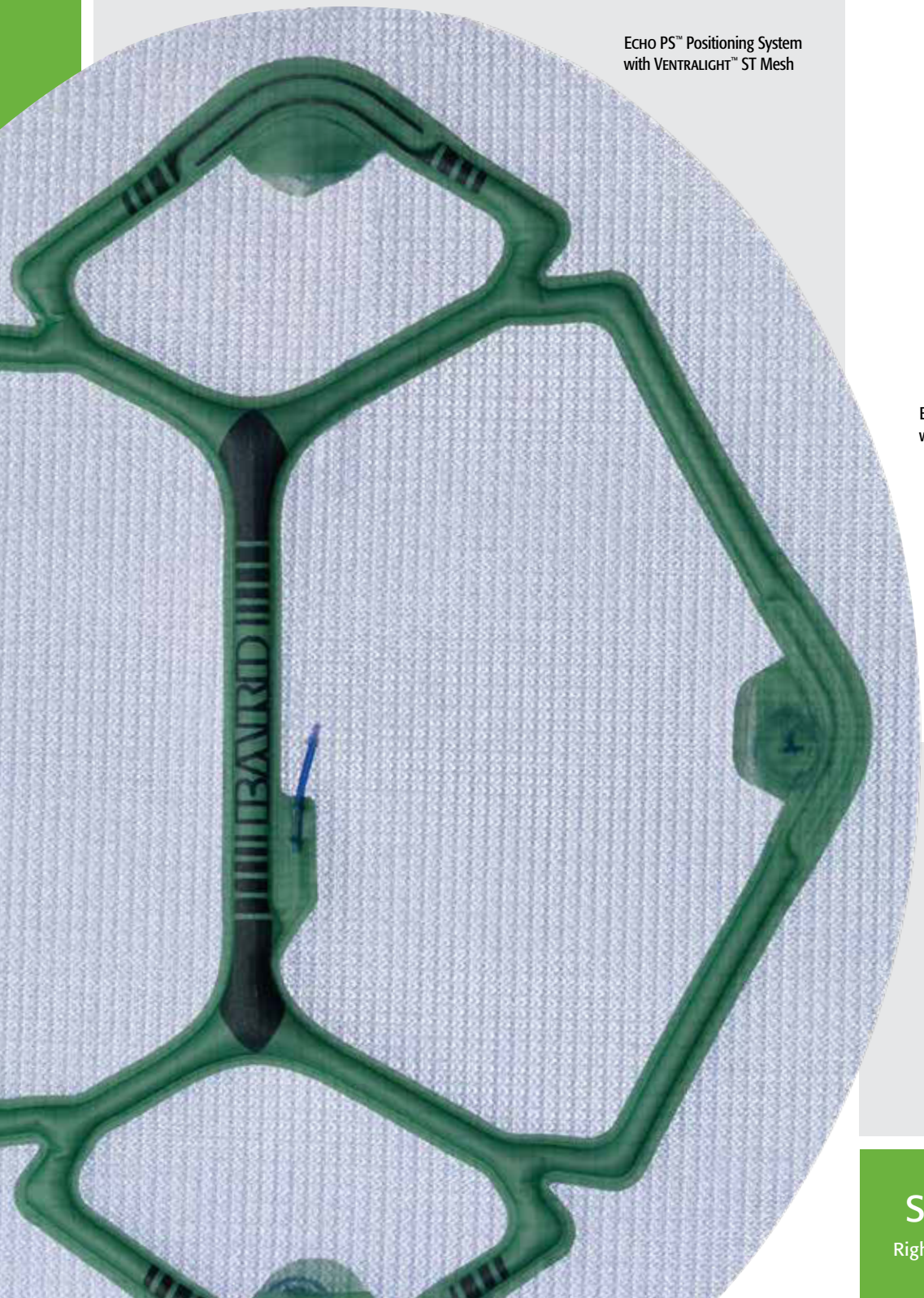
Echo PS™ Positioning System

with Ventralight™ ST Mesh or Composix™ L/P Mesh

BARD
DAVOL INC.

