

Thoracolumbar Solutions

Vitality[®] Spinal Fixation System

Surgical Technique Guide

Vitality Spinal System

Surgical Technique

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Description, Indications and Contraindications

DESCRIPTION

The Vitality Spinal Fixation System is a thoracolumbar and sacroiliac fixation system. The system consists of a variety of screw types, iliac screws, connectors and rods to achieve an implant construct as necessary for the individual case. The system includes instruments for inserting, securing and removing the implants. The implant system is intended to be removed after solid fusion has occurred.

The Vitality System implants are made from medical grade titanium alloy and medical grade cobalt chromium alloy. Implants made from medical grade titanium, medical grade titanium alloy, and medical grade cobalt chromium may be used together. Never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same implant construct. All implants are single use only and should not be reused under any circumstances.

The Vitality Spinal Fixation System is compatible with the Virage® OCT Spinal Fixation System Rods, Instinct® Java[™] Spinal Fixation System Rods and Hooks, and Universal Clamp® Spinal Fixation System.

INDICATIONS

The Vitality Spinal Fixation System implants are non-cervical spinal fixation devices intended for posterior pedicle screw fixation (T1–S2/ilium), posterior hook fixation (T1–L5), or anterolateral fixation (T8–L5). Pedicle screw fixation is indicated for skeletally mature patients and for adolescent patients.

These devices are indicated as an adjunct to fusion for all of the following indications: degenerative disc disease (defined as discogenic back pain with degeneration of the disc confirmed by history and radiographic studies), spondylolisthesis, trauma (i.e., fracture or dislocation), deformities or curvatures (i.e., scoliosis, kyphosis, and/or lordosis, Scheuermann's Disease), tumor, stenosis, pseudoarthrosis and/or failed previous fusion. When used as an adjunct to fusion, the Vitality Spinal Fixation System is intended to be used with autograft and/or allograft.

In addition, the Vitality Spinal Fixation System is intended for treatment of severe spondylolisthesis (Grade 3 and 4) of the L5–S1 vertebra in skeletally mature patients receiving fusion by autogenous bone graft, having implants attached to the lumbosacral spine and/or ilium with removal of the implant after attainment of a solid fusion. Levels of pedicle screw fixation for these patients are L3–sacrum/ilium.

When used for posterior non-cervical pedicle screw fixation in pediatric patients, the Vitality System implants are indicated as an adjunct to fusion to treat adolescent idiopathic scoliosis. The Vitality System is intended to be used with autograft and/or allograft. Pediatric pedicle screw fixation is limited to a posterior approach.

The use of the Vitality Spinal Fixation System in skeletally mature patients may include the fixation of the Instinct Java Spinal Fixation System hooks, APEX Spinal System™ hooks, or fixation of the Universal Clamp Spinal Fixation System to the rods of the Vitality Spinal Fixation System. The Vitality Spinal Fixation System may also be used in skeletally immature patients when connected with the Universal Clamp Spinal Fixation System.

In order to achieve additional levels of fixation in skeletally mature patients, the Vitality Spinal Fixation System may be connected to the Virage OCT Spinal Fixation System and the Instinct Java Spinal Fixation System offered by Zimmer Spine, using rod connectors.

CONTRAINDICATIONS

The Vitality System is not designed or sold for any use except as indicated. DO NOT USE THE VITALITY SYSTEM IMPLANTS IN THE PRESENCE OF ANY CONTRAINDICATION.

- Insufficient bone quantity, severe osteoporosis, or other condition that might compromise rigid fixation of the device.
- A history of infection, active systemic infection or infection localized to the site of the proposed implantation.
- Suspected or documented metal allergy or intolerance.
- A disorder affecting the normal process of bone remodelling, including but not limited to severe osteoporosis involving the spine, excessive bone reabsorption, osteopenia, a primary or metastatic tumor involving the spine, or certain metabolic disorders of osteogenesis.
- Iliac screws and offset connectors should not be used in cases of tumor or trauma of the sacrum, when additional screw fixation in S1 is not possible.
- Other relative contraindications include obesity, pregnancy, certain degenerative diseases, and foreign body sensitivity. In addition, the patient's occupation or activity level or mental capacity may be relative contraindications to this surgery. Specifically, some patients may, because of their occupation or lifestyle, or because of conditions such as mental illness, alcoholism or drug abuse, place undue stresses on the implant.

Implant Overview

The Vitality Spinal Fixation System provides a comprehensive solution for rigid spinal fixation from the thoracic spine to the ilium.

The Vitality System includes multiple screw options; monoaxial, polyaxial, uniplanar, reduction and iliac. All screw types are available in multiple diameters and lengths designed to secure to either 5.5 or 6mm rods in titanium or cobalt chromium — which provide different strength and stiffness options.

Color	Diameter	Lengths	Increments
Gold	4.0mm	20–50mm	5mm
Magenta	4.5mm	20–50mm	5mm
Green	5.0mm	20–60mm	5mm
Blue	5.5mm	25-60mm	5mm
Gold	6.0mm	25-60mm	5mm
Light Blue	6.5mm	25–65mm	5mm
Green	7.5mm	30–65mm 70–120mm (Iliac)	5mm 10mm (Iliac)
Gold	8.5mm	30–65mm 70–120mm (Iliac)	5mm 10mm (Iliac)
Light Blue	9.5mm	30–60mm 70–120mm (Iliac)	5mm 10mm (Iliac)
Purple	10.5mm	30–60mm 70–120mm (Iliac)	5mm 10mm (Iliac)

All Vitality screws incorporate a T27 hexalobe drive feature, one of the largest in the industry, and 30% stronger than the T25 hexalobe, designed to reduce driver breakage.*

All Vitality screws incorporate an optimized attachment feature designed to simplify the engagement of multiple instruments, providing a solid connection for manipulation. All Vitality System non-monoaxial screws have Zimmer's proprietary friction fit head to hold the desired position and facilitate rod placement, maximizing efficiency and safety during the procedure.*

The Vitality System's dual lead screws require fewer revolutions to insert, improving surgeon efficiency by allowing them to insert screws twice as fast as comparable single lead screws without sacrificing pull-out strength.*

The Vitality System screws offer a fully threaded screw shank designed to improve the starting characteristics of the screw.

The Vitality System screw shank is designed to improve bone-screw fixation while reducing insertion torque. Optimization of the amount of bone material compacted between the threads was accomplished by reducing the thread material profile and optimizing thread pitch and major and minor diameter of the screw.

The Vitality System's iliac screws offer a low pitch, dual lead thread designed to minimize insertion torque and require fewer revolutions to insert, in an effort to reduce surgeon fatigue and the potential for driver breakage.

The Vitality System's closure top incorporates a blunt start, dual lead, reverse angle thread designed to improve starting engagement, advance quickly and help prevent head splay.

The Vitality System also offers a variety of implant options including multiple rod to rod connectors, lateral offset connectors (iliac), fixed and adjustable transverse connectors, 5.5 and 6.0mm pre-cut, curved and straight titanium and cobalt chromium rods.

The Vitality System deformity rods include reference markings every 1cm along the rod and a large hex end feature for de-rotation maneuvers. The Vitality System instrumentation is designed to treat a wide variety of spinal pathologies to allow surgeons the flexibility to build constructs that meet the anatomical challenges associated with complex spine procedures.

The Vitality System instrumentation is designed for ergonomic comfort and surgical efficiency. The offering of reduction/manipulation instruments supports complex spinal surgery with ease of use and expediency of implantation at their core.

Surgical Technique



Patient Positioning

Fig. 1 🔺

Place the patient on a radiolucent operating table in the prone position. Drape the patient for posterior spinal fusion.

Pedicle Preparation

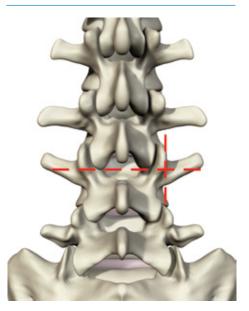


Fig. 2 🔺

PEDICLE TARGETING

Precise positioning of the pedicle entry point is essential. Proper orientation of the pedicle screw is dependent upon the position of the pilot hole. The pilot hole should be started where a line through the middle of the transverse process crosses a vertical line at the lateral edge of the facet joints.

The following Surgical Technique Guide describes the recommended placement and use of all Vitality Spinal Fixation System components.

Pedicle Preparation (cont.)



Fig. 3 🔺

AWL

Using the Awl, pierce the bone cortex at the entry point.

NOTE: The Thoracic Bone Awl creates a 2.75mm wide by 8mm deep pilot hole and the Lumbar Bone Awl creates a 4mm wide by 10mm deep pilot hole.



PROBE

Insert the Pedicle Probe through the pilot hole into the pedicle to create a path to guide the screw through the pedicle into the vertebral body. A depth gauge on the Probe indicates the insertion depth. Determine the sagittal orientation of the screw and the degree of convergence appropriate for the patient's anatomy.

CONFIRM PEDICLE INTEGRITY

After removing the Pedicle Probe, verify the integrity of the pedicle and the vertebral body walls using the Ball Tip Probe. When fully inserted, a forceps can be clamped onto the Ball Tip Probe to determine the hole depth for choosing the screw length.

NOTE: Optional pedicle markers, for fluoroscopic visualization, are available upon request.



Pedicle Screw Insertion







Fig. 6 🔺

TAPPING

Connect the appropriate diameter Tap to the Straight, Palm or Ratcheting T-Handle. Insert the Tap into the pedicle and rotate it clockwise. A depth gauge on the Tap indicates the hole depth. Remove the Tap by turning it counterclockwise.

NOTE: The Vitality System offers taps that are true to labeled size.

Fig. 7 🔺

SELECTING APPROPRIATE PEDICLE SCREW

Depending on the spinal pathology being treated, a surgeon may choose to utilize different types of pedicle screws. Polyaxial screws are generally the most commonly utilized screw. Uniplanar screws will most often be utilized at the apex of a scoliotic curve because they are fixed in the medial-lateral plane. Uniplanar screws provide additional stability during vertebral body derotation maneuvers to help restore global balance. Monoaxial screws can be utilized at the apex of a scoliotic curve as they also provide additional stability during vertebral body derotation maneuvers.

NOTE: It is recommended that reduction instrumentation is used when placing monoaxial screws at the end of a construct. This will ensure the rod is fully seated in the screw head prior to introducing and final tightening the closure top.

Fig. 8 🔺

SCREW DRIVER ASSEMBLY

Connect the Ratcheting Straight or T-Handle to place the appropriate screw on the standard Polyaxial Screw Driver by inserting the Screw Driver tip into the female hexalobe on the screw shank. Secure the polyaxial screw by turning the standard Polyaxial Screw Driver sleeve clockwise into the screw head.

The Polyaxial Screw Driver sleeve may be locked by pushing the button on the secondary lock and sliding the collar forward. This secure locking system prevents screw loosening and toggle during insertion. Confirm the collar is fully engaged and locked.

NOTE: An optional Screw Driver Sleeve may be used during this step. To connect, slide the Sleeve over the Screw Driver until it is fully engaged on the retaining feature. The Sleeve must be assembled prior to loading the pedicle screw.

Instruments



Handles 07.02108.001 Fixed Handle-Palm 07.02051.001 Ratcheting Handle-Straight 07.02052.001 Ratcheting T-Handle Taps 07.02088.001 (3.5mm) 07.02088.003 (4.5mm) 07.02088.005 (5.5mm) 07.02088.007 (6.5mm) 07.02088.009 (7.5mm) 07.02088.011 (8.5mm) Standard Screw Driver 07.02054.001



Screw Driver Sleeve — Standard 07.02131.001

Pedicle Screw Insertion (cont.)

Rod Insertion



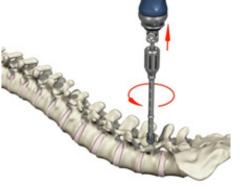




Fig. 9 🔺

SCREW INSERTION

Insert the screw through the prepared pedicle until it reaches the desired depth.

SCREW DRIVER REMOVAL

Fig. 10 🔺

Release the Standard Screw Driver by pushing the button on the screw driver lock and pulling the sleeve toward the handle. Turn the sleeve counterclockwise to loosen the screw driver from the screw head.

