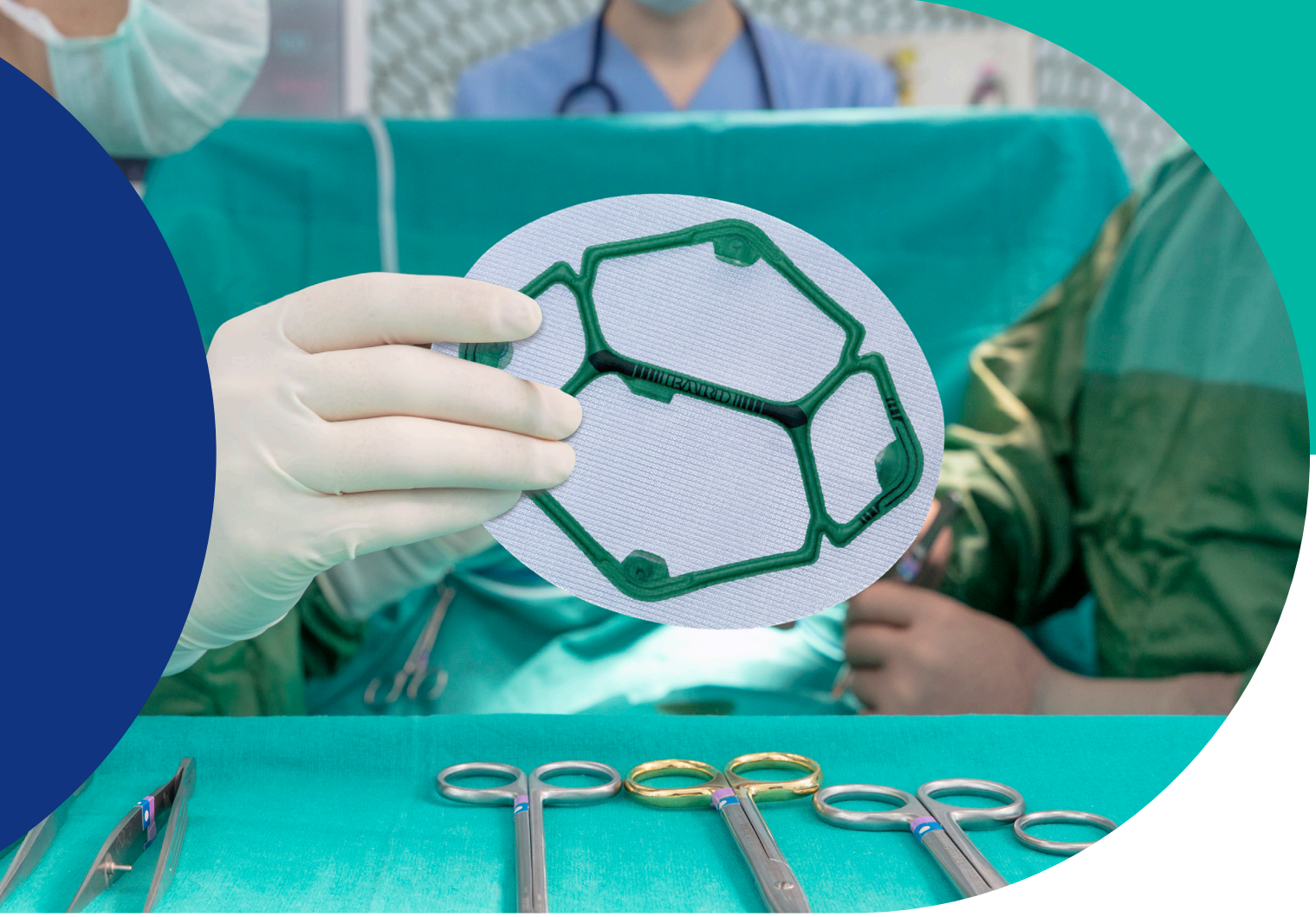


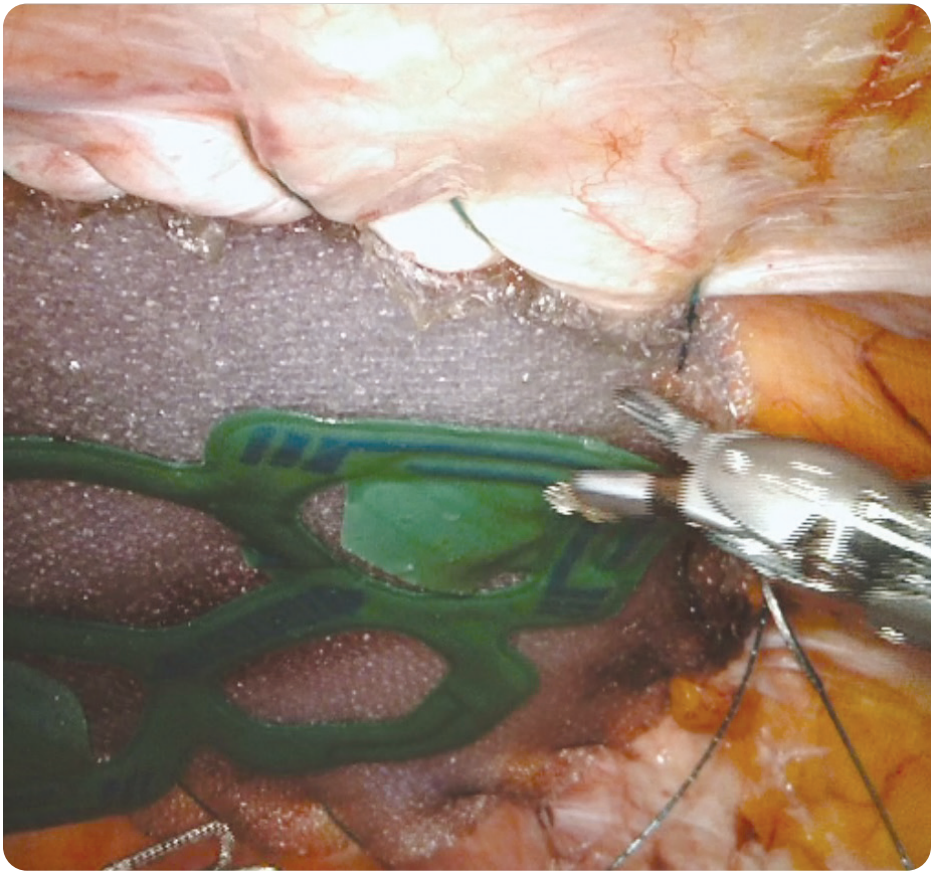
Ventralight™ ST Mesh with Echo PS™ Positioning System

For laparoscopic ventral hernia repair

BD

For an efficient, reproducible repair

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



The Echo PS™ Positioning System is a low profile balloon that comes preattached to Ventralight™ ST 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

