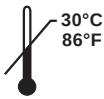
BARD

DAVOL INC.

PHASIX™ ST Mesh

A Resorbable Mesh with a Resorbable Hydrogel Coating
for Soft Tissue Reconstruction

INSTRUCTIONS FOR OPEN AND LAPAROSCOPIC USE




Resorbable


Single Use

Do Not Resterilize

℞ Only STERILE EO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PRODUCT DESCRIPTION

PHASIX™ ST Mesh is a fully resorbable mesh with a resorbable hydrogel coating. It is a sterile mesh prosthesis designed for the reinforcement and reconstruction of soft tissue deficiencies. PHASIX™ ST Mesh is co-knitted using poly-4-hydroxybutyrate (P4HB) and polyglycolic acid (PGA) fibers. P4HB is produced from a naturally occurring monomer and is processed into monofilament fibers and then knitted into a surgical mesh. P4HB degrades through a process of hydrolysis and a hydrolytic enzymatic digestive process. 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 observed in preclinical studies within 12 to 18 months, indicate loss in mechanical integrity and strength of the mesh. While fiber segments were observed at 18 months, they continued to degrade[1]. PHASIX™ ST Mesh is coated on the PGA surface with a resorbable, chemically modified sodium hyaluronate (HA), carboxymethylcellulose (CMC) and polyethylene glycol (PEG) based hydrogel. The fascial side of the mesh allows for a prompt fibroblastic response through the interstices of the mesh, allowing for complete tissue ingrowth, similar to P4HB mesh alone. The visceral side of the mesh is a resorbable hydrogel coating, separating the mesh from underlying tissues and organ surfaces to help minimize tissue attachment to the mesh. Shortly after hydration in saline, the biopolymer coating becomes a hydrated gel that is resorbed from the site in less than 30 days[1].

INDICATIONS

PHASIX™ ST Mesh 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, including hiatal hernias.

CONTRAINDICATIONS

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

WARNINGS

1. **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.**
2. **Ensure proper orientation; the coated side of the prosthesis 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 viscera. (Reference *Surface Orientation* section.)**
3. **The safety and effectiveness of PHASIX™ ST Mesh in bridging repairs has not been evaluated or established.**
4. **The use of any synthetic mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh and it is not recommended.**
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 removal of the mesh.**
6. **To prevent recurrences when repairing hernias, PHASIX™ ST 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.**
7. **For hiatal hernia repair, the use of PHASIX™ ST Mesh circumferentially around the esophagus is not recommended.**
8. **For hiatal hernia repair, the use of PHASIX™ ST Mesh to bridge the hiatus is not recommended.**
9. **The safety and effectiveness of PHASIX™ ST Mesh in the following applications has not been evaluated or established:**
   a. **Pregnant women**
   b. **Pediatric use**
   c. **Neural and Cardiovascular tissue**
10. **Product should be used once exterior foil pouch has been opened. Do not store for later use.**
11. **Unused portions of the prosthesis should be discarded. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard mesh with care to prevent risk of transmission of viral and other infections.**
12. **This device is provided sterile and has been designed for single use only. Reuse, resterilization, reprocessing and/or repackaging of any portion of the PHASIX™ ST Mesh may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the 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.**

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[1]Preclinical data on file at C. R. Bard, Inc. Results may not correlate to performance in humans.

13. **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 prosthesis. 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. The safety and effectiveness of the mesh has not been evaluated in the presence of malignancies in the abdominopelvic cavity.

ADVERSE REACTIONS

In preclinical testing, PHASIX™ ST 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. Possible complications in hiatal hernia repair may include esophageal erosion and dysphagia related to crural fibrosis.

DIRECTIONS FOR USE

The safety and effectiveness of PHASIX™ ST Mesh in bridging repairs has not been evaluated or established. Every effort should be made to close the midline defect prior to mesh use.

Sizing

The PHASIX™ ST Mesh can be tailored without fraying or unraveling and offers bi-directional elasticity to adapt to various stresses encountered in the body. Use a sharp surgical instrument (scissors) to trim the mesh. To minimize chance of recurrence, trim the mesh such that it is large enough to provide sufficient overlap beyond the margins of the defect. If the material is cut too small, tension may be placed on the suture line, which may result in a recurrence of the original defect. Please follow established surgical guidelines.

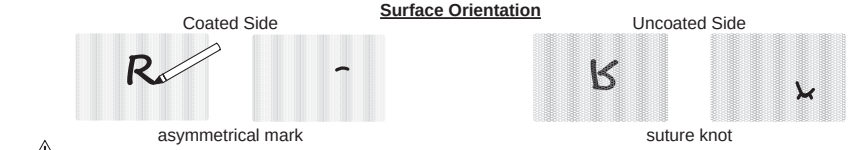
Fixation

Permanent or absorbable fixation devices or long-term absorbable monofilament sutures are recommended to properly secure the device. The method of securing the mesh should be determined by surgeon preference and the nature of the reconstruction to provide for adequate tissue fixation and to prevent reherniation. Care should be taken to ensure that the mesh is adequately fixated to the abdominal wall.

Surface Orientation

It is extremely important that this product be oriented correctly to function as intended. The visceral side of the PHASIX™ ST Mesh is designed to temporarily separate tissue surfaces and minimize tissue attachment to the mesh. Place the smooth, resorbable, hydrogel coated side of the prosthesis against those surfaces where minimal tissue attachment is desired, i.e., against bowel or other visceral structures. The uncoated, textured mesh side should face the surface where tissue ingrowth is desired. The uncoated mesh surface should never be placed against the bowel or other visceral structures. To distinguish the hydrogel coated side of the mesh from the uncoated side of the mesh, an asymmetrical mark (below) can be drawn on the coated side of the mesh with a surgical marker, and/or suture knots can be tied on the uncoated mesh side prior to hydration. The safety and effectiveness of PHASIX™ ST Mesh in combination with solutions other than saline have not been tested.

