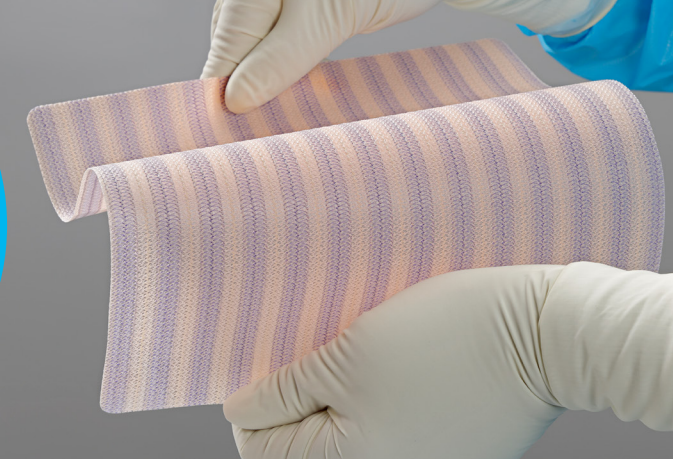
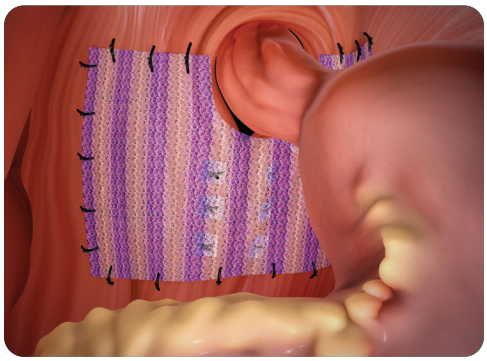
Phasix™ ST Mesh for hiatal hernia repair

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

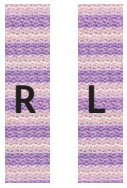


Hiatal hernia repair options have evolved over the years with the primary goal of a long-term repair.

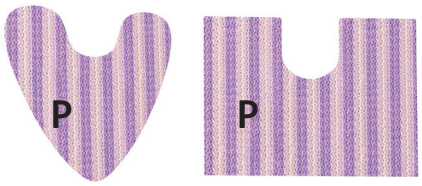
Since 2018 Phasix™ ST Mesh has been indicated for use in the reinforcement of soft tissue, where weakness exists.



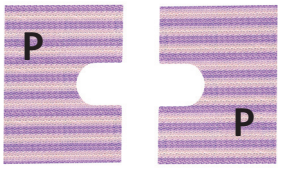
Cut mesh for customization



Pledgets



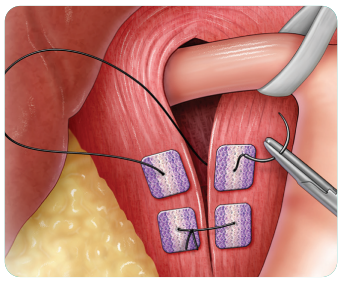
Heart or U shape

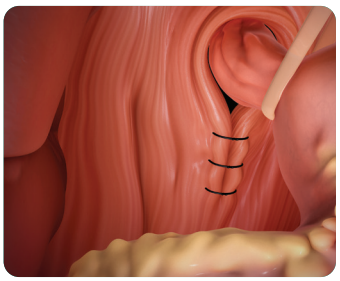


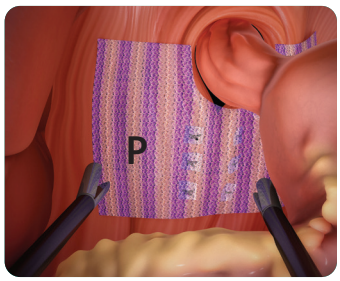
C Shape or Reverse C shape

Placing mesh

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







Closure of crura

Phasix™ ST Mesh boasts 15 publications relating to use in hiatal hernia repairs, two of which address outcomes up to five years.

Changing the standard of hiatal hernia care since 2018.

