Ventrio™ ST Hernia Patch

Featuring Sepra™ Technology

BD

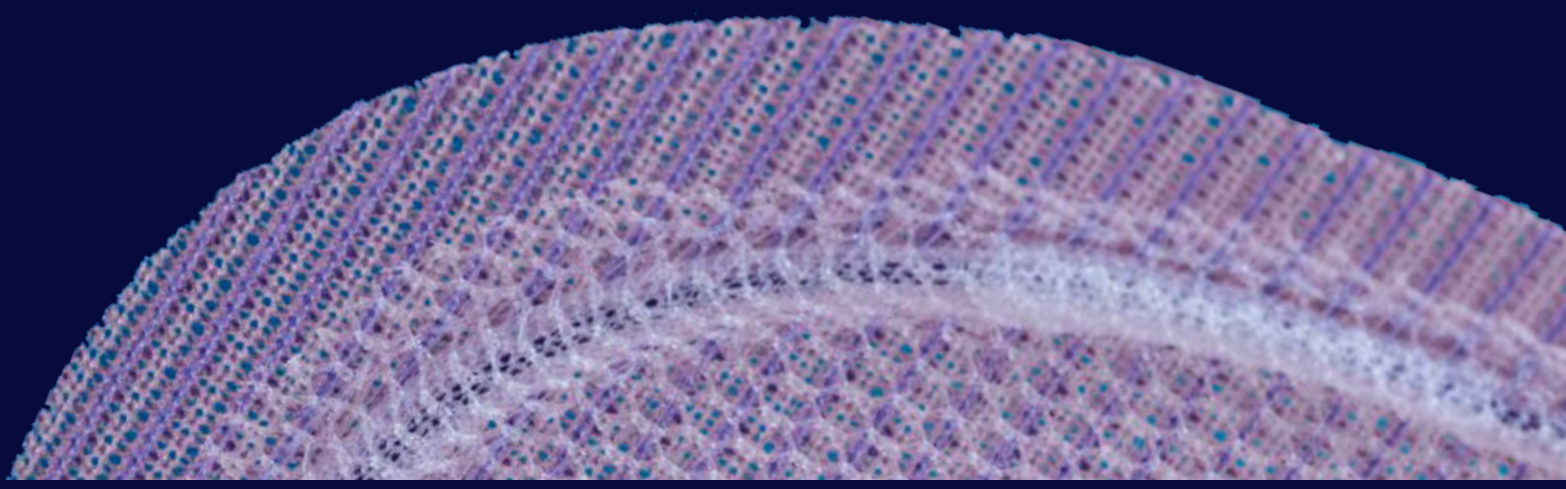
The Ventrio™ ST Hernia Patch featuring Sepra™ Technology

An extensively studied barrier with more than 10 publications and used clinically since 2007.

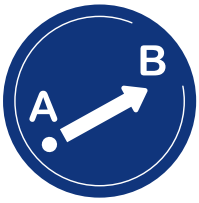
Unique hydrogel barrier swells to minimize tissue attachment to the visceral side of the mesh.[1]

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]



It begins with a hydrogel barrier. It ends with a strong, long-term repair.



Easy

- Provides the benefits of a laparoscopic repair through the ease of an open anterior incision.
- SorbaFlex™ Memory Technology allows the patch to "spring open," lay flat to maintain shape and then fully absorbs over time.[1]
- Simplifies placement and positioning of the patch throughout the ventral hernia repair.

Efficient

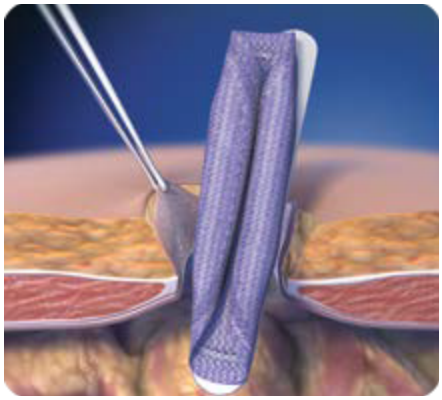
- Unique pocket aids in the proper placement and positioning of the patch.
- Designed to facilitate the use of mechanical fixation devices and/or sutures.
- Available in a variety of shapes and sizes to accommodate defect sizes and locations.

