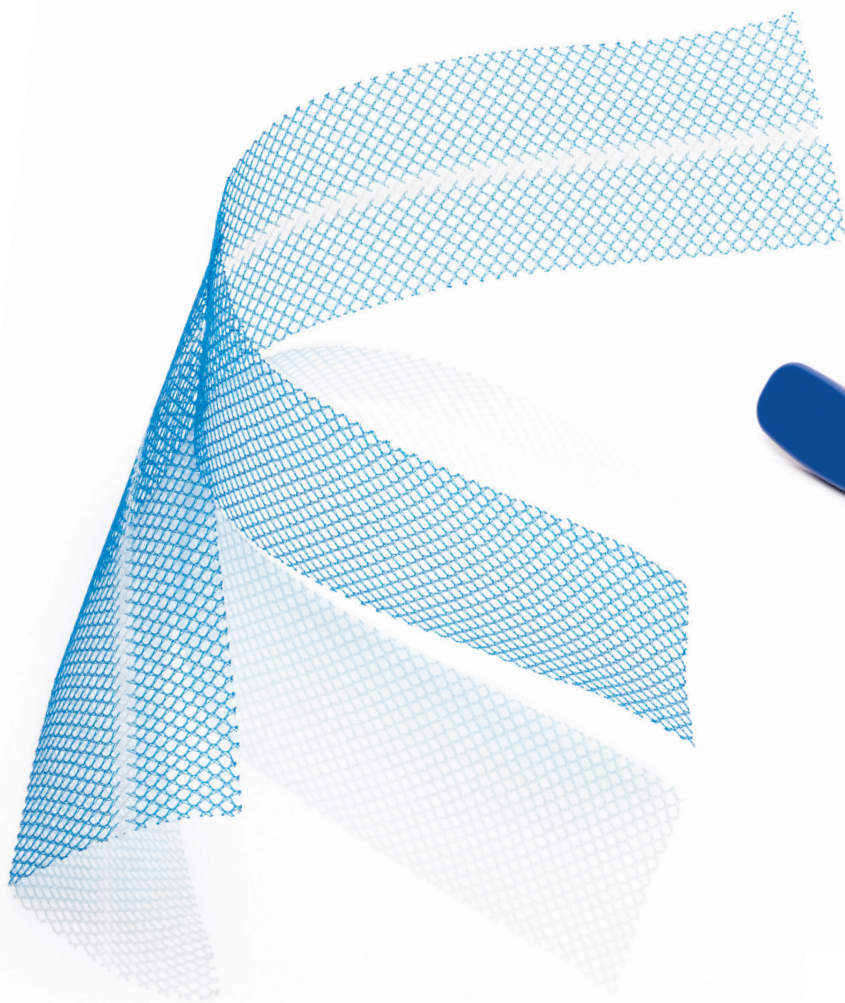




Upsilon™ Y-Mesh and Colpassist™ Vaginal Positioning Device

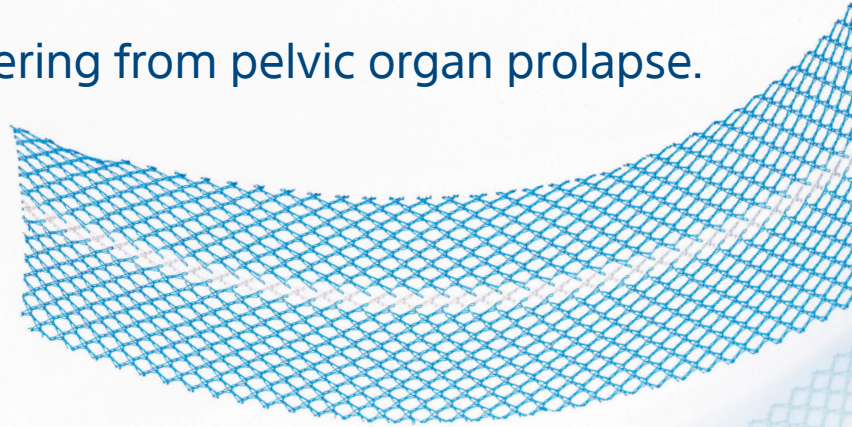
Designed to deliver low density, high
durability and exceptional handling



Upsylon™ Y-Mesh

Upsylon Y-Mesh is designed to deliver both low density and high durability, through exceptional handling and dynamic, tear-resistant design —

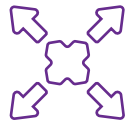
so you can treat patients suffering from pelvic organ prolapse.