Surface Orientation



⚠ Caution: The uncoated mesh surface should never be placed against the bowel or other visceral structures.

LAPAROSCOPIC USE

The PHASIX™ ST Mesh when used laparoscopically should be used to buttress the primary closure of a ventral hernia defect. The safety and effectiveness of PHASIX™ ST Mesh in bridging repairs has not been clinically evaluated or established. Every effort should be made to close the defect prior to use. A component release or a similar procedure may be required to achieve primary closure in larger defects.

It is extremely important that this product be oriented correctly. Place the resorbable, hydrogel coated side of the prosthesis against those surfaces where minimal tissue attachment is desired, i.e., against bowel or other visceral structures.

Marking the Mesh and Suture Placement

If sutures are being placed or the mesh is being marked prior to insertion, do so before hydration in saline. (See *Surface Orientation* for more detail.)

Rolling the Mesh

The mesh can be rolled to facilitate insertion. If rolling is preferred, the mesh should be hydrated in saline for no more than 1-3 seconds and then rolled immediately. The mesh must be rolled with the resorbable coating inside about its long axis (lengthwise) to protect the resorbable coating during mesh insertion.

Laparoscopic Mesh Insertion

PHASIX™ ST Mesh should be hydrated in saline for no more than 1-3 seconds just prior to laparoscopic placement. To protect the resorbable coating during laparoscopic mesh insertion, insert the prosthesis through the trocar using a rigid instrument, such as non-serrated, 5 mm forceps; do not force the prosthesis through trocar. If PHASIX™ ST Mesh is hydrated longer than 3 seconds and/or does not easily deploy down the trocar, replace trocar and retry with the next available larger sized trocar.

A minimum sized trocar is recommended for the laparoscopic delivery of PHASIX™ ST Mesh (see the table below for recommended trocar size).

Product Code	Prosthesis Size	Product Shape	Trocar Size* (minimum)
1200008	8 cm (3 in)	Circle	12 mm
1200011	11 cm (4.5 in)	Circle	12 mm
1200015	15 cm (6 in)	Circle	12 mm
1201325	13 cm x 25 cm (5 in x 10 in)	Rectangle	12 mm
1201020	10 cm x 20 cm (4 in x 8 in)	Rectangle	12 mm
1201010	10 cm x 10 cm (4 in x 4 in)	Square	12 mm
1200710	7 cm x 10 cm (3 in x 4 in)	Rectangle	12 mm
1201015	10 cm x 15 cm (4 in x 6 in)	Rectangle	12 mm
1201520	15 cm x 20 cm (6 in x 8 in)	Rectangle	12 mm
1202025	20 cm x 25 cm (8 in x 10 in)	Rectangle	15 mm
1202530	25 cm x 30 cm (10 in x 12 in)	Rectangle	15 mm
1203035	30 cm x 35 cm (12 in x 14 in)	Rectangle	18 mm

***** If a proximal cap is available on the trocar, removing the proximal cap can help facilitate deployment. Deployment capability may vary depending on rolled mesh size and graspers/trocars used.

OPEN USE

The safety and effectiveness of PHASIX™ ST Mesh in bridging repairs has not been clinically evaluated or established. Every effort should be made to close the defect prior to use.

It is extremely important that this product be oriented correctly. Place the resorbable, hydrogel coated side of the prosthesis against those surfaces where minimal tissue attachment is desired or required, i.e., against bowel or other visceral structures.

Mesh hydration is not required prior to open placement. The method of securing the mesh should be determined by surgeon preference.

USE FOR HIATAL HERNIA REPAIR

The PHASIX™ ST Mesh should be used to buttress the primary closure of a crural defect. The safety and effectiveness of PHASIX™ ST Mesh in bridging repairs has not been clinically evaluated or established. Every effort should be made to close the crural defect prior to use.

It is extremely important that this product be oriented correctly. Place the resorbable, hydrogel coated side of the prosthesis against those surfaces where minimal tissue attachment is desired, i.e., against bowel or other visceral structures.

Marking the Mesh

If the mesh is being marked prior to insertion, do so before hydration in saline. (See *Surface Orientation* for more detail.)

Sizing

Use a sharp surgical instrument (scissors) to trim the mesh prior to implantation. To minimize chance of recurrence, trim the mesh such that it is large enough to provide sufficient overlap beyond the margins of the defect and to fit the patient's anatomy. If the material is cut too small, tension may be placed on the suture line, which may result in a recurrence of the original defect. The use of PHASIX™ ST circumferentially around the esophagus is not recommended. It is extremely important that the mesh is not placed immediately abutting the esophagus and allows for a border of native tissue between the mesh and esophagus. Please follow established surgical guidelines.

Fixation

The method of securing the mesh should be determined by surgeon preference and the nature of the reconstruction to provide for adequate tissue fixation and to prevent re-herniation. Care should be taken to ensure that the mesh is adequately fixated to the diaphragm with appropriate consideration of surrounding anatomical structures.

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.

PATIENT RECORD LABEL

Patient record labels that identify the type, size and lot number of the implant are attached to every package. One label should be incorporated into the patient's permanent medical record to clearly identify the device that was implanted. If you experience a product failure, please contact Davol, Inc. at 1-800-556-6275 for instructions on returning the product.

	Contents		Resorbable		Circle
	Do not use if the center of the temperature indicator is black		Actual size		Rectangle
	Do not use if package is damaged	Rx Only	U. S. Federal law restricts this device to sale by or on the order of a physician		Square