CapSure™ Permanent Fixation System

BD

Traditional challenges in permanent fixation for hernia repair

Permanent fixation devices facilitate a strong long-term repair but may be associated with some challenges.

Clinical complications from exposed metal points including adhesions to fasteners[1]

Difficulties securing large pore mesh may impact hernia repair outcomes[1]

Deployment challenges and device reliability issues can disrupt procedures[1]

1. Evaluation of a novel permanent capped helical coil fastener in a porcine model of laparoscopic ventral hernia repair. Arnab Majumder, Mojtaba Fayezizadeh, William W. Hope, Yuri W. Novitsky. Surgical Endoscopy. April, 2016

Fastener level indicator

15 and 30

Available in both 15 and 30 fastener count options

Rotary drive system

Allows smooth deployment

Low resistance ergonomic trigger

Easy to deploy trigger with an audible click indicates that fastener is fully deployed

Comfort grip handle

Designed to fit wide range of surgeon hand sizes

Confidence redefined

Covered

- Smooth polyetheretherketone (PEEK) cap eliminates exposed metal tip and helps minimize adhesions to the fastener[1]

Strong

- Fixates into Cooper's ligament and underlying structures

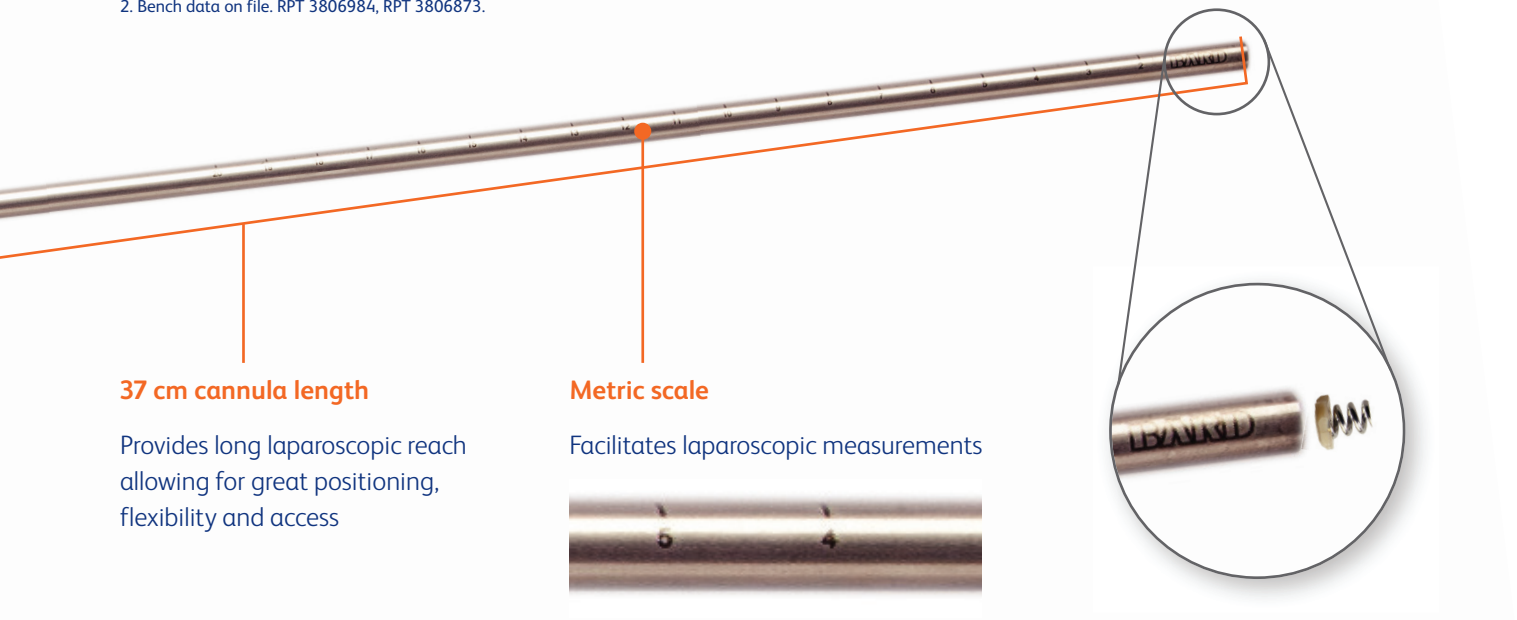
Reliable

- Comfortable handle and easy to deploy trigger
- Consistent fastener deployment and depth of tissue purchase
- Reliable, secure fixation regardless of mesh pore size[2]
- Improved fixation with large pore meshes due to larger cap surface area of fastener versus Fixation Device with Titanium tacks[2]

