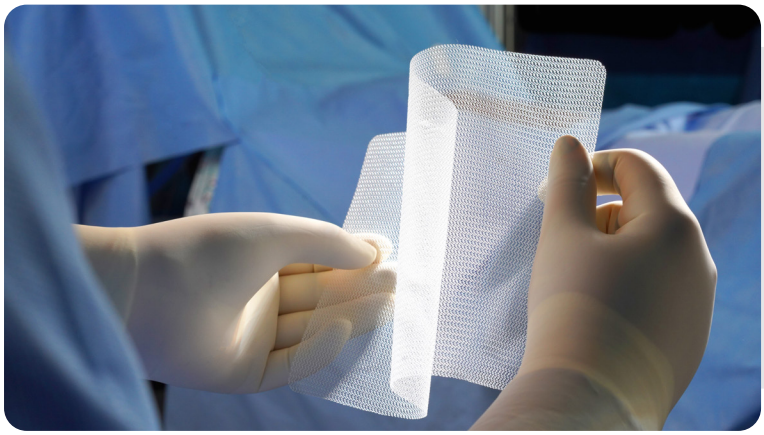
Phasix™ Mesh: Confidence Justified.

Trust is nothing with out proof.
-Blaise Pascal

Material composition and structure matter.[1,2]



65+ peer reviewed clinical publications

Published **5+ year** clinical outcomes

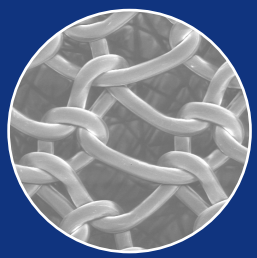
Phasix™ Mesh with P4HB technology is the category leading bioabsorbable hernia mesh.

Composed of P4HB, a material derived from a natural fermentation process, Phasix™ Mesh acts as a lattice for tissue regeneration, encouraging cells to migrate into its open pore monofilament structure, and allow stronger, organized collagen to be built and healthy blood vessels to form.[3–8] As P4HB is absorbed, the body naturally responds by producing antimicrobial peptides (AMPs). Phasix Mesh demonstrates promising results in the presence of bacteria. [8,9]

Material Structure can impact the host response.[1]

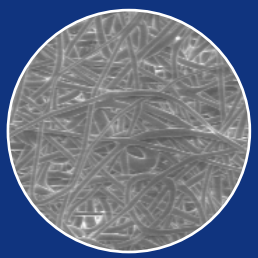
Hernia mesh studies have shown the benefits of monofilament mesh and the change in care away from multifilament.[10]

- Monofilament mesh design allows for a prompt fibroblastic response through the open interstices of the mesh.
- Materials with intricate designs offer increased surface area and crevices that bacteria can exploit to evade tissue integration, neovascularization, antibiotic treatments, and the body's inflammatory responses.[2]
- It has been reported that the surface area of multifilament materials is 157% higher than monofilament materials.[2]

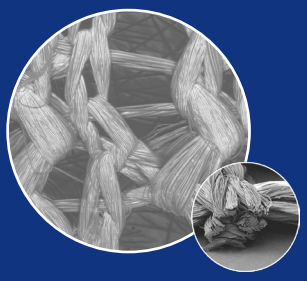


Phasix™ Mesh

Transorb™



GORE® BIO-A®



TIGR® Matrix

BD

Synthetic trimethylene carbonate (TMC) meshes are not Phasix™ Mesh.

	Phasix™ Mesh	Gore® Bio-A® Tissue Reinforcement	Transorb	TIGR® resorbable matrix
Product Category	**Bioabsorbable Monofilament[11]**	Synthetic Resorbable Multifiber[11]	Synthetic Resorbable Monofilament[12]	Synthetic Resorbable Multifilament[11]
Material	**P4HB[1]**	TMC/PGA-Based[11]	TMC/PLLA-Based[12]	TMC/PGA/PLA-Based[11]
Resorption Time	**12–18 Months[11]**	6 Months[11]	36–60 months[14]	36 Months[11]
Number of Clinical Publications	**65+**	20	3.5	9
Interval of long-term Clinical Evidence	**5 years**	1 year	0	3.5 years
Fiber Diameter	**166µm[11]**	3.38µm[11]	10–40µm	10–40µm[11]
Pore Size	**0.25mm[11,12]**	NA[1]	1–1.4 mm	1.0mm[11,12]
Mesh Thickness	**0.9±0.1[12]**	0.0202 in[14]	1.7±0.1[12]	0.687 mm
FDA clearance date	**2015**	2003	2024	2010
Degradation Method	**Hydrolysis, metabolized into CO2 & H2O**	Hydrolysis	Hydrolysis	Hydrolysis

