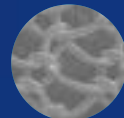
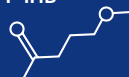


BD is the only company that offers Proprietary P4HB technology

P4HB



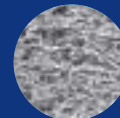
Phasix™ Mesh



Transorb™



GORE® BIO-A®



GORE® ENFORM



TIGR® Matrix

Phasix™ Mesh

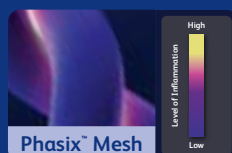
Trimethylene carbonate-based (TMC) mesh

Natural to the human body

- ✓ Naturally derived^{2,4}
- ✓ P4HB is a polymer containing butyrate, which is naturally found in the human body^{4,5}

- ✗ Chemically synthesized
- ✗ Foreign, made from materials not found in the human body

Antimicrobial peptide defense



- ✓ Monofilament, macroporous scaffold resists bacterial colonization and supports tissue healing^{4,5}
- ✓ P4HB activates the body's own immune defenses by upregulating antimicrobial peptides, the body's first line defense against infection^{2,3,6,7}



- ✗ Multifilament meshes have been shown to trap bacteria between fibers, creating a niche for biofilm formation and persistent infection²
- ✗ No data reported on antimicrobial peptides response

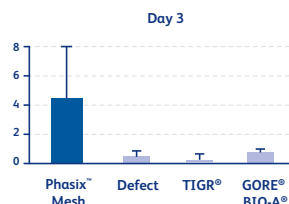
Healthy tissue regeneration

- ✓ Elicits a pro-remodeling response, providing natural healing to regenerate tissue^{2,6}

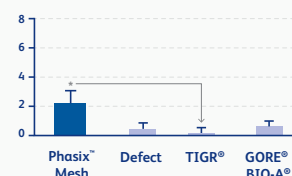
- ✗ No pro-remodeling response^{2,6}

Phasix™ Mesh is associated with an early pro-regenerative response compared to other materials^{2,6}

*Statistically significant $p < 0.05$



Day 7



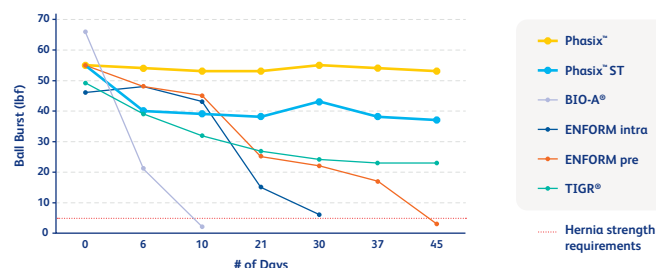
Predictable long-term strength

- ✓ Proven strength and low recurrence backed by multiple 5-year publications¹
- ✓ Exceeds hernia strength requirements¹²
- ✓ Phasix™ Mesh retained 87% of its strength at 45 days¹

- ✗ No or limited 5-year data to understand long-term consequences¹
- ✗ Some lost nearly all its strength and failed to meet hernia repair strength requirements¹

TMC-based meshes lose strength over time¹

*Statistically significant $p < 0.05$



Phasix™ offers a versatile P4HB bioabsorbable mesh portfolio, designed to meet the demands of diverse procedures

Proprietary bioabsorbable surgical platforms

Open, laparoscopic, and robotic

	Flat	Barrier flat
Phasix™ Mesh		
TMC	Transorb™ TIGR® BIO-A® ENFORM	⊘

	Phasix™ Mesh	TIGR®	Transorb™	BIO-A® / ENFORM
Product category	Bioabsorbable	Synthetic resorbable	Synthetic resorbable	Synthetic resorbable
Material	P4HB	TMC + PGA + PLA	TMC + PLLA	TMC + PGA
Resorption time	12–18 months	~3 years	~36–60 months	~6 months
# Peer-reviewed clinical publications	100+	9+	0	15+ / 1

P4HB = poly-4-hydroxybutyrate

Phasix™ Mesh

INDICATIONS: 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 including prophylactic use to reinforce surgical incisions.

CONTRAINDICATIONS: Because Phasix™ Mesh is fully resorbable, it should not be used in repairs where permanent wound or organ support from the mesh is required.

WARNINGS: 1. Phasix™ Mesh must not be put in direct contact with the bowel or viscera. 2. The use of any mesh or patch in a contaminated or infected wound can lead to fistula formation and/or extrusion of the mesh. 3. Mesh manufacture involves exposure to tetracycline hydrochloride and kanamycin sulfate. The safety and product use for patients with hypersensitivities to these antibiotics is unknown. The use of this mesh in susceptible patients with known allergies to tetracycline hydrochloride or kanamycin sulfate should be avoided. 4. The safety and effectiveness of Phasix™ Mesh in the following applications has not been evaluated or established: a. Pregnant or breastfeeding women b. Pediatric use c. Neural and cardiovascular tissue. 5. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require the removal of the mesh. 6. To prevent recurrences when repairing hernias or to prevent occurrences when reinforcing surgical incisions prophylactically, the mesh should be sized with appropriate overlap for the size and location of the defect or surgical incision, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 7. The mesh is supplied sterile. Prior to use, carefully examine package and product to verify neither is damaged and that all seals are intact. Do not use if the foil pouch or package is damaged or open, or if the center of the temperature indicator on the foil pouch is black. 8. This mesh has been designed for single use only. Reuse, reprocessing, resterilization, or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilization, or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness, or death of the patient or end user. 9. If unused Phasix™ Mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations to prevent risk of transmission of viral infections. 10. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 11. This mesh is not for the use of treatment of stress urinary incontinence. 12. Phasix™ Mesh has not been studied for use in breast reconstructive surgeries.

PRECAUTIONS: 1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this mesh. Users should be familiar with mesh strength and size requirements. Improper selection, placement, positioning, and fixation of the mesh can cause subsequent undesirable results. 3. Clinical data in accordance with EU MDR has not been established for laparoscopic/robotic procedures. 4. The safety and effectiveness of Phasix™ Mesh in the proximity of existing or excised cancer has not been established.

ADVERSE REACTIONS: In preclinical testing, Phasix™ Mesh elicited a minimal tissue reaction characteristic of foreign body response to a substance. The tissue reaction resolved as the mesh was resorbed. Possible complications may include, but are not limited to infection, seroma, pain, mesh migration, wound dehiscence, hemorrhage, adhesions, hematoma, inflammation, allergic reaction, extrusion, erosion, fistula formation and recurrence of the hernia or soft tissue defect.

Please consult product labels and instruction for use for indications, contraindications, hazards, warnings, and precautions.

References 1. Data on file. 2. Preclinical data on file. Results may not correlate to clinical outcomes. 3. Stoikes NFN, et al. *Hernia*. 2017;21(5):771-782. doi:10.1007/s10029-017-1638. 4. Deeken CR, et al. *ISRN Surg*. 2013;2013:238067. Published 2013 May 28. 5. Martin DP, et al. *Biochem Eng J*. 2003;16(2):97-105. 6. Pineda Molina C, et al. *Tissue Eng Part A*. 2019;25(9-10):693-706. 7. Klinge U, et al. *J Biomed Mater Res*. 2002;63(6):765-771. 8. Pineda Molina C, et al. *Biomaterials*. 2021;267:120493.

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