

NaviGuide™

Percutaneous Access Needle

General Information

Name of Product

NaviGuide™ Percutaneous Access Needle

Product Description

The NaviGuide device is comprised of a hollow outer cannula, conically grouped tri-facet trocar with locking hub, and adjustable slider with a radiopaque ring.

Manufacturer: Boston Scientific

Manufacturer Federal Tax ID: 04 269 5240

Supplement/Replace current in-house products: This product can replace or supplement your existing percutaneous access needle.

UPN Number	GTIN	Catalog Number	Gauge	Length
M0067001310	08714729953364	700-131	18g	12cm
M0067001320	08714729953371	700-132	18g	16cm
M0067001330	08714729953388	700-133	18g	20cm

Regulatory

Is this product FDA cleared for this intended use?

The NaviGuide device is intended to facilitate access into the renal pelvis, and to advance guidewires into the collecting system in an antegrade manner. The NaviGuide device is categorized as a Class I device per 21 CFR 878.4200, which is exempt from the premarket notification procedures in 21 CFR Subpart E of Part 807. This means that the **FDA does not require 510(k) clearance** in order to market this product in the United States.

What Class of device under the FDA is this considered? Class I Exempt

Does the product/device have an FDA investigational device exemption (IDE)? No



Utilization

Is this item/technology on contract with GPOs and/or IDNs? Please speak to your Boston Scientific Sales Representative for the contract status of specific GPOs and IDNs.

Ship unit: Each

Mode of transportation: FedEx™ Delivery

Minimum order quantity? No

Lead time in working days? 1-2 days

What are the dimensions of the package?

M0067001310 – 5.5" x 12"

M0067001320 – 5.5" x 15"

M0067001330 – 5.5" x 15"

Method of purchase: 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 3-year shelf life

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

What specific departments/clinical areas will use the product/procedure? Urology Operating Room (OR) and Interventional Radiology Suite

What department(s) will use and/or be affected by this product? OR, Cysto Suite, Urology Suite and Purchasing and Interventional Radiology Suite

Is there a requirement for staff training? A brief in-service by a Boston Scientific Representative is recommended for the OR staff prior to use.

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 Boston Scientific Representative is recommended for the OR staff prior to use.

Does the product/procedure require a company representative to be present to operate equipment or to provide assistance to the physicians? No

Is there any other equipment involved with the use of this product that will need to be leased, purchased, consigned or rented? No

Will this equipment interface with any other equipment/supplies currently utilized at this facility?

The cannula hub can interface with standard male luer fittings.

Material/Environment

Does this product contain metal substances that may affect tests and/or procedures performed on patients? Yes, the metal in the device is radiopaque.

If yes, is this product MRI safe? No

Is this considered an implantable device? No

Does this item and its packaging contain detectable latex? No

Is this a pharmaceutical or contain any pharmaceutical product? No

Does the product require a Material Safety Data Sheet? No

Is this product reusable? No, it is single use.

What additional waste or recycle costs are anticipated? None

Does the product contain:

- Mercury? No
- PVC? No
- Phthalates? No
- Halogenated flame retardants/halogenated organic chemicals (HOCs)? No
- Persistent bio-accumulative toxic compounds (PBTs)? No

Reimbursement

Is this product reimbursable by insurance? The procedures for which it is used are reimbursable. Billing guides with respective coding and Medicare reimbursement for PCNL and Nephrostomy are available upon request. For additional coding and reimbursement information, contact your local Territory Manager or the Urology and Pelvic Health Reimbursement Help Desk at (508) 683-4022.

What is the Medicare Pass-Through Code (aka C-code or HCPCS)? There are no applicable Medicare C-codes for this product.

Is this a patient-chargeable product? "Patient chargeable" is a colloquial term used by hospitals to convey that a device/supply is appropriately charged to the patient's account (i.e. as a distinct line item on the patient's claim) in the hospital/facility's patient accounting or AR system. It does not mean that the patient is actually charged directly for the device/supply nor would an insured patient ever pay an additional amount "out of pocket" for the device/supply. The fact that a hospital/facility chooses to designate certain devices/supplies (e.g. single-use devices) as "patient chargeable" will not in and of itself result in immediate increased reimbursement for the hospital/facility. It will allow

CMS to better factor the true cost of the procedure into future Medicare reimbursement rate settings. It may also help in negotiations with private payers by more clearly demonstrating novel device costs that have been introduced to a procedure.