1. Evaluation of a Novel Permanent Capped Helical Coil Fastener in a Porcine Model of Laparoscopic Ventral Hernia Repair. Arnab Majumder, Mojtaba Fayezizadeh, William W. Hope, Yuri W. Novitsky. Surgical Endoscopy. April, 2016

Preclinical data. Results may not correlate to performance in humans.

2. Bench data on file. RPT 3806984, RPT 3806873.



37 cm cannula length

Provides long laparoscopic reach allowing for great positioning, flexibility and access

Metric scale

Facilitates laparoscopic measurements

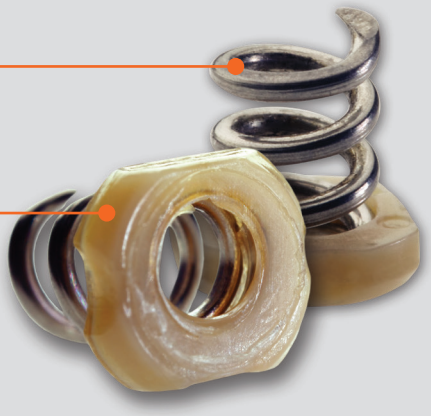
Redefined fastener design

316L stainless steel

316L stainless steel is a surgical stainless steel commonly used in biomedical implants that are put under pressure including bone screws and prostheses.

Smooth PEEK cap

- Cap is made from polyetheretherketone (PEEK). PEEK is an inert organic thermoplastic polymer[1], considered an advanced biomaterial.
- PEEK is used in many medical implants[1] including dental implants, heart valves and stents, and joint prostheses.



1. Evaluation of a novel permanent capped helical coil fastener in a porcine model of laparoscopic ventral hernia repair. Arnab Majumder, Mojtaba Fayezizadeh, William W. Hope, Yuri W. Novitsky. Surgical Endoscopy. April, 2016

Designed for optimized clinical benefits

A 90 day preclinical adhesion study demonstrated stronger results with the CapSure™ Permanent Fixation System vs. Fixation Device with Titanium tacks

Evaluation of a Novel Permanent Capped Helical Coil Fastener in a Porcine Model of Laparoscopic Ventral Hernia Repair

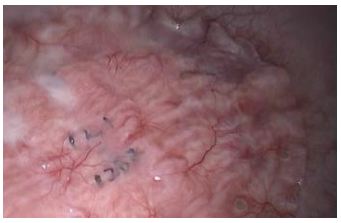
Arnab Majumder, Mojtaba Fayezizadeh, William W. Hope, Yuri W. Novitsky. Surgical Endoscopy. April, 2016

- Significantly less adhesion coverage
- Greater percentage of properly engaged fasteners
- Greater mesh/tissue integration
- Shielding exposed fastener points on the visceral mesh surface with polymer caps is suggested by the data to reduce adhesion formation and aid in mesh fixation and integration.

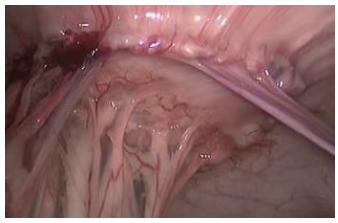
Preclinical data. Results may not correlate to performance in humans.

