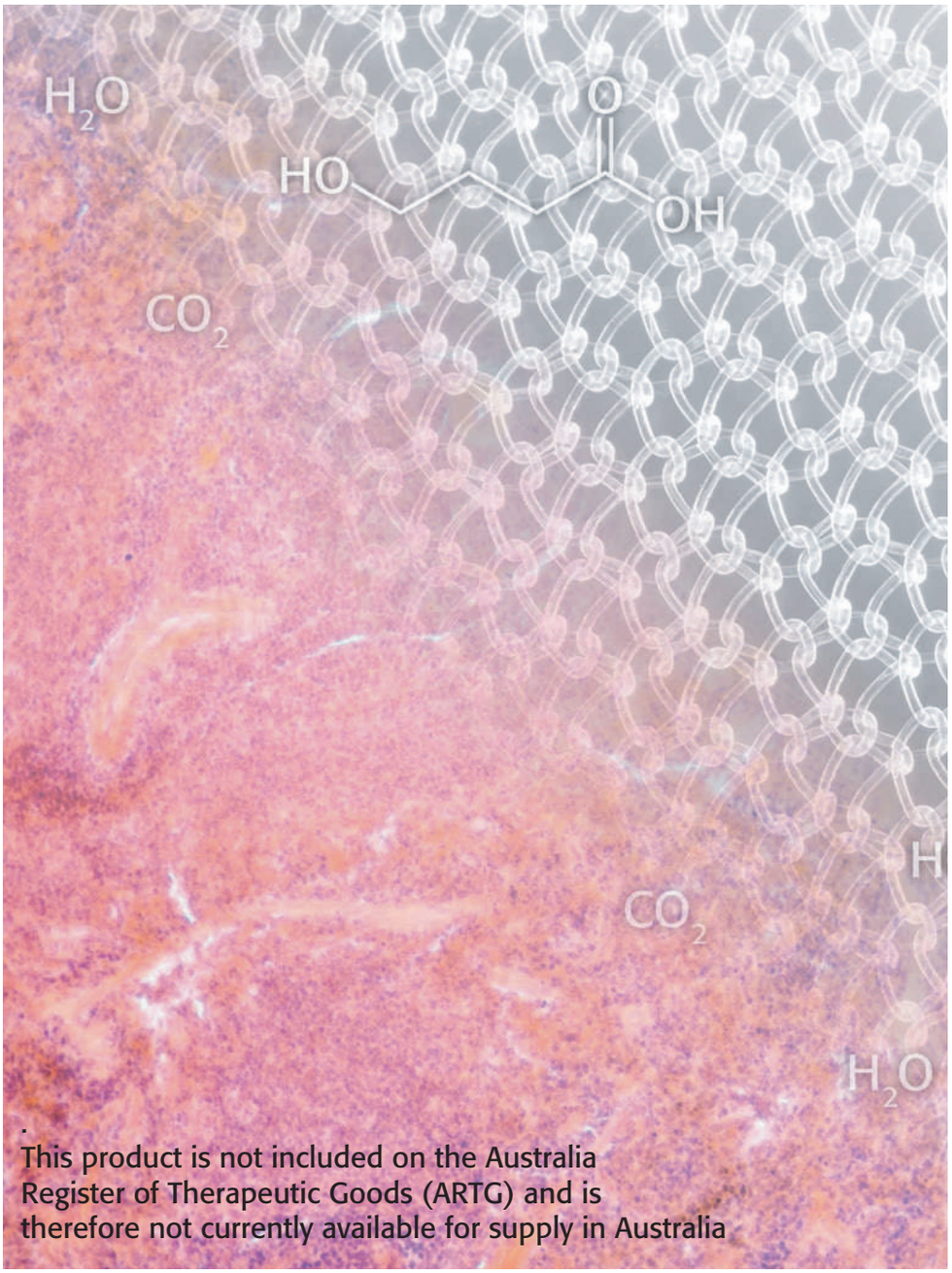
Phasix™ ST Mesh

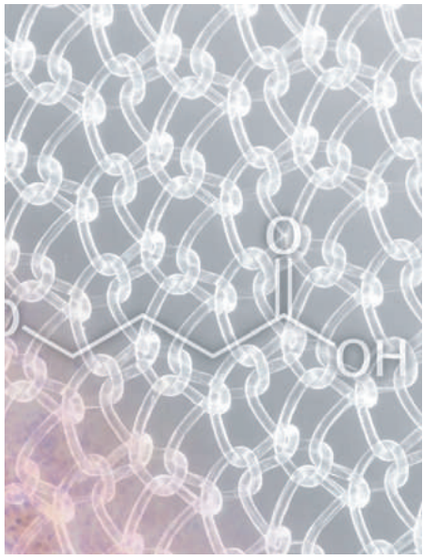
Fully Resorbable Scaffold Featuring Proven Sepra® Technology

BD

BARD
has joined BD

Designed to enable functional tissue remodeling for a strong repair





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This product is not included on the Australia Register of Therapeutic Goods (ARTG) and is therefore not currently available for supply in Australia

SOFT TISSUE REPAIR

Right Procedure. Right Product. Right Outcome.

Phasix™ ST Mesh

Challenges With High-Risk Patients

Patients with previous wound infection and comorbidities experience higher rates of surgical site occurrences (SSO) and surgical site infections (SSI). The increased rate of early complications can impact the long-term patient outcome with a mesh or biologic hernia repair. Modified hernia grading scale shown below:[1]

Grade 1	Grade 2	Grade 3
▪ Low risk of complications ▪ No history of wound infection	▪ Smoker ▪ Obese ▪ Diabetes ▪ History of wound infection	▪ Clean-Contaminated ▪ Contaminated ▪ Dirty
SSO = 14%	SSO = 27%	SSO = 46%

Commonly Used Mesh

For high-risk/comorbid patients, surgeons have had to choose between permanent synthetic meshes and biologic grafts—and their inherent pros and cons.

Permanent synthetic meshes

Advantages

- Easy to use[2]
- Reduced recurrence vs. primary closure
- Can also be used robotically and laparoscopically

Disadvantages

- Postoperative complications can lead to mesh removal or reoperation[3]

Now there's PHASIX™ ST Mesh

Biologic grafts

Advantages

- Naturally derived material
