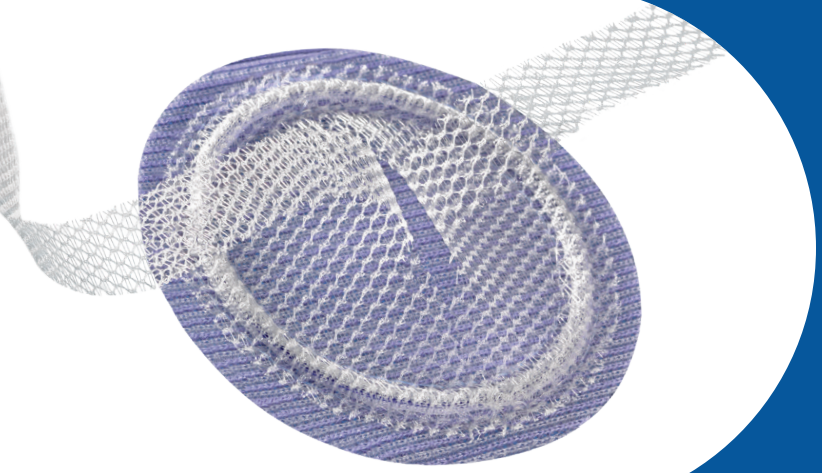
Absorbable barrier mesh portfolio

For ventral hernia repair featuring Sepra® technology

BD

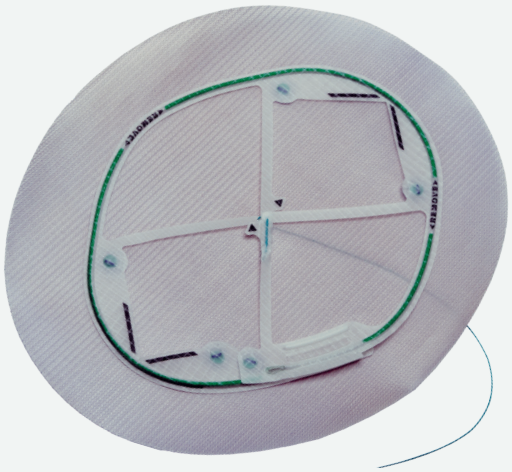
Proven solutions

Our ST family of synthetic ventral hernia repair products combine materials used in general surgery for many years to deliver proven benefits to you and your patients. Featuring a proven Sepra® technology absorbable hydrogel barrier together with uncoated polypropylene mesh creates a unique combination – one that allows for rapid tissue ingrowth and minimizes tissue attachment.[1]



Ventralex™ ST Hernia Patch

Ventrio™ ST Hernia Patch



Ventralight™ ST Mesh with Echo 2™ Positioning System

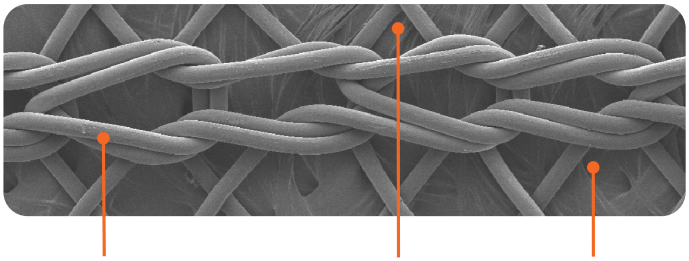
1. Preclinical data on file at BD. Results may not correlate to performance in humans.

Uncoated monofilament polypropylene

Over 40 years of proven results in hernia repair.

- Allows for a fast fibrotic response for a strong repair.
- Provides a long-term repair with minimized recurrence.

