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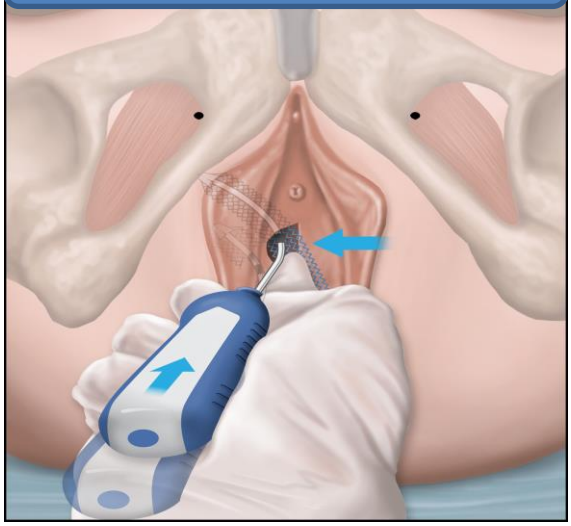
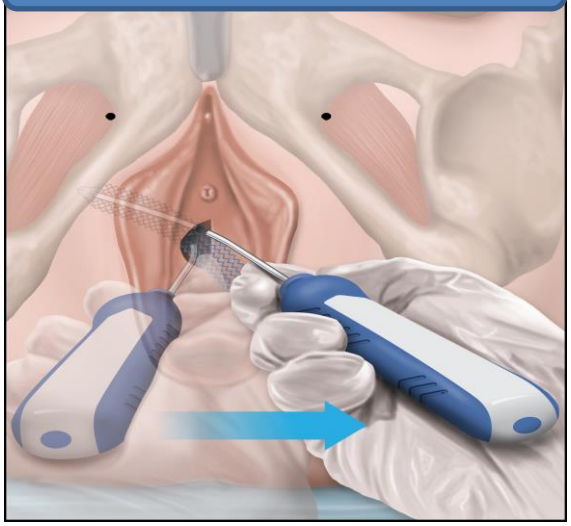
Solyx™ Single Incision Sling System: *This is a high-level overview of procedural steps and is not intended to be inclusive of all instructional information provided in the labeling. Please refer to the instructions for use for complete information.*

Step 1. Ipsilateral Insertion



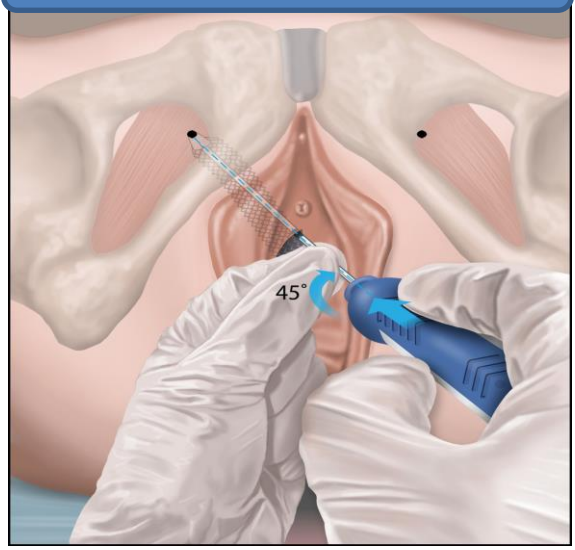
- **Mark the Groin**: Palpate landmarks and mark the groin area at the superior medial aspect of the obturator foramen, about 3 cm lateral to the clitoris on both sides.
- **Make Incision:** Create a 1-1.5 cm incision and dissect towards the interior portion of the inferior pubic ramus at a 45º angle from the midline.
- **Insert the Trocar:** Insert the trocar through the dissection tunnel, keeping the handle just off the midline on the same side as the anchor insertion.
- **Advance through periurethral tissue:** Push the trocar forward through the periurethral tissue until the black mark on the trocar is 1-2 mm outside the incision. If you go past this point, withdraw the trocar until it is correctly positioned. You may feel a pop as it passes through the periurethral tissue.
- **Maintain Trocar Position:** Ensure the trocar handle remains:
  - On the same side as the anchor placement.
  - Parallel to the patient.
  - Unrotated, with the white portion facing the ceiling.

