Robotic hernia repair

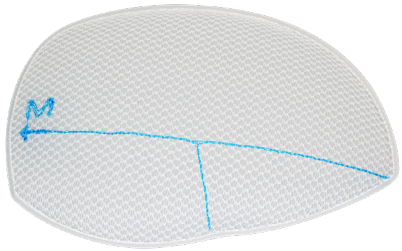
Mesh portfolio for robotic hernia repair

BD

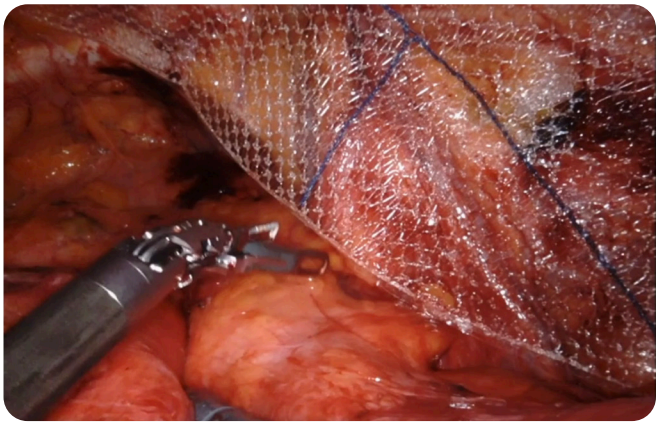
3DMax™ MID Anatomical Mesh

Robotically compatible, clinically proven with over 2 million implants[1]

3DMax™ MID Anatomical Mesh



- 3D-contoured anatomical shape to conform to the inguinal anatomy for easy positioning. [1]
- Medium weight, open pore monofilament polypropylene mesh that retains its shape following laparoscopic or robotic introduction.[1, 2, 3]
- Anatomical orientation lines and built-in recoil memory allow for easier positioning than a conventional flat mesh and enhance the speed and simplicity of the placement [1,2]. The 3DMax™ Mesh portfolio has been clinically proven effective without fixation.[2]

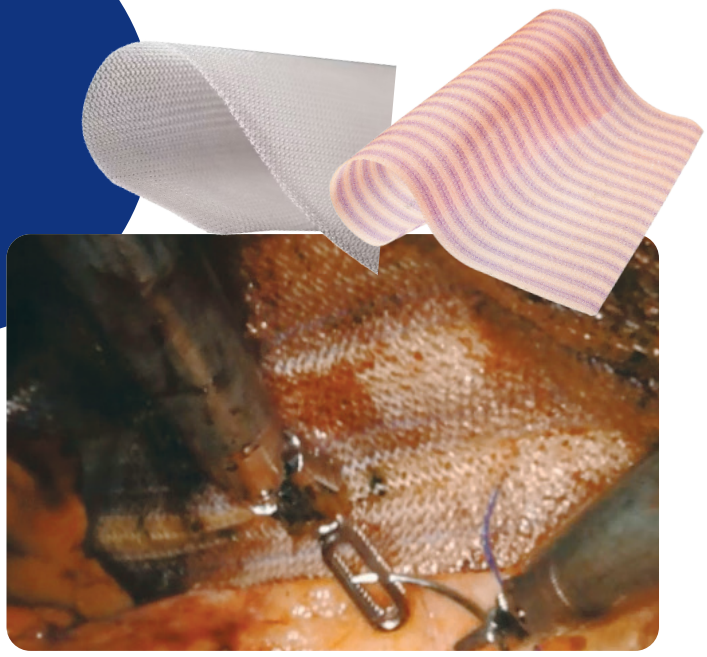


Phasix™ Mesh and Phasix™ ST Mesh

Natural. Not Permanent. Proven Results.
Bioresorbable Phasix™ Mesh is transforming hernia care with long-term strength and positive clinical outcomes for a less complicated future. [2, 3]