Laparoscopic ventral hernia repair



Echo PS™ Positioning System
with Ventralight™ ST Mesh

Echo PS™ Positioning System
with Composix™ L/P Mesh

KEY BENEFITS

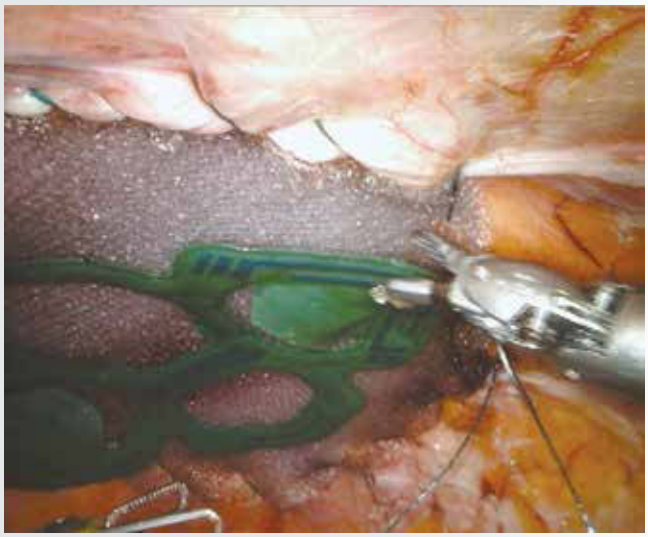
- Easy Insertion
- Effortless Placement and Positioning
- Assisted Fixation
- Compatible with Robotic Surgical Systems

SOFT TISSUE REPAIR

Right Procedure. Right Product. Right Outcome.

Compatible with Robotic Surgical Systems

The Echo PS™ Positioning System provides traditional laparoscopic advantages to robotic surgical systems.



Echo PS™ Positioning System with Ventralight™ ST Mesh or Composix™ L/P Mesh

For an efficient, reproducible repair

The Echo PS™ Positioning System is a low profile balloon that comes preattached to either Ventralight™ ST Mesh or Composix™ L/P Mesh. When inflated, the Echo PS™ Positioning System facilitates the deployment (including unrolling, positioning and placement) of the mesh during laparoscopic ventral hernia repair. Upon completion of initial perimeter fixation, the balloon is deflated quickly and completely removed from the body.

