Uphold™ LITE Vaginal Support System with Capio™ SLIM Suture Capturing Device

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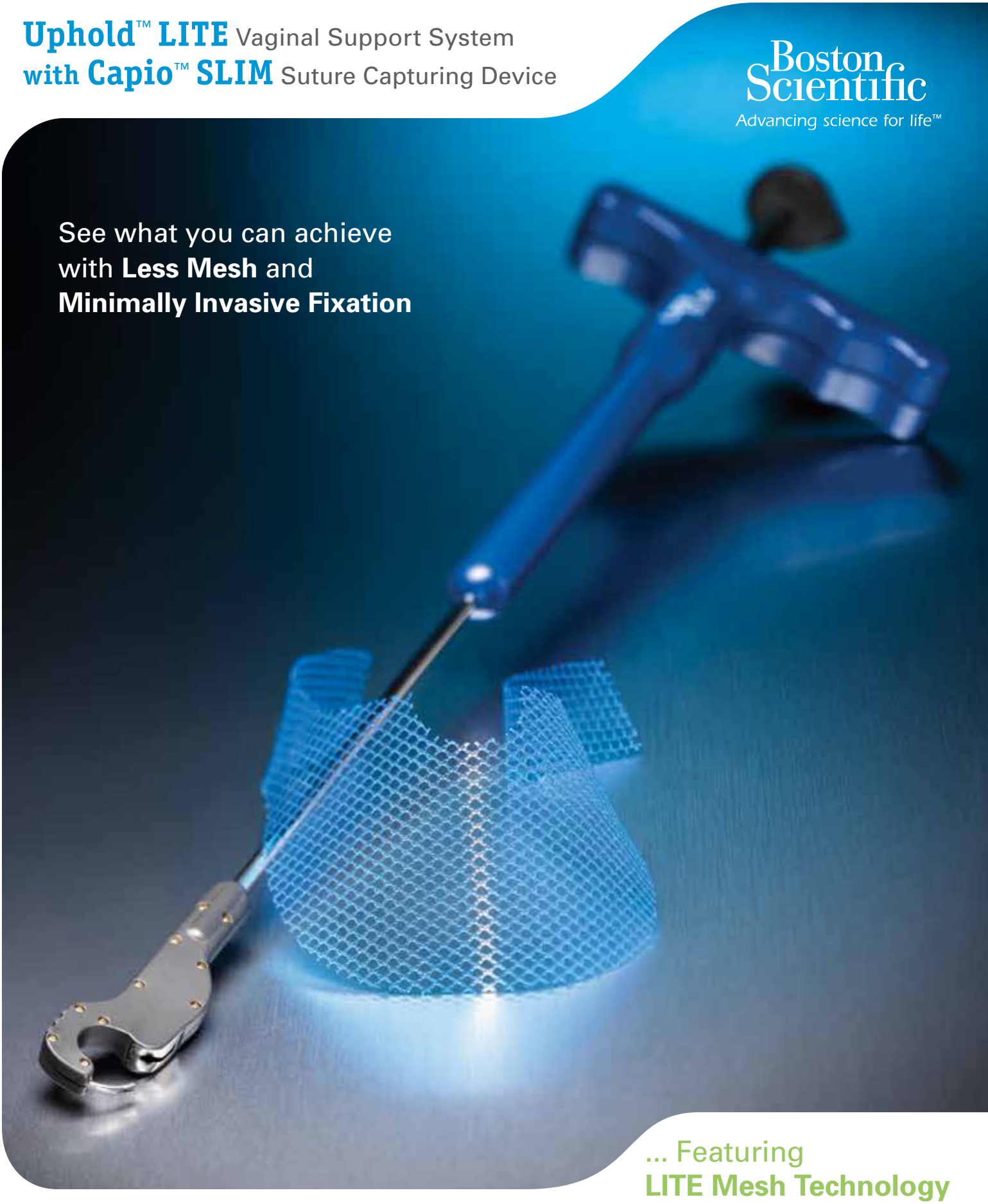
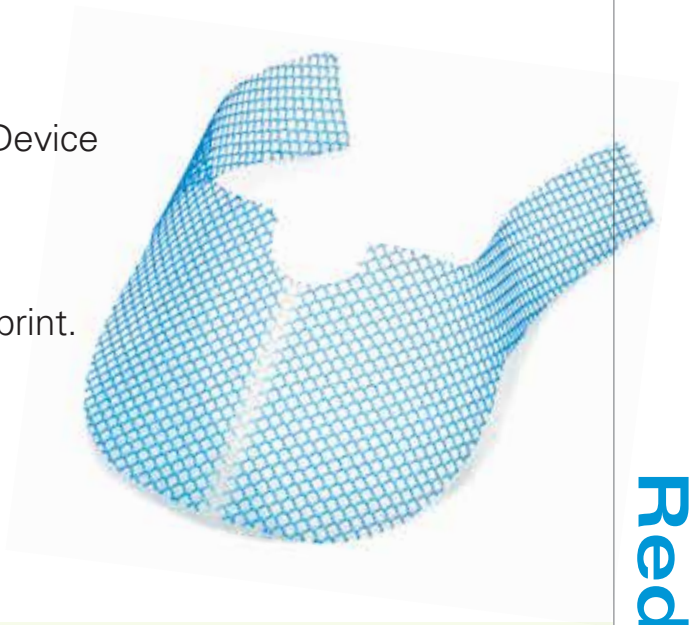


