patient required extended hospitalization as a result of the adverse event. Factors cited that may have contributed to the adverse event include history of anterior pouch, where the physician feels the perforation occurred. Physician¿s opinion regarding the cause of the adverse event is that it was secondary to a perforation of the left atrial anterior roof. The adverse event was not attributed to any bwi product or equipment issues. Transseptal puncture was performed with an unspecified needle and a st. Jude medical agilis small curve sheath. There is no information regarding generator parameters, generator settings, power titration, overall ablation time at the site of injury, or last ablation cycle time at the site

									of injury. It was noted that there was no ablation at the site of injury. Irrigated catheter flow was set at 2 ml/min for maintenance. Patient received anticoagulant during the procedure with activated clotting time maintained at approximately 350 seconds. It was noted that this event did not occur in a stereotactic lab. There is no information regarding spi value. Smarttouch catheter was in close proximity to the lasso catheter, which was in the right superior pulmonary vein (rspv), near the site of injury. Smarttouch catheter was zeroed after the initial warm-up phase, post catheter connection to the carto 3 patient interface unit. Carto 3 system did not indicate to re-zero the catheter. It was also noted, that upon connection of soundstar catheter, prior to insertion in the patient, a constant magnetic sensor error (6150) displayed. Cable was exchanged without resolution. Soundstar catheter was exchanged and the issue resolved. The sc2000 ultrasound system was in use. The soundstar catheter was not reprocessed. Soundstar catheter was connected to both the carto and the ultrasound system when the issue occurred. Mapping catheter was not connected to the carto prior to connecting the soundstar catheter. Other devices connected to the carto 3 system included a generator, bard recording system, and a siemens fluoroscopy machine. Cartosound/uls was selected on the carto 3 system. Soundstar catheter was outside of the body at the time of the error. The issue occurred prior to the procedure, upon connection of the catheter. The soundstar catheter was not in the patient at the time of the error. There were no errors on the carto, as the image never appeared. This issue with the soundstar catheter is not mdr reportable because the potential that it could cause or contribute to a death, serious injury, or other significant adverse event is remote. Manufacturer narrative: since the product was not returned for analysis, no product

									failure analysis can be conducted and no determination of possible contributing factors could be made. As such, the investigation will be closed. If the complaint device is received in the future we will reopen the complaint and perform the investigation as appropriate. The device history record (dhr) was reviewed and no anomalies were found related to this complaint. In addition, the dhr review verifies that the device was manufactured in accordance with documented specification and procedures. Concomitant products: soundstar eco catheter (model# 10439011 serial (b)(4)), carto 3 system (model# unknown serial# unknown), lasso catheter (model# unknown lot# unknown), st. Jude medical agilis small curve sheath (model# unknown lot# unknown), sc2000 ultrasound system (model# unknown serial# unknown), smartablate generator (model# unknown serial# unknown), bard recording system (model# unknown serial# unknown), siemens fluoroscopy (model# unknown serial# unknown). (b)(4).
7266126	06/02/2018	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	13/02/2018	KNW	MAMMOTOME ST	Detachment Of Device Component; Activation, Positioning or Separation Problem	Device Embedded In Tissue or Plaque	Post right-breast stereotactic biopsy, there was a failure of the tissue marker to deploy correctly. The plastic sheath broke off in the breast. The retained piece was visualized during post imaging.
3008492462-2018-00023	06/02/2018	Injury	DEVICOR MEDICAL PRODUCTS, INC.	22/03/2018	NEU	MAMMOMARK	Device Damaged by Another Device	Foreign Body In Patient	It was reported by the sales rep that during the procedure, post right-breast stereotactic biopsy, there was a failure of the tissue marker to deploy correctly. The plastic sheath broke off in the breast. The retained piece was visualized during post imaging. Manufacturer narrative: the mammomark biopsy site identifier is intended for use after an open surgical or percutaneous breast biopsy procedure to the biopsy site. The device is not available for analysis, which precludes a full investigation and analysis of the root cause. Our mammotome vacuum assisted biopsy probes contain extremely sharp edges along

									the aperture opening to effectively excise tissue. Removing the marker delivery system separately from the probe aperture once the spring is exposed creates the possibility of it catching on one of these edges. As a mitigation step to address this risk, we provide instructions within the instructions for use: directions: remove the delivery system and mammotome probe together as a single unit from the site, properly dispose and obtain images to confirm marker placement. Based on the patient consequence of an unintended piece of the device in the biopsy site, and the additional surgical procedure to remove, and pursuant to 21 cfr 803, we are submitting this medwatch report.
2021898-2019-00208	02/02/2018	Injury	MEDTRONIC NEUROSURGERY	29/05/2019	JXG	UNKNOWN STRATA VALVE/SHUNT	Appropriate Term/Code Not Available; Migration	Complaint, Ill-Defined	Michael karsy, md, phd, hussam abou-al-shaar, md, christian a. Bowers, md, and richard h. Schmidt, md, phd. Treatment of idiopathic intracranial hypertension via stereotactic placement of biventriculo-peritoneal shunts. Journal of neurosurgery 130 (2019). Doi: 10.3171/2017.8.jns162927. Objective: idiopathic intracranial hypertension (iih), or pseudotumor cerebri, is a complex and difficult-to-manage condition that can lead to permanent vision loss and refractory headaches if untreated. Traditional treatment options, such as unilateral ventriculoperitoneal (vp) or lumboperitoneal (lp) shunt placement, have high complication and failure rates and often require multiple revisions. The use of bilateral proximal catheters has been hypothesized as a method to improve shunt survival. The use of stereotactic technology has improved the accuracy of catheter placement and may improve treatment of iih, with fewer complications and greater shunt patency time. Methods: the authors performed a retrospective chart review for all patients with iih who underwent stereotactic placement of biventriculo-peritoneal (bvp) shunt catheters from 2008 to 2016 at their institution. Bilateral proximal catheters were y-connected to a

									strata valve with a single distal catheter. We evaluated clinical, surgical, and ophthalmological variables and outcomes. Results: most patients in this series of 34 patients (mean age 34.4 ± 8.2 years, mean body mass index 38.7 ± 8.3 kg/m2; 91.2% were w omen) undergoing 41 shunt procedures presented with headache (94.1%) and visual deficits (85.3%). The mean opening pressure was 39.6 ± 9.0 cm h2o. In addition, 50.0% had undergone previous unilateral shunt placement, and 20.6% had undergone prior optic nerve sheath fenestration. After bvp shunt placement, there were no cases of proximal catheter obstruction and only a single case of valve obstruction at 41.9 months, with a mean follow-up of 24.8 ± 20.0 months. Most patients showed improvement in their headache (82.4%), subjective vision (70.6%), and papilledema (61.5% preoperatively vs 20.0% postoperatively, p = 0.02) at follow-up. Additional primary complications included 4 patients with migration of their distal catheters out of the peritoneum (twice in 1 patient), and an infection of the distal catheter after catheter dislodgment. The proximal obstructive shunt complication rate in this series (2.9%) was lower than that with lp (53.5%) or unilateral vp (37.8%) shunts seen in the literature. Conclusions: this small series suggests that stereotactic placement of bvp shunt catheters appears to improve shunt survival rates and presenting symptoms in patients with iih. Compared with unilateral vp or lp shunts, the use of bvp shunts may be a more effective and more functionally sustained method for the treatment of iih. Reported events: 5 patients (14.7%) required additional shunt related surgery. Of the 34 patients who underwent bvp shunt placement, 3 patients had 1 revision and 2 patients had 2 revisions, resulting in 41 total shunt placements. Of these, only 1 patient¿s (2.9%) vp shunt malfunction was due to a proximal obstruction. In this case, an obstructed valve was replaced 41.9

									months after initial placement, but the proximal catheter was found to be patent. Four patients underwent revision of their distal peritoneal catheter. In 1 patient, the distal catheter was transected during unrelated abdominal surgery and required replacement. The other 3 patients had migration of the catheter out of the peritoneum, causing an abdominal wall pseudocyst. All except one occurred initially within the 1st postoperative month. Migration of the catheter occurred a second time in 1 patient at 16 months. In another of these patients, the repair was further complicated by an abdominal wall infection after revision, requiring removal and eventual replacement of the entire shunt system. Manufacturer narrative: age or date of birth: please note that this age is the average age of the patients reported in the article, as the actual age of patients involved was not provided. Sex: please note that this is the gender of the majority of patients reported in the article as the actual genders of patients involved was not provided. Date of event: please note that this date is based off the date of publication of the article as the actual event date was not provided. If information is provided in the future, a supplemental report will be issued.
2021898-2019-00207	02/02/2018	Malfunction	MEDTRONIC NEUROSURGERY	29/05/2019	JXG	UNKNOWN STRATA VALVE/SHUNT	Insufficient Information	Therapeutic Effects, Unexpected; Visual Impairment	Michael karsy, md, phd, hussam abou-al-shaar, md, christian a. Bowers, md, and richard h. Schmidt, md, phd. Treatment of idiopathic intracranial hypertension via stereotactic placement of biventriculoperitoneal shunts. Journal of neurosurgery 130 (2019). Doi: 10.3171/2017.8.jns162927. Objective idiopathic intracranial hypertension (iih), or pseudotumor cerebri, is a complex and difficult-to-manage condition that can lead to permanent vision loss and refractory headaches if untreated. Traditional treatment options, such as unilateral ventriculoperitoneal (vp) or lumboperitoneal (lp) shunt placement, have high complication and failure rates and

									oftenrequire multiple revisions. The use of bilateral proximal catheters has been hypothesized as a method to improve shunt survival. The use of stereotactic technology has improved the accuracy of catheter placement and may improve treatment of iih, with fewer complications and greater shunt patency time. Methods the authors performed a retrospective chart review for all patients with iih who underwent stereotactic placement of biventriculoperitoneal (bvp) shunt catheters from 2008 to 2016 at their institution. Bilateral proximal catheters were y-connected to a strata valve with a single distal catheter. We evaluated clinical, surgical, and ophthalmological variables and outcomes. Results most patients in this series of 34 patients (mean age 34.4 ± 8.2 years, mean body mass index 38.7 ± 8.3 kg/m2; 91.2% were w omen) undergoing 41 shunt procedures presented with headache (94.1%) and visual deficits (85.3%). The meanopening pressure was 39.6 ± 9.0 cm h2o. In addition, 50.0% had undergone previous unilateral shunt placement, and 20.6% had undergone prior optic nerve sheath fenestration. After bvp shunt placement, there were no cases of proximal catheter obstruction and only a single case of valve obstruction at 41.9 months, with a mean follow-up of 24.8 ± 20.0 months. Most patients showed improvement in their headache (82.4%), subjective vision (70.6%), and papilledema (61.5% preoperatively vs 20.0% postoperatively, p = 0.02) at follow-up. Additional primary complications included 4 patients with migration of their distal catheters out of the peritoneum (twice in 1 patient), and an infection of the distal catheter after catheter dislodgment. The proximal obstructive shunt complication rate in this series (2.9%) was lower than that with lp (53.5%) or unilateral vp (37.8%) shunts seen in the literature. Conclusions this small series suggests that stereotactic placement of bvp shunt catheters appears to improve shunt survival

									rates and presenting symptoms in patients with iih. Compared with unilateral vp or lp shunts, the use of bvp shunts may be a more effective and more functionally sustained method for the treatment of iih. Reported events. 4 patients (11.8%) did not show improvements in their headaches. 5 patients (14.7%) did not show improvements in their vision. 3 patients (20%) did not report show improvements in their papilledema. 4 patients had worsening visual acuity. Manufacturer narrative: please note that this age is the average age of the patients reported in the article, as the actual age of patients involved was not provided. Please note that this is the gender of the majority of patients reported in the article as the actual genders of patients involved was not provided. Please note that this date is based off the date of publication of the article as the actual event date was not provided. If information is provided in the future, a supplemental report will be issued.
3007566237-2018-01092	26/01/2018	Injury	MEDTRONIC NEUROMODULATION	13/04/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage; Unspecified Infection; Laceration(s); Pain	Summary: objective the authors¿ aim in this study was to evaluate placement accuracy and clinical outcomes in patients who underwent implantation of deep brain stimulation devices with the aid of frame-based stereotaxy and intraoperative mri after induction of general anesthesia. Methods thirty-three patients with movement disorders (27 with parkinson¿s disease) underwent implantation of unilateral or bilateral deep brain stimulation systems (64 leads total). All patients underwent the implantation procedure with standard frame-based techniques under general anesthesia and without microelectrode recording. Mr images were acquired immediately after the procedure and fused to the preoperative plan to verify accuracy. To evaluate clinical outcome, different scales were used to assess quality of life (eq-5d), activities of daily living (unified parkinson¿s disease rating scale [updrs] part ii), and motor function (updrs part iii during off- and on-medication and

									off- and on stimulation states). Accuracy was assessed by comparing the coordinates (x, y, and z) from the preoperative plan and coordinates from the tip of the lead on intraoperative mri and postoperative ct scans. Results the eq-5d score improved or remained stable in 71% of the patients. When in the off medication/on stimulation state, all patients reported significant improvement in updrs iii score at the last follow-up (p < 0.001), with a reduction of 25.2 points (46.3%) (sd 14.7 points and 23.5%, respectively). There was improvement or stability in the updrs ii scores for 68% of the parkinson¿s patients. For 2 patients, the stereotactic error was deemed significant based on intraoperative mri findings. In these patients, the lead was removed and replaced after correcting for the error during the same procedure. Postoperative lead revision was not necessary in any of the patients. Based on findings from the last intraoperative mri study, the mean difference between the tip of the electrode and the planned target was 0.82 mm (sd 0.5 mm, p = 0.006) for the x-axis, 0.67 mm (sd 0.5 mm, p < 0.001) for the y-axis, and 0.78 mm (sd 0.7 mm, p = 0.008) for the z-axis. On average, the euclidian distance was 1.52 mm (sd 0.6 mm). In patients who underwent bilateral implantation, accuracy was further evaluated comparing the first implanted side and the second implanted side. There was a significant mediolateral (x-axis) difference (p = 0.02) in lead accuracy between the first (mean 1.02 mm, sd 0.57 mm) and the second (mean 0.66 mm, sd 0.50 mm) sides. However, no significant difference was found for the y- and z-axes (p = 0.10 and p = 0.89, respectively). Conclusions frame-based dbs implantation under general anesthesia with intraoperative mri verification of lead location is safe, accurate, precise, and effective compared with standard implantation performed using awake intraoperative physiology. More clinical

									trials are necessary to directly compare outcomes of each technique. Reported events: one (1) patient experienced an intra-operative surgical complication that included a small, asymptomatic hemorrhage without significant mass effect. No surgical intervention was required. One (1) patient experienced a surgical complication that included persistent pain at the implantable neurostimulator (ins) site. The pain resolved after the ins was re-implanted on the opposite side. One (1) patient experienced a surgical complication that included a post-operative wound infection 1 month after surgery. The patient was treated with oral antibiotics and implantable neurostimulator (ins) replacement. One (1) patient experienced a surgical complication that included a post-operative wound infection at the implantable neurostimulator (ins) site, 3 months after surgery. The patient was treated with oral antibiotics and implantable neurostimulator (ins) replacement. One (1) patient presented with a traumatic laceration of the scalp near 1 lead. The patient was treated with antibiotics for a wound infection at an unspecified location and underwent an implantable neurostimulator (ins) removal. This event occurred one month after surgery. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: the reported age reflects the mean age of the patients reported in the literature article. The reported sex reflects that of the majority of the patients reported in the literature article (17 female; 16 male). Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Product code mhy was chosen as it reflects the majority of the patients reported in the literature article. The main component of the system. Other relevant device(s) are: product id: neu_unknown_lead, serial/lot #: unknown;

									product id: neu_ins_stimulator, serial/lot #: unknown. Matias, c. M., frizon, l. A., nagel, s. J., lobel, d. A., machado, a. G. (2018). Deep brain stimulation outcomes in patients implanted under general anesthesia with frame-based stereotaxy and intraoperative mri. Journal of neurosurgery, 1-7. Doi:10.3171/2017.7.jns171166. If information is provided in the future, a supplemental report will be issued.
3008492462-2018-00014	26/01/2018	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	23/02/2018	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE	Device Operates Differently Than Expected	No Consequences Or Impact To Patient	The sales rep reported that during procedure the st tech noticed cores were not present in cup. After further investigation, she discovered tissue in purple vacuum tubing. She was able to retrieve the tissue, which in fact contained calcs. Manufacturer narrative: the revolve stereotactic probe is a sterile, single-patient use device that may be used with imaging guidance to excise a tissue sample for diagnosis. The device has not been returned to the manufacturer for evaluation which prevents a full investigation and analysis of the root cause at this time. However, this failure mode has been identified in the risk management file and has been shown to occur if the tissue strips contained in the sample management system are not fully aligned or seated properly as instructed within the ifu. Although no serious injuries occurred, upon consultation with devicor's medical department, this failure mode has been determined to be a reportable malfunction. Thus, pursuant to 21 cfr 803, we are submitting this medwatch report.
3007566237-2018-01093	26/01/2018	Malfunction	MEDTRONIC NEUROMODULATION	13/04/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Malposition of Device	No Known Impact Or Consequence To Patient	Summary: objective the authors¿ aim in this study was to evaluate placement accuracy and clinical outcomes in patients who underwent implantation of deep brain stimulation devices with the aid of frame-based stereotaxy and intraoperative mri after induction of general anesthesia. Methods thirty-three patients with movement disorders (27 with parkinson¿s disease) underwent implantation of unilateral or bilateral deep brain stimulation systems (64 leads total). All patients underwent the implantation procedure with

									standard frame-based techniques under general anesthesia and without microelectrode recording. Mr images were acquired immediately after the procedure and fused to the preoperative plan to verify accuracy. To evaluate clinical outcome, different scales were used to assess quality of life (eq-5d), activities of daily living (unified parkinson¿s disease rating scale [updrs] part ii), and motor function (updrs part iii during off- and on-medication and off- and on stimulation states). Accuracy was assessed by comparing the coordinates (x, y, and z) from the preoperative plan and coordinates from the tip of the lead on intraoperative mri and postoperative ct scans. Results the eq-5d score improved or remained stable in 71% of the patients. When in the off medication/on stimulation state, all patients reported significant improvement in updrs iii score at the last follow-up ($p < 0.001$), with a reduction of 25.2 points (46.3%) (sd 14.7 points and 23.5%, respectively). There was improvement or stability in the updrs ii scores for 68% of the parkinson¿s patients. For 2 patients, the stereotactic error was deemed significant based on intraoperative mri findings. In these patients, the lead was removed and replaced after correcting for the error during the same procedure. Postoperative lead revision was not necessary in any of the patients. Based on findings from the last intraoperative mri study, the mean difference between the tip of the electrode and the planned target was 0.82 mm (sd 0.5 mm, $p = 0.006$) for the x-axis, 0.67 mm (sd 0.5 mm, $p < 0.001$) for the y-axis, and 0.78 mm (sd 0.7 mm, $p = 0.008$) for the z-axis. On average, the euclidian distance was 1.52 mm (sd 0.6 mm). In patients who underwent bilateral implantation, accuracy was further evaluated comparing the first implanted side and the second implanted side. There was a significant mediolateral (x-axis) difference ($p = 0.02$) in lead accuracy between the first (mean 1.02 mm, sd 0.57

									mm) and the second (mean 0.66 mm, sd 0.50 mm) sides. However, no significant difference was found for the y- and z-axes (p = 0.10 and p = 0.89, respectively). Conclusions frame-based dbs implantation under general anesthesia with intraoperative mri verification of lead location is safe, accurate, precise, and effective compared with standard implantation performed using awake intraoperative physiology. More clinical trials are necessary to directly compare outcomes of each technique. Reported events: there was a significant stereotactic error found via an intraoperative mri for 1 patient. The lead was removed and replaced after correcting for the error during the same procedure. An error of 3.0 mm lateral to the intended target was reported. The health care provider (hcp) speculated that this error may be related to the stereotactic correction they applied after evaluating the extent and direction of error on the intraoperative scan after the first lead was implanted in one hemisphere. There was a significant stereotactic error found via an intraoperative mri for 1 patient. The lead was removed and replaced after correcting for the error during the same procedure. An error of 2.5 mm medial and 1.0 posterior to the planned target was reported. The health care provider (hcp) speculated that this error may be related to the stereotactic correction they applied after evaluating the extent and direction of error on the intraoperative scan after the first lead was implanted in one hemisphere. In an unknown amount of patients who underwent bilateral implantation, there was a significant mediolateral (x-axis) difference i n lead accuracy between the first and the second lead implants. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: age: the reported age reflects the mean age of the patients reported in the literature article. : the

									reported sex reflects that of the majority of the patients reported in the literature article (17 female; 16 male). Date of event: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Product code mhy and pma# p960009 were used as they reflect the majority of the patients who were implanted for parkinson's disease reported in the literature article. The main component of the system. Other relevant device(s) are: product id: neu_unknown_lead, serial/lot #: unknown. Matias, c. M., frizon, l. A., nagel, s. J., lobel, d. A., machado, a. G. (2018). Deep brain stimulation outcomes in patients implanted under general anesthesia with frame-based stereotaxy and intraoperative mri. Journal of neurosurgery, 1-7. Doi:10.31 71/2017.7.jns171166. If information is provided in the future, a supplemental report will be issued.
3003923584 -2018- 00008	20/01/2018	Injury	PRO MED INSTRUMENTS GMBH	27/02/2018	HBL	DORO® SKULL CLAMP	Device Operates Differently Than Expected	Laceration(s)	Customer service was contacted on (b)(6) 2018 from distributor. Distributor stated that: the head still could move, when clamping the head of the patient. Further information received on (b)(6): patient had an lesion on the scalp performed procedure was a stereotactic craniotomy. The incident happened when the surgeon was closing the skin. Manufacturer narrative: it is very unlikely that one of the detected deviations has contributed to the reported event. We suspect, that maybe the pinning technique has been not optimal as described in the instruction manual: "adjust the skull clamp to the width of the patient's head in the manner that the two skull pins in the rocker arm are equidistant from the centerline of the head and the single skull pin at the extension assembly is in line with this centerline."
3007566237 -2018- 01025	20/01/2018	Injury	MEDTRONIC NEUROMODULAT ION	09/04/2018	MHY	UNKNOWN IMPLANTABL E NEUROSTIM ULATOR	Malposition of Device	No Known Impact Or Consequence To Patient	Summary: individual motor improvement after deep brain stimulation (dbs) of the subthalamic nucleus (stn) for parkinson¿s disease (pd) varies considerably. Stereotactic targeting of the dorsolateral

									sensorimotor part of the stn is considered paramount for maximizing effectiveness, but studies employing the midcommissural point (mcp) as anatomical reference failed to show correlation between dbs location and motor improvement. The medial border of the stn as reference may provide better insight in the relationship between dbs location and clinical outcome. Motor improvement after 12 months of 65 stn dbs electrodes was categorized into nonresponding, responding and optimally responding body-sides. Stereotactic coordinates of optimal electrode contacts relative to both medial stn border and mcp served to define theoretic dbs ¿hotspots¿. Using the medial stn border as reference, significant negative correlation (pearson¿s correlation -0.52, p < 0.01) was found between the euclidean distance from the center of stimulation to this dbs hotspot and motor improvement. This hotspot was located at 2.8 mm lateral, 1.7 mm anterior and 2.5 mm superior relative to the medial stn border. Using mcp as reference, no correlation was found. The medial stn border proved superior compared with mcp as anatomical reference for correlation of dbs location and motor improvement, and enabled defining an optimal dbs location within the nucleus. We therefore propose the medial stn border as a better individual reference point than the currently used mcp on preoperative stereotactic imaging, in order to obtain optimal and thus less variable motor improvement for individual patients with pd following stn dbs. Reported events: one patient underwent repositioning of one deep brain stimulation (dbs) lead. Relevant patient medical history included diagnosis of parkinson's disease with average duration 11 years. The following device specifics were provided: lead model 3389. Manufacturer narrative: bot m, schuurman pr, odekerken vjj, verhagen r, contarino fm, de bie rma, van den munckhof p. Deep brain stimulation for parkinson's disease: defining the optimal

									location within the subthalamic nucleus. J neurol neurosurg psychiatry. 2018; 0:1¿6. Doi:10.1136/(b)(4). This value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Concomitant medical product: product id: 3389, lot# unknown, product type: lead. Information references the main component of the system. Other relevant device(s) are: product id: 3389, serial/lot #: unknown, ubd: , udi#: asku. If information is provided in the future, a supplemental report will be issued. - [bot_11_deep.pdf].
3008492462-2018-00025	18/01/2018	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	29/03/2018	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE	Failure To Adhere Or Bond	No Consequences Or Impact To Patient	It was reported by the affiliate that during the procedure no possibility of putting a needle in the holster. Manufacturer narrative: the revolve stereotactic probe is a sterile, single-patient use device that may be used with imaging guidance to excise a tissue sample for diagnosis. One (b)(4) was received in what appeared to be unused condition. Probe was reported by the customer to be unable to be attached to a holster. Cutter gear was then manually turned a total of 8 full turns before the probe could be properly attached to holster. Probe was then disassembled for further investigation. During disassembly, breast tissue was found in the cutter. Follow-up with the customer indicated that the "needle was used, only inserting it in the chest and one cut, but at once the needle discharged from the holster. Later, it was not possible to set it up". The customer holster was not returned for evaluation. Without the customer holster a root cause cannot be confirmed. Due to the discovery of the tissue within the cutter, event was reassessed for reportability against the result of the investigation. Following consultation with our medical director, due

									to the potential to cause or contribute to death or serious injury as a result of potential missed or lost tissue samples, pursuant to 21 cfr 803, this failure mode was determined to be a reportable malfunction. Thus, we are submitting this medwatch report.
2020394-2018-00140	15/01/2018	Malfunction	BARD PERIPHERAL VASCULAR, INC.	21/02/2018	FZP	GELMARK ULTRA MARKERS	Separation Failure; Detachment of Device or Device Component	No Consequences Or Impact To Patient	It was reported that post breast tissue marker placement under stereotactic guidance, the marker applicator tip was noted to have detached. There was no reported patient injury.it was reported that post breast tissue marker placement under stereotactic guidance, two marker applicators deployed part of the marker after removal from the probe. There was no reported patient injury. Manufacturer narrative: no medical records or no medical images have been made available to the manufacturer. The device has been returned to the manufacturer for evaluation. As the lot number for the device was provided, a review of the device history records is currently being performed. The investigation of the reported event is currently underway. The information provided by bard represents all of the known information at this time. Despite good faith efforts to obtain additional information, the complainant / reporter was unable or unwilling to provide any further patient, product, or procedural details to bard. Manufacturer narrative: after further review of the additional information received and the product returned details, the information indicates a failure to separate. It was reported that post breast tissue marker placement under stereotactic guidance, two marker applicators deployed part of the marker after removal from the probe, which resulted in the device failing to separate, not detachment of the device. There was no reported patient injury. After receipt of this information, this event was reassessed and determined to be not mdr reportable. However, an initial mdr has already been submitted; therefore, the purpose of this supplemental report is to

									document the change in reportability classification.
3007566237-2018-01056	13/01/2018	Malfunction	MEDTRONIC NEUROMODULATION	11/04/2018	MHY	ACTIVA	Malposition of Device	Therapeutic Effects, Unexpected; Complaint, Ill-Defined	Akram, h., dayal, v., mahlknecht, p., georgiev, d., hyam, j., foltynie, t., . . . Zrinzo, l. (2018). Connectivity derived thalamic segmentation in deep brain stimulation for tremor. Neuroimage: clinical, 18, 130-142. Doi:10.1016/j.nicl.2018.01.008 summary: the ventral intermediate nucleus (vim) of the thalamus is an established surgical target for stereotactic ablation and deep brain stimulation (dbs) in the treatment of tremor in parkinson's disease (pd) and essential tremor (et). It is centrally placed on a cerebello-thalamo cortical network connecting the primary motor cortex, to the dentate nucleus of the contralateral cerebellum through the dentato-rubro-thalamic tract (drt). The vim is not readily visible on conventional mr imaging, so identifying the surgical target traditionally involved indirect targeting that relies on atlas-defined coordinates. Unfortunately, this approach does not fully account for individual variability and requires surgery to be performed with the patient awake to allow for intraoperative targeting confirmation. The aim of this study is to identify the vim and the drt using probabilistic tractography in patients that will undergo thalamic dbs for tremor. Four male patients with tremor dominant pd and five patients (three female) with et underwent high angular resolution diffusion imaging (hardi) (128 diffusion directions, 1.5mm isotropic voxels and b value=1500) preoperatively. Patients received vim-dbs using an mr image guided and mr image verified approach with indirect targeting. Postoperatively, using parallel graphical processing unit (gpu) processing, thalamic areas with the highest diffusion connectivity to the primary motor area (m1), supplementary motor area (sma), primary sensory area (s1) and contralateral dentate nucleus were identified. Additionally, volume of tissue activation (vta) corresponding to active dbs contacts

									were modelled. Response to treatment was defined as 40% reduction in the total fahn-tolosa-martin tremor rating score (ftmtrs) with dbs-on, one year from surgery. Three out of nine patients had a suboptimal, long-term response to treatment. The segmented thalamic areas corresponded well to anatomically known counterparts in the ventrolateral (vl) and ventroposterior (vp) thalamus. The dentate-thalamic area, lay within the m1-thalamic area in a ventral and lateral location. Streamlines corresponding to the drt connected m1 to the contralateral dentate nucleus via the dentate-thalamic area, clearly crossing the midline in the mesencephalon. Good response was seen when the active contact vta was in the thalamic area with highest connectivity to the contralateral dentate nucleus. Non-responders had active contact vtas outside the dentate-thalamic area. We conclude that probabilistic tractography techniques can be used to segment the vl and vp thalamus based on cortical and cerebellar connectivity. The thalamic area, best representing the vim, is connected to the contralateral dentate cerebellar nucleus. Connectivity based segmentation of the vim can be achieved in individual patients in a clinically feasible timescale, using hardi and high performance computing with parallel gpu processing. This same technique can map out the drt tract with clear mesencephalic crossing. Reported events: an unknown amount of patients had a poor response or unacceptable side-effects during implant. In this case, the lead was removed and the process was repeated following appropriate targeting adjustments. Manufacturer narrative: the reported age reflects the average age of the patients reported in the literature article. The reported sex reflects that of the majority of the patients reported in the literature article. Please note that this date is based off of the date of acceptance of the article as the event dates were not provided in the published literature. The device was

									used for an off label indication; if information is provided in the future, a supplemental report will be issued.
1222780-2018-00026	11/01/2018	Injury	HOLOGIC, INC	14/02/2018	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Adverse Event Without Identified Device or Use Problem	Hemorrhage/Bleeding	It was reported a physician performed an eviva breast biopsy on (b)(6) 2018 and the patient started to bleed "profusely". The physician aborted the procedure and removed the needle to stop the bleeding. It is unknown if further medical intervention was required. Manufacturer narrative: the device is not being returned therefore, a failure analysis of the complaint device cannot be completed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications. Currently unable to establish a relationship or impact to the reported observation. Internal reference complaint #(b)(4).
3007566237-2018-00899	05/01/2018	Injury	MEDTRONIC NEUROMODULATION	27/03/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATION ELECTRODE	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage	Summary: background: intracerebral hemorrhage (ich) is the most feared complication in deep brain stimulation (dbs) surgery. The aim of the study was to evaluate patient safety and outcome using laser doppler flowmetry (ldf) as guidance tool during dbs implantations. Methods: an ldf probe adapted for the stereotactic system was used as guide for creation of the trajectory. The microcirculation along 83 preplanned trajectories was measured with the guide during dbs surgery for movement disorders. The microvascular blood flow levels were investigated for all measurement positions. Medical record and postoperative radiology were retrospectively reviewed. Results: of 2,963 measurement positions, 234 (7.9%) showed at least a doubled blood flow compared to the surrounding tissue. Of these 2.2% had a more than 5 times higher blood flow in front of the probe tip. Along 1 trajectory, a small ich was detected during surgery. Increased blood flow was more common close to sulci and verticals. Conclusion: real-time ldf measurement of the microcirculation using a forward-looking probe during dbs surgery can detect blood

									flow peaks and further minimize the risk of developing ich. No separate guide tube is necessary as the probe also creates the trajectory for the dbs lead. Reported event: a patient undergoing implantation of a deep brain stimulation (dbs) lead had the stereotactic frame detach during the surgery, so the surgery was ¿inhibited.¿ during the surgery their laser doppler flowmetry (ldf) system showed an atypical measurement that was later confirmed to be bleeding on a postoperative ct scan, which discovered a small asymptomatic intracranial hemorrhage along the trajectory of the lead. The patient ultimately returned 3 months later for a new dbs surgery. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: age/date of birth. This value is the average age of the patients reported in the article as specific patients could not be identified. Sex. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Zsigmond, p., hemm-ode, s., wardell, k. Optical measurements during deep brain stimulation lead implantation: safety aspects. Stereotact funct neurosurg. 2018; 95(6):392-399. Doi: 10.1159/000484944. If information is provided in the future, a supplemental report will be issued.
3005985723-2018-00053	05/01/2018	Malfunction	MAKO SURGICAL CORP.	03/02/2018	OLO	3.0 RIO® ROBOTIC ARM - MICS	Output Problem; Insufficient Information	No Known Impact Or Consequence To Patient	When impacting the cup our distance remaining number started at 22mm and finished at 14mm proud. End effector was fully seated, our checkpoints passed, and there was not tissue behind the cup. Xray was used by the surgeon to confirm the cup was fully seated. Tha case with a slight delay to take x-rays to ensure the surgeon was happy with the cup placement.when impacting the cup our distance remaining

									number started at 22mm and finished at 14mm proud. End effector was fully seated, our checkpoints passed, and there was not tissue behind the cup. Xray was used by the surgeon to confirm the cup was fully seated. Tha case with a slight delay to take x-rays to ensure the surgeon was happy with the cup placement. Manufacturer narrative: reported event: an event regarding the inaccurate impaction values involving 3.0 rio robotic arm - mics, catalog: 209999 was reported. Method & results: device history review: a review of the dhr associated with (b)(4) found quality inspection procedures successfully passed. Complaint history: based on the device identification (pn 209999) the complaint databases were reviewed from 2011 to present for similar reported events regarding proud impaction values. There were 2 other reported events ((b)(4) and (b)(4)). Conclusion: the reported proud values and impactor option selected were observed in system vplog. A checkpoint error of 2.1mm was seen in the cup reaming page, which could result from a loose base array. A further loosening of the base array during impaction could be a potential cause for the proud values seen on screen. No system malfunction was detected. Manufacturer narrative: as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available.
3005985723-2018-00052	04/01/2018	Malfunction	MAKO SURGICAL CORP.	03/02/2018	OLO	PELVIC ARRAY ASSY	Insufficient Information	No Known Impact Or Consequence To Patient	When impacting the cup the vizadisc popped off the same peg. It was fully seated. There seems to be an issue with the peg that the vizadisc attaches to. When dr. (b)(6) was impacting the cup, the vizadisc popped off the peg. Tha case. The vizadisc was discarded. Manufacturer narrative: as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available.

3005985723-2018-00051	03/01/2018	Malfunction	MAKO SURGICAL CORP.	02/02/2018	OLO	HANDPIECE MICS	Fracture; Insufficient Information	No Known Impact Or Consequence To Patient	Mako mics handpiece broke towards end of case. Surgeon able to complete surgery without impact on patient or time. Manufacturer narrative: as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available.
MW5074476	02/01/2018	NA	DEVICOR MEDICAL PRODUCTS, INC.	09/01/2018	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE	Device Inoperable; Device Operates Differently Than Expected	No Information	Mammotome stereotactic probe would not allow us to perform the biopsy once we had found lesion and targeted. This was discovered when it was tested prior to being used on the patient.
3005985723-2018-00050	02/01/2018	Malfunction	MAKO SURGICAL CORP.	02/02/2018	OLO	3.0 RIO® ROBOTIC ARM - MICS	Insufficient Information	No Known Impact Or Consequence To Patient	Tka case where posterior medial chamfer cuts were 2mm deep to plan. Manufacturer narrative: as part of normal complaint follow-up, an evaluation of the event has been initiated by mako surgical. A supplemental report will be submitted when additional information becomes available.
1717344-2020-00301	01/01/2018	Death	COVIDIEN MFG DC BOULDER	17/03/2020	GEI	UNKNOWN RF ELECTRODE	Adverse Event Without Identified Device or Use Problem	Death	According to the literature study performed, 891 consecutive patients were treated by stereotactic rf ablation (srfa). A total of 177 of these patients with hepatic dome tumors were selected by using a nearest neighbor propensity score for this retrospective study. A median of 2 tumors (1¿11) were treated per ablation session (in total 204 sessions), including 111 patients (62.7%) with additional tumors outside of the hepatic dome. The total major complication rate was 12.3% (25 of 204). Out of 177 patients, 1 death occurred following ablation of colorectal liver metastasis due to major bleeding. ¿srfa was successfully completed according to plan in all 238 tumors (technical success rate 100%).¿ manufacturer narrative: (b)(4). (transient pulmonary failure, bilateral effusin, pleural effusion, thoracenteses,pneumothoraces) title feasibility, safety, and long-term efficacy of stereotatic radiofrequency ablation for tumors adjacent to the diaphragm in the hepatic dome: a case-control study source european radiology, volume 30, 2020 (950-

									960) date of publication online: 5 september 2019. If information is provided in the future, a supplemental report will be issued.
1717344-2020-00302	01/01/2018	Injury	COVIDIEN MFG DC BOULDER	17/03/2020	GEI	UNKNOWN RF ELECTRODE	Adverse Event Without Identified Device or Use Problem	No Code Available	According to the literature study performed, 891 consecutive patients were treated by stereotactic rf ablation (srfa). A total of 177 of these patients with hepatic dome tumors were selected by using a nearest neighbor propensity score for this retrospective study. A median of 2 tumors (1¿11) were treated per ablation session (in total 204 sessions), including 111 patients (62.7%) with additional tumors outside of the hepatic dome. The total major complication rate was 12.3% (25 of 204). Out of 177 patients, 2 cases had thermal injuries of the diaphragm lead to a local defect that had to be surgically repaired, 1 patient had developed liver failure after treatment of 2 hccs (5cm and 3cm) requiring salvage liver transplantation, 1 case had thermal injury of the bowel that had to be repaired surgically. This complication was related to simultaneous thermal ablation of an additional tumor in segment vi in the same session. 1 patient had transient pulmonary failure with bilateral effusions, 5 patients had pleural effusions requiring thoracenteses. A total of 14/25 (56%) major complications were successfully treated by the interventional radiologist in the same anesthesia session by placing a thoracostomy tube in 5 patients with pneumothoraces and by transarterial embolization in nine patients with hepatic hemorrhages, respectively. ¿srfa was successfully completed according to plan in all 238 tumors (technical success rate 100%).¿ manufacturer narrative: (b)(4). Title feasibility, safety, and long-term efficacy of stereostatic radiofrequency ablation for tumors adjacent to the diaphragm in the hepatic dome: a case-control study source european radiology, volume 30, 2020 (950-960) date of publication online: 5 september 2019. If

									information is provided in the future, a supplemental report will be issued.
3007566237-2018-00994	01/01/2018	Injury	MEDTRONIC NEUROMODULATION	06/04/2018	MRU	ACTIVA	Migration or Expulsion of Device	Muscle Spasm(s); Therapeutic Response, Decreased	Summary: the frequency of deep brain stimulation (dbs) complications is low; however, lead migration is a common way dbs therapy can become ineffective. We present a case of a (b)(6) male with generalized dystonia who underwent bilateral gpi dbs lead placement. The efficacy of the dbs system was diminished over two years and one of the leads was noted to be displaced on skull x-rays and confirmed with a head ct. During surgery to replace it, bone growth within the burr hole site was noted to have occurred and determined to be the cause for the lead migration. This is the first known case reporting osteogenesis at the burr hole site as a cause of lead migration. This complication should be kept in mind when performing dbs in children to refine a surgical technique that could prevent osteogenesis at the burr hole. Reported event: a (b)(6) male experienced increasing myoclonic activity, especially in the left side of the body, twenty-two months after implant surgery. It was thought that the dbs effectiveness had decreased. Ct scans and skull x-rays were obtained, and showed that the right dbs lead had migrated superiorly about 1 cm compared to prior (post-operative) images, out of the gpi location it had been in previously, with a new intracranial curvature close to the burr hole site. All the extracranial extensions and contacts looked unchanged compared to the prior skull x-ray images. Explorative surgery to revise the dbs lead was performed. Intraoperatively it was noticed that about 90% of the burr hole had been filled in and covered by newly formed bone, growing from deep to superficial, which explained the lead migration in the direction of the surface. The faster rate of bone growth in pediatric patients was concluded to have caused the upward migration of the lead. It was noted the inferior bony rim was removed as well as all of the exposed dura

									ma ter within the burr hole area at the time of initial lead placement. The authors noted they did not disregard the concept that the dura mater edges could have been involved in the new bone formation. The bone was removed with kerrison rongeurs, the old lead removed and a new lead was inserted stereotactically through a stereotactic head frame platform into the right gpi. Surgery was performed under general anesthesia. Upon follow-up, the patient's symptoms improved with an overall decrease in dystonic activity. Relevant patient medical history included secondary dystonia due to cerebral palsy, generalized severely disabling dystonic, opisthotonic like myoclonic jerks and history of prematurity, being born at (b)(6) gestation. The following device specifics were provided: lead model 3389, ins model 37601. Manufacturer narrative: date of event. Please note that this date is based off of the publication year provided as the event dates were not provided in the published literature, nor was a full publication date available in the article. It was not possible to match this event with any previously reported event. Concomitant medical products: product id: 3389, lot# unknown, product type: lead. The main component of the system. Other relevant device(s) are: product id: 3389, serial/lot #: unknown, udi#: asku. Citation: brimley c, kershenovich a. Deep brain stimulation lead migration in a child secondary to osteogenesis at the burr hole site. Interdisciplinary neurosurgery. 2018; 12:27-29. Doi: 10.1016/j.inat.2017.09.009. If information is provided in the future, a supplemental report will be issued.
1723170-2018-01653	31/12/2017	Injury	MEDTRONIC NAVIGATION, INC. (LOUISVILLE)	16/04/2018	GEX	SYSTEM 002-1100 15W THERMAL THERAPY	Adverse Event Without Identified Device or Use Problem	Paralysis; Iatrogenic Source; No Code Available	The attached journal article was forwarded by a medtronic representative. Use of the thermal therapy system was reported. Spinal laser interstitial thermal therapy (litt) appears to be a promising novel modality for treatment of epidural metastatic spine disease in patients who are poor candidates for larger-scale oncologic spinal surgery and can act synergetically with spinal

									stereotactic radiosurgery to maximize local control and palliate pain. Heat monitoring is based on mri gradient-echo acquisition, because of the temperature sensitivity of the proton resonance frequency. This difference in phases estimates the temperature of the tissue on a pixel-by-pixel basis. The authors use a 38-m "repetion" time (tr) and 20 flip angle. The acquisition matrix is 256 128 over fields of view of 24 to 32 cm, with single 3-mm slices acquired each 5 to 6 seconds. The interface between the dura and the tumor is selected to a temperature limit of 48c to 50c (fig. 5). Any movement may deteriorate the thermal map. Therefore, the authors perform the laser ablation under ventilatory arrest and close monitoring by the anesthesiologist. The ablation is performed in cycles. The authors limit each cycle of laser activation to no more than 120 seconds with a goal of achieving a total of 4 minutes of ablation. In between activations, the patient¿s ventilation is resumed and the oxygen saturation is returned to 100%. Upon completion of the procedure, t1-weighted images are obtained precontrast and postcontrast under respiratory arrest. Both images are fused, and the nonenhancing component is subtracted from the image, emphasizing the enhancing tissue. The acute coagulative necrosis is well demonstrated by this technique, and an immediate assessment of the effectiveness of the procedure can be inferred. Nineteen patients underwent this treatment: 14 men and 5 women with a median age of 58 years. One patient had transient l1 monoparesis after the procedure, which resolved after 8 weeks. One patient required salvage surgical intervention because of delayed progressive neurologic deterioration. Two patients had in-field epidural progression after ssrs at 16 and 33 weeks after the procedure and were treated with another slitt procedure. Conclusion: as percutaneous navigation, imaging, and litt technology improve,

									broader applicability of this minimally invasive technique in spinal oncology is foreseen. Manufacturer narrative: correction: medtronic received information that, from the author of the literature, there was no allegation of deficiency against the medtronic product in use and that the ablation system functioned as designed. Manufacturer narrative: patient identifier not available from the article. Patient age and patient sex not made available the journal article or by the authors. The article reports that the mean patient age was 58 and the consisted of male patients in the study. Therefore 58 year old and male were used. Patient weight not available from the article. Event date is approximated. Date provided is when the journal article was published which was in 2017. Citation: jonathan g. Thomas, md, wajd n. Al-holou, md, dhiego chaves de almeida bastos et al. A novel use of the intraoperative mri for metastatic spine tumors laser interstitial thermal therapy for percutaneous treatment of epidural metastatic spine disease . (2017) neurosurg clin n am 28 (2017) 513¿524 http://dx.doi.org/10.1016/j.nec.2017.05.006. The exact system information could not be determined as it was not provided. However, the system listed on this form was at the address listed in the article during the time some of the surgeries were completed. Device udi not provided as actual product used for this study is unknown. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. Multiple attempts have been made to obtain additional information. No further information provided in the journal article or from the authors. The author could not provide any additional information or insight as he was not at the site when the surgeries were performed. No request for service have been received from the customer regarding these events. No parts have been replaced or returned to the manufacturer for

									evaluation. Medtronic navigation is filing this mdr to ensure visibility to a patient event as a result of a procedure that utilized medtronic navigation's thermal therapy system. There is no allegation to suggest that medtronic navigation's device caused or contributed to the reported event. Device not returned by customer.
3008492462-2018-00008	22/12/2017	Injury	DEVICOR MEDICAL PRODUCTS, INC.	08/02/2018	NEU	HYDROMARK BREAST BIOPSY SITE MARKER	Adverse Event Without Identified Device or Use Problem	Hypersensitivity/Allergic reaction; Reaction; Patient Problem/Medical Problem	The sales rep reported that patient had an allergic reaction to hydromark. They are running allergy tests on patient to determine if in fact it is the hydromark. Manufacturer narrative: the hydromark breast biopsy site marker is used to mark tissue during a percutaneous breast biopsy procedure, be visible under ultrasound for at least 6 weeks, and be permanently visible by x-ray and mri. One hydromark marker, product code 4010-02-15-t3, was placed at the time of the initial biopsy. The procedure was completed with no known patient hypersensitivity or immune response at that time. Patient then presented to the er later in the evening with hives, shortness of breath and swelling of the tongue. Patient was treated with steroids and benadryl and released. Patient returned to the er two additional times all within 24 hours. An allergist was consulted and it was recommend that the marker be removed. Patient was then scheduled for a stereotactic procedure to remove the marker. Marker was removed from patient breast by dr. Jean warner within 48 hours of initial placement. Patient's symptoms improved once the marker was removed. It was recommended that the patient undergo allergy testing. However, due to complications with the iv during the er visits (phlebitis) this cannot be conducted for another 6 weeks. Patient's biopsy results came back benign. No testing on the specific device has been conducted. The applicator portion was disposed of at the conclusion of the biopsy procedure per internal medical facility procedures. However, sensitivity, cytoxicity and other reaction testing was conducted as part of

									the initial qualification of this device. No known reactions similar to those reported in this event were reported during this testing. Although it could not be concluded that our device caused or contributed to this event, due to the reported adverse event as well as medical consultation on similar events, this has been determined to be reportable pursuant to 21 cfr 803. As such, we are submitting this medwatch report.
2020394-2018-00164	16/12/2017	Malfunction	BARD PERIPHERAL VASCULAR, INC.	27/02/2018	NEU	SENOMARK BREAST TISSUE MARKER	Separation Failure; Detachment of Device or Device Component	No Consequences Or Impact To Patient	It was reported that during breast marker placement under stereotactic guidance, the marker allegedly remained in the marker applicator. There was no reported patient injury. Manufacturer narrative: manufacturing review: the device history records have been reviewed and this lot met all release criteria. There was nothing found to indicate there was a manufacturing related cause for this event. Investigation summary: one partial senomark marker applicator was returned for evaluation. The marker applicator was returned with the distal end of the applicator detached. One pushpad was returned within the marker applicator and the wireform was not returned. Therefore, the investigation is confirmed for the identified detachment and inconclusive for the reported failure to separate issue. The definitive root cause for the reported failure to separate and identified tip detachment could not be determined based upon the available information. It is unknown whether patient and/or procedural issues contributed to the event. Labeling review: the current senomark breast tissue marker instructions for use (ifu) state: general information and device description: -the marker contains resorbable polyglycolic acid (pga) pads, one polyethylene glycol (peg) push pad, and one titanium or stainless steel wireform. The pads are visible via ultrasound for approximately 3 weeks and are essentially resorbed in approximately 12 weeks. The syringe-like applicator fits within the encor probe to access the biopsy cavity. The pads are deployed from the

									applicator through the biopsy device into the biopsy cavity. Contraindications: -there are no known contraindications. Warnings: -this device has been designed for single use only. Reuse of this device bears the risk of cross-patient contamination, as medical devices with long and small lumina, joints, and/or crevices between components are difficult or impossible to clean. -do not resterilize. -avoid the use of excessive force during removal of the applicator to preventBreakage of the applicator tip. Precautions: -the device should only be used by physicians trained in percutaneous biopsy procedures. -maintain correct alignment of the yellow indicator key with the red arrow of the biopsy probe when dispending pads. Ensure that all pads are dispensed. Potential complications: potential complications that may be associated with the use of senomark biopsy site marker are similar to those associated with the use of other biopsy marking devices. The information provided by bard represents all of the known information at this time. Despite good faith efforts to obtain additional information, the complainant / reporter was unable or unwilling to provide any further patient, product, or procedural details to bard.
3008492462-2018-00004	14/12/2017	Malfunction	DEVICOR MEDICAL PRODUCTS, INC.	16/01/2018	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE	Device Contamination with Chemical or Other Material	No Consequences Or Impact To Patient	The sales rep reported that a piece of plastic went into 1st chamber. Procedure was completed with the device. Manufacturer narrative: the revolve stereotactic probe is a sterile, single-patient use device that may be used with imaging guidance to excise a tissue sample for diagnosis. The device was discarded by the customer which prevents a full investigation and analysis of the root cause at this time. Although no serious injuries occurred, upon consultation with devicor's medical department, this failure mode has been determined to be evaluated as a reportable malfunction. Thus, pursuant to 21 cfr 803, we are submitting this medwatch report.

