Mid-Urethral Sling Systems

Product Review for the Purchasing Committee

Advantage™ and Advantage Fit™ Systems

Lynx™ System

Obtryx™ System

Obtryx™ II System

Solyx™ SIS System

Transvaginal Mid-Urethral Sling System

Suprapubic Mid-Urethral Sling System

Transobturator Mid-Urethral Sling System

Single Incision Sling System

Always there.
Dedicated to Women’s Health
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Advantage and Advantage Fit Transvaginal Sling Systems

All Boston Scientific mid-urethral sling systems, including the Advantage and Advantage Fit Systems, use the Advantage Mesh platform. Over 750,000 Advantage Mesh slings have been implanted to date.

**Advantage Mesh slings: De-Tangled Polypropylene Material**
The Advantage Mesh has a suburethral segment that is de-tanged. The heat-sealed edge is designed to be smooth and resist deformation during tensioning. The suburethral mesh segment is designed to maintain its integrity. Additionally, the de-tanged mesh will potentially reduce irritation to the urethral wall.

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**DE-TANG​ED POLYPROPYLENE MATERIAL**

- Designed to Reduce Irritation
  The polypropylene mesh is de-tanged in the suburethral portion to potentially reduce irritation to the anterior urethral wall.
- Resists Deformation
  The suburethral portion of the mesh is de-tanged to resist deformation.

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**Advantage Transvaginal Mid-Urethral Sling System**
The Advantage System is an innovative mid-urethral sling that offers several advancements in delivery and tensioning, including an ergonomic delivery device handle designed to provide tactile sensation and a curved needle tip to fit behind the pubic bone.

**Advantage Fit Transvaginal Mid-Urethral Sling System**
The Advantage Fit System is designed to meet the requirements of today’s physicians. Features like a 46% thinner needle and 17% tighter curve are intended to reduce insertion force and leave the tape closer to the pubic bone. Additionally, the pusher is designed for ergonomic finger placement for greater needle stability and control during delivery.

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1. As compared to the Advantage Transvaginal Sling System
**ADVANTAGE™ DELIVERY DEVICE**

**Delivery Device**
- Non-skid grip designed to prevent hands from slipping during the intra-operative manipulation
- Ergonomic handle is designed to fit into operator’s palm allowing for ambidextrous use
- Hard surface of the back rim provides tactile sensation from the distal tip to the physician’s hand potentially indicating contact with a solid surface like bone

**Curved Needle Tip**
- Needle curve is designed anatomically to fit behind the pubic bone, reducing the chance for adjacent organ injury
- Needle is 5mm in diameter

**Dilator Pusher**
- Extends the dilator tube 2.3cm beyond the distal tip of the needle and is designed to provide the physician enough space to clamp the dilator

**ADVANTAGE™ MESH SLING**

**Centering Tab**
- Blue centering tab identifies the center of the mesh and provides for equal distribution of mesh on each side of the urethra
- Designed to allow counter tension to be applied on only the sleeve to help preserve mesh integrity
- Tab designed to be grasped and manipulated while giving a secure hold on the sleeve

**Mesh Assembly**
- Mesh is free floating in the protective sleeve
- Ultra-smooth bond to dilator designed to facilitate a seamless transition with no “lip” to catch on tissue

**Dilator Tube**
- Smooth tapered tip is designed to slide through tissue
- Slip on-Slip off design facilitates perioperative manipulation

**ADVANTAGE FIT™ DELIVERY DEVICE**

**Delivery Device**
- Ergonomically-designed handle to fit into the physician’s palm allowing for ambidextrous use

**Curved Needle Tip**
- 2.7mm curve is designed to fit behind the pubic bone and potentially reduce the chance of adjacent organ injury

**Dilator Pusher**
- The delivery device has been designed with a pusher for ergonomic finger placement for greater needle stability and control during delivery
Regulatory Letters

January 11, 2017

Dear Valued Customer,

Thank you for your inquiry regarding Boston Scientific product, Advantage™ System. *This information is provided in response to your direct request regarding the regulatory status of these products and may not be used for any other purpose without the expressed written permission of Boston Scientific.*

<table>
<thead>
<tr>
<th>M0068502000</th>
<th>Advantage™ System</th>
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<tr>
<td>M0068502110</td>
<td>Advantage Fit™ System</td>
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The Advantage™ System is marketed in accordance with US Food and Drug Administration (FDA) regulations 21 CFR 878.3300 and 21 CFR 876.4730. The 510K that supports this product was originally cleared by the FDA on April 3, 2002 via 510(k) K020110 and subsequently revised on September 13, 2013 to clarify the Indication for Use Page in the treatment for stress urinary incontinence. Attached you will find a copy of this updated clearance letter.

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

Sincerely,

Regulatory Affairs

Enclosure
September 13, 2013

Boston Scientific Corporation
Urology and Gynecology Division
% Lorraine M. Hanley
Director
One Boston Scientific Place
Natick, MA 01760

Re: K020110
Trade/Device Name: Advantage™ System, Advantage™ Fit System and Lynx™ System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated (Date on orig SE ltr): January 9, 2002
Received (Date on orig SE ltr): January 11, 2002

Dear Lorraine M. Hanley,

This letter corrects our substantially equivalent letter of April 3, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
FDA 510K Clearance Letter (cont.)

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use Statement

Boston Scientific Corporation

Indications for Use Statement

510(k) Number (if Known): K020110

Device Name: Advantage™ System, Advantage™ Fit System and Lynx™ System

Indications For Use:
The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use __X__ AND/OR Over-The-Counter Use ______ (21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line. Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician trained in use of surgical mesh for repair of stress urinary incontinence.

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.

This product is intended for use only by clinicians with adequate training and experience in the surgical treatment of stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.

The Advantage™ System and the Advantage Fit™ System are sterile, single use systems, consisting of one delivery device and one mesh assembly. Each mesh assembly is comprised of a polypropylene knitted mesh protected by a disposable plastic sleeve. At the distal ends of the mesh assembly are two dilators designed to be placed over the needle end of the delivery device. The disposable delivery device consists of a handle with a curved needle, and a pusher component. The delivery device is designed to facilitate the passage of the mesh assembly through bodily tissues for transvaginal placement.

The mesh implant is intended as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

CONTRAINDICATIONS:
A mesh implant is contraindicated in the following patients:
- Pregnant patients, patients with the potential for future growth or patients that are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

Dual manufactured product; no change in content as of January 11, 2017.

For current version refer to the DFU packaged with the product.
GENERAL WARNING

The risks and benefits of performing a suburethral sling procedure in the following patients should be carefully considered:

- Careful consideration should be given to performing this procedure for patients with untreated coagulopathies or who are being treated with either anticoagulants or antiplatelet agents.
- Patients with hypertension or vasoconstrictive reflex.
- Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires a cystoscopy repair, it should be done prior to the suburethral sling procedure.
- Vaginal and urinary tract infection should be treated prior to suburethral sling implantation procedure.
- User should be familiar with surgical procedures and techniques involving nonabsorbable meshes.
- The patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myopathy, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. The above pathophysiologic conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation, either by transvaginal, suprapubic, or transobturator route.
- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- Retroperitoneal bleeding can occur. Check carefully before releasing patient from the hospital.
- Cystoscopy must be performed to confirm bladder integrity.
- Do not remove the protective plastic sleeve covering the mesh implant until proper position has been confirmed.
- Ensure the mesh is placed tension free under the mid-urethra.

POST PROCEDURAL WARNING

- If subsequent infection occurs, follow appropriate medical intervention practices.
- The patient should be advised that future pregnancies may negate the effects of this procedure and the patient may again become incontinent.

PRECAUTIONS

- The use of polypropylene mesh in urogynecologic procedures such as the treatment of stress urinary incontinence, regardless of the route of delivery (transvaginal, supra pubic or transobturator), has been associated with cases of erosion. Erosion has been reported in bladder, vagina, urethra, ureter, and bowel. Treatment of the erosion may require surgical removal.
- As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myopathy, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. The above pathophysiologic conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation, either by transvaginal, suprapubic, or transobturator route.
- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- Retroperitoneal bleeding can occur. Check carefully before releasing patient from the hospital.
- Cystoscopy must be performed to confirm bladder integrity.
- Do not remove the protective plastic sleeve covering the mesh implant until proper position has been confirmed.
- Ensure the mesh is placed tension free under the mid-urethra.

ADVERSE EVENTS

The following adverse events have been reported due to suburethral sling placement, but are not limited to:

- Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.
- Physician should determine when it is suitable for each patient to return to normal activities.
- Patients should be counseled when to resume vigorous activities (heavy lifting, exercise), and intercourse after the procedure.
- Should dysuria, bleeding or other problems occur, the patient should be instructed to immediately contact the physician.
- Do not use any mechanical means of contact with the mesh (such as clips, staples, etc.) within the urethral support region of the mesh as mechanical damage to the mesh may occur.
- Avoid excessive tension on the mesh during handling.

- Examination of the wound site and surrounding area should be performed prior to discharge from the hospital.
- Patients should be counseled when to resume normal activities.
- Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.
- Physician should determine when it is suitable for each patient to return to normal activities.
- Patients should be counseled when to resume vigorous activities (heavy lifting, exercise), and intercourse after the procedure.
- Should dysuria, bleeding or other problems occur, the patient should be instructed to immediately contact the physician.
- Do not use any mechanical means of contact with the mesh (such as clips, staples, etc.) within the urethral support region of the mesh as mechanical damage to the mesh may occur.
- Avoid excessive tension on the mesh during handling.

- The occurrence of these events may require surgical intervention and possible removal of the entire mesh.
- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Allergic reaction has been reported.

Known risks of surgical procedures for the treatment of incontinence include:

- pain, ongoing pain (pelvic, vaginal, groin/thigh, dyspareunia)
- infection
- detrusor instability
- complete failure of the procedure
- voiding dysfunction (incontinence, mild to moderate incontinence due to incomplete urethral support or due to overactive bladder)
- bruising, bleeding (vaginal, hematoma formation)
- abscess
- vaginal discharge
- dehiscence of vaginal incision
- edema and erythema at the wound site
- perforation or laceration of vessels, nerves, bladder, urethra or bowel

In some instances the response to these events may persist as a permanent condition after the intervention.
**DFU: Advantage™ & Advantage Fit™ Transvaginal Mid-Urethral Sling Systems**

**Directions for Use (cont.)**

**HOW SUPPLIED**
The Advantage™ System and Advantage Fit™ System are sterile, single use systems consisting of one (1) delivery device and one (1) mesh assembly. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible. Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that devices are used prior to the expiration date on the package label.

**OPERATION INSTRUCTIONS**

**NOTE:** Review image above for part description.

**Operational Instructions Prior to Use**
The Advantage System and Advantage Fit System are supplied sterile and are intended for single patient use only. Carefully examine the system to verify that neither the contents nor the sterilized package has been damaged in shipment. DO NOT USE if the sterile barrier on product is damaged. Immediately return damaged product to Boston Scientific. Verify that neither the contents nor the sterilized package has been damaged. Systems consisting of one (1) delivery device and one (1) mesh assembly.

**WARNING:** Make sure that the bladder is empty prior to initiating the use of this product. Ensure that the bladder, urethra and other important landmarks are properly identified.