See what you can achieve with **Less Mesh** and **Minimally Invasive Fixation**

... Featuring
LITE Mesh Technology

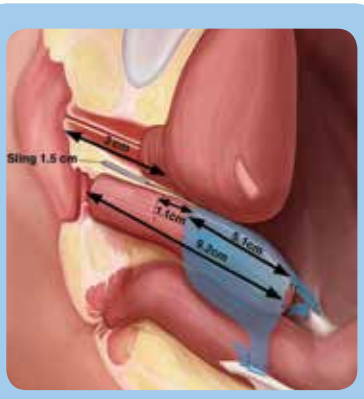
Uphold™ LITE Vaginal Support System

The Uphold LITE Mesh builds on the Uphold Device experience. This kit is configured for support and coverage of both the apical and anterior compartments yet offers a smaller mesh footprint. Now using LITE Mesh technology, a next generation light-weight mesh.



Smaller Mesh Footprint

is designed to minimize mesh material. A physician designed placement procedure may avoid mesh overlapping the incision line and may subsequently reduce the risk of exposure.[1]



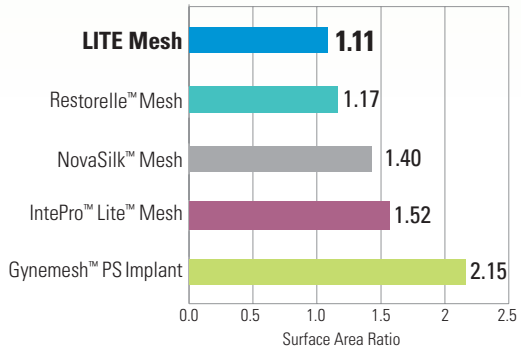
In a study, 70 patients were measured with a total average vaginal length of 9.2 cm. The final distance between the mesh and incision = 1.1 cm.

Dimensions based on clinical research from the University of Chicago

LITE Mesh Technology

LITE Mesh is more than just light-weight mesh. It reduces the implant surface area to minimize the amount of mesh that comes in contact with the patient's tissues.

Comparison of Mesh Surface Area Ratios[2]



Surface Area Ratio Comparison

- **27% lower** than the Elevate Device IntePro Lite Mesh
- **21% lower** than Exair NovaSilk Mesh

Reduces the amount of mesh

Uphold™ LITE Vaginal Support System *with* Capio™ SLIM Suture Capturing Device

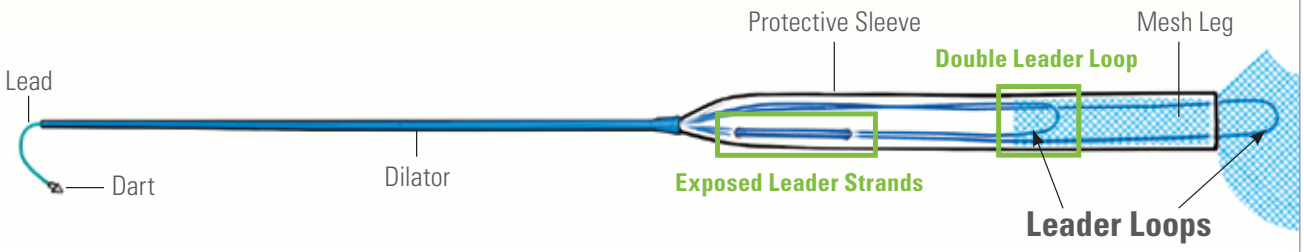
The Uphold LITE System enables an intra-vaginal, trocar-free prolapse repair with mesh adjustability designed to achieve Level I support while the Capio SLIM Suture Capturing Device is designed to facilitate accurate, consistent and controlled placement with a small incision.