Repeat pedicle preparation and screw insertion steps for all of the screws.

ROD SELECTION AND BENDING

The Vitality System offers multiple rod diameter and material choices. Surgeons should select the rod that is appropriate for their patient's needs.

The system includes a rod template that can be used to determine rod length and desired contour. The Rod Template should be inserted into screw heads and contoured to fully seat within the screw head. Appropriate length can be determined using the length markings on the rod template.

Use the French Rod Bender to prepare and contour the rods with progressive bends until obtaining a shape similar to that defined by the Rod Template. Pre-contoured versions simplify the initial approximation.

NOTE: The surgeon should reference the markings on the rod to achieve contours in the desired place.

Instruments



Rod Templates 07.02099.001 (100mm) 07.02099.002 (250mm)



French Rod Bender 07.02092.001

Closure Top Insertion



Fig. 12 🔺

SCREW ADJUSTMENT / ROD INSERTION

The Head-Height Adjuster can be used to adjust screw head alignment prior to rod insertion. To adjust screw height, fully insert the Head Height Adjuster into the screw shank and turn to the desired height. To adjust head orientation, insert the Head Height Adjuster into the screw head and turn to ensure screw heads are in proper orientation for rod insertion.

Fig. 13 🔺

Use the Rod Holder to position the rod within the screw heads. A Rod Gripper or Vise Grip is also available if necessary.

Fig. 14 🔺

Insert the Closure Top Starter or Dual Ended Closure Top Starter into the open hexalobe drive interface. Align the Driver with the screw head and introduce the closure top. Turn the closure top until it comes into contact with the rod. Do not final tighten. Repeat this procedure for inserting all closure tops.



Rod to Rod Connectors

The Vitality System offers a variety of different style zto-rod connectors which connect to

3.5mm, 5.5mm and 6.0mm rods. Depending on the style of connector that is being used, a closure top or connector set screw will be used in conjunction with the appropriate Final Driver, Torque Limiting Handle and Counter Torque to final lock the rod-to-rod connectors.

NOTE: The Rod-to-Rod Connector Forceps can be used to assist with placing any of the connectors onto the rods.

NOTE: The Counter Torque should be used adjacent to the selected connector along the rod to provide adequate counter torque when final tightening.

The Vitality Spinal Fixation System offers five instrument options for rod reduction. Full rod reduction into the screw housing is recommended prior to securing with the closure top.

Rod Reduction Options

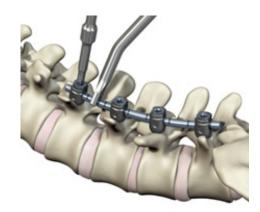


Fig. 16 🔺

OPTION 1: ROD PUSHER

For slight reduction, the Rod Pusher can be used to directly introduce the rod into the screw head. Use the Closure Top Starter or Dual Ended Closure Top Starter to introduce the closure top into the screw head. Turn the closure top until it comes into contact with the rod. Do not final tighten.



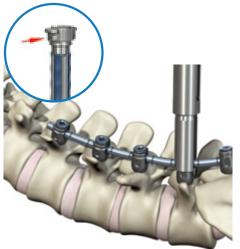
Instruments



Fig. 17 🔺

OPTION 2: ROD ROCKER

For moderate reduction, the Rod Rocker may be used. Align the prongs of the Rod Rocker in the medial and lateral slots on the screw head. Close and lock the Rod Rocker and use the Rod Rocker as a lever to introduce the rod into the screw head. Once the rod is fully reduced into the screw head, use the Closure Top Starter or Dual Ended Closure Top Starter to introduce the closure top into the screw head. Turn the closure top until it comes in contact with the rod. Do not final tighten.



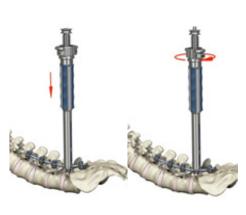


Fig. 18 🔺

OPTION 3: TOWER REDUCER

When the rod is above the screw head, the Tower Reducer may be used to seat the rod. Ensure that the Tower Reducer is fully open by rotating the knob counterclockwise or by pressing release button and pushing the inner shaft completely down. Engage the rim of the screw head by pressing the Tower Reducer down gently onto the screw head until fully seated.

Fig. 19 🔺

OPTION 3: TOWER REDUCER; REDUCTION

Rotate the knob at the proximal end of the reducer clockwise until the rod is fully reduced into the screw head. The Tower Reducer offers 30mm of reduction capability. For additional leverage during the reduction maneuver, attach the Tower Reducer T-Handle to the top of the Reducer. Once the rod is fully reduced, introduce the closure top using the Closure Top Starter — Reducer down the Tower Reducer. Turn clockwise until provisionally tight.

NOTE: To engage the rod more quickly, push and hold the release button. Slide the outer shaft of the Reducer downward until it engages the rod. Rotate handle clockwise at the proximal end of the Reducer to reduce the rod into the screw head.

Instruments



Rod Rocker 07.02093.001



Tower Reducer 07.02097.001



Tower Reducer T-Handle 07.02132.001



Fig. 20 🔺

Confirm the rod is fully reduced by looking at the laser mark reduction lines on the outer sleeve. The inner and outer sleeve lines should match when the rod is fully reduced. Once the rod is fully reduced into the screw head, use the Closure Top Starter — Reducer to introduce the closure top into the screw head. Turn the closure top until it comes in contact with the rod. Do not final tighten.

OPTION 3: TOWER REDUCER; REMOVAL

Fig. 21 🔺

To remove the Tower Reducer, turn the handle a half turn counterclockwise, push and hold the button at the proximal end of the reducer, push down on the center threaded inner reduction sleeve and gently lift the Tower Reducer off of the screw head.

NOTE: This instrument requires disassembly for proper cleaning.

OPTION 4: SINGLE ACTION ROD REDUCER; PLACEMENT/ENGAGEMENT

Fig. 22

When the rod is above the screw head, the Single Action Rod Reducer may be used to seat the rod. Ensure the Reducer is fully open and engage the medial and lateral rims of the screw head by pressing the Single Action Rod Reducer down gently onto the screw head.



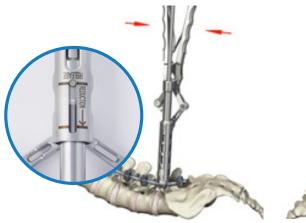


Fig. 23 🔺

OPTION 4: SINGLE ACTION ROD REDUCER; ROD REDUCTION

Slowly squeeze the handles together, sliding the external sleeve down to seat the rod into the screw head. The ratchet allows controlled reduction and maintains position until the closure top is placed.

NOTE: The Single Action Rod Reducer offers 20mm of reduction capability.



Fig. 24 🔺

OPTION 4: SINGLE ACTION ROD REDUCER; CLOSURE TOP INSERTION

Once the rod is fully reduced into the screw head, use the Closure Top Starter — Reducer to introduce the closure top into the screw head. Turn the closure top clockwise until it comes in contact with the rod. Do not final tighten.

To remove the Single Action Rod Reducer, release the ratchet, open the handles and disconnect the Reducer from the screw head.

OPTION 5: TUBE ROD PUSHER

The Tube Rod Pusher can be used to align the rod with the screw head. Position the Tube Rod Pusher over the rod and manipulate alignment to the screw head.

Once the rod is positioned within the screw head, use the Rod Pusher to position the rod into the screw head. Use the Closure Top Starter or Dual Ended Closure Top Starter to introduce the closure top into the screw head. Turn the closure top until it comes in contact with the rod. Do not final tighten.

Instruments



Reduction Screws





Fig. 25 🔺

SCREW DRIVER ASSEMBLY — REDUCTION SCREWS

For reduction screws, connect the Reduction Screw Driver to the desired Ratcheting Handle.

Fig. 26 🔺

REDUCTION SCREW DRIVER ASSEMBLY

Place the appropriate length screw on the Reduction Screw Driver by inserting the Screw Driver tip into the female hexalobe on the screw shank. Secure the reduction screw by turning the Screw Driver retention sleeve clockwise. The Polyaxial Screw Driver sleeve may be locked by pushing the button on the secondary lock and sliding the collar forward. This secure locking system prevents screw loosening and toggle during insertion. Confirm the collar sleeve is fully engaged and locked.

REDUCTION SCREW INSERTION

Insert the reduction screw through the prepared pedicle until it reaches the desired height.

Instruments



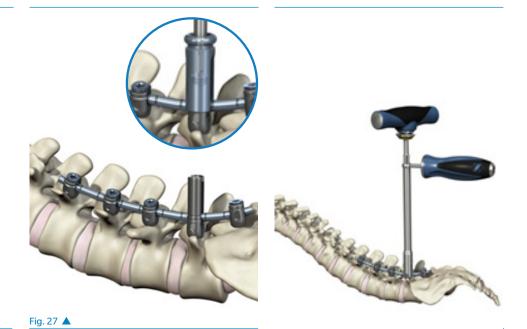
Ratcheting Handle — Straight 07.02051.001



Ratcheting Handle — T-Handle **07.02052.001**



Reduction Screw Driver 07.02058.001



REDUCTION SCREW DRIVER REMOVAL

Release the Reduction Screw Driver by pushing the button on the secondary lock and pulling the collar toward the handle. The retention sleeve can then be turned counterclockwise to loosen the Screw Driver from the screw head. Repeat this procedure for all reduction screws.

ROD PLACEMENT

Insert the rod into the reduction screw head.

Reduction Tab Sleeves are recommended to protect the reduction tabs during rod reduction. After the rod is placed within the screw head, slide the Reduction Tab Sleeve over the reduction screw head.

Use the Closure Top Starter to insert the closure top into the reduction screw.

NOTE: Shear-off closure tops are not compatible with reduction screws.

REDUCTION

Using either the Closure Top Starter or the Torque Limiting T-Handle with Final Driver, advance the closure top until the rod is fully seated and the closure top is provisionally tight.

Remove the Reduction Tab Sleeve. Connect the Final Driver to the 90 in-lbs Torque Limiting handle. Pass the Final Driver through the Counter Torque and engage the Final Driver tip into the closure top. Slide the Counter Torque over the reduction screw head and final tighten the closure top using the 90 in-lbs Torque Limiting Handle. Turn the Final Closure Top Driver clockwise until the 90 in-lbs Torque Limiting Handle clicks over a minimum of two times.

NOTE: Final tightening should not be completed until all compression or distraction maneuvers have been completed.

NOTE: The Reduction Tab Sleeve must be removed prior to using the Counter Torque to final tighten the closure top.

Instruments



Reduction Tab Sleeve
07.02120.001



T27 Closure Top Starter 07.02068.001



Torque Limiting Handle – 90 in-Ibs 07.02053.001 T27 Final Driver **730M0017**

Counter Torque 07.02095.001

Compression and Distraction (If Necessary)

Fig. 30 🔺

(IF NECESSARY)

COMPRESSION AND DISTRACTION

To compress two screws simultaneously, place

the Compressor against the screws' tulip heads

and squeeze the handle. Compression can also

locking one screw using the Closure Top Starter

and compressing off of the provisionally locked

be performed sequentially by provisionally

screw. When the compression maneuver is complete, provisionally lock the compressed

To distract two screws simultaneously, place the Distractor against the screws' tulip heads and squeeze the handle. Distraction can also be performed sequentially by provisionally locking one screw using the Closure Top Starter and distracting off of the provisionally locked screw. When the distraction maneuver is complete, provisionally lock the distracted screw and

screw and release the Compressor.

release the Distractor.

Rod Manipulations Options

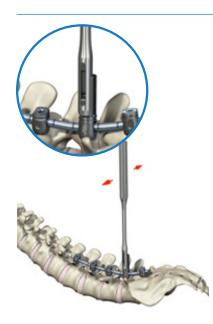


Fig. 29 🔺

TAB REMOVAL

Use the Reduction Tab Breaker to remove the reduction screw tabs. Bending the tab medial to lateral will release it from screw head.

Repeat for the second tab.

NOTE: Reduction screw tabs may have rough edges after removal which should be handled with care.



Fig. 31 🔺

OPTION 1: SAGITTAL PLANE IN SITU BENDING (IF NECESSARY)

Provisionally tighten the implants using the Closure Top Starter. To achieve sagittal plane correction, the in situ Sagittal Benders may be used.

