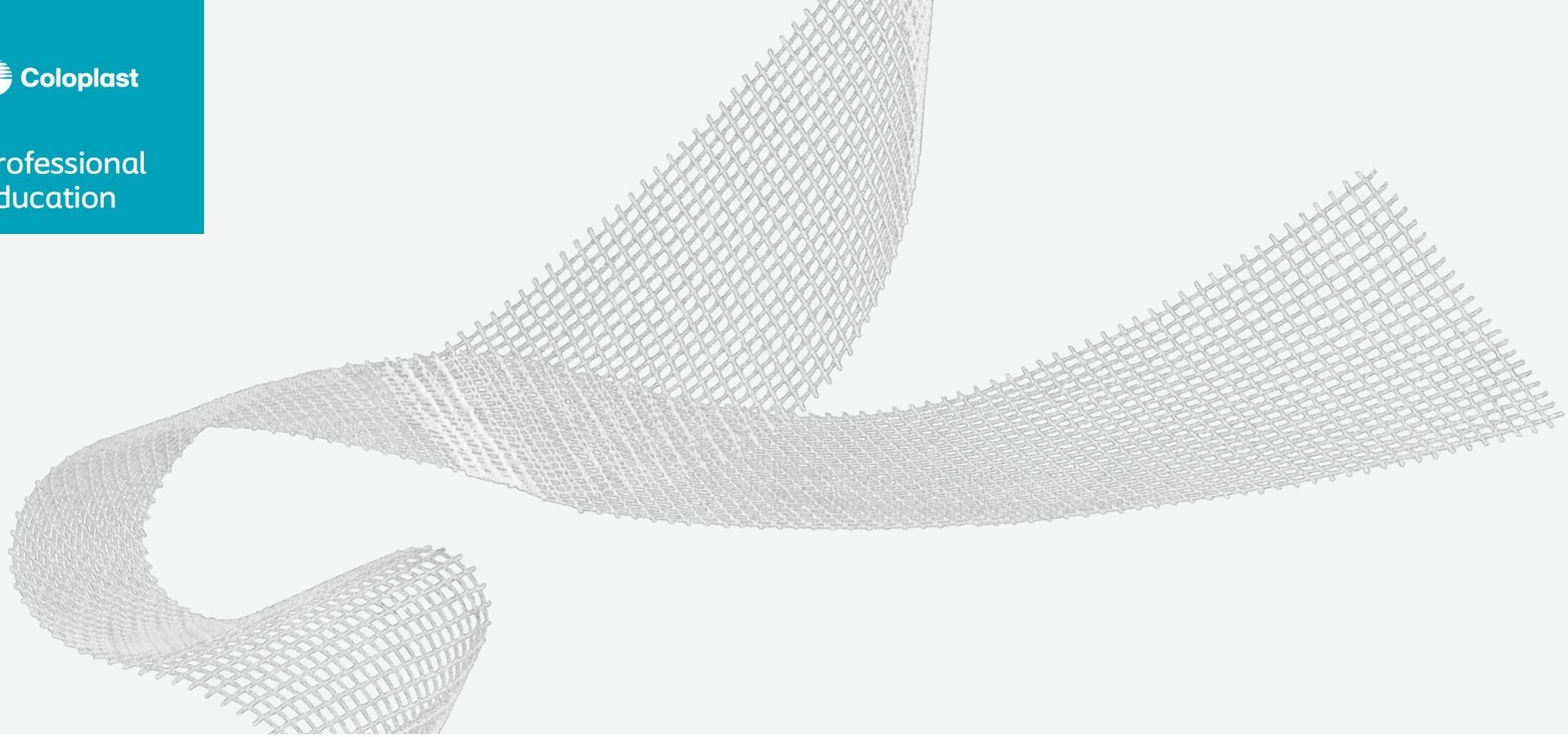
Coloplast

Professional Education



Restorelle® Mesh for POP Repair

Restorelle® Mesh for POP Repair

Distinguished faculty

Faculty Name

MD, FACOG, FACS

Account affiliation

City, ST

Coloplast

Physician presentation disclaimer

The following materials are presented for general information purposes only. Coloplast is compensating me for this professional education [or training] presentation.

There are certain segments that I may personalize, based upon my own experience in performing this procedure. These will be distinguished as such during the presentation. To the extent they go beyond Coloplast's written materials, these should be recognized as my individual medical opinions and not the opinions or endorsements of the company.

It is obvious with this, and every other surgical procedure, that you use your own independent judgment that you have received sufficient information and training to proficiently perform the procedure. This lecture and demonstration is intended as a supplement to your own education and training and is not a substitute for your own medical judgment.

I have provided substantial time for questions in this presentation and encourage and welcome any questions that you have.

Objectives

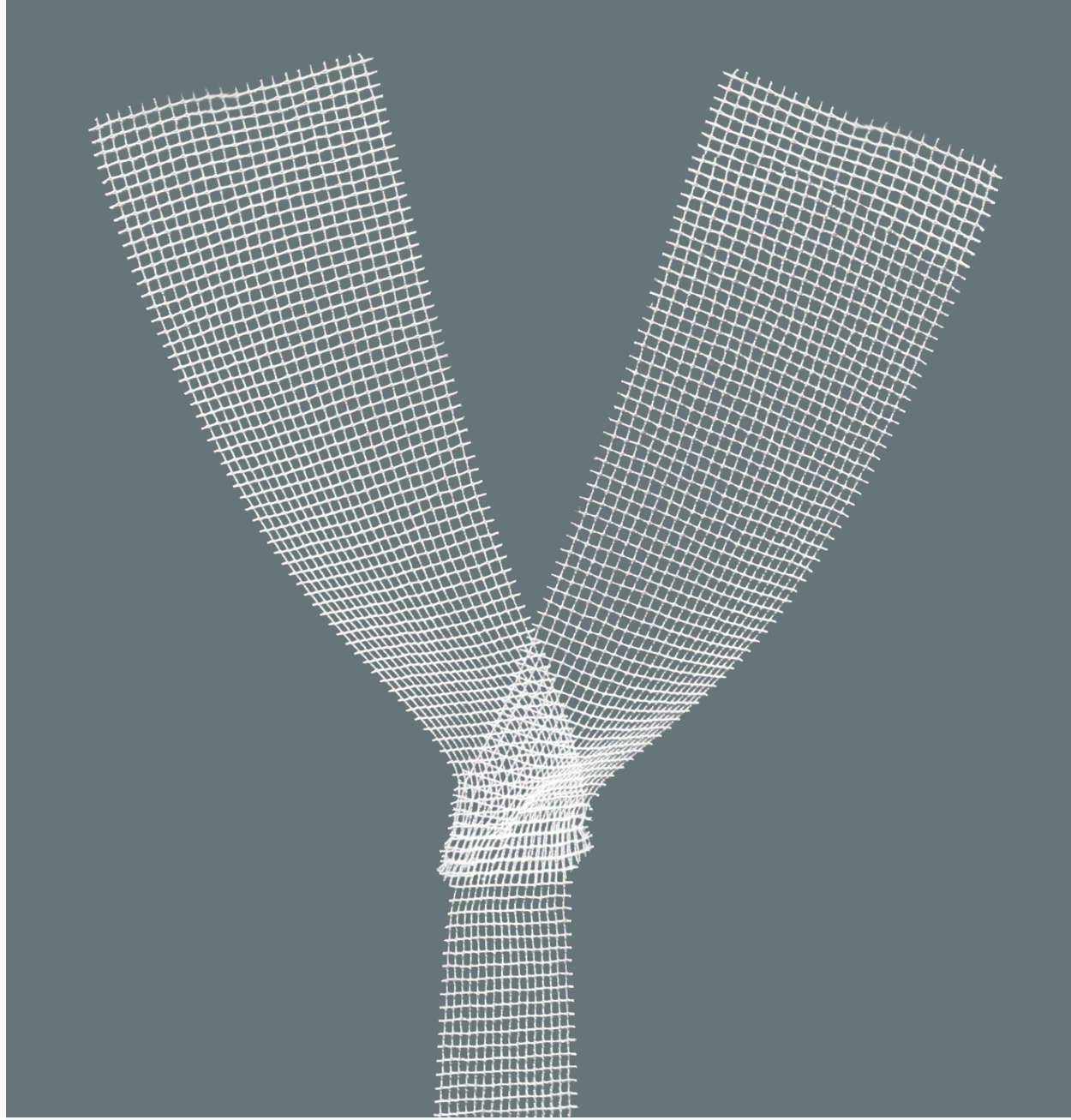
Communicate the **History and Evolution of Mesh**

