Restorelle® | **Meridian®**

Polypropylene Mesh and Vaginal Positioning System

Purposefully designed

Transabdominal Pelvic Organ Prolapse Repair

Coloplast

Restorelle® Y, Y Contour, Flat Mesh

Mesh for Transabdominal Pelvic Organ Prolapse Repair

Restorelle® Y and Y Contour pre-shaped mesh is used as a bridging material for sacrocolposuspension/ sacrocolpopexy (transabdominal placement via laparotomy, laparoscopic, or robotic approach).

- Pores **maintain structural integrity**, decreasing the effects of stress shielding.
- **Sacral tail** maintains strength during robotic, laparoscopic, or open placement.
- **Visibility** allows for intraoperative manipulation and suturing.
- **Mesh junction** that touches cuff remains lightweight and macroporous.

Safe & Effective

- **94% clinical cure rate**[1]
  - **<1%** erosion rate[2]
  - **Low incidence** of de novo dyspareunia[2]

97% Patient Satisfaction[1]

- **Restores** patient anatomy[2]
- **Renews** quality of life[2]
- **Non-palpable** to patient and partner[2]

Extensively studied with consistent results

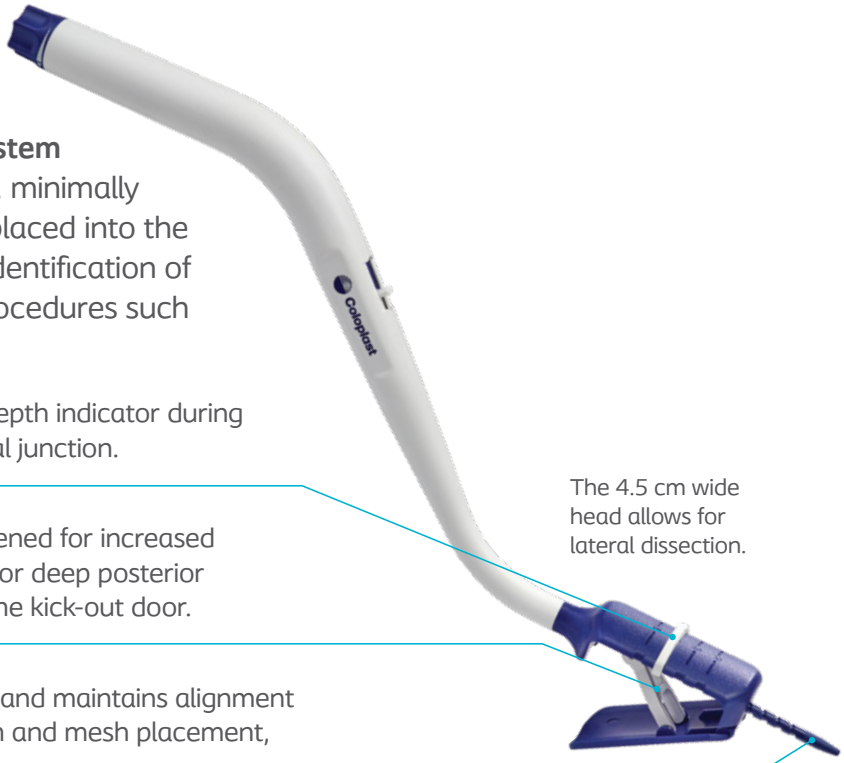
Designed by a
Urogynecologist
for the ***female pelvic floor***

#1 ***Y-mesh*** on the market

Ultra lightweight with high long-term success rates[3]

Meridian®

Vaginal Positioning System



Meridian® Vaginal Positioning System (VPS) 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 during surgical procedures such as sacrocolpopexy.

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.

The 4.5 cm wide head allows for lateral dissection.