Phasix™ Mesh. Challenging the standard of care since 2013.

The **ONLY** biologically derived absorbable mesh.* The most peer reviewed clinical publications. Phasix™ Mesh promotes the maturation of stronger tissue.

Phasix™ Mesh

Indications. 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. **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, the mesh should be sized with appropriate overlap for the size and location of the defect, 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. 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 package insert for more detailed safety information and instructions for use.**

References:

1. Amid PK, Shulman AG, Lichtenstein IL, Hakakha M. Biomaterials for abdominal wall hernia surgery and principles of their applications. Langenbecks Arch Chir. 1994;379(3):168-171. **2.** Halaweish I, Harth K, Broome AM, Voskerician G, Jacobs MR, Rosen MJ. Novel in vitro model for assessing susceptibility of synthetic hernia repair meshes to Staphylococcus aureus infection using green fluorescent protein-labeled bacteria and modern imaging techniques. Surg Infect (Larchmt). 2010;11(5):449-454. **3.** Preclinical and clinical data on file. Results may not correlate to clinical outcomes. Healthy tissue is defined by tissue with abundant mature collagen (as indicated by positive type I collagen staining) and vascularization (as shown by positive CD31 and smooth muscle actin stains) has quickly integrated into the scaffold. **4.** Martin DP, Badhwar A, Shah DV, et al. Characterization of poly-4-hydroxybutyrate mesh for hernia repair applications. J Surg Res. 2013;184(2):766-773. doi:10.1016/j.jss.2013.03.044 **5.** Deeken CR, Matthews BD. Characterization of the Mechanical Strength, Resorption Properties, and Histologic Characteristics of a Fully Absorbable Material (Poly-4-hydroxybutyrate-PHASIX Mesh) in a Porcine Model of Hernia Repair. ISRN Surg. 2013;2013:238067. **6.** Williams SF, Martin DP, Moses AC. The History of GalaFLEX P4HB Scaffold. Aesthet Surg J. 2016;36(suppl 2):S33-S42. **7.** Scott JR, Deeken CR, Martindale RG, Rosen MJ. Evaluation of a fully absorbable poly-4-hydroxybutyrate/absorbable barrier composite mesh in a porcine model of ventral hernia repair. Surg Endosc. 2016;30(9):3691-3701. **8.** Data generated in a preclinical model. Data may not correlate to performance in humans. **9.** No mesh is indicated for use in infected or contaminated fields. **10.** Baylón K, Rodríguez-Camarillo P, Elías-Zúñiga A, Díaz-Elizondo JA, Gilkerson R, Lozano K. Past, Present and Future of Surgical Meshes: A Review. Membranes (Basel). 2017;7(3):47. **11.** Pineda, Catalina & Giglio, Ross & Gandhi, Riddhi & Sicari, Brian & Londono, Ricardo & Hussey, George & Bartolacci, Joseph & Luque, Lina & Cramer, Madeline & Dziki, Jenna & Crapo, Peter & Badylak, Stephen. (2018). Comparison of the host macrophage response to synthetic and biologic surgical meshes used for ventral hernia repair. Journal of Immunology and Regenerative Medicine. 3. 10.1016/j.regen.2018.12.002. **12.** Vestberg, R., Lecuivre, J., Radlovic, A. et al. A novel self-gripping long-term resorbable mesh providing temporary support for open primary ventral and incisional hernia. J Mater Sci: Mater Med 34, 59 (2023). **13.** K233661 Transorb™ 510(k) **14.** Data on file RDLR3807865.

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