NOTE: Choose the appropriate diameter Sagittal Bender based on the diameter of rod being used.

Instruments



Reduction Tab Breaker 07.02074.001



07.02090.001 (multilevel)



Distractor 07.02109.001 07.02110.001 (multilevel)

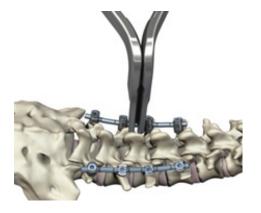


T27 Closure Top Starter 07.02068.001



In Situ Sagittal Benders (5.5mm) 07.02091.001 (left) 07.02091.002 (right) In Situ Sagittal Benders (6mm) 07.02102.001 (left) 07.02102.002 (right)

Final Locking — Torque Limiting





OPTION 2: CORONAL PLANE IN SITU BENDING (IF NECESSARY)

To achieve coronal plane correction, the *in situ* Coronal Benders may be used.





Fig. 33 🔺

ROD DEROTATION (IF NECESSARY)

A Rod Gripper or Vise Grip can be used to rotate the rod into the correct orientation and ensure proper position within the screw heads.

NOTE: If using a rod with a hex end, the Hex End Rod Rotation Tool can be used to assist with rod derotation.

Once rod reduction, compression/distraction, and manipulation maneuvers have been completed, all of the closure tops must be final locked. If monoaxial screws are used at the proximal or distal end of a construct, it is highly recommended that reduction instruments are used to ensure closure top and rod are fully seated prior to final locking. Fig. 34 🔺

When using the torque closure top, connect the Final Driver to the 90 in-lbs Torque Limiting Handle. Pass the Final Driver through the Counter Torque and insert it into the hexalobe drive interface on the closure top. While applying appropriate counter torque, turn the Final Closure Top Driver clockwise until the 90 in-lbs Torque Limiting Handle clicks over a minimum of two times.

NOTE: Visually confirm the Final Driver tip full engagement in the closure top before sliding the counter torque over the screw head.

NOTE: Always use the 90 in-lbs Torque Limiting Handle for final tightening closure tops.



Final Locking — Shear Off

Iliac Fixation (If Necessary)



Fig. 35 🔺

Instruments

When using the shear-off closure top, use the Shear-Off Final Driver. Pass the Shear-Off Final Driver through the Counter Torque and engage the hex interface on the shear-off closure top. While applying appropriate counter torque, turn the Final Shear-Off Driver clockwise until the hex drive feature on the shear-off closure top breaks off.

NOTE: The shear-off closure top will snap off at 90 in-Ibs.

To empty the snapped off portion of the closure top, turn the Shear-Off Final Driver upside-down. A rod may be used to push out any caps that remain in the Driver.

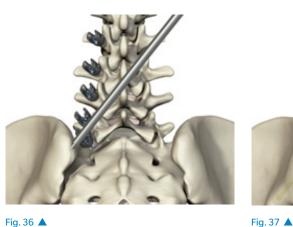
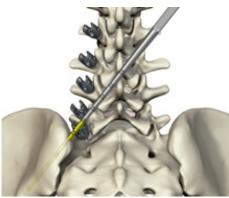


Fig. 36 🔺

AWL

After selecting the entry point, use the Awl to pierce the bone cortex and create a pilot hole.



ILIAC PROBE

Determine the optimal trajectory of the screw pathway based on the patient's anatomy. Insert the Iliac Probe through the pilot hole into the ilium to create a path to guide the screw. Reference the depth indicators on the Iliac Probe shaft to ensure the probe reaches the desired depth.





Fig. 38 🔺

CONFIRM PATHWAY INTEGRITY

After removing the Iliac Probe, verify the integrity of the cortical walls by using the Ball Tip Probe. When fully inserted, forceps can be clamped onto the Ball Tip Probe to mark the hole depth and assist in iliac screw selection.

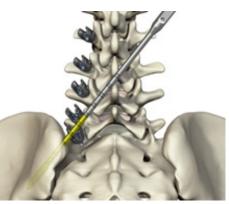


Fig. 39 🔺

TAPPING

Connect the appropriate diameter Iliac Tap to the desired Handle. Insert the Iliac Tap into the ilium and advance the threads by rotating the handle clockwise. After removing the tap by rotating counterclockwise, verify the integrity of the cortical walls again using the Ball Tip Probe.

NOTE: The Vitality System offers taps that are true to labeled size.



Fig. 40 🔺

SCREW INSERTION

Attach the appropriate size iliac screw to the screw driver assembly. Insert the iliac screw into the pilot hole and advance it to the desired dorsal height by turning the Standard Screw Driver clockwise.

Instruments

Ball Tip Probe

07.02115.001

07.02117.001

(Single Ended Stiff)

(Dual Ended Stiff/Flexible)



Ratchetin **07.0205**2



Ratcheting T-Handle 07.02052.001



lliac Tap 07.02114.007 (6.5mm) 07.02114.009 (7.5mm) 07.02114.011 (8.5mm) 07.02114.013 (9.5mm) Standard Screw Driver

07.02054.001

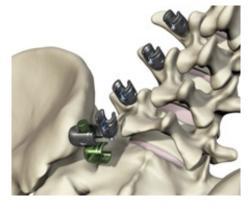


Fig. 41 🔺

LATERAL OFFSET CONNECTOR PLACEMENT

Open or closed lateral offset connectors are utilized to facilitate rod placement and bridge the construct between the iliac screw and rod. Determine the appropriate length open or closed lateral offset connector. Place the lateral offset connector in the screw head of the open or closed iliac screw in a preferred orientation.

Both Open and Closed Lateral Connectors options are available in straight (0 degree), or 15 degree and 25 degree angles. (see page 47)



J. 42 🛋

CLOSURE TOP PLACEMENT — **ILIAC SCREWS** While holding the lateral offset connector in place, insert a closure top and provisionally tighten the closure top on the tulip head of the iliac screw with the Closure Top Starter.

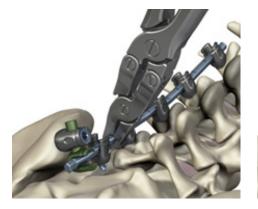
NOTE: At least 2mm of the offset connector rod should extend beyond the tulip head before tightening the closure top.

SCREW DRIVER REMOVAL

To release the Screw Driver, push the retention collar button and pull the collar toward the handle. Turn the sleeve counterclockwise to loosen the Screw Driver from the tulip head.

Instruments





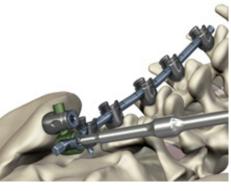


Fig. 43 🔺

ROD INSERTION

Select the appropriate length rod and cut to a desired length. Rods may be bent to facilitate placement. Place the rod in the lateral offset connector, followed by each remaining cephalad pedicle screw.

CLOSURE TOP INSERTION — LATERAL OFFSET CONNECTORS

Fig. 44

Provisionally tighten the closure top in the saddle of the lateral offset connector with the Closure Top Starter. Fig. 45 ▲

LATERAL OFFSET CONNECTOR FINAL LOCKING

Connect the Final Driver to the Torque Limiting Handle. Pass the Final Driver through the Counter Torque and engage the Final Driver tip into the closure top. Slide the Counter Torque over the lateral connector head and final tighten the closure top using the 90 in-lbs Torque Limiting Handle. Turn the Final Closure Top Driver clockwise until the 90 in-lbs Torque Limiting Handle clicks a minimum of two times. Repeat for the closure top on the iliac screw.

NOTE: The lateral offset connector should be final tightened before final locking the closure top on the iliac screw.

The iliac screws and offset connectors provide additional stabilization for an S1 screw. It is recommended that iliac screws are used in conjunction with S1 screw fixation.

Instruments

T27 Closure Top Starter

07.02068.001



90in.lbs 07.02053.001 T27 Final Driver

730M0017



07.02095.001

Transverse Connector Options



Fig. 46

A transverse connector may be used at the surgeon's discretion if additional construct stability is desired.

The Vitality System offers both adjustable and fixed transverse connectors. Ensure the appropriate size of transverse connector is selected to match the rod diameter.

NOTE: 5.5mm rods use the light blue transverse connectors and 6mm rods use the green transverse connectors.

Fig. 47 🔺

TRANSVERSE CONNECTOR CALIPER

Use the Transverse Connector Caliper to determine the appropriate size transverse connector. Place the ends of the Caliper directly onto each rod at the desired location for connector placement. The corresponding measurement reading provides the suggested length of the connector. The Transverse Connector Caliper has dedicated markings that correlate to both the appropriate length implant and the location in the caddy.

NOTE: A-E refer to adjustable transverse connectors and 1-6 refer to fixed transverse connectors.

ADJUSTABLE TRANSVERSE CONNECTOR PLACEMENT

Confirm that the center set screw is loose to allow for free range of motion prior to placing the adjustable transverse connector onto the rod construct. Fixate each end of the connector to each rod by pushing anteriorly on the set screw using the Set Screw Starter. Final lock each end of the transverse connector to the rod using the T20 Final Driver, 50 in-lbs Torque Limiting Handle and Transverse Connector Counter Torque. Turn the T20 Final Driver clockwise until the 50 in-lbs Torque Limiting Handle clicks over a minimum of two times.

NOTE: The Transverse Connector Counter Torque has a "Medial" marking indicating the orientation of the instrument when locking the set screws on the rod.

Instruments



Transverse Connector Caliper 07.02111.001



T20 Set Screw Starter 07.02119.001



Torque Limiting Handle -50 in-lbs 07.02118.001

T20 Final Driver 07.02063.001



Transverse Connector Counter Torque 07.02121.001

Final Construct



Fig. 49 🔺

Final lock the middle transverse connector set screw last using the same T20 Final Driver and Torque Limiting Handle. Turn the T20 Final Driver clockwise until the 50 in-Ibs Torque Limiting Handle clicks over a minimum of two times.

NOTE: Make sure the same size transverse connector and rod (5.5mm or 6.0mm) are used together.





Fig. 51 🔺

Re-check all connections of the final construct. Intraoperative radiographic image of the final construct should be taken to confirm the desired construct is achieved prior to wound closure.

FIXED TRANSVERSE

Fig. 50 🔺

CONNECTOR PLACEMENT

Once the appropriate length fixed transverse connector has been identified, fixate each end of the connector to each rod by pushing anteriorly on the set screw using the Set Screw Starter. Make sure the same size rod and fixed transverse connector are used together. Final lock each end of the transverse connector to the rod using the T20 Final Driver, 50 in-lbs Torque Limiting Handle and Transverse Connector Counter Torque. Turn the T20 Final Driver clockwise until the 50 in-lbs Torque Limiting handle clicks over a minimum of two times.

Instruments



T20 Set Screw Starter 07.02119.001



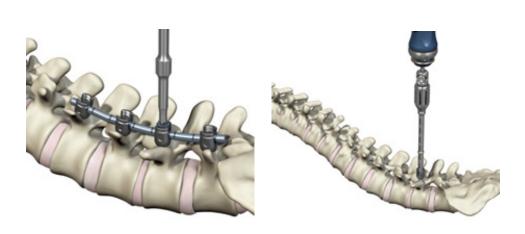
Torque Limiting Handle – 50 in-Ibs 07.02118.001

T20 Final Driver 07.02063.001



Transverse Connector Counter Torque 07.02121.001

Removal or Revision



REMOVE CLOSURE TOPS (IF NECESSARY)

Remove the closure tops by turning the closure top counterclockwise using the Final Closure Top Driver. The Counter Torque may be used to provide additional leverage to loosen the closure top. When all closure tops have been removed, the rod may be removed manually or by using the Rod Holder.

NOTE: If the closure top interface is damaged, the Easy Out Removal Driver can be used to loosen the closure top.

REMOVE IMPLANTED SCREW

Once closure tops are removed, the Pedicle Screw Removal Driver can be used to remove an implanted screw. Connect the Pedicle Screw Removal Driver to a Quick Connect Ratcheting Straight or T-Handle. Engage the distal tip of the Pedicle Screw Removal Driver in the base of the screw head. Slide the outer sleeve of the Driver down and rotate the sleeve clockwise to securely lock the Driver onto the screw head. Remove the pedicle screw by rotating the handle and Screw Driver counterclockwise.



