Capio™ SLIM
Suture Capturing Device

Product Review for
the Purchasing Committee
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Product Overview
Product Overview: Capio SLIM Suture Capturing Device

The Capio SLIM Suture Capturing Device features a reduced profile to minimize the space required within the surgical field, easy suture loading and a funnel shaped catch, designed for consistent ease of use.

- 70% Reduction in Shaft Diameter
- Easy Suture Dart Loading
- New “funnel” suture dart catch design
- 36% Reduction in Head Width
- Ergonomic Handle Providing 3 Finger Grip
## Comprehensive Specs

### Comparison to Capio™ Open Access Suture Capturing Device

<table>
<thead>
<tr>
<th></th>
<th>Shaft Diameter (mm)</th>
<th>Head Width (mm)</th>
<th>Device Weight (g)</th>
<th>Carrier Diameter (mm)</th>
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<tbody>
<tr>
<td><strong>Capio SLIM Suture Capturing Device</strong>*</td>
<td>3.0</td>
<td>6.3</td>
<td>38.2</td>
<td>1.2</td>
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<tr>
<td><strong>Capio Suture Capturing Device</strong></td>
<td>10.1</td>
<td>9.8</td>
<td>45.4</td>
<td>1.2</td>
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<tr>
<td><strong>% Difference</strong></td>
<td>70%</td>
<td>36%</td>
<td>16%</td>
<td>Same</td>
</tr>
</tbody>
</table>

*Measurements were recorded using one (1) of each device. Data on file at Boston Scientific.

**Head width and device weight values are an average of five (5) device measurement recordings. Shaft diameter values are an average of fifteen (15) device measurement recordings. Data on file at Boston Scientific.
Comparison of Device Heads

Building on the history and reducing the profile, the Capio SLIM Suture Capturing Device features one of the smallest device profiles and carrier diameter while keeping the same bite depth as the current Capio Open Access Suturing Device.

Figure 1: Comparison of Device Heads illustrates the difference in carrier diameter amongst these fixation devices. The Capio SLIM Suture Capturing Device carrier diameter is 45% less than the FIXT Suturing Device and 43% less than the Digitex Suture Delivery System.

Fixation Device Comparison

<table>
<thead>
<tr>
<th></th>
<th>Shaft Diameter (mm)</th>
<th>Head Width (mm)</th>
<th>Device Weight (g)</th>
<th>Carrier Diameter (mm)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Capio OPEN ACCESS</td>
<td>10.1</td>
<td>9.8</td>
<td>45.4</td>
<td>1.2</td>
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<tr>
<td>Suture Capturing Device**</td>
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<td></td>
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<td></td>
</tr>
<tr>
<td>Capio SLIM</td>
<td>3.0</td>
<td>6.3</td>
<td>38.2</td>
<td>1.2</td>
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<tr>
<td>Suture Capturing Device*</td>
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</tr>
<tr>
<td>Digitex Suture Delivery System*</td>
<td>9.5</td>
<td>9.6</td>
<td>133.3</td>
<td>2.1</td>
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<tr>
<td>FIXT Suturing Device*</td>
<td>4.8</td>
<td>6.9</td>
<td>121.1</td>
<td>2.2</td>
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</table>

Figure 2: Fixation Device Comparison illustrates the device profile differences amongst these fixation devices. The Capio SLIM Suture Capturing Device has the smallest device profile based on the following measurements: shaft diameter, head width and device weight.

*Measurements were recorded using one (1) of each device.
**Head width and device weight values are an average of five (5) device measurement recordings. Shaft diameter values are an average of fifteen (15) device measurement recordings. Data on file at Boston Scientific.
Exempt Letter

January 11, 2013

Dear Valued Customer,

Thank you for your inquiry regarding the Capio™ SLIM Suture Capturing Device. This information is provided in response to your direct request for regulatory information and may not be used for any other purpose without the expressed written permission of Boston Scientific Corporation.

