

## **Upsylon™ Traditional Y Mesh**

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

### **Intended Use/Indications for Use**

Upsylon 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**

Upsylon 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**

Potential adverse events, any of which may be ongoing, include but are not limited to: Abscess, Adhesion formation, Allergic reaction (hypersensitivity), Bruising, Bleeding (hematoma formation), Constipation, Dehiscence, De novo detrusor instability, Dyspareunia, Pain with intercourse that may not resolve, Sexual dysfunction; including the inability to have intercourse, Erosion into organs; exposure/extrusion into vagina, Exposed mesh may cause pain or discomfort to the patient's partner during intercourse, Failure to resolve a patient's prolapse, Fistula formation (acute or chronic), Foreign body reaction (acute or chronic), Granulation tissue formation, Hemorrhage, Infection, Inflammation (acute or chronic), Injury to ureter, Scarring/scar contracture, Mesh contracture, Tissue contracture, Necrosis, Nerve injury, Organ

perforation, Pain (pelvic, vaginal, groin/thigh, dyspareunia) (acute or chronic), Perforation or laceration of vessels, nerves, bladder, or bowel may occur during placement, Post-operative bowel obstruction, Prolapse/recurrent prolapse, Vaginal shortening or stenosis that may result in dyspareunia and/or sexual dysfunction, Voiding dysfunction (incontinence, temporary or permanent lower urinary tract obstruction, difficulty urinating, pain with urination, overactive bladder, and retention). The occurrence of one or more of these complications may require treatment or surgical intervention. In some instances, the complication may persist as a permanent condition after the 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.

## **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.

All trademarks are the property of their respective owners.

©2021 Boston Scientific Corporation or its affiliates. All rights reserved.

WH-264301-AD JUL 2021