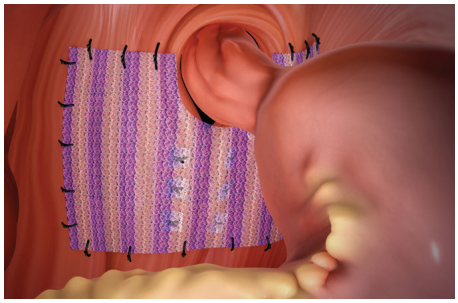
Phasix™ ST Mesh

Hiatal hernia

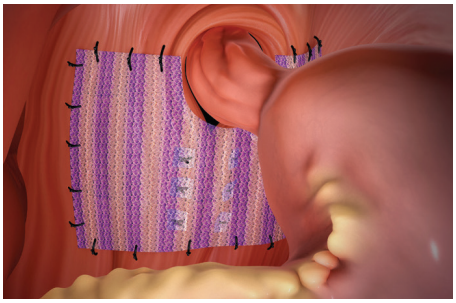
A durable repair without permanent material[1,2]

Phasix™ ST Mesh with a proven hydrogel barrier for hiatal hernia repair

Phasix™ ST Mesh combines two technologies into one product: monofilament bioresorbable Phasix™ Mesh and a proven hydrogel barrier based on Sepra Technology.[3] Phasix™ ST Mesh provides a durable scaffold for soft tissue repair.[4]



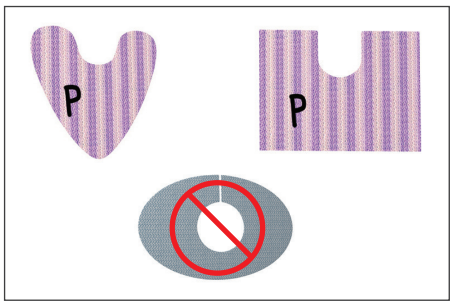
Designed to reinforce and conform to the crural repair in hiatal hernia procedures[3]



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 oesophagus.[5,6]

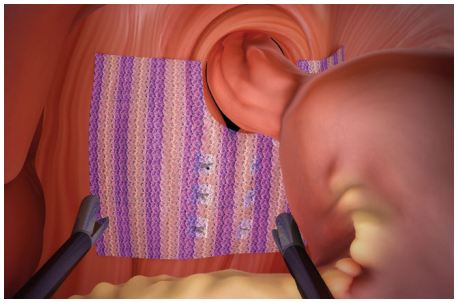
Note: The use of Phasix™ ST Mesh in bridging repairs has not been clinically evaluated. Every effort should be made to close the crural defect prior to use.[3]



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. Hydrate the mesh in saline for 1-3 seconds (laparascopic only) and introduce through the trocar with the uncoated mesh side facing out.[3]

Note: For hiatal hernia repair, the use of Phasix™ ST Mesh circumferentially around the oesophagus is not recommended.[3]



Placement

Phasix™ ST Mesh should be used to buttress the primary closure of a crural defect.

Place the resorbable, hydrogel coated side of the prosthesis against those surfaces where minimal tissue attachment is desired, i.e., against bowel or other visceral structures.

Phasix™ ST Mesh should be placed over the margins of the defect with sufficient overlap beyond the margins, and to fit patient's anatomy.[3,6]

BD

Phasix™ ST Mesh - clinical data in paraesophageal hernias (PEH)[5,6]

Studies evaluating recurrence of PEH using Phasix™ ST Mesh

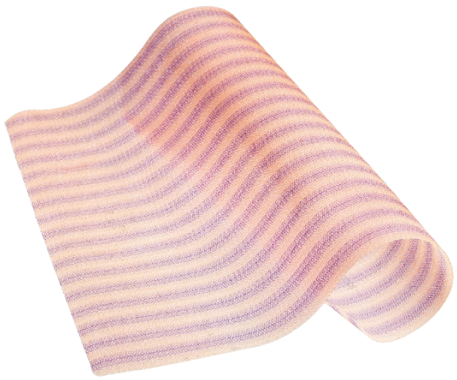
Author	Year	Title	Patients	Follow-Up	Recurrences and timing	Mesh complications
DeMeester, et al.[5]	2019	Combination of surgical technique and bioresorbable mesh reinforcement of the crural repair leads to low early hernia recurrence rates with laparoscopic paraesophageal hernia repair	50	1 year	8% (4 patients) within 1 year	None
Tonucci, et al.[6]	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	None

