Lynx™ Ultra System

Suprapubic Mid-Urethral Sling

REF M0068503060

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℞ ONLY

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.

REUSE WARNING

For single use only. Do not reuse, reprocess, or resterilize the delivery device or mesh sling assembly. 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.

WARNING

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

DEVICE DESCRIPTION

The Lynx Ultra System is a sterile, single-use device, consisting of two delivery devices and one mesh sling assembly. The mesh sling assembly is comprised of a polypropylene knitted mesh protected by disposable sleeves, two dilators, and one center tab. At the distal end of the mesh sling assembly there are association loops which are designed to be placed in the needle slot at the distal end of each delivery device. The disposable delivery devices consist of a handle with a curved needle. The delivery devices are designed to facilitate the passage of the mesh sling assembly through bodily tissues per a suprapubic sling procedure.

Contents

Two single-use delivery devices and one single-use mesh sling assembly.

Operating Principle

The mesh sling acts as a backboard to support the urethra during stress and straining events to prevent urine leakage.

BSC (MB eIFU Template 8.2677 x 11.6929 A4, 92524324F), eIFU, MB, LYNX ULTRA SYSTEM, US, 51510965-01A

Materials

The delivery device needles are constructed of stainless steel and therefore may contain the following substance defined as CMR 1B in a concentration above 0.1% weight by weight:

Cobalt; CAS No. 7440-48-4; EC No. 231-158-0

Current scientific evidence supports that medical devices manufactured from stainless steel containing cobalt do not cause an increased risk of cancer or adverse reproductive effects. A device specific evaluation has determined that the presence of cobalt does not present a risk within the clinical use of this device.

The mesh suburethral slings are made from blue knitted polypropylene.

Table 1. Mesh Implant Materials

Material	Amount
Polypropylene	99.8% - 100%
Blue colorant	0% - 0.2%

Non-pyrogenic

The device covered by this Instructions for Use document meets pyrogen limit specifications.

INTENDED USE/INDICATIONS FOR USE

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

The Lynx Ultra System delivery device is intended for use as an aid in insertion, placement, fixation, and anchoring of the Lynx Ultra surgical mesh during urogynecological procedures.

CONTRAINDICATIONS

The mesh suburethral sling 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.

WARNINGS

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.
  - Hypertonic bladders or vesicoureteral reflux.
  - Bladder prolapse because of anatomical distortion.
  - Vaginal and urinary tract infections. Treat infections prior to a suburethral sling implantation procedure.
- The user should be familiar with surgical procedures and techniques involving nonabsorbable meshes.
- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- Mesh is considered a permanent implant. Removal of the mesh or correction of mesh related complications may involve multiple surgeries.
- Complete removal of the mesh may not be possible and additional surgeries may not always fully correct the complications.

POST-PROCEDURE WARNINGS

- 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, suprapubic, or transobturator), has been associated with cases of erosion. Erosion has been reported in the 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 routes.
- Bleeding can occur. Check carefully before releasing the patient from the hospital.
- Cystoscopy must be performed to confirm bladder integrity.
- Do not remove the protective plastic sleeves covering the mesh implant until the proper position has been confirmed.
- Ensure that the mesh is placed without tension under the mid-urethra.
- The use of this device should be done with the understanding that subsequent infection may require removal of the mesh.
- The physician should determine when it is suitable for the 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, any of which may be ongoing, but are not limited to:

- As with all implants, local irritation at the wound site and/or a foreign body response may occur. Foreign body reaction may be acute or chronic.
- Pain (pelvic, vaginal, groin/thigh, suprapubic, dyspareunia) (acute or chronic)
- Dyspareunia
- Tissue responses to the mesh implant could include:
    - Erosion into organs (urethra, bladder, or other surrounding tissues); exposure/extrusion into the vagina. Mesh contact with urine via erosion/exposure/extrusion may result in stone formation.
    - Scarring/scar contracture
    - Necrosis
    - Fistula formation (acute or chronic)
    - Inflammation (acute or chronic)
    - Mesh contracture
    - Tissue contracture
    - Vaginal shortening or stenosis which may result in dyspareunia and/or sexual dysfunction
    - Pain with intercourse that may not resolve

- Exposed mesh may cause pain or discomfort to the patient's partner during intercourse
- Sexual dysfunction, including the inability to have intercourse.

