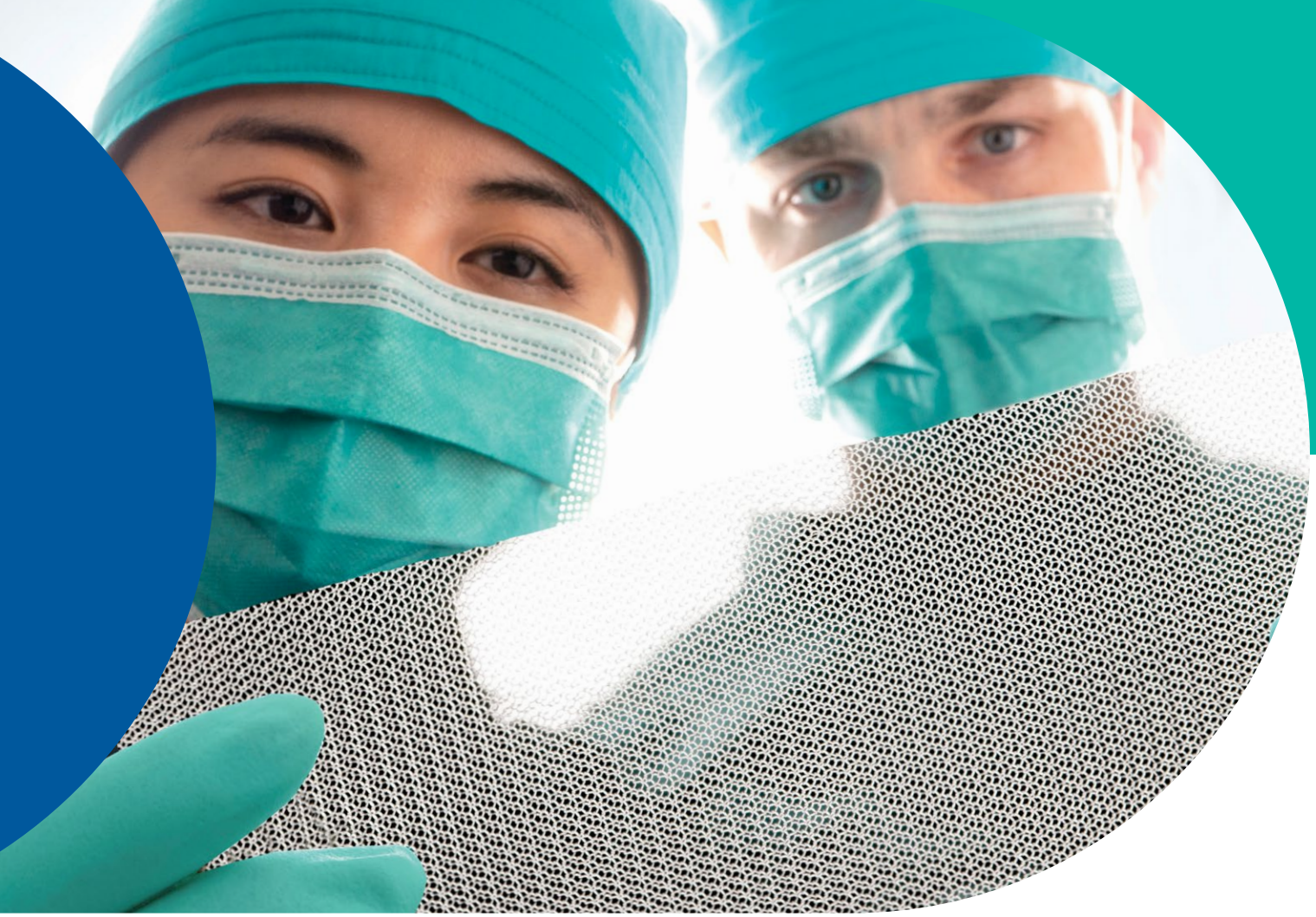


# Phasix™ Mesh

## Natural. Not Permanent. Proven Results.

Bioresorbable Phasix™ Mesh is transforming hernia care with long-term strength[1] and positive clinical outcomes for a less complicated future.[2,3]

BD

# A reliable alternative to permanent mesh

With rapid tissue ingrowth and long-lasting strength,[1] Phasix™ Mesh provides a strong, reliable repair when patients need it most.[4]

- Monomer form (4HB) is natural to the body[1]
- Rapid tissue incorporation[1]
- Organized and functional collagen at the repair site[1]

## Improved healing from the start

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

# Proven performance from a reliable partner

With over 185,000 implants[1] 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[4] | More than 35 clinical studies[2,12–20] | More than 3,000 patients studied[2,5,12-20] | Proven clinical outcomes at 5 years[6,22] |
| Low recurrence[2–12,20] | Low surgical site infection (SSI)[2–12,20] | Low seroma rates[2–12,20] | Associated with improved quality of life[6,7] |

# The Phasix™ 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:

Healthy tissue ingrowth

Predictable durability

Promising results in the presence of bacteria

The Phasix™ Response

# 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.[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.[9,10,11]

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

SCAN ME

*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.

