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## Phasix<sup>™</sup> Mesh Natural. Not Permanent. Proven Results.

Bioresorbable Phasix<sup>™</sup> Mesh is transforming hernia care with long-term strength¹ and positive clinical outcomes for a less complicated future.<sup>2,3</sup>







Monomer form (4HB) is natural to the body<sup>1</sup>



Rapid tissue incorporation<sup>1</sup>



Organized and functional collagen at the repair site<sup>1</sup>

## Improved healing from the start

Composed of material derived from a fermentation process, Poly-4-hydroxybutyrate (P4HB), Phasix<sup>®</sup> Mesh provides critical strength during the initial healing phase with rapid tissue ingrowth and vascularization through its open-pore monofilament structure.<sup>1</sup>

# Proven performance from a reliable partner

With over 185,000 implants¹ across the Phasix™ Mesh family, BD is celebrating over 50 years of hernia repair excellence. BD is committed to providing an innovative hernia portfolio that focuses on improving clinical outcomes for better patient care.

Over 185,000 implants<sup>4</sup>

More than 35 clinical studies<sup>2,12-20</sup>

More than 3,000 patients studied<sup>2,5,12-20</sup> Proven clinical outcomes at 5 years<sup>6,22</sup>

Low recurrence<sup>2-12,20</sup>

Low surgical site infection (SSI)<sup>2-12,20</sup>

Low seroma rates<sup>2-12,20</sup>

Associated with improved quality of life<sup>6.7</sup>

## The Phasix<sup>™</sup> Mesh Response

Describes the impact Phasix Mesh has on the regenerative "tissue" response once implanted in an animal model. Pre-clinical data suggests there are **three main components** of the Phasix Response:

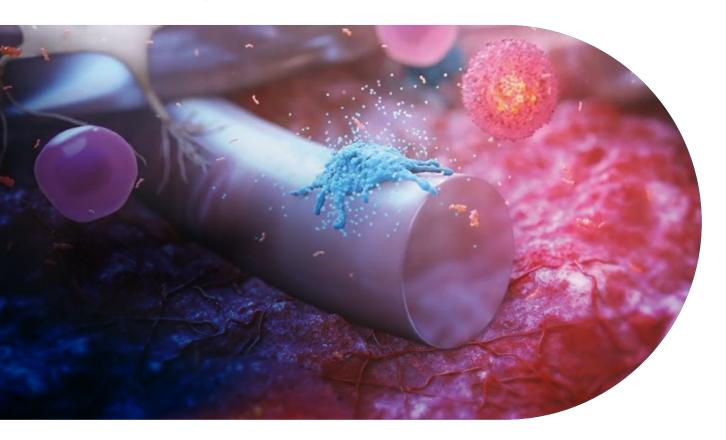






Pre-clinical and in vitro testing have shown that Phasix Mesh rapidly incorporates while the body naturally initiates an early "repair" response by preferentially up-regulating the anti-inflammatory macrophage. 9,10,11

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.<sup>9,10,11</sup>



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

### Predictable strength for the long run

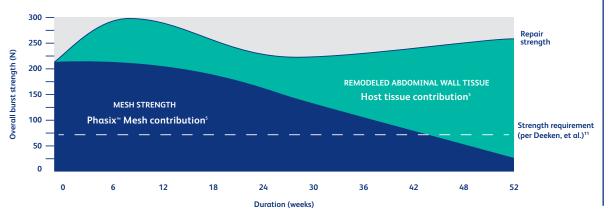
Phasix Mesh gradually and predictably degrades within 12 to 18 months via hydrolysis leaving behind a durable, functional repair with over 3x the strength of the native abdominal wall.

Pre-clinical data suggests:



### Repair strength over time in a 52 Week Pre-clinical Model<sup>6</sup>

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.

