

AdVance™

Male Sling System

Step-by-step implantation procedure summary



STEP 1: Patient positioning and initial dissection

- A. Prepare the perineum according to the hospital's standard operating procedure.
- B. Position the patient in the dorsal lithotomy position with legs bent at ≤ 90 degrees and the knees not farther than shoulder width apart.
- C. A Foley catheter may be placed at the start of the procedure to assist with identifying the urethra and corpus spongiosum.
- D. To aid in dissection, a marking pen may be used to mark the incision approximately 1 cm from the anus and a low midline perineal incision is made through the skin and carried deeper through Colles' fascia. Electrocautery may be used to dissect through subcutaneous tissue.
- E. Utilize the retractor system provided to obtain adequate exposure.



STEP 2: Mobilization of the bulbar urethra

- A. Identify the bulbospongiosus muscle; open it in the midline either with electrocautery or sharp dissection to expose the corpus spongiosum.
- B. Continue dissection laterally to allow mobilization of the corpus spongiosum.
- C. Dissect superficial muscle fibers off the corpus spongiosum; proceed to the central tendon.
- D. Use a marking pen or tack suture to mark the distal aspect of the central tendon insertion site to the corpus spongiosum.
- E. Lift the corpus spongiosum anteriorly; this aids in the visualization of the central tendon. Then gradually incise the fibrous portion of the central tendon from the corpus spongiosum.
- F. Continue dissection gradually, pausing frequently, until 2–4 cm of proximal corpus spongiosum displacement is achieved.
- G. Note: Care should be taken in the central tendon dissection to avoid injury to the urethra.



STEP 3: Locate and mark helical needle insertion sites, make stab incisions

- A. Remove the retractor.
- B. Identify the adductor longus tendon and mark if desired.
- C. The needle insertion site is identified by going one finger breath below the insertion point of the adductor longus tendon, in the groin crease, lateral to the ischial pubic ramus.
- D. The spinal needle included in the AdVance™ Male Sling System kit may be used to probe the bone, find its edge and help confirm the insertion site.
- E. Make a small incision at the identified site; the helical needle will be placed through this incision.
- F. Repeat the steps for the contralateral side; confirm both stab incisions lie in a straight line perpendicular to the corpus spongiosum.



STEP 4: Helical needle passage

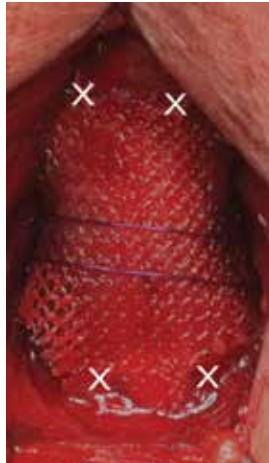
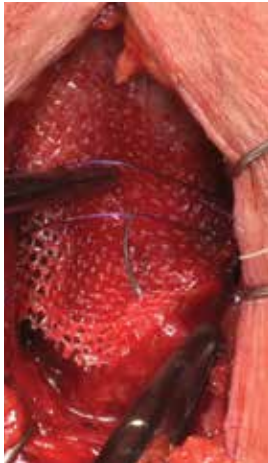
- A. Hold the correct helical needle at a 45 degree angle to the midline incision.
- B. Place a finger of the opposite hand into the perineal incision. The finger should be at the apex of the triangle formed by the bulbar urethra medially and the ischiopubic ramus laterally, to receive the needle tip and protect the corpus spongiosum from inadvertent injury.
- C. Insert and advance the needle tip along the lateral edge of the pubic ramus; continue to advance the needle until two "pops" are felt.
- D. Stop advancing the needle and turn a quarter turn.
- E. Identify the needle tip with the protecting hand index finger. Once the needle tip is felt pull the needle tip back slightly, drop the handle toward the midline and rotate the helical needle so the needle tip comes out as high as possible in the apex of the pubic triangle.
- F. The proper exit point of the needle tip is high in the triangle formed by the pelvic bones.





