Bioabsorbable mesh for hernia repair

Know your options

	GORE® BIO-A® Tissue Reinforcement	BD® PHASIX Mesh
	Instructions for Use	
Indications for use / Indications	**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.**	BD® PHASIX Mesh is indicated to reinforce soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result.[1]
Refer to *Instructions for Use* for a complete description of all warnings, precautions, and contraindications. ℞ Only		
Contraindications	**The GORE® BIO-A® Tissue Reinforcement is contraindicated for use in reconstruction of cardiovascular defects.** **Because GORE® BIO-A® Tissue Reinforcement is absorbable, it is 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]
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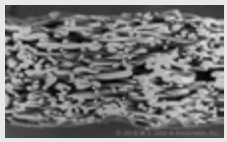
	Device Description	
Material	**Synthetic bioabsorbable poly (glycolide: trimethylene carbonate) copolymer (PGA: TMC)**	Synthetic fully resorbable poly-4-hydroxybutyrate (P4HB)
Absorption time	**Targeted absorption period of 6–7 months to facilitate a positive physiological response during the wound healing 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	
Hiatal / paraesophageal hernia repair	• **More than 105,000 hiatal configured devices sold[3]** • **Clinical literature cites more than 1,000 repairs[3]** • **Mean follow-up of 5 years reported[4], 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[5]**	• Limited clinical literature[5] • No published clinical follow-up reported on hiatal and paraesophageal hernia repair beyond the 18 month resorption time period of the mesh[5]
Complex ventral hernia repair	• **Supported by the most extensive body of positive clinical results over 10 years[5]** • **Proven low recurrence rates in high risk AWR patients[5]** • **Proven low complication rates in high risk AWR patients[5]** • **ZERO reported complete mesh removals due to infection[5]**	• First clinical publications in 2016[5] • Three reported complete mesh removals due to infection[6]

GORE BIO-A® TISSUE REINFORCEMENT

10 YEARS positive clinical results

Complex and high-risk repairs
Ventral hernia
Hiatial hernia
Demonstrated economic value

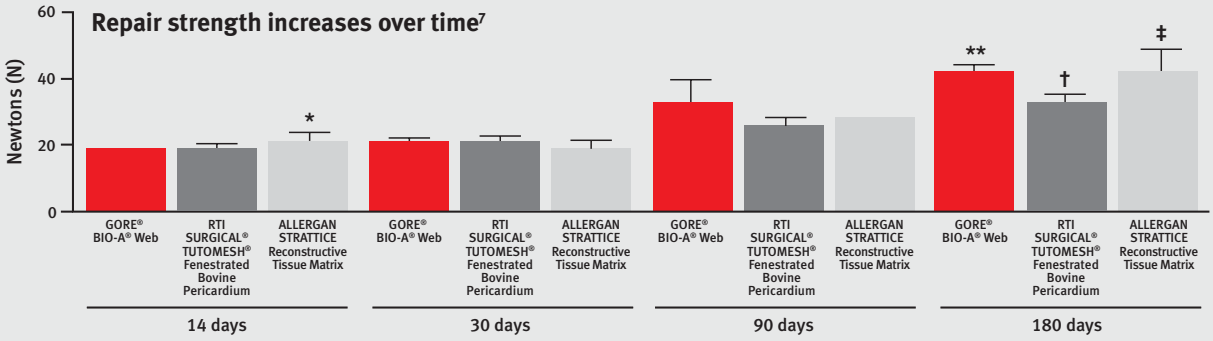
- MORE than 250 publications
- LOW recurrence rates in hiatal hernias
- LOW recurrence rates in complex ventral hernias
- OVER 1,700 patients in the clinical literature
- NO long-term mesh-related complications

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.

GORE® BIO-A® Tissue Reinforcement is fully absorbed and replaced by a robust layer of organized collagen, leaving behind only a strong repair[7]



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™ Mesh Fully Resorbable Implant for Soft Tissue Reconstruction [*Instructions for Use*]. Warwick, RI: Davol, Inc; 2016. 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. Data on file, W. L. Gore & Associates, Inc; Flagstaff, AZ.
4. 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. In press.
5. Literature search and summary (included Bard Phasix Mesh and Bard Phasix ST Mesh). (data on file 2018; W. L. Gore & Associates, Inc.; Flagstaff, AZ.)
6. LaPere DB, Lundgren MP, Rosato EL, *et al*. Single instituion 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.
7. 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.

For more information visit goremedical.com/eu/btr

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Products listed may not be available in all markets.