- Like all foreign bodies, the mesh may potentiate an existing infection.
- Allergic reaction has been reported.
- Known risks of surgical procedures for the treatment of incontinence include:
  - Pain, ongoing pain (pelvic, vaginal, groin/thigh, suprapubic, dyspareunia)
  - Severe, chronic pain
  - Apareunia
  - Leg weakness
  - Infection
  - De novo detrusor instability
  - Complete failure of the procedure/failure to resolve a patient's stress urinary incontinence
  - Voiding dysfunction (incontinence, temporary or permanent lower urinary tract obstruction, difficulty urinating, pain with urination, overactive bladder, and retention)
  - Bruising, bleeding (vaginal, hematoma formation)
  - Abscess
  - Vaginal discharge
  - Dehiscence of the vaginal incision
  - Edema and erythema at the wound site
  - Perforation or laceration of the vessels, nerves, bladder, urethra, bowel, or other tissues may occur during placement.

The occurrence of these events may require surgical intervention and possible removal of the entire mesh. In some instances, these events may persist as a permanent condition after surgical intervention or other treatment.

HOW SUPPLIED

Device Details

The Lynx Ultra System is provided sterile using an ethylene oxide process. The device is packaged in a tray sealed with a lid which acts as a sterile barrier.

- Do not use if package is damaged or unintentionally opened before use.
- Do not use if labeling is incomplete or illegible.
- Do not use past the "Use By" date displayed on the product label.

Handling and Storage

This product has no special handling or storage requirements.

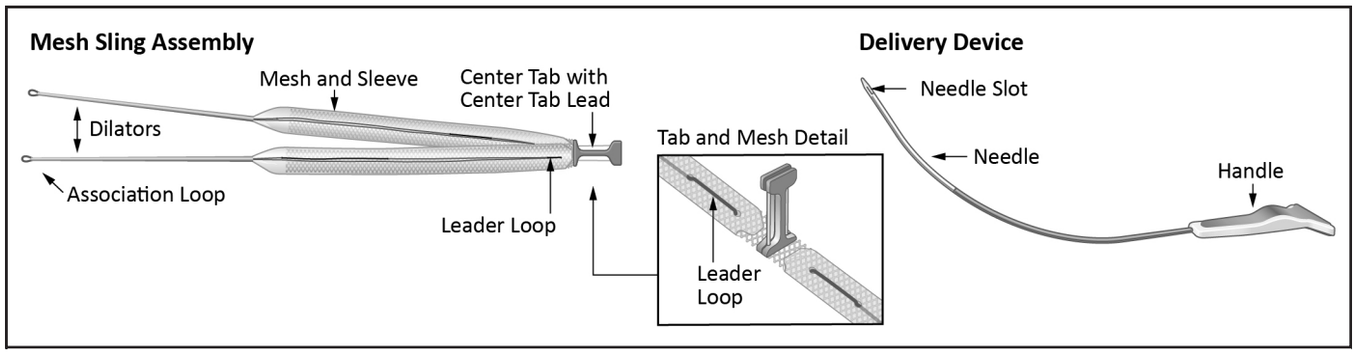

Figure 1. The Lynx Ultra System Mesh Sling Assembly and Delivery Device

OPERATIONAL INSTRUCTIONS

Prior to Use

1. Ensure the sterile packaging is not open, torn, or punctured and the product is not damaged. Immediately return damaged product to Boston Scientific.
2. Prepare and drape the patient following standard surgical practice.

Note: The device design is intended to facilitate a percutaneous approach utilizing a suprapubic technique. Refer to Figure 1 for a parts description.

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.

Procedure

Sling Placement

1. Prepare 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. Insert one needle through one abdominal incision. Using a downward vertical motion, move the needle to 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.

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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. The bladder must be emptied after cystoscopy.
6. Once it is determined that the bladder is intact, engage one association loop to the distal end of each needle (see Figure 2) protruding through the vagina.

