

Navigator™ HD

Ureteral Access Sheath

Boston
Scientific



New Product Committee Guide

General Information

Name of Product:

Navigator HD Ureteral Access Sheath

Product Codes

Product Code	Size	Unit
M0062502210	11/13 Fr x 28 cm	Each
M0062502220	11/13 Fr x 36 cm	Each
M0062502230	11/13 Fr x 46 cm	Each
M0062502240	12/14 Fr x 28 cm	Each
M0062502250	12/14 Fr x 36 cm	Each
M0062502260	12/14 Fr x 46 cm	Each
M0062502270	13/15 Fr x 28 cm	Each
M0062502280	13/15 Fr x 36 cm	Each
M0062502290	13/15 Fr x 46 cm	Each

Description:

The Navigator HD Ureteral Access Sheath is an upgrade of the Navigator Ureteral Access Sheath leveraging the same performance characteristics of Navigator with additional features to improve usability and access to the ureteral tract. Additional features include – single tapered flexible dilator tip, improved transition from dilator to sheath, higher durometer sheath and dilator shaft, improved coating, and a 12/14Fr size.

Manufacturer: Boston Scientific

Manufacturer Federal Tax ID: 04 269 5240

Will this product replace or supplement a current in-house product?

Yes, the current Navigator Ureteral Access Sheath will remain available for sale. For some accounts the Navigator HD Ureteral Access Sheath may be a supplement to what is currently being used. For other accounts this may replace existing ureteral access sheaths that are currently being used.

Briefly describe this product and other required components/accessories, specific items and their product numbers. Please include information as to whether in-house support is needed for use of product during OR cases.

A guidewire is needed to track the access sheath up the ureter. No additional in-house support is required, however a brief in-service by a BSC rep is suggested.

Clinical Outcomes

What clinical improvements does this product provide?

New stiffer sheath, shorter tip, improved transition and coating, and sizes are all designed to treat a greater range of patients and give physicians more options depending on patient type.



Navigator™ HD

Ureteral Access Sheath

Regulatory

Is this product FDA cleared for this intended use?

Yes, the Navigator HD Ureteral Access Sheath is indicated for use in endoscopic procedures to facilitate the passage of endoscopes, urological instruments and for the injection of fluids into the urinary tract.

What is the FDA classification of this device?

The Navigator HD Ureteral Access Sheath will be marketed in the US in accordance with the U.S. 21 code of Federal Regulations as an ureteral access sheath. Ureteral Access Sheaths are Class II devices and are subject to the premarket notifications (510(k)) process.

Cost/Utilization

Is this item/technology on contract with GPOs and/or IDNs?

Please speak to your Boson Scientific sales representative for the contract status of specific GPOs and IDNs.

Ship Unit: 1 UOM Each

Mode of transportation: FedEx® Delivery

Minimum order quantity? No

Lead Time in working days? 1-2 days

What are the dimensions of the shipping carton container?

The carton for the single is 4" x 1" x 23".

What is the list price per each unit or unit of utilization?

Product Code	Size	Price
M0062502210	11/13 Fr x 28 cm	\$182
M0062502220	11/13 Fr x 36 cm	\$182
M0062502230	11/13 Fr x 46 cm	\$182
M0062502240	12/14 Fr x 28 cm	\$182
M0062502250	12/14 Fr x 36 cm	\$182
M0062502260	12/14 Fr x 46 cm	\$182
M0062502270	13/15 Fr x 28 cm	\$182
M0062502280	13/15 Fr x 36 cm	\$182
M0062502290	13/15 Fr x 46 cm	\$182

Method of Purchase:

The purchase would be an outright purchase.

Does this item require special storage considerations?

Per the DFU, store in a cool, dry, dark place.

Is this a dated product? Yes, with a 2 year shelf life.

What department(s) will use and/or be affected by this product?

Operating Room, Cysto Suite, Urology Suite and purchasing

Will there be additional implementation costs, such as installation, cost of education, impact on equipment, or additional space?

No, however a brief in-service by a BSC is suggested prior to use.

Will this product require evaluation by any of the following departments?

- **Epidemiology/Infection Control?** No
- **Safety and Security?** No
- **Bio Engineering Maintenance?** No
- **Pathology/Labs?** No

Does this product contain metal substances that may affect tests and or procedures performed on patients?

