Sensor™

PTFE-Nitinol Guidewire with Hydrophilic Tip

Boston Scientific
Advancing science for life™

New Product Guide

General Information

Name of Product:
The Sensor PTFE-Nitinol Guidewire with Hydrophilic Tip

Product Description:
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. The Sensor Guidewire is constructed of a kink-resistant nitinol core with a 5cm hydrophilic coated floppy tip that is designed to facilitate access past obstructions and through tortuous anatomy. Its smooth PTFE coating provides a low coefficient of friction to facilitate advancement and catheter tracking yet is designed to have better handling characteristics than a standard, completely hydrophilic wire.

The Sensor Guidewire is also available in a Dual-Flex configuration that features a 10cm flexible proximal end designed to ease the passage of a flexible ureteroscope.

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 hydrophilic guidewires, like Glidewire™ Guidewire and HiWire™ Wire Guide.

Order Number	GTIN Number	Diameter	Length	Tip	Taper
Sensor PTFE-Nitinol Guidewire with Hydrophilic Tip					
M006**670305**1	08714729302650	0.035 in	150cm	Straight	3cm
M006**670306**1	08714729302667	0.035 in	150cm	Angled	3cm
M006**670309**1	08714729257318	0.038 in	150cm	Straight	3cm
M006**670310**1	08714729257325	0.038 in	150cm	Angled	3cm
Unit: Box 5					
Sensor Dual-Flex PTFE-Nitinol Guidewire with Hydrophilic Tip (Features a 10cm flexible proximal end)					
M006**670308**1	08714729302681	0.035 in	150cm	Straight	3cm
M006**670301**1	08714729302612	0.035 in	150cm	Angled	3cm
M006**670312**1	08714729257349	0.038 in	150cm	Straight	3cm
M006**670302**1	08714729302629	0.038 in	150cm	Angled	3cm
Unit: Box 5					

Clinical Outcomes

What studies have been conducted with the product?

- Holden T, Pedro RN, Hendlin K, et al. Evidence based instrumentation for flexible ureteroscopy: A review. *J Endourology*. 2008;22(7):1423-6.
- Liguori G, Antoniolli F, Trombetta C, et al. Comparative experimental evaluation of guidewire use in urology. *Urology*. 2008;72(2):286-9.
- Sarkissian C, Korman E, Hendlin K, et al. Systemic evaluation of hybrid guidewires: Shaft stiffness, lubricity, and tip configuration. *Urology*. 2012;79(3):513-7.
- Sarkissian C, Paz A, Zigman O, et al. Safety and efficacy of a novel ureteral occlusion device. *Urology*. 2012;80(1):32-7.

What clinical improvement does the requested product provide? How might this product improve the level of patient satisfaction?
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. It is designed to reduce the time spent manipulating and exchanging multiple wires during a case. Often, fully hydrophilic guidewires are exchanged after initial access for guidewires, such as PTFE guidewires, that are more secure working wires. 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.

Journal Article Citation:

"As these hybrid wires incorporate the various features of individual wires, they decrease the need for multiple wires and maintenance of a large inventory."[1]

Sensor™

PTFE-Nitinol Guidewire with Hydrophilic Tip

Clinical Outcomes (continued)

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."[1]

"Sensor Dual-Flex Guidewire had not only the least dangerous tip (P<0.01) on the tip buckling and tip piercing force tests, but also lower friction values on the friction guide test."[2]

"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." [2]

"Sensor Dual Flex guidewire offers significant advantages when needing to bypass obstruction and is my typical first choice in those situations. It, too, has a shaft rigidity sufficient for advancing stents under fluoroscopic control without buckling and has reasonable friction such that it will not 'slip out.' I have rarely found that I have to use more than the initial choice of guidewire in these cases."[2] (Editorial Comment)

"Sensor may serve as a more secure 'safety wire,' because it required the greatest extraction force, therefore reducing the likelihood of accidentally sliding out from its intended position."[3]

"The more flexible tip of the Sensor may provide an advantage for maneuvering around occluding obstructions in tight spots."[3]

Regulatory

Is this product FDA approved for this intended use? Yes. The Sensor PTFE-Nitinol Guidewire with Hydrophilic Tip is intended to facilitate the placement of endourological instruments during diagnostic or interventional procedures.

