Phasix™ Mesh Family

Committed partner. Full portfolio. Backed by data.

Experience the difference of a reliable alternative to permanent mesh

Phasix™ Mesh family highlights

Over 153,000 implants globally[1]

More than 10 clinical studies[2]

More than 950 patients studied[2]

Proven clinical outcomes[2]

Phasix™ Mesh

PI	Year	Title	Patients	Mean follow-up (months)	Recurrence	Seroma	Surgical site infection
Buell	2021	Long-term outcomes in complex abdominal wall reconstruction repaired with absorbable biologic polymer scaffold (poly-4-hydroxybuturate)	Phasix™ Mesh 31, Strattice™ 42	60	Phasix™ Mesh 12.9%, Strattice™ 38.1% (p = 0.017)	N/A	Phasix™ Mesh 12.9%, Strattice™ 31.0% (p = 0.071)
Roth	2021	Prospective, multicenter study of P4HB (Phasix™) mesh for hernia repair in cohort at risk for complications: 3 year follow-up	82	36	17.9%	6.6%	9.3%
Levy/Spector	2020	Poly-4-hydroxybutyrate (Phasix™) mesh onlay in complex abdominal wall repair	105	36	17%	6%	5%
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%	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 abdominalbased free flaps	66	NR	NR	Phasix™ Mesh 0%, Polypropylene mesh 10%, Primary closure 16.7% (p<0.05)	NR

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Phasix™ Mesh (cont.)							
PI	**Year**	**Title**	**Patients**	**Mean follow-up (months)**	**Recurrence**	**Seroma**	**Surgical site infection**
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	NR	Phasix™ Mesh 2.5%, No mesh 3.1% (p = 0.75)	Phasix™ Mesh 1.3%, No mesh 2.5%, (p = 0.45)
Buell	2016	Initial experience with biologic polymer scaffold (poly-4-hydroxybuturate) in complex abdominal wall reconstruction	73	NR	Phasix™ Mesh 6.5%, Strattice™ 23.8% (p = 0.049)	Time to drain removal: Phasix™ Mesh 10 days, Strattice™ 14 days (p = 0.002)	Phasix™ Mesh 12.9%, Strattice™ 31.0% (p = 0.073)
Novitsky (Poster)	2016	Prospective multicenter evaluation of ventral/incisional hernia repair with poly-4-hydroxybutyrate mesh (Phasix™)	25	18.3±2.1	4%	4%	8%
Roth (Poster)	2016	Phasix™ prospective vs. Strattice™ and permanent synthetic retrospective arms	126	24 mo.	Phasix™ Mesh 0%, Uncoated biologics 18%, Permanent synthetics 8%	Phasix™ Mesh 13%, Uncoated biologics 21%, Permanent synthetics 4%	Phasix™ Mesh 0%, Uncoated biologics, 18%, Permanent synthetics 18%
Phasix™ ST Mesh							
PI	**Year**	**Title**	**Patients**	**Mean follow-up (months)**	**Recurrence**	**Seroma**	**Surgical site infection**
Abdelmoaty/ DeMeester	2019	Combination of Surgical Technique and Bioresorbable Mesh Reinforcement of the Crural Repair Leads to Low Early Hernia Recurrence Rates with Laparoscopic Paraesophageal Hernia Repair	50	12	8%	NR	NR
Tonucci	2019	Safety and Efficacy of Crura Augmentation with Phasix ST Mesh for Large Hiatal Hernia: 3-Year Single-Center Experience	73	17	3.2%	NR	NR

1. Data on file. Phasix™ Mesh, Phasix™ ST Mesh, Phasix™ Plug, Phasix™ ST Mesh with Open Positioning System, and Phasix™ ST Mesh with Echo 2™ Positioning System. As of February 28, 2021. **2.** Available upon request.

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.** Phasix™ Mesh must not be put in direct contact with bowel or viscera. 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. 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. 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. 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.

Phasix™ ST Mesh Indications. Phasix™ ST Mesh is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as for the repair of hernias, including hiatal hernias. **Contraindications.** Because Phasix™ ST Mesh is fully resorbable, it should not be used in repairs where permanent wound or organ support from the mesh is required. **Warnings.** 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 patients with known allergies to tetracycline hydrochloride or kanamycin sulfate should be avoided. Ensure proper orientation; the coated side of the prosthesis should be oriented against the bowel or sensitive organs. Do not place the uncoated mesh side against the bowel. There is a risk for adhesion formation or erosions when the uncoated mesh side is placed in direct contact with the bowel or viscera. (Reference Surface Orientation section.) The safety and effectiveness of Phasix™ ST Mesh in bridging repairs has not been evaluated or established. The use of any synthetic mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh and it is not recommended. 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 mesh. For hiatal hernia repair, the use of Phasix™ ST Mesh circumferentially around the esophagus is not recommended. For hiatal hernia repair, the use of Phasix™ ST Mesh to bridge the hiatus is not recommended. The safety and effectiveness of Phasix™ ST Mesh in the following applications has not been evaluated or established: Pregnant women, Pediatric use, Neural and Cardiovascular tissue. **Precautions.** The safety and effectiveness of Phasix™ ST Mesh has not been evaluated in the presence of malignancies in the abdominopelvic cavity. **Adverse Reactions.** In preclinical testing, Phasix™ ST 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, seroma, adhesion, hematoma, pain, infection, inflammation, allergic reaction, hemorrhage, extrusion, erosion, migration, fistula formation, and recurrence of the hernia or soft tissue defect. Possible complications in hiatal hernia repair may include esophageal erosion and dysphagia related to crural fibrosis.

Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions and instructions for use.

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