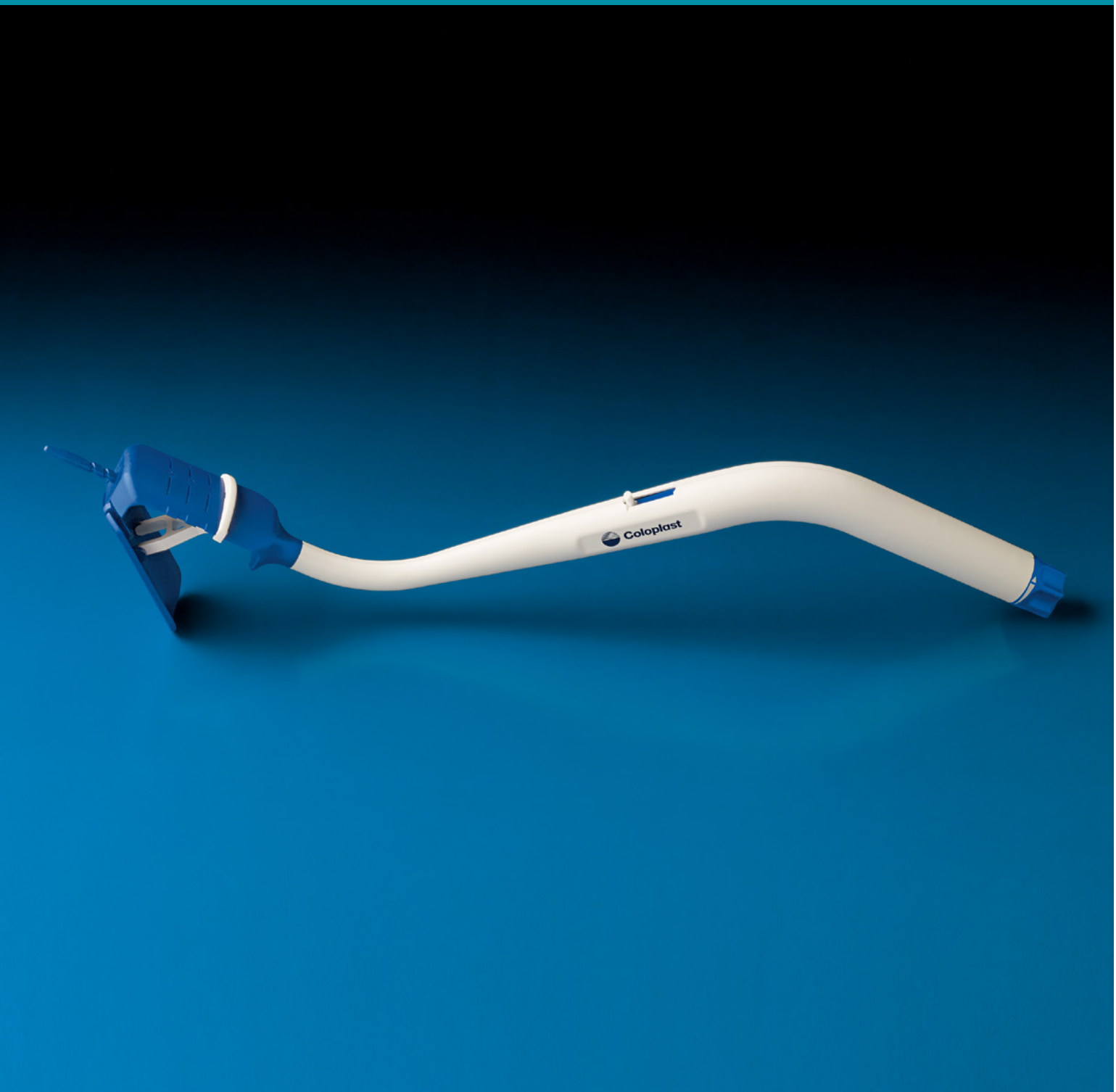
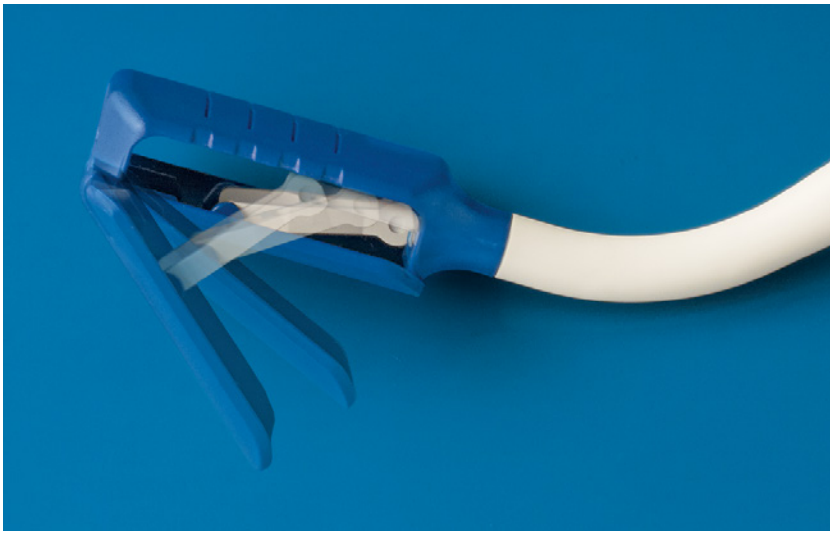
Meridian® *VPS*
Restorelle® *Y Contour*

