AdVance™ XP Male Sling System

Boston Scientific
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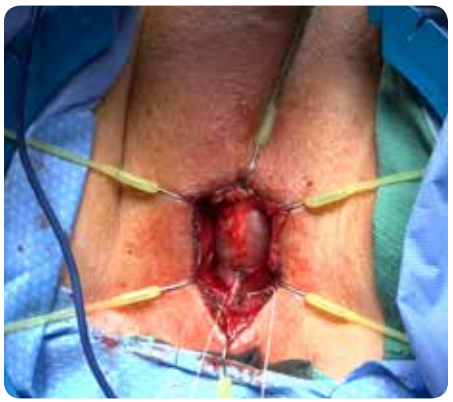
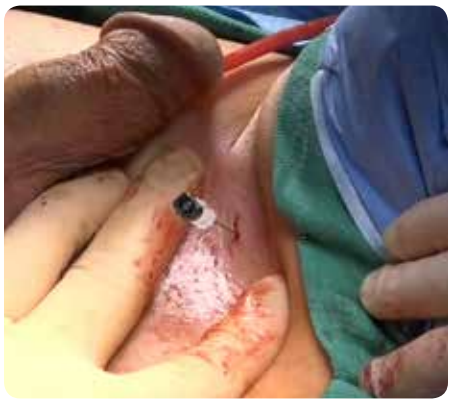
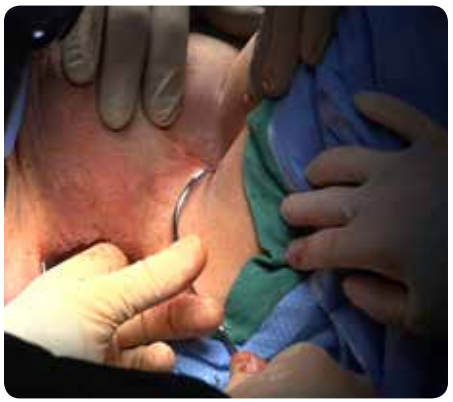
Step-by-Step Implantation Procedure







Step 1: Patient Positioning and Initial Dissection

- Position the patient in a dorsal lithotomy position, legs aligned to patient's shoulders, bent at <90° angle and slightly spread
- A Foley catheter may be placed at the start of the procedure to assist with identifying the urethra and corpus spongiosum
- Make a low, midline perineal incision through the skin through Colles' fascia
- A Lone Star™ retractor is included to provide adequate exposure

Note: *Lone Star is a registered trademark of CooperSurgical, Inc.*

Step 2: Isolation of the Central Tendon

- Identify the bulbospongiosus muscle; open it in the midline either with electrocautery or sharp dissection to expose the corpus spongiosum laterally
- Mobilize the corpus spongiosum proximally to the central tendon
- Identify the central tendon by lifting the proximal bulb anteriorly providing counter traction
- Use a biodegradable suture to mark the distal aspect of the central tendon insertion site to the corpus spongiosum
- While mobilizing the urethra, gradually incise the fibrous portion of the central tendon until 2-4 cm of proximal displacement is achieved

Note: *Care should be taken to avoid injury to the urethra.*

Step 3: Locate Helical Trocar Insertion Site

- Identify the adductor longus tendon and mark if desired
- The helical trocar insertion site is located one finger breadth below the insertion point of the adductor longus tendon, in the groin crease, lateral to the ischiopubic ramus
- A needle may be used to probe the bone, find its edge and help confirm the insertion site
- Make a small incision at the identified site

Repeat these steps on the contralateral side; confirm both stab incisions lie in a straight line perpendicular to the corpus spongiosum.

Step 4: Helical Trocar Passage

- Hold the helical trocar handle at a 45˚ angle to the midline incision with trocar against the patient's buttock
- Place your index finger of the opposite hand into the perineal incision. The index finger should be at the apex of the triangle formed by the corpus spongiosum medially, the symphysis pubis above, and the ischiopubic ramus laterally, to receive the needle tip and protect the corpus spongiosum from inadvertent injury
- Insert and advance the helical trocar tip along the lateral edge of the ischiopubic ramus; continue to advance the trocar straight through the obturator externus and obturator internus muscles
- Stop advancing the trocar and drop the trocar handle toward the midline to align the trocar path
- Rotate the trocar until the tip meets your finger, and bring the trocar tip high into the apex of the symphysis pubis and ischial pubic ramus

Repeat these steps on the contralateral side.