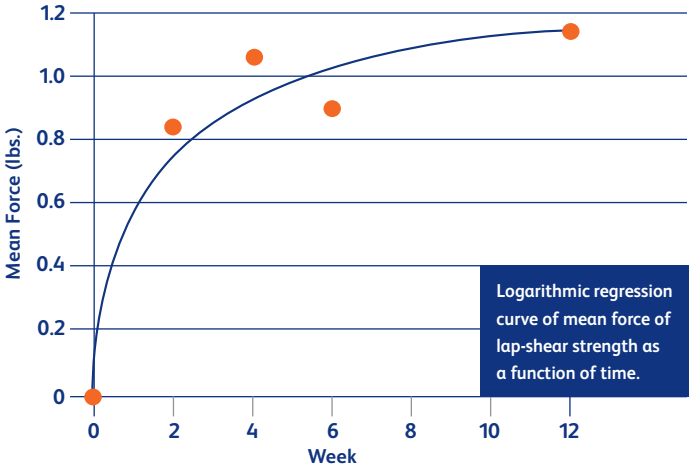
The monofilament polypropylene side of Ventralight™ ST Mesh (25x)



Uncoated monofilament polypropylene mesh

Hydrogel barrier

Strength of tissue ingrowth in a preclinical study[2]



74% of the 12-week strength is achieved by 2 weeks postoperatively.[2,3]

Uncoated polypropylene allows for the majority of tissue ingrowth and strength to occur in the first two weeks after placement of a composite hernia prosthesis.[1]

Sepra® technology absorbable barrier

10+ published studies

- Used clinically since 2007.
- Unique hydrogel barrier swells to minimize tissue attachment to the visceral side of the mesh.[1]
- Bioresorbable PGA fibers reinforce the integrity of the hydrogel barrier by binding it to the polypropylene mesh.
- The hydrogel barrier resorbs within 30 days providing visceral protection during the critical healing period.[1]

Long-term outcome on the use of the Ventralight™ ST Hernia Patch in laparoscopic ventral hernia repair[5]

Results – 61 patients, 23 mean month follow up	
Recurrence	1 (2%)
Operative complications	0 (0%)
Seroma	2 (3%)
Mean length of stay	4 days (range 2–17)
Mild persistent discomfort	2 (3%)

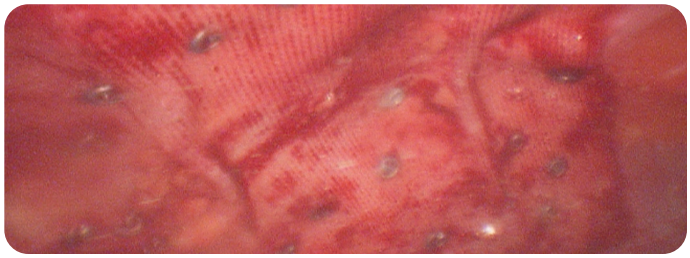
Sepramesh™ IP Composite* – a clinical study[4]

A single-arm, single-center, retrospective study with prospective follow-up of laparoscopic ventral hernia repair utilizing the Bard® Sepramesh™ IP Composite.

Andrew Archer, DO, Stephen Fleischer, DO, Rhett Lohman, DO, Edward Caldwell, DO. Grandview Medical Center, Dept. of Surgery, Dayton, OH.

Results – 90 patients, 3 year follow up	
Hernia recurrence	1 (1.1%)
Postoperative subxiphoid hernia	1 (1.1%)
Mean procedure time (min)	41.4 ± 20.6

Two additional adverse events (seroma and abdominal pain) were also reported.



47 year-old male with Sepramesh™ IP Composite 4 months after surgery

*Sepramesh™ is the base mesh used on both Ventrio™ ST and Ventralex™ ST Mesh.

1. Preclinical data on file at BD. Results may not correlate to performance in humans.
2. Majercik, S. et al. Strength of tissue attachment to mesh after ventral hernia repair with synthetic composite mesh in a porcine model. *Surg Endosc.* 2006 Nov;20(11):1671-4.
3. Results may not correlate to performance in humans. **4.** Study was sponsored by BD. Dr. Archer is a paid consultant for BD. **5.** Tollens T, Topal H, Lucardie A, Vermeiren K, Aelvoet C. Long-term outcome on the use of the Ventralight™ ST Hernia Patch in laparoscopic ventral hernia repair. *Surg Technol Int.* 2015 May;26:157-61.