* Recurrence was defined as any size hernia identified on postoperative barium upper gastrointestinal study (UGI) or oesophago-gastro-duodenoscopy (EGD).[5]

** Recurrence was defined as the maximal length of stomach >2cm above the diaphragmatic impression at endoscopy and/or barium swallow study.[6]

Product codes

Product Code	Shape		Dimensions
1200008	Round	◯	8 cm
1200011	Round	◯	11cm
1200015	Round	◯	15cm
1200710	Rectangle	☐	7cm x 10cm
1201010	Square	☐	10cm x 10cm
1201015	Rectangle	☐	10cm x 15cm
1201020	Rectangle	☐	10cm x 20cm
1201325	Rectangle	☐	13cm x 25cm
1201520	Rectangle	☐	15cm x 20cm
1202025	Rectangle	☐	20cm x 25xm
1202530	Rectangle	☐	25cm x 30cm
1203035	Rectangle	☐	30cm x 35cm



References: 1. Roth JS, Anthone GJ, Selzer DJ, *et al.* Prospective, multicenter study of P4HB (Phasix™) mesh for hernia repair in cohort at risk for complications: 3-Year follow up. Annals of Medicine and Surgery. 2021; 61:1-7. **2.** Martin DP, Badwhar A, Shah DV, et al. Characterization of poly-4-hydroxybutyrate mesh for hernia repair applications. J Surg Research. 2013;184(2):766-773. doi: 10.1016/j.jss.2013.03.044. **3.** Instructions For Use: Phasix™ ST Mesh - A Resorbable Mesh with a Resorbable Hydrogel Coating for Soft Tissue Reconstruction **4.** Deeken CR, Matthews BD. Characterization of the Mechanical Strength, Resorption Properties, and Histologic Characteristics of a Fully Absorbable Material (Poly-4-hydroxybutyrate—PHASIX™ Mesh)in a Porcine Model of Hernia Repair. ISRN Surg. 2013; May 28;2013:238067.doi: 10.1155/2013/238067. **5.** Abdelmoaty WF, Dunst CM, Filicori F, 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;24(7):1477-148. **6.** Tonucci, TP., Asti, E., Sironi, A, *et al.* Safety and Efficacy of Crura Augmentation with Phasix ST Mesh for Large Hiatal Hernia: 3-Year Single-Center Experience. J LapEndo & Adv Surg Tech. 2019; 0: 1-4. DOI: 10.1089/lap.2019.0726.

INDICATIONS. Phasix™ ST Mesh is indicated for use in the 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.** 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. **2.**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.) **3.** The safety and effectiveness of Phasix™ ST Mesh in bridging repairs has not been evaluated or established. **4.** 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. **5.** 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. **6.** To prevent recurrences when repairing hernias, Phasix™ ST Mesh must be large enough to provide sufficient overlap beyond the margins of the repair/primary closure. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. **7.** For hiatal hernia repair, the use of Phasix™ ST Mesh circumferentially around the esophagus is not recommended. **8.** For hiatal hernia repair, the use of Phasix™ ST Mesh to bridge the hiatus is not recommended.**9.**The safety and eff ectiveness of Phasix™ ST Mesh in the following applications has not been evaluated or established:a. Pregnant women b.Pediatric use c.Neural and cardiovascular tissue **10.** Product should be used once exterior foil pouch has been opened. Do not store for later use. **11.** Unused portions of the prosthesis should be discarded. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fl uids, discard mesh with care to prevent risk of transmission of viral and other infections. **12.** This device is provided sterile and has been 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 device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilization, or repackaging may also create a risk of contamination of the device 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 device may lead to injury, illness, or death of the patient or end user. **13.** 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. **14.** When using Phasix™ ST Mesh laparoscopically or robotically in IPOM placement, appropriate surgical technique is recommended to reestablish the fascial integrity of the abdominal wall. As Phasix™ ST Mesh is a bioresorbable mesh, and does not provide permanent wound support, robust fascial closure and management of tension during closure is important to reduce possible hernia recurrence. In the event recurrence is suggested or noted, the clinician should evaluate additional therapeutic or surgical options. **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. **PRECAUTIONS 1.** Please read all instructions prior to use. **2.** Only physicians qualifi ed in the appropriate surgical techniques should use this prosthesis. Users should be familiar with strength and mesh size requirements. Improper selection, placement, positioning and fi xation of the mesh can cause subsequent undesirable results. **3.** The safety and eff ectiveness 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, infl ammation, 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.

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