- Potentially reduces need for mesh removal if a complication occurs[4]

Disadvantages

- Accelerated degradation in the presence of bacteria may lead to mesh failure/higher recurrence rate[5,6]
- Some biologics may be difficult to fixate and handle[2]

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

[1]Kanters AE, Krpata DM, Blatnik JA, Novitsky YM, Rosen MJ. "Modified hernia grading scale to stratify surgical site occurrence after open ventral hernia repairs." Journal of the American College of Surgeons 215.6 (2012): 787-93.

[2]Internal market research, data on file, 2015.

[3]Liang MK, Li LT, Nguyen MT, Berger RL, Hicks SC, Kao LS. "Abdominal reoperation and mesh explantation following open ventral hernia repair with mesh." The American Journal of Surgery 208.4 (2014): 670-76.

[4]Itani KM, et al. "Prospective study of single-stage repair of contaminated hernias using a biologic porcine tissue matrix: the RICH Study." Surgery 2012; 152(3): 498-505.

[5]Annor AH, Tang ME, Pui CL, Ebersole GC, Frisella MM, Matthews BD, Deeken CR. "Effect of enzymatic degradation on the mechanical properties of biological scaffold materials." Surgical Endoscopy 26.10 (2012): 2767-778.

[6]Harth KC, et al. "Effect of surgical wound classification on biologic graft performance in complex hernia repair: an experimental study." Surgery 2013; 153(4): 481-492.

Phasix™ Mesh Family: The Next Phase in Challenging Hernia Repair[2]

Based on preclinical data, Phasix™ Mesh slowly remodels as the abdominal wall heals, ultimately restoring strength to the abdominal wall.[1]

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.

