
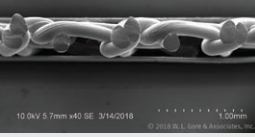




# Bioabsorbable mesh for hernia repair

## Know your options

	<b>GORE® BIO-A® Tissue Reinforcement</b>	<b>BD® PHASIX Mesh</b>
<b>Instructions for Use</b>		
<b>Intended Use / Indication</b>	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. <sup>1</sup>
<small>Refer to <i>Instructions for Use</i> for a complete description of all warnings, precautions, and contraindications.  Only</small>		
<b>Contraindications / precautions</b>	<b>Not for reconstruction of cardiovascular defects.</b> 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. <sup>1</sup>
<small>Refer to <i>Instructions for Use</i> for a complete description of all warnings, precautions, and contraindications.  Only</small>		
<b>Device Description</b>		
<b>Material</b>	Synthetic bioabsorbable poly (glycolide: trimethylene carbonate) copolymer (PGA: TMC)	Synthetic fully resorbable poly-4-hydroxybutyrate (P4HB)
<b>Absorption time</b>	Targeted absorption period of <b>6–7 months</b> 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.
<b>Material structure SEM (50x cross section)</b>	Laminar 3D web  Thickness of new tissue generated	Monofilament 2D knit <sup>2</sup> 
<b>Characterization evaluation between fully absorbable biomaterials</b>	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”. <sup>3</sup>	
<b>Clinical Applications</b>		
<b>Hiatal / paraesophageal hernia repair</b>	<ul style="list-style-type: none"> <li>• More than 81,000 hiatal configured devices sold<sup>4</sup></li> <li>• Clinical literature cites more than 1,000 repairs<sup>4</sup></li> <li>• Mean follow-up beyond 3 years reported<sup>5</sup></li> <li>• No reports of erosion or infection in the clinical literature<sup>5</sup></li> </ul>	<ul style="list-style-type: none"> <li>• Limited clinical literature<sup>5</sup></li> <li>• No clinical follow-up reported beyond the 18 month resorption time period of the mesh<sup>5</sup></li> </ul>
<b>Complex ventral hernia repair</b>	<ul style="list-style-type: none"> <li>• Supported by the most extensive body of positive clinical results over 10 years<sup>5</sup></li> <li>• Proven low recurrence rates in high risk AWR patients<sup>5</sup></li> <li>• Proven low complication rates in high risk AWR patients<sup>5</sup></li> <li>• ZERO reported complete mesh removals due to infection<sup>5</sup></li> </ul>	<ul style="list-style-type: none"> <li>• First clinical publications in 2016<sup>5</sup></li> <li>• Three reported complete mesh removals due to infection<sup>6</sup></li> </ul>

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Complex and high-risk repairs  
 Ventral hernia  
 Hiatal hernia  
 Demonstrated economic value<sup>7</sup>

- 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](http://goremedical.com/btr)



### W. L. GORE & ASSOCIATES, INC.

Flagstaff, AZ 86004

+65.67332882 (Asia Pacific) 800.437.8181 (United States)  
 00800.6334.4673 (Europe) 928.779.2771 (United States)

[goremedical.com](http://goremedical.com)

Refer to *Instructions for Use* for a complete description of all warnings, precautions, and contraindications. ℞ only

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