Laparoscopic absorbable barrier mesh with Sepra® technology

Ventralight™ ST Mesh with Echo 2™ Positioning System

For laparoscopic ventral hernia repair

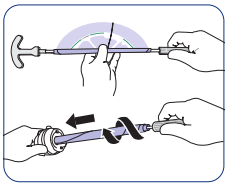
- Ventralight™ ST Mesh features a low profile, medium weight mesh designed to facilitate trocar deployment and mechanical fixation.
- The Echo 2™ Positioning System is a depolyment and positioning device that comes attached to Ventralight™ ST Mesh and facilitates mesh positioning and centering over the hernia defect, for a consistent, reproducible technique.
- Available in a variety of shapes and sizes (mesh introducer provided with most sizes).

Literature supports positioning system technology for:

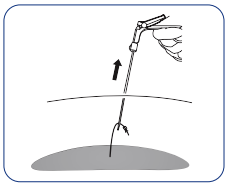
- Accurate mesh placement, positioning, and overlap.[1,2]
- Decreasing operative time.[1,2]

1. Hydrate

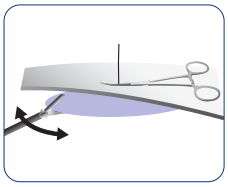
2. Roll and insert



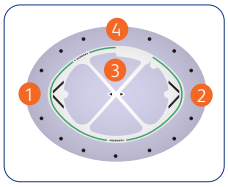
3. Deploy and hoist



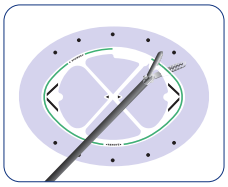
4. Position and center



5. Fixate



6. Frame removal



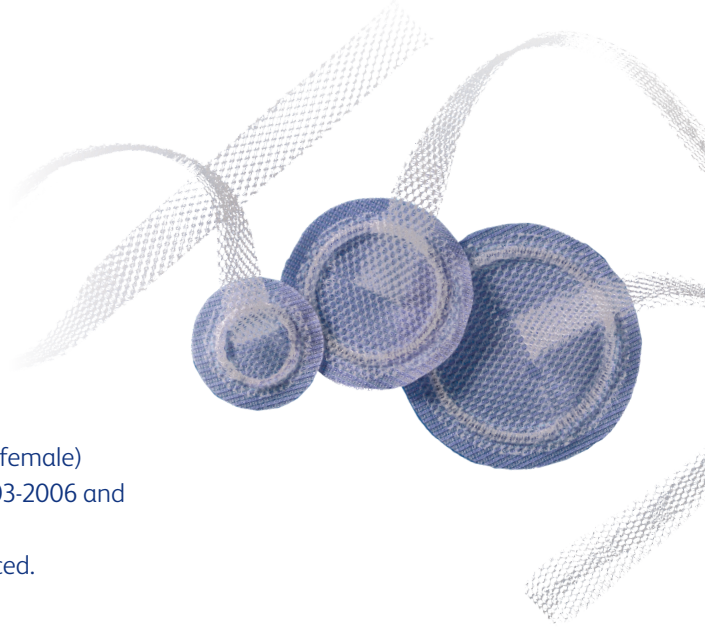
Fixation with OptiFix™ Absorbable or CapSure™ Permanent Fixation Systems

The OptiFix™ Absorbable Fixation System has been engineered inside and out to provide surgeon confidence and secure fixation in a reliable, easy to use, and ergonomic design.

The CapSure™ Permanent Fixation system is designed to address the traditional challenges of permanent fixation by providing surgeons strong and reliable fixation in an easy to use delivery system.