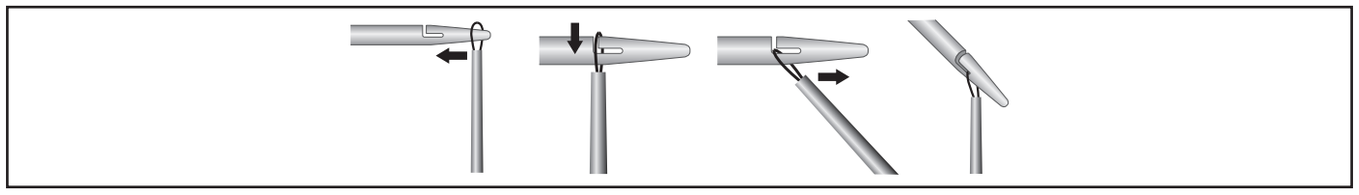

Figure 2. Engaging the association loops

7. Pull the needles up through the abdominal incisions. Ensure that the mesh sling assembly is not twisted with the blue center tab positioned suburethrally, facing outward.

WARNING

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

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

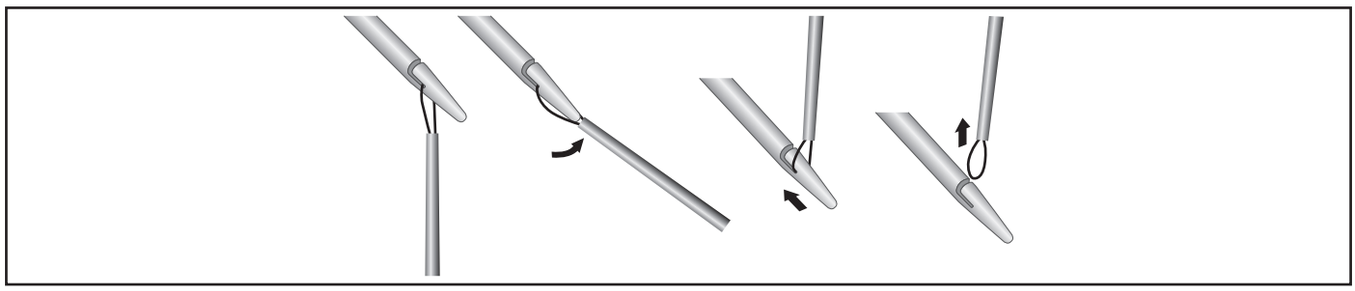


Figure 3. Removing the association loops

Mesh Tensioning

1. Pull upwards on the dilators to bring the blue center tab to approximately 1 to 2 cm outside the vaginal introitus so that both the center tab and the bottom portion of the leader loops are visible and accessible. Refer to Figure 4.

Note: If the mesh assembly is inadvertently drawn in so that the leader loops are not visible and accessible, it is recommended that the ends of the sleeves be grasped to withdraw the mesh assembly from the vaginal incision allowing for visualization of the leader loops.

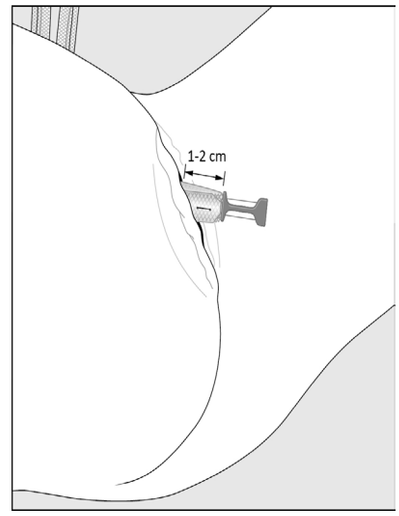


Figure 4. Center Tab position

2. Locate the leader loops, one on each side of the blue center tab. Each leader loop is accessible on both sides of the sleeve. Refer to Figure 5.