Vaginal Positioning System
Maximal visualization. Measurable depth.



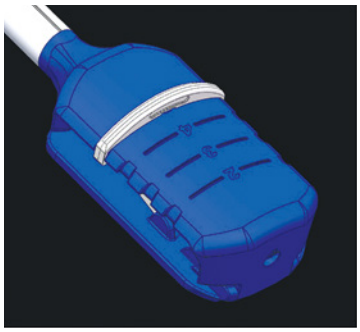
Engineered to deliver visualization

Meridian® Vaginal Positioning System is an adjustable, ergonomic, minimally invasive single use device that is placed into the vagina to stabilize and aid in the identification of all components of the vagina during surgical procedures such as sacrocolpopexy.



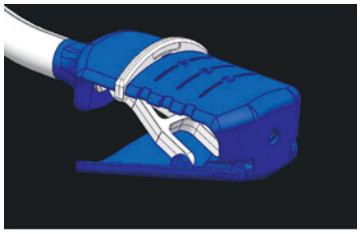
Use Principles:

- Based on evaluation of the anatomical position of the vesicourethral junction relative to the vaginal apex, position the rib to maximize anterior dissection. If the cervix is present, insert the pin into the key-hole slot at the tip of the device
- Insert into the vagina with the rib and indicator window facing anteriorly and visible.
- During the posterior dissection, turn knob clockwise on the end of the device to open the kick-out door.
- Indicator window specifies how far the kick-out door on the head is open: blue=open, white=closed.
- Tilt device anteriorly to enable anterior dissection. Dissect anterior compartment to level of rib for graft placement.
- Visualize vaginal position by adjusting kick-out door and tilting as needed.
- Retract kick-out door by turning the knob counter clockwise while visualizing the indicator window.

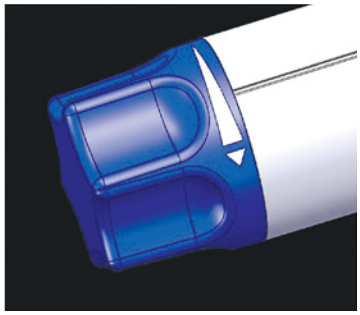


The 4.5 cm wide head allows for lateral dissection.

