Lynx™
Suprapubic Mid-Urethral Sling System

Product Overview

Regulatory Information

Directions for Use
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.

**Product Overview: Lynx™ Suprapubic Mid-Urethral Sling System**

**Lynx Suprapubic Sling System**

- **Suburethral Portion**
  - De-tanged Edges
  - 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.

**DE-TANGED POLYPROPYLENE MATERIAL**
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 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

Boston Scientific Corporation

CONFIDENTIAL

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S
Directions for Use

**Lynx™ System**
Suprapublic Mid-Urethral Sling

**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 crossinfection, 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.

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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.
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 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.

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.

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

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

Figure 2: Association Loop Engagement

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.

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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 reflux.
- Take special care in cases of bladder prolapse because of anatomical distortion if the patient requires a cystotomic 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, ureter, and bowel. Treatment of the erosion may require surgical removal.
- As with all surgical procedures, certain risks 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.

- 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/erosion of the mesh through the vaginal or urethral mucosa, bladder wall or other surrounding tissue
  - scarring/scar contracture
  - device migration
  - fistula formation and inflammation
  - abscess
  - 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

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- 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. Handling, cleaning, sterilization 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
Data on file. Bench test results may not necessarily be indicative of clinical performance. Results from case studies are not predictive of results in other cases. Results in other cases may vary.

All images are owned by Boston Scientific.

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.