30 day Laparoscopic fastener assessment

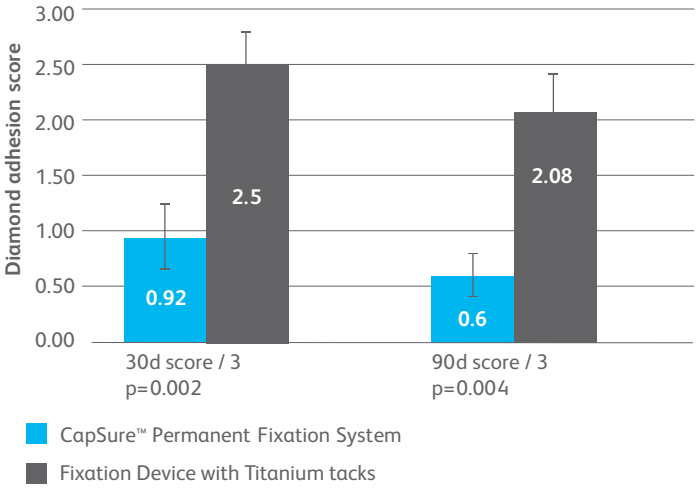
CapSure™ Permanent Fixation System



Fixation Device with Titanium tacks



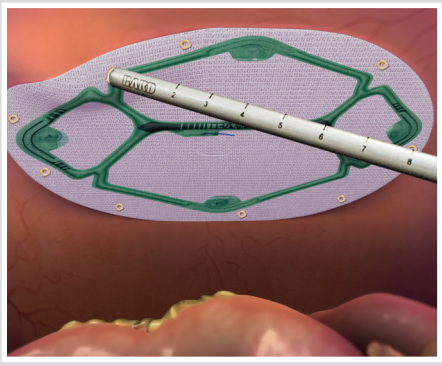
Average 30 vs. 90 day diamond adhesion score

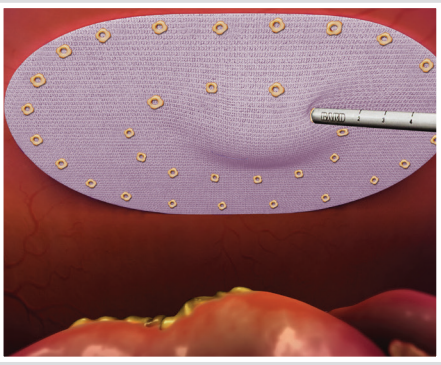


Technique-driven outcomes

With Ventralight™ ST Mesh with Echo PS™ 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[1]
- Compatible in lap ventral with all BD mesh configurations including Ventralight™ ST Mesh and Ventrio™ ST Hernia Patch

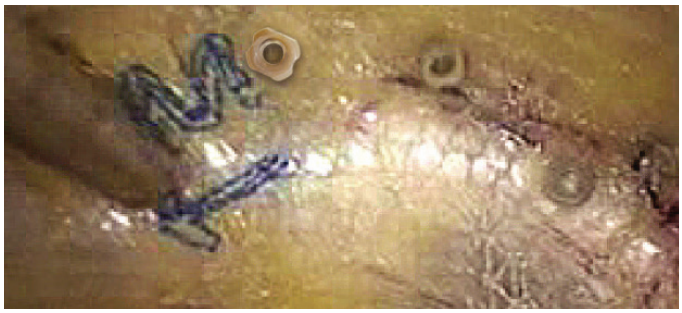




1. Bench data on file. RPT 3806984, RPT 3806873.

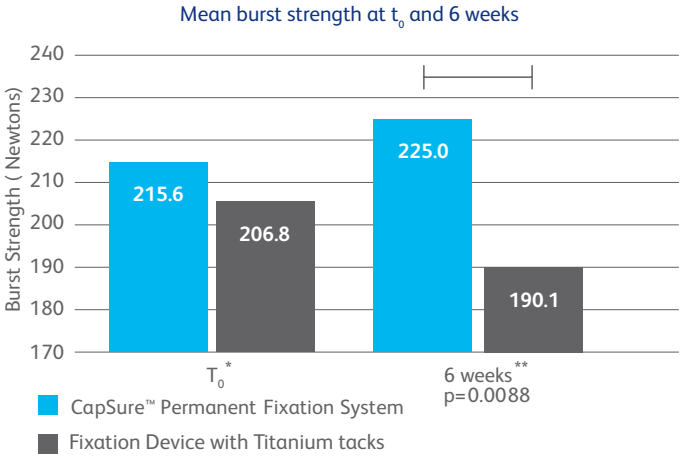
Strong repair

CapSure™ Permanent Fixation System fastener easily penetrates Cooper's ligament and underlying structures, equivalent to a Fixation Device with Titanium tacks



Preclinical data. Results may not correlate to performance in humans.

