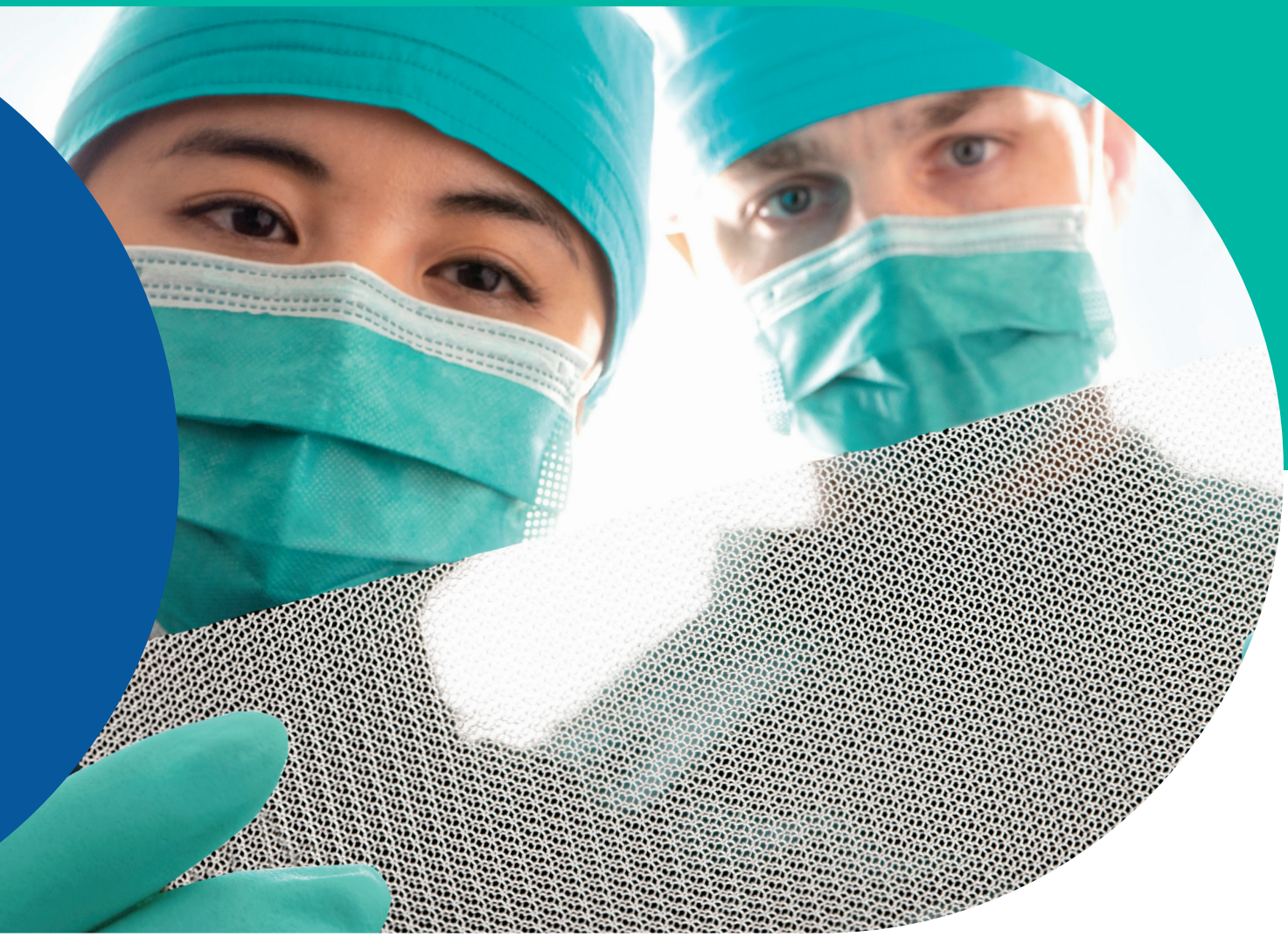


Phasix™ Mesh

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]

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.

- 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]

- 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: the three components

The Phasix™ 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

*No mesh is indicated for use in contaminated or infected wounds.

