Obtryx™ II

Transobturator Mid-urethral Sling System

Product Overview
Ordering Information
Regulatory Information
Directions for Use
Clinical/Scientific Data
Reimbursement Guide

Product Review for the Purchasing Committee
How can we continue to innovate our family of mid-urethral slings that have already been the products of choice for nearly 800,000 patients? By creating the same reliable mesh in an easy-to-see, optical blue color. So whatever your preferred surgical approach, Advantage™ Blue mesh provides improved visibility so you can treat your patients with confidence.

**Improved visibility. Evidence based.**
- The same mesh properties as our patented Advantage mesh, which is documented in more than 35 publications to date
- The easy-to-see, optical blue color helps to improve your visibility for more accurate intra-operative sling tensioning and makes it easier to locate post-operatively

**Trusted polypropylene mesh**
- Mesh thickness: 0.66 mm
- Pore size: 1182 μm
- Fiber size (diameter): 0.15 mm
- Weight: 100 g/m²
**Needle**
- Designed to facilitate transobturator device passage
- Two needle configurations (curved and halo) allow physicians to choose their preferred approach (curved and halo sold separately)

**Association loop**
- Facilitates needle and mesh engagement and removal

**Blue dilator leg**
- Designed to create a smooth transition from the needle to the mesh assembly
- Improves intra-operative visibility in the event of vaginal perforation
- Minimizes the force needed to deliver the mesh assembly through the patient’s anatomy

**Mesh assembly**
- No sleeve coverage under the suburethral segment to allow for mesh visibility and to aid in precise placement
- Reduced plastic sleeve minimizes the force needed to remove mesh assembly

**Blue centering tab**
- Allows for proper alignment of the center of the mesh under the urethra. It also allows the physician to apply counter tension to the sling while preserving the mesh integrity.
Fundamental difference in mesh design philosophy

<table>
<thead>
<tr>
<th>Feature</th>
<th>BSC</th>
<th>J&amp;J</th>
<th>Coloplast</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pore size (microns)²</td>
<td>1182</td>
<td>1379</td>
<td>374</td>
</tr>
<tr>
<td>Density (g/m²)</td>
<td>100</td>
<td>100</td>
<td>70</td>
</tr>
<tr>
<td>Elasticity</td>
<td>High</td>
<td>High</td>
<td>Low</td>
</tr>
<tr>
<td>Knit pattern</td>
<td>Tricot</td>
<td>Tricot</td>
<td>Warp knit, pillar stitch with inlay</td>
</tr>
<tr>
<td>Edge design</td>
<td>Tanged²</td>
<td>Tanged</td>
<td>Sealed</td>
</tr>
<tr>
<td>Color</td>
<td>Clear and Blue¹</td>
<td>Blue</td>
<td>Clear</td>
</tr>
</tbody>
</table>

Nearly 800,000 Boston Scientific mid-urethral slings with Advantage™ mesh have been implanted.

Ordering Information

Obtryx™ II Transobturator Mid-urethral Sling Systems

<table>
<thead>
<tr>
<th>Product code</th>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>M0068504110</td>
<td>Obtryx™ II Transobturator Sling System - Curved</td>
<td>2 Delivery Devices and 1 Mesh Assembly</td>
</tr>
<tr>
<td>M0068505110</td>
<td>Obtryx™ II Transobturator Sling System - Halo</td>
<td>2 Delivery Devices and 1 Mesh Assembly</td>
</tr>
</tbody>
</table>

2. Heat sealed mid-section
3. Advantage Blue mesh available for Advantage Fit, Advantage, Lynx, Obtryx II and Solyx
Regulatory Information

Regulatory Letter

January 8, 2018

Dear Valued Customer,

Thank you for your inquiry regarding Boston Scientific product, Obtryx™ II 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>Product Code</th>
<th>Description</th>
<th>Quantity</th>
</tr>
</thead>
<tbody>
<tr>
<td>M0068504110</td>
<td>Obtryx™ II System (Curved)</td>
<td>Single</td>
</tr>
<tr>
<td>M0068505110</td>
<td>Obtryx™ II System (Halo)</td>
<td>Single</td>
</tr>
</tbody>
</table>

The Obtryx™ II System is marketed in accordance with the 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 October 10, 2012 via 510(k) K121754. Attached you will find a copy of this 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
FDA 510K Clearance Letter

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

Re: K1231754
Trade/Device Name: Obtryx II System
Regulation Number: 21 CFR§ 878.3500
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 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/CentersOffices/CDRH/CDRHO ffices/ucm115809.htm](http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHO ffices/ucm115809.htm) for the Center for Devices and Radiological Health’s (CDRH’s) Office of Compliance. Also, please note the regulation entitled, “Mistreatment 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](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](http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm).