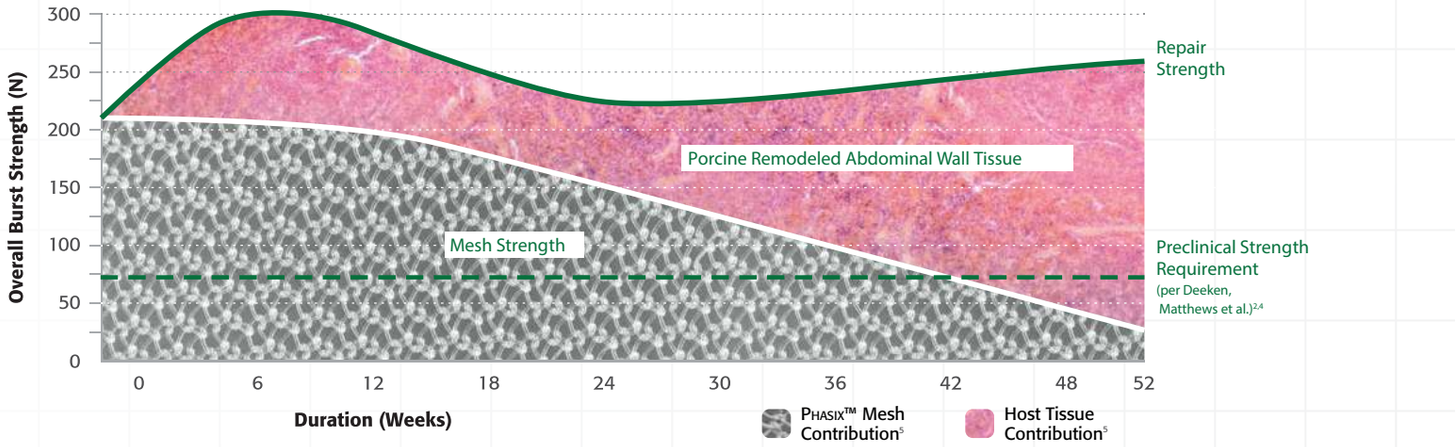
Results: In this porcine model, Phasix™ Mesh total repair strength was more than 3 times the strength required for hernia repair based on preclinical testing conducted by Deeken, Matthews et al.

Preclinical Data suggests:

3x strength requirement[1]

Long-Term Repair Strength in a Preclinical Model[3]

Per Deeken, Matthews et al.



Preclinical Data Demonstrates that Phasix™ Mesh:

Repairs

The open monofilament mesh structure provides early integration and repair strength.[1]

Remodels

Vascular integration and incorporation continues, with abundant mature collagen at 52 weeks. Gradually transfers load to native tissue over time.[1]

Restores

As Phasix™ Mesh is remodeled, it is replaced with functional tissue, ultimately resulting in a strong repair at one year.[1]

[1]Preclinical data on file at C. R. Bard, Inc. P hasix™ ST Mesh shows similar mechanical strength over time to P hasix™ Mesh in a preclinical model. Results may not correlate to clinical performance in humans.

[2]Preclinical data on file. Results may not correlate to clinical performance in humans.

[3]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 Surgery 2013; 1-12.

[4]Deeken CR, Abdo MS, Frisella MM, Matthews BD. "Physicomechanical evaluation of absorbable and nonabsorbable barrier composite meshes for laparoscopic ventral hernia repair." Surgical Endoscopy 25.5 (2010): 1541-552.

[5]Estimated from Standard Curve in manuscript (Martin, et al. JSR 2013).

Phasix™ ST Mesh

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
- P4HB scaffold has been used clinically for hernia repair for 5 years[7]

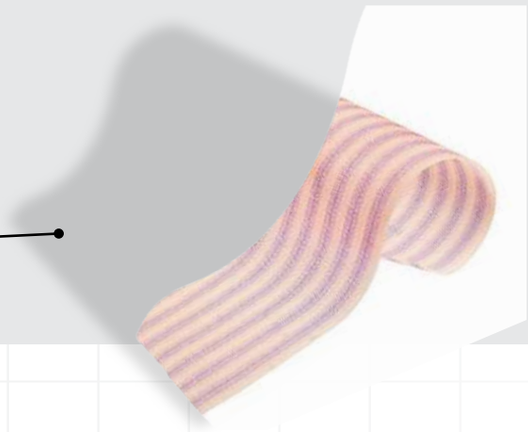
Sepra® Hydrogel Barrier

- 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

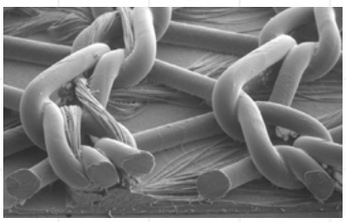
- Handles, sutures and fixates like a synthetic mesh
- Facilitates trocar deployment during laparoscopic placement

