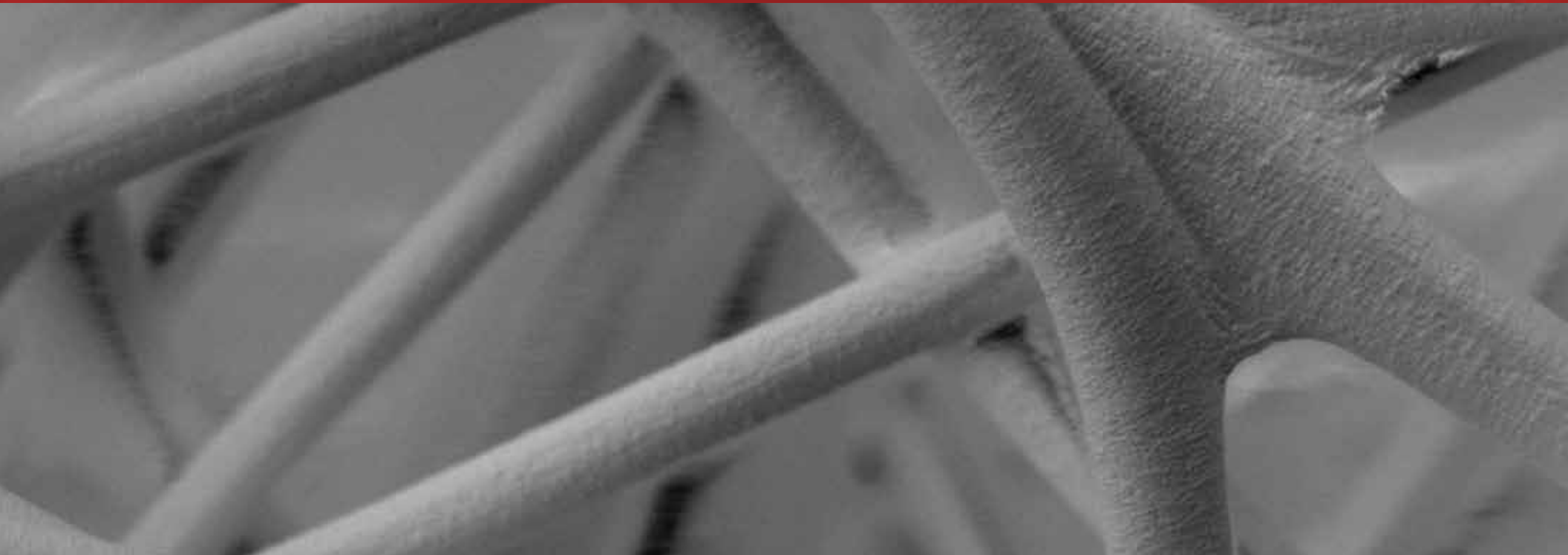


GORE® BIO-A® Tissue Reinforcement



PERFORMANCE through innovation



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CLINICAL NEED

Additional support for tissue without increased risks associated with permanent materials^{1, 2}

What are the risks?

- Erosion
- Infection
- Seroma
- Wound dehiscence
- Enterocutaneous fistulae

¹ Davis SS Jr. Current controversies in paraesophageal hernia repair. *Surgical Clinics of North America* 2008;88(5):959-978.

² Bruening K, Butler CE, Ferzoco S, *et al*; The Ventral Hernia Working Group. Incisional ventral hernias: review of the literature and recommendations regarding the grading and technique of repair. *Surgery* 2010;148(3):544-558.



Managing Risk of Complications in Complex Cases

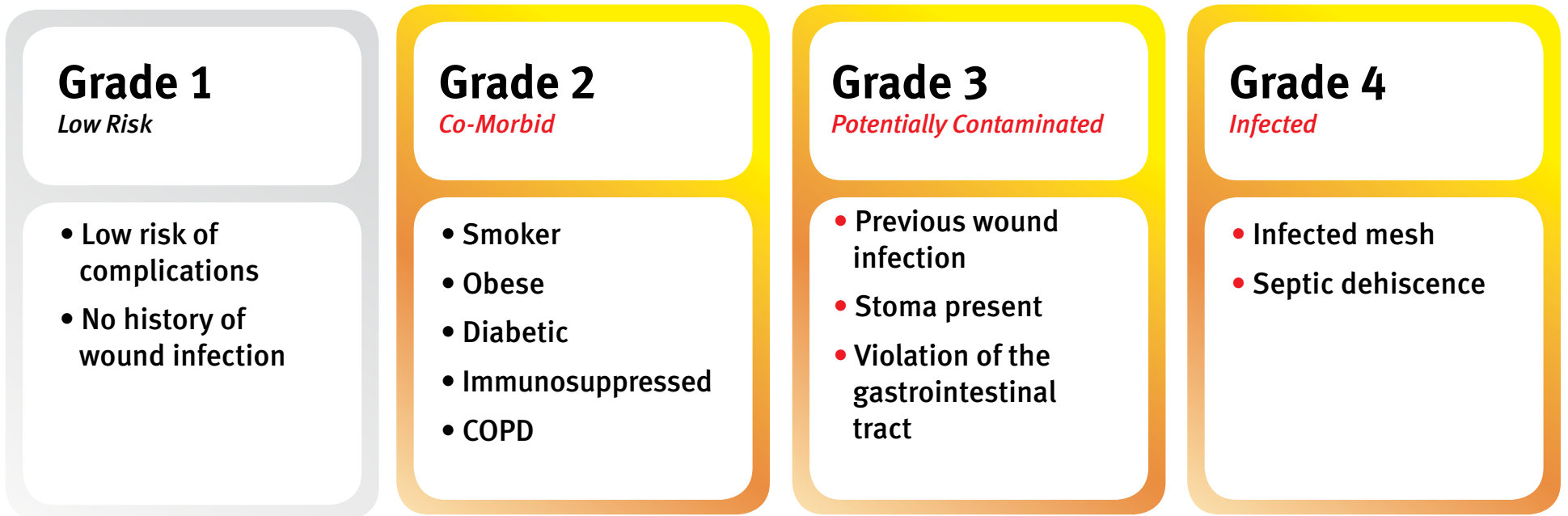


Fig 1. Hernia grading system: assessment of risk for surgical site occurrences. Wound infection defined as being contained within the skin or subcutaneous tissue (superficial), or involving the muscle and/or fascia (deep).³

³ Breuing K, Butler CE, Ferzoco S, *et al*; The Ventral Hernia Working Group. Incisional ventral hernias: review of the literature and recommendations regarding the grading and technique of repair. *Surgery* 2010;148(3):544-558.

SOLUTION

Reinforcement material that functions as a scaffold for patient's own cells to create tissue and replace material over time, leaving no permanent mesh behind.