1. LeBlanc K. Proper mesh overlap is a key determinant in hernia recurrence following laparoscopic ventral and incisional hernia repair *Hernia.* 2016 Feb;20(1):85-99. **2.** Tollens T, Topal H, Ovaere S, Beunis A, Vermeiren K, Aelvoet C. Prospective analysis of ventral hernia repair using the Ventralight™ ST hernia patch. *Surg Technol Int.* 2013 Sep;23:113-6.

Open absorbable barrier mesh with Sepra® technology



Ventralex™ ST Hernia Patch

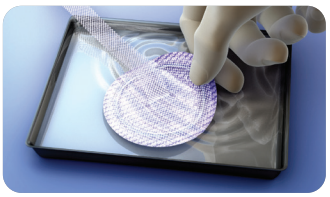
For umbilical hernia repair

- Pocket and strap facilitates placement, positioning and fixation.
- SorbaFlex™ Memory Technology allows the patch to "spring open," lay flat to maintain shape and then fully absorbs over time.[3]
- Three sizes available

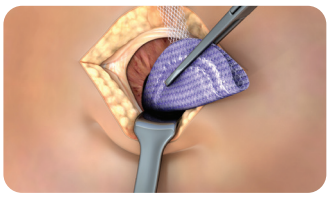
Proven technique[1]

- 88 patients (69 male, 19 female) were evaluated from 2003-2006 and 89 Ventralex™ Hernia Patches were placed.
- Zero hernia recurrences.

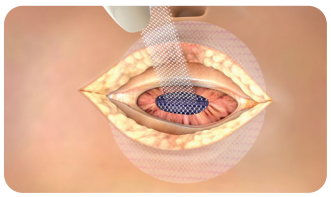
1. Hydrate



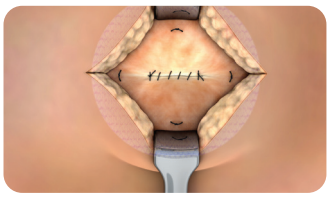
2. Fold and insert



3. Position and secure



4. Close



Ventrio™ ST Hernia Patch

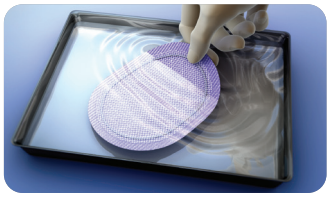
For open ventral hernia repair

- Unique pocket aids in the proper placement and postioning of the patch and facilitates the use of mechanical fixation devices and/or sutures.
- SorbaFlextm Memory Technology allows the patch to "spring open," lay flat to maintain shape and then fully absorbs over time.[3]
- Available in a variety of shapes and sizes to accommodate defect sizes and locations

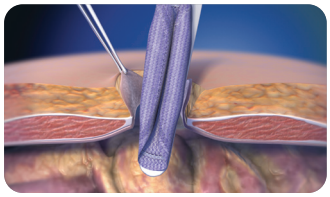
Proven technique[2]

- The design of the Ventrio™ ST Hernia Patch allows the use of the familiar CK™/ Ventrio™ Hernia Patch technique for open ventral hernia repair.
- Technique resulted in a 1% recurrence rate in 455 patients.

