New Product Guide

General Information

Name of Product:
ZIPwire Nitinol Hydrophilic Guidewire

Product Description:
The ZIPwire Guidewire is a nitinol wire with a low friction hydrophilic coating designed for ureteral access. It is intended to facilitate the placement of endourological instruments during diagnostic or interventional procedures.

Manufacturer: Boston Scientific

Manufacture Federal Tax ID: 04 269 5240

Will this product replace or supplement a current in-house product?
This device will replace hydrophilic guidewires, like Glidewire™ Guidewire and HiWire™ Wire Guide.

Order Number | GTIN Number | Diameter | Length | Tip | Shaft Stiffness | Taper
---|---|---|---|---|---|---
**Standard ZIPwire Guidewire**
M00630200B1 | 08714729802433 | 0.018 in | 150cm | Straight | Standard | 3cm
M00630201B1 | 08714729802457 | 0.025 in | 150cm | Straight | Standard | 3cm
M00630212B1 | 08714729839149 | 0.032 in | 150cm | Straight | Standard | 3cm
M00630205B1 | 08714729767161 | 0.035 in | 150cm | Straight | Standard | 3cm
M00630210B1 | 08714729802556 | 0.038 in | 150cm | Straight | Standard | 3cm
M00630213B1 | 08714729839156 | 0.038 in | 260cm | Straight | Standard | 3cm
M00630202B1 | 08714729802440 | 0.025 in | 150cm | Angled | Standard | 3cm
M00630214B1 | 08714729839163 | 0.035 in | 150cm | Straight | Standard | 8cm
M00630203B1 | 08714729802464 | 0.035 in | 150cm | Angled | Standard | 8cm
M00630215B1 | 08714729839170 | 0.038 in | 150cm | Straight | Standard | 8cm
M00630207B1 | 08714729802501 | 0.038 in | 150cm | Angled | Standard | 8cm

**Stiff ZIPwire Guidewire**
M00630216B1 | 08714729839187 | 0.025 in | 150cm | Straight | Stiff | 3cm
M00630217B1 | 08714729839194 | 0.025 in | 150cm | Angled | Stiff | 3cm
M00630222B1 | 08714729755326 | 0.035 in | 150cm | Straight | Stiff | 3cm
M00630223B1 | 08714729767192 | 0.035 in | 150cm | Angled | Stiff | 3cm
M00630225B1 | 08714729761808 | 0.038 in | 150cm | Straight | Stiff | 3cm
M00630226B1 | 08714729802532 | 0.038 in | 150cm | Angled | Stiff | 3cm

**Bentson-Type ZIPwire Guidewire**
M00630214B1 | 08714729839163 | 0.035 in | 150cm | Straight | Standard | Bentson 8cm
M00630203B1 | 08714729802464 | 0.035 in | 150cm | Angled | Standard | Bentson 8cm
M00630215B1 | 08714729839170 | 0.038 in | 150cm | Straight | Standard | Bentson 8cm
M00630207B1 | 08714729802501 | 0.038 in | 150cm | Angled | Standard | Bentson 8cm

**Bentson-Type Stiff ZIPwire Guidewire**
M00630224B1 | 08714729802495 | 0.035 in | 150cm | Straight | Stiff | Bentson 5cm
M00630221B1 | 08714729802488 | 0.035 in | 150cm | Angled | Stiff | Bentson 5cm
M00630227B1 | 08714729802549 | 0.038 in | 150cm | Straight | Stiff | Bentson 5cm
M00630228B1 | 08714729802525 | 0.038 in | 150cm | Angled | Stiff | Bentson 5cm

Unit: Box 5
ZIPwire™
Nitinol Hydrophilic Guidewire

Clinical Outcomes

What clinical performance does the requested product provide?
How might this product improve the level of patient satisfaction?
The ZIPwire Guidewire is a nitinol wire with a low friction hydrophilic coating designed for reliable ureteral access and reduced trauma. The lubricious coating and the kink-resistant core of the guidewire allow for consistent access to the urinary tract, which is necessary for endourological treatment of stones.

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 9” x 9” x 1.5”.
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

Regulatory

Is this product FDA cleared for this intended use? Yes. The ZIPwire Hydrophilic Guidewire is intended to facilitate the placement of endourological instruments during diagnostic or interventional procedures.