3007566237-2018-00776	13/12/2017	Injury	MEDTRONIC NEUROMODULATION	14/03/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Bacterial Infection; Erosion; Staphylococcus Aureus; Skin Erosion; Post Traumatic Wound Infection; Fluid Discharge	Summary: scalp erosion in patients with deep brain stimulation (dbs) hardware is an uncommon complication that lacks a clearly defined management strategy. Previous studies have described various therapies including conservative treatment with antibiotics and surgical debridement with or without hardware removal. Objectives: the aim of this study was to review the efficacy of a hardware-sparing management strategy for the treatment of scalp erosion. Methods: five patients with previous dbs implantation presented with scalp erosion and visible hardware exposure at the calvarial burr hole site, and underwent tension-free, vascularized, rotational scalp flap, with preservation of the leads under the pericranium. Two of the procedures were performed after an unsuccessful attempt at primary closure and 3 as a primary procedure. Each patient was followed clinically for at least 14 months postoperatively to evaluate for wound healing and adverse effects. Results: the median duration from initial dbs hardware implantation to erosion and revision surgery was 12 months (range 1.5¿62 months). Three patients were documented to have positive intraoperative cultures in spite of the absence of purulence. At the last follow- up, all patients were noted to have complete wound healing and no evidence of infection or erosion. Conclusions: dbs scalp erosion can be managed by rotational scalp flap without hardware removal, even in cases where infection is identified. Reported events: patient 1: a (b)(6) woman with bilateral subthalamic nucleus (stn) deep brain stimulation (dbs) for parkinson's disease (pd) experienced an erosion at the right frontal burr hole location 1.5 months after implant. They also suggested this patient demonstrated persistent wound drainage almost immediately after surgery. They were initially treated with scalp debridement and primary closure of the wound because the scalp erosion was less than 1 cm in size but developed recurrent

									erosion within 2 months and thus required an additional revision surgery in which they were treated with a rotational scalp flap. The patient¿s intraoperative wound swabs were negative for infection. The authors stated that at =14 months later at the last follow-up the patient was observed to have a well-healed incision with healthy flaps, functional dbs hardware, and no evidence of infection, local pain, or woundBreakdown. Patient 2: a (b)(6) man with bilateral stn-dbs for pd experienced an erosion at the left frontal burr hole location 12 months after implant. They underwent a revision surgery in which the issue was treated with a rotational scalp flap. The patient¿s intraoperative wound swabs were negative for infection. After 20 months of follow-up the patient was observed to have a well-healed incision with healthy flaps, functional dbs hardware, and no evidence of infection, local pain, or woundBreakdown. Patient 3: a (b)(6) man with bilateral stn-dbs for pd experienced an erosion at the right frontal burr hole location 4 months after implant. After the initial surgery they was purportedly prone to persistently scratch their incision and they also sustained a head injury, ¿possibly leading to inoculation.¿ they were initially treated with scalp undermining/advancement, debridement, and primary closure of the wound because the scalp erosion was less than 1 cm in size. The patient¿s intraoperative wound culture grew (b)(6) and they were placed on vancomycin. They developed recurrent erosion within 2 months and thus required an additional revision surgery in which they were treated with a rotational scalp flap and a left-thigh-split-thickness skin graft, after which they were placed on vancomycin and piperacillin/tazobactam. The authors stated that at the last follow-up 18 months later the patient was observed to have a well-healed incision with healthy flaps, functional dbs hardware, and no evidence of infection, local pain, or

									woundBreakdown. Patient 4: a (b)(6) woman with bilateral globus pallidus internus (gpi)-dbs for pd experienced an erosion at the right frontal burr hole location 34 months after implant. They underwent a revision surgery in which the issue was treated with a rotational scalp flap and a left-thigh-split-thickness skin graft. The patient¿s intraoperative wound culture grew escherichia coli and they were placed on oral ciprofloxacin. After 15 months of follow-up the patient was observed to have a well-healed incision with healthy flaps, functional dbs hardware, and no evidence of infection, local pain, or woundBreakdown. Patient 5: a (b)(6) woman with bilateral ventral intermediate nucleus of the thalamus (vim)-dbs for essential tremor (et) experienced an erosion at the right frontal burr hole location 62 months after implant. They underwent a revision surgery in which the issue was treated with a rotational scalp flap and a left-thigh-split-thickness skin graft. The patient¿s intraoperative wound culture grew both proteus mirabilis and streptococcus viridans so they were placed on oral sulfamethoxazole/trimethoprim. Less than a month later they developed a 1.4 cm scalp ulceration along the rotational incision that required an additional excisional debridement and primary closure. There was no reported exposure of hardware as a result and the wound healed well without further treatment. After 14 months of follow-up the patient was observed to have a well-healed incision with healthy flaps, functional dbs hardware, and no evidence of infection, local pain, or woundBreakdown. Patients were reportedly implanted with either 3387 or 3389 leads, however it was not possible to ascertain any further specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: age/date of birth. This value is the median age of the patients reported in the article as

									specific patients could not be identified. Sex. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. The main component of the system. Other relevant device(s) are: product id: neu_unknown_lead, serial/lot #: unknown; staudt, md., pourtaheri, n., lakin, ge., soltanian, ht., miller, jp. Surgical management of deep brain stimulator scalp erosion without hardware removal. Stereotact funct neurosurg. 2017; 95(6):385-391. Doi: 10.1159/000484323. If information is provided in the future, a supplemental report will be issued.
3007566237-2018-00979	06/12/2017	Malfunction	MEDTRONIC NEUROMODULATION	04/04/2018	MFR	ACTIVA PRIMARY CELL WITH SENSING	Migration or Expulsion of Device	Therapeutic Effects, Unexpected; No Code Available	Summary: background: deep brain stimulation (dbs) of the subcallosal cingulate (scc) is an emerging experimental therapy for treatment-resistant depression. New developments in scc dbs surgical targeting are focused on identifying specific axonal pathways for stimulation that are estimated from preoperatively collected diffusion-weighted imaging (dwi) data. However, brain shift induced by opening burr holes in the skull may alter the position of the target pathways. Objectives: quantify the effect of electrode location deviations on tractographic representations for stimulating the target pathways using longitudinal clinical imaging datasets. Methods: preoperative mri and dwi data (planned) were coregistered with postoperative mri (1 day, near-term) and ct (3 weeks, long-term) data. Brain shift was measured with anatomical control points. Electrode models corresponding to the planned, near-term, and long-term locations were defined in each hemisphere of 15 patients. Tractography analyses were performed using estimated stimulation volumes as seeds centered on the different electrode positions. Results: mean brain shift of 2.2 mm was observed in the near-

									term for the frontal pole, which resolved in the long-term. However, electrode displacements from the planned stereotactic target location were observed in the anterior-superior direction in both the near-term (mean left electrode shift: 0.43 mm, mean right electrode shift: 0.99 mm) and long-term (mean left electrode shift: 1.02 mm, mean right electrode shift: 1.47 mm). Dbs electrodes implanted in the right hemisphere (second-side operated) were more displaced from the plan than those in the left hemisphere. These displacements resulted in 3.6% decrease in pathway activation between the electrode and the ventral striatum, but 2.7% increase in the frontal pole connection, compared to the plan. Remitters from six-month chronic stimulation had less variance in pathway activation patterns than the n on-remitters. Conclusions: brain shift is an important concern for scc dbs surgical targeting and can impact connectomic analyses. Reported events: the authors reported that on average patients with deep brain stimulation (dbs) of the subcallosal cingulate (scc) displayed significant brain shift in the frontal pole, which was accompanied by pneumocephalus based on mr images. The brain shift was reportedly posterior and inferior, coinciding with the expected effects of gravity and in the range of 0-5 mm with an average of 2.2 ± 1.56 mm. The total mean pneumocephalus volume was 1770 ± 1185 mm3. The left and right volumes were 528 ± 679 mm3 and 1239 ± 1101 mm3, respectively. Notably, the right side was always the second to be implanted. Comparing the 1-day postoperative and 3-weeks postoperative electrode locations compared to preoperative planned electrode location a significant displacement in the anterior direction was observed: in the left hemisphere on the long-term images (mean shift = 1.02 mm) relative to both the planned and near-term images (mean shift = 0.43 mm). There was also significant

									displacement of the electrode in the right in the anterior and superior directions was noted in the right hemisphere in the long-term images (mean shift = 1.47 mm) relative to the right planned and near-term location (mean shift = 0.99 mm). Using probabilistic tractography the authors estimated that these electrode ¿displacements¿ resulted in a 3.6% decrease in pathway activation between the electrode and ventral striatum and a 2.7% increase in the frontal pole connection compared to plan. They noted that despite this the overall pathway activation pattern the overall pathway activation pattern maintained the intended scc dbs ¿tractography blueprint¿ at each of the available time points. The brain shift reportedly resolved in the long term. 6 patients in 'cohort 2' were reportedly implanted with 37604 activa pc+s neurostimulators and 3387 model leads, however it was not possible to ascertain any additional specific device information from the article (i.e. Serial/lot numbers) or to match the reported event with any previously reported event. Manufacturer narrative: age/date of birth. This value is the average age of the patients reported in the article as specific patients could not be identified. Sex. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. The main component of the system. Other relevant device(s) are: product id: 3387, serial/lot #: unknown. Full citation:choi, ks., noecker, am., riva-posse, p., rajendra, jk., gross, re., mayberg, hs., mcintyre,cc. Impact of brain shift on subcallosal cingulate deep brain stimulation. Brain stimul. 2018; 11(2):445-453. Doi: 10.1016/j.brs.2017.12.001. (b)(4) used for report of "total mean pneumocephalus volume was 1770 ± 1185 mm3; brain shift".

									If information is provided in the future, a supplemental report will be issued.
1723170-2018-02074	04/12/2017	Injury	MEDTRONIC NAVIGATION, INC. (LOUISVILLE)	15/05/2018	GEX	LASER 9735552 15W 980NM - VISUALASE	Adverse Event Without Identified Device or Use Problem	Headache; Memory Loss/Impairment; Neurological Deficit/Dysfunction; Visual Disturbances; Dysphasia; Ambulation Difficulties	The journal article was forwarded by medtronic representative. Article indicated the use of laser abrasion system. The study was performed between january 2012 and october 2015. A total of 36 patients (with 50 lesions) were included in the study. There were 16 male and 20 female patients in total. The median age of the patients was 51 years. A total of 14 lesions demonstrated an increase in lesion volume (based on t1 post contrast images) that was sustained after litt. One of these failed to respond to a first litt treatment and was treated a second time with litt. After failing the second treatment, the patient underwent surgical resection. Three other lesions were treated with resection after demonstrating sustained increase in tumor volume after litt. Histological examination revealed that two of the resected tumors had active tumor and two were consistent with radiation necrosis. For the remaining patients, two were treated with further radiation, four either died from their extracranial disease or were transferred to hospice, one patient was lost to follow-up, and one patient, with two lesions, was treated with chemotherapy. Sixteen patients (44%) experienced post-operative neurological complications (with some experiencing more than one). Nine patients had motor disturbances, eight patients suffered from an unsteady gait, five patients had visual disturbances, two patients had sensory disturbances, two patients developed aphasia, one patient had difficulty with memory, and one patient developed headaches. Eight patients (50%) were managed expectantly, four patients (25%) were managed with either physical, speech, or occupational therapy, one patient (6.25%) was managed with pain medications and steroids, one patient (6.25%) managed with continued steroids, one patient (6.25%) had an adjustment to their seizure medications, and one patient¿s

									(6.25%) clinical picture was complicated by new metastasis in a different location that was treated with radiosurgery. A total of 9 patients (56.3%) eventually had improvement of their post-operative complications. Four patients (25%) had no change in their post-operative complications at their 1 and 3 month follow-ups. Two patients (12.5%) developed progressive disease, which made it difficult to assess their neurological status. One patient (6.25%) had progressive worsening of post-operative complications at 1 and 3 month follow-up. We identified the anatomic location of the lesion with respect to patients experiencing complications. The benefit of using litt is that it is a modality that can treat either necrosis or progressive tumor. Litt is effective for this patient population with a majority of patients experiencing a decrease in the size of the lesion and perilesional edema. The research results confirm the findings reported in other studies that describe an immediate increase in edema and lesion size after litt treatment, followed by a gradual decrease and improvement in symptoms. This increase in size is temporary, with a reduction in size after 6 months post-treatment. Possible causes for this initial increase in lesion size include inflammatory response and tissue necrosis caused by the ablation. The increase in lesion size and edema post-operatively helps explain the relatively high rate of complications that were seen post-operatively. However, these complications were not severe enough to prevent the majority of patients from being discharged within 24 h. Litt is an effective option for patients with metastatic brain tumors that have progressed despite prior treatment with stereotactic radiosurgery. Smaller tumor size may predict better response to litt.the attached journal article was forwarded by medtronic representative. Article indicated the use of laser ablation system. The study was performed between january 2012 and

									october 2015. A total of 36 patients (with 50 lesions) were included in the study. There were 16 male and 20 female patients in total. The median age of the patients was 51 years. A total of 14 lesions demonstrated an increase in lesion volume (based on t1 post contrast images) that was sustained after litt. One of these failed to respond to a first litt treatment and was treated a second time with litt. After failing the second treatment, the patient underwent surgical resection. Three other lesions were treated with resection after demonstrating sustained increase in tumor volume after litt. Histological examination revealed that two of the resected tumors had active tumor and two were consistent with radiation necrosis. For the remaining patients, two were treated with further radiation, four either died from their extracranial disease or were transferred to hospice, one patient was lost to follow-up, and one patient, with two lesions, was treated with chemotherapy. Sixteen patients (44%) experienced post-operative neurological complications (with some experiencing more than one). Nine patients had motor disturbances, eight patients suffered from an unsteady gait, five patients had visual disturbances, two patients had sensory disturbances, two patients developed aphasia, one patient had difficulty with memory, and one patient developed headaches. Eight patients (50%) were managed expectantly, four patients (25%) were managed with either physical, speech, or occupational therapy, one patient (6.25%) was managed with pain medications and steroids, one patient (6.25%) managed with continued steroids, one patient (6.25%) had an adjustment to their seizure medications, and one patient¿s (6.25%) clinical picture was complicated by new metastasis in a different location that was treated with radiosurgery. A total of 9 patients (56.3%) eventually had improvement of their post-operative complications. Four patients (25%) had no

									change in their post-operative complications at their 1 and 3 month follow-ups. Two patients (12.5%) developed progressive disease, which made it difficult to assess their neurological status. One patient (6.25%) had progressive worsening of post-operative complications at 1 and 3 month follow-up. We identified the anatomic location of the lesion with respect to patients experiencing complications. The benefit of using litt is that it is a modality that can treat either necrosis or progressive tumor. Litt is effective for this patient population with a majority of patients experiencing a decrease in the size of the lesion and perilesional edema. The research results confirm the findings reported in other studies that describe an immediate increase in edema and lesion size after litt treatment, followed by a gradual decrease and improvement in symptoms. This increase in size is temporary, with a reduction in size after 6 months post-treatment. Possible causes for this initial increase in lesion size include inflammatory response and tissue necrosis caused by the ablation. The increase in lesion size and edema post-operatively helps explain the relatively high rate of complications that were seen post-operatively. However, these complications were not severe enough to prevent the majority of patients from being discharged within 24 h. Litt is an effective option for patients with metastatic brain tumors that have progressed despite prior treatment with stereotactic radiosurgery. Smaller tumor size may predict better response to litt. Manufacturer narrative: additional fdps have been applied. Manufacturer narrative: correction: system type corrected to laser ablation system. Manufacturer narrative: the article reports that the mean patient age was 51 and the consisted of female patients in the study. Therefore (b)(6) year old and female were used. Event date is approximated. Date provided is when the journal article was published. Citation: vivek

									b. Beechar, sujit s. Prabhu, dhiego bastos, jeffrey s. Weinberg, r. Jason stafford, david fuentes, kenneth r. Hess and ganesh rao. Volumetric response of progressing post-srs lesions treated with laser interstitial thermal therapy (2017). Journal of neuro-oncology (2018) 137:57¿65. Https://doi.org/10.1007/s11060-017-2694-3. The exact system information could not be determined as it was not provided. However, the system listed on this form was at the address listed in the article during the time some of the surgeries were completed. Device udi not provided as actual product used for this study is unknown. Multiple attempts have been made to obtain additional information. No further information provided in the journal article or from the authors. The author could not provide any additional information or insight as he was not at the site when the surgeries were performed. No request for service have been received from the customer regarding these events. No parts have been replaced or returned to the manufacturer for evaluation. Medtronic navigation is filing this mdr to ensure visibility to a patient event as a result of a procedure that utilized medtronic navigation's laser abrasion system. There is no allegation to suggest that medtronic navigation's device caused or contributed to the reported event. Device not returned by customer.
1723170-2019-01238	01/12/2017	Injury	MEDTRONIC NAVIGATION, INC	20/03/2019	GEX	VISUALASE GUIDED ABLATION SYSTEM	Insufficient Heating	Tissue Damage; Therapeutic Response, Decreased	Medtronic received information that, following a laser induced thermal therapy (litt) procedure in regards to an epileptic foci, a second procedure was required following insufficient treatment of the right precuneus, posteriorand restrospenial cingulated cortex after a stereotactic laser ablation (slah) procedure. It was noted that the patient had a history of multiple sclerosis and a right mesial temporal love sclerosis prior to the initial procedure. No additional information was provided.medtronic received information that the original treatment was insufficient

									to control the seizures. It was reported that the ablation system operated as designed and there was no allegation of deficiency against the system. It was noted the patient continued to have seizures and that they underwent intracranial monitoring followed by additional laser ablation. Manufacturer narrative: patient sex not available from the site. Patient weight not available from the site. No additional information has been provided/submitted to the manufacturer for an evaluation to be conducted. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued.
3004785967-2019-01724	08/11/2017	Injury	MEDTRONIC NAVIGATION, INC (LITTLETON)	02/10/2019	IZL	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Hematoma; Unspecified Infection	Citation: frizon l.a., shao j., maldonado-naranjo a.l., lobel d.a., nagel s.j., fernandez h.h., machado a.g. 2018. The safety and efficacy of using the o-arm intraoperative imaging system for deep brain stimulation lead implantation. Neuromodulation 2018; 21: 588¿592. Doi: 10.1111/ner.12744. Summary: introduction: accurate electrode implantation is a major goal of deep brain stimulation (dbs) surgery. Intraoperative physiology with microelectrode recording (mer) is routinely used to refine stereotactic accuracy during awake electrode implantation. Recently, portable imaging systems such as the o-arm have become widely available and can be used in isolation or in association with mer to guide dbs lead placement. The aim of this study was to evaluate how the routine use of the o-arm affected dbs surgery safety, efficiency, and outcomes. Methods: two cohorts of patients with parkinson¿s disease who underwent mer-guided awake subthalamic dbs lead implantation with and without o-arm were compared. We examined the total number of microelectrode and macroeletrode passes during each surgery, procedure duration, surgical complications, lead revisions, and motor outcomes. Results: a total of 50 procedures in 41 unique patients were analyzed, of which 26

									were performed without o-arm and 24 performed without the o-arm. The mean number of microelectrode passes was 2.46 (sd = 0.99) in the group without o-arm utilization, compared to 1.29 (sd = 0.75) in the group with o-arm usage (p <(><<)> 0.001). A significant reduction was also found in procedure duration (p = 0.016). No differences were found in motor outcomes between groups. Conclusion: the use of the o-arm during dbs lead implantation was associated with significantly fewer brain cannulations for microel ectrode recording as well as reduced surgical time. Reported events: one patient presented with a postoperative infection and was treated with lead removal and antibiotic therapy. The lead was re-implanted four months later. One patient presented with a postoperative asymptomatic subdural hematoma. The patient was monitored and no further surgery was necessary. Manufacturer narrative: patient information was not included in the journal article. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date the article was accepted as the event dates were not provided in the published literature. Article citation is included. No procode provided as the system is unknown. System product number and serial number not provided in journal article. Udi not available for this system. No 510k provided as system is unknown. No evaluation was performed as this event was reported in literature. Device manufacturing date is unavailable. If information is provided in the future, a supplemental report will be issued.
3007566237-2018-00843	08/11/2017	Injury	MEDTRONIC NEUROMODULATION	20/03/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Device Operates Differently Than Expected	Hematoma; Hemorrhage, Subdural; Therapeutic Effects, Unexpected; Post Operative	Summary: introduction: accurate electrode implantation is a major goal of deep brain stimulation (dbs) surgery. Intraoperative physiology with microelectrode recording (mer) is routinely used to refine stereotactic accuracy during awake electrode implantation. Recently, portable imaging

								Wound Infection	systems such as the o-arm have become widely available and can be used in isolation or in association with mer to guide dbs lead placement. The aim of this study was to evaluate how the routine use of the o-arm affected dbs surgery safety, efficiency, and outcomes. Methods: two cohorts of patients with parkinson¿s disease who underwent mer-guided awake subthalamic dbs lead implantation with and without o-arm were compared. We examined the total number of microelectrode and macroelectrode passes during each surgery, procedure duration, surgical complications, lead revisions, and motor outcomes. Results: a total of 50 procedures in 41 unique patients were analyzed, of which 26 were performed without o-arm and 24 performed without the o-arm. The mean number of microelectrode passes was 2.46 ((b)(4)) in the group without o-arm utilization, compared to 1.29 ((b)(4)) in the group with o-arm usage ($p < 0.001$). A significant reduction was also found in procedure duration ((b)(4)). No differences were found in motor outcomes between groups. Conclusion: the use of the o-arm during dbs lead implantation was associated with significantly fewer brain cannulations for microelectrode recording as well as reduced surgical time. Reported events: a patient with subthalamic nucleus (stn) deep brain stimulation (dbs) for parkinson's disease (pd) experienced postoperative infection, which was treated with lead removal and antibiotic therapy. The lead was reimplanted 4 months later. A patient with stn-dbs for pd had a lead revision due to lead failure. Three patients with stn-dbs for pd had lead revisions due to limited benefits following surgery. A patient with stn-dbs for pd experienced an asymptomatic subdural hematoma, which was detected on routine postoperative ct. All patients were implanted with 3389 leads, but it was not possible to ascertain any other specific device information from the article or to match the reported event

									with any previously reported event. Manufacturer narrative: please note that this date is based off the date that the article was accepted for publication as the event dates were not provided in the published literature. Information references the main component of the system. Other relevant device(s) are: product id: 3389, serial/lot #: unknown, ubd: , udi#:. Frizon, la., shao, j., maldonado-naranjo, al., lobel, da., nagel, sj., fernandez, hh., machado, ag. The safety and efficacy of using the o-arm intraoperative imaging system for deep brain stimulation lead implantation. Neuromodulation. 2017. Doi: 10.1111/ner.12744. If information is provided in the future, a supplemental report will be issued.
3007566237-2018-00407	31/10/2017	Injury	MEDTRONIC NEUROMODULATION	08/02/2018	MFR	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Break; Human-Device Interface Problem	Apnea; Unspecified Infection; Urinary Retention; Cognitive Changes	Summary: we previously found that electrical stimulation in the anterior limb of the internal capsule/bed nucleus of the stria terminalis (ic/bst) alleviates depressive symptoms in severe treatment-resistant obsessive-compulsive disorder (ocd) patients. Here we tested the hypothesis that electrical stimulation in either ic/bst or in the inferior thalamic peduncle (itp) effectively reduces depressive symptoms in treatment-resistant major depressive disorder (trd). In a double-blind crossover design, the effects of electrical stimulation at both targets were compared in trd patients. The 17-item hamilton depression rating scale (ham-d) was the primary outcome measure. During the first crossover, patients received ic/bst stimulation versus no stimulation in random order (2 × 1 weeks). During the second crossover (3 × 2 months), patients received ic/bst versus itp versus no stimulation. Patients and evaluators were blinded for stimulation conditions. All patients (n = 7) were followed up for at least 3 years (3¿8 years) after implantation. Six patients completed the first crossover and five patients completed the second. During the first crossover, mean (s.d.) Ham-d scores were 21.5 (2.7) for no stimulation and 11.5

									(8.8) for ic/bst stimulation. During the second crossover, ham-d scores were 15.4 (7.5) for no stimulation, 7.6 (3.8) for ic/bst stimulation and 11.2 (7.5) for itp stimulation. The final sample size was too small to statistically analyze this second crossover. At last follow-up, only one patient preferred itp over ic/bst stimulation. Two patients, with a history of suicide attempts before implantation, committed suicide during the follow-up phases of this study. Our data indicate that, in the long term, both itp and ic/bst stimulation may alleviate depressive symptoms in patients suffering from trd. Reported events: pli 10: an unknown number of patients with deep brain stimulation (dbs) leads bilaterally targeting the internal capsule/bed nucleus of the stria terminalis (ic/bst) and the inferior thalamic peduncle (itp) for treatment resistant depression (trd) experienced cognitive/behavioral adverse events that were reportedly stimulation induced. Under stimulation of the ic/bst the authors reported: 1 instance of intrusive thoughts about violent suicide; 1 instance of hearing the voice of their deceased sister; 1 instance of a feeling of derealization; 1 instance of disruption of social skills; 1 instance of increased impulsivity; and 2 instances of concentration difficulties. Under stimulation of the itp the authors reported: 1 instance of obsessive counting; and 1 instance of compulsive stealing. Pli 20: a patient who received 4 dbs leads bilaterally targeting the ic/bst and the itp for trd reportedly had a surgery/device related adverse event relating to their leads being ¿conversely labelled¿ resulting in the itp being stimulated when they expected the ic/bst to be stimulated. This reportedly led to an additional surgical procedure. Pli 30: a patient with dbs leads bilaterally targeting the ic/bst and the itp for trd experienced damage of the internal capsule electrode. This reportedly led to an additional surgical procedure. Pli 40: a patient with dbs leads

									bilaterally targeting the ic/bst and the itp for trd experienced an infection around the stereotactic frame attachment site. Pli 50: 2 patients with dbs leads bilaterally targeting the ic/bst and the itp for trd experienced an infection around the implantable neurostimulator (ins). This reportedly led to an additional surgical procedure. Pli 60: a patient with dbs leads bilaterally targeting the ic/bst and the itp for trd experienced sleep apnea that was reportedly induced by stimulation of the itp. Pli 70: a patient with dbs leads bilaterally targeting the ic/bst and the itp for trd experienced urinary retention that was reportedly induced by stimulation of the ic/bst. The authors reported that patients were eventually implanted with model 37612 activa rc's, however the original ins models were not stated. They also reported patients 1-5 received 3387 and patients 6-7 received 3389 model leads. It was not possible to ascertain any additional specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: this value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. The device was used in an off-label manner; the main component of one of the systems involved in the reported events; other applicable components are: product id: neu_unknown_lead, lot# unknown, product type: lead. Product id: neu_ins_stimulator, lot# unknown, product type: implantable neurostimulator. Raymaekers, s., luyten, l., bervoets, c., gabriels, l., nuttin, b. Deep brain stimulation for treatment-resistant major depressive disorder: a comparison of two targets and long-term follow-up. Transl psychiatry. 2017; 7(10):e1251.

									Doi:10.1038/tp.2017.66. If information is provided in the future, a supplemental report will be issued. (b)(4).
3007566237-2018-00160	17/10/2017	Injury	MEDTRONIC NEUROMODULATION	12/01/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Erosion; Hematoma; Intracranial Hemorrhage; Dysphasia; Confusion/ Disorientation	Summary: objective ventral intermediate nucleus deep brain stimulation (dbs) for essential tremor is traditionally performed with in traoperative test stimulation and conscious sedation, without general anesthesia (ga). Recently, the authors reported retrospective data on 17 patients undergoing dbs after induction of ga with standardized anatomical coordinates on t1-weighted mri sequences used for indirect targeting. Here, they compare prospectively collected data from essential tremor patients undergoing dbs both with ga and without ga (non-ga). Methods clinical outcomes were prospectively collected at baseline and 3-month follow-up for patients undergoing dbs surgery performed by asingle surgeon. Stereotactic, euclidean, and radial errors of lead placement were calculated. Functional (activities of daily living), quality of life (quality of life in essential tremor [quest] questionnaire), and tremor severity outcomes were compared between groups. Results fifty-six patients underwent surgery: 16 without ga (24 electrodes) and 40 with ga (66 electrodes). The mean baseline functional scores and quest summary indices were not different between groups (p = 0.91 and p = 0.59, respectively). Non-ga and ga groups did not differ significantly regarding mean postoperative percentages of functional improvement (non-ga, 47.9% vs ga, 48.1%; p = 0.96) or quest summary indices (non-ga, 79.9% vs ga, 74.8%; p = 0.50). Accuracy was comparable between groups (mean radial error 0.9 ± 0.3 mm for non-ga and 0.9 ± 0.4 mm for ga patients) (p = 0.75). The mean euclidean error was also similar between groups (non-ga, 1.1 ± 0.6 mm vs ga, 1.2 ± 0.5 mm; p = 0.92). No patient had an intraoperative complication, and the number of postoperative complications was not different between groups (non-ga, n = 1 vs ga, n = 10; p = 0.16). Conclusions dbs

									performed with the patient under ga to treat essential tremor is as safe and effective as traditional dbs surgery with intraoperative test stimulation while the patient is under conscious sedation without ga. Reported events: 1. An (b)(6) woman with unilateral ventral intermediate nucleus of the thalamus (vim) deep brain stimulation (dbs) for essential tremor experienced a postoperative 1.3 × 1.3 × 1.5¿cm lead track hemorrhage, causing the patient to became confused and modestly aphasic. The authors reported that clopidogrel was detected in her system afterward, despite it having been discontinued for 6 days preoperatively. The patient was discharged home 3 days postoperatively with a stable hematoma size, and at 3-month follow-up only had mild residual aphasia. 2. A (b)(6) man receiving bilateral vim-dbs leads for essential tremor had 2 episodes of cranial woundBreakdown that require surgical revision. No additional wound complications had been noted as of the 16-month follow-up. All patients were reportedly implanted with 3387 model leads, but it was not possible to ascertain any additional specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: this value is the average age of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Information references the main component of one of the systems involved in the reported events; other applicable components are: product id 3387, product type lead. Product id 3387, product type lead. Product id neu_ins_stimulator, product type: implantable neurostimulator. Chen t, mirzadeh z, chapple km, lambert, m., evidente, vgh., moguel-cobos, g., oravivattunakul, s., mahant, p., ponce, fa. Intr aoperative test stimulation versus

									stereotactic accuracy as a surgical end point: a comparison of essential tremor outcomes after ventral intermediate nucleus deep brain stimulation. J neurosurg. 2017:1-9. Doi: 10.3171/2017.3.jns162487.
3007566237-2018-00359	12/10/2017	Injury	MEDTRONIC NEUROMODULATION	05/02/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Edema; Facial Nerve Paralysis; Headache; Intracranial Hemorrhage; Memory Loss/Impairment; Seizures; Visual Impairment; Dysphasia; Ambulation Difficulties; Cognitive Changes; Confusion/ Disorientation	Summary: object: we review our experience with parkinson's disease (pd) patients who underwent subthalamic nucleus (stn) deep brain stimulation (dbs) and then developed noninfectious, non-hemorrhagic, delayed, symptomatic brain edema associated with a dbs lead. Methods: all pd patients who underwent stn dbs lead implantation from 2007 to 2015 were included. The same neurosurgeon performed all surgeries, typically in staged fashion, utilizing single pass microelectrode recordings (mer) within a stereotactic frame. A brain ct was obtained in recovery and subsequently if indicated. Results: there were 189 patients who underwent 363 stn lead implantations among which 35 (9.6%) represent re-implantations of removed leads in 28 (14.8%) patients. Among the 363 stn leads implanted, there were 12(3.3%) cases of delayed symptomatic edema associated with a dbs lead involving 10 (5.3%) of the patients studied. Of the 328 leads representing first-time operations, there were 9 (2.1%) cases of delayed symptomatic edema in 7 (3.7%) patients, one of whom (14.3%) presented with seizures. For lead re-implantations, there were 3 (8.6%) cases of the brain edema in 3 (10.7%) patients; all presenting with seizures. For the 35 re-implantations, the trajectory to target was the same or very similar via the same burr hole as prior surgery in 17 (48.6%); 3 (17.6%) of whom developed edema. There was no case of brain edema in the 18 re-operated cases using a different burr opening. Edema patients were treated with a course of anticonvulsant medication and dexamethasone. Lead-associated edema resolved over generally a 4 to 6-week course. Conclusions: noninfectious, non-hemorrhagic, delayed, symptomatic brain

									edema occurs in approximately 3% of implanted leads and is more common in re-implantations (9%) compared to new implantations (2%). In re implantations, the edema is more common when the same trajectory is used (18%) compared to a new trajectory (0%). The edema generally occurs 3 to 8 days after implantation, although immediate post-op ct is normal and seizures are a common presenting feature. Reported events: 1. Patient 1: a (b)(6)-year-old who received deep brain stimulation (dbs) leads targeting the subthalamic nucleus (stn) for parkinson's disease (pd) experienced headache, mild confusion, and balance problems associated with their initial right-side implant, and mild difficulties with gait, speech, and seizure associated with their second as symptoms of edema. The patient had a ct scan which demonstrated findings consistent with vasogenic edema characterized by a low attenuation hypodense area associated with the dbs lead. Patients were admitted to the hospital, placed on dexamethasone, 6 mg iv q6h for 1 to 3 days after a 6 to 8 mg iv loading dose, and then tapered off over a 2 to 3-week course. Levetiracetam 500 mg po/iv bid was given for seizure prophylaxis. In the absence of seizures following admission, no patient reported increase in neurologic signs or symptoms and in most cases, within 24¿36 h following admission, there was evidence of at least partial clinical improvement. Patients remained in hospital until considered clinically and radiographically stable and discharged on dexamethasone 4 mg po q6 to 8h (tapered to off over 10¿14 days) and anticonvulsant medication. Follow up outpatient brain cts were obtained and there was complete or near complete resolution of the lead-associated hypodensity at the time of the final ct and prior to proceeding with neurostimulator and extension implantation. The patient was ultimately taken off seizure medication without seizure recurrence. 2. Patient 1: a (b)(6)-

									year-old who received dbs leads targeting the stn for pd experienced seizures following reimplantation of the right lead as symptoms of edema. The patient had a ct scan which demonstrated findings consistent with vasogenic edema characterized by a low attenuation hypodense area associated with the dbs lead. Patients were admitted to the hospital, placed on dexamethasone, 6 mg iv q6h for 1 to 3 days after a 6 to 8 mg iv loading dose, and then tapered off over a 2 to 3-week course. Levetiracetam 500 mg po/iv bid was given for seizure prophylaxis. In the absence of seizures following admission, no patient reported increase in neurologic signs or symptoms and in most cases, within 24¿36 h following admission, there was evidence of at least partial clinical improvement. Patients remained in hospital until considered clinically and radiographically stable and discharged on dexamethasone 4 mg po q6 to 8h (tapered to off over 10¿14 days) and anticonvulsant medication. Follow up outpatient brain cts were obtained and there was complete or near complete resolution of the lead-associated hypodensity at the time of the final ct and prior to proceeding with neurostimulator and extension implantation. The patient was ultimately taken off seizure medication without seizure recurrence. 3. Patient 2: a (b)(6)-year-old who received dbs leads targeting the stn for pd experienced intermittent confusion and word finding difficulty, memory difficulty, and hesitancy in speech as symptoms of edema. The patient had a ct scan which demonstrated findings consistent with vasogenic edema characterized by a low attenuation hypodense area associated with the dbs lead. Patients were admitted to the hospital, placed on dexamethasone, 6 mg iv q6h for 1 to 3 days after a 6 to 8 mg iv loading dose, and then tapered off over a 2 to 3-week course. Levetiracetam 500 mg po/iv bid was given for seizure prophylaxis. In the

									absence of seizures following admission, no patient reported increase in neurologic signs or symptoms and in most cases, within 24¿36 h following admission, there was evidence of at least partial clinical improvement. Patients remained in hospital until considered clinically and radiographically stable and discharged on dexamethasone 4 mg po q6 to 8h (tapered to off over 10¿14 days) and anticonvulsant medication. Follow up outpatient brain cts were obtained and there was complete or near complete resolution of the lead-associated hypodensity at the time of the final ct and prior to proceeding with neurostimulator and extension implantation. 4. Patient 3: a (b)(6)-year-old who received dbs leads targeting the stn for pd experienced a seizure as a symptom of edema. The patient had a ct scan which demonstrated findings consistent with vasogenic edema characterized by a low attenuation hypodense area associated with the dbs lead. Patients were admitted to the hospital, placed on dexamethasone, 6 mg iv q6h for 1 to 3 days after a 6 to 8 mg iv loading dose, and then tapered off over a 2 to 3-week course. Levetiracetam 500 mg po/iv bid was given for seizure prophylaxis. In the absence of seizures following admission, no patient reported increase in neurologic signs or symptoms and in most cases, within 24¿36 h following admission, there was evidence of at least partial clinical improvement. Patients remained in hospital until considered clinically and radiographically stable and discharged on dexamethasone 4 mg po q6 to 8h (tapered to off over 10¿14 days) and anticonvulsant medication. Follow up outpatient brain cts were obtained and there was complete or near complete resolution of the lead-associated hypodensity at the time of the final ct and prior to proceeding with neurostimulator and extension implantation. The patient was ultimately taken off seizure medication without seizure recurrence. 5. Patient 4: a (b)(6)-

									year-old who received dbs leads targeting the stn for pd experienced diplopia as a symptom of edema. The patient had a ct scan which demonstrated findings consistent with vasogenic edema characterized by a low attenuation hypodense area associated with the dbs lead. Patients were admitted to the hospital, placed on dexamethasone, 6 mg iv q6h for 1 to 3 days after a 6 to 8 mg iv loading dose, and then tapered off over a 2 to 3-week course. Levetiracetam 500 mg po/iv bid was given for seizure prophylaxis. In the absence of seizures following admission, no patient reported increase in neurologic signs or symptoms and in most cases, within 24¿36 h following admission, there was evidence of at least partial clinical improvement. Patients remained in hospital until considered clinically and radiographically stable and discharged on dexamethasone 4 mg po q6 to 8h (tapered to off over 10¿14 days) and anticonvulsant medication. Follow up outpatient brain cts were obtained and there was complete or near complete resolution of the lead-associated hypodensity at the time of the final ct and prior to proceeding with neurostimulator and extension implantation. 6. Patient 5: a (b)(6)-year-old who received dbs leads targeting the stn for pd experienced a seizure as a symptom of edema. The patient had a ct scan which demonstrated findings consistent with vasogenic edema characterized by a low attenuation hypodense area associated with the dbs lead. Patients were admitted to the hospital, placed on dexamethasone, 6 mg iv q6h for 1 to 3 days after a 6 to 8 mg iv loading dose, and then tapered off over a 2 to 3-week course. Levetiracetam 500 mg po/iv bid was given for seizure prophylaxis. In the absence of seizures following admission, no patient reported increase in neurologic signs or symptoms and in most cases, within 24¿36 h following admission, there was evidence of at least partial clinical improvement. Patients remained in hospital

									until considered clinically and radiographically stable and discharged on dexamethasone 4 mg po q6 to 8h (tapered to off over 10¿14 days) and anticonvulsant medication. Follow up outpatient brain cts were obtained and there was complete or near complete resolution of the lead-associated hypodensity at the time of the final ct and prior to proceeding with neurostimulator and extension implantation. The patient was ultimately taken off seizure medication without seizure recurrence. 7. Patient 6: a (b)(6)-year-old who received dbs leads targeting the stn for pd experienced intermittent word finding difficulty as symptoms of edema. The patient had a ct scan which demonstrated findings consistent with vasogenic edema characterized by a low attenuation hypodense area associated with the dbs lead. Patients were admitted to the hospital, placed on dexamethasone, 6 mg iv q6h for 1 to 3 days after a 6 to 8 mg iv loading dose, and then tapered off over a 2 to 3-week course. Levetiracetam 500 mg po/iv bid was given for seizure prophylaxis. In the absence of seizures following admission, no patient reported increase in neurologic signs or symptoms and in most cases, within 24¿36 h following admission, there was evidence of at least partial clinical improvement. Patients remained in hospital until considered clinically and radiographically stable and discharged on dexamethasone 4 mg po q6 to 8h (tapered to off over 10¿14 days) and anticonvulsant medication. Follow up outpatient brain cts were obtained and there was complete or near complete resolution of the lead-associated hypodensity at the time of the final ct and prior to proceeding with neurostimulator and extension implantation. 8. Patient 7: a (b)(6)-year-old who received dbs leads targeting the stn for pd experienced slowness of speech and word finding difficulties as symptoms of edema. The patient had a ct scan which demonstrated findings consistent with

									vasogenic edema characterized by a low attenuation hypodense area associated with the dbs lead. Patients were admitted to the hospital, placed on dexamethasone, 6 mg iv q6h for 1 to 3 days after a 6 to 8 mg iv loading dose, and then tapered off over a 2 to 3-week course. Levetiracetam 500 mg po/iv bid was given for seizure prophylaxis. In the absence of seizures following admission, no patient reported increase in neurologic signs or symptoms and in most cases, within 24¿36 h following admission, there was evidence of at least partial clinical improvement. Patients remained in hospital until considered clinically and radiographically stable and discharged on dexamethasone 4 mg po q6 to 8h (tapered to off over 10¿14 days) and anticonvulsant medication. Follow up outpatient brain cts were obtained and there was complete or near complete resolution of the lead-associated hypodensity at the time of the final ct and prior to proceeding with neurostimulator and extension implantation. The patient was ultimately taken off seizure medication without seizure recurrence. 9. Patient 8: a (b)(6)-year-old who received dbs leads targeting the stn for pd experienced a word finding difficulties, mild intermittent confusion and mild gait problems as symptoms of edema. The patient had a ct scan which demonstrated findings consistent with vasogenic edema characterized by a low attenuation hypodense area associated with the dbs lead. Patients were admitted to the hospital, placed on dexamethasone, 6 mg iv q6h for 1 to 3 days after a 6 to 8 mg iv loading dose, and then tapered off over a 2 to 3-week course. Levetiracetam 500 mg po/iv bid was given for seizure prophylaxis. In the absence of seizures following admission, no patient reported increase in neurologic signs or symptoms and in most cases, within 24¿36 h following admission, there was evidence of at least partial clinical improvement. Patients remained in hospital until considered clinically and

									radiographically stable and discharged on dexamethasone 4 mg po q6 to 8h (tapered to off over 10¿14 days) and anticonvulsant medication. Follow up outpatient brain cts were obtained and there was complete or near complete resolution of the lead-associated hypodensity at the time of the final ct and prior to proceeding with neurostimulator and extension implantation. 10. Patient 9: a (b)(6)-year-old who received dbs leads targeting the stn for pd experienced progressive headaches as a symptom of edema. The patient had a ct scan which demonstrated findings consistent with vasogenic edema characterized by a low attenuation hypodense area associated with the dbs lead. Patients were admitted to the hospital, placed on dexamethasone, 6 mg iv q6h for 1 to 3 days after a 6 to 8 mg iv loading dose, and then tapered off over a 2 to 3-week course. Levetiracetam 500 mg po/iv bid was given for seizure prophylaxis. In the absence of seizures following admission, no patient reported increase in neurologic signs or symptoms and in most cases, within 24¿36 h following admission, there was evidence of at least partial clinical improvement. Patients remained in hospital until considered clinically and radiographically stable and discharged on dexamethasone 4 mg po q6 to 8h (tapered to off over 10¿14 days) and anticonvulsant medication. Follow up outpatient brain cts were obtained and there was complete or near complete resolution of the lead-associated hypodensity at the time of the final ct and prior to proceeding with neurostimulator and extension implantation. 11. Patient 10: a (b)(6)-year-old who received dbs leads targeting the stn for pd experienced right facial droop as a symptom of edema. The patient had a ct scan which demonstrated findings consistent with vasogenic edema characterized by a low attenuation hypodense area associated with the dbs lead. Patients were admitted to the hospital,

									placed on dexamethasone, 6 mg iv q6h for 1 to 3 days after a 6 to 8 mg iv loading dose, and then tapered off over a 2 to 3-week course. Levetiracetam 500 mg po/iv bid was given for seizure prophylaxis. In the absence of seizures following admission, no patient reported increase in neurologic signs or symptoms and in most cases, within 24¿36 h following admission, there was evidence of at least partial clinical improvement. Patients remained in hospital until considered clinically and radiographically stable and discharged on dexamethasone 4 mg po q6 to 8h (tapered to off over 10¿14 days) and anticonvulsant medication. Follow up outpatient brain cts were obtained and there was complete or near complete resolution of the lead-associated hypodensity at the time of the final ct and prior to proceeding with neurostimulator and extension implantation. 12. Patient 1: a (b)(6)-year-old who received dbs leads targeting the stn for pd had the right lead removed for unspecified reasons. The authors provided multiple examples of reasons leads would be removed, including infection, lack of efficacy, side-effects, or hardwareBreakage. 13. Patient 3: a (b)(6)-year-old who received dbs leads targeting the stn for pd had the right lead removed for unspecified reasons. The authors provided multiple examples of reasons leads would be removed, including infection, lack of efficacy, side-effects, or hardwareBreakage. 14. Patient 5: a (b)(6)-year-old who received dbs leads targeting the stn for pd had the left lead removed for unspecified reasons. The authors provided multiple examples of reasons leads would be removed, including infection, lack of efficacy, side-effects, or hardwareBreakage. 15. Twentyfive patients with dbs leads targeting the stn for pd had a lead removed for unspecified reasons. The authors provided multiple examples of reasons leads would be removed, including infection, lack of efficacy, side-effects, or hardwareBreakage. 16. One patient

									experienced postoperative seizure related to delayed lead-associated hemorrhage. Patients were implanted with either 3387 or 3389 model leads and model 7426, 37602, 37601, or 37603 neurostimulators. It was not possible to ascertain any additional specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: this value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. The main component of one of the systems involved in the reported events; other applicable components are: product id: neu_unknown_lead, lot# unknown, product type: lead. Nazzaro, jm., pahwa, r., lyons, ke. Symptomatic, non-infectious, non-hemorrhagic edema after subthalamic nucleus deep brain stimulation surgery for parkinson's disease. Journal of the neurological sciences. 2017; 383:42-46. Doi: 10.1016/j.jns.2017.10.003. If information is provided in the future, a supplemental report will be issued. (b)(4).
3008492462-2018-00003	11/10/2017	Injury	DEVICOR MEDICAL PRODUCTS	10/01/2018	KNW	MAMMOTOME REVOLVE STEREOTACTIC PROBE	Adverse Event Without Identified Device or Use Problem	Hematoma	The sales rep reported that patient experienced severe bleeding requiring surgery and inpatient admission (1d). Malignant findings. Manufacturer narrative: the revolve stereotactic probe is a sterile, single-patient use device that may be used with imaging guidance to excise a tissue sample for diagnosis. A stereotactic breast biopsy procedure using a mammotome revolve vacuum-assisted biopsy system was conducted on (b)(6) 2017 during which it was reported that the patient was noted to have a hematoma forming on her breast immediately. Pressure was applied on the area of the biopsy for about 30 minutes, which initially looked stable but was noted

									to have some enlargement on the area of the hematoma, thus a surgical consult requested. Patient was then admitted to the hospital for overnight observation. It was noted that the patient has been on blood thinners since suffering a stroke in 2009 which could have been a contributing factor. The patient was discharged from the hospital within 24 hours. Post discharge patient follow-up information is not available. The possibility of bleeding exists with any biopsy procedure and some biopsies will have it more than others, based on the anatomy of the patient and the lesion. However, due to the patient being admitted to the hospital for further evaluation and pursuant to 21 cfr 803 this is a reportable adverse event thus, we are submitting this medwatch report.
1717344-2019-01230	03/10/2017	Injury	COVIDIEN MFG DC BOULDER	01/10/2019	GEI	UNKNOWN RF ELECTRODE	Adverse Event Without Identified Device or Use Problem	Pulmonary Valve Stenosis	(B)(4): according to literature source of study performed between may 2010 and april 2015, 16 patients with a total of 17 lung tumors were enrolled and treated with stereotactic body radiation therapy (sbrt). Twelve patients received radio frequency ablation (rfa), and 3 received microwave ablation (mwa). One patient fell at home after receiving stereotactic body radiation therapy (sbrt), did not received heat-based ablation (hba) per protocol, and was lost to follow-up. For rfa, covidien electrodes (covidien, (b)(4)) were used, and for mwa, the neuwave system (non-medtronic products) was used. This study identified 1 grade 3 bronchial stenosis. Manufacturer narrative: title: a prospective phase 2 study evaluating safety and efficacy of combining stereotactic body radiation therapy with heat-based ablation for centrally located lung tumors source: 2018, international journal of radiation oncology received oct 3, 2017, and in revised form feb 2, 2018. Accepted for publication mar 13, 2018. If information is provided in the future, a supplemental report will be issued. [(b)(4)].
3005985723-2018-00025	20/09/2017	Malfunction	MAKO SURGICAL CORP.	17/01/2018	OLO	CPCI MOTION CONTROL	Communication or Transmission	No Known Impact Or	A surgeon was performing a makoplasty partial knee arthroplasty using the robotic arm interactive orthopedic system (rio).