Convey the importance of the **Restorelle® Mesh Design**

Analyze the fundamentals of the Restorelle Mesh Procedure

Agenda

01. Pelvic Organ Prolapse Prevalence and Need
02. History and Evolution of Mesh
03. Restorelle® Mesh Design
04. Clinical Data
05. Meridian® Vaginal Positioning System
06. Patient Journey
07. Procedural Video



Coloplast

01

Pelvic organ prolapse

Prevalence and need

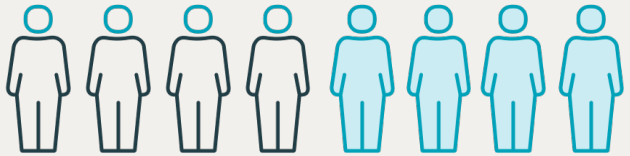
Coloplast

Pelvic organ prolapse (POP) prevalence

About

50% ***of US women 50-79 years of age***

will experience some form of prolapse[1]



The number of women in the US with symptomatic POP will be almost **5 million** by 2050[2]

[1] Barber, M.D., Maher, C. Epidemiology and outcome assessment of pelvic organ prolapse. *Int Urogynecol J* 24,1783-1790 (2013).
[2] Wu JM. Forecasting the prevalence of pelvic floor disorders in US women: 2010 to 2050. *Obstet Gynecol.* 2009;114(6)1278-83.

Coloplast's commitment_

Improve treatment options
for women

Provide better solutions
for surgeons

Focus to reduce costs
to the system

Pelvic organ prolapse repair options

Transabdominal

Restorelle® Y-Mesh

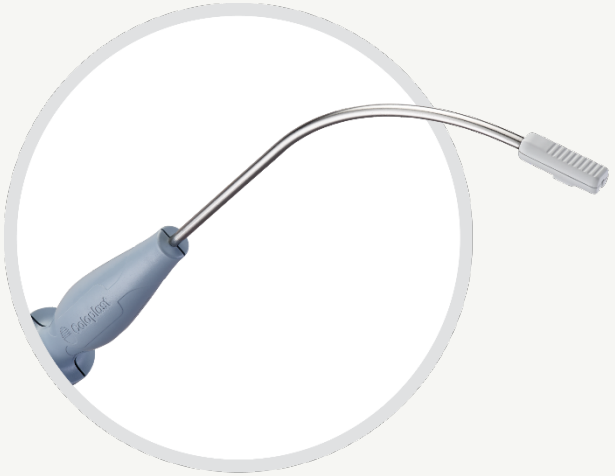
Transvaginal

Axis™ Allograft

Suspend® Allograft

Fixation

Saffron™ Fixation



Coloplast

02

History

Evolution of mesh

Coloplast

Evolution of synthetic mesh

Standard[1]

≥ 70 < 140 g/m^2

Light[1]

