



BD[®] Umbilical Hernia Solutions

BD[®] Ventralex[™] ST Hernia Patch

BD[®] Phasix[™] Mesh and BD[®] Phasix[™] ST Mesh



BD[®] Umbilical Hernia Solutions



Non-absorbable

Ventrex[™] ST Hernia Patch

Launched in 2011

For further product information:



Preperitoneal and intraabdominal placement



Easy

The Ventrex[™] ST Hernia Patch's **simple technique** is clinically proven for reliable umbilical hernia repairs.¹

Three sizes available for coverage of defects of various sizes.



Efficient

Pocket and strap design facilitates placement, positioning and lateral fixation.²

SorbaFlex[™] Memory Technology allows the patch to "self-deploy" and lay flat to maintain shape, and then the memory ring fully absorbs over time.²



Proven

Ventrex[™] ST Hernia Patch: **over 1.5 million** implants globally.

Absorbable

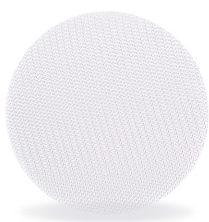
Experience the difference of a reliable alternative to permanent mesh

Phasix[™] Mesh and Phasix[™] ST Mesh

Made from Poly-4-hydroxybuterate (P4HB)

Launched in 2013

For further product information:



Extraperitoneal placement



Preperitoneal and intraabdominal placement

Pre-clinical data suggests there are three main attributes of the Phasix[™] Mesh:



Healthy tissue ingrowth^{3,4,5}



Predictable durability^{1,5}

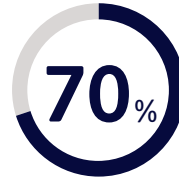


Colonisation resistance⁶

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of patients have a desire for a non-permanent mesh repair option, according to survey data⁶



of surgeons would be willing to respond to patient mesh preferences⁶

Enhanced patient quality of life

Talwar, et al showed patient quality of life following hernia repair with Phasix[™] Mesh can improve immediately and continues to improve up to 5 years following repair.⁷



Catalogue information

Non-absorbable

Ventrex[™] ST Hernia Patch

Product Item ID	Shape	Dimensions
5950007G	Round	4.3 cm
5950008G	Round	6.4 cm
5950009G	Round	8.0 cm

Absorbable

Phasix[™] Mesh

Product Item ID*	Shape	Dimensions
1190100G	Round	7.6 cm

Phasix[™] ST Mesh

Product Item ID*	Shape	Dimensions
1200008G	Round	8.0 cm
1200011G	Round	11 cm

*Larger sizes available

Relevant studies and publications

Committed partner.
Full portfolio. Backed by data.

Ventrelex [™] ST Hernia Patch						
Publication	Patients	Mean follow-up	Recurrence	Seroma	SSI	Why use Ventrelex [™] ST ?
Umbilical hernia repair with composite prosthesis: A single-centre experience J.L. Porrero, et al. (Hernia, 2019)	1,359 (93.4% preperitoneal space)	4.1 years	3.9% (only 1.8% required reoperation)	N/A	1.3%	<p>“Composite prostheses have a memory ring that helps to deploy the prosthesis in the preperitoneal space, and so, surgery is easier and faster.”</p> <p>“Another reason to use a composite prosthesis is that dissection of the preperitoneal space can be difficult. In these cases, the peritoneum can be left opened. Therefore, using a composite prosthesis is safer.”</p>
Ventrelex [™] ST hernia patch repair for small umbilical hernia is safe and effective: A retrospective cohort study J.M. Hiekkaranta, et al. (Journal of Abdominal Wall Surgery, 2023)	488 (84.8% preperitoneal space)	68 months	2.5% (12/488)	0.6%	3.3%	<p>“Hernia repair using a ventral patch is considered a quick and elegant procedure.”</p> <p>“It is not easy to avoid peritoneal tears during the preperitoneal space dissection or mesh placement pass relatively small hernia port. Because of this it might be beneficial to use mesh with antiadhesive barrier even when mesh is placed preperitoneally.”</p>
Patient-reported outcome measures 2 years after treatment of small ventral hernias using monofilament polypropylene patch covered with an absorbable hydrogel barrier on its visceral side J.F. Gilon, et al. (International Journal of Abdominal Wall and Hernia Surgery, 2018)	108	2 years (93 patients with 2-year FU - phone questionnaire)	3.2% (3/93) (only 1 reoperation)	0.9%	0*	<p>“Compared with their preoperative status evaluated with the same questionnaire (baseline), the improvement of their quality of life at 2-year follow-up was highly statistically significant (P < 0.001).”</p> <p>“These small patches allow to treat small hernias with a unique small incision; the procedure is quick and well suited for 1-day surgery; their implantation does not require wide parietal dissections entailing risks of pain, seromas, or hematomas; their fixation does not require a single or double crown of staples nor a transfascial suture.”</p>

