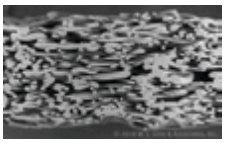
GORE® BIO-A®
Tissue Reinforcement

Bioabsorbable mesh for hernia repair

Know your options

Instructions for use	GORE® BIO-A® Tissue Reinforcement	BD® PHASIX Mesh
Indications for use/ Indications	The GORE® BIO-A® Tissue Reinforcement is intended for use in the reinforcement of soft tissue, including hiatal and ventral hernia repair as suture-line reinforcement.	BD® PHASIX Mesh is indicated to reinforce soft tissue where weakness exists, in patients undergoing abdominal, plastic, and reconstructive surgery in ventral hernia repair and other abdominal fascial defect procedures.[1]
Contraindications	The GORE® BIO-A® Tissue Reinforcement is contraindicated for use in reconstruction of cardiovascular defects. The GORE® BIO-A® Tissue Reinforcement is absorbable and contraindicated for use in patients requiring permanent support from the device.	Because BD® PHASIX Mesh is fully resorbable, it should not be used in repairs where permanent wound or organ support from the mesh is required.[1]

Device Description	GORE® BIO-A® Tissue Reinforcement	BD® PHASIX Mesh
Material	Synthetic bioabsorbable poly (glycolide: trimethylene carbonate) copolymer (PGA:TMC)	Synthetic fully resorbable poly-4-hydroxybutyrate (P4HB)
Absorption time	Targeted absorption period of 6–7 months to facilitate a positive physiological response during the wound healing cycle when most needed and avoid the risk for long-term mesh-related complications.	Per IFU, absorption of the mesh material will be essentially complete within 12 to 18 months. Not verified / observed in clinical literature.
Material structure SEM (40x–50x cross section)	Laminar 3D web scaffold  Robust layer of new tissue generated	Monofilament 2D knit[2] 

Clinical Applications	GORE® BIO-A® Tissue Reinforcement	BD® PHASIX Mesh
Hiatal/ paraesophageal hernia repair	■ More than 130,000 hiatal configured devices sold.* ■ Clinical literature cites more than 1,850 repairs.[4] ■ Mean follow-up of 5 years reported,[3] which is 53–54 months beyond the 6–7 month resorption time period of the mesh. ■ No reports of erosion or infection in the clinical literature.[4]	■ Limited clinical literature.[4]
Complex ventral hernia repair	■ Supported by an extensive body of positive clinical results over 10 years[4] ■ Proven low recurrence rates in high risk AWR patients[4] ■ Proven low complication rates in high risk AWR patients[4] ■ Zero reported complete mesh removals due to infection[4]	■ First clinical publications in 2016[4] ■ Three reported complete mesh removals due to infection[5]

* Data on file 2023, W. L. Gore & Associates, Inc; Flagstaff, AZ.

Together, improving life

Over 10 years of positive clinical results

More than 250 publications, low recurrence rates in hiatal hernias, low recurrence rates in complex ventral hernias, over 2,000 patients in the clinical literature and no long-term mesh related complications reported.

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.

Complex and high-risk repairs

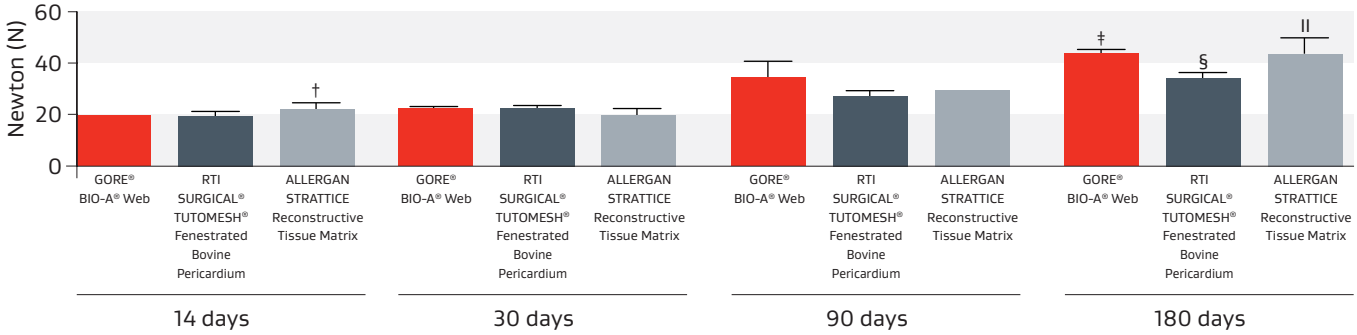
Ventral hernia

Hiatal hernia

Demonstrated economic value

GORE® BIO-A® Tissue Reinforcement is fully absorbed and replaced by a robust layer of organized collagen, leaving behind a strong repair[6]

Repair strength increases over time[6]



The results (Newtons) were expressed as the mean ± SEM at 14, 30, 90 and 180 days post-implantation. GORE® BIO-A® Web:†, vs. 14 days and 30 days ($P < 0.01$). RTI SURGICAL® TUTOMESH® Fenestrated Bovine Pericardium:†, vs. 90 days ($P < 0.01$);§, vs. 14 days and 90 days ($P < 0.05$) and 30 days ($P < 0.01$). ST (ALLERGAN STRATTICE Reconstructive Tissue Matrix): ||, vs. 14 days and 30 days ($P < 0.05$).

References

1. Phasix™ ST Mesh Fully Resorbable Implant for Soft Tissue Reconstruction [Instructions for Use]. Warwick, RI: Davol, Inc; 2015. PK3799200. 1611R. **2.** Kim M, Oommen B, Ross SW, *et al.* The current status of biosynthetic mesh for ventral hernia repair. *Surgical Technology International* 2014;25:114-121. **3.** Boru CE, Coluzzi MG, de Angelis F, Silecchia G. Long-term results after laparoscopic sleeve gastrectomy with concomitant posterior cruroplasty: 5-year follow-up. *Journal of Gastrointestinal Surgery* 2020;24(9):1962-1968. **4.** W. L. Gore & Associates, Inc. *Clinical Evaluation Report for GORE® BIO-A® Tissue Reinforcement.* Flagstaff, AZ: W. L. Gore & Associates, Inc; 2023. [Clinical Evaluation Report – CER]. MD114935. Rev 13. **5.** 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. **6.** 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.

Consult Instructions for Use
eifu.goremedical.com

Refer to *Instructions for Use* at eifu.goremedical.com for a complete description of all applicable indications, warnings, precautions and contraindications for the markets where this product is available. ℞ Only

Products listed may not be available in all markets.

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