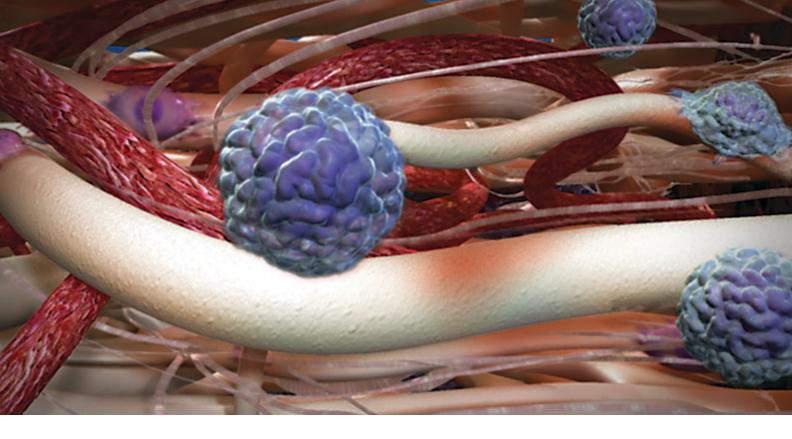


Matrix for tissue generation and healing





Valuable alternative for complex soft tissue reinforcement

Intended for use in the reinforcement of soft tissue, GORE® BIO-A® Tissue Reinforcement is a uniquely designed web of biocompatible synthetic polymers that is gradually absorbed by the body.

Its 3D matrix of open, highly interconnected pores facilitates cell infiltration and tissue generation, leaving no permanent material behind.

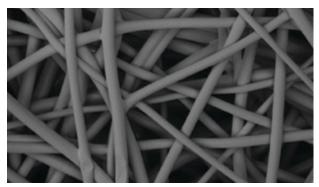
- 100% synthetic, bioabsorbable tissue scaffold
- Rapid cell population and vascularization
- Replaced 1:1 with native tissue
- Versatile for numerous applications
- Offers performance plus value

Gore bioabsorbable technology is proven and trusted. It is backed by more than 20 years of research and clinical use, with a record of reliability in numerous parts of the body including:

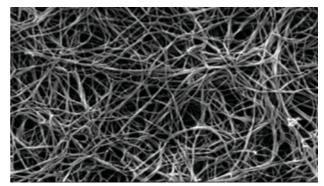
- Mouth
- Abdominal wall
- Colon
- Stomach
- Lungs
- Liver
- Stomach
- Pancreas
- Pancieas
- Spleen

Structure: Open, highly porous 3D web

With a 3D matrix with highly interconnected pores, GORE® BIO-A® Tissue Reinforcement provides tunnels for cell migration, resulting in a structure that is similar to a collagen fiber network.



GORE® BIO-A® Tissue Reinforcement (SEM 100x)



Collagen gel.1

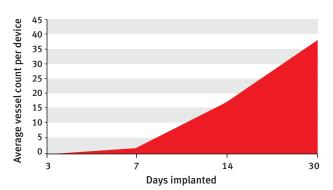
Material: 100% synthetic, bioabsorbable tissue scaffold

GORE® BIO-A® Tissue Reinforcement is constructed with a proven, 100 percent bioabsorbable material, poly(glycolide: trimethylene carbonate) (PGA:TMC) fibers. Without the risks associated with biologics, this synthetic tissue scaffold provides uniformity and consistency.

Derived neither from human nor animal tissue, GORE® BIO-A® Tissue Reinforcement is designed to break down primarily by hydrolysis. Within one to two weeks, the patient's cells migrate into the scaffold and begin generating vascularized soft tissue.

Gradually over approximately six to seven months, the material is absorbed by the body and replaced 1:1 with the patient's own favorable type I collagen.

Vascularity within devices increases over time²



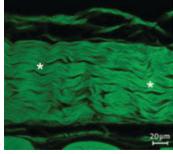
Generate quality tissue fast

Collagen deposition

Within device * * 20 µm

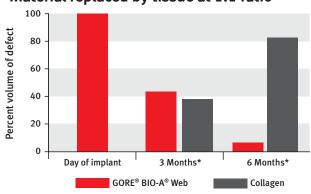
30 days: Collagen strands organized, blood vessel present (arrow).²

Quantity and quality mimics native tissue



Adjacent native rabbit abdominal fascia. Organized collagen strands.²

Material replaced by tissue at 1:1 ratio³



*Cells and blood vessels make up remaining volume.

Versatile for numerous applications

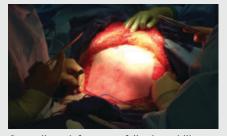
The GORE® BIO-A® Tissue Reinforcement is intended for use in the reinforcement of soft tissue. Examples where the GORE® BIO-A® Tissue Reinforcement may be used are hiatal and ventral hernia repair as suture-line reinforcement. Applications include:

Paraesophageal / hiatal hernia repair



Onlay following primary closure of crura. 4,5

Abdominal wall reconstruction



Suture line reinforcement following midline closure.⁶

Ventral / incisional hernia repair



Reoperation for symptomatic bulging of a lumbar incisional hernia.⁷

Performance plus value

Ease of use for surgeon and hospital



- No soaking, refrigeration, or tracking required
- Trimmable
- Three-year shelf life
- Available in large sizes up to 20 cm x 30 cm
- Good value per square cm

Product configuration and sizing chart



CATALOGUE NUMBER	Size
HH0710E	7 cm x 10 cm*
FS0808E	8 cm x 8 cm
FS0915E	9 cm x 15 cm
FS1030E	10 cm x 30 cm
FS2020E	20 cm x 20 cm
FS2030E	20 cm x 30 cm

^{*} Configured for hiatal hernia repair.

- 1. Photo courtesy of Biophysical Society and Christopher B. Raub, Vinod Suresh, Tatiana Krasieva, Julia Lyubovitsky, Justin D. Mih, Andrew J. Putnam, Bruce J. Tromberg and Steven C. George University of California Irvine.
- 2. Berman A. A Rabbit Model for the Biomechanical and Histological Assessment of Suture Line Wound Healing. Flagstaff, AZ: W. L. Gore & Associates, Inc.; 2009. Final Report. 1978SC.
- 3. Morales-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.
- 4. Ehrlich TB. GORE® BIO-A® Tissue Reinforcement in Hiatal Hernia Repair. Flagstaff, AZ. W. L. Gore & Associates, Inc; 2008. [Case report]. AM2969-EN1.
- 5. Zehetner J, Demeester SR, Ayazi S, et al. Laparoscopic versus open repair of paraesophageal hernia: the second decade. Journal of the American College of Surgeons 2011:212(5):813-820.
- 6. Jacobsen GR, Chao JJ. Clinical use of GORE® BIO-A® Tissue Reinforcement in ventral hernia repair using the components separation technique. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2018. [Case series]. AX0286-EN2.
- 7. Photo courtesy of M.A. García-Ureña, MD.



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Refer to Instructions for Use for a complete description of all warnings, precautions, and contraindications. R_{xort}

Products listed may not be available in all markets.