The Phasix™ Response

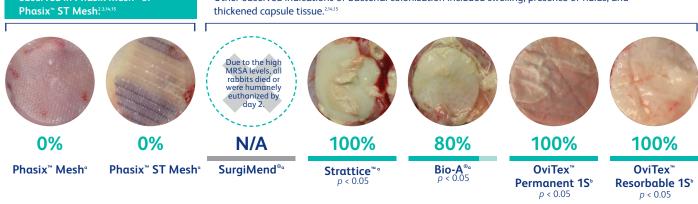
## Promising results in the presence of bacteria

In pre-clinical testing, Phasix<sup>™</sup> 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.<sup>12,14</sup>

#### Bacteria colonization 7 days post inoculation in preclinical testing<sup>1</sup>

Pockets with recoverable bacteria (%)

No presence of bacterial colonization observed in Phasix Mesh™ or Phasix™ ST Mesh<sup>2,3,34,15</sup> 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 consule tissue <sup>2,14,15</sup>



a 5x10<sup>7</sup> inoculation of MRSA, N=5 rabbits

(%) Percentage of recoverable bacteria

No mesh is indicated for use in an infected or contaminated field.

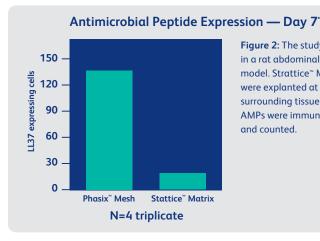


Figure 2: The study was performed in a rat abdominal partial thickness defect model. Strattice™ Matrix and Phasix™ Mesh were explanted at 7 days and the mesh and surrounding tissue was analyzed histologically. AMPs were immunofluorescently labeled, and counted.

b 1x10° inoculation of MRSA, N=5 rabbits

### Follow the data to a new standard of care

### Phasix<sup>™</sup> Mesh



### **New Standard of Care**

- Expert consensus panel established that a bioabsorbable mesh should be the standard of care for hernias.<sup>21</sup>
- Roth, et.al have shown that long term outcomes with Phasix Mesh showed results similar to permanent mesh.<sup>20</sup>



### **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.7



### **Cost savings**

- Budget impact analysis has shown Phasix\* Mesh may result in a decrease in the total hospital buget of about \$158.87 million, with a savings per patient of about \$799.55.<sup>22</sup>
- Phasix Mesh also results in \$9,570 savings per case when compared to Strattice Matrix.<sup>6</sup>

### **Product Codes**

Product Code	Shape	Dimensions
1190011	Round	4.5" (11 cm)
1190100	Round	3"x 3" (7.6 cm)
1190200	Rectangle	4" x 6" (10.2 x 15.2 cm)
1190300	Rectangle	6" x 8" (15.2 x 20.3 cm)
1190400	Rectangle	8" x 10" (20.3 x 25.4 cm)
1190500	Rectangle	10" x 12" (25.4 x 30.5 cm)
1190616	Rectangle	2.4" x 6.3" (6 x 16 cm)
1190808	Square	3" x 3" (8 x 8 cm)
1190816	Rectangle	3" x 6.3" (8 x 16 cm)
1190820	Rectangle	3" x 8" (8 x 20 cm)
1191010	Square	4" x 4" (10 x 10 cm)
1191020	Rectangle	4" x 8" (10 x 20 cm)

Product Code	Shape	Dimensions
1191025	Rectangle	4" x 10" (10 x 25 cm)
1191525	Rectangle	6" x 10" (15 x 25 cm)
1191530	Rectangle	6" x 12" (15 x 30 cm)
1192020	Square	8" x 8" (20 x 20 cm)
1192030	Rectangle	8" x 12" (20 x 30 cm)
1192040	Rectangle	8" x 16" (20 x 40 cm)
1192540	Rectangle	10" x 16" (25 x 40 cm)
1193030	Square	12" x 12" (30 x 30 cm)
1193045	Rectangle	12" x 18" (30 x 45 cm)
1193535	Square	14" x 14" (35 x 35 cm)
1194040	Square	16" x 16" (40 x 40 cm)
1194545	Square	18" x 18" (45 x 45 cm)
1195050	Square	19.5" x 19.5" (50 x 50 cm)

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