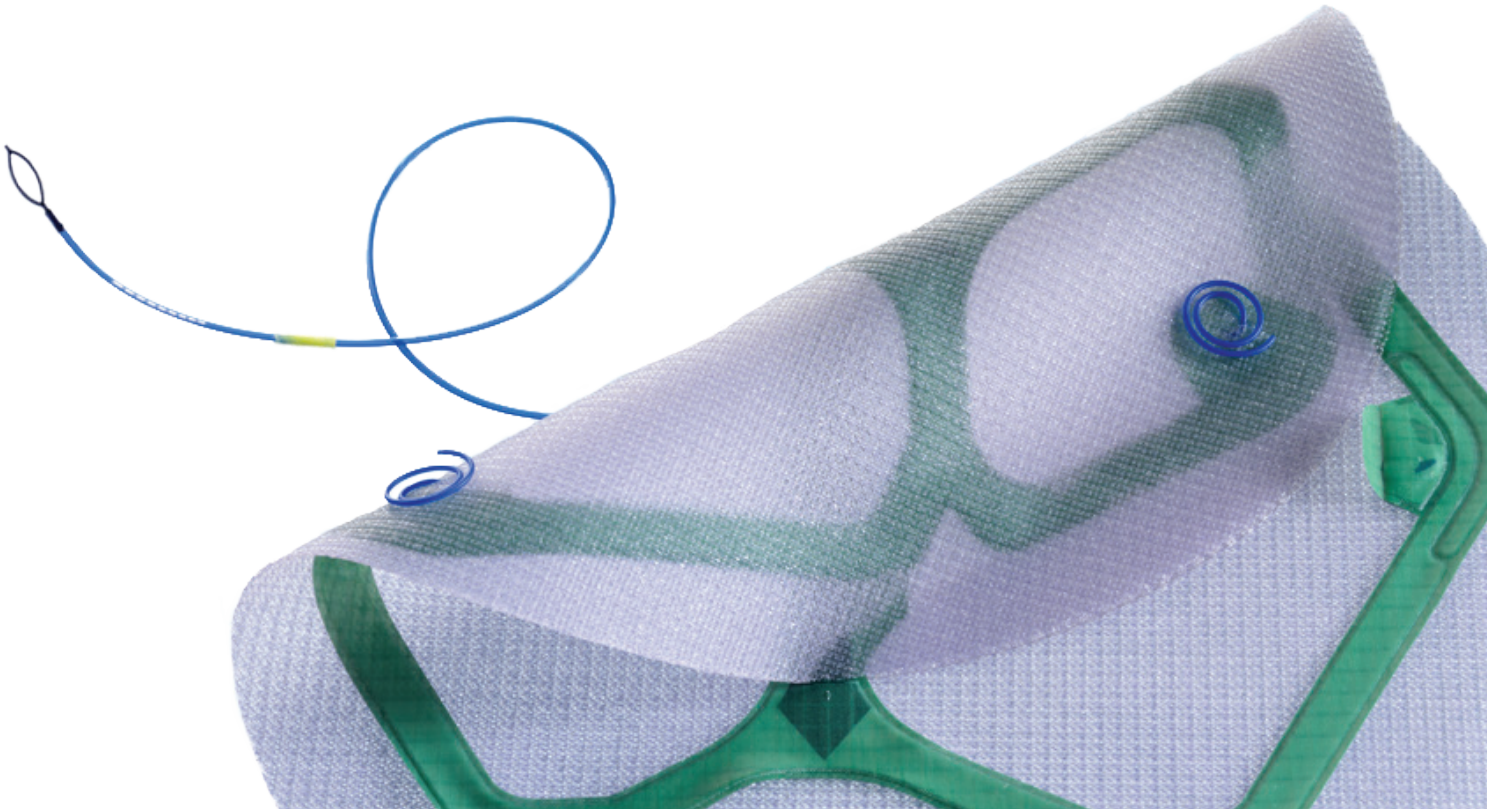
- The prepackaged Introducer Tool holds the mesh in place, ensuring a tight, uniform roll
- The positioning system and the mesh are low profile, facilitating trocar deployment