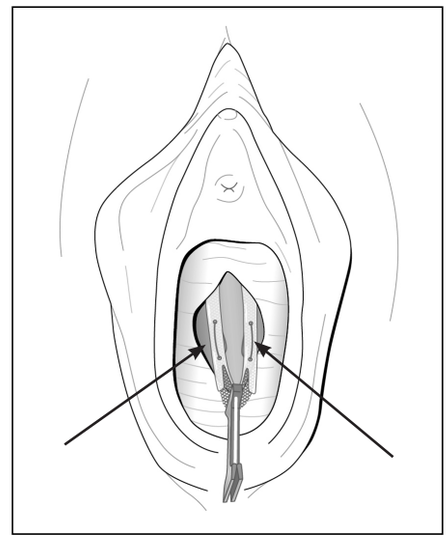
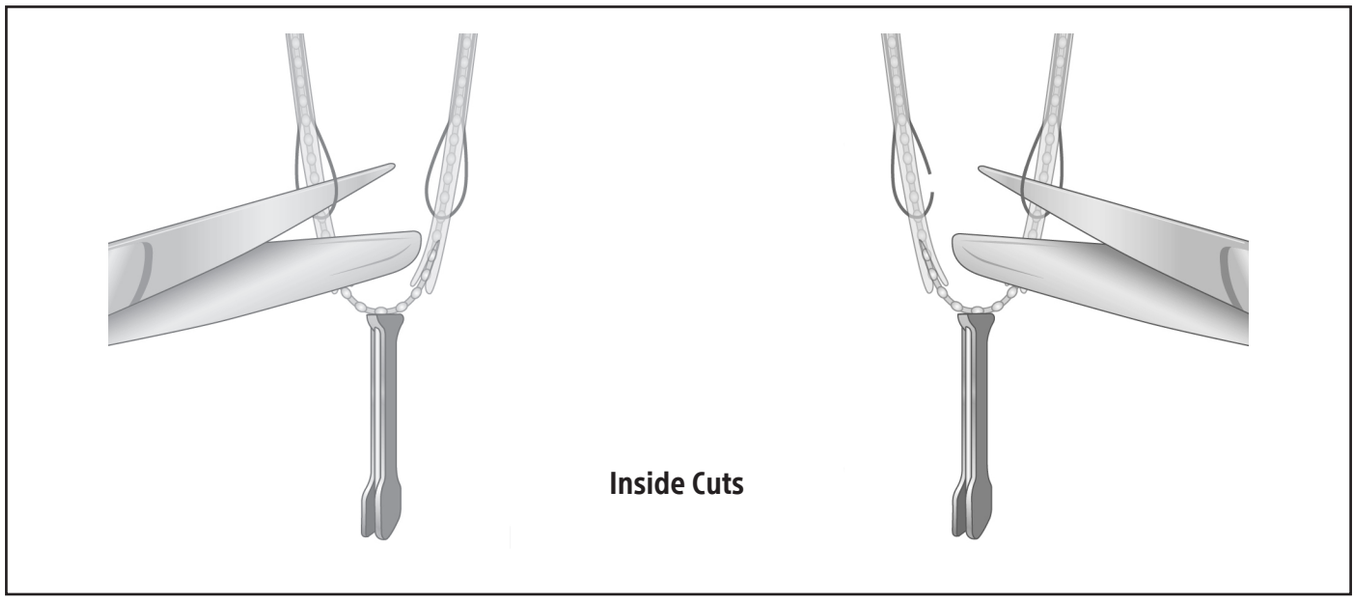


