

Science behind it.
Life ahead of it.



Our Story

Over 10 years ago, a urogynecologist set out to develop a mesh specifically with a woman's anatomy in mind.

He created Restorelle® Smartmesh®.

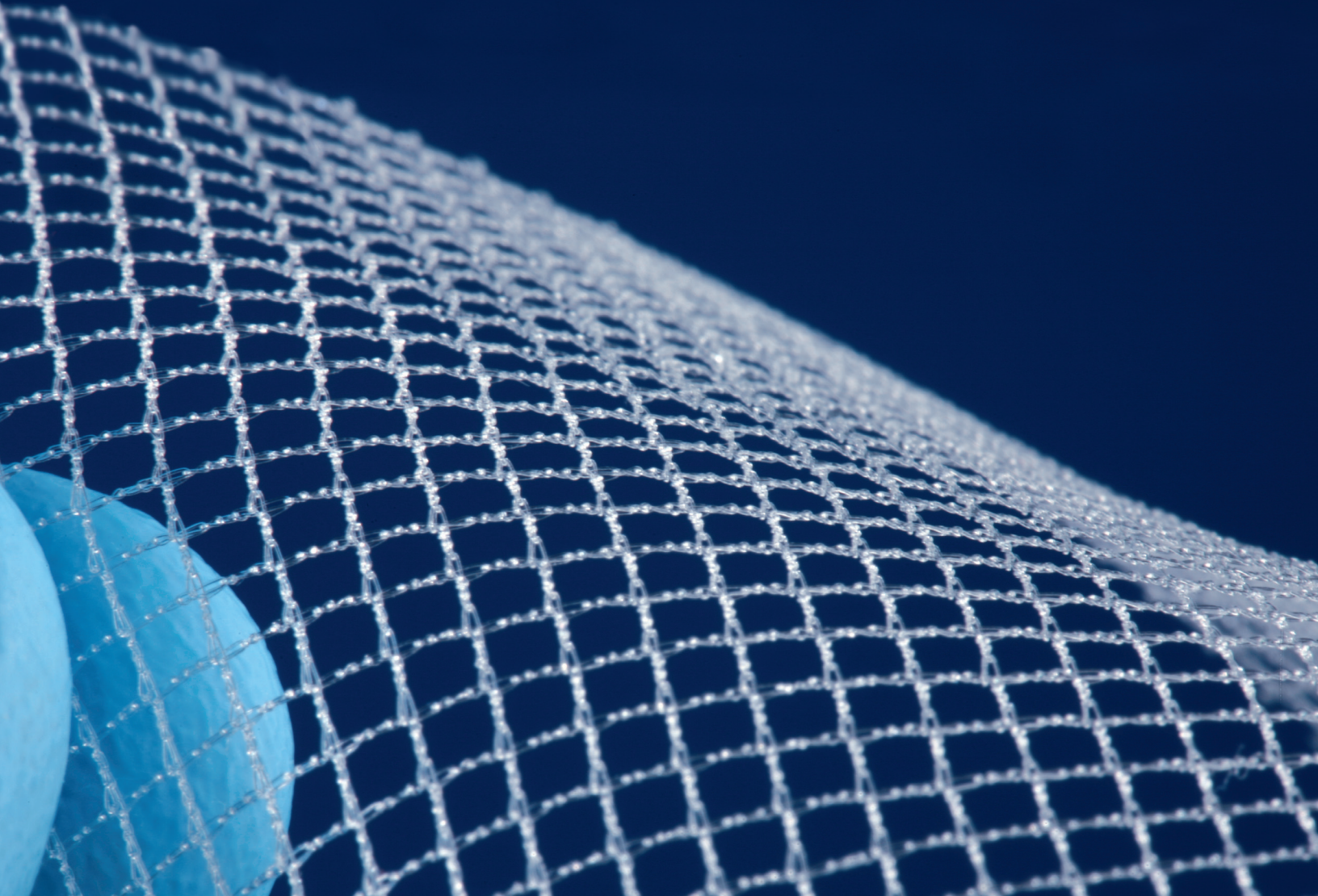
In 2001, Dr. James Browning began to develop a low impact medical device for the treatment of pelvic organ prolapse. He believed that the standard material of the time, a stiff mesh commonly used in abdominal hernia surgery, simply was not ideal for a woman's unique anatomy and healing requirements.

What he created was Restorelle Smartmesh: A physiologically compatible, ultra lightweight mesh that encourages superior collagen growth for optimal results.