What Class of device under the FDA is this considered?
The ZIPwire Hydrophilic Guidewire is marketed in the US in accordance with US 21 Code of Federal Regulations 876.5130(b)(2) (Ureteral Stylet (Guidewire)). Per 876.5130(b)(2), ureteral styles (guidewires) are exempt from the premarket notification (510(k)) requirements in subpart E of 21 CFR part 807, subject to the limitations in 876.9. This means that the FDA does not require 510(k) clearance in order to market ZIPwire Hydrophilic Guidewires within the US. Boston Scientific distributes ZIPwire Hydrophilic Guidewires on behalf of Lake Region Medical.

Does the product/device have an FDA investigational device exemption (IDE)? 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 (a metal alloy of nickel and titanium) and tungsten. 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

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 Medicare Pass-Through Code for this product 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.

<table>
<thead>
<tr>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Ureteroscopic Stone Removal without Lithotripsy with Ureteral Stent Insertion</td>
<td>0162</td>
<td>52352 – Cystourethroscopy, with ureteroscopy and/or pyeloscopy, with removal or manipulation of calculus (ureteral catheterization is included)</td>
<td>56.0 – Transurethral removal of obstruction from ureter or renal pelvis</td>
<td>592.0 – Calculus of kidney</td>
<td>668 – Transurethral procedures with major complication or comorbidity (MCC)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>52332 – Cystourethroscopy, with insertion of indwelling ureteral stent (e.g., Gibbons or double-J type)</td>
<td></td>
<td>592.1 – Calculus of ureter</td>
<td>669 – Transurethral procedures with complication or comorbidity (CC)</td>
</tr>
<tr>
<td>Ureteroscopic Stone Removal with Lithotripsy</td>
<td>0163</td>
<td>52353 – Cystourethroscopy, with ureteroscopy and/or pyeloscopy; with lithotripsy (ureteral catheterization is included)</td>
<td>56.0 – Transurethral removal of obstruction from ureter or renal pelvis</td>
<td>592.0 – Calculus of kidney</td>
<td>668 – Transurethral procedures with major complication or comorbidity (MCC)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>52332 – Cystourethroscopy, with insertion of indwelling ureteral stent (e.g., Gibbons or double-J type)</td>
<td></td>
<td>592.1 – Calculus of ureter</td>
<td>669 – Transurethral procedures with complication or comorbidity (CC)</td>
</tr>
<tr>
<td>Percutaneous Nephrolithotomy</td>
<td>0429</td>
<td>50080 – Percutaneous nephrostolithotomy or pyelolithotomy, with or without dilation, endoscopy, lithotripsy, stenting or basket extraction; up to 2cm</td>
<td>55.03 – Percutaneous nephrostomy without fragmentation</td>
<td>592.0 – Calculus of kidney</td>
<td>659 – Kidney &amp; ureter procedures for non-neoplasm with major complication or comorbidity (MCC)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>50081 – Percutaneous nephrostolithotomy or pyelolithotomy, with or without dilation, endoscopy, lithotripsy, stenting or basket extraction; over 2cm</td>
<td></td>
<td>592.9 – Urinary calculus, unspecified</td>
<td>660 – Kidney &amp; ureter procedures for non-neoplasm with complication or comorbidity (CC)</td>
</tr>
<tr>
<td></td>
<td></td>
<td>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</td>
<td></td>
<td></td>
<td>661 – Kidney &amp; ureter procedures for non-neoplasm without CC/MCC</td>
</tr>
<tr>
<td></td>
<td></td>
<td>50392 – Introduction of intracatheter or catheter into renal pelvis for drainage and/or injection, percutaneous</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>50395 – Introduction of guide into renal pelvis and/or ureter with dilation to establish nephrostomy tract, percutaneous</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>50205 – Cystourethroscopy, with ureteral catheterization, with or without irrigation, instillation or ureteropyelography, exclusive or radiologic service</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>52332 – Cystourethroscopy, with insertion of indwelling ureteral stent (e.g., Gibbons or double-J type)</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>74420-26 – Urography, retrograde, with or without KUB</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>74475-6 – Introduction of intracatheter or catheter into renal pelvis for drainage and/or injection, percutaneous, radiological supervision and interpretation</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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

---

CPT® Copyright 2012 American Medical Association. All rights reserved. CPT® is a registered trademark of the American Medical Association. Applicable FARS/DFARS Restrictions Apply to Government Use. Fee schedules, relative value units, conversion factors and/or related components are not assigned by the AMA, are not part of CPT®, and the AMA is not recommending their use. The AMA does not directly or indirectly practice medicine or dispense medical services. The AMA assumes no liability for data contained or not contained herein.

Relevant Reimbursement Codes:

-  The patient’s medical record must support the existence and treatment of the complication or comorbidity.
-  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 labeling supplied with each device. Information for use only in countries with applicable health authority registrations. Material not intended for use in France.