Figure 5. Leader Loops: One on each side of the center tab

3. Cut each leader loop on either the inside OR the outside as shown in Figure 6. Complete only one cut per loop.



OR

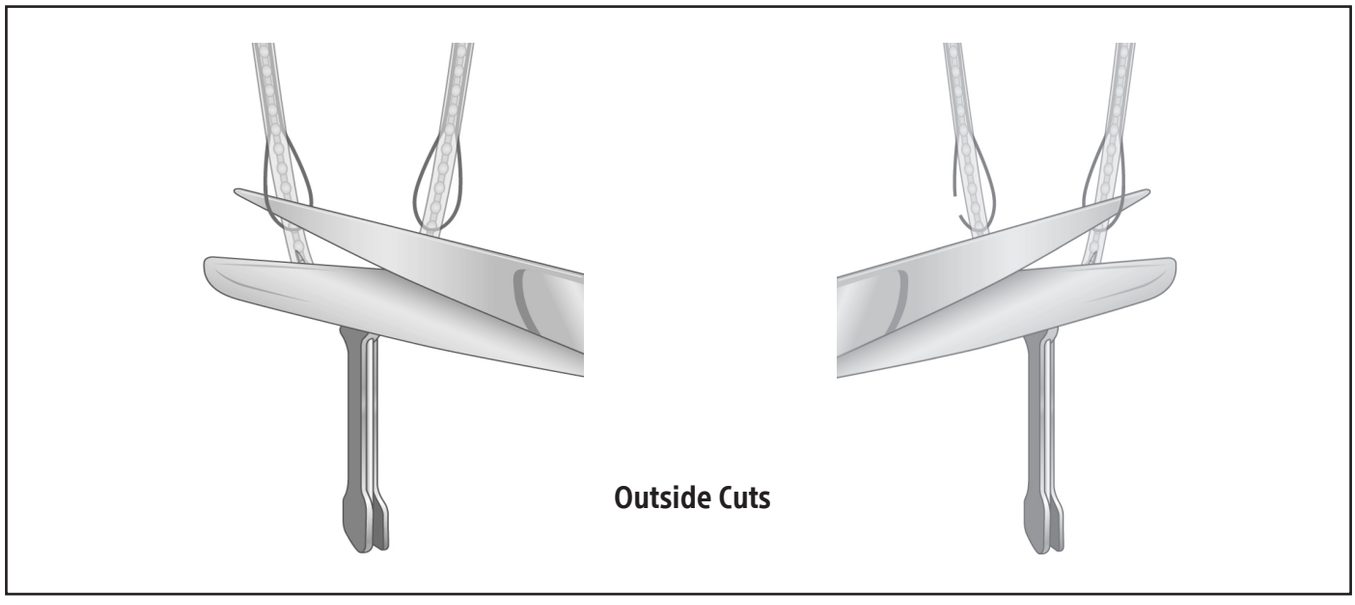


Figure 6: Leader Loop Cuts - Inside or outside cuts

4. Ensure both leader loops on either inside or outside are cut.

Note: Leave the center tab attached as this provides a visual guide to the mesh position during final tensioning and sleeve removal.

5. Once the leader loops are cut, the sleeve and mesh can move independently. Grasp both the sleeve and mesh when completing subsequent mesh assembly adjustments as shown in Figure 7.