≥ 35 < 70 g/m^2

***Ultra*-lightweight[2]**

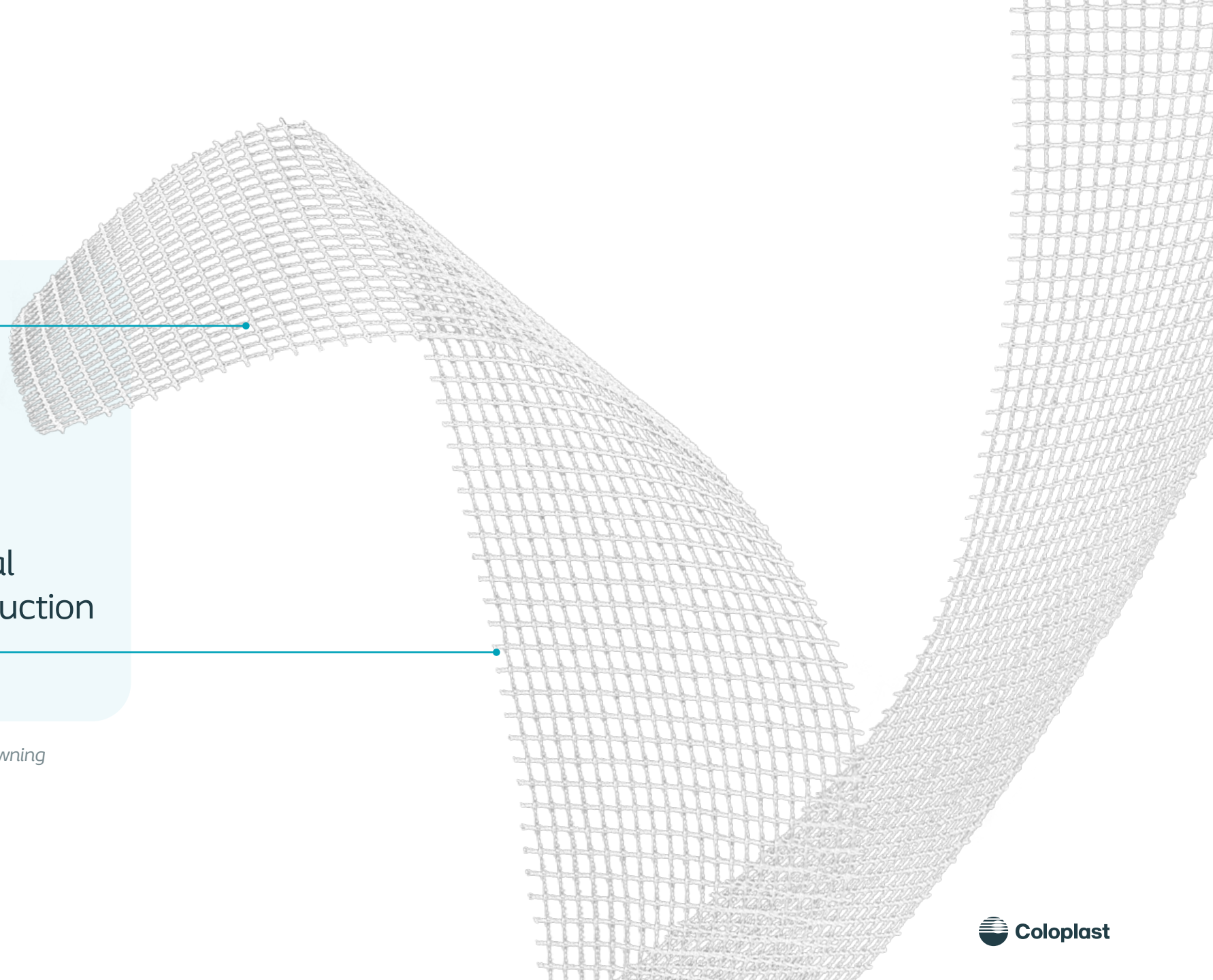
< 35 g/m^2

[1] Coda, Lamberti, and Martorana. Classification of prosthetics used in hernia repair based on weight and biomaterial; *Hernia* 2012; 16:19-20.
[2] Data on file

Restorelle® Mesh

Made from type-1 knitted, microporous polypropylene monofilament

Isotropic multi-directional stretch, warp knit construction **eliminates fraying**



Developed by Urogynecologist, Dr. James Browning

Coloplast

03

Design

Restorelle® Mesh

Coloplast

Restorelle® Y Polypropylene Mesh

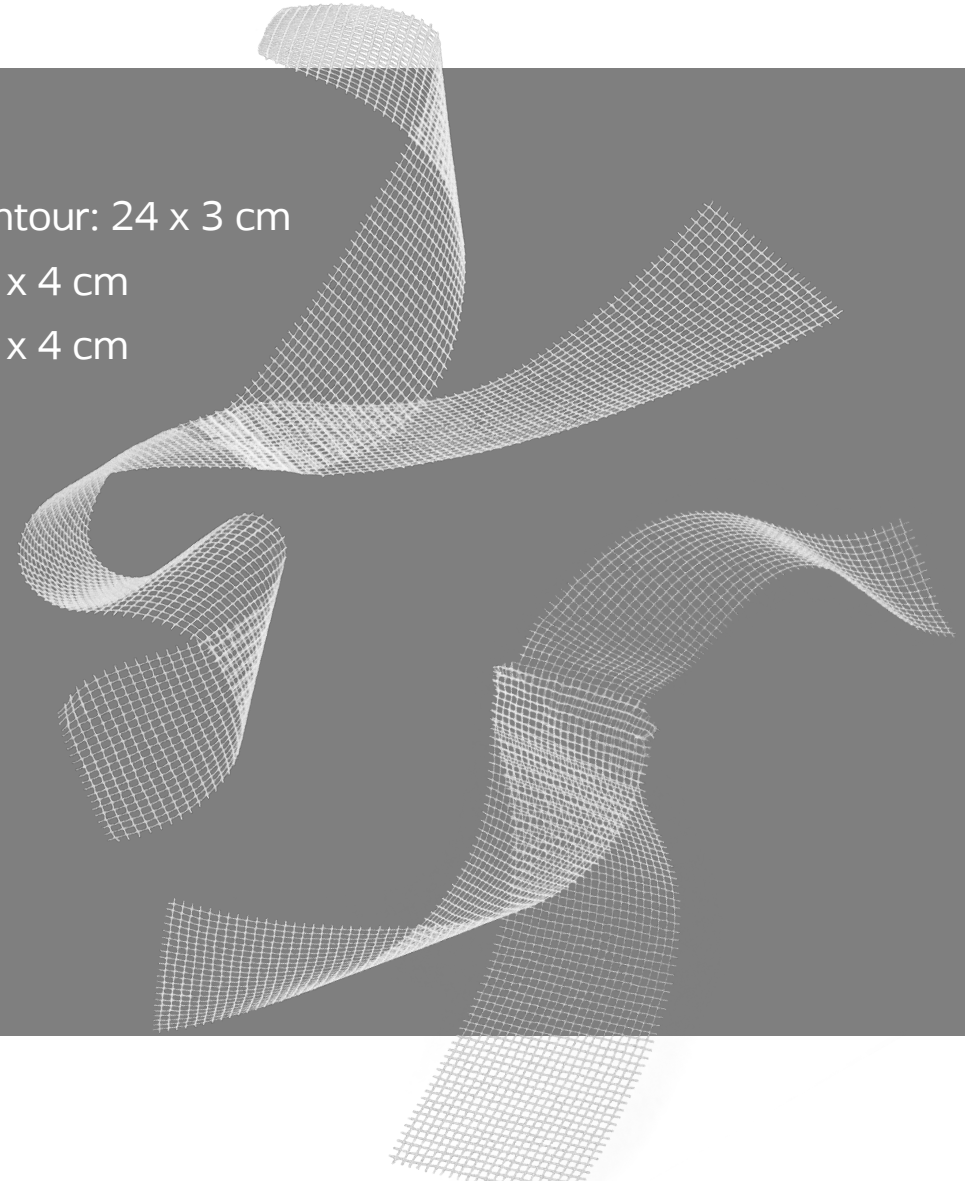
Restorelle restores patient anatomy and renews quality of life for optimal outcomes[1]

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

[1] Data on file.