**Preparation of the System for Use**

**FIGURE 1**

**STEPS FOR USE**

1. After preparation of the lower abdominal and vaginal operative sites, create two small transverse abdominal incisions approximately 0.5 cm to 1 cm on each side of the midline just above the symphysis. 
2. Make a 1.0 cm to 1.5 cm vertical midline incision on the anterior vaginal wall at the level of the mid-urethra. Dissect bilaterally to the interior portion of the inferior pubic ramus at the 45° angle off the midline creating a pathway for delivery device placement.
3. Resting the tip of the needle on the palmar surface of the non-dominant index finger, gently introduce the delivery device into the vaginal incision and advance it anterolaterally to the lateral edge of the dissected space and then perforate the pubocervical and endopelvic fascia.
4. After perforating the endopelvic fascia, use your fingertip, and guide the distal end of the needle superiority along the posterior surface of the pubic bone. The curved part of the needle should rest in the operator’s non-dominant hand during advancement of the device.
5. Carefully pass the needle through the space of Retzius and perforate the rectus muscle and rectus sheath. Guide the device into the ipsilateral abdominal incision until the needle tip is exposed through the incision.

**WARNING:** Make sure the delivery device needle and mesh assembly pass sufficiently lateral to the urethra and bladder so that neither is injured.

6. When the needle tip/dilator tube assembly extends extra-abdominally, advance the dilator pusher on the handle forward toward the needle tip end of the Delivery Device. This will cause the dilator tube to advance beyond the tip of the needle.
7. Grasp the dilator by placing a clamp or hemostat on the free end of the dilator end to temporarily secure it extra-abdominally.
8. While holding the dilator in position, withdraw the needle from inside the dilator and out of the vagina. If the dilator should retract back into the abdomen, advance the needle until the proximal end of the dilator abuts the distal end of the cannula and redeploy the Dilator/Mesh Assembly until the needle tip/dilator tube assembly exits extra-abdominally.
9. Repeat steps 1–8 on the contralateral side.
10. With both dilator tubes in place, cystoscopy must be performed to confirm bladder integrity. If the blue dilator is seen in the bladder, remove the Dilator/Mesh Assembly. Visually inspect the Dilator/Mesh Assembly for integrity. If the Dilator/Mesh Assembly is intact, reload the Delivery Device and redeploy the Dilator/Mesh Assembly. The bladder must be emptied after cystoscopy.
11. Once desired sling placement is achieved, prepare to remove the protective sleeve from the mesh. See Figure 3 in the Tension Mesh/Sleeve Removal Section.

**Removal Section.**

**Directions for Use (cont.)**

**FIGURE 2**

**Preparation of the System for Use**

1. Orient the Delivery Device handle so that the needle end is positioned away from the user and the needle tip is positioned upward.
2. Load the proximal end of the dilator tube by holding the dilator/sleeve joint and placing it over the distal end of the needle.
3. Slide the dilator tube over the needle until the dilator’s proximal end abuts the distal end of the dilator pusher.
4. While holding the dilator in position, withdraw the needle from inside the dilator and out of the vagina. If the dilator should retract back into the abdomen, advance the needle until the proximal end of the dilator abuts the distal end of the cannula and redeploy the Dilator/Mesh Assembly until the needle tip/dilator tube assembly exits extra-abdominally.
5. Repeat steps 1–8 on the contralateral side.

**WARNING:** Make sure the delivery device needle and mesh assembly pass sufficiently lateral to the urethra and bladder so that neither is injured.

**FIGURE 3**

**Preparation of the System for Use**

1. After preparation of the lower abdominal and vaginal operative sites, create two small transverse abdominal incisions approximately 0.5 cm to 1 cm on each side of the midline just above the symphysis. 
2. Make a 1.0 cm to 1.5 cm vertical midline incision on the anterior vaginal wall at the level of the mid-urethra. Dissect bilaterally to the interior portion of the inferior pubic ramus at the 45° angle off the midline creating a pathway for delivery device placement.
3. Resting the tip of the needle on the palmar surface of the non-dominant index finger, gently introduce the delivery device into the vaginal incision and advance it anterolaterally to the lateral edge of the dissected space and then perforate the pubocervical and endopelvic fascia.
4. After perforating the endopelvic fascia, use your fingertip, and guide the distal end of the needle superiority along the posterior surface of the pubic bone. The curved part of the needle should rest in the operator’s non-dominant hand during advancement of the device.
5. Carefully pass the needle through the space of Retzius and perforate the rectus muscle and rectus sheath. Guide the device into the ipsilateral abdominal incision until the needle tip is exposed through the incision.

**WARNING:** Make sure the delivery device needle and mesh assembly pass sufficiently lateral to the urethra and bladder so that neither is injured.

6. When the needle tip/dilator tube assembly extends extra-abdominally, advance the dilator pusher on the handle forward toward the needle tip end of the Delivery Device. This will cause the dilator tube to advance beyond the tip of the needle.
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11. Once desired sling placement is achieved, prepare to remove the protective sleeve from the mesh. See Figure 3 in the Tension Mesh/Sleeve Removal Section.

**Removal Section.**

**Directions for Use (cont.)**

**FIGURE 2**

**Preparation of the System for Use**

1. Orient the Delivery Device handle so that the needle end is positioned away from the user and the needle tip is positioned upward.
2. Load the proximal end of the dilator tube by holding the dilator/sleeve joint and placing it over the distal end of the needle.
3. Slide the dilator tube over the needle until the dilator’s proximal end abuts the distal end of the dilator pusher.
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5. Repeat steps 1–8 on the contralateral side.

**WARNING:** Make sure the delivery device needle and mesh assembly pass sufficiently lateral to the urethra and bladder so that neither is injured.

**FIGURE 3**

**Preparation of the System for Use**

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2. Make a 1.0 cm to 1.5 cm vertical midline incision on the anterior vaginal wall at the level of the mid-urethra. Dissect bilaterally to the interior portion of the inferior pubic ramus at the 45° angle off the midline creating a pathway for delivery device placement.
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5. Carefully pass the needle through the space of Retzius and perforate the rectus muscle and rectus sheath. Guide the device into the ipsilateral abdominal incision until the needle tip is exposed through the incision.

**WARNING:** Make sure the delivery device needle and mesh assembly pass sufficiently lateral to the urethra and bladder so that neither is injured.

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8. While holding the dilator in position, withdraw the needle from inside the dilator and out of the vagina. If the dilator should retract back into the abdomen, advance the needle until the proximal end of the dilator abuts the distal end of the cannula and redeploy the Dilator/Mesh Assembly until the needle tip/dilator tube assembly exits extra-abdominally. **WARNING:** If excessive resistance is encountered during advancement/withdrawal, stop and determine remedial action prior to proceeding.
9. Repeat steps 1–8 on the contralateral side.
10. With both dilator tubes in place, cystoscopy must be performed to confirm bladder integrity. If the blue dilator is seen in the bladder, remove the Dilator/Mesh Assembly. Visually inspect the Dilator/Mesh Assembly for integrity. If the Dilator/Mesh Assembly is intact, reload the Delivery Device and redeploy the Dilator/Mesh Assembly. The bladder must be emptied after cystoscopy.
11. Once desired sling placement is achieved, prepare to remove the protective sleeve from the mesh. See Figure 3 in the Tension Mesh/Sleeve Removal Section.

**Removal Section.**
Tension Mesh/Sleeve Removal

1. Adjust the mesh/sleeve by pulling upwards on the dilators so that the blue centering tab is centered below the urethra.

2. Appropriately tension the mesh/sleeve according to physician preference.

3. Grasp the blue centering tab and cut the tab through the center of the punch hole (see Figure 3) ensuring that both halves of the blue tab are completely removed from the vaginal canal.

4. Pull upwards on the dilators to remove the sleeve out of the body.

5. Verify the tension of the Mesh and adjust mesh as necessary.

6. Once the desired tension has been achieved, gently push downward on the abdomen, cut the distal ends of the mesh and confirm that those ends retract into the incision.

7. Close the incision in the usual manner.

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, handling, storage, cleaning and sterilization of this instrument as well as other factors beyond BSC's control directly affect the instrument and the results obtained from its use. 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.
Directions for Use (cont.)

Dual manufactured product; no change in content as of January 11, 2017.
For current version refer to the DFU packaged with the product.
Lynx™
Suprapubic Mid-Urethral Sling System

Product Overview
Regulatory Information
Directions for Use
Lynx Suprapubic Sling System

The Lynx Suprapubic Mid-Urethral Sling System featuring Advantage™ Mesh is designed to offer the surgeon a system for treating stress urinary incontinence that is distinctive and maneuverable. It is distinctive with heat-sealed edges throughout the suburethral segment of the mesh. This de-tanged suburethral segment is designed to potentially reduce irritation to the urethral wall, as well as resist deformation. The delivery device is designed to maneuver through challenging tissue with a smoother association mechanism. The needle is longer than many existing market devices, providing additional length which may assist in negotiating larger abdomens.

**DE-TANGED POLYPROPYLENE MATERIAL**

- **Designed to Potentially Reduce Irritation**
  The polypropylene mesh is de-tanged in the suburethral portion to potentially reduce irritation to the anterior urethral wall.
- **Resists Deformation**
  The suburethral portion of the mesh is de-tanged to reduce risk that the mesh will experience deformation during tensioning. The suburethral mesh segment is designed to maintain its integrity.

**REMOVABLE ENGAGEMENT MECHANISM**
Handle
- Non-skid grip is designed to prevent hand from slipping during intra-operative manipulations

Centering Tab
- Blue centering tab identifies the center of the mesh and provides for equal distribution of mesh on each side of the urethra
- Allows for counter tension to be applied on only the mesh sleeve to help preserve mesh integrity
- Tab is designed to be grasped and manipulated while giving a secure hold on sleeve

Mesh Assembly
- Mesh is free-floating in the protective sleeve allowing sleeve to absorb the tensioning load

Association Loop
- Facilitates needle engagement and removal
- Designed for smooth transition from loop to mesh allowing for minimal disruption to tissue

Needle
- Colored needle sleeve is designed to enhance visibility during cystoscopy
- Needle designed to facilitate suprapubic device passage

ADVANTAGE™ MESH
January 11, 2017

Dear Valued Customer,

Thank you for your inquiry regarding Boston Scientific product, Lynx™ System (Suprapubic). This information is provided in response to your direct request regarding the regulatory status of these products and may not be used for any other purpose without the expressed written permission of Boston Scientific.

M0068503000 Lynx™ System Single

The Lynx™ System is marketed in accordance with US Food and Drug Administration (FDA) regulations 21 CFR 878.3300 and 21 CFR 876.4730. The 510K that supports this product was originally cleared by the FDA on April 3, 2002 via 510(k) K020110 and subsequently revised on September 13, 2013 to clarify the Indication for Use Page in the treatment for stress urinary incontinence. Attached you will find a copy of this updated clearance letter.

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

Sincerely,

Regulatory Affairs

Enclosure
September 13, 2013

Boston Scientific Corporation
Urology and Gynecology Division
% Lorraine M. Hanley
Director
One Boston Scientific Place
Natick, MA 01760

Re: K020110
Trade/Device Name: Advantage™ System, Advantage™ Fit System and Lynx™ System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated (Date on orig SE ltr): January 9, 2002
Received (Date on orig SE ltr): January 11, 2002

Dear Lorraine M. Hanley,

This letter corrects our substantially equivalent letter of April 3, 2002.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use Statement

510(k) Number (if Known): K020110

Device Name: Advantage™ System, Advantage™ Fit System and Lynx™ System

Indications For Use:
The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use _X_ AND/OR Over-The-Counter Use
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(Please do not write below this line-continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
Directions for Use

**DIRECTIONS FOR USE**

**Caution:** Federal Law (USA) restricts this device to sale by or on the order of a physician trained in use of surgical mesh for repair of stress urinary incontinence.

**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.

**WARNING**

This product is intended for use only by clinicians with adequate training and experience in the surgical treatment of stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.