Longitudinal stripes aid with orientation and visibility during placement

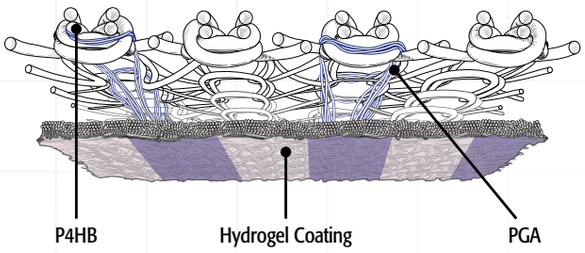


Why Monofilament Matters

Monofilament mesh designs have been deemed more biocompatible and less susceptible to bacterial adherence and colonization.[2,3,4,5,6]



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



[1]Preclinical data on file at C. R. Bard, Inc. Results may not correlate to clinical performance in humans.

[2]Nguyen PT, Asarias JR, Pierce LM. "Influence of a new monofilament polyester mesh on inflammation and matrix remodeling." J Invest Surg 2012; 25: 330

[3]Bryan N, Ahswin H, Smart NJ, Bayon Y, Hunt JA. "In vitro activation of human leukocytes in response to contact with synthetic hernia meshes." Clin Biochem 2012; 45: 672

[4]Aydinuraz K, Agalar C, Agalar F, Ceken S, Buruyurek N, Voral T. "In vitro S. epidermidis and S. aureus adherence to composite and lightweight polypropylene grafts." J Surg Res 2009; 157: e79.

[5]Amid PK, Shulman AG, Lichtenstein IL, Hakaha M. "Biomaterials for abdominal wall hernia surgery and principles of their applications." Langenbecks Archive Chir 1994; 379(3): 168-71.

[6]Klinge U, Junge B, Spellerberg B, Piroth C, Klosterhalfen B, Schumpelick V. "Do multifilament alloplastic meshes increase the infection rate? Analysis of the polymeric surface, the bacterial adherence, and the in vivo consequences in a rat model." J Biomed Mater Res (Appl Biomater) 2002; (63): 765-771.

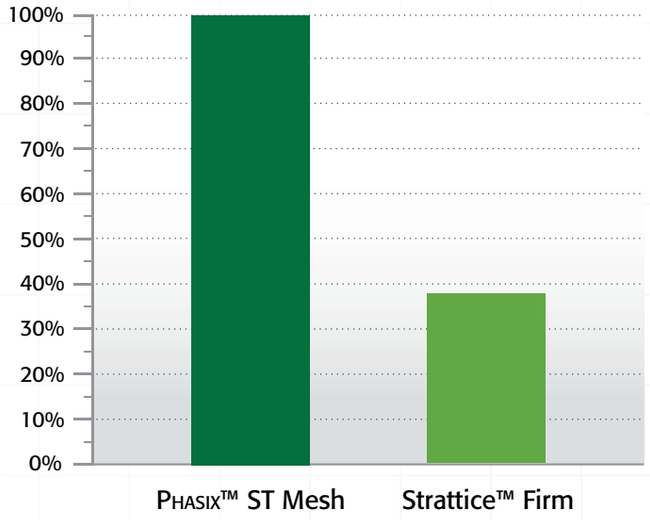
[7]Long-term clinical data not yet available.

Preclinical Studies Demonstrate Strength and Incorporation

Study objective: Characterize the mechanical strength properties of Phasix™ ST Mesh as compared to Strattice™ Firm in the presence of bacteria (MRSA) at 56 days.

Study design: New Zealand White Rabbits were bilaterally implanted with Phasix™ ST Mesh and Strattice™ Firm (n=20). Each device location was then inoculated with clinically isolated MRSA ($5x10^7$) using catheters. At 56 days post implantation/inoculation, the implant sites were tested for mechanical strength (ball burst).