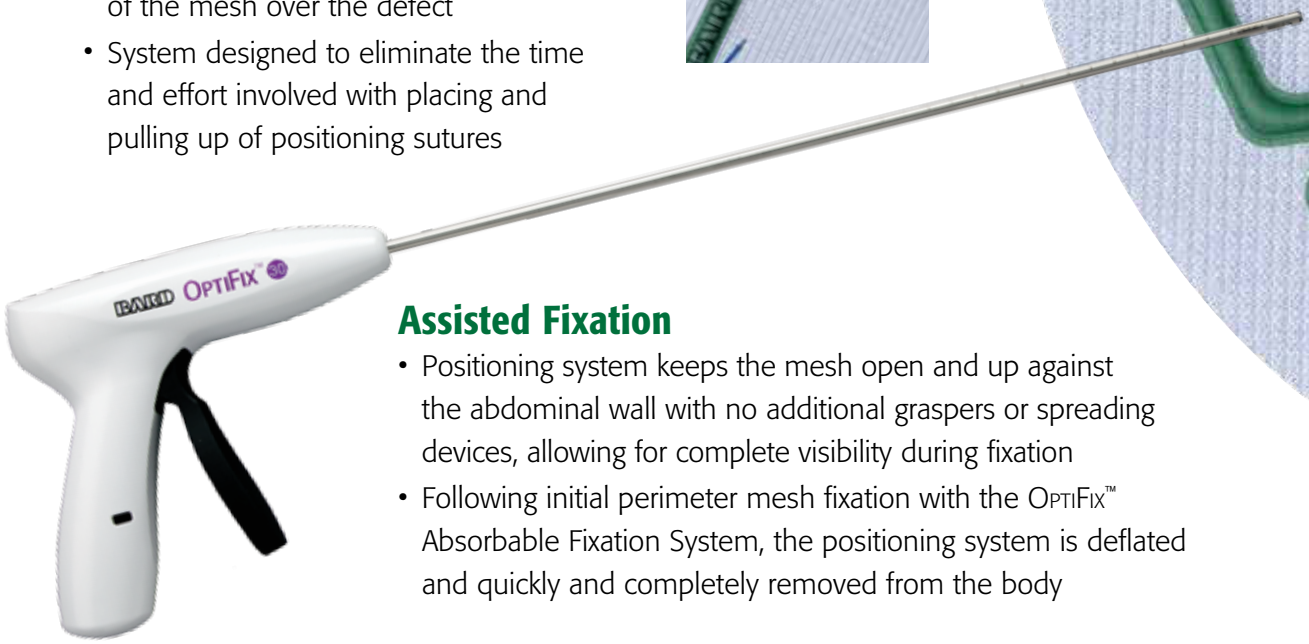
KEY BENEFITS

Easy Insertion

- The prepackaged Introducer Tool holds the mesh in place, ensuring a tight, uniform roll
- The positioning system and the mesh are low profile, facilitating trocar deployment

Effortless Placement and Positioning

- Mesh easily unrolls and opens during inflation
- No additional trocar site is needed to hold the mesh in place
- Positioning system design and orientation markers allow for ease of orientation (anterior vs. posterior side, long vs. short axis, and the midline of the mesh)
- System designed to facilitate centering of the mesh over the defect
- System designed to eliminate the time and effort involved with placing and pulling up of positioning sutures

