Transabdominal Repair
with *Restorelle*®
**Restorelle® was designed specifically for women.**

In 2001, urogynecologist Dr. James Browning began to develop a new mesh product for the treatment of pelvic organ prolapse. What was created was Restorelle, a more physiologically compatible, ultra lightweight mesh that supports collagen growth and works in concert with the patient’s own tissue for optimum safety and efficacy. It renews and restores a woman’s body, as well as improves her quality of life. Restorelle is backed by science with over 15 years of implant history.
Ultra lightweight. And strong. Perfectly meshed together.

The patented polypropylene design

A: 1.8 mm macropores
B: 100 micron interstitial pores
C: 80 micron fiber

- Constructed with uniform 1.8 mm macropores and 100 micron interstitial pores. 80 micron fibers – less than a human hair
- Pore sizes critical for ideal tissue healing processes
- Simultaneously allows bacteria fighting properties and encourages collagen growth
- Less fibrosis, chronic inflammation and foreign body reactions observed in smartmesh performance
- The mechanical properties, material type, pore size and shape of surgical mesh directly influences tissue ingrowth

Greater biocompatibility

In a canine integration histology study, two types of monofilament polypropylene mesh were compared with different pore sizes, mass densities, and burst strengths.
Tests performed at 90 days postoperatively:
- 71% more mature type 1 collagen growth reported in Restorelle.
- Less fibrosis.
- Less chronic inflammation and foreign body complications.
- Post-implant strength of Restorelle was as strong or stronger than the heavier-weight mesh.
Ease of handling for procedural efficiency.

Restorelle Y has a tailored low elastic, unidirectional design that maintains structural integrity and vaginal length.

**Ultra lightweight**
The low mesh mass and memory allow for easy passage through laparoscopic ports.

**Clear visualization**
The transparency of the mesh allows for direct visualization of anatomical landmarks for enhanced intraoperative manipulation and suturing.

**Procedural efficiency**
The large 1.8 mm macropores allow for easy passage of suture through the mesh without needles.

**Low memory**
The Restorelle hydrophillic like properties and low memory allow for ease of placement, draping and laydown during fixation.
Fronted by safety. Backed by science.

Restorelle restores patient anatomy and inspires quality of life for optimal results

Single-center prospective study comparing preoperative and 12-month postoperative objective and subjective assessments using POP-Q, PFDI-20, PFIQ-7 and PISQ-12.

Ultra lightweight Restorelle Y eliminated the mesh-related complications in the first post-operative year without sacrificing efficacy.

97% patient surgical satisfaction (SSQ)

94% clinical cure

0 erosions or exposures

Improved bowel function after robotic sacrocolpopexy

Single-center prospective study comparing preoperative and postoperative bowel function after robotic sacrocolpopexy utilizing a lightweight polypropylene Y mesh.

Patients were grouped according to perineorrhaphy versus no perineorrhaphy and bowel function scores were examined.

RSC was associated with significant improvements in bowel function as measured by CRADI-8 as well as improvements in quality of life measured by CRADIQ-7.

70% complete resolution of splinting

12 month follow up

39% of patients needed to splint to complete bowel movement
RESTORELLE TRANSABDOMINAL BRIEF STATEMENT

Indications

Restorelle Transabdominal products are indicated for use as a bridging material for sacrocolposuspension / sacrocolpopexy (laparotomy, laparoscopic, or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

Contraindications:

- Restorelle Transabdominal products should not be used in infants, children, pregnant women, or in women planning future pregnancies, or any patient with future growth potential, because the mesh will not stretch significantly as the patient grows.
- Restorelle Transabdominal products should not be used in those on anticoagulant therapy or with bleeding diatheses or those with active or latent infection in the operative field or those with a urinary tract infection.

Warnings/Precautions:

- Restorelle should only be used by appropriately qualified and properly trained medical practitioners. Users should be familiar with surgical procedures utilizing non-absorbable meshes and should have experience in the management of potential complications from placement of synthetic grafts before employing Restorelle.

Adverse Reactions:

Possible adverse reactions include pain, infection, erosion, extrusion, exposure, contracture and procedure failure may occur. Serious adverse tissue responses or infection may require removal of mesh.

See IFU for detailed information regarding the implant procedure, Warnings/Precautions, Adverse reactions, prior to using this product. For further information, call Coloplast Corp at 1-800-258-3476 and/or consult the company website at www.coloplast.com.

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

REFERENCES


MERIDIAN BRIEF STATEMENT

Indications

The Meridian Vaginal Positioning System is intended for use in general gynecological surgery to assist in the position and manipulation of the vagina. The device can be used with tactile feedback and/or direct visualization.

Contraindications:

The Meridian Vaginal Positioning System should not be used in patients who are pregnant or have an IUD in place or in cases where the surgeon deems it inadvisable or finds it difficult to insert device.

Warnings/Precautions:

- Each device should be carefully examined prior to surgery and continuously monitored throughout the surgical procedure to ensure the structural integrity of the device is not compromised in any way.
- The procedure to insert the device requires a good knowledge of local anatomy and the correct use of the manipulator in order to avoid damage to adjacent anatomical structures. Do not use excessive force during the insertion and movement of the device within the vagina.

Adverse Reactions:

Possible adverse reactions associated with manipulators include: cramping or discomfort, infection, perforation, bleeding, muscle spasms and tissue damage.

See the device manual for detailed information regarding the implant procedure, warnings/precautions, adverse reactions, prior to using this product.

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- Restorelle Transabdominal products should not be used in those on anticoagulant therapy or with bleeding diatheses or those with active or latent infection in the operative field or those with a urinary tract infection.

Warnings/Precautions:

- Restorelle should only be used by appropriately qualified and properly trained medical practitioners. Users should be familiar with surgical procedures utilizing non-absorbable meshes and should have experience in the management of potential complications from placement of synthetic grafts before employing Restorelle.

Patients should be counseled that there are alternative non-mesh prolapse surgeries, and the reason for choosing a mesh procedure should be explained. Physician should also obtain patient consent to surgery with an understanding of the postoperative risks and potential complications of mesh surgery.

Adverse Reactions:

Possible adverse reactions include pain, infection, erosion, extrusion, exposure, contracture and procedure failure may occur. Serious adverse tissue responses or infection may require removal of mesh.

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