CALDERA MEDICAL

Vertessa® Lite Y-Mesh

Polypropylene Mesh for Sacrocolpopexy

Instructions for Use

STERILE EO Sterilized using ethylene oxide

Do not reuse

R_X only Prescription Use Only

Manufactured by:
Caldera Medical, Inc.
5171 Clareton Drive
Agoura Hills, CA 91301 USA
www.calderamedical.com

Ordering Information
Phone: 1.818.879.6555
Facsimile: 1.818.879.6556

ENGLISH

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 Y-Mesh may be used as a bridging material for sacrocolposuspension/sacrocolpopexy (laparotomy; laparoscopic, or robotically-assisted approach) where surgical treatment for vaginal vault prolapse is warranted.

CONTRAINDICATIONS

- Pregnant patients or patients planning future pregnancies.
- Patients with a urinary tract infection or with an infection in the operative field.
- Implantation into areas with active and latent infection.
- Infants, children, or any patient with future growth potential.

ADVERSE REACTIONS

- Potential adverse reactions are those associated with surgery using implantable mesh materials of this type, including hematoma, seroma, urinary incontinence, urinary retention/obstruction, urethral or ureteral obstruction or laceration, voiding or defecatory dysfunction, pain, infection potentiation, wound dehiscence, nerve damage,

recurrent prolapse, abscess or adhesion formation, fistula formation, contracture, scarring, and mesh exposure, extrusion or erosion which may occur though the vagina, bowel or other viscera, foreign body response or reaction and inflammation.

- 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, and narrowing of the vaginal wall.
- Dissection for pelvic floor repair procedures may impair normal voiding for a variable length of time.

WARNINGS AND PRECAUTIONS

- Physicians should have experience in management of the potential complications resulting from abdominal 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 Y-Mesh Polypropylene Mesh for Sacrocolpopexy implants should only be used by a surgeon familiar with surgical procedures and techniques for sacrocolpopexy and the use of non-absorbable mesh.
- 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.
- Vertessa® Lite Y-Mesh Polypropylene Mesh for Sacrocolpopexy implants may activate an existing or latent infection reaction or sepsis.
- Patients should be counseled to refrain from heavy lifting, intercourse, and exercise for a minimum of six (6) weeks after the procedure. A physician 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 Y-Mesh Polypropylene Mesh for Sacrocolpopexy 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.
- Avoid tension on the mesh during handling and positioning to prevent damage to the mesh or unfavorable patient outcomes.
- 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.
- Cystoscopy is recommended to confirm bladder and ureter integrity.
- The safety and effectiveness of Vertessa® Lite Y-Mesh for pelvic organ prolapse repair by the transvaginal route has not been evaluated.

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DESCRIPTION
Vertessa® Lite Y-Mesh 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. The Vertessa® Lite Y-Mesh device is designed such that it may be trimmed, without unraveling, to different widths and lengths to fit each patient's anatomical requirements.

PRODUCT TRACEABILITY
Traceability labels are attached to every Vertessa® Lite Y-Mesh 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 Y-Mesh Polypropylene Mesh for Sacrocolpopexy implants are sterilized by ethylene oxide. Do not re-sterilize this product. Do not use if package is opened or damaged. Do not use after the expiration date.

PACKAGING
Vertessa® Lite Y-Mesh Polypropylene Mesh for Sacrocolpopexy is individually packaged in two sealed pouches. If the pouch is opened or damaged do not use.

STORAGE
Vertessa® Lite Y-Mesh Polypropylene Mesh for Sacrocolpopexy is recommended to be stored at room temperature in a clean dry place.

Note: Standard operative techniques for a sacrocolpopexy procedure should be followed with using Vertessa® Lite Y-Mesh Polypropylene Mesh for Sacrocolpopexy implants.

INSTRUCTIONS FOR USE (APPLICATION)
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 Y-Mesh into the desired size. Suture one of the vaginal flaps to the posterior vaginal wall.

6. Attach the other vaginal flap of the Y-Mesh to the anterior vaginal wall. Ensure that the graft is placed such that the apex of the Y is aligned with the apex of the vagina.

7. The sacral flap of the Y-Mesh configuration is then pulled up to the sacrum and, after appropriate tensioning it is secured to the sacrum with surgeon's choice of suture.

8. Any excess mesh is cut and removed.

9. The peritoneum is now closed over the mesh, placing all mesh material in the retroperitoneal space.

10. Close using standard techniques.

Vertessa® Lite Y-Mesh Instruction For Use (IFU) is available for viewing or download here: https://www.calderamedical.com/medical-professionals/product-instructions-for-use. All Caldera Medical IFU documents are available in print form at no additional cost upon request. If you would like to request a copy please contact us at 818.879.6555, fax 818.276.8400 or email info@calderamedical.com.

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