Restorelle® Y and Y Contour

Mesh for transabdominal pelvic organ prolapse repair



Sizes

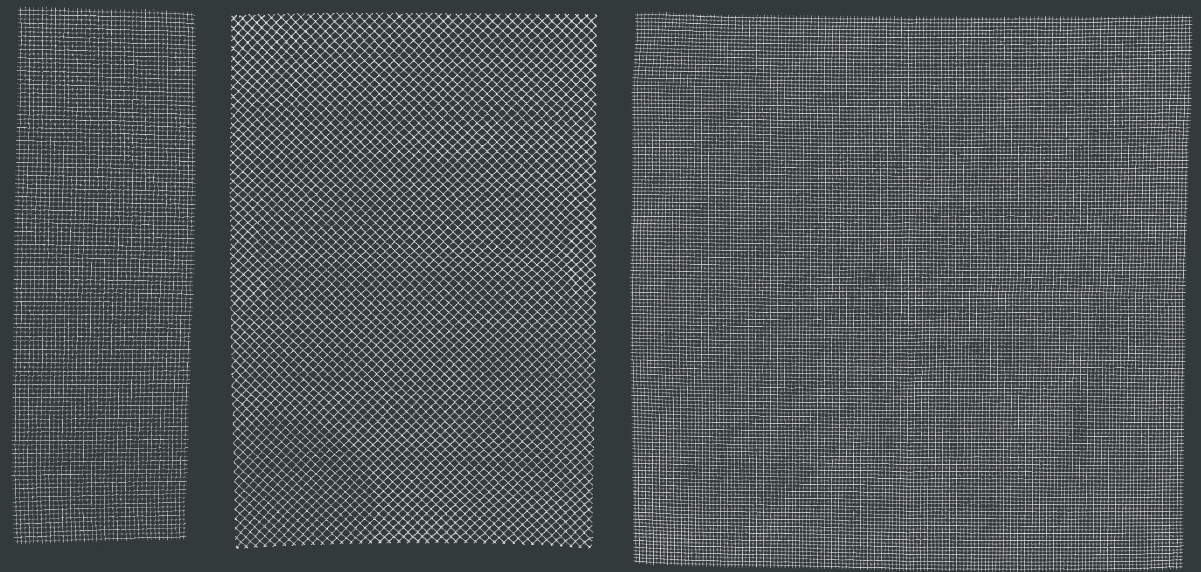
- Y Contour: 24 x 3 cm
- Y: 24 x 4 cm
- Y: 27 x 4 cm

Restorelle® Flat M, L & XL

Mesh for transabdominal pelvic organ prolapse repair

Sizes

- Restorelle M: 15 x 10 cm
- Restorelle L: 24 x 8 cm
- Restorelle XL: 30 x 30 cm



04

Clinical data

Restorelle® Mesh

Coloplast

Restorelle® vs. standard polypropylene mesh

Canine histology study[1]

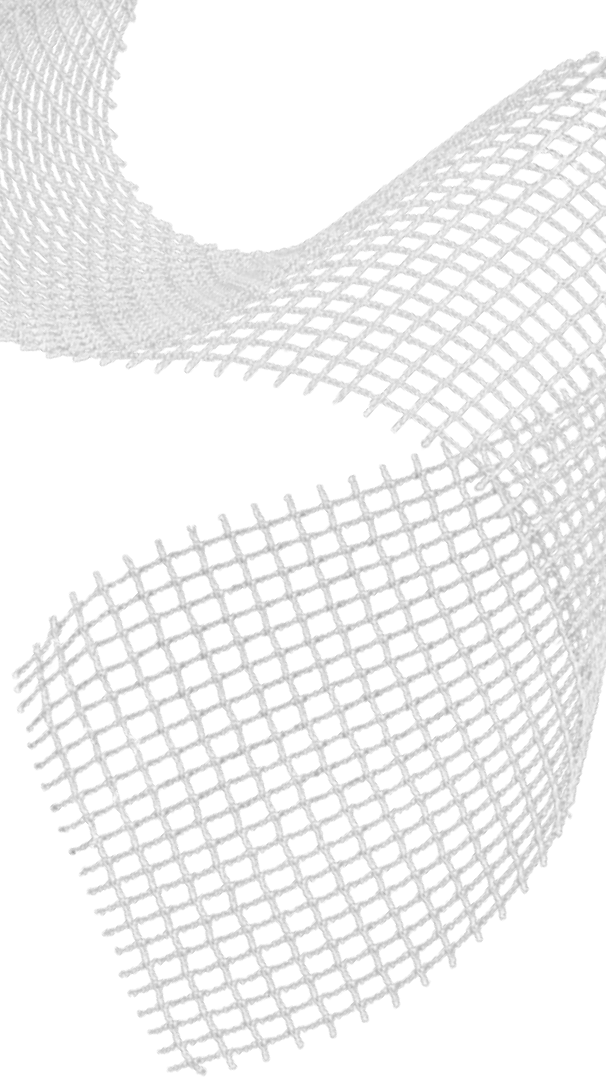
71% ***more mature***
type 1 collagen growth

Less ***fibrosis***

Less ***chronic inflammation***
and foreign body complications

Restorelle demonstrated
enhanced ***biocompatibility***
and provided an effective repair

Post-implant strength of Restorelle was
as strong ***or stronger***
than the heavier weight mesh



Characteristics	Restorelle® Mesh	Prolene™
Pore size major (mm)	1.6-2.0	0.64-0.92
Mass density (kg/m^2)	0.019	0.085
Pre-Implant Burst strength (N)	106.11 ± 10.95	383.32 ± 37.91
90 days post implant	11.33± 3.44 (kN) (11330 N)	8.92±4.35 (kN) (8920 N)

[1] Greca, Souza-Filho, Giovanini, Rubin, Kuenzer, Reese, and Araujo. The influence of porosity on the integration histology of two polypropylene meshes for the treatment of abdominal wall defects in dogs. *Hernia* 2008; 12: 45-49.

Coloplast

Available prolapse mesh today

Manufacturer	Weight (g/m)[2]	Pore Size (mm)[1]	Porosity (%)[1]	Stiffness (N/mm)[1]
Coloplast	19	3.24	78	0.18
Boston Scientific	25	2.8	72	0.2
Caldera	21	2.25	N/A	N/A
Ethicon	42	N/A	62	0.29

A comparison of Gynemesh PS (Ethicon) to SmartMesh (Coloplast) and UltraPro (Ethicon) concluded:

> ***"Deterioration of the mechanical properties of the vagina was highest following implantation with the stiffest mesh[2,3]"***

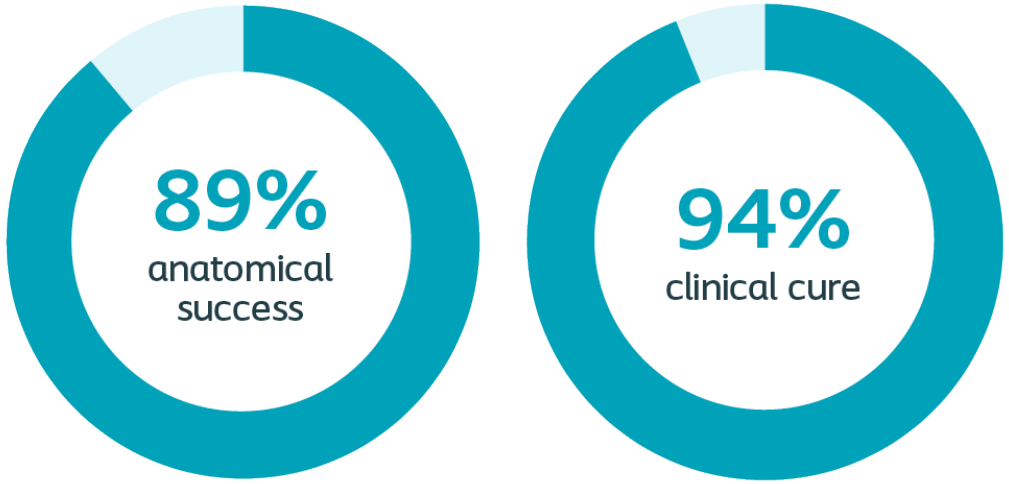
[1] Liang, Knight, Abramowitch, and Moalli. Exploring the basic science of prolapse meshes; *Curr Opin Obstet Gynecol* 2016; 28:412-419.
[2] Feola, Abramowitch, Knight, Palcsey, Nolfi, Feola, Stein and Moalli. Impact of vaginal synthetic prolapse meshes on the mechanics of the host tissue response. *BJOG* 2013; 120(2): 224-232.
[3] Data from non-human testing

Prospective study of an ultra-lightweight polypropylene y-mesh for robotic sacrocolpopexy (2012)

International Urogynecology Journal

Key Outcomes

No mesh erosions or mesh-related complications occurred



Introduction and hypothesis:

To prospectively evaluate the use of a particular polypropylene Y mesh for robotic sacrocolpopexy.