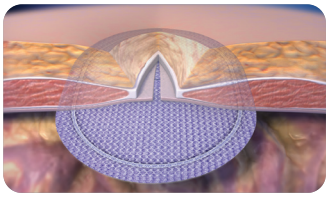
1. Hydrate



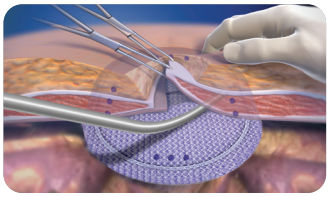
2. Roll and insert



3. Place and position



4. Secure



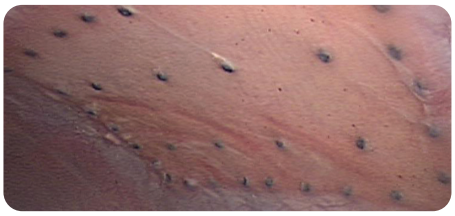
1. D .F. Martin, R. F. Williams, T. Mulrooney, and G. R. Voeller. Ventralex mesh in umbilical/epigastric hernia repairs: clinical outcomes and complications *Hernia*. 2008 Aug; 12(4):379-83.
2. Iannitti, D. et. al. Technique and Outcomes of Abdominal Incisional Hernia Repair Using a Synthetic Composite Mesh: A Report of 455 Cases. *Journal of the American College of Surgeons*. 2008 Jan; 206 (1):83-8. Dr. Iannitti is a paid consultant for BD. **3.** Preclinical data on file at BD. Results may not correlate to performance in humans.

Preclinical absorbable barrier outcomes[1]

Ventralight™ ST Mesh

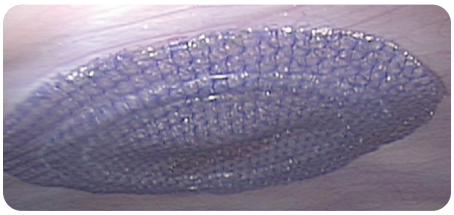
Initial implant

4 weeks

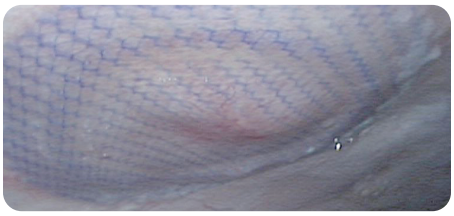


Ventralex™ ST Hernia Patch

Initial implant

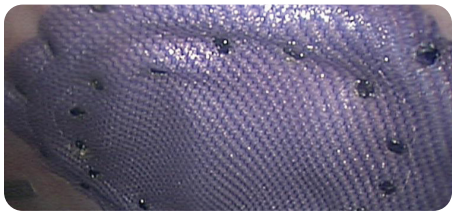


2 weeks

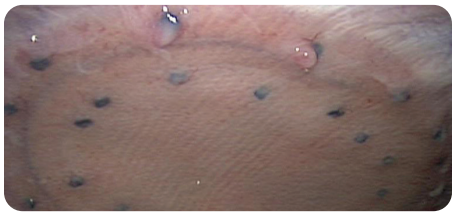


Ventrio™ ST Hernia Patch

Initial implant



2 weeks



Ordering info

Ventralight™ ST Mesh with Echo 2™ Positioning System

Cat. no.	Shape	Dimensions	Mesh introducer included	
5990011G	Circle	4.5" (11 cm)	No	☐
5991015G	Ellipse	4" x 6" (10 cm x 15 cm)	No	☐
5990015G	Circle	6" (15 cm)	Yes	☐
5991520G	Ellipse	6" x 8" (15 cm x 20 cm)	Yes	☐
5991525G	Oval	6" x 10" (15 cm x 25 cm)	Yes	☐
5991823G	Ellipse	7" x 9" (18 cm x 23 cm)	Yes	☐
5990020G	Circle	8" (20 cm)	Yes	☐
5992025G	Ellipse	8" x 10" (20 cm x 25 cm)	Yes	☐
5992533G	Ellipse	10" x 13" (25 cm x 33 cm)	Yes	☐
5993035G	Ellipse	12" x 14" (30 cm x 35 cm)	No	☐

Ventrio™ ST Hernia Patch

Cat. no.	Shape	Dimensions	
5950010G	Small circle	3.0" (7.6 cm) diameter	☐
5950020G	Large circle	4.5" (11.4 cm) diameter	☐
5950030G	Small oval	3.1" x 4.7" (8.0 cm x 12.0 cm)	☐
5950040G	Medium oval	4.3" x 5.5" (11.0 cm x 14.0 cm)	☐
5950050G	Large oval	5.4" x 7.0" (13.8 cm x 17.8 cm)	☐
5950060G	Midline	6.1" x 10.1" (15.5 cm x 25.7 cm)	☐
5950070G	Extra large oval	7.7" x 9.7" (19.6 cm x 24.6 cm)	☐
5950080G	Extra large oval	8.7" x 10.7" (22.1 cm x 27.1 cm)	☐
5950090G	Extra large oval	10.8" x 13.7" (27.4 cm x 34.9 cm)	☐

