Vertessa® Lite

Polypropylene Mesh for Sacrocolpopexy

Instructions for Use

Manufactured by:
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Instructions for Use

CAUTION
Federal Law restricts use of this device to physicians trained in implanting synthetic mesh to treat pelvic organ prolapse.

CAUTION
Read all Information contained in this product label including Indications, Contraindications, Warnings, Precautions, Adverse Reactions, Instructions for Use, etc., prior to using this product.

INDICATIONS
Vertessa® Lite may be used for the repair of uterine or vaginal vault prolapse that requires support material. It may be used in open or laparoscopic abdominal procedures.

CONTRAINDICATIONS
- Patients with sensitivity or allergies to polypropylene.
- Pregnant patients or patients planning future pregnancies. Patients should be counseled that future pregnancy may negate the effect of surgical repair.
- Patients with a urinary tract infection or with an infection in the operative field.
- Implantation into areas with active and latent infection.
- Any pathology which would compromise implant or implant placement.
- This device must not be implanted in patients while on anticoagulants, aspirin, non-steroidal anti-inflammatory agents, or in those with bleeding disorders.
- This device should not be implanted into patients with autoimmune connective tissue disease or disorders.
- Infants, children, or any patient with future growth potential.
- It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, of the contraindications associated with the use of this product.

WARNINGS
- Physicians should have experience in management of the potential complications resulting from abdominal laparoscopic or robotic placement of surgical mesh.
- The reuse of a single-use device can affect its safety, performance, and effectiveness, exposing the patient and staff to unnecessary risk. Additionally, the reuse of a single-use device has legal implications.
- Vertessa® Lite Polypropylene Mesh implants should only be used by a surgeon familiar with surgical procedures and techniques for sacrocolpopexy and the use of non-absorbable mesh. Use with attention to patient anatomy and procedure dissection technique to avoid damage to vessels, nerves, bladder, ureter, bowel and vaginal wall. Standard surgical practices should be followed for pelvic floor procedures as well as for the management of contaminated or infected wounds.
- The risks and benefits of using Vertessa® Lite Polypropylene Mesh for Sacrocolpopexy implants should be considered in patients.

- Physicians should conduct a thorough assessment of each patient to determine their suitability for a synthetic mesh implant, including patients with a compromised immune system, any condition that would compromise healing, or history of prior abdominal or pelvic surgeries.
- It is the responsibility of the physician to advise the prospective patients or their representatives, prior to surgery, of the warnings and precautions associated with the use of this product and the associated surgical risks.
- The patient should be counseled that alternative pelvic floor repair treatments may be appropriate, and the reason for choosing a mesh procedure should be explained. Obtain patient consent prior to surgery and ensure that the patient has an understanding of the postoperative risks and potential complications of transabdominal mesh surgery.
- Patients should be counseled that mesh is considered a permanent implant and some complications may arise with either or both the implanted mesh or the surgery. Multiple surgeries may be required to remove or correct mesh related complications and additional surgeries may not always fully correct the complications. Complete removal of mesh may not be possible. Each patient tissue responds may respond in varying degrees.
- As with all surgical procedures, certain risk factors or underlying conditions 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.), active infection in or near the surgical site, or more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events. 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
- Prolapse repair may unmask pre-existing incontinence conditions.
- Vertessa® Lite Polypropylene Mesh implants may activate an existing or latent infection reaction or sepsis.
- Avoid tension on the mesh during handling and positioning to prevent damage to the mesh or unfavorable patient outcomes.
- There should be an appropriate margin of mesh extending beyond the suture line. Sutures should not be placed at the mesh edge, but a minimum of 1 cm from the mesh edge. Inadequate suturing of the graft to the pelvic tissues may lead to failure of the repair.
- Do not let Vertessa® Lite Polypropylene Mesh implants come into contact with sharp objects (e.g., staples, clips, or clamps) which could cause damage to the mesh.
- Cystoscopy is recommended to confirm bladder and ureter integrity.
- A digital rectal exam should be performed to detect possible rectal perforation.
- Patients should be counseled to refrain from heavy lifting, intercourse, and exercise for a period of time after the procedure. The implanting surgeon should determine when it is suitable for each patient to return to normal activities.
- In the event that infection presents post procedure, the Vertessa® Lite mesh implant may have to be removed or revised.
- If bleeding, dysuria, or other problems occur, the patient should be instructed to contact the physician immediately.

