Solyx™ Single Incision Sling System

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 urethral 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 patients 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.
  - Patients with renal insufficiency or upper urinary tract obstruction.
  - 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 a suburethral sling implantation procedure.
  - User should be familiar with surgical procedures and techniques involving non-absorbable meshes.
  - This product is intended for use only by physicians 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 tension free under the mid-urethra.
**Adverse Events**

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

- Abscess
- Allergic reaction
- Bleeding
- Bruising/Hematoma
- Dehiscence of vaginal incision
- Detrusor Instability
- Dyspareunia
- Edema/Erythema
- Erosion/Exposure
- Extrusion
- Fistula
- Hemorrhage
- Incontinence
- Infection
- Inflammation
- Irritation
- Migration of device from desired location
- Organ perforation
- Overactive bladder
- Pain
- Urinary Retention
- Urinary Tract Obstruction
- Vessel/Nerve Injury
- Vaginal Discharge

**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 use of surgical mesh for repair of stress urinary incontinence.

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