Two options:

Harvest human or animal tissue and remove cells to leave scaffold behind

- Biologics

NEW ALTERNATIVE: Create synthetic tissue scaffold

- Bioabsorbable web

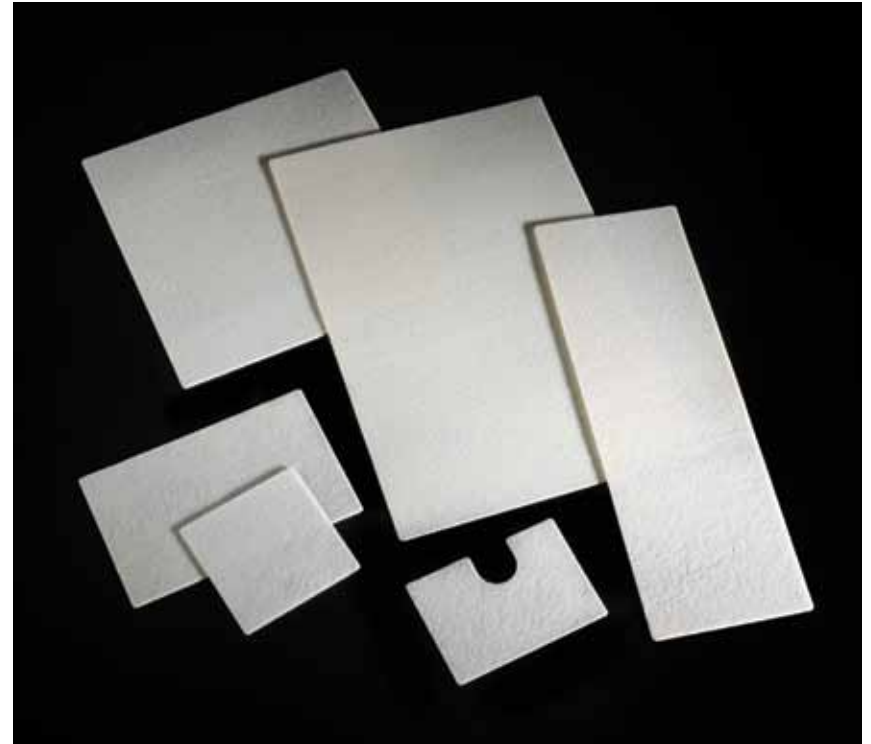


NEW CHOICE FOR COMPLEX SOFT TISSUE REINFORCEMENT

Gore® BIO-A® Tissue Reinforcement

Bioabsorbable synthetic 3D matrix designed to facilitate tissue generation and healing.

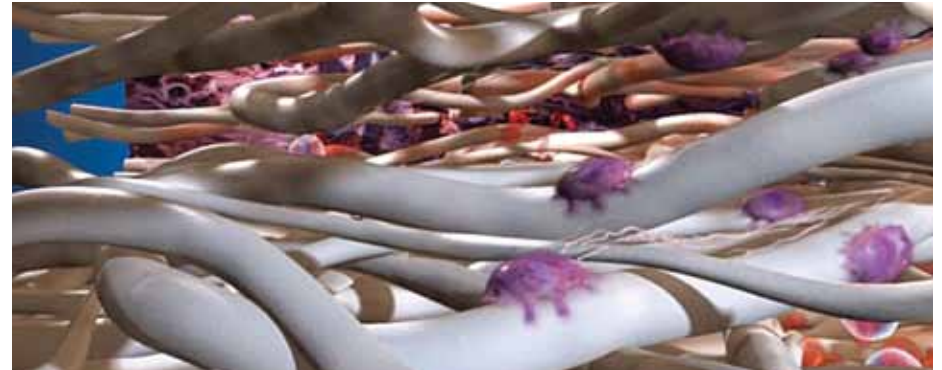
- 100% synthetic, bioabsorbable tissue scaffold
- Rapid cell population and vascularization
- Versatile for numerous applications
- Offers performance and value



GORE® BIO-A® Web Technology: How It Works



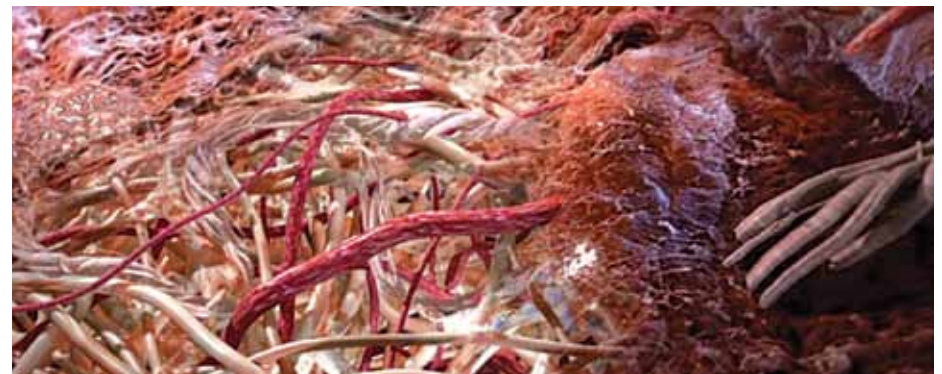
Upon implantation, blood wicks into the web and proteins adsorb to the material surface as an acute inflammatory reaction begins.



Nearby fibroblasts start proliferating and migrate into the web. As fibroblasts infiltrate the 3D scaffold, the first strands of collagen are deposited. Soon, capillaries bud and granulation tissue begins to form.



Numerous blood vessels form, bringing nutrients to the developing tissue. As the numbers of fibroblasts increase, the area fills with collagen. Macrophages surround the fibers which continue to absorb primarily through hydrolysis.



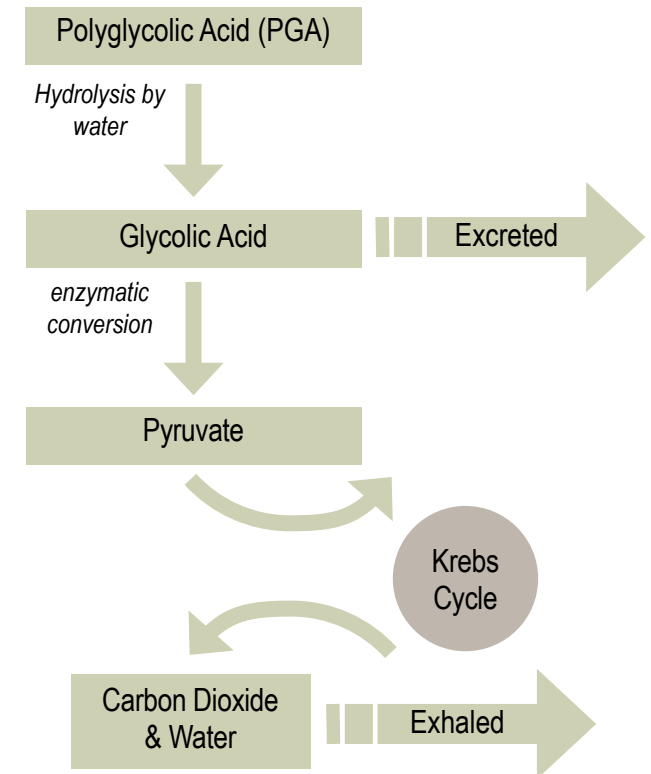
The new extracellular matrix matures with dense collagen fibers filling the tissue scaffold. Over a period of approximately six months, the GORE® BIO-A® Tissue Reinforcement absorbs naturally into the body and is successfully replaced with the patient's own vascularized soft tissue.