Effortless placement and positioning

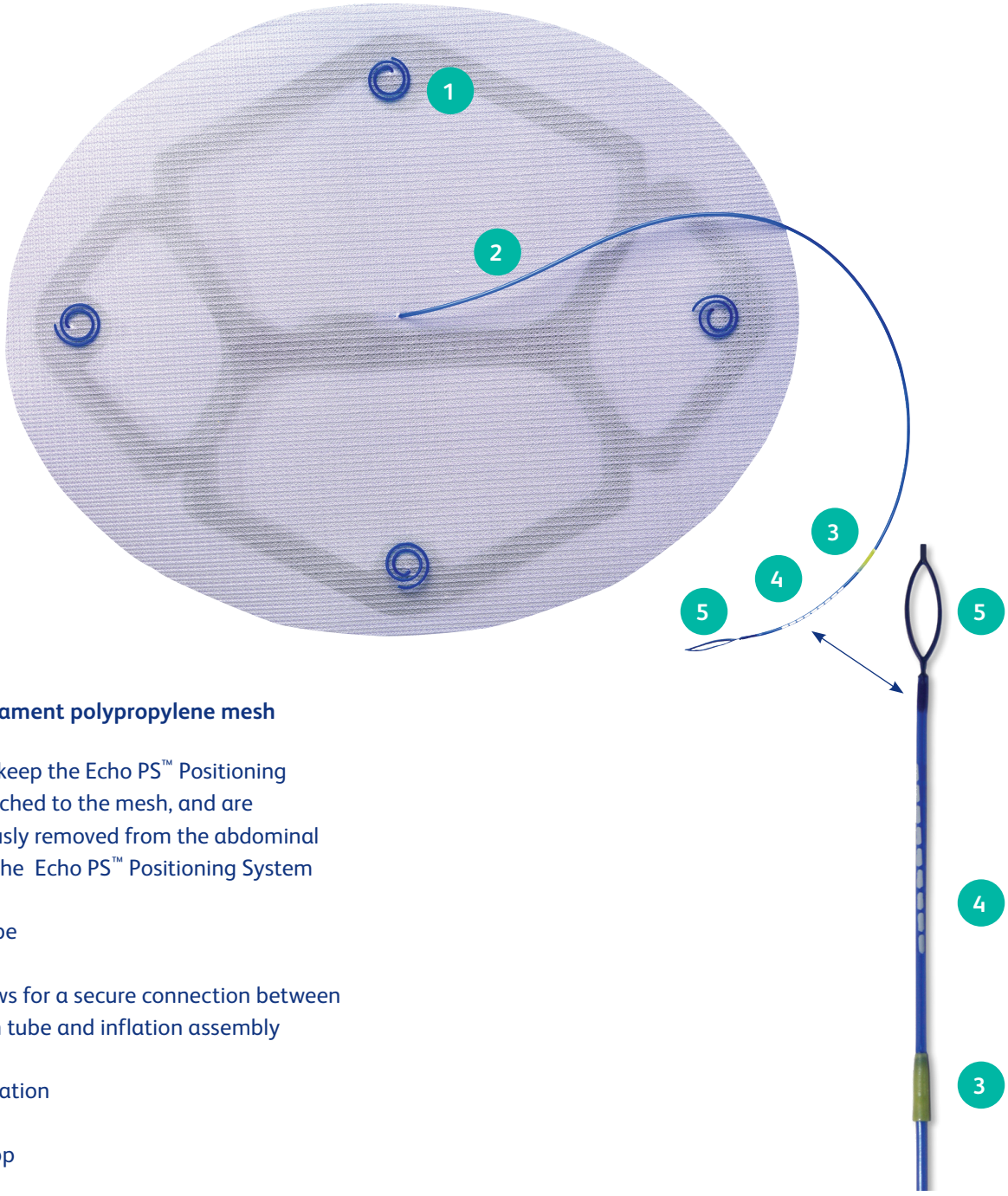
- Mesh easily unrolls and opens during inflation
- No additional trocar site is needed to hold the mesh in place
- Positioning system design and orientation markers allow for ease of orientation (anterior vs. posterior side, long vs. short axis, and the midline of the mesh)
- System designed to facilitate 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 Ventralight™ ST Mesh, requiring no assembly or specialty instruments.