**DEVICE DESCRIPTION**

The Lynx™ System is a sterile, single use system consisting of two (2) delivery devices and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh protected by a disposable plastic sleeve. At the distal ends of the mesh assembly there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a curved needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for suprapubic placement.

**INDICATIONS FOR USE**

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

**CONTRAINDICATIONS**

The mesh suburethral sling implant is contraindicated in the following patients:

- Pregnant patients, patients with potential for future growth or patients that are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.
Prior to Use
The Lynx™ Sling System is supplied sterile and is intended for single patient use only. Carefully examine the system to verify that neither the contents nor the sterilized package have been damaged in shipment. DO NOT USE if sterile barrier on product is damaged. Immediately return damaged product to Boston Scientific.
The design of the Lynx System allows the operator a percutaneous approach utilizing suprapubic technique. See Figure 1 for parts description.

Figure 1: Parts Description

Prepare and drape the patient using standard surgical practice.

WARNING: Assure that the bladder is empty prior to initiating the use of this product. Ensure that the bladder, urethra and other important landmarks are properly identified.

Steps to Use
1. Prepare the lower abdominal and vaginal operative sites. Create two (2) small transverse abdominal incisions approximately 0.5 cm to 1.0 cm on each side of the midline just above the symphysis.
2. Make a 1.0 cm to 1.5 cm vertical midline incision on the anterior vaginal wall at the level of the mid-urethra. Dissect bilaterally to the interior portion of the inferior pubic ramus at the 45° angle off the midline creating a pathway for delivery device placement.
3. Insert one (1) needle through one (1) abdominal incision, moving the needle downward in a vertical motion, pierce through the rectus fascia into the Space of Retzius. Guide the distal end of the needle down along the posterior surface of the pubic bone through the vaginal incision.
4. Repeat Step 3 on the contralateral side with the second needle.

WARNING: Make sure the delivery device and mesh assembly pass sufficiently lateral to the urethra and bladder so that neither is injured.

5. With both needles in place, cystoscopy must be performed to confirm bladder integrity. If a needle is seen in the bladder, remove the needle. Visually inspect the needle for integrity. If the needle is intact, repeat Step 3 after emptying the bladder.
6. Once it is determined that the bladder is intact, engage one (1) association loop to the distal end of each needle (see Figure 2) protruding through the vagina.

WARNING: If excessive force is encountered during advancement/withdrawal, stop and determine remedial action prior to proceeding.

7. Pull the needles up through the abdominal incisions. Be sure that the mesh assembly is not twisted and lies flat under the urethra, with the blue centering tab positioned suburethrally, facing outward.

8. Remove the association loops from the needles (see Figure 3).

9. Next see section “Tension Mesh/Sleeve Removal”

Tension Mesh/Sleeve Removal
1. Adjust the mesh/sleeve by pulling upwards on the dilators so that the blue centering tab is centered below the urethra.
2. Appropriately tension the mesh/sleeve according to physician preference.
3. Grasp the blue centering tab and cut the tab through the center of the punch hole (see Figure 4) ensuring that both halves of the blue tab are completely removed from the vaginal canal.
4. Pull upwards on the dilators to remove the sleeve leaving the mesh in place. Verify the tension of the mesh and adjust as necessary.

Figure 2: Association Loop Engagement

Figure 3: Association Loop Removal

Figure 4: Tension Mesh/Sleeve Removal

Dual manufactured product; no change in content as of January 11, 2017.
For current version refer to the DFU packaged with the product.
5. Gently push downward on the abdomen, cut the distal ends of the mesh and confirm that those ends retract into the abdominal incisions.

6. Close all incisions according to usual methods.

**GENERAL WARNING**

The risks and benefits of performing a suburethral sling procedure in the following should be carefully considered:
- Careful consideration should be given to performing this procedure for patients with untreated coagulopathies or who are being treated with either anticoagulants or antiplatelet agents.
- Patients with hypertonic bladders or vesicoureteral reflex.
- Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires a cystocele repair, it should be done prior to the suburethral sling procedure.
- Vaginal and urinary tract infection should be treated prior to a suburethral sling implantation procedure.
- User should be familiar with surgical procedures and techniques involving nonabsorbable mesh.
- Good surgical practices should be followed for management of contamination or infected wounds.
- Mesh is considered a permanent implant. Removal of mesh or correction of mesh related complication may involve multiple surgeries.
- Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

**POST PROCEDURAL WARNING**

- If subsequent infection occurs, follow appropriate medical intervention practices.
- The patient should be advised that future pregnancies may negate the effects of this procedure and the patients may again become incontinent.

**PRECAUTIONS**

- The use of polypropylene mesh in urogynecologic procedures such as the treatment of stress urinary incontinence, regardless of the route of delivery (transvaginal, suprapubic or transobturator), has been associated with cases of erosion. Erosion has been reported in bladder, vagina, urethra, antrum, and bowels. Treatment of the erosion may require surgical removal.
- As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvis. The above pathophysiologic conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation, either by transvaginal, suprapubic or transobturator route.
- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- Retropubic bleeding can occur. Check carefully before releasing patient from the hospital.
- Cystoscopy must be performed to confirm bladder integrity.
- Do not remove the protective plastic sleeve covering the mesh implant until proper position has been confirmed.
- Ensure the mesh is placed tension free under the mid-urethra.
- Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.
- Physician should determine when it is suitable for each patient to return to normal activities.
- Patients should be counseled when to resume vigorous activities (heavy lifting, exercise), and intercourse after the procedure.
- Should dysuria, bleeding or other problems occur, the patient should be instructed to immediately contact the physician.
- Do not use any mechanical means of contact with the mesh (such as clips, staples, etc.) within the urethral support region of the mesh, as mechanical damage to the mesh may occur.
- Avoid excessive tension on the mesh during handling.

**ADVERSE EVENTS**

The following adverse events have been reported due to suburethral sling placement, but are not limited to:
- As with all implants, local irritation at the wound site and/or a foreign body response may occur.
- Tissue responses to the mesh implant could include:
  - Erosion/exposure/extrusion of the mesh through the vaginal or urethral mucosa, bladder wall or other surrounding tissue
  - Scarring/cystocele
  - Device migration
  - Fistula formation and inflammation
- The occurrence of these events may require surgical intervention and possible removal of the entire mesh.
- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Allergic reaction has been reported.
- Known risks of surgical procedures for the treatment of incontinence include:
  - Pain, ongoing pain (pelvic, vaginal, groin/thigh, dyspareunia)
  - Infection
  - Detrusor instability
  - Complete failure of the procedure
  - Voiding dysfunction (incontinence, mild to moderate incontinence due to incomplete urethral support or due to overactive bladder)
  - Bruising, bleeding (vaginal, hematoma formation)
  - Abscess
Directions for Use (cont.)

- vaginal discharge
- dehiscence of vaginal incision
- edema and erythema at the wound site
- perforation or laceration of vessels, nerves, bladder, urethra or bowel may occur during placement.

The occurrence of these events may require surgical intervention. In some instances the response to these events may persist as a permanent condition after the intervention.

STORAGE

Store at controlled room temperature. Rotate inventory so that products are used prior to the expiration date on package label. Do not use if package is opened or damaged. 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 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 instrument.

Handling, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures, and other matters beyond BSC’s control directly affect the instrument and the results obtained from its use. 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 instrument.

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Notes
Obtryx™
Transobturator Mid-Urethral Sling System

Product Overview
Regulatory Information
Directions for Use
Obtryx Transobturator Sling System

The Obtryx Transobturator Mid-Urethral Sling System featuring Advantage™ Mesh is designed to offer surgeons a distinctive and versatile transobturator approach for treating stress urinary incontinence. The Advantage Mesh Assembly is distinctive because of features that set it apart from the competition. The mesh has heat-sealed edges throughout the suburethral segment. This de-tangled suburethral segment is designed to potentially reduce irritation to the urethral wall, as well as resist deformation. Additionally, the mesh offers a protective sleeve that is designed to absorb the load during tensioning. The delivery device is designed to be versatile by offering a removable association mechanism and two needle configurations, Halo and Curved, which allow physicians to choose the needle that meets their preference for placing the sling through the obturator foramen.

DE-TANGED POLYPROPYLENE MATERIAL

- Designed to Reduce Irritation
  The polypropylene mesh is de-tangled in the suburethral portion to potentially reduce irritation to the urethral wall.
- Resists Deformation
  The suburethral portion of the mesh is de-tangled to resist deformation.
**Needle Design**
- Needle designed to facilitate device passage through the obturator foramen
- Two needle configurations allow physicians to choose the needle that meets their preference

**Association Loop**
- Facilitates needle engagement and removal
- Designed for smooth transition from loop to mesh allowing for minimal disruption to tissue

**Mesh Assembly**
- Blue centering tab identifies the center of the mesh and provides for equal distribution of mesh on each side of the urethra
- Allows for counter tension to be applied on only the mesh sleeve to help preserve mesh integrity
- Tab is easy to grasp and manipulate while providing a secure hold on sleeve
- No sleeve overlap under the urethra is designed for smoother sleeve separation during removal through tissue
January 11, 2017

Dear Valued Customer,

Thank you for your inquiry regarding Boston Scientific product, Obtryx™ System. This information is provided in response to your direct request regarding the regulatory status of these products and may not be used for any other purpose without the expressed written permission of Boston Scientific.

<table>
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<th>Code</th>
<th>Description</th>
<th>Quantity</th>
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<tr>
<td>M0068504000</td>
<td>Obtryx™ System (Curved)</td>
<td>Single</td>
</tr>
<tr>
<td>M0068505000</td>
<td>Obtryx™ System (Halo)</td>
<td>Single</td>
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The Obtryx™ System is marketed in accordance with U.S. Food and Drug Administration (FDA), regulations 21 CFR 878.3300 and 21 CFR 876.4730. This product was cleared to market by the FDA on April 14, 2004 via 510(k) K040787 and subsequently revised on September 13, 2013 to clarify the Indication for Use Page in the treatment for stress urinary incontinence. Attached you will find a copy of this updated clearance letter.

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

Sincerely,

Regulatory Affairs

Enclosure
September 13, 2013

Boston Scientific Corporation
Urology and Gynecology Division
% Janet A. McGrath
Regulatory Affairs Specialist
One Boston Scientific Place
Natick, MA 01760

Re: K040787
Trade/Device Name: Obtryx™ System (Halo or Curved) and Prefyx PPS™ System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical mesh
Regulatory Class: II
Product Code: OTN
Dated (Date on orig SE ltr): March 24, 2004
Received (Date on orig SE ltr): April 1, 2004

Dear Janet A. McGrath,

This letter corrects our substantially equivalent letter of April 14, 2004.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.
Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use Statement

510(k) Number (if known): K040787

Device Name: Obtryx™ System (Halo or Curved) and Prefyx PPS™ System

Indications For Use:
The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use _X_ AND/OR Over-The-Counter Use
(21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
Warnings

Contents supplied STERILE using 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 Obtryx™ Sling System - Curved is a sterile, single use system consisting of two (2) delivery devices and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh protected by a disposable plastic sleeve. At the distal ends of the mesh assembly there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen.

Indications for Use

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Contraindications

The mesh suburethral sling implant is contraindicated in the following patients:

- Pregnant patients, patients with potential for future growth or patients that are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology such as blood supply limitations or infections that would compromise healing.
DIRECTIONS FOR USE

Prior to Use

The Obtryx™ Sling System - Curved is supplied sterile and is intended for single patient use only. Carefully examine the system to verify that neither the contents nor the sterilized package has been damaged in shipment. DO NOT USE if sterile barrier on product is damaged. Immediately return damaged product to Boston Scientific.