BIOABSORBABLE CHEMISTRY

GORE® BIO-A® Tissue Reinforcement = PGA:TMC copolymers

- ▶ Manufactured polymers, not tissue derived
- ▶ Designed to break down primarily by hydrolysis
 - Over a specific time frame
 - Into specific degradation components which can be cleared by the body
- ▶ Designed to be user-friendly
 - Long shelf life
 - Minimal item to item variability
 - No special storage or preparation required
 - No reliance on tissue supply or tissue bank processing

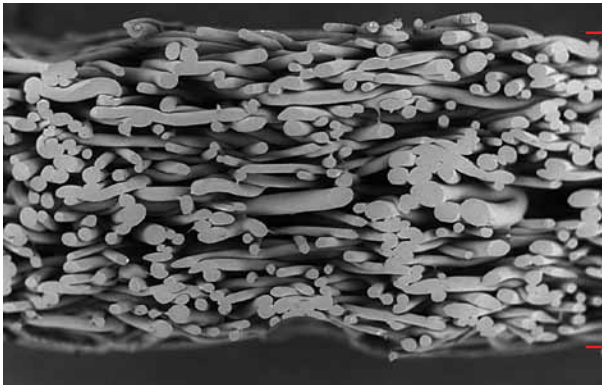


3D TISSUE SCAFFOLD – MATERIAL STRUCTURE

Need: Robust tissue layer

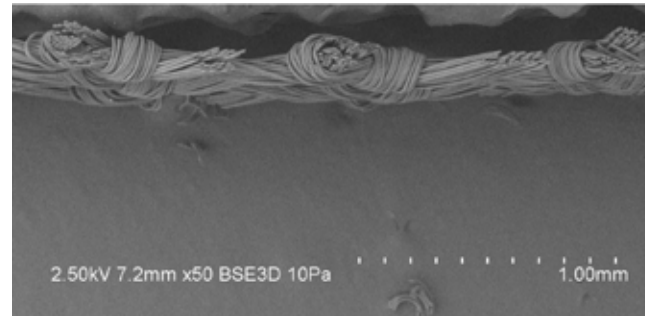
Solution: 3 Dimensional web

Mag 50x



GORE® BIO-A® Tissue Reinforcement

Thickness of
new tissue
generated



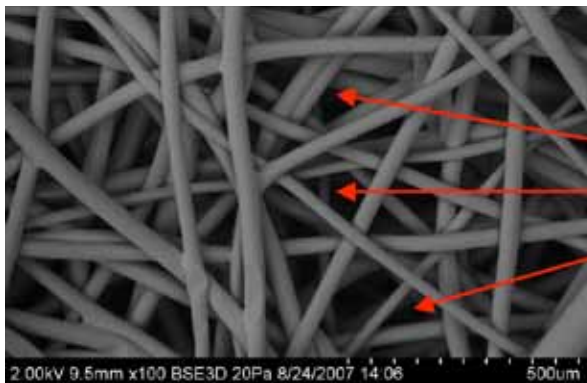
2D Bioabsorbable Knitted Mesh

Mag 50x

Need: Rapid cell migration and vascularization

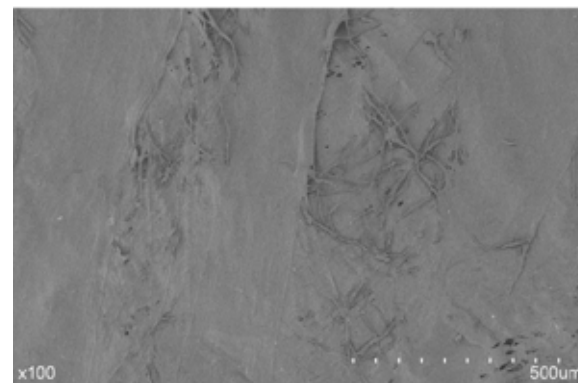
Solution: Large & interconnected pores

Mag 100x



GORE® BIO-A® Tissue Reinforcement

Open
Pores



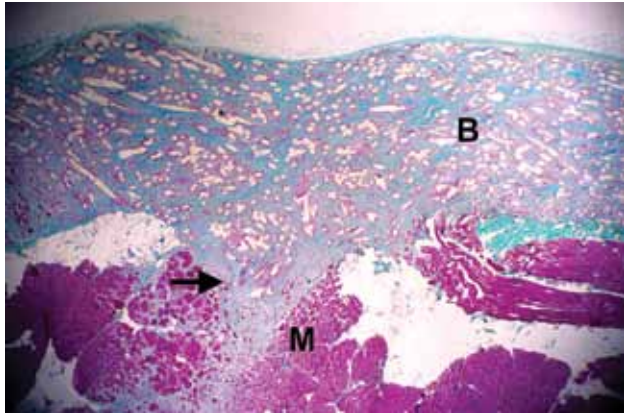
Biologic: Small Intestinal Submucosa

Mag 100x



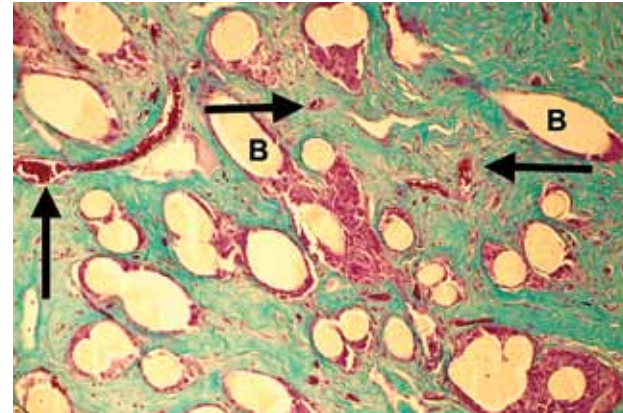
TISSUE SCAFFOLD – COLLAGEN DEPOSITION

Tissue Replaces Matrix of GORE® BIO-A® Tissue Reinforcement



GORE® BIO-A® Tissue Reinforcement web (B) over the incision (arrow). Tissue incorporates the muscle (M), fills the incision with collagen and seals the wound.

2.5x Trichrome, Rabbit Linea Alba 30 day



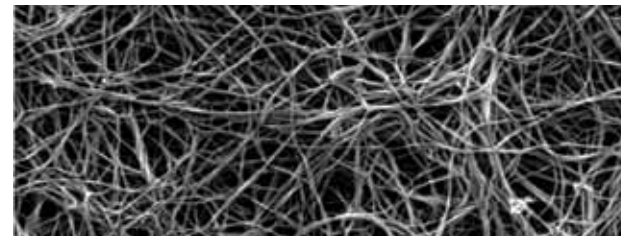
GORE® BIO-A® Tissue Reinforcement web fibers (B) are incorporated with collagen (blue-green). Numerous blood vessels (arrows) are scattered throughout.