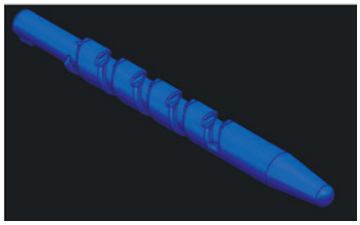
The snap-on adjustable rib is a distal depth indicator during anterior dissection to the vesicourethral junction.



The kick-out door is designed to be opened for increased visualization and acts as a backboard for deep posterior suturing.

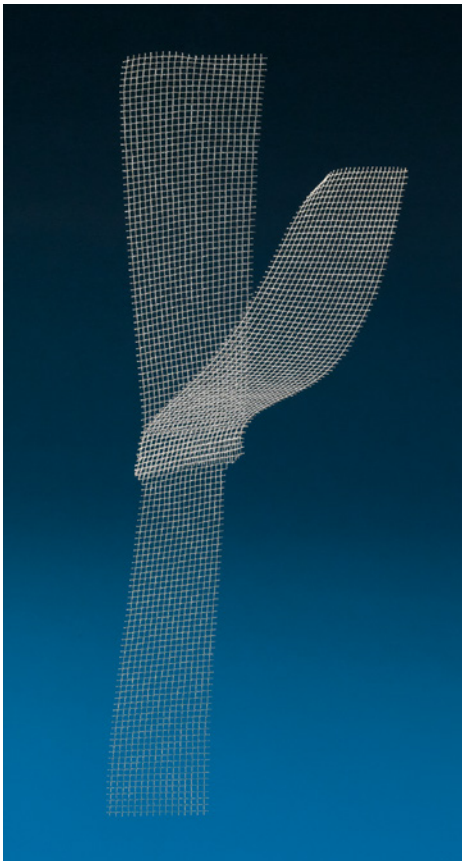


The knob on the end opens the kick-out door.



Adjustable cervical pin engages cervix and maintains alignment at apex during dissection, manipulation and mesh placement, when needed.

Restorelle® Smartmesh® Technology Allows for Draping and Laydown on Vaginal Cuff

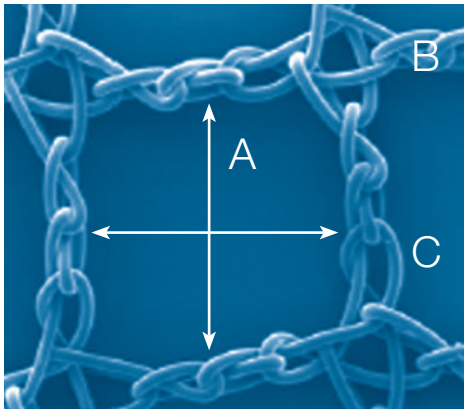


- Visibility allows for intraoperative manipulation and suturing.
- Low mesh mass and memory accomodates easy passage through laparoscopic ports.
- Large 1.8 mm macropores enable suturing without needles.
- Tailored uni-directional design maintains structural integrity from sacrum to the vagina.
- No rough edges or weak seams.
- Polypropylene locked stitched mesh arms enhance the structural integrity of the prosthesis.
- Easily customizable to fit the patient's anatomy.

Patented polypropylene design offering an ultra-lightweight mesh for Female Pelvic Health[5]

Constructed with uniform 1.8 mm macropores and 100 micron interstitial pores. 80 micron fibers—less than the size of a human hair—offer less implantable material at the interstitial pore junctions.[2]

The mechanical properties, material type, pore size and shape of surgical mesh directly influences tissue ingrowth.[4]



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

1. Salamon, Lewis, Priestley, Gurshumov, Culligan (2013). Prospective study of an ultra-lightweight polypropylene Y-mesh for robotic sacrocolpopexy. *Int Urogyn*.
2. Gurette N. Ultra-lightweight polypropylene "Y" graft for robotic-assisted sacrocolpopexy: Retrospective anatomic and functional outcomes. *Female Pelvic Medicine and Reconstructive Surgery.* Vol. 18 (Suppl. 2): S205-06. Sept/Oct, Poster 248.
3. Greca F H et al (2007). The influence of porosity on the integration histology of two abdominal wall defects in dogs. *Hernia*. (12) 45-49.
4. Pourdeyhini (1989). Porosity of surgical mesh fabrics: New technology. *J Biomed. Mater Res: Applied Biomaterials*. Vol 23, No. A1 145-152.
5. Restorelle is covered by US patents* owned exclusively by Coloplast. *US. Pat. Nos. 7,594,921; 8,100,924; 8,157,821 and 8,157,822.