						ASSEMBLY 3.0 ROHS	Problem; Connection Problem	Consequence To Patient	During the case, connection error not fixable by the bypass cable occurred causing a delay >30 mins. Another robot had to be brought into the room to complete the case. This did not negatively impact the case, the outcome was successful, and there was no harm to the patient.a surgeon was performing a makoplasty partial knee arthroplasty using the robotic arm interactive orthopedic system (rio). During the case, connection error not fixable by the bypass cable occurred causing a delay >30 mins. Another robot had to be brought into the room to complete the case. This did not negatively impact the case, the outcome was successful, and there was no harm to the patient. Manufacturer narrative: "reported event: (b)(4) was showing connection error not fixable by the bypass cable. Device evaluation and results: per fsr 0339: replaced cpci assembly. Product history review a review of device history records shows that on 09/24/2009 1 device was/were inspected and 1 device was/were placed on nc/npr/qt: (b)(4), revealed that the non-conformance is/are not related to the failure alleged in this compliant. Complaint history review a review of complaints in catsweb and trackwise related to p/n 211123, (b)(4) shows no additional complaints related to the failure in this investigation. Conclusions: performed all the required tests; tests passed with success. Corrective action/preventive action: no action is required at this time as there is no indication to suggest a product non-conformity or unanticipated hazard." manufacturer narrative: reported event: (b)(4) was showing connection error not fixable by the bypass cable. Device evaluation and results: per (b)(4): replaced cpci assembly. Product history review a review of device history records shows that on 09/24/2009 1 device was/were inspected and 1 device was/were placed on nc/npr/qt: (b)(4), revealed that the non-conformance is/are not related to the

									failure alleged in this compliant. Complaint history review a review of complaints in catsweb and trackwise related to p/n 211123, serial number (b)(4) shows no additional complaints related to the failure in this investigation. Conclusions: performed all the required tests; tests passed with success. Corrective action/preventive action: no action is required at this time as there is no indication to suggest a product non-conformity or unanticipated hazard."
3007566237-2018-00042	09/09/2017	Injury	MEDTRONIC NEUROMODULATION	02/01/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Electromagnetic Compatibility Problem	Facial Nerve Paralysis; Headache; Intracranial Hemorrhage; Hemorrhage, Subdural; Paresis; Seizures; Complaint, Ill-Defined; Coma; Cognitive Changes; Confusion/ Disorientation; No Code Available	Summary: intraoperative magnetic resonance imaging (imri) is increasingly used to implant deep brain stimulator (dbs) electrodes. The approach has the advantages of a high targeting accuracy, minimization of brain penetrations, and allowance of implantation under general anesthesia. The hemorrhagic complications of imri-guided dbs implantation have not been studied in a large series. We report on the incidence and characteristics of hemorrhage during these procedures. Methods: hemorrhage incidence was assessed in a series of 231 imri procedures (374 electrodes implanted). All patients had movement disorders and the subthalamic nucleus or the globus pallidus internus was typically targeted. Hemorrhage was detected with intra- or postoperative mri or postoperative computed tomography. Hemorrhage was classified based on its point of origin and clinical impact. Results: hemorrhage and symptomatic hemorrhage were detected during 2.4 and 1.1% of electrode implantations, respectively. The hemorrhage origin was subdural/ subarachnoid (n = 3), subcortical (n = 5), or deep (n =1). Factors that contributed to hemorrhage included unintentional crossing of a sulcus and resistance at the pial membrane, which produced cortical depression and a rebound hemorrhage. Delayed hemorrhage occurred in 2 patients and was attributed to premature reintroduction of anticoagulation therapy or air intrusion into the cranial cavity.

									Conclusions: hemorrhage was readily apparent on intraoperative imaging, and hemorrhage rates for imri-guided dbs implantations were comparable to those for conventional implantation approaches. Reported events: patient 5: a (b)(6)-year-old patient receiving globus pallidus internus (gpi) deep brain stimulation (dbs) for movement disorders experienced an acute onset subcortical hemorrhage during the implantation procedure. Although the patient remained asymptomatic they were held overnight in the icu and started on a prophylactic anti-epileptic agent, and stayed hospitalized for 3 days. The authors suggested that the burr hole placement which necessitated crossing of a sulcus contributed to the hemorrhage in this patient. Patient 8: a (b)(6)-year-old male patient with dbs for movement disorders experienced a subdural hemorrhage following the implantation procedure that left the patient comatose, confused, and with facial weakness within 48 hours of surgery. The authors attributed the patient¿s subdural hematoma to substantial air infiltration into their cerebral cavity stretching a bridging vessel. Shortly after the patient was extubated, they reportedly complained of a severe headache, followed by mental status changes that rapidly progressed to obtundation. They were reintubated and a ct scan revealed a large subdural hematoma that necessitated emergent craniotomy for evacuation. A ct scan 1-week later showed a substantially reduced blood product and mass effect. The patient remained in the hospital for 20 days. Patient 1: a (b)(6)-year-old patient receiving deep brain stimulation (dbs) for movement disorders experienced an asymptomatic acute onset subcortical hemorrhage during the implantation procedure. The patient remained hospitalized for 2 days. Patient 2: a (b)(6)-year-old patient receiving dbs of the subthalamic nucleus (stn) for movement disorders experienced an asymptomatic acute onset deep (basal ganglia)

									hemorrhage during the implantation procedure. The patient remained in the hospital for 1 day. Patient 3: a (b)(6)-year-old patient receiving dbs for movement disorders experienced an asymptomatic acute onset subdural hemorrhage during the implantation procedure. The patient remained in the hospital for 2 days. Patient 4: a (b)(6)-year-old patient receiving dbs for movement disorders experienced an asymptomatic acute onset subcortical hemorrhage during the implantation procedure. The patient remained in the hospital for 1 day. Patient 6: a (b)(6)-year-old patient receiving dbs for movement disorders experienced an acute onset subdural hemorrhage during the implantation procedure that resulted in a generalized seizure. The patient remained in the hospital for 2 days. Patient 7: a (b)(6)-year-old patient receiving dbs for movement disorders experienced an acute onset subcortical hemorrhage during the implantation procedure that resulted in left hemiparesis and behavior changes. The authors stated that this hemorrhage occurred because of resistance from the pia mater; using a blunt mandrel to try to penetrate the cortical surface they stated that imaging showed deformation of the cortical surface, producing a rebound hemorrhage. The patient remained hospitalized for 11 days. It was noted that since this case the surgical procedure was altered to use a sharp mandrel to initially penetrate the cortical surface, before switching to the blunt version, and since this change no additional rebound hemorrhages have occurred. The patient remained in the hospital for 11 days. Patient 9: a (b)(6)-year-old male patient with dbs for movement disorders experienced a subcortical hemorrhage that resulted in a generalized seizure and word-finding difficulty within 48 hours of surgery. The patient had a history of multiple, unprovoked deep venous thrombosis events requiring chronic warfarin therapy,

									so he was bridged with enoxaparin until the day before surgery in consultation with the hematology service, with plans to restart this the day after surgery given the high risk of thromboembolism. The procedure was performed without evidence of hemorrhage intraoperatively or on the post-implantation scan. A ct scan on the morning of postoperative day 1 was normal. Enoxaparin was restarted that afternoon, and several hours later the patient had a witnessed seizure. A repeat ct scan showed an acute 2.5-cm subcortical hemorrhage around one of the leads. He subsequently was asymptomatic and did not require any further intervention besides short-term seizure prophylaxis. The patient remained in the hospital for 6 days. Two patients experienced a subtle hemorrhage at the target depth that was detected via intraoperative imaging but could not be seen on post-implantation imaging. It was noted that in these cases the ¿ceramic mandrel¿ did not produce any artifact during the procedure but the lead itself produced a large enough artifact to potentially obscure the post-implantation imaging. One patient experienced a subtle subcortical hemorrhage that was detected via intraoperative imaging but could not be seen on post -implantation imaging. It was noted that in these cases the ¿ceramic mandrel¿ did not produce any artifact during the procedure but the lead itself produced a large enough artifact to potentially obscure the post-implantation imaging. Patients were reportedly implanted with either 3389-28 or 3389-40 leads. However, it was not possible to ascertain any additional specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: other applicable components are: product id: 3389, lot# unknown, product type: lead. Martin, aj., starr, pa., ostrem, jl., larson, ps. Hemorrhage detection and incidence during magnetic resonance-guided deep brain

									stimulator implantations. Stereotact funct neurosurg. 2017; 95(5):307-314. Doi: 10.1159/000479287 c64343 - used for verbatim of: "air infiltration into their cerebral cavity". If information is provided in the future, a supplemental report will be issued.
1723170-2018-03866	16/08/2017	Malfunction	MEDTRONIC NAVIGATION, INC. (LOUISVILLE)	17/08/2018	HAW	STEALTHSTATION S7 SYSTEM	Imprecision	No Patient Involvement	The journal article was forwarded by medtronic representative. Article indicated the use of surgical navigation system. The aim of the present work was to determine the total statistical error of targeting stereotactic instruments to deep intracerebral targets using a frameless navigation system with multispiral computed tomography (msct) and mri scanners. Measurements were made in conditions of reference elements rigidly fixed to the skull imitator by simultaneous use of an oreol stereotactic manipulator and frameless neuronavigation systems. Total targeting errors were assessed by phantom modeling with maximal approximation to the conditions of stereotactic brain surgery, starting with scanning on a tomograph and ending with targeting the instrument to the aiming point. Targeting to the aiming points of the phantom used the ¿virtual elongation¿ function of the probe, just as in actual stereotactic operations [8]. The extent of virtual elongation of the probe was 95 mm, such that the tip of the virtually elongated probe was positioned in the isocenter of the arch of the stereotactic manipulator. Of the eight reference fiducials attached to the phantom surface and serving to register it with the navigation system, four were located at the level of the horizontal plate of the phantom. Seven markers simulating ct targets and four imitating mri targets were attached to this plate. Two further mri targets were located on the sagittal plate of the phantom. Four more fiducials were positioned about 10 cm above the horizontal plate of the phantom. Targeting errors were measured on ct targets using msct images of the phantom in the following regimes: with registration of

									the phantom at all eight reference fiducials; with the phantom registered at the four fiducials located at the level of the internal horizontal plane; with the phantom registered using the four fiducials located 10 cm above the horizontal plane; with the phantom registered on the basis of the outline of its surface, not using the reference fiducials (the tracer method). Measurement of targeting errors using mri images of the phantom were made using the following regimes: with simultaneous ct/mri registration of the phantom image using the eight reference fiducials detected by ct, assessing errors on targeting the instrument to the mri targets; with the mri image of the phantom registered at the eight reference fiducials (without use of ct), the errors of targeting the instrument to the mri targets were measured. The measurement results are shown in table 1. Total errors were random and depended on the errors in all the technical elements involved in the process of computerized preparation and stereotactic targeting of the instrument to the aiming point. These errors cannot be excluded using these technical devices, though they have to be addressed in specific stereotactic neurosurgical tasks. Reported issue: error measurement results 1) with registration of the phantom at all eight reference fiducials: error magnitude, 0.87 +/- 0.33 2) with the phantom registered at the four fiducials located at the level of the internal horizontal plane; error magnitude, 0.48 +/- 0.35 3) with the phantom registered using the four fiducials located 10 cm above the horizontal plane; error magnitude, 0.84 +/- 0.5 4) with the phantom registered on the basis of the outline of its surface, not using the reference fiducials (the tracer method). Measurement of targeting errors using mri images of the phantom were made using the following regimes: error magnitude, 1.4 +/- 0.54 5) with simultaneous ct/mri registration of the phantom image using the eight reference fiducials detected by ct,

									assessing errors on targeting the instrument to the mri targets; error magnitude, 0.92 +/- 0.31 6) with the mri image of the phantom registered at the eight reference fiducials (without use of ct); error magnitude, 0.91 +/- 0.56. Manufacturer narrative: correction: medtronic received new information from the author that the issue reported was not caused by medtronic system used for this study. If this information was available during the initial review, the reported issue would not be have been considered as a reportable event. Manufacturer narrative: citation: kholyvain a. Nizkovolos v. Bogdan a. Assessment of the targeting quality of a stereotactic instrument to an aiming point in the brain using a frameless navigation system. Biomedical engineering (2018) vol. 52; no.2 pp. 92-95. Doi 10.1007/s10527-018-9790-3. The exact system information could not be determined as it was not provided. However, the system listed on this form was at the address listed in the article during the time some of the surgeries were completed. Device udi not provided as actual product used for this study is unknown. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. No further information provided in the journal article or from the authors. The author could not provide any additional information or insight as he was not at the site when the surgeries were performed. No request for service have been received from the customer regarding these events. No parts have been replaced or returned to the manufacturer for evaluation. Medtronic navigation is filing this mdr to ensure visibility to a patient event as a result of a procedure that utilized medtronic navigation's surgical navigation system. There is no allegation to suggest that medtronic navigation's device caused or contributed to the reported event. Device not returned by customer.

1723170-2019-04928	01/08/2017	Malfunction	MEDTRONIC NAVIGATION, INC	18/09/2019	HAW	MEDTRONIC NAVIGATION	Imprecision	Unspecified Infection; Tissue Damage	Citation: michael karsy, md, phd, hussam abou-al-shaar, md, christian a. Bowers, md, and richard h. Schmidt, md, phd. Treatment of idiopathic intracranial hypertension via stereotactic placement of biventriculoperitoneal shunts. Summary: objective idiopathicintracranial hypertension (iih), or pseudotumor cerebri, is a complex and difficult-to-manage condition that can lead to permanent vision loss and refractory headaches if untreated. Traditional treatment options, such as unilateral ventriculoperitoneal (vp) or lumboperitoneal (lp) shunt placement, have high complication and failure rates and often require multiple revisions. The use of bilateral proximal catheters has been hypothesized as a method to improve shunt survival. The use of stereotactic technology has improved the accuracy of catheter placement and may improve treatment of iih, with fewer complications and greater shunt patency time. Methods the authors performed a retrospective chart review for all patients with iih who underwent stereotactic placement of biventr iculoperitoneal (bvp) shunt catheters from 2008 to 2016 at their institution. Bilateral proximal catheters were y-connected to a strata valve with a single distal catheter. We evaluated clinical, surgical, and ophthalmological variables and outcomes. Results most patients in this series of 34 patients (mean age 34.4 ± 8.2 years, mean body mass index 38.7 ± 8.3 kg/m2; 91.2% were women) undergoing 41 shunt procedures presented with headache (94.1%) and visual deficits (85.3%). The mean opening pressure was 39.6 ± 9.0 cm h2o. In addition, 50.0% had undergone previous unilateral shunt placement, and 20.6% had undergone prior optic nerve sheath fenestration. After bvp shunt placement, there were no cases of proximal catheter obstruction and only a single case of valve obstruction at 41.9 months, with a mean follow-up of 24.8 ± 20.0 months. Most patients showed improvement in their

									headache (82.4%), subjective vision (70.6%), and papilledema (61.5% preoperatively vs 20.0% postoperatively, p = 0.02) at follow-up. Additional primary complications included 4 patients with migration of their distal catheters out of the peritoneum (twice in 1 patient), and an infection of the distal catheter after catheter dislodgment. The proximal obstructive shunt complication rate in this series (2.9%) was lower than that with lp (53.5%) or unilateral vp (37.8%) shunts seen in the literature. Conclusions this small series suggests that stereotactic placement of bvp shunt catheters appears to improve shunt survival rates and presenting symptoms in patients with iih. Compared with unilateral vp or lp shunts, the use of bvp shunts may be a more effective and more functionally sustained method for the treatment of iih. Reported events: accusation of suboptimal accuracy because of excessive electromagnetic interference from metallic components in the operative field. One patient experienced a vp shunt malfunction due to a proximal obstruction. It was reported that the valve was replaced at 41.9months after the procedure. One patient had a transected distal catheter during an unrelated abdominal surgery and required replacement. Two patients experienced a migration of the catheter outside of the peritoneum, resulting in an abdominal wall pseudocyst, where it was noted the issue occurred in the 1st post-operative month. One patient experienced a migration of the catheter outside of the peritoneum, resulting in an abdominal wall pseudocyst, where it was noted the issue occurred in the 16th post-operative month. Additionally, the patient had further complications due to the an abdominal wall infection after revision, requiring removal and replacement of the shunt system. Manufacturer narrative: patient age is the mean value of the patients in the study. Patient gender is the majority value of the patients in the study. Device lot number, or

									serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. Reported events 2-5 noted are adverse events that the product listed in section d did not cause or contribute to. 510(k) is not provided as the value is dependent on the device lot number/serial number. If information is provided in the future, a supplemental report will be issued.
3007566237-2018-03507	31/07/2017	Malfunction	MEDTRONIC NEUROMODULATION	04/12/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Malposition of Device	No Known Impact Or Consequence To Patient	Summary: aim: deep brain stimulation (dbs) surgeries are multi-faceted and the various steps are interconnected. Since its first imp lamentation, the method of dbs surgery has undergone changes. We have encountered several expected and also non-expected perioperative technical complications in the past seventeen years. Here, we describe the stereotactic frame, stereotactic localizer and planning station related complications and how we have managed them as much as possible. Material and methods: this study is a retrospective qualitative analysis of the documented technical events encountered during dbs surgeries from 1999 onwards. We have collected these events from a cohort of approximately 921 dbs electrodes implantations from the centers of the authors. Results: stereotactic frame related complications included movement related fixation problems, head anatomy related problems, and lack of maintenance related issues. Localizer related complications were compatibility issues of the stereotactic localizer and planning station, field of view effect on fiducials, air bubbles in localizers using liquid solutions, and disengaged localizer effect. Planning station related complications included image fusion failures and cerebrospinal fluid signal effect on image fusion. Conclusion: the road to success in dbs therapy passes through the ability to cope with surgical and technical complications. Each step is unconditionally connected to the other, and detection of

									the problems that can be encountered in advance and preparations for these negative conditions are the key to success for the group responsible for executing the therapy. We are still learning from these events and advance our surgical approaches. Reported events: 1 patient receiving dbs experienced a misplaced electrode during the postoperative imaging phase due to images obtained with a disengaged or not fully engaged localizer that then caused the fiducials to not show the right points on the radiological images. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. See attached literature article. Manufacturer narrative: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Concomitant medical products: product id: neu_unknown_lead, lot#: unknown, product type: lead. Alptekin, o., kocabicak, e., gubler, fs., ackermans, l., kubben, pl., temel, y. Perioperative technical complications in deep brain stimulation surgeries. Turk neurosurg. 2018; 28(3):483-489. Doi: 10.5137/1019-5149.jtn.20042-17.1. If information is provided in the future, a supplemental report will be issued.
3007566237-2018-00664	14/07/2017	Malfunction	MEDTRONIC NEUROMODULATION	06/03/2018	MRU	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Migration or Expulsion of Device; Material Deformation	No Known Impact Or Consequence To Patient	Summary: background: deep brain stimulation is an effective and safe technique. Displacement of the electrode relative to the optimal stimulation site can lead to insufficient effect and sometimes to the need of operative electrode re-position. Objective: this study was aimed to analyse targeting accuracy of deep brain stimulation electrode implantation to subthalamic nucleus (stn) and globus pallidus internus (gpi). It detected possible causes of inaccuracy and prevalent shift to certain direction. Methods: targeting accuracy was analysed in 47 patients with parkinson´s disease (pd) and 11 patients with dystonia with bilateral implantation of deep brain stimulation electrodes between years 2009

									and 2016. Results: a shift of electrode to prevalent direction was observed on the left side to medial and posterior and on the right side to lateral direction. Greater shift was observed on the left side and in a higher angulation of trajectory laterally. Movement of the electrode, because of its traction in anchoring device, was identified as a possible factor for prevalent electrode shift. Calibration of stereotactic coordinates to correct prevalent shift was used. Conclusion: targeting inaccuracy is the result of accumulation of errors in individual steps of electrode implantation. Direction of the shift can be random or it can be toward a prevalent direction. A correction of prevalent error can prevent a suboptimal electrode placement. 1. An unclear number of patients with globus pallidus internus (gpi)-deep brain stimulation (dbs) for dystonia experienced a shift of the right electrode lateral to the planned trajectory and bending of the electrode with ¿medial convexity.¿ the authors reported an average vector error in the x-axis of 0.8 mm and 0.06 mm in the y-direction. On the left side of the brain the noted vector errors were 0.5 mm in the x-axis and 0.41 mm in the y-axis. Notably, the authors only described errors of greater than 2 mm as ¿potentially important.¿ it was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: date of event. Please note that this date is based off the date that the article was accepted for publication as the event dates were not provided in the published literature. The main component of the system involved in the reported event; other applicable components are: product id: neu_unknown_lead, lot# unknown, product type: lead. Kloc, m., kosutzka, z., steno, j., valkovic, p. Prevalent placement error of deep brain stimulation electrode in movement disorders (technical considerations). Bratisl lek listy. 2017; 118(11):647-653. Doi:

									10.4149/bll_2017_123. If information is provided in the future, a supplemental report will be issued.
3007566237-2018-00665	14/07/2017	Injury	MEDTRONIC NEUROMODULATION	06/03/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Migration or Expulsion of Device; Unstable; Material Deformation	Therapeutic Effects, Unexpected; No Code Available	Summary: background: deep brain stimulation is an effective and safe technique. Displacement of the electrode relative to the optimal stimulation site can lead to insufficient effect and sometimes to the need of operative electrode re-position. Objective: this study was aimed to analyse targeting accuracy of deep brain stimulation electrode implantation to subthalamic nucleus (stn) and globus pallidus internus (gpi). It detected possible causes of inaccuracy and prevalent shift to certain direction. Methods: targeting accuracy was analysed in 47 patients with parkinson´s disease (pd) and 11 patients with dystonia with bilateral implantation of deep brain stimulation electrodes between years 2009 and 2016. Results: a shift of electrode to prevalent direction was observed on the left side to medial and posterior and on the right side to lateral direction. Greater shift was observed on the left side and in a higher angulation of trajectory laterally. Movement of the electrode, because of its traction in anchoring device, was identified as a possible factor for prevalent electrode shift. Calibration of stereotactic coordinates to correct prevalent shift was used. Conclusion: targeting inaccuracy is the result of accumulation of errors in individual steps of electrode implantation. Direction of the shift can be random or it can be toward a prevalent direction. A correction of prevalent error can prevent a suboptimal electrode placement. Reported events: a patient with subthalamic nucleus (stn) deep brain stimulation (dbs) for parkinson's disease (pd) had a 3.6 mm shift of the left electrode, in the plane of the stimloc in a medial direction towards the center of the burr hole. This error reportedly required an operative repositioning of the electrode because of insufficient stimulation effect. Angulation and bending of the electrode was noticed intracranially. Specifically, they

									had 3 mm of electrode bending and a shift of the lead in the stimloc device. The authors added that there were several patients with errors close 2 mm with pneumocephalus on postoperative ct. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: it was not possible to ascertain specific device information from the article or to match the events reported with previously reported events. The main component of one of the systems involved in the reported events; other applicable components are: product id: neu_unknown_lead, lot# unknown, product type: lead. Product id: neu_stimloc_acc, lot# unknown, product type: accessory. Kloc, m., kosutzka, z., steno, j., valkovic, p. Prevalent placement error of deep brain stimulation electrode in movement disorders (technical considerations). Bratisl lek listy. 2017; 118(11):647-653. Doi: 10.4149/bll_2017_123 " if information is provided in the future, a supplemental report will be issued.
3007566237-2018-00667	14/07/2017	Malfunction	MEDTRONIC NEUROMODULATION	06/03/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Migration or Expulsion of Device; Unstable; Material Deformation	No Code Available	Summary: background: deep brain stimulation is an effective and safe technique. Displacement of the electrode relative to the optimal stimulation site can lead to insufficient effect and sometimes to the need of operative electrode re-position. Objective: this study was aimed to analyse targeting accuracy of deep brain stimulation electrode implantation to subthalamic nucleus (stn) and globus pallidus internus (gpi). It detected possible causes of inaccuracy and prevalent shift to certain direction. Methods: targeting accuracy was analysed in 47 patients with parkinson´s disease (pd) and 11 patients with dystonia with bilateral implantation of deep brain stimulation electrodes between years 2009 and 2016. Results: a shift of electrode to prevalent direction was observed on the left side to medial and posterior and on the right side to lateral direction. Greater shift

									was observed on the left side and in a higher angulation of trajectory laterally. Movement of the electrode, because of its traction in anchoring device, was identified as a possible factor for prevalent electrode shift. Calibration of stereotactic coordinates to correct prevalent shift was used. Conclusion: targeting inaccuracy is the result of accumulation of errors in individual steps of electrode implantation. Direction of the shift can be random or it can be toward a prevalent direction. A correction of prevalent error can prevent a suboptimal electrode placement. Reported events: 1. 8 patients with either stn-dbs for pd experienced a left shift of their electrode in the plane of the stimloc in a medial direction towards the center of the burr hole. The average error from the intended target in the x-axis was 1.875 mm, and an unknown error in the y-direction. The maximum observed error in the x-axis in this group was 2.4 mm and 5 patients had =2 mm. All of these patients also reportedly had between 0.4 and 1.5 mm of electrode bending and a shift of the lead in the stimloc device. Notably, the authors only described errors of greater than 2 mm as ¿potentially important,¿ and added that there were several patients with errors close 2 mm with pneumocephalus on postoperative ct. 2. 6 patients with either stn-dbs for pd experienced a left electrode shift of less than a 0.9 mm in the x-axis in the plane of the stimloc. The average error from the intended target in the x-axis was 0.45 mm and an unknown error in the y-direction. All of these patients also reportedly had between 0.5 and 1.3 mm of electrode bending. Notably, the authors only described errors of greater than 2 mm as ¿potentially important.¿ the 3. 3 patients with either stn-dbs for pd experienced a left electrode shift of between 0.1-1.4 mm in the x-axis and an unknown shift in the y-axis, with the definitive electrode close to the margins of the burr hole. The authors reported an average vector error in the y-

									axis of the left lead of 0.24 mm. Notably, the authors only described errors of greater than 2 mm as ¿potentially important.¿ 4. An unclear number of patients with either stn-dbs for pd experienced a shift of the right electrode lateral to the planned trajectory and bending of the electrode with ¿medial convexity.¿ the authors reported an average vector error in the x-axis of 0.55 mm and 0.24 mm in the y-direction. Notably, the authors only described errors of greater than 2 mm as ¿potentially important.¿ it was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: other applicable components are: product id: neu_unknown_lead, product type: lead. Product id: neu_stimloc_acc, product type: accessory. Product id: neu_unknown_lead, product type: lead. Product id: neu_unknown_lead, product type: lead. Product id: neu_unknown_lead, product type: lead. Kloc, m., kosutzka, z., steno, j., valkovic, p. Prevalent placement error of deep brain stimulation electrode in movement disorders (technical considerations). Bratisl lek listy. 2017; 118(11):647-653. Doi: 10.4149/bll_2017_123 . If information is provided in the future, a supplemental report will be issued.
9612186-2017-00007	30/06/2017	Malfunction	ELEKTA INSTRUMENT AB	28/02/2018	IWB	LEKSELL STEREOTACTIC SYSTEM	Fitting Problem	No Known Impact Or Consequence To Patient	It was reported by the customer that when carrying out a scanner, the leksell support fits into the examination table at the point where the scanner head is normally inserted. During the mobilisation of an anesthetised patient, users were able to see that the fixation system of the leksell support at the examination table was not locked, so the support was mobilised with the patient. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed. Email address updated. Establishment name updated. Resubmitting form 3500a due to an administrative error. It was requested by

									fda medwatch program department to re-submit the initial report as there was no record of initial report submission in emdr system. Correction ticked.
1723170-2018-03437	15/06/2017	Injury	MEDTRONIC NAVIGATION, INC. (LOUISVILLE)	13/07/2018	HAW	STEALTHSTATION TREON TREATMENT GUIDANCE SYSTEM	Imprecision	Intracranial Hemorrhage; Tissue Damage	The attached journal article was forwarded by medtronic representative. Article indicated the use of surgical imaging and navigation system. This is medical device report (mdr) one of two. See 1723170-2018-03438 for the other case. Intraoperative imaging must supply data that can be used for accurate stereotactic navigation. This information should be at least as accurate as that acquired from diagnostic imagers. The aim of this study was to compare the stereotactic accuracy of an updated compact intraoperative mri (imri) device based on a 0.15-t magnet to standard surgical navigation on a 1.5-t diagnostic scan mri and to navigation with an earlier model of the same system. Methods: the accuracy of each system was assessed using a water-filled phantom model of the brain. Data collected with the new system were compared to those obtained in a previous study assessing the older system. The accuracy of the new imri was measured against standard surgical navigation on a 1.5-t mri using t1-weighted (w) images. The mean error with the imri using t1w images was lower than that based on images from the 1.5-t scan (1.24 vs. 2.43 mm). T2w images from the newer imri yielded a lower navigation error than those acquired with the prior model (1.28 vs. 3.15 mm). Improvements in magnet design can yield progressive increases in accuracy, validating the concept of compact, low-field imri. Avoiding the need for registration between image and surgical space increases navigation accuracy. Manufacturer narrative: patient information was unavailable from the article. Event date is approximated. Date provided is when the journal article was published. Citation: markowitz, daniel; lin, dishen; salas, sussan; kohn, nina; schulder, michael. ¿compact intraoperative mri: stereotactic accuracy

									and future directions.¿ stereotactic and functional neurosurgery, 95, 2017: 197-204. The exact system information could not be determined as it was not provided. However, the system listed on this form was at the address listed in the article during the time some of the surgeries were completed. Device udi not provided as actual product used for this study is unknown. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. No further information provided in the journal article or from the authors. The author could not provide any additional information or insight as he was not at the site when the surgeries were performed. No request for service have been received from the customer regarding these events. No parts have been replaced or returned to the manufacturer for evaluation. Medtronic navigation is filing this mdr to ensure visibility to a patient event as a result of a procedure that utilized medtronic navigation's imaging guidance system and surgical navigation system. There is no allegation to suggest that medtronic navigation's device caused or contributed to the reported event. (b)(4).
1723170-2018-03438	15/06/2017	Injury	MEDTRONIC NAVIGATION, INC. (LOUISVILLE)	13/07/2018	HAW	STEALTHSTATION TREON TREATMENT GUIDANCE SYSTEM	Insufficient Information	Tissue Damage	The attached journal article was forwarded by medtronic representative. Article indicated the use of surgical imaging and navigation system. This is medical device report (mdr) two of two. See 1723170-2018-03437 for the other case. Intraoperative imaging must supply data that can be used for accurate stereotactic navigation. This information should be at least as accurate as that acquired from diagnostic imagers. The aim of this study was to compare the stereotactic accuracy of an updated compact intraoperative mri (imri) device based on a 0.15-t magnet to standard surgical navigation on a 1.5-t diagnostic scan mri and to navigation with an earlier model of the same system. Methods: the accuracy of each system was assessed using a water-filled phantom

									model of the brain. Data collected with the new system were compared to those obtained in a previous study assessing the older system. The accuracy of the new imri was measured against standard surgical navigation on a 1.5-t mri using t1-weighted (w) images. The mean error with the imri using t1w images was lower than that based on images from the 1.5-t scan (1.24 vs. 2.43 mm). T2w images from the newer imri yielded a lower navigation error than those acquired with the prior model (1.28 vs. 3.15 mm). Improvements in magnet design can yield progressive increases in accuracy, validating the concept of compact, low-field imri. Avoiding the need for registration between image and surgical space increases navigation accuracy. Manufacturer narrative: event date is approximated. Date provided is when the journal article was published. Citation: markowitz, daniel; lin, dishen; salas, sussan; kohn, nina; schulder, michael. ¿compact intraoperative mri: stereotactic accuracy and future directions.¿ stereotactic and functional neurosurgery, 95, 2017: 197-204. The exact system information could not be determined as it was not provided. However, the system listed on this form was at the address listed in the article during the time some of the surgeries were completed. Device udi not provided as actual product used for this study is unknown. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. No further information provided in the journal article or from the authors. The author could not provide any additional information or insight as he was not at the site when the surgeries were performed. No request for service have been received from the customer regarding these events. No parts have been replaced or returned to the manufacturer for evaluation. Medtronic navigation is filing this mdr to ensure visibility to a patient event as a result of a procedure that utilized medtronic

									navigation's imaging guidance system and surgical navigation system. There is no allegation to suggest that medtronic navigation's device caused or contributed to the reported event. (b)(4). Not returned by customer.
1723170-2018-03429	10/06/2017	Malfunction	MEDTRONIC NAVIGATION, INC. (LITTLETON)	13/07/2018	OXO	O-ARM 1000 IMAGING SYSTEM 3RD EDITION	Imprecision	No Known Impact Or Consequence To Patient	The attached journal article was forwarded by medtronic representative. Article indicated the use of image guidance system. Objective: to determine the accuracy of intraoperative computed tomography (ict) in localizing deep brain stimulation (dbs) electrodes by comparing this modality with postoperative magnetic resonance imaging (mri). Background: optimal lead placement is a critical factor for the outcome of dbs procedures and preferably confirmed during surgery. Ict offers 3-dimensional verification of both microelectrode and lead location during dbs surgery. However, accurate electrode representation on ict has not been extensively studied. Methods: dbs surgery was performed using the leksell stereotactic g frame. Stereotactic coordinates of 52 dbs leads were determined on both ict and postoperative mri and compared with intended final target coordinates. The resulting absolute differences in x (medial-lateral), y (anterior-posterior), and z (dorsal-ventral) coordinates (x, y, and z) for both modalities were then used to calculate the euclidean distance. Results: euclidean distances were 2.7 ± 1.1 and 2.5 ± 1.2 mm for mri and ict, respectively (p = 0.2). Conclusion: postoperative mri and ict show equivalent dbs lead representation. Intraoperative localization of both microelectrode and dbs lead in stereotactic space enables direct adjustments. Verification of lead placement with postoperative mri, considered to be the gold standard, is unnecessary. Manufacturer narrative: patient identifier and weight were unavailable from the attached journal article or by the authors. Patient age and patient sex not made available the attached journal article or by the authors. The article reports that the

									mean patient age was 61 years old and the consisted of male patients in the study. Therefore (b)(6) and male were used. Event date is approximated. Date provided is when the journal article was published. Citation: bot m, munckhof pvd, bakay r, et al. (2017). Accuracy of intraoperative computed tomography during deep brain stimulation procedures: comparison with postoperative magnetic resonance imaging. Stereotactic and functional neurosurgery, 95:183-188. Doi: 10.1159/000475672. The exact system information could not be determined as it was not provided. However, the system listed on this form was at the address listed in the article during the time some of the surgeries were completed. Device udi not provided as actual product used for this study is unknown. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. No further information provided in the journal article or from the authors. The author could not provide any additional information or insight as he was not at the site when the surgeries were performed. No request for service have been received from the customer regarding these events. No parts have been replaced or returned to the manufacturer for evaluation. Medtronic navigation is filing this mdr to ensure visibility to a patient event as a result of a procedure that utilized medtronic navigation's imaging system. There is no allegation to suggest that medtronic navigation's device caused or contributed to the reported event.
1723170-2020-03358	01/04/2017	Injury	MEDTRONIC NAVIGATION, INC	21/12/2020	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Swelling/ Edema	Citation: malignant cerebral edema associated with radiation and laser ablation for brain tumors maraka s.; karam a.; walbert t.; lee i. Neurology (2017) 88:16 supplement 1. Date of publication: 1 apr 2017 objective: our aim was to investigate whether laser interstitial thermal therapy (litt) and radiotherapy (rt) in close succession to each other induced worsening symptomatic cerebral edema.

									Background: litt is an image-guided technique that uses high temperatures to ablate pathological tissue and is commonly used for rec urrent or deeply seated tumors. Some patients are also treated with adjuvant rt. Design/methods: we retrospectively reviewed records of patients who underwent visualase litt at our institution (march 2014-february 2016) and rt less than 60 days apart. Magnetic resonance imaging (mri) brain and clinical information were reviewed at three time points (pre-treatment, post-litt, and post-rt). Data is presented as a median (range). Results: we studied 10 patients with brain tumor; 8 glioblastoma, 1 anaplastic astrocytoma, and 1 metastasis, 6 (60%) were men, age at treatment was 61.5 (52-76) years. There were 6 cortical versus 4 subcortical tumors. The majority of patients underwent litt followed by rt except for 2. Time interval between litt and rt was 24 (9-43) days. Increased ablation volume post-litt compared to pre-operatively tumor volume was seen in 9 patients with a mean enlargement of 15% overall. Rt treatments included external beam fractionated radiation treatment (ebrt) (n=8), ebrt with stereotactic radiosurgery (srs) (n=1), and fractionated srs (n=1). Pre-treatment mri showed cerebral edema in 9 patients. Post-litt mri showed worsening cerebral edema in 4 patients, 3 were symptomatic (1 had disease progression). One patient who received rt prior to litt had asymptomatic cerebral edema post-rt that improved post-litt. Post-rt mri showed worsening symptomatic cerebral edema in a patient who had ebrt+srs. Avastin was used in 1 patient and 2 patients had prolonged use of steroids (>65 days). Conclusions: litt and rt treatment can induce symptomatic cerebral edema which can be effectively managed with steroids and/or avastin. Treating physicians need to be cognizant of this risk. Reported event(s): post treatment mri showed worsening cerebral edema in 4 patients; 3 were symptomatic (1 haddisease

									progression). Manufacturer narrative: patient age is the mean value of patients in the abstract. Patient gender is the majority value of patients in the study. Patient weight not available from the site. Event date is the publication date of the abstract. Device lot number, or serial number, unavailable. Facility and address not populated as the facility was not provided in the abstract provided. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
3007566237-2019-00596	23/01/2017	Injury	MEDTRONIC NEUROMODULATION	12/03/2019	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Malposition of Device	Dysphagia/ Odynophagia; Neurological Deficit/Dysfunction; Therapeutic Effects, Unexpected; Ambulation Difficulties; No Code Available	Park, s.c. , lee, c.s. , kim, s.m., choi, e.j., lee, d.h., lee, j.k. Magnetic resonance imaging distortion and targeting errors from strong rare earth metal magnetic dental implant requiring revision. Turkish neurosurgery. 29(1):134-140, 2019 doi:10.5137/1019-5149.jtn.19327-16.1 summary: recently, the use of magnetic dental implants has been re-popularized with the introduction of strong rare earth metal, for example, neodymium, magnets. Unrecognized magnetic dental implants can cause critical magnetic resonance image distortions. We report a case involving surgical failure caused by a magnetic dental implant. A (b)(6) year-old man underwent deep brain stimulation for medically insufficiently controlled parkinson¿s disease. Stereotactic magnetic resonance imaging performed for the first deep brain stimulation showed that the overdenture was removed. However, a dental implant remained and contained a neodymium magnet, which was unrecognized at the time of imaging; the magnet caused localized non-linear distortions that were the largest around the dental magnets. In the magnetic field, the subthalamic area was distorted by a 4.6 mm right shift and counter clockwise rotation. However, distortions were visually subtle in the operation field and small for distant stereotactic markers, with approximately

									1¿2 mm distortions. The surgeon considered the distortion to be normal asymmetry or variation. Stereotactic marker distortion was calculated to be in the acceptable range in the surgical planning software. Targeting errors, approximately 5 mm on the right side and 2 mm on the left side, occurred postoperatively. Both leads were revised after the removal of dental magnets. Dental magnets may cause surgical failures and should be checked and removed before stereotactic surgery. Our findings should be considered when reviewing surgical precautions and making distortion-detection algorithm improvements. Reported events: a (b)(6) year-old male patient with an 18-year history of parkinson¿s disease had been treated with medications. The patient was indicated for dbs. Preoperatively, the levodopa equivalent dose was 1960 mg and the patient was taking levodopa, sustained release levodopa, ropinirole 12 mg, and amantadine 100 mg. Preoperatively, the unified parkinson¿s disease rating scale part iii scores for medication off and on were 56 and 28, respectively, with 50% improvements in the levodopa challenge test. Quadripolar dbs electrodes were bilaterally used for stn. In the preoperative stereotactic imaging, distortions near the magnetic implants were severe with image deformation and signal loss. Distortions in areas closer to the dental magnets were as large as 11¿22 mm in the lower nasal septums. In the axial image at the subthalamic area level, distortion involving a shift of approximately 4.6 mm occurred. However, image shape changes were unrecognizable. Bony structure distortions were confused with normal nasal septal deviations and asymmetry at this level. The image distortion in the target area may have been aggravated by stereotactic marker shifts, which may have re sulted in a larger total error of = 5.9 mm. This distortion caused large errors at postoperative lead locations, which were 5.4 mm on the right

									side and 2.7 mm on the left side from the intended targets. In the initial operation, we routinely inserted 3 microelectrodes initially and inserted additional microelectrodes when needed. Therefore, anterior, center, and lateral electrodes were initially inserted. Right-side microelectrode recordings were obtained at the point of -10 mm from the target. Because stn multiunit activities and irregular spikes were poor in three tracks, an additional two tracks (medial and posterior) were recorded. Among the five tracks, stn signals were found only in the anterior and posterior microelectrodes. During anterior electrode stimulation, no symptom improvement was observed. Symptoms improved with the bradykinesia and the rigidity grade decreased from 2 to 0 at 2 v, 60 ¿s, and 130 hz intraoperative posterior track stimulation. From 3 v, facial dystonia appeared, and the stimulation voltage was not increased further. However, there were no tracks better than the posterior track, and the electrode was inserted into the posterior track. The electrode tip was located at the target when checked by intraoperative radiography with a c-arm. For the left side, stn microelectrode recording signals and symptom improvement from macrostimulations were best in the lateral track. A lead was inserted into the lateral track. Because the direction of distortion was toward the right side, the selection of the lateral track (the electrode at the furthest left) was also correct and the approximate 4-mm deviation caused by the distortion was reduced by approximately 50%. No hemorrhagic complications occurred. Postoperative stimulation settings to minimize side effects were right 0¿ electrode, 3.5 v, 90 ¿s, 90 hz, and left 2+1¿ electrode, 90 ¿s, and 90 hz. Initially after the first dbs, levodopa equivalent doses were 1360 mg. At 10 months after the first operation the levodopa equivalent dose increased to 1727 mg. We speculated that the stimulation-induced swallowing

									difficulty and drooling are related to the right pyramidal tract stimulations from the right electrode location close to these structures. Freezing of gait was not improved by the stimulation and sometimes worsened. After the failure of the first surgery, the authors suspected mri distortions from a dental implant as the cause. After removal, the distortions were almost completely reduced. Three tracks, including the anterior, center, and lateral tracks, were used for bilateral microelectrode recordings and macrostimulations. The stn signals were better than those at the first operations. For both sides, the anterior tracks were selected on the basis of intraoperative microelectrode recordings and symptom improvement caused by stimulation. Both leads were revised. Postopera tively, with stimulation, the tremor grade was 0, the bradykinesia and rigidity grades improved from 2 to 0, gait disturbance was grade 1, and stooped posture was grade 2. After the revision, swallowing difficulty and drooling side effects disappeared, and the patient¿s global impression scale of improvement for the revision was 1+. Medication was reduced to 600 mg levodopa equivalent dose. Three months after the revision, the stimulation frequencies were lowered from 130 hz to 80 hz, which resulted in partial improvement in freezing of gait in the lower frequency stimulation suggested in the literature. The patient was followed for 15 months after the revision. The medication was increased to 900 mg per day in the last follow-up. Manufacturer narrative: concomitant medical products: product id: 3389, lot# unknown, product type: lead. Product id: 3389, lot# unknown, product type: lead. Other relevant device(s) are: product id: 3389, serial/lot #: unknown. Product id: 3389, serial/lot #: unknown. If information is provided in the future, a supplemental report will be issued.
1723170-2019-02816	05/01/2017	Injury	MEDTRONIC NAVIGATION, INC	31/05/2019	GEX	VISUALASE GUIDED	Adverse Event	Seizures	Citation: allen l. Ho, md, eric. S. Sussman, md, arjun v. Pendarkar, md, scheherazade