Phasix™ Mesh

Phasix™ ST Mesh

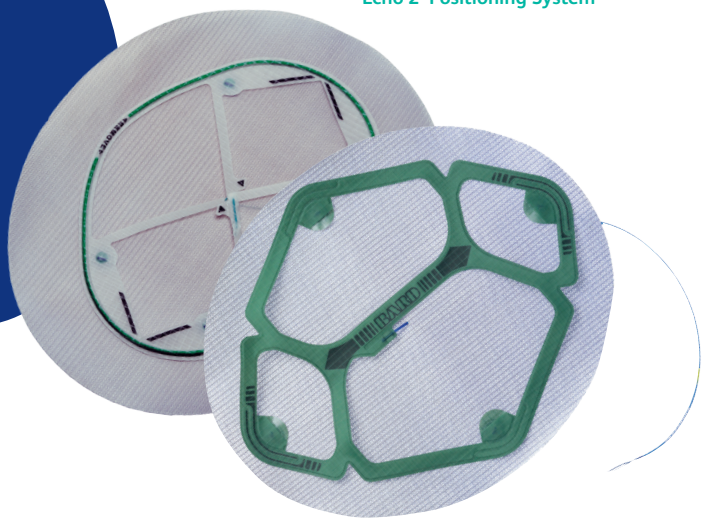


- Provides the repair strength of a synthetic mesh and the remodeling characteristics of a biologic.
- Handles, sutures and fixates like a synthetic mesh.
- Gradually and predictably degrades within 12 to 18 months, leaving behind a durable, functional repair over 3x the strength of the native abdominal wall, as demonstrated in an animal model.[4]

1. Data on file at BD, includes implants of 3DMax™ Mesh, 3DMax™ Light Mesh and 3DMax™ MID Anatomical Mesh. 2. Bell, Price. Laparoscopic inguinal hernia repair using an anatomically contouredthree-dimensional mesh. Surgical Endoscopy. 2003:17:1784-1788. 3. Tanoue, K., Okino, H., Kanazawa, M. et al. Single-incision laparoscopic transabdominal preperitoneal mesh hernioplasty: results in 182 Japanese patients. Hernia. 2016 Dec;20(6):797-803. 4. Deeken CR, Abdo MS, Frisella MM, Matthews BD. "Physicomechanical evaluation of absorbable and nonabsorbable barrier composite meshes for laparoscopic ventral hernia repair." Surgical Endoscopy 25.5 (2010): 1541-552.

Ventralight™ ST Mesh with Echo 2™ and Echo PS™ Positioning Systems

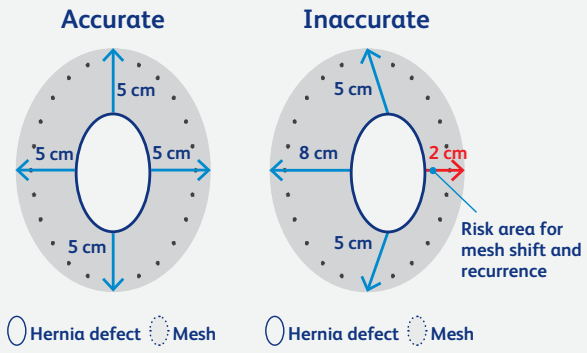
Consistent, reproducible technique



Ventralight™ ST Mesh with Echo 2™ Positioning System

Ventralight™ ST Mesh with Echo PS™ Positioning System

- The Echo 2™ Positioning System is a deployment and positioning device that comes attached to Ventralight™ ST Mesh to facilitate mesh positioning and centering over the hernia defect.
- The Echo PS™ Positioning System is a low-profile balloon that comes attached to Ventralight™ ST Mesh. When inflated, Echo PS™ facilitates the unrolling and deployment of the mesh over the hernia defect.

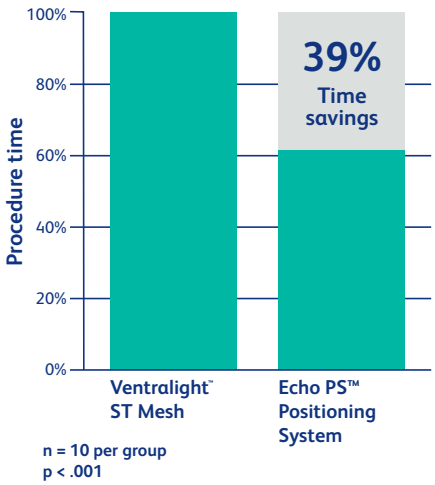


Accurately centered mesh with appropriate overlap has shown to reduce the risk of mesh shift and recurrence. Inaccurate mesh overlap in laparoscopic ventral hernia repair can result in postoperative mesh shift and recurrence.[1,2]

Reduce OR time[3]