Restorelle Smartmesh: Backed by data.[1]

Prospective study comparing preoperative and 12-month postoperative objective and subjective assessments via the Pelvic Organ Prolapse Quantification (POP-Q), the Pelvic Floor Distress Inventory, Short Form 20 (PFDI-20); the Pelvic Floor Impact Questionnaire, Short Form 7 (PFIQ-7); and the Pelvic Organ Prolapse/Urinary Incontinence Sexual Questionnaire 12 (PISQ-12).

- **n=120, 118 available at 1 year follow-up.**
- **94% objective "clinical cure" rate.**
- **No sacrocolpopexy mesh-related complications, no exposures or erosions, and no reoperations due to the mesh.**
- **No cystotomies, no bowel injuries, no conversions to laparotomies, and no blood transfusions.**
- **51% of patients avoided sexual intercourse pre-op due to pain, 0% avoided intercourse post–op due to pain.**
- **97% patient satisfaction rate (SSQ-8).**

- **In a canine integration histology study[3], two types of monofilament polypropylene mesh were compared with different pore sizes, mass densities, and burst strengths.**

  Tests performed on the 90th post-operative day resulted in:*

  - **71% more mature type 1 collagen growth reported in Smartmesh.**
  - **Less fibrosis.**
  - **Less chronic inflammation and foreign body complications.**
  - **Post-implant strength of Smartmesh was as strong or stronger than the heavier-weight mesh.**

*Clinical relevance in human anatomy is unknown

Ordering Information Call Toll-Free (800) 258-3476

Description	Order Number
Restorelle® M 15x10cm	501320
Restorelle XL 30x30cm	501330
Restorelle L 24x8cm	501440
Restorelle Y 24x4cm	501420
Restorelle Y 27x4cm	501430
Restorelle Y Contour 24x3cm	50152
Meridian® Vaginal Positioning System	52080
Meridian VPS with Restorelle Y Contour	52081

Coloplast Payment Policy
Terms: Net 30 days; all items priced F.O.B. shipping point. Prices and specifications subject to change without incurring obligation.

Returned Goods Policy
Authorization must be received from Coloplast prior to the return of merchandise. Merchandise returned must have all manufacturers' seals intact and be received within 30 days from date of invoice to be eligible for full credit or replacement. Please contact the Coloplast Urology Products Customer Service Department for details. To obtain a Return Authorization Number, call (800) 258-3476, or fax (866) 216-4161. Returned products may be subject to restocking charges.

Product Information Disclosure
Coloplast excludes all warranties, whether written or oral, statutory, expressed or implied, by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability, fitness or design. Coloplast shall not be liable for any direct, incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this product. No representation or other affirmation of fact, including but not limited to statements regarding suitability for use, or performance of the product shall be or be deemed to be a warranty by Coloplast for any purpose. Coloplast neither assumes nor authorizes any other or additional liability or responsibility in connection with this product.

Caution
Federal (USA) law restricts these devices to sale by or on the order of a physician.

Pricing
Coloplast reserves the right to change its prices without notice.

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.

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.

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

See IFUs for detailed information regarding the implant procedure, deivice use, warnings/precautions, and adverse reactions, prior to using these products. For further information, call Coloplast Corp at 1-800-258-3476 and/or consult the company website at www.coloplast.us.

CAUTION: Federal (USA) law restricts these devices to sale by, or on, the order of a physician.

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