OptiFix™ Absorbable Fixation System

BD

Challenges and opportunities in absorbable fixation

Absorbable fixation devices can provide important benefits, however, may be also associated with certain challenges, such as:

- Excessive deployment force may cause tissue trauma and bleeding[1]
- Fasteners may be difficult to see laparoscopically potentially leading to the placement of unnecessary fasteners
- Device may be uncomfortable or awkward to deploy in smaller sized hands and may be sensitive to surgeon technique

OptiFix™ Absorbable Fixation System

The OptiFix™ Absorbable Fixation System has been engineered inside and out to provide secure fixation and ergonomic design.

15 and 30

Available in both 15 and 30 fastener count options

Spring loaded trigger

- Releases stored energy to smoothly deliver fasteners through mesh and into tissue with a low counterpressure requirement.
- Helps ensure consistent fastener deployment

Comfort grip handle

Designed to fit a wide range of surgeon hand sizes

Outcome-driven fixation

The OptiFix™ Absorbable Fixation System fastener is made from Poly(D, L)-lactide and is designed for optimal performance. Fastener features include:

Smooth fastener head

- Minimizes the potential for tissue attachment[1]
- Helps ensure mesh is securely fixated

Hollow core design

- Allows tissue ingrowth through the fastener[1]

Angled tip

- Easily penetrates mesh and tissue

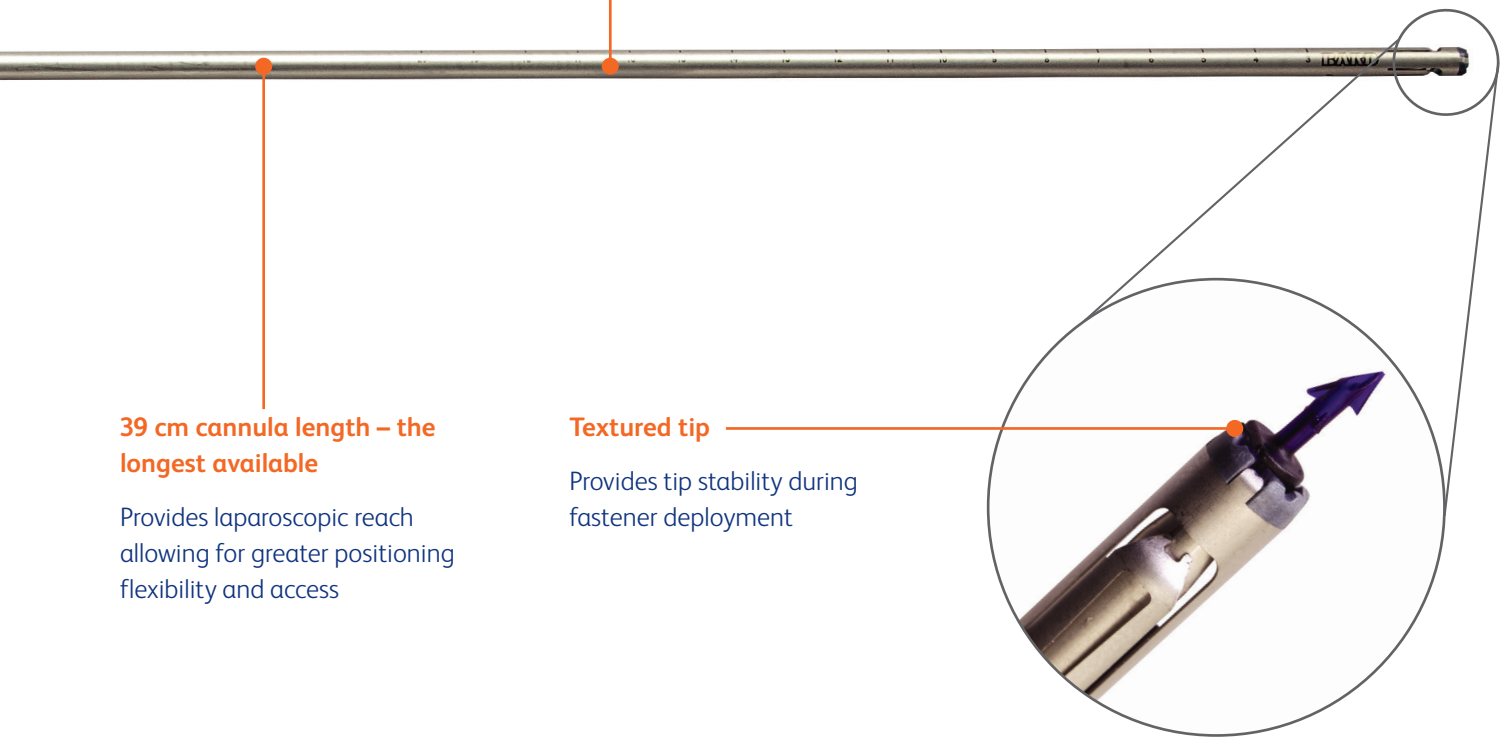
Stabilizers

- Enhances tissue holding strength
- Helps prevent the fastener from backing out

Enlargement

Metric scale

Facilitates laparoscopic measurements



39 cm cannula length – the longest available

Provides laparoscopic reach allowing for greater positioning flexibility and access

Textured tip

Provides tip stability during fastener deployment

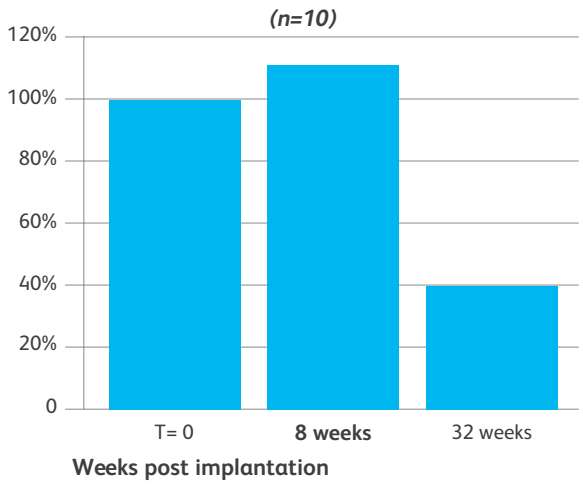
Optimally designed fixation system for outcome-driven results

1 Preclinical data on file. Results may not correlate to clinical outcomes. Reports RPT3806568, RPT3803790.

Fixate with confidence

OptiFix™ Absorbable Fixation System fasteners provide secure fixation during the postoperative healing period then slowly resorb over time.

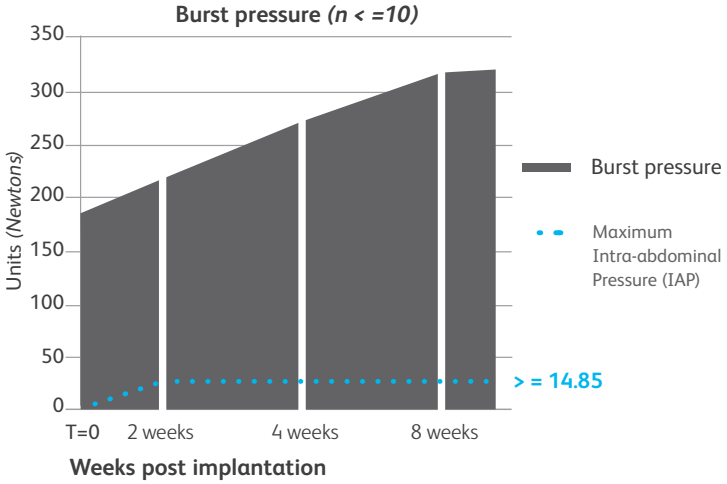
Baseline strength retention[2]



OptiFix™ Absorbable Fixation System fastener maintains its strength through the crucial healing period, then begins to resorb.

2. Bench data on file.

Burst pressure over time in a porcine model[3]



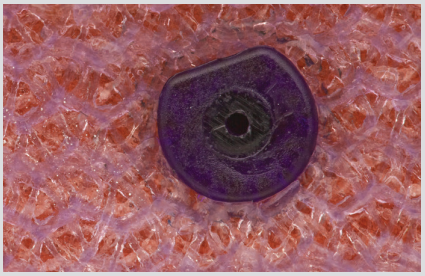
Minimal degradation of the fastener during the healing period, along with aggressive tissue ingrowth maintains burst pressures at approximately 7x the Intra-abdominal Pressure (IAP) requirement needed for the repair.