25x Trichrome, Rabbit Linea Alba 30 day

Bioabsorbable Web Structure Similar to a Collagen Fiber Network



GORE® BIO-A® Tissue Reinforcement

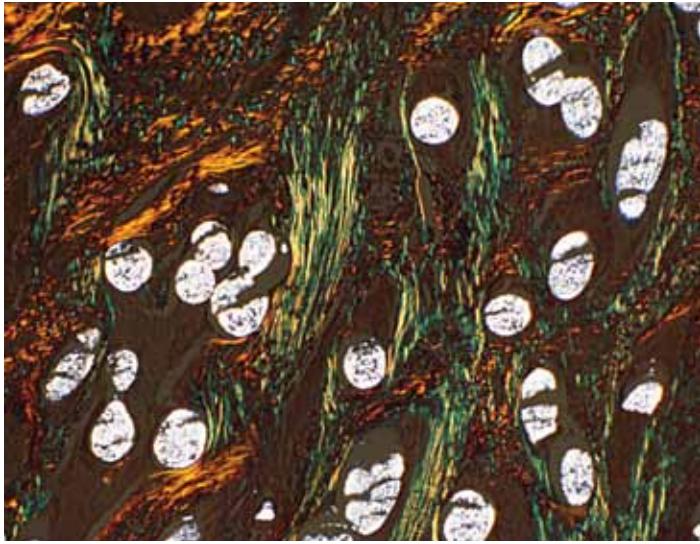


Collagen Gel⁴

⁴ Photo courtesy of Biophysical Society and Christopher B. Raub, Vinod Suresh, Tatiana Krasieva, Julia Lyubovitsky, Justin D. Mihn, Andrew J. Putnam, Bruce J. Tromberg, and Steven C. George – University of California Irvine

TISSUE SCAFFOLD – TYPE OF COLLAGEN

1 month - Rabbit

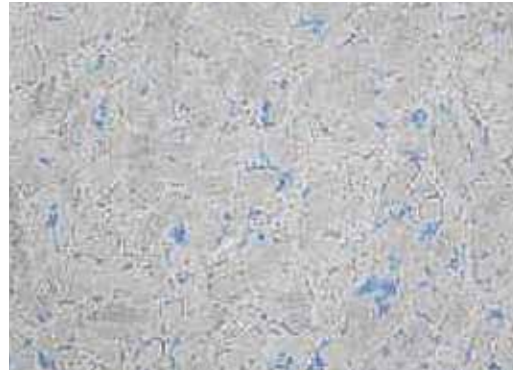


GORE® BIO-A® Tissue Reinforcement web is filled with type III collagen (yellow-green) and type I collagen (orange). Fibers are refractile (white).
PicroSirius Red with Polarized Light 25x

3 months - Human⁵



Collagen type I (brown)



Collagen type III (brown)

Collagen: type I > type III
Immunohistochemistry 10x

13 months - Human⁵



Collagen type I (brown)



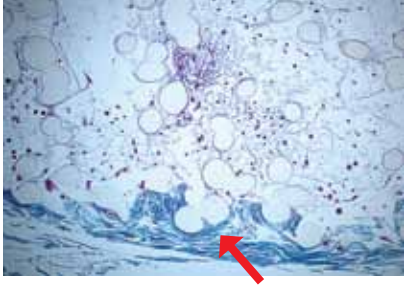
Collagen type III (brown)

Dominance of type I collagen
Immunohistochemistry 10x

Normal Wound Healing

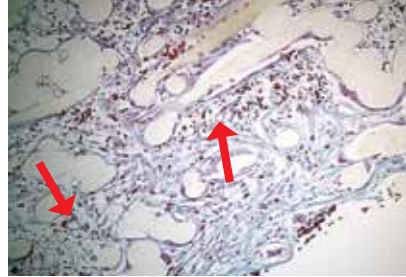
⁵GORE® BIO-A® Hernia Plug

TISSUE SCAFFOLD - RAPID CELL POPULATION AND VASCULARIZATION⁶



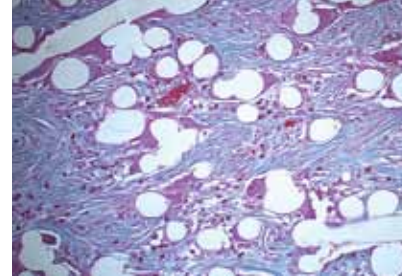
3 Days:

As early as three days, the material is firmly embedded into native tissue (arrow). Cellular infiltration is present with lymphocytes, macrophages and erythrocytes.



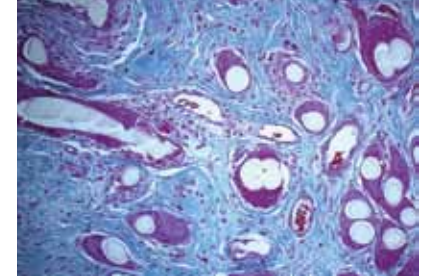
7 Days:

As wound healing progresses, strands of collagen and capillary proliferation (arrows) are evident.



14 Days:

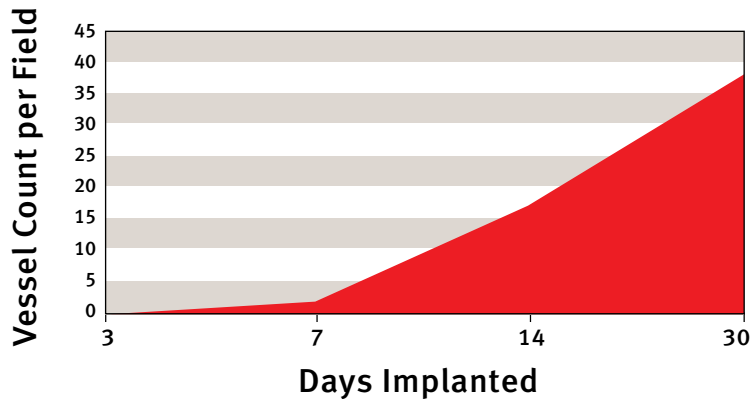
Dense fibrocollagenous tissue forms an early cellular scaffold as the material starts to absorb. Blood vessels are present between the material fibers.



30 Days:

Native tissue is seamlessly incorporated within the GORE[®] BIO-A[®] Material.

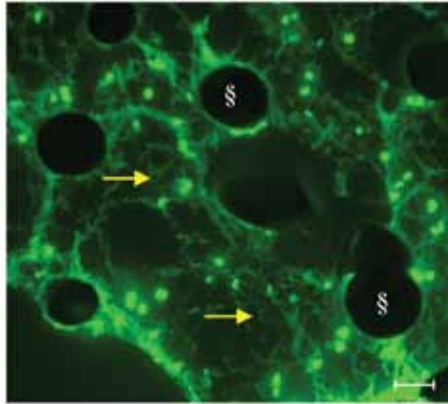
Vessels in Device



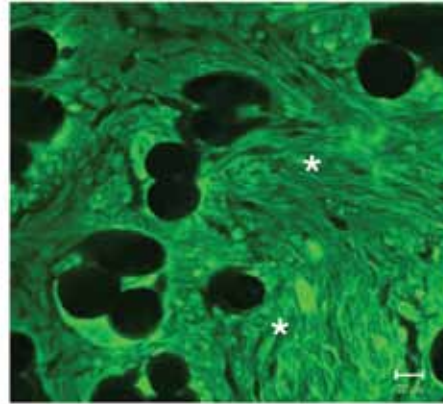
⁶Milligan's Trichrome 20x. Histology of abdominal wall explant in rabbit. Data on file.