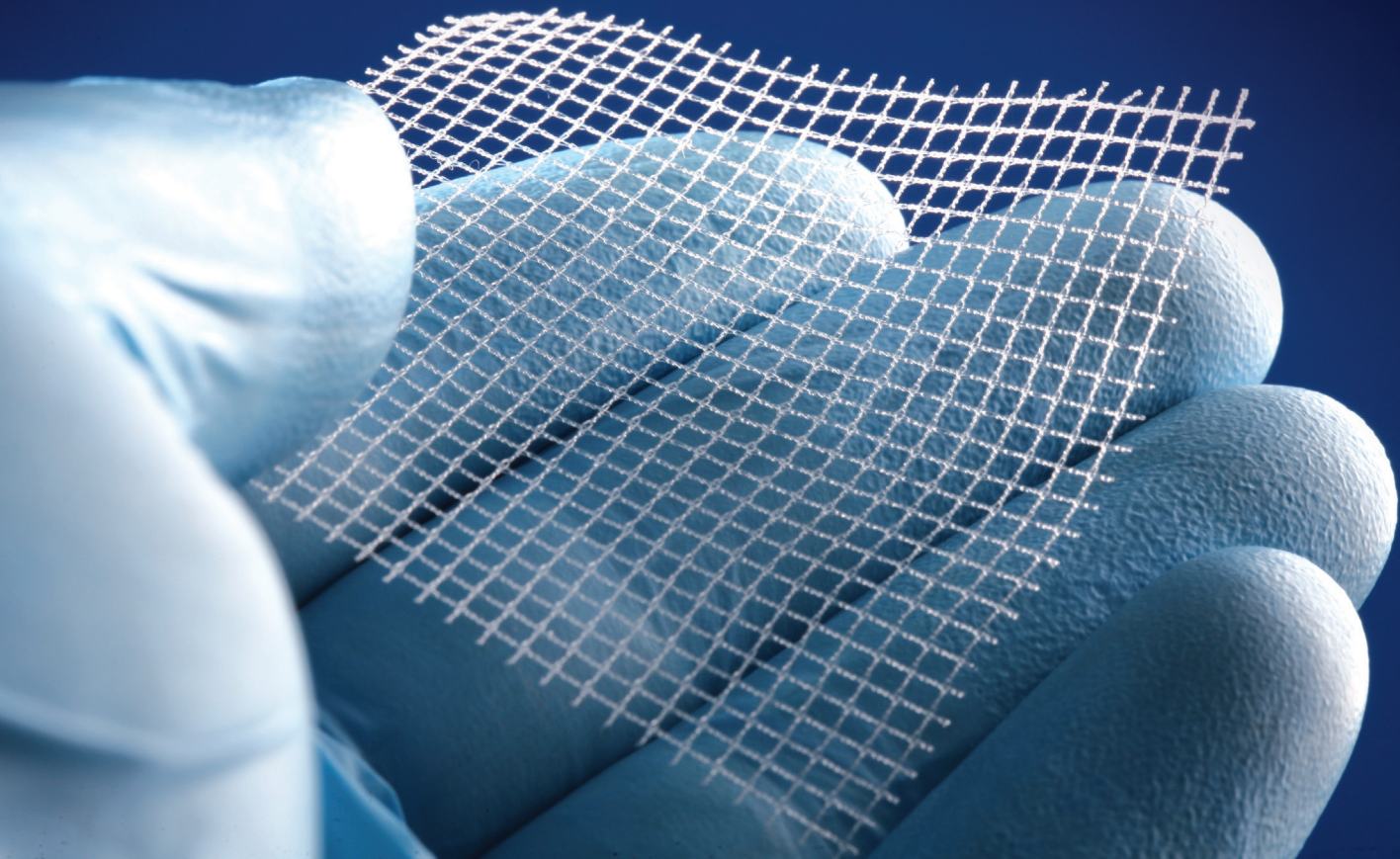
More importantly, he created a mesh that renews and restores a woman's body, as well as her quality of life.

Today, Restorelle Smartmesh continues to be the only mesh designed with a woman's anatomy and tissue healing requirements in mind. So you can be confident knowing you are working with a mesh backed by safety and science. And she can be confident knowing that there is life after prolapse.

Simply put, Restorelle Smartmesh is engineered to deliver better outcomes — for you, and for her.



