

Better AWR outcomes. Reinforced by data.



GORE® BIO-A® Tissue Reinforcement — 3D bioabsorbable scaffold providing a proven solution for a wide range of high risk abdominal wall reconstruction cases



The 3D bioabsorbable tissue-building scaffold that avoids risk for mesh-related complications after the targeted absorption period of six to seven months

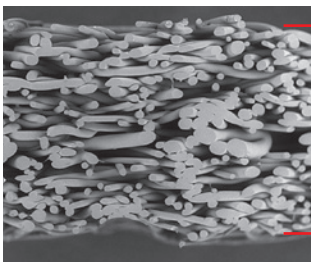
Disruptive technology:

- Unique 3D scaffold constructed of 67% PGA / 33% TMC
- Highly interconnected, optimal pore structure elicits tissue response
- Targeted bioabsorption period supports the critical healing process over six to seven months
- Material is consistently absorbed by hydrolysis

Answers concerns associated with longer-term resorbable and permanent mesh:

- Cells infiltrate and form vascularized soft tissue, with 1:1 tissue replacement and the formation of dense, organized collagen
- No permanent material left behind
- Leaves behind only a strong repair¹

Unique 3D structure with optimal pore size



Thickness of new tissue generated in the 3D web scaffold

3D web scaffold of GORE® BIO-A® Tissue Reinforcement (SEM 50x).

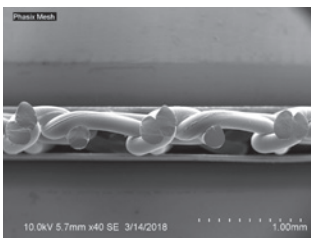
Clinical challenge – complex patients...complex repairs



High-risk parastomal repair with isolation of stoma. Photo courtesy of M.A. García-Ureña, MD.



Midline ventral hernia repair. Photo courtesy Dr. Marco Harmaty, The Mount Sinai Hospital, NY.



2D BARD® DAVOL PHASIX Monofilament knit mesh (SEM 50x).

10
YEARS
positive
clinical results

Complex and high-risk repairs
Ventral hernia
Hiatal hernia

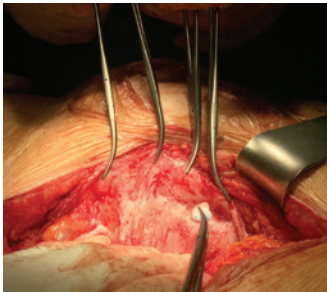
- MORE than 150 publications
- LOW recurrence rates in hiatal hernias
- LOW recurrence rates in complex ventral hernias
- OVER 1700 patients in the clinical literature
- NO risk for long-term mesh-related complications
- Demonstrated economic value



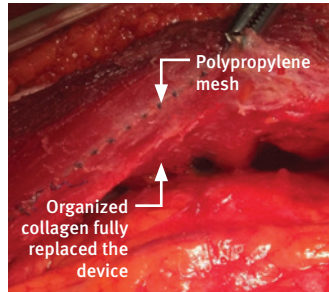
GORE® BIO-A® Web Technology – Over 20 years of demonstrated clinical and financial value

Long-term outcomes

- GORE® BIO-A® Tissue Reinforcement 18 months after incisional hernia repair of a bilateral TAR*
- Bottom arrow shows robust layer of organized collagen that fully replaced the GORE® BIO-A® Tissue Reinforcement mesh over the peritoneum
- No risk of long-term complications from GORE® BIO-A® Tissue Reinforcement after six to seven months

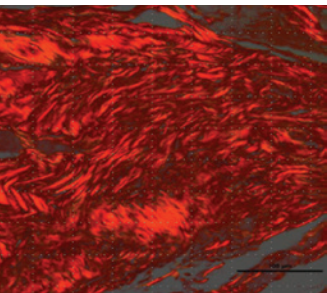


Robust layer of organized collagen formed and fully replaced the device; no permanent material left in the body.
Photo courtesy of M.A. García-Ureña, MD.

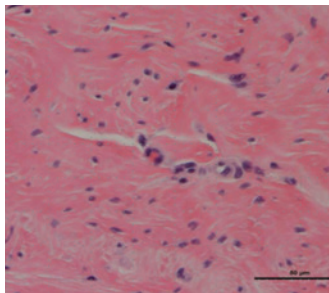


18 month view, post hernia repair. Robust layer of organized collagen fully replaced the device.
Photo courtesy of M.A. García-Ureña, MD.

Clinical observation after 18 months



The collagen type I is birefringent orange-red, highly oriented and densely packed with thick collagen fibers. Picrosirius red stain and polarized light microscopy.
Photo courtesy of M.A. García-Ureña, MD.



Mature densely packed vascularized collagen HE Stain.
Photo courtesy of M.A. García-Ureña, MD.

The surgeon perspective

Garth R. Jacobsen, MD, director of hernia surgery and associate professor of surgery at the University of California in San Diego, California, presented his experience with GORE® BIO-A® Tissue Reinforcement in 140 patients between 2009 and 2016 (G. R. Jacobsen, MD, unpublished data, February 2017).

- Patients had an average age of 56 years, a mean BMI of 29 kg/m², and a mean defect size of 109 cm²
- Two-thirds of patients had CDC Class I wounds

“The [GORE® BIO-A® Tissue Reinforcement] will perform at least as well, if not better, than a biologic when used appropriately, and has the absolute benefit of a significantly reduced cost profile. The ease of use is an added advantage to the surgeon.”

— Garth Jacobsen, MD, FACS

At a mean follow-up of 908 days following placement of GORE® BIO-A® Tissue Reinforcement, **only eight patients (6%) experienced a recurrence, which appears to be unassociated with wound class, anterior or posterior approach, or underlay vs onlay placement.**

Currently, Dr. Jacobsen uses GORE® BIO-A® Tissue Reinforcement in clean wounds, high risk, and complex repairs. Data from this single center retrospective review is currently being submitted for publication.²



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* Transversus abdominis muscle release (TAR)

1. Pascual G, Sotomayor S, Rodríguez M, Pérez-Köhler B, Bellón JM. Repair of abdominal wall defects with biodegradable laminar prostheses: polymeric or biological? *PLoS One* 2012;7(12):e52628.
2. Allison ND, Bruce J-M, Cobb WS, et al; W. L. Gore & Associates, Inc. Optimizing outcomes for complex hernia repair and bariatric procedures: Medical Mastery Course Series in Advanced Surgical Techniques. [Special Report]. *General Surgery News* 2017;1-8. SR165. AW0376-EN1

Refer to *Instructions for Use* for a complete description of all warnings, precautions, and contraindications. ^{Rx only}

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