Obtryx™ II Transobturator Mid-Urethral Sling System with PrecisionBlue™ Design

Prescriptive Information

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

Intended Use/Indications for Use

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

Contraindications

A mesh implant is contraindicated in the following patients:

- Pregnant patients, patients with 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 resterilize.

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 should be carefully considered:

    - Women planning future pregnancies.
    - Overweight women (weight parameters to be determined by the physician).
    - Patients with blood coagulation disorder.
    - Patients with compromised immune system or any other conditions that would compromise healing.
    - 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 placement.

- Vaginal and urinary tract infection should be treated prior to implantation
- User should be familiar with surgical procedures and techniques involving non-absorbable meshes before using the Obtryx II System
- This product is intended for use only clinicians with adequate training and experience in treatment of female stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.
- User should note the importance of placing the mesh without tension under mid-urethra.
- Good surgical practices should be followed for management of contamination or infected wounds.
- Bleeding can occur. Check carefully before releasing patient from the hospital

Potential Complications

The following complications 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 may occur.
- Tissue responses to the implant could include vaginal 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 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.
- Known risks of surgical procedures for the treatment of incontinence include pain, infection, erosion, device migration, complete failure of the procedure resulting in incontinence and mild to moderate incontinence due to incomplete support or overactive bladder.
- In addition to the above listed potential complications, allergic reaction, abscess, detrusor instability, pain (pelvic, vaginal, groin, dyspareunia), bleeding (vaginal, hematoma formation), vaginal discharge, dehiscence of vaginal incision, nerve damage, edema and erythema at the wound site have been reported due to suburethral sling procedure.
- It has also been reported that orthostatic symptoms, fatigue and shortness of breath may occur due to the potential development of bleeding, including occult bleeding

Cautions

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

CAUTION: Federal (USA) 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.