Ventralex™ ST Hernia Patch

Cat. no.	Shape	Dimensions	
5950007G	Small circle with strap	4.3 cm diameter small circle	☐
5950008G	Medium circle with strap	6.4 cm diameter medium circle	☐
5950009G	Large circle with strap	8.0 cm diameter large circle	☐

OptiFix™ Absorbable Fixation System

Cat. no.	Description	Qty.	
0113126G	30 Absorbable fasteners	5/case	☐
0113127G	15 Absorbable fasteners	5/case	☐

CapSure™ Permanent Fixation System

Cat. no.	Description	Qty.	
0113230G	30 Permanent fasteners	5/case	☐
0113215G	15 Permanent fasteners	5/case	☐

Order form

☐ Please add these products to my preference card.

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

☐ I would like to trial these products.

Purchase order number _____ Date _____

Catalog number(s) _____ Quantity _____

Surgeon's signature _____

1. Preclinical data on file at BD. Results may not correlate to performance in humans.

Ventralex™ ST Hernia Patch CE-Marked Indications. Ventralex™ ST Hernia Patch is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving the repair of ventral, incisional, and umbilical hernias. **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 that there may be a possibility for adhesion formation when the polypropylene is placed in contact with the bowel or viscera. **Warnings.** 1. The use of any permanent mesh or patch in a contaminated or infected wound could lead to 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 the removal of the mesh. 3. If the unused mesh has been in contact with instruments or supplies used on a patient or contaminated with bodily fluids, discard with care to prevent the 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 fascial tissue. 5. This mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh 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 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 device may lead to injury, illness, or death of the patient or end user. 7. This 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. Ensure proper orientation; the bioresorbable 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 mesh is placed in direct contact with the bowel or viscera. 9. Do not cut or reshape any portion of the Ventralex™ ST Hernia Patch, except for the polypropylene positioning strap, as this could impact its effectiveness. Care should be taken not to cut or nick the SorbaFlex™ PDO monofilament. If the SorbaFlex™ PDO monofilament is cut or damaged during insertion or fixation, additional complications may include but are not limited to, bowel or skin perforation and infection. 10. Follow proper folding techniques for all patches as described in these Instructions for Use as other folding techniques may potentially compromise the SorbaFlex™ PDO monofilament. 11. To ensure a strong repair, the mesh should be secured with tacks or sutures through the polypropylene mesh straps or positioning pocket. 12. Excess positioning strap material above the fixation line must be cut off and discarded to eliminate excess material from remaining in the body. 13. When used to repair deficiencies caused by trocars, the mesh should be used under endoscopic guidance or direct visualization. 14. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 15. 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 mesh. 3. Care should be taken not to cut or nick the SorbaFlex™ PDO monofilament during fixation. 4. The safety and effectiveness of Ventralex™ ST Hernia Patch has not been evaluated in clinical studies in the presence of malignancies in the abdominopelvic cavity. **Adverse Reactions.** Possible complications may include, but are not limited to, seroma, adhesions, hematomas, pain, infection, inflammation, extrusion, erosion, migration, fistula formation, allergic reaction, and recurrence of the ernia or soft tissue defect. If the SorbaFlex™ PDO monofilament is cut or damaged during insertion or fixation, additional complications may include bowel or skin perforation and infection.and infection. **Please consult package insert for more detailed safety information and instructions for use.**