Instrument Disassembly Instructions



The Vitality System includes instruments that require disassembly prior to cleaning. The following identifies those instruments and the appropriate instructions for disassembly.

TOWER REDUCER

To disassemble the Tower Reducer, press the release button while pushing the distal end of the inner portion of instrument out of the outer portion. Once the threaded section of the inner component is clear of the button, it can be pulled completely out of the outer body of the reducer.

SCREW DRIVER, MODULAR

To disassemble the Modular Screw Driver, press the proximal end of the outer locking sleeve collar down and turn the main body of the sleeve clockwise. This will release the back portion from the rest of the locking sleeve collar and allow the outer sleeve to be removed over the inner Screw Driver shaft.

Tray Layouts

Prep Instruments 1 07.02136.401



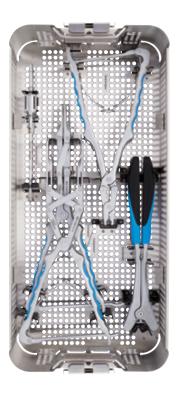


Quick Connect - Ratcheting Handle - Straight207.02051.001Quick Connect - Ratcheting T-Handle107.02052.001Quick Connect - Ratcheting T-Handle107.02054.001Screw Driver, Standard207.02060.001Head - Height Adjuster107.02064.001Rod Holder107.02067.001Pedicle Probe - Straight, Lumbar107.02072.001Pedicle Probe - Curved, Lumbar Lenke107.02077.001Pedicle Probe - Straight, Lumbar Lenke107.02077.001Pedicle Probe - Straight, Lumbar Lenke107.02079.001Pedicle Probe - Straight, Lumbar Lenke1	Part Number	Description	Quantity
07.02052.001 T-Handle 1 07.02054.001 Screw Driver, Standard 2 07.02060.001 Head – Height Adjuster 1 07.02064.001 Rod Holder 1 07.02064.001 Pedicle Probe – Straight, Lumbar 1 07.02067.001 Pedicle Probe – Curved, Lumbar Lenke 1 07.02072.001 Pedicle Probe – Curved, Lumbar Lenke 1 07.02077.001 Pedicle Probe – Straight, Lumbar Lenke 1 07.02077.001 Pedicle Probe – Straight, Lumbar Lenke 1 07.02079.001 Pedicle Probe – Curved, Lumbar 1	07.02051.001	, 5	2
07.02060.001 Head – Height Adjuster 1 07.02064.001 Rod Holder 1 07.02067.001 Pedicle Probe – Straight, Lumbar 1 07.02072.001 Pedicle Probe – Curved, Lumbar Lenke 1 07.02072.001 Pedicle Probe – Curved, Lumbar Lenke 1 07.02077.001 Bone Awl 1 07.02077.001 Pedicle Probe – Straight, Lumbar Lenke 1 07.02079.001 Pedicle Probe – Curved, Lumbar Lenke 1	07.02052.001		1
07.02064.001Rod Holder107.02067.001Pedicle Probe – Straight, Lumbar107.02072.001Pedicle Probe – Curved, Lumbar Lenke107.02076.001Bone Awl107.02077.001Pedicle Probe – Straight, Lumbar Lenke107.02077.001Pedicle Probe – Straight, Lumbar Lenke107.02079.001Pedicle Probe – Curved, Lumbar Lenke1	07.02054.001	Screw Driver, Standard	2
07.02067.001Pedicle Probe – Straight, Lumbar107.02072.001Pedicle Probe – Curved, Lumbar Lenke107.02076.001Bone Awl107.02077.001Pedicle Probe – Straight, Lumbar Lenke107.02079.001Pedicle Probe – Curved, Lumbar Lenke1	07.02060.001	Head — Height Adjuster	1
07.02072.001Pedicle Probe - Curved, Lumbar Lenke107.02076.001Bone Awl107.02077.001Pedicle Probe - Straight, Lumbar Lenke107.02079.001Pedicle Probe - Curved, Lumbar1	07.02064.001	Rod Holder	1
07.02072.001 Lenke 1 07.02076.001 Bone Awl 1 07.02077.001 Pedicle Probe — Straight, Lumbar Lenke 1 07.02079.001 Pedicle Probe — Curved, Lumbar 1	07.02067.001	Pedicle Probe — Straight, Lumbar	1
07.02077.001Pedicle Probe — Straight, Lumbar Lenke107.02079.001Pedicle Probe — Curved, Lumbar1	07.02072.001		1
07.02077.001 Lenke 1 07.02079.001 Pedicle Probe – Curved, Lumbar 1	07.02076.001	Bone Awl	1
	07.02077.001	-	1
07.02088.001 Tap 3.5mm 1	07.02079.001	Pedicle Probe — Curved, Lumbar	1
	07.02088.001	Tap 3.5mm	1

Part Number	Description	Quantity
07.02088.003	Tap 4.5mm	1
07.02088.005	Tap 5.5mm	1
07.02088.007	Tap 6.5mm	1
07.02088.009	Tap 7.5mm	1
07.02088.011	Tap 8.5mm	1
07.02099.001	Rod Template — 100mm	1
07.02099.002	Rod Template — 250mm	1
07.02108.001	Quick Connect — Fixed Handle — Palm	1
07.02115.001	Ball Tip Probe — Single Ended Stiff — Standard	1
07.02117.001	Ball Tip Probe — Dual Ended Stiff/ Flexible — Standard	1
07.02131.001	Screwdriver Sleeve — Standard	2

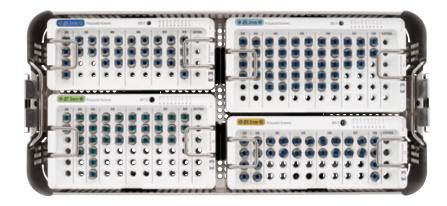
Manipulation Instruments 2





Catalog Number	Description	Kit Quantity
07.02061.001	Pedicle Screw Removal Driver	1
07.02089.001	Compressor	1
07.02092.001	French Rod Bender	1
07.02093.001	Rod Rocker	1
07.02096.001	Single Action Reducer	1
07.02097.001	Tower Reducer	1
07.02100.001	Rod Gripper	1
07.02101.001	Rod Pusher	1
07.02109.001	Distractor	1
07.02132.001	Tower Reducer T-Handle	1

5.5 – 8.5 Polyaxial Screws 3



Part Number	Description	Quantity
07.02000.030	Polyaxial Screw, ø5.5mm × 30mm	4
07.02000.031	Polyaxial Screw, ø5.5mm × 35mm	4
07.02000.032	Polyaxial Screw, ø5.5mm × 40mm	6
07.02000.033	Polyaxial Screw, ø5.5mm × 45mm	6
07.02000.034	Polyaxial Screw, ø5.5mm × 50mm	6
07.02000.035	Polyaxial Screw, ø5.5mm × 55mm	4
07.02000.072	Polyaxial Screw, ø6.5mm × 30mm	4
07.02000.073	Polyaxial Screw, ø6.5mm × 35mm	4
07.02000.074	Polyaxial Screw, ø6.5mm × 40mm	10
07.02000.075	Polyaxial Screw, ø6.5mm × 45mm	10
07.02000.076	Polyaxial Screw, ø6.5mm × 50mm	10
07.02000.077	Polyaxial Screw, ø6.5mm × 55mm	6
07.02000.078	Polyaxial Screw, ø6.5mm × 60mm	2

Part Number	Description	Quantity
07.02000.114	Polyaxial Screw, ø7.5mm × 30mm	2
07.02000.115	Polyaxial Screw, ø7.5mm × 35mm	4
07.02000.116	Polyaxial Screw, ø7.5mm × 40mm	6
07.02000.117	Polyaxial Screw, ø7.5mm × 45mm	6
07.02000.118	Polyaxial Screw, ø7.5mm × 50mm	6
07.02000.119	Polyaxial Screw, ø7.5mm × 55mm	6
07.02000.120	Polyaxial Screw, ø7.5mm × 60mm	2
07.02004.156	Polyaxial Screw, ø8.5mm × 30mm	4
07.02004.157	Polyaxial Screw, ø8.5mm × 35mm	4
07.02004.158	Polyaxial Screw, ø8.5mm × 40mm	4
07.02004.159	Polyaxial Screw, ø8.5mm × 45mm	4
07.02004.160	Polyaxial Screw, ø8.5mm × 50mm	4
07.02004.161	Polyaxial Screw, ø8.5mm × 55mm	4
07.02004.162	Polyaxial Screw, ø8.5mm × 60mm	4

Transverse Connector, Reduction, Fixation (4) 07.02136.404

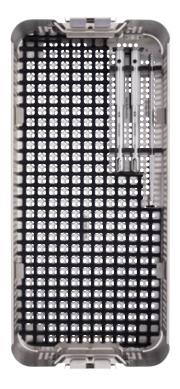




Catalog Number	Description	Kit Quantity
07.02001.032	Polyaxial Reduction Screw, ø5.5mm × 40mm	4
07.02001.033	Polyaxial Reduction Screw, ø5.5mm × 45mm	4
07.02001.034	Polyaxial Reduction Screw, ø5.5mm × 50mm	4
07.02001.074	Polyaxial Reduction Screw, ø6.5mm × 40mm	4
07.02001.075	Polyaxial Reduction Screw, ø6.5mm × 45mm	4
07.02001.076	Polyaxial Reduction Screw, ø6.5mm × 50mm	4
07.02001.077	Polyaxial Reduction Screw, ø6.5mm × 55mm	4
07.02001.116	Polyaxial Reduction Screw, ø7.5mm × 40mm	4
07.02001.117	Polyaxial Reduction Screw, ø7.5mm × 45mm	4
07.02001.118	Polyaxial Reduction Screw, ø7.5mm × 50mm	4
07.02001.119	Polyaxial Reduction Screw, ø7.5mm × 55mm	4
07.02010.001	ø5.5–6.0 Standard Closure Top	40
07.02011.001	ø5.5–6.0 Shear Off Closure Top	40
07.02013.002	Rod, Ti 5.5mm × 450mm, Straight	1
07.02014.002	Rod, Ti ø5.5 × 25mm, Straight	2
07.02014.003	Rod, Ti ø5.5 Ti × 30mm, Straight	2
07.02014.004	Rod, Ti ø5.5 × 35mm, Straight	2
07.02014.005	Rod, Ti ø5.5 × 40mm, Straight	2
07.02015.002	Rod, ø5.5 × 25mm, Curved	2
07.02015.003	Rod, ø5.5 × 30mm, Curved	2
07.02015.004	Rod, ø5.5 × 35mm, Curved	2

Catalog Number	Description	Kit Quantity
07.02015.005	Rod, ø5.5 × 40mm, Curved	2
07.02015.006	Rod, ø5.5 × 45mm, Curved	2
07.02015.007	Rod, ø5.5 × 50mm, Curved	2
07.02015.008	Rod, ø5.5 × 55mm, Curved	2
07.02015.009	Rod, ø5.5 × 60mm, Curved	2
07.02015.010	Rod, ø5.5 × 65mm, Curved	2
07.02015.011	Rod, ø5.5 × 70mm, Curved	2
07.02015.012	Rod, ø5.5 × 75mm, Curved	2
07.02015.013	Rod, ø5.5 × 80mm, Curved	2
07.02015.014	Rod, ø5.5 × 85mm, Curved	2
07.02015.015	Rod, ø5.5 × 90mm, Curved	2
07.02015.016	Rod, ø5.5 × 95mm, Curved	2
07.02015.017	Rod, ø5.5 × 100mm, Curved	2
07.02015.018	Rod, ø5.5 × 105mm, Curved	2
07.02015.019	Rod, ø5.5 × 110mm, Curved	2
07.02015.020	Rod, ø5.5 × 115mm, Curved	2
07.02015.021	Rod, ø5.5 × 120mm, Curved	2
07.02016.002	Rod, CoCr 5.5mm × 450mm, Straight	1
07.02030.001	Transverse Connector, Adjustable, 33–36mm Wide × 5.5mm	2
07.02030.002	Transverse Connector, Adjustable, 36–41mm Wide × 5.5mm	2
07.02030.003	Transverse Connector, Adjustable, 41–51mm Wide × 5.5mm	2
07.02030.004	Transverse Connector, Adjustable, 51–70mm Wide × 5.5mm	2
07.02030.005	Transverse Connector, Adjustable, 70–90mm Wide × 5.5mm	2
07.02058.001	Reduction Screwdriver — Standard	1
07.02063.001	T20 Set Screw Driver — Final	2
07.02074.001	Reduction Tab Removal Tool	1
07.02111.001	Caliper — Transverse Connector	1
07.02118.001	Torque Limiting Handle — 50 in-Ibs	1
07.02119.001	T20 Set Screw Starter	2
07.02120.001	Reduction Tab Sleeve	6
07.02121.001	Counter Torque — Transverse Connector	1
07.02131.002	Screwdriver Sleeve — Reduction	1

