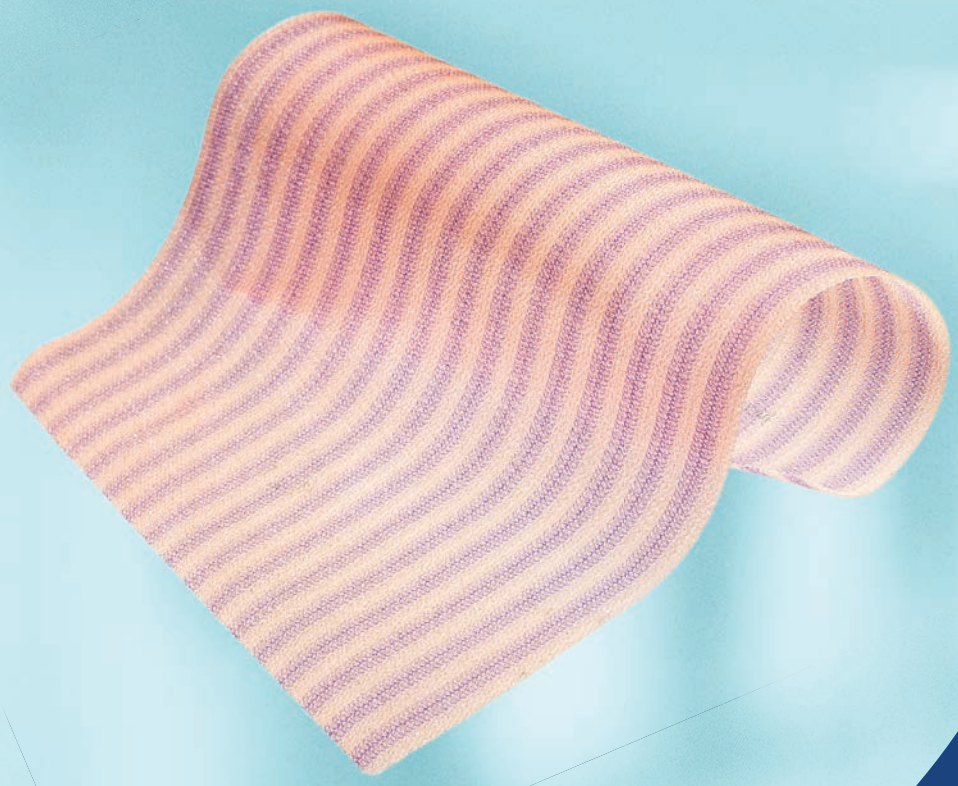


Phasix™ ST Mesh

Natural. Not Permanent. Proven Results.

Bioresorbable scaffold featuring proven Sepra® Technology

BD

Unique mesh design

Phasix™ ST Mesh combines two market-leading technologies into one product: monofilament resorbable Phasix™ Mesh and a proven hydrogel barrier based on Sepra® technology.

Phasix™ Mesh

- Biologically derived monofilament scaffold: Poly-4-hydroxybuterate (P4HB)
- Monomer form (4HB) is a naturally occurring human metabolite found in the brain, heart, liver, kidney, and muscle
- Phasix™ Mesh is backed by multiple 5 year studies, showing durable outcomes.

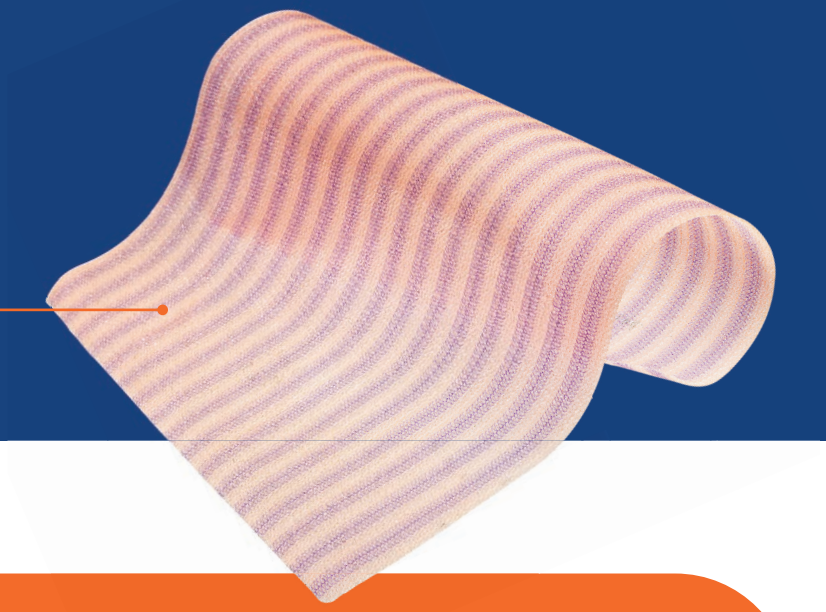
Hydrogel Barrier based on Sepra® Technology

