

Step-by-Step Implantation Procedure



Step 1: Patient Positioning and Initial Dissection

- Position the patient in a dorsal lithotomy position, legs aligned to patients shoulders, bent at <math><90^\circ</math> 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



Step 2: Mobilization of the Bulbar Urethra

- 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
- 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
- The spinal needle included with the Advance XP Male Sling System Kit 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 incision lie in a straight line perpendicular to the corpus spongiosum



Step 4: Helical Trocar Passage

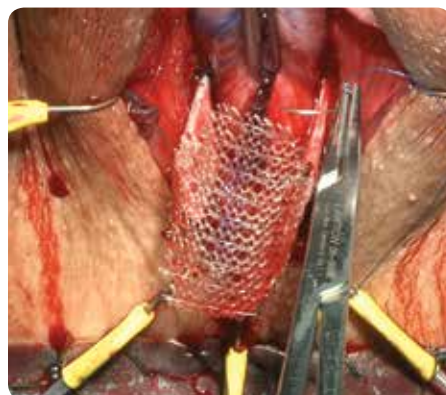
- Hold the helical trocar handle at a 45° angle to the midline incision
- Place a finger of the opposite hand into the perineal incision. The finger should be at the apex of the triangle formed by the bulbar urethra medially and the ischiopubic ramus laterally, to receive the needle tip and protect the corpus spongiosum from inadvertent injury
- Insert and advance the helical trocar tip along the lateral edge of the pubic ramus; continue to advance the trocar straight until two "pops" are felt
- 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 pubic triangle

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Step 5: Connecting Sling to Trocar

- Connect sling to trocar tip until it clicks into place. Make sure blue dot is facing away from the urethra
- Rotate the trocar back along the same insertion pathway to pull sling through obturator foramen and out the stab incision
- Pull sling through so the center of the sling is to the patient's midline, but no further
- 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 above the hemostat (toward the helical trocar)
- Repeat steps with the contralateral helical trocar



Step 6: Suture Sling to Bulb

- 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 insertion point previously marked with a stitch
- Use absorbable suture to affix the mesh sling to the corpus spongiosum



Step 7: Tension Sling

- The Foley catheter may be removed or left in place during tensioning
- Simultaneously pull both ends of the sling to observe approximately 2-4 cm proximal repositioning of the bulb
- Flexible cystoscopy is recommended during tensioning to ensure no urethral injury and to confirm coaptation of the external sphincter is achieved. Once coaptation is observed, stop tensioning the sling
- To ensure the sling is not over-tensioned, place your finger inside the incision in the apex between the sling and ramus. There should be a finger space between the sling and the ischiopubic ramus



Step 8: Sheath Removal and Final Steps

- Once correct positioning is achieved, remove both inner protective Tyvek® liner and outer plastic sheath simultaneously by pulling straight up. You may want to place your finger between the sling and ramus to ensure additional tensioning is not applied during this step
- Close the bulbospongiosum muscle and the remaining incision in several layers after irrigation and hemostasis

Note: Tyvek® is a registered trademark of DuPont™