Anterior side

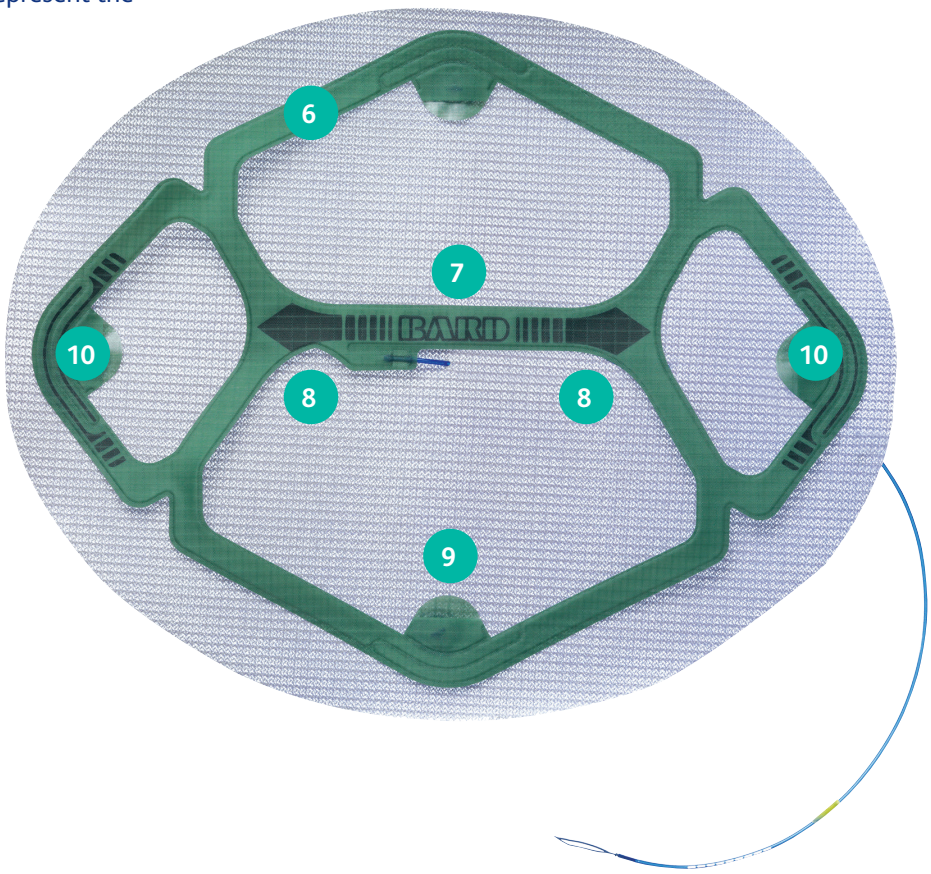
Uncoated monofilament polypropylene mesh

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

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

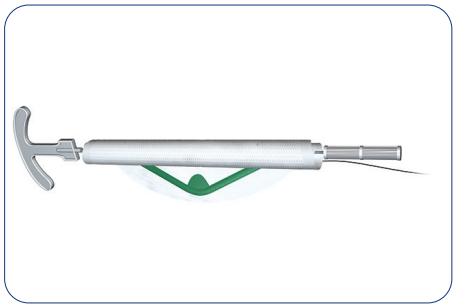


Also included

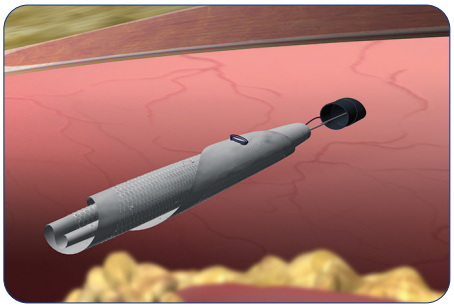
Introducer Tool facilitates rolling and insertion of mesh

