

# AdVance™ XP Male Sling System

## Prescriptive Information

Refer to the device directions for use for complete instructions on device use.

### Indications

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

### Contraindications

Contraindications associated with the use of the AdVance XP Male Sling System include patients with:

- urinary tract infections;
- blood coagulation disorders;
- a compromised immune system or any other condition that would compromise healing;
- renal insufficiency and upper urinary tract relative obstruction.

### Warnings and Precautions

#### *General Warnings*

- Only physicians who have been trained as to its use should use the AdVance XP Male Sling System.
- The AdVance XP Male Sling System must not be re-sterilized or re-used.
- Inspect the packaging for visible damage prior to use. Any damage to the sterile barriers renders the device non sterile.
- Do not use product beyond the indicated expiration date.
- Only the innermost pouch may be introduced into the sterile field.
- Physicians should be familiar with surgical procedures and techniques involving non-absorbable meshes before using the AdVance XP Male Sling System device.
- Good surgical practice should be followed for management of contaminated or infected wounds.
- Urinary tract infection should be treated prior to implantation

### ***Procedural Warnings***

- Do not insert the AdVance XP Male Sling System needles with an approach that deploys the needle from the perineum to the obturator.
- Take care to avoid vessel perforation. Observe patient for any signs of retropubic or periurethral bleeding.

### ***Device Related Warnings***

- Non-functional instruments should not be used and should be returned to Boston Scientific.
- Do not use the AdVance™ XP Male Sling System if the package is opened or damaged, as sterility may be compromised.

### ***General Precautions***

- The implantation of this device should only be considered for adult patients whom the physician determines are appropriate surgical candidates.
- The risks and benefits of using the AdVance XP Male Sling System procedure should be carefully considered on patients with:
  - blood coagulation;
  - compromised immune systems or any other conditions that would compromise healing;
  - renal insufficiency and upper urinary tract obstruction.
- The possibility of urgency incontinence should be carefully considered before a sling implant is conducted. It is recommended that:
  - good bladder function (bladder capacity > 250 ml and post void residual urine < 50 ml) be demonstrated by candidates for a male sling;
  - the presence of bladder neck or urethral strictures be ruled out for male sling candidates;
  - a condition involving cystitis, urethritis or prostatitis be ruled out for male sling candidates;
  - detrusor instability of a neurological origin be ruled out for male sling candidates.
- A 6 month period of non-invasive treatment (e.g., behavior modification, bladder exercises, biofeedback, extra corporeal magnetic stimulation of the pelvic floor, or drug therapy) is recommended before a sling implant is considered for males with stress urinary incontinence.

### ***Procedural Precautions***

- Check for bleeding and pelvic organ dysfunction due to intraoperative vessel or nerve damage associated with anomalous location, during needle passage through the medial area of the obturator foramen membrane.
- It is important to verify the tension and placement of the sling prior to closure.
- Do not remove the plastic sheath until the sling is in its desired position.
- If during the procedure it becomes necessary to remove the sling, cut the sling near its midline and draw the sling arms out of the patient by pulling on the distal (connector) ends.
- Do not contact the sling with any staples, clips, or other instruments which may damage the mesh.

### ***Post-Procedure Precautions***

- Acute inflammatory tissue reaction and transitory local irritation has been reported with the use of the absorbable suture.
- After several (2-3) weeks post-implant, the mesh becomes fixated by in-growth of surrounding tissues and cannot be entirely removed. However, the urethral repositioning may be reversed by cutting through the center of the mesh to release the tension.
- Patients should be counseled on abstaining from heavy lifting, strenuous exercise, and intercourse for a minimum of 6 weeks. Patients may return to other normal daily activities at the physician's discretion, often one to two weeks post procedure.
- If dysuria, bleeding, or other problems occur, the patient should be instructed to call the surgeon immediately.

### ***Device Related Precautions***

- Do not use any part of the AdVance™ XP Male Sling System beyond the indicated expiration date.
- To maintain sterility, only the innermost package of the sling should be introduced into the sterile field.
- Store the AdVance XP Male Sling System in a clean, dry, area away from direct sunlight and at room temperature.

### **Adverse Events**

- As with all implants, local irritation at the wound site and/or a foreign body response may occur.

- Tissue responses to the implant could include extrusion, erosion through the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation and inflammation. The occurrence of these responses may require removal of the entire sling.
- Like all foreign bodies, the sling may allow an existing infection to propagate.
- Incorrect sling tension may cause temporary or permanent lower urinary tract obstruction and retention of urine which may require surgical intervention.
- Unintended damage to muscle, tissue, nerves, or vessels.

Known risks of surgical procedures for the treatment of incontinence include: allergic reaction, prolonged procedure, scar tissue, toxicity, hematoma, perforation, exposure to biohazardous material, unretrieved device fragment, pain, infection, erosion, device migration, bleeding, pelvic organ dysfunction, injury (urethra, corpus spongiosum, nerve) and malposition, and complete failure of the procedure, resulting in incontinence and mild to moderate urinary incontinence due to incomplete support or overactive bladder.

This is not a complete list of precautions. All precautions can be found in the product labeling supplied with each device.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

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