Strength Retention in Presence of MRSA (t=0 vs. 56 Days)[1]



Results:

100% Phasix™ ST Mesh

39% Strattice™ Firm

Phasix™ ST Mesh maintained 100% of its original strength while the Strattice™ Firm maintained 39% of its strength at 56 days in the presence of bacteria (MRSA).[1]

Preclinical data suggests that dermal scaffolds are susceptible to enzymatic degradation, which can be unpredictable and may lead to early graft failure.[1,2,3] Phasix™ ST Mesh degrades predictably, primarily through hydrolysis.[1,4]

[1]Preclinical data on file at C. R. Bard, Inc. Results may not correlate to clinical performance in humans.

[2]Annor AH, Tang ME, Pui CL, Ebersole GC, Frisella MM, Matthews BD, Deeken CR. "Effect of enzymatic degradation on the mechanical properties of biological scaffold materials." Surgical Endoscopy 26.10 (2012): 2767-778.

[3]Cole WC, Balent EM, Masella PC, Kajiura LN, Matsumoto KW, Pierce LM. "An experimental comparison of the effects of bacterial colonization on biologic and synthetic meshes." Hernia 19.2 (2014): 197-205.

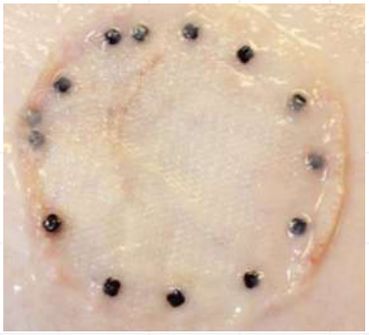
[4]Martin DP, Williams SF. "Medical applications of Poly-4-hydroxybutyrate: A strong flexible absorbable biomaterial." Biochemical Engineering Journal 16.2 (2003): 97-105.

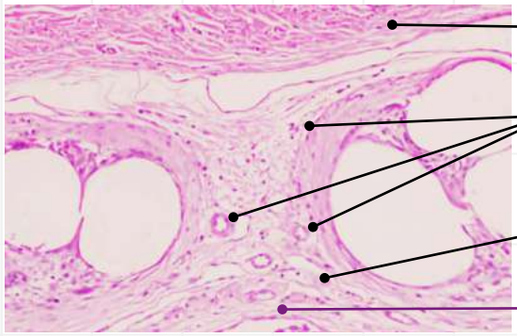
Phasix™ ST Mesh

Preclinical Studies Demonstrate a Transition to Functional Tissue

At 12 weeks, Phasix™ ST Mesh is well incorporated with new vascularized tissue and minimal inflammatory response. A new peritoneal layer has been laid down in place of the ST barrier. By 48 weeks, Phasix™ ST Mesh continues to be remodeled and is replaced with mature functional tissue.[1]

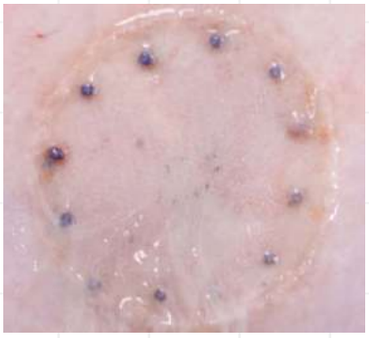
12 weeks

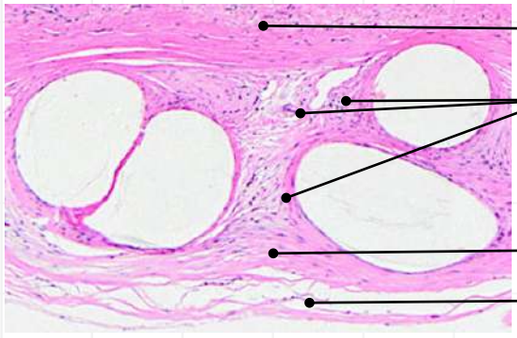




Phasix™ ST Mesh, H&E, 10X

48 weeks

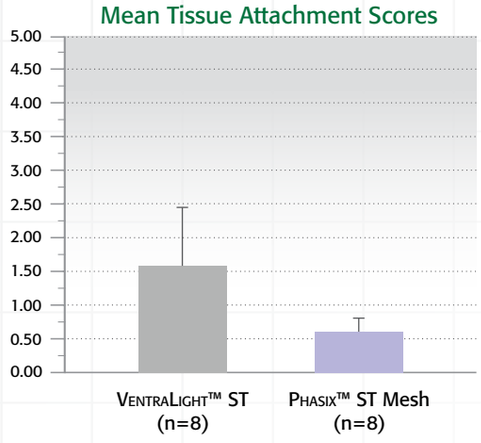




Phasix™ ST Mesh, H&E, 10X

Minimizing Tissue Attachment

In a preclinical porcine study, Phasix™ ST Mesh showed minimal tissue attachment at 4 weeks. When compared to Ventralight ™ ST in the same study, Phasix™ ST Mesh exhibited a similar reduction in tissue attachment ($p = 0.72$).[1]