						LASER ABLATION SYSTEM	Without Identified Device or Use Problem		le, md, allessandra mantovani, md, alaine c. Keebaugh, phd, david r. Drover, md, gerald a. Grant, md, max wintermark, md, mas, mba, and casey h. Halpern, md improved operative efficiency using a real-time mri-guided stereotactic platform for laser amygdalohippocampotomy. J neurosurg 128:1165-1172, 2018. Summary: objective mr-guided laser interstitial thermal therapy (mrglitt) is a minimally invasive method for thermal destruction of benign or malignant tissue that has been used for selective amygdalohippocampal ablation for the treatment of temporal lobe epilepsy. The authors report their initial experience adopting a real-time mri-guided stereotactic platform that allows for completion of the entire procedure in the mri suite. Methods between october 2014 and may 2016, 17 patients with mesial temporal sclerosis were selected by a multidisciplinary epilepsy board to undergo a selective amygdalohippocampal ablation for temporal lobe epilepsy using mrglitt. The first 9 patients underwent standard laser ablation in 2 phases (operating room [or] and mri suite), whereas the next 8 patients underwent laser ablation entirely in the mri suite with the clearpoint platform. A checklist specific to the real-time mri-guided laser amydalohippocampal ablation was developed and used for each case. For both cohorts, clinical and operative information, including average case times and accuracy data, was collected and analyzed. Results there was a learning curve associated with using this real-time mri-guided system. However, operative times decreased in a linear fashion, as did total anesthesia time. In fact, the total mean patient procedure time was less in the mri cohort (362.8 ± 86.6 minutes) than in the or cohort (456.9 ± 80.7 minutes). The mean anesthesia time was significantly shorter in the mri cohort (327.2 ± 79.9 minutes) than in the or cohort (435.8 ± 78.4 minutes, p = 0.02). Conclusions the real-time mri platform for mrglitt can be adopted in an

									expedient manner. Reported events: or cohort ((b)(4)). Post-operative transient partial third cranial nerve palsy and aseptic meningitis. A self-limited ileus. Persistent headaches in a single patient with a prior migraine disorder. A seizure within three months of the procedure. Mri cohort ((b)(4)). A seizure within three months of the procedure. Manufacturer narrative: patient age is mean average of patients from the mri cohort in study. Patient gender is the majority value from the mri cohort. Patient weight not available from the site. Event date is the accepted date of the article by the publication. No parts have been received by the manufacturer for evaluation. If information is provided in the future, a supplemental report will be issued.
1723170-2019-02817	05/01/2017	Injury	MEDTRONIC NAVIGATION, INC	31/05/2019	GEX	VISUALASE GUIDED LASER ABLATION SYSTEM	Adverse Event Without Identified Device or Use Problem	Headache; Nerve Damage; Seizures; Meningitis	Citation: allen l. Ho, md, eric. S. Sussman, md, arjun v. Pendarkar, md, scheherazade le, md, allessandra mantovani, md, alaine c. Keebaugh, phd, david r. Drover, md, gerald a. Grant, md, max wintermark, md, mas, mba, and casey h. Halpern, md improved operative efficiency using a real-time mri-guided stereotactic platform for laser amygdalohippocampotomy. J neurosurg 128:1165-1172, 2018. Summary: objective mr-guided laser interstitial thermal therapy (mrglitt) is a minimally invasive method for thermal destruction of benign or malignant tissue that has been used for selective amygdalohippocampal ablation for the treatment of temporal lobe epilepsy. The authors report their initial experience adopting a real-time mri-guided stereotactic platform that allows for completion of the entire procedure in the mri suite. Methods between october 2014 and may 2016, 17 patients with mesial temporal sclerosis were selected by a multidisciplinary epilepsy board to undergo a selective amygdalohippocampal ablation for temporal lobe epilepsy using mrglitt. The first 9 patients underwent standard laser ablation in 2 phases (operating room [or] and mri suite), whereas the next 8 patients underwent laser ablation entirely in the mri

									suite with the clearpoint platform. A checklist specific to the real-time mri-guided laser amydalohippocampal ablation was developed and used for each case. For both cohorts, clinical and operative information, including average case times and accuracy data, was collected and analyzed. Results there was a learning curve associated with using this real-time mri-guided system. However, operative times decreased in a linear fashion, as did total anesthesia time. In fact, the total mean patient procedure time was less in the mri cohort (362.8 ± 86.6 minutes) than in the or cohort (456.9 ± 80.7 minutes). The mean anesthesia time was significantly shorter in the mri cohort (327.2 ± 79.9 minutes) than in the or cohort (435.8 ± 78.4 minutes, p = 0.02). Conclusions the real-time mri platform for mrglitt can be adopted in an expedient manner. Reported events: or cohort ((b)(4)). Post-operative transient partial third cranial nerve palsy and aseptic meningitis. A self-limited ileus. Persistent headaches in a single patient with a prior migrane disorder 4. A seizure within three months of the procedure. Mri cohort (pe: a seizure within three months of the procedure. Manufacturer narrative: patient age is mean average of patients from the or cohort in study. Patient gender is the majority value from the or cohort. Patient weight not available from the site. Event date is the accepted date of the article by the publication. No parts have been received by the manufacturer for evaluation. If information is provided in the future, a supplemental report will be issued.
1723170-2020-03406	01/01/2017	Injury	MEDTRONIC NAVIGATION, INC	23/12/2020	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage; Paresis; Numbness	Stereotactic laser ablation of symptomatic cavernous malformations: imaging and clinical outcomes malcolm j.; stern m.; drane d.; gross r.; willie j. Stereotactic and functional neurosurgery (2017) 95 supplement 1 (427). Date of publication: 2017 embase link https://www.embase.com/search/results?subaction=viewrecord & id=l617437086 & from=export introduction: mri-guided laser

									interstitial thermal therapy (stereotactic laser ablation, sla) is a novel, minimally invasive treatm ent of symptomatic cerebral cavernous malformations (ccms). We describe clinical/imaging outcomes of the largest series of sla for ccms to date. Methods: twenty consecutive patients with presumed ccm and medically refractory epilepsy, intractable headaches, or aggressive natural history (bleeding, neurological deficit) underwent anatomic mri. Epilepsy patients also underwent functional mri, eeg, pet, and n europsychometric testing. Patients underwent stereotactic twist-drill craniostomy and insertion of a salinecooled laser fiber delivering 980-nm diode laser energy (visualase, medtronic); one large thalamic ccm underwent 3 distinct stereotactic trajectories entering the ccm at same point to minimize risk of hemorrhage. Mri provided accuracy confirmation and near-real-time thermography. Patients underwent clinical and imaging follow-up. Results: ccm locations were temporal (11), frontal (4), parietal (2), thalamic (2), and pallidal (1). Complications occurred only in subcortical cases, and included transient scalp numbness (thalamus, n=1), transient hemiparesis associated with hemorrhage (pallidum, n=1), and worsening hemiparesis persistent at early follow-up (thalamus, n=1). Eleven of 12 epileptic patients with >1-year follow-up were seizure-free (92% engel class 1 outcome) from ablation alone. All 6 remaining epilepsy patients with 1-year follow-up were improved. All ten ccms with postoperative imaging >6 mo revealed clear involution. Conclusion: minimally invasivemr-guided ablation of symptomatic ccms is an effective alternative to open resection. Neurological complications were location-dependent. Operative hemorrhage rate was 1/20 (5%) overall, and 0/17 for cortical cases. Additional experience and longer follow-up are needed. Reported event(s): 1. One report of hemiparesis associated with hemorrhage (pallidum case)

									2. One report of worsening hemiparesis persistant at early follow up (thalamus case). Manufacturer narrative: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Includes the article citation. If information is provided in the future, a supplemental report will be issued.
3007566237-2018-02125	01/01/2017	Injury	MEDTRONIC NEUROMODULATION	17/07/2018	MRU	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Malposition of Device; Adverse Event Without Identified Device or Use Problem	Cerebrospinal Fluid Leakage; Hematoma; Post Operative Wound Infection	Summary: objective: deep brain stimulation (dbs) has been shown to be efficacious in the treatment of primary dystonia (idiopathic and inherited dystonia). There is less experience in, however, secondary dystonia (acquired dystonia). Since patients with secondary dystonia, who are often more disabled, may be more vulnerable to postoperative complications we aimed to investigate the 30-day morbidity in a large cohort of patients with secondary dystonia operated over a period of 19 years. Methods: from 1997 until 2016, a total of 49 patients (27 women and 22 men; mean age 43,5 years (range 13-77)) with secondary dystonia underwent dbs with electrodes implanted either in the thalamic nucl. Ventralis intermedius (vim) or the posteroventral lateral globus pallidus internus (gpi). Most frequent cause of for dystonia was cerebral palsy in 17 patients. Results: there were no intraoperative complications or complications in the early postoperative period related to surgery. The electrode location was corrected in 2 instances. Two patients developed a wound infection, one patient had a subdural hematoma and subcutaneous collection of cerebrospinal fluid (csf). Three weeks after dbs the subdural hematoma and csf resolved. Conclusion: the 30-day morbidity rate in dbs for secondary dystonia is comparable to th at in primary dystonia. Dbs surgery may be offered to patients with secondary dystonia without concerns about higher morbidity. Reported events: 2 patients with dbs for secondary dystonia experienced a wound infection. Two (2) patients with deep brain stimulation (dbs)

									for secondary dystonia underwent surgery to correct the lead location. One (1) patient with dbs for secondary dystonia experienced a subdural hematoma and collection of cerebrospinal fluid (csf) which resolved by 3 weeks after implant. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued. Manufacturer narrative: age/date of birth. This value is the average age of the patients reported in the article as specific patients could not be identified. Sex. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Date of event. Please note that this date is based off of the year of publication of the article as the event dates were not provided in the published literature. The main component of the system. Other relevant device(s) are: product id: neu_unknown_lead, serial/lot #: unknown. Wloch, a., mahmoud, a., saryyeva, a., blahak, c., wolf, m., schrader, c., runge, j., krauss, j.k. Complications of deep brain stimulation for secondary dystonia in the early postoperative period (30-day morbidity): experience in 49 patients. Stereotactic and functional neurosurgery (2017) 95 supplement 1 (240). If information is provided in the future, a supplemental report will be issued.
3007566237-2018-02145	01/01/2017	Injury	MEDTRONIC NEUROMODULATION	18/07/2018	MRU	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Malposition of Device; Positioning Problem	Neurological Deficit/Dysfunction; Therapeutic Response, Decreased; No Code Available	Summary/reported event: an (b)(6) boy with globus pallidus internus (gpi) deep brain stimulation (dbs) for treatment of dyt-6 positive generalized dystonia since 2 years prior developed severe dystonic storm. After implantation of dbs electrodes at (b)(6) his condition had improved for more than 2 years. Upon the occurrence of dystonic storm, re-programing of dbs could not ameliorate the severe status dystonics. Only sedation with high dose benzodiazepines, baclofen, gabapentin and trihexyphenidyl resulted in transient

									improvement. Results: the bmfdr motor score on admission was 138. Mri imaging showed positioning of the dbs electrodes in the globus pallidus internus (gpi), however, more lateral and posterior than at the usual target. It was decided to reimplant the gpi electrodes and to implant thalamic vim electrodes in addition. Early postoperatively this resulted in marked and immediate improvement of dystonic storm (bmfdrs 100,5). At 12-month follow-up, there was remarkable benefit and the patient could walk and attend school without medication. Conclusion: dystonic storm may develop despite periods of beneficial response to pallidal dbs for several years. If electrodes are no optimally placed in the posteroventral lateral gpi, repositioning should be considered, which might not only abate status dystonics, but also provide lasting benefits. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. See attached literature article. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued. Manufacturer narrative: please note that this date is based off of the year of publication of the article as the event dates were not provided in the published literature. Information references the main component of the system. Other relevant device(s) are: product id: neu_unknown_lead. Ascencao, l.c., van egmond, m.e., oterdoom, m., saryyeva, a., runge, j., abdallat, m., tijssen, m.a.j., krauss, j.k. Improvement of dystonic storm after relocation of pallidal electrodes in dyt-6 positive generalized dystonia. Stereotactic and functional neurosurgery (2017) 95 supplement 1 (201). If information is provided in the future, a supplemental report will be issued. (b)(4).
1723170-2018-00898	26/12/2016	Injury	MEDTRONIC NAVIGATION, INC. (LOUISVILLE)	27/02/2018	HAW	STEALTHSTATION S7 SYSTEM	Imprecision	Injury; Iatrogenic Source	The attached journal article was forwarded by a medtronic representative. Use of the navigation system was reported. The study was performed between december 2007

									and february 2015 for 38 consecutive patient with 40 cystic metastases underwent ommaya reservoir implantation at our institution. Patient age ranged from 42 to 86 years (median: 62.5). The number of male patients was 20 (52.6%). Ultrasound echography was used to insert the tube. For cases with a deep or eloquent tumor location, surgical navigation was used include the surgical navigation system was used to assure safety and accuracy. For all 40 metastatic lesions, 17 (42.5%) had tube tips that were located at the center (group a), 21 were (52.5%) deep (group b), and 2 were (5%) shallow (group c). Compared to group b (p = 0.029) and group c (p = 0.012) (fig. 4). Additional surgical procedures (reservoir re-implantation or tumor removal by craniotomy) occurred in 3 cases in group b and in 2 cases in group c due to inadequate volume reduction. There were no additional surgeries performed in group a. There were no significant complications (i.e., hemorrhage, new neurologic deficits, infection, tract dissemination) as a result of these additional surgical procedures in groups b and c. In conclusion, author stated that in order to ensure adequate volume reduction using an ommaya reservoir in the treatment of cystic brain metastases prior to stereotactic radiosurgery, the tip of the reservoir tube should be placed at the center of the tumor cyst. Manufacturer narrative: patient age and patient sex were not available by the journal article authors. Estimated based on the journal article information. There were 38 patients participated this study, and 20 patients were male. Average age was reported as 62.5 years old. Therefore, male and 63 years old were used. Event date is approximated. Date provided is when the journal article was accepted. Citation: akito oshima, toshikazu kimura, atsuya akabane, and kensuke kawai. Optimal implantation of ommaya reservoirs for cystic metastatic brain tumors preceding gamma knife radiosurgery. Journal of clinical

									neuroscience 39 (2017) 199-202. Http://dx.doi.org/10.1016/j.jocn.2016.12.042 the exact system information could not be determined as it was not provided. However, the system listed on this form was at the address listed in the article during the time some of the surgeries were completed. Device udi not provided as this product is no longer manufactured multiple attempts have been made to obtain additional information. No further information provided in the journal article or from the authors. The author could not provide any additional information or insight as he was not at the site when the surgeries were performed. No request for service have been received from the customer regarding these events. No parts have been replaced or returned to the manufacturer for evaluation. Medtronic navigation is filing this mdr to ensure visibility to a patient event as a result of a procedure that utilized medtronic navigation's image guidance system. There is no allegation to suggest that medtronic navigation's device caused or contributed to the reported event. Author indicated there were no catheter malfunction, early infection or death.
1723170-2018-04896	15/12/2016	Injury	MEDTRONIC NAVIGATION, INC. (LOUISVILLE)	20/09/2018	HAW	STEALTHSTATION TREON TREATMENT GUIDANCE SYSTEM	Adverse Event Without Identified Device or Use Problem	Infarction, Cerebral; Visual Impairment; Meningitis; No Code Available; Hydrocephalus	The journal article was forwarded by medtronic representative. Article indicated the use of surgical navigation system. Objective: we report surgical results and complications of endoscopic endonasal skull base surgery for giant pituitary adenomas. Methods: this study included 34 pituitary adenomas >40 mm treated by endoscopic endonasal skull base surgery between 2002 and 2015. Removal rates, symptoms, and complications were analyzed by direction of tumor extension. Results: average tumor size was 45.5 mm. Near-total resection was achieved in 16 of 34 (47.1%) cases. Near-total resection was achieved significantly more often in anterior extension types and round tumor in superior extension types compared with multiple extension types. The average residual amount in 18 partial

									resection cases was 30.2% of preoperative volume, with no significant difference between groups. Regrowth after partial resection occurred in 8 cases, but repeated surgery or stereotactic radiotherapy controlled tumor growth and improved symptoms. Postoperative improvement of visual field deficits was achieved in 23 of 25 (92.0%) cases. Postoperative complications included visual deterioration (n [1), cerebrospinal fluid leakage (n [2), and cerebral infarction secondary to perforator injury (n [2). Symptomatic intratumoral hemorrhage occurred in 1 multiple extension type. Conclusions: endoscopic endonasal skull base surgery enables less invasive and safer removal of various extension types of giant pituitary adenomas. Preservation of visual function is essential. Two-stage surgery or partial resection with additional treatments is possible without complications if a sufficient amount of resection is performed. In cases in which insufficient resection may be expected, alternative treatment, including combined simultaneous resection, should be considered. Reported adverse event : 4 new anterior hormonal deficiency, 7 permanent diabetes insipidus, 2 csf leakage , 2 meningitis , 1 visual deterioration , 2 cerebral infarction , 1 hydrocephalus. Manufacturer narrative: patient identifier and weight were unavailable from the attached journal article or by the authors. Patient age and patient sex not made available the attached journal article or by the authors. The article reports that the mean patient age was 59 and the consisted of female patients in the study. Therefore 59 years old and female were used. Event date is approximated. Date provided is when the journal article was accepted. Citation: yano s, hide t, & shinojima n. Efficacy and complications of endoscopic skull base surgery for giant pituitary adenomas. World neurosurg. (2017) 99:533-542. Http://dx.doi.org/10.1016/j.wneu.2016.12.

									068. The exact system information could not be determined as it was not provided. However, the system listed on this form was at the address listed in the article during the time some of the surgeries were completed. Device udi not provided as actual product used for this study is unknown. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. No further information provided in the journal article or from the authors. The author could not provide any additional information or insight as he was not at the site when the surgeries were performed. No request for service have been received from the customer regarding these events. No parts have been replaced or returned to the manufacturer for evaluation. Medtronic navigation is filing this mdr to ensure visibility to a patient event as a result of a procedure that utilized medtronic navigation's surgical navigation system. There is no allegation to suggest that medtronic navigation's device caused or contributed to the reported event. Device not returned by customer.
3007566237-2019-02143	11/10/2016	Injury	MEDTRONIC NEUROMODULATION	17/10/2019	OLM	IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Emotional Changes; Irritability	Doshi pk. Mania induced by stimulation following dbs of the bed nucleus of stria terminalis for obsessive-compulsive disorder. Stereotact funct neurosurg. 2016; 94(5):326. 10.1159/000449066. Summary: anterior capsulotomy and stimulation of the anterior limb of the capsule have been used to treat intractable obsessive-compulsive disorder (ocd). On longer-term follow-up of patients undergoing anterior limb of internal capsule stimulation it was found that the responders had the electrode closure to the bed nucleus of the stria terminalis (bst). Reported events: 1. One patient became very active after implant. Initially, the patient was very happy to conclude a business deal whilst still in the hospital. Over the next two or three days, the patient's behavior became even more 'energetic'. They would stay awake through

									the night and go out of the ward and smoke cigarettes. The psychiatrist attending interpreted this as a mania, but the family told them that this was something the patient expressed in the past and not to overreact to it. The drugs were appropriately adjusted to calm the patient down. Following discharge, the patient developed a full-blown mania. They became very aggressive and had to be virtually restrained. The patient was brought to the police station to ensure the safety of other family members. When the patient was brought back, they burnt down a section of the house in retribution. The patient was then taken to a psychiatric center, where they were hospitalized. The implantable neurostimulator (ins) was turned off and this brought an immediate resolution to the mania symptoms, but the ocd returned. Every time the ins was switched on, the mania returned. On readmission, they switched off the implantable pulse generator and started slowly stimulating one side at a time, titrating the symptoms. It was found that channel 1 was the side responsible for his mania symptoms, as when they stimulated to 2.5 v and above, though the ocd symptoms improved, the mania returned. On stimulating channel 2 there was a good response to his ocd symptoms at around 4 v, keeping all other parameters the same. Therefore they finally set the patient up on 1¿, 2+, 90/130/0.5 in channel 1 and 9¿, 10+, 90/130/3.5 in channel 2, with good control of the patient's ocd without mania. The following device specifics were provided: lead model 3389. Manufacturer narrative: doshi pk. Mania induced by stimulation following dbs of the bed nucleus of stria terminalis for obsessive-compulsive disorder. Stereotact funct neurosurg. 2016; 94(5):326. 10.1159/000449066. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. It was not possible to ascertain specific device

									information from the article or to match the events reported with previously reported events. Correspondence has been sent to the author of the article inquiring about individual patient information and additional information regarding the reported events. If information is provided in the future, a supplemental report will be issued. (b)(4).
3007566237-2018-00686	11/10/2016	Death	MEDTRONIC NEUROMODULATION	07/03/2018	MHY	SOLETRA	Adverse Event Without Identified Device or Use Problem	Seizures; Therapeutic Response, Decreased; Cognitive Changes; Cancer	Summary/reported events: a (b)(6) -year-old man with bilateral subthalamic nucleus (stn) deep brain stimulation (dbs) for parkinson's disease (pd) experienced significant improvement in motor fluctuation and levodopa induced dyskinesia after the start of therapy and the patient was satisfied with the results of the therapy, but 7 years after the start of therapy their family complained of worsening of the patient¿s cognition and attenuation of the stimulation effects. During this period, the patient experienced general convulsion for the first time. The patient¿s skull x-ray and mr imaging showed a brain tumor occurring bilaterally around the dbs electrodes. A gd-enhanced mr image shows the brain tumor occurring from the subcortical white matter of the left frontal lobe and extending to the subcortical white matter of the right frontal lobe passing through the corpus callosum. This is a typical invasion pattern of glioblastoma multiforme (gbm), that is, the butterfly type. The brain tumor existed from the subcortical white matter to the corpus callosum bilaterally around the dbs lead, but did not extend in the direction of the contact points of the lead. In (b)(6) of 2008, the tumor in the left frontal lobe was partially removed, and its histopathological analysis confirmed it to be gbm. Radiation therapy and chemotherapy were started, but the growth of gbm continued, and we lost this patient 2 months after partial tumor resection. The authors observed that the glioblastoma did not extend toward the contact points of the lead and they speculated that dbs stimulation did not induce development of glioma, and that it

									may in fact have inhibited the extension of the cancer in this direction. They added that the glioblastoma exhibited a typical extension pattern of the ¿butterfly-type invasion.¿ in light of these observations they speculated that the glioblastoma occurred spontaneously but ultimately noted that there remained ¿a very slight possibility that continuous electrical brain stimulation itself induced the development of the brain glioma.¿ the authors reported the patient was implanted with a soletra (model 7426) neurostimulator. However, it was not possible to ascertain any additional specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: please note that the actual date of death was not provided in the literature article; this date is based on the date of article publication. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Information references the main component of the system involved in the reported event; other applicable components are: product id: neu_unknown_lead, lot# unknown, product type: lead. Yamamoto, t., fukaya, c., obuchi, t., watanabe, m., ohta, t., kobayashi, k., oshima, h., yoshino, a. Glioblastoma multiforme developed during chronic deep brain stimulation for parkinson disease. Stereotactic funct neurosurg. October 2016:320-325. Doi:10.1159 /000448925. If information is provided in the future, a supplemental report will be issued.
3004209178-2020-12849	07/04/2016	Injury	MDT PUERTO RICO OPERATIONS CO	27/07/2020	LKK	SYNCHROMED II	Migration or Expulsion of Device	No Known Impact Or Consequence To Patient	Information was received from a healthcare professional via operative notes from (b)(6)2016 regarding a patient receiving an unknown medication via an implanted pump. On (b)(6)2020 it was reported that the patient¿s preoperative and postoperative diagnoses were, ¿retained malfunctioning pain pump, l4-5 and l5-s1 degenerative disc disease and degenerative joint disease with listhesis, instability, and

									pseudoclaudication symptoms¿. No infusion system related symptoms were reported. The procedure performed was noted to be, ¿removal of retained malfunctioning pain pump and pain pump catheter, followed by l4-5, l5-s1 redo decompressive laminectomies with bilateral medial facetectomies and foraminotomies, bilateral l4, l5, s1, and segmental fixation and fusion using pedicle screws and rods with autograft bone, harvesting morselized autograft bone, microsurgical techniques, o-arm stereotactic localization¿. The indication for the procedure was noted to be, ¿this patient has had difficulty with chronic pain. She has had previous lumbar discectomies on 2 occasions remotely. She has had a pain pump inserted for pain control, which is no longer functional. Her workup reveals the above finding. She has failed long-term conservative management and has elected to proceed with surgical treatment¿. During the procedure, it was found that the catheter had become dislodged, and was only at the level of the spinous process and did not extend into the spinal canal. Once the pump and catheter were removed, the physician proceeded with the remainder of the scheduled lumbar procedures. It was noted that there were no intraoperative complications and upon completion of the procedure the patient was taken to the recovery room in satisfactory condition. No further complications were reported/anticipated. Manufacturer narrative: concomitant medical products: product id: 8731sc, serial#:(b)(4), implanted: (b)(6) 2010, explanted: (b)(6) 2016, product type: catheter. Other relevant device(s) are: product id: 8731sc, serial/lot #: (b)(4), ubd: 01-may-2011, udi#: (b)(4). If information is provided in the future, a supplemental report will be issued.
8043933-2018-00006	28/03/2016	Injury	BRAINLAB AG	12/03/2018	HAW	CRANIAL NAVIGATION SOFTWARE	Insufficient Information	Infarction, Cerebral	Brainlab became aware on feb 9, 2018 that permanent patient injuries are alleged as a result of a cranial surgery performed on (b)(6) 2016 with brainlab stereotactic

						(VERSION 3.1)			guidance. Manufacturer narrative: a comprehensive investigation of this event is not possible at this point of time, since neither the involved brainlab device, nor any further relevant information from the hospital regarding this surgery are available to brainlab. Brainlab considers the investigation closed at this time. Should additional information be received, the information will be reviewed, investigation will be re-opened as required and brainlab will issue a follow-up report to the fda as appropriate.
1645337-2019-21520	01/01/2016	Injury	MENTOR TEXAS	16/10/2019	FTR	MENTOR MEMORYGEL BREAST IMPLANT	Material Rupture	Capsular Contracture; No Code Available	This report contains the supplemental information for mentor psr reference number (b)(4). It was reported that a (b)(6) hispanic female patient underwent a primary breast augmentation with a 450cc mentor memorygel breast implant and experienced postoperative left-sided grade iii capsular contracture and rupture. The rupture was visualized via mri performed in 2016. As a result, the patient underwent bilateral removal and replacement on (b)(6) 2019. The patient has a history of right stereotactic core biopsy at the age of (b)(6). Manufacturer narrative: this report contains the supplemental information for mentor psr reference number (b)(4). This device report is being submitted late as a result of the exemption transition period following the revocation of mentor¿s psr exemption #e2007003. Investigation summary: according to the information received, it was reported a rupture on a breast implant and capsular contracture. During evaluation of the sample, it was found to be ruptured at the edge of the device. No other anomalies were discovered. A manufacturing record evaluation was performed for the finished device number 5905866, and no non-conformances related to the reported complaint condition were identified. A possible cause for the condition reported is due to excessive force to the chest; trauma; compression during mammographic imaging; and severe capsular contracture. Capsular contracture

									in the patient¿s breast is the result of the body¿s individual physiological response to the implantation of a foreign object in soft tissue. Capsular contracture is a known complication associated with these devices and is referenced in our current product insert data sheet. The reported complaint was confirmed. It should be noted that as part of our quality process, each device is visually inspected and functionally tested during manufacturing to ensure the device meets the required specifications prior to shipment. Due to external causes, no further investigation will be conducted at this time. Reason for device explant and/or reoperation: left-sided capsular contracture, rupture. Concomitant medical products: 450cc mentor memorygel breast implant(catalog #:3504501bc, serial #: (b)(4)). Manufacturer¿s reference number: pc-000412511
1723170-2018-01087	21/11/2015	Death	MEDTRONIC NAVIGATION, INC. (LOUISVILLE)	09/03/2018	HAW	STEALTHSTATION S7 SYSTEM	Adverse Event Without Identified Device or Use Problem	Death; Hemorrhage, Cerebral; Iatrogenic Source	The attached journal article was forwarded by a medtronic representative. Use of navigation system was reported. This is medical device report (mdr) one of two. See 1723170-2018-01094 for the second mdr. One hundred nine stereotactic ommaya reservoir placement procedures were performed between 1998 and 2013 for central nervous system involvement of various malignancies. The mean patient age was 51 years. The study cohort consisted of 47 male patients (43%). End points reviewed included rate of successful placement, revision, removal, procedure-related neurological morbidity, infection, intracranial hemorrhage, conversion to ventriculoperitoneal shunt (vps), direct parenchymal toxicity, and 30 day in-hospital mortality. One patient had platelet level of 3 on the morning of surgery and had previously responded to platelet transfusions with an appropriate increase. However, despite intra-operative transfusion of 12 units of platelets, the patient experienced intra-operative bleeding after an initially clear csf pass. Severe thrombocytopenia remained

									refractory to transfusions, and the surgery was aborted without leaving any implant. The hemorrhage grew slowly over the next several days with the platelet level remaining refractory to transfusions. The patient was eventually listed as do not resuscitate and died. One patient had a post-operative ct scan without acute blood, started therapeutic enoxaparin, and developed altered mental status on pod 3 with tract hemorrhage and intraventricular hemorrhage noted on ct scan, developed status epilepticus, and eventually died. Seventy-one (65%) patients had their death documented in this hospital records. Nineteen of those 71 died within 30 days of their ommaya surgery. Future studies in this area should include newer stereotaxy systems, such as those that are electromagnetically guided, and direct comparisons among systems, including the frameless and frame-based systems. Manufacturer narrative: patient identifier and weight were unavailable from the attached journal article or by the authors. Patient age and patient sex not made available the attached journal article or by the authors. The article reports that the mean patient age was 51 and the consisted of 47 male patients in the study. Therefore 51 years old and male were used. The date of death is unknown, so the date of accepted was used. Event date is approximated as it was reported to have occurred. The exact system information could not be determined as it was not provided. However, the system listed on this form was at the address listed in the article during the time some of the surgeries were completed. Device udi not provided as this product is no longer manufactured. Citation: benjamin c. Kennedy, lauren t. Brown, ricardo j. Komotar, and guy m. Mckhann ii. Stereotactic catheter placement for ommaya reservoirs. (2016). Journal of clinical neuroscience 27 (2016) 44¿47. Http://dx.doi.org/10.1016/j.jocn.2015.11.005. Device manufacturing date is

									dependent on lot number/serial number, therefore, unavailable. Multiple attempts have been made to obtain additional information. No further information provided in the journal article or from the authors. The author could not provide any additional information or insight as he was not at the site when the surgeries were performed. No request for service have been received from the customer regarding these events. No parts have been replaced or returned to the manufacturer for evaluation. Per the journal article, the cause of death are not confirmed or provided by authors. Medtronic navigation is filing this mdr to ensure visibility to a patient event as a result of a procedure that utilized medtronic navigation's system. There is no allegation to suggest that medtronic navigation's device caused or contributed to the reported event. Not returned by customer.
1723170-2018-01094	21/11/2015	Injury	MEDTRONIC NAVIGATION, INC. (LOUISVILLE)	09/03/2018	HAW	STEALTHSTATION S7 SYSTEM	Adverse Event Without Identified Device or Use Problem	Hemorrhage, Cerebral; Iatrogenic Source	The attached journal article was forwarded by a medtronic representative. Use of navigation system was reported. This is medical device report (mdr) two of two. See 1723170-2018-01087 for the first mdr. Per table 1, complications listed below: total patients 109 (100). Accuracy : normal sized ventricles 74/109 (68) , only one catheter pass 107/109 (98) , had post-operative scan 93/109 (85) , good radiographic placement 92/93 (99) . Complications : total peri-operative complications 7/109 (6.4) , hemorrhagic complications 7/109 (6.4) , symptomatic hemorrhage 4/109 (3.7) , peri-operative malfunctions 3/109 (2.8) , delayed malfunctions 1/109 (0.9) , peri-operative infections 1/109 (0.9) , delayed infections 3/109 (2.8) , conversion to vps 4/109 (3.7) . The initial scan showed good placement in 92/93 (99%) scans. The one initial scan showing suboptimal placement showed the catheter too deep with a kink in the catheter in the frontal white matter and the reservoir just outside the burr hole, suggesting post-placement migration prior to the ct scan. All other 92 catheters were

									judged by the attending neurosurgeon to be in good position with all the catheter holes within the ventricular system, without need to be replaced, pulled back, or advanced. Future studies in this area should include newer stereotaxy systems, such as those that are electromagnetically guided, and direct comparisons among systems, including the frameless and frame-based systems. Manufacturer narrative: patient identifier and weight were unavailable from the attached journal article or by the authors. Patient age and patient sex not made available the attached journal article or by the authors. The article reports that the mean patient age was 51 and the consisted of 47 male patients in the study. Therefore 51 years old and male were used. Event date is approximated as it was reported to have occurred. The exact system information could not be determined as it was not provided. However, the system listed on this form was at the address listed in the article during the time some of the surgeries were completed. Device udi not provided as this product is no longer manufactured citation: benjamin c. Kennedy, lauren t. Brown, ricardo j. Komotar, and guy m. Mckhann ii. Stereotactic catheter placement for ommaya reservoirs. (2016). Journal of clinical neuroscience 27 (2016) 44¿47. Http://dx.doi.org/10.1016/j.jocn.2015.11.005. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. Multiple attempts have been made to obtain additional information. No further information provided in the journal article or from the authors. The author could not provide any additional information or insight as he was not at the site when the surgeries were performed. No request for service have been received from the customer regarding these events. No parts have been replaced or returned to the manufacturer for evaluation. Medtronic navigation is filing this mdr to ensure visibility to a patient

									event as a result of a procedure that utilized medtronic navigation's system. There is no allegation to suggest that medtronic navigation's device caused or contributed to the reported event. Not returned by customer.
8105467	24/09/2015	Malfunction	HOLOGIC, INC.	27/11/2018	IZH	MULTICARE PLATINUM STEREOTACTIC BREAST BIOPSY DEVICE	Break; Incorrect, Inadequate or Imprecise Result or Readings	No Known Impact Or Consequence To Patient	Wile performing daily qc on the stereotactic unit, the tech discovered that the needle test was out of limits and the compression paddle lock was broken. Due to this event the patient/exam double stereo scheduled for today was not able to be done and a single score biopsy had to be completed in the ultrasound dept. Patient will possibly have to return on another day to have the stereotactic biopsy done.
1723170-2020-03401	01/08/2015	Injury	MEDTRONIC NAVIGATION, INC	23/12/2020	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Hemorrhage/Bleeding; Visual Impairment; Insufficient Information	Laser interstital thermal therapy: lessons learned pruitt r.; gamble a.; mehta a.; schulder m. Journal of neurosurgery (2015) 123:2 (a533-a534). Date of publication: august 2015 embase link https://www.embase.com/search/results?subaction=viewrecord <(>&<)>id=l72190590<(>&<)>from=export introduction: complications of laser interstitial thermal therapy (litt) are seemingly underreported. We discuss how we have modified our technique in the context of technical and treatment-related complications. Methods: saline-cooled laser probes (medtronic visualase, houston tx) were inserted using intraoperative mri (imri) (5 patients), frameless stereotaxy (fs, in 2), or frame-based in 28. Litt was done in a 1.5 tesla diagnostic mri (dmri). 35 patients were treated, 15 with brain tumors, 1 with a filum terminale ependymoma, 15 with mesial temporal lobe epilepsy (mtle), and 4 with hypothalamic hamartomas (hh). Results: laser misplacement occurred in two patients; in one fs was used for tumor targeting, and in one with mtle, the laser was suboptimally placed when an alignment rod was not inserted beforehand. No other patients with a stereotactic frame sustained laser misplacement. Two mtle patients had hemorrhage from laser insertion, one with a superior quadrantanopsia, and one was

									asymptomatic. Four patients had complications from the litt treatment itself. Two with brain tumors developed deficits from laser hyperthermia, one affecting the brainstem, and another the primary motor cortex. The patient with the filum terminale ependymoma developed a paraparesis postoperatively. In one patient with glioblastoma, treatment was aborted when the saline coolant flow ceased and the laser tip overheated. Conclusions: complications of litt can result from laser misplacement, laser insertion, and laser treatment. Our lessons learned include: 1) a stereotactic frame provides optimal laser placement; 2) in patients where a long laser placement is needed, an alignment rod should be inserted before the laser; 3) preoperative cta with mr fusion can be used to avoid vascular injury; 4) critical structures should not be treated with the full hyperthermia dose to minimize the risk of neurological complications; 5) intraspinal litt should be used with caution; and 6) saline coolant flow must remain continuous. Reported event(s): 1. One mtle patient experienced hemorrhage from laser insertion with superior quadrantanopsia 2. One mtle patient had a hemorrhage from laser insertion but was asymptomatic 3. One patient had complications from litt treatment itself. The patient developed deficits from laser hyperthermia, affecting the brainstem 4. One patient had complications from litt treatment itself. The patient developed deficits from laser hyperthermia, affecting the primary motor cortex 5. One patient had complications from litt treatment itself. One patient with filum terminale ependymoma developed a paraparesis post-operatively. Manufacturer narrative: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Includes the article citation. The literature article is attached. If information is provided in the future, a supplemental report will be issued.

1723170-2020-03402	01/08/2015	Malfunction	MEDTRONIC NAVIGATION, INC	23/12/2020	GEX	MEDTRONIC NAVIGATION	Use of Device Problem; Excessive Heating	No Clinical Signs, Symptoms or Conditions	Hold for ab 12.28 laser interstital thermal therapy: lessons learned pruitt r.; gamble a.; mehta a.; schulder m. Journal of neurosurgery (2015) 123:2 (a533-a534). Date of publication: august 2015 embase link https://www.embase.com/search/results?subaction viewrecord & id=l72190590 & from export introduction: complications of laser interstitial thermal therapy (litt) are seemingly underreported. We discuss how we have modified our technique in the context of technical and treatment-related complications. Methods: saline-cooled laser probes (medtronic visualase, houston tx) were inserted using intraoperative mri (imri) (5 patients), frameless stereotaxy (fs, in 2), or frame-based in 28. Litt was done in a 1.5 tesla diagnostic mri (dmri). 35 patients were treated, 15 with brain tumors, 1 with a filum terminale ependymoma, 15 with mesial temporal lobe epilepsy (mtle), and 4 with hypothalamic hamartomas (hh). Results: laser misplacement occurred in two patients; in one fs was used for tumor targeting, and in one with mtle, the laser was suboptimally placed when an alignment rod was not inserted beforehand. No other patients with a stereotactic frame sustained laser misplacement. Two mtle patients had hemorrhage from laser insertion, one with a superior quadrantanopsia, and one was asymptomatic. Four patients had complications from the litt treatment itself. Two with brain tumors developed deficits from laser hyperthermia, one affecting the brainstem, and another the primary motor cortex. The patient with the filum terminale ependymoma developed a paraparesis postoperatively. In one patient with glioblastoma, treatment was aborted when the saline coolant flow ceased and the laser tip overheated. Conclusions: complications of litt can result from laser misplacement, laser insertion, and laser treatment. Our

									lessons learned include: a stereotactic frame provides optimal laser placement; in patients where a long laser placement is needed, an alignment rod should be inserted before the laser; preoperative cta with mr fusion can be used to avoid vascular injury; critical structures should not be treated with the full hyperthermia dose to minimize the risk of neurological complications; intraspinal litt should be used with caution; and saline coolant flow must remain continuous. Reported event(s): laser misplacement occurred inone patient where frameless stereotaxy (fs) was used for tumor targeting laser misplacement occurred in one patient with mtle. The laser was suboptimally placed when an alignment rod was not inserted beforehand one patient had complications from litt treatment itself. The treatment was aborted in a patient with glioblastoma after the saline coolant flow ceased and the laser tip overheated. Manufacturer narrative: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. B5 includes the article citation. The literature article is attached. If information is provided in the future, a supplemental report will be issued.
1723170-2020-02862	15/06/2015	Injury	MEDTRONIC NAVIGATION, INC	02/11/2020	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Headache; Hematoma; Unspecified Infection; Nausea; Pain; Skin Irritation; Vomiting; Depression	Citation: francisco a. Ponce, wael f. Assad, kelly d. Foote, william s. Anderson, g. Rees cosgrove, gordon h. Baltuch, kara beasley, donald e. Reymers, esther s. Oh, steven d. Targum, gwenn s. Smith, constantin. Bilateral deep brain stimulation of the fornix for alzheimer's disease: surgical safety in the advance trial. J neurosurgery, 2016, 125, http://thejns.org/doi/abs/10.3171/2015.6.jns15716 abstract: objective: this report describes the stereotactic technique, hospitalization, and 90-day perioperative safety of bilateral deep brain stimulation (dbs) of the fornix in patients who underwent dbs for the treatment of mild, probable alzheimer¿s disease (ad). Methods: the advance trial is a multicenter, 12-month,

									double-blind, randomized, controlled feasibility study being conducted to evaluate the safety, efficacy, and tolerability of dbs of the fornix in patients with mild, probable ad. Intraoperative and perioperative data were collected prospectively. All patients underwent postoperative mri. Stereotactic analyses were performed in a blinded fashion by a single surgeon. Adverse events (aes) were reported to an independent clinical events committee and adjudicated to determine the relationship between the ae and the study procedure. Results: between june 6, 2012, and april 28, 2014, a total of 42 patients with mild, probable ad were treated with bilateral fornix dbs (mean age 68.2 ± 7.8 years; range 48.0¿79.7 years; 23 men and 19 women). The mean planned target coordinates were x = 5.2 ± 1.0 mm (range 3.0¿7.9 mm), y = 9.6 ± 0.9 mm (range 8.0¿11.6 mm), z = -7.5 ± 1.2 mm (range -5.4 to -10.0 mm), and the mean postoperative stereotactic radial error on mri was 1.5 ± 1.0 mm (range 0.2¿4.0mm). The mean length of hospitalization was 1.4 ± 0.8 days. Twenty-six (61.9%) patients experienced 64 aes related to the study procedure, of which 7 were serious aes experienced by 5 patients (11.9%). Four (9.5%) patients required return to surgery: 2 patients for explantation due to infection, 1 patient for lead repositioning, and 1 patient for chronic subdural hematoma. No patients experienced neurological deficits as a result of the study, and no deaths were reported. Conclusions: accurate targeting of dbs to the fornix without direct injury to it is feasible across surgeons and treatment centers. At 90 days after surgery, bilateral fornix dbs was well tolerated by patients with mild, probable ad. Reported events. One patient underwent prolonged hospitalization due to headaches on post-operative day 1. Nausea and vomiting were noted on day 2. Three patients experienced dermatological events including bruising, dermatitis and rash. Six patients

									experienced fatigue. 6 patients experienced gastrointestinal issues including nausea and vomiting. 3 patients experienced urinary retention. 12 patients experienced headaches. 3 patients experienced pain/discomfort in the neck/shoulder/mastoid. One lead was reported to have been misplaced. One patient experienced a chronic & subacute hematoma. One patient experienced an infection. Five patients experienced mental status changes including confusion, delirium and depression. Manufacturer narrative: patient age is the mean value of patients in the study. Patient gender is the majority value of patients in the study. Patient weight not available from the site. Event date is the accepted date of the publication. Device lot number, or serial number, unavailable. 510(k) is dependent upon and is therefore, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. Additional fdp codes: (b)(4). If information is provided in the future, a supplemental report will be issued.
1723170-2019-04512	12/06/2015	Injury	MEDTRONIC NAVIGATION, INC	18/08/2019	HAW	RENAISSANCE SYSTEM	Adverse Event Without Identified Device or Use Problem	Hemorrhage, Extradural	The following event was reported in literature: abstract: frame-based stereotactic interventions are considered the gold standard for brain biopsies, but they have limitations with regard to flexibility and patient comfort because of the bulky head ring attached to the patient. Frameless image guidance systems that use scalp fiducial markers offer more flexibility and patient comfort but provide less stability and accuracy during drilling and biopsy needle positioning. Head-mounted robot¿guided biopsies could provide the advantages of these 2 techniques without the downsides. The goal of this study was to evaluate the feasibility and safety of a robotic guidance device, affixed to the patient¿s skull through a small mounting platform, for use in brain biopsy procedures. This was a retrospective study of 37 consecutive patients who presented

									with supratentorial lesions and underwent brain biopsy procedures in which a surgical guidance robot was used to determine clinical outcomes and technical procedural operability. The portable head-mounted device was well tolerated by the patients and enabled stable drilling and needle positioning during surgery. Flexible adjustments of predefined paths and selection of new trajectories were successfully performed intraoperatively without the need for manual settings and fixations. The patients experienced no permanent deficits or infections after surgery. The head-mounted robot¿guided approach presented here combines the stability of a b one-mounted set-up with the flexibility and tolerability of frameless systems. By reducing human interference (i.e., manual parameter settings, calibrations, and adjustments), this technology might be particularly useful in neurosurgical interventions that necessitate multiple trajectories. Reported events: one patient undergoing cranial biopsy experienced an epidural hematoma. During the procedure, a 3 mm drill hole had was created followed by a stab incision of the dura. The hematoma was revealed on postoperative ct images and required a craniotomy. The patient did not experience any postoperative deficits. Manufacturer narrative: please note that this date is based off the date of publication of the article as the actual event date was not provided. The reported event was from the following literature article: grimm f, naros g, gutenberg a, keric n, giese a, gharabaghi a. Blurring the boundaries between frame-based and frameless stereotaxy: feasibility study for brain biopsies performed with the use of a head-mounted robot. Journal of neurosurgery. 2015. Doi: 10.3171/2014.12.jns141781. If information is provided in the future, a supplemental report will be issued.