*No postoperative complications

Relevant studies and publications

Phasix[™] Mesh: Proven clinical outcomes.

Phasix [™] Mesh and Phasix ST [™] Mesh						
Publication	Patients	Mean follow-up	Recurrence	Seroma	SSI	Why use Phasix [™] Mesh?
<p>Long-Term, Prospective, Multicenter Study of Poly-4-Hydroxybutyrate Mesh (Phasix Mesh) for Hernia Repair in Cohort at Risk for Complication: 60-Month Follow-Up</p> <p>J.S. Roth, et al. (Journal of the American College of Surgeons, 2022)</p>	121	5 years	<p>Onlay & retrorectus mesh placement: 22% (20/121)</p> <p>Only retrorectus mesh placement: 11.4% (10/88)</p>	N/A	2.8%	<p>"No mesh-related complications were identified beyond the early postoperative period, and none of the patients developed mesh infection or mesh-related complications throughout the entirety of the study period."</p> <p>"Five-year outcomes after ventral and incisional hernia repair with P4HB mesh are associated with infrequent complications and durable hernia repair outcomes."</p>
<p>Five-Year Follow-Up of a Slowly Resorbable Biosynthetic P4HB Mesh (Phasix) in VHWG Grade 3 Incisional Hernia Repair</p> <p>L.M. Van den Dop, et al. (Annals of Surgery Open, 2023)</p>	61	5 years	15.9%	11.5%	11.5%	<p>"Hernia repair with Phasix mesh in high-risk patients (VHWG 3, body mass index >28) demonstrated a recurrence rate of 15.9%, low pain scores, no mesh-related complications or reoperations for chronic pain between the 2- and 5-year follow-up."</p>
<p>Comparative long-term effectiveness between ventral hernia repairs with biosynthetic and synthetic mesh</p> <p>B.G. Morrison, et al. (Surgical Endoscopy, 2023)</p>	<p>Phasix: 101</p> <p>Synthetic: 338</p>	Up to 5 years	<p>Phasix: 7.9%</p> <p>Synthetic: 9.2%</p>	<p>Phasix: 16.8%</p> <p>Synthetic: 9.2%</p>	<p>sSSI</p> <p>Phasix: 6.9%</p> <p>Synthetic: 7.4%</p> <p>dSSI</p> <p>Phasix: 10.9%</p> <p>Synthetic: 9.8%</p>	<p>"Using Kaplan-Meier analysis, synthetic mesh and biosynthetic mesh result in comparable hernia recurrence rates and surgical site infection rates in abdominal wall reconstruction patients with follow-up to as long as five years."</p>

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Contact your sales rep to learn more