Durable

Extraordinary strength at a lightweight density

- High tensile strength designed to resist tearing¹
- Greater resistance to tearing at attachment point than market-leading competitor³
- Durable design reduces potentially risk of suture pullout¹
- Intentionally designed to be above ultralight weight where mesh construct can be susceptible to a greater probability of early repair failure⁴



Dynamic Design

Mesh properties designed to match physiologic characteristics of the vaginal wall

- Pore size optimized to help promote mesh integration²
- Trimmable and customizable to meet patient needs without fraying or unraveling



Exceptional Handling

Handling characteristics designed for positioning, placement, and fixation

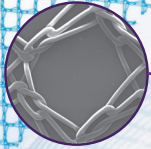
- Blue color and centering line provide enhanced visualization and orientation¹
- Unique finishing process that is designed to help the mesh lay flat during fixation¹
- Enhanced with the Colpassist™ Vaginal Positioning Device to help create flat suturing surface and provide multi-direction vaginal manipulation¹



Blue color and centering line
enhanced visualization and orientation
during placement



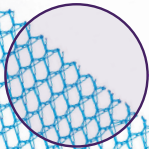
Light mesh weight: 25 g/m² intentionally
above ultralight weight region to
resist tearing¹



Thickness: 190 microns



Suture pull-out strength: 18.3 N
designed to reduce the risk of suture
pull out¹



Pore size: 2.8 mm³
Optimal pore size (diameter $\geq 1.0\text{mm}$)
promotes tissue integration,² facilitates
passage of needle and sutures¹



Colpassist™ Vaginal Positioning Device

The Colpassist Vaginal Positioning Device is the first device specifically designed for vaginal positioning in gynecologic procedures and as a suturing platform for vaginal wall fixation during sacrocolpopexy.

- Two size end options create a flat suturing surface
- Multi-direction vaginal manipulation during dissection and mesh placement

Figure 1: Picture of posterior dissection performed with Colpassist Vaginal Positioning Device providing positioning.



Always there.

As a global leader in women's health, Boston Scientific is steadfast in our commitment to helping women and all patients live better and healthier lives. Through the power of partnership, we offer industry-leading clinical support, and medical and patient education programs and resources.

To learn more about how Upsilon and Colpassist can help you treat patients with pelvic organ prolapse, contact your Boston Scientific representative or visit [bostonscientific.com](https://www.bostonscientific.com).

Ordering Information

Order Number	Description	Unit
M0068318200	Upsilon Y-Mesh	Each
M0068318210	Colpassist Vaginal Positioning Device	Each
M0068318220	Upsilon Y-Mesh and Colpassist Vaginal Positioning Device Kit	Each

References:

1. Data on File at BSC. (Durability testing: tensile and tear resistance)
2. Barone, W. et al; Textile properties of synthetic prolapse mesh in response to uniaxial loading, *AJOG* 2016.
3. Data on File at Boston Scientific. Full width product samples (one side of attachment in each grip) were tested using a 1" gage length at a speed of 5" per minute using a constant rate of extension tensile tester (n=15)
4. Askew, A. et al; Does Mesh Weight Affect Time to Failure After Robotic-Assisted Laparoscopic Sacrocolpopexy? *Female Pelvic Medicine & Reconstructive Surgery*, Sep 2020.

Potential adverse events for Upsilon Y-Mesh, any of which may be ongoing, include but are not limited to: Abscess (swollen area within the body tissue, containing a buildup of pus), Adhesion formation (when a scar extends from within one area to another), Allergic reaction (hypersensitivity) to the implant, Bruising, Bleeding, Constipation, Dehiscence (opening of the incision after surgery), De novo detrusor instability (involuntary contraction of the bladder wall leading to an urge to urinate), Dyspareunia (pain during sexual intercourse) that may not resolve, Sexual dysfunction (difficulty with sexual response, desire, orgasm or pain); including the inability to have intercourse, Erosion into organs; exposure/extrusion into vagina (when the mesh goes through the vagina into other organs or surrounding tissue), Exposed mesh may cause pain or discomfort to the patient's partner during intercourse, Fistula formation (a hole/passage that develops through the wall of the organs) which may be acute or chronic, Foreign body reaction (body's inflammatory response to the implant) which may be acute or chronic, Granulation tissue formation (reddish connective tissue that forms on the surface when a wound is healing), Hematoma formation (a pool of blood under the skin/bruising), Hemorrhage (profuse bleeding), Infection, Inflammation (redness, heat, pain or swelling at the surgical site as a result of the surgery) which may be acute or chronic, Injury to ureter (the duct that urine passes from the kidneys to the bladder), Scarring/scar contracture (tightening of the scar), Mesh contracture (mesh shrinkage), Tissue contracture (tightening of the tissue) Necrosis (death of living tissue in a small area), Nerve injury (injury to the nerve fiber), Organ perforation (a hole in or damage to these or other tissues that may happen during placement), Pain: pelvic, vaginal, groin/thigh, dyspareunia-which may become severe, Perforation or laceration of vessels, nerves, bladder, or bowel (a hole in or damage to these or other tissues that may happen during placement), Post-operative bowel obstruction (blockage that keeps food or liquid from passing through the small or large intestines), Prolapse/recurrent prolapse (complete failure of the procedure), Vaginal shortening or stenosis which 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 (involuntary leakage of urine or reduced or complete inability to empty the bladder). 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.

For Upsilon Y-Mesh: Caution: Federal (USA) law 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.

For Colpassist Vaginal Positioning Device: Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Please refer to package insert provided with these products for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using these products.

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