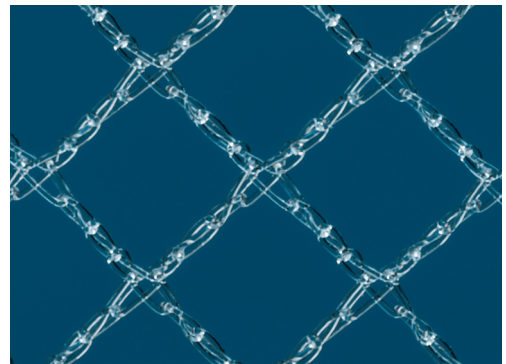
Designed specifically for women and their tissue healing requirements



Restores patient anatomy and renews quality of life for optimal outcomes

- **93.5% clinical cure rate¹**
- **99% cure rate transvaginally^{2, 3, 4}**
- **Less than 1% erosion rate^{1, 2, 6}**
- **Low incidence of de novo dyspareunia^{2, 5, 6}**
- **Vaginal elasticity maintained⁵**
- **Non-palpable to patient and partner⁵**
- **Significant bowel function improvement^{6, 7}**

Used clinically since 2004



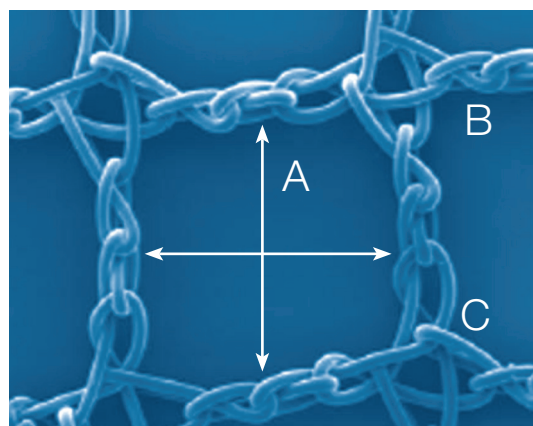
Smartmesh® Technology

Restorelle® Smartmesh is engineered to deliver better outcomes

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 junctions²

- Pore sizes critical for ideal tissue healing processes¹⁰
- Simultaneously encourages both bacteria fighting properties and collagen growth^{9, 11}
- Less fibrosis, chronic inflammation and foreign body reactions observed in Smartmesh⁹

The mechanical properties, material type, pore size and shape of surgical mesh directly influences tissue ingrowth¹²



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



Ultra-lightweight with Significant Strength

Patented polypropylene design is the lightest weight mesh available in Female Pelvic Health⁸

- 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 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

Comparison Scientific Study findings⁹:

Pre-implant

Characteristics	Mpathy (Smartmesh®)	Prolene™
Pore size major (mm)	1.6-2.0	0.64-0.92
Mass density (kg/m ²)	0.019	0.085
Burst strength (N*)	106.11 ± 10.95	383.32 ± 37.91

*newtons

Post-operative

90 day results	Mpathy (Smartmesh)	Prolene
Burst Strength (kN**)	11.33 ± 3.44	8.92 ± 4.35

**kilonewtons

Surgical Handling and Orientation Ease

Superior Draping and Laydown on Vaginal Cuff

- Easily view anatomical landmarks and suture positioning
- Low mesh memory fits through ports and easily rolls and unrolls to assess placement
- Improves procedural efficiency during surgery without having to stitch, lift up mesh and repeat
- Large 1.8 mm macropores enable suturing without needles
- Tailored uni-directional design maintains structural integrity from the sacrum to the vagina
- No rough edges or weak seams