The design of the Obtryx Sling System - Curved allows the operator a percutaneous approach utilizing a transobturator technique. See Figure 1 for parts description.

Handle
Needle
Needle Slot
Dilator
Association loop
Mesh Centering Tab

Figure 1: Parts Description

Prepare and drape the patient using standard surgical practice.

WARNING
Assure that the bladder is empty prior to initiating the use of this product. Ensure that the bladder, urethra and other important landmarks are properly identified.

Steps to Use

1. Prepare the skin lateral to the inferior pubic ramus and vaginal operative sites.
2. Make a 1.0 cm to 1.5 cm vertical midline incision on the anterior vaginal wall at the level of the mid-urethra. Dissect bilaterally to the interior portion of the inferior pubic ramus at the 45° angle off the midline creating a pathway for delivery device placement.
3. Create a vertical skin incision large enough to insert tip of needle just lateral to the edge of the inferior pubic ramus at the junction where the inferior pubic ramus and the adductor longus muscle meet. Repeat on the contralateral side.

WARNING
If excessive force is encountered during advancement/withdrawal, stop and determine remedial action prior to proceeding.

4. Grasp the device handle and insert one (1) needle through one (1) skin incision, piercing through the obturator muscle and obturator membrane. Turn the handle at the 45° angle medial towards the midline. Place the opposite hands forefinger into the lateral dissection of the vaginal incision, placing the fingertip on the distal end of the needle. Guide the distal end of the needle around the inferior pubic ramus through the vaginal incision, maintaining contact with the finger.

WARNING
Pay careful attention to avoid the adductor longus tendon with the delivery device.

WARNING
Make sure the delivery device and mesh assembly pass sufficiently lateral to the urethra in order to avoid urethral injury.

5. Engage one (1) association loop to the distal end of the needle (see Figure 2) protruding through the vagina.

Figure 2: Association Loop Engagement

6. Pull the needle out through the skin incision. Be sure that the mesh assembly is not twisted and lies flat under the urethra, with the blue centering tab positioned suburethrally, facing outward.
7. Remove the association loop from the needle (see Figure 3).

Figure 3: Association Loop Removal

8. Repeat Steps 4-7 on the contralateral side with the second needle.
9. Cystoscopy may be performed at this time, to be determined at the physician’s discretion.
10. Next see section “Tension Mesh/Sleeve Removal.”

Tension Mesh/Sleeve Removal

1. Adjust the mesh/sleeve by pulling outwards on the dilators so that the blue centering tab is centered below the urethra.
2. Appropriately tension the mesh/sleeve according to physician preference.
Directions for Use (cont.)

3. Grasp the blue centering tab and cut the tab through the center of the punch hole (see Figure 4) ensuring that both halves of the blue tab are completely removed from the vaginal canal.

4. Pull outwards on the dilators to remove the sleeve leaving the mesh in place.

5. Verify the tension of the mesh and adjust as necessary.

6. Gently push downward on the skin incisions, cut the distal ends of the mesh and confirm that those ends retract into the skin incisions.

7. Close all incisions according to usual methods.

GENERAL WARNING:
The risks and benefits of performing a suburethral sling procedure in the following should be carefully considered:

• Careful consideration should be given to performing this procedure for patients with untreated coagulopathies or who are being treated with either anticoagulants or antiplatelet agents.

• Patients with hypertonic bladders or vesico ureteral reflux.

• Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires a cystocele repair, it should be done prior to the suburethral sling procedure.

• Vaginal and urinary tract infection should be treated prior to a suburethral sling implantation procedure.

• User should be familiar with surgical procedures and techniques involving nonabsorbable meshes.

• Good surgical practices should be followed for management of contamination or infected wounds.

• Mesh is considered a permanent implant. Removal of mesh or correction of mesh related complication may involve multiple surgeries.

• Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

POST PROCEDURAL WARNING

• If subsequent infection occurs, follow appropriate medical intervention practices.

• The patient should be advised that future pregnancies may negate the effects of this procedure and the patients may again become incontinent.

ADVERSE EVENTS
The following adverse events have been reported due to suburethral sling placement, but are not limited to:

• As with all implants, local irritation at the wound site and/or a foreign body response may occur.

• Tissue responses to the mesh implant could include:
  • erosion/exposure/extrusion of the mesh through the vaginal or urethral mucosa, bladder wall or other surrounding tissue
  • scarring/scar contracture
  • device migration
  • fistula formation and inflammation

The occurrence of these responses events may require surgical intervention and possible removal of the entire mesh.

• Like all foreign bodies, the mesh may potentiate an existing infection.

• Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.

• Allergic reaction has been reported.

• Known risks of surgical procedures for the treatment of incontinence include:
  • pain, ongoing pain (pelvic, vaginal, groin/thigh, dyspareunia)
  • infection
  • detrusor instability
  • complete failure of the procedure
  • voiding dysfunction (incontinence, mild to moderate incontinence due to incomplete urethral support or due to overactive bladder)
  • bruising, bleeding (vaginal, hematoma formation)
  • abscess
  • vaginal discharge
  • dehiscence of vaginal incision
  • edema and erythema at the wound site
  • perforation or laceration of vessels, nerves, bladder, urethra or bowel

The occurrence of these events may require surgical intervention. In some instances the response to these events may persist as a permanent condition after the intervention.

PRECAUTIONS

• The use of polypropylene mesh in urogynecologic procedures such as the treatment of stress urinary incontinence, regardless of the route of delivery (transvaginal, suprapubic or transobturator), has been associated with cases of erosion. Erosion has been reported in bladder, vagina, urethra, ureter, and bowel. Treatment of the erosion may require surgical removal.

Dual manufactured product; no change in content as of January 11, 2017.
For current version refer to the DFU packaged with the product.
• As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. The above pathophysiologic conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation, either by transvaginal, suprapubic or transobturator route.
• Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
• Bleeding can occur. Check carefully before releasing patient from the hospital.
• Do not remove the protective plastic sleeve covering mesh implant until proper position has been confirmed.
• Ensure the mesh is placed without tension under the mid-urethra.
• Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.
• Physician should determine when it is suitable for each patient to return to normal activities.
• Patients should be counseled when to resume vigorous activities (heavy lifting, exercise), and intercourse after the procedure.
• Should dysuria, bleeding or other problems occur, the patient should be instructed to immediately contact the physician.
• Do not use any mechanical means of contact with the mesh (such as clips, staples etc.) within the urethral support region of the mesh as mechanical damage to the mesh may occur.
• Avoid excessive tension on the mesh during handling.

STORAGE
Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label. Do not use if package is damaged.

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. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC’s control directly affect the instrument and the results obtained from its use. 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.

Lot
Lot
Lot
Lot
Lot
Directions for Use (cont.)

Dual manufactured product; no change in content as of January 11, 2017.
For current version refer to the DFU packaged with the product.
Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician trained in use of surgical mesh for repair of stress urinary incontinence.

**DIRECTIONS FOR USE**

**WARNING**

Contents supplied STERILE using 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.

**WARNING**

This product is intended for use only by clinicians with adequate training and experience in the surgical treatment of stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.

**DEVICE DESCRIPTION**

The Obtryx™ Sling System - Halo is a sterile, single use system consisting of two (2) delivery devices (one patient right and one patient left) and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh protected by a disposable plastic sleeve. At the distal ends of the mesh assembly there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen.

**INDICATIONS FOR USE**

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

**CONTRAINDICATIONS**

The mesh suburethral sling implant is contraindicated in the following patients:

- Pregnant patients, patients with potential for future growth or patients that are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

Dual manufactured product; no change in content as of January 11, 2017. For current version refer to the DFU packaged with the product.
Directions for Use (cont.)

DIRECTIONS FOR USE

Prior to Use
The Obtryx™ Sling System - Halo is supplied sterile and is intended for single patient use only. Carefully examine the system to verify that neither the contents nor the sterilized package has been damaged in shipment. DO NOT USE if sterile barrier on product is damaged. Immediately return damaged product to Boston Scientific.

The design of the Obtryx Sling System - Halo allows the operator a percutaneous approach utilizing a transobturator technique. See Figure 1 for parts description.

Prepare and drape the patient using standard surgical practice.

WARNING
Assure that the bladder is empty prior to initiating the use of this product. Ensure that the bladder, urethra and other important landmarks are properly identified.

Steps to Use
1. Prepare the skin lateral to the inferior pubic ramus and vaginal operative sites.
2. Make a 1.0 cm to 1.5 cm vertical midline incision on the anterior vaginal wall at the level of the mid-urethra. Dissect bilaterally to the interior portion of the inferior pubic ramus at the 45° angle off the midline creating a pathway for delivery device placement.
3. Create a vertical skin incision large enough to insert tip of needle just lateral to the edge of the inferior pubic ramus at the junction where the inferior pubic ramus and the adductor longus muscle meet. Repeat on the contralateral side.

WARNING
If excessive force is encountered during advancement/withdrawal, stop and determine remedial action prior to proceeding.

4. Grasp the device handle for the patient’s left side with the right hand. Place the left forefinger into the lateral dissection of the vaginal incision. Place the needle tip into the skin incision perpendicular to the skin with the handle at a 45° angle parallel with the thigh.

WARNING
Pay careful attention to avoid the adductor longus tendon with the delivery device.

5. Putting the left thumb on the outside of the needle curve, apply a downward force, piercing through the obturator muscle and membrane.
6. Rotate the needle medially around the inferior pubic ramus to meet the left hand forefinger. Guide the needle tip through the vaginal incision.
7. Engage one (1) association loop to the distal end of the needle (see Figure 2) protruding through the vagina.
8. Pull the needle out through the skin incision. Be sure that the mesh assembly is not twisted and lies flat under the urethra, with the blue centering tab positioned suburethrally, facing outward.
9. Remove the association loop from the needle (see Figure 3).

10. Repeat Steps 4-9 on the contralateral side with the second needle.
11. Cystoscopy may be performed at this time, to be determined at the physician’s discretion.
12. Next see section “Tension Mesh/Sleeve Removal.”

Tension Mesh/Sleeve Removal
1. Adjust the mesh/sleeve by pulling outwards on the dilators so that the blue centering tab is centered below the urethra.
2. Appropriately tension the mesh/sleeve according to physician preference.
3. Grasp the blue centering tab and cut the tab through the center of the punch hole (see Figure 4) ensuring that both halves of the blue tab are completely removed from the vaginal canal.
As with all implants, local irritation at the wound site and/or a foreign body response may occur.

The following adverse events have been reported due to suburethral sling placement, but are not limited to:

- As with all implants, local irritation at the wound site and/or a foreign body response may occur.
- Pain, ongoing pain (pelvic, vaginal, groin/hip, dyspareunia)
- Infection
- Detrusor instability
- Complete failure of the procedure
- Voiding dysfunction (incontinence, mild to moderate incontinence due to incomplete urethral support or due to overactive bladder)
- Bruising, bleeding (vaginal, hematoma formation)
- Abscess
- Vaginal discharge
- Dehiscence of vaginal incision
- Edema and erythema at the wound site
- Perforation or laceration of vessels, nerves, bladder, urethra or bowel may occur during placement.

The occurrence of these events may require surgical intervention. In some instances the response to these events may persist as a permanent condition after the intervention.

**PRECAUTIONS**

- The use of polypropylene mesh in urogynecologic procedures such as the treatment of stress urinary incontinence, regardless of the route of delivery (transvaginal, suprapubic or transobturator), has been associated with cases of erosion. Erosion has been reported in bladder, vagina, urethra, uterine and bowel. Treatment of the erosion may require surgical removal.
- As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. These pathophysiologic processes should be understood and should not be ignored when considering if the patient is an appropriate candidate for mesh implantation, either by transvaginal, suprapubic or transobturator route.
- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- Bleeding can occur. Check carefully before releasing patient from the hospital.