The Capio™ SLIM Suture Capturing Device, Open Access, order number M0068318250 as packaged contains 1 device within an outer box. In addition a multi pack version containing 5 devices within an outer box, order number M0068318251, will be available soon. These devices comply with U.S. FDA Regulation 21 CFR 876.4730, Manual gastroenterology-urology surgical instrument and accessories, and are 510(k) exempt devices. FDA does not require a 510(k) premarket notification for this device type.

The following Capio™ Sutures are manufactured by Teleflex Medical, Inc and are distributed by Boston Scientific for use with the Capio SLIM Suture Capturing Devices noted above:

- M0068331131 – Non-absorbable braided polyester suture with 2 tapercut needles
- M0068331141 – Non-absorbable braided polyester suture with 1 tapercut needle & 1 T26mm ½ circle needle
- M0068331231 – Non-absorbable polypropylene monofilament suture with 2 tapercut needles
- M0068331241 – Non-absorbable polypropylene monofilament suture with 1 tapercut needle & 1 T26mm ½ circle needle
- M0068332131 – Absorbable, coated, braided PGA suture with 2 tapercut needles
- M0068331371 – Monodek absorbable, monofilament PDO suture with 1 tapercut needle & 1 T26mm ½ circle needle

Please contact your local sales representative or Boston Scientific directly should you have any additional questions or require additional information.

Sincerely,

Regulatory Affairs
DFU: Capio SLIM Suture Capturing Device

Capio™ SLIM
Suture Capturing Device

Directions for Use

Capio™ SLIM
OPEN ACCESS
Suture Capturing Device

Caution:
Federal Law (USA) restricts this device to sale by or on the order of a physician.

WARNING
Contents supplied STERILE using an ethylene oxide (EO) process. Do not use if sterile barrier is damaged. If damage is found, call your Boston Scientific representative.

For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

DEVICE DESCRIPTION
The Capio SLIM Suture Capturing Device was designed to be used by the physician to facilitate the consistent placement of sutures in difficult to access locations during open surgical procedures. The Capio SLIM Device was designed to throw, catch and retrieve sutures in one step. The device consists of a one-hand-activated plunger at the proximal end, a tubular shaft and a curved needle driver at the distal end. Depressing the plunger actuates the carrier and drives the suture/dart through the tissue. The needle is automatically caught by the device’s needle catch mechanism for easy suture tying, or the device may be re-loaded for additional suture throws.

Sutures sold separately.

Contents
(1) Capio SLIM Suture Capturing Device

INTENDED USE/INDICATIONS FOR USE
The Capio SLIM Suture Capturing Device is intended for use in general suturing applications during open surgery to assist in the placement of suture material in tissues at the operative site. The Capio SLIM Suture Capturing Device is to be used with sensory and/or direct visual control.

WARNINGS
- Punctures or lacerations of vessels, nerves, bladder, urethra or bowel may occur during placement and may require surgical repair.
- Once the suturing action has begun, do not turn, rotate or torque the Capio SLIM Device. To do so, may result in injury.

English DFU for illustrative purposes only. Please refer to current version of the DFU.
CONTRAINDICATIONS
The use of the Capio™ SLIM Suture Capturing Device is contraindicated as follows:
- For placing sutures into or through bone.

ADVERSE EVENTS
Potential complications associated with the use of the Capio SLIM Device include, but are not limited to:
- bleeding
- dyspareunia
- infection
- inflammatory reaction
- injury to internal organs/tissue including perforation and occlusion
- injury to vessels and nerves
- pain

PRECAUTIONS
- Use only size 0 Capio Sutures with the Capio SLIM Suture Capturing Device.
- The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.
- The Capio SLIM Suture Capturing Device is not intended to be used to manipulate tissue, organ or bone.
- Do not bend or alter the device as this may result in mechanical damage to the device.

DIRECTIONS FOR USE
Directions for Open Surgical Procedure
Refer to Technique Tips section for added assistance.

1. Place the suture dart into the carrier at the distal end of the Capio SLIM Suture Capturing Device. Engage the suture dart into the carrier by gently pulling down on the suture, ensuring that the dart is pulled completely into the carrier. (Refer to Figure 2.)

   Note: When loading a dart into the device, verify that the dart is properly positioned in the carrier. The tip of the dart should not protrude from the Capio Device tip.