The Navigator HD Ureteral Access Sheath contains a radiopaque tantalum marker band at the distal end and the sheath is made of a metal coil.

If yes is this product MRI safe?

The Navigator Ureteral Access Sheath is not MRI safe, however the sheath is used to access the ureter to treat the stone then removed at the end of the procedure.

Does this item and its packaging contain no detectable latex? Yes

Is this product reusable? No, the Navigator HD Ureteral Access Sheath is single use.

What additional waste or recycle costs are anticipated? None

Reimbursement

GuidePoint

Simplifying Reimbursement

Is this product reimbursable by insurance?

The procedures for which it is used are reimbursable. Billing guides with respective coding and estimated Medicare national average reimbursement for Ureteroscopy with and without Lithotripsy are available online at www.bostonscientific.com/reimbursement. For additional coding and reimbursement information, contact your local Territory Manager or the Urology Reimbursement Help Desk at UroWH.reimb@bsci.com or 1-508-683-4022.

What is the Medicare Pass-Through Code (aka C-code or HCPCS)?

This device does not have a Medicare Pass-Through Code.

Is this a patient-chargeable product?

Yes. The appropriate Revenue Code for the Navigator™ HD Ureteral Access Sheath is 272 – Medical/Surgical Supplies and Devices-Sterile Supply. Medicare does not dictate a provider’s charge structure or how it itemizes those charges. Section 2202.8 of the Medicare Provider Reimbursement Manual dealing with Ancillary Services (e.g. operating room) does not specifically address which items are part of the basic (routine) charge and which are charged in addition to the basic charge. Medicare is on record that it is up to the individual hospital to determine whether to and how to itemize the charge for a specific supply. However, Medicare does require that charges billed on the CMS-1450 form (aka UB-04) be aggregated under the appropriate Revenue Code.

Relevant Reimbursement Codes:

Payer policies will vary and should be verified prior to treatment for limitations on diagnosis, coding or site of service requirements. The coding options listed within this guide are commonly used codes and are not intended to be an all-inclusive list. We recommend consulting your relevant manuals for appropriate coding options.

Procedure Name	APC Code	CPT® Code	ICD-9-CM Procedure Code	ICD-9-CM Diagnosis Code	Possible MS-DRG Assignment
Ureteroscopy	0162	52352 – Cystourethroscopy with Ureteroscopy and/or pyeloscopy; with removal or manipulation of calculus (ureteral catheterization is included)	56.0 – Transurethral removal of obstruction from ureter and renal pelvis	592.0 – Calculus of kidney 592.1 – Calculus of ureter 592.9 – Urinary calculus, unspecified	668 – Transurethral procedures with major complication or comorbidity (MCC) ¹ 669 – Transurethral procedures with complication or comorbidity (CC) 670 – Transurethral procedures without CC/MCC
	0163	52353 – Cystourethroscopy, with Ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)			

For additional coding and reimbursement questions please contact our Urology Reimbursement Help Desk at UroWH.reimb@bsci.com OR 1-508- 683-4022.



Is this product MRI safe?

The Navigator™ HD Ureteral Access Sheath is not MRI safe, however the product is used to facilitate the passage of endoscopes and then removed.

If safe is there potential for altered imaging? No

Is this considered an implantable device? No

Does this item and its packaging contain no detectable latex? Yes

Is this a pharmaceutical or contain any pharmaceutical product? No

Does the product require a Material Safety Data Sheet? No

Is this product reusable?

The Navigator HD Ureteral Access Sheath is single use.

What additional waste or recycle costs are anticipated? None

Does this product qualify as hazardous waste? No

Does the product contain:

- **Mercury?** No
- **PVC?** No
- **Phthalates?** None known
- **Halogenated flame retardants/halogenated organic chemicals (HOCs)?** No
- **Persistent bio-accumulative toxic compounds (PBTs)?** No



Navigator™ HD Ureteral Access Sheath
Three lengths available - 28 cm, 36 cm, 46 cm

¹The patient's medical record must support the existence and treatment of the complication or comorbidity.

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Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician. Refer to package insert provided with the product for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using this product.

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