# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>Clinical Need</td>
<td>2</td>
</tr>
<tr>
<td>Bioabsorbable Web Technology</td>
<td>6</td>
</tr>
<tr>
<td><strong>GORE® BIO-A® Tissue Reinforcement</strong></td>
<td></td>
</tr>
<tr>
<td>Indications and Applications</td>
<td>16</td>
</tr>
<tr>
<td>Performance and Value</td>
<td>23</td>
</tr>
<tr>
<td>Sizing Chart</td>
<td>24</td>
</tr>
<tr>
<td>Clinical History</td>
<td>25</td>
</tr>
<tr>
<td>Rely on Gore</td>
<td>26</td>
</tr>
</tbody>
</table>
Additional support for tissue without increased risks associated with permanent materials\textsuperscript{1, 2}

What are the risks?

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


Managing Risk of Complications in Complex Cases

Grade 1
Low Risk
- Low risk of complications
- No history of wound infection

Grade 2
Co-Morbid
- Smoker
- Obese
- Diabetic
- Immunosuppressed
- COPD

Grade 3
Potentially Contaminated
- Previous wound infection
- Stoma present
- Violation of the gastrointestinal tract

Grade 4
Infected
- Infected mesh
- Septic dehiscence

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

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
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.
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

**BIOABSORBABLE CHEMISTRY**

- Polyglycolic Acid (PGA)
- Hydrolysis by water
- Glycolic Acid
- Enzymatic conversion
- Pyruvate
- Krebs Cycle
- Carbon Dioxide & Water
- Exhaled
- Excreted
**3D TISSUE SCAFFOLD – MATERIAL STRUCTURE**

**Need:** Robust tissue layer  
**Solution:** 3 Dimensional web

![Mag 50x Image]

Thickness of new tissue generated

*GORE® BIO-A® Tissue Reinforcement*

**Need:** Rapid cell migration and vascularization  
**Solution:** Large & interconnected pores

![Mag 100x Image]

Open Pores

*GORE® BIO-A® Tissue Reinforcement*

*Biologic: Small Intestinal Submucosa*
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

Bioabsorbable Web Structure Similar to a Collagen Fiber Network

GORE® BIO-A® Tissue Reinforcement

Collagen Gel⁴

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

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_

Normal Wound Healing

3 months - Human

Collagen type I (brown)

Collagen type III (brown)

Collagen: type I > type III

Immunohistochemistry 10x

13 months - Human

Collagen type I (brown)

Collagen type III (brown)

Dominance of type I collagen

Immunohistochemistry 10x

¹GORE® BIO-A® Hernia Plug
TISSUE SCAFFOLD - RAPID CELL POPULATION AND VASCULARIZATION\textsuperscript{6}

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.

\begin{center}
\begin{tikzpicture}
\begin{axis}[
    title={Vessels in Device},
    ybar stacked,
    ymajorgrids=true,
    bar width=20pt,
    ymin=0,
    ymax=45,
    xtick={1,2,3,4},
    xticklabels={3,7,14,30},
    xticklabel style={anchor=north west,rotate=90},
    width=\textwidth,
]
\addplot[fill=red] coordinates {
    (1,45)
    (2,40)
    (3,35)
    (4,30)
};
\addplot[fill=blue] coordinates {
    (1,40)
    (2,35)
    (3,30)
    (4,25)
};
\addplot[fill=green] coordinates {
    (1,35)
    (2,30)
    (3,25)
    (4,20)
};
\addplot[fill=yellow] coordinates {
    (1,30)
    (2,25)
    (3,20)
    (4,15)
};
\addplot[fill=purple] coordinates {
    (1,25)
    (2,20)
    (3,15)
    (4,10)
};
\addplot[fill=orange] coordinates {
    (1,20)
    (2,15)
    (3,10)
    (4,5)
};
\addplot[fill=gray] coordinates {
    (1,15)
    (2,10)
    (3,5)
    (4,0)
};
\end{axis}
\end{tikzpicture}
\end{center}

\textsuperscript{6}Milligan’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 (§)

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 Replacement

Calculated by Histological Image Analysis

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.

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

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

TRANVERSE 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.\textsuperscript{12,13}

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


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.
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

<table>
<thead>
<tr>
<th>Options</th>
<th>Biologics</th>
<th>GORE® BIO-A® Tissue Reinforcement</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Product Function</strong></td>
<td>• Tissue scaffold as soft tissue reinforcement (e.g., suture line reinforcement)</td>
<td></td>
</tr>
</tbody>
</table>
| **Ease of Use, OR Preparation** | • Some require soaking / hydration  
• Some require refrigerated storage  
• Human tissue requires hospital tracking  
• Some can be inconsistent in thickness, stiffness, and/or handling | • No required prep  
• 3 year shelf life  
• Consistent & uniform |
| **Material**             | • Human or animal tissue  
• Potential for virus and unknown pathogen transmission | • Synthetic - No risk of disease transfer |
| **Structure**            | • Varies in thickness and porosity  
• Crosslinking may slow cell infiltration and vascularization | • Consistent - 3D, open, porous structure promotes rapid cell infiltration, vascularization |
| **Economic Argument**    | • Range in price: up to ~ $30/cm²*                                      | • Cost effective alternative: < $8/cm² |

---

A VALUABLE ALTERNATIVE TO BIOLOGICS

Product configuration and sizing

<table>
<thead>
<tr>
<th>PRODUCT</th>
<th>SIZE</th>
</tr>
</thead>
<tbody>
<tr>
<td>HH0710</td>
<td>7 cm x 10 cm*</td>
</tr>
<tr>
<td>FS0808</td>
<td>8 cm x 8 cm</td>
</tr>
<tr>
<td>FS0915</td>
<td>9 cm x 15 cm</td>
</tr>
<tr>
<td>FS1030</td>
<td>10 cm x 30 cm</td>
</tr>
<tr>
<td>FS2020</td>
<td>20 cm x 20 cm</td>
</tr>
<tr>
<td>FS2030</td>
<td>20 cm x 30 cm</td>
</tr>
</tbody>
</table>

*Configured for hiatal hernia repair
GORE BIOABSORBABLE CLINICAL HISTORY

Staple Line Reinforcement

Soft Tissue Defects

SEAMGUARD® BIOABSORBABLE
STAPLE LINE REINFORCEMENT

GORE® BIO-A® TISSUE REINFORCEMENT

HEMIA PLUG

FISTULA PLUG
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