GORE® BIO-A® Tissue Reinforcement: GENERATE QUALITY TISSUE FAST

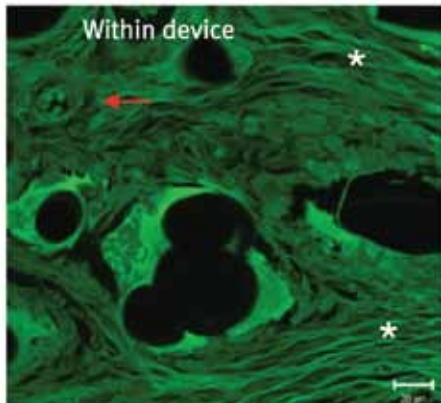
Collagen Deposition†



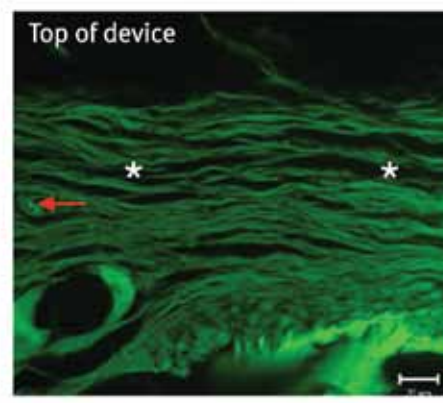
3 days: **Fibrin strands** (arrows) between material fibers (S)



14 days: Early extracellular matrix with **collagen** (*)

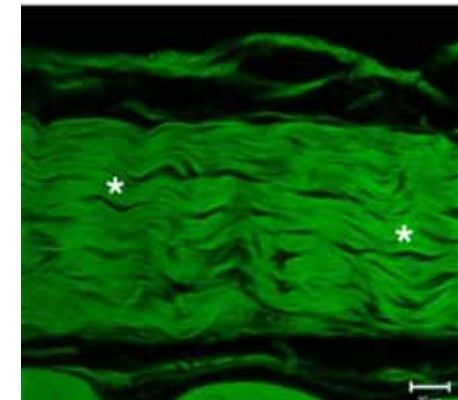


30 days: **Collagen strands organized, blood vessels present** (arrows)



GORE® BIO-A® Tissue Reinforcement

Quantity & Quality
mimics native tissue

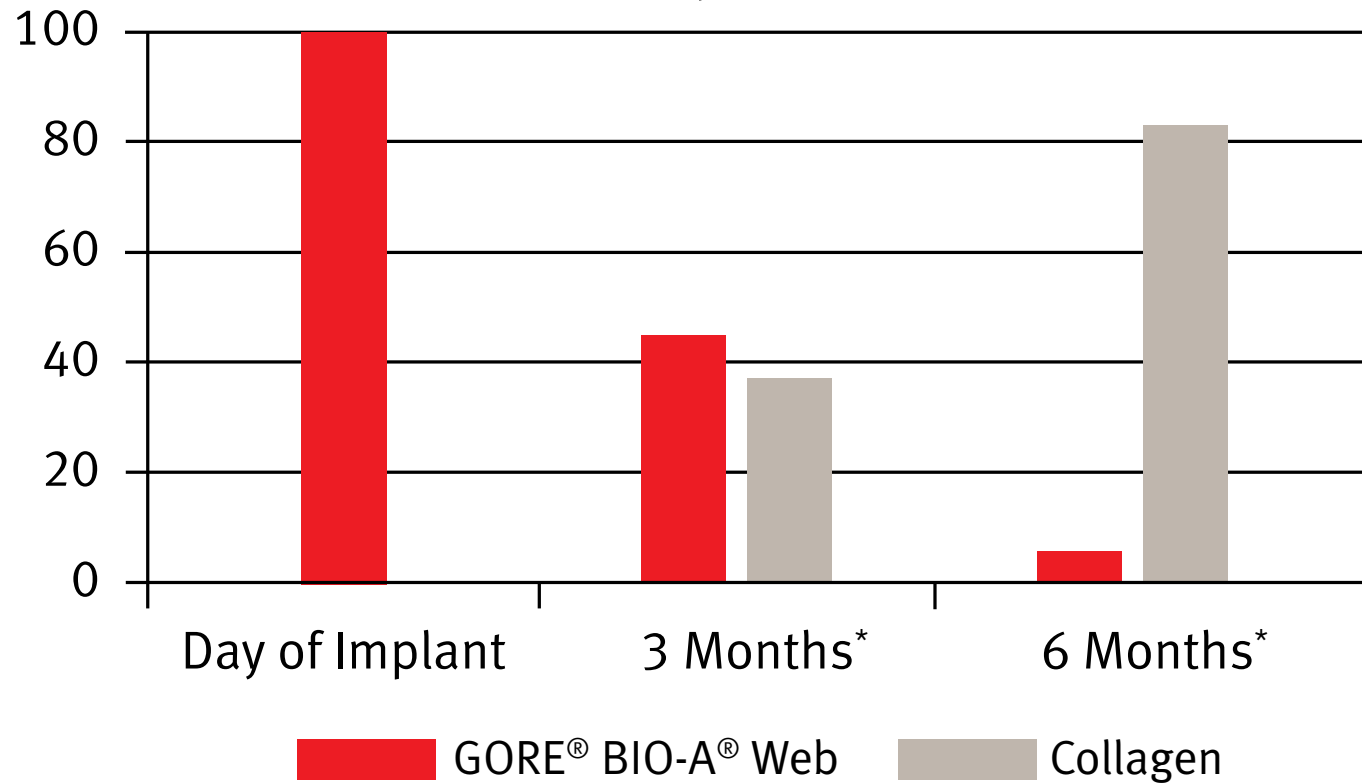


Adjacent **native** rabbit abdominal fascia
Organized collagen strands (*)

† GORE® BIO-A® Tissue Reinforcement; Rabbit abdominal wall implant. Data on file.

TISSUE FILLS THE SCAFFOLD

Volume of Material = Volume of Tissue: 1:1 Replacement⁷



*Cells & Blood Vessels Make Up Remaining Volume

Calculated by Histological Image Analysis

⁷Morales-Conde S, Flores M, Fernández V, Morales-Méndez S. Bioabsorbable vs polypropylene plug for the “Mesh and Plug” inguinal hernia repair. Poster presented at the 9th Annual Meeting of the American Hernia Society; February 9-12, 2005; San Diego, CA.



GORE® BIO-A® Tissue Reinforcement

Indicated for: Use in reinforcement of soft tissue

- Hernia repair (non-load bearing applications)
- Muscle flap reinforcement
- Suture line reinforcement
- General tissue reconstructions

Contraindicated for:

- Reconstruction of cardiovascular defects



VERSATILE FOR NUMEROUS APPLICATIONS

- Hiatal Hernia / Paraesophageal Hernia
- Component Separation
- Ostomies
- TRAM Flap
- Abdominoperineal Resection

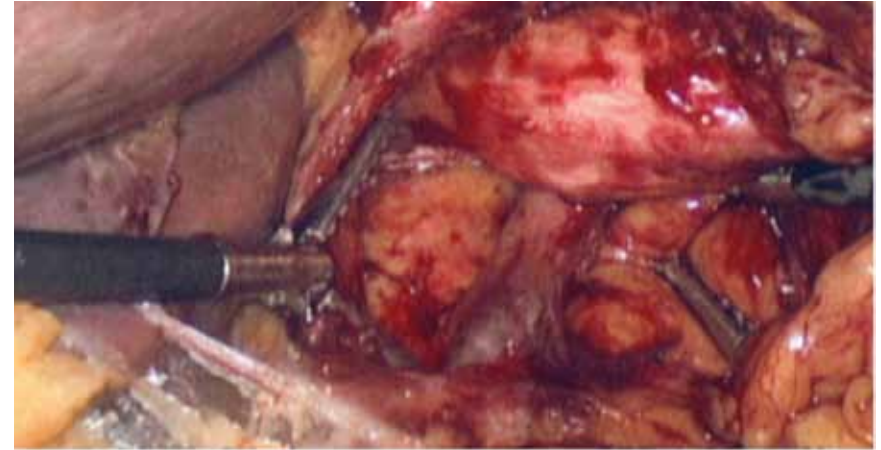


HIATAL HERNIA / PARAESOPHAGEAL HERNIA

Clinical Need: Recurrence of primary repair of hiatal/paraesophageal hernias is 12 - 42%.^{8,9,10}

Solution: Reinforcement with biologic materials shown to reduce recurrence rate at short term follow up compared to primary repair.