Prepackaged inflation assembly inflates balloon

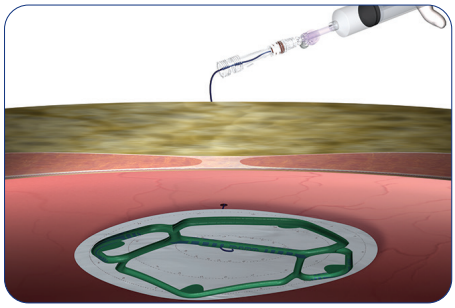
Basic steps for a reproducible repair



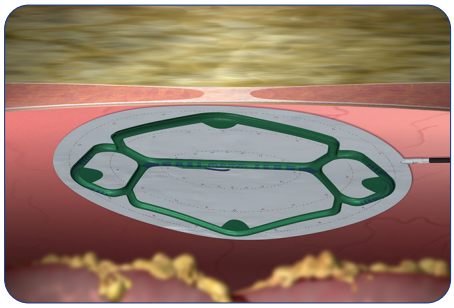
1 Roll



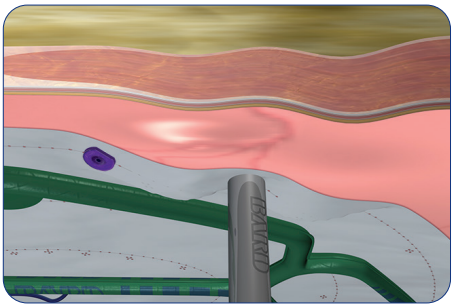
2 Insert



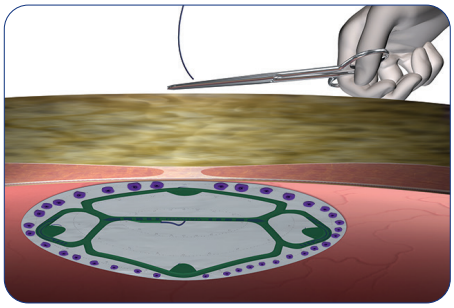
3 Inflate



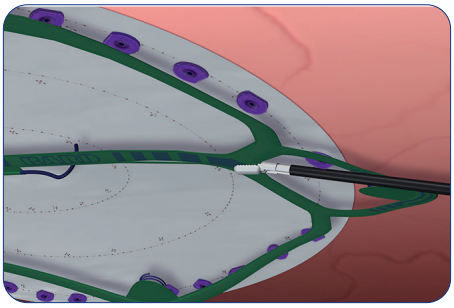
4 Position



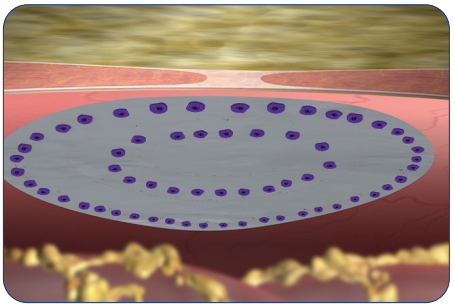
5 Initially fixate



6 Deflate



7 Remove Echo PS™ Positioning System



8 Complete fixation

Ordering information

Ventralight™ ST Mesh with Echo PS™ Positioning

Product code	Qty.	Shape	Dimensions
5954450G	1/cs	Circle	4.5" (11.4 cm)
5954460G	1/cs	Ellipse	4" x 6" (10.2 cm x 15.2 cm)
5954600G	1/cs	Circle	6" (15.2 cm)
5954680G	1/cs	Ellipse	6" x 8" (15.2 cm x 20.3 cm)
5954610G	1/cs	Oval	6" x 10" (15.2 cm x 25.4 cm)
5954790G	1/cs	Ellipse	7" x 9" (17.8 cm x 22.9 cm)
5954800G	1/cs	Circle	8" (20.3 cm)
5954810G	1/cs	Ellipse	8" x 10" (20.3 cm x 25.4 cm)
5954113G	1/cs	Ellipse	10" x 13" (25.4 cm x 33 cm)
5954124G	1/cs	Rectangle	12" x 14" (30.5 cm x 35.6 cm)