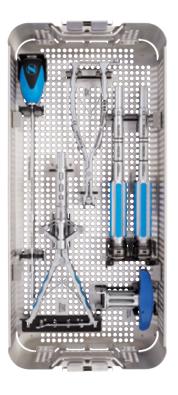




Catalog Number	Description	Kit Quantity
07.02053.001	Torque Limiting Handle — 90 in-Ibs	1
07.02065.001	T27 Easy Out Removal Driver	1
730M0017	T27 Driver — Final	2
07.02068.001	T27 Closure Top Starter	2
07.02069.001	T27 Closure Top Starter — Reducer	1
07.02073.001	Shear-Off Final Closure Top Driver	1
07.02095.001	Counter-Torque	1
07.02103.001	T27 Dual Ended Closure Top Starter	2
07.02133.001	Tube Rod Pusher	2

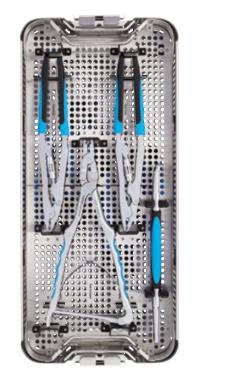
Complex Instruments 1 6 07.02136.406

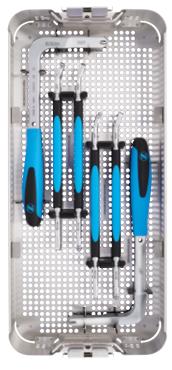




Catalog Number	Description	Kit Quantity
07.02069.001	T27 Closure Top Starter — Reducer	1
07.02076.002	Bone Awl — Small	1
07.02078.001	Pedicle Probe — Thoracic, Curved	1
07.02080.001	Pedicle Probe — Thoracic, Straight	1
07.02090.001	Compressor — Multi-Level	1
07.02093.001	Rod Rocker	1
07.02096.001	Single Action Reducer	1
07.02097.001	Tower Reducer	2
07.02099.003	Rod Template — 470mm	1
07.02110.001	Distractor — Multi-Level	1
07.02132.001	Tower Reducer T-Handle	1

Complex Instruments 2 7





Catalog Number	Description	Kit Quantity
07.02091.001	Sagittal Bender — 5.5mm, Left	1
07.02091.002	Sagittal Bender — 5.5mm, Right	1
07.02100.001	Rod Gripper	1
07.02102.001	Sagittal Bender — 6.0mm, Left	1
07.02102.002	Sagittal Bender — 6.0mm, Right	1
07.02104.001	Vise Grips	2
07.02124.001	Coronal Bender — 5.5/6.0mm, Left	1
07.02124.002	Coronal Bender — 5.5/6.0mm, Right	1
07.02127.001	Hex End Rod Rotation Tool	1

Complex Rods 8

Catalog Number	Description	Kit Quantity
07.02013.001	Rod, Ti 5.5mm × 300mm, Straight	3
07.02013.003	Rod, Ti 5.5mm × 510mm, Straight	3
07.02016.001	Rod, CoCr 5.5mm × 300mm, Straight	3
07.02016.003	Rod, CoCr 5.5mm × 510mm, Straight	3
07.02017.021	Rod, CoCr 5.5mm × 120mm, Straight	2
07.02017.023	Rod, CoCr 5.5mm × 130mm, Straight	2
07.02017.025	Rod, CoCr 5.5mm × 140mm, Straight	2
07.02017.027	Rod, CoCr ø5.5 × 150mm, Straight	2
07.02017.029	Rod, CoCr ø5.5 × 160mm, Straight	2
07.02019.001	Rod, Ti 6.0mm × 300mm, Straight	3
07.02019.003	Rod, Ti 6.0mm × 510mm, Straight	3
07.02022.001	Rod, CoCr 6.0mm × 300mm, Straight	3
07.02022.003	Rod, CoCr 6.0mm × 510mm, Straight	3
07.02023.021	Rod, CoCr ø6.0 × 120mm, Straight	2
07.02023.023	Rod, CoCr ø6.0 × 130mm, Straight	2
07.02023.025	Rod, CoCr ø6.0 × 140mm, Straight	2
07.02023.027	Rod, CoCr ø6.0 × 150mm, Straight	2
07.02023.029	Rod, CoCr ø6.0 × 160mm, Straight	2
07.02048.001	Transverse Connector, Fixed, 21mm × 5.5mm	2
07.02048.002	Transverse Connector, Fixed, 23mm × 5.5mm	2
07.02048.003	Transverse Connector, Fixed, 25mm × 5.5mm	2
07.02048.004	Transverse Connector, Fixed, 27mm × 5.5mm	2
07.02048.005	Transverse Connector, Fixed, 29mm × 5.5mm	2
07.02048.006	Transverse Connector, Fixed, 31mm × 5.5mm	2
07.02048.017	Transverse Connector, Fixed, 21mm Wide × 6.0mm	2
07.02048.018	Transverse Connector, Fixed, 23mm Wide × 6.0mm	2
07.02048.019	Transverse Connector, Fixed, 25mm Wide × 6.0mm	2
07.02048.020	Transverse Connector, Fixed, 27mm Wide × 6.0mm	2
07.02048.021	Transverse Connector, Fixed, 29mm Wide × 6.0mm	2
07.02048.022	Transverse Connector, Fixed, 31mm Wide × 6.0mm	2

4.0 – 5.5 Polyaxial Screws 9

Catalog Number	Description	Kit Quantity
07.02000.001	Polyaxial Screw, ø4.0mm × 20mm	2
07.02000.002	Polyaxial Screw, ø4.0mm × 25mm	4
07.02000.003	Polyaxial Screw, ø4.0mm × 30mm	4
07.02000.004	Polyaxial Screw, ø4.0mm × 35mm	4
07.02000.005	Polyaxial Screw, ø4.0mm × 40mm	4
07.02000.006	Polyaxial Screw, ø4.0mm × 45mm	4
07.02000.010	Polyaxial Screw, ø4.5mm × 20mm	2
07.02000.011	Polyaxial Screw, ø4.5mm × 25mm	4
07.02000.012	Polyaxial Screw, ø4.5mm × 30mm	4
07.02000.013	Polyaxial Screw, ø4.5mm × 35mm	4
07.02000.014	Polyaxial Screw, ø4.5mm × 40mm	4
07.02000.015	Polyaxial Screw, ø4.5mm × 45mm	4
07.02000.020	Polyaxial Screw, ø5.0mm × 25mm	4
07.02000.021	Polyaxial Screw, ø5.0mm × 30mm	4
07.02000.022	Polyaxial Screw, ø5.0mm × 35mm	4
07.02000.023	Polyaxial Screw, ø5.0mm × 40mm	4
07.02000.024	Polyaxial Screw, ø5.0mm × 45mm	4
07.02000.025	Polyaxial Screw, ø5.0mm × 50mm	4
07.02000.029	Polyaxial Screw, ø5.5mm × 25mm	2
07.02000.030	Polyaxial Screw, ø5.5mm × 30mm	4
07.02000.031	Polyaxial Screw, ø5.5mm × 35mm	4
07.02000.032	Polyaxial Screw, ø5.5mm × 40mm	4
07.02000.033	Polyaxial Screw, ø5.5mm × 45mm	4
07.02000.034	Polyaxial Screw, ø5.5mm × 50mm	4
07.02000.035	Polyaxial Screw, ø5.5mm × 55mm	4
07.02000.036	Polyaxial Screw, ø5.5mm × 60mm	4

6.0 – 7.5 Polyaxial Screws 10

Catalog Number	Description	Kit Quantity
07.02000.050	Polyaxial Screw, ø6.0mm × 25mm	2
07.02000.051	Polyaxial Screw, ø6.0mm × 30mm	6
07.02000.052	Polyaxial Screw, ø6.0mm × 35mm	6
07.02000.053	Polyaxial Screw, ø6.0mm × 40mm	6
07.02000.054	Polyaxial Screw, ø6.0mm × 45mm	6
07.02000.055	Polyaxial Screw, ø6.0mm × 50mm	6
07.02000.056	Polyaxial Screw, ø6.0mm × 55mm	6
07.02000.057	Polyaxial Screw, ø6.0mm × 60mm	4
07.02000.072	Polyaxial Screw, ø6.5mm × 30mm	4
07.02000.073	Polyaxial Screw, ø6.5mm × 35mm	6
07.02000.074	Polyaxial Screw, ø6.5mm × 40mm	10
07.02000.075	Polyaxial Screw, ø6.5mm × 45mm	10
07.02000.076	Polyaxial Screw, ø6.5mm × 50mm	10
07.02000.077	Polyaxial Screw, ø6.5mm × 55mm	8
07.02000.078	Polyaxial Screw, ø6.5mm × 60mm	4
07.02000.114	Polyaxial Screw, ø7.5mm × 30mm	4
07.02000.115	Polyaxial Screw, ø7.5mm × 35mm	4
07.02000.116	Polyaxial Screw, ø7.5mm × 40mm	6
07.02000.117	Polyaxial Screw, ø7.5mm × 45mm	6
07.02000.118	Polyaxial Screw, ø7.5mm × 50mm	6
07.02000.119	Polyaxial Screw, ø7.5mm × 55mm	6
07.02000.120	Polyaxial Screw, ø7.5mm × 60mm	4

4.5 – 8.5 Reduction Screws

07.02136.411

Part Number	Description	Quantity	Part Number	Description
07.02001.011	Polyaxial Reduction Screw, ø4.5mm × 25mm	2	07.02001.078	Polyaxial Reduction Screw, ø6.5mm × 60mm
07.02001.012	Polyaxial Reduction Screw, ø4.5mm × 30mm	4	07.02001.114	Polyaxial Reduction Screw, ø7.5mm × 30mm
07.02001.013	Polyaxial Reduction Screw, ø4.5mm × 35mm	4	07.02001.115	Polyaxial Reduction Screw, ø7.5mm × 35mm
07.02001.014	Polyaxial Reduction Screw, ø4.5mm × 40mm	4	07.02001.116	Polyaxial Reduction Screw, ø7.5mm × 40mm
07.02001.015	Polyaxial Reduction Screw, ø4.5mm × 45mm	4	07.02001.117	Polyaxial Reduction Screw, ø7.5mm × 45mm
07.02001.029	Polyaxial Reduction Screw, ø5.5mm × 25mm	2	07.02001.118	Polyaxial Reduction Screw, ø7.5mm × 50mm
07.02001.030	Polyaxial Reduction Screw, ø5.5mm × 30mm	4	07.02001.119	Polyaxial Reduction Screw, ø7.5mm × 55mm
07.02001.031	Polyaxial Reduction Screw, ø5.5mm × 35mm	4	07.02001.120	Polyaxial Reduction Screw, ø7.5mm × 60mm
07.02001.032	Polyaxial Reduction Screw, ø5.5mm × 40mm	4	07.02005.156	Polyaxial Reduction Screw, ø8.5mm × 30mm
07.02001.033	Polyaxial Reduction Screw, ø5.5mm × 45mm	4	07.02005.157	Polyaxial Reduction Screw, ø8.5mm × 35mm
07.02001.034	Polyaxial Reduction Screw, ø5.5mm × 50mm	4	07.02005.158	Polyaxial Reduction Screw, ø8.5mm × 40mm
07.02001.035	Polyaxial Reduction Screw, ø5.5mm × 55mm	4	07.02005.159	Polyaxial Reduction Screw, ø8.5mm × 45mm
07.02001.072	Polyaxial Reduction Screw, ø6.5mm × 30mm	4	07.02005.160	Polyaxial Reduction Screw, ø8.5mm × 50mm
07.02001.073	Polyaxial Reduction Screw, ø6.5mm × 35mm	4	07.02005.161	Polyaxial Reduction Screw, ø8.5mm × 55mm
07.02001.074	Polyaxial Reduction Screw, ø6.5mm × 40mm	6	07.02005.162	Polyaxial Reduction Screw, ø8.5mm × 60mm
07.02001.075	Polyaxial Reduction Screw, ø6.5mm × 45mm	6		
07.02001.076	Polyaxial Reduction Screw, ø6.5mm × 50mm	6		
07.02001.077	Polyaxial Reduction Screw, ø6.5mm × 55mm	4		