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]

*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

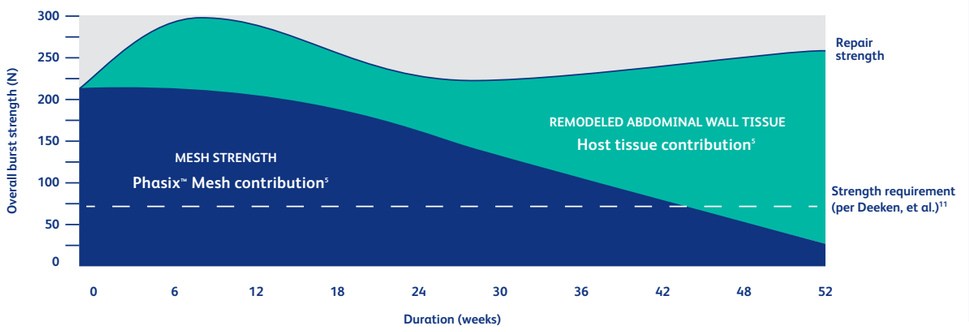
Phasix™ Mesh gradually and predictably degrades within 12 to 18 months via hydrolysis leaving behind a durable, functional repair with over 3x the strength of the native abdominal wall.[1]

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

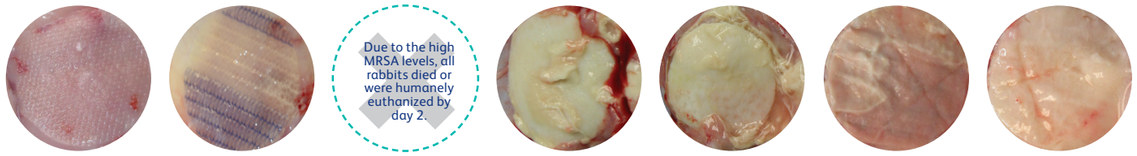
In pre-clinical testing, Phasix™ Mesh has demonstrated promising results in the presence of MRSA. As degradable mesh is remodeled, the body naturally responds by producing antimicrobial peptides (AMPs). Traditionally, immunology studies link AMP's to fighting bacteria.[12,14]

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]



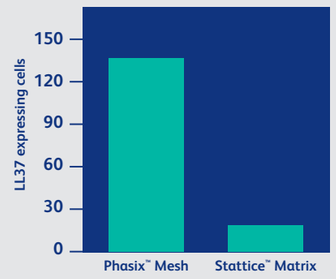
0%	0%	N/A	100%	80%	100%	100%
Phasix™ Mesh[a]	Phasix™ ST Mesh[a]	SurgiMend®[a]	Strattice™[a] $p < 0.05$	Bio-A®[a] $p < 0.05$	OviTex™ Permanent 1S[b] $p < 0.05$	OviTex™ Resorbable 1S[b] $p < 0.05$

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
1190100G	Round	3"x 3" (7.6 cm)
1190200G	Rectangle	4" x 6" (10.2 x 15.2 cm)
1190300G	Rectangle	6" x 8" (15.2 x 20.3 cm)
1190400G	Rectangle	8" x 10" (20.3 x 25.4 cm)
1190500G	Rectangle	10" x 12" (25.4 x 30.5 cm)
1190820G	Rectangle	3" x 8" (8 x 20 cm)
1191530G	Rectangle	6" x 12" (15 x 30 cm)
1192040G	Rectangle	8" x 16" (20 x 40 cm)
1193045G	Rectangle	12" x 18" (30 x 45 cm)
1195050G	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 abdominal, plastic, and reconstructive surgery in ventral hernia repair and other abdominal fascial defect procedures.

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 the bowel or viscera.
2. The use of any mesh or patch in a contaminated or infected wound can lead to fistula formation and/or extrusion of the mesh.
3. Mesh manufacture involves exposure to tetracycline hydrochloride and kanamycin sulfate. The safety and product use for patients with hypersensitivities to these antibiotics is unknown. The use of this mesh in susceptible patients with known allergies to tetracycline hydrochloride or kanamycin sulfate should be avoided.
4. The safety and effectiveness of Phasix™ Mesh in the following applications has not been evaluated or established: a. Pregnant or breastfeeding women b. Pediatric use c. Neural and cardiovascular tissue.
5. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require the removal of the mesh.
6. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue.
7. The mesh is supplied sterile. Prior to use, carefully examine package and product to verify neither is damaged and that all seals are intact. Do not use if the foil pouch or package is damaged or open, or if the center of the temperature indicator on the foil pouch is black.
8. This mesh has been designed for single use only. Reuse, reprocessing, resterilization, or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilization, or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the mesh may lead to injury, illness, or death of the patient or end user.
9. If unused Phasix™ Mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations to prevent risk of transmission of viral infections.
10. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach.
11. This mesh is not for the use of treatment of stress urinary incontinence.
12. Phasix™ Mesh has not been studied for use in breast reconstructive surgeries.

Precautions:

1. Please read all instructions prior to use.
2. Only physicians qualified in the appropriate surgical techniques should use this mesh. Users should be familiar with mesh strength and size requirements. Improper selection, placement, positioning, and fixation of the mesh can cause subsequent undesirable results.
3. Clinical data in accordance with EU MDR has not been established for laparoscopic/robotic procedures.
4. The safety and effectiveness of Phasix™ Mesh in the proximity of existing or excised cancer has not been established.

Adverse Reactions
In preclinical 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 recurrence 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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