2. Position the device with the distal tip in the desired location against the tissue to be sutured as shown in Figure 3 and hold firmly in place.

3. Fully depress the plunger in one continuous motion, as shown in Figures 3 and 4, to pass the suture through the tissue.

   Note: Once the suturing action has been initiated, completely depress the plunger. Do not stop mid-stitch and allow the dart to reverse direction. It is important to maintain pressure against the tissue with the device to ensure that the dart penetrates the tissue and latches into the catch.

4. Unplunge. Release plunger and verify it is back in its original position. This allows the carrier to retract into the housing, leaving the dart in the catch and the suture through the tissue as shown in Figure 5 and 6.

5. Remove the Capio™ SLIM Suture Capturing Device (Figure 6) from the incision.

6. Remove the dart from the catch by holding onto the suture and sliding the dart up toward the handle to the key hole slot. If additional suturing is required, the surgeon may repeat Steps 1 through 6.

7. Complete surgical procedure as desired. Ensure darts are properly discarded.

TECHNIQUE TIPS
Read and understand the following technique tips for the Capio SLIM Suture Capturing Device.
- During use, secure suture with thumb to maintain adequate dart tension in carrier. To facilitate suture capture during use, hold the proximal end of the device in one hand with thumb securing suture in the slot on the driver button and suture grasped under the thumb. (Refer to Figure 7.) Position the distal head of the device against the tissue to be sutured as described in detail in the prior section.

English DFU for illustrative purposes only. Please refer to current version of the DFU.
Product Review Capio™ SLIM Suture Capturing Device (cont.)

**Figure 7.**

- Between each throw, rinse/soak the head of device in sterile saline while plunging and unplunging the driver button to help clear the distal tip of tissue and blood.

**Steps to Remove a Device Fragment**

1. In the event the device breaks and a fragment is in the patient, assess to determine if it can be located and removed without damage to the surrounding anatomy. Use caution not to disturb the operative site until it is located to avoid pushing it further from view.

2. If the fragment is in direct view it should be grasped with a fine needle driver or forceps and returned to the manufacturer along with the device for investigation.

3. If the fragment is not in direct view, use of x-ray studies may help to localize its location. Radiologic assistance should be utilized to guide dissection and retrieve the fragment, minimizing injury to surrounding tissue.

**HOW SUPPLIED**

**Handling and Storage**

Store in a cool, dry, dark place. Do not use if package is opened or damaged. Use the device prior to the “Use by” date noted on the product label. Do not use if labeling is incomplete or illegible.

**WARRANTY**

Boston Scientific Corporation (BSC) warrants that reasonable care has been used in the design and manufacture of this instrument. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability or fitness for a particular purpose. BSC’s obligation under this warranty is limited to the repair or replacement of this instrument and BSC shall not be liable for any incidental or consequential loss, damage or expense directly or indirectly arising from the use of this instrument. BSC neither assumes, nor authorizes any other person to assume for it, any other or additional liability or responsibility in connection with this instrument.

BSC assumes no liability with respect to instruments reused, reprocessed or resterilized and makes no warranties, express or implied, including but not limited to merchantability or fitness for a particular purpose, with respect to such instruments.
Product Review for the Purchasing Committee

Sterilized using ethylene oxide.
Esterilizado por óxido de etileno.
Stérilisé à l’oxyde d’éthylène.
Mit Ethylenoxid sterilisiert.
Sterilizzato con ossido di etilene.
Gesteriliseerd met ethyleenoxide.
Esterilizado por óxido de etileno.

Do not use if package is damaged.
No usar si el envase está dañado.
Ne pas utiliser si l’emballage est endommagé.
Bei beschädigter Verpackung nicht verwenden.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada.

SterilEO

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Product Review: Capio™ SLIM Suture Capturing Device

Reimbursement Guide: Capio SLIM Suture Capturing Device

Reimbursement

Is this product reimbursable by insurance?
The procedures for which it is used are reimbursable. Billing guides with respective coding and estimated Medicare reimbursement for relevant pelvic floor reconstruction procedures are available online at www.bostonscientific.com/reimbursement. For additional coding and reimbursement information, contact your local Territory Manager or the Women’s Health Reimbursement Help Desk at UroWH.reimb@bsci.com OR (508) 683-4022.