- The safety and effectiveness of Vertessa® Lite for pelvic organ prolapse repair by the transvaginal route has not been evaluated.

ADVERSE REACTIONS

- Adverse events are known to occur with transabdominal synthetic mesh procedures and implants. Adverse events following mesh implantation may be de novo, persistent, worsening, transient, or permanent
- Potential adverse reactions are those associated with surgery using implantable mesh materials of this type, including but not limited to: urinary incontinence, urinary retention/obstruction, urethral or ureteral obstruction or laceration, voiding or defecatory dysfunction (e.g., dysuria, urinary retention, incomplete emptying, straining, positional voiding, weak stream), suture erosion, mesh exposure, extrusion or erosion which may occur though the vagina, bowel or other viscera, foreign body response or reaction and inflammation (acute or chronic), local irritation, mesh migration, de novo and/or worsening dyspareunia, bladder storage dysfunction (e.g., increased daytime frequency, urgency, overactive bladder or nocturia), urinary tract infection, de novo, recurrent or worsening prolapse in untreated compartment, vaginal scarring, tightening, rigidity, shortening and/or contracture, acute or chronic pain, infection potentiation, abnormal vaginal discharge, wound dehiscence, nerve damage, abscess (acute or delayed), or adhesion formation, fistula formation, hypersensitivity or other immune reaction, allergic reactions, hematoma, seroma, bleeding, delayed wound healing, perforation or injury of soft tissue (e.g., ligaments, muscles, nerves, vessels), structures, or organs (e.g., bowel, rectum, bladder, urethra, ureters, vagina), bowel obstruction, constipation and/or fecal incontinence, and/or anal sphincter incompetence, ileus, dehiscence, hemorrhage, neurologic and/or neuromuscular symptoms (acute or chronic), necrosis, granuloma, palpable mesh (patient and/or partner), Sexual dysfunction, Partner pain and/or discomfort during intercourse.
- Punctures or laceration of vessels, nerves, bladder, urethra or bowel may occur during mesh placement and may require surgical repair.
- Potential adverse reactions are those associated with pelvic organ prolapse repair procedures, including pelvic pain, pain with intercourse, partner pain during intercourse, vaginal rigidity and narrowing of the vaginal wall.
- Dissection for pelvic floor repair procedures may impair normal voiding for a variable length of time.
- The occurrence of these events may require partial or complete removal of the mesh. 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. There may be unresolved pain with or without mesh explantation of the mesh.
- May lead to serious injury or even death.
- The information provided is not comprehensive with regard to product risks.

PACKAGING
Vertessa® Lite Polypropylene Mesh for Sacrocolpopexy implants are contained within a double sealed pouch. If the pouch is open or damaged, do not use.

PRODUCT LABELING SYMBOLS
Symbols utilized on Vertessa® Lite labeling are in compliance with ISO 15223. A glossary of symbols can be accessed here: www.calderamedical.com. To request a printed copy, please contact us at +1.818.879.6555, fax at +1.818.879.6556 or info@calderamedical.com.

Symbol	Title/ Meaning / Referent	Symbol	Title / Meaning / Referent
	Manufacturer		Non-sterile
	Date of Manufacture		Keep Dry
	Use by Date		Do Not Re-use
	Batch Code		Consult Instructions for Use
	Catalogue number		Consult Instructions for Use, or For Instructions for Use Refer to
	Sterilized Using Ethylene Oxide		Caution
	Do Not Resterilize		Packaging Unit
	Do Not Use If Package Is Damaged		Prescription Only

PRODUCT TRACEABILITY
Traceability labels are attached to every Vertessa® Lite Polypropylene Mesh for Sacrocolpopexy pouch to identify the type and lot number of each device. This label should be affixed to the patient's permanent medical record to clearly identify the device so patients can be notified in the event of a product recall.

STERILIZATION
Vertessa® Lite Polypropylene Mesh for Sacrocolpopexy are provided sterile and labeled for single use only. Vertessa® Lite implants are terminally sterilized by ethylene oxide (EO). Packaging should not be opened until time of use.

- Do not re-sterilize this product.
- Do not use if package is opened or damaged.
- Do not use after the expiration date.

STORAGE
Vertessa® Lite Polypropylene Mesh for Sacrocolpopexy implants must be stored at room temperature in a clean dry place.