1723170-2020-03336	01/06/2015	Injury	MEDTRONIC NAVIGATION, INC	18/12/2020	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Hemorrhage/Bleeding; Visual Impairment	Citation: safety and efficacy of using stereotactic laser ablation (sla) for mr negative epileptic foci. Ciricillo s.f.; chez m.; ghassemi a. Journal of neurosurgery (2015) 122:6 (a1562). Date of publication: june 2015 introduction: 20-30% of temporal lobe epilepsy patients (tle) and 20-40% of those with extratemporal lobe epilepsy (etle) show no evidence of underlying lesion on mri (mri-negative) (carne2004) . The current study evaluates the safety and efficacy of using stereotactic laser ablation (sla) for mr negative epileptic foci. Methods: 22 children and 6-adults with medically refractory focal epilepsy were evaluated with video eeg, 3-tesla mri, fmri, meg (22 - patients) and pet (3-patient) with 6 temporal and 21 extra-temporal foci.the patients had sla (visualase, inc.houston, tx) with frameless navigation (brainlab, inc.). All had intraoperative eeg monitoring in mri, thereby showing pre-ablation and post-ablation spike data. 10 patients had depth electrodes through laser placement burr holes. The cooled laser applicator is mr-compatible (1.6mm in diameter) ,which enabled real time mr temperature imaging. Seizure outcome was noted for 4- 24 months post-ablation. Results: 17 patients showed seizure freedom (65%), 5 had <(><<)> 75 % reduction, 2 had no improvement, and 4 had very short follow up (<(> <<)> 4 months). All the mesial temporal and focal frontal cases (100%) remain seizure free and 11/21(53%) extra-temporal cases are seizure free. 1-mesial temporal patient had a superior quandrantopsia. Other minor complications were placement hemorrhage of no clinical significance in 2 patients. The average los was <(><<)> 24 hours. Conclusions: sla , in combination with meg, is a valuable safe new tool to achieve seizure freedom in mr negative cases (both temporal and extra-temporal). Additionally, sla may offer options to those patients resistant to traditional craniotomy option. Reported events: -one patient who underwent mesial

									temporal ablation had a superior quandrantopsia. -two patients experienced placement hemorrhages of no clinical significance. Manufacturer narrative: patient age not available from the site. Patient sex not available from the site. Patient weight not available from the site. Event date is the publication date of the abstract. Device lot number, or serial number, unavailable. Facility and address not populated as the facility was not provided in the abstract provided. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2019-02795	01/05/2015	Injury	MEDTRONIC NAVIGATION, INC	30/05/2019	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Hematoma; Post Operative Wound Infection	Citation: world neurosurg. (2019) 122: e1588-e1591. Background: significant progress in hardware and surgical techniques for sacroiliac joint (sij) fusion surgeries has facilitated safer and more efficacious procedures for patients. Triangular-shaped implants for sij fusions are the most-studied devices and have demonstrated good short-term and long-term clinical outcomes. Reports on cylindrical threaded implants are very limited. Owing to biomechanical differences in the implants and the surgical techniques required for their placement, previously reported results may not be applicable to cylindrical threaded implants. The aim of this study was to report preliminary clinical experience with minimally invasive sij fusion using intraoperative stereotactic navigation and the rialto si fusion system. Methods: we retrospectively reviewed 24 patients who underwent sij fusions between may 2015 and october 2017 performed by a single surgeon. Results: mean total satisfaction score was 89.0% 27.6%. A statistically significant reduction (p [0.0028) in low back pain scores was noted from an average baseline score of 6.6 2.4 to 3.7 3.3 postoperatively. Leg pain scores decreased from 4.8 3.8 to 1.5 2.9 (p [0.0034). Mean

									surgical time was 53.0 13.9 minutes. It took significantly longer (p [0.0089) to perform the initial 13 cases (59.9 15.2 minutes) compared with subsequent cases (45.4 7.3 minutes). Estimated blood loss was minimal (10.4 5.2 ml). Conclusions: minimally invasive si joint fusion using cylindrical threaded implants can be safely performed with minimal morbidity and good clinical outcomes. Adverse events: 2 patients had symptomatic subcutaneous hematomas, which resolved spontaneously. 2 patients had superficial wound infections treated with antibiotics. One patient developed an osteophyte on the lateral aspect of the implant. Because of symptomatic pain localized to that area, an osteophytectomy was performed 1 year after the index surgery with an improvement in patient symptoms. Manufacturer narrative: age or date of birth: the average age of the 24 patients is 62.2 years. Sex: there were 3 male patients and 21 female patients. Weight: patient weight not available from the site. Date of event: event date is approximated as it was reported that the surgeries occurred between may 2015 and october 2017. Description of problem or event: there was no allegation of malfunction of the system. Lot #, serial #: device lot number, or serial number and model number were unavailable. Udi #: udi not available for this system at time of filing. Pma/510k: the pma/ 510 (k) number is unavailable since the model number is unknown. Device evaluated by mfr: the device was not returned, so no analysis was conducted. Manufacture date: device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
3007566237-2018-01555	01/05/2015	Injury	MEDTRONIC NEUROMODULATION	24/05/2018	MRU	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Malposition of Device	Muscle Spasm(s); Neurological Deficit/Dysfunction; Test Result	Summary: background: dyt6 dystonia can have an unpredictable clinical course and the result of deep brain stimulation (dbs) of the internal part of the globus pallidus (gpi) is known to be less robust than in other forms of autosomal dominant dystonia.

									Patients who had previous stereotactic surgery with insufficient clinical benefit form a particular challenge with very limited other treatment options available. Case report: a pediatric dyt6 patient unexpectedly deteriorated to status dystonicus 1 year after gpi dbs implantation with good initial clinical response. After repositioning the dbs electrodes the status dystonicus resolved. Discussion: this case study demonstrates that medication-resistant status dystonicus in dyt6 dystonia can be reversed by relocation of pallidal electrodes. This case highlights that repositioning of dbs electrodes may be considered in patients with status dystonicus, especially when the electrode position is not optimal, even after an initial clinical response to dbs. Reported events: a (b)(6) male patient was implanted with bilateral globus pallidus internus (gpi) deep brain stimulation (dbs) electrodes for dyt6 dystonia using direct mri guided stereotactic targeting, but a postoperative tomography scan showed that the actual electrode positions were more lateral than intended. In spite of this the patient responded well to the therapy and 1 year after the implantation, he could walk without support, and had a clearly improved hand function and speech (burke-fahn-marsden dystonia rating scale (bfmdrs)-m of 69 and bfmdrs-d of 14). However, after the first year the effect of pallidal stimulation decreased and at 15 months postoperatively ((b)(6)) his clinical status progressively deteriorated to status dystonicus (sd), requiring hospital admission. Constipation was considered as a possible trigger and was treated by laxatives without success. No other possible triggers were identified. Despite symptomatic treatment with trihexyphenidyl (6 mg/day, (b)(6)), gabapentin (300 mg/ day), and clonazepam (1.0 mg/day) and reprogramming of the dbs settings, he developed severe episodes of generalized dystonic spasms, which

									progressed to continuous abnormal postures and sustained contractions. This was accompanied by metabolic derangements (creatine kinase levels up to 920 iu/l), exhaustion, pain, sleep disturbance, dysphagia, and cachexia. Since this is a potentially life-threatening situation, the patient was admitted to an intensive care unit (icu). On the icu, pharmacological treatment with high doses of benzodiazepines (up to intravenous midazolam 1 mg/kg/hour and enteral clonazepam 3.6 mg/ day, (b)(6)), clonidine (intravenous 105 mg/day), chloral hydrate (1,250 mg/day), baclofen (12.5 mg/day), gabapentin (900 mg/ day), and trihexyphenidyl (8 mg/day) had only limited effect. Nevertheless, he experienced less discomfort, less pain, and the metabolic derangements resolved. However, he suffered from severe adverse effects, especially drowsiness. When subsequently decreasing the dosages, the dystonic movements and the discomfort became more severe. After 4 weeks on the icu, his condition deteriorated to a total bfmdrs score of 138. After extensive multidisciplinary and multicenter deliberation it was decided to reposition the pallidal electrodes to a more dorsal and more medial position, and the new target was further refined by microelectrode recording. After the repositioning of the dbs electrodes the sd ameliorated to a bfmdrs score of 100 after 1 week, and medication dosages were drastically reduced. Six months after the second surgery he was able to walk short distances unaided and attend school without medication (bfmdrs-m 64, bfmdrs-d 15). At present, the duration after repositioning of the electrodes in 24 months, and the clinical condition of the patient was still reportedly improving gradually at the time of publication. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer

									narrative: the main component of the system. Other relevant device(s) are: product id: 3387, serial/lot #: unknown, implanted: (b)(6) 2015, product type: lead. Citation: oterdoom, dlm., van egmond, me., ascencao, lc., van dijk, jmc., saryyeva, a., beudel, m., runge, j., de koning, tj., abdallat, m., eggink, h., tijssen, maj., krauss, jk. Reversal of status dystonicus after relocation of pallidal electrodes in dyt6 generalized dystonia. Tremor other hyperkinet mov (n y). 2018; 8:530. Doi: 10.7916/d82f90dx. If information is provided in the future, a supplemental report will be issued.
1723170-2020-03384	01/01/2015	Injury	MEDTRONIC NAVIGATION, INC	23/12/2020	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Hematoma	Stereotactic laser amygdalo-hippocampotomy for mesial temporal lobe epilepsy: collective experience from seven single-center, prospective, investigator-initiated studies objectives gross r.; willie j.; helmers s.; meador k.j.; laroche s.; faught r.e.; gedzelman e.; sharan a.; sperling m.; marsh r.; cascino g.; worrell g.; shih j.j.; wharen r.; tatum w.; popli g.; laxton a.; couture d.; weinand m.; labiner d.; mehta a.; harden c.; woodrum d.; watson r.; patwardhan r. Epilepsy currents (2015) 15 suppl. 1 (346). Date of publication: january-february 2015 embase link https://www.embase.com/search/results?subaction=viewrecord <(>&<)>id=l71845453<(>&<)>from=export rationale: to evaluate effectiveness, safety, and related findings following stereotactic laser amygdalohippocampotomy (slah), a minimally invasive option to open anterior temporal lobectomy and selective amygdalohippocampectomy for mesial temporal lobe epilepsy (mtle). Methods:data from 7 centers enrolling 66 adult subjects with medically resistant mtle that underwent slah (visualase, houston, tx) at least 6 mo prior was collected via validated case report forms (crfs); 44 subjects reached 12 mo follow-up. Only subjects with completed data are reported: 11 and 6 subjects had incomplete data at 6 and 12 mo follow-up, respectively, due to late

									patient visits or the site not collecting 6 mo data. Each center had irb approval for its respective single-center, investigator-initiated study. Screening and follow-up visits were arranged per protocol at a given center, with some variation per center. Demographic, medical history, and medical/surgical care data were also gathered, along with seizure outcome. Results: for the subjects with data available, age was 43±14 (range 19-75). 66% were female. Mesial temporal sclerosis (mts) was reported in 70%. Duration of epilepsy was 25±18 years (range 2-68, n=43), and subjects had taken a median of 6 anti-epileptic drugs (range 2-11, n=43) prior to slah. The most common pre-ablation seizure type was complex partial, with some exhibiting simple partial and secondarily generalized seizures as well. At 6-mo follow-up of all available subjects since the beginning of slah being performed (8/2011), 53% of subjects (n=55) wereengel i (free of disabling seizures). At one-year follow-up, analysis of all available reported adult data showed 55% subjects achieving engel i status (n=38); 7 had non-disabling simple partial seizures (engel ib) with 1 occurring only within the first month post-ablation. Seizure-free rates were 61% in subjects with mts and 53% in those without at 6 mo, but this was not statistically significant (p=0.28, two-tailed fisher's exact test). Two hemorrhages occurred: 1 subdural hematoma with no transient or permanent neurological deficit; 1 temporal lobe hematoma with visual field deficit that recovered. Overall there were 4 visual field deficit <(>&<)> transient subjective diplopia (1); transient confusion/difficulty with expression (3), anxiety (5) and other psychological problems of uncertain relation to ablation, superficial skin erythema, and headache (8 episodes in 7 subjects), among other reported events of uncertain relation to ablation. Steroids were given post-operative period ranging from 4 to 15 days at most centers. Median length

									of stay was 1 day. Anti-epileptic medications were kept constant throughout the one-year course by most centers, and altered based upon high blood levels or seizure activity. Conclusions: slah achieved engel 1 outcome in the majority of subjects at 6- and 12-month follow-up, with acceptable saftey. Further prospective study, with greater numbers of subjects, will help elucidate and/or strengthen these findings. Reported event(s): 1. One patient experienced a subdural hematoma with no transient or permanent neurologicaldeficit 2. One patient with a temporal lobe hematoma experienced visual field deficit that recovered. Manufacturer narrative: this value is the average age of the patients reported in the article as specific patients could not be identified. This value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Includes the article citation. The literature article is attached. If information is provided in the future, a supplemental report will be issued.
1723170-2020-03335	01/01/2015	Injury	MEDTRONIC NAVIGATION, INC	18/12/2020	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage	Outcomes of stereotactic laser ablation for treatment-resistant epilepsy in the pediatric population with 1 year follow-up curry d.; shetty a.; wilfong a. Epilepsy currents (2015) 15 suppl. 1 (556). Date of publication: january-february 2015 rationale: approximately, 3 million people in the united stated have epilepsy and it is estimated that at least one-third of them continue to have seizures despite adequate treatment with anti-seizure medication. An estimated 2500 pediatric patients are eligible for epilepsy surgery yearly in the united states. Surgery is vastly underutilized, about 15%, due to its invasiveness and morbidity. Stereotactic laser ablation (sla) for localized epileptic foci is an exciting alternative for surgical candidates and here, we will discuss the

									safetyand one year post-operative seizure outcomes after sla(n=23). Methods: all patients (n=23) were considered candidates for resective epilepsy surgery by the hospital comprehensive epilepsy surgery conference. The irb approved protocol was for pediatric patients (2-18 y.o.) With medically intractable, focal, lesional epilepsy. Epileptic foci had varied etiologies (hh: 14, fcds: 5, mts: 3, ts: 1). 6 patients underwent repeat procedures. An fda-cleared surgical laser ablation system (visualase thermal therapy system; visualase, inc., houston, tx) was employed in this work. The cooled laser applicator is mr-compatible (1.6mm in diameter) with a central 400-¿m core silica fiberoptic applicator with 1 cm or 3 mm light-diffusing tips. An mr-compatible head frame was used to navigate the laser applicator to the targeted focus. Magnetic resonance temperature imaging (mrti) was accomplished using a fast field echo (ffe) sequence (single or multiple slices) field of view: 24 cm; acquisition matrix: 256 by 128; echo time: 20 ms; repetition time: 45 ms; flip angle: 30 degrees; band width: 12.6 khz). After a test dose of 3-4w for 15-45 seconds to confirm applicator position, doses of 5-12w for 45-120 seconds were used to ablate the focus. Safety limits (> 50°c) were placed near the margin of the desired thermal ablation zone to protect critical structures like the optic tract, fornix and mammalothalamic tract. After completion of the ablation procedure, post ablation t1-weighted plus gadolinium contrast (t1 + gd) series were acquired. Follow-up period was > 1 year for all patients. Results: 65 % of all patients had seizure freedom. 93% of the hh pts were seizure free and 60 % of the fcd pts were seizure free. No surgical complications were noted. 3 had short term memory loss which resolved. There was a single incident of sub-clinical subarachnoid hemorrhage, which required no intervention. Average los was 1 day. Conclusions: in the current

									study, stereotactic laser ablation (sla) for epileptic foci has demonstrated rates of seizure freedom that to open surgical results, especially as seen in the hh patients. Excellent outcomes with low morbidity reduced los and ability to stage procedures, offers a real option for the large treatment-resistant pediatric patient population. Reported event(s): single incident of sub-clinical subarachnoid hemorrhage which required no intervention. Manufacturer narrative: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Section includes the article citation. If information is provided in the future, a supplemental report will be issued.
1723170-2020-03316	01/01/2015	Injury	MEDTRONIC NAVIGATION, INC	17/12/2020	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Muscle Weakness; Dysphasia; Convulsion/Seizure	Citation: alison dolce, daniel curry and angus wilfong. Corpus callosotomy with stereotactic laser ablation in a pediatric patient epilepsy currents (2015) 15 suppl. 1 (349). Date of publication: january-february 2015 rationale: corpus callosotomy is a valuable palliative surgical treatment option for patients with medically intractable epilepsy and has been shown to be especially effective in those patients with drop attacks (atonic or tonic) and seizures that rapidly secondarily generalize. There are numerous potential surgical and neurological complications associated with conventional open surgical callosotomy as well as concerns regarding radiation overexposure in pediatric patients with the less invasive radiosurgical callosotomy. An alternative minimally invasive treatment option, with reduced side effects, is essential; therefore, we performed an anterior two-thirds callosotomy with stereotactic laser ablation (sla). Methods: we describe a ten year old girl with medically intractable localization-related epilepsy with multifocal onset secondarily generalized seizures, associated with extensive bilateral polymicrogyria. Despite management with multiple antiepileptic medications, the ketogenic diet, and vagus

									nerve stimulation, this patient continued to have disabling atonic drop seizures. Given the refractory nature of her seizures, an anterior two-thirds corpus callosotomy was completed via minimally invasive mr-guided stereotactic laser ablation (sla), with a primary goal to reduce the number of atonic seizures. The procedure was performed using a recently fda approved laser surgery system (visualase, inc.). Results: the patient demonstrated significant clinical improvement after sla of the corpus callosum and was free of atonic seizures for four months after surgery. She then experienced a recurrence of atonic seizures, but at a significantly decreased frequency as well as a decreased number of daytime atypical absence and myoclonic seizures. She also developed an increase in nocturnal tonic seizures following the procedure. The patient experienced a transient decrease in speech, alien hand syndrome and difficulty with ambulation that completely resolved by four months. She also experienced decreased strength in her left arm and leg that has continued to improve with therapy. As the patient tolerated the procedure extremely well with no injury to surrounding tissue or vascular structures, we suspect that her longer than expected recovery was likely a consequence of our inability to use steroids in the pre and postoperative period due to her being on the ketogenic diet. Additional benefit as reported by the family was a significant improvement in speech, cognition and overall quality of life. Conclusions: the concept of treatment of epileptogenic foci in children using laser ablation has been recently reported and considered a safe and effective therapeutic option. To our knowledge, there is no description of its use as a minimally invasive neurosurgical technique to perform a corpus callosotomy. Our result suggests that corpus callosotomy using sla, a novel therapeutic approach, may be a radiosurgical callosotomy in these carefully selected cases of medically

									intractable epilepsy. Reported events: -the subject experienced increased nocturnal tonic seizures, a transient decrease in speech, alien hand syndrome and difficulty with ambulation that was resolved by four months. There was noted decreased strength in the patient's left arm and leg, that has improved continuously post-operative. Manufacturer narrative: patient weight not available from the site. Event date is the date the literature was published. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2018-06253	01/01/2015	Injury	MEDTRONIC NAVIGATION, INC	13/12/2018	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Hemorrhage, Cerebral; Neurological Deficit/Dysfunction	Citation callovini, g. M., telera, s., sherkat, s., sperduti, i., callovini, t., carapella, c. M. (2018). How is stereotactic brain biopsy evolving? A multicentric analysis of a series of 421 cases treated in rome over the last sixteen years. Clinical neurology and neurosurgery, 174, 101-107. Doi:10.1016/j.clineuro.2018.09.020 a b s t r a c t objective: in recent decades, frame-based (fbb) and frame-less stereotactic brain biopsy (flb) have played a crucial role in defining the diagnosis and management of expanding intracranial lesions in critical areas. During the same period, there have been significant advances in diagnostic imaging, a shift in surgical strategies towards extensive resection in gliomas and new molecular classification of brain tumors. Taking these advances into account, we have evaluated whether significant changes have occurred over the last sixteen years of our clinical practice in terms of frequency, indications, target selection, and the histologic results of stereotactic brain biopsy (sbb) procedures. Patients and methods: we analyzed a series of 421 sbb cases treated between january 2002 and june 2017 in three major neurosurgical institutes in rome, serving a

									total of 1.5 million people. Within this series, 94.8% of patients underwent fbb, while, more recently, flb was performed in 5.2% of cases. The entire period under consideration, running from 2002 to 2017, has been further stratified into four-year time-frames (2002¿2005,2006¿2009,2010¿2013,2014¿2017) for the purpose of analysis. Results: the diagnostic yield was 97%. Final diagnoses revealed tumors in 90% of cases and non-neoplastic masses in 7%, while 3% of cases were not conclusive. The morbidity rate was 3% (12 cases) and mortality was 0.7% (3 cases). Intra-operative frozen sections were made in 78% of biopsies. In our three institutes, the number of sbbs decreased steadily throughout the time-frames under consideration. We have also observed a statistically significant reduction in biopsy procedures in lobar lesions, while those performed on the basal ganglia increased and the number of sbbs of multiple masses and lesions of the corpus callosum remained stable. Primary central nervous system diagnosis of lymphomas (pcnsl) was the sole di agnosis whose incidence increased significantly conclusions: over the last sixteen years, we have witnessed a significant decrease in sbb procedures and a modification in target selection and histologic results. Despite the significant evolution of neuroimaging, an accurate non-invasive diagnosis of intracranial expanding lesions has not yet been achieved. Furthermore, the most recent who classification of brain tumors (2016), which incorporates molecular and morphological features, has boosted the need for molecular processing of tissue samples in all expanding brain lesions. For these reasons, it is likely that sbbs will continue to be performed in specific cases, playing a significant role in diagnostic confirmation by providing tissue samples, so as to better assess the biology and the prognosis of cerebral lesions, as well as their sensitivity to standard radio-

									chemotherapy or to new molecular target therapies. Important information the stealthstation navigus frameless passive biopsy system was used for flb procedures on 22 patients out of 421 and only at one site, san giovanni beginning in 2015. Reported events overall morbidity was 3% (13/421): transient neurological deficit occurred in 6 cases, while 7 patients suffered permanent deficits symptomatic cerebral hemorrhage requiring craniotomy occurred in six cases: three gbm, two pcnsl, and one abscess. These adverse events are morbidity from 421 cases. There are no distinctions between adverse events from surgeries completed with the stealthstation navigus frameless passive biopsy system and the other system used. There was no allegation of malfunction of the navigation device. Manufacturer narrative: patient information was unavailable from the site. The median age of the patients was 63.5. There were 216 males and 205 females in the study. The adverse events reported are adverse events from the entire study; a total of 421 patients. The navigation device was used on 22 patients and there is no information attributing any of those adverse events to the surgeries performed with the navigation device. Event date is approximated as it was reported that the surgeries conducted with the device started in the beginning of 2015 at san giovanni. Citation callovini, g. M., telera, s., sherkat, s., sperduti, i., callovini, t., carapella, c. M. (2018). How is stereotactic brain biopsy evolving? A multicentric analysis of a series of 421 cases treated in rome over the last sixteen years. Clinical neurology and neurosurgery, 174, 101-107. Doi:10.1016/j.clineuro.2018.09.020. Refer to the article using: doi:10.1016/j.clineuro.2018.09.020. Device lot number, or serial number, unavailable. Udi not available for this system at time of filing. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. The device was not

									returned, so no analysis was conducted. If information is provided in the future, a supplemental report will be issued.
1723170-2018-06254	01/01/2015	Death	MEDTRONIC NAVIGATION, INC	13/12/2018	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Death	Citation callovini, g. M., telera, s., sherkat, s., sperduti, i., callovini, t., carapella, c. M. (2018). How is stereotactic brain biopsy evolving? A multicentric analysis of a series of 421 cases treated in rome over the last sixteen years. Clinical neurology and neurosurgery, 174, 101-107. Doi:10.1016/j.clineuro.2018.09.020 a b s t r a c t objective: in recent decades, frame-based (fbb) and frame-less stereotactic brain biopsy (flb) have played a crucial role in defining the diagnosis and management of expanding intracranial lesions in critical areas. During the same period, there have been significant advances in diagnostic imaging, a shift in surgical strategies towards extensive resection in gliomas and new molecular classification of brain tumors. Taking these advances into account, we have evaluated whether significant changes have occurred over the last sixteen years of our clinical practice in terms of frequency, indications, target selection, and the histologic results of stereotactic brain biopsy (sbb) procedures. Patients and methods: we analyzed a series of 421 sbb cases treated between january 2002 and june 2017 in three major neurosurgical institutes in rome, serving a total of 1.5 million people. Within this series, 94.8% of patients underwent fbb, while, more recently, flb was performed in 5.2% of cases. The entire period under consideration, running from 2002 to 2017, has been further stratified into four-year time-frames (2002¿2005,2006¿2009,2010¿2013,2014¿2017) for the purpose of analysis. Results: the diagnostic yield was 97%. Final diagnoses revealed tumors in 90% of cases and non-neoplastic masses in 7%, while 3% of cases were not conclusive. The morbidity rate was 3% (12 cases) and mortality was 0.7% (3 cases). Intra-operative frozen sections were made in 78% of biopsies. In

									our three institutes, the number of sbbs decreased steadily throughout the time-frames under consideration. We have also observed a statistically significant reduction in biopsy procedures in lobar lesions, while those performed on the basal ganglia increased and the number of sbbs of multiple masses and lesions of the corpus callosum remained stable. Primary central nervous system diagnosis of lymphomas (pcnsl) was the sole di agnosis whose incidence increased significantly conclusions: over the last sixteen years, we have witnessed a significant decrease in sbb procedures and a modification in target selection and histologic results. Despite the significant evolution of neuroimaging, an accurate non-invasive diagnosis of intracranial expanding lesions has not yet been achieved. Furthermore, the most recent who classification of brain tumors (2016), which incorporates molecular and morphological features, has boosted the need for molecular processing of tissue samples in all expanding brain lesions. For these reasons, it is likely that sbbs will continue to be performed in specific cases, playing a significant role in di agnostic confirmation by providing tissue samples, so as to better assess the biology and the prognosis of cerebral lesions, as well as their sensitivity to standard radio-chemotherapy or to new molecular target therapies. Important information the stelthstation navigus frameless passive biopsy system was used for flb procedures on 22 patients out of 421 and only at one site, san giovanni beginning in 2015. Reported events post-operative mortality rate, as a direct consequence of such hemorrhages after biopsy procedures, was 0.7% (3/421): one gbm, one lymphoma, and one abscess. The mortality is from 421 cases. There are no distinctions between the mortality from surgeries completed with the stealthstation navigus frameless passive biopsy system and the other system used. Manufacturer narrative: patient information

									was unavailable from the site. The median age of the patients was 63.5. There were 216 males and 205 females in the study. The deaths reported are deaths from the entire study; a total of 421 patients. The navigation device was used on 22 patients and there is no information attributing any of deaths to the surgeries performed with the navigation device. The dates of the deaths are unavailable. Event date is approximated as it was reported that the surgeries conducted with the device started in the beginning of 2015 at san giovanni. Citation callovini, g. M., telera, s., sherkat, s., sperduti, i., callovini, t., carapella, c. M. (2018). How is stereotactic brain biopsy evolving? A multicentric analysis of a series of 421 cases treated in rome over the last sixteen years. Clinical neurology and neurosurgery, 174, 101-107. Doi:10.1016/j.clineuro.2018.09.020. Refer to the article using: doi:10.1016/j.clineuro.2018.09.020. Device lot number, or serial number, unavailable. Udi not available for this system at time of filing. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. The device was not returned, so no analysis was conducted. If information is provided in the future, a supplemental report will be issued.
1723170-2018-05486	01/01/2015	Injury	MEDTRONIC NAVIGATION, INC	02/11/2018	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Memory Loss/Impairment	Citation: the impact of stereotactic laser ablation at a typical epilepsy center. Petito, gabrielle t. Et al. Epilepsy <(>&<)> behavior, volume 78, 37 ¿ 44. Https://doi.org/10.1016/j.yebeh.2017.10.041 summary: purpose: stereotactic laser ablation (sla) is a novel form of epilepsy surgery for patients with drug-resistant focal epilepsy. We evaluated one hundred consecutive surgeries performed for patients with epilepsy to address the impact of sla on our therapeutic approach, as well as patient outcomes. Methods: a retrospective, single center analysis of the last one hundred neurosurgeries for epilepsy was performed from 2013 to 2015. Demographics, surgical procedures,

									and postoperative measures were assessed up to 5 years to compare the effect of sla on outcome. Confidence intervals (ci) and comparative tests of proportions compared outcomes for sla and resective surgery. Procedural categorical comparison used chi-square and kaplan¿meier curves. Student t-test was utilized for single variables such as age at procedure and seizure onset. Results: one hundred surgeries for epilepsy yielded thirty-three slas and twenty-one resections with a mean of 21.7-month and 21.3-month follow-up, respectively. The temporal lobe was the most common target for sla (92.6%) and resection (75%). A discrete lesion was present on brain magnetic resonance imaging (mri) in 27/32 (84.4%) of sla patients compared with 7/20 (35%) of resection patients with a normal mri. Overall, 55¿60% of patients became seizure-free (sf). Four of five patients with initial failure to sla became sf with subsequent resection surgery. Complications were more frequent with resection although sf outcomes did not differ (chi square; p = 0.79). Stereotactic laser ablation patients were older than those with resections (47.0 years vs. 35.4 years, p = 0.001). The mean length of hospitalization prior to discharge was shorter for sla (1.18 days) compared with open resection (3.43 days; sd: 3.16 days) (p= 0.0002). Conclusion: we now use sla as a first line therapy at our center in patients with lesional temporal lobe epilepsy (tle) before resection. Seizure-free outcome with sla and resection was similar but with a shorter length of stay. Long-term follow-up is recommended to determine sustained sf status from sla. Reported event: (b)(6) male with post-operative memory loss/forgetfulness. Manufacturer narrative: patient weight was not included in article. Please note that only the year the procedure was performed was provided. Article citation included. Please note that the system information was not included in the journal article and is unavailable. No

									parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2018-05487	01/01/2015	Injury	MEDTRONIC NAVIGATION, INC	02/11/2018	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Memory Loss/Impairment	Citation: the impact of stereotactic laser ablation at a typical epilepsy center. Petito, gabrielle t. Et al. Epilepsy & behavior, volume 78, 37 ¿ 44. Https://doi.org/10.1016/j.yebeh.2017.10.041 summary: purpose: stereotactic laser ablation (sla) is a novel form of epilepsy surgery for patients with drug-resistant focal epilepsy. We evaluated one hundred consecutive surgeries performed for patients with epilepsy to address the impact of sla on our therapeutic approach, as well as patient outcomes. Methods: a retrospective, single center analysis of the last one hundred neurosurgeries for epilepsy was performed from 2013 to 2015. Demographics, surgical procedures, and postoperative measures were assessed up to 5 years to compare the effect of sla on outcome. Confidence intervals (ci) and comparative tests of proportions compared outcomes for sla and resective surgery. Procedural categorical comparison used chi-square and kaplan¿meier curves. Student t-test was utilized for single variables such as age at procedure and seizure onset. Results: one hundred surgeries for epilepsy yielded thirty-three slas and twenty-one resections with a mean of 21.7-month and 21.3-month follow-up, respectively. The temporal lobe was the most common target for sla (92.6%) and resection (75%). A discrete lesion was present on brain magnetic resonance imaging (mri) in 27/32 (84.4%) of sla patients compared with 7/20 (35%) of resection patients with a normal mri. Overall, 55¿60% of patients became seizure-free (sf). Four of five patients with initial failure to sla became sf with subsequent resection surgery. Complications were more frequent with resection although sf outcomes did not

									differ (chi square; p = 0.79). Stereotactic laser ablation patients were older than those with resections (47.0 years vs. 35.4 years, p = 0.001). The mean length of hospitalization prior to discharge was shorter for sla (1.18 days) compared with open resection (3.43 days; sd: 3.16 days) (p= 0.0002). Conclusion: we now use sla as a first line therapy at our center in patients with lesional temporal lobe epilepsy (tle) before resection. Seizure-free outcome with sla and resection was similar but with a shorter length of stay. Long-term follow-up is recommended to determine sustained sf status from sla. Reported event: (b)(6)-year-old female with post-operative memory loss. Manufacturer narrative: patient weight was not included in article. Please note that only the year the procedure was performed was provided. Article citation included. Please note that the system information was not included in the journal article and is unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
3007566237-2018-00687	14/09/2014	Injury	MEDTRONIC NEUROMODULATION	07/03/2018	MHY	UNKNOWN IMPLANTABLE NEUROSTIMULATOR	Adverse Event Without Identified Device or Use Problem	Facial Nerve Paralysis; Memory Loss/Impairment; Muscle Weakness; Neurological Deficit/Dysfunction; Paresis; Dysphasia; Ambulation Difficulties; Cognitive Changes; Confusion/ Disorientation; Cancer; Hydrocephalus	Summary/reported events: a (b)(6) male with the left-side dominant pd (hoehn <(>&<)> yahr stage 3) underwent bilateral stn-dbs in (b)(6) 2008. Following the next six years, a stable significant decrease in severity of parkinsonian symptoms, motor fluctuations, and drug-induced dyskinesia was observed. In (b)(6) 2014, they observed a progressive deterioration of neurological state resulting in weakness of the left limbs and unsteady gait. Transient speech disturbance and confusion appeared in (b)(6) 2014. Mri revealed anintracerebral tumor of the right thalamus and cerebral peduncle around the lead with obstructive hydrocephaly. Neurological examination showed prominent ataxia, left-sided hemiparesis, vertical gaze palsy, executive dysfunction, and memory impairment. Stereotactic biopsy of the tumor and

									ventriculo-peritoneal shunting was performed simultaneously. Cerebral symptoms and balance disturbances partially regressed after shunting. Biopsy result was glioblastoma multiforme. Subsequent radio- and chemotherapy was scheduled. Dbs-system was not explanted due to preserved strong dbs effect and significant worsening of parkinsonian symptoms in off-stimulation condition. Etiology of glioblastoma remains unclear. Current clinical observation alone could not prove a relationship between dbs and development of malignant glioma in the area of electrode implantation and electrostimulation. The authors concluded that, most likely, they observed two independent states, accidental case of glioblastoma formation in a dbs-patient. However, probability of tumor induction by electromagnetic field of dbs-electrode could not be excluded. It was not possible to ascertain specific device information from the article or to match the reported event with any previously reported event. Manufacturer narrative: updating event to reflect "life-threatening" outcome based on additional medical review. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: the main component of the system involved in the reported event; other applicable components are: product id: neu_unknown_lead, lot# unknown, product type: lead. Tomskiy, a., gamaleya, a., gubareva, n., latyshev, y., kobyakov, g., shishkina, l., pronin, i. A case of thalamic malignant glioma formation in a patient with stn-dbs for parkinson¿s disease. Mov disord. 2016; 31 (supplement 2): s39. Doi: 10.1002/mds.26688. If information is provided in the future, a supplemental report will be issued.
1723170-2020-03352	01/05/2014	Injury	MEDTRONIC NAVIGATION, INC	21/12/2020	GEX	VISUALASE	Adverse Event Without Identified	Cerebrospinal Fluid Leakage; Intracranial Hemorrhage; Memory	Citation: daniel curry, anil shetty, angus a. Wilfong. Outcomes of stereotactic laser ablation for treatment-resistant epilepsy in the pediatric population with 1 year follow-up. Stereotactic and functional

							Device or Use Problem	Loss/Impairment	neurosurgery (2014) 92 suppl. 1 (11). Date of publication: may 2014 abstract: introduction: approximately 7600 new cases of pediatric epilepsy occur each year and it is estimated that at least one-third of them with be refractory to medical management. Pediatric epilepsy surgery is vastly underutilized (~400 /year) due to its invasiveness and morbidity. Stereotactic laser ablation (sla) is a minimally invasive alternative for surgical candidates. We present the safety and patient outcomes in twenty patients. Methods: twenty patients with medically intractable lesional epilepsy, ages 2-18, underwent an irb-approved focus ablation. Epileptic foci had varied etiologies (hh:12,fcds:4,mts:3,ts:1). An fda-cleared surgical laser ablation system (visualase thermal therapy system; visualase, inc., houston, tx) was employed in this work. The cooled laser applicator (1.6 mm in diameter) includes a fiberoptic applicator with either a 1 cm or a 3 mm lightdiffusing tip. Framed stereotaxy was used to target the lesion and mr thermography was utilized. After a test dose of 3-4 w confirmed applicator position, doses of 5-12 w for 45-120 seconds were used to ablate the foci. Safety limits (50°c) were placed near the margin of the desired thermal ablation zone to protect critical structure. Postablation dwi, t1-weighted plus gadolinium contrast (t1 + gd), and ffe series were acquired. Follow-up period was from 11-41 months. Results: 13 patients were seizure free after one ablation, 3 after a second procedure. In the 19 pts with > 1 year follow-up, 11 achieved engel 1 status. 6 patients underwent repeat procedures, three ablations and three craniotomies. Complications included 3 transient short term memory dysfunctions, one sub-clinical subarachnoid hemorrhage, and one csf leak. Average los was 1 day. Conclusions: stereotactic laser ablation (sla) for epileptic foci has demonstrated rates of seizure freedom that match / are comparable to open surgical results. Low

									morbidity, reduced los and ability to stage procedures, along with the safety of real-time mr guided ablation are advantages. Reported events: -three patients experienced transient short term memory dysfunctions. -one patient experienced a sub-clinical subarachnoid hemorrhage. -one cerebrospinal fluid (csf) leak occurred. Manufacturer narrative: patient age not available from the site. Patient sex not available from the site. Patient weight not available from the site. Event date is the publication date of the abstract. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2020-03326	01/01/2014	Injury	MEDTRONIC NAVIGATION, INC	18/12/2020	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Convulsion/Seizure	Citation: jonathan lopez, brent o'neil, michael handler, kevin chapman. Laser ablation: a new therapeutic option for children with pharmacoresistant lesional epilepsy. Epilepsy currents. 2014 (14 suppl. 1 (434)). Rationale: a substantial number of children with pharmacoresistant epilepsy have seizures related to focal lesions. There is mounting evidence that surgical resection or ablation of such lesions and associated seizure foci in the brain during childhood results in significant improvement of seizure control andquality of life; however, not all lesions are amenable to traditional neurosurgical approaches. Stereotactic laser ablation has been demonstrated by others to be successful in children with epilepsy and is described in detail by curry et al. (2012).we report the first five consecutive cases of children with pharmacoresistant lesional epilepsy who underwent laser thermal ablation at our center. Methods: since january 2013, five children were selected to undergo this procedure (table 1). Imaging had revealed focal lesions and noninvasive studies were adequate to determine the extent of the focus of seizure onset. Stereotaxic positioning of laser

									catheters was followed by mri-guided laser interstitial thermal therapy (litt) using the visualase thermal therapy system (visualase, inc., houston, tx). Results: four children underwent a single procedure. One with a dysembryoplastic neuroepithelial tumor and another with periventricular nodular heterotopia underwent implantation of a single fiber. Two patients, both with focal cortical dysplasia, underwent implantation of two laser fibers as the size and conformation of their lesions was not amenable to single catheter ablation. One child with a giant hypothalamic hamartoma (patient 5) first underwent craniotomy and partial resection, followed by two litt procedures resulting in partial ablations. Post-operative length of stay ranged from 1-3 days, the novelty of the procedure resulting in stays that were longer than necessary. The patient with the giant hamartoma had catheters which were imperfectly placed, reducing their efficacy. Other than this, there were no unexpected complications. All patients had substantial and worthwhile seizure reduction following litt procedures: three are seizure free, one has had rare recurrent seizures related to non-adherence to medical regimen, and one (patient 5) has had rare clusters of tonic seizures. Conclusions: mri-guided litt is a recently approved treatment that may significantly decrease the cost and comorbidities associated with open surgical resection in a select group of children with lesional epilepsy. Further study is needed to determine whether effectiveness is comparable to open lesionectomy. Reported events: -one patient had rare clusters of tonic seizures. -one patient had rare re-current seizures related to non-adherence to medical regimen. Manufacturer narrative: patient age not available from the site. Patient sex not available from the site. Patient weight not available from the site. Event date is the publication date of the abstract. Device lot number, or serial number, unavailable. E)

									facility and address not populated as the facility was not provided in the abstract provided. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2020-03341	01/01/2014	Injury	MEDTRONIC NAVIGATION, INC	18/12/2020	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage; Memory Loss/Impairment; Paresis; Appropriate Clinical Signs, Symptoms, Conditions Term/Code Not Available	Complications of mr-guided stereotactic laser ablation of hypothalamic hamartomas in the treatment of intractable gelastic epilepsy in childhood; a multi-center study curry d.; wilfong a.; tovar-spinoza z.; madsen j.; takeoka m.; yoshor d.; viswanathan a.; ojemann j. Epilepsy currents (2014) 14 suppl. 1 (449). Date of publication: january-february 2014 embase link https://www.embase.com/search/results?subaction=viewrecord id=l71433784 & from=export rationale: hypothalamic hamartoma is a rare but disabling epileptic syndrome that imparts severe refractory gelastic seizures, frequently presenting with epileptic encephalopathy. Surgery to cure gelastic seizures has traditionally been open and highly morbid. Recently minimally invasive techniques have designed to decrease operative morbidity. We present the safety profile of the multi-center experience of the use of mr-guided stereotactic laser thermoablation (sla) in the treatment of hypothalamic hamartoma. Methods: 23 pediatric patients from five epilepsy centers presented with intractable epilepsy associated with hypothalamic hamartoma. An irb approved protocol was for pediatric patients (2-18 y.o.) With medically intractable, focal, lesional epilepsy. An fda-cleared surgical laser ablation system (visualase thermal therapy system; visualase, inc., houston, tx) was employed in this work. The cooled laser applicator is mr-compatible (1.6mm in diameter) with a central 400-¿m core silica fiberoptic applicator with 1 cm and 3 mm lightdiffusing tips. Framed and frameless stereotaxy was used to navigate the laser

									applicator to the targeted foci. Magnetic resonance temperature imaging (mrti) was used to test dose at 3-4w for 15-45 seconds to confirm applicator position, doses of 5-8w for 45-120 seconds were used to ablate the foci. Safety limits (50°c) were placed near the margin of the desired thermal ablation zone to protect critical structures like the optic tract, fornix and mammalothalamic tract. After completion of the ablation procedure, post ablation t1-weighted plus gadolinium contrast (t1 + gd) and dwi series were acquired. Follow-up period was from 1-32months results: seizure freedom was obtained in 81% of the patients. Of the ten patients that are more than one year post-ablation, 9 are seizure free. In the 13 patients with <(><<)> 1 year follow-up, 10 achieved seizure freedom and 3had seizure reduction. Three patients achieved seizure freedom after 2nd procedure no permanent surgical complications (di, memory impairment, hormonal changes, hemiparesis, visual changes) were noted. One patient has transient short-term memory loss, hyperthermia and hyperphagia prior to the institution of preablation high does steroids. There was a single incident of subclinical subarachnoid hemorrhage; there were two episodes of transient hemiparesis, and three episodes of transient short-term memory deficit. There were three target inaccuracies, one with a rigid frame, two with a frameless system. There was one subgaleal csf collection. Average los was 2.15 days. Conclusions: mr-guided sla for hypothalamic hamartomas appears to be a safe and effective alternative to open surgical resection in children with intractable epilepsy. Real-time, feedbackcontrolled ablation within the mr scanner, along with the minimally invasive approach, likely contributed to the low morbidity. Reported event(s): 1. One patient experienced subclinical subarachnoid hemorrhage 2. Two episodes of transient hemiparesis 3. Three episodes of transient

									short-term memory deficit 4. One reported subgaleal csf colection. Manufacturer narrative: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Includes the article citation. Literature article attached. If information is provided in the future, a supplemental report will be issued.
1723170-2020-03318	01/01/2014	Injury	MEDTRONIC NAVIGATION, INC	17/12/2020	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage	Angus wilfong, a. Shetty and daniel curry. Outcomes and safety profile of stereotactic laser ablation for treatment-resistant epilepsy in the pediatric population. Epilepsy currents, 2014 14 suppl. 1 (120). Rationale: treatment resistant epilepsy is common in children and leads to substantial morbidity. For select patients, surgical techniques can be highly effective. In controlled trials, epilepsy surgery has been shown to be superior to medical therapy with seizure freedom rates of 70 - 80%. Despite this success, surgery for epilepsy is underutilized in the united states with only 1,500 cases performed yearly. This may in part be due to concerns regarding the invasiveness and morbidity associated with traditional surgical techniques. Stereotactic laser ablation (sla) is a minimally invasive alternative for select surgical candidates. This report reviews the safety and clinical outcomes following sla of 23 patients at a single children¿s hospital. Methods: this study was approved by the baylor college of medicine irb and all patients were seen in the comprehensive epilepsy program at texas children¿s hospital, houston, tx. The patients were considered candidates for traditional resective epilepsy surgery and were offered sla as an alternative. Epileptic foci had varied etiologies: 14 hypothalamic hamartomas, 4 focal cortical dysplasia, 3 hippocampal sclerosis, 1 developmental tumor, and 1 tuberous sclerosis complex. An fda-cleared surgical laser ablation system (visualase thermal therapy system; visualase, inc., houston, tx) was employed. The cooled laser applicator is mrcompatible (1.6mm in diameter) with a central 400-¿m

									core silica fiberoptic applicator with a 1 cm light-diffusing tip. An mrcompatible head frame was used for stereotactic navigation. Magnetic resonance temperature imaging (mrti) was accomplished using a fast field echo (ffe) sequence field of view. After a test dose of 3-4 watts for 15-45 seconds to confirm applicator position, doses of 5-12 watts for 45-120 seconds were used to ablate the foci. Safety limits were placed near the margin of the desired thermal ablation zone to protect critical structures. After completion of the ablation procedure, post-ablation t1-weighted plus gadolinium contrast mri series were acquired. Follow-up period was from 13-35 months. Results: in 9 patients with 1 year or more follow-up, 7 or 9 are seizure-free (engel 1) with one patient having had 2 separate ablations. In the 14 patients with less than 1 year follow-up, 11 are seizure-free with one patient having had 2 separate ablations. Of the remaining 3 patients, 2 had a 50% seizure reduction and 1 had no change. There were no surgical complications other than a single asymptomatic minor subarachnoid hemorrhage. Average hospital length of stay was 1 day. Conclusions: stereotactic laser ablation of epileptic foci in children is possible and this early experience suggests robust efficacy and safety for a number of different lesions. In appropriate patients, the minimally invasive approach, high degree of precision and brief hospital stay makes sla an attractive alternative to craniotomy. More importantly, sla may increase the acceptance of a surgical treatment for epilepsy to patients and their families thereby reducing the enormous treatment gap that currently exists. Reported events: -one asymptomatic minor hemorrhage occurred. Manufacturer narrative: patient age not available from the site. Patient sex not available from the site. Patient weight not available from the site. Event date is the publication date of the article/abstract. Device lot number, or serial number, unavailable. No parts have been

									received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2018-05478	01/01/2014	Injury	MEDTRONIC NAVIGATION, INC	02/11/2018	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Memory Loss/Impairment	Citation: the impact of stereotactic laser ablation at a typical epilepsy center. Petito, gabrielle t. Et al. Epilepsy & behavior, volume 78, 37 ¿ 44. Https://doi.org/10.1016/j.yebeh.2017.10.041 summary: purpose: stereotactic laser ablation (sla) is a novel form of epilepsy surgery for patients with drug-resistant focal epilepsy. We evaluated one hundred consecutive surgeries performed for patients with epilepsy to address the impact of sla on our therapeutic approach, as well as patient outcomes. Methods: a retrospective, single center analysis of the last one hundred neurosurgeries for epilepsy was performed from 2013 to 2015. Demographics, surgical procedures, and postoperative measures were assessed up to 5 years to compare the effect of sla on outcome. Confidence intervals (ci) and comparative tests of proportions compared outcomes for sla and resective surgery. Procedural categorical comparison used chi-square and kaplan¿meier curves. Student t-test was utilized for single variables such as age at procedure and seizure onset. Results: one hundred surgeries for epilepsy yielded thirty-three slas and twenty-one resections with a mean of 21.7-month and 21.3-month follow-up, respectively. The temporal lobe was the most common target for sla (92.6%) and resection (75%). A discrete lesion was present on brain magnetic resonance imaging (mri) in 27/32 (84.4%) of sla patients compared with 7/20 (35%) of resection patients with a normal mri. Overall, 55¿60% of patients became seizure-free (sf). Four of five patients with initial failure to sla became sf with subsequent resection surgery. Complications were more frequent with resection although sf outcomes did not

									differ (chi square; p = 0.79). Stereotactic laser ablation patients were older than those with resections (47.0 years vs. 35.4 years, p = 0.001). The mean length of hospitalization prior to discharge was shorter for sla (1.18 days) compared with open resection (3.43 days; sd: 3.16 days) (p= 0.0002). Conclusion: we now use sla as a first line therapy at our center in patients with lesional temporal lobe epilepsy (tle) before resection. Seizure-free outcome with sla and resection was similar but with a shorter length of stay. Long-term follow-up is recommended to determine sustained sf status from sla. Reported event: 71- year-old male with post-operative memory loss/forgetful. Manufacturer narrative: patient weight was not included in article. Please note that only the year the procedure was performed was provided. Article citation included. Please note that the system information was not included in the journal article and is unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2018-05481	01/01/2014	Injury	MEDTRONIC NAVIGATION, INC	02/11/2018	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Headache; Visual Impairment; Anxiety	Citation: the impact of stereotactic laser ablation at a typical epilepsy center. Petito, gabrielle t. Et al. Epilepsy & behavior, volume 78, 37 ¿ 44. Https://doi.org/10.1016/j.yebeh.2017.10.041 summary: purpose: stereotactic laser ablation (sla) is a novel form of epilepsy surgery for patients with drug-resistant focal epilepsy. We evaluated one hundred consecutive surgeries performed for patients with epilepsy to address the impact of sla on our therapeutic approach, as well as patient outcomes. Methods: a retrospective, single center analysis of the last one hundred neurosurgeries for epilepsy was performed from 2013 to 2015. Demographics, surgical procedures, and postoperative measures were assessed up to 5 years to compare the effect of sla