Following primary closure of crura, GORE® BIO-A® Tissue Reinforcement placed prior to Nissen Fundoplication.



Visualization of hiatal defect



Reinforcement of crural closure

⁸ Horgan S, Eubanks TR, Jacobsen G, *et al.* Repair of paraesophageal hernias. *Am J Surg.* 1999;177:354-358.

⁹ Hashemi M, Peters JH, DeMeester TR, *et al.* Laparoscopic repair of large type III hiatal hernia: objective follow-up reveals high recurrence rate. *J Am Coll Surg.* 2000;190:554-561.

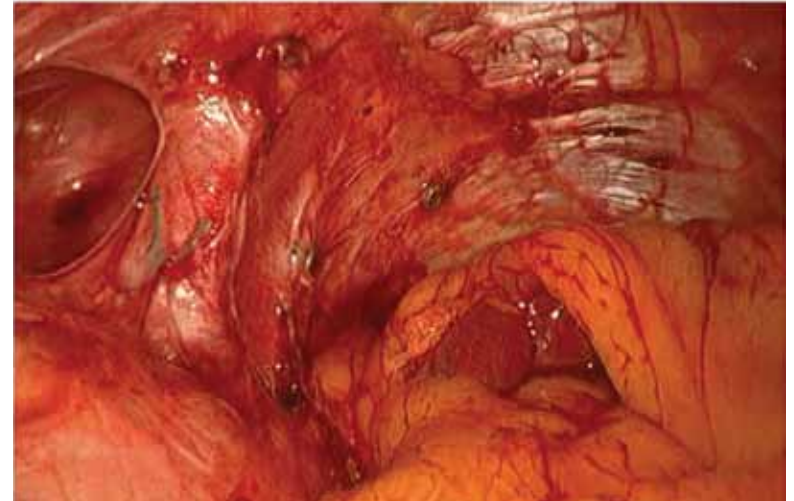
¹⁰ Mattar SG, Bowers SP, Galloway KD, *et al.* Long-term outcome of laparoscopic repair of paraesophageal hernia. *Surg Endosc.* 2002;16:745-749.



GUIDED TISSUE GENERATION IN HIATAL HERNIA REPAIR With GORE® BIO-A® Tissue Reinforcement

8 Month Post-Op View

GORE® BIO-A® Tissue Reinforcement used for posterior suture-line reinforcement of crural closure. Surgical tacks were used as fixation of the product.* Patient subsequently developed an unrelated anterior hernia. Anterior hernia was later repaired and reinforced with GORE® BIO-A® Tissue Reinforcement.



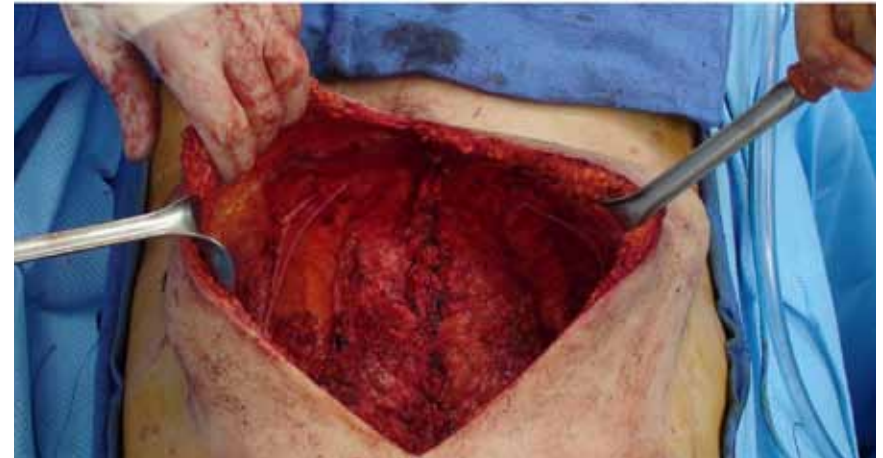
*Choice of fixation is surgeon preference. The method of fixation is not promoted by Gore. When fixing any product to the hiatus, care should be given not to damage nearby thoracic structures.



VENTRAL HERNIA – COMPONENT SEPARATION AND REINFORCEMENT OF MIDLINE CLOSURE

Clinical Need: Additional support for suture line closure during complex ventral hernia without increased risks associated with permanent materials.

Solution: Reinforcement of suture line with bioabsorbable synthetic matrix designed to facilitate tissue generation and healing.



Primary midline fascial closure following component separation technique



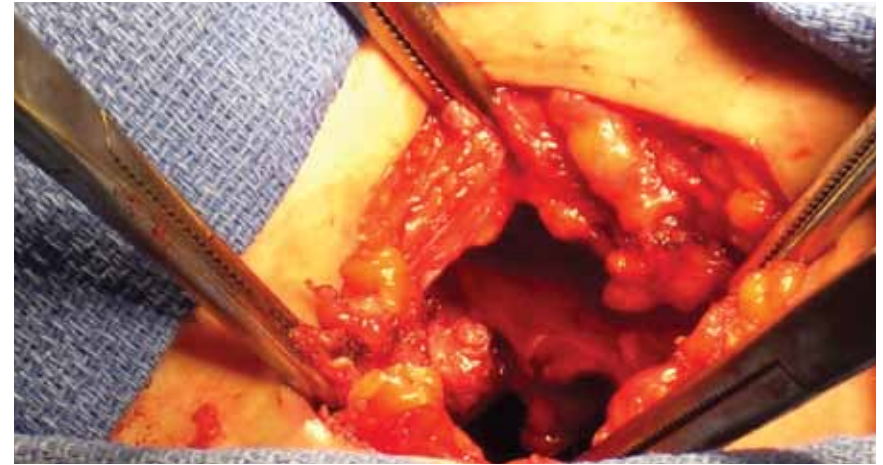
Placement of GORE® BIO-A® Tissue Reinforcement for suture line reinforcement



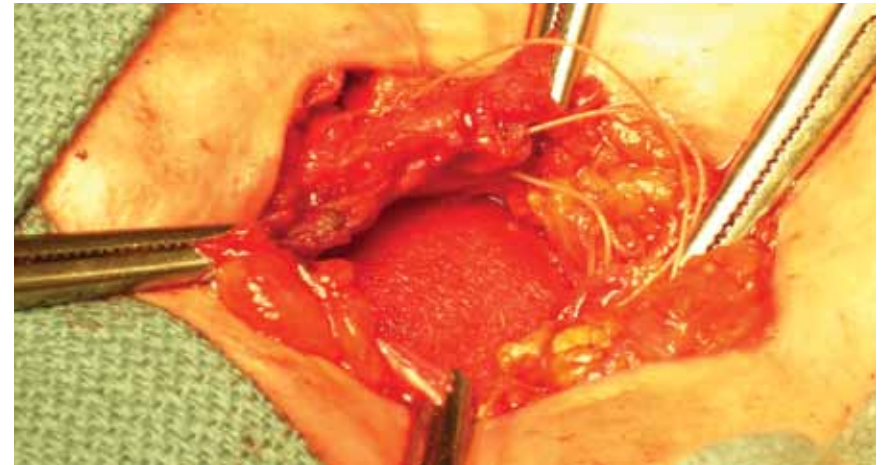
STOMA REVERSAL

Clinical Need: Incidence of stoma site hernia reported up to 32% following colostomy reversal.¹¹

Solution: Following colostomy take down, posterior sheath closed primarily, then GORE® BIO-A® Tissue Reinforcement placed between rectus muscle and anterior sheath and anterior sheath closed primarily.



