Xenform™ Soft Tissue Repair Matrix

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

Intended Use/Indications for Use

Xenform Soft Tissue Repair Matrix is intended for use as a soft tissue patch to reinforce soft tissue where weakness exists and for the surgical repair of damaged or ruptured soft tissue membranes. It is specifically indicated for the repair of colon, rectal, urethral, and vaginal prolapse; reconstruction of the pelvic floor; and procedures such as sacrocolposuspension and urethral sling.

Contraindications

Xenform Soft Tissue Repair Matrix is contraindicated for use in any patient in whom soft tissue implants are contraindicated. These patients include those with:

- Pathology of the soft tissue into which the Xenform Soft Tissue Repair Matrix is to be placed.
- Known history of hypersensitivity to collagen or bovine products.
- Any pathology which would compromise implant placement.
- Any pathology that would limit blood supply and compromise healing.
- Patients diagnosed with autoimmune connective tissue disease.
- Pre-existing local or systemic infection. Treat the infection with the appropriate antiseptics and/or antibiotics to eliminate the infection before using Xenform Soft Tissue Repair Matrix.

Warnings

Patients should be counseled to refrain from heavy lifting, exercise and intercourse for a minimum of six (6) weeks after the procedure. Physician should determine when it is suitable for each patient to return to normal activities.

Precautions

- Surgical treatment of female pelvic organ prolapse should be performed by clinicians with training and experience in the placement of surgical biologic grafts for treatment of pelvic floor disorders and in management of complications resulting from procedures.

- 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 or transabdominal route.

- The use of mesh in urogynecologic procedures such as the treatment of pelvic organ prolapse, regardless of the route of delivery (transvaginal or transabdominal), has been associated with cases of erosion. Erosion has been reported in bladder, vagina, urethra and ureter, and bowel. Treatment of the erosion may require surgical removal.
Adverse Events

Potential Adverse Events associated with the Xenform Soft Tissue Matrix include, but are not limited to:

- Erosion/extrusion/exposure;
- Pain, ongoing pain, discomfort, irritation;
- Infection/sepsis potentiation/abscess formation;
- Bleeding (bruising, hematoma, hemorrhage, post-operative bleeding);
- Dyspareunia;
- Organ perforation/fistula formation;
- Ureteral injury/obstruction;
- Urinary incontinence and/or fecal incontinence;
- Urinary retention;
- Foreign body reaction;
- Vaginal shortening or stenosis;
- Recurrent prolapse;
- Allergy, hypersensitivity or other immune reaction;
- Adhesion formation;
- Vessel/Nerve injury;
- Acute or chronic inflammation;
- Vaginal discharge;
- Dehiscence and/or necrosis;
- Constipation/defecatory dysfunction;
- Granulation tissue formation.

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.

CAUTION: Federal (USA) Law restricts this device to sale by or on the order of a physician

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