Step 2. Contralateral Swing



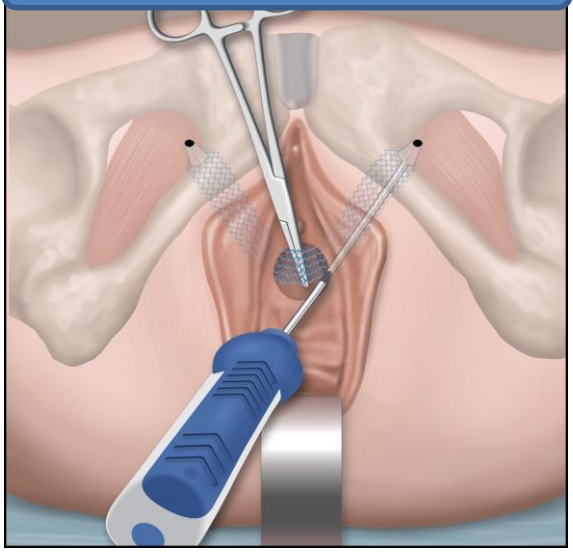
- **Maintain Parallel Handle**: Ensure the handle stays parallel to the patient.
- **Swing the Handle**: Move the handle past the midline to the opposite side until it touches the patient's thigh.
- **Check the Black Mark**: Make sure the black mark on the trocar needle stays outside the incision during swing.

Step 3. 45° Push



- **Rotate the Handle:** Rotate the handle to about a 45º angle so the blue arrows on the inside of the handle align with the pre-marked groin target.
- **Push Forward**: Place your palm on the blue dot at the base of the handle. Keep the handle at a 45º angle and, without lowering your hand, push straight forward with slow and controlled force, towards the groin mark. Use your other hand to help control the movement. Advance anchor into the obturator internus muscle; another pop may be felt.
- **Check the Black Mark**: The black mark on the trocar needle should be 1-2 mm inside the incision.
- **Release the Anchor**: Hold the blue collar on the trocar with one hand and pull the handle back until you feel two clicks. Then, pull the trocar out of the incision.
- **Prepare for the Other Side**: Make sure the mesh is lying flat without twisting, load the second anchor, and repeat the steps on the other side.

Tensioning by Placement

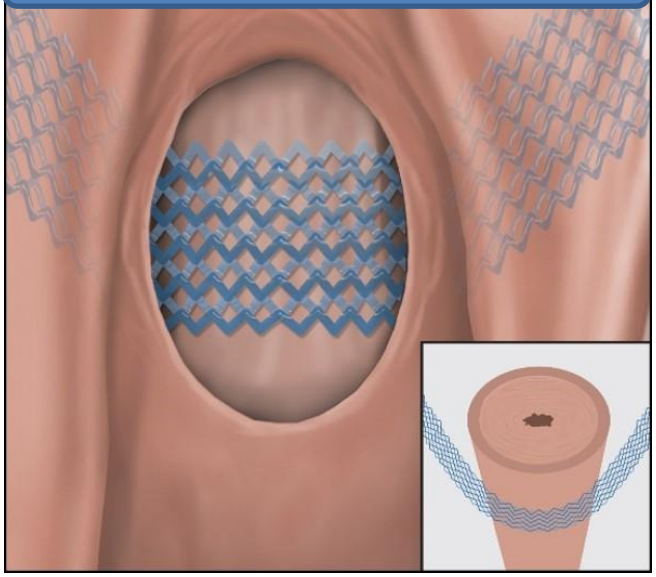


- **Pause and Assess:** Before deploying the second anchor, pause to check the tension.
- **Drop the Handle:** Gently lower the handle and use your preferred instrument (like a hemostat) to assess the mesh tension.
- **Adjust Tension:** Make small forward and backward movements to adjust the tension as needed.
- **Achieve Proper Tension:** Do not release the second anchor until the proper tension is achieved.