3. Preclinical data on file. Results may not correlate to clinical outcomes. Reports RPT3805719, RPT3805720, RPT3805721.

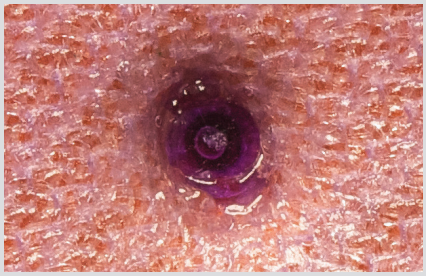
See the difference

Fastener visibility and mesh retention surface area

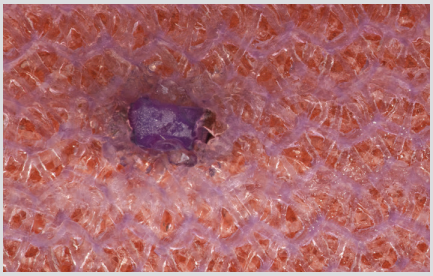
5X magnification*



OptiFix™ Absorbable Fixation System
9.0 mm



Device with PGLA tacks
8.6 mm



Device with Fixation straps
1.8 mm

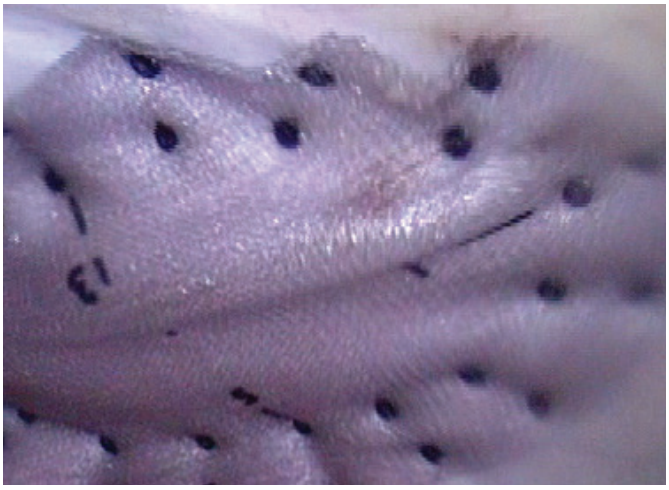
Higher fastener surface area coverage results in more visible fasteners and more secure mesh fixation.

* BD bench data on file. RPT 3806969.

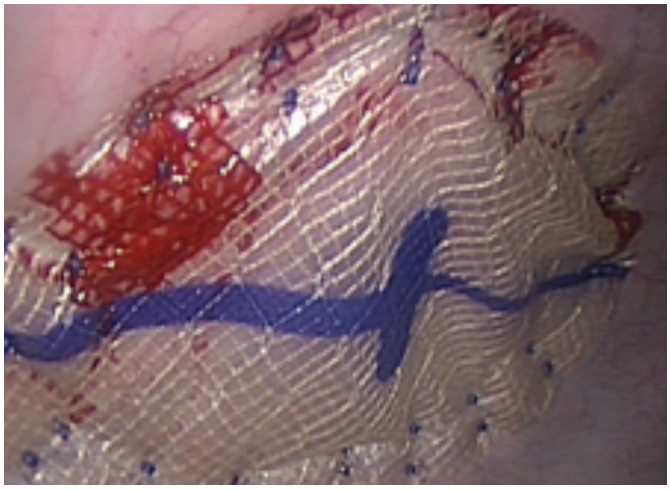
Controlled deployment

Optimized deployment force and fastener head geometry ensures secure fixation and may minimize trauma and bleeding.

In a preclinical study, OptiFix™ Absorbable Fixation System demonstrated significantly less fastener site hemorrhaging than Device with Fixation straps. OptiFix™ Absorbable Fixation System experienced 9X less incidents of bleeding than Device with Fixation straps.[4,5]



OptiFix™ Absorbable Fixation System

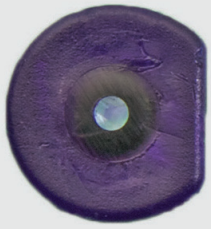


Device with Fixation straps

4. Preclinical data on file. Results may not correlate to clinical outcomes. Report RPT3806568.

5. Preclinical data on file. Results may not correlate to clinical outcomes. Report RPT3803790.

OptiFix™ has 5X more mesh retaining surface than Device with Fixation straps*



OptiFix™ Absorbable Fixation System

Device with Fixation straps

* BD bench data on file. RPT 3806969.