- Hydrogel barrier on posterior side minimizes visceral tissue attachment[1]
- Uncoated P4HB monofilament allows for tissue ingrowth on the anterior side[1]
- Resorbs within 30 days[1]
- Used clinically since 2007

Phasix™ ST Mesh

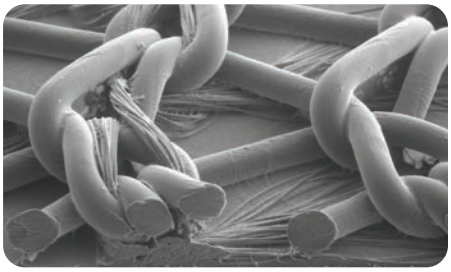
- Handles, sutures and fixates like a synthetic mesh
- Facilitates trocar deployment during laparoscopic placement

Longitudinal stripes aid with orientation and visibility during placement

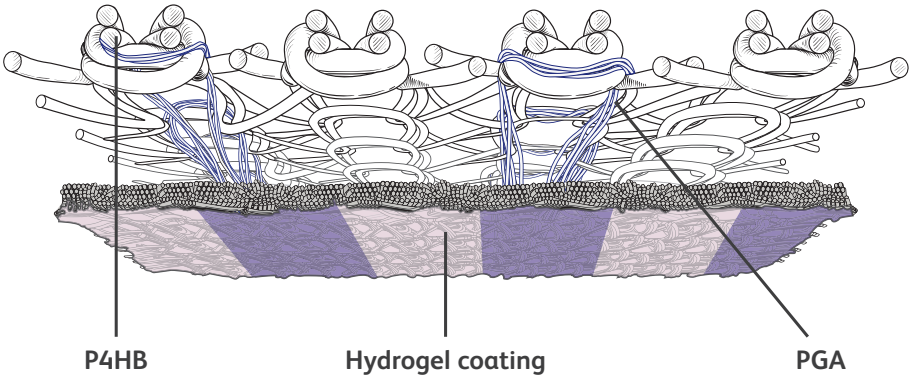


Why monofilament matters

Monofilament mesh designs have been deemed more biocompatible and less susceptible to bacterial adherence and colonization.[2-6]



Phasix™ ST Mesh
Knitted monofilament base P4HB scaffold SEM Photo, 20X



Phasix™ Mesh:
The next phase in hernia repair

Pre-clinical data suggests there are three main components of the Phasix™ Response:

Healthy tissue ingrowth

Predictable durability

Promising results in the presence of bacteria

Healthy tissue ingrowth

Pre-clinical and in vitro testing have shown that Phasix™ Mesh rapidly incorporates while the body naturally initiates an early "repair" response by preferentially up-regulating the anti-inflammatory macrophage.[7, 8, 9]

Pre-clinical data suggests that an early upregulation in anti-inflammatory macrophages leads to a regenerative repair while other materials preferentially up-regulate the pro-inflammatory macrophage leading to fibrosis and encapsulation.[7, 8, 9]

Scan the QR code to see the full mechanism of action of Phasix™ Mesh

*No mesh is indicated for use in contaminated or infected wounds.
Pre-clinical and in vitro data on file. Results may not correlate to clinical performance in humans.

Predictable durability

In pre-clinical models, Phasix™ Mesh rapidly integrated, resulting in a strong functional repair.