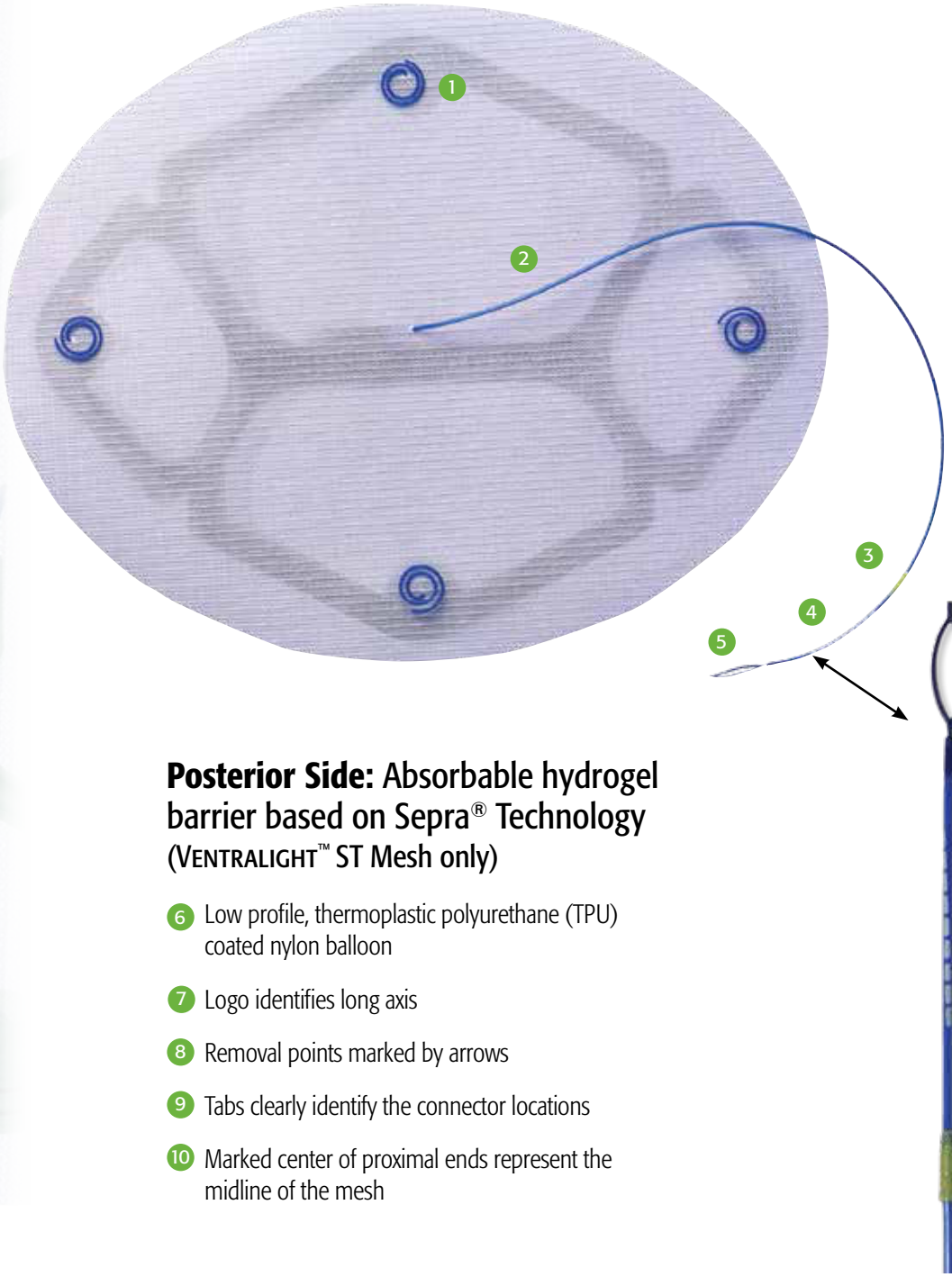


Assisted Fixation

- Positioning system keeps the mesh open and up against the abdominal wall with no additional graspers or spreading devices, allowing for complete visibility during fixation
- Following initial perimeter mesh fixation with the OptiFix™ Absorbable Fixation System, the positioning system is deflated and quickly and completely removed from the body

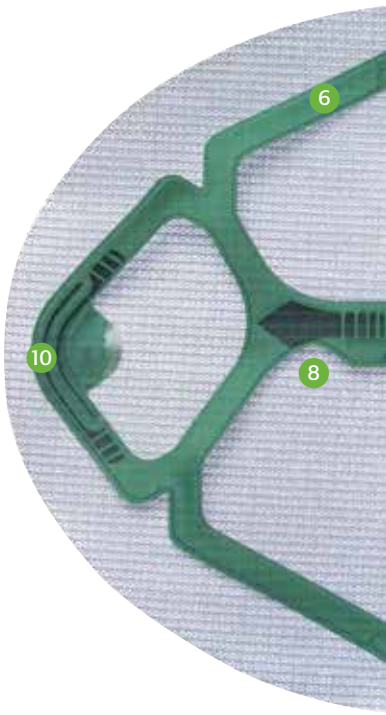
The Echo PS™ Positioning System comes preattached to either Ventralight™ ST Mesh or Composix™ L/P Mesh, requiring no assembly or specialty instruments

Anterior Side: Uncoated monofilament polypropylene mesh



1. Connectors keep the Echo PS™ Positioning System attached to the mesh, and are simultaneously removed from the abdominal cavity with the Echo PS™ Positioning System
2. Inflation tube
3. Anchor allows for a secure connection between the inflation tube and inflation assembly
4. Tube cut location
5. Retrieval loop

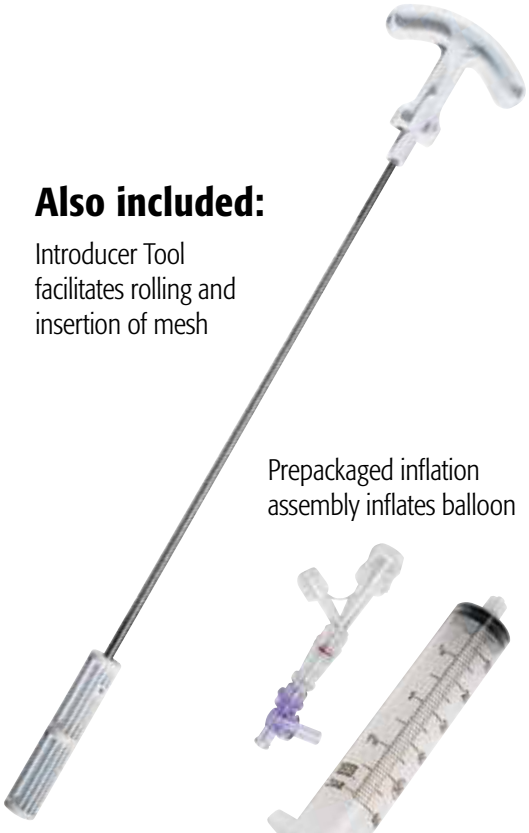
Posterior Side: Absorbable hydrogel barrier based on Sepra® Technology (Ventralight™ ST Mesh only)



