Uphold Lite™ Vaginal Support Systems

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

The safety and effectiveness of the Uphold™ Lite Vaginal Support Systems compared to conventional surgical repair for pelvic organ prolapse have not been demonstrated in randomized controlled clinical trials. In the United States, substantial equivalence of the Uphold Vaginal Support Systems to synthetic mesh has been demonstrated through bench top testing.

Intended Use/Indications for Use
The Uphold Lite Vaginal Support Systems are indicated for tissue reinforcement and stabilization of fascial structures of the pelvic floor in vaginal wall prolapse, where surgical treatment is intended, either as mechanical support or bridging material for the fascial defect.

Contraindications
The Uphold Lite Synthetic Mesh is contraindicated for use in any patient in whom soft tissue implants are contraindicated. In addition patients with:

- Pathology of the soft tissue into which the Uphold Lite Synthetic Mesh is to be placed.
- Pregnant patients, or patients that are considering future pregnancies.
- The potential of future growth (e.g. infants, children).
- Any pathology, including known or suspected uterine pathology, which would compromise implant placement.
- Any pathology that would limit blood supply and compromise healing (e.g. decreased blood supply to organs as a result of treatments such as radiation therapy, chemotherapy).
- Presence of known or suspected cancer of the vagina, cervix, or uterus.
- Blood coagulation disorder.
- Autoimmune connective tissue disease.
- Renal insufficiency and upper urinary tract obstruction.
- Pre-existing local or systemic infection. Treat the infection with the appropriate antiseptics and/or antibiotics to eliminate the infection before placing the Uphold Lite Synthetic Mesh.

Warnings/Potential Complications

- Hysterectomy may be needed in the future; Use of mesh may make future hysterectomies more difficult due to tissue in-growth and scarring.
- Cervical length must be evaluated during the preoperative workup; Patients with cervical elongation may not be appropriate candidates for apical repair procedures; Cervical amputation may be considered for patients with cervical elongation who choose to undergo the procedure.
- Continued screening and surveillance for cervical and uterine disease may be required; Regular pelvic exam, Pap test and endometrial biopsies should be continued as medically indicated.
- Performing apical repair for cases involving uterine enlargement, in the presence of benign disease, should be at the physician’s discretion; an enlarged uterus may compromise the effectiveness of the procedure in some cases.
- Should dysuria, bleeding or other problems occur, the patient should be instructed to contact the physician immediately.
- 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.
• In the event that infection presents post procedure, the entire mesh may have to be removed or revised.
• Like all foreign bodies, the mesh may potentiate an existing infection reaction or sepsis.
• Tissue responses to the implant could include local irritation at the wound site, vaginal erosion or exposure though the urethra or other surrounding tissue, migration of the device from the desired location, fistula formation, foreign body reaction, and inflammation. The occurrence of these responses may require removal or revision of the mesh.
• Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
• Mild to moderate incontinence may occur due to incomplete support.
• Excess tension may cause temporary or permanent lower urinary tract obstruction and retention.
• Known risks of surgical procedures for the treatment of prolapse include pain, infection, erosion/exposure, device migration, complete failure of the procedure resulting in recurrent or de novo prolapse and/or incontinence.
• Perforation or lacerations of vessels, nerves, bladder, urethra, or bowel may occur during placement and may require surgical repair.
• A digital rectal exam should be performed to detect possible rectal perforation.
• Cystoscopy is recommended to confirm bladder integrity or detect possible bladder or ureteral perforation.
• Overweight women may be prone to intraoperative and postoperative complications.
• Do not turn, rotate or torque the Capio™ SLIM Device during actuation. To do so may result in injury.

Adverse Events
Potential adverse reactions that are associated with gynecological surgical mesh include:
• Pain, ongoing pain, discomfort, irritation;
• Infection/sepsis potentiation/abscess formation;
• Bleeding (bruising, hematoma, hemorrhage, post-operative bleeding);
• Dyspareunia;
• Organ perforation/fistula formation;
• Ureteric injury;
• Ureter obstruction;
• Urinary incontinence;
• Urinary retention;
• Retained foreign body (foreign body reaction);
• Neuro-muscular problems;
• Vaginal shortening or stenosis, mesh and/or tissue contracture;
• Recurrent prolapse;
• Allergy, hypersensitivity or other immune reaction;
• Adhesion formation;
• Vessel/nerve injury/perforation;
• Inflammation (acute or chronic);
• Vaginal discharge;
• Dehiscence and/or necrosis;
• Wound dehiscence;
• Constipation/defecatory dysfunction;
• Granulation tissue formation;
• Surgical site wound irritation, erythema, edema;
Cautions/Precautions

- Surgical treatment of female pelvic organ prolapse should be performed by clinicians with training and experience in the minimally-invasive placement of surgical mesh devices for treatment of pelvic floor disorders and in management of complications resulting from procedures.
- Training on the use of the Uphold™ Lite Vaginal Support Systems is recommended and available. Contact your company sales representative to arrange for this training.
- The physician is advised to consult this DFU and the medical literature regarding techniques, complications and hazards associated with the intended 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 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.
- Individual patients’ anatomy may vary greatly, for each procedure it is important that the intended planes for mesh placement and the intended location for leg placement are planned and known for each individual patient. Employment of imaging methods before and after mesh placement may aid in proper mesh placement and confirm absence of injury to non-target anatomical structures.
- Standard surgical practices should be followed for pelvic floor procedures as well as for the management of contaminated or infected wounds.
- The procedure should be performed with care, using the Capio™ SLIM Suture Capturing Device provided with the system to reduce the risk of perforation or laceration of any vessels, nerves, bladder, urethra and bowel.
- Avoid excessive tension on the mesh during handling and positioning to prevent damage to the device.
- Do not remove the protective plastic sleeve covering mesh legs until proper position has been confirmed.
- Avoid excess tensioning of the mesh when positioning to avoid over correction of the defect.
- Take special care in cases of bladder prolapse because of anatomical distortion.
- Use only size 0 Capio Sutures with the Capio SLIM Suture Capturing Device.
- Do not affix mesh with any staples, clips, or clamps as mechanical damage to the mesh may occur.
- Do not bend or alter the Capio SLIM Suture Capturing Device as this may result in mechanical damage to the device.

Caution: Federal Law (USA) restricts this device to sale by or on the order of a physician. Physicians should be trained in the minimally-invasive placement of surgical mesh devices for treatment of pelvic floor disorders and in management.

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