

Upsilon™ Traditional Y Mesh

Refer to the device Directions for Use for complete instructions on device use.

Intended Use/Indications for Use

Upsilon Mesh is intended for use as a bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy, laparoscopic or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

Contraindications

Upsilon Mesh 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 synthetic mesh is to be placed.
- Patients with future growth potential, pregnant patients, or patients that are considering future pregnancies.
- An anatomy that compromises device implant or pathology that limits blood supply or compromises healing.
- Autoimmune connective tissue disease.
- Pre-existing local or systemic infection.
- Blood coagulation disorder.

Warnings

- The effectiveness of this product has not been evaluated in a prospective randomized clinical trial.
- The implant procedure carries risk of infection and bleeding, inherent with open, laparoscopic, or robotic procedures.
- In the event of post procedure infection, the entire mesh may have to be removed.
- Perforations or lacerations of vessels, nerves, bladder, ureters, urethra or bowel may occur during placement and may require surgical repair.
- Mesh is considered a permanent implant. 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.
- Perforations or lacerations of vessels, nerves, bladder, ureters, urethra or bowel may occur during placement and may require surgical repair.
- As with all foreign bodies, the mesh may potentiate an existing infection reaction or sepsis.
- 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.

Adverse Events

- Adhesion formation
- Allergic reaction (hypersensitivity)
- Constipation
- Dehiscence

- Dyspareunia
- Erosion or extrusion
- Fistula formation
- Granulation tissue formation
- Hemorrhage
- Infection
- Inflammation (acute or chronic)
- Injury to ureter
- Mesh and or tissue contracture
- Necrosis
- Nerve injury
- Organ perforation
- Pain, ongoing pain
- Post-operative bowel obstruction
- Prolapse/Recurrent prolapse
- Urinary and or fecal incontinence
- Urinary retention
- Vaginal shortening or stenosis

Precautions

- Physicians should be trained in the placement of surgical mesh devices for treatment of pelvic floor disorders and in management of complications resulting from these procedures.
- Standard surgical practices should be followed for pelvic floor procedures as well as for the management of contaminated or infected wounds.
- An assessment of each patient should be made to determine their suitability for a synthetic mesh procedure, considering the patient's prior abdominal or pelvic surgeries.
- 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 polypropylene 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, ureter, and bowel. Treatment of the erosion may require surgical removal.
- Aseptic technique must be adhered to throughout procedure.
- Do not use product if past the date of expiration.
- It is recommended that patients be counseled to refrain from heavy lifting, exercise, and intercourse for a minimum of six (6) weeks after the procedure. Follow physician's recommendations.
- It is recommended that patients be counseled to contact their physician in the case of post-operative bleeding, dysuria or other problems.
- There should be an appropriate margin of mesh extending beyond the suture line. Inadequate suturing of the mesh material to the pelvic tissue may lead to failure of the repair and recurrence of the prolapse.
- Future pregnancy may negate the effect of surgical repair.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician trained in performing mesh procedures for surgical repair of pelvic organ prolapse.

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