									on outcome. Confidence intervals (ci) and comparative tests of proportions compared outcomes for sla and resective surgery. Procedural categorical comparison used chi-square and kaplan¿meier curves. Student t-test was utilized for single variables such as age at procedure and seizure onset. Results: one hundred surgeries for epilepsy yielded thirty-three slas and twenty-one resections with a mean of 21.7-month and 21.3-month follow-up, respectively. The temporal lobe was the most common target for sla (92.6%) and resection (75%). A discrete lesion was present on brain magnetic resonance imaging (mri) in 27/32 (84.4%) of sla patients compared with 7/20 (35%) of resection patients with a normal mri. Overall, 55¿60% of patients became seizure-free (sf). Four of five patients with initial failure to sla became sf with subsequent resection surgery. Complications were more frequent with resection although sf outcomes did not differ (chi square; p = 0.79). Stereotactic laser ablation patients were older than those with resections (47.0 years vs. 35.4 years, p = 0.001). The mean length of hospitalization prior to discharge was shorter for sla (1.18 days) compared with open resection (3.43 days; sd: 3.16 days) (p= 0.0002). Conclusion: we now use sla as a first line therapy at our center in patients with lesional temporal lobe epilepsy (tle) before resection. Seizure-free outcome with sla and resection was similar but with a shorter length of stay. Long-term follow-up is recommended to determine sustained sf status from sla. Reported event: (b)(6)-year-old male with post-operative visual field defect, headache, anxiety. Manufacturer narrative: patient weight was not included in article. Please note that only the year the procedure was performed was provided. Article citation included. Please note that the system information was not included in the journal article and is unavailable. No parts have been received by the manufacturer for evaluation. Device

									manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2018-05482	01/01/2014	Injury	MEDTRONIC NAVIGATION, INC	02/11/2018	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Memory Loss/Impairment	Citation: the impact of stereotactic laser ablation at a typical epilepsy center. Petito, gabrielle t. Et al. Epilepsy and behavior, volume 78, 37 ¿ 44. Https://doi.org/10.1016/j.yebeh.2017.10.041. Summary: purpose: stereotactic laser ablation (sla) is a novel form of epilepsy surgery for patients with drug-resistant focal epilepsy. We evaluated one hundred consecutive surgeries performed for patients with epilepsy to address the impact of sla on our therapeutic approach, as well as patient outcomes. Methods: a retrospective, single center analysis of the last one hundred neurosurgeries for epilepsy was performed from 2013 to 2015. Demographics, surgical procedures, and postoperative measures were assessed up to 5 years to compare the effect of sla on outcome. Confidence intervals (ci) and comparative tests of proportions compared outcomes for sla and resective surgery. Procedural categorical comparison used chi-square and kaplan¿meier curves. Student t-test was utilized for single variables such as age at procedure and seizure onset. Results: one hundred surgeries for epilepsy yielded thirty-three slas and twenty-one resections with a mean of 21.7-month and 21.3-month follow-up, respectively. The temporal lobe was the most common target for sla (92.6%) and resection (75%). A discrete lesion was present on brain magnetic resonance imaging (mri) in 27/32 (84.4%) of sla patients compared with 7/20 (35%) of resection patients with a normal mri. Overall, 55¿60% of patients became seizure-free (sf). Four of five patients with initial failure to sla became sf with subsequent resection surgery. Complications were more frequent with resection although sf outcomes did not differ (chi square; p = 0.79). Stereotactic laser ablation patients were older than

									those with resections (47.0 years vs. 35.4 years, p = 0.001). The mean length of hospitalization prior to discharge was shorter for sla (1.18 days) compared with open resection (3.43 days; sd: 3.16 days) (p= 0.0002). Conclusion: we now use sla as a first line therapy at our center in patients with lesional temporal lobe epilepsy (tle) before resection. Seizure-free outcome with sla and resection was similar but with a shorter length of stay. Long-term follow-up is recommended to determine sustained sf status from sla. Reported event: (b)(6) male with post-operative memory loss. Manufacturer narrative: patient weight was not included in article. Date of event: please note that only the year the procedure was performed was provided. Article citation included. Please note that the system information was not included in the journal article and is unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2018-05483	01/01/2014	Injury	MEDTRONIC NAVIGATION, INC	02/11/2018	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Headache; Anxiety; Depression	Citation: the impact of stereotactic laser ablation at a typical epilepsy center. Petito, gabrielle t. Et al. Epilepsy <(>&<)> behavior, volume 78, 37 ¿ 44. Https://doi.org/10.1016/j.yebeh.2017.10.041 summary: purpose: stereotactic laser ablation (sla) is a novel form of epilepsy surgery for patients with drug-resistant focal epilepsy. We evaluated one hundred consecutive surgeries performed for patients with epilepsy to address the impact of sla on our therapeutic approach, as well as patient outcomes. Methods: a retrospective, single center analysis of the last one hundred neurosurgeries for epilepsy was performed from 2013 to 2015. Demographics, surgical procedures, and postoperative measures were assessed up to 5 years to compare the effect of sla on outcome. Confidence intervals (ci) and comparative tests of proportions compared

									outcomes for sla and resective surgery. Procedural categorical comparison used chi-square and kaplan¿meier curves. Student t-test was utilized for single variables such as age at procedure and seizure onset. Results: one hundred surgeries for epilepsy yielded thirty-three slas and twenty-one resections with a mean of 21.7-month and 21.3-month follow-up, respectively. The temporal lobe was the most common target for sla (92.6%) and resection (75%). A discrete lesion was present on brain magnetic resonance imaging (mri) in 27/32 (84.4%) of sla patients compared with 7/20 (35%) of resection patients with a normal mri. Overall, 55¿60% of patients became seizure-free (sf). Four of five patients with initial failure to sla became sf with subsequent resection surgery. Complications were more frequent with resection although sf outcomes did not differ (chi square; p = 0.79). Stereotactic laser ablation patients were older than those with resections (47.0 years vs. 35.4 years, p = 0.001). The mean length of hospitalization prior to discharge was shorter for sla (1.18 days) compared with open resection (3.43 days; sd: 3.16 days) (p= 0.0002). Conclusion: we now use sla as a first line therapy at our center in patients with lesional temporal lobe epilepsy (tle) before resection. Seizure-free outcome with sla and resection was similar but with a shorter length of stay. Long-term follow-up is recommended to determine sustained sf status from sla. Reported event: (b)(6) female with post-operative headaches, anxiety, depressionreported event: (b)(6)-year-old male with post-operative headaches, anxiety, depression. Manufacturer narrative: patient weight was not included in article. Please note that only the year the procedure was performed was provided. Article citation included. Please note that the system information was not included in the journal article and is unavailable. No parts have been received by the manufacturer for evaluation. Device

									manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued.
1723170-2018-05484	01/01/2014	Injury	MEDTRONIC NAVIGATION, INC	02/11/2018	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Headache; Seizures	Citation: the impact of stereotactic laser ablation at a typical epilepsy center. Petito, gabrielle t. Et al. Epilepsy <(>&<)> behavior, volume 78, 37 ¿ 44. Https://doi.org/10.1016/j.yebeh.2017.10.041 summary: purpose: stereotactic laser ablation (sla) is a novel form of epilepsy surgery for patients with drug-resistant focal epilepsy. We evaluated one hundred consecutive surgeries performed for patients with epilepsy to address the impact of sla on our therapeutic approach, as well as patient outcomes. Methods: a retrospective, single center analysis of the last one hundred neurosurgeries for epilepsy was performed from 2013 to 2015. Demographics, surgical procedures, and postoperative measures were assessed up to 5 years to compare the effect of sla on outcome. Confidence intervals (ci) and comparative tests of proportions compared outcomes for sla and resective surgery. Procedural categorical comparison used chi-square and kaplan¿meier curves. Student t-test was utilized for single variables such as age at procedure and seizure onset. Results: one hundred surgeries for epilepsy yielded thirty-three slas and twenty-one resections with a mean of 21.7-month and 21.3-month follow-up, respectively. The temporal lobe was the most common target for sla (92.6%) and resection (75%). A discrete lesion was present on brain magnetic resonance imaging (mri) in 27/32 (84.4%) of sla patients compared with 7/20 (35%) of resection patients with a normal mri. Overall, 55¿60% of patients became seizure-free (sf). Four of five patients with initial failure to sla became sf with subsequent resection surgery. Complications were more frequent with

									resection although sf outcomes did not differ (chi square; p = 0.79). Stereotactic laser ablation patients were older than those with resections (47.0 years vs. 35.4 years, p = 0.001). The mean length of hospitalization prior to discharge was shorter for sla (1.18 days) compared with open resection (3.43 days; sd: 3.16 days) (p= 0.0002). Conclusion: we now use sla as a first line therapy at our center in patients with lesional temporal lobe epilepsy (tle) before resection. Seizure-free outcome with sla and resection was similar but with a shorter length of stay. Long-term follow-up is recommended to determine sustained sf status from sla. Reported event: (b)(6) female with post-operative left temporal seizures and headaches manufacturer narrative: patient weight was not included in article. Please note that only the year the procedure was performed was provided. Article citation included. Please note that the system information was not included in the journal article and is unavailable. No parts have been received by the manufacturer for evaluation. Evice manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2018-05485	01/01/2014	Injury	MEDTRONIC NAVIGATION, INC	02/11/2018	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Memory Loss/Impairment; Seizures; Depression	Citation: the impact of stereotactic laser ablation at a typical epilepsy center. Petito, gabrielle t. Et al. Epilepsy & behavior, volume 78, 37 ¿ 44. Https://doi.org/10.1016/j.yebeh.2017.10.041 summary: purpose: stereotactic laser ablation (sla) is a novel form of epilepsy surgery for patients with drug-resistant focal epilepsy. We evaluated one hundred consecutive surgeries performed for patients with epilepsy to address the impact of sla on our therapeutic approach, as well as patient outcomes. Methods: a retrospective, single center analysis of the last one hundred neurosurgeries for epilepsy was performed from 2013 to 2015. Demographics, surgical procedures, and postoperative measures were assessed

									up to 5 years to compare the effect of sla on outcome. Confidence intervals (ci) and comparative tests of proportions compared outcomes for sla and resective surgery. Procedural categorical comparison used chi-square and kaplan¿meier curves. Student t-test was utilized for single variables such as age at procedure and seizure onset. Results: one hundred surgeries for epilepsy yielded thirty-three slas and twenty-one resections with a mean of 21.7-month and 21.3-month follow-up, respectively. The temporal lobe was the most common target for sla (92.6%) and resection (75%). A discrete lesion was present on brain magnetic resonance imaging (mri) in 27/32 (84.4%) of sla patients compared with 7/20 (35%) of resection patients with a normal mri. Overall, 55¿60% of patients became seizure-free (sf). Four of five patients with initial failure to sla became sf with subsequent resection surgery. Complications were more frequent with resection although sf outcomes did not differ (chi square; p = 0.79). Stereotactic laser ablation patients were older than those with resections (47.0 years vs. 35.4 years, p = 0.001). The mean length of hospitalization prior to discharge was shorter for sla (1.18 days) compared with open resection (3.43 days; sd: 3.16 days) (p= 0.0002). Conclusion: we now use sla as a first line therapy at our center in patients with lesional temporal lobe epilepsy (tle) before resection. Seizure-free outcome with sla and resection was similar but with a shorter length of stay. Long-term follow-up is recommended to determine sustained sf status from sla. Reported event: (b)(6)-year-old male with one post-operativeBreakthrough seizure, memory loss/forgetfulness, depression. Manufacturer narrative: patient weight was not included in article. Please note that only the year the procedure was performed was provided. Article citation included. Please note that the system information was not included in the journal article and is

									unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2020-03385	01/01/2014	Malfunction	MEDTRONIC NAVIGATION, INC	23/12/2020	GEX	MEDTRONIC NAVIGATION	Use of Device Problem	No Clinical Signs, Symptoms or Conditions	Complications of mr-guided stereotactic laser ablation of hypothalamic hamartomas in the treatment of intractable gelastic epilepsy in childhood; a multi-center study curry d.; wilfong a.; tovar-spinoza z.; madsen j.; takeoka m.; yoshor d.; viswanathan a.; ojemann j. Epilepsy currents (2014) 14 suppl. 1 (449). Date of publication: january-february 2014 embase link https://www.embase.com/search/results?subaction=viewrecord <(>&<)>id=l71433784<(>&<)>from=export rationale: hypothalamic hamartoma is a rare but disabling epileptic syndrome that imparts severe refractory gelastic seizures, frequently presenting with epileptic encephalopathy. Surgery to cure gelastic seizures has traditionally been open and highly morbid. Recently minimally invasive techniques have designed to decrease operative morbidity. We present the safety profile of the multi-center experience of the use of mr-guided stereotactic laser thermoablation (sla) in the treatment of hypothalamic hamartoma. Methods: 23 pediatric patients from five epilepsy centers presented with intractable epilepsy associated with hypothalamic hamartoma. An irb approved protocol was for pediatric patients (2-18 y.o.) With medically intractable, focal, lesional epilepsy. An fda-cleared surgical laser ablation system (visualase thermal therapy system; visualase, inc., houston, tx) was employed in this work. The cooled laser applicator is mr-compatible (1.6mm in diameter) with a central 400-¿m core silica fiberoptic applicator with 1 cm and 3 mm lightdiffusing tips. Framed and frameless stereotaxy was used to navigate the laser applicator to the targeted foci. Magnetic

									resonance temperature imaging (mrti) was used to test dose at 3-4w for 15-45 seconds to confirm applicator position, doses of 5-8w for 45-120 seconds were used to ablate the foci. Safety limits (50°c) were placed near the margin of the desired thermal ablation zone to protect critical structures like the optic tract, fornix and mammalothalamic tract. After completion of the ablation procedure, post ablation t1-weighted plus gadolinium contrast (t1 + gd) and dwi series were acquired. Follow-up period was from 1-32months results: seizure freedom was obtained in 81% of the patients. Of the ten patients that are more than one year post-ablation, 9 are seizure free. In the 13 patients with <(><<)> 1 year follow-up, 10 achieved seizure freedom and 3had seizure reduction. Three patients achieved seizure freedom after 2nd procedure no permanent surgical complications (di, memory impairment, hormonal changes, hemiparesis, visual changes) were noted. One patient has transient short-term memory loss, hyperthermia and hyperphagia prior to the institution of preablation high does steroids. There was a single incident of subclinical subarachnoid hemorrhage; there were two episodes of transient hemiparesis, and three episodes of transient short-term memory deficit. There were three target inaccuracies, one with a rigid frame, two with a frameless system. There was one subgaleal csf collection. Average los was 2.15 days. Conclusions: mr-guided sla for hypothalamic hamartomas appears to be a safe and effective alternative to open surgical resection in children with intractable epilepsy. Real-time, feedbackcontrolled ablation within the mr scanner, along with the minimally invasive approach, likely contributed to the low morbidity. Reported event(s): there were 3 target inaccuracies. Manufacturer narrative: please note that this date is based off of the date of publication of the article as the event dates were not provided in the

									published literature. Includes the article citation. Literature article attached. If information is provided in the future, a supplemental report will be issued.
3004785967-2020-00978	06/11/2013	Injury	MEDTRONIC NAVIGATION, INC (LITTLETON)	25/08/2020	OXO	O-ARM 1000 IMAGING SYSTEM	Failure to Power Up; Application Program Freezes, Becomes Nonfunctional	No Known Impact Or Consequence To Patient	Medtronic received information regarding an imaging system being used in a cranial resection. It was reported that the system would not boot. The pendent on the image acquisition system (ias) stopped at the initializing stage. It was confirmed the system was not in estop mode and the dongle was fully seeded. The manufacturer representative tried several different boot sequences with no improvement. The procedure was aborted and rescheduled for a later date. Additional information was received stating that the patient was not under anesthesia, but was pinned in a stereotactic frame. It was also reported that the surgery was rescheduled. There was no incision made to the patient. Additional information was received stating that the rescheduled procedure was completed successfully. Manufacturer narrative: other relevant device(s) are: product id: bi31000146, serial/lot #: (b)(4); product id: bi31000118, serial/lot #: (b)(4). The unique identifier was not available at the time of reporting. The manufacturer representative went to the site to test the imaging system. The reported issue was confirmed and parts were replaced. The h-vltg tank was returned to the manufacture for evaluation. After testing it was found that there was a small filament primary coil (pins h and g of j1) that were open. An electrical failure was observed. The controller was returned to the manufacture for evaluation. After testing it was found that there was no failure found. The manufacture date was not available at the time of reporting. If information is provided in the future, a supplemental report will be issued.
1723170-2020-03329	01/06/2013	Injury	MEDTRONIC NAVIGATION, INC	18/12/2020	GEX	VISUALASE	Adverse Event Without Identified	Visual Impairment	Citation: laser ablation surgery for mesial temporal, lateral temporal, and extratemporal foci with and without lesion; successful integration of msi, fmri, and eeg and brainlab technology for non-invasive

							Device or Use Problem		localization and destruction of epileptic foci using stereotactic laser ablation (sla) chez m.; ghassemi a.; ciricillo s.; lepage c.; sekhon a.; low r.; seminario-lopez n. Epilepsia (2013) 54 suppl. 3 (181). Date of publication: june 2013 purpose: to present a less invasive technique for epilepsy surgery treatment combining surface eeg, msi (magnetic source imaging) and fmri combined with brainlab localization to enable minimally invasive mri guided stereotactic laser ablation (sla) of epileptogenic foci. Method: six children and 4-adults with medically refractory focal epilepsy were evaluated with video eeg, 3-tesla mri, fmri, msi (9- patients) and pet (1-patient). Two adults had mesial temporal sclerosis, three had frontal foci, one had superior non-dominant right superior temporal gyrus focus, one had sub-wernickes left superior-temporal gyrus, one had deep left cingulate gyrus focus near the posterior body of the corpus callosum, and one each of right and left occipital/temporal/parietal foci. Three-patients required 2-separate laser probes to be placed, and 1- patient required 3-laser probes. Ten- patients had sla (visualase, inc.) With frameless navigation (brainlab, inc.). All had intraoperative eeg monitoring in mri using plastic electrodes (ives) placed over ablation region on the cranial surface before mri guidance of laser ablation, thereby showing pre-ablation and post-ablation spike data. Pre-procedure msi scans were performed in all patients: 9-patients via ucsf biomagnetic imaging center, ctf systems, and 1- patient via pet scan, no msi. Preoperative eeg monitoring and fmri was done on all patients. Results: all patients showed resolution (8) or diminished number (2) of pre-ablation spikes on intra-procedure eeg taken immediately post-ablation. Seven-patients with single or multiple probe sla were pain-free, eating, and ambulatory within 6-8 h post-ablation and discharged within 24-h. Three-patients were discharged on post-surgery day 2. To date,

									2/3 frontal, both mesial temporal, both occipital, 1-cingulate, and 1/2 lateral temporal laser ablations remain seizure free. Only 1- mesial temporal patient had a superior quandrantopsia. Nine of ten participants have no known permanent undesirable sequelae. Improved eeg and cognitive functionwas noted after full post-operative recovery, correlating with reduced seizures. Reported event(s): 1. One mesial-temporal patient experienced superior quandrantopsia. Manufacturer narrative: patient age not available from the site. Patient sex not available from the site. Patient weight not available from the site. Event date is the publication date of the abstract. Device lot number, or serial number, unavailable. Facility and address not populated as the facility was not provided in the abstract provided. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2020-03343	01/05/2013	Injury	MEDTRONIC NAVIGATION, INC	18/12/2020	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Visual Impairment	Stereotactic laser ablation of epileptic foci: a novel, minimally invasive technique for intractable epilepsy willie j.t.; gowda a.; saindane a.; nour s.; gross r.e. Stereotactic and functional neurosurgery (2013) 91 suppl. 1 (7). Date of publication: may 2013 embase link https://www.embase.com/search/results?subaction=viewrecord <(>&<)>id=l71073445<(>&<)>from=export introduction: stereotactic laser ablation of epileptic foci - by computer-controlled laser induced interstitial thermal therapy (litt) with real-time magnetic resonance thermal image guidance - is a novel minimally invasive technique to treat intractable seizures with potential advantages over traditional open resective surgery. Here we report our experience in 11 epilepsy patients: 9 with mesial temporal lobe epilepsy (mtle), 1 with cavernous malformation (cm) and 1 with hypothalamic

									hamartoma (hh). Methods: a saline-cooled fiber optic laser applicator(visualase, inc.) Was inserted under general anesthesia utilizing a crw stereotactic frame (n=7) or clearpoint system (n=4). Laser energy was delivered during continuous mr imaging. Temperature-sensitive phase images and estimates of thermal damage during heating were superimposed on anatomical images in real-time. Standard mri scans were obtained immediately post-procedure, with reimaging at 6 months. Prospective baseline and post-operative seizure diaries, quality of life measures, and neuropsychometric testing were performed. Results: nine patients (10 procedures; ages 18-64) had mtle, 8 with =6 month follow-up. All five patients with mesial temporal sclerosis (mts) have had excellent or good epilepsy outcomes (engel 1 (n=4); engel 2 (n=1)), whereas patients without mts (n=3) had poor outcomes (engel 3-4). One patient with temporal lobe cm is seizure free at 6 months, and one patient with hh no longer experiences gelastic seizures. One serious complication, a visual field defect, occurred in one patient due to initial stereotactic rod misalignment. Conclusions: stereotactic laser ablation of epileptic foci is a promising, minimally invasive therapy for intractable epilepsy. Prel iminary limited results indicate that seizure outcomes in mtle might differ in patients with and without mts. Laser treatment of cavernous malformations and hypothalamic hamartomas is also promising. The safety and efficacy of this novel technique needs to be carefully evaluated with larger cohorts over longer periods of follow-up. (figure presented). Reported event(s): one patient experienced a serious complication of a visual field deficit defect due to stereotactic rod misalignment. Manufacturer narrative: please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Includes the article citation. If

									information is provided in the future, a supplemental report will be issued.
1723170-2020-00487	10/03/2013	Injury	MEDTRONIC NAVIGATION, INC	24/02/2020	HAW	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Hemorrhage/Bleeding	Citation: shinya nagahisa, takeya watabe, hikaru sasaki, yuya nishiyama, takuro hayashi, mitsuhiro hasegawa, yuichi hirose. Surgical navigation-assisted endoscopic biopsy is feasible for safe and reliable diagnosis of unresectable solid brain tumors. Neurosurg rev (2013) 36:595-601. Doi: 10.1007/s10143-013-0467-9. Abstract: abstract stereotactic biopsy has been validated for tissue sampling of deep-seated lesions that cannot be easily resected via open craniotomy. However, some inherent problems including the inability to directly observe the lesion and difficulty in confirming hemostasis limit its usefulness. To overcome these issues, we used the endoscope in brain tumor biopsy, for not only intraventricular tumors but also intraparenchymal tumors. The rigid scope was used in association with a surgical navigation system for intraparenchymal lesions via a transcortical route. There were no useful anatomical landmarks when the trajectory to the lesions was decided; therefore, surgical navigation system was required for the transcortical procedures. The endoscopic procedure described here was attempted in 21 cases of intraparenchymal lesions between january 2007 and february 2012. A definitive diagnosis was obtained in all cases, and genetic analysis was performed when required. Serious postsurgical hemorrhage or neurological deficits were not observed in any cases. Endoscopic surgery provides a clear view of the target and makes it easier to differentiate tumor tissue from normal brain tissue. Moreover, the endoscope helped to confirm hemostasis during the procedure. Thus, endoscopic biopsy has the potential to contribute toward safe and reliable diagnosis of brain tumors. Reported events: one (b)(6) year old female patient experienced a slight bleed which was observed on a post-operative computed tomography (ct) scan. No neurological

									deterioration was observed, so the patient was treated conservatively. Manufacturer narrative: patient weight not available from the site. Device lot number, or serial number, unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. 510(k) not provided as system identifier not provided. If information is provided in the future, a supplemental report will be issued.
1723170-2020-03344	01/03/2013	Injury	MEDTRONIC NAVIGATION, INC	20/12/2020	GEX	MEDTRONIC NAVIGATION	Adverse Event Without Identified Device or Use Problem	Insufficient Information	Preliminary experience with magnetic resonance temperature imaging (mrti) and stereotactic laser ablation (sla) for hippocampal sclerosis (hs) sharan a.d.; wu c.; shetty a.; skidmore c.t.; curry d.j.; wilfong a.a.; marsh w.r.; worrell g.a.; watson r.e.; vangompel j.j.; sperling m.r. Epilepsy currents (2013) 13 suppl. 1 (287). Date of publication: march-april 2013 embase link https://www.embase.com/search/results?subaction=viewrecord & id=l71196835 & from=export rationale: patients with unilateral hippocampal sclerosis (hs) represent the most suitable candidates for epilepsy surgery; however, the risk of cognitive decline and the invasiveness of an open craniotomy is a limiting concern - particularly with hs of the dominant-hemisphere. Minimally invasive stereotactic laser ablation (sla) using a 980nm diode laser may enable precise ablation of seizure foci with sparing of eloquent neocortical structures. Methods: patients were candidates for sla if eeg revealed seizures originating in the temporal lobe while mri showed concordant mesial temporal sclerosis. Preoperative evlauation also included neuropsychological evaluation. Frame-based navigation was used to intro duce a 1.6mm diameter mr-compatible laser applicator housing a 1cm long diffusing tip optical fiber into the amygdalohippocampal complex (ahc) from a temporo-occipital trajectory. The nearinfrared laser ablation system (visualase, inc, houston, tx) used consists of a 15w 980nm diode laser, a

									light-diffusing tip, and magnetic-resonance thermal imaging (mrti) software. This laser produces a cylindrical to ellipsoid light distribution in the tissue along the axis of the diffusing element. Ahc ablation was performed with 2 exposures of 10-12w for 90-130sec. Mrti was performed using proton resonance frequency (prf) phase difference imaging techniques using a fast field echo (ffe) sequence. Temperature was monitored and safety limits (>50degc) were placed near critical structures such as the optic tract, cerebral arteries, and hypothalamus. Temperatures at these pre-designated locations were set to terminate laser delivery if heating was excessive. Post-ablation t1- weighted gadolinium series confirmed areas of thermal ablation. Results: five patients at 3 institutions (2 females and 3 males), ages 16-65, presented with 2-20 seizures/month. Preoperative mri demonstrated hs alone in 4 patients, and hs in addition to a second lesion in 1 patient. Trajectories used were appropriate for controlled thermal ablation of desired structures and volumes as confirmed by mri. Post-ablation t1-weighted gadolinium series demonstrated a mean ablation volume of 3.65+/-0.93cc (2.18-4.91cc). Average length of stay was 1 day. Asymptomatic delayed hemorrhage within the ablation site was observed in 1 patient. There were no other surgical related complications. After follow-up of 3-13 months, all patients were improved with regard to seizure control with some experiencing seizure remission. Poorer outcomes were associated with smaller volumes of ablation, the presence of another radiographic lesion or seizure focus, or abrupt discontinuation of aeds. Conclusions: sla has promise as a treatment for refractory epilepsy secondary to hs. Seizures appear to respond to this minimally invasive therapy; and the procedure is associated with much less discomfort and a shorter hospital stay than conventional resective surgery. A larger study appears

									warranted by these preliminary results. Patient characteristics and outcomes after 3-13 months of follow-up. Engel classification of outcomes are provided only if at least 6 months of follow-up were available. (table presented). Reported event(s): 1. One patient experienced an asymptomatic delayed hemorrhage within the ablation site. Manufacturer narrative: this value reflects the gender of the majority of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. If information is provided in the future, a supplemental report will be issued.
1723170-2020-03332	12/02/2013	Injury	MEDTRONIC NAVIGATION, INC	18/12/2020	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Fever; Headache; Nerve Damage; Cognitive Changes; Insufficient Information	Citation: stereotactic-guided laser ablation of epileptogenic abnormalities in intractable focal epilepsy: preliminary results chatman m.; britton j.; cascino g.; shin c.; worrell g.; richard marsh w..w. Neurology (2013) 80:1 meeting abstracts. Date of publication: 12 feb 2013 objective: to evaluate the efficacy of stereotactic-guided laser ablation in intractable focal epilepsy. Background: resection of epileptogenic lesions is effective in treating intractable focal epilepsy. Resection usually entails a craniotomy, scalp and dural incisions which may lead to discomfort, cosmetic concerns and often entails > 3 day hospital stay. A new technique for tissue ablation using a stereotactic-guided laser-tipped catheter (visualase®) provides the means to perform lesionectomy via a burr hole and the potential for shorter hospital stay. Design/methods: we reviewed results of stereotactic-guided laser ablation in five patients with focal epilepsy (mesial temporal sclerosis (mts) n=3, hypothalamic hamartoma (hh) n =2). Results: the three mts patients averaged 64.2 partial seizures per month prior to surgery. Median length of stay = 2 days (range, 1-5), [median length of stay for temporal lobectomy in 2011 = 3 days (range, 2-10)]. Two patients have been

									seizure free since surgery, one experienced multiple auras during week 1 which resolved. One patient experienced a brachial plexitis shortly after hospital discharge, thought unrelated to his procedure; one experienced an exacerbation of bipolar disorder and suicidality. Two patients with hh were treated, median length of stay = 2 days. Mean seizure frequency prior to the procedure was 41.5 partial seizures per month. One patient has had three partial seizures over the four months since surgery, the other has experienced a 50% reduction in seizure frequency. One patient was hospitalized three days after the procedure with transient fever and hyponatremia attributed to acute hy pothalamic dysfunction which resolved. Conclusions: stereotactic-guided laser ablation is a potential new option in the management of focal epilepsy. Potential advantages include shorter length of stay. A randomized trial comparing this technique to standard surgical management would help establish whether there are advantages in efficacy and long-term side effects over resective surgery. Reported event(s): 1. One patient experienced multiple auras during the first week which resolved 2. One patient experienced brachial plexitis shortly after discharge (thought unrelated to procedure) 3. One patient experienced exacerbation of bipolar disorder and suicidality 4. One patient was hospitalized three days after the procedure with transient fever and hyponatremia attributed to acute hypothalamic dysfunction which resolved. Manufacturer narrative: patient age not available from the site. Patient sex not available from the site. Patient weight not available from the site. Event date is the publication date of the abstract. Device lot number, or serial number, unavailable. Facility and address not populated as the facility was not provided in the abstract provided. No parts have been received by the manufacturer for evaluation. Device

									manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2020-03333	12/02/2013	Injury	MEDTRONIC NAVIGATION, INC	18/12/2020	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage; Appropriate Clinical Signs, Symptoms, Conditions Term/Code Not Available	Citation: minimally invasive stereotactic laser ablation (sla) of hypothalamic hamartomas (hh) curry d.; wilfong a.; cascino g.; worrell g.; marsh r.; viswanathan a.; yoshor d.; takeoka m.; madsen j.; shetty a. Neurology (2013) 80:1 meeting abstracts. Date of publication: 12 feb 2013 objective: to study the feasibility of minimally-invasive stereotactic laser ablation for epileptogenic hh. Background: surgical intervention for hh has been limited due to modest outcomes (37- 50% seizure freedom), difficult location, and associated surgical morbidity (7-10% permanent). Stereotactic radiosurgery has also demonstrated modest results. Seizures are primarily gelastic, medically intractable and may occur every few minutes. Patients often develop progressive intellectual deterioration and disordered behavior. Design/methods: patients (n=13 ped:11 adult:2) with intractable gelastic epilepsy underwent stereotactic frame-based placement of mr-compatible laser catheter (1.6mm dia) through a 3.2mm twist drill hole. An fda-cleared laser surgery system (visualase; visualase, inc., houston, tx) was utilized to monitor the ablation of epileptogenic foci with real-time mri thermometry. After confirmation test at ~ 3w, higher doses of 6-10 w for 50-120 seconds were used for sla. Temperature limits were set to protect nearby structures like the hypothalamus, basilar artery, fornices, or mamillothalamic tracts. Results: there were no permanent surgical complications, neurological deficits, or neuroendocrine disturbances. One pt had transient di, another with prolonged hospitalization after dilantin toxicity, and another with a minor subarachnoid hemorrhage. The average los was 2 days. Seizure freedom was obtained in 8 of the 13 cases (61%), 72% in the pediatric patients. Engel 1 status was achieved in 2 of

									the 3 cases. Conclusions: sla was demonstrated to be a safe and effective minimally invasive tool to treat hh. Seizure freedom was achieved without surgical comorbidity and reduced los. Real-time mri thermometry enabled protection of adjacent critical structures. The best results from treatment of the hh will likely result if the treatment occurs before the evolution of the seizure pattern into a widespread secondary generalized epilepsy. Sla provides a precise minimally invasive tool in the neurosurgeon's armamentarium for first-line intervention and in cases where srs and surgery have failed. Reported event(s): 1. One patient had transient di 2. One patient experienced prolonged hospitalization after dilantin toxicity 3. One patient experienced a minor subarachnoid hemorrhage. Manufacturer narrative: event date is the publication date of the abstract. Device lot number, or serial number, unavailable. Facility and address not populated as the facility was not provided in the abstract provided. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1717344-2021-01464	01/01/2013	Injury	COVIDIEN MFG DC BOULDER	26/10/2021	GEI	UNKNOWN COOL-TIP RF ABLATION GENERATOR	Adverse Event Without Identified Device or Use Problem	Perforation; Intra-Abdominal Hemorrhage	According to the literature study of radiofrequency ablation versus stereotactic body radiation therapy for small (= 3 cm) hepatocellular carcinoma: a retrospective comparison analysis, between january 2013 and december 2013, rfa procedures were performed percutaneously under ultrasound guidance using a 200-w cool tip generator set. There were 266 patients in the study and one patient had grade 4 intra-abdominal hemorrhage and one patient with a grade 2 diaphragmatic injury. Manufacturer narrative: title: radiofrequency ablation versus stereotactic body radiation therapy for small (= 3 cm) hepatocellular carcinoma: a retrospective comparison analysis, source: 2021, journal

									of gastroenterology and hepatology foundation and john wiley & sons australia, ltd. If information is provided in the future, a supplemental report will be issued.
1723170-2018-05480	01/01/2013	Injury	MEDTRONIC NAVIGATION, INC	02/11/2018	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Visual Impairment	Citation: the impact of stereotactic laser ablation at a typical epilepsy center. Petito, gabrielle t. Et al. Epilepsy and behavior, volume 78, 37 ¿ 44. Https://doi.org/10.1016/j.yebeh.2017.10.041. Summary: purpose: stereotactic laser ablation (sla) is a novel form of epilepsy surgery for patients with drug-resistant focal epilepsy. We evaluated one hundred consecutive surgeries performed for patients with epilepsy to address the impact of sla on our therapeutic approach, as well as patient outcomes. Methods: a retrospective, single center analysis of the last one hundred neurosurgeries for epilepsy was performed from 2013 to 2015. Demographics, surgical procedures, and postoperative measures were assessed up to 5 years to compare the effect of sla on outcome. Confidence intervals (ci) and comparative tests of proportions compared outcomes for sla and resective surgery. Procedural categorical comparison used chi-square and kaplan¿meier curves. Student t-test was utilized for single variables such as age at procedure and seizure onset. Results: one hundred surgeries for epilepsy yielded thirty-three slas and twenty-one resections with a mean of 21.7-month and 21.3-month follow-up, respectively. The temporal lobe was the most common target for sla (92.6%) and resection (75%). A discrete lesion was present on brain magnetic resonance imaging (mri) in 27/32 (84.4%) of sla patients compared with 7/20 (35%) of resection patients with a normal mri. Overall, 55¿60% of patients became seizure-free (sf). Four of five patients with initial failure to sla became sf with subsequent resection surgery. Complications were more frequent with resection although sf outcomes did not differ (chi square; p = 0.79). Stereotactic laser ablation patients were older than

									those with resections (47.0 years vs. 35.4 years, p = 0.001). The mean length of hospitalization prior to discharge was shorter for sla (1.18 days) compared with open resection (3.43 days; sd: 3.16 days) (p= 0.0002). Conclusion: we now use sla as a first line therapy at our center in patients with lesional temporal lobe epilepsy (tle) before resection. Seizure-free outcome with sla and resection was similar but with a shorter length of stay. Long-term follow-up is recommended to determine sustained sf status from sla. Reported event: (b)(6) female with post-operative visual field defect. Manufacturer narrative: patient weight was not included in article. Date of event: please note that only the year the procedure was performed was provided. Article citation included. Please note that the system information was not included in the journal article and is unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is provided in the future, a supplemental report will be issued.
1723170-2018-05479	01/01/2013	Injury	MEDTRONIC NAVIGATION, INC	02/11/2018	GEX	VISUALASE	Adverse Event Without Identified Device or Use Problem	Headache; Memory Loss/Impairment; Depression	Citation: the impact of stereotactic laser ablation at a typical epilepsy center. Petito, gabrielle t. Et al. Epilepsy <(>&<)> behavior, volume 78, 37 ¿ 44. Https://doi.org/10.1016/j.yebeh.2017.10.041 summary: purpose: stereotactic laser ablation (sla) is a novel form of epilepsy surgery for patients with drug-resistant focal epilepsy. We evaluated one hundred consecutive surgeries performed for patients with epilepsy to address the impact of sla on our therapeutic approach, as well as patient outcomes. Methods: a retrospective, single center analysis of the last one hundred neurosurgeries for epilepsy was performed from 2013 to 2015. Demographics, surgical procedures, and postoperative measures were assessed up to 5 years to compare the effect of sla on outcome. Confidence intervals (ci) and comparative tests of proportions compared

									outcomes for sla and resective surgery. Procedural categorical comparison used chi-square and kaplan¿meier curves. Student t-test was utilized for single variables such as age at procedure and seizure onset. Results: one hundred surgeries for epilepsy yielded thirty-three slas and twenty-one resections with a mean of 21.7-month and 21.3-month follow-up, respectively. The temporal lobe was the most common target for sla (92.6%) and resection (75%). A discrete lesion was present on brain magnetic resonance imaging (mri) in 27/32 (84.4%) of sla patients compared with 7/20 (35%) of resection patients with a normal mri. Overall, 55¿60% of patients became seizure-free (sf). Four of five patients with initial failure to sla became sf with subsequent resection surgery. Complications were more frequent with resection although sf outcomes did not differ (chi square; p = 0.79). Stereotactic laser ablation patients were older than those with resections (47.0 years vs. 35.4 years, p = 0.001). The mean length of hospitalization prior to discharge was shorter for sla (1.18 days) compared with open resection (3.43 days; sd: 3.16 days) (p= 0.0002). Conclusion: we now use sla as a first line therapy at our center in patients with lesional temporal lobe epilepsy (tle) before resection. Seizure-free outcome with sla and resection was similar but with a shorter length of stay. Long-term follow-up is recommended to determine sustained sf status from sla. Reported event: (b)(6) male with post-operative headache, memory loss, depression. Manufacturer narrative: patient weight was not included in article. Please note that only the year the procedure was performed was provided. Article citation included. Please note that the system information was not included in the journal article and is unavailable. No parts have been received by the manufacturer for evaluation. Device manufacturing date is dependent on lot number/serial number, therefore, unavailable. If information is

									provided in the future, a supplemental report will be issued.
1723170-2020-03390	01/01/2013	Injury	MEDTRONIC NAVIGATION, INC	23/12/2020	GEX	MEDTRONIC NAVIGATION	Use of Device Problem	No Clinical Signs, Symptoms or Conditions	Early experience with minimally invasive epilepsy surgery using laser ablation in a pediatric cohort miller i.; ragheb j.; bhatia s.; hyslop a. Epilepsy currents (2013) 13 suppl. 1 (130-131). Date of publication: march-april 2013 embase link https://www.embase.com/search/results?subaction=viewrecord &id=l71196487 & from=export rationale: the visualase system has been fda-approved for thermal ablation of soft tissue in neurosurgery since 2007. It has many th eoretical advantages over conventional neurosurgical resection, including smaller exposure, shorter recovery, and less pain. The system also allows real-time mr guidance, which may further improve safety and surgical accuracy. Whether these benefits are observed in children undergoing epilepsy surgery has not yet been reported. Methods: miami children's hospital began using the visualase system in may, 2011. We report on the clinical history, surgical approach, and outcomes for all five patients with intractable epilepsy who have been treated using visualase since that time. Intraoperative neuronavigation included both the leksell stereotactic system, as well as the brainlab navigational system. Results: a total of five patients with intractable epilepsy underwent surgery at miami children's hospital between 5/2011 and 6/2012. The mean age at surgery was 14.9 years (range 11.5 to 18), with the mean age of epilepsy onset of 7.6 years (range 4-10.7). Of five patients undergoing visualase surgery, there were six total procedures. The only complication observed was placement-related: one patient was converted to conventional resection, one patient required a second visualase ablation, and three were satisfactory. Mean length of stay was 1.6 days (range 1-2). The were no complications from infection, bleeding, or unintended neurological injury. Two patients were engel class i (seizure

									free) after visualase surgery, one of whom required a second visualase ablation. In the remainder, one patient was engel class iii, one patient was engel class iv, and the fifth patient was engel class i following conversion to conventional resection. Conclusions: minimally invasive epilepsy surgery in children is safe and effective. Length of stay is shorter than conventional surgery, and we experienced no unanticipated complications. The biggest factor determining success was precise placement of the laser fiber, and complete destruction of the epileptogenic zone. Visualase is a promising mode of treatment for intractable pediatric epilepsy; small, deep lesions (such as those seen in tuberous sclerosis) may be particularly amenable to this approach. (figure presented). Reported event(s): 1. One patient was converted to a conventional resection due to a placement related issue 2. One patient required a second ablation manufacturer narrative: this value is the average age of the patients reported in the article as specific patients could not be identified. Please note that this date is based off of the date of publication of the article as the event dates were not provided in the published literature. Includes the article citation. The literature article is attached. If information is provided in the future, a supplemental report will be issued.
1226420-2018-00035	01/10/2011	Injury	MEDTRONIC ADVANCED ENERGY, LLC	08/02/2018	KNW	UNKNOWN INTACT HANDLE	Adverse Event Without Identified Device or Use Problem	Hematoma	Article: the breast lesion excision system (bles) under stereotactic guidance cannot be used as a therapeutic tool in the excision of small areas of microcalcifications in the breast objective: the breast lesion excision system (bles) is a new, automatic percutaneous breast biopsy device that excises single large specimens using radiofrequency cutting. The aim of this study was to determine whether bles, under stereotactic guidance, can be used as a therapeutic tool in the assessment of small areas of microcalcifications in the breast by providing samples with clear margins. Results: bles revealed fourteen (41.1%)

									high-risk lesions, ten (29.4%) ductal carcinomas in situ, and ten (29.4%) invasive cancers. Identical results between bles and surgery were seen in 17/34 (50%) lesions. Surgery confirmed total excision of bles in 15/34 (44.1%) lesions. Underestimation was seen in 2/34 (5.8%) lesions. Conclusion: bles allows accurate diagnosis of small areas of microcalcifications, with few underestimates. Bles is a diagnostic, but cannot be considered to be a therapeutic tool in the case of suspicious microcalcifications because total excision was seen in only 44.1% of these lesions. Studies are needed to address the therapeutic benefit of this procedure in solid lesions. Adverse events: minor complications were observed in seven patients (20.5%), comprising small hematomas with a diameter of less than 4.5 cm (n = 3) and prolonged, but self-limiting bleeding (n= 4). There were no patient identifiers within the article, therefore the patients will be reported as a whole and no other records will be created. Manufacturer narrative: product event: (b)(4). Patient information unable to be obtained despite a good faith effort made to obtain the information from the customer. A good faith effort will be made to obtain the applicable information relevant to the report. If information is provided in the future, a supplemental report will be issued.
1226420-2018-00036	01/10/2011	Injury	MEDTRONIC ADVANCED ENERGY, LLC	08/02/2018	KNW	UNKNOWN INTACT CONSOLE	Adverse Event Without Identified Device or Use Problem	Hematoma	Article: the breast lesion excision system (bles) under stereotactic guidance cannot be used as a therapeutic tool in the excision of small areas of microcalcifications in the breast objective: the breast lesion excision system (bles) is a new, automatic percutaneous breast biopsy device that excises single large specimens using radiofrequency cutting. The aim of this study was to determine whether bles, under stereotactic guidance, can be used as a therapeutic tool in the assessment of small areas of microcalcifications in the breast by providing samples with clear margins. Results: (b)(4). Studies are needed to

									address the therapeutic benefit of this procedure in solid lesions. (b)(4). There were no patient identifiers within the article, therefore the patients will be reported as a whole and no other records will be created. Manufacturer narrative: (b)(4) patient information unable to be obtained despite a good faith effort made to obtain the information from the customer. If information is provided in the future, a supplemental report will be issued.
1226420-2018-00037	01/10/2011	Injury	MEDTRONIC ADVANCED ENERGY, LLC	08/02/2018	KNW	UNKNOWN INTACT WAND	Adverse Event Without Identified Device or Use Problem	Hematoma	Article: the breast lesion excision system (bles) under stereotactic guidance cannot be used as a therapeutic tool in the excision of small areas of microcalcifications in the breast objective: the breast lesion excision system (bles) is a new, automatic percutaneous breast biopsy device that excises single large specimens using radiofrequency cutting. The aim of this study was to determine whether bles, under stereotactic guidance, can be used as a therapeutic tool in the assessment of small areas of microcalcifications in the breast by providing samples with clear margins. (b)(4). There were no patient identifiers within the article, therefore the patients will be reported as a whole and no other records will be created. Manufacturer narrative: (b)(4) patient information unable to be obtained despite a good faith effort made to obtain the information from the customer. If information is provided in the future, a supplemental report will be issued.
1226420-2018-00029	01/06/2010	Injury	MEDTRONIC ADVANCED ENERGY, LLC	08/02/2018	KNW	UNKNOWN INTACT HANDLE	Adverse Event Without Identified Device or Use Problem	Hematoma; Unspecified Infection	Article: margin-free excision of small solid breast carcinomas using the intact breast lesion excision system®: is it feasible? Doi 10.1007/s12282-017-0802-z background: the breast lesion excision system ® (bles) is a stereotactic vacuum-assisted breast biopsy device that utilizes radiofrequency in order to excise non-palpable mammographic lesions for pathologic diagnosis. The purpose of this study was to evaluate the efficacy of bles in performing complete, margin-free excisions of small solid carcinomas. Results: ductal carcinoma in situ (dcis) was diagnosed in 5 patients

									and invasive carcinoma (ic) in 45 patients, at primary bles pathology report. Tumor-free resection margins (<(><<)> 0.5 and <(><<)> 1 mm) were accomplished in only 8/24 subcentimeter cases (33.3%). Absence of residual disease upon surgical excision was confirmed in 23/24 subcentimeter cases (95.8%) and 2/26 of the cases measuring > 1 cm (7.69%). Statistical analysis revealed that mammographic size was the only significant prognostic factor for complete excision (i.e., with no residual disease in the biopsy cavity) of a malignant lesion. Conclusions our results indicate that it is possible, when using the bles device, to completely excise small (= 10 mm) breast carcinomas that appear radiologically as solid lesions. This subset of patients should be investigated regarding the therapeutic potential of this method. Complications were encountered after the procedure in 2 cases (4%) and included one case with a hematoma that was managed conservatively, and one post-procedural case of a wound infection that was treated with oral antibiotics. There were no patient identifiers within the article, therefore the patients will be reported as a whole and no other records will be created. Manufacturer narrative: product event: (b)(4). Patient information unable to be obtained despite a good faith effort made to obtain the information from the customer. A good faith effort will be made to obtain the applicable information relevant to the report. If information is provided in the future, a supplemental report will be issued.
1226420-2018-00030	01/06/2010	Injury	MEDTRONIC ADVANCED ENERGY, LLC	08/02/2018	KNW	UNKNOWN INTACT CONSOLE	Adverse Event Without Identified Device or Use Problem	Hematoma; Unspecified Infection	Article: margin-free excision of small solid breast carcinomas using the intact breast lesion excision system®: is it feasible? Doi 10.1007/s12282-017-0802-z background: the breast lesion excision system ® (bles) is a stereotactic vacuum-assisted breast biopsy device that utilizes radiofrequency in order to excise non-palpable mammographic lesions for pathologic diagnosis. The purpose of this study was to evaluate the efficacy of bles in performing