Instructions For Use

Ventrex[™] ST Hernia Patch

Indications The Ventrex[™] ST Hernia Patch is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving the repair of ventral, incisional, and umbilical hernias. **Contraindications.** 1. Do not use this mesh in infants, children, or pregnant women, whereby future growth may be compromised by the use of such mesh materials. 2. The use of this mesh has not been studied in breastfeeding or pregnant women. 3. Do not use this mesh for the reconstruction of cardiovascular defects. 4. Literature reports that there may be a possibility for adhesion formation when the polypropylene is placed in contact with the bowel or viscera. **Warnings.** 1. The use of any permanent mesh or patch in a contaminated or infected wound could lead to fistula formation and/or extrusion of the mesh. 2. If an infection develops, treat the infection aggressively. Consideration should be given regarding the need to remove the mesh. An unresolved infection may require the removal of the mesh. 3. If the unused mesh has been in contact with instruments or supplies used on a patient or contaminated with bodily fluids, discard with care to prevent the risk of transmission of viral infections. 4. To prevent recurrences when repairing hernias, the mesh should be sized with appropriate overlap for the size and location of the defect, taking into consideration any additional clinical factors applicable to the patient. Careful attention to mesh fixation placement and spacing will help prevent excessive tension or gap formation between the mesh and fascial tissue. 5. This mesh is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 6. This mesh has been designed for single use only. Reuse, resterilization, reprocessing and/or repackaging may compromise the structural integrity and/or essential material and design characteristics that are critical to the overall performance of the mesh and may lead to mesh failure which may result in injury to the patient. Reuse, reprocessing, resterilization, or repackaging may also create a risk of contamination of the mesh and/or cause patient infection or cross infection, including, but not limited to, the transmission of infectious diseases from one patient to another. Contamination of the device may lead to injury, illness, or death of the patient or end user. 7. This mesh should be used once the exterior foil pouch has been opened. Do not store for later use. Unused portions of the mesh should be discarded. 8. Ensure proper orientation; the bioresorbable coated side of the mesh should be oriented against the bowel or sensitive organs. Do not place the polypropylene side against the bowel. There may be a possibility for adhesion formation when the mesh is placed in direct contact with the bowel or viscera. 9. Do not cut or reshape any portion of the Ventrex[™] ST Hernia Patch, except for the polypropylene positioning strap, as this could impact its effectiveness. Care should be taken not to cut or nick the SorbaFlex[™] PDO monofilament. If the SorbaFlex[™] PDO monofilament is cut or damaged during insertion or fixation, additional complications may include but are not limited to, bowel or skin perforation and infection. 10. Follow proper folding techniques for all patches as described in these Instructions for Use as other folding techniques may potentially compromise the SorbaFlex[™] PDO monofilament. 11. To ensure a strong repair, the mesh should be secured with tacks or sutures through the polypropylene mesh straps or positioning pocket. 12. Excess positioning strap material above the fixation line must be cut off and discarded to eliminate excess material from remaining in the body. 13. When used to repair deficiencies caused by trocars, the mesh should be used under endoscopic guidance or direct visualization. 14. This mesh is not for the use of repair of pelvic organ prolapse via transvaginal approach. 15. This mesh is not for the use of treatment of stress urinary incontinence. **Precautions.** 1. Please read all instructions prior to use. 2. Only physicians qualified in the appropriate surgical techniques should use this mesh. 3. Care should be taken not to cut or nick the SorbaFlex[™] PDO monofilament during fixation. 4. The safety and effectiveness of Ventrex[™] ST Hernia Patch has not been evaluated in clinical studies in the presence of malignancies in the abdominopelvic cavity. **Adverse Reactions.** Possible complications may include, but are not limited to, seroma, adhesions, hematomas, pain, infection, inflammation, extrusion, erosion, migration, fistula formation, allergic reaction, and recurrence of the 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.

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 product labels and inserts for any indications, contraindications, hazards, warnings, precautions and instructions for use.

Please note, not all products, services or features of products and services may be available in your local area. Please check with your local BD representative.

References 1. Martin, et al. Ventrex mesh in umbilical/epigastric hernia repairs: clinical outcomes and complications. *Hernia*. 2008 Aug;12(4):379-83. 2. Preclinical data on file. Results may not correlate to performance in humans. 3. Badyalak, et al. Macrophage phenotype as a predictor of constructive remodeling following the implantation of biologically derived surgical mesh materials. *Elsevier* (2012). 4. Mantovani, et al. The chemokine system in diverse forms of macrophage activation and polarization. *Trends in Immunology*, 004;25(12):677-686. 5. Deeken CR, Matthews BD. Characterization of the mechanical strength, resorption properties, and histologic characteristics of a fully absorbable material (Poly-4-hydroxybutyrate—PHASIX[™] Mesh) in a porcine model of hernia repair. *ISRN Surgery* 2013; 1-12. 6. Stoikes, et al. Characterization of host response, resorption, and strength properties, and performance in the presence of bacteria for fully absorbable biomaterials for soft tissue repair. *Hernia*. 2017 Oct;21(5):771-782. 7. BD Data on file. 8. Talwar, et al. Shifting the goalpost in ventral hernia care: 5-year outcomes after ventral hernia repair with poly-4-hydroxybutyrate Mesh. *Hernia*. 2022 Dec;26(6):1635-1643.

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