**GENERAL WARNING**

The risks and benefits of performing a suburethral sling procedure in the following should be carefully considered:

- Careful consideration should be given to performing this procedure for patients with untreated coagulopathies or who are being treated with either anticoagulants or antplatelet agents.
- Patients with hypertonic bladders or vesico ureteral reflux.
- Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires a cystocele repair, it should be done prior to the suburethral sling procedure.
- Tissue responses to the mesh implant could include:
  - Erosion/Exposure/Extrusion of the mesh through the vaginal or urethral mucosa, bladder wall or other surrounding tissue
  - Scarring/scar contracture
  - Device migration
  - Fistula formation and inflammation
- The occurrence of these events may require surgical intervention and possible removal of the entire mesh.
- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Allergic reaction has been reported.
- Known risks of surgical procedures for the treatment of incontinence include:
  - Perforation or laceration of vessels, nerves, bladder, urethra or bowel may occur during placement.

**POST PROCEDURAL WARNING**

- If subsequent infection occurs, follow appropriate medical intervention practices.
- The patient should be advised that future pregnancies may negate the effects of this procedure and the patients may again become incontinent.
Product Overview: Obtryx™ Transobturator Mid-Urethral Sling System

- Do not remove the protective plastic sleeve covering mesh implant until proper position has been confirmed.
- Ensure the mesh is placed without tension under the mid-urethra.
- Use of this device should be done with the understanding that subsequent infection may require removal of the mesh. By 2017, no change in content as of January 11, 2017.
- Physician should determine when it is suitable for each patient to return to normal activities.
- Patients should be counseled when to resume vigorous activities (heavy lifting, exercise), and intercourse after the procedure.
- Should dysuria, bleeding or other problems occur, the physician should be instructed to immediately contact the physician.

STORAGE
Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label. Do not use if package is opened or damaged. 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. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC’s control directly affect the instrument and the results obtained from its use. 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.

For current version refer to the DFU packaged with the product.
Product Review for the Purchasing Committee

Advantage and Advantage Fit Systems
Lynx System
Obtryx II System
Solyx System
Clinical / Scientific Data
Reimbursement and Ordering Info

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Dual manufactured product; no change in content as of January 11, 2017. For current version refer to the DFU packaged with the product.
Obtryx™ II
Transobturator Mid-Urethral Sling System

Product Overview
Regulatory Information
Directions for Use
The Obtryx II Sling System with PrecisionBlue Design is a transobturator sling with enhanced features that are designed to provide smooth sling placement, intra-operative adjustability with minimal tissue disruption and increased physician visualization to aid in precise sling placement.

**Smooth Sling Placement**
The Obtryx II Sling System is designed with thin dilator legs to allow ease of placement when traveling through the anatomy and transitioning around the bone. The plastic sleeves have smooth edges; and the dilator legs allow untwisting of the sling when necessary.

**Intra-operative Adjustability with Minimal Tissue Disruption**
The Obtryx II Sling System is designed to allow inter-operative adjustability with minimal tissue disruption. The centering tab and dilator legs act as a system to allow the physician to adjust the sling intra-operatively according to their preferences. The centering tab not only marks the center of the sling, but is a tool to aid in tensioning. Physicians can use the dilator legs and centering tab to adjust the sling to achieve their desired tensioning.

**Increased Physician Visualization**
Mesh color can obviously be advantageous in enhancing visibility. The Obtryx II Sling System has blue mesh and dilator legs that can be seen during placement and cystoscopy to help ensure the sling is placed according to physician preferences. The mesh color can also be beneficial if there was a need to view the sling post-surgery. There is no sleeve coverage in the suburethral segment, which allows the physician to see how the mesh implant sits against the urethra without having to pull back the sleeves.

The Three Elements of PrecisionBlue Design
**Needle Design**

- Needle tip length is designed to facilitate device passage through the obturator foramen
- Two needle configurations allow physicians to choose the needle that meets their preference

**Association Loop**

- Designed to facilitate needle engagement and removal

**Dilator Legs**

- Designed to create a small delivery track due to thin leg size and provides smooth delivery of the sling through the anatomy allowing for minimal tissue disruption

**Centering Tab**

- No sleeve coverage under the sub-urethral segment to allow for visibility and to aid in precise placement
- Blue centering tab identifies the center of the mesh and provides for equal distribution of mesh on each side of the urethra
- The centering tab can be used to aid in tensioning the mesh implant
A Comparative Transobturator Sling Matrix

The PrecisionBlue™ Design is a set of enhanced features designed to provide smooth sling placement, intra-operative adjustability with minimal tissue disruption and increased physician visualization that aids in precise sling placement.

<table>
<thead>
<tr>
<th>Transobturator Device</th>
<th>Sling Delivery Force</th>
<th>Mesh Holding Force</th>
<th>Sleeve Removal Force</th>
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<td>AMS MonArc™ Sling System</td>
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</tr>
</tbody>
</table>

The Obtryx II Sling System requires
- 54% less delivery force than the MonArc Sling
- 70% less than Bard Align TO Sling
- 62% less than TVT-O
- 69% less than Gynecare TVT-Abbrevo Sling

without sacrificing holding force.

The Obtryx II Sling System requires
- 91% less sleeve removal force than the MonArc Sling and Bard Align TO Sling
- 77% less than TVT-O
- 87% less than TVT-Abbrevo System

For all comparisons: Data on file with Boston Scientific

<sup>1</sup> Bench test sample size n=4. Test performed using a cadaver. Results from case studies not predictive of results in other cases. Results in other cases may vary.

<sup>2</sup> Bench test sample size n=15. Test performed using a cadaver. Results from case studies not predictive of results in other cases. Results in other cases may vary.

<sup>3</sup> Bench test sample size n=4. Test performed using a cadaver. Results from case studies not predictive of results in other cases. Results in other cases may vary.
## Characteristics of Transobturator Slings Systems

<table>
<thead>
<tr>
<th>Transobturator Device</th>
<th>Boston Scientific Obtryx™ II Sling System</th>
<th>Boston Scientific Obtryx Sling System</th>
<th>AMS MonArc™ Sling</th>
<th>Bard Align™ TO Sling</th>
<th>Gynecare TVT-O Sling</th>
<th>Gynecare TVT Abbrevio™ Sling</th>
<th>Coloplast Aris™ Sling</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Trocar Design</strong>⁴</td>
<td>Two options - Halo and Curved</td>
<td>Two options - Halo and Curved</td>
<td>Three options - MonArc, MonArc C, Standard MonArc</td>
<td>Two options - Halo and Hook</td>
<td>Helical passers with Winged Guided Insertion Zone tool</td>
<td>Helical passers with Winged Guided Insertion Zone tool</td>
<td>Two options - Flat curved and helical introducers</td>
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<tr>
<td><strong>Approach</strong>⁵</td>
<td>Outside In</td>
<td>Outside In</td>
<td>Outside In</td>
<td>Outside In</td>
<td>Inside Out</td>
<td>Inside Out</td>
<td>Outside In</td>
</tr>
<tr>
<td><strong>Mesh edges/Features</strong>⁴</td>
<td>Tanged/De-tanged (heat sealed mid-section)</td>
<td>Tanged/De-tanged (heat sealed mid-section)</td>
<td>Tanged/Tensioning Suture</td>
<td>Tanged</td>
<td>Tanged</td>
<td>Tanged</td>
<td>Not tanged, sealed edges</td>
</tr>
<tr>
<td><strong>Mesh Thickness</strong>⁴</td>
<td>0.66 mm</td>
<td>0.66 mm</td>
<td>0.66 mm</td>
<td>0.62 mm</td>
<td>0.63 mm</td>
<td>0.63 mm</td>
<td>0.27 mm</td>
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<tr>
<td><strong>Pore Size</strong>⁴</td>
<td>1182 um</td>
<td>1182 um</td>
<td>1000 um</td>
<td>1160 um</td>
<td>1379 um</td>
<td>1379 um</td>
<td>374 um</td>
</tr>
<tr>
<td>**Fiber Size (diameter)**⁴</td>
<td>0.15 mm</td>
<td>0.15 mm</td>
<td>0.15 mm</td>
<td>0.13 mm</td>
<td>0.15 mm</td>
<td>0.15 mm</td>
<td>0.08 mm</td>
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<tr>
<td>**Weight (g/M²)**⁴</td>
<td>100</td>
<td>100</td>
<td>110</td>
<td>81</td>
<td>100</td>
<td>100</td>
<td>70</td>
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<tr>
<td><strong>Mesh Color</strong>⁵</td>
<td>Blue</td>
<td>White</td>
<td>White</td>
<td>White</td>
<td>Blue</td>
<td>Blue</td>
<td>White</td>
</tr>
<tr>
<td><strong>Center Tab</strong>⁵</td>
<td>Plastic tab marks center and can be used to aid in intra-operative tensioning</td>
<td>Plastic tab marks center</td>
<td>Blue dot mark center</td>
<td>Peel off sticker marks center</td>
<td>No center tab, split in sleeve marks center</td>
<td>Plastic tab on suture loop marks center</td>
<td>No center tab</td>
</tr>
<tr>
<td><strong>Sleeve coverage at suburethral segment</strong>⁵</td>
<td>No sleeve coverage</td>
<td>Sleeve coverage</td>
<td>Covered, split in sleeve</td>
<td>Sleeve coverage</td>
<td>Covered, split in sleeve</td>
<td>Split in sleeve at center</td>
<td>No sleeve coverage on the entire sling</td>
</tr>
</tbody>
</table>

---


⁵ MUS Sling Comparison Review
October 18, 2012

Dear Valued Customer,

Thank you for your inquiry regarding Boston Scientific product Obtryx™ II System - Transobturator Sling System with PrecisionBlue™ Design. This information is provided in response to your direct request for information concerning the regulatory status of these products within the USA and may not be used for any other purpose without the expressed written permission of Boston Scientific.

Obtryx™ II System - Transobturator Sling System with PrecisionBlue™ Design is marketed in accordance with the U.S. Food and Drug Administration (FDA) regulations 21 CFR 878.3300. This product was cleared to market by the FDA on October 10, 2012 via 510(k) K121754. Attached you will find a copy of this clearance letter.

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

Sincerely,

Regulatory Affairs

enclosure
Ms. Janet A. McGrath  
Principal Specialist Global Regulatory Affairs  
Boston Scientific Corporation  
100 Boston Scientific Way, M21  
MARLBOROUGH MA 01752

Re: K121754  
Trade/Device Name: Obtryx II System  
Regulation Number: 21 CFR § 878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: II  
Product Code: OTN  
Dated: September 19, 2012  
Received: September 20, 2012

Dear Ms. McGrath:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA).

You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 896. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device adverse events).
device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRHOFFices/um115809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

[Signature]

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use Statement

S10(k) Number (if Known): K121754

Device Name: Obtryx II System

Indications For Use:
The mesh transplant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from hypermobility and/or intrinsic sphincter deficiency.

Prescription Use X AND/OR Over-The-Counter Use (21 CFR 801 Subpart D)

Concurrence of CDRII, Office of Device Evaluation (ODE)

Traditional S10(k)
Obtryx II System
Directions for Use - Curved Needle

Dual manufactured product; no change in content as of January 11, 2017. For current version refer to the DFU packaged with the product.
Obtryx™ II System

Transobturator Sling System with PrecisionBlue™ Design

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician trained in the use of surgical mesh for repair of stress urinary incontinence.