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

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? Yes

Is this a pharmaceutical or contain any pharmaceutical product? No

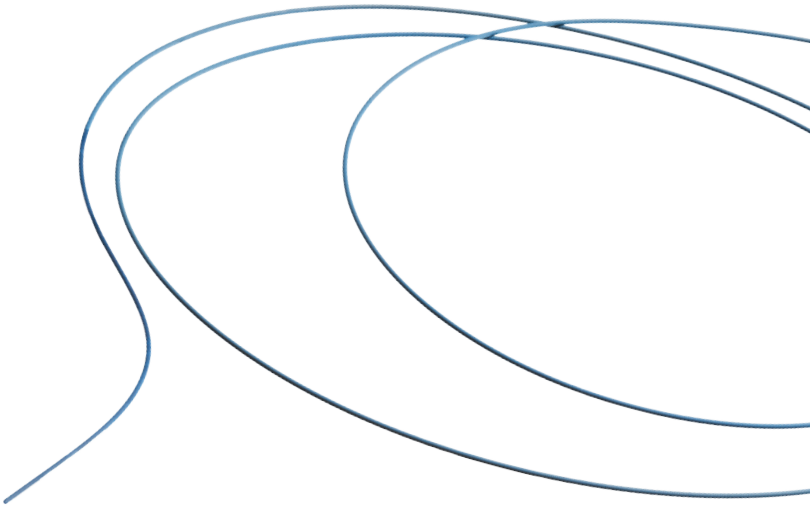
Does the product require a Material Safety Data Sheet? No

Is this product reusable? 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

GUIDEPOINT Reimbursement Resources

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?
Yes. The appropriate Revenue Code 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.

See last page for Relevant Reimbursement Codes and important information about the uses and limitations of this document.

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
Ureteroscopic Stone Removal without Lithotripsy with Ureteral Stent Insertion	**0162** **0162**	**52352** – Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with removal or manipulation of calculus (ureteral catheterization is included) **52332** – Cystourethroscopy, with insertion of indwelling ureteral stent (e.g., Gibbons or double-J type)	**56.0** – Transurethral removal of obstruction from ureter or 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)[4] **669** – Transurethral procedures with complication or comorbidity (CC)[4] **670** – Transurethral procedures without CC/MCC
Ureteroscopic Stone Removal with Lithotripsy	**0163** **0162**	**52353** – Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included) **52332** – Cystourethroscopy, with insertion of indwelling ureteral stent (e.g., Gibbons or double-J type)	**56.0** – Transurethral removal of obstruction from ureter or 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)[4] **669** – Transurethral procedures with complication or comorbidity (CC)[4] **670** – *Transurethral procedures without CC/MCC*
Percutaneous Nephrolithotomy	**0429** **0429** **0162** **0161** **0162** **0162** **0162** **0278** **0161**	**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 **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 **50392** – Introduction of intracatheter or catheter into renal pelvis for drainage and/or injection, percutaneous **50395** – Introduction of guide into renal pelvis and/or ureter with dilation to establish nephrostomy tract, percutaneous **52005** – Cystourethroscopy, with ureteral catheterization, with or without irrigation, instillation, or ureteropyelography, exclusive or radiologic service **52332** – Cystourethroscopy, with insertion of indwelling ureteral stent (e.g., Gibbons or double-J type) **74420-26** – Urography, retrograde, with or without KUB **74475-6** – Introduction of intracatheter or catheter into renal pelvis for drainage and/or injection, percutaneous, radiological supervision and interpretation	**55.03** – Percutaneous nephrostomy without fragmentation **55.04** – Percutaneous nephrostomy with fragmentation	**592.0** – Calculus of kidney **592.9** – Urinary calculus, unspecified	**659** – Kidney & ureter procedures for non-neoplasm with major complication or comorbidity (MCC)[4] **660** – Kidney & ureter procedures for non-neoplasm with complication or comorbidity (CC)[4] **661** – Kidney & ureter procedures for non-neoplasm without CC/MCC

[1] Holden T, Pedro RN, Hendlin K, et al. Evidence based instrumentation for flexible ureteroscopy: A review. *J Endourology.* 2008;22(7):1423-6.
[2] Liguori G, Antoniolli F, Trombetta C, et al. Comparative experimental evaluation of guidewire use in urology. *Urology.* 2008;72(2):286-9.
[3] Sarkissian C, Korman E, Hendlin K, et al. Systemic evaluation of hybrid guidewires: Shaft stiffness, lubricity, and tip configuration. *Urology.* 2012;79(3):513-7.

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

Boston Scientific
Advancing science for life™

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752-1234
www.bostonscientific.com

Ordering Information
1.888.272.1001

URO-133415-AB MAR/2016