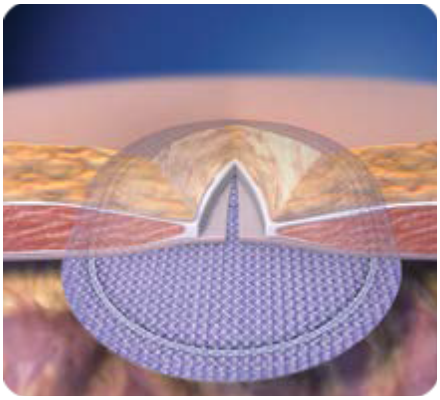
Proven

- Hydrogel barrier is based on Sepra™ Technology.
- Uncoated monofilament polypropylene mesh allows for complete tissue ingrowth leading to a strong repair.
- Materials have been used in general surgery for years with demonstrated clinical success.[2]

Easy

The Ventrio™ ST Hernia Patch's unique design provides the benefit of laparoscopic repair through the ease of a smaller incision.





Intraabdominal placement through a small open incision[3]

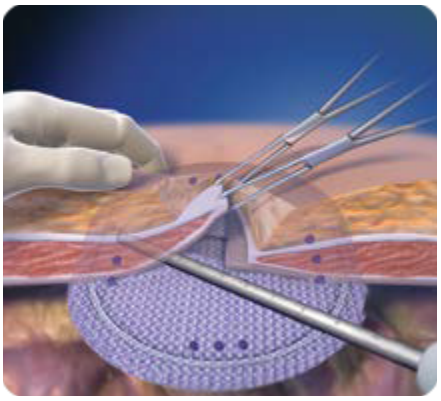
- No preperitoneal lateral dissection may reduce surgical time and lead to quick patient recovery.
- Minimized dissection may reduce the chance of infection and seroma as well as the need for drains.
- The unique SorbaFlex™ Memory Technology permits rolling of the patch for easy insertion, allowing the patch to "spring open," lay flat to maintain shape and then fully absorbs over time.

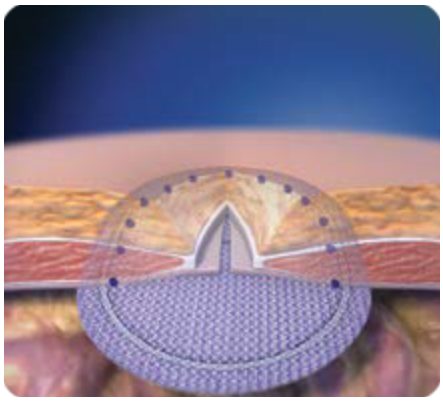
Established Technique Supported by Published Clinical Data[3]

- The design of the Ventrio™ ST Hernia Patch allows the use of the familiar Ventrio™ Hernia Patch technique for open ventral hernia repair.
- Technique is peer reviewed and supported by published clinical data.[2]

Efficient

The unique positioning pocket aids in proper placement and positioning, while also allowing the use of mechanical fixation, for a quick efficient repair. The monofilament polypropylene results in strong tissue incorporation within a short period of time, providing the long-term strength of the repair.





Variety of sizes available

Ventrio™ ST Hernia Patch is available in a variety of shapes and sizes to meet your surgical needs dependent on defect size and location. A unique mid-line oval shaped patch designed for multiple defects is also available.

Mechanical fixation

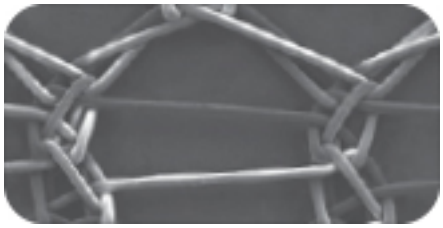
The Ventrio™ ST Hernia Patch is compatible in both open and laparoscopic ventral procedures with the OptiFix™ Absorbable Fixation System and the CapSure™ Permanent Fixation System.