Sincerely yours,

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):  K121754

Device Name: Obtryx II System

Indications For Use:

The mesh implant 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)  (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)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number  K121754

Traditional 510(k)
Obtryx II System
Directions for Use

Curved Needle

Obtryx™ II
System
CURVED
Transobturator Sling with
PrecisionBlue™ Design

TABLE OF CONTENTS
WARNING ........................................................................................... 3
WARNING ........................................................................................... 3
DEVICE DESCRIPTION.................................................................... 3
INDICATIONS FOR USE .................................................................. 3
CONTRAINDICATIONS ................................................................... 3
HOW SUPPLIED ............................................................................. 4
Handling and Storage .................................................................. 4
DIRECTIONS FOR USE ....................................................................... 4
Prior to Use .................................................................................... 4
WARNING ........................................................................................... 4
WARNING ........................................................................................... 4
WARNING ........................................................................................... 5
WARNING ........................................................................................... 5
TENSION MESH/SLEEVE REMOVAL ............................................... 5
GENERAL WARNING ......................................................................... 6
POST PROCEDURAL WARNING ...................................................... 6
ADVERSE EVENTS ............................................................................ 6
PRECAUTIONS ................................................................................ 7
WARRANTY ........................................................................................ 8

Dual manufactured product; no change in content as of January 22, 2018.
For current version refer to the DFU packaged with the product.

Product Review for the Purchasing Committee
Obtryx™ II System

Transobturator Sling with PrecisionBlue™ Design

**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 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.

**CONTRAINICATIONS**

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.
- 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 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.

**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.

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 medially towards the midline. Place the opposite hand’s forefinger into the lateral dissection of the vaginal incision, placing the finger tip 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.
Product Review for the Purchasing Committee

Obtryx™ II Transobturator Mid-urethral Sling System

Dual manufactured product; no change in content as of January 22, 2018.
For current version refer to the DFU packaged with the product.

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 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 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, 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, 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, with respect to such instruments.
Do Not Resterilize
No reestimular
Ne pas restériliser
Nicht erneut sterilisieren
Non risterilizzare
Niet opnieuw steriliseren
Não reesterilize

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

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

For single use only. Do not reuse.
Para uso único. No use reutilizar.
À usage unique. Ne pas réutiliser.
Non usare il prodotto se la confezione è danneggiata.
Niet gebruiken als de verpakking is beschadigd.
Não utilize se a embalagem estiver danificada.

Dual manufactured product; no change in content as of January 22, 2018.
For current version refer to the DFU packaged with the product.

Obtryx™ II Transobturator Mid-urethral Sling System
Obtryx™ II Transobturator Mid-urethral Sling System

Product Review for the Purchasing Committee

Dual manufactured product; no change in content as of January 22, 2018.
For current version refer to the DFU packaged with the product.
Halo Needle

Obtryx™ II System
HALO
Transobturator Sling with PrecisionBlue™ Design

Directions for Use  

TABLE OF CONTENTS
WARNING ........................................................................................... 3
WARNING ...................................................................................... 3
DEVICE DESCRIPTION ..................................................................... 3
INDICATIONS FOR USE ................................................................. 3
CONTRAINDICATIONS .................................................................. 3
HOW SUPPLIED .............................................................................. 4
Handling and Storage .................................................................. 4
DIRECTIONS FOR USE ................................................................. 4
Prior to Use .................................................................................... 4
WARNING ........................................................................................ 4
WARNING ...................................................................................... 5
WARNING ...................................................................................... 5
TENSION MESH/SLEEVE REMOVAL .......................................... 5
GENERAL WARNING ..................................................................... 6
POST PROCEDURAL WARNING .................................................. 6
ADVERSE EVENTS ......................................................................... 6
PRECAUTIONS ............................................................................... 7
WARRANTY .................................................................................... 8

Dual manufactured product; no change in content as of January 22, 2018.
For current version refer to the DFU packaged with the product.
Obtryx™ II Transobturator Mid-urethral Sling System

H A L O
Transobturator Sling with PrecisionBlue™ Design

Obtryx™ II Transobturator Mid-urethral Sling System

Transobturator Sling with PrecisionBlue™ Design

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 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 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 (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.
WARNING

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

6. Rotate the needle medially around the inferior pubic ramus to meet the left hand forefinger. Guide the needle tip through the vaginal incision.