Fixate with confidence

Preferred ergonomic feel and design

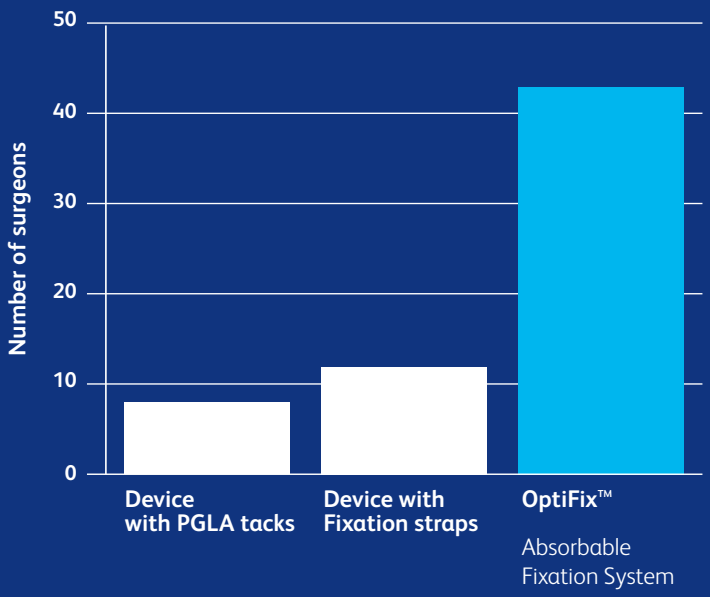
Surgeon Feedback[6] – Surgeons prefer the handling of OptiFix™ Absorbable Fixation System versus other fixation devices

In a blind preference test assessing surgeons' preference of device comfort, trigger force, and overall fit, feel and fire, OptiFix™ Absorbable Fixation System was preferred nearly 4x more frequently than the next closest competitor.

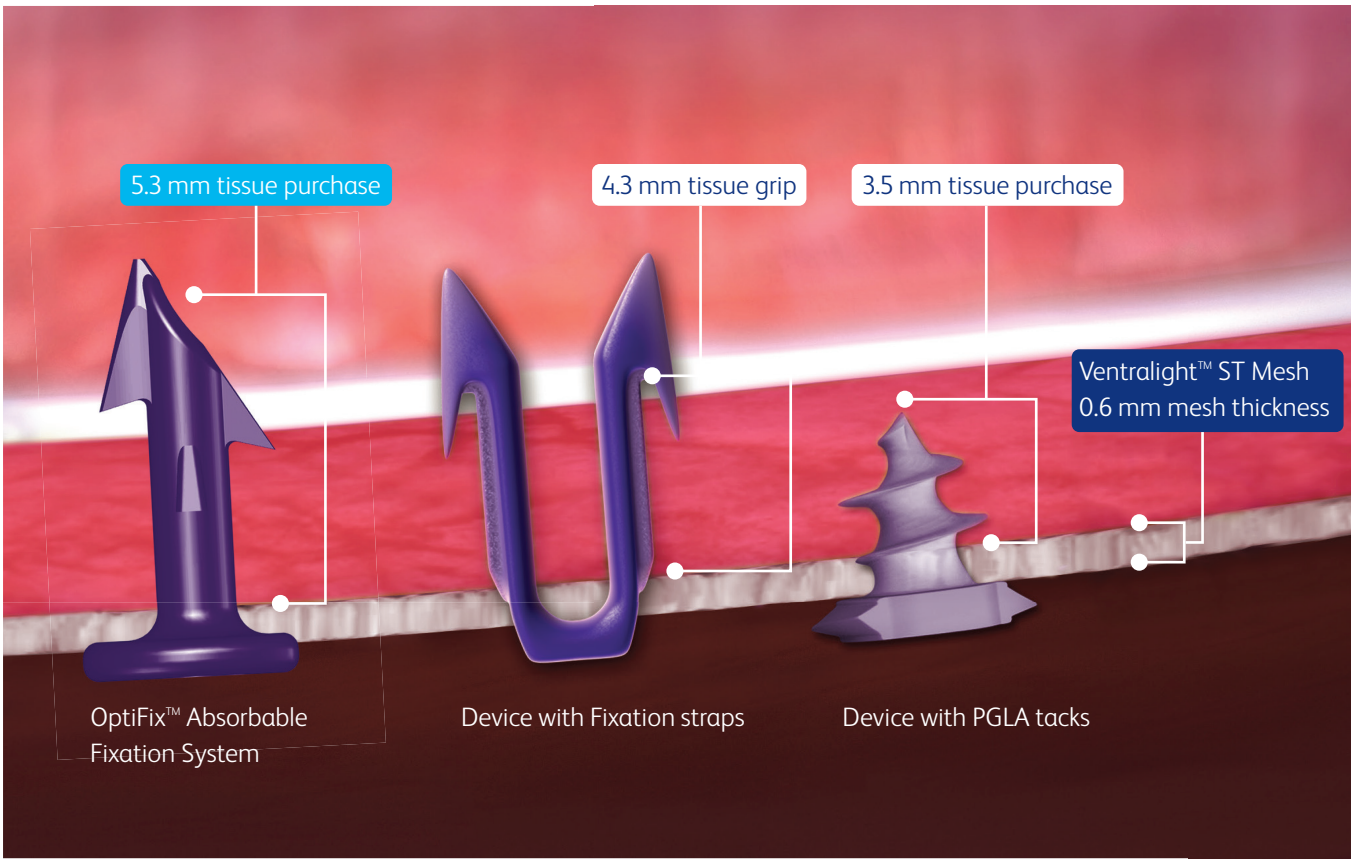
A fixation device designed with the surgeon and patient in mind.