BD

Authors, Article Title, Journal, Year	Product	Patients	Mean Follow-up (months)	Recurrence	QOL*
McKay SC, et. al. Five-Year Outcomes from a Prospective Study on the Safety and Efficacy of Phasix-ST Mesh Use at the Hiatus During Paraesophageal Hernia Repair. *J Am Coll Surg.* Published online April 24, 2024	Phasix™ ST	50	60	25%	
Panici Tonucci T, et.al., Does crural repair with biosynthetic mesh improve outcomes of revisional surgery for recurrent hiatal hernia? *Hernia.* Published online March 29, 2024.	Phasix™ ST Mesh	104 (60- Phasix™ Mesh)	55	20.2%	✓
Aiolfi A, et. al. Medium-term safety and efficacy profile of paraesophageal hernia repair with Phasix-ST mesh: a single-institution experience. *Hernia.* 2022 Feb;26(1):279-286.	Phasix™ ST Mesh	68	27	8.8%	✓
Clapp, B., et.al. Does bioabsorbable mesh reduce hiatal hernia recurrence rates? A meta-analysis. *Surg Endosc.* 2023 Mar;37(3):2295-2303.	Phasix™ ST Mesh	963 (73 Phasix™ ST)	27	8.0%	✓
K S Viswanath, Yirupaiahgari. Giant Hiatal Hernia and P4HB Phasix™ ST Mesh Hiatoplasty Outcomes. Clinical research and clinical trials, 2024.	Phasix™ ST Mesh	44	24	9.1%	
Panici Tonucci et. al. Safety and Efficacy of Crura Augmentation with Phasix™ ST Mesh for Large Hiatal Hernia: 3-Year Single-Center Experience. *J Laparoendosc Adv Surg Tech A.* 2020 Apr;30(4):369-372.	Phasix™ ST Mesh	73	17	3.2%	
Siemssen B, et. al.,. Medium term (> 12 months) outcomes after laparoscopic hiatal hernia repair without conventional fundoplication using PH4B-mesh implant (Phasix™) in 176 reflux patients: experience and technique. *Hernia.* 2024 Oct;28(5):1641-1647.	Phasix™	176	22	3%	✓
Aiolfi A., et. al. Laparoscopic posterior cruroplasty: a patient tailored approach. *Hernia.* 2022 Apr;26(2):619-626.	Phasix™ Mesh	Phasix™ ST Mesh: 39 No Mesh: 102	21	2.1%	
Konstantinidis H, et. al., Surgical treatment of large and complicated hiatal hernias with the new resorbable mesh with hydrogel barrier (Phasix™ ST): a preliminary study. *J Robot Surg.* 2023 Feb;17(1):141-146.	Phasix ST™ Mesh	60	21	0.0%	
Fair, L., et al. Coated poly-4-hydroxybutyrate (Phasix™ ST) mesh is safe and effective for hiatal hernia repair: our institutional experience and review of the literature. Surgical Endoscopy 2023	Phasix ST™ Mesh	230/221	20 +/- 14.6	4.8 %/ 8.8%	✓
Aiolfi, A.,.et. Al. Patient-tailored algorithm for laparoscopic cruroplasty standardization: comparison with hiatal surface area and medium-term outcomes. *Langenbecks Arch Surg.* 2022 Sep;407(6):2537-2545.	Phasix ST™ Mesh	Phasix™ ST Mesh: 23 No Mesh: 27	18.6	12%	✓
Panici Tonucci et. al. Safety and Efficacy of Crura Augmentation with Phasix™ ST Mesh for Large Hiatal Hernia: 3-Year Single-Center Experience. *J Laparoendosc Adv Surg Tech A.* 2020 Apr;30(4):369-372.	Phasix ST™ Mesh	73	17	3.2%	
Abdelmoaty, W. 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.**	Phasix ST™ Mesh	50	12	8.0%	
Ukegjini, K, et. al, Hiatus hernia repair with a new-generation biosynthetic mesh: a 4-year single-center experience. *Surg Endosc.* 2023 Jul;37(7):5295-5302.	Phasix ST™ Mesh	97	12	13.0%	
Salehi N, et al. Comparative anatomic and symptomatic recurrence outcomes of diaphragmatic suture cruroplasty versus biosynthetic mesh reinforcement in robotic hiatal and paraesophageal hernia repair. *Surg Endosc.* 2024 Nov;38(11):6476-6484.	Phasix™ ST	503	12	Phasix 17.2% Suture 42.2%	

These articles are organized by longest to shortest term follow up.

Revision date: January 10,2025

*** QOL= Quality of Life**

**** BD funded**

Phasix™ ST Mesh INDICATIONS: Phasix™ ST Mesh is indicated for use in the reinforcement of abdominal soft tissue, where weakness exists, in ventral and hiatal hernia repair procedures. 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: 1.Mesh 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 mesh in patients with known allergies to tetracycline hydrochloride or kanamycin sulfate should be avoided. 2. Ensure proper orientation; the coated side of the mesh 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.) 3. The safety and effectiveness of Phasix™ ST Mesh in bridging repairs has not been evaluated or established. 4. The safety and effectiveness of Phasix™ ST Mesh in laparoscopic/robotic ventral hernia repair procedures has not been evaluated or established. 5. The use of any 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. 6. 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. 7. To prevent recurrences when repairing hernias, 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. 8. For hiatal hernia repair, the use of Phasix™ ST Mesh circumferentially around the esophagus is not recommended. 9. For hiatal hernia repair, the use of Phasix™ ST Mesh to bridge the hiatus is not recommended. 10. The safety and effectiveness of Phasix™ ST Mesh in the following applications has not been evaluated or established: a. Pregnant or breastfeeding women b. Pediatric use 11. Product should be used once exterior foil pouch has been opened. Do not store for later use. 12. Unused portions of the mesh should be discarded. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard mesh with care to prevent risk of transmission of viral and other infections. 13. This mesh is designed for single use only. Reuse, resterilization, reprocessing and/or repackaging of any portion of the Phasix™ ST Mesh 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 meshfailure 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. 14. This 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. 15. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 16. This mesh is not for the use of treatment of stress urinary incontinence. 17. This mesh is not for use of repair of neural and cardiovascular tissue. 18. Phasix™ ST 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 strength and mesh size requirements. Improper selection, placement, positioning and fixation of the mesh can cause subsequent undesirable results. 3. The safety and effectiveness of the mesh has not been evaluated in the presence of malignancies in the abdominopelvic cavity. 4. The safety and effectiveness of Phasix™ ST Mesh in the proximity of existing or excised cancer has not been established. 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 note, not all products, services or features of products and services may be available in your local area. Please check with your local BD representative and consult package insert for more detailed safety information and instructions for use.

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