Obtryx™ II Transobturator Mid-Urethral Sling System with PrecisionBlue™ Design (Curved and Halo)

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

Intended Use/Indications for Use

The mesh implant is intended as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Contraindications

A mesh implant is contraindicated in the following patients:

- Pregnant patients, patients with the potential for future growth or patients that are considering future pregnancies.
- Any patients with soft tissue pathology into which the implant is to be placed.
- Patients with any pathology which would compromise implant placement.
- Patients with any pathology, such as blood supply limitations or infections that would compromise healing.

Warnings

For single use only. Do not reuse, Reprocess or resterilze.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policy.

General Warnings

The risks and benefits of performing a suburethral sling procedure in the following patients should be carefully considered:

- Careful consideration should be given to performing this procedure for patients with untreated coagulopathies or who are being treated with either anticoagulants or antiplatelet agents.
- Patients with hypertonic bladders or vesico ureteral reflux.
- Take special care in cases of bladder prolapse because of anatomical distortion. If the patient requires a cystocele repair, it should be done prior to the suburethral sling procedure.
- Vaginal and urinary tract infection should be treated prior to a suburethral sling implantation procedure.
- User should be familiar with surgical procedures and techniques involving nonabsorbable meshes.
- Good surgical practices should be followed for management of contamination or infected wounds.
- Mesh is considered a permanent implant. Removal of mesh or correction of mesh related complication may involve multiple surgeries.
- Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

Adverse Events

The following adverse events have been reported due to suburethral sling placement, but are not limited to:

- As with all implants, local irritation at the wound site and/or a foreign body response may occur.
- Tissue responses to the mesh implant could include:
  - erosion/exposure/extrusion of the mesh through the vaginal or urethral mucosa,
  - bladder wall or other surrounding tissue
  - scarring/scar contracture
  - device migration
  - fistula formation and inflammation

The occurrence of these events may require surgical intervention and possible removal of the entire mesh.

- Like all foreign bodies, the mesh may potentiate an existing infection.
- Excess tension may cause temporary or permanent lower urinary tract obstruction and
- retention.
- Allergic reaction has been reported.
- Known risks of surgical procedures for the treatment of incontinence include:
  - pain, ongoing pain (pelvic, vaginal, groin/thigh, dyspareunia)
  - infection
  - detrusor instability
  - complete failure of the procedure
  - voiding dysfunction (incontinence, mild to moderate incontinence due to incomplete urethral support or due to overactive bladder)
  - bruising, bleeding (vaginal, hematoma formation)
  - abscess
  - vaginal discharge
  - dehiscence of vaginal incision
  - edema and erythema at the wound site
  - perforation or laceration of vessels, nerves, bladder, urethra or bowel may occur during placement.

The occurrence of these events may require surgical intervention. In some instances the response to these events may persist as a permanent condition after the intervention.

Cautions

Cautions and Precautions can be found in the product labeling supplied with each device.

CAUTIONS: Federal (US) Law restricts this device to sale by or on the order of a physician trained in the use of surgical mesh for repair of stress urinary incontinence.

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