Capio SLIM Suture Capturing Device

- **A reduced profile** to minimize the space required within the surgical field
- **Trocar-free approach** with no external incisions that provides direct access to the sacrospinous ligament
- Designed for **controlled placement without dart fixation** to reduce trauma to the SSL

Uphold Device Leg Technology

- Enables **bi-directional adjustability**
- **No lateral arms** are required, similar to sacrocolpopexy
- **No suture tie down**



Uphold LITE System Similarities with Abdominal Sacrocolpopexy (ASC)[1]

- Zone of Aa mesh coverage
- Absence of overlap between mesh and vaginal wound
- Suspend mesh and apex to a cephalad fixation
- No paravaginal fixation, even for advanced AA prolapse

Uphold LITE System Procedural Differences from ASC[1,3]

- No entry into the abdominal/peritoneal cavity
- Hysterectomy not required
- No abdominal incisions
- Minimal instrumentation
- Shorter operative times

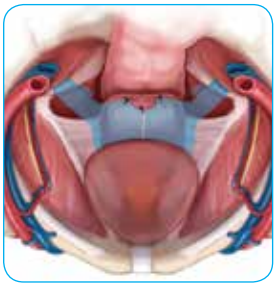
Enables minimally invasive fixation

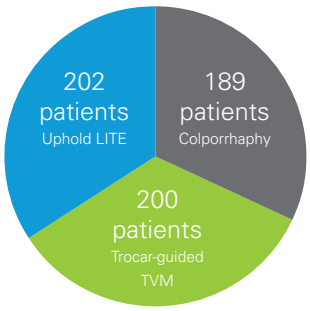
Clinical Data

Intra- and perioperative morbidity following pelvic organ prolapse repair using a transvaginal suture capturing mesh device compared to trocar guided transvaginal mesh and traditional colporraphy

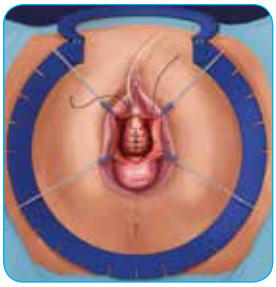
A 24 site, prospective study with 202 patients treated with the Uphold™ LITE System found there were **no significant differences in intra- and perioperative morbity when compared to traditional colporrhaphy**. There were 3 cases of bladder injury and 2 cases of repoeration from pelvic pain. The most frequent post-operative adverse event was difficulty with bladder emptying.

Altman D, Mooller BK, Mikkola T, Gunnarsson J, Ellstrom EM, Falconer C. Intra- and perioperative morbidity following pelvic organ prolapse repair using a transvaginal suture capturing mesh device compared to trocar guided transvaginal mesh and traditional colporraphy. **Neurology and Urodynamics** 2013;32(6):873-874





591 Total Patients



Clinical Outcomes Using a Transvaginal Suture Capturing Mesh Device For Apical Prolapse

In a prospective, 24 site Uphold LITE System study with 202 patients, **all changes for POP-Q points Aa, Ba, C, and D were statistically significant (p>0.001) at 1 year** while changes in TVL measurements were statistically nonsignfiicant. The POP-Q scores for the 139 patients who received the Uphold LITE System only, improved from 1.5 to -1.8 (Ba) and .2 to -4.7 (C) at 12 months. The POP-Q scores for the 63 patients who underwent the Uphold LITE System with anterior colporrhaphy improved from 1.4 to -1.4 (Ba) and 0.1 to -4.3 (C). 2% of patients underwent reoperation for revision or removal of mesh because of mesh exposure while 3% of patients were treated for pain.