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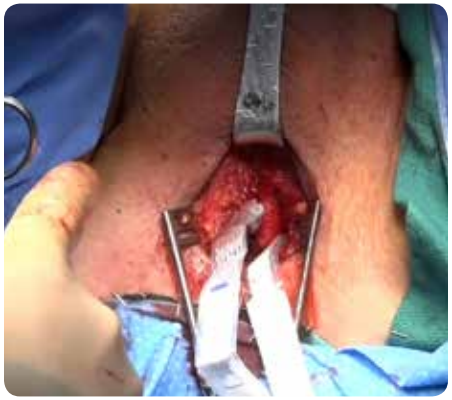

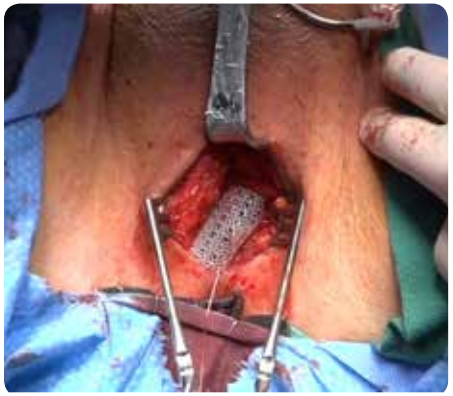

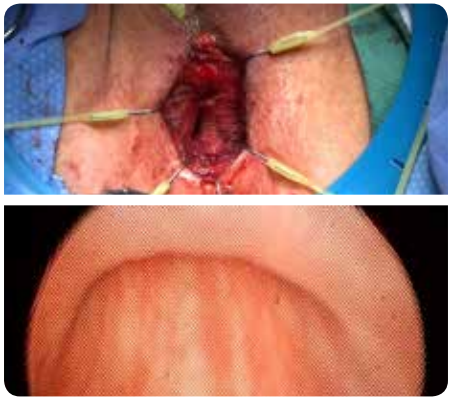

Step 5: Connecting Sling to Trocar

- Connect sling to trocar tip until it clicks into place
- Rotate the trocar back along the same insertion pathway to pull sling through the obturator foramen and out the skin incision
- Pull sling through so the center of the sling is in the midline of the corpus spongiosum

Note: *At this point, it is optional to remove the helical trocars from the sling arms. Review how to do this in Step 8. You may choose to remove the trocars from the sling arm after tensioning.*

Step 6: Suture Sling to Corpus Spongiosum

- Position the sling so that it lies flat against the corpus spongiosum being careful not to tension the sling
- The proximal edge of the sling should align with the central tendon marking suture and secured to the corpus spongiosum
- Use another absorbable suture to pex the distal portion of the mesh sling to the corpus spongiosum

Step 7: Tension Sling

- Foley needs to be removed prior to cystoscopy
- During flexible cystoscopy, simultaneously pull both arms of the sling until circumferential coaptation is observed. Once coaptation is observed, **STOP** tensioning the sling
- Inspection of the mesh perineally will reveal an indented configuration of the corpus spongiosum; variable depending on the anatomy of the patient

Step 8: Sheath Removal

- Once correct positioning is achieved, remove both inner protective Tyvek® sheath and outer plastic sheath one arm at a time
- To remove trocars from sling arms, clamp a hemostat slightly below the blue mark on the end portion of the sling sheath; be sure to capture the entire width of the sling with the hemostat
- Cut the sheath below the blue dot on the sling arm
- Repeat steps with the contralateral helical trocar
- To prevent additional tensioning while removing the sling arms, secure one arm of the sling near the corpus spongiosum to provide counter traction and stability during removal of the sheaths. This should be performed on the contralateral side
- Close the bulbospongiosus muscle and the remaining incision in several layers after irrigation and hemostasis

Note: *Tyvek is a registered trademark of DuPont*

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