RESTORELLE® Y POLYPROPYLENE MESH FOR SACROCOLPOSUSPENSION/SACROCOLPOPEXY BRIEF STATEMENT

Indications
Restorelle Y is indicated for use as a bridging material for sacrocolposuspension/sacrocolpopexy (transabdominal placement via laparotomy, laparoscopic, or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

Contraindications
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. The Restorelle Y is contraindicated for use in patients with the following conditions:

- Pregnancy or desire for future pregnancy
- Potential for further growth (e.g., adolescents)
- Pre-existing local or systemic infection. Treat the infection with the appropriate antiseptics and/or antibiotics to eliminate the infection before placing the Restorelle Y mesh.
- Taking anti-coagulant therapy
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Sensitivity/allergy to polypropylene

Warnings and Precautions
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.

Warnings
Restorelle Y mesh should only be used by physicians familiar with the surgical procedures and techniques involving non-absorbable mesh and who have adequate education and experience in the treatment of pelvic organ prolapse.

A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh procedure.

The patient should be counseled that alternative incontinence 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.

Patient counseling should include a discussion that the mesh to be implanted is a permanent implant and that some complications associated with the implanted mesh may require additional surgery; repeat surgery may not resolve these complications. Serious adverse tissue responses or infection may require removal of mesh, and complete removal of the mesh may not always be possible. Individuals may have varying degrees of collagen laydown that may result in scarring.

As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events.

The risks and benefits of using Restorelle Y should be considered in patients.

Any future pregnancy could negate the benefits of this surgical procedure. Patients should report any bleeding, pain, abnormal vaginal discharge or sign of infection that occur at any time.

Do not use product that has damaged or opened packaging, or has expired, as sterility may be compromised.

The procedure to insert the Restorelle Y mesh requires good knowledge of pelvic anatomy.

Cystoscopy should be performed to confirm bladder and urethral integrity.

A digital rectal exam should be performed to detect possible rectal perforation.

Avoid placing excessive tension on the Restorelle Y mesh implant during placement and adjustment to maintain mesh integrity.

There should be an appropriate margin of mesh extending beyond the fixation points.

Inadequate fixation of the mesh material to the pelvic tissue may lead to failure of the repair and recurrence of the prolapse.

Precautions
Restorelle Y mesh is provided sterile (ethylene oxide sterilization) and is for single-use only.

Use caution to prevent intraoperative injury to adjacent pelvic structures.

Do not let the Restorelle Y come into contact with sharp objects (e.g., staples, clips, or clamps) which could cause damage to the mesh.

Potential Complications
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 complications include, but are not limited to, abscess (acute or delayed), adhesion/scar formation, allergy, hypersensitivity or other immune reaction, bleeding, hemorrhage or hematoma, bowel obstruction, constipation and/or defecatory dysfunction, fecal incontinence and/or anal sphincter incompetence, ileus, dehiscence, delayed wound healing, extrusion, erosion or exposure of mesh into the vagina or other structures or organs, fistula formation, infection, inflammation (acute or chronic), local irritation, mesh migration, necrosis, de novo and/or worsening dyspareunia, neuromuscular symptoms (acute or chronic), pain (acute or chronic), partner pain and/or discomfort during intercourse, perforation or injury of soft tissue (e.g., ligaments, muscles, nerves, vessels), structures, or organs (e.g., bowel, rectum, bladder, urethra, ureters, vagina), seroma, suture erosion, bladder storage dysfunction (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), ureteral obstruction, urinary tract infection, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, straining, positional voiding, weak stream), de novo or worsening prolapse in untreated compartment, granulation tissue formation, palpable mesh (patient and/or partner), recurrent prolapse, sexual dysfunction, vaginal discharge (abnormal) and vaginal scarring, tightening, rigidity, shortening and/or contracture.

The occurrence of adverse events may require one or more revision surgeries, including removal of the mesh.

Complete removal of the mesh may not always be possible, and additional surgeries may not always fully correct the complications.

There may be unresolved pain with or without mesh explantation.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company Website at www.coloplast.com.