**WARNING**

Contents supplied STERILE using 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 diseases(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.

**WARNING**

This product is intended for use only by clinicians with adequate training and experience in the surgical treatment of stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.

**DEVICE DESCRIPTION**

The Obtryx II System is a sterile, single use system consisting of two (2) delivery devices and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh with dilator legs and a center tab. At the distal ends of the dilator legs there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen.

**INDICATIONS FOR USE**

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

**CONTRAINDICATIONS**

The mesh suburethral sling implant is contraindicated in the following patients:

- Pregnant patients, patients with potential for future growth or patients that are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

**HOW SUPPLIED**

The device is supplied sterile. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

**DIRECTIONS FOR USE**

Prior to Use

Carefully examine the system to verify that neither the contents nor the sterilized package has been damaged in shipment. DO NOT USE if sterile barrier on product is damaged. Immediately return damaged product to Boston Scientific.

The design of the Obtryx™ II System allows the operator a percutaneous approach utilizing a transobturator technique. See Figure 1 for parts description.

**Handling and Storage**

Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label.

**Figure 1: Parts Description**

Prepare and drape the patient using standard surgical practice.

**WARNING**

Assure that the bladder is empty prior to initiating the use of this product. Ensure that the bladder, urethra and other important landmarks are properly identified.

**Steps to Use**

1. Prepare the skin lateral to the inferior pubic ramus and vaginal operative sites.
2. Make a 1.0 cm to 1.5 cm vertical midline incision on the anterior vaginal wall at the level of the mid-urethra. Dissect bilaterally to the interior portion of the inferior pubic rami at the 45° angle off the midline creating a pathway for delivery device placement.
3. Create a vertical skin incision large enough to insert tip of needle just lateral to the edge of the inferior pubic rami at the junction where the inferior pubic rami and the adductor longus muscle meet. Repeat on the contralateral side.
4. Grasp the device handle and insert one (1) needle through one (1) skin incision, piercing through the obturator muscle and obturator membrane. Turn the handle at the 45° angle medial towards the midline. Place the opposite hand's forefinger into the lateral dissection of the vaginal incision, placing the fingertips on the distal end of the needle. Guide the distal end of the needle around the inferior pubic rami through the vaginal incision, maintaining contact with the finger.
5. Engage one (1) association loop to the distal end of the needle (see Figure 2) protruding through the vagina.

**Figure 2: Association Loop Engagement**

Dual manufactured product; no change in content as of January 11, 2017.

For current version refer to the DFU packaged with the product.
Directions for Use: Curved Needle (cont.)

6. Pull the needles out through the skin incision. Be sure that the mesh assembly is not twisted and lies flat under the urethra, with the blue center tab positioned suburethrally, facing outward.

7. Remove the association loop from the needle (see Figure 3).

Figure 3: Association Loop Removal

8. Repeat Steps 4-7 on the contralateral side with the second needle.

9. Cystoscopy may be performed at this time, to be determined at the physician's discretion.

10. Next see section “Tension Mesh/Sleeve Removal.”

TENSION MESH/SLEEVE REMOVAL

1. Adjust the mesh/sleeve by pulling outwards on the dilators so that the blue center tab is centered below the urethra.

2. Appropriately tension the mesh/sleeve according to physician preference.

3. Once proper tension is achieved, cut the leader loop that is on the outside of the sleeve that is connecting the dilator leg and sleeve to the mesh. Pull outward on the dilator to remove the sleeve leaving the mesh in place. Repeat on the other side. (See Figure 4).

4. Grasp the blue center tab and cut the center tab lead located on the vaginal side of the center tab to release the tab from the mesh. Remove the center tab and center tab lead from the vaginal canal.

5. Gently pushing downward on the skin incisions, cut the distal ends of the mesh and confirm that those ends retract into the skin incisions.

6. Close all incisions per standard practice.

• The patient should be advised that future pregnancies may negate the effects of this procedure and the patients may again become incontinent.

ADVERSE EVENTS

The following adverse events have been reported due to suburethral sling placement, but are not limited to:

• As with all implants, local irritation at the wound site and/or a foreign body response may occur.

• Tissue responses to the mesh implant could include:
  - erosion/exposure/erosion of the mesh through the vaginal or urethral mucosa, bladder wall or other surrounding tissue
  - scarring/tissue contracture
  - device migration
  - fistula formation and inflammation

The occurrences of these events may require surgical intervention and possible removal of the entire mesh.

• Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.

• Allergic reaction has been reported.

• Known risks of surgical procedures for the treatment of incontinence include:
  - pain, ongoing pain (pelvic, vaginal, groin/thigh, dyspareunia)
  - infection
  - detrusor instability
  - complete failure of the procedure
  - voiding dysfunction (incontinence, mild to moderate incontinence due to incomplete urethral support or due to overactive bladder)
  - bruising, bleeding (vaginal, hematoma formation)
  - abscess
  - vaginal discharge
  - dehiscence of vaginal incision
  - edema and erythema at the wound site
  - perforation or laceration of vessels, nerves, bladder, urethra or bowel may occur during placement.

The occurrence of these events may require surgical intervention. In some instances the response to these events may persist as a permanent condition after the intervention.

PRECAUTIONS

• The use of polypropylene mesh in urogynecologic procedures such as the treatment of stress urinary incontinence regardless of the route of delivery (transvaginal, suprapubic or transobturator), has been associated with cases of erosion. Erosion has been reported in bladder, vagina, urethra, ureter, and bowel. Treatment of the erosion may require surgical removal.

• As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. The above pathophysiologic conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation, either by transvaginal, suprapubic or transobturator route.

• Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.

• Bleeding can occur. Check carefully before releasing patient from the hospital.

• Do not remove the protective plastic sleeve covering mesh implant until proper position has been confirmed.

• Ensure the mesh is placed without tension under the mid-urethra.

• Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.

• Physician should determine when it is suitable for each patient to return to normal activities.

• Patients should be counseled when to resume vigorous activities (heavy lifting, exercises), and intercourse after the procedure.

• Should dysuria, bleeding or other problems occur, the patient should be instructed to immediately contact the physician.
• Do not use any mechanical means of contact with the mesh (such as clips, staples etc.) within the urethral support region of the mesh as mechanical damage to the mesh may occur.

• Avoid excessive tension on the mesh during handling.

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. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC’s control directly affect the instrument and the results obtained from its use. 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 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.
Directions for Use: Curved Needle (cont.)

Sterilized using ethylene oxide.

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<thead>
<tr>
<th>Country</th>
<th>Local Contact</th>
</tr>
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<tr>
<td>AUS</td>
<td>Australian Sponsor Address</td>
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<td>ARG</td>
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</tr>
<tr>
<td>BRA</td>
<td>Brazil Local Contact</td>
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Directions for Use: Halo Needle

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Dual manufactured product; no change in content as of January 11, 2017.
For current version refer to the DFU packaged with the product.
**Obtryx™ II System**

Transobturator Sling System with PrecisionBlue™ Design

**Directions for Use: Halo Needle (cont.)**

### Handling and Storage

Store at a controlled room temperature. Do not expose to organic solvents, ionizing radiation or ultraviolet light. Rotate inventory so that products are used prior to the expiration date on package label.

### DIRECTIONS FOR USE

Prior to Use

Carefully examine the system to verify that neither the contents nor the sterilized package has been damaged in shipment. DO NOT USE if sterile barrier on product is damaged. Immediately return damaged product to Boston Scientific.

The design of the Obtryx™ II System allows the operator a percutaneous approach utilizing a transobturator technique. See Figure 1 for parts description.

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

#### FREEZE, IT ONLY

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician trained in use of surgical mesh for repair of stress urinary incontinence.

**WARNING**

- Contents supplied STERILE using 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 re-use, reprocess or resterilize. Re-use, 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. Re-use, reprocessing or resterilization may 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.
- All use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

**WARNING**

This product is intended for use only by clinicians with adequate training and experience in the surgical treatment of stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.

**DEVICE DESCRIPTION**

The Obtryx II System is a sterile, single use system consisting of two (2) delivery devices (one patient right and one patient left) and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh with dilator legs and a center tab. At the distal ends of the dilator legs there are association loops designed to be placed in the needle slot of the distal end of the delivery device. The disposable delivery device consists of a handle with a stainless steel needle. The needle is designed to facilitate the passage of the mesh assembly through bodily tissues for placement through the obturator foramen.

**INDICATIONS FOR USE**

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

**CONTRAINDICATIONS**

The mesh suburethral sling implant is contraindicated in the following patients:

- Pregnant patients, patients with potential for future growth or patients that are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

**HOW SUPPLIED**

The device is supplied sterile. Do not use if package is opened or damaged. Do not use if labeling is incomplete or illegible.

---

**Figure 1: Parts Description**

![Diagram of Halo Needle](image)

Prepare and drape the patient using standard surgical practice.

**WARNING**

Assure that the bladder is empty prior to initiating the use of this product. Ensure that the bladder, urethra and other important landmarks are properly identified.

**Steps to Use**

1. Prepare the skin lateral to the inferior pubic ramus and vaginal operative sites.
2. Make a 1.0 cm to 1.5 cm vertical midline incision on the anterior vaginal wall at the level of the mid-urethra. Dissect bilaterally to the inferior pubic rami at the 45° angle off the midline creating a pathway for delivery device placement.
3. Create a vertical skin incision large enough to insert tip of needle just lateral to the edge of the inferior pubic rami at the junction where the inferior pubic rami and the adductor longus muscle meet. Repeat on the contralateral side.
4. Grasp the device handle for the patient’s left side with the right hand. Place the left forefinger into the lateral dissection of the vaginal incision. Place the needle tip into the skin incision perpendicular to the skin with the handle at a 45° angle parallel with the thigh.
5. Putting the left thumb on the outside of the needle curve, apply a downward force, piercing through the obturator muscle and membrane.
6. Rotate the needle medially around the inferior pubic rami to meet the left hand forefinger. Guide the needle tip through the vaginal incision.
7. Engage one (1) association loop to the distal end of the needle (see Figure 2) protruding through the vagina.
Directions for Use: Halo Needle (cont.)

1. Adjust the mesh/sleeve by pulling outwards on the dilators so that the tension mesh/sleeve removal

2. Appropriately tension the mesh/sleeve according to physician preference.

11. Cystoscopy may be performed at this time, to be determined at the figure 3: Association Loop Removal

12. Next see section "Tension Mesh/Sleeve Removal."

TENSION MESH/SLEEVE REMOVAL

1. Adjust the mesh/sleeve by pulling outwards on the dilators so that the blue center tab is centered below the urethra.
2. Appropriately tension the mesh/sleeve according to physician preference.
3. Once proper tension is achieved, cut the leader loop that is on the outside of the sleeve that is connecting the dilator leg and sleeve to the mesh. Pull outward on the dilator to remove the sleeve leaving the mesh in place. Repeat on the other side. (See Figure 4).

Figure 3: Association Loop Removal

Figure 4: Tension Mesh/Sleeve Removal

4. Grasp the blue center tab and cut the center tab lead located on the side of the center tab to release the tab from the mesh. Remove the center tab and center tab lead from the vaginal canal.
5. Gently pushing downward on the skin incisions, cut the distal ends of the mesh and confirm that those ends retract into the skin incisions.
6. Close all incisions per standard practice.

