

Repliform[®]

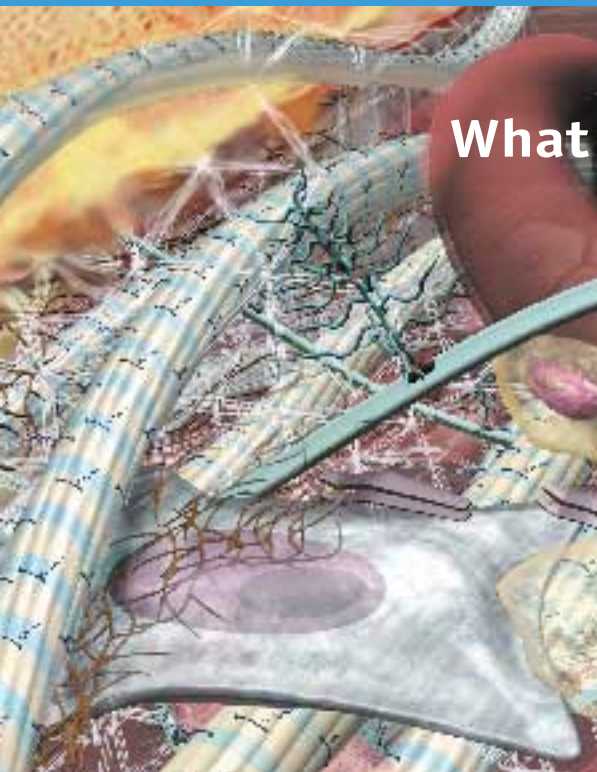
Tissue Regeneration Matrix

Boston
Scientific

**Guided Tissue
Regeneration**



REPLIFORM® Tissue Regeneration Matrix

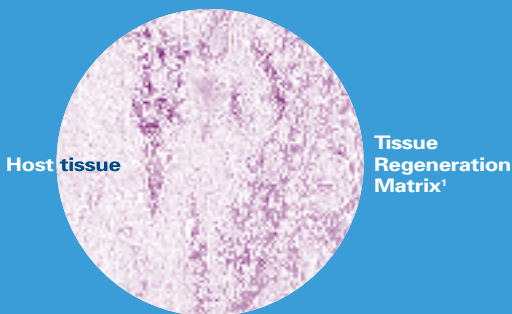


What if?

What if the body were able to regenerate soft tissue loss just as it continually replaces damaged or inadequate tissue? Rather than triggering a scarring response, the healing process would restore tissue to its original structural, functional and physiological condition. In a perfect world, the ideal state of healing would parallel intrinsic human tissue regeneration.

A biologic framework.

Repliform regenerative human tissue matrix supports the biologic framework for organizing the same tissue regeneration process that the body continually undergoes to repair damaged or inadequate tissue. Because the components remain in their natural biologically active state, Repliform matrix is immediately recognized as a human tissue, revascularizing, remodeling and transitioning into host tissue. The outcome is tissue that grows and ages normally. To date, this soft tissue regeneration matrix has been used successfully in more than 550,000 grafts and implants, from skin grafting to reconstructive surgical procedures, to challenging abdominal wall repair (AlloDerm®), to pelvic organ prolapse for pelvic floor reconstruction and sling procedures (Repliform matrix).



Histological studies indicate that over time, the Repliform matrix becomes indistinguishable from the surrounding host tissue.

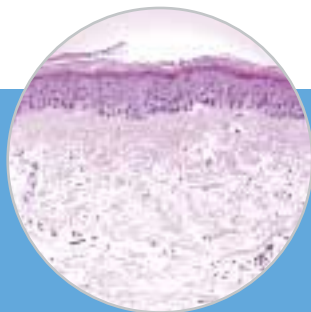
REPLIFORM® TISSUE REGENERATION MATRIX

More than 550,000 Implants

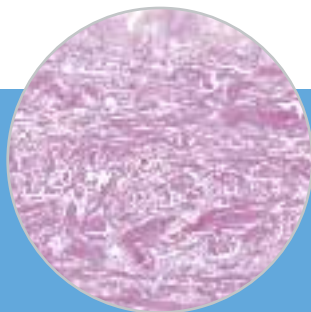


Proven safety, versatility and efficacy with more than 550,000 grafts and implants to date. First used as a dermal replacement for the treatment of severe burns in 1994, this soft tissue regeneration matrix exhibits remarkable versatility and has been used in a variety of soft tissue replacements. The fact remains that 25% of prolapse repairs recur within 5 years.² Traditional Kelly plication is a short-term compromise with contemporary thought being that suturing together poor tissue to poor tissue may not provide adequate long-term support.