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

Minneapolis, MN
04/26/2021 PM-03856

RESTORELLE® M, L AND XL POLYPROPYLENE MESH FOR SACROCOLPOSUSPENSION/SACROCOLPOPEXY BRIEF STATEMENT

Indications
Restorelle M, Restorelle L and Restorelle XL are indicated for use as a bridging material for sacrocolposuspension/sacrocolpopexy (transabdominal placement via laparotomy, laparoscopic, or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

Contraindications
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. The Restorelle M, L and XL are contraindicated for use in patients with the following conditions:

- Pregnancy or desire for future pregnancy
- Potential for further growth (e.g., adolescents)
- Pre-existing local or systemic infection. Treat the infection with the appropriate antiseptics and/or antibiotics to eliminate the infection before placing the Restorelle M, L or XL mesh.
- Taking anti-coagulant therapy
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Sensitivity/allergy to polypropylene

Warnings and Precautions
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.

Warnings
The Restorelle M, L and XL mesh should only be used by physicians familiar with the surgical procedures and techniques involving non-absorbable mesh and who have adequate education and experience in the treatment of pelvic organ prolapse.

A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh procedure.

The patient should be counseled that alternative pelvic organ prolapse treatments may be appropriate, and the reason for choosing a surgical 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.

Patient counseling should include a discussion that the mesh to be implanted is a permanent implant and that some complications associated with the implanted mesh may require additional surgery; repeat surgery may not resolve these complications. Serious adverse tissue responses or infection may require removal of mesh, and complete removal of the mesh may not always be possible. Individuals may have varying degrees of collagen laydown that may result in scarring.

As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events.

The risks and benefits of using Restorelle M, L or XL should be considered in patients.

Any future pregnancy could negate the benefits of this surgical procedure. Patients should report any bleeding, pain, abnormal vaginal discharge or sign of infection that occur at any time.

Do not use product that has damaged or opened packaging, or has expired, as sterility may be compromised.

The procedure to insert the Restorelle M, L or XL requires good knowledge of pelvic anatomy.

Cystoscopy should be performed to confirm bladder and urethral integrity.

A digital rectal exam should be performed to detect possible rectal perforation.

Avoid placing excessive tension on the Restorelle M, L or XL mesh implant during placement and adjustment to maintain mesh integrity.

There should be an appropriate margin of mesh extending beyond the fixation points.

Inadequate fixation of the mesh material to the pelvic tissue may lead to failure of the repair and recurrence of the prolapse.

Precautions
Restorelle M, L and XL mesh is provided sterile (ethylene oxide sterilization) and is for single-use only.

Use caution to prevent intraoperative injury to adjacent pelvic structures.

Do not let the Restorelle M, L or XL come into contact with sharp objects (e.g., staples, clips, or clamps) which could cause damage to the mesh.

Potential Complications
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 complications include, but are not limited to, abscess (acute or delayed), adhesion/scar formation, allergy, hypersensitivity or other immune reaction, bleeding, hemorrhage or hematoma, bowel obstruction, constipation and/or defecatory dysfunction, fecal incontinence and/or anal sphincter incompetence, ileus, dehiscence, delayed wound healing, extrusion, erosion or exposure of mesh into the vagina or other structures or organs, fistula formation, infection, inflammation (acute or chronic), local irritation, mesh migration, necrosis, de novo and/or worsening dyspareunia, neuromuscular symptoms (acute or chronic), pain (acute or chronic), partner pain and/or discomfort during intercourse, perforation or injury of soft tissue (e.g., ligaments, muscles, nerves, vessels), structures, or organs (e.g., bowel, rectum, bladder, urethra, ureters, vagina), seroma, suture erosion, bladder storage dysfunction (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), ureteral obstruction, urinary tract infection, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, straining, positional voiding, weak stream), de novo or worsening prolapse in untreated compartment, granulation tissue formation, palpable mesh (patient and/or partner), recurrent prolapse, sexual dysfunction, vaginal discharge (abnormal) and vaginal scarring, tightening, rigidity, shortening and/or contracture.

The occurrence of adverse events may require one or more revision surgeries, including removal of the mesh.

Complete removal of the mesh may not always be possible, and additional surgeries may not always fully correct the complications.