Quantity

07.02136.412

Iliac Screws 12

Part Number	Description	Quantity
07.02025.003	Lateral Offset Connector — Open, S00°, 20mm	1
07.02025.005	Lateral Offset Connector — Open, S00°, 30mm	1
07.02025.009	Lateral Offset Connector — Open, S00°, 50mm	1
07.02025.025	Lateral Offset Connector — Open, L15°, 20mm	1
07.02025.027	Lateral Offset Connector — Open, L15°, 30mm	1
07.02025.031	Lateral Offset Connector — Open, L15°, 50mm	1
07.02025.047	Lateral Offset Connector — Open, R15°, 20mm	1
07.02025.049	Lateral Offset Connector — Open, R15°, 30mm	1
07.02025.053	Lateral Offset Connector — Open, R15°, 50mm	1
07.02025.069	Lateral Offset Connector — Open, L25°, 20mm	1
07.02025.071	Lateral Offset Connector — Open, L25°, 30mm	1
07.02025.075	Lateral Offset Connector — Open, L25°, 50mm	1
07.02025.091	Lateral Offset Connector — Open, R25°, 20mm	1
07.02025.093	Lateral Offset Connector — Open, R25°, 30mm	1
07.02025.097	Lateral Offset Connector — Open, R25°, 50mm	1
07.02026.003	Lateral Offset Connector — Closed, S00°, 20mm	1
07.02026.005	Lateral Offset Connector — Closed, S00°, 30mm	1
07.02026.009	Lateral Offset Connector — Closed, S00°, 50mm	1
07.02026.025	Lateral Offset Connector — Closed, L15°, 20mm	1
07.02026.027	Lateral Offset Connector — Closed, L15°, 30mm	1
07.02026.031	Lateral Offset Connector — Closed, L15°, 50mm	1
07.02026.047	Lateral Offset Connector — Closed, R15°, 20mm	1
07.02026.049	Lateral Offset Connector — Closed, R15°, 30mm	1
07.02026.053	Lateral Offset Connector — Closed, R15°, 50mm	1
07.02026.069	Lateral Offset Connector — Closed, L25°, 20mm	1
07.02026.071	Lateral Offset Connector — Closed, L25°, 30mm	1
	. ,	

Part Number	Description	Quantity
07.02026.075	Lateral Offset Connector — Closed, L25°, 50mm	1
07.02026.091	Lateral Offset Connector — Closed, R25°, 20mm	1
07.02026.093	Lateral Offset Connector — Closed, R25°, 30mm	1
07.02026.097	Lateral Offset Connector — Closed, R25°, 50mm	1
07.02027.001	Rod Connector – Lateral, Open, 2 Screw, 5.5/6.0mm	4
07.02027.002	Rod Connector — Lateral, Open, 2 Screw, 3.5mm	2
07.02028.001	Rod Connector — Lateral, Closed, 4 Screw, 5.5/6.0mm	2
07.02028.002	Rod Connector — Lateral, Closed, 4 Screw, 3.5mm	2
07.02029.001	Rod Connector — Axial, Closed, 5.5/6.0mm	2
07.02029.002	Rod Connector — Axial, Closed, 3.5mm	2
07.02032.001	Rod Connector, Lateral, Closed, 2 Screw, 5.5/6.0mm × 5.5/6.0mm	2
07.02032.002	Rod Connector, Lateral, Closed, 2 Screw, 5.5/6.0mm × 3.5mm	2
07.02033.001	Rod Connector, Lateral, Hybrid, 2 Screw, 5.5/6.0mm × 5.5/6.0mm	4
07.02033.002	Rod Connector, Lateral, Hybrid, 2 Screw, 5.5/6.0mm × 3.5mm	2
07.02034.001	Rod Connector, Side-Side, Four Screw, Hybrid, 5.5/6.0mm × 5.5/6.0mm	2
07.02034.002	Rod Connector, Side-Side, Four Screw, Hybrid, 3.5mm	2
07.02035.001	Rod Connector, Lateral, Channel	4
07.02050.122	Polyaxial Open Iliac Screw, ø7.5mm × 70mm	2
07.02050.124	Polyaxial Open Iliac Screw, ø7.5mm × 80mm	2
07.02050.126	Polyaxial Open Iliac Screw, ø7.5mm × 90mm	2
07.02050.128	Polyaxial Open Iliac Screw, ø7.5mm × 100mm	2
07.02050.130	Polyaxial Open Iliac Screw, ø7.5mm × 110mm	2
07.02050.132	Polyaxial Open Iliac Screw, ø7.5mm × 120mm	2
07.02050.164	Polyaxial Open Iliac Screw, ø8.5mm × 70mm	2
07.02050.166	Polyaxial Open Iliac Screw, ø8.5mm × 80mm	2
07.02050.168	Polyaxial Open Iliac Screw, ø8.5mm × 90mm	2
07.02050.170	Polyaxial Open Iliac Screw, ø8.5mm × 100mm	2

Part Number	Description	Quantity
07.02050.172	Polyaxial Open Iliac Screw, ø8.5mm × 110mm	2
07.02050.174	Polyaxial Open Iliac Screw, ø8.5mm × 120mm	2
07.02050.206	Polyaxial Open Iliac Screw, ø9.5mm × 70mm	2
07.02050.208	Polyaxial Open Iliac Screw, ø9.5mm × 80mm	2
07.02050.210	Polyaxial Open Iliac Screw, ø9.5mm × 90mm	2
07.02050.212	Polyaxial Open Iliac Screw, ø9.5mm × 100mm	2
07.02050.214	Polyaxial Open Iliac Screw, ø9.5mm × 110mm	2
07.02050.216	Polyaxial Open Iliac Screw, ø9.5mm × 120mm	2
07.02050.248	Polyaxial Open Iliac Screw, ø10.5mm × 70mm	2
07.02050.250	Polyaxial Open Iliac Screw, ø10.5mm × 80mm	2
07.02050.252	Polyaxial Open Iliac Screw, ø10.5mm × 90mm	2
07.02050.254	Polyaxial Open Iliac Screw, ø10.5mm × 100mm	2
07.02050.256	Polyaxial Open Iliac Screw, ø10.5mm × 110mm	2
07.02050.258	Polyaxial Open Iliac Screw, ø10.5mm × 120mm	2
07.02112.001	Pedicle Probe — Iliac	1
07.02114.007	Tap 6.5mm — Iliac	1
07.02114.009	Tap 7.5mm — Iliac	1
07.02114.011	Tap 8.5mm — Iliac	1
07.02114.013	Tap 9.5mm — Iliac	1
07.02123.001	Holder — Rod-to-Rod Connector	1

9.5 – 10.5 Polyaxial Screws (13) 07.02136.413

Catalog Number	Description	Kit Quantity
07.02004.198	Polyaxial Screw, ø9.5mm × 30mm	2
07.02004.199	Polyaxial Screw, ø9.5mm × 35mm	2
07.02004.200	Polyaxial Screw, ø9.5mm × 40mm	4
07.02004.201	Polyaxial Screw, ø9.5mm × 45mm	4
07.02004.202	Polyaxial Screw, ø9.5mm × 50mm	4
07.02004.203	Polyaxial Screw, ø9.5mm × 55mm	2
07.02004.204	Polyaxial Screw, ø9.5mm × 60mm	2
07.02004.240	Polyaxial Screw, ø10.5mm × 30mm	2
07.02004.241	Polyaxial Screw, ø10.5mm × 35mm	2
07.02004.242	Polyaxial Screw, ø10.5mm × 40mm	4
07.02004.243	Polyaxial Screw, ø10.5mm × 45mm	4
07.02004.244	Polyaxial Screw, ø10.5mm × 50mm	4
07.02004.245	Polyaxial Screw, ø10.5mm × 55mm	2
07.02004.246	Polyaxial Screw, ø10.5mm × 60mm	2

4.5 – 6.5 Uniplanar Screws [14]

07.02136.414

Catalog Number	Description	Kit Quantity
07.02042.011	Uniplanar Screw, ø4.5mm × 25mm	2
07.02042.012	Uniplanar Screw, ø4.5mm × 30mm	6
07.02042.013	Uniplanar Screw, ø4.5mm × 35mm	6
07.02042.014	Uniplanar Screw, ø4.5mm × 40mm	6
07.02042.015	Uniplanar Screw, ø4.5mm × 45mm	4
07.02042.020	Uniplanar Screw, ø5.0mm × 25mm	2
07.02042.021	Uniplanar Screw, ø5.0mm × 30mm	6
07.02042.022	Uniplanar Screw, ø5.0mm × 35mm	6
07.02042.023	Uniplanar Screw, ø5.0mm × 40mm	6
07.02042.024	Uniplanar Screw, ø5.0mm × 45mm	6
07.02042.025	Uniplanar Screw, ø5.0mm × 50mm	2
07.02042.029	Uniplanar Screw, ø5.5mm × 25mm	2
07.02042.030	Uniplanar Screw, ø5.5mm × 30mm	6
07.02042.031	Uniplanar Screw, ø5.5mm × 35mm	6
07.02042.032	Uniplanar Screw, ø5.5mm × 40mm	6
07.02042.033	Uniplanar Screw, ø5.5mm × 45mm	6
07.02042.034	Uniplanar Screw, ø5.5mm × 50mm	2
07.02042.071	Uniplanar Screw, ø6.5mm × 25mm	2
07.02042.072	Uniplanar Screw, ø6.5mm × 30mm	4
07.02042.073	Uniplanar Screw, ø6.5mm × 35mm	6
07.02042.074	Uniplanar Screw, ø6.5mm × 40mm	6
07.02042.075	Uniplanar Screw, ø6.5mm × 45mm	4
07.02042.076	Uniplanar Screw, ø6.5mm × 50mm	2

4.5 – 6.5 Uniplanar Reduction Screws 15 07.02136.415

Catalog Number	Description	Kit Quantity
07.02047.011	Uniplanar Reduction Screw, ø4.5mm × 25mm	2
07.02047.012	Uniplanar Reduction Screw, ø4.5mm × 30mm	6
07.02047.013	Uniplanar Reduction Screw, ø4.5mm × 35mm	6
07.02047.014	Uniplanar Reduction Screw, ø4.5mm × 40mm	6
07.02047.015	Uniplanar Reduction Screw, ø4.5mm × 45mm	4
07.02047.020	Uniplanar Reduction Screw, ø5.0mm × 25mm	2
07.02047.021	Uniplanar Reduction Screw, ø5.0mm × 30mm	6
07.02047.022	Uniplanar Reduction Screw, ø5.0mm × 35mm	6
07.02047.023	Uniplanar Reduction Screw, ø5.0mm × 40mm	6
07.02047.024	Uniplanar Reduction Screw, ø5.0mm × 45mm	6
07.02047.025	Uniplanar Reduction Screw, ø5.0mm × 50mm	2
07.02047.029	Uniplanar Reduction Screw, ø5.5mm × 25mm	2
07.02047.030	Uniplanar Reduction Screw, ø5.5mm × 30mm	6
07.02047.031	Uniplanar Reduction Screw, ø5.5mm × 35mm	6
07.02047.032	Uniplanar Reduction Screw, ø5.5mm × 40mm	6
07.02047.033	Uniplanar Reduction Screw, ø5.5mm × 45mm	6
07.02047.034	Uniplanar Reduction Screw, ø5.5mm × 50mm	2
07.02047.071	Uniplanar Reduction Screw, ø6.5mm × 25mm	2
07.02047.072	Uniplanar Reduction Screw, ø6.5mm × 30mm	4
07.02047.073	Uniplanar Reduction Screw, ø6.5mm × 35mm	6
07.02047.074	Uniplanar Reduction Screw, ø6.5mm × 40mm	6
07.02047.075	Uniplanar Reduction Screw, ø6.5mm × 45mm	4
07.02047.076	Uniplanar Reduction Screw, ø6.5mm × 50mm	2