Proven

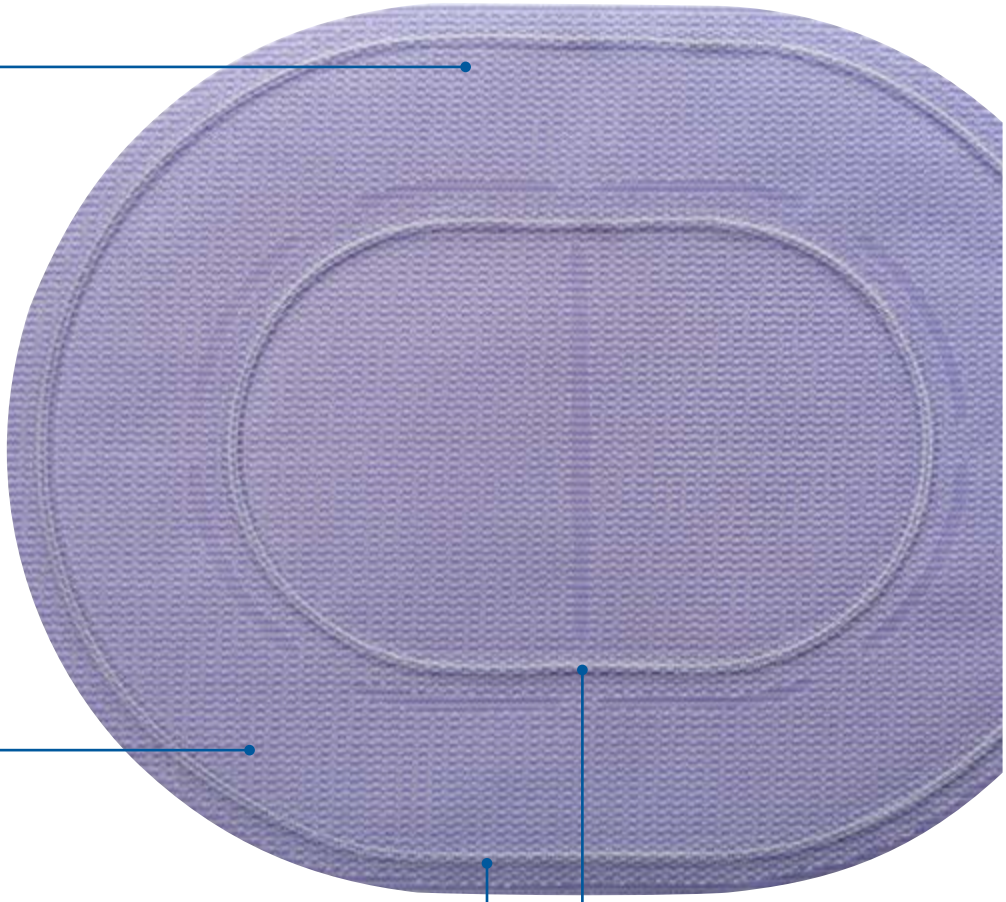
The Ventrio™ ST Hernia Patch combines materials used in general surgery for many years to deliver proven benefits to you and your patients.

Uncoated monofilament polypropylene mesh

- Over 40 years of proven results in hernia repair.
- Allows a fast fibrotic response for a strong repair.
- Provides a long-term repair with minimized recurrence.



Open pore mesh design. 35x magnification.



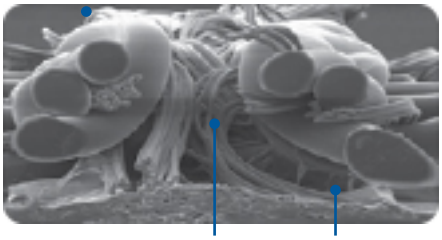
Sepramesh™ IP Composite

- Hydrogel barrier is based on the Sepra™ technology which has more than 10 publications and used clinically since 2007.
- Unique hydrogel barrier swells to minimize tissue attachment to the visceral side of the mesh.[1]
- Resorbs within 30 days providing visceral protection during the critical healing process.
- Bioresorbable PGA fibers reinforce the integrity of the hydrogel barrier by binding it to the polypropylene mesh.

