Brief Summary Document

Product
IFU #51173322-01

Rx Statement
CAUTION: Federal law (USA) restricts this device to sale by or on the order of a licensed practitioner.

The AdVance XP Male Sling System should only be used by or under the supervision of physicians with an advanced understanding of sub-urethral sling devices and disease states that result in incontinence. A thorough understanding of the technical principles, clinical applications, and risk associated with this procedure is necessary before using this device.

Prior to use, please refer to all applicable "Instructions for Use" for more information on Intended Use/Indications for Use, Contraindications, Warnings, Precautions, Potential Adverse Events, and Operator's Instructions.

Indications for Use

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

- 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.

Precautions

- The implantation of this device should only be considered for adult patients whom the physician determines are appropriate surgical candidates.

- 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.

- 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.
- 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.
- 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.

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 continued incontinence and mild to moderate urinary incontinence due to incomplete support or overactive bladder.