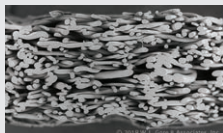
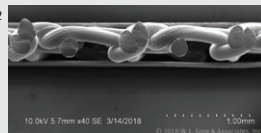




Bioabsorbable mesh for hernia repair

Know your options

GORE® BIO-A® Tissue Reinforcement		BD® PHASIX Mesh
Instructions for Use		
Intended Use / Indication	GORE® BIO-A® Tissue Reinforcement is intended for use in the reinforcement of soft tissue. Examples of applications where the GORE® BIO-A® Tissue Reinforcement may be used include hernia repair as suture-line reinforcement, muscle flap reinforcement, and general tissue reconstructions.	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 <i>Instructions for Use</i> for a complete description of all warnings, precautions, and contraindications. Rx Only		
Contraindications / precautions	Not for reconstruction of cardiovascular defects. The GORE® BIO-A® Tissue Reinforcement is not designed to be a load-bearing prosthesis and is therefore not recommended for the permanent bridging of fascial defects.	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
Refer to <i>Instructions for Use</i> for a complete description of all warnings, precautions, and contraindications. Rx Only		
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.	Absorption of the mesh material will be essentially complete within 12 to 18 months.
Material structure SEM (50x cross section)	Laminar 3D web 	Monofilament 2D knit ² 
Thickness of new tissue generated		
Characterization evaluation between fully absorbable biomaterials	Stoikes <i>et al.</i> , which studied the preclinical strength between GORE® BIO-A® Tissue Reinforcement and BD® PHASIX Mesh concluded “Both full resorbable scaffolds evaluated in this study exceeded the baseline strength requirements of a mesh material deemed appropriate for hernia repair applications”. ³	
Clinical Applications		
Hiatal / paraesophageal hernia repair	• More than 81,000 hiatal configured devices sold⁴ • Clinical literature cites more than 1,000 repairs⁴ • Mean follow-up beyond 3 years reported⁵ • No reports of erosion or infection in the clinical literature⁵	• Limited clinical literature⁵ • No clinical follow-up reported beyond the 18 month resorption time period of the mesh⁵
Complex ventral hernia repair	• Supported by the most extensive body of positive clinical results over 10 years⁵ • Proven low recurrence rates in high risk AWR patients⁵ • Proven low complication rates in high risk AWR patients⁵ • ZERO reported complete mesh removals due to infection⁵	• First clinical publications in 2016⁵ • Three reported complete mesh removals due to infection⁶



Complex and
high-risk repairs
Ventral hernia
Hiatal hernia
Demonstrated
economic value⁷

- MORE than 150 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
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.



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. Stoikes NFN, Scott JR, Badhwar A, Deeken CR, Voeller GR. Characterization of host response, resorption, and strength properties, and performance in the presence of bacteria for fully absorbable biomaterials for soft tissue repair. *Hernia* 2017;21(5):771-782.
4. Data on file, W. L. Gore & Associates, Inc; Flagstaff, AZ.
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 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.
7. W. L. Gore & Associates, Inc. *Proven Outcomes, Reduced Costs for Complex Hernia Repairs*. Flagstaff, AZ: W. L. Gore & Associates, Inc; 2018. [Case report]. AX0283-EN1.

For more information visit goremedical.com/btr



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Refer to *Instructions for Use* for a complete description of all warnings, precautions, and contraindications. ^{Rx only}

Products listed may not be available in all markets.

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