Phasix™ ST Mesh
Fully Resorbable Scaffold Featuring Proven Sepra® Technology

Designed to enable functional tissue remodeling for a strong repair

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:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Advantages</th>
<th>Disadvantages</th>
</tr>
</thead>
<tbody>
<tr>
<td>Grade 1</td>
<td>Low risk of complications</td>
<td>Smoker</td>
</tr>
<tr>
<td></td>
<td>No history of wound infection</td>
<td>Obese</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Diabetes</td>
</tr>
<tr>
<td></td>
<td></td>
<td>History of wound infection</td>
</tr>
<tr>
<td></td>
<td><strong>SSO = 14%</strong></td>
<td></td>
</tr>
<tr>
<td>Grade 2</td>
<td>Smoker</td>
<td>Clean-Contaminated</td>
</tr>
<tr>
<td></td>
<td>Obese</td>
<td>Contaminated</td>
</tr>
<tr>
<td></td>
<td>Diabetes</td>
<td>Dirty</td>
</tr>
<tr>
<td></td>
<td><strong>SSO = 27%</strong></td>
<td></td>
</tr>
<tr>
<td>Grade 3</td>
<td>Clean-Contaminated</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Contaminated</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Dirty</td>
<td></td>
</tr>
<tr>
<td></td>
<td><strong>SSO = 46%</strong></td>
<td></td>
</tr>
</tbody>
</table>

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
  - Reduced recurrence vs. primary closure
  - Can also be used robotically and laparoscopically

- **Disadvantages**
  - Postoperative complications can lead to mesh removal or reoperation

Biologic grafts

- **Advantages**
  - Naturally derived material
  - Potentially reduces need for mesh removal if a complication occurs

- **Disadvantages**
  - Accelerated degradation in the presence of bacteria may lead to mesh failure/higher recurrence rate
  - Some biologics may be difficult to fixate and handle

Now there’s Phasix™ ST Mesh

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.

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2 Internal market research, data on file, 2015.
Phasix™ Mesh Family: The Next Phase in Challenging Hernia Repair

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

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

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

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


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

**Sepra® Hydrogel Barrier**

- Hydrogel barrier on posterior side minimizes visceral tissue attachment
- Uncoated P4HB monofilament allows for tissue ingrowth on the anterior side
- Resorbs within 30 days
- 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.

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1 Preclinical data on file at C. R. Bard, Inc. Results may not correlate to clinical performance in humans.
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
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 (5x10⁷) 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)

- **Results:**
  - 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 on file at C. R. Bard, Inc. Results may not correlate to clinical performance in humans.**
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

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 include1,2:

• 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

Phasix™ ST Mesh

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, hematomata, 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.