D Altman, T Mikkola, K Mooller bek, J Gunnarsson, M Ellstrom eng, C. Falconer, Clinical Outcomes Using a Transvaginal Suture Capturing Mesh Device For Apical Prolapse, **Female Pelvic Medicine & Reproductive Surgery** 2014; 20(4 Suppl):S283

POP-Q Outcomes 1 Year after Uphold LITE System Surgery								
	Aa		Ba		C		TVL	
	Baseline	**1 yr**	**Baseline**	**1 yr**	**Baseline**	**1 yr**	**Baseline**	**1 yr**
139 (Uphold Device Only)	1.1	-1.6	1.5	-1.8	0.2	-4.7	8.2	7.7
63 (Uphold Device + Anterior Colphorraphy)	1.0	-1.4	1.4	-1.4	0.1	-4.3	8.5	8.0

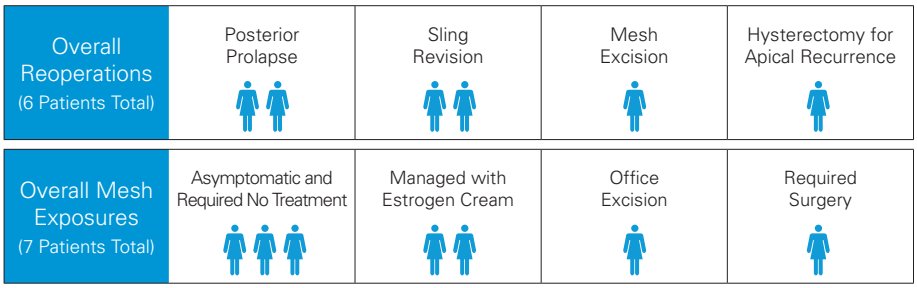
Designed to achieve optimal outcomes

Clinical Data (cont.)

A multicenter, prospective trial to evaluate mesh-augmented sacrospinous hysteropexy for uterovaginal prolapse

99 women with uterine prolapse were evaluated in a prospective study at 3 FPMRS referral centers and treated with the Uphold™ System. The **overall anatomic success rate at 12 months using Ba < -1 was 97.7% and C < ½ TVL 96.6%**. All subjective questionnaire scores improved at 12-month compared to pre-op. The overall exposure rate was 6.52% (7 pts). 1 patient required excision surgery; 2 patients were managed with estrogen cream; 1 patiet underwent in-office excision; and the remaining 3 patients were asymptomatic and required no treatment. The overall reoperation rate was 7.53% which included patients with posterior prolapse (2), sling revision (2), mesh excision(1) and hysterectomy for apical recurrence (1).

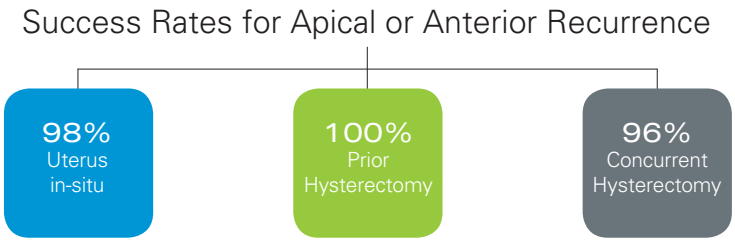
K. E. Jirschele, M. J. Seitz, Y Zhou, P. L. Rosenblatt, P Culligan, P. K. Sand. A multicenter, prospective trial to evaluate mesh-augmented sacrospinous hysteropexy for uterovaginal prolapse **Int Urogynecol Journal** 2014; (TBD)



Minimal mesh repair for apical and anterior prolapse: initial anatomical and subjective outcomes

In a retrospective cohort study of the first 115 consecutive patients treated with the Uphold System with a median follow-up of 12.1 months, **anterior recurrence was observed in one patient (0.8%) when defined as Ba > 0. Apical recurrence was observed in 2 patients (1.7%) when defined as C>0**. The rate for mesh exposure was 3/115 (2.6%). Dysparunia rates dropped from 13.4% preoperatively to 9.3% postoperatively. There were no reports of pain or dyspareunia requiring implant removal. PFDI scores improved in all domains, and 93% of the patients who completed the SSQ reported they were satisfied and would choose the surgery again.

Vu MK, Letko J, Jirschele K, Gafni-Kane A, Nguyen A, Du H, Goldberg RP. Minimal mesh repair for apical and anterior prolapse: initial anatomical and subjective outcomes. **International Urogynecology Journal** 2012;23(12):1753-61



Utero-vaginal suspension using a bilateral vaginal anterior sacrospinous fixation with mesh. (Preliminary results)

In a single site, retrospective study, where 5 surgeons completed 59 consecutive Uphold System procedures, 56 were available for follow-up. With a mean follow-up of 12 months, 93% of patients (52 of 56) achieved anterior and apical success when Ba and C/D points were less than -1. 2 patients (3.5%) had a surgical revision from a vaginal mesh exposure and 1 patient had unilateral pudendal pain postoperatively. 4 patients experienced denovo dysparunia while 98% of the patients (55 of 56) assessed the success of their procedure in a subjective manner as being very satisfied or satisfied.