☐ 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 _____

Ventralight™ ST Mesh with Echo PS™ Positioning System **CE-Marked Indications. INDICATIONS** Ventralight™ ST Mesh is indicated for use in he reconstruction of soft tissue deficiencies. in the repair of ventral, incisional, and umbilical hernias. The Echo PS™ Positioning System is intended to be used to facilitate he delivery of the Ventralight™ ST Mesh during laparoscopic hernia repair. **Contraindications.** 1. Do not use this mesh in infants, children. or pregnant women, Whereby future growth may be compromised by the use of such mesh materials. 2. The use of this mesh has not been studied in breastfeeding or pregnant women. 3. Do not use this mesh for the reconstruction of cardiovascular defects. 4. literature reports there is a possibility for adhesion formation when the polypropylene is placed in direct contact with he bower or viscera. **Warnings.** 1.The use of any permanent mesh in a contaminated or infected wound could lead to infection, fistula formation, and/or extrusion of the mesh.2. 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.3.If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of viral infections.4.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 fascia! tissue.5.This device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use.6.This device has been designed for single use only. Reuse, resterilization, reprocessing and/or repackaging 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.7.The mesh should be used once the exterior foil pouch has been opened. Do not store for later use. Unused portions of the mesh should be discarded.8.Ensure proper orientation; the coated side of the mesh should be oriented against the bowel or sensitive organs. Do not place the polypropylene side against the bowel. There may be a possibility for adhesion formation when the polypropylene side is placed in direct contact with the bowel or viscera(reference Surface Orientation section).9. Do not apply sharp, heat emitting, or ultrasonic tools (such as scissors, needles, tackers, diathermic tools, etc.) to the Echo psn• Positioning System.10. The Echo psn• Positioning System should not be used with any other hernia mesh aside from those with which it comes pre-attached/packaged.11. Ventralight™ ST 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) must be removed from the patient and appropriately discarded. It is not part of the permanent implant.12.Discard Introducer Tool and all components of the Echo ps Positioning System (including the inflation adapter and syringe) after ...-... use. This product may be a potential _ Biohazard. Handle and dispose in accordance with accepted medical practice and applicable local, state, and federal laws and regulations. 13.This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach.14. This mesh is not for the use of treatment of stress urinary incontinence.**Precautions.**1.Please read all instructions prior to use. 2.Only physicians qualified in the appropriate surgical techniques should use this device. 3.The safety and effectiveness of Ventralight™ ST Mesh with EchO PS™ Positioning System has not been evaluated in clinical studies for the presence of malignancies in the abdominopelVic cavity. 4.Visualization must be maintained throughout the course of the entire procedure.Additionally, laparoscopic removal of the Echo PS™ Positioning System must be performed under sufficient visualization of he entire device and surrounding anatomy to ensure proper removal. 5.Do not trim the mesh. This will affect the interface between the mesh and positioning system. **Adverse Reactions.**Possible complications may include, but are not limited to, seroma, adhesion, hematoma, pain, infec ion, inflammation, extrusion. erosion, migration. fistula formation, allergic reaction, and recurrence of the hernia or soft tissue defect.