Conclusion:

The use of this ultra-lightweight Y mesh for sacrocolpopexy eliminated the mesh-related complications in the first postoperative year, and provided significant improvement in subjective and objective outcomes.

View the abstract

Charbel G. Salamon, Christa Lewis, Jennifer Priestley, Emil Gurshumov, and Patrick J. Culligan. Prospective study of an ultralightweight polypropylene Y mesh for robotic sacrocolpopexy, *Int Urogynecol J* DOI 10.1007/s00192-012-2021-7.

A Prospective Randomized Trial Comparing Restorelle Y-Mesh and Flat Mesh for Laparoscopic and Robotic-Assisted Laparoscopic Sacrocolpopexy (2019)

Female Pelvic Medicine & Reconstructive Surgery

Primary Effectiveness Objective

Excellent subjective and objective outcomes between the two meshes

Aim:

To compare case and mesh placement times between Restorelle Y-mesh and flat mesh. The secondary objective was to compare subjective and objective outcomes between the 2 mesh configurations.

Conclusion:

Case and mesh placement times do not differ in patients undergoing LSC or RSC with either Restorelle Y-mesh or flat mesh. At 6 months, subjective and objective successes were 94% and 100%, respectively.

View the abstract

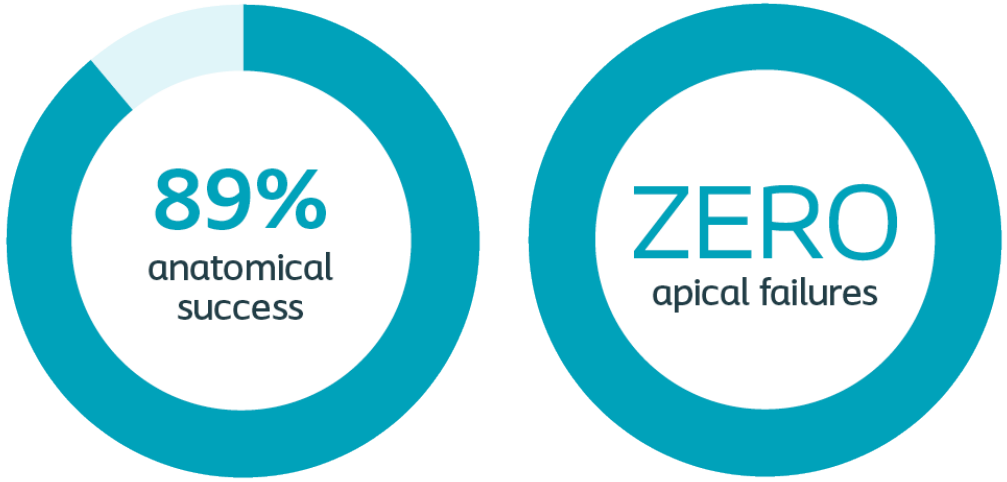
Cecile A. Ferrando, MD, MPH and Marie Fidela R. Paraiso, MD. A Prospective Randomized Trial Comparing Restorelle Y Mesh and Flat Mesh for Laparoscopic and Robotic-Assisted Laparoscopic Sacrocolpopexy, AUGS Special Issue Submission, *Female Pelvic Med Reconstr Surg* 2019;25: 83-87.

Long-Term Outcomes of Robotic-Assisted Laparoscopic Sacrocolpopexy Using Lightweight Y-Mesh (2020)

Female Pelvic Medicine & Reconstructive Surgery

Primary Effectiveness Objective

Excellent objective and subjective outcomes at 5 years



Aim:
To describe anatomic and symptomatic outcomes after Robotic-assisted laparoscopic sacrocolpopexy (RALS) using very lightweight polypropylene Y-mesh.

Conclusion:
The study found excellent objective and subjective long-term outcomes for RASC using very lightweight polypropylene Y-mesh.

View the abstract

Patrick J. Culligan, MD, Christa Lewis, DO, Jennifer Priestley, PhD, and Nyarai, Mushonga, MD. Long-Term Outcomes of Robotic-Assisted Laparoscopic Sacrocolpopexy Using Lightweight Y-Mesh, *Female Pelvic Med Reconstr Surg* 2020; 26: 202–206.

Post-market surveillance

Restorelle® Mesh demonstrates equivalent or favorable performance compared to other mesh products in numerous studies[1]

A number of post-market studies on mesh have established that meshes with **low density, low stiffness, and high porosity have improved tissue responses**

The studies address:

- Vaginal muscle thickness & contractility
- Nerve density
- Collagen & elastin properties
- Inflammation mediator levels (MMP-1/MMP-2) and others
- Erosion or mesh-related complications
- Mesh placement times
- Subjective and objective outcomes

1. Please refer to slides 33-40 for the list of studies

Clinical Data with Effective Outcomes

What are the outcomes?

Women experiencing POP deserve a clinically proven and effective solution that lasts. Prolapse repair procedures have effective outcomes.

88%

of patients were “satisfied” or “very satisfied”[1]

87%

of patients stated they would definitely “do it all over again” if they had the chance[1]

86%

stated they “would definitely recommend to a friend”[1]

[1] Culligan, P. J., Lewis, C., Priestley, J., & Mushonga, N. (2020). Long-Term Outcomes of Robotic-Assisted Laparoscopic Sacrocolpopexy Using Lightweight Y-Mesh. *Female pelvic medicine & reconstructive surgery*, 26(3), 202–206. https://doi.org/10.1097/SPV.0000000000000788

05

Meridian®

Vaginal Positioning System

Coloplast

Meridian® Vaginal Position System

Transabdominal pelvic organ prolapse repair

Stabilization to aid in identification of vaginal structures

Adjustable pin engages cervix and maintains alignment at apex

Head shape

- Flatness of head allows presentation of vaginal tissue (4.5 cm wide/8 cm long)

Posterior kick-out door (moves toward sacrum) pushes posterior compartment toward surgeon, allowing easier visualization and fixation

