TRANSVAGINAL SINGLE INCISION SLING SYSTEMS

Solyx™ SIS 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 as a suburethral sling for the treatment of stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

The Solyx SIS Delivery Device is intended for use as an aid in insertion, placement, fixation, and anchoring of Solyx SIS surgical mesh during urogynaecological procedures.

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.
- This product is intended for use only by clinicians with adequate training and experience in the surgical treatment of stress urinary incontinence (SUI). The physician is advised to consult the medical literature regarding techniques, complications and hazards associated with the intended procedures.

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.

Precautions

- The use of polypropylene mesh in urogynecologic procedures such as the treatment of stress urinary incontinence, regardless of the route of delivery (transvaginal, suprapubic or transobturator) has been associated with cases of erosion. Erosion has been reported in the bladder, vagina, urethra, ureter, and bowel. Treatment of the erosion may require surgical removal.
- As with all surgical procedures, certain risk factors are known to impact patient outcomes in the pelvic floor which include, but are not limited to, impaired vascularity (e.g. diabetes, smoking status, estrogen status, pelvic floor radiation exposure, etc.), age, pelvic floor myalgia, impaired wound healing (e.g. diabetes, steroid usage, etc.), or active infection in or near the surgical site. The above pathophysiologic conditions must be considered when determining whether the patient is an appropriate candidate for mesh implantation, either by transvaginal, suprapubic or transobturator route.
- Standard surgical practices should be followed for the suburethral sling procedure as well as for the management of contaminated or infected wounds.
- Bleeding can occur. Check carefully before releasing the patient from the hospital.
- Physician should determine when it is suitable for each patient to return to normal activities.
- Patients should be counseled when to resume to vigorous activities (heavy lifting, exercise), and intercourse after the procedure.
- Use of this device should be done with the understanding that subsequent infection may require removal of the mesh.
- Should dysuria, bleeding or other problems occur, the patient should be instructed to immediately contact the physician.
- Do not use any mechanical means of contact with the mesh (such as clips, staples etc.) within the urethral support region of the mesh as mechanical damage to the mesh may occur.

Adverse Events

The following adverse events have been reported due to suburethral sling placement, any of which may be ongoing, but are not limited to: As with all implants, local irritation at the wound site and/or a foreign body response may occur, Foreign body reaction may be acute or chronic, Pain (pelvic, vaginal, groin/thigh, suprapubic, dyspareunia) (acute or chronic), Dyspareunia, Tissue responses to the mesh implant could include: erosion into organs (urethra, bladder or other surrounding tissues); exposure/extrusion into the vagina, Mesh contact with urine via erosion/exposure/extrusion may result in stone formation, scarring/scar contracture, Necrosis, fistula formation (acute or chronic), inflammation (acute or chronic), Mesh contracture, Tissue contracture, Vaginal shortening or stenosis that may result in dyspareunia and/or sexual dysfunction, Pain with intercourse that may not resolve, Exposed mesh may cause pain or discomfort to the patient's partner during intercourse, Sexual dysfunction, including the inability to have intercourse. Like all foreign bodies, the mesh may potentiate an existing infection. Allergic reaction has been reported. Known risks of surgical procedures for the treatment of incontinence include: pain, ongoing pain (pelvic, vaginal, groin/thigh, suprapubic, dyspareunia), Severe, chronic pain, Apareunia, Leg weakness, Infection, De novo detrusor instability, Complete failure of the procedure/failure to resolve a patient's stress urinary incontinence, Voiding dysfunction (incontinence, temporary or permanent lower urinary tract obstruction, difficulty urinating, pain with urination, overactive bladder, and retention), 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 following additional adverse events have been reported for the Solyx SIS System: Dysuria, Hematuria. The occurrence of these events may require surgical intervention and possible removal of the entire mesh. In some instances, these events may persist as a permanent condition after surgical intervention or other treatment. Removal of mesh or correction of mesh-related complications may involve multiple surgeries. Complete removal of mesh may not be possible and additional surgeries may not always fully correct the complications.

Cautions

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

CAUTION: 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.