Stoma site defect dissected



Anterior sheath closed over GORE® BIO-A® Tissue Reinforcement

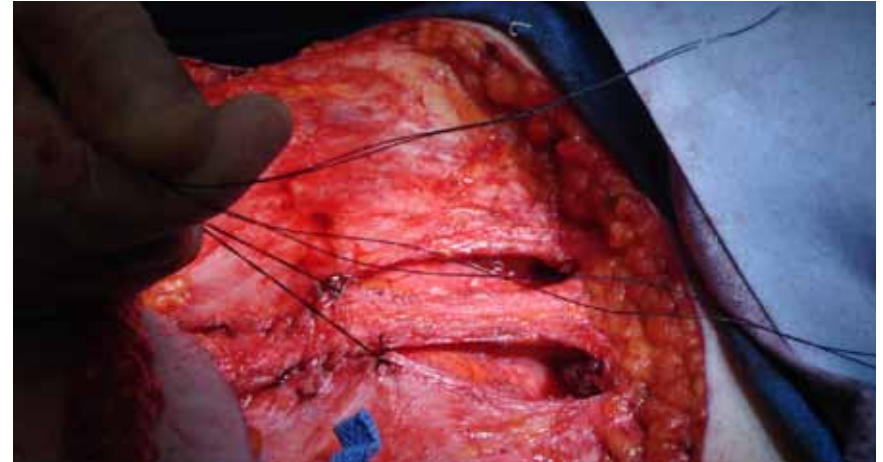
¹¹Guzman-Valdivia G. Hernia. 2008 Oct; 12(5): 471-4.



TRANSVERSE RECTUS ABDOMINIS MYOCUTANEOUS FLAP REINFORCEMENT AFTER BREAST RECONSTRUCTION

Clinical Need: For various types of TRAM procedures, up to 9% rate of hernia at donor site and up to 15% occurrence of abdominal bulge without hernia at donor site.^{12,13}

Solution: Reinforcement of suture line at rectus muscle donor site.



Closure of Anterior Sheath for Rectus Muscle Donor



Placement of GORE® BIO-A® Tissue Reinforcement for Rectus Muscle Donor Site Reinforcement

¹²Watterson PA, Bostwick J 3rd, Hester TR Jr, Bried JT, Taylor GI. TRAM flap anatomy correlated with a 10-year clinical experience with 556 patients. *Plast Reconstr Surg.* 2006 May; 117(6):1711-9.

¹³Garvey PB, Buchel EW, Pockaj BA, Casey WJ 3rd, Gray RJ, Hernandez JL, Samson TD. DIEP and pedicled TRAM flaps: a comparison of outcomes. *Plast Reconstr Surg.* 2006 May; 117(6): 1711-9.



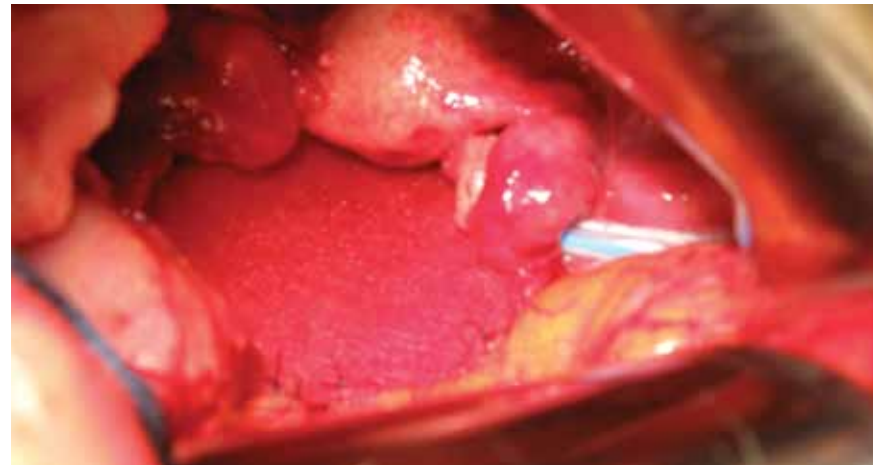
ABDOMINOPERINEAL RESECTION

Clinical Need: Reinforcing the pelvic floor after primary closure of pelvic defect.

Solution: GORE® BIO-A® Tissue Reinforcement is shown reinforcing the pelvic floor after primary closure. The repair excludes the bowel from the pelvis.



Pelvic defect following abdominoperineal resection



Pelvic floor reinforcement using GORE® BIO-A® Tissue Reinforcement



OFFERS PERFORMANCE PLUS VALUE

Ease of use for surgeon and hospital

- No special handling, storage or tracking requirements
- Requires no soaking or stretching
- Trimmable
- Three year shelf life
- Available in large sizes up to 20 cm x 30 cm
- Good value per cm²