4.0 – 7.5 Monoaxial Screws 16

07.02136.416

Catalog Number	Description	Kit Quantity
07.02040.001	Monoaxial Screw, ø4.0mm × 20mm	2
07.02040.002	Monoaxial Screw, ø4.0mm × 25mm	2
07.02040.003	Monoaxial Screw, ø4.0mm × 30mm	4
07.02040.004	Monoaxial Screw, ø4.0mm × 35mm	4
07.02040.005	Monoaxial Screw, ø4.0mm × 40mm	2
07.02040.006	Monoaxial Screw, ø4.0mm × 45mm	2
07.02040.010	Monoaxial Screw, ø4.5mm × 20mm	2
07.02040.011	Monoaxial Screw, ø4.5mm × 25mm	2
07.02040.012	Monoaxial Screw, ø4.5mm × 30mm	4
07.02040.013	Monoaxial Screw, ø4.5mm × 35mm	4
07.02040.014	Monoaxial Screw, ø4.5mm × 40mm	4
07.02040.015	Monoaxial Screw, ø4.5mm × 45mm	4
07.02040.028	Monoaxial Screw, ø5.5mm × 20mm	2
07.02040.029	Monoaxial Screw, ø5.5mm × 25mm	2
07.02040.030	Monoaxial Screw, ø5.5mm × 30mm	4
07.02040.031	Monoaxial Screw, ø5.5mm × 35mm	4
07.02040.032	Monoaxial Screw, ø5.5mm × 40mm	4
07.02040.033	Monoaxial Screw, ø5.5mm × 45mm	4
07.02040.034	Monoaxial Screw, ø5.5mm × 50mm	4
07.02040.072	Monoaxial Screw, ø6.5mm × 30mm	2
07.02040.073	Monoaxial Screw, ø6.5mm × 35mm	4
07.02040.074	Monoaxial Screw, ø6.5mm × 40mm	4
07.02040.075	Monoaxial Screw, ø6.5mm × 45mm	4
07.02040.076	Monoaxial Screw, ø6.5mm × 50mm	4
07.02040.077	Monoaxial Screw, ø6.5mm × 55mm	2
07.02040.114	Monoaxial Screw, ø7.5mm × 30mm	2
07.02040.115	Monoaxial Screw, ø7.5mm × 35mm	4
07.02040.116	Monoaxial Screw, ø7.5mm × 40mm	4
07.02040.117	Monoaxial Screw, ø7.5mm × 45mm	4
07.02040.118	Monoaxial Screw, ø7.5mm × 50mm	2

6.0 Rods (17) 07.02136.417

Catalog Number	Description	Kit Quantity
07.02019.002	Rod, Ti ø6.0mm × 450mm, Straight	1
07.02020.002	Rod, Ti ø6.0 × 25mm, Straight	2
07.02020.003	Rod, Ti ø6.0 × 30mm, Straight	2
07.02020.004	Rod, Ti ø6.0 × 35mm, Straight	2
07.02020.005	Rod, Ti ø6.0 × 40mm, Straight	2
07.02021.002	Rod, Ti ø6.0 × 25mm, Curved	2
07.02021.003	Rod, Ti ø6.0 × 30mm, Curved	2
07.02021.004	Rod, Ti ø6.0 × 35mm, Curved	2
07.02021.005	Rod, Ti ø6.0 × 40mm, Curved	2
07.02021.006	Rod, Ti ø6.0 × 45mm, Curved	2
07.02021.007	Rod, Ti ø6.0 × 50mm, Curved	2
07.02021.008	Rod, Ti ø6.0 × 55mm, Curved	2
07.02021.009	Rod, Ti ø6.0 × 60mm, Curved	2
07.02021.010	Rod, Ti ø6.0 × 65mm, Curved	2
07.02021.011	Rod, Ti ø6.0 × 70mm, Curved	2
07.02021.012	Rod, Ti ø6.0 × 75mm, Curved	2
07.02021.013	Rod, Ti ø6.0 × 80mm, Curved	2
07.02021.014	Rod, Ti ø6.0 × 85mm, Curved	2
07.02021.015	Rod, Ti ø6.0 × 90mm, Curved	2
07.02021.016	Rod, Ti ø6.0 × 95mm, Curved	2
07.02021.017	Rod, Ti ø6.0 × 100mm, Curved	2
07.02021.018	Rod, Ti ø6.0 × 105mm, Curved	2
07.02021.019	Rod, Ti ø6.0 × 110mm, Curved	2
07.02021.020	Rod, Ti ø6.0 × 115mm, Curved	2
07.02021.021	Rod, Ti ø6.0 × 120mm, Curved	2
07.02022.002	Rod, CoCr ø6.0mm × 450mm, Straight	1
07.02030.006	Transverse Connector, Adjustable, 33–36mm Wide × 6.0mm	2
07.02030.007	Transverse Connector, Adjustable, 36–41mm Wide × 6.0mm	2
07.02030.008	Transverse Connector, Adjustable, 41–51mm Wide × 6.0mm	2
07.02030.009	Transverse Connector, Adjustable, 51–70mm Wide × 6.0mm	2
07.02030.010	Transverse Connector, Adjustable. 70–90mm Wide × 6.0mm	2

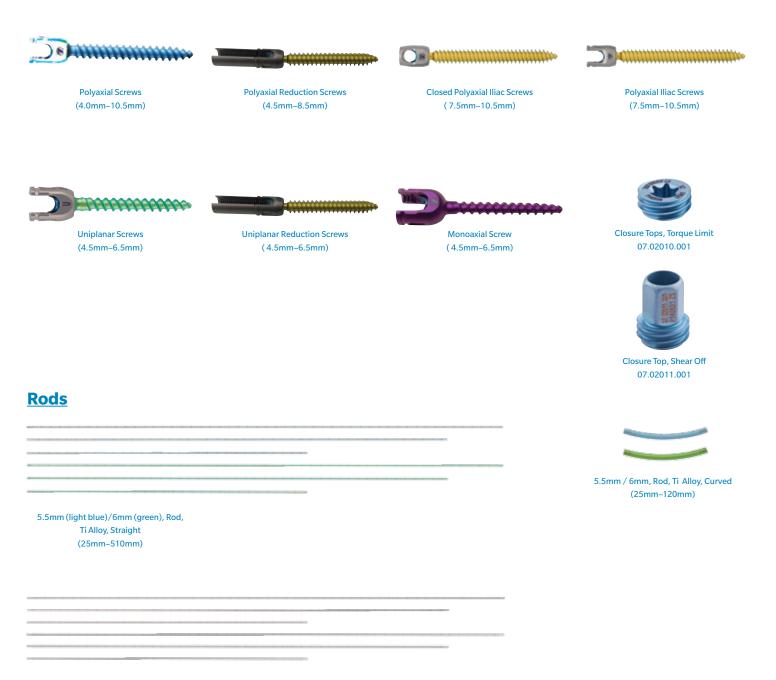
Closed Iliac Screws 07.02136.418



Catalog Number Kit Quantity Description 2 07.02012.122 Polyaxial Closed Iliac Screw, ø7.5mm × 70mm 07.02012.124 Polyaxial Closed Iliac Screw, ø7.5mm × 80mm 2 2 07.02012.126 Polyaxial Closed Iliac Screw, ø7.5mm × 90mm 07.02012.128 Polyaxial Closed Iliac Screw, ø7.5mm × 100mm 2 07.02012.130 Polyaxial Closed Iliac Screw, ø7.5mm × 110mm 2 07.02012.132 Polyaxial Closed Iliac Screw, ø7.5mm × 120mm 2 07.02012.164 Polyaxial Closed Iliac Screw, ø8.5mm × 70mm 2 07.02012.166 Polyaxial Closed Iliac Screw, ø8.5mm × 80mm 2 07.02012.168 Polyaxial Closed Iliac Screw, ø8.5mm × 90mm 2 07.02012.170 Polyaxial Closed Iliac Screw, ø8.5mm × 100mm 2 07.02012.172 Polyaxial Closed Iliac Screw, ø8.5mm × 110mm 2 07.02012.174 Polyaxial Closed Iliac Screw, ø8.5mm × 120mm 2 07.02012.206 Polyaxial Closed Iliac Screw, ø9.5mm × 70mm 2 2 07.02012.208 Polyaxial Closed Iliac Screw, ø9.5mm × 80mm Polyaxial Closed Iliac Screw, ø9.5mm × 90mm 07.02012.210 2 07.02012.212 Polyaxial Closed Iliac Screw, ø9.5mm × 100mm 2 07.02012.214 Polyaxial Closed Iliac Screw, ø9.5mm × 110mm 2 07.02012.216 Polyaxial Closed Iliac Screw, ø9.5mm × 120mm 2 2 07.02012.248 Polyaxial Closed Iliac Screw, ø10.5mm × 70mm 07.02012.250 Polyaxial Closed Iliac Screw, ø10.5mm × 80mm 2 Polyaxial Closed Iliac Screw, ø10.5mm × 90mm 07.02012.252 2 07.02012.254 Polyaxial Closed Iliac Screw, ø10.5mm × 100mm 2 07.02012.256 Polyaxial Closed Iliac Screw, ø10.5mm × 110mm 2 07.02012.258 Polyaxial Closed Iliac Screw, ø10.5mm × 120mm 2

Implant Visual Guide

Screws and Closure Tops



5.5mm / 6mm Rod, Cobalt Chrome, Straight (120–510mm)

Connectors



Lateral Offset Connector, Open (20mm–50mm) 07.02025.XXX



Rod Connector, Axial, Closed 07.02029.001 (5.5/6mm) 07.02029.002 (3.5mm)



Lateral Offset Connector, Closed (20mm–50mm) 07.02026.XXX



Rod Connector, Lateral, Closed 07.02032.001 (5.5/6mm) 07.02032.002 (3.5mm)



Rod Connector, Lateral, Open 07.02027.001 (5.5/6mm) 07.02027.002 (3.5mm)



Rod Connector, Lateral, Hybrid 07.02033.001 (2 screw 5.5/6mm) 07.02033.002 (2 screw 3.5mm) 07.02034.001 (4 screw 5.5/6mm) 07.02034.002 (4 screw 3.5mm)



Rod Connector, Lateral, Closed 07.02028.001 (5.5/6mm) 07.02028.002 (3.5mm)



Rod Connector, Lateral, Channel 07.02035.001



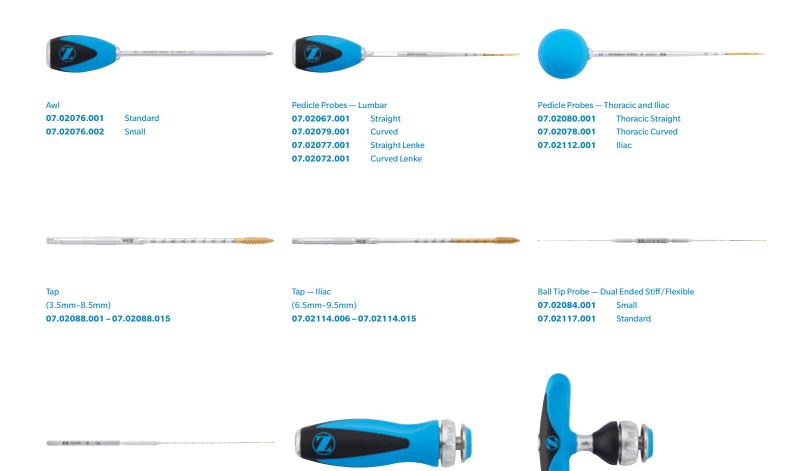
Adjustable Transverse Connector (32mm–90mm) 07.02030.001-005 (5.5mm) 07.02030.006-010 (6mm)