The Phasix™ Response

# Predictable durability

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

## Predictable strength for the long run

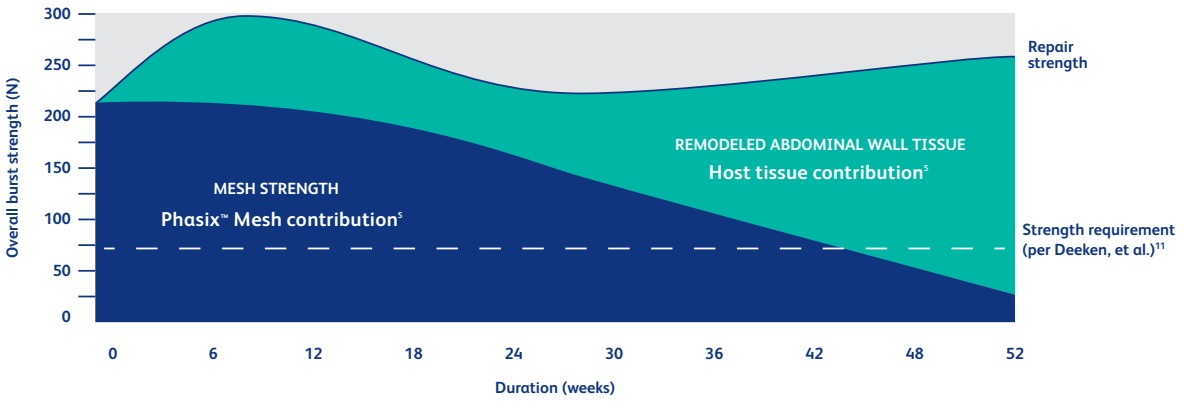
Phasix™ Mesh gradually and predictably degrades within 12 to 18 months via hydrolysis leaving behind a durable, functional repair with over 3x the strength of the native abdominal wall.[1]

**Pre-clinical data suggests:**

**3x** strength requirement

**Repair strength over time in a 52 Week Pre-clinical Model[6]**

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.

The Phasix™ Response

# 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.[12,14]

## Bacteria colonization 7 days post inoculation in preclinical testing[1]

Pockets with recoverable bacteria (%)

**No presence of bacterial colonization observed in Phasix Mesh™ or Phasix™ ST Mesh:**[2,3,14,15]

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.[2,14,15]


| 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] $p < 0.05$ |

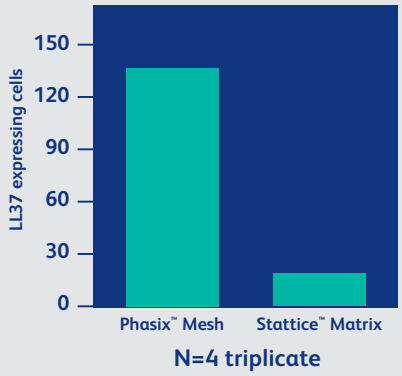
a $5x10^7$ inoculation of MRSA, N=5 rabbits

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.*[21]
- 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.[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.[22]
- Phasix™ Mesh also results in $9,570 savings per case when compared to Strattice™ Matrix.[6]

SCAN ME

**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.

# 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) |

**Indications for use** Phasix™ Mesh is indicated to reinforce soft tissue where weakness exists in patients undergoing plastic and reconstructive surgery, or for use in procedures involving soft tissue repair, such as the repair of hernia or other fascial defects that require the addition of a reinforcing or bridging material to obtain the desired surgical result. **Contraindications** 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 bowel or viscera. 2. 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 susceptible patients with known allergies to tetracycline hydrochloride or kanamycin sulfate should be avoided. 3. The safety and effectiveness of Phasix™ Mesh in the following applications has not been evaluated or established: a. Pregnant women b. Pediatric use c. Neural and cardiovascular tissue 4. 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 device. 5. To prevent reoccurrences when repairing hernias, the Phasix™ Mesh must be large enough to provide sufficient overlap beyond the margins of the defect. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. **Adverse Reactions** In pre-clinical 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 reoccurrence of the hernia or soft tissue defect.

**Please consult product labels and inserts for any indications, contraindications, hazards, warnings, precautions, and instructions for use.**

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