GENERAL WARNING

The risks and benefits of performing a suburethral sling procedure in the following should be carefully considered:
- Careful consideration should be given to performing this procedure for patients with untreated coagulopathies or who are being treated with either anticoagulants or antiplatelet agents.
- Patients with hypotonic bladders or vesicoureteral reflux.
- Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires a cystocele repair, it should be done prior to the suburethral sling procedure.
- Vaginal and urinary tract infection should be treated prior to a suburethral sling implantation procedure.
- User should be familiar with surgical procedures and techniques involving nonabsorbable meshes.
- Good surgical practices should be followed for management of contamination or infected wounds.
- Mesh is considered a permanent implant. Removal of mesh or correction of mesh related complication may involve multiple surgeries.

- Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

POST PROCEDURAL WARNING

- If subsequent infection occurs, follow appropriate medical intervention practices.
- The patient should be advised that future pregnancies may negate the effects of this procedure and the patients may again become incontinent.

ADVERSE EVENTS

The following adverse events have been reported due to suburethral sling placement, but are not limited to:
- As with all implants, local irritation at the wound site and/or a foreign body response may occur.
- Tissue responses to the mesh implant could include:
  - erosion/exposure/extrusion of the mesh through the vaginal or urethral mucosa, bladder wall or other surrounding tissue
  - scarring/scar contracture
  - device migration
  - fistula formation and inflammation

The occurrence of these events may require surgical intervention and possible removal of the entire mesh.
- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Allergic reaction has been reported.
- Known risks of surgical procedures for the treatment of incontinence include:
  - pain, ongoing pain (pelvic, vaginal, groin, thigh, dyspareunia)
  - infection
  - detrusor instability
  - complete failure of the procedure
  - voiding dysfunction (incontinence, mild to moderate incontinence due to incomplete urethral support or due to overactive bladder)
  - bruising, bleeding (vaginal, hematoma formation)
  - abscess
  - vaginal discharge
  - dehiscence of vaginal incision
  - edema and erythema at the wound site
  - perforation or laceration of vessels, nerves, bladder, urethra or bowel may occur during placement.

The occurrence of these events may require surgical intervention. In some instances the response to these events may persist as a permanent condition after the intervention.

PRECAUTIONS

- The use of polypropylene mesh in urogynecologic procedures such as the treatment of stress urinary incontinence regardless of the route of delivery (transvaginal, suprapubic or transobturator), has been associated with cases of erosion. Erosion has been reported in bladder, vagina, urethra, uterus, and bowel. Treatment of the erosion may require surgical removal.
- As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. The above pathophysiologic conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation, either by transvaginal, suprapubic or transobturator route.
- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- Bleeding can occur. Check carefully before releasing patient from the hospital.
- Do not remove the protective plastic sleeve covering mesh implant until proper position has been confirmed.
- Ensure the mesh is placed without tension under the mid-urethra.
- Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.
Directions for Use: Halo Needle (cont.)

- Physician should determine when it is suitable for each patient to return to normal activities.
- Patients should be counseled when to resume vigorous activities (heavy lifting, exercise), and intercourse after the procedure.
- Should dysuria, bleeding or other problems occur, the patient should be instructed to immediately contact the physician.
- Do not use any mechanical means of contact with the mesh (such as clips, staples etc.) within the urethral support region of the mesh as mechanical damage to the mesh may occur.
- Avoid excessive tension on the mesh during handling.

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. Handling, storage, cleaning and sterilization of this instrument as well as other factors relating to the patient, diagnosis, treatment, surgical procedures and other matters beyond BSC's control directly affect the instrument and the results obtained from its use. 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.
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For current version refer to the DFU packaged with the product.
Solyx™
Single Incision Sling System

Product Overview
Regulatory Information
Directions for Use
Solyx Single-Incision Sling System

The Solyx SIS System is a single incision sling system designed to be a potentially more efficient option in the treatment of stress urinary incontinence. The Solyx System is an innovative mid-urethral sling system that offers several advancements in delivery and tensioning – all built on the proven Advantage™ Mesh platform. The Solyx SIS System mesh is 9cm long. The Solyx SIS System is designed for minimal dissection which simplifies sling placement and reduces risk.

**DE-TANGED POLYPROPYLENE MATERIAL**

- **De-Tanged Edges**
  - Designed to Reduce Irritation
  - The polypropylene mesh is de-tanged in the suburethral portion to potentially reduce irritation to the urethral wall.
- **Suburethral Portion**
  - Resists Deformation
  - The suburethral portion of the mesh is de-tanged to resist deformation.
Mesh Carrier

- The barb design is intended to track smoothly through tissue
- Snap-fit to delivery device is designed to help prevent premature carrier slip off

Delivery Device

- Designed to seat carrier where placed
- Ergonomic handle design

Ability to Tighten

- Tensioning by delivery device advancement
- Carrier snap-fit on delivery device tip designed to facilitate placement control

Ability to Loosen

- With carrier snap-fit on the delivery device tip, the delivery device is designed to allow retraction if needed

Note: Once the carrier is deposited in tissue, it is not designed to be reconnected onto the shaft tip for additional tension/adjustment

- Mesh assembly placement is designed to be away from critical structures, such as the obturator bundle
January 11, 2017

Dear Valued Customer,

Thank you for your inquiry regarding Boston Scientific product, Solyx SIS™ System. This information is provided in response to your direct request regarding the regulatory status of these products and may not be used for any other purpose without the expressed written permission of Boston Scientific.

| M0068507000 | Solyx SIS™ System | Single |

The Solyx SIS™ System is marketed in accordance with USA Food and Drug Administration (FDA) regulations 21 CFR 878.3300 and 21 CFR 876.4730. The 510K that supports this product was originally cleared by the FDA on August 27, 2008 via 510(k) K081275 and subsequently updated on September 28, 2012. Attached you will find a copy of the updated clearance letter.

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

Sincerely,

Regulatory Affairs

Enclosure
Ms. Janet A. McGrath  
Principal Regulatory Affairs Specialist  
Boston Scientific Corporation  
100 Boston Scientific Way  
MARLBOROUGH MA 01752

Re: K081275  
Trade/Device Name: Surgical Mesh, (SIS)  
Regulation Number: 21 CFR §878.3300  
Regulation Name: Surgical mesh  
Regulatory Class: II  
Product Code: PAH  
Dated: August 13, 2008  
Received: August 14, 2008

Dear Ms. McGrath:

This letter corrects our substantially equivalent letter of August 27, 2008.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA’s issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must
comply with all the Act’s requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CenterRefPages/CDRH/CDRHOffice/industry115809.htm for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. Also, please note the regulation entitled, “Misbranding by reference to premarket notification” (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH’s Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

[Signature]

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal, and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure
Indications for Use Statement

510(k) Number (if Known): K081275

Device Name: Surgical Mesh, (SIS)

Indications For Use:

The mesh implant is intended for use as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Prescription Use __X__ AND/OR Over-The-Counter Use (21 CFR 801 Subpart D)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concerence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K081275
Directions for Use

Solyx™
SIS System

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For current version refer to the DFU packaged with the product.
### Solyx™ SIS System

**Instructions for Use**

The mesh implant is intended for use as a suburethral sling through the obturator internus muscle. The delivery device is designed to facilitate the passage of the mesh assembly through bodily tissues for placement into the obturator internus muscle.

**Contraindications**

A mesh implant is contraindicated in the following patients:

- Patients with any pathology that would limit blood supply or growth or patients who are considering future pregnancies.
- Patients with hypertonic bladders or vesico ureteral reflux.
- Careful consideration should be given to performing this procedure for patients with untreated coagulopathies or who are being treated with either anticoagulants or antiplatelet agents.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology that would limit blood supply or infections that would compromise healing.

**Warnings**

- Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.
- If subsequent infection occurs, follow appropriate medical intervention practices.
- Treatment of the erosion may require surgical removal.
- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- Bleeding can occur. Check carefully before releasing patient from the hospital.
- Ensure the mesh is placed tension free under the mid-urethra.
- Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.
- Physician should determine when it is suitable for each patient to return to normal activities.
- Patients should be counseled when to resume vigorous activities (heavy lifting, exercise), or active infection in or near the surgical site. The above pathophysiological conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation, either by transvaginal, suprapubic or transobturator route.
- Warnings 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.

**Device Description**

The Solyx SIS (Single Incision Sling) System is a sterile single use system consisting of one (1) delivery device and one (1) mesh assembly. The mesh assembly is comprised of a polypropylene knitted mesh with polypropylene carries at each end of the distal mesh. The carrier is designed to be placed on the tip of the delivery device. The disposable delivery device consists of a handle, a stainless steel shaft and a deployment mechanism. The delivery device is designed to facilitate the passage of the mesh assembly through bodily tissues for placement into the obturator internus muscle.

---

**General Warning**

The risks and benefits of performing a suburethral sling procedure in the following patients should be carefully considered:

- Vaginal and urinary tract infection should be treated prior to a suburethral sling implantation procedure.
- User should be familiar with surgical procedures and techniques involving nonabsorbable meshes.
- Good surgical practices should be followed for the management of contamination or infected wounds.
- Mesh is considered a permanent implant. Removal of mesh or correction of mesh related complications may involve multiple surgeries.

**Post Procedural Warning**

- Good surgical practices should be followed for the management of contamination or infected wounds.
- User should be familiar with surgical procedures and techniques involving nonabsorbable meshes.
- As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. The above pathophysiological conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation, either by transvaginal, suprapubic or transobturator route.

**Contraindications**

- The use of polypropylene mesh in urogynecologic procedures such as the treatment of stress urinary incontinence, regardless of the route of delivery (transvaginal, suprapubic or transobturator), has been associated with cases of erosion. Erosion has been reported in bladder, vagina, urethra and ureter, and bowel.
- Treatment of the erosion may require surgical removal.
- As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. The above pathophysiological conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation, either by transvaginal, suprapubic or transobturator route.
- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- Bleeding can occur. Check carefully before releasing patient from the hospital.
- Ensure the mesh is placed tension free under the mid-urethra.
- Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.
- Physician should determine when it is suitable for each patient to return to normal activities.
- Patients should be counseled when to resume vigorous activities (heavy lifting, exercise), or active infection in or near the surgical site. The above pathophysiological conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation, either by transvaginal, suprapubic or transobturator route.
Directions for Use (cont.)

Do not use any mechanical means of contact with the mesh (such as clips, staples, etc.) within the urethral support region of the mesh as mechanical damage to the mesh may occur.

Avoid excessive tension on the mesh during handling.

ADVERSE EVENTS
The following adverse events have been reported due to suburethral sling placement, but are not limited to:

- As with all implants, local irritation at the wound site and/or a foreign body may occur.
- Tissue responses to the mesh implant could include:
  - erosion/exposure/ extrusion of the mesh through the vaginal or urethral mucosa, bladder wall or other surrounding tissue
  - scarring/scar contracture
  - device migration
  - fistula formation and inflammation

The occurrences of these events may require surgical intervention and possible removal of the entire mesh.

- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
- Allergic reaction has been reported.
- Known risks of surgical procedures for the treatment of incontinence include:
  - pain, ongoing pain (pelvic, vaginal, groin/thigh, dyspareunia)
  - infection
  - detrusor instability
  - complete failure of the procedure
  - voiding dysfunction (incontinence, mild to moderate incontinence due to incomplete urethral support or due to overactive bladder)
  - bruising, bleeding (vaginal, hematoma formation)
  - abscess
  - vaginal discharge
  - dehiscence of vaginal incision
  - edema and erythema at the wound site
  - Perforation or laceration of vessels, nerves, bladder or urethra may occur during placement.

The occurrence of these events may require surgical intervention. In some instances the response to these events may persist as a permanent condition after the intervention.

HOW SUPPLIED
The Solyx™ SIS System is a sterile, single use system consisting of one (1) delivery device and one (1) mesh assembly. Do not use if packaging is opened or damaged. Do not use if labeling is incomplete or illegible.