Rivaux G, Fatton B, Leouzey V, Cayrac M, Boileau L, de Tayrac R. [Utero-vaginal suspension using a bilateral vaginal anterior sacrospinous fixation with mesh. Preliminary results]. **Prog Urol** 2012;22(17):1077-83

Designed to achieve optimal outcomes

Procedural Step Summary

Uphold™ LITE Vaginal Support System with Capio™ SLIM Suture Capturing Device

1. The Anterior vaginal wall is grasped in the midline using a series of Allis clamps.

2. An incision is made in the anterior vaginal wall at the level of bladder neck. The incision should be no closer than 2cm from the cervix, to minimize overlap of mesh and incision. Above this incision, preserve a mid-urethral fold in the event that a mid-urethral sling placement is desired.

3. Sharply dissect the tissue plane until the descending pubic rami are palpable on each side, creating a flap in the anterior wall. Once accessed, use finger sweeps in a downward and medial motion to clean off the side wall and create a smooth tunnel toward the ischial spines bilaterally.

The sacrospinous ligaments are then carefully cleared of any fibrous or fatty tissue by gentle sweeping the index finger medially from the ischial spine.

4. Load the dart of the Uphold LITE Device leg assembly onto the carrier at the distal end of the Capio SLIM Suture Capturing Device. Place the loaded tip of Capio SLIM Device onto the desired location of the SSL medial to the ischial spine and hold in place with gentle pressure.

Depress the Capio Device Driver Button to drive the mesh leg through, but not over, the ligament. Release and if necessary, pull the driver button back to allow the carrier to retract into the housing. Pull the leg through the tissue by withdrawing the Capio Device.

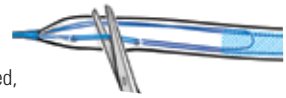
5. Repeat on the patient's contralateral side.

6. Perform an anterior colporrhaphy if desired, which may reduce / shorten the dimensions of the anterior compartment.

7. Three absorbable tacking sutures may be placed to attach the mesh 'crescent' to the 12, 3, and 9 o'clock positions of the vaginal cuff or paracervical ring. Push the apex up with a finger, tenaculum, or sponge stick.

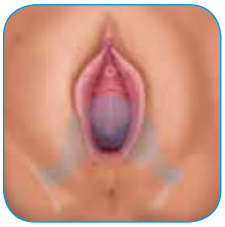
8. With a finger inside the vagina to gauge tension and assess the apical anatomy, pull the Uphold LITE Device legs into place until the cervix / apex feels secure in its natural position.

9. Avoid excessive tensioning of the mesh when positioning to avoid over correction of the defect. Once final positioning is confirmed, the leg assemblies are grasped and the two leader loop sutures located outside of the protective sleeves are cut. The leg assemblies are gently pulled to remove, leaving only the mesh in place.



Close the incision.

Note:
At the discretion of the physician, a Posterior repair and / or mid-urethral sling may be performed according to product indications through separate incisions.



Order Number	Description
M006831817**0**	Uphold LITE Vaginal Support System with Capio SLIM Suture Capturing Device Includes: (1) Capio SLIM Suture Capturing Device and (1) Uphold LITE Mesh Assembly

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[1] Vu, M.K., et al. Minimal mesh repair for apical and anterior prolapse: initial anatomical and subjective outcomes. Int Urogynecol J, doi: 10.1007/s00192-012-1780-5
[2] Data on file. Surface area ratio and fiber length within 1cm² of mesh were calculated from measured mesh weight (g/m²) and measure fiber diameter.
[3] Walters, et al. Surgical Treatment of Vaginal Apical Prolapse, Obstet Gynecol 2013;121:354-74

Accordingly for transvaginal pelvic organ prolapse mesh kits –
CAUTION: Federal Law (USA) restricts this device to sale by or on the order of a physician trained in use of surgical mesh for transvaginal repair of pelvic organ prolapse. Refer to package insert provided with the product for complete Indications for Use, Contraindications, Warnings, Precautions, Adverse Events, and Instructions prior to using this product.
CAUTION: The law restricts these devices to sale by or on the order of a physician. Information for the use only in countries with applicable health authority product registration.

Products are labeled for individual use and concomitant repairs are at the discretion of the physician.

Bench test results may not necessarily be indicative of clinical performance. Results from case studies are not predictive of results in other cases. Results in other cases may vary.

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