Phasix™ ST Mesh

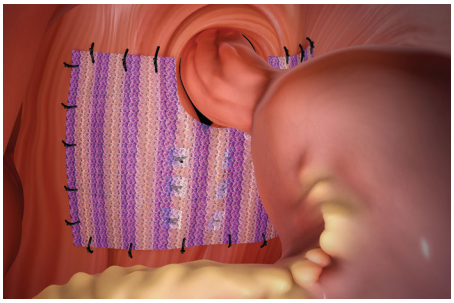
Hiatal hernia

The only bioresorbable mesh with a proven hydrogel barrier for hiatal hernia repair

Phasix™ ST Mesh combines two market-leading technologies into one product: monofilament bioresorbable Phasix™ Mesh and a proven hydrogel barrier based on Sepra® technology. Phasix™ ST Mesh supports functional healing, resulting in a strong remodeled repair.[1,2,3]

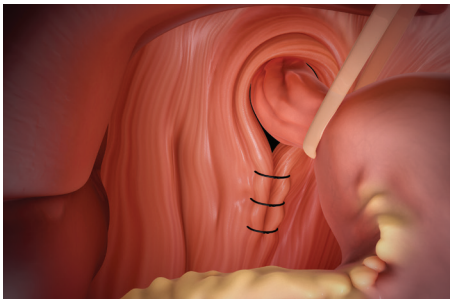
Benefits of Phasix™ ST Mesh for laparoscopic or robotic procedures:

- Low-profile design facilitates trocar deployment during laparoscopic placement
- Handles, sutures and fixates like a synthetic mesh
- Extensively studied hydrogel barrier—more than 10 published studies



Designed to reinforce and conform to the crural repair in hiatal hernia procedures

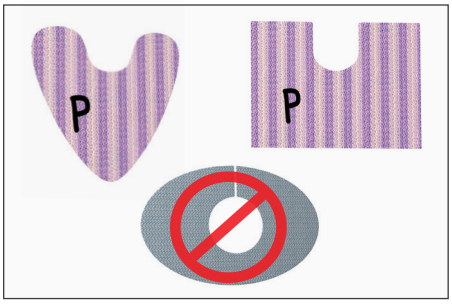
Closure of crura



The crural defect should be closed using the surgeon's preferred method, while also ensuring it is not too tight around the esophagus.

Note: For hiatal hernia repair, the use of Phasix™ ST Mesh to bridge the hiatus is not recommended.

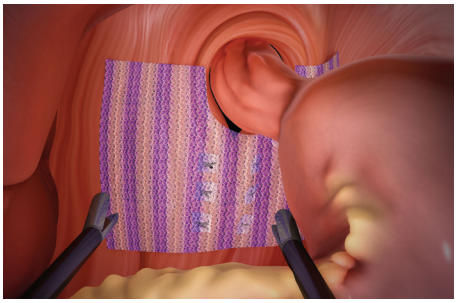
Cut and hydrate



While dry, cut the Phasix™ ST Mesh to size based on surgeon preference, anatomical requirements, and to provide sufficient overlap of the defect. Mark the barrier side for orientation. Quickly dip to hydrate the mesh and introduce through the trocar with the uncoated mesh side facing out.

Note: For hiatal hernia repair, the use of Phasix™ ST Mesh circumferentially around the esophagus is not recommended.

Placement



Place Phasix™ ST Mesh with the uncoated mesh side toward the crura and the barrier facing out toward the abdominal cavity. Phasix™ ST Mesh should be placed over the closed crural defect with sufficient overlap of the defect.