STEP 5: Connecting sling to needle, pull mesh arm through stab incision

- Connect the sling to the needle by pressing the white connector onto the needle tip until it clicks into place.
- Ensure the sutures that are incorporated into the sling are facing away from the corpus spongiosum.
- Rotate the needle backwards along the insertion pathway to pull the sling through the obturator foramen and out through the stab incision.
- Pull enough to bring the center of the sling to the patient's midline, but no farther.
- 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 (towards the helical needle).
- Repeat steps 4–5 for the contralateral side.
- Reminder: The sling needs to be placed high in the pelvic triangle around the ischiopubic rami and inferior to the pubis.



STEP 6: Suture sling to bulbospongiosum

- Replace the retractor to facilitate sling attachment to the corpus spongiosum.
- Position the sling so it lies flat against the bulbospongiosum and the proximal edge of the center rectangular section is aligned with the central tendon insertion point previously marked.
- Use absorbable 2.0 or 3.0 suture to affix the four corners of the center rectangular portion of the sling to the bulbospongiosum. It is important to take a good bite of the bulbospongiosum and to pass the suture at least two pores from the edge of the sling to ensure sufficient fixation.



STEP 7: Sling tensioning

- 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 of proximal movement of the corpus spongiosum.
- Cystoscopy may be performed during tensioning to ensure no urethral injury, and to confirm proper coaptation of the external sphincter and sling placement.
- If proper relocation of the corpus spongiosum and coaptation of the external sphincter is observed, the Foley catheter can be replaced at the surgeon's discretion.
- Unclamp the hemostats to remove the sheath, spread the sheath open to separate it from the mesh and use the hemostats to slide the sheath off the mesh arms.



STEP 8: Closure

- The mesh arms can be trimmed at the level of the subcutaneous tissue at the stab groin incisions or, alternately, may be tunneled subcutaneously back to the perineal incision then trimmed.
- Irrigate the wound site and close all layers, including the bulbospongiosus muscle using absorbable suture. Ensure all dead space is closed to prevent the formation of a seroma or a hematoma.
- Close the skin with a running suture.

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STEP 9: Post-operative care

- A. Antibiotic prophylaxis should be given at the surgeon's discretion.
- B. The patient's ability to empty his bladder should be confirmed, prior to discharge.
- C. Refrain from heavy lifting, strenuous exercise and intercourse for at least six weeks.
- D. Resume normal daily activities at surgeon's discretion.
- E. Stool softeners may be prescribed to prevent straining with bowel movement.
- F. Pain medication may be prescribed for short-term pain management.

Quick view of key procedural steps

In summary, key procedural steps include:

- A. The legs should be bent at approximately 90 degrees, spread no farther than shoulder width apart.
- B. Thoroughly mobilize the bulbospongiosum by gradually incising the fibrous portion of the central tendon, pausing frequently to check for bulb mobility, until 2–4 cm proximal displacement can be achieved.
- C. Utilize the percutaneous or spinal needle, to identify the optimal location of needle passage.
- D. When passing the helical needle, protect the corpus spongiosum by placing a finger into the perineal incision to receive the needle tip.
- E. The needle tip should enter the perineal incision at the apex of the triangle formed by the pelvic bones.
- F. Perform flexible cystoscopy to ensure proper sling placement and sufficient tensioning to achieve desired urethral coaptation.

Prior to use, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events.

CAUTION: Federal (U.S.) Law restricts this device to sale by or on the order of a physician. This product is only intended for physicians trained in its use.

INDICATIONS: The AdVance™ Male Sling System is intended for the placement of a suburethral sling for the treatment of male stress urinary incontinence (SUI).

CONTRAINDICATIONS: Patients with urinary tract infections, blood coagulation disorders, a compromised immune system or any other condition that would compromise healing, with renal insufficiency, and upper urinary tract relative obstruction.

POTENTIAL ADVERSE EVENTS: Extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation and inflammation. Rx Only



Boston Scientific Corporation
300 Boston Scientific Way, Marlborough, MA 01752
www.amsmenshealth.com

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