Transverse Connector, Fixed (21mm-31mm) 07.02048.001-006 (5.5mm) 07.02048.017-022 (6mm)

Instrument Visual Guide

Pedicle Preparation



Ball Tip Probe - Single Ended 07.02115.001 Stiff, Standard 07.02116.001

Flexible, Standard



Fixed Handle — Palm 07.02108.001

Ratcheting Handle - Straight 07.02051.001

Ratcheting T-Handle 07.02052.001

Screw Insertion





 ${\it Screw \, Driver \, Sleeve - Standard}$ 07.02131.001



Rod Manipulation/Insertion

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Rod Templates 07.02099.001	100mm

07.02099.001 07.02099.002 07.02099.003 250mm 470mm

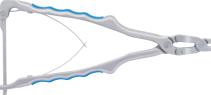




Rod Holder 07.02064.001

All and

Rod Gripper 07.02100.001



Rod Reduction



Single Action Rod Reducer 07.02096.001



Tower Reducer
07.02097.001



Tower Reducer T-Handle 07.02132.001



Rod Rocker 07.02093.001



Rod Pusher 07.02101.001

07.02102.001

07.02102.002



Tube Rod Pusher 07.02133.001

Rod Manipulation



Coronal Benders -- 5.5/6.0mm 07.02124.001 Left 07.02124.002 Right



6.0mm, Left

6.0mm, Right



Vise Grip 07.02104.001



Hex End Rod Rotation Tool 07.02127.001

Compression and Distraction





Compressor — Multi-Level 07.02090.001



Distractor 07.02109.001



Distractor Multi-Level 07.02110.001

Compressor

07.02089.001

Final Tightening





Shear-Off Final Driver 07.02073.001



Counter Torque **07.02095.001**



T27 Closure Top Starter 07.02068.001



Torque Limiting Handle 90 in-Ibs 07.02053.001

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T27 Dual Ended Closure Top Starter **07.02103.001** 51

T27 Closure Top Starter — Reducer **07.02069.001**

Transverse Connector Insertion





Torque Limiting Handle — 50 in-lbs 07.02118.001



Caliper — Transverse Connector 07.02111.001

T20 Final Driver 07.02063.001



Counter Torque — Transverse Connector 07.02121.001

Reduction Screw Instruments



Reduction Screw Driver — Standard 07.02058.001



Screw Driver Sleeve — Reduction 07.02131.002



Reduction Tab Sleeve 07.02120.001

C providence and the

Reduction Tab Breaker 07.02074.001

Rod-to-Rod Connector Instruments

Removal Instruments





Rod-to-Rod Connector Holder 07.02123.001

Removal Driver 07.02061.001

T27 Easy Out 07.02065.001

Optional Instruments



Fixed Handle — Straight 07.02106.001



Ratcheting Handle — Palm 07.02105.001



Pedicle Markers 07.02085.001 07.02086.001

85.001Small Bulb86.001Large Bulb



Screw Driver Sleeve — Short 07.02131.003



Fixed T-Handle 07.02107.001



Alignment Tool **07.02094.001**



Screw Driver — Multi-Piece 07.02087.001



Pivoting Axial Handle 07.02130.001

111	where a lateral framework ()	-]
111	manual a reason manuscript CE	-1

Scoli Rod Benders -- Flat 07.02113.001 Left 07.02113.002 Right



Screw Driver — Short 07.02055.001



Reduction Screwdriver — Short 07.02128.001

 Ball Tip Probes — Single Ended

 07.02082.001
 Stiff, Small

 07.02083.001
 Flexible, Small

 Taps (Optional)

 07.02088.002
 4.0mm

 07.02088.004
 5.0mm

 07.02088.006
 6.0mm

 07.02088.008
 7.0mm

 07.02088.010
 8.0mm

 07.02088.010
 8.0mm

 07.02088.012
 9.0mm

 07.02088.014
 10.0mm

 Iliac Taps (Optional)

 07.02114.000
 6.0mm

 07.02114.008
 7.0mm

 07.02114.010
 8.0mm

 07.02114.012
 9.0mm

 07.02114.014
 10.mm

Warnings and Precautions

Following are specific warnings, precautions, and adverse effects associated with use of the Vitality System that should be understood by the surgeon and explained to the patients. General surgical risk should be explained to the patients prior to surgery.

- Implantation of the Vitality System should be performed only by experienced spinal surgeons
- All implants are intended for single use only. Single-use devices should not be re-used. Possible risks associated with re-use of single-use devices include:
- Mechanical malfunction
- Transmission of infectious agents
- Metal sensitivity has been reported following exposure to orthopedic implants. The most common metallic sensitivities (nickel, cobalt, and chromium) are present in medical grade stainless steel and cobalt-chrome alloys.
- Universal precautions should be observed by all end users that work with contaminated or potentially contaminated medical devices. Caution should be exercised when handling devices with sharp points or cutting edges to prevent injuries during and after surgical procedures and reprocessing.
- Warning: The safety and effectiveness of pedicle screw spinal systems have been established only for spinal conditions with significant mechanical instability or deformity requiring fusion with instrumentation. These conditions are significant mechanical instability or deformity of the thoracic, lumbar, and sacral spine secondary to severe spondylolisthesis (grades 3 and 4) of the L5-S1 vertebra, degenerative spondylolisthesis with objective evidence of neurological impairment, fracture, dislocation, scoliosis, kyphosis, spinal tumor, and failed previous fusion (pseudoarthrosis). The safety and effectiveness of these devices for any other conditions are unknown.
- Warning: The safety and effectiveness of this device has not been established for

use as part of a growing rod construct. The device is only intended to be used when definitive fusion is being performed at all instrumented levels.

- Additional Warnings for Pediatric Patients: The use of pedicle screw fixation in the pediatric population may present additional risks when patients are of smaller stature and skeletally immature. Pediatric patients may have smaller spinal structures (pedicle diameter or length) that may preclude the use of pedicle screws or increase the risk of pedicle screw malpositioning and neurological or vascular injury. Patients who are not skeletally mature undergoing spinal fusion procedures may have reduced longitudinal spinal growth, or may be at risk for rotational spinal deformities (the "crankshaft phenomenon") due to continued differential growth of the anterior spine.
- Precaution: The implantation of pedicle screw spinal systems should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system because this is a technically demanding procedure presenting a risk of serious injury to the patient.
- Additional Precautions for Pediatric Patients: The implantation of pedicle screw spinal systems in pediatric patients should be performed only by experienced spinal surgeons with specific training in the use of this pedicle screw spinal system in pediatric patients because this is a technically demanding procedure presenting a risk of serious injury to the patient. Preoperative and operating procedures, including knowledge of surgical techniques, good reduction, and proper selection and placement of the implants are important considerations in the successful utilization of the system in pediatric patients. The selection of the proper size, shape and design of the implant for each patient is crucial to the safe use of this device in pediatric patients.

Additional preoperative, intraoperative, and postoperative warnings and precautions:

PREOPERATIVE

- Usage of automated cleaning processes without supplemental manual cleaning may not result in adequate cleaning of instruments.
- Proper handling, decontamination

 (including pre-rinsing, washing, rinsing
 and sterilization), storage and utilization
 are important for the long and useful life
 of all surgical instruments. Even with correct
 use, care and maintenance, they should
 not be expected to last indefinitely. This is
 especially true for cutting instruments (e.g.,
 bone awls/drills) and driving instruments
 (e.g., drivers). These items are often
 subjected to high loads and/or impact
 forces. Under such conditions, breakage
 can occur, particularly when the item is
 corroded, damaged, nicked or scratched.
- Never use titanium, titanium alloy, and/or cobalt chromium with stainless steel in the same implant construct; otherwise, galvanic corrosion may occur.
- Zimmer does not specify the maximum number of times a re-usable instrument may be re-used. The useful life of these instruments is highly dependent on a number of factors including the frequency and manner in which they are used and the handling they experience in between uses. Inspection and, where appropriate, functional testing prior to using, is the best way to determine whether or not an individual device should be used.

INTRAOPERATIVE

- If contouring of the implant is necessary for optimal fit, the contouring should be gradual and avoid any notching or scratching of the implant surface. Do not repeatedly or excessively bend the implant. Do not reverse bend the rods.
- · Pedicle bone integrity should be verified

- Care should be taken during pedicle preparation to avoid penetrating too deep.
- Care should be taken during bone preparation to avoid damage to the pedicle and to the surgical instruments.
- Care should be taken to minimize soft tissue damage during surgery.
- Care should be taken to avoid removing excess material from the lamina.
- Care should be taken to avoid crossthreading screws and closure tops.
- If any implant or instrument comes in contact with a non-sterile surface it should not be used.

POSTOPERATIVE

- Adequately instruct the patient. Postoperative care and the patient's ability and willingness to follow instructions are one of the most important aspects of successful bone healing. The patient must be made aware of the limitations of the implant and that physical activity and full weight bearing have been implicated in fracture. The patient should understand that an implant is not as strong as normal, healthy bone and will fracture if excessive demands are placed on it in the absence of complete bone healing. An active, debilitated, or demented patient who cannot properly use weight-supporting devices may be particularly at risk during postoperative rehabilitation.
- The Vitality System is a temporary internal fixation device. Internal fixation devices are designed to stabilize the operative site during the normal healing process. After healing occurs, these devices serve no functional purpose and should be removed. Implant removal should be followed by adequate postoperative management to avoid fracture or refracture.

ADVERSE EFFECTS

Complications and adverse reactions have been reported with the use of similar spinal instrumentation systems. These adverse effects, including the possibility of death, should be discussed with the patient prior to surgery.

- Non-union, delayed union
- Bending or fracture of implant. Fraying, kinking, loosening, bending or breaking of any or all implant components.
- · Loosening of or migration of the implant
- Metal sensitivity or allergic reaction to a foreign body
- Infection
- Decrease in bone density due to stress shielding
- Pain, discomfort, or abnormal sensations due to the presence of the device
- Loss of the natural curvature of the spine
- Modification of the spinal geometric corrections of the vertebral and/or intervertebral height and/or of the reduction in spinal deformities
- Vascular and/or nerve damage due to surgical trauma or presence of the device.
- Neurological difficulties including bowel and/or bladder dysfunction, impotence, retrograde ejaculation and paraesthesia.
- Bursitis
- Dural leak
- Paralysis
- Death
- Erosion of blood vessels due to the proximity of the device, leading to hemorrhage and/ or death
- Additional surgery may be required to correct any of these potential adverse effects.
- Additional Potential Adverse Events for Pediatric Patients:
 - Inability to use pedicle screw fixation due to anatomic limitations (pedicle dimensions, distorted anatomy)
 - 2. Pedicle screw malpositioning, with or without neurological or vascular injury
 - 3. Proximal or distal junctional kyphosis
 - 4. Pancreatitis

Other adverse events related to pedicle screw fixation, such as screw or rod bending, breakage, or loosening, may also occur in pediatric patients, and pediatric patients may be at increased risk for device-related injury because of their smaller stature.

Notes

Disclaimer: This documentation is intended exclusively for physicians and is not intended for laypersons. Information on the products and procedures contained in this document is of a general nature and does not represent and does not constitute medical advice or recommendations. Because this information does not purport to constitute any diagnostic or therapeutic statement with regard to any individual medical case, each patient must be examined and advised individually, and this document does not replace the need for such examination and/or advice in whole or in part.



Caution: Federal (USA) law restricts this device to sale by or on the order of a physician. Rx Only. For product information, including indications, contraindications, warnings, precautions, potential adverse effects and patient counseling information, see the package insert and www.zimmerbiomet.com.

eLabeling

The Instructions for Use can be accessed online by visiting the website and using the KEY-CODE provided on the product label and as shown below. Additional translations are also available in electronic format for download. To request a paper copy of the Instructions for Use, contact Zimmer Biomet Spine at the phone number provided.



Consult Instructions for Use on this website http://IFU.zimmer.com Key-Code: 07.02199.001



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