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

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.**1. This device is not intended for use except as indicated. 2. Do not use this device where hemostasis cannot be verified visually after application. 3. 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. 4. 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 ofthe fastener below the fastener head is 6.1 mm, the fastener head is another 0.6 mm (total 6.7 mm).5. This device should not be used in tissues that have a direct anatomic relationship to major vascular structures.This would include the deployment of fasteners in the diaphragm in the vicinity of the pericardium,aorta, or inferior vena cava during diaphragmatic hernia repair. **Warnings.** 1. The OptiFix™ Absorbable Fixation System is intended for Single Use Only – DO NOT RESTERILIZE. 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 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. 2. Do not use beyond the expiration date on the package. 3. 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. 4. As with any implant material the presence of bacterial contamination may enhance bacterial infectivity. Accepted surgical practice must be followed with respect to drainage and closure of infected or contaminated wounds. 5. Users should be familiar with surgical procedures and techniques involving synthetic absorbable materials before employing OptiFix™ Absorbable Fixation System fasteners for wound closure, as the risk of wound dehiscence may vary with the site of application and the material used.6. 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. **Precautions.**1. Please read all instructions before using the OptiFix™ Absorbable Fixation System.2. Only persons having adequate medical training and familiarity with surgical techniques should perform surgical procedures. Consult the medical literature relative to technique, complications and hazards prior to any surgical procedure. 3. The OptiFix™ Absorbable Fixation System can be used with most 5 mm trocars. Ensure compatibility by inserting the device into the trocar prior to introduction into the patient. The OptiFix™ Absorbable Fixation System should enter and exit the trocar easily without excessive force. The use of too much force could damage the instrument. 4. Counterpressure should be applied on the target area. Avoid placing hand/finger directly over the area where fastener is being deployed to prevent injury. 5. Use caution when deploying the OptiFix™ fastener over or in proximity to underlying bone, vessels, nerves, or viscera. The intended fixation site should be assessed to ensure that while the tissue is compressed the total distance from the surface of the tissue to any underlying structures is greater than the length of the OptiFix™ fastener. 6. Insertion of fasteners is possible into some collagenous structures such as ligaments and tendons, but is NOT possible directly into bone or cartilage. This may damage the device and result in compromised fixation strength. 7. Care should be taken not to use excessive counterpressure as this may damage the distal tip of the device as well as the mesh and/or tissue.8. If the device locks and cannot be separated from a fastener that has been deployed into mesh and/or tissue, place a grasper adjacent to the deployed fastener and pull to free the device. If needed, you may use laparoscopic scissors to cut below the fastener head. The remaining portion of the fastener stem left in the mesh can be removed with graspers. The device should then be discarded and a new device should be used.9. If the fastener does not deploy properly, remove the device from the patient and test the device in gauze to ensure proper fastener deployment. Once proper fastener deployment is confirmed, the device may be reinserted into the patient. **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. **Instruction for use.**1. Take the OptiFix™ Absorbable Fixation System out of the sterile package using sterile technique.2. Bring the prosthesis (mesh) or tissue into position. For tissue approximation, be sure that adequate overlapof tissue exists.3. For laparoscopic ventral hernia repair it is recommended to reduce the pneumoperitoneum appropriately for better abdominal wall compliance and optimal fastener depth penetration.4. Place the tip of the OptiFix™ Absorbable Fixation System at the desired location perpendicular to the mesh or tissue and apply adequate counter pressure. Different types of mesh may require different amounts of counterpressure. Adjust angle and counterpressure appropriately.5. Counterpressure should be applied to ensure the fastener is fully deployed. Compress handpiece actuation lever in a single, complete and uninterrupted stroke to drive an absorbable fastener through the mesh into the tissue. Keep consistent pressure on the distal tip of the device through the entire stroke. Release the actuation lever allowing it to return completely to its resting position. After each deployment, each fastener should be visually assessed for proper placement against the mesh or tissue. Repeat this procedure until all required fasteners are deployed. 6. The fasteners should be placed entirely in tissue and the head of the fastener should be firm against the mesh or tissue in order to achieve the best fixation performance. If the fastener head is not flush in mesh or tissue, laparoscopic scissors can be used to cut the fastener head off and a grasper can be used to remove the head of the fastener. Place another fastener in the same vicinity. 7. After successful deployment of all required fasteners, handle and dispose of in accordance with any local and federal laws regarding medical waste. **Storage.**Store the OptiFix™ Absorbable Fixation System in a dry environment at room temperature. Avoid prolonged exposure to elevated temperatures. It is for single use only. 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.

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

- Not all products, services, claims or features of products and services may be available or valid in your local area. Please check with your local BD Representative.
- This material is intended for Health Care Professionals only
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