- Do not expose product to direct sunlight, humid environments, or extreme temperatures.
- Do not use after the expiration date.
- Do not use if the product packaging is damaged or open prior to use

NATURAL RUBBER LATEX STATEMENT
Vertessa® Lite Polypropylene Mesh for Sacrocolpopexy is not made with natural rubber latex. Vertessa® Lite Polypropylene Mesh for Sacrocolpopexy is not processed with or manufactured in the presence of natural rubber latex.

MAGNETIC RESONANCE IMAGING (MRI) STATEMENT
Vertessa® Lite Polypropylene Mesh for Sacrocolpopexy are MRI safe.

VERTESSA® LITE
Guide for Use

The following instruction is meant as a guideline only and does not replace proper surgical technique, clinical judgment and surgical training.

DESCRIPTION
Vertessa® Lite Polypropylene Mesh for Sacrocolpopexy is comprised of macroporous monofilament polypropylene mesh and is designed for the repair of uterine or vaginal vault prolapse via the abdominal route. Vertessa® Lite, is designed such that it may be trimmed, without unraveling, to different widths and lengths to fit each patient's anatomical requirements.

SURGICAL IMPLANT TECHNIQUES
Note: The instructions provided are for general use of Vertessa® Lite Polypropylene Mesh for Sacrocolpopexy, it is not a comprehensive guide for surgical technique repair of uterine or vaginal vault prolapse via the abdominal route and is not a substitute for appropriate training and experience. Vertessa® Lite Polypropylene Mesh for Sacrocolpopexy implants are intended to be used only by surgeons trained in the surgical treatment for the repair of uterine or vaginal vault prolapse via the abdominal route and also trained in the use of Vertessa® Lite Polypropylene Mesh for Sacrocolpopexy. Adverse reactions may occur notwithstanding the training and experience of the surgeon. Variations in use may occur due to surgeon technique, patient anatomy and other surgical factors.

INSTRUCTIONS FOR USE
1. Identify the iliac vessels, the vaginal apex, the Douglas pouch and the sacral promontory. An End to End anastomosis (EEA) sizer is placed in the vagina to aid in identifying the vaginal apex.
2. The overlying peritoneum is then incised at the line between bladder and vagina to mobilize the anterior vaginal wall. Using sharp and blunt dissection the bladder is dissected off of the vaginal apex.
3. The posterior vaginal wall is then mobilized and dissected off the rectum by opening the recto-vaginal space.
4. The peritoneum overlay of the promontory is then incised, and care is taken to avoid damage to the vessels or the ureter. The presacral space is dissected until the anterior longitudinal ligament overlying the sacrum is visualized and the peritoneal incision is then extended to the vaginal cuff. Maintain visualization of the right ureter throughout this portion of the procedure to avoid injury.
5. Cut Vertessa® Lite mesh into the desired size. Suture to the posterior vaginal wall using surgeon's choice of suture.
6. Cut and introduce a second strap of Vertessa® Lite mesh and secure to the anterior vagina using surgeon's choice of suture.
7. The mesh may be fashioned into a Y-shape using permanent monofilament suture either prior to or after being introduced. Suture one flap to the anterior vaginal wall and the other flap to the posterior vaginal wall using surgeon's choice of suture.
8. The remaining sacral flap(s) of mesh is/are then pulled up to the sacrum and after appropriate tensioning, it is secured to the sacrum with the surgeon's choice of suture. If two straps of mesh are used, the suture is passed through both pieces of mesh, through the anterior longitudinal ligament, and then brought back through both pieces of mesh.

9. Any excess mesh is cut and removed.
10. The peritoneum is now closed over the mesh, placing all mesh material in the retroperitoneal space.
11. Close using standard techniques.

POST OPERATIVE CARE:

- A catheter and vaginal packing with estrogen or other fluid can be used at the discretion of the surgeon.
- Physician should determine post operative care plan and when it is suitable for each patient to return to normal activities.
- The patient should be instructed to contact the surgeon immediately should dysuria, bleeding, pain, discharge, signs of infection or other problems occur.

PRODUCT DISPOSAL

Discard any open and or used devices and packaging according to your facility's policies and procedures concerning biohazardous materials and waste.

To learn more about, Vertessa® Lite Polypropylene Mesh for Sacrocolpopexy implants, other products for pelvic organ prolapse, incontinence, product evaluations and training, contact Caldera Medical at +1.818.879.6555 or visit our website at www.calderamedical.com.