Equivalent strength to a Fixation Device with Titanium tacks at t_0 but greater strength over time



Burst strength testing demonstrated that in a porcine model CapSure™ Permanent Fixation System fixated Ventralight™ ST Mesh had a greater *(4.3%)* burst strength at t_0 and significantly higher *(18.4%)* peak burst strength at 6 weeks post-implantation than did a Fixation Device with Titanium tacks fixated Ventralight™ ST Mesh at the same time point *(p = .0088)*.

*** Porcine abdominal wall tissue. Animal data may not correlate to performance in humans**

**** Porcine 6 week implant study. Animal data may not correlate to performance in humans**

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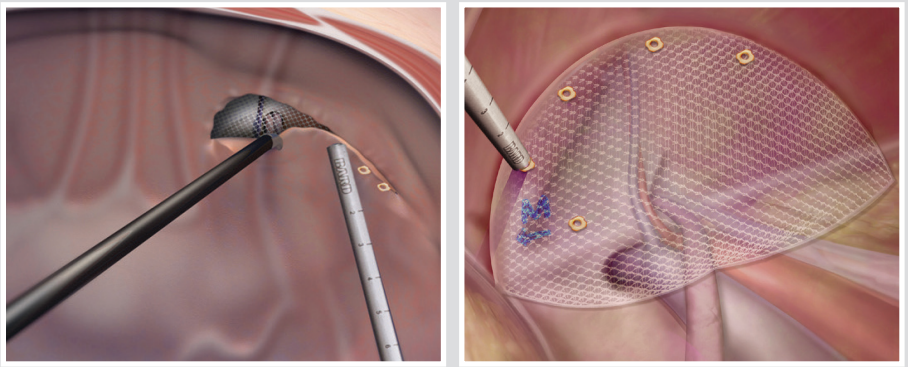
With 3DMax™ Light Mesh in laparoscopic inguinal procedures

- Able to fixate into Cooper's ligament and underlying structures
- Facilitates ease in reapproximation of the peritoneum for a TAPP repair



Reliable

- Rotary drive system with a comfortable handle and easy to deploy trigger, with an average delivery force that is 30% less than a Fixation Device with Titanium tacks[1]
- Consistent fastener deployment and depth of tissue purchase – preclinical studies demonstrated more favorable fastener seating results versus a Fixation Device with Titanium tacks[1]
- Available in 15 and 30 fastener count devices providing significant savings per device over Fixation Device with Titanium tacks, for repairs where 15 or less fasteners are required

Preclinical data. Results may not correlate to performance in humans. RPT3806605

CapSure™ Permanent Fixation System in Bard® Soft Mesh

Fasteners demonstrated in artificial tissue. RPT 3806873.

Fixation Device with Titanium tacks in Bard® Soft Mesh

CapSure™ Permanent Fixation System fasteners have 2X the mesh surface area coverage to hold mesh in place ensuring secure fixation and more visible fasteners. Bench testing with 3DMax™ Light demonstrates that CapSure™ Permanent Fixation System is 15X more likely to retain large pore mesh versus Fixation Device with Titanium tacks.[1]

1 Bench top data on file. Report RPT # 3806984. Results may not correlate to performance in humans.

Comparison Summary

Features	CapSure™ Permanent Fixation System[1]	Fixation Device with Titanium tacks[2]
Fastener configuration	Helical coil with integrated polymer head 3 revolutions	Helical coil 2 ½ revolutions
Fastener head	Polymer (PEEK) head No exposed metal tip	None Exposed metal tip
Wire diameter and depth of purchase	0.018” 3.2 mm	0.025” 3.2 mm
Preclinical data demonstrating design minimizes adhesions to the fastener	Yes	No
Fixates into Cooper’s ligament and underlying structures	Yes	Yes
Provides optimal fixation with large pore mesh	Yes	Not optimized for use with large pore mesh
Fastener level indicator	Yes	None
15 and 30 count option	Yes	30 count only

1. RPT3806984, RPT 3806873
2. Competitive product reference (as of June 2022): https://www.medtronic.com/covidien/en-us/products/hernia-repair/fixation-products.html

Ordering information

Prodoct code	Qty.	Configuration
0113230G	5/case	30 Permanent Fasteners
0113215G	5/case	15 Permanent Fasteners

