Hernia procedures can be complex.

Choosing the right mesh doesn't have to be.

With over 40,000[1] implants and 36 months of clinical data[2], Phasix™ Mesh offers surgeons and patients a reliable choice for hernia repair.

With rapid tissue ingrowth, longer lasting strength than other bioresorbable mesh,[3] and promising results in complex conditions,[2,4,5] Phasix™ Mesh creates a strong, durable repair with no foreign material left behind.[4,5]

Long term 3-year data

Roth et. al. High risk ventral and incisional hernia repair. 3-year follow-up of 121 complex high risk patients with an average of 2 co-morbidities, range 1-6.

Low recurrence rate[2]

	18 months	36 months
Overall recurrence	**9%**	**15.7%**
Recurrence rate following correct overlap protocol*	**2.5%**	**10%**

*Phasix™ Mesh was to be positioned with edges extending beyond margins of defect by at least 5 cm.

Low surgical site infection[2]

9% at both 18 months and 36 months

Zero mesh removals[2]

in 121 patients in high risk ventral hernia repairs

BD is celebrating over 50[6] years of hernia repair excellence

Experience the difference of the Phasix™ Mesh family, a reliable alternative to permanent mesh.

Over 75,000 implants[7]

9 clinical studies[8]

More than 600 patients studied[8]

Proven clinical outcomes[2,8] out to 3 years

1. Phasix™ Mesh. Data on file. March 14, 2019. **2.** Roth JS, Anthone GJ, Selzer DJ, et al. Prospective evaluation of poly-4-hydroxybutyrate mesh in CDC class I/high-risk ventral and incisional hernia repair: 36-month follow-up. SAGES 2019. **3.** In preclinical testing compared to Bio-A®, Vicyrl® Mesh, and OviTex™ Resorbable Mesh. Data on file. Results may not correlate to clinical performance in humans. **4.** Data on file. Preclinical testing. Data may not correlate to clinical performance in humans. **5.** In preclinical testing compared to Bio-A®, Vicyrl® Mesh, and OviTex™ Resorbable Mesh. Data on file. Results may not correlate to clinical performance in humans. **6.** Data on file. **7.** Data on file. Phasix™ Mesh, Phasix™ ST Mesh, Phasix™ Plug Mesh. March 14, 2019. **8.** Roth JS, et al. Prospective evaluation of poly-4-hydroxybutyrate mesh in CDC class I/high-risk ventral and incisional hernia repair: 18-month follow-up. *Surg Endosc.* 2018 Apr;32(4):1929-1936. Roth JS, et al. Ventral hernia repair with poly-4-hydroxybutyrate mesh. *Surg Endosc.* 2018 Apr;32(4):1689-1694. Buell JF, et al. Initial experience with biologic polymer scaffold (Poly-4-hydroxybutyrate) in complex abdominal wall reconstruction. *Ann Surg.* 2017 Jul;266(1):185-188. Wormer BA, et al. Reducing postoperative abdominal bulge following deep inferior epigastric perforator flap breast reconstruction with onlay monofilament Poly-4-Hydroxybutyrate biosynthetic mesh. *J Reconstr Microsurg.* 2017 Jan;33(1):8-18.Chang EI, et al. Optimizing donor site closure following bilateral breast reconstruction with abdominal-based free flaps. *J Plast Reconstr Aesthet Surg.* 2018 Feb;71(2):269-271. Novitsky YW, et al. Prospective multicenter evaluation of ventral/incisional hernia repair with Poly-4-hydroxybutyrate mesh (*Phasix*™). Presented at AWR 2016. Millikan KW, et al. Outcomes in complex ventral hernia repair with anterior component separation in class III obesity patients. *Am J Surg.* 2018 Mar;215(3):458-461. DeMeester, S. Use of Fully Bioresorbable Poly-4-Hydroxybutyrate Mesh for Reinforcement of Crural Closure During Para-Esophageal Hernia Repair. Presented at SAGES 2018. Lundgren, M.P. et al. Anterior Component Separation and Phasix Mesh Placement with or without Panniculectomy: 175 Patients. Presented at ASC 2019.

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Proven clinical outcomes out to three years

Phasix™ Mesh							
PI	Year	Title	Patients	Mean F/U months	Recurrence	Seroma	Surgical site infection
Roth	2019	Prospective evaluation of poly-4-hydroxybutyrate mesh in CDC class I/high-risk ventral and incisional hernia repair:3-year follow-up	121	36	15.7% Recurrence rate following correct overlap protocol: 10%	6.6%	9.1%
Lundgren	2019	Anterior component separation and Phasix™ Mesh placement with or without panniculectomy	175		15.4%	12%	9%
Roth	2017	Prospective evaluation of poly-4-hydroxybutyrate mesh in CDC class I/high-risk ventral and incisional hernia repair: 18-month follow-up	121	18	9% Recurrence rate following correct overlap protocol: 2.5%	6%	9%
Roth	2017	Ventral hernia repair with poly-4-hydroxybutyrate mesh	31	24	0%	12.9%	0%
Chang	2017	Optimizing donor site closure following bilateral breast reconstruction with abdominal-based free flaps	66	N/R	N/R	Phasix™ 0%, Polypropylene mesh 10%, Primary closure 16.7% (*p<0.05*)	N/R
Wormer	2016	Reducing postoperative abdominal bulge following deep inferior: epigastric perforator flap breast reconstruction with onlay monofilament poly-4-hydroxybutyrate biosynthetic mesh	319	16.4±11.1	N/R	Phasix™ 2.5%, No mesh 3.1% (*p Value 0.75*)	Phasix™ 1.3%, No mesh 2.5%, (*p Value 0.45*)
Buell	2016	Initial experience with biologic polymer scaffold (poly-4-hydroxybuturate) in complex abdominal wall reconstruction	73	N/R	Phasix™ 6.5% Strattice™ 23.8% (*p Value 0.049*)	Time to drain removal: Phasix™ 10 days, Strattice™ 14 days (*p Value 0.002*)	Phasix™ 12.9%, Strattice™ 31.0 (*p Value 0.073*)
Novitsky	2016	Prospective multicenter evaluation of ventral/incisional hernia repair with poly-4-hydroxybutyrate mesh (*Phasix™*)	25	18.3±2.1	4%	4%	8%
Roth	2016	Phasix™ prospective vs. Strattice™ and permanent synthetic retrospective arms	126	24 months	Phasix™ 0% Uncoated biologics 18%, Permanent synthetics 8%	13%	0%

Indications for use (*U.S.*)
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.

Indications for use (*EU*)
Phasix™ Mesh is indicated to reinforce soft tissue where weakness exists in patients undergoing abdominal plastic and reconstructive surgery, or for use in procedures involving soft tissue repair of ventral or inguinal hernias, or other abdominal 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 bowel or viscera.
2. Device manufacture involves exposure to tetracycline hydrochloride and kanamycin sulfate. The safety and product use for patients with hypersensitivities to these antibiotics is unknown. Use of this device in susceptible patients with known allergies to tetracycline hydrochloride or kanamycin sulfate should be avoided.
3. The safety and effectiveness of Phasix™ Mesh in the following applications has not been evaluated or established:
   a. Pregnant women
   b. Pediatric use
   c. Neural and cardiovascular tissue
4. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the device.
5. To prevent recurrences when repairing hernias, the Phasix™ Mesh must be large enough to provide sufficient overlap beyond the margins of the defect Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue.

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 inserts for any indications, contraindications, hazards, warnings, precautions, and instructions for use.

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DAV/PHSX/0319/0295