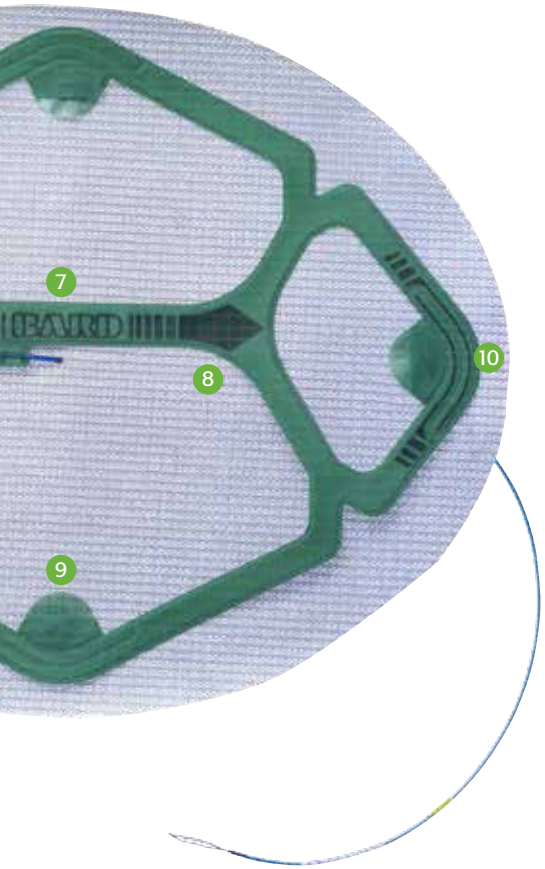
6. Low profile, thermoplastic polyurethane (TPU) coated nylon balloon
7. Logo identifies long axis
8. Removal points marked by arrows
9. Tabs clearly identify the connector locations
10. Marked center of proximal ends represent the midline of the mesh

Also included:

Introducer Tool facilitates rolling and insertion of mesh

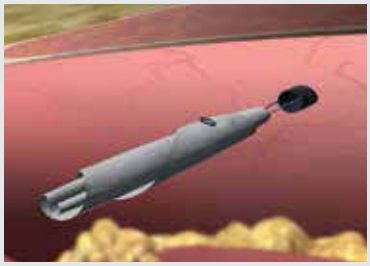


Prepackaged inflation assembly inflates balloon



Basic Steps for a Reproducible Repair

Roll

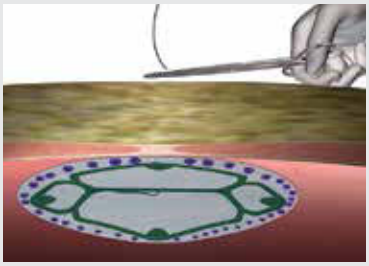


Insert

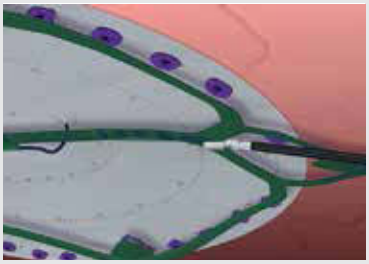
Inflate

Position

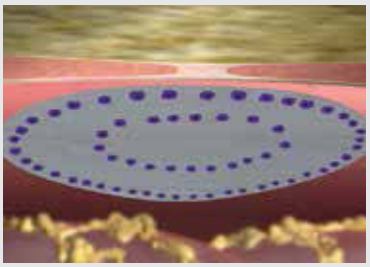
Initially Fixate



Deflate



Remove Echo PS™ Positioning System



Complete Fixation

Echo PS™ Positioning System with Ventralight™ ST Mesh or Composix™ L/P Mesh

Ventralight™ ST Mesh with Echo PS™ Positioning System

Catalog Number	Shape	Mesh Size	
5955450	Circle	4.5" (11.4 cm)	☐
5955460	Ellipse	4" x 6" (10.2 cm x 15.2 cm)	☐
5955600	Circle	6" (15.2 cm)	☐
5955800	Circle	8" (20.3 cm)	☐
5955680	Ellipse	6" x 8" (15.2 cm x 20.3 cm)	☐
5955610	Oval	6" x 10" (15.2 cm x 25.4 cm)	☐
5955790	Ellipse	7" x 9" (17.8 cm x 22.9 cm)	☐
5955810	Ellipse	8" x 10" (20.3 cm x 25.4 cm)	☐
5955113	Ellipse	10" x 13" (25.4 cm x 33.0 cm)	☐
5955124	Rectangle	12" x 14" (30.5 cm x 35.6 cm)	☐
5955000	Reorder Code for Echo PS™ Positioning System Inflation Assembly (6/cs)		☐