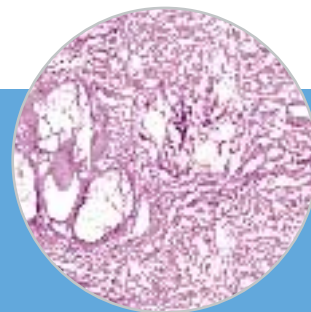
Prolapse repair augmented with the Repliform matrix may help to restore proper vaginal form and function without scarification while providing a healthy new fascia plane for added support. Repair natural vaginal form and function with Repliform matrix.



Normal human skin: A network of normally aligned and organized collagen and elastin, epidermis and skin cells.¹



Repliform tissue regeneration matrix: A complex, intact, acellular matrix with biologic proteins including networks of collagen and hyaluronan, elastin and proteoglycans.¹



Standard freeze-drying: Standard freeze-drying rapidly disrupts the matrix by creating ice crystals that propagate throughout the tissue, forcing the matrix apart and causing permanent damage. The resulting allograft is recognized as a foreign body. This can lead to inflammation and/or resorption and ultimate graft failure. By contrast, tissue regeneration matrix utilizes a patented amorphous freeze-drying process to maintain the intact matrix.¹

STRONG AND INTACT

As strong as synthetics³, yet far more pliable; proprietary process results in an intact matrix.

EXCELLENT HANDLING PROPERTIES

Retains tensile characteristics to ensure excellent handling for intraoperative manipulation, sizing, shaping and suturing; requires no change in procedures.

VERSATILE ACELLULAR MATRIX

Exhibits remarkable versatility to regenerate into many types of tissue ranging from gingiva to fascia; designed to restore structure, function and physiology (AlloDerm).

REDUCES THE RISK OF INFECTION AND REJECTION

Rapidly revascularizes and remodels into native tissue, minimizing the risk of infection and rejection; safe for use in compromised surgical sites.⁴

REDUCES COSTLY COMPLICATIONS

Demonstrated to have fewer complications than synthetics, including seroma, dehiscence, recurrence, infection and adhesion formation; may reduce length of stay and associated medical costs.⁵

SAFE

Screened according to the American Association of Tissue Banks guidelines to ensure clinical safety.

Let tissue regeneration begin. From the mobilization of stem cells to the ongoing regeneration of host tissue, the human body continually replaces damaged or inadequate tissue throughout life. Now, with Repliform matrix technology, it is possible for the body to regenerate soft tissue in the same extraordinary way. Through a carefully orchestrated process of removing cellular components from donated human tissue and freeze-drying to provide long-term, off-the-shelf storage, Repliform matrix becomes the soft tissue it replaces. That is the beauty of tissue regeneration with Repliform matrix.

ORDERING INFORMATION

Repliform® Tissue Regeneration Matrix		
Order Number	Description	Size (cm)
M0068202400	Tissue Regeneration Matrix	2 x 4
M0068202410	Tissue Regeneration Matrix	2 x 7
M0068202420	Tissue Regeneration Matrix	3 x 7
M0068202430	Tissue Regeneration Matrix	4 x 7
M0068202440	Tissue Regeneration Matrix	2 x 12
M0068202450	Tissue Regeneration Matrix	5 x 10
M0068202460	Tissue Regeneration Matrix	6 x 12
Packaged one (1) per box.		

¹ Data on file at LifeCell Corporation

² Shull, *American Journal of Obstetrics and Gynecology*, 166:1764-71.

³ Silverman, Holton, Sawan, Goldberg. *Hernia*, June 8, 2004. Volume 10.1007.1-13

⁴ Hirsch, *Repair of an Abdominal Wall Defect after a Salvage Laparotomy for Sepsis*. American College of Surgeons, February, 2004. Vol. 198. No. 2 Buinewicz, Rosen, *Acellular Cadaveric Dermis (AlloDerm): A New Alternative for Abdominal Hernia Repair*. Annals of Plastic Surgery. February, 2004. Vol. 52, No. 2

⁵ Buinewicz, Colony, Smith, *The Use of Human Acellular Tissue Matrix in Abdominal Wall Reconstruction*. A Clinical Monograph Series. LifeCell 2003. MLC 144-01. Rev. A.

Refer to package insert provided with the product for complete instructions for use including Indications for Use, Contraindications, Potential Complications, Warnings and Cautions.

Repliform matrix is exclusively distributed in the U.S. by Boston Scientific and is intended for use for the repair or replacement of damaged or inadequate integumental tissue.

Repliform matrix and AlloDerm are processed by LifeCell Corporation, an accredited member of the American Association of Tissue Banks. Donors are screened by medical records, social history and serological testing.

Repliform matrix complies with U.S. regulations in 21 CFR part 1270 and 1271 – Human Tissue Intended for Transplantation.

AlloDerm and Repliform are trademarks of LifeCell Corporation.

Results from case studies are not predictive of results in other cases. Results in other cases may vary.

**Boston
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Delivering what's next.™

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