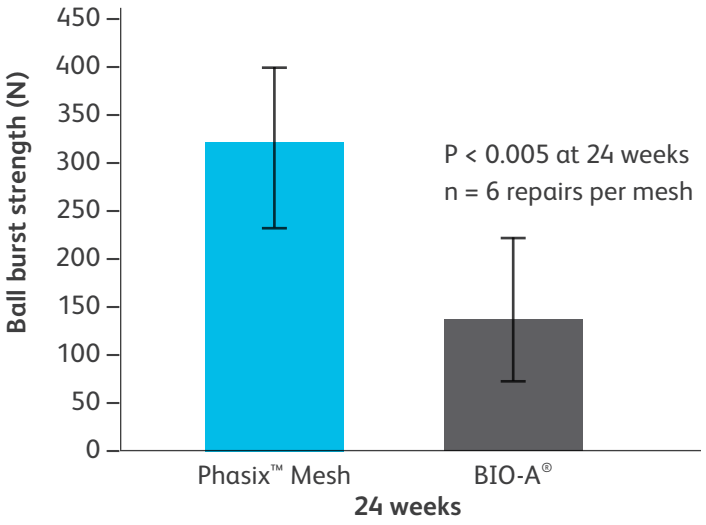
Proven technology that remodels like a biologic with the strength of a synthetic

Preclinical data[1,2]

Methods: BIO-A® Tissue Reinforcement and Phasix™ Mesh were implanted into the retromuscular of the porcine abdominal wall model and fixated over closed muscular defects. Burst strength testing was performed at 24 weeks.

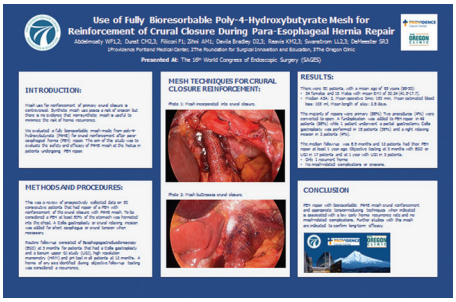
Results: Phasix™ Mesh repairs were significantly stronger than BIO-A® repairs at 24 weeks.

2.3x strength of Bio-A® at **24** weeks



Preliminary clinical data suggests[3,4]

ZERO mesh related complications and **ONE** recurrent hernia


Use of Fully Bioresorbable Poly-4-Hydroxybutyrate Mesh for Reinforcement of Crural Closure During Para-Esophageal Hernia Repair

INTRODUCTION:

METHODS AND PROCEDURES:

MESH TECHNIQUES FOR CRURAL CLOSURE REINFORCEMENT:

RESULTS:

CONCLUSION

Prospective evaluation of Phasix™ ST Mesh in hiatal hernia repair

Dr. Steven DeMeester, MD

Interim review of 50 patients with 8.5 month follow-up

*One year follow-up to come

Results: 50 patients, with a mean age of 65 years *(98–30)*:

- 34 females and 16 males with mean BMI of 30.24 *(41.5–17.7)*.
- Median ASA: 2, mean operative time: 150 min, mean estimated blood loss: 103 mL, mean length of stay: 2.8 days. The majority of repairs were primary *(88%)*. Two procedures *(4%)* were converted to open. A fundoplication was added to PEH repair in 49 *(98%)* patients while one patient underwent a partial gastrectomy. Collis gastroplasty was performed in 18 patients *(36%)* and a right relaxing incision in two patients *(4%)*. The median follow-up was 8.5 months and 12 patients had their PEH repair at least one year ago. Objective testing at three months with EGD or UGI in 17 patients and at one year with UGI in three patients.
- Only one recurrent hernia.
- No mesh-related complications or erosions.

1. Preclinical data on file; results may not correlate to clinical performance in humans. **2.** Deeken, CR., Badhwar A, Gagne DH. Comparison of the mechanical properties of two fully resorbable meshes in a porcine model. Presented at ASR 2016. **3.** DeMeester, SR, et al. Use of fully bioresorbable poly-4-hydroxybutyrate mesh for reinforcement of crural closure during para-esophageal hernia repair. Presented at SAGES 2018. **4.** The data represents unpublished preliminary results of a small, single-institution, single-surgeon, non-randomized study.

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 of the instructions for use)*. 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 the 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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