Overall mesh handling time

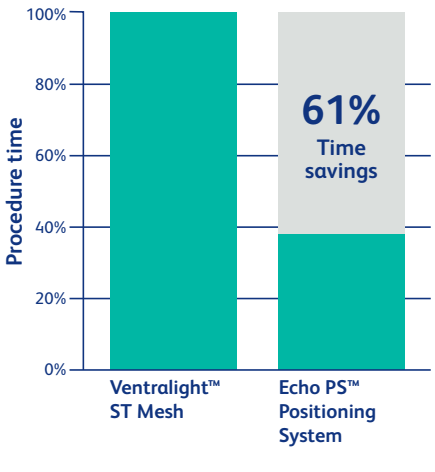
Time includes mesh preparation, positioning and fixation



n = 10 per group
p < .001

Mesh positioning time

Time from mesh in abdomen to placement of first tack



Ventralight™ ST mesh with Echo™ PS demonstrated a 39% time savings vs. mesh alone, placed with 4 transfascial sutures. When looking at the mesh positioning portion of the procedure, Echo PS™ demonstrated a 61% time savings.

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.** Liang MK, Clapp ML, Garcia A, Subramanian A, Awad SS. Mesh shift following laparoscopic ventral hernia repair. *J Surg Res.* 2012 Sep;177(1):e7-13. **3.** Preclinical data on file at BD. Results may not correlate to clinical performance in humans.

3DMax™ MID Anatomical Mesh

Product Item ID	Shape	Dimensions	Qty.
0116310	Medium left	8 cm x 14 cm (3" x 5")	1/cs
0116311	Large left	10 cm x 16 cm (4" x 6")	1/cs
0116312	X-Large left	12 cm x 17 cm (5" x 7")	1/cs
0116320	Medium right	8 cm x 14 cm (3" x 5")	1/cs
0116321	Large right	10 cm x 16 cm (4" x 6")	1/cs
0116322	X-Large right	12 cm x 17 cm (5" x 7")	1/cs

Ventralight™ ST Mesh with Echo 2™ Positioning System

Product Item ID	Shape	Dimensions	Qty.
5990011G	Circle	11 cm (4.5")	1/cs
5990015G	Circle	15 cm (6")	1/cs
5990020G	Circle	20 cm (8")	1/cs
5991015G	Ellipse	10 cm x 15 cm (4" x 6")	1/cs
5991520G	Ellipse	15 cm x 20 cm (6" x 8")	1/cs
5991525G	Oval	15 cm x 25 cm (6" x 10")	1/cs
5991823G	Ellipse	18 cm x 23 cm (7" x 9")	1/cs
5992025G	Ellipse	20 cm x 25 cm (8" x 10")	1/cs
5992533G	Ellipse	25 cm x 33 cm (10" x 13")	1/cs

Ventralight™ ST Mesh with Echo PS™ Positioning System

Product Item ID	Shape	Dimensions	Qty.
5955450G	Circle	11.4 cm (4.5")	1/cs
5955460G	Ellipse	10.2 cm x 15.2 cm (4" x 6")	1/cs
5955600G	Circle	15.2 cm (6")	1/cs
5955680G	Ellipse	15.2 cm x 20.3 cm (6" x 8")	1/cs
5955610G	Oval	15.2 cm x 25.4 cm (6" x 10")	1/cs
5955790G	Ellipse	17.8 cm x 22.9 cm (7" x 9")	1/cs
5955800G	Circle	20.3 cm (8")	1/cs
5955810G	Ellipse	20.3 cm x 25.4 cm (8" x 10")	1/cs
5955113G	Ellipse	25.4 cm x 33 cm (10" x 13")	1/cs
5955124G	Rectangle	30.5 cm x 35.6 cm (12'' x 14'')	1/cs

Phasix™ Mesh

Product Item ID	Shape	Dimensions	Qty.
1190100G	Round	7.6 cm (3" x 3")	1/cs
1190616G	Rectangle	6 x 16 cm (2"x 6")	1/cs
1190820G	Rectangle	8 x 20 cm (3'' x 8'')	1/cs
1190830G	Rectangle	8 x 30 cm (3'' x 12'')	1/cs
1191040G	Rectangle	10 x 40 cm (4'' x 16'')	1/cs
1190845G	Rectangle	8 x 45 cm (3'' x 18'')	1/cs
1190200G	Rectangle	10.2 x 15.2 cm (4"x 6")	1/cs
1190300G	Rectangle	15.2 x20.3 cm (6"x 8")	1/cs
1190400G	Rectangle	20.3 x 25.4 cm (8"x 10")	1/cs
1190500G	Rectangle	25.4 x 30.5 cm (10"x 12")	1/cs
1191025G	Rectangle	10 x 25 cm (4'' x 10'')	1/cs
1191525G	Rectangle	15 x 25 cm (6'' x 10'')	1/cs
1191530G	Rectangle	15 x 30 cm (6"x 12")	1/cs
1192030G	Rectangle	20 x 30 cm (8'' x 12'')	1/cs
1192040G	Rectangle	20 x 40 cm (8"x 16")	1/cs
1193045G	Rectangle	30 x 45 cm (12"x 18")	1/cs