6. Survey of surgeons attending an international surgical conference. Data on file.

Overall preference for fit, feel and fire[6]



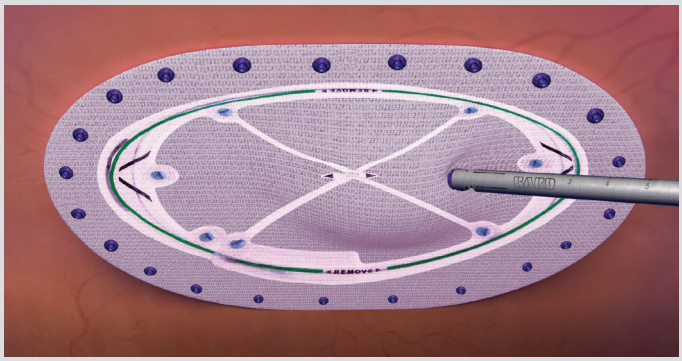
Point of tissue penetration comparison

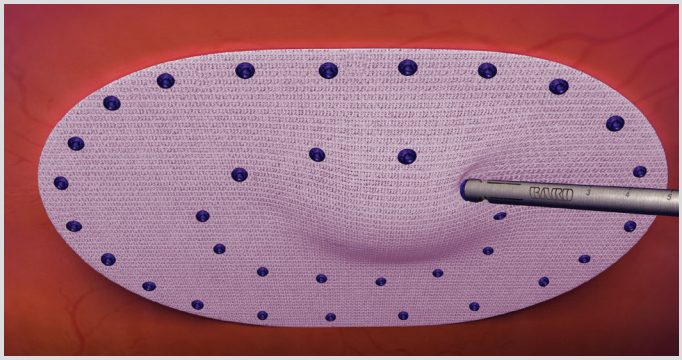


OptiFix™ Absorbable Fixation System supports your procedure of choice

With Ventralight™ ST Mesh with Echo 2™ Positioning System in Laparoscopic Ventral Procedures

- Provides secure fixation in laparoscopic ventral procedures
- Penetrates and holds larger pore mesh as well as dual layer and/or smaller pore mesh
- Compatible in lap ventral with all Bard® Mesh configurations including Ventralight™ ST Mesh, and Ventrio™ ST Hernia Patch





Ordering information

Prodoct code	Qty.	Configuration
0113126	5/case	30 Absorbable Fasteners
0113127	5/case	15 Absorbable Fasteners

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. 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. 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.

Ventralight™ ST Mesh with Echo 2™ Positioning System

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 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 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 product package insert for more detailed safety information and instructions for use.

Ventralight™ ST Mesh

Indications: Ventralight™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies in 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 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 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 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 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. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 10. 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. The safety and effectiveness of Ventralight™ ST Mesh 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 hernia or soft tissue defect. Please consult product package insert for more detailed safety information and instructions for use.

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. 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. 8. 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. 9. 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). 10. 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. 11. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 12. 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.

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