Predictable strength for the long run

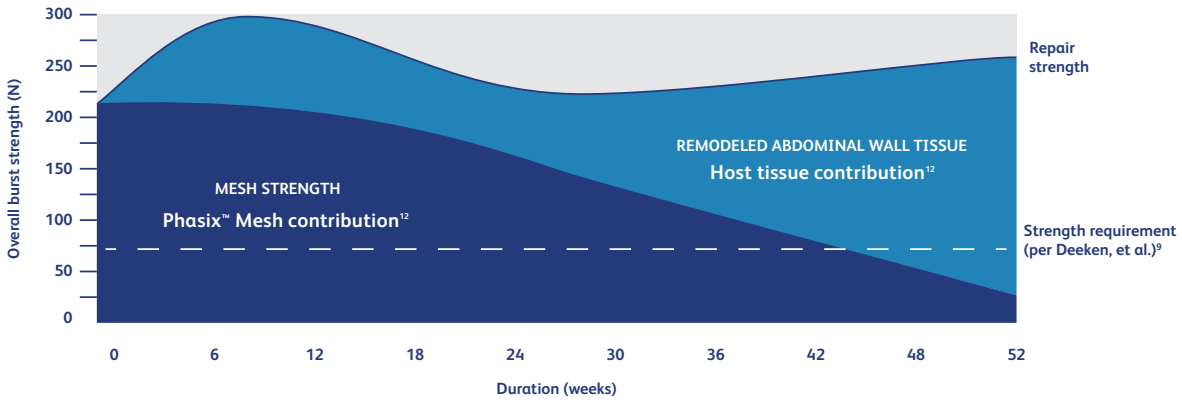
Phasix™ Mesh gradually and predictably degrades within 12 to 18 months via hydrolysis leaving behind a durable, functional repair with over 3x the strength of the native abdominal wall.[10]

Pre-clinical data suggests:

3x strength requirement

Repair strength over time in a 52 Week Pre-clinical Model[11]

Gradual transfer of strength from mesh to functional tissue



Sustained long-term repair strength after Phasix™ Mesh remodels

Study Design: A 3-centimeter round defect was created in the ventral abdominal wall of 25 pigs. Phasix™ Mesh was fixated directly over the defect with SorbaFix™ resorbable tacks. Ball burst testing was conducted at 6, 12, 26, and 52 weeks.

Results: In this porcine model, Phasix™ Mesh total repair strength was more than 3 times the strength required for hernia repair based on pre-clinical testing conducted by Deeken and Matthews.

No mesh is indicated for use in contaminated or infected wounds.
Pre-clinical and in vitro data on file. Results may not correlate to clinical performance in humans.

Promising results in the presence of bacteria

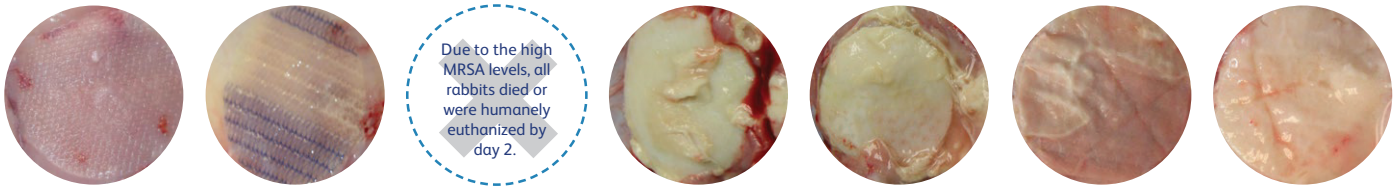
In pre-clinical testing, Phasix™ Mesh has demonstrated promising results in the presence of MRSA. As degradable mesh is remodeled, the body naturally responds by producing antimicrobial peptides (AMPs). Traditionally, immunology studies link AMP's to fighting bacteria.[13, 14]

Bacteria colonization 7 days post inoculation in preclinical testing[10]

Pockets with recoverable bacteria (%)

No presence of bacterial colonization observed in Phasix Mesh™ or Phasix™ ST Mesh.[14,15,16,17]

Presence of abscess (white material) observed in SurgiMend®*, Strattice™, Bio-A®, and OviTex™. Other observed indications of bacterial colonization included swelling, presence of fluids, and thickened capsule tissue.[14,15,17]



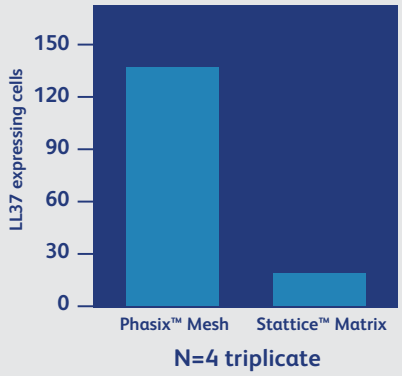
0%	0%	N/A	100%	80%	100%	100%
Phasix™ Mesh[a]	Phasix™ ST Mesh[a]	SurgiMend®[a]	Strattice™[a] $p < 0.05$	Bio-A®[a] $p < 0.05$	OviTex™ Permanent 1S[b] $p < 0.05$	OviTex™ Resorbable 1S[b] $p < 0.05$

a $5x10^{18}$ inoculation of MRSA, N=5 rabbits

b $1x10^{6}$ inoculation of MRSA, N=5 rabbits

(%) Percentage of recoverable bacteria **No mesh is indicated for use in an infected or contaminated field.**