[1]Preclinical data on file at C. R. Bard, Inc. Results may not correlate to clinical performance in humans.

Versatile Techniques

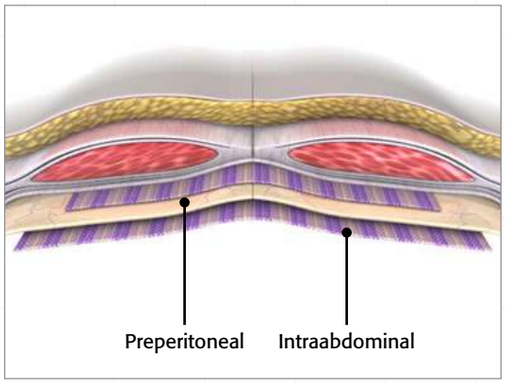
Phasix™ ST Mesh may be placed in either an intraabdominal or preperitoneal position after primary hernia defect closure. Primary hernia defect closure should be achieved prior to placing the mesh.

Hernia Defect Closure

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[1,2]:

- 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



Laparoscopic Defect Closure

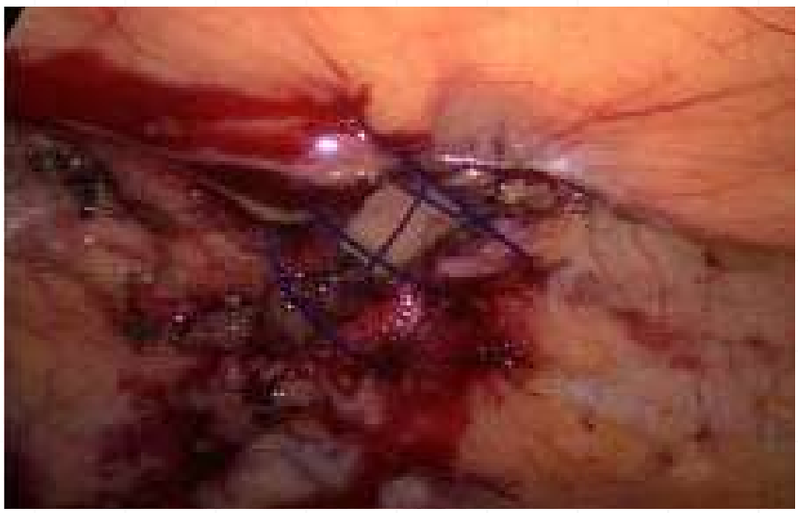


Photo courtesy of Sean Orenstein, MD
Oregon Health and Science University

[1]Novitsky YW. "Bridging versus closing the defect during laparoscopic ventral hernia repair." The SAGES Manual of Hernia Repair (2012): 439-44.

[2]Gonzalez AM, et al. "Laparoscopic ventral hernia repair with primary closure versus no primary closure of the defect: Potential benefits of the robotic technology." Int J Med Robotics Comput Assist Surg 11.2 (2014): 120-25.

Phasix™ ST Mesh

Product Codes

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 (8″ x 10″)
1202530G	Rectangle	25 cm x 30 cm (10″ x 12″)
1203035G	Rectangle	30 cm x 35 cm (12″ x 14″)

Order Form

☐ Please add these marked products to my preference card.

☐ I would like to have these marked products in stock.

☐ I would like to trial these marked products.

Purchase Order Number _____ Date _____

Catalog Number(s) _____ Quantity _____

Surgeon's Signature _____

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.

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.

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.

Please consult package insert for more detailed safety information and instructions for use. This product is not included on the Australia Register of Therapeutic Goods (ARTG) and is therefore not currently available for supply in Australia.

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