Boston Scientific
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Sensor™

Nitinol Guidewire with Hydrophilic Tip

New product guide

General information

Name of product
The Sensor Nitinol Guidewire with Hydrophilic Tip

Product description
This kink-resistant, nitinol core hybrid wire combines a flexible hydrophilic tip, PTFE-coated body, and dual-flex proximal end to ease passage and minimize the risk of expensive scope damage.[1] The coil-to-core design provides direct tactile feedback which helps communicate movement of the wire back to the urologist.[1] Sensor is the most versatile member[2-4] of the Boston Scientific guide wire portfolio – and the gold standard in hybrid guidewires.[1]

Manufacturer: Boston Scientific

Manufacturer Federal Tax ID: 04 269 5240

Will this product replace or supplement a current in-house product?
This device may supplement or replace other hydrophilic and/or standard guidewires.

Sensor Nitinol Guidewire with Hydrophilic Tip (Features a 10cm flexible proximal end)					
M0066703081	08714729302681	0.035 in	150cm	Straight	3cm
M0066703011	08714729302612	0.035 in	150cm	Angled	3cm
M0066703121	08714729257349	0.038 in	150cm	Straight	3cm
M0066703021	08714729302629	0.038 in	150cm	Angled	3cm

Unit: Box 5

Clinical advantages

What clinical advantage does the requested product provide? How might this product improve the level of patient experience?
Patients undergoing kidney stone treatment deserve access to proven technology. Sensor Guidewire, the global market leader for over two decades,[1] remains the preferred hybrid wire technology for kidney stone procedures.[1] The Sensor PTFE-Nitinol Guidewire with Hydrophilic Tip is a hybrid guidewire that combines the access of a nitinol hydrophilic wire with the handling of a PTFE wire. Often, fully hydrophilic guidewires are exchanged after initial access for a working guidewire, such as PTFE guidewires. The Sensor Guidewire is designed to be used as both an access wire and a working wire, reducing the number of guidewires used during a procedure.[2-4]

Journal article citations

"As these hybrid wires incorporate the various features of individual wires, they decrease the need for multiple wires and maintenance of a large inventory."[4]

"We believe that to achieve safe access to the urinary system, the Sensor™ Dual Flex Guidewire might be preferable because of its non-injurious tip and more lubricious shaft."[5]

"The more flexible tip of the Sensor may provide an advantage for maneuvering around occluding obstructions in tight spots."[6]

Regulatory

Is this product FDA approved for this intended use? The Sensor Guidewire is marketed in accordance with FDA regulations per 21 CFR 876.5130 and, as such, is exempt from 510(k) clearance by the FDA. This means that the FDA does not require a 510(k) in order to market this product within the USA.

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

What Class of device under the FDA is this considered? The Sensor Guidewire is a Class I device in US and, as such, is exempt from 510(K) clearance by the FDA.

Cost / 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: Box 5

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 shipping carton for a box of 5 is 8" x 10" x 1 1/4".

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 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)

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

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, purchase consigned or rented? No

Will this equipment interface with any other equipment/ supplies currently utilized at this facility? No

What is the average length of procedure time to use this product/perform this procedure (surgery minutes)?
45 minutes for ureteroscopy, 60 minutes for percutaneous nephrolithotomy.

Material / environment

Does this product contain metal substances that may affect tests and/or procedures performed on patients?
Yes. This guidewire contains nitinol, which is a metal alloy of nickel and titanium, and tungsten in the tip. However, the guidewire is removed at the conclusion of the procedure.

If yes, is this product MRI safe? No

Is this considered an implantable device? No

Does this item and its packaging contain no detectable latex?
Sensor Guidewire has been tested to ASTM D6499-03 Standard Test Method for the Immunological Measurement of Antigenic Protein in Natural Rubber. However, FDA's Final Guidance for Industry and Food and Drug Administration Staff - Recommendations for Labeling Medical Products to Inform Users That the Product or Product Container Is Not Made With Natural Rubber Latex (issued December 2, 2014) indicates that "latex-free" and "does not contain latex" labeling statements are not sufficiently specific, not necessarily scientifically accurate, and may be misunderstood or applied too widely; therefore, it is inappropriate to include such statements in medical product labeling. No current test method or combination of test methods available at this time can demonstrate the absence of proteins or components from natural rubber latex that may cause allergic reactions in susceptible individuals.

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 this product qualify as hazardous waste? No

Does the product contain:

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

Reimbursement

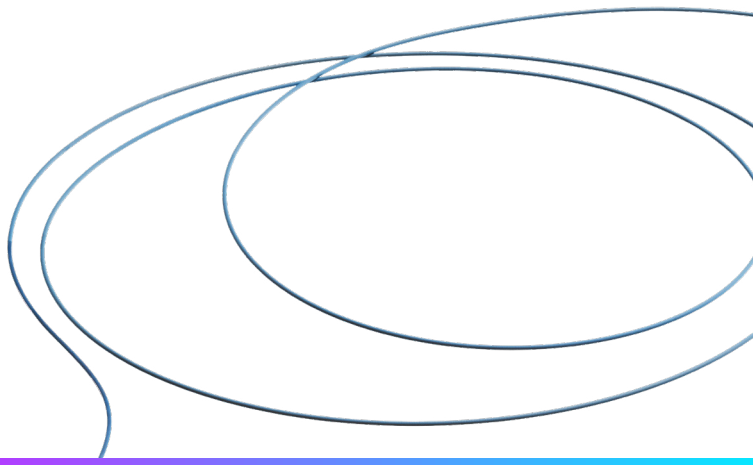
Is this product reimbursable by insurance?
The procedures for which it is used are reimbursable. Billing guides with respective coding and Medicare reimbursement for Ureteroscopy with and without Lithotripsy and PCNL are available upon request. For additional coding and reimbursement information, contact your local Territory Manager or the Urology Reimbursement Help Desk at (508) 683-4022.

