Phasix™ ST Mesh with Open Positioning System

A Bioresorbable Hydrogel Coated Mesh with Positioning System for Open Ventral Hernia Repair

INSTRUCTIONS FOR USE

fr MODE D’EMPLOI
de GEBRAUCHSANWEISUNG
it ISTRUZIONI PER L’USO
es INSTRUCCIONES DE USO
nl GEBRUIKSAANWIJZING
pt INSTRUÇÕES DE UTILIZAÇÃO
el ΟΔΗΓΙΕΣ ΧΡΗΣΗΣ
da BRUGERVEJLEDNING
sv BRUKSANVISNING
fi KÄYTTÖOHJEET
no BRUKSANVISNING
pl INSTRUKCJA UŻYCIA
hu HASZNÁLATI UTASÍTÁS
cs NÁVOD K POUŽITÍ
tr KULLANIM TALIMATI
ru ИНСТРУКЦИЯ ПО ПРИМЕНЕНИЮ
zh 使用说明
ko 사용 설명서
PHASIX™ ST Mesh with Open Positioning System
A Biodegradable Hydrogel Coated Mesh with Positioning System for Open Ventral Hernia Repair

INSTRUCTIONS FOR USE (IFU)

DESCRIPTION

Mesh

PHASIX™ ST Mesh with Open Positioning System is a low profile biodegradable coated mesh with a preinserted removable positioning system (accessory), designed for the reinforcement of soft-tissue deficiencies during open ventral hernia repair.

The mesh is a fully biodegradable sterile device containing two distinct layers stitched together with poly-4-hydroxybutyrate (P4HB) monofilament to form an outer anterior pocket for the accessory, and an inner anterior pocket to aid in approximation of the mesh to the abdominal wall. The anterior layer consists of PHASIX™ Mesh which is composed of P4HB monofilament. The posterior layer consists of PHASIX™ ST Mesh which is composed of P4HB monofilament, knitted with polyglycolic acid (PGA) fibers. The PGA surface is coated with a biodegradable, chemically modified sodium hyaluronate (HA), carboxymethylcellulose (CMC) and a polyethylene glycol (PEG) based hydrogel. The anterior fascial side of the mesh allows for a prompt fibroblastic response through the interstices of the mesh, allowing for complete tissue ingrowth. The posterior visceral side of the mesh is a bioresorbable hydrogel coating, separating the mesh from underlying tissues and organ surfaces to help minimize the tissue attachment to the mesh. Shortly after hydration, the biodegradable coating becomes a hydrated gel that is resorbed from the site in less than 30 days1.

P4HB is produced from a naturally occurring monomer that is processed into monofilament fibers then knitted into a surgical mesh. P4HB degrades through two processes, hydrolysis and hydrolytic enzymatic digestion. It has been developed to reinforce areas where weakness exists while minimizing the variability of resorption rate (loss of mass) and strength to provide support throughout the expected healing period. Preclinical implantation studies indicate that resorption of the P4HB fibers is minimal throughout the 12-week expected healing period and up to 26 weeks post implantation. Significant degradation of the mesh fibers was observed in preclinical studies within 12 to 18 months and indicates loss in mechanical integrity and strength of the mesh. While fiber segments were observed at 18 months, they continued to degrade1.

Open Positioning System

The removable open positioning system is an accessory consisting of a polypropylene filament attached to a polytetrafluoroethylene (PTFE) guide by an ultrasonic staking process. The accessory comes preinserted within the mesh pocket to aid with placement, positioning, and fixation and is removed following the initial fixation. The center marking on the guide will aid with proper centering and orientation over the defect.

INDICATIONS

PHASIX™ ST Mesh with Open Positioning System 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. The open positioning system is intended to facilitate the placement, positioning and fixation of the mesh during open ventral hernia repair.

CONTRAINDICATIONS

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

WARNINGS

1. The mesh is the only implantable component of the device. The accessory (positioning guide and handle) must be removed from the patient and appropriately discarded. It is not part of the permanent implant.

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 patients with known allergies to tetracycline hydrochloride or kanamycin sulfate should be avoided.

3. Ensure proper orientation; the coated side of the device 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 viscer (reference Surface Orientation section).

4. Deviation from recommended instructions and/or procedural steps within this IFU may result in disruption or delamination of the hydrogel barrier of the mesh. Hydrogel disruption or delamination may cause an unexpected increase in adhesion formation in the area where it is disrupted.

5. The safety and effectiveness of the mesh in bridging repairs have not been evaluated or established.

6. The safety and effectiveness of the mesh in the following applications have not been evaluated or established:
   a. Pregnant women
   b. Pediatric use
   c. Neural and cardiovascular tissue
   d. Presence of malignancies in the abdominopelvic cavity.

7. Do not apply sharp, pointed, cautery devices, or ultrasonic tools (such as scissors, needles, tackers, diathermic tools, etc.) to the accessory (positioning guide and handle).

8. Product should be used once exterior foil pouch has been opened. Do not store for later use.

9. Discard the accessory (positioning guide and handle) after use as it may be a potential biohazard. Handle and dispose of the accessory in accordance with accepted medical practice and applicable local, state and federal laws and regulations. If the device has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard the device with care to prevent risk of transmission of viral and other infections.

10. This device is provided sterile and has been designed for single use only. Reuse, resterilization, repackaging of any component of the device may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device.

CONTRAINDICATIONS

- Do not apply sharp, pointed, cautery devices, or ultrasonic tools (such as scissors, needles, tackers, diathermic tools, etc.) to the accessory (positioning guide and handle).
- Product should be used once exterior foil pouch has been opened. Do not store for later use.
- Discard the accessory (positioning guide and handle) after use as it may be a potential biohazard.