What is the Medicare Pass-Through Code (aka C-code or HCPCS)?
This Medicare Pass-Through Code for this product is C2631 (repair device, urinary, incontinence, without sling graft).

Is this a patient-chargeable product?
Yes. The appropriate Revenue Code for Capio SLIM 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:

<table>
<thead>
<tr>
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<td>Level VI Female Reproductive Procedures</td>
<td>0195</td>
<td>57240 – Anterior colporrhaphy, repair of cystocele with or without repair of urethrocele</td>
<td>70.50 - Repair of cystocele and rectocele</td>
<td>618.00 - Unspecified prolapse of vaginal walls</td>
<td>748 - Female reproductive system reconstructive procedures</td>
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<td>57259 – Posterior colporrhaphy, repair of rectocele with or without perinorrhaphy</td>
<td>70.52 - Repair of rectocele</td>
<td>618.01 - Cystocele, midline</td>
<td>662 - Minor bladder procedures with major complication or comorbidity (MCC)</td>
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<td>57260 – Combined anteroposterior colporrhaphy</td>
<td>70.53 - Repair of cystocele and rectocele with graft or prosthesis</td>
<td>618.02 - Cystocele, lateral</td>
<td>663 - Minor bladder procedures with complication or comorbidity (CC)</td>
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<td>57267 – Insertion of mesh or other prosthesis for repair of pelvic floor defect, each site, (anterior, posterior compartment), vaginal approach (List separately in addition to code for primary procedure)</td>
<td>70.54 - Repair of cystocele with graft or prosthesis (Anterior colporrhaphy)</td>
<td>618.04 - Rectocele</td>
<td>664 - Minor bladder procedures without CC/MCC</td>
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<td>57270 – Combined anteroposterior colporrhaphy</td>
<td>70.55 - Repair of rectocele with graft or prosthesis (Posterior colporrhaphy)</td>
<td>618.09 - Other prolapse of vaginal walls without mention of uterine prolapse</td>
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<td></td>
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<td>618.81 - Incompetence or weakening of pubocervical tissue</td>
<td>618.82 - Incompetence or weakening of rectovaginal tissue</td>
<td></td>
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</table>

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

For additional coding and reimbursement questions please contact our Women’s Health Reimbursement Help Desk at UroWH.reimb@bsci.com OR (508) 683-4022.
# Ordering Information

## Capio™ Slim Suture Capturing Device

<table>
<thead>
<tr>
<th>Order Number</th>
<th>Description</th>
<th>Unit</th>
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<tbody>
<tr>
<td>M0068318250</td>
<td>Capio SLIM Suture Capturing Device</td>
<td>bx 1</td>
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<tr>
<td>M0068318261</td>
<td>Capio SLIM Suture Capturing Device</td>
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## Capio Sutures

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<th>Description</th>
<th>Size</th>
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<tr>
<td>M0068332131</td>
<td>Absorbable, coated braided PGA, double armed with TC tapercut needle (dart), 48&quot;</td>
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<td>bx 12</td>
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<tr>
<td>M0068331141</td>
<td>Non-absorbable, coated braided polyester, double armed with TC tapercut needle (dart) and a T 26mm 1/2 circle taper needle, 36&quot;</td>
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<tr>
<td>M0068331241</td>
<td>Non-absorbable, polypropylene monofilament, double armed with TC tapercut needle (dart) and a T 26mm 1/2 circle taper needle, 36&quot;</td>
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<td>bx 12</td>
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<tr>
<td>M0068331371</td>
<td>Monodek™ Absorbable, monofilament PDO, double armed with TC tapercut needle (dart) and a T 26mm 1/2 circle taper needle, 48&quot;</td>
<td>0</td>
<td>bx 12</td>
</tr>
</tbody>
</table>
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Caution: Federal Law (USA) restricts these devices to sale by or on the order of a physician. Refer to package insert provided with these products for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using these products.