What is the Medicare Pass-Through Code (aka C-code or HCPCS)?
The applicable Medicare Pass-Through Code for this device is C1769 – guidewire.

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 setting. 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.

Procedure Name	APC Code	CPT® Code	ICD-10-PCS Procedure Code	ICD-10-CM Diagnosis Code	Possible MS-DRG Assignment
Ureteral Stent Insertion	**5374**	**52332** – Cystourethroscopy, with insertion of indwelling ureteral stent (e.g., Gibbons or double-J type)	**0T768DZ** – Dilation of Right Ureter with Intraluminal Device, Via Natural or Artificial Opening Endoscopic **0T778DZ** – Dilation of Left Ureter with Intraluminal Device, Via Natural or Artificial Opening Endoscopic **0T788DZ** – Dilation of Bilateral Ureters with Intraluminal Device, Via Natural or Artificial Opening Endoscopic	**N13.2 –** Hydronephrosis with renal and ureteral calculous obstruction **N20.0** – Calculus of kidney **N20.1** – Calculus of ureter **N20.2** – Calculus of kidney with calculus of ureter **N20.9 –** Urinary calculus, unspecified	**668** – Transurethral procedures with major complication or comorbidity (MCC)* **669** – Transurethral procedures with complication or comorbidity (CC)* **670** – Transurethral procedures without CC/MCC
Ureteroscopic Stone Removal with or without Lithotripsy	**5375**	**52352** – Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with removal or manipulation of calculus (ureteral catheterization is included) **52353** – Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included) **52356** – Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy including insertion of indwelling ureteral stent (eg, Gibbons or double-J type)	**0TC38ZZ** – Extirpation of Matter from Right Kidney Pelvis, Via Natural or Artificial Opening Endoscopic **0TC48ZZ** – Extirpation of Matter from Left Kidney Pelvis, Via Natural or Artificial Opening Endoscopic **0TC68ZZ** – Extirpation of Matter from Right Ureter, Via Natural or Artificial Opening Endoscopic **0TC78ZZ** – Extirpation of Matter from Left Ureter, Via Natural or Artificial Opening Endoscopic **0TF38ZZ** – Fragmentation in Right Kidney Pelvis, Via Natural or Artificial Opening Endoscopic **0TF48ZZ** – Fragmentation in Left Kidney Pelvis, Via Natural or Artificial Opening Endoscopic **0TF68ZZ** – Fragmentation in Right Ureter, Via Natural or Artificial Opening Endoscopic **0TF78ZZ** – Fragmentation in Left Ureter, Via Natural or Artificial Opening Endoscopic		**668** – Transurethral procedures with major complication or comorbidity (MCC)* **669** – Transurethral procedures with complication or comorbidity (CC)* **670** – Transurethral procedures without CC/MCC
Percutaneous Nephrolithotomy	**5376**	**50080** – Percutaneous nephrostolithotomy or pyelostolithotomy, with or without dilation, endoscopy, lithotripsy, stenting or basket extraction: up to 2cm **50081** – Percutaneous nephrostolithotomy or pyelostolithotomy, with or without dilation, endoscopy, lithotripsy, stenting or basket extraction: over 2cm	**0TC03ZZ** – Extirpation of Matter from Right Kidney, Percutaneous Approach **0TC04ZZ** – Extirpation of Matter from Right Kidney, Percutaneous Endoscopic Approach **0TC13ZZ** – Extirpation of Matter from Left Kidney, Percutaneous Approach **0TC14ZZ** – Extirpation of Matter from Left Kidney, Percutaneous Endoscopic Approach **0TC33ZZ** – Extirpation of Matter from Right Kidney Pelvis, Percutaneous Approach **0TC34ZZ** – Extirpation of Matter from Right Kidney Pelvis, Percutaneous Endoscopic Approach **0TC43ZZ** – Extirpation of Matter from Left Kidney Pelvis, Percutaneous Approach **0TC44ZZ** – Extirpation of Matter from Left Kidney Pelvis, Percutaneous Endoscopic Approach **0TF33ZZ** – Fragmentation in Right Kidney Pelvis, Percutaneous Approach **0TF34ZZ** – Fragmentation in Right Kidney Pelvis, Percutaneous Endoscopic Approach **0TF43ZZ** – Fragmentation in Left Kidney Pelvis, Percutaneous Approach **0TF44ZZ** – Fragmentation in Left Kidney Pelvis, Percutaneous Endoscopic Approach		**659** – Kidney & ureter procedures for non-neoplasm with major complication or comorbidity (MCC)* **660** – Kidney & ureter procedures for non-neoplasm with complication or comorbidity (CC)* **661** – Kidney & ureter procedures for non-neoplasm without CC/MCC

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

1. Data on file with Boston Scientific.
2. Kai Chi Chan K, Neal N. A guided guide to the guide wire. *Urology News*. 2020 May/June;24(4).
3. Wetherell DR, Ling D, Ow D, et al. Advances in ureteroscopy. *Transl Androl Urol*. 2014 Sep;3(3):321-7.
4. Holden T, Pedro RN, Hendlin K, et al. Evidence-based instrumentation for flexible ureteroscopy: a review. *J Endourol*. 2008 Jul;22(7):1423-6.
5. Liguori G, Antoniolli F, Trombetta C, et al. Comparative experimental evaluation of guidewire use in urology. *Urology*. 2008 Aug;72(2):286-9.
6. Sarkissian C, Korman E, Hendlin K, et al. Systemic evaluation of hybrid guidewires: Shaft stiffness, lubricity, and tip configuration. *Urology*. 2012 Mar;79(3):513-7.

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