

# 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**

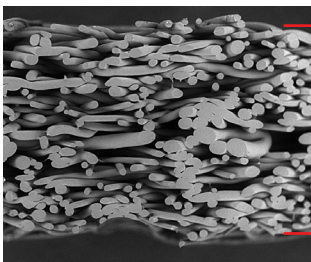
### Disruptive technology:

- 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:

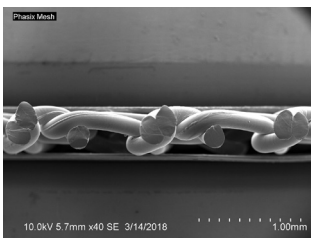
- Cells infiltrate and form vascularized soft tissue, with 1:1 tissue replacement and the formation of dense, organized collagen
- No permanent material left behind
- Leaves behind only a strong repair<sup>1</sup>

### 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).



2D BARD® DAVOL PHASIX Monofilament knit mesh (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.

**10**  
YEARS  
positive  
clinical results

Complex and high risk repairs

Ventral hernia  
Hiatal hernia

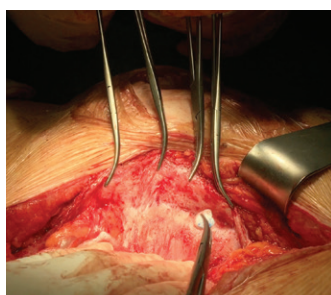
- MORE than 150 publications
- LOW recurrence rates in hiatal hernias
- LOW recurrence rates in complex ventral hernias
- OVER 1700 patients in the clinical literature
- NO risk for long-term mesh-related complications
- Demonstrated economic value



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

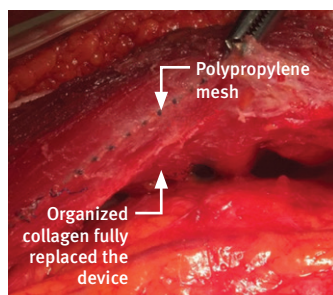
## Outcomes post implantation

- 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.

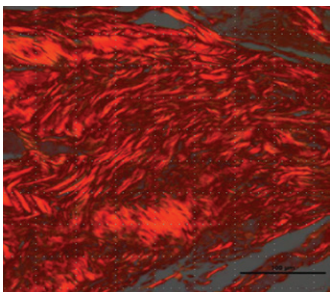
Photo courtesy of M.A. García-Ureña, MD.



18 month view, post hernia repair. Robust layer of organized collagen fully replaced the device.

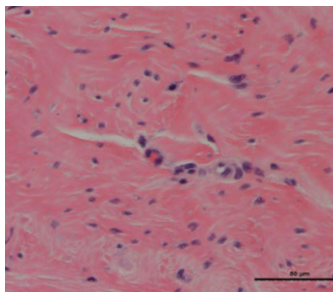
Photo courtesy of M.A. García-Ureña, MD.

## 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.

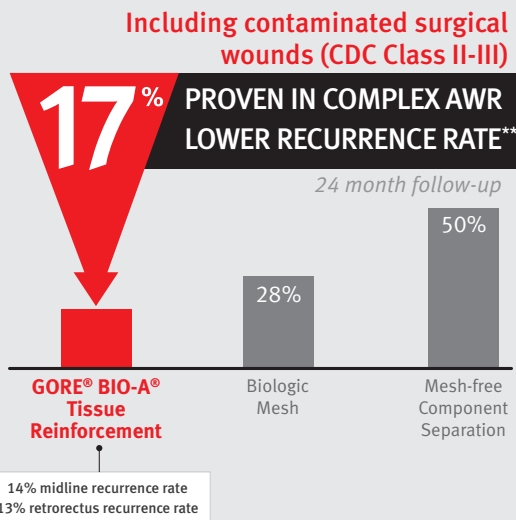
Photo courtesy of M.A. García-Ureña, MD.



Mature densely packed vascularized collagen HE Stain.

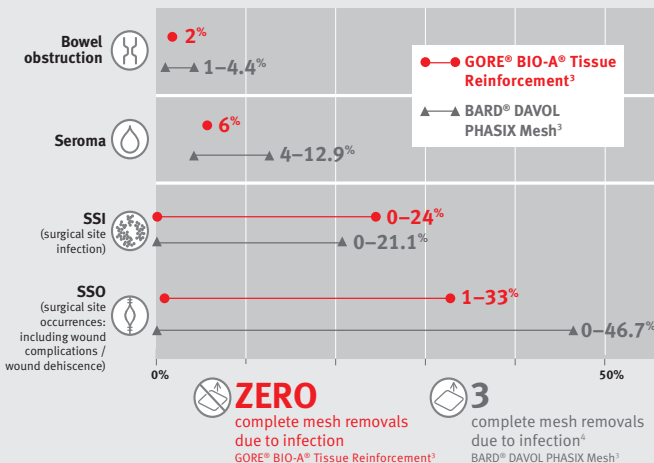
Photo courtesy of M.A. García-Ureña, MD.

## Prospective, multicenter clinical study results<sup>2</sup>



GORE® BIO-A® Tissue Reinforcement offers proven low complication rates in high risk AWR patients<sup>3</sup> vs. BARD® DAVOL PHASIX Mesh.

## Proven LOW complication rates



\* Transversus abdominis muscle release (TAR)

\*\* Refer to the COBRA Study Results at <https://www.goremedical.com/sites/g/files/ypypipe801/files/resources/assets/2018-06/RP1708.pdf>

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. Rosen M, Bauer JJ, Harmaty M, et al. Multicenter, prospective, longitudinal study of the recurrence, surgical site infection, and quality of life after contaminated ventral hernia repair using biosynthetic absorbable mesh: the COBRA Study. *Annals of Surgery* 2017;265(1):205-211.
3. Literature search and summary. (data on file 2018; W. L. Gore & Associates, Inc.; Flagstaff, AZ.)
4. LaPere DB, Lundgren MP, Rosato EL, et al. Single institution Phasix mesh outcomes in a population of primarily complicated/recurrent hernias. Presented at the 11th Annual Academic Surgical Congress; February 2-4, 2016; Jacksonville, FL. Abstract 69.16.



**W. L. Gore & Associates, Inc.**  
Flagstaff, AZ 86004

+65.67332882 (Asia Pacific)  
00800.6334.4673 (Europe)  
928.779.2771 (United States)  
800.437.8181 (United States)

[goremedical.com](http://goremedical.com)

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