The designation of a given device/supply as "patient chargeable" is entirely up to the discretion and policy of the individual hospital/facility. 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 (non-routine). 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 device/supply or alternatively, incorporate it into overhead (e.g. via the OR charge). However, Medicare does require that whatever method is chosen be applied consistently. They also require that charges billed on the CMS-1450 form (aka UB-04) be aggregated under the appropriate Revenue Code.

The appropriate Revenue Code is 272 – Medical/Surgical Supplies and Devices-Sterile Supply.

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.

CPT Codes	
50080	Percutaneous nephrostolithotomy or pyelostolithotomy, with or without dilation, endoscopy, lithotripsy, stenting, or basket extraction; up to 2 cm
50081	Percutaneous nephrostolithotomy or pyelostolithotomy, with or without dilation, endoscopy, lithotripsy, stenting, or basket extraction; over 2 cm
50395	Introduction of guide into renal pelvis and/or ureter with dilation to establish nephrostomy tract, percutaneous
50430	Injection procedure for antegrade nephrostogram and/or ureterogram, complete diagnostic procedure including imaging guidance (eg, ultrasound and fluoroscopy) and all associated radiological supervision and interpretation; new access
50431	Injection procedure for antegrade nephrostogram and/or ureterogram, complete diagnostic procedure including imaging guidance (eg, ultrasound and fluoroscopy) and all associated radiological supervision and interpretation; existing access
50432	Placement of nephrostomy catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation
50433	Placement of nephroureteral catheter, percutaneous, including diagnostic nephrostogram and/or ureterogram when performed, imaging guidance (eg, ultrasound and/or fluoroscopy) and all associated radiological supervision and interpretation, new access
50561	Renal endoscopy through established nephrostomy or pyelostomy, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service; with removal of foreign body or calculus
52005	Cystourethroscopy, with ureteral catheterization, with or without irrigation, instillation, or ureteropyelography, exclusive of radiologic service
52332	Cystourethroscopy, with insertion of indwelling ureteral

ICD-10-CM (Diagnoses Codes)	
N20.0	Calculus of kidney
N20.1	Calculus of ureter
N20.9	Urinary calculus, unspecified

Possible DRG Assignments	
659	Kidney and ureter procedures for non-neoplasm with major complication or comorbidity (MCC)
660	Kidney and ureter procedures for non-neoplasm with complication or comorbidity (CC)
661	Kidney and ureter procedures for non-neoplasm without (CC/MCC)

ICD-10-PCS Codes (Inpatient Procedure Codes)	
0T9030Z	Drainage of Right Kidney with Drainage Device, Percutaneous Approach
0T9130Z	Drainage of Left Kidney with Drainage Device, Percutaneous Approach
0TC03ZZ	Extirpation of Matter from Right Kidney, Percutaneous Approach
0TC13ZZ	Extirpation of Matter from Left Kidney, Percutaneous Approach
0TC43ZZ	Extirpation of Matter from Left Kidney Pelvis, Percutaneous Approach
0TC33ZZ	Extirpation of Matter from Right Kidney Pelvis, Percutaneous Approach
0TC14ZZ	Extirpation of Matter from Left Kidney, Percutaneous Endoscopic Approach
0TC04ZZ	Extirpation of Matter from Right Kidney, Percutaneous Endoscopic Approach
0TC44ZZ	Extirpation of Matter from Left Kidney Pelvis, Percutaneous Endoscopic Approach
0TC34ZZ	Extirpation of Matter from Right Kidney Pelvis, Percutaneous Endoscopic Approach
0T9140Z	Drainage of Left Kidney with Drainage Device, Percutaneous Endoscopic Approach
0T9040Z	Drainage of Right Kidney with Drainage Device, Percutaneous Endoscopic Approach
0T9340Z	Drainage of Right Kidney Pelvis with Drainage Device, Percutaneous Endoscopic Approach
0T9430Z	Drainage of Left Kidney Pelvis with Drainage Device, Percutaneous Approach
0T9440Z	Drainage of Left Kidney Pelvis with Drainage Device, Percutaneous Endoscopic Approach
0TF43ZZ	Fragmentation in Left Kidney Pelvis, Percutaneous Approach
0TF44ZZ	Fragmentation in Left Kidney Pelvis, Percutaneous Endoscopic Approach
0TF33ZZ	Fragmentation in Right Kidney Pelvis, Percutaneous Approach
0TF34ZZ	Fragmentation in Right Kidney Pelvis, Percutaneous Endoscopic Approach



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Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France.

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Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
www.bostonscientific.com

Ordering Information
1.888.272.1001

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