Antimicrobial Peptide Expression — Day 7*



N=4 triplicate

Figure 2: The study was performed in a rat abdominal partial thickness defect model. Strattice™ Matrix and Phasix™ Mesh were explanted at 7 days and the mesh and surrounding tissue was analyzed histologically. AMPs were immunofluorescently labeled, and counted.

No mesh is indicated for use in contaminated or infected wounds.
Pre-clinical and in vitro data on file. Results may not correlate to clinical performance in humans.

Follow the data to a new standard of care

Phasix™ Mesh

New Standard of Care

- Expert consensus panel established that a bioabsorbable mesh should be the standard of care for hernias.*[19]
- Roth, et.al have shown that long term outcomes with Phasix™ Mesh showed results similar to permanent mesh.[20]

Patient Quality of Life

- 5-year outcomes have shown that patient quality of life following hernia repair with Phasix™ Mesh can improve immediately and continues to improve up to 5 years following repair. Concluding that quality of life should be the primary outcomes of success.[18]

Cost savings

- Budget impact analysis has shown Phasix™ Mesh may result in a decrease in the total hospital budget of about $158.87 million, with a savings per patient of about $799.55.[21]
- Phasix™ Mesh also results in $9,570 savings per case when compared to Strattice™ Matrix.[11]

See the full growing body of clinical evidence

*Grade 2-3
Conversion rate based on 1£=$1.08, original savings: Total hospital £153 million, per patient £770.

Commonly used mesh

Surgeons have had to choose between permanent synthetic meshes and biologic grafts — and their inherent pros and cons.

Permanent synthetic meshes

- Easy to use[24]
- Reduced recurrence vs. primary closure
- Can also be used robotically and laparoscopically
- Postoperative complications can lead to mesh removal or reoperation[25]

Phasix™ ST Mesh

A biologically derived scaffold with a hydrogel barrier for intraabdominal placement that is bioabsorbable. It has been designed to provide the repair strength of a synthetic mesh and the remodeling characteristics of a biologic.