There may be unresolved pain with or without mesh explantation.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company Website at www.coloplast.com.

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Minneapolis, MN
04/26/2021 PM-03862

RESTORELLE® Y CONTOUR™ POLYPROPYLENE MESH FOR SACROCOLPOSUSPENSION/SACROCOLPOPEXY BRIEF STATEMENT

Indications
Restorelle Y Contour is indicated for use as a bridging material for sacrocolposuspension/sacrocolpopexy (transabdominal placement via laparotomy, laparoscopic, or robotic approach) where surgical treatment for vaginal vault prolapse is warranted.

Contraindications
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. The Restorelle Y Contour is contraindicated for use in patients with the following conditions:

- Pregnancy or desire for future pregnancy
- Potential for further growth (e.g., adolescents)
- Pre-existing local or systemic infection. Treat the infection with the appropriate antiseptics and/or antibiotics to eliminate the infection before placing the Restorelle Y Contour mesh.
- Taking anti-coagulant therapy
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Sensitivity/allergy to polypropylene

Warnings and Precautions
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 effectiveness of Restorelle Y Contour has not been validated by a prospective, randomized clinical trial.

Warnings
The Restorelle Y Contour mesh should only be used by physicians familiar with the surgical procedures and techniques involving non-absorbable mesh and who have adequate education and experience in the treatment of pelvic organ prolapse.

A thorough assessment of each patient should be made to determine the suitability of a synthetic mesh procedure.

The patient should be counseled that alternative pelvic organ prolapse 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.

Patient counseling should include a discussion that the mesh to be implanted is a permanent implant and that some complications associated with the implanted mesh may require additional surgery; repeat surgery may not resolve these complications. Serious adverse tissue responses or infection may require removal of mesh, and complete removal of the mesh may not always be possible. Individuals may have varying degrees of collagen laydown that may result in scarring.

As with all surgical procedures, patients with certain underlying conditions may be more susceptible to postoperative bleeding, impaired blood supply, compromised/delayed healing, or other complications and adverse events.

The risks and benefits of using Restorelle Y Contour should be considered in patients.

Any future pregnancy could negate the benefits of this surgical procedure. Patients should report any bleeding, pain, abnormal vaginal discharge or sign of infection that occur at any time.

Do not use product that has damaged or opened packaging, or has expired, as sterility may be compromised.

The procedure to insert the Restorelle Y Contour requires good knowledge of pelvic anatomy.

Cystoscopy should be performed to confirm bladder and urethral integrity.

A digital rectal exam should be performed to detect possible rectal perforation.

Avoid placing excessive tension on the Restorelle Y Contour mesh implant during placement and adjustment to maintain mesh integrity.

There should be an appropriate margin of mesh extending beyond the fixation points.

Inadequate fixation of the mesh material to the pelvic tissue may lead to failure of the repair and recurrence of the prolapse.

Precautions
Restorelle Y Contour mesh is provided sterile (ethylene oxide sterilization) and is for single-use only.

Use caution to prevent intraoperative injury to adjacent pelvic structures.

Do not let the Restorelle Y Contour come into contact with sharp objects (e.g., staples, clips, or clamps) which could cause damage to the mesh.

Potential Complications
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 complications include, but are not limited to, abscess (acute or delayed), adhesion/scar formation, allergy, hypersensitivity or other immune reaction, bleeding, hemorrhage or hematoma, bowel obstruction, constipation and/or defecatory dysfunction, fecal incontinence and/or anal sphincter incompetence, ileus, dehiscence, delayed wound healing, extrusion, erosion or exposure of mesh into the vagina or other structures or organs, fistula formation, infection, inflammation (acute or chronic), local irritation, mesh migration, necrosis, de novo and/or worsening dyspareunia, neuromuscular symptoms (acute or chronic), pain (acute or chronic), partner pain and/or discomfort during intercourse, perforation or injury of soft tissue (e.g., ligaments, muscles, nerves, vessels), structures, or organs (e.g., bowel, rectum, bladder, urethra, ureters, vagina), seroma, suture erosion, bladder storage dysfunction (e.g., increased daytime frequency, urgency, nocturia, overactive bladder, urinary incontinence), ureteral obstruction, urinary tract infection, voiding symptoms (e.g., dysuria, urinary retention, incomplete emptying, straining, positional voiding, weak stream), de novo or worsening prolapse in untreated compartment, granulation tissue formation, palpable mesh (patient and/or partner), recurrent prolapse, sexual dysfunction, vaginal discharge (abnormal) and vaginal scarring, tightening, rigidity, shortening and/or contracture.