WARNING

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

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

Figure 2: Association Loop Engagement

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 center tab positioned suburethrally, facing outward.

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

Figure 3: Association Loop Removal

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 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 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 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.

• 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.

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, 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, 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, with respect to such instruments.
Obtryx™ II Transobturator Mid-urethral Sling System

Do Not Reuse

Do not re-sterilize.

Ne pas résteriliser.

Nicht erneut sterilisieren.

Non risterilizzare.

Niet opnieuw steriliseren.

Não reesterilize.

Sterilized using ethylene oxide.

Esterilizado monouso. Desestereilizado por óxido de etileno.

Stérilisé à l’oxyde d’éthylène.

Sterilizzato con ossido di etilene.

Gesteriliseerd met ethyleenoxide.

Do not use if package is damaged.

Do not use if package is damaged.

Ne pas utiliser si l’emballage est dégommé.

Nicht verwenden, wenn die Verpackung beschädigt ist.

Non usare il prodotto se la confezione è danneggiata.

Niet gebruiken als de verpakking is beschadigd.

Não utilize se a embalagem estiver danificada.

Use By

Fecha de caducidad.

Date limite d’utilisation.

Verwendbar bis.

Usare entro.

Uiterste gebruiksdatum.

Validade.

Australian Sponsor Address

Dirección del patrocinador australiano.

Adresse du promoteur australien.

Adresse des australien Sponsor.

Indirizzo sponsor australiano.

Endereço do Patrocinador Australiano.

Argentina Local Contact

Contacto local en Argentina.

Contacto local en Argentine.

Locales en Argentina.

Contacto local por el Argentina.

Contactos en Argentina.

For single use only. Do not reuse.

Para uso único. No reutilizar.

À usage unique. Ne pas réutiliser.


Esclusivamente monouso. Non riutilizzare.

Uitsluitend voor eenmalig gebruik. Niet opnieuw gebruiken.

Apenas para uma única utilização. Não reutilize.

Catalog Number
Número de catálogo
Numéro de catalogue
Bestell-Nr.
Numero di catalogo
Catalogusnummer
Referência

Consult instructions for use.

Consultar las instrucciones de uso.

Consulter le mode d’emploi.

Gebrauchsanweisung beachten.

Consultare le istruzioni per l’uso.

Raadpleeg instructies voor gebruik.

Consulte as Instruções de Utilização

Contents
Contenido
Contenu
Inhalt
Contenuto
Inhoud
Contenido

EC REP

EU Authorized Representative
Representante autorizado en la UE
Représentant agréé UE
Autorisierter Vertreter in der EU
Rappresentante autorizzato per l’UE
Erkend vertegenwoordiger in EU
Representante Autorizado na U.E.

Legal Manufacturer
Fabricante legal
Fabricant légal
Berechtigter Hersteller
Fabbricante legale
Wettelijke fabrikant
Fabbricante Legal

Lot
Lote
Lot
Lotto
Partij
Lote

Recyclable Package
Envase reciclable
Emballage recyclable
Wiederverwertbare Verpackung
Confezione riciclabile
Recyclebare verpakking
Embalagem Reciclável

Australian Sponsor Address
Dirección del patrocinador australiano
Adresse du promoteur australien
Adresse des australien Sponsor
Indirizzo sponsor australiano
Endereço do Patrocinador Australiano

Argentina Local Contact
Contacto local en Argentina
Contacto local en Argentine
Locales en Argentina
Contacto local por el Argentina
Contactos en Argentina

For single use only. Do not reuse.
Para uso único. No reutilizar.
À usage unique. Ne pas réutiliser.
Esclusivamente monouso. Non riutilizzare.
Uitsluitend voor eenmalig gebruik. Niet opnieuw gebruiken.
Apenas para uma única utilização. Não reutilize.

Dual manufactured product; no change in content as of January 22, 2018.