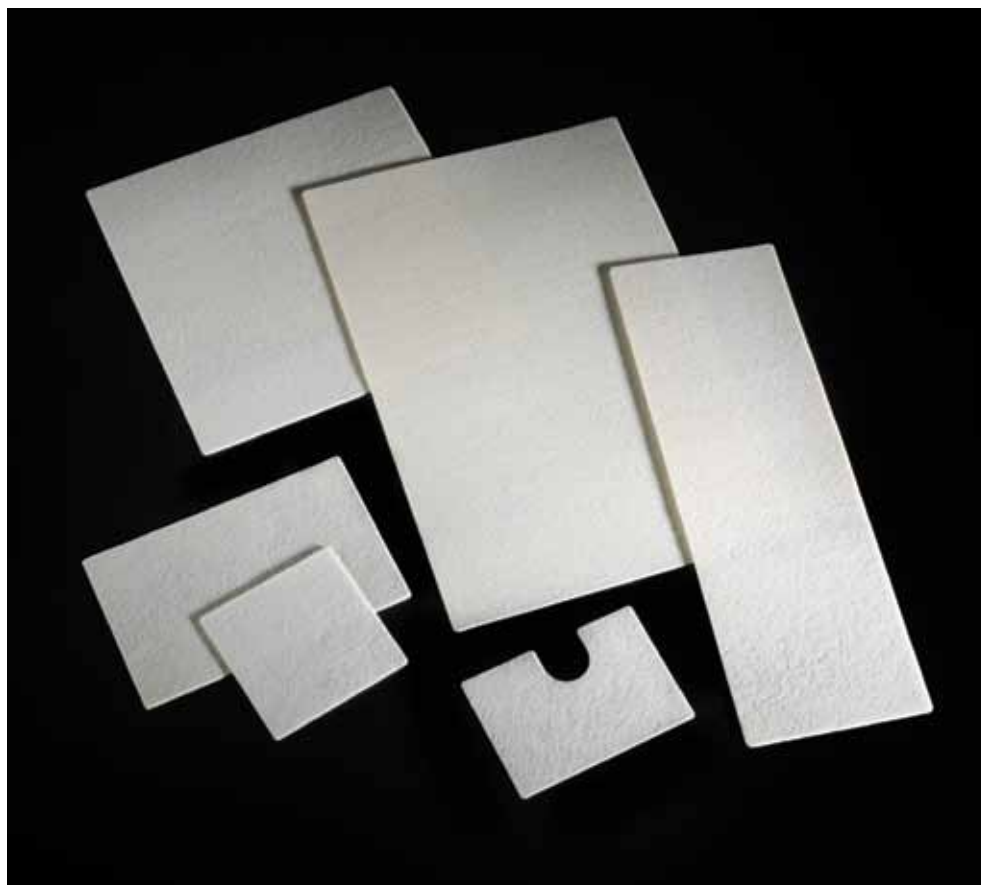
SOFT TISSUE REINFORCEMENT OPTIONS

Options	Biologics	GORE® BIO-A® Tissue Reinforcement
Product Function	<ul style="list-style-type: none"> • Tissue scaffold as soft tissue reinforcement (e.g., suture line reinforcement) 	
Ease of Use, OR Preparation	<ul style="list-style-type: none"> • Some require soaking / hydration • Some require refrigerated storage • Human tissue requires hospital tracking • Some can be inconsistent in thickness, stiffness, and / or handling 	<ul style="list-style-type: none"> • No required prep • 3 year shelf life • Consistent & uniform
Material	<ul style="list-style-type: none"> • Human or animal tissue • Potential for virus and unknown pathogen transmission 	<ul style="list-style-type: none"> • Synthetic - No risk of disease transfer
Structure	<ul style="list-style-type: none"> • Varies in thickness and porosity • Crosslinking may slow cell infiltration and vascularization 	<ul style="list-style-type: none"> • Consistent - 3D, open, porous structure promotes rapid cell infiltration, vascularization
Economic Argument	<ul style="list-style-type: none"> • Range in price: up to ~ \$30/cm²* 	<ul style="list-style-type: none"> • Cost effective alternative: < \$8/cm²

* Schuster R, Singh J, Safadi BY, Wren SM, The use of acellular dermal matrix for contaminated abdominal wall defects: wound status predicts success. *The American Journal of Surgery* 192 (2006) 594-597.



A VALUABLE ALTERNATIVE TO BIOLOGICS



Product configuration and sizing

PRODUCT CATALOGUE NUMBER	SIZE
HH0710	7 cm x 10 cm*
FS0808	8 cm x 8 cm
FS0915	9 cm x 15 cm
FS1030	10 cm x 30 cm
FS2020	20 cm x 20 cm
FS2030	20 cm x 30 cm

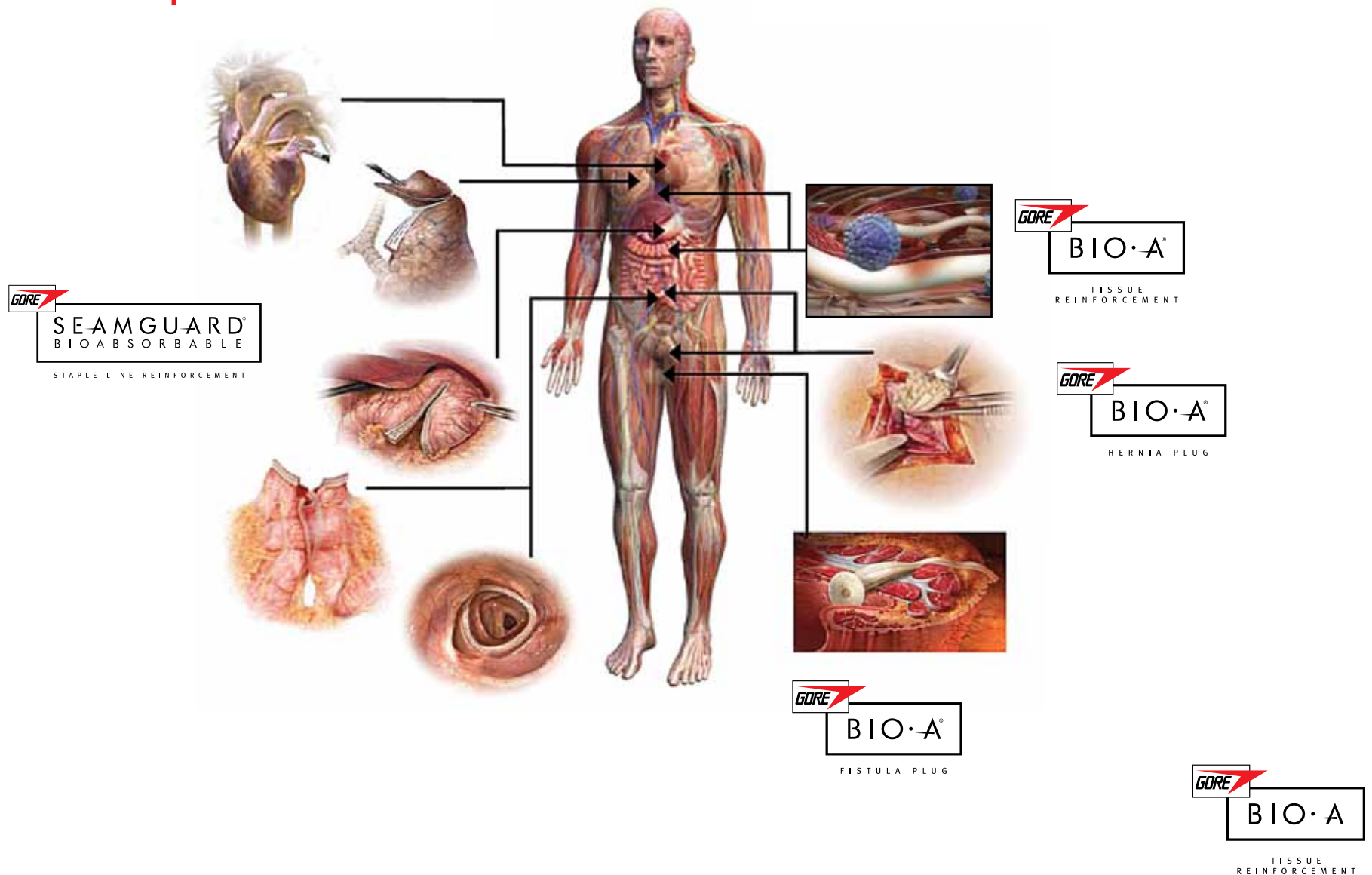
*Configured for hiatal hernia repair



GORE BIOABSORBABLE CLINICAL HISTORY

Staple Line Reinforcement

Soft Tissue Defects



RELY ON GORE

Innovation, Integrity, Trust, Collaboration

- ▶ Sales Team: Non-commission
 - Focus on clinical support
 - Long term relationship
- ▶ Inventory Management
 - Trade out product approaching expiration date
 - Aid in product selection
- ▶ 24/7 Customer Service
 - Free overnight delivery
 - Electronic ordering via GHX and EDI capability
- ▶ Partnering with Health Care Providers
 - Education - In-service programs, conferences, courses
 - Library of training and educational videos
 - Medical reference and information services
 - Histology services





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