REPLICATED TABLE

<table>
<thead>
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<th>Product Codes (REF)</th>
<th>Dimensions</th>
<th>Shape</th>
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<tr>
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<td>12” x 14” (30 cm x 35 cm)</td>
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1 Preclinical data on file at C. R. Bard, Inc. Results may not correlate to performance in humans.

Figure 1 Assembled device

Figure 2 Expanded view of components
device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilization, or repackaging may also create a risk of contamination of the device 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 device may lead to injury, illness, or death of the patient or end user.

11. Do not cut or reshape the PHASEX™ ST Mesh with Open Positioning System, as this could impact its effectiveness.

12. To ensure a strong repair, the mesh should be secured with tacks or sutures through the anterior P4HB mesh or full mesh. Suturing or tacking on edge of mesh alone is not recommended.

13. To prevent recurrences when repairing hernias, the mesh must be large enough to provide sufficient overlap beyond the margins of the repair/primary closure. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue.

14. The use of any synthetic mesh in a contaminated or infected wound could lead to fistula formation and/or extrusion of the device and is not recommended.

15. 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.

16. 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.

PRECAUTIONS
1. Please read all instructions prior to use.
2. Only physicians qualified in the appropriate surgical techniques should use this device. Users should be familiar with strength and mesh size requirements. Improper selection, placement, positioning and fixation of the mesh can cause subsequent undesirable results.
3. Care should be taken not to damage or nick the accessory (positioning guide and handle) during fixation.

ADVERSE REACTIONS
In preclinical testing, the 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, hematoma, pain, infection, inflammation, allergic reaction, hemorrhage, extrusion, erosion, migration, fistula formation and recurrence of the hernia or soft tissue defect.

INSTRUCTIONS FOR USE
The safety and effectiveness of the mesh in bridging repairs has not been evaluated or established. Every effort should be made to close the defect.

Mesh Selection
The chosen mesh size should be large enough to provide sufficient overlap beyond the margins of the defect, following established surgical principles. If the chosen mesh size is too small, tension may be placed on the suture line, which may result in a recurrence of the original defect.

Note: Ensure adequate dissection in the appropriate tissue plane (i.e., intraperitoneal or preperitoneal) to accommodate the chosen mesh size.

Placement Technique
Hydration of the device for 1-3 seconds is recommended. Roll the device for insertion into the abdomen. All meshes must be rolled with the bioresorbable hydrogel coated side facing out. The smaller sized devices (15 cm width or smaller) should be rolled in half along the long axis, and all other devices should be rolled into thirds along the long axis (Figure 3). The rolled device is then inserted into the intra-abdominal space with the bioresorbable hydrogel coated side facing the viscera (Figure 4).

Surface Orientation
It is extremely important that this product is oriented correctly. Place the bioresorbable hydrogel coated side of the device against those surfaces where minimal tissue attachment is desired or required, i.e., against bowel or other visceral structures. The uncoated P4HB mesh side should face the surface where tissue ingrowth is desired. The uncoated P4HB mesh surface should never be placed against the bowel or other visceral structures.

Positioning/Centering
Insert the rolled mesh and guide it into the abdominal cavity with the bioresorbable hydrogel coating facing the viscera. Ensure enough dissection prior to placement. Place the mesh and guide into selected tissue plane and release with the handle remaining outside the abdominal cavity. Once released, the mesh will be deployed. Sweep the mesh with your finger to ensure there is no viscera between the mesh and abdominal wall as visceral injury could occur. The center marking will aid with proper centering and orientation over the defect (Figure 5).

Initial Fixation
Once the mesh has been positioned with the appropriate overlap and orientation, initial fixation can be performed into the anterior pocket of the mesh using tack fixation, suture fixation, or both. Fixate the perimeter of the mesh 1-2 mm away from the sew line of the anterior pocket. Adequate fixation is required prior to removal of the accessory (positioning guide and handle) to prevent unintended movement of the mesh (Figures 6 and 7).

Removal
Following adequate fixation, the accessory (positioning guide and handle) must be removed using the handle. Pull the handle towards you and then upwards (Figure 8). Surgical gauze can be used to aid in preventing fluid splatter during removal. Verify that the handle and the guide are fully intact after removal, and then discard appropriately.
Final Fixation
Bard absorbable fixation devices or absorbable monofilament sutures are recommended to properly secure the device with spacing of 1-2 cm between fixation points. Fixate the mesh 1-2 mm away from the sew line of the anterior pockets. If other fixation devices are used, they must be indicated for use in hernia repair. The method of securing the device should be determined by surgeon preference and the nature of the reconstruction to provide for adequate tissue fixation and to prevent reherniation. During defect closure, the inner anterior pocket can be fixated to ensure approximation of the mesh to the abdominal wall (Figure 9).

STORAGE
Store at room temperature (not to exceed 30°C). Avoid prolonged exposure to elevated temperatures. If the center of the temperature indicator on the box is black, check the temperature indicator on the foil pouch. If the center of the temperature indicator on the foil pouch is black, do not use the product.

TRACEABILITY
A traceability label which identifies the type, size and lot number of the device is attached to every package. This label should be affixed to the patient’s permanent medical record to clearly identify the device which was implanted.

If you experience a product failure, please contact Davol, Inc. at 1-800-556-6275 for instructions on returning the product.

RADIOPAQUE
Non-clinical testing performed demonstrated that the handle of the accessory is visible through a body mimic.

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