Ergonomic design allows for more natural hand positioning

Coloplast

06

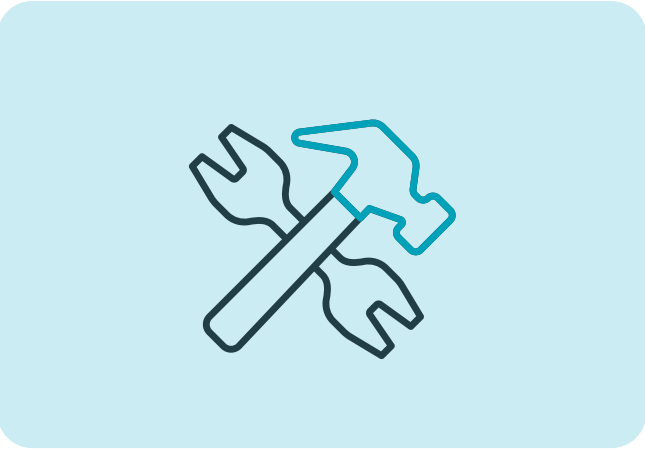
Patient journey

Patient selection, tips and tricks, post-procedure

Coloplast

Patient Selection

Indication:
Restorelle M, L and XL, Restorelle Y, and Restorelle Y Contour 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.



Restorelle® Mesh Implantation Physician Tips and Tricks

Dissection	Mesh placement	Tensioning	Suturing

07

Procedural video

Restorelle® Mesh

Coloplast

Restorelle® Y Mesh

Robotic Sacrocolpopexy Post Hysterectomy

Emily Cole, MD

Studies

Restorelle® Mesh

Coloplast

Restorelle Post-Market Bench and Animal Data

Author (Year)	Study Objective	Methods	Findings
Greca (2008)	To compare integration histology of two types of monofilament polypropylene mesh with different pore sizes, mass densities and burst strengths when used for full-thickness abdominal wall defect repairs in dogs	Two types of monofilament polypropylene mesh with different pore sizes, mass densities and burst strengths were used to repair two identical paired full-thickness abdominal wall defects in ten dogs, in order to compare their integration histology 90 days after implantation. On one side a standard mesh, Prolene® (Ethicon), was sutured to the borders of the defect, while on the other a new ultralightweight macroporous mesh, Mpathy® mesh, was used.	• Restorelle SmartMesh demonstrated greater biocompatibility and provided an effective repair • Mesh vaginal complex burst strength similar 90 days post-implant between Restorelle SmartMesh and Prolene mesh
Liang (2012)	To compare the impact of the prototype prolapse mesh Gynemesh PS with that of two new generation lower stiffness meshes, UltraPro and SmartMesh, on vaginal morphology and structural composition.	Fifty (50) rhesus macaques were implanted with Gynemesh PS (n = 12), UltraPro with its blue line perpendicular to the longitudinal axis of vagina (n = 10), UltraPro with its blue line parallel to the longitudinal axis of vagina (n = 8) or SmartMesh (n = 8) via sacrocolpopexy following hysterectomy. Shamoperated animals (n = 12) served as controls	• The tissue mechanical properties of the underlying and associated grafted vagina deteriorated following implantation with the stiffer mesh Gynemesh PS but not the lower stiffness meshes UltraPro and Smartmesh. • Smooth muscle thickness for Restorelle and Gynemesh UltraPro not significantly different than sham and thicker than Gynemesh PS • Mature elastin content for Restorelle not significantly different than sham and higher than both Gynemesh UltraPro and PS
Feola (2013)	To define the impact of prolapse mesh on the biomechanical properties of the vagina by comparing Gynemesh PS (Ethicon) to lower stiffness meshes (Restorelle Smartmesh, Coloplast; and Gynemesh UltraPro, Ethicon)	Meshes were implanted via sacrocolpopexy after hysterectomy and compared with sham. Because its stiffness is highly directional, UltraPro was implanted in two directions: UltraPro Perpendicular (less stiff) and UltraPro Parallel (more stiff), with the indicated direction referring to the position of the blue orientation lines relative to the longitudinal axis of the vagina. The mesh–vaginal complex (MVC) was excised in toto after 3 months	• Vaginal Contractility: Restorelle (48% reduction) outperformed both Gynemesh PS (80% reduction) and Gynemesh UltraPro (68% Parallel orientation) • Mesh Vaginal Complex (MVC) stiffness: Restorelle Smartmesh and Gynemesh PS statistically similar to sham while Gynemesh UltraPro significantly higher (48% Perpendicular, 46% Parallel)

Restorelle Post-Market Bench and Animal Data

Author (Year)	Study Objective	Methods	Findings
Feola (2013)	To compare porosity, anisotropic index, and stiffness of different mesh products.	Porosity, anisotropic index, and stiffness of Gynemesh PS (n=8), the prototype polypropylene mesh for prolapse repair, was compared with four newer generation mesh produces: UltraPro (n=5), SmartMesh (n=5), Novasilk (n=5), and Polyform (n=5).	• Restorelle SmartMesh had highest porosity (78%) vs Novasilk (72%), Gynemesh UltraPro (69%), Gynemesh PS (64%), & Polyform (58%) • Restorelle SmartMesh was the least stiff mesh (11N/mm) vs Novasilk (16N/mm), Gynemesh UltraPro (22N/mm), Polyform (28N/mm), & Gynemesh PS (28N/mm)
Feola (2014)	Varying degrees of nonlinear mechanical behavior arising from geometric differences of urogynecological meshes.	Uniaxial tension was applied along perpendicular directions, and then the tensile behavior of the meshes was determined utilizing a co-rotational finite element model, with an imbedded linear or fiber recruitment local stress-strain relationship	• Both meshes exhibited a highly nonlinear stress-strain behavior; Restorelle had no significant differences between the two perpendicular directions, while UltraPro had a 93% difference in the ow (initial) stiffness (p=0.009) between loading directions.
Liang (2015)	The impact of polypropylene mesh implantation on vaginal collagen and elastin metabolism was analyzed using a nonhuman primate model to further delineate the mechanism of mesh induced complications.	Forty-nine middle-aged parous rhesus macaques underwent surgical implantation of 3 synthetic meshes via sacrocolpopexy. Gynemesh PS (n = 12) (Ethicon, Somerville, NJ) and 2 lower-weight, higher porosity, lower-stiffness meshes (UltraPro [n = 19] [Ethicon] and Restorelle [n = 8] [Coloplast, Minneapolis, MN]) were implanted, in which UltraPro was implanted with its blue orientation lines perpendicular (low stiffness direction, n = 11) and parallel (high stiffness direction, n = 8) to the longitudinal axis of the vagina. Sham-operated animals were used as controls (n = 10). Twelve weeks after surgery, the mesh-tissue complex was excised and analyzed.	• Heavier, stiffer, and less porous mesh likely lead to increased MMP activity resulting in compromised tissue. • Mature elastin degradation for Restorelle Smartmesh not significantly different than sham and lower than both Gynemesh UltraPro and PS • Collagen degradation for content for Restorelle Smartmesh and Gynemesh UltraPro not significantly different than sham and lower than Gynemesh PS.