Translucence enables clear visualization



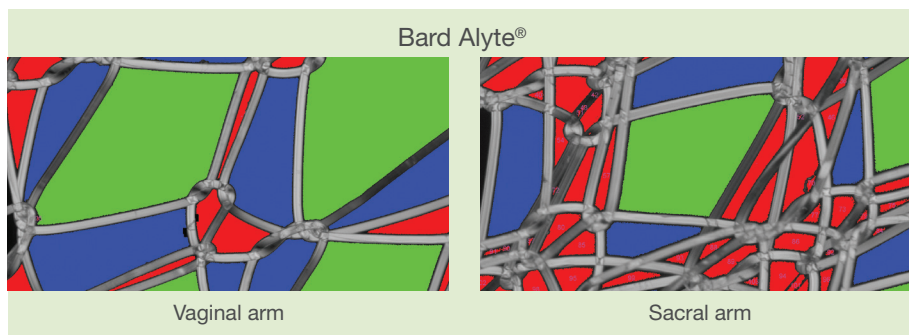
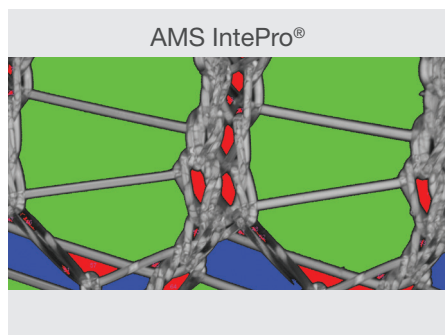
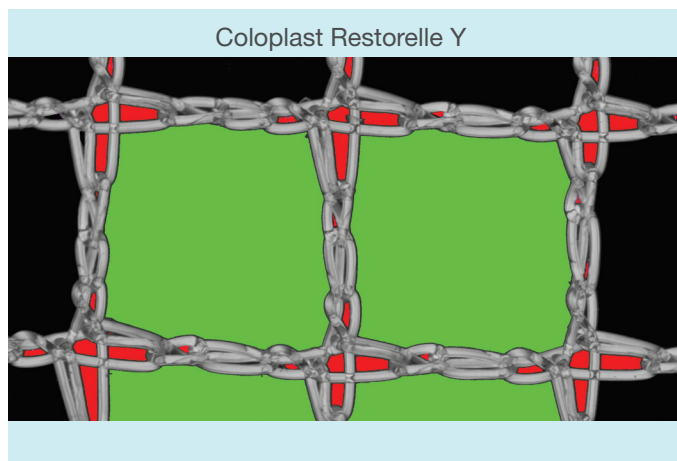
Ease of mesh rolling to access posterior wall



Restorelle® Smartmesh® is Engineered to Deliver Better Outcomes

Sacrocolpopexy Mesh Comparison

Pore Measurements and
Polarized Light Testing: Optical Magnification (15x)¹³








Pore Characteristics¹

	Pore Size (h x w mm)	Pore Area (mm ²)	Flexural Rigidity (mg x m)	Filament Diameter (mm)
Restorelle Y	1.71 x 1.71	2.84	47	0.079
Bard Alyte				
Vaginal arms	2.58 x 1.57	2.21	103	0.083
Sacral arm	1.92 x 1.21	1.22	223	0.083
AMS Y	1.21 x 2.21	2.12	100	0.107

- Restorelle Smartmesh engineering, knit design, uniform macropores and interstitial pores allow for ideal bacteria fighting and tissue ingrowth.⁹
- Restorelle Smartmesh has the largest pore area, smallest filament diameter and lowest flexural rigidity. These important physicomachanical properties provide a comparison to in vivo performance.¹⁰
- AMS and Bard pore characteristics shown in red, blue and green represent haphazard pore structures which may impact physiologic activity.

Solutions for Pelvic Floor Restoration

Coloplast offers treatment options for site-specific repair, anterior, posterior and vaginal vault prolapse.

Restorelle® Graft Options		Approach	Method	Fixation Devices
Restorelle Y 24 cm x 4 cm, 27 cm x 4 cm Restorelle Y Contour 24 cm x 3 cm 		Transabdominal	Laparotomy, laparoscopic or robotic	
Restorelle M, XL M = 15 cm x 10 cm, XL = 30 cm x 30 cm 		Transabdominal	Customization based on physician preference Laparotomy, laparoscopic or robotic	
Restorelle L 24 cm x 8 cm 		Transabdominal	Customization based on physician preference Laparotomy, laparoscopic or robotic	
DirectFix A 16 cm x 11 cm 	DirectFix P 14 cm x 15 cm 	Transvaginal	Single incision repair	Digitex® Suture Delivery System, Stat Tack™, or AbsorbaTack™

Fixation Technologies

Novel fixation solutions available for efficient placement and surgical procedural preferences



Digitex® Suture Delivery System

Restorelle® Smartmesh®

The advantages are clear.

Designed specifically for women and their tissue healing requirements

Restores patient anatomy and renews quality of life for optimal outcomes with less implantable material

Ultra-lightweight at 19g/m²

Patented, physiologically compatible polypropylene design is the lightest weight mesh available in Female Pelvic Health

Significant strength

71% more mature type 1 collagen ingrowth leading to increased implant strength at 90 days vs. a heavier mesh

Engineered to deliver better outcomes

Smartmesh technology – backed by scientific and clinical data – encourages tissue healing properties and collagen ingrowth resulting in less fibrosis and foreign body reactions

Tailored isotropic uni-directional bias

Maintains structural integrity from the sacrum to the vagina

Ease of surgical handling and orientation

Low mesh memory enables optimal intraoperative handling. Hydrophilic properties allow mesh to drape and contour easily to vaginal structures

Proprietary warp knit construction

The mesh does not fray when cut and trimmed

A full array of product solutions

Customization for varied patient anatomy and surgical procedural approaches. Addresses all classes of defects and provides strong apical support. Coloplast is the only company offering the same mesh technology for both transvaginal and transabdominal repair

References

¹Salamon et al. (2011). Prospective cohort study of robotic sacrocolpopexy using lightweight polypropylene Y-mesh. Presented at the 40th Global Congress of Minimally Invasive Gynecology (AAGL), Hollywood, FL.

