A material option that provides a strong durable repair without long-term foreign material. BARD’s Phasix™ material provides you and your patients an option for inguinal hernia repair that provides a strong durable repair, without permanent foreign material.
Material Value
Chronic pain is a serious complication that can occur after repair of groin hernia.¹ The development of chronic pain after herniorrhaphy has been attributed to several mechanisms, including damage to sensory nerves and mesh inguinodynia.² PHASIX™ Plug and Patch provides the advantages of a clinically proven technique³ with a fully resorbable mesh to potentially further reduce the risk of chronic pain.

Material Science
PHASIX™ Plug and Patch is constructed of monofilament Poly-4-Hydroxybutyrate (P4HB), a fully resorbable synthetic material developed by MIT scientists. The monomer form of the substance, (4HB) occurs naturally and is widely distributed in the tissues of mammals (including humans).⁴ P4HB has been available for clinical use since 2007.

Material Structure
PHASIX™ Plug and Patch is a woven monofilament mesh that provides immediate short-term support similar to traditional non-resorbable meshes but provides a scaffold that enables remodeling to host tissue over time. The PHASIX™ Plug and Patch supports host tissue formation at the repair site and predictably and gradually degrades via hydrolysis such that mechanical strength is gone within 12 to 18 months, and while fiber segments were observed at 18 months, they continue to degrade until fully resorbed, as demonstrated in a preclinical study.⁵ Suture pull-out, tear and ball burst strength of PHASIX™ Mesh are comparable to traditional BARD® polypropylene mesh and the performance of PHASIX™ Mesh is above the threshold values set by Deeken et. al., for resorbable and non-resorbable barrier composite meshes.⁶,⁷,⁸

<table>
<thead>
<tr>
<th>Mesh Type (N=10)</th>
<th>Suture Retention Strength, parallel/perpendicular (N)</th>
<th>Tear Resistance, parallel/perpendicular (N)</th>
<th>Ball Burst Strength (N/cm)</th>
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</thead>
<tbody>
<tr>
<td>PHASIX™ Mesh</td>
<td>40 / 45</td>
<td>37 / 50</td>
<td>149</td>
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<tr>
<td>BARD® Mesh</td>
<td>54 / 36</td>
<td>46 / 49</td>
<td>213</td>
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<td>Threshold values suggested as suitable properties for hernia repair applications</td>
<td>&gt;20 N</td>
<td>&gt;20 N</td>
<td>&gt;50 N/cm</td>
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</tbody>
</table>

⁵Preclinical data on file at C. R. Bard, Inc. Results may not correlate to performance in humans.
⁸Benchtop testing data on file at C. R. Bard, Inc.
Material Integration and Performance

**PHASIX™ Plug and Patch** allows the assembly of new collagen around a macroporous scaffold which resorbs slowly over time and is replaced with new host collagen.9

**Study Type:** Preclinical Study - 25 male Yucatan mini-pigs (33.7-41.8 kg)

**Objective:** Demonstrate the strength over time of PHASIX™ Plug

**Study Design:** Preperitoneal bridge defect repair. A 3 cm round full thickness defect was created in the ventral abdominal wall. Phasix™ Plug was fixated through the defect with suture. Ball burst testing and histopathology were conducted at T=0, 6 weeks, 12 weeks, 26 weeks, and 52 weeks.

**Results:** Significant strength over time and early tissue in-growth at bridged site was demonstrated.

![Repair Strength Over Time - PHASIX™ Plug 52 Week Preclinical Data](image)

Repair strength remained significantly above the native abdominal wall throughout the 52 week mesh absorption period (P<0.05 for all time-points).9

Material Impact

**PHASIX™ Plug and Patch** provides the high levels of early strength needed to support tissue healing and gradually shifts mechanical load to the host tissue as the repair matures.9

Preclinical testing confirmed early tissue in-growth, vascular integration and incorporation of the PHASIX™ Plug into the ventral abdominal wall. Abundant mature collagen has formed around the remaining fibers at 52 weeks.9

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9 Preclinical data on file at C. R. Bard, Inc. Results may not correlate to performance in humans.
**Mesh Design and Placement**

Like the Bard® PerFix™ Plug, the Phasix™ Plug is designed with pleated edges that conform readily to defects of various sizes and shapes and inner petals that allow the plug to maintain its fluted form. The Phasix™ Plug and Patch may be implanted using the Millikan Modified Technique to create a multi-layered, tension free repair that is indicated for reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects.10,11

**Product Codes**

<table>
<thead>
<tr>
<th>Product Code</th>
<th>Quantity</th>
<th>Sizes</th>
<th>Dimensions</th>
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<tbody>
<tr>
<td>1190600</td>
<td>1/cs</td>
<td>Small</td>
<td>1.0” x 1.4” (2.5 cm x 3.6 cm)</td>
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<tr>
<td>1190601</td>
<td>1/cs</td>
<td>Medium</td>
<td>1.3” x 1.6” (3.3 cm x 4.1 cm)</td>
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<tr>
<td>1190602</td>
<td>1/cs</td>
<td>Large</td>
<td>1.5” x 1.9” (4.1 cm x 4.8 cm)</td>
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<tr>
<td>1190603</td>
<td>1/cs</td>
<td>Extra Large</td>
<td>1.4” x 2.0” (3.8 cm x 5.1 cm)</td>
</tr>
</tbody>
</table>

**Indications**

The Phasix™ Plug and Patch is indicated for reinforcement of soft tissue where weakness exists, in procedures involving soft tissue repair, such as groin hernia defects.

**Contraindications**

Because Phasix™ Plug and Patch is fully resorbable, it should not be used in repairs where permanent wound or organ support from the mesh is required.

**Warnings**

Placement of Phasix™ Plug and Patch in direct contact with bowel or viscera is not recommended. The safety and product use for patients with hypersensitivities to tetracycline hydrochloride or kanamycin sulfate is unknown. Use of this device in patients with known allergies to these antibiotics should be avoided. The safety and effectiveness of Phasix™ Plug and Patch in pediatric use and use in pregnant women has not been established. If an infection develops, treat the infection aggressively. An unresolved infection may require removal of the device.

**Adverse Reactions**

Possible complications include infection, seroma, pain, mesh migration, wound dehiscence, hemorrhage, adhesions, hematoma, inflammation, extrusion and recurrence of the hernia or soft tissue defect. Please consult package insert for more detailed safety information and instructions for use.

To learn more, contact your local BARD sales representative or call 1.800.556.6275

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