Restorelle Post-Market Bench and Animal Data

Author (Year)	Study Objective	Methods	Findings
Brown (2015)	To determine the predominant cell type (macrophage, T lymphocyte, B lymphocyte, mast cell) within the area of implantation of the prototypical polypropylene mesh, Gynemesh PS; and to determine the phenotypic profile (M1 proinflammatory, M2 antiinflammatory) of the macrophage response to 3 different polypropylene meshes: Gynemesh PS, and 2 lower-weight, higher-porosity meshes, UltraPro and Restorelle	Sacrocolpopexy was performed following hysterectomy in rhesus macaques. Sham-operated animals served as controls. At 12 weeks post-surgery, the vagina-mesh complex was excised and the host inflammatory response was evaluated. Hematoxylin and eosin was used to perform routine histomorphologic evaluation. Identification of leukocyte (CD45+) subsets was performed by immunolabeling for CD68 (macrophage), CD3 (Tlymphocyte), CD20 (B lymphocyte), and CD117 (mast cell). M1 and M2 macrophage subsets were identified using immunolabeling (CD86+ and CD206+, respectively), and further evaluation was performed using enzyme-linked immunosorbent assay for 2 M1 (tumor necrosis factor-alpha and interleukin [IL]- 12) and 2 M2 (IL-4 and IL-10) cytokines.	• Restorelle had increased expression of anti-inflammatory cytokine IL-10 compared to Gynemesh PS. • Cellular responses increased for all meshes above sham response with Restorelle SmartMesh and Gynemesh UltraPro significantly lower than Gynemesh PS. • At 12 weeks post-surgery the host response to mesh consists predominantly of activated, proinflammatory M1 macrophages at 12 weeks post-surgery which is attenuated with implantation of lighter-weight, higher-porosity mesh.
Barone (2016)	To determine the effect of tensile loading and pore orientation on mesh porosity and pore dimensions.	The porosity and pore diameter of 4 currently available prolapse meshes (Gynemesh PS, UltraPro Artisyn, Restorelle, Alyte Y-mesh) were examined in response to uniaxial tensile loads of 0.1, 5, and 10 N while mimicking clinical loading conditions. The textile properties were compared with those observed for the unloaded mesh. In addition to the various pore geometries, 3 orientations of Restorelle (0-, 5-, 45-degree offset) and 2 orientations of UltraPro (0-, 90- degree offset) were examined.	• Restorelle 0 – degree offset (square pore) was the only mesh whose porosity was not significantly reduced on application of load. At 10N of force, all mesh groups other than Restorelle 0 – degree and Restorelle 5 – degree offset experienced such large pore reductions that the mesh structure grossly appeared as a solid piece of polypropylene.
Jallah (2016)	The impact of prolapse mesh on vaginal smooth muscle structure and function.	Three months following implantation of 3 meshes (Gynemesh, UltraPro, Restorelle) with distinct textile and mechanical properties, mesh tissue implants were evaluated for smooth muscle contraction, innervation, receptor function and innervation density	• The impact varied by mesh property, as mesh stiffness was a significant predictor of the negative affect on muscle function and nerve density, whereas mesh and weight were predictors of receptor function.

Restorelle Post-Market Bench and Animal Data

Author (Year)	Study Objective	Methods	Findings
Ulrich D (2016)	Changes in pelvic organ prolapse mesh mechanical properties following implantation in rats.	Four (4) mesh products (Gynemesh, UltraPro, Polyform Lite, and Restorelle) were mechanically assessed before and after implantation. Assessments included: stiffness and permanent extension following cyclic loading and breaking load of preimplanted mesh, explanted mesh-tissue complexes, and explanted meshes were assessed using a multi-axial (ball-burst method)	• After 90 days of implantation, significant decreases in stiffness and breaking load, and increased permanent extension was observed.

Published Restorelle Transabdominal Clinical Data

Author (Year)	Study Objective	Methods	Findings
Salamon (2013)	The primary outcome of the study, "anatomical success" rate, was 89%. Anatomical success rate was defined in accordance with the NIH definition of POPQ system stage 0 or 1. A significant improvement in all POP-Q parameters from pre operation to 12 months follow-up was noted ($p < 0.0001$)	Single-arm prospective study, all 120 women with stage II or greater apical prolapse scheduled to undergo a robotic sacrocolpopexy with Restorelle Y ultra-lightweight polypropylene Y mesh with follow-up of 6 months and 12 months.	• No mesh exposures or erosions, sacrocolpopexy mesh-related complications, wound related complications, infectious morbidities, or reoperations due to the mesh within first postop vaginal exams. • The use of an ultralightweight polypropylene Y mesh produced significant anatomical and functional improvements. • Use of this Restorelle Y eliminated mesh related complications in the first postop year without sacrificing the efficacy of the sacrocolpopexy.
Lewis (2014)	Determine bowel function changes 12 months after robotic sacrocolpopexy	Single-center prospective cohort study evaluating bowel function 12 months after robotic sacrocolpopexy between 2007 and 2011. Bowel function symptoms were measured by the Colorectal-Anal Distress Inventory, Short Form 8 (CRADI-8). 393/423 (93%) completed a 12-month follow-up.	• Mean CRADI-8 scores at baseline and 12 months were 21.1 (20) and 7.3 (11), respectively (P G 0.0001). • Mean CRAIQ-7 scores at baseline and 12 months were 11.1 (20) and 2.4 (9), respectively (P G 0.0001) • Robotic sacrocolpopexy was associated with significant improvements in bowel function as measured by CRADI-8 as well as improvements in impact on quality of life as measured by CRAIQ-7.

Published Restorelle Transabdominal Clinical Data

Author (Year)	Study Objective	Methods	Findings
Nosti (2015)	Retrospective study with prospective follow-up to compare mesh related complications at the time of total vaginal hysterectomy with laparoscopic sacrocolpopexy (TVH-LSC) versus laparoscopic placement of sacrocolpopexy mesh at time of laparoscopic supracervical hysterectomy (LSH-LSC)	In the TVH-LSC group, 112 of the 123 (91%) surgeries used the Restorelle ultra-lightweight, macroporous, monofilament, polypropylene meshes implanted via the transvaginal approach to treat POP. In the LSH-LSC group, 45 of 59 (76%) surgeries used the Restorelle ultra-lightweight, macroporous, monofilament, polypropylene meshes for treatment of pelvic organ prolapse (POP) via the transabdominal route.	• No differences in intraoperative/postoperative complications or subjective/objective success between groups. • Both groups had similar rates of suture erosion (1% vs 2%, P = 1.0) and granulation tissue (10% vs 7%, P = 0.6) which, with the exception of 1 patient, was managed in office. All cases occurred in patients where Goretex was utilized to secure mesh. • Groups were not reported by mesh brand
Kenton (2016)	To report outcomes and complications in approximately 450 women who underwent isolated minimally invasive abdominal sacrocolpopexy (ASC) for the management of pelvic organ prolapse (POP)	Retrospective review of EMRs of women who underwent minimally invasive (232 women) ASC (laparoscopic ASC [LASC] or (226 women) robotic ASC [RASC]) for symptomatic POP. Polypropylene mesh was used and the decision to reperitonealize the mesh was left to surgeon discretion. Data collected included demographics, Pelvic Floor Distress Inventory questionnaire, intraoperative and postoperative details, and POP quantification. A soft polypropylene mesh, Gynemesh or Restorelle, was attached to the anterior and posterior vagina.	• Both the LASC and RASC routes were associated with high anatomic success rates, significant improvement in pelvic floor symptoms, and few complications • 5 women (1.1%) had a vaginal mesh erosion (2 RASC, 3 LASC), 3 of which underwent a concomitant supracervical hysterectomy • Minimally invasive ASC without additional concomitant vaginal procedures is an effective and safe procedure for the surgical management of POP with low rates of reoperation and complications. • Results were not reported by mesh brand.