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

Product Review for the Purchasing Committee
## Clinical/Scientific Data

<table>
<thead>
<tr>
<th>Lead Author</th>
<th>Title</th>
<th>Publication/Conference</th>
<th>Year</th>
</tr>
</thead>
<tbody>
<tr>
<td>Brennand EA, et al.</td>
<td>Five years after midurethral sling surgery for stress incontinence: Obesity continues to have an impact on outcomes</td>
<td>Int Urogynecol J.</td>
<td>2017</td>
</tr>
<tr>
<td>Ross S, et al.</td>
<td>Transobturator tape versus retropubic tension-free vaginal tape for stress urinary incontinence: 5-year safety and effectiveness outcomes following a randomised trial</td>
<td>Int Urogynecol J.</td>
<td>2016</td>
</tr>
<tr>
<td>Tarcan T, et al.</td>
<td>Safety and efficacy of retropubic or transobturator midurethral slings in a randomized cohort of Turkish women</td>
<td>Urol Int.</td>
<td>2014</td>
</tr>
<tr>
<td>Arunkalaivanan A, et al.</td>
<td>Efficacy and safety of transobturator tape (Obtryx) in women with stress urinary incontinence and intrinsic sphincter deficiency: Results from international Obtryx registry</td>
<td>ICS Meeting</td>
<td>2010</td>
</tr>
<tr>
<td>Costa P.</td>
<td>Comparisons of safety and efficacy of the Obtryx Sling and Advantage Mid-urethral Sling for the treatment of stress urinary incontinence: Propensity matching results in a large international registry</td>
<td>AAGL</td>
<td>2010</td>
</tr>
<tr>
<td>Robert M, et al.</td>
<td>Patient expectations, subjective improvement and objective cure: Is there a difference between the transobturator tape and the tension free vaginal tape procedure?</td>
<td>Neurol Gynecol and Urodynamics</td>
<td>2009</td>
</tr>
<tr>
<td>Costa P.</td>
<td>Safety of sub-mid urethral tapes: Report on 3 and 12 months follow-up on 1198 patients in an international registry</td>
<td>J Urol.</td>
<td>2008</td>
</tr>
<tr>
<td>Costa P.</td>
<td>Results of retropubic and transobturator placement of sub-mid urethral tapes (M.U.T.) in first international registry: Results on 984 patients at 3 and 12 months</td>
<td>ICS</td>
<td>2007</td>
</tr>
<tr>
<td>Costa P.</td>
<td>First international registry on sub-mid urethral tapes (M.U.T.) implanted by retropubic of trans-obturator route: Preliminary results on 700 patients</td>
<td>EAU</td>
<td>2007</td>
</tr>
<tr>
<td>Hogston P.</td>
<td>Single surgeon experience with 125 transobturator sling procedures</td>
<td>Int Urogynecol J./ IUGA</td>
<td>2011</td>
</tr>
<tr>
<td>Wilson C, et al.</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>
</tr>
</tbody>
</table>
Reimbursement Guide

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.

<table>
<thead>
<tr>
<th>Procedure Name</th>
<th>APC Code</th>
<th>CPT Code</th>
<th>ICD-10-PCS Procedure Codes</th>
<th>ICD-10-CM Diagnosis Codes</th>
<th>Possible MS-DRG Assignment¹</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Sling operation for stress incontinence (eg, fascia or synthetic)</td>
<td>OTSC42Z – Reposition Bladder Neck, Percutaneous Endoscopic Approach</td>
<td>N36.42 – intrinsic Sphincter Deficiency (ISD)</td>
<td>662 – Minor bladder procedures with major complication or comorbidity (MCC)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>OTUC07Z – Supplement Bladder Neck with Autologous Tissue Substitute, Open Approach</td>
<td>N36.41 – Hypermobility of the urethra</td>
<td>663 – Minor bladder procedures with complication or comorbidity (CC)</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>OTUC0KZ – Supplement Bladder Neck with Nonautologous Tissue Substitute, Open Approach</td>
<td></td>
<td>664 – Minor bladder procedures without MCC/CC</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>OTUC47Z – Supplement Bladder Neck with Autologous Tissue Substitute, Percutaneous Endoscopic Approach</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>OTUC4KZ – Supplement Bladder Neck with Nonautologous Tissue Substitute, Percutaneous Endoscopic Approach</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>OTUC77Z – Supplement Bladder Neck with Autologous Tissue Substitute, Via Natural or Artificial Opening</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>OTUC7KZ – Supplement Bladder Neck with Nonautologous Tissue Substitute, Via Natural or Artificial Opening</td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>OTUC87Z – Supplement Bladder Neck with Nonautologous Tissue Substitute, Via Natural or Artificial Opening</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

¹ 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.
CAUTION: Federal (US) law 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. Refer to package insert provided with this product for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using this product.

All trademarks are the property of their respective owners. All images are owned by Boston Scientific.