The Ventrio™ ST Hernia Patch CE-Marked Indications. The Ventrio™ ST Hernia Patch is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair of ventral, incisional, and umbilical hernias. **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 that there may be a possibility for adhesion formation when the polypropylene is placed in contact with the bowel or viscera. **Warnings.** 1. The use of any permanent mesh or patch in a contaminated or infected wound could lead to 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 the removal of the mesh. 3. If the unused mesh has been in contact with instruments or supplies used on a patient or contaminated with bodily 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 fascial tissue. 5. This mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh 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 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. 7. This 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. Ensure proper orientation; the bioresorbable 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 mesh is placed in direct contact with the bowel or viscera. 9. Do not cut or reshape the Ventrio™ ST Hernia Patch, as this could impact its effectiveness. Care should be taken not to cut or nick the SorbaFlex™ PDO monofilament duringinsertion or fixation. If the SorbaFlex™ PDO monofilament is cut or damaged, additional complications may include but are not limited to, bowel or skin perforation and infection. 10. Follow proper folding techniques for all patches as described in these Instructions for Use as other folding techniques may compromise the SorbaFlex™ PDO monofilament (Figure 2). 11. To ensure a strong repair, the mesh should be secured with tacks or sutures through the polypropylene mesh structure or full mesh. Suturing or tacking on the edge of the mesh alone is not recommended. 12. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 13. 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 mesh. 3. Care should be taken not to cut or nick the SorbaFlex™ PDO monofilament during fixation. 4. The safety and effectiveness of Ventrio™ ST Hernia Patch has not been evaluated in clinical studies in the presence of malignancies in the abdominopelvic cavity. **Adverse Reactions.** Possible complications include, but are not limited to, seroma, adhesions, hematomas, pain, infection, inflammation, extrusion, erosion, migration, fistula formation, allergic reaction, and recurrence of the hernia or soft tissue defect. If the SorbaFlex™ PDO monofilament is cut or damaged during insertion or fixation, additional complications may include bowel or skin perforation and infection. **Please consult package insert for more detailed safety information and instructions for use.**

Ventralight™ ST Mesh with Echo 2™ Positioning System CE-Marked Indications. Ventralight™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies in the repair of ventral, incisional, and umbilical hernias. The Echo 2™ Positioning System is intended to facilitate the delivery and positioning 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 may be a possibility for adhesion formation when the polypropylene is placed in contact with the bowel or viscera. **Warnings.** 1. The use of any permanent mesh or patch in a contaminated or infected wound can lead to 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 fascial tissue. 5. This device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This device is 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. This 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 (see “Surface Orientation”). 9. Do not apply sharp, pointed, cautery devices, or ultrasonic tools (such as scissors, needles, tackers, diathermic tools, etc.) to the Echo 2™ Positioning System frame. 10. This device contains superelastic nitinol wire; do not cut and avoid direct contact/coupling with active surgical electrodes. 11. Ventralight™ ST Mesh is the only permanent implant component of the device. The Echo 2™ Positioning System (which includes deployment frame, center hoisting suture and all connectors) must be removed from the patient and appropriately discarded. It is not part of the permanent implant. 12. The Echo 2™ Positioning System should not be used with any other hernia mesh aside from those with which it comes
pre-attached/packaged. 13. Discard the Echo 2™ Positioning System (including the frame, center hoisting suture, all connectors and Mesh Introducer) after use. These may be a potential biohazard. Handle and dispose in accordance with accepted medical practice and applicable local, state and federal laws and regulations. 14. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 15. 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 and trained in the appropriate surgical techniques should use this device. 3. The safety and effectiveness of the device 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 2™ Positioning System must be performed under sufficient visualization of the entire device and surrounding anatomy to ensure proper removal. 5. Do not trim the mesh. This will affect the interface between the mesh and the positioning system. **Adverse Reactions.** Possible complications may include, but are not limited to, seroma, adhesion, hematoma, pain, infection, 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 open and laparoscopic 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 of the 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. This product is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 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. 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. **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. Avoid excessive trigger force as this may damage the device. 7. 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. 8. 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. 9. 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. 10. 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. 11. The safety and effectiveness of the OptiFix™ Absorbable Fixation System have not been evaluated or established in pregnant or breastfeeding women. 12. This device contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight: Cobalt; CAS No. 7440-48-4; EC No. 231-158-0. Current scientific evidence supports that medical devices manufactured from stainless-steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects. For more information, please consult the ECHA website: https://echa.europa.eu/home. **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. **Please consult package insert for more detailed safety information and instructions for use.**