Phasix™ ST Mesh

Product Item ID	Shape	Dimensions	Qty.
1200008G	Round	8 cm (3")	1/cs
1200011G	Round	11 cm (4.5")	1/cs
1200015G	Round	15 cm (6")	1/cs
1200710G	Rectangle	7 cm x 10 cm (3" x 4")	1/cs
1201010G	Square	10 cm x 10 cm (4" x 4")	1/cs
1201015G	Rectangle	10 cm x 15 cm (4" x 6")	1/cs
1201020G	Rectangle	10 cm x 20 cm (4" x 8")	1/cs
1201325G	Rectangle	13 cm x 25 cm (5" x 10")	1/cs
1201520G	Rectangle	15 cm x 20 cm (6" x 8")	1/cs
1202025G	Rectangle	20 cm x 25 cm (8" x 10")	1/cs
1202530G	Rectangle	25 cm x 30 cm (10" x 12")	1/cs
1202535G	Rectangle	30 cm x 35 cm (12" x 14")	1/cs

3DMax™ MID Anatomical Mesh

Indications. The 3DMax™ MID Anatomical Mesh is indicated for use in the reinforcement of soft tissue where weakness exists in the repair of inguinal hernias. **Contraindications**. 1. Do not use this mesh in infants, children or pregnant or breastfeeding women, whereby future growth may be compromised by use of such mesh material. 2. Literature reports that there may be a possibility for adhesion formation when polypropylene mesh is placed in direct 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 bodily fluids, discard mesh 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, 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 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. To avoid injury, careful attention is required if fixating the mesh in the presence of nerves, vessels or the spermatic cord. Fastener penetration into underlying tissue containing nerves or blood vessels may result in the need for medical/surgical intervention, cause serious injury or permanent impairment to a body structure. 8. This device is not for the use of repair of pelvic organ prolapse. 9. This device 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 appropriate surgical techniques should use this mesh. 3. Do not cut or reshape the 3dmax™ MID anatomical mesh as this may affect its effectiveness. 4. Use an appropriately sized trocar to allow mesh to slide down the trocar with minimal force.**Adverse reactions.** Possible complications may include, but are not limited to, seroma, adhesion, hematoma, pain, infection, inflammation, extrusion, erosion, migration, fistula formation, allergic reaction, wound dehiscence and recurrence of the hernia or soft tissue defect. **Instructions for use:** It is recommended to use 8 mmor larger internal diameter trocar trocar· to introduce 3DMax™ MID Anatomical Mesh. ·If the trocar has a proximal cap, removing it can help facilitate insertion of the device. Insertion forces may vary depending on rolled device size and graspers/trocar used .

Ventralight™ ST Mesh 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.

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 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 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.

Phasix™ Mesh

Indications. Phasix™ Mesh is indicated to reinforce soft tissue where weakness exists, in patients undergoing abdominal, plastic, and reconstructive surgery in ventral hernia repair and other abdominal fascial defect procedures including prophylactic use to reinforce surgical incisions.**Contraindications.** Because Phasix™ Mesh is fully resorbable, it should not be used in repairs where permanent wound or organ support from the mesh is required. **Warnings.** 1.Phasix™ Mesh must not be put in direct contact with the bowel or viscera. 2. The use of any mesh or patch in a contaminated or infected wound can lead to fistula formation and/or extrusion of the mesh.3. Mesh manufacture involves exposure to tetracycline hydrochloride and kanamycin sulfate. The safety and product use for patients with hypersensitivities to these antibiotics is unknown. The use of this mesh in susceptible patients with known allergies to tetracycline hydrochloride or kanamycin sulfate should be avoided.4. The safety and effectiveness of Phasix™ Mesh in the following applications has not been evaluated or established: a. Pregnant or breastfeeding women. b. Pediatric use. c. Neural and cardiovascular tissue. 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 the removal of the mesh. 6. To prevent recurrences when repairing hernias or to prevent occurrences when reinforcing surgical incisions prophylactically, the mesh should be sized with appropriate overlap for the size and location of the defect or surgical incision, 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. 7. The mesh is supplied sterile. 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. 8. This mesh 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 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. 9. If unused Phasix™ Mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, handle and dispose of in accordance with accepted medical practice and applicable local, state, and federal laws and regulations to prevent risk of transmission of viral infections. 10. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 11. This mesh is not for the use of treatment of stress urinary incontinence. 12. Phasix™ Mesh has not been studied for use in breast reconstructive surgeries. **Precautions.** 1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this mesh. Users should be familiar with mesh strength and size requirements. Improper selection, placement, positioning, and fixation of the mesh can cause subsequent undesirable results. 3. Clinical data in accordance with EU MDR has not been established for laparoscopic/robotic procedures. 4. The safety and effectiveness of Phasix™ Mesh in the proximity of existing or excised cancer has not been established. **Adverse reactions.** In preclinical testing, Phasix™ Mesh elicited a minimal tissue reaction characteristic of foreign body response to a substance. The tissue reaction resolved as the mesh was resorbed. Possible complications may include, but are not limited to infection, seroma, pain, mesh migration, wound dehiscence, hemorrhage, adhesions, hematoma, inflammation, allergic reaction, extrusion, erosion, fistula formation and recurrence of the hernia or soft tissue defect.