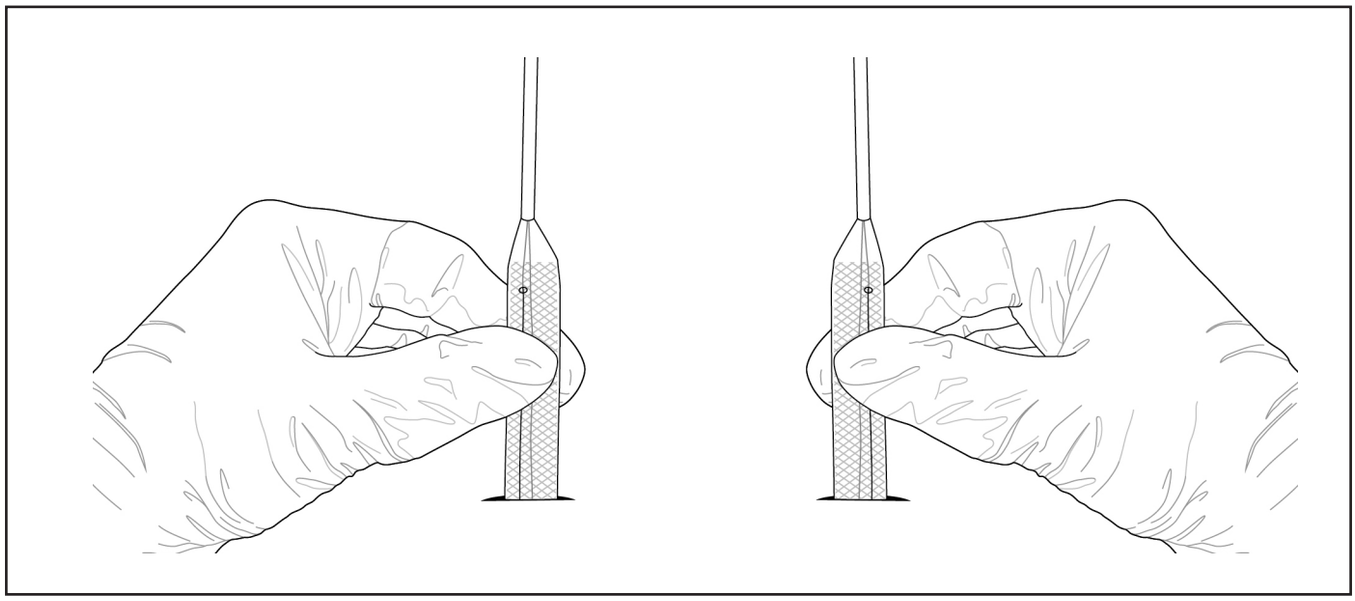


Figure 7: Grasp sleeve and mesh for tensioning

6. Grasp the mesh arms (see Figure 7) and pull upwards so that the blue center tab is centered below the urethra. Ensure that the mesh sling assembly lies flat under the urethra.
7. Appropriately tension the mesh/sleeve according to physician preference.

Sleeve and Center Tab Removal

1. Once proper tension is achieved, pull upwards on the dilators to remove the sleeves and leader loops, leaving the mesh in place (see Figure 8).

Note: Ensure that the position of the blue center tab is maintained below the urethra during sleeve removal.

2. If significant resistance is encountered during sleeve removal, stop and assess the situation before proceeding. Verify that the leader loop within both sleeves of the mesh assembly have been fully cut.

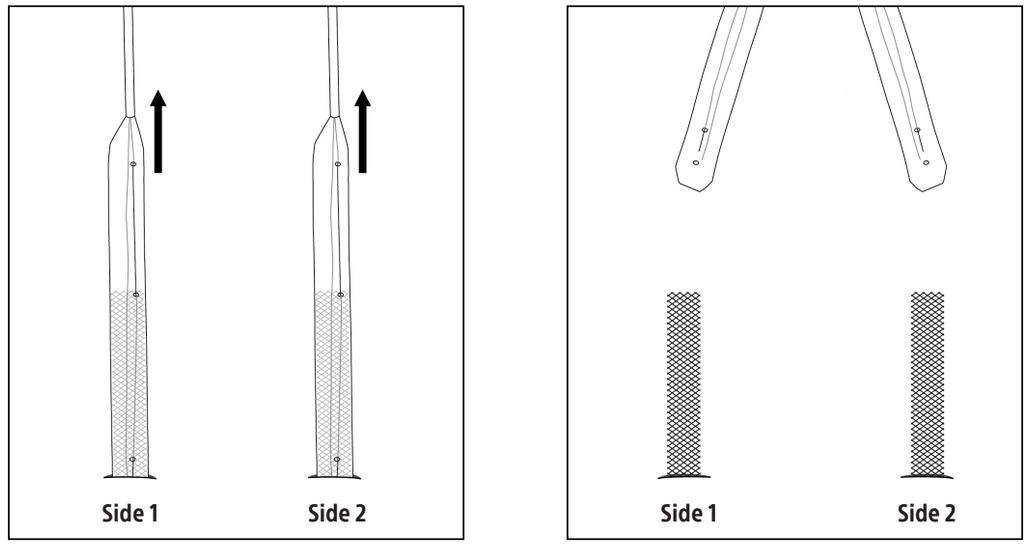


Figure 8: Remove the sleeves

3. Grasp the blue center tab and cut only one side of the center tab lead (see Figure 9) to release the center tab from the mesh. Remove the center tab and center tab lead from the vaginal canal.

