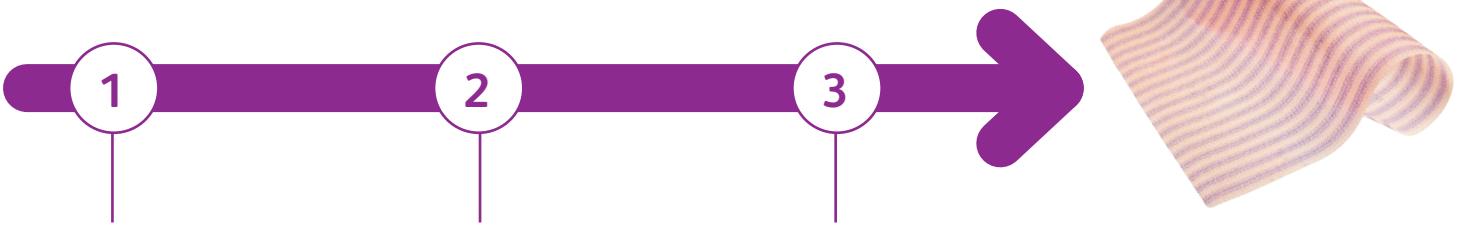
Clinical overview of hiatal hernia repair

The evolution of hiatal hernia repair



Primary suture closure

- High recurrence rates evaluated[1]
- **Range of recurrences: 22–59%[2,3]**

Permanent synthetic mesh

- Risk of esophageal erosion and mesh shrinkage[4]
- **Range of recurrences: 0–43%[5]**

Biologic mesh

- High recurrence rates with high cost[1]
- **Range of recurrences 54–56%[3,5]**

Phasix™ ST Mesh

Surgeons need a material that provides a repair without long-term mesh complications

- Early clinical results indicate a strong repair[4] and early remodeling[6]

Table 1: Studies evaluating recurrence of PEH after hernia repair

PI	Year	Title	Patients	Mesh	Follow-up	Recurrences and timing	Recurrences defined as	Mesh complications
Watson	2019	Five year follow-up of a randomized controlled trial of laparoscopic repair of very large hiatus hernia with sutures versus absorbable versus nonabsorbable mesh.	126	Primary suture, Surgisis® and TiMesh™	Clinical: 5 years Objective: 3–4 years	Primary suture: 39% Surgisis®: 56% TiMesh™: 43% • During first 6 months, 23% were found in primary suture repairs	Any amount of stomach above diaphragm	**SIS biologic:** Esophageal perforation **Permanent:** Gastric perforation
Galvani	2016	Robotic-assisted paraesophageal hernia repair: initial experience at a single institution.	61	Gore® Bio-A®	Median 24 months	42% within 24 months	Unknown	None

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Table 1: Studies evaluating recurrence of PEH after hernia repair (cont.)

PI	Year	Title	Patients	Mesh	Follow-up	Recurrences and timing	Recurrences defined as	Mesh complications
Oelschlager	2011	Biologic prosthesis to prevent recurrence after laparoscopic paraesophageal hernia repair: long-term follow-up from a multicenter, prospective, randomized trial	60	Primary suture and Surgisis®	4.8 years	Primary suture: 59% Surgisis®: 54% • During first 6 months, 24% were found in primary suture repairs	Recurrences defined as >2 cm of stomach above diaphragm	None
Granderath	2005	Laparoscopic nissen fundoplication with prosthetic hiatal closure reduces postoperative intrathoracic wrap herniation.	100	Primary suture and polypropylene	1 year	Primary suture: 26% Polypropylene: 8%	Unknown	None
Frantzides	2002	A prospective, randomized trial of laparoscopic polytetrafluoroethylene (PTFE) patch repair vs. simple cruroplasty for large hiatal hernia.	72	Primary suture and PTFE	3.3 ± 1.7 years; median 2.5 years	Primary suture: 22% PTFE: 0% within first 6 months	Symptomatic, unknown unit of measure	None

Table 2: Studies evaluating recurrence of PEH using Phasix™ ST Mesh

PI	Year	Title	Patients	Follow-up	Recurrences and timing	Recurrences defined as	Mesh complications
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	1 year	8% (4 patients) within 1 year	Any amount of stomach above diaphragm	None
Tonucci	2019	Safety and efficacy of crura augmentation with Phasix™ ST Mesh for large hiatal hernia: 3 year single-center experience	73	Median 17 months	3.2% (2 patients) 12 and 16 months	>2 cm of stomach above diaphragm	None

1. Kohn GP, et al. Guidelines for the management of hiatal hernia. *Surg Endosc.* 2013 Dec;27(12):4409-28. **2.** Frantzides, C, et al. A prospective, randomized trial of laparoscopic polytetrafluoroethylene (PTFE) patch repair vs. simple cruroplasty for large hiatal hernia. *Archives of Surgery.* 2002, 137(6), pp.649-652. **3.** Oelschlager, B, et al. Biologic prosthesis to prevent recurrence after laparoscopic paraesophageal hernia repair: long-term follow-up from a multicenter, prospective, randomized trial. *American College of Surgeons.* 2011, 213(6). **4.** DeMeester, Steven R, et al. Combination of surgical technique and bioresorbable mesh reinforcement of the crural repair leads to low early hernia recurrence rates with laparoscopic paraesophageal hernia repair. *J Gastrointest Surg.* 2020, Jul;24(7):1477-1481. **5.** Watson, D, et al. Five year follow-up of a randomized controlled trial of laparoscopic repair of very large hiatus hernia with sutures versus absorbable versus nonabsorbable mesh. *Annals of Surgery.* 2019. **6.** Preclinical data on file; results may not correlate to clinical performance in humans.

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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