²Data on file.

³Hawthorn R. et al. (2007). Use of ultra lightweight mesh in vaginal vault repair to minimise complications: A two centre observational study. The British International Congress of Obstetrics & Gynaecology.

⁴Alinsod R. (2008). Long term outcomes of vaginal pelvic floor repair using an ultra lightweight mesh. Presented at the 37th Global Congress of Minimally Invasive Gynecology (AAGL), Las Vegas, NV.

⁵North, C.E. et al. (2005). A preliminary study to compare the vaginal palpability of two different mesh materials used for laparoscopic sacrocolpopexy. International Urogynecology Journal.

⁶North C.E. et al. (2007). The anatomical and functional outcome of laparoscopic sacrocolpopexy using an ultra lightweight polypropylene mesh. International Urogynecology Journal, 18 (Suppl 1):S107-S244.

⁷Lewis et al. (2011). Bowel function after robotic sacrocolpopexy. Presented at the 40th Global Congress of Minimally Invasive Gynecology (AAGL), Hollywood, FL.

⁸Restorelle is covered by US patents* owned exclusively by Coloplast. *U.S. Pat. Nos. 7,594,921; 8,100,924; 8,157,821; and 8,157,822.

⁹Greca F.H. et al. (2007). The influence of porosity on the integration histology of two polypropylene meshes for the treatment of abdominal wall defects in dogs. Hernia, (12), 45-49.

¹⁰Deeken et al. (2011). Physicomechanical Evaluation of Polypropylene, Polyester, and Polytetrafluoroethylene Meshes for Inguinal Hernia Repair. J Am Coll Surg 2011;212:68-79.

¹¹Marois Y, et al (2000). Biostability, inflammatory response, and healing characteristics of fluoropolyester-knit mesh in the repair of experimental abdominal hernias. Artif Organs 24:533-543.

¹²Pourdeyhimi. (1989). Porosity of surgical mesh fabrics: New technology. J. Biomed. Mater. Res.: Applied Biomaterials. Vol. 23, No. A1. 145-152.

¹³Values obtained using Olympus Digital Scope with a polarizer lens.

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

Description	Order Number
Restorelle M 15x10cm	501320
Restorelle XL 30x30cm	501330
Restorelle L Rect 24x8cm	501440
Restorelle Y Shaped 24x4cm	501420
Restorelle Y Shaped 27x4cm	501430
Restorelle Y Contour 24x3cm	501520
Restorelle Direct Fix Anterior	501450
Restorelle Direct Fix Posterior	501460

Fixation Options	
Digitex Fixation Device- 4 per box	52025
Digitex Fixation Cartridge: 0-0, PP with needle, 12 per box	52026
Digitex Fixation Cartridge: 2-0, PP with needle, 12 per box	52027
Digitex Fixation Cartridge: 0-0, 12 per box NEEDLELESS	52028
Digitex Fixation Cartridge: 2-0, 12 per box NEEDLELESS	52029
Digitex Fixation Cartridge: 0-0 Absorbable PDO with Needle, 12 per box	520300
Digitex Fixation Cartridge: 2-0 Absorbable PDO with Needle, 12 per box	520310
Digitex Fixation Cartridge: 0-0 Absorbable PGA with Needle, 12 per box	520320
Digitex Fixation Cartridge: 2-0 Absorbable PGA with Needle, 12 per box	520330
Stat Tack, 1 per box	501260
AbsorbaTack, 1 per box	501270

Coloplast Payment Policy

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

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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.

Coloplast – Your partner in Female Pelvic Health

Coloplast is a Danish company, globally represented in 33 countries, with a 50-year legacy of listening and responding to the needs of our customers. We develop, manufacture and market medical devices and services in ostomy care, wound care, surgical urology and continence care, striving to improve the quality of life for people with intimate healthcare needs. With a continuously evolving portfolio of female pelvic health products, Coloplast is working to provide solutions that help improve quality of life for women globally.