Also Available:

Composix™ L/P Mesh with Echo PS™ Positioning System

Catalog Number	Shape	Mesh Size	
0144680	Ellipse	6.2" x 8.2" (15.9 cm x 21.0 cm)	☐
0144610	Oval	6.2" x 10.2" (15.9 cm x 26.1 cm)	☐
0144790	Ellipse	7.2" x 9.2" (18.4 cm x 23.5 cm)	☐
0144810	Ellipse	8.2" x 10.2" (21.0 cm x 26.1 cm)	☐
0144113	Ellipse	10.2" x 13.2" (26.1 cm x 33.7 cm)	☐
0144114	Rectangle	10.2" x 14.2" (26.1 cm x 36.2 cm)	☐

Order Form

☐ Please add these marked products to my preference card.

☐ I would like to have these marked products in stock.
(Reference catalog numbers checked)

☐ I would like to trial these marked products.

Purchase Order Number _____ Date _____

Catalog Number(s) _____ Quantity _____

Surgeon's Signature _____

Echo PS™ Positioning System with Ventralight™ ST Mesh or Composix™ L/P Mesh

Indications
Ventralight™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias. Composix™ L/P Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias and chest wall defects. The Echo PS™ Positioning System is intended to be used to facilitate the delivery of soft tissue prostheses during laparoscopic hernia repair.

Contraindications
Do not use Ventralight™ ST Mesh in infants or children whereby future growth will be compromised by use of such material.

Do not use Ventralight™ ST Mesh for the reconstruction of cardiovascular defects.

Literature reports there may be a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowel or viscera.

Warnings
Ventralight™ ST Mesh/Composix™ L/P Mesh is the only permanent implant component of the device. The inflation adapter and syringe are to be kept external to the patient and discarded after use. The Echo PS™ Positioning System (including the balloon, all connectors, and inflation tube) is to be removed from the patient and appropriately discarded as it is not part of the permanent implant.

The Echo PS™ Positioning System should not be used with any other hernia prosthesis aside from those with which it comes pre-attached/packaged.

Precautions
Do not trim the mesh. This will affect the interface between the mesh and positioning system.

Adverse Reactions
Possible complications include seroma, adhesions, hematomas, inflammation, extrusion, fistula formation, infection, allergic reaction, and recurrence of the hernia or soft tissue defect.

OptiFix™ Absorbable Fixation System

Indications
The OptiFix™ Absorbable Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

Contraindications
Contraindications associated with laparoscopic and open surgical procedures relative to mesh fixation apply, including but not limited to:

- Fixation of vascular or neural structures
- Fixation of bone and cartilage
- Situations with insufficient ingrowth of tissue into the mesh over time, which could result in inadequate fixation once the fastener is absorbed.

Carefully inspect the area in the vicinity of the tissue being fastened to avoid inadvertent penetration of underlying structures such as nerves, vessels, viscera or bone. Use of the OptiFix™ Absorbable Fixation System in the close vicinity of such underlying structures is contraindicated. For reference, the length of the fastener below the fastener head is 6.1 mm, the fastener head is another 0.6 mm (total 6.7 mm).

Warnings
The device may not fixate through prosthetics derived from biologic material such as xenografts and allografts. Prosthetic should be evaluated for compatibility prior to use. After use, the OptiFix™ Absorbable Fixation System may be a potential biohazard. Handle and dispose of in accordance with any local and federal laws regarding medical waste.

Adverse Reactions
Adverse reactions and potential complications associated with fixation devices such as the OptiFix™ Absorbable Fixation System may include, but are not limited to the following: hemorrhage; pain, edema and erythema at wound site; allergic reaction to Poly(D, L)-lactide; infection/septicemia; hernia recurrence/wound dehiscence.

To learn more, contact your local Bard Representative or call 1.800.556.6275.

Please consult package insert for more detailed safety information and instructions for use.

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