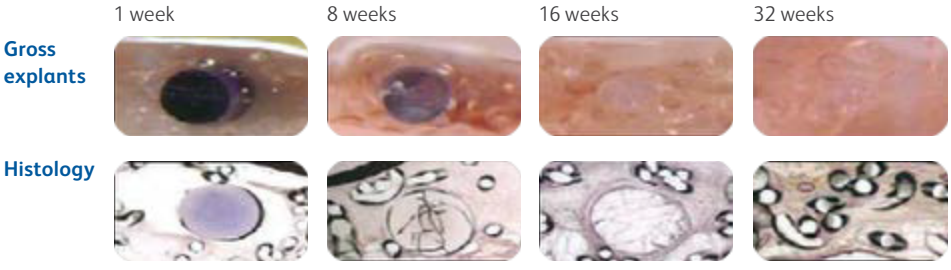
SorbaFlex™ Memory Technology

- Polydioxanone (PDO) monofilament is commonly used in other well-known surgical products (e.g. suture).
- Unique in its flexibility and tensile strength, it facilitates patch insertion and proper placement.
- Absorption via hydrolysis is essentially complete in 24–32 weeks.[1]

Cross section view



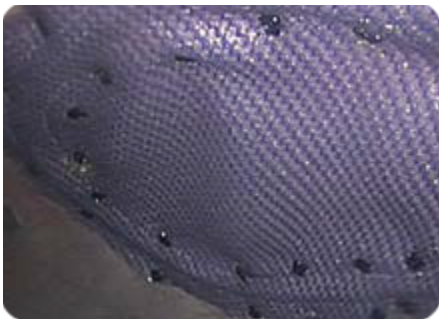
PGA Bioresorbable coating



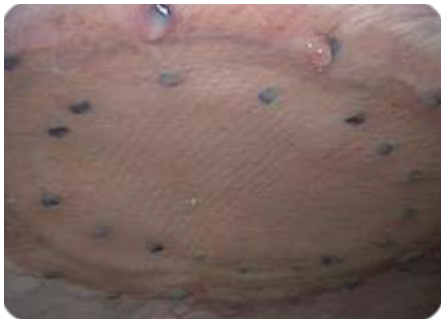
These images are from a porcine study using the Ventrio™ Hernia Patch which contains the same SorbaFlex™ Memory Technology.[1]

Clinical success

Ventrio™ ST Hernia Patch preclinical results[4]

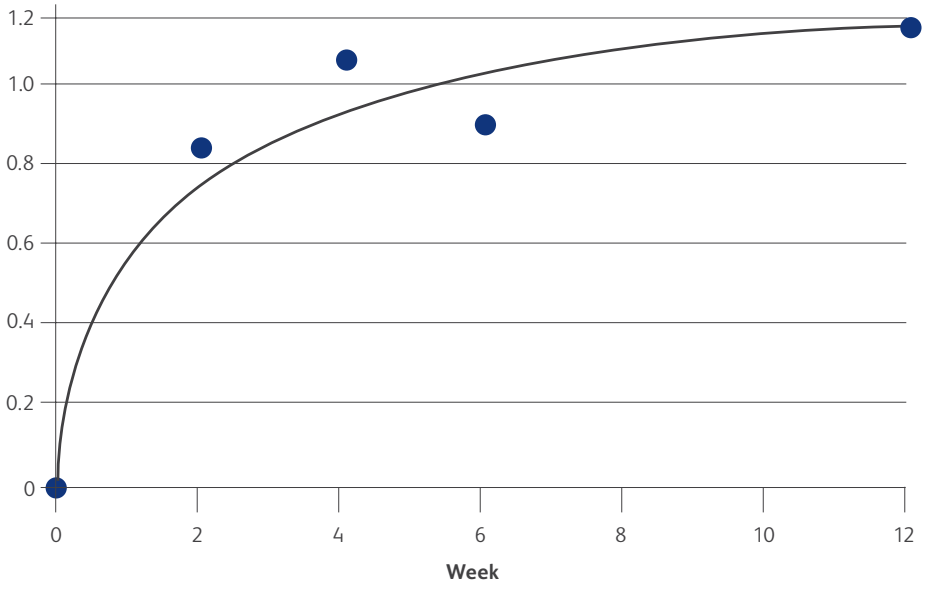


Initial implant



2 weeks

Strength of tissue ingrowth in a preclinical study[5]