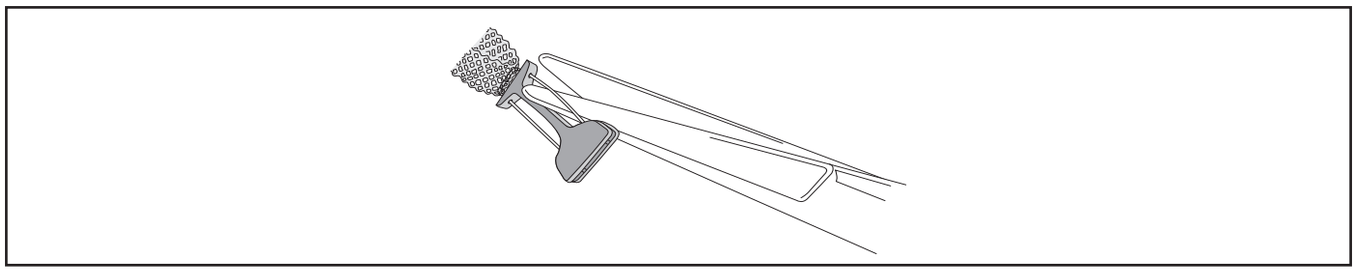


Figure 9: Cutting the center tab lead

4. Verify the tension of the mesh and adjust as necessary.
5. Once the desired tension has been achieved, gently push downward on the abdomen, cut the distal ends of the mesh and confirm that the mesh ends retract into the skin incisions.
6. Close all incisions per standard practice.

Disposal

To minimize the risk of infection or microbial hazards after use, dispose device and packaging as follows:

After use, device may contain biohazardous substances. The device and packaging should be treated and disposed of as biohazardous waste or have them treated and disposed of in accordance with any applicable hospital, administrative, and/or local government regulations. Use of a biohazardous container with biological hazard symbol is recommended. Untreated biohazardous waste should not be disposed of in the municipal waste system.

This device contains a sharps hazard. Take precautions to ensure that sharps are handled properly. Dispose of all sharps directly into a sharps disposal container labeled with a biological hazard symbol. Sharps waste should be safely disposed of using available sharps waste channels in accordance with hospital, administrative, and/or local government policy.

Post-Procedure

Any serious incident that occurs in relation to this device should be reported to the manufacturer, and to the relevant local regulatory authority.

MRI SAFETY INFORMATION

The sling materials are composed of materials that are electrically nonconductive, nonmetallic, and nonmagnetic, and pose no known hazards resulting from exposure to any MR environment. Therefore, the mesh suburethral slings are considered MR Safe.

PATIENT COUNSELING INFORMATION

Prior to the use of this device, discuss the benefits and risks of the mesh sling, the alternate therapies available for the treatment of stress urinary incontinence, and obtain the patient's informed consent.

Brief the patient on any contraindications, warnings, precautions, adverse events, and post-procedure instructions outlined in this document that are of relevance to the patient. Explain that the mesh suburethral sling is MR Safe. Advise the patient when moderate and strenuous activities, as well as intercourse, may be resumed. If discomfort while urinating, bleeding, or other problems occur, the patient should contact their physician.

Expected Lifetime of the Implant

Advise the patient that the mid-urethral sling is a permanent mesh implant that is intended to remain functional to treat stress urinary incontinence over their lifetime. Although the outcome of the surgery is intended to be permanent, the functional life expectancy of the mesh may be impacted by unpredictable future factors such as: changes in pelvic anatomy, changes in body structure, new pelvic floor conditions such as urge incontinence or prolapse, and/or surgeries that may occur after implantation to address potential mesh related complications.

Advise the patient that the materials of the device are biocompatible and nonbiodegradable.

WARRANTY

For device warranty information, visit (www.bostonscientific.com/warranty).

EU Importer: Boston Scientific International B.V., Vestastraat 6, 6468 EX Kerkrade, The Netherlands

SYMBOL DEFINITIONS

Commonly used medical device symbols that appear on the labeling are defined at www.bostonscientific.com/SymbolsGlossary

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Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752 USA
USA Customer Service +1-888-272-1001

www.bostonscientific.com

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