									complete, margin-free excisions of small solid carcinomas. Results: ductal carcinoma in situ (dcis) was diagnosed in 5 patients and invasive carcinoma (ic) in 45 patients, at primary bles pathology report. Tumor-free resection margins (<(><<)> 0.5 and <(><<)> 1 mm) were accomplished in only 8/24 subcentimeter cases (33.3%). Absence of residual disease upon surgical excision was confirmed in 23/24 subcentimeter cases (95.8%) and 2/26 of the cases measuring > 1 cm (7.69%). Statistical analysis revealed that mammographic size was the only significant prognostic factor for complete excision (i.e., with no residual disease in the biopsy cavity) of a malignant lesion. Conclusions our results indicate that it is possible, when using the bles device, to completely excise small (= 10 mm) breast carcinomas that appear radiologically as solid lesions. This subset of patients should be investigated regarding the therapeutic potential of this method. Complications were encountered after the procedure in 2 cases (4%) and included one case with a hematoma that was managed conservatively, and one post-procedural case of a wound infection that was treated with oral antibiotics. There were no patient identifiers within the article, therefore the patients will be reported as a whole and no other records will be created. Manufacturer narrative: (b)(4) patient information unable to be obtained despite a good faith effort made to obtain the information from the customer. If information is provided in the future, a supplemental report will be issued.
1226420-2018-00031	01/06/2010	Injury	MEDTRONIC ADVANCED ENERGY, LLC	08/02/2018	KNW	UNKNOWN INTACT WAND	Adverse Event Without Identified Device or Use Problem	Hematoma; Unspecified Infection	Article: margin-free excision of small solid breast carcinomas using the intact breast lesion excision system®: is it feasible? Doi 10.1007/s12282-017-0802-z background: the breast lesion excision system ® (bles) is a stereotactic vacuum-assisted breast biopsy device that utilizes radiofrequency in order to excise non-palpable mammographic lesions for pathologic diagnosis. The purpose of this study was to evaluate the efficacy of bles in performing

									complete, margin-free excisions of small solid carcinomas. Results: ductal carcinoma in situ (dcis) was diagnosed in 5 patients and invasive carcinoma (ic) in 45 patients, at primary bles pathology report. Tumor-free resection margins (<(><<)> 0.5 and <(><<)> 1 mm) were accomplished in only 8/24 subcentimeter cases (33.3%). Absence of residual disease upon surgical excision was confirmed in 23/24 subcentimeter cases (95.8%) and 2/26 of the cases measuring > 1 cm (7.69%). Statistical analysis revealed that mammographic size was the only significant prognostic factor for complete excision (i.e., with no residual disease in the biopsy cavity) of a malignant lesion. Conclusions our results indicate that it is possible, when using the bles device, to completely excise small (= 10 mm) breast carcinomas that appear radiologically as solid lesions. This subset of patients should be investigated regarding the therapeutic potential of this method. Complications were encountered after the procedure in 2 cases (4%) and included one case with a hematoma that was managed conservatively, and one post-procedural case of a wound infection that was treated with oral antibiotics. There were no patient identifiers within the article, therefore the patients will be reported as a whole and no other records will be created. Manufacturer narrative: product event: (b)(4). Patient information unable to be obtained despite a good faith effort made to obtain the information from the customer. If information is provided in the future, a supplemental report will be issued.
1820334-2018-01216	19/03/2010	Injury	COOK INC	03/05/2018	KRD	UNKNOWN	Flaked	Stroke/CVA; Foreign Body Reaction; Decreased Respiratory Rate	A journal article was reviewed, "hydrophilic polymer emboli: an under-recognized iatrogenic cause of ischemia and infarct" which discussed the concern that there is potential for embolization of materials introduced into the vasculature due to the increased use of percutaneous intravascular diagnostic and therapeutic devices; specifically hydrophilic polymer coating of these devices. The article included case

									studies and 6 of the case studies included patients that underwent procedures where cook devices were used. The author reported a 36-year-old woman with a history of gastric bypass (performed 2 years before admission) presented with altered mental status, behavioral and postural changes, and decreased respiration. Mri of the brain revealed t2/flair hyperintensities involving the deep and subcortical white matter, left cerebral peduncle, and middle cerebellar peduncles. The clinico-radiological findings were suggestive of a demyelinating process. Four-vessel cerebral angiogram showed no evidence of vasculitis. Stereotactic biopsy of the right occipital cortex performed 13 days after angiography showed intravascular aggregates of lamellated, non-polarizable, non-refractile colorless foreign material with arterial occlusion, and intravascular foreign body reaction, recognized even at the time of frozen section. Two arteries (measuring 188 and 600 mm in diameter) were affected in three tissue sections examined. One vessel showed linear stenosis and/or occlusion along a longitudinal course of 4mm. Fibrinoid necrosis, microthrombus formation, and luminal fibrosis with focal recanalization were identified. Neuronal hypoxic ischemic changes and nodular areas of neovascularization were also noted adjacent to the occluded vessels." additional information regarding event details has been requested, but is not available at this time. Refer to medwatches with manufacturer report numbers as follows for the other cases: 1820334-2018-01124, 1820334-2018-01125, 1820334-2018-01217, 1820334-2018-01218, 1820334-2018-01219. Manufacturer narrative: blank fields on this form indicate the information is unknown, or unavailable. Common name & product code = unavailable as the device lot number, rpn, and gpn are unknown. Cerebral angiography (4 vessel): 5f terumo-angled glide catheter, terumo-angled

									guidewire, bentson wire (cook), 6f perclose. (b)(4). Pma/510(k) number = unavailable as the device lot number, rpn, and gpn are unknown. Pma/510(k) number = pre-amendment. This report includes information known at this time. A follow-up report will be submitted should additional relevant information become available. Mehta et al., (2010), hydrophilic polymer emboli: an under-recognized iatrogenic cause of ischemia and infarct. Vol 23, pp 921-930 modern pathology, retrieved from: www.modernpathology.org - attachment: [metha_hydrophilic polymer emboli.pdf].
3015145560-2021-00001		Injury	FOSUN PHARMA USA INC	21/03/2021	KXG	NASOPHARYNGEAL SWAB	Adverse Event Without Identified Device or Use Problem	Cerebrospinal Fluid Leakage; Headache; Pain; Encephalocele	This literature case, derived from a full text scientific article, was received on 09-mar-2021. It described a (b)(6) female patient who had traumatic skull base injury during a nasopharyngeal swab for covid-19 resulting in cerebrospinal fluid rhinorrhea (pt: cerebrospinal fluid leakage and head injury). Case report: a (b)(6) female presented to the hospital after experiencing severe pain during a nasopharyngeal (np) swab for coronavirus disease 2019 (covid-19) followed by 2 days of persistent clear watery rhinorrhea that worsened with leaning forward. She also noticed persistent headache and metallic tasting postnasal drip. The patient had no history of head trauma or surgery. She was otherwise healthy. Initial examination, including nasal endoscopy, was unremarkable other than a small amount of clear right-sided nasal drainage. The patient underwent a computed tomography scan, which demonstrated a subtle defect in the posterior right cribriform plate. She then underwent magnetic resonance imaging, which demonstrated a small encephalocele projecting from the olfactory fossa of the right superior nasal cavity. It was decided to explore and perform a skull base repair. The patient was taken to the operating room the following day for endoscopic endo-nasal approach with stereotactic navigation. The posterior cribriform and ethmoid roof were not visualized with lateralization of

									the middle turbinate, and so it was removed, and its mucosa harvested for a free graft. This allowed visualization of a small encephalocele just anterior to the sphenoid rostrum at the junction between the cribriform and ethmoid roof. Valsalva resulted in visible pulsation and increased flow of cerebrospinal fluid (csf). The surrounding bone and mucosa were removed, exposing the dura. The encephalocele was reduced with bipolar cautery. The free mucosal graft was then placed over the expanse of the exposed dura and csf leak. Cessation of the csf leak was confirmed. Surgicel was then placed around the margin of the graft, and dural sealant was applied. This was followed by gelfoam, and a sponge packing. The patient was placed on sinus precautions and observed overnight. She progressed appropriately and was discharged the following day. She was seen in follow-up on postoperative day 9 and reported resolution of all symptoms. The nasal sponge was removed at that time. Nasal endoscopy demonstrated appropriately healing mucosa and no signs of a persistent csf leak. Author's comment: csf leak should be considered in patients with watery rhinorrhea or salty or metallic taste postnasal drip following an np swab. This case highlights the need for education of proper np swab technique for healthcare providers and education of the signs and symptoms of csf rhinorrhea for patients. Furthermore, alternate testing methods should be considered in patients with known distortions in nasal or skull base anatomy, history of sinus or skull base surgery, or conditions that may pre-dispose the patient to skull base erosion. Literature citation: paquin r, ryan l, vale fl, rutkowski m, byrd jk. Csf leak after covid[?]19 nasopharyngeal swab: a case report. Laryngoscope. 2021; 00:1-3. Company comment: a patient had traumatic skull base injury during a nasopharyngeal swab for covid-19 resulting in cerebrospinal fluid

									rhinorrhea (cerebrospinal fluid leakage and head injury). This patient had no history of head trauma or surgery, and found to have a subtle defect in the posterior right cribriform plate after nasopharyngeal swab was performed, which resulted in cerebrospinal fluid leakage. In response to these events, patient was successfully treated in the hospital with a surgical exploration and performed skull base repair. Considering the case information, the causality of cerebrospinal fluid leakage and head injury is assessed as possible with nasopharyngeal swab. The case is considered serious due to medical significance of events cerebrospinal fluid leakage and head injury which resulted in hospitalization and required a surgical intervention. The events cerebrospinal fluid leakage and head injury are unlisted.
9612186-2020-00010		Injury	ELEKTA INSTRUMENT AB	02/10/2020	HAW	LEKSELL GAMMA KNIFE	Adverse Event Without Identified Device or Use Problem	Bradycardia	Whilst performing/completing a literature search the following case was found: christensen re, nause-]osthoff rc, waldman jc, spratt de, hearn jwd. Adverse events in radiation oncology: a case series from wake up safe, the pediatric anesthesia quality improvement initiative. Pediatr anesth. 2019; 29:265-270. Https://doi.org/10.1111/pan.1356. (b)(6) year-old asa 3 male for radiosurgery of brain tumor in head frame. Nurse noted pulling on circuit and tape peeling off face. Team went in after radiation powered down. Wheezing heard, albuterol given chest rise noted. Direct laryngoscopy by nurse anesthetist noted ett through cords. Endtidal carbon dioxide lost. Laryngoscopy by attending showed ett through cords but head frame hindering view. Help called, frame removed, bradycardia arrest. Epinephrine through ett and intravenous, other anesthesiologist laryngoscopy with frame off, ett in esophagus. Reintubated with rapid improvement in saturation and return of pulse. 1.5 min chest compressions. Admitted to intensive care. Woke up hour later with no deficits. Noted that usual device to secure ett to prevent pulling was

									missing that day. Anesthesiologist covering one site and nurse anesthetist with additional anesthesiologist called for help. Failure to obtain or act on available information. Interpersonal conflict, crowding (lack of space). Manufacturer narrative: from the literature report it can be concluded that a (b)(6) year-old patient was treated with the gamma knife (stereotactic radiosurgery) under anaesthesia. Due to improper fastening of the endotracheal tube, the tube came out of position during treatment. When trying to intubate the patient again it took 3 laryngoscopies before it was determined that the endotracheal tube had been re-positioned correctly in the oesophagus. Bradycardic cardiac arrest occurred, and the patient was taken to the intensive care unit and woke there without apparent deficits. The investigation concluded the root cause is not related to the leksell gamma knife and its accessories. Therefore leksell gamma knife did not have any malfunction and is working as designed and intended. The root cause is determined to be the lack of securing the intubation tube before the gamma knife treatment and the delayed removal of the g-frame in order to successfully re-intubate the patient.
2021898-2019-00413		Injury	MEDTRONIC NEUROSURGERY	15/11/2019	JXG	UNKNOWN CATHETER	Adverse Event Without Identified Device or Use Problem	Hemorrhage/Bleeding; Hemorrhage, Cerebral; Hiccups; Unspecified Infection; Urinary Tract Infection	Zhu hongyu, zhai xiaodong, meng wenbo, cheng yuefei, yin shangjiong, zhao peilin, wang hongsheng. Stereotactic minimally invasive surgical treatment for hypertensive cerebellar hemorrhage. Chin j neurotrauma surg 3 (2017). Doi: 10.3877/cma.j.issn.2095-9141.2017.03.005. Abstract objective to investigate the therapeutic effect of ct-guided stereotactic minimal invasive and drainage for hypertensive cerebellar hemorrhage. Methods twenty-three cases of hypertensive cerebellar hemorrhage patients treated with stereotactic minimally invasive drainage were retrospectively analyzed in our hospital from january 2013 to june 2016, compared the efficacy with the other 23 patients who underwent

									posterior fossa craniotomy with hematoma removal at the same time period. The amount of bleeding of two groups were both 10~20 ml. The stereostatic group was given ct guided stereotactic minimal invasive and drainage treatment, after operation, poured urokinase into the hematoma to dissolved it. The craniotomy group was performed posterior cranial fossa craniotomy after general anesthesia and the hemotoma was removaled by the microsurgery, after operation, the hemostasis, dehydration etc were given to the patients. Results the average hospitalization days of the stereostatic group was significantly shorter than the craniotomy group (p=0.01). The postoperative complication of the stereostatic group less than the craniotomy group (p =0.03). The emptying time of hematoma of the stereostatic group langer than the craniotomy group (p=0.04). The activities of daily living classification after six months treatment of the stereostatic group no statistical difference with the craniotomy group (p= 0.33). Conclusion the stereotactic minimal invasive and drainage for cerebellar hemorrhage could achieve considerable reset effect compare with the posterior cranial fossa craniotomy, and it was accurate positioning, little injury, less complication, shorter hospitalization and so on. The ster eotactic minimal invasive and drainage for hypertensive cerebellar hemorrhage is worthy for the clinical popularization and application. Reported events. Rebleeding occurred in 4.35% of patients in both groups. In the stereotactic group (those who used medtronic edm), rebleeding was determined as observing on postoperative ct a larger hematoma volume than the volume of the original hematoma minus the amount that was drained. Other complications occurred at a rate of 8.69% in the stereotactic group and 34.78% in the control group. The authors state that ¿postoperative complications were primarily pulmonary infection, upper digestive tract

									bleeding, urinary tract infection, and persistent hiccup¿. Manufacturer narrative: if information is provided in the future, a supplemental report will be issued.
3004608878-2019-01019		Injury	INTEGRA LIFESCIENCES CORPORATION OH/USA	30/09/2019	HAW	CRW SYSTEM	Adverse Event Without Identified Device or Use Problem	Hematoma; Seizures	Asian journal of neurosurgery (2019) published ¿venture in 101 cranial punctures: a comparative study between frame-based versus frameless biopsy of 101 intracranial space occupying lesion¿. Presumptive diagnosis based solely on the clinical picture and imaging was not sufficient to provide appropriate treatment with certainty and hence histopathological confirmation of intracranial space occupying lesion (icsol) is essential. Needle biopsy via stereotactic frame-based or frameless neuronavigation technique was efficient procedure. The objective of the study was to compare their accuracy and efficacy and safety. Methods: this was a single-center retrospective analytical cross-sectional nonprobability purposive study conducted in the center among 101 patients during a period of 5 years from 2014 to 2018. Two techniques were used: frame-based stereotactic using the cosman-robert-wells (crw) frame; and frameless neuronavigation-guided in which image acquisition was done from magnetic resonance imaging image loaded compact disc and patient registered in stealth, neuronavigation system, an infrared led-based system. Head of patient was shaved after general anesthesia and head fixed with three pins clamp on mayfield. A biopsy was done by dedicated neurosurgeons. The selection of technique was based on the surgeon preference. Results: out of 101 patients, frame-based stereotactic biopsy was done among 55 patients (54.4%) while 46 patients (45.6%) underwent frameless stealth neuronavigation guided biopsy. Male to female ratio was 2.1:1. Age ranged from 5 to 82 years. 54.5% (55 patients) have deeper location of tumor while 45.5% (46 patients) have lobar location of tumor. Frontal (16.8%) and thalamic (13.8%) were the common site. Mean size of tumor was

									3.0 +/- 0.85cms. There was statistically significant difference in operative duration among study groups. Overall diagnostic yield was 89.1%. Glioma was the most common (50.5%) diagnosis. Glioblastoma who grade iv was 37.6% followed by lymphoma (12.8%). Overall, postoperative morbidity was 4.9%. Two patients developed seizure among frame-based stereotactic group while tract hematoma was present in one case of each study group which were managed conservatively. One patient in frameless neuronavigation group developed neurological deficit. The mean duration of hospital stay was 11.83 +/- 10.13 days (range: 4¿42 days). There was no mortality in any groups. In a study done by kreth et al., 0.9% developed hemorrhage-related complication. As reported by krieger et al. Of 3500 stereotactic biopsies, they had one procedure-related death, seven significant hemorrhages including subdural and epidural hematomas, five seizures (1.4%), and two infections. Conclusion: needle biopsy through frameless or frame-based technique is a safe and efficient procedure. Both techniques have a high diagnostic yield. Reasons for negative biopsy were missed target or retrieval of gliotic tissue from the target lesion. High-volume prospective study is recommended to attest these inferences. Manufacturer narrative: the device was not returned to the manufacturer for analysis. The plant investigation is in progress and a supplemental medwatch report will be submitted upon completion of the investigation. Doi: 10.4103/ajns.ajns_137_18.
3004608878-2019-01030		Injury	INTEGRA LIFESCIENCES CORPORATION OH/USA	30/09/2019	HAW	NASHOLD BIOPSY NEEDLE (DISPOS)	Adverse Event Without Identified Device or Use Problem	Exsanguination; Neurological Deficit/Dysfunction	This is 1 of 4 reports. The journal of neurological surgery (2019) published "frame-based stereotactic biopsy: description and association of anatomical, radiologic, and surgical variables with diagnostic yield in a series of 407 cases". Stereotactic biopsy is a versatile, minimally invasive technique to obtain tissue safely

									from intracranial lesions for their histologic diagnosis and therapeutic management. The objective of the study was to determine the anatomical, radiologic, and technical factors that can affect the diagnostic yield of this technique. Methods: this retrospective study evaluated 407 patients who underwent stereotactic biopsies in the past 34 years between 1982, when this technique was first used in their institution, and 2016 were retrieved and evaluated. The surgical methodology changed through time, distinguished by three distinct periods. The surgical methodology used throughout the decades was determined by the equipment available in the hospital at the time. Different stereotactic frames, neuroimaging tests, and planning programs were used. During period 1 (1982-1991), todd-wells (radionics) was used; period 2 (1991-2011), cosman-roberts-wells (crw) (integra) along with the nashold biopsy needle (integra) were used; and period 3 (2011-2016) leksell (electra instruments) was used. Statistical analysis was performed with spss v. 23 for windows (spss inc.) Using parametric tests. The 407 patients who had undergone stereotactic biopsy in department, 143 in period 1 (35.2%), 213 in period 2 (52.3%), and 51 in period 3 (12.5%). The average age of the patients in the series was 53.8 years. Most of the patients were in the fifth and sixth decades of life (47.6%), with an average of 57 years of age (range 3-86 years old). Fourteen (3.4%) were pediatric (patients 16 years of age). The sex ratio was 1.8:1, with 265 men (65.1%) and 142 women (34.9%). Most lesions were on the left side (41.8%). The frontal region was the most frequently biopsied anatomical region (24.8%), and the cerebellum (1%) and brainstem (1%) were the least. After histologic evaluation, the most frequently diagnosed pathologies were tumor in 78.8%, followed by vascular pathology (i.e., hemorrhagic or ischemic stroke) in 5.4%, radionecrosis in 0.5%, and neurologic pathology (multiple sclerosis) in

									0.2%. The most frequently diagnosed tumor was a high-grade glioma (42.8%); the biopsies were nondiagnostic in 9.6%. Forty patients (9.8%) had symptomatic intracranial hemorrhages (worsened the level of consciousness and/or produced new neurologic deficits after the biopsy). Most of those patients improved significantly in the following days. Twenty-three of the patients (57.5%) were discharged with a karnofsky performance status greater than 80. During period 2, hemorrhagic complications: karnofsky performance status less than or equal to 70 at discharge was 8. Morbidity was 5.65% (n = 17). The procedure-associated mortality was 0.98% (n = 4). During period 2, mortality was 1. The overall diagnostic yield of our stereotactic biopsies was 90.4%, and there were no statistically significant differences in the diagnostic yields among the three methodological periods (p = 0.864). Intraoperative biopsy improved accuracy (p = 0.024). Biopsies of deep lesions (p = 0.043), without contrast enhancement (p = 0.004), edema (p = 0.036), extensive necrosis (p = 0.028), or a large cystic component (p = 0.023) resulted in a worse diagnostic yield. Neurosurgeons inexperienced in stereotactic techniques obtained more nondiagnostic biopsies (p = 0.043). Experience was the clearest predictive factor of diagnostic yield (odds ratio: 4.049). Overall, 39 of the biopsies (9.6%) were nondiagnostic. This result was consistent with previous reports. Of those, 2% (n = 8) were inconclusive, and 7.6% (n = 31) were negative. In these patients, the stereotactic biopsy was repeated once in 71.7% of the cases (n = 28) and twice in 10.2% of the cases (n = 4). In this series of 407 patients, 82 (20.1%) underwent craniotomies after the biopsy. The main reasons were either surgical resection of the lesion was considered the best treatment strategy after histologic results (64.7%; n = 53) or there were doubts about these histologic results because of the

									clinical condition and the neuroimaging tests of the patient (26.8%; n = 22). In seven patients (8.5%), the indication for surgery was based on not obtaining a diagnosis by stereotactic methods. Conclusion: increased experience in stereotactic techniques, use of the most suitable magnetic resonance imaging sequences during biopsy planning, and intraoperative evaluation of the sample before finalizing the collection are recommended features and ways to improve the diagnostic yield of this technique. Manufacturer narrative: the device is not expected to be returned to the manufacturer for analysis. The plant investigation is in progress and a supplemental medwatch report will be submitted upon completion of the investigation. Linked to mfg. Report numbers: 3004608878-2019-01031, 3004608878-2019-01032, and 3004608878-2019-01033. Doi: https://doi.org/10.1055/s-0038-1676597.
3004608878-2019-01036		Injury	INTEGRA LIFESCIENCES CORPORATION OH/USA	30/09/2019	HAW	CRW SYSTEM	Adverse Event Without Identified Device or Use Problem	Hemorrhage, Cerebral; Neurological Deficit/Dysfunction; Injury	This is 3 of 4 reports. Clinical neurology and neurosurgery (2017) published "how is stereotactic brain biopsy evolving? A multicentric analysis of a series of 421 cases treated in rome over the last sixteen years". Objective: in recent decades, frame-based (fbb) and frame-less stereotactic brain biopsy (flb) have played a crucial role in defining the diagnosis and management of expanding intracranial lesions in critical areas. During the same period, there have been significant advances in diagnostic imaging, a shift in surgical strategies towards extensive resection in gliomas and new molecular classification of brain tumors. Taking these advances into account, the authors have evaluated whether significant changes have occurred over the last sixteen years of their clinical practice in terms of frequency, indications, target selection, and the histologic results of stereotactic brain biopsy (sbb) procedures. Patients and methods: they analyzed a series of 421 sbb cases treated

									between january 2002 and june 2017 in three major neurosurgical institutes in rome, serving a total of 1.5 million people. Within this series, 94.8% of patients underwent fbb using the cosman-roberts-wells (crw ¿ integra) stereotactic frame, while, more recently, flb was performed in 5.2% of cases using the stealthstation navigus frameless passive biopsy system (medtronic, inc.). All selected patients underwent stereotactic biopsy with a nashold needle through a standard burr hole. The entire period under consideration, running from 2002 to 2017, has been further stratified into four-year time-frames (2002¿2005, 2006¿2009, 2010¿2013, 2014¿2017) for the purpose of analysis. The median age of the patients was 63.5 (range 5¿82 years). 216 were male and 205 were female. Results: the diagnostic yield was 97%. Final diagnoses revealed tumors in 90% of cases and non-neoplastic masses in 7%, while 3% of cases were not conclusive. Overall morbidity was 3% (13/421): transient neurological deficits occurred in 6 cases, while 7 patients suffered permanent deficits. Symptomatic cerebral hemorrhage requiring craniotomy occurred in six cases: three glioblastoma (gbm), two primary central nervous system lymphoma (pcnsl), and one abscess. Post-operative mortality rate, as a direct consequence of such hemorrhages after biopsy procedures, was 0.7% (3/421): one gbm, one lymphoma, and one abscess. Intra-operative frozen sections were made in 78% of biopsies. In our three institutes, the number of sbbs decreased steadily throughout the time-frames under consideration. They have also observed a statistically significant reduction in biopsy procedures in lobar lesions, while those performed on the basal ganglia increased and the number of sbbs of multiple masses and lesions of the corpus callosum remained stable. Primary central nervous system diagnosis of lymphomas (pcnsl) was the sole diagnosis whose incidence

									increased significantly. Conclusions: over the last sixteen years, we have witnessed a significant decrease in sbb procedures and a modification in target selection and histologic results. Despite the significant evolution of neuroimaging, an accurate non-invasive diagnosis of intracranial expanding lesions has not yet been achieved. Furthermore, the most recent who classification of brain tumors (2016), which incorporates molecular and morphological features, has boosted the need for molecular processing of tissue samples. Manufacturer narrative: the device is not expected to be returned to the manufacturer for analysis. The plant investigation is in progress and a supplemental medwatch report will be submitted upon completion of the investigation. Linked to mfg. Report numbers: 3004608878-2019-01034, 3004608878-2019-01035, and 3004608878-2019-01037. (b)(4).
3004608878-2019-01031		Death	INTEGRA LIFESCIENCES CORPORATION OH/USA	30/09/2019	HAW	NASHOLD BIOPSY NEEDLE (DISPOS)	Adverse Event Without Identified Device or Use Problem	Death	This is 2 of 4 reports. The journal of neurological surgery (2019) published "frame-based stereotactic biopsy: description and association of anatomical, radiologic, and surgical variables with diagnostic yield in a series of 407 cases". Stereotactic biopsy is a versatile, minimally invasive technique to obtain tissue safely from intracranial lesions for their histologic diagnosis and therapeutic management. The objective of the study was to determine the anatomical, radiologic, and technical factors that can affect the diagnostic yield of this technique. Methods: this retrospective study evaluated 407 patients who underwent stereotactic biopsies in the past 34 years between 1982, when this technique was first used in their institution, and 2016 were retrieved and evaluated. The surgical methodology changed through time, distinguished by three distinct periods. The surgical methodology used throughout the decades was determined by the equipment available in the hospital at the time. Different stereotactic frames,

									neuroimaging tests, and planning programs were used. During period 1 (1982-1991), todd-wells (radionics) was used; period 2 (1991-2011), cosman-roberts-wells (crw) (integra) along with the nashold biopsy needle (integra) were used; and period 3 (2011-2016) leksell (electra instruments) was used. Statistical analysis was performed with spss v. 23 for windows (spss inc.) Using parametric tests. The 407 patients who had undergone stereotactic biopsy in department, 143 in period 1 (35.2%), 213 in period 2 (52.3%), and 51 in period 3 (12.5%). The average age of the patients in the series was 53.8 years. Most of the patients were in the fifth and sixth decades of life (47.6%), with an average of 57 years of age (range 3-86 years old). Fourteen (3.4%) were pediatric (patients 16 years of age). The sex ratio was 1.8:1, with 265 men (65.1%) and 142 women (34.9%). Most lesions were on the left side (41.8%). The frontal region was the most frequently biopsied anatomical region (24.8%), and the cerebellum (1%) and brainstem (1%) were the least. After histologic evaluation, the most frequently diagnosed pathologies were tumor in 78.8%, followed by vascular pathology (i.e., hemorrhagic or ischemic stroke) in 5.4%, radionecrosis in 0.5%, and neurologic pathology (multiple sclerosis) in 0.2%. The most frequently diagnosed tumor was a high-grade glioma (42.8%); the biopsies were nondiagnostic in 9.6%. Forty patients (9.8%) had symptomatic intracranial hemorrhages (worsened the level of consciousness and/or produced new neurologic deficits after the biopsy). Most of those patients improved significantly in the following days. Twenty-three of the patients (57.5%) were discharged with a karnofsky performance status greater than 80. During period 2, hemorrhagic complications: karnofsky performance status less than or equal to 70 at discharge was 8. Morbidity was 5.65% (n = 17). The procedure-associated mortality was 0.98% (n = 4). During period 2,

									mortality was 1. The overall diagnostic yield of our stereotactic biopsies was 90.4%, and there were no statistically significant differences in the diagnostic yields among the three methodological periods (p = 0.864). Intraoperative biopsy improved accuracy (p = 0.024). Biopsies of deep lesions (p = 0.043), without contrast enhancement (p = 0.004), edema (p = 0.036), extensive necrosis (p = 0.028), or a large cystic component (p = 0.023) resulted in a worse diagnostic yield. Neurosurgeons inexperienced in stereotactic techniques obtained more nondiagnostic biopsies (p = 0.043). Experience was the clearest predictive factor of diagnostic yield (odds ratio: 4.049). Overall, 39 of the biopsies (9.6%) were nondiagnostic. This result was consistent with previous reports. Of those, 2% (n = 8) were inconclusive, and 7.6% (n = 31) were negative. In these patients, the stereotactic biopsy was repeated once in 71.7% of the cases (n = 28) and twice in 10.2% of the cases (n = 4). In this series of 407 patients, 82 (20.1%) underwent craniotomies after the biopsy. The main reasons were either surgical resection of the lesion was considered the best treatment strategy after histologic results (64.7%; n = 53) or there were doubts about these histologic results because of the clinical condition and the neuroimaging tests of the patient (26.8%; n = 22). In seven patients (8.5%), the indication for surgery was based on not obtaining a diagnosis by stereotactic methods. Conclusion: increased experience in stereotactic techniques, use of the most suitable magnetic resonance imaging sequences during biopsy planning, and intraoperative evaluation of the sample before finalizing the collection are recommended features and ways to improve the diagnostic yield of this technique. Manufacturer narrative: the device is not expected to be returned to the manufacturer for analysis. The plant investigation is in progress and a

									supplemental medwatch report will be submitted upon completion of the investigation. Linked to mfg. Report numbers: 3004608878-2019-01030, 3004608878-2019-01032, and 3004608878-2019-01033. Doi: https://doi.org/10.1055/s-0038-1676597.
3004608878-2019-01032		Injury	INTEGRA LIFESCIENCES CORPORATION OH/USA	30/09/2019	HAW	CRW SYSTEM	Adverse Event Without Identified Device or Use Problem	Intracranial Hemorrhage; Neurological Deficit/Dysfunction	This is 3 of 4 reports. The journal of neurological surgery (2019) published "frame-based stereotactic biopsy: description and association of anatomical, radiologic, and surgical variables with diagnostic yield in a series of 407 cases". Stereotactic biopsy is a versatile, minimally invasive technique to obtain tissue safely from intracranial lesions for their histologic diagnosis and therapeutic management. The objective of the study was to determine the anatomical, radiologic, and technical factors that can affect the diagnostic yield of this technique. Methods: this retrospective study evaluated 407 patients who underwent stereotactic biopsies in the past 34 years between 1982, when this technique was first used in their institution, and 2016 were retrieved and evaluated. The surgical methodology changed through time, distinguished by three distinct periods. The surgical methodology used throughout the decades was determined by the equipment available in the hospital at the time. Different stereotactic frames, neuroimaging tests, and planning programs were used. During period 1 (1982-1991), todd-wells (radionics) was used; period 2 (1991-2011), cosman-roberts-wells (crw) (integra) along with the nashold biopsy needle (integra) were used; and period 3 (2011-2016) leksell (electra instruments) was used. Statistical analysis was performed with spss v. 23 for windows (spss inc.) Using parametric tests. The 407 patients who had undergone stereotactic biopsy in department, 143 in period 1 (35.2%), 213 in period 2 (52.3%), and 51 in period 3 (12.5%). The average age of the patients in the series was 53.8 years. Most of the patients were in the fifth and sixth decades

									of life (47.6%), with an average of 57 years of age (range 3-86 years old). Fourteen (3.4%) were pediatric (patients 16 years of age). The sex ratio was 1.8:1, with 265 men (65.1%) and 142 women (34.9%). Most lesions were on the left side (41.8%). The frontal region was the most frequently biopsied anatomical region (24.8%), and the cerebellum (1%) and brainstem (1%) were the least. After histologic evaluation, the most frequently diagnosed pathologies were tumor in 78.8%, followed by vascular pathology (i.e., hemorrhagic or ischemic stroke) in 5.4%, radionecrosis in 0.5%, and neurologic pathology (multiple sclerosis) in 0.2%. The most frequently diagnosed tumor was a high-grade glioma (42.8%); the biopsies were nondiagnostic in 9.6%. Forty patients (9.8%) had symptomatic intracranial hemorrhages (worsened the level of consciousness and/or produced new neurologic deficits after the biopsy). Most of those patients improved significantly in the following days. Twenty-three of the patients (57.5%) were discharged with a karnofsky performance status greater than 80. During period 2, hemorrhagic complications: karnofsky performance status less than or equal to 70 at discharge was 8. Morbidity was 5.65% (n = 17). The procedure-associated mortality was 0.98% (n = 4). During period 2, mortality was 1. The overall diagnostic yield of our stereotactic biopsies was 90.4%, and there were no statistically significant differences in the diagnostic yields among the three methodological periods (p = 0.864). Intraoperative biopsy improved accuracy (p = 0.024). Biopsies of deep lesions (p = 0.043), without contrast enhancement (p = 0.004), edema (p = 0.036), extensive necrosis (p = 0.028), or a large cystic component (p = 0.023) resulted in a worse diagnostic yield. Neurosurgeons inexperienced in stereotactic techniques obtained more nondiagnostic biopsies (p = 0.043). Experience was the clearest predictive factor of diagnostic yield (odds

									ratio: 4.049). Overall, 39 of the biopsies (9.6%) were nondiagnostic. This result was consistent with previous reports. Of those, 2% (n = 8) were inconclusive, and 7.6% (n = 31) were negative. In these patients, the stereotactic biopsy was repeated once in 71.7% of the cases (n = 28) and twice in 10.2% of the cases (n = 4). In this series of 407 patients, 82 (20.1%) underwent craniotomies after the biopsy. The main reasons were either surgical resection of the lesion was considered the best treatment strategy after histologic results (64.7%; n = 53) or there were doubts about these histologic results because of the clinical condition and the neuroimaging tests of the patient (26.8%; n = 22). In seven patients (8.5%), the indication for surgery was based on not obtaining a diagnosis by stereotactic methods. Conclusion: increased experience in stereotactic techniques, use of the most suitable magnetic resonance imaging sequences during biopsy planning, and intraoperative evaluation of the sample before finalizing the collection are recommended features and ways to improve the diagnostic yield of this technique. Manufacturer narrative: the device is not expected to be returned to the manufacturer for analysis. The plant investigation is in progress and a supplemental medwatch report will be submitted upon completion of the investigation. Linked to mfg. Report numbers: 3004608878-2019-01030, 3004608878-2019-01031, 3004608878-2019-01033. Doi: https://doi.org/10.1055/s-0038-1676597.
3004608878-2019-01033		Death	INTEGRA LIFESCIENCES CORPORATION OH/USA	30/09/2019	HAW	CRW SYSTEM	Adverse Event Without Identified Device or Use Problem	Death	This is 4 of 4 reports. The journal of neurological surgery (2019) published "frame-based stereotactic biopsy: description and association of anatomical, radiologic, and surgical variables with diagnostic yield in a series of 407 cases". Stereotactic biopsy is a versatile, minimally invasive technique to obtain tissue safely from intracranial lesions for their histologic

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3004608878-2019-01037		Injury	INTEGRA LIFESCIENCES CORPORATION OH/USA	30/09/2019	HAW	CRW SYSTEM	Adverse Event Without Identified Device or Use Problem	Death	This is 4 of 4 reports. Clinical neurology and neurosurgery (2017) published "how is stereotactic brain biopsy evolving? A multicentric analysis of a series of 421 cases treated in rome over the last sixteen years". Objective: in recent decades, frame-based (fbb) and frame-less stereotactic brain biopsy (flb) have played a crucial role in defining the diagnosis and management of expanding intracranial lesions in critical areas. During the same period, there have been significant advances in diagnostic imaging, a shift in surgical strategies towards extensive resection in gliomas and new molecular classification of brain tumors. Taking these advances into account, the authors have evaluated whether significant changes have occurred over the last sixteen years of their clinical practice in terms of frequency, indications, target selection, and the histologic results of stereotactic brain biopsy (sbb) procedures. Patients and methods: they analyzed a series of 421 sbb cases treated between january 2002 and june 2017 in

									three major neurosurgical institutes in rome, serving a total of 1.5 million people. Within this series, 94.8% of patients underwent fbb using the cosman-roberts-wells (crw ¿ integra) stereotactic frame, while, more recently, flb was performed in 5.2% of cases using the stealthstation navigus frameless passive biopsy system (medtronic, inc.). All selected patients underwent stereotactic biopsy with a nashold needle through a standard burr hole. The entire period under consideration, running from 2002 to 2017, has been further stratified into four-year time-frames (2002¿2005, 2006¿2009, 2010¿2013, 2014¿2017) for the purpose of analysis. The median age of the patients was 63.5 (range 5¿82 years). 216 were male and 205 were female. Results: the diagnostic yield was 97%. Final diagnoses revealed tumors in 90% of cases and non-neoplastic masses in 7%, while 3% of cases were not conclusive. Overall morbidity was 3% (13/421): transient neurological deficits occurred in 6 cases, while 7 patients suffered permanent deficits. Symptomatic cerebral hemorrhage requiring craniotomy occurred in six cases: three glioblastoma (gbm), two primary central nervous system lymphoma (pcnsl), and one abscess. Post-operative mortality rate, as a direct consequence of such hemorrhages after biopsy procedures, was 0.7% (3/421): one gbm, one lymphoma, and one abscess. Intra-operative frozen sections were made in 78% of biopsies. In our three institutes, the number of sbbs decreased steadily throughout the time-frames under consideration. They have also observed a statistically significant reduction in biopsy procedures in lobar lesions, while those performed on the basal ganglia increased and the number of sbbs of multiple masses and lesions of the corpus callosum remained stable. Primary central nervous system diagnosis of lymphomas (pcnsl) was the sole diagnosis whose incidence increased significantly. Conclusions: over

									the last sixteen years, we have witnessed a significant decrease in sbb procedures and a modification in target selection and histologic results. Despite the significant evolution of neuroimaging, an accurate non-invasive diagnosis of intracranial expanding lesions has not yet been achieved. Furthermore, the most recent who classification of brain tumors (2016), which incorporates molecular and morphological features, has boosted the need for molecular processing of tissue samples. Manufacturer narrative: the device is not expected to be returned to the manufacturer for analysis. The plant investigation is in progress and a supplemental medwatch report will be submitted upon completion of the investigation. Linked to mfg. Report numbers: 3004608878-2019-01034, 3004608878-2019-01035, and 3004608878-2019-01036. Https://doi.org/10.1016/j.clineuro.2018.09.020.
3004608878-2019-01034		Injury	INTEGRA LIFESCIENCES CORPORATION OH/USA	30/09/2019	HAW	NASHOLD BIOPSY NEEDLE (DISPOS)	Adverse Event Without Identified Device or Use Problem	Hemorrhage, Cerebral; Neurological Deficit/Dysfunction; Injury	This is 1 of 4 reports. Clinical neurology and neurosurgery (2017) published "how is stereotactic brain biopsy evolving? A multicentric analysis of a series of 421 cases treated in rome over the last sixteen years". Objective: in recent decades, frame-based (fbb) and frame-less stereotactic brain biopsy (flb) have played a crucial role in defining the diagnosis and management of expanding intracranial lesions in critical areas. During the same period, there have been significant advances in diagnostic imaging, a shift in surgical strategies towards extensive resection in gliomas and new molecular classification of brain tumors. Taking these advances into account, the authors have evaluated whether significant changes have occurred over the last sixteen years of their clinical practice in terms of frequency, indications, target selection, and the histologic results of stereotactic brain biopsy (sbb) procedures. Patients and methods: they analyzed a series of 421 sbb cases treated

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3004608878-2019-01035		Injury	INTEGRA LIFESCIENCES CORPORATION OH/USA	30/09/2019	HAW	NASHOLD BIOPSY NEEDLE (DISPOS)	Adverse Event Without Identified Device or Use Problem	Death	This is 2 of 4 reports. Clinical neurology and neurosurgery (2017) published "how is stereotactic brain biopsy evolving? A multicentric analysis of a series of 421 cases treated in rome over the last sixteen years". Objective: in recent decades, frame-based (fbb) and frame-less stereotactic brain biopsy (flb) have played a crucial role in defining the diagnosis and management of expanding intracranial lesions in critical areas. During the same period, there have been significant advances in diagnostic imaging, a shift in surgical strategies towards extensive resection in gliomas and new molecular classification of brain tumors. Taking these advances into account, the authors have evaluated whether significant changes have occurred over the last sixteen years of their clinical practice in terms of frequency, indications, target selection, and the histologic results of stereotactic brain biopsy (sbb) procedures. Patients and methods: they