CapSure™ Permanent Fixation System CE-Marked Indications. The CapSure™ Permanent Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during laparoscopic surgical procedures in ventral and inguinal 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 surgical procedures relative to mesh fixation apply, including but not limited to: fixation of vascular or neural structures and in ischemic or necrotic tissue. 4. Carefully inspect the area in the vicinity of the tissue being fastened to avoid inadvertent penetration of underlying structures such as bone, nerves, vessels, and viscera. Use of the CapSure™ Permanent Fixation System in the close vicinity of such underlying structures is contraindicated. For reference, the length of the fastener below the fastener head is 3.2 mm, the fastener head is another 1 mm (total 4.2 mm). 5. This device should not be used in tissues that have a direct anatomic relationship to major vascular or nerve structures. This includes the deployment of tacks in the diaphragm in the vicinity of the pericardium, aorta, or inferior vena cava during diaphragmatic hernia repair. **Warnings**. 1. The CapSure™ Permanent 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. This product is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 4. Verify mechanical and electrical compatibility of devices from different manufacturers prior to using them together in a procedure. 5. Prosthetics should be evaluated for compatibility prior to use. 6. Users should be familiar with surgical procedures and techniques involving permanent materials before employing CapSure™ Permanent Fixation System fasteners for wound closure, as the risk of wound dehiscence may vary with the site of application and the material used. 7. 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. After use, the CapSure™ Permanent Fixation System may be a potential biohazard. Handle and dispose of in accordance with any local and federal laws regarding medical waste. **Precautions.** 1. Please read all instructions before using the CapSure™ Permanent 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 CapSure™ Permanent 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 CapSure™ Permanent Fixation System should enter and exit the trocar easily without excessive force. The use of too much force could damage the instrument. 4. Adequate counter pressure should be applied on the target area. Avoid placing hand or finger directly over the area where fastener is being deployed to prevent injury. 5. Use caution when applying the CapSure™ 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 CapSure™ fastener. 6. Care should be taken not to use excessive counter pressure as this may damage the tissue, the material being fixated, and/or the device. 7. If the device locks and cannot be separated from a fastener that has been deployed into mesh and/or tissue, rotate the device counterclockwise to free the fastener from the tissue and/or to free the device. If the fastener does not deploy properly, remove the device from the patient and test the device in gauze to ensure proper fastener deployment, otherwise discard the device appropriately and use a new CapSure™ Permanent Fixation System. Once proper fastener deployment is confirmed, the device may be reinserted into the patient. 8. The safety and effectiveness of CapSure™ Permanent Fixation System have not been evaluated or established in pregnant or breast feeding women. 9. This device contains the following substance(s) defined as CMR 1B in a concentration above 0.1% weight by weight: Cobalt; CAS No. 7440-48-4; EC No. 231-158-0. Current scientific evidence supports that medical devices manufactured from stainless-steel alloys containing cobalt do not cause an increased risk of cancer or adverse reproductive effects. For more information, please consult the ECHA website: https://echa.europa.eu/home **Adverse Reactions**. Adverse reactions and potential complications associated with fixation devices such as the CapSure™ Permanent Fixation System. may include, but are not limited to the following: hemorrhage, pain, edema and erythema at wound site; septicemia/infection; hernia recurrence/wound dehiscence, erosion and allergic response in patients with known sensitivities to PEEK and metals contained in 316L stainless steel, including chromium, nickel, copper, and iron. **Please consult package insert for more detailed safety information and instructions for use.**

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