Published Restorelle Transabdominal Clinical Data

Author (Year)	Study Objective	Methods	Findings
Fayyad (2017)	Retrospective cohort study of 159 patients undergoing laparoscopic sacrohysteropexy to manage uterine prolapse using single sheet mesh	144/159 patients completed the follow up assessment. At each visit, the prolapse symptoms were assessed using the prolapse quality-of-life (P-QoL) questionnaire and objectively with the use of the Pelvic Organ Prolapse Quantification (POPQ) score. The subjective outcomes were also evaluated with the use of the Patient Global Impression of Improvement (PGII) questionnaires. Perioperative complications and further surgery for prolapse were evaluated. Restorelle Flat mesh was attached to the posterior aspect of the cervix at the level of the uterosacral ligaments and extended to the level of the uterine isthmus bilaterally.	• Pre-operatively, 85% (135/159) had uterine prolapse stage 2. Postoperatively, 95.1% (137/144) of women had anatomical success rate defined as stage 0 uterine descent. • 82% (118/144) of women reported cure of prolapse symptoms and feeling "much better" or "very much better" on postoperative PGII assessment. • 8 women (5%) became pregnant following laparoscopic sacrohysteropexy / 7 had full term pregnancies and 1 had a miscarriage.

Published Restorelle Transabdominal Clinical Data

Author (Year)	Study Objective	Methods	Findings
Paraiso (2019)	The primary objective of this study was to compare case and mesh placement times between Restorelle Y mesh and flat mesh. The secondary objective was to compare subjective and objective outcomes between the 2 mesh configurations.	Prospective, randomized trial of 59 women undergoing laparoscopic (LSC) or robotic (RSC) sacrocolpopexy for posthysterectomy vaginal prolapse. Subjects were predetermined to undergo either an LSC or RSC and randomized to Y mesh or flat mesh. 30 patients were implanted with Y mesh (17 LSC, 13 RSC) and 29 implanted with flat mesh (18 LSC, 11 RSC). Case and mesh placement times were defined as incision time to time of closure and time from mesh introduced into the abdomen to placement of the last sacral stitch, respectively. All subjects underwent Pelvic Organ Prolapse Quantification System examination and completed the 20-item Pelvic Floor Disability Index preoperatively, at 6 (55 patients) , 12, and 24 months.	• Mean case time for all patients was 204.4 ± 48 minutes, with no difference between the groups. • Mean mesh placement time for all patients was 46.1 ± 13.5 minutes also with no difference between the mesh groups. • Mesh placement time between the mesh groups also did not differ by route of surgery. • At 6 months, there were no mesh erosions, and overall subjective success and objective success were 94% and 100%, respectively, with no difference between the 2 mesh types.
Dwyer (2019)	Explore the functional and anatomical outcomes and mesh adverse events of women following the surgical treatment of vaginal vault prolapse by laparoscopic sacrocolpopexy (LSCP)	Retrospective review of the outcome of a consecutive series of 156/231 women treated with a laparoscopic sacrocolpopexy (LSCP) since 2005 using the same techniques we published in a previous study (Smith ARB et al – LTR of LSCP – BJOG Int J OBGYN 2005) but employing an ultralightweight polypropylene mesh, Restorelle flat mesh.	• 89% of participants reported that they felt their post-operative condition had improved. • POP-Q results revealed that the median position of C changed from -3 preop to -7 post-operatively • No mesh complications were identified during the course of the study. • LSCP performed with an ultra- lightweight polypropylene mesh improves patient's functional and anatomical outcome. • The diagnosis of a single mesh extrusion within this patient cohort suggests that ultra-lightweight mesh is associated with a lower risk of a mesh extrusion than LSCP performed with heavier mesh.

Restorelle® M, L and XL, Restorelle® Y, and Restorelle® Y Contour Polypropylene Mesh - Brief Statement

Indications
Restorelle M, L and XL, Restorelle Y, and Restorelle Y Contour 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, Restorelle Y, and Restorelle Y Contour 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, Restorelle Y, or Restorelle Y Contour mesh
- Taking anticoagulant therapy
- Any condition, including known or suspected pelvic pathology, which could compromise implant or implant placement
- Sensitivity/allergy to polypropylene

Warnings & 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
Restorelle M, L and XL, Restorelle Y, and 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 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.

Patient Warnings
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 and XL, Restorelle Y, and Restorelle Y Contour should be considered in patients with:
• Age-related underlying conditions • Autoimmune disease • Coagulation disorder • Connective tissue disorder • Debilitated or immunocompromised state
• Diabetes • Pelvic radiation therapy or chemotherapy
• Physical characteristics (e.g., body mass index)
• Smoking-related underlying conditions
• Urinary tract anomalies.

Restorelle® M, L and XL, Restorelle® Y, and Restorelle® Y Contour Polypropylene Mesh - Brief Statement

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.

Procedure Warnings
Avoid placing excessive tension on the Restorelle M, L and XL, Restorelle Y, and 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.

Procedure Precautions
Use caution to avoid neurovascular injury. Observe patient for any signs of abnormal bleeding or clinical signs of nerve damage.

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.

Adverse events may include but are not limited to:
• Abscess (acute or delayed) • Adhesion/scar formation • Allergy, hypersensitivity or other immune reaction • Bleeding, hemorrhage or hematoma • Bowel Related (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 • Pain Related (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 • Urinary Related (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) • Vaginal Related (De novo or worsening prolapse in untreated compartment, Granulation tissue formation, Palpable mesh (patient and/or partner), Recurrent prolapse, Sexual dysfunction, Vaginal discharge (abnormal), 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
PM-30439 02.24

Meridian® VPS™ Vaginal Positioning System - Brief Statement

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

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

Warnings & Precautions
These devices must only be used by trained and experienced professionals.

Potential Complications
Adverse events associated with vaginal manipulators 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
PM-04816 03.2024

Coloplast

Coloplast

PM-33042 06.2024