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2210968-2018-76727		Injury	ETHICON INC.	24/10/2018	GAR	NUROLON NYLON SUTURE UNKNOWN PRODUCT	Adverse Event Without Identified Device or Use Problem	Unspecified Infection; Not Applicable	It was reported via journal article: title: "novel approach to securing deep brain stimulation leads: technique and analysis of lead migration,Breakage, and surgical infection." authors: gabrielle a. White-dzuro a wendell lake b ilyas m. Eli c joseph s. Neimat, . Citation: stereotact funct neurosurg. 2016; 94: 18¿23. Doi: 10.1159/000442893. Deep brain stimulation (bds) is a beneficial therapy for parkinson¿s disease, essential tremor, and several other disorders. Fixation of the electrode during dbs surgery is an important aspect of the procedure. The authors have developed an alternative method for securing leads that utilizes a titanium hemoclip and cement. This technique is described, and the rates of complications are compared to conventional methods of securing leads. A total of 291 dbs operations performed by a single surgeon were retrospectively analyzed. During the

									surgical procedure, using neurolon 4-0 suture (ethicon), the lead is tied to the pericranium in two separate places as it is coiled around the bur hole. The boot and lead cover are placed on the leads, and the devices are tunneled to a subgaleal pocket. The wound is then closed in layers. Reported complications included surgical site infection (n-9), leadFractures (n-4), and lead migration (n-8) which required surgical readjustment of the position of dbs leads. The authors described a method for securing dbs leads and showed an acceptable incidence of hardware complications when compared to the conventional method. The authors feel this technique has improved cosmetic results and should be considered as a method for securing dbs leads. Manufacturer narrative: (b)(4). This report is related to a journal article; therefore, no product will be returned for analysis and the batch history records cannot be reviewed as the lot number has not been provided. Citation: stereotact funct neurosurg. 2016; 94: 18¿23. Doi: 10.1159/000442893. (b)(4).
9612186-2018-00004		Malfunction	ELEKTA INSTRUMENT AB	01/10/2018	HAW	LEKSELL STEREOTACTIC SYSTEM	Adverse Event Without Identified Device or Use Problem	Burn(s); Burn, Thermal	The customer reported that during the mr scan whilst using the frame patients have experienced burn marks. Based on the available information actual injury has occurred. Manufacturer narrative: (b)(4). Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed.
1037905-2018-00246		Injury	COOK ENDOSCOPY	11/06/2018	NEU	ECHOTIP ULTRA FIDUCIAL NEEDLE	Adverse Event Without Identified Device or Use Problem	Hematoma	During a fiducial placement procedure, the physician used a cook echotip ultra fiducial needle. The following is the subject case report in its entirety: el hajj ie, easler jj, sherman s, al-haddad m. Intramural duodenal hematoma post eus-guided placement of fiducial radiopaque markers. Digestive and liver disease 2018; 50: 201. "a (b)(6) man presented with painless jaundice. Abdominal ct showed head of the pancreas mass. Eus-fna confirmed adenocarcinoma. Ercp was performed with sphincterotomy/stent placement. Case was

									reviewed at our pancreas tumor board: borderline resectable tumor, recommended upfront neoadjuvant chemoradiation. Patient was referred for eus-guided fiducial placement before stereotactic body radiation therapy (sbrt). With the linear echoendoscope positioned in the duodenal lumen, a preloaded fiducial in a 22g needle echotip ultra fiducial needle was deployed in the tumor. Maneuver was repeated for a total of 3 fiducials. The patient presented 2 days later with abdominal pain/bilious vomiting. Abdominal ct: no pneumoperitoneum/pancreatitis, markedly distended stomach with fluid retention suggestive of gastric outlet obstruction, and circumferential/diffuse wall thickening/intramural hyperdensity/luminal narrowing of the duodenal bulb/proximal d2 suggestive of intramural duodenal hematoma (idh). The patient was managed conservatively. An 18fr nasogastric tube was placed and connected to low intermittent suction. His symptoms gradually improved over 4¿5 days. Upper gi series at day-6 confirmed the absence of residual mechanical obstruction. Fiducials are radiopaque markers implanted into a cancer lesion for localization and accurate treatment delivery during sbrt. Eus-guided fiducial placement fluoroscopy guidance, permits placement of fiducials into lesions in close proximity to the gi tract and often in locations that are difficult to access with alternative methods. Several series reported safe and successful eus-guided implantation of fiducials into primary or metastatic pancreatic cancer, among many other cancers. This is the first report of idh post eus-guided fiducial placement. A combination of echoendoscope torquing, and repeated punctures of a hypervascular pancreatic tumor through the duodenal wall may have contributed to this complication. Idh generally resolves with conservative management, occasionally requiring percutaneous, endoscopic or surgical drainage." there was no device malfunction

									alleged in the published case report. Manufacturer narrative: investigation evaluation: a product evaluation was not performed in response to this report because the product said to be involved was not provided to cook for evaluation. The report could not be confirmed. A review of the device history record could not be conducted because the lot number was not provided. Investigation conclusion: we could not conduct a complete investigation because the product said to be involved was not returned for evaluation. A definitive cause for the reported observation could not be determined. The instructions for use states under the potential complications: "potential complications associated with gastrointestinal endoscopy include, but are not limited to: perforation, hemorrhage, aspiration, fever, infection, allergic reaction to medication, hypotension, respiratory depression or arrest, cardiac arrhythmia or arrest." the instructions for use states under the potential complications: "potential complications from extra-luminal eus guided procedures may include infection, hemorrhage, perforation and tumor seeding." prior to distribution, all echotip ultra fiducial needle are subjected to a visual inspection for product integrity. Corrective action: corrective action is not warranted at this time based on the quality engineering risk assessment. Quality assurance will continue to monitor for complaint trends and reassess the risk assessment results as post market feedback continues to become available.
9612186-2017-00011		Injury	ELEKTA INSTRUMENT AB	23/02/2018	HAW	LEKSELL STEREOTACTIC SYSTEM	Adverse Event Without Identified Device or Use Problem	Fall; Pain; Blood Loss	The customer reported that a patient fell off from the leksell stereotqactic frame just before mri scanning. The patient complained of pain at the pin fixation site and bled slightly. The physician fixed the frame again to the patient and continued treatment. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed. The

									following has been updated: email address updated. Establishment name updated. Resubmitting form 3500a due to an administrative error. It was requested by fda medwatch program department to re-submit the initial report as there was no record of initial report submission in emdr system. Follow up? Correction.
9612186-2018-00001		Malfunction	ELEKTA INSTRUMENT AB	21/02/2018	HAW	LEKSELL STEREOTACTIC SYSTEM	Adverse Event Without Identified Device or Use Problem	No Consequences Or Impact To Patient	Patient moved during final shot. When treatment completed noted that frame was completely loose from patients head. With ~15 treatment positions completed and ~57 minutes of beam-on time remaining, the treatment was stopped in order to re-sedate the patient. The patient was re-sedated and the frame fixation, holding the patient's head in a fixed position, was observed to be fitted as expected. The sedation kept the patient still for 47 of the remaining 57 minutes. Two minutes after starting the final treatment position, planned for a small 0.7cc volume designated as site 16, the patient awoke and started significant movement. The patient was instructed in (b)(6) "don't move you have 10 minutes left" and the patient stopped moving. At 4:58pm, when the treatment was completed the patient couch brought the patient out and it was immediately recognized that the frame was no longer fixed to the patient's head (1st time in 8681 treatments that something like this has happened). The patient's large head was resting on the back of the frame similar to the original frame fixation position. The anterior and posterior fixation pin tips were approximately 29 mm above the pin marks on the skin in the z-axis direction. The head would have shifted relatively little in either the x or y directions. There were no skin lacerations and there was fresh (not dried) blood on the back left frame fixation post. Manufacturer narrative: during an internal review of cases it was found that due to an error with e-submitter this incident had not been submitted. There is no product malfunction and there was no serious injury to the patient. "this medical event, if it

									occurred, is not expected to have detrimental effects on the patient. The patient will be followed with added attention given to site 16." the posts were still firmly attached to the frame and there was no damage to the fixation screws. The patient's head appeared as expected after frame removal. The frame has been used again since the incident. It is concluded that the combination of patient skull size and the significant movement of the patient, when waking from sedation, at the end of the treatment(applying extra force to the fixation screws) is the cause of the frame loosening. No damage to the equipment has been reported and is therefore excluded to be causing the incident. No update to product documentation such as ifu or training has been identified. The customer is an experienced user with over 8600 treated patients.
9612186-2018-00003		Malfunction	ELEKTA INSTRUMENT AB	20/09/2018	HAW	LEKSELL STEREOTACTIC SYSTEM	Adverse Event Without Identified Device or Use Problem; Insufficient Information	No Known Impact Or Consequence To Patient; No Information	The customer reported that whilst performing a biopsy an incident occurred and the patient experienced bleeding afterwards. Manufacturer narrative: the customer was contacted several times in order to obtain the equipment for investigation. Unfortunately all attempts to obtain the equipment were unsuccessful and no further action is possible at this time. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed.
9612186-2018-00002		Malfunction	ELEKTA INSTRUMENT AB	25/07/2018	HAW	LEKSELL STEREOTACTIC SYSTEM	Adverse Event Without Identified Device or Use Problem; Insufficient Information	Burn(s); Burn, Thermal	The customer reported that during the mr scan whilst using the frame patients have experienced burn marks. Based on the available information actual injury has occurred. Manufacturer narrative: (b)(4). Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed. Serial numbers - (b)(4).
3003418325-2018-00006		Injury	INTEGRA LIFESCIENCES CORP	15/03/2018	NQR	DURASEAL, UNKNOWN	Appropriate Term/Code Not Available	Infarction, Cerebral; Meningitis	World neurosurgery (2017) published ¿candida meningitis after transphenoidal surgery: a single institution case-series and literature review¿ which discussed three

									case presentations of patients with giant skull base tumors who developed post-surgical candida meningitis, each with vastly different clinical courses and outcomes. Duraseal and duragen were used for each of the patients. This is a case of a (b)(6) male who underwent a frameless stereotactic expanded endoscopic transnasal resection of a world health organization (who) i planum sphenoidale meningioma. Closure products used in surgery included duragen, a nasoseptal flap, surgicel, duraseal, nasopore, alloderm, and a 30 ml foley catheter balloon. Vancomycin was administered intraoperatively. There were no perioperative complications. Post-operative brain mri demonstrated no evidence of residual tumor. Approximately 4 days post-operatively, the patient began acting impulsively; drinking water from a faucet, picking his nose, removing his peripheral intravenous lines, and refusing interventions. Eight days post-operatively, he developed fever, increasing white blood cell count, and somnolence warranting transfer to the neuroscience intensive care unit (nsicu). A lumbar puncture was performed, and profile was consistent with meningitis, with a significant hypoglycorrhachia. Cerebrospinal fluid (csf) cultures were negative, however, blood cultures were positive for fusobacterium necrophorum. Prior to this result, the patient was treated empirically with intravenous (iv) vancomycin, cefepime, and metronidazole. It was determined by the infectious disease team that fusobacterium necrophorum was the likely the cause of meningitis. Vancomycin was then discontinued, and he was treated with cefepime and metronidazole. His neurological exam continued to decline and a head computed tomography (ct) 10 days after surgery revealed new hydrocephalus, requiring placement of a right frontal external ventricular drain. Thirteen days post-operatively, he developed a focal neurological decline, no longer moving his

									right upper extremity and only withdrawing his right lower extremity. An mri/mrv demonstrated evidence of infection within the surgical cavity, as well as acute ischemic infarct of the left anterior cerebral artery distribution and bilateral basal ganglia. A cerebral angiogram, demonstrated moderate to severe vasospasm involving the left internal carotid artery (ica) and a1 segments, and occlusion of the left a2 segment. Moderate vasospasm was also observed in the right supraclinoid ica. Intra-arterial verapamil infusion resulted in significant improvement. Endoscopic transnasal exploration and washout was performed emergently and purulent material was encountered within the sellar surgical site; culture swabs were positive for candida glabrata. Mean arterial pressures were augmented to the 100s mmhg. The following day, he was noted to have left gaze deviation and worsening neurological exam, no longer moving his left extremities. Head ct revealed a trapped left ventricle and a left-sided external ventricular drain was placed. Electroencephalogram revealed focal neuronal dysfunction localized to the left temporal lobe but no epileptiform abnormalities. Subsequent imaging revealed a new right inferior frontal infarct. The patient was intubated, not opening his eyes, flexing his upper extremities to noxious stimuli, and triple flexing his lower extremities. Placement of an open tracheotomy tube and percutaneous endoscopic gastrostomy was performed. He continued to be treated for his infection with metronidazole, cefepime, amphotericin b, and flucytosine (with prior 8-day course of vancomycin). A permanent csf diversion and placement of a right frontal ventriculoperitoneal shunt, in addition to an endoscopic assisted septostomy were performed 34 days after the initial surgical resection. By 6 weeks postoperatively, the patient slightly improved neurologically and was discharged to longterm acute care. He

									remained nonverbal and would withdraw his right upper extremity while spontaneously moving his left upper extremity and triple flexing bilateral lower extremities. Five months after surgery, he was alert, saying some simple sentences, and following simple commands using his upper extremities, while contractured and diplegic in his lower extremities. Manufacturer narrative: the device was not returned to the manufacturer for physical evaluation. The serial/lot number was not provided therefore a dhr review could not be performed. However, at the time of manufacturing, records from each manufacturing lot are thoroughly reviewed to ensure that products are released meeting all quality release specifications. The complaint is unconfirmed. The root cause could not be determined. Manufacturer narrative: to date the device involved in the reported incident has not been received for evaluation. The plant investigation is in progress and a supplemental medwatch report will be submitted upon completion of the investigation. Linked to mfg report number: 1121308-2018-00021 (same patient) other mfg. Report numbers: 3003418325-2018-00007, 1121308-2018-00022, 3003418325-2018-00008, 1121308-2018-00023.
3004608878-2018-00035		Malfunction	INTEGRA LIFESCIENCES CORPORATION OH/USA	12/03/2018	HBL	MAYFIELD COMPOSITE SERIES SKULL CLAMP	Bent; Unintended Movement	No Known Impact Or Consequence To Patient	An integra sales representative reported that the a3059 mayfield composite series skull clamp was used during a neurosurgery with a robotic stereotactic assistance (rosa) robot. However, the surgeon observed a slight bent or movement of the skull clamp and had to reposition during the case. The surgeon decided to use a metal skull clamp going forward. In addition, a fifteen minute delay in surgery was noted. There was no injury reported and no medical revision was conducted. Additional information has been requested. Manufacturer narrative: additional information received from the sales representative on 09mar2018: the date of the incident and serial number of

									the device were unknown. There was no specific impact of the 15-minute delay in surgery beyond inconvenience. Investigation completed 21mar2018: it was reported that the device was not being returned by the customer for evaluation at this time. A device history record (dhr) review could not be performed due to no serial or lot number provided. The complaint could not be confirmed. Root cause is not determined at this time. Manufacturer narrative: to date the device involved in the reported incident has not been received for evaluation. The plant investigation is in progress and a supplemental medwatch report will be submitted upon completion of the investigation.
1030489-2020-01143		Injury	WARSAW ORTHOPEDICS	25/08/2020	KWP	CD HORIZON SPINAL SYSTEM	Break	BoneFracture(s)	Information was received from a healthcare provider via a manufacturer representative regarding a patient with t12 burstFracture with retropulsed bone into the canal resulting in cauda equina compression and intractable pain. It was reported that patient underwent 7 surgeries, 4 were for broken rods. On (b)(6) 2017 patient underwent left thoracoabdominal minimally invasive approach with t12 vertebrectomy plus reconstruction of t12 vertebral body using medtronic altitude expandable cage, endplate, augmented with autologous bone. On (b)(6) 2017, patient underwent a surgery for chest tube removal. Patient again suffered from t12 burstFracture, status post t12 vertebrectomy with re-construction. On (b)(6) 2017, patient underwent t9-l3 fusion using solera 5.5 instrumentation, augmented with allograft bone intertransverse process from t9-l3 level. On (b)(6) 2017, patient again had loosening of hardware pedicle screws. Bilateral l3 pedicleFracture status post t12 vertebrectomy with reconstruction and posterior t9 to l3 fusion.posterior t7-t9 fusion, posterior l3 to the sacrum fusion, instrumentation from t7 to the ileum was performed. Also intraoperative, stealth stereotactic navigation with o-arm was

									used. On (b)(6) 2017,as the patient had t7Fracture with kyphotic angulation at the t6-t7 level causing associated cord compression. Revision surgery was performed. T6-t7 thoracic laminectomy with reduction of t7Fracture.posterior t4-t7 fusion with new rods placed t4 to pelvis. Use of intraoperative stealth stereotactic navigation and o-arm. On (b)(6) 2018, patient was diagnosed withFractured right-sided lumbar hardware involving the rod between l2-l4. Exploration of lumbar fusion was performed as a procedure. As a result revision of right-sided lumbar hardware was performed. On (b)(6) 2018, patient was diagnosed with bilateral thoracolumbar rodFracture. Thoracolumbar wound exploration was performed as a procedure. As a result ,there was a revision of bilateral thoracolumbar hardware. On (b)(6) 2019, patient was diagnosed with bilateral rodFracture directly above the l4 pedicle screws resulting in severe low back pain. As a result,revision lumbar spine surgery was performed from t12 to the ilium using a dual rod construction. Manufacturer narrative: no product was returned. With the available information, a contributing factor or cause for the reported event could not be identified. Thus, no corrective action was possible at this time. If at a later date the product returns this investigation would be re-opened. We would continue to monitor for trends as more definitive data was collected. If information is provided in the future, a supplemental report will be issued.
1030489-2020-01144		Injury	WARSAW ORTHOPEDICS	25/08/2020	KWP	CD HORIZON SPINAL SYSTEM	Break	BoneFracture(s)	Information was received from a healthcare provider via a manufacturer representative regarding a patient with t12 burstFracture with retropulsed bone into the canal resulting in cauda equina compression and intractable pain. It was reported that patient underwent 7 surgeries, 4 were for broken rods. On feb 7, 2017 patient underwent left thoracoabdominal minimally invasive approach with t12 vertebrectomy plus reconstruction of t12 vertebral body using

									medtronic altitude expandable cage, endplate, augmented with autologous bone. On (b)(6) 2017, patient underwent a surgery for chest tube removal. Patient again suffered from t12 burstFracture, status post t12 vertebrectomy with re-construction. On (b)(6) 2017, patient underwent t9-l3 fusion using solera 5.5 instrumentation, augmented with allograft bone intertransverse process from t9-l3 level. On (b)(6) 2017, patient again had loosening of hardware pedicle screws. Bilateral l3 pedicleFracture status post t12 vertebrectomy with reconstruction and posterior t9 to l3 fusion.posterior t7-t9 fusion, posterior l3 to the sacrum fusion, instrumentation from t7 to the ileum was performed. Also intraoperative, stealth stereotactic navigation with o-arm was used. On (b)(6) 2017, as the patient had t7Fracture with kyphotic angulation at the t6-t7 level causing associated cord compression. Revision surgery was performed. T6-t7 thoracic laminectomy with reduction of t7Fracture.posterior t4-t7 fusion with new rods placed t4 to pelvis. Use of intraoperative stealth stereotactic navigation and o-arm. On (b)(6) 2018, patient was diagnosed withFractured right-sided lumbar hardware involving the rod between l2-l4. Exploration of lumbar fusion was performed as a procedure. As a result revision of right-sided lumbar hardware was performed. On (b)(6) 2018, patient was diagnosed with bilateral thoracolumbar rodFracture. Thoracolumbar wound exploration was performed as a procedure. As a result ,there was a revision of bilateral thoracolumbar hardware. On (b)(6) 2019, patient was diagnosed with bilateral rodFracture directly above the l4 pedicle screws resulting in severe low back pain. As a result, revision lumbar spine surgery was performed from t12 to the ilium using a dual rod construction. Manufacturer narrative: no product was returned. With the available information, a contributing factor or cause for the reported event could

									not be identified. Thus, no corrective action was possible at this time. If at a later date the product returns this investigation would be re-opened. This investigation was considered closed. We would continue to monitor for trends as more definitive data was collected. If information is provided in the future, a supplemental report will be issued.
1030489-2020-01145		Injury	WARSAW ORTHOPEDICS	25/08/2020	KWP	CD HORIZON SPINAL SYSTEM	Break	BoneFracture(s); Pain	Information was received from a healthcare provider via a manufacturer representative regarding a patient with t12 burstFracture with retropulsed bone into the canal resulting in cauda equina compression and intractable pain. It was reported that patient underwent 7 surgeries, 4 were for broken rods. On (b)(6) 2017 patient underwent left thoracoabdominal minimally invasive approach with t12 vertebrectomy plus reconstruction of t12 vertebral body using medtronic altitude expandable cage, endplate, augmented with autologous bone. On (b)(6) 2017, patient underwent a surgery for chest tube removal. Patient again suffered from t12 burstFracture, status post t12 vertebrectomy with re-construction. On (b)(6) 2017, patient underwent t9-l3 fusion using solera 5.5 instrumentation, augmented with allograft bone intertransverse process from t9-l3 level. On (b)(6) 2017, patient again had loosening of hardware pedicle screws. Bilateral l3 pedicleFracture status post t12 vertebrectomy with reconstruction and posterior t9 to l3 fusion. Posterior t7-t9 fusion, posterior l3 to the sacrum fusion, instrumentation from t7 to the ileum was performed. Also intraoperative, stealth stereotactic navigation with o-arm was used. On (b)(6) 2017, as the patient had t7Fracture with kyphotic angulation at the t6-t7 level causing associated cord compression. Revision surgery was performed. T6-t7 thoracic laminectomy with reduction of t7Fracture.posterior t4-t7 fusion with new rods placed t4 to pelvis. Use of intraoperative stealth stereotactic navigation and o-arm. On (b)(6) 2018,

									patient was diagnosed withFractured right-sided lumbar hardware involving the rod between l2-l4. Exploration of lumbar fusion was performed as a procedure. As a result revision of right-sided lumbar hardware was performed. On (b)(6) 2018, patient was diagnosed with bilateral thoracolumbar rodFracture. Thoracolumbar wound exploration was performed as a procedure. As a result ,there was a revision of bilateral thoracolumbar hardware. On (b)(6) 2019, patient was diagnosed with bilateral rodFracture directly above the l4 pedicle screws resulting in severe low back pain. As a result,revision lumbar spine surgery was performed from t12 to the ilium using a dual rod construction. Manufacturer narrative: no product was returned. With the available information, a contributing factor or cause for the reported event could not be identified. Thus, no corrective action was possible at this time. If at a later date the product returns this investigation would be re-opened. This investigation was considered closed. We would continue to monitor for trends as more definitive data was collected. If information is provided in the future, a supplemental report will be issued.
1526439-2020-00183		Injury	DEPUY SPINE INC	06/01/2020	OLO	EXPEDIUM SI POLY-DRIVER ASSY	Break	No Consequences Or Impact To Patient; Foreign Body In Patient	It was reported that on an unknown date, four (4) custom short hand expedium single innie poly driver and one (1) regular expedium driver broke intraoperatively. Procedure was successfully completed with a 20 minute surgical delay. There was no patient harm/consequence. This is report 1 of 5 for (b)(4). Manufacturer narrative: if the information is unknown, not available or does not apply, the section/field of the form is left blank. Initial reporter is company sales representative. The device was received, the investigation is in progress, no conclusion could be drawn at the time of filing this report. Device was used for treatment, not diagnosis. If information is obtained that was not available for the initial medwatch, a follow-up medwatch will be filed as appropriate.

1526439-2020-00184		Injury	DEPUY SPINE INC	06/01/2020	OLO	XPDM QUICK-CON SI POLY SCWDRVR	Break	No Consequences Or Impact To Patient; Foreign Body In Patient	It was reported that on an unknown date, four (4) custom short hand expedium single innie poly driver and one (1) regular expedium driver broke intraoperatively. Procedure was successfully completed with a 20 minute surgical delay. There was no patient harm/consequence. This is report 2 of 5 for (b)(4). Manufacturer narrative: if the information is unknown, not available or does not apply, the section/field of the form is left blank. Initial reporter is company sales representative the device was received, the investigation is in progress, no conclusion could be drawn at the time of filing this report. Device was used for treatment, not diagnosis. If information is obtained that was not available for the initial medwatch, a follow-up medwatch will be filed as appropriate.
1526439-2020-00186		Injury	DEPUY SPINE INC	06/01/2020	OLO	EXPEDIUM SI POLY-DRIVER ASSY	Break	No Consequences Or Impact To Patient; Foreign Body In Patient	It was reported that on an unknown date, four (4) custom short hand expedium single innie poly driver and one (1) regular expedium driver broke intraoperatively. Procedure was successfully completed with a 20 minute surgical delay. There was no patient harm/consequence. This is report 3 of 5 for (b)(4). Manufacturer narrative: initial reporter is company sales representative. The device was received, the investigation is in progress, no conclusion could be drawn at the time of filing this report. Device was used for treatment, not diagnosis. If information is obtained that was not available for the initial medwatch, a follow-up medwatch will be filed as appropriate.
1526439-2020-00189		Injury	DEPUY SPINE INC	06/01/2020	OLO	EXPEDIUM SI POLY-DRIVER ASSY	Break	No Consequences Or Impact To Patient; Foreign Body In Patient	It was reported that on an unknown date, four (4) custom short hand expedium single innie poly driver and one (1) regular expedium driver broke intraoperatively. Procedure was successfully completed with a 20 minute surgical delay. There was no patient harm/consequence. This is report 4 of 5 for (b)(4). Manufacturer narrative: if the information is unknown, not available or does not apply, the section/field of the form is left blank. Initial reporter is company sales representative. The device was received, the investigation is in progress, no

									conclusion could be drawn at the time of filing this report. Device was used for treatment, not diagnosis. If information is obtained that was not available for the initial medwatch, a follow-up medwatch will be filed as appropriate.
1526439-2020-00196		Injury	DEPUY SPINE INC	06/01/2020	OLO	EXPEDIUM SI POLY-DRIVER ASSY	Break	No Consequences Or Impact To Patient; Foreign Body In Patient	It was reported that on an unknown date, four (4) custom short hand expedium single innie poly driver and one (1) regular expedium driver broke intraoperatively. Procedure was successfully completed with a 20 minute surgical delay. There was no patient harm/consequence. This is report 5 of 5 for (b)(4). Manufacturer narrative: if the information is unknown, not available or does not apply, the section/field of the form is left blank. Initial reporter is company sales representative. The device was received, the investigation is in progress, no conclusion could be drawn at the time of filing this report. Device was used for treatment, not diagnosis. If information is obtained that was not available for the initial medwatch, a follow-up medwatch will be filed as appropriate.
2951250-2019-01529		Injury	BAYER PHARMA AG	30/04/2019	HHS	ESSURE	Break; Insufficient Information; Migration	Uterine Perforation; Foreign Body In Patient; Device Embedded In Tissue or Plaque	This spontaneous case was reported by a lawyer and describes the occurrence of deviceBreakage ("it was noted that some portion of the metal was still within the myometrium"), device expulsion ("it was noted that some portion of the metal was still within the myometrium"), embedded device ("essure micro-insert embedded in myometrium [device dislocation] (10254)"), genital haemorrhage ("bleeding") and autoimmune disorder ("autoimmune-like symptoms") in an adult female patient who had essure inserted for female sterilisation. The occurrence of additional non-serious events is detailed below. The patient's medical history included gravida ii and parity 2. Concurrent conditions included ear infection and ear noises. On (b)(6) 2013, the patient had essure inserted. In 2013, the patient experienced adnexa uteri pain ("pain went to the fallopian tube"), abdominal pain ("pain to the left side of the belly, it went all the way to left side"), arthralgia ("pain went

									to the hip"), pain in extremity ("pain down to the leg") and paraesthesia ("a biting and pulsating pain. It is like an electric shock going all the way to the left leg."). On an unknown date, the patient experienced deviceBreakage (seriousness criteria medically significant and intervention required), device expulsion (seriousness criteria medically significant and intervention required), embedded device (seriousness criteria medically significant and intervention required), genital haemorrhage (seriousness criterion medically significant), autoimmune disorder (seriousness criterion medically significant), pelvic pain ("pain") and neuromyopathy ("neuromuscular problems") and was found to have weight increased ("weight gain"). Essure was removed on (b)(6) 2018. At the time of the report, the deviceBreakage, device expulsion, embedded device, genital haemorrhage, autoimmune disorder, pelvic pain, neuromyopathy and weight increased outcome was unknown and the adnexa uteri pain, abdominal pain, arthralgia, pain in extremity and paraesthesia had not resolved. The reporter provided no causality assessment for abdominal pain, adnexa uteri pain, arthralgia, pain in extremity and paraesthesia with essure. The reporter considered autoimmune disorder, deviceBreakage, device expulsion, embedded device, genital haemorrhage, neuromyopathy, pelvic pain and weight increased to be related to essure. Diagnostic results (normal ranges are provided in parenthesis if available): nuclear magnetic resonance imaging - in (b)(6) 2015: uterus 8.8x4.5. No suspicious mass. Small partially cystic lesion towards the fundus may represent a small partially cystic myoma of 8mm. Pathology test - on (b)(6) 2018: breast, left, medial, stereotactic vacuum assisted core biopsy. - non proliferative fibrocystic changes with microcalcification (calcium oxalate). - mammary duct ectasia; on (b)(6) 2018: right fallopian tube- it consists of a 8.7 cm in

									length 0.6 cm in diameter fimbriated fallopian tube. Sectioning reveals a pinpoint lumen, and a 2.3 cm in length and 0.2 cm in diameter shiny gray metallic coil at the proximal end of the isthmus. Left fallopian tube. It consists of a 7.1 cm in length 0.6 cm in diameter fimbriated portion of fallopian tube. Present at the proximal end of the isthmus is a 4.0 cm in length 0.2 cm in diameter shiny gray metallic coil.. Ultrasound scan vagina - in (b)(6) 2014: b/l essure catheters; otherwise normal pelvic ultrasound. X-ray - in (b)(6) 2014: bilateral essure device noted. Concerning the injuries reported in this case, the following ones were confirmed in patient¿s medical records: pelvic pain , abdominal pain, concerning the injuries reported in this case, the following ones were added from patient¿s medical records: deviceBreakage, device embedment, device expulsion. Quality-safety evaluation of ptc: final assessment: for cases where a device failure during insertion is reported, we conduct an investigation of any returned device. For cases where an insert is removed at a later time after insertion, we typically do not conduct an inspection of the insert. In this case, no product was returned. Since we have no valid lot number for this case, we were unable to conduct a review of the manufacturing batch record. We are unable to confirm any quality defect or device malfunction at this time. There was no event reported which indicates a new technical failure mode for the device. Medical assessment: the reported medical events are not necessarily indicative of a quality defect. No batch number was reported therefore a technical batch investigation is not possible. The technical assessment concluded unconfirmed quality defect. Based on the available information, there is no evidence of a quality defect thus there is no relationship between the reported medical events and a quality defect. Most recent follow-up information incorporated above includes: on 23-apr-

									2019: pfs and mr received. Reporters information updated. Events:pain, bleeding, neuromuscular problems, autoimmune-like symptoms , weight gain , deviceBreakage, device embedment , device expulsion were added. Lab data, medical history were added. Incident: no lot number or device sample was received in this case. We will conduct a review of our complaint records and other non-conformances data; should any new and reportable information become available from our investigation, this will be provided in a supplementary report.
9612186-2019-00010		Malfunction	ELEKTA INSTRUMENT AB	20/11/2019	HAW	LEKSELL STEREOTACTIC SYSTEM	Calibration Problem	No Information	Report received via a third party. The customer reported a dbs target inaccuracy. Manufacturer narrative: the user reported a shift of the dbs lead placement when the leksell stereotactic system. The deviation main direction is y and it is larger than 1.5 mm. An extensive investigation has been completed by elekta and brainlab (third-party) and it can be concluded that the equipment used is old, defective and has an unknown service record. It has also been observed on post-operative images that brain shift has occurred. The most probable reason for the reported shift is the usage of the old and defective frame and/or the brain shift seen.
1723170-2019-02359		Malfunction	MEDTRONIC NAVIGATION, INC	14/05/2019	HAW	NA	Computer Software Problem	No Patient Involvement	Medtronic received information regarding a navigation system event having occurred outside of procedure. It was reported that during a stereotactic dbs demo, after loading exams and while reviewing them in the select patient and planning tasks some of the slices for different exams appeared blank or distorted. This occurred for multiple exams for different patient datasets. After rebooting the system, the exams appeared correctly, and the issue was not able to be reproduced." no patient present. Manufacturer narrative: product event summary: planning station cranial 3.0.2 exam data appear blank/distorted. If information is provided in the future, a supplemental report will be issued.

9612186-2021-00001		Malfunction	ELEKTA INSTRUMENT AB	01/04/2021	HAW	LEKSELL STEREOTACTIC SYSTEM	Connection Problem; Material Integrity Problem	Insufficient Information; No Clinical Signs, Symptoms or Conditions	The customer reported that the fixation screws does not feel rigid when mounted in the disposable inserts. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed. This mdr concerns disposable inserts and fixation screws which is used with the leksell stereotactic frame. The disposable inserts themselves are labelled single use. However, the fixation screws and the leksell stereotactic system are not labelled single use.
9612186-2019-00006		Malfunction	ELEKTA INSTRUMENT AB	21/10/2019	HAW	LEKSELL STEREOTACTIC SYSTEM	Device Displays Incorrect Message; Compatibility Problem	No Consequences Or Impact To Patient; No Known Impact Or Consequence To Patient	Mr fiducial box use error. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed.
9612186-2018-00007		Malfunction	ELEKTA INSTRUMENT AB	17/12/2018	HAW	LEKSELL STEREOTACTIC SYSTEM	Device Slipped; Insufficient Information	No Known Impact Or Consequence To Patient	The customer noted that the frame had slipped before treatment completed. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed.
1222780-2020-00008		Malfunction	HOLOGIC, INC	10/01/2020	KNW	EVIVA STEREOTACTIC BREAST BIOPSY SYSTEM	Difficult to Open or Close	No Known Impact Or Consequence To Patient	It was reported that on unknown date, during a breast biopsy procedure, there were no faults noted in the device prior to insertion. Post insertion into breast, it was noted that the device was not retrieving samples. The device was removed from the breast in biopsy mode. Then a second device was opened and "all seemed good pre insertion into the breast. Then again not getting proper samples, at this stage they noticed a kink in the clear tubing at the top of the device (where samples should come out). They then squeezed this kinked part, the samples then came through and they finished the procedure this way." no third device used. No additional details available. Manufacturer narrative: the device is not being returned therefore, a failure analysis of the complaint device cannot be completed. If additional relevant information is received or device evaluation

									completed, a supplemental medwatch will be filed. Device history record (dhr) review was conducted for the reported identification number. The lot was released meeting all qa specifications.
3002250546-2021-00002		Malfunction	FHC, INC.	13/07/2021	HAW	WAYPOINT STEREOTACTIC SYSTEM	Inaccurate Information	No Clinical Signs, Symptoms or Conditions	While using a mp-kit-p-eo (multioblique (pmt) waypoint stereotactic system, physician found the platform was labeled with the incorrect depth numbers. There was no harm to patient as physician identified the issue and proceeded accordingly.
9612186-2019-00004		Malfunction	ELEKTA INSTRUMENT AB	15/03/2019	HAW	LEKSELL STEREOTACTIC SYSTEM	Labelling, Instructions for Use or Training Problem; Product Quality Problem	No Information	The customer reported that they are concerned regarding the accuracy of the arc of the g frame. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed.
9612186-2018-00006		Malfunction	ELEKTA INSTRUMENT AB	04/12/2018	HAW	LEKSELL VANTAGE STEREOTACTIC SYSTEM	Loose or Intermittent Connection; Defective Component	No Known Impact Or Consequence To Patient	The customer reported that the slide carrier screw is loose. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed.
9612186-2018-00005		Malfunction	ELEKTA INSTRUMENT AB	13/11/2018	HAW	LEKSELL VANTAGE STEREOTACTIC SYSTEM	Malposition of Device; No Apparent Adverse Event	No Known Impact Or Consequence To Patient; No Information	A third party supplier to a customer has reported that dbs electrodes, which have been implanted with the leksell vantage frame have shifted in a medial-posterior direction and a revision surgery is required. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed.
2020394-2018-00219		Malfunction	BARD PERIPHERAL VASCULAR, INC.	11/03/2018	KNW	ENCOR DRIVER	Mechanical Problem	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, the driver and probe allegedly continued to cut an additional four samples without depressing the foot pedal and the probe did not rotate. There was no reported patient injury.it was reported that during a stereotactic breast biopsy, the driver and probe allegedly continued to cut an additional four samples without depressing the foot pedal and the probe did not rotate. There was no reported patient injury. Manufacturer narrative: no medical records and no medical images were provided to the manufacturer. The serial

									number of the device was provided. The device history records are currently under review. The device has been returned for evaluation. The investigation is currently underway. The information provided by bard represents all of the known information at this time. Despite good faith efforts to obtain additional information, the complainant / reporter was unable or unwilling to provide any further patient, product, or procedural details to bard. Manufacturer narrative: manufacturing review: the device history records have been reviewed and this lot met all release criteria. There was nothing found to indicate there was a manufacturing related cause for this event. Investigation summary: one encor driver was returned to the service center for service and repair. No visual anomalies were noted to the returned driver. The returned driver successfully passed all functional testing without issue. Therefore, the investigation is unconfirmed for the reported mechanical issue (e.g., sampling without selection). Per the reported event details, "sampling started using the foot pedal and it would only sample one section of the clock face. Once the foot pedal released, it continued to sample". The driver used in the event was returned to the manufacturing site for service and repair. Per the service record, the returned driver was successfully functionally tested without issue. The driver passed all functional testing and the reported issue could not be replicated. The reported foot pedal used in the event was not returned for service and repair . Although the foot pedal may have contributed to the reported event, the definitive root cause for the reported mechanical issue could not be determined based upon the provided information. It is unknown whether procedural issues contributed to the event. Labeling review: the review of the ifu (instructions for use), indications, warnings, precautions, cautions, possible complications, and

									contraindications showed that the product labeling is adequate.
2020394-2018-00218		Malfunction	BARD PERIPHERAL VASCULAR, INC.	11/03/2018	KNW	ENCOR DRIVER	Mechanical Problem	No Consequences Or Impact To Patient	It was reported that during a stereotactic breast biopsy, the driver and probe allegedly continued to cut an additional four samples without depressing the foot pedal and the probe did not rotate. There was no reported patient injury. Manufacturer narrative: no medical records or no medical images have been made available to the manufacturer. The device has been returned to the manufacturer for evaluation. As the serial number for the device was provided, a review of the device history records is currently being performed. The investigation of the reported event is currently underway.the information provided by bard represents all of the known information at this time. Despite good faith efforts to obtain additional information, the complainant / reporter was unable or unwilling to provide any further patient, product, or procedural details to bard.
1030489-2019-00598		Malfunction	MEDTRONIC SOFAMOR DANEK USA, INC.	05/06/2019	NDN	CEMENT, BONE, VERTEBROPLASTY	Migration	Stenosis	Patients covered in the literature: 30 (gender: 22 males, 8 females; mean age: 60 years; age range:35¿81 years) it was reported in a literature titled "change in the cross-sectional area of thecal sac following balloon kyphoplasty for pathological vertebral compressionFractures prior to spine stereotactic radiosurgery" that 30 patients, who had spine metastasis and symptomatic pathological vertebral compressionFractures, underwent balloon kyphoplasty at a total of 41 vertebrae. Post-op, 10 out of the 41 augmented levels showed a decreased cross-sectional area of the thecal sac. Asymptomatic extravertebral cement extravasation was observed in 20 treated levels with no extravasated cement extending beyond the treated level. Minor ventral epidural pmma extravasation was encountered at 8 levels; 1 treated level (l1) in the group was associated with a decreased cross-sectional area of the thecal sac post-bkp. No bone fragments were displaced into the spinal canal, and no

									patient developed any neurological sequela related to the procedure. Nearly all patients (96%) reported at least some degree of improvement in their movement-related back pain. The vas score showed an average improvement from 7.3 pre bkp to 3.3 post-bkp. However, according to the literature. In patients with pre-existing epidural disease and destruction of the posterior vertebral body cortex who are undergoing bkp for pathologicalFractures, there is an increased risk of further mass effect upon the thecal sac and the potential to alter the srs treatment planning. Manufacturer narrative: neither the device nor films of applicable imaging studies were returned to the manufacturer for evaluation. Therefore, we are unable to determine the definitive cause of the reported event. If information is provided in the future, a supplemental report will be issued.
1820334-2018-00481		Injury	COOK INC	21/02/2018	KRD	NESTER PLATINUM EMBOLIZATION COIL	Migration or Expulsion of Device	No Code Available	A case of cardiac migration of a liver fiducial was reported by the customer in a journal article. This occurred in an (b)(6) patient planned for stereotactic body radiation therapy (sbrt) in the context of oligometastatic gastric cancer. For image-guidance, three nester embolization coils were planned to be implanted using computed tomography (ct) imaging. Prior to the placement of each coil, the location of the tip of the delivery needle was confirmed by ct imaging. During the procedure, the third coil unexpectedly migrated through the hepatic vein to the inferior vena cava and lodged at the vena cava/right atrial junction. The patient remained asymptomatic and was referred immediately for endovascular coil extraction. Using fluoroscopic guidance, an en snare retrieval system was introduced through a jugular catheter, successfully grasped the coil and was removed. The patient was kept overnight for observation and no immediate or delayed complications were encountered due to the migration or retrieval of the coil. The patient subsequently went on to be treated using

									the remaining fiducials. Manufacturer narrative: investigation - evaluation: a review of the complaint history, documents, instructions for use (ifu) and quality control was conducted during the investigation. Clinical assessment: there is no lot number or device rpn for reference. There is no information regarding the catheter type or size used during the procedure. Nestor embolization coils are packaged with ifu t_ce_nec. Per the ifu, ¿nestor embolization coils are not recommended for use with polyurethane catheter or catheters with sideports. If a catheter with sideports is used, the embolus may lodge in the sideport or pass inadvertently through it.¿ there is no information regarding the wire guide type or size used in the procedure. There is no information regarding the positioning of the catheter or wire guide during deployment of the embolization coil. When a coil migrates, there is a potential the coil could block or partially block flow to critical arteries resulting in ¿serious harm¿ (harm resulting in permanent impairment of body structure/function). At this time, the clinical assessment cannot eliminate any possible causes for this event such as product handling, medical procedure, other device compatibility, device failure, or manufacturing related causes the complaint device was not returned; therefore, no physical examinations could be performed. Additionally, the lot number of the device is not known; accordingly, a review of the device history record and complaint lot search could not be conducted. Manufacturing documentation was reviewed and confirmed that steps are in place to ensure each device is inspected and contains relevant ifu instructions. However, without the exact rpn, it cannot be determined which manufacturing instructions and specifications were used for this device. The root cause is likely product use related. Embolization coils were not designed to be used as a marker for sbrt (stereotactic body radiation

									therapy) and the ifu does not indicate for them to be used as such. Taking into consideration that embolization coils should, as stated in the ifu, "not be left too close to the inlets of arteries and should be intermeshed with previously placed coils" it is possible that using the coil as a marker and not as a method to block vessels could have given the coil a lack of space or support structure that it needed in order to stay in place. User technique could also be a potential cause of device failure if the positioning of the catheter during deployment was at an undesirable location or angle or the coil size selected was not appropriate for the patient's vessel. Additional root causes could be manufacturing related (product out of specification) and preparation for use. We will continue our monitoring of similar complaints and have notified the appropriate personnel of this event. Per the quality engineering risk assessment no further action is required. Manufacturer narrative: date of event: journal article was published in (b)(6) 2014. (b)(4). Citation: valentine, k., cabrera, t., roberge d., (2014), implanting metal fiducials to guide sterotactic liver radiation: mcgill experience and review of current devices, techniques, and complications., technology in cancer resears and treatment, vol. 13 (3) pgs:253-258. This report includes information known at this time. A follow up report will be submitted should additional relevant information become available.
9612186-2019-00003		Malfunction	ELEKTA INSTRUMENT AB	15/03/2019	HAW	LEKSELL STEREOTACTIC SYSTEM	Product Quality Problem; No Apparent Adverse Event	No Information	The customer reported a deviation on the left side of the elekta g-frame. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed.
2020394-2019-05666		Malfunction	BARD PERIPHERAL VASCULAR, INC.	17/12/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem	No Patient Involvement	It was reported that during preparation for a stereotactic breast biopsy, the device allegedly had an air leak at the sample chamber during calibration. There was no reported patient contact. Manufacturer narrative: a customer notification was

									issued for the encor breast biopsy probe for specific product code/lot number combinations. The affected product code/lot number combinations may be at risk of experiencing a leak between the probe and the tissue collection chamber, which could result in minimal suction, leakage, minimal or no tissue sample obtained, or an egress of fluids from the device. A root cause investigation and field action determination was conducted as a result of an increase in complaints for leaks, suction issues, and failure to obtain samples. The investigation included an extensive manufacturing review, risk documentation review for the three reported malfunctions, and evaluations performed on the returned devices. The investigation identified that one of the features on the trap chamber was under specified and during the implementation of a new trap chamber (b)(4) mold, one of the dimensions changed and went undetected, creating a difference between the amount of space that the seal has between the trap chamber and the front seal cap. This gap between the trap chamber and front seal cap resulted in conditions that led to a higher likelihood of leaks, suction issues, and failure to obtain samples. All reported complaints from the affected product code/lot number combinations that are possibly related to the gap between the trap chamber and front seal cap have been classified as leak, suction issues), or failure to obtain samples. This reported complaint is from an affected lot number that was reported for one of these trap chamber issues. (b)(4), (expiry date 10/2020).
2020394-2019-05668		Malfunction	BARD PERIPHERAL VASCULAR, INC.	17/12/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem	No Patient Involvement	It was reported that during preparation for a stereotactic breast biopsy, the device allegedly had an air leak at the sample chamber during calibration. There was no reported patient contact. Manufacturer narrative: a customer notification was issued for the encor breast biopsy probe for specific product code/lot number combinations. The affected product

									code/lot number combinations may be at risk of experiencing a leak between the probe and the tissue collection chamber, which could result in minimal suction, leakage, minimal or no tissue sample obtained, or an egress of fluids from the device. A root cause investigation and field action determination was conducted as a result of an increase in complaints for leaks, suction issues, and failure to obtain samples. The investigation included an extensive manufacturing review, risk documentation review for the three reported malfunctions, and evaluations performed on the returned devices. The investigation identified that one of the features on the trap chamber was under specified and during the implementation of a new trap chamber (b)(4) mold, one of the dimensions changed and went undetected, creating a difference between the amount of space that the seal has between the trap chamber and the front seal cap. This gap between the trap chamber and front seal cap resulted in conditions that led to a higher likelihood of leaks, suction issues, and failure to obtain samples. All reported complaints from the affected product code/lot number combinations that are possibly related to the gap between the trap chamber and front seal cap have been classified as leak, suction issues), or failure to obtain samples. This reported complaint is from an affected lot number that was reported for one of these trap chamber issues. (b)(4), (expiry date 10/2020).
2020394-2019-05664		Malfunction	BARD PERIPHERAL VASCULAR, INC.	17/12/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem	No Patient Involvement	It was reported that during preparation for a stereotactic breast biopsy, the device allegedly had an air leak at the sample chamber during calibration. There was no reported patient contact. Manufacturer narrative: a customer notification was issued for the encor breast biopsy probe for specific product code/lot number combinations. The affected product code/lot number combinations may be at risk of experiencing a leak between the probe and the tissue collection chamber,

									which could result in minimal suction, leakage, minimal or no tissue sample obtained, or an egress of fluids from the device. A root cause investigation and field action determination was conducted as a result of an increase in complaints for leaks, suction issues, and failure to obtain samples. The investigation included an extensive manufacturing review, risk documentation review for the three reported malfunctions, and evaluations performed on the returned devices. The investigation identified that one of the features on the trap chamber was under specified and during the implementation of a new trap chamber (b)(4) mold, one of the dimensions changed and went undetected, creating a difference between the amount of space that the seal has between the trap chamber and the front seal cap. This gap between the trap chamber and front seal cap resulted in conditions that led to a higher likelihood of leaks, suction issues, and failure to obtain samples. All reported complaints from the affected product code/lot number combinations that are possibly related to the gap between the trap chamber and front seal cap have been classified as leak, suction issues), or failure to obtain samples. This reported complaint is from an affected lot number that was reported for one of these trap chamber issues. (b)(4), (expiry date 10/2020).
2020394-2019-05669		Malfunction	BARD PERIPHERAL VASCULAR, INC.	17/12/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem	No Patient Involvement	It was reported that during preparation for a stereotactic breast biopsy, the device allegedly had an air leak at the sample chamber during calibration. There was no reported patient contact. Manufacturer narrative: a customer notification was issued for the encor breast biopsy probe for specific product code/lot number combinations. The affected product code/lot number combinations may be at risk of experiencing a leak between the probe and the tissue collection chamber, which could result in minimal suction, leakage, minimal or no tissue sample obtained, or an egress of fluids from the

									device. A root cause investigation and field action determination was conducted as a result of an increase in complaints for leaks, suction issues, and failure to obtain samples. The investigation included an extensive manufacturing review, risk documentation review for the three reported malfunctions, and evaluations performed on the returned devices. The investigation identified that one of the features on the trap chamber was under specified and during the implementation of a new trap chamber (b)(4) mold, one of the dimensions changed and went undetected, creating a difference between the amount of space that the seal has between the trap chamber and the front seal cap. This gap between the trap chamber and front seal cap resulted in conditions that led to a higher likelihood of leaks, suction issues, and failure to obtain samples. All reported complaints from the affected product code/lot number combinations that are possibly related to the gap between the trap chamber and front seal cap have been classified as leak, suction issues), or failure to obtain samples. This reported complaint is from an affected lot number that was reported for one of these trap chamber issues. (b)(4), (expiry date 10/2020).
2020394-2019-05667		Malfunction	BARD PERIPHERAL VASCULAR, INC.	17/12/2019	KNW	ENCOR BIOPSY PROBE	Suction Problem	No Patient Involvement	It was reported that during preparation for a stereotactic breast biopsy, the device allegedly had an air leak at the sample chamber during calibration. There was no reported patient contact. Manufacturer narrative: a customer notification was issued for the encor breast biopsy probe for specific product code/lot number combinations. The affected product code/lot number combinations may be at risk of experiencing a leak between the probe and the tissue collection chamber, which could result in minimal suction, leakage, minimal or no tissue sample obtained, or an egress of fluids from the device. A root cause investigation and field action determination was conducted as a result of an increase in complaints for leaks,

									suction issues, and failure to obtain samples. The investigation included an extensive manufacturing review, risk documentation review for the three reported malfunctions, and evaluations performed on the returned devices. The investigation identified that one of the features on the trap chamber was under specified and during the implementation of a new trap chamber (b)(4) mold, one of the dimensions changed and went undetected, creating a difference between the amount of space that the seal has between the trap chamber and the front seal cap. This gap between the trap chamber and front seal cap resulted in conditions that led to a higher likelihood of leaks, suction issues, and failure to obtain samples. All reported complaints from the affected product code/lot number combinations that are possibly related to the gap between the trap chamber and front seal cap have been classified as leak, suction issues), or failure to obtain samples. This reported complaint is from an affected lot number that was reported for one of these trap chamber issues. (b)(4), (expiry date 10/2020).
9612186-2017-00009		Malfunction	ELEKTA INSTRUMENT AB	27/02/2018	IWB	LEKSELL STEREOTACTIC SYSTEM	Therapeutic or Diagnostic Output Failure	No Known Impact Or Consequence To Patient	It was reported that the customer is assuming inaccurate targeting/inaccuracy of the system. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed.
9612186-2019-00012		Malfunction	ELEKTA INSTRUMENT AB	16/12/2019	HAW	LEKSELL VANTAGE STEREOTACTIC SYSTEM	Unintended Movement; Material Too Soft/Flexible	No Patient Involvement; No Known Impact Or Consequence To Patient	During verification of vantage frame adapter it was observed that there is a risk of shifting the frame versus the adapter in x-direction when holding the frame and adapter on the side. The interface is similar in the vantage frame holder and there is a risk that the same or similar shift can occur during handling. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed.
9612186-2019-00011		Malfunction	ELEKTA INSTRUMENT AB	20/11/2019	HAW	LEKSELL STEREOTACTIC SYSTEM	Use of Device Problem	No Consequences Or Impact To Patient	The customer reported that the patient came out of the vantage frame during a dbs (deep brain stimulation) case. Manufacturer narrative: the investigation was completed

									by conducting a thorough evaluation of the product and the reported information. The root cause has been established that the user did not have the correct sizes of firmfix available, but used a firmfix which was too long and resulted in a non-perpendicular or optimal fixation. It was noted that the firmfix ruler was not available when the fixation took place. When the patient started to cough, the non-optimal fixation did not hold the patient rigid enough and the patient slipped out of the fixation. The user confirmed that the patient did not experience any injury due to the incident.
9612186-2019-00008		Malfunction	ELEKTA INSTRUMENT AB	29/10/2019	HAW	LEKSELL VANTAGE STEREOTACTIC SYSTEM	Use of Device Problem	No Consequences Or Impact To Patient	The customer reported that electrodes implanted showed a consistent caudal shift of the target. Manufacturer narrative: the investigation found that the electrodes implanted showed a consistent caudal shift of the target. No injuries to the patient have been reported but the shift seen has resulted in displacement of the dbs (deep brain stimulation). The root cause investigation has shown that the cause was that the mri fiducial box was pushed against the inner surface of the head coil resulting in a shift of the stereotactic reference. The information and warnings in the instructions for use are sufficient for proper handling of leksell® vantagetm stereotactic system.
9612186-2019-00001		Malfunction	ELEKTA INSTRUMENT AB	15/02/2019	HAW	LEKSELL STEREOTACTIC SYSTEM	Use of Device Problem; Malposition of Device; Activation, Positioning or Separation Problem	No Information	The customer reported that the dbs lead did not implant correctly. Manufacturer narrative: the manufacturer's investigation is on-going and further information will be provided once the investigation has completed.