CapSure™

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

Ventralight™ ST with Echo PS™ 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 PS™ Positioning System is intended to be used to facilitate the delivery of the Ventralight™ ST Mesh during laparoscopic hernia repair. **Contraindications.** 1. Do not use this mesh in infants, children, or pregnant women, whereby future growth may be compromised by the use of such mesh materials. 2. The use of this mesh has not been studied in breastfeeding or pregnant women. 3. Do not use this mesh for the reconstruction of cardiovascular defects. 4. Literature reports there is a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowel or viscera. **Warnings.** 1. The use of any permanent mesh in a contaminated or infected wound could lead to infection, fistula formation, and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require removal of the mesh. 3. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard with care to prevent risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and 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 has been designed for single use only. Reuse, resterilization, reprocessing and/or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the device and may lead to device failure which may result in injury to the patient. Reuse, reprocessing, resterilization, or repackaging may also create a risk of contamination of the device and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient or end user. 7. The mesh should be used once the exterior foil pouch has been opened. Do not store for later use. Unused portions of the mesh should be discarded. 8. Ensure proper orientation; the coated side of the mesh should be oriented against the bowel or sensitive organs. Do not place the polypropylene side against the bowel. There may be a possibility for adhesion formation when the polypropylene side is placed in direct contact with the bowel or viscera (reference Surface Orientation section). 9. Do not apply sharp, heat emitting, or ultrasonic tools (such as scissors, needles, tackers, diathermic tools, etc.) to the Echo PS™ Positioning System. 10. The Echo PS™ Positioning System should not be used with any other hernia mesh aside from those with which it comes pre-attached/packaged. 11. Ventralight™ ST Mesh is the only permanent implant component of the device. The inflation adapter and syringe are to be kept external to the patient and discarded after use. The Echo PS™ Positioning System (including the balloon, all connectors, and inflation tube) must be removed from the patient and appropriately discarded. It is not part of the permanent implant. 12. Discard Introducer Tool and all components of the Echo PS™ Positioning System (including the inflation adapter and syringe) after use. This product may be a potential biohazard. Handle and dispose in accordance with accepted medical practice and applicable local, state, and federal laws and regulations. 13. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 14. This mesh is not for the use of treatment of stress urinary incontinence. **Precautions.** 1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this device. 3. The safety and effectiveness of Ventralight™ ST Mesh with Echo PS™ Positioning System has not been evaluated in clinical studies for the presence of malignancies in the abdominopelvic cavity. 4. Visualization must be maintained throughout the course of the entire procedure. Additionally, laparoscopic removal of the Echo PS™ Positioning System must be performed under sufficient visualization of 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 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.**

3DMax™ Light Mesh

Indications: The 3DMax™ Light Mesh is indicated for use in the reinforcement of soft tissue where weakness exists, in the repair of inguinal hernias. **Contraindications:** 1. Literature reports that there may be a possibility for adhesion formation when polypropylene mesh is placed in direct contact with the bowel or viscera. 2. Do not use polypropylene mesh in infants and children, whereby future growth will be compromised by use of such material. **Warnings:** 1. This device is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 2. This device is for single use only. Do not resterilize or reuse any portion of the 3DMax™ Light Mesh. 3. This device has been designed for single use only. 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. 4. The use of any permanent mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the prosthesis. 5. 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 device. 6. To prevent recurrences when repairing hernias, the prosthesis should be large enough to extend beyond the margins of the defect. 7. To avoid injury, careful attention is required if fixating the mesh in the presence of nerves and vessels. **Precautions:** 1. Please read all instructions prior to use. 2. Only physicians qualified in appropriate surgical techniques should use this prosthesis. 3. Do not cut or reshape the 3DMax™ Light Mesh as this may affect its effectiveness. 4. Use an appropriate sized trocar to allow mesh to slide down the trocar with minimal force. 5. If fixation is used, Bard® permanent or absorbable fixation devices or nonabsorbable monofilament sutures are recommended to properly secure the device. If other fixation devices are used, they must be indicated for use in hernia repair. 6. If fixation is used, care should be taken to ensure that the mesh is adequately fixated to the abdominal wall. If necessary, additional fasteners and/or sutures should be used. **Adverse reactions:** Possible complications include seromas, adhesions, hematomas, inflammation, extrusion, fistula formation and recurrence of the hernia or soft tissue defect.

Ventralight™ ST

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

Contact a BD sales representative to schedule an appointment

or visit bd.com for more information.

Please consult product labels and inserts for any indications, contraindiciations, hazards, warnings, precautions and instructions for use.

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