Solyx™ Single Incision Sling System:

This is a high-level overview of tensioning in the procedure.

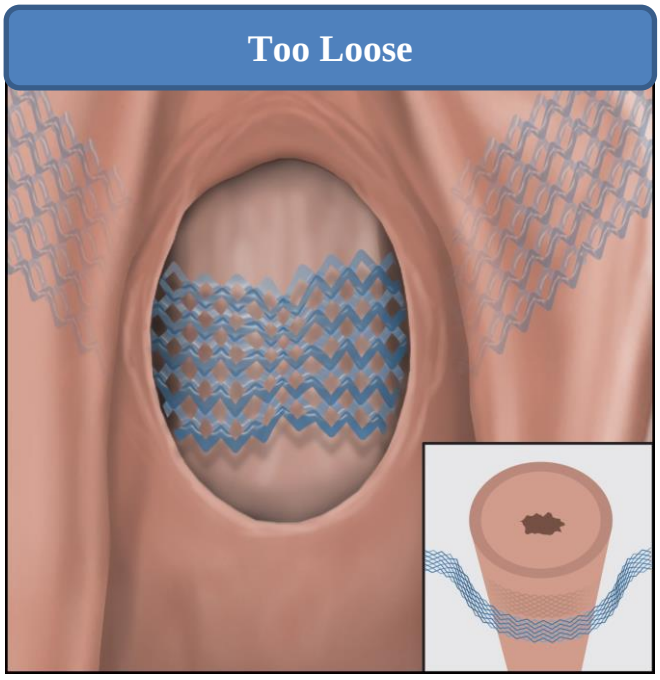
Proper Tension



To achieve proper tensioning, ensure:

- Mesh is lying flat and in contact with urethra without visible space or excess tension.
- You can fit a small instrument behind the mesh and when removed the mesh returns to its original position.

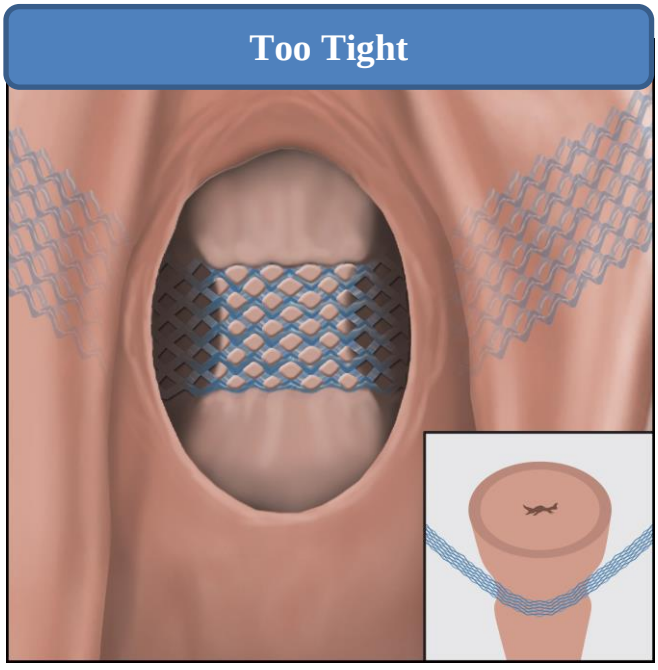
Too Loose



When the mesh is too loose:

- Mesh is not lying flat due to excess space.
- A gap is seen between mesh and urethra.

Too Tight



When the mesh is too tight:

- Mesh may begin to narrow in width.
- Mesh is pinching the urethra.

Caution: U.S. Federal 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 these products. Please refer to entire Solyx Single Incision Sling System ™ Directions for Use prior to using this device.

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 that 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 vaginal incision, Edema and erythema at the wound site, Perforation or laceration of vessels, nerves, bladder, urethra or bowel may occur during placement. The following additional adverse events have been reported for the Solyx SIS System: Dysuria, Hematuria. 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. Removal of mesh or correction of mesh-related complications may involve multiple surgeries. Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

WH-662602- AC DEC 2024