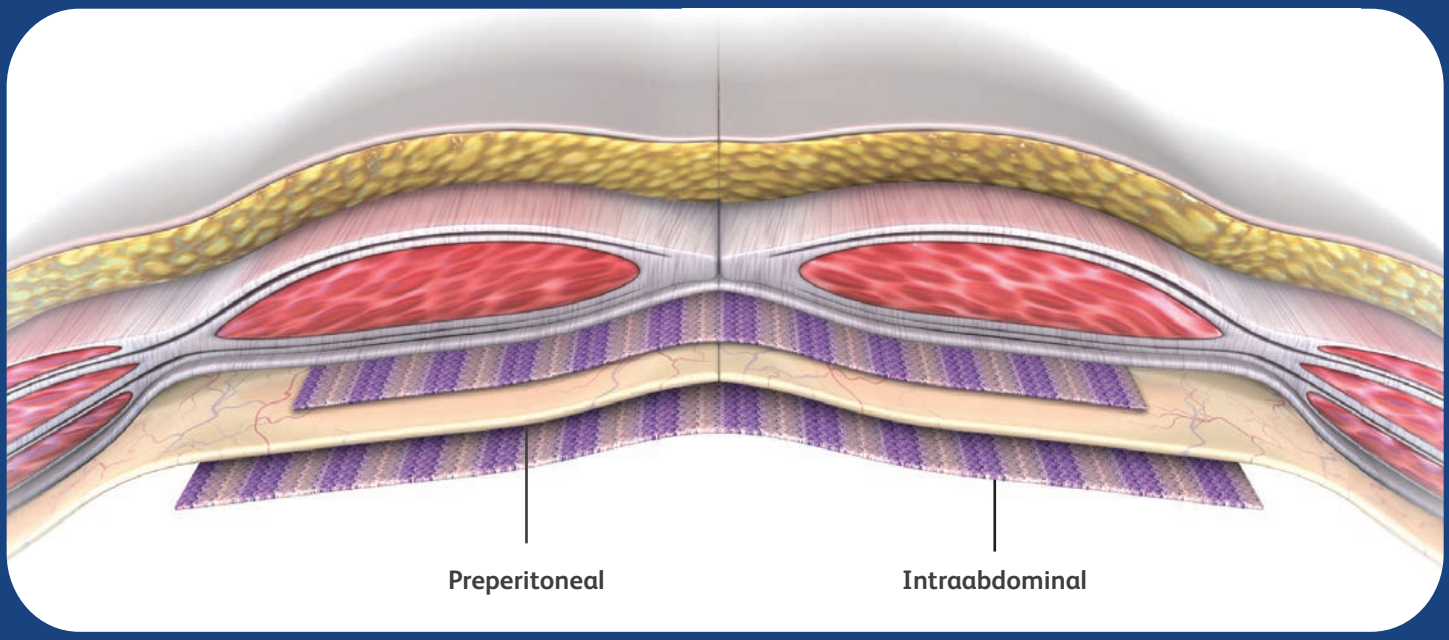
Biologic grafts

- Naturally derived material
- Potentially reduces need for mesh removal if a complication occurs[26]
- Accelerated degradation in the presence of bacteria may lead to mesh failure/ higher recurrence rate[27,28]
- Some biologics may be difficult to fixate and handle[2]

Phasix™ ST Mesh may be placed in either an intraabdominal or preperitoneal position after primary hernia defect closure. Primary hernia defect closure should be achieved prior to placing the mesh.

Hernia defect closure can be achieved through an open or minimally invasive approach (i.e., laparoscopic, robotic). Recent studies suggest potential advantages of defect closure include:[22,23]

- Decreased "dead" space, which can reduce the risk of postoperative seromas
- May contribute to restoration of a functional abdominal wall
- May reduce postoperative bulging at the hernia defect site



Product codes Phasix™ ST Mesh

Product code	Shape	Dimensions
1200008G	Round	8 cm *(3")*
1200011G	Round	11 cm *(4.5")*
1200015G	Round	15 cm *(6")*
1200710G	Rectangle	7 cm x 10 cm *(3" x 4")*
1201010G	Square	10 cm x 10 cm *(4" x 4")*
1201015G	Rectangle	10 cm x 15 cm *(4" x 6")*
1201020G	Rectangle	10 cm x 20 cm *(4" x 8")*
1201325G	Rectangle	13 cm x 25 cm *(5" x 10")*
1201520G	Rectangle	15 cm x 20 cm *(6" x 8")*
1202025G	Rectangle	20 cm x 25 cm
1202530G	Rectangle	25 cm x 30 cm
1203035G	Rectangle	30 cm x 35 cm

Indications. Phasix™ Mesh is indicated to reinforce soft tissue where weakness exists, in patients undergoing abdominal, plastic, and reconstructive surgery in ventral hernia repair and other abdominal fascial defect procedures. **Contraindications.** 1. 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.** 1. Phasix™ Mesh must not be put in direct contact with the bowel or viscera. 2. The use of any mesh or patch in a contaminated or infected wound can lead to fistula formation and/or extrusion of the mesh. 3. Mesh manufacture involves exposure to tetracycline hydrochloride and kanamycin sulfate. The safety and product use for patients with hypersensitivities to these antibiotics is unknown. The use of this mesh in susceptible patients with known allergies to tetracycline hydrochloride or kanamycin sulfate should be avoided. 4. The safety and effectiveness of Phasix™ Mesh in the following applications has not been evaluated or established: a. Pregnant or breastfeeding women b. Pediatric use c. Neural and cardiovascular tissue. 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 the removal of the mesh. 6. To prevent recurrences when repairing hernias, the 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. 7. The 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. 8. This mesh has been designed for single use only. Reuse, reprocessing, resterilization, or repackaging 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 mesh failure 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. 9. If unused Phasix™ Mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations to prevent risk of transmission of viral infections. 10. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 11. This mesh is not for the use of treatment of stress urinary incontinence. 12. Phasix™ 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 mesh strength and size requirements. Improper selection, placement, positioning, and fixation of the mesh can cause subsequent undesirable results. 3. Clinical data in accordance with EU MDR has not been established for laparoscopic/robotic procedures. 4. The safety and effectiveness of Phasix™ Mesh in the proximity of existing or excised cancer has not been established. **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. Please consult product package insert for more detailed safety information and instructions for use.

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 mesh failure 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. 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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 package insert for more detailed safety information and instructions for use.

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