Phasix™ ST Mesh

Indications. Phasix™ ST Mesh is indicated for use in the reinforcement of abdominal soft tissue, where weakness exists, in ventral and hiatal hernia repair procedures. **Contraindications**. Because Phasix™ ST Mesh is fully resorbable, it should not be used in repairs where permanent wound or organ support from the mesh is required. **Warnings**. 1.Mesh manufacture involves exposure to tetracycline hydrochloride and kanamycin sulfate. The safety and product use for patients with hypersensitivities to these antibiotics is unknown. Use of this mesh in patients with known allergies to tetracycline hydrochloride or kanamycin sulfate should be avoided. 2. Ensure proper orientation; the coated side of the mesh should be oriented against the bowel or sensitive organs. Do not place the uncoated mesh side against the bowel. There is a risk for adhesion formation or erosions when the uncoated mesh side is placed in direct contact with the bowel or viscera. (Reference Surface Orientation section.) 3. The safety and effectiveness of Phasix™ ST Mesh in bridging repairs has not been evaluated or established. 4. The safety and effectiveness of Phasix™ ST Mesh in laparoscopic/robotic ventral hernia repair procedures has not been evaluated or established. 5. The use of any mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh and it is not recommended. 6. 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. 7. To prevent recurrences when repairing hernias, 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. 8. For hiatal hernia repair, the use of Phasix™ ST Mesh circumferentially around the esophagus is not recommended. 9. For hiatal hernia repair, the use of Phasix™ ST Mesh to bridge the hiatus is not recommended. 10. The safety and effectiveness of Phasix™ ST Mesh in the following applications has not been evaluated or established: a. Pregnant or breastfeeding women b. Pediatric use 11. Product should be used once exterior foil pouch has been opened. Do not store for later use. 12. Unused portions of the mesh should be discarded. If unused mesh has been in contact with instruments or supplies used on a patient or contaminated with body fluids, discard mesh with care to prevent risk of transmission of viral and other infections. 13. This mesh is designed for single use only. Reuse, resterilization, reprocessing and/or repackaging of any portion of the Phasix™ ST Mesh 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. 14. This mesh is supplied sterile. 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. 15. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 16. This mesh is not for the use of treatment of stress urinary incontinence. 17. This mesh is not for use of repair of neural and cardiovascular tissue. 18. Phasix™ ST Mesh has not been studied for use in breast reconstructive surgeries. **Precautions**. 1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this mesh. Users should be familiar with strength and mesh size requirements. Improper selection, placement, positioning and fixation of the mesh can cause subsequent undesirable results. 3. The safety and effectiveness of the mesh has not been evaluated in the presence of malignancies in the abdominopelvic cavity. 4. The safety and effectiveness of Phasix™ ST Mesh in the proximity of existing or excised cancer has not been established. **Adverse reactions**. In preclinical testing, Phasix™ ST Mesh elicited a minimal tissue reaction characteristic of foreign body response to a substance. The tissue reaction resolved as the mesh was resorbed. Possible complications may include, but are not limited to, seroma, adhesion, hematoma, pain, infection, inflammation, allergic reaction, hemorrhage, extrusion, erosion, migration, fistula formation and recurrence of the hernia or soft tissue defect. Possible complications in hiatal hernia repair may include esophageal erosion and dysphagia related to crural fibrosis. **Please consult package insert for more detailed safety information and instructions for use. This product may not be available in your country. Please contact your local BD sales representative for more information.** ,

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