Logarithmic regression curve of mean force of lap-shear strength as a function of time. **74% of the 12-week strength is achieved by 2 weeks postoperatively.[5,6]**

Sepramesh™ IP Composite – a preclinical study[7]

120 day comparative analysis of adhesion grade and quantity, mesh contraction, and tissue response to a novel omega-3 fatty acid bio-resorbable barrier macroporous mesh after intraperitoneal placement.

Pierce, R., Perrone, J., Abdelrahman, N., Sexton, J., Walcutt, J., Frisella, M., Matthews, B. Surgical Innovation. 2009 Mar; 16(1): 46-54.8

Mesh	N	Adhesion grade (1–4)	Adhesion coverage (%)	Mesh contraction (%)
Sepramesh™ IP Composite	**6**	**1.0 ± 0.0**	**0.0 ± 0.0**	**6.4 ± 8.4**
Lightweight polypropylene flat mesh	12	1.7 ± 1.1	10.7 ± 19.8	9.1 ± 8.3
Polypropylene with Omega 3 coating	6	1.2 ± 0.4	3.0 ± 7.3	3.3 ± 2.1
Composix	10	1.9 ± 1.2	24.8 ± 37.0	7.2 ± 7.1
Dual-surface polytetrafluoroethylene mesh(ePTFE) material	10	1.3 ± 0.9	1.4 ± 4.4	39.0 ± 6.0
Monofilament Polyester Mesh®	6	1.2 ± 0.4	0.8 ± 2.0	14.7 ± 5.0
Polypropylene with ORC & polydioxanone polymer	6	2.8 ± 1.0	28.8 ± 16.1	29.7 ± 12.5

Ordering information

Product code	Qty.	Shape	Dimensions	
5950030G	1/cs	Small oval	3.1" x 4.7" (8.0 cm x 12.0 cm)	☐
5950040G	1/cs	Medium oval	4.3" x 5.5" (11.0 cm x 14.0 cm)	☐
5950050G	1/cs	Large oval	5.4" x 7.0" (13.8 cm x 17.8 cm)	☐
5950010G	1/cs	Small circle	3.0" (7.6 cm) diameter	☐
5950020G	1/cs	Large circle	4.5" (11.4 cm) diameter	☐
5950070G	1/cs	Extra large oval	7.7" x 9.7" (19.6 cm x 24.6 cm)	☐
5950080G	1/cs	Extra large oval	8.7" x 10.7" (22.1 cm x 27.1 cm)	☐
5950090G	1/cs	Extra large oval	10.8" x 13.7" (27.4 cm x 34.9 cm)	☐
5950060G	1/cs	Midline	6.1" x 10.1" (15.5 cm x 25.7 cm)	☐

CapSure™ Permanent Fixation System
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 t his 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.

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 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. 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.

Ventrio™ ST Hernia Patch

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. 8. 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 during insertion 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. **Adversereactions.** 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.

1 Preclinical data on file at BD. Results may not correlate to performance in humans. **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. **3** Please see the "Patch Technique" section in the Instructions for Use. **4** Images are from a porcine study using the Ventrio™ ST Hernia Patch. Data on file. **5** 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. **6** Results may not correlate to performance in humans. **7** Preclinical results may not correlate to performance in humans. **8** Dr. Matthews is a paid consultant for BD. Financial support for the study was supplied by Atrium Medical Corporation.

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.

Disclaimer: Please consult product labels and instruction for use for indications, contraindications, hazards, warnings, and precautions

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