The occurrence of adverse events may require one or more revision surgeries, including removal of the mesh.

Complete removal of the mesh may not always be possible, and additional surgeries may not always fully correct the complications.

There may be unresolved pain with or without mesh explantation.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company Website at www.coloplast.com.

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

Minneapolis, MN
04/26/2021 PM-03860

MERIDIAN® VPS™
BRIEF STATEMENT

Indications
The Meridian VPS is a single use device intended to assist in the position and manipulation of the vagina during gynecologic surgical procedures such as sacrocolpopexy.

Contraindications
The Meridian VPS is contraindicated for use in patients with the following conditions:

- Pregnancy
- Intrauterine Device (IUD) present
- Physician deems use inadvisable

Warnings
The procedure to insert the device requires a good knowledge of local anatomy and the correct use of the manipulator in order to avoid perioperative damage to adjacent anatomical structures.

Avoid using excessive force during vaginal insertion, manipulation and removal of the device.

Precautions
Reuse of this single use product may create a potential harm to the physician, medical staff and/or patient.

To reduce the risk of perforation, if any resistance is felt when inserting the vaginal positioning system, do not force the vaginal positioning system against the resistance.

Potential Complications
Adverse events may include, but are not limited to: adverse tissue reaction, bleeding, cramping or discomfort, damage to blood vessels, nerves, connective tissue and other adjacent structures, infection, muscle spasms, organ perforation and injury, pain, and tissue damage.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company Website at www.coloplast.com.

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

Minneapolis, MN
12/20/2021 PM-04816

Restorelle® offers pre-shaped Y mesh or flat mesh that can be customized for varied patient anatomy and procedure approaches.

To Order Call Toll-Free 800.258.3476

These products may be ordered directly from Coloplast.

Restorelle Y Mesh

Dimensions (cm)	Purchase UOM	Qty per UOM	Item
Restorelle Y			
24 x 4	EA	1	501420
27 x 4	EA	1	501430
Restorelle Y Contour			
24 x 3	EA	1	501520

Restorelle Flat Mesh

Dimensions (cm)	Purchase UOM	Qty per UOM	Item
Restorelle M			
15 x 10	EA	1	501320
Restorelle L			
24 x 8	EA	1	501440
Restorelle XL			
30 x 30	EA	1	501330

Restorelle Y Contour + Meridian Kit

Contains	Purchase UOM	Qty per UOM	Item
Restorelle Y Contour	EA	1	52081
Meridian VPS	EA	1	

Meridian VPS

Description	Purchase UOM	Qty per UOM	Item
Meridian® VPS	EA	1	52080

References
1. Data on file with Coloplast.
2. Salamon CG, Lewis C, Priestley J, Gurshumov E, Culligan PJ. Prospective study of an ultra-lightweight polypropylene Y mesh for robotic sacrocolpopexy. *Int Urogynecol J*. 2013 Aug;24(8):1371-5. doi: 10.1007/s00192-012-2021-7. Epub 2013 Jan 8. PMID: 23296684.
3. Culligan PJ, Lewis C, Priestley J, Mushonga N. Long-Term Outcomes of Robotic-Assisted Laparoscopic Sacrocolpopexy Using Lightweight Y-Mesh. *Female Pelvic Med Reconstr Surg*. 2020 Mar;26(3):202-206. doi: 10.1097/SPV.0000000000000788. PMID: 31688526.

Coloplast Corp. Minneapolis, MN 55411 / Interventional Urology Surgical Support 1-800-258-3476

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