Store in a cool, dry, dark place. Rotate inventory so that devices are used prior to the expiration date displayed on package label.

OPERATIONAL INSTRUCTIONS
Prior to Use
The Solyx SIS System is supplied sterile and is intended for single patient use only. Carefully examine the system to verify that neither the contents nor the sterilized package has been damaged in shipment. DO NOT USE if the sterile barrier or product is damaged. Immediately return damaged product to Boston Scientific. The design of the Solyx SIS System allows the operator a transvaginal route of delivery. See Figure 1 for parts description.
Directions for Use (cont.)

**PRECAUTION**

Hold each side of the mesh carrier (See Figure 3) to avoid possible glove puncture.

*Figure 3: Mesh Assembly Placement onto Delivery Device*

5. Insert the delivery device into the dissection pathway targeting placement of the carrier at a 45° angle off the midline. (See Figure 5) Advance the delivery device towards the obturator foramen just lateral to the inferior pubic ramus (See Figure 5) until the midline mark on the delivery device is approximately at the midline position under the urethra. Deposit the carrier by gripping the deployment mechanism with one hand and pulling the delivery device handle back with the other hand (See Figure 6). This action will deposit the carrier into surrounding muscle tissue releasing it from the delivery device.

**NOTE:** Once the carrier is deposited in tissue, it is not designed to be reconnected onto the shaft tip for additional tension/adjustment.

**WARNING**

If excessive resistance is encountered during advancement/withdrawal, stop and determine remedial action prior to proceeding.

*Figure 4: Mesh Orientation on Delivery Device*

*Figure 5.

*Figure 6.

*Figure 7.

6. Remove the delivery device from the incision. Bring the deployment mechanism back to start position, flush with the handle (See Figure 7).

**NOTE:** Once the carrier is deposited in tissue, it is not designed to be reconnected onto the shaft tip for additional tension/adjustment.

7. Place the second mesh carrier onto the delivery device following instructions from Step 4. Make sure that the mesh is not twisted so that it will lie flat under the urethra when placement is complete.

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For current version refer to the DFU packaged with the product.
Directions for Use (cont.)

8. Insert the delivery device into the dissection pathway on the contralateral side targeting placement of the carrier at a 45° angle off the midline (See Figure 8). Advance the delivery device towards the obturator foramen just lateral to the inferior pubic ramus (See Figure 8) until appropriate mesh placement is achieved. Deposit the carrier by gripping the deployment mechanism with one hand and pulling the delivery device handle back with the other hand (See Figure 8). This action will deposit the carrier into surrounding muscle tissue, releasing it from the delivery device.

Figure 8: Contralateral Delivery Device Placement

9. Remove the delivery device from the incision.
10. Cystoscopy may be performed at this time, to be determined at the physician's discretion.
11. Close incisions according to usual methods.

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, with no warranties, express or implied, including but not limited to, any implied warranties of merchantability 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 assumes no liability with respect to such instruments. 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.

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Do Not Resterilize
No resterilizar
Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize

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

Sterile
Esterilizado
Étérilisé
Mit Ethylenoxid sterilisiert.
Sterilizzato
Gesteriliseerd
Esterilizado por óxido de etileno.

STERILE EO

Recyclable Package

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DFU: Solyx™ SIS System

Notes
### Clinical/Scientific Data

**Advantage™ System**

<table>
<thead>
<tr>
<th>Lead Author</th>
<th>Title</th>
<th>Publication/Conference</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Basu, M</td>
<td>Three-year results from a randomised trial of a retropubic mid-urethral sling vs the Miniarc single incision sling for SUI</td>
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**Advantage System / Obtryx™ System**

<table>
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<tbody>
<tr>
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<td>Efficacy and Safety of Transobturator Tape (Obtryx) in Women with Stress Urinary Incontinence and Intrinsic Sphincter Deficiency Results from International Obtryx Registry</td>
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</table>

**CAUTION:** Federal Law (USA) restricts these devices to sale by or on the order of a physician trained in use of surgical mesh for repair of stress urinary incontinence. 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.
Obtryx™ System

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<td>TVT and TOT: a comparison between these two techniques based on our clinical experience</td>
<td>Urologia</td>
<td>2011</td>
</tr>
<tr>
<td>Wilson, C</td>
<td>Short-term Efficacy of a Transobturator Sling in Women Veterans with a history of Sexual Trauma</td>
<td>MAAUA</td>
<td>2010</td>
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Clinical/Scientific Data (cont.)

**Lynx™ System**

<table>
<thead>
<tr>
<th>Lead Author</th>
<th>Title</th>
<th>Publication/Conference</th>
<th>Year</th>
</tr>
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<tbody>
<tr>
<td>Noblett, K</td>
<td>Lynx midurethral sling system: a 1-year prospective study on efficacy and safety</td>
<td>International Urogynecology Journal</td>
<td>2008</td>
</tr>
</tbody>
</table>

**Solyx™ SIS System**

<table>
<thead>
<tr>
<th>Lead Author</th>
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</tr>
</thead>
<tbody>
<tr>
<td>Serels, S</td>
<td>Preliminary findings with the Solyx™ single-incision sling system in female stress urinary incontinence</td>
<td>International Urogynecology Journal</td>
<td>2010</td>
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<tr>
<td>Serels, S</td>
<td>Cadaveric Assessment of Synthetic Mid-Urethral Sling Placement</td>
<td>Open J of Urology</td>
<td>2011</td>
</tr>
<tr>
<td>Serels, S</td>
<td>Safety and Efficacy of the Solyx Single Incision Sling System for the Treatment of SUI: Preliminary Results</td>
<td>UroToday International</td>
<td>2011</td>
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<tr>
<td>Serels, S</td>
<td>Cadaveric Assessment of Immediate Pull-Out Strength of the Three Common Synthetic Sling Approaches; Single Incision, Retropubic, and Transobturator</td>
<td>ICS/IUGA</td>
<td>2010</td>
</tr>
<tr>
<td>Serels, S</td>
<td>Long Term Follow up of the Solyx Single Incision Sling in the Treatment of Female Stress Urinary Incontinence (SUI)</td>
<td>Open J of Urology</td>
<td>2014</td>
</tr>
</tbody>
</table>
Reimbursement Guide & Ordering Information

Advantage™ & Advantage Fit™
Transvaginal Mid-Urethral Sling Systems

Lynx™
Suprapubic Mid-Urethral Sling System

Obtryx™
Transobturator Mid-Urethral Sling System

Obtryx™ II
Transobturator Mid-Urethral Sling System

Solyx™ SIS System
Single Incision Sling System
Reimbursement Guide

Reimbursement for Mid-Urethral Slings

Is this product reimbursable by insurance?
The procedures for which it is used are reimbursable. Billing guides with respective coding and estimated Medicare National Average reimbursement for sling operation for stress incontinence procedures are available online at www.bostonscientific.com/reimbursement. For additional coding and reimbursement information, contact your local Territory Manager or the Urology and Women’s Health Reimbursement Help Desk at UroWH.reimb@bsci.com or 1-508-683-4022.

What is the Medicare Pass-Through Code (aka C-code or HCPCS)?
The Medicare Pass-Through Code for this product is C1771 (repair device, urinary, incontinence, with sling graft).

Is this a patient-chargeable product?
“Patient chargeable” is a colloquial term used to convey that a device/supply is appropriately charged to the patient’s account (i.e. as a distinct line item on the patients 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 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.
**Reimbursement**

**Relevant Reimbursement Codes:**
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<tbody>
<tr>
<td>Sling Procedure</td>
<td>5415</td>
<td>57288 – Sling operation for stress incontinence (eg. fascia or synthetic)</td>
<td>0TSC0ZZ – Reposition Bladder Neck, Open Approach</td>
<td>0TQD0ZZ – Repair Urethra, Open Approach</td>
<td>748 – Uterine and Adnexa Procedures for Nonmalignancy with CC/MCC1</td>
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<td>0TSC4ZZ – Reposition Bladder Neck, Percutaneous Endoscopic Approach</td>
<td>0TQD3ZZ – Repair Urethra, Percutaneous Approach</td>
<td>662 – Minor bladder procedures with major complication or comorbidity (MCC)</td>
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<td>0TU07ZZ – Supplement Bladder Neck with Autologous Tissue Substitute, Open Approach</td>
<td>0TQD4ZZ – Repair Urethra, Percutaneous Endoscopic Approach</td>
<td>663 – Minor bladder procedures with complication or comorbidity (CC)</td>
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<td>0TU0KZZ – Supplement Bladder Neck with Autologous Tissue Substitute, Open Approach</td>
<td>0TQD7ZZ – Repair Urethra, Via Natural or Artificial Opening</td>
<td>664 – Minor bladder procedures without MCC/CC</td>
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<td>0TU07Z – Supplement Bladder Neck with Autologous Tissue Substitute, Percutaneous Endoscopic Approach</td>
<td>0TQD0ZZ – Repair Urethra, Via Natural or Artificial Opening Endoscopic</td>
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<td>0TU04ZZ – Supplement Bladder Neck with Synthetic Substitute, Open Approach</td>
<td>0TQD0ZZ – Repair Urethra, Via Natural or Artificial Opening Endoscopic</td>
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<td>0TU04JZ – Supplement Bladder Neck with Synthetic Substitute, Percutaneous Endoscopic Approach</td>
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<tr>
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<td></td>
<td>0TU08JZ – Supplement Bladder Neck with Synthetic Substitute, Via Natural or Artificial Opening</td>
<td>0TQD0ZZ – Repair Urethra, Via Natural or Artificial Opening Endoscopic</td>
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For additional coding and reimbursement questions please contact our Urology and Pelvic Health Reimbursement Help Desk at UroPH.reimb@bsci.com OR 1-508-683-4022.
Ordering Info for Mid-Urethral Slings

Advantage™ & Advantage Fit™

Transvaginal Mid-Urethral Sling Systems

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Product Name</th>
</tr>
</thead>
<tbody>
<tr>
<td>M0068502000</td>
<td>Advantage System (single unit)</td>
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<tr>
<td>M0068502110</td>
<td>Advantage Fit System (single unit)</td>
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Each System includes One (1) Delivery Device and One (1) Mesh Assembly

Lynx™

Suprapubic Mid-Urethral Sling System

<table>
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<th>Product Code</th>
<th>Product Name</th>
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<tr>
<td>M0068503000</td>
<td>Lynx System (single unit)</td>
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System includes Two (2) Delivery Devices and One (1) Mesh Assembly
### Obtryx™

**Transobturator Mid-Urethral Sling System**

<table>
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<th>Product Code</th>
<th>Product Name</th>
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<tr>
<td>M0068504000</td>
<td>Obtryx System - Curved (single unit)</td>
</tr>
<tr>
<td>M0068505000</td>
<td>Obtryx System - Halo (single unit)</td>
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</table>

Each System includes Two (2) Delivery Devices and One (1) Mesh Assembly

### Obtryx™ II

**Transobturator Mid-Urethral Sling System**

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<th>Product Code</th>
<th>Product Name</th>
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<tr>
<td>M0068504110</td>
<td>Obtryx II System - Curved (single unit)</td>
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<tr>
<td>M0068505110</td>
<td>Obtryx II System - Halo (single unit)</td>
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Each System includes Two (2) Delivery Devices and One (1) Mesh Assembly

### Solyx™ SIS System

**Single Incision Sling System**

<table>
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<th>Product Code</th>
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<tr>
<td>M0068507000</td>
<td>Solyx SIS System (single unit)</td>
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</table>

Each System includes One (1) Delivery Device and One (1) Mesh Assembly