Ventralight™ ST Mesh

Featuring Sepra™ Technology

BD

Proven Sepra™ Technology in a low profile, lightweight mesh

Sepra™ Technology

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

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

Bioresorbable PGA fibers reinforce the integrity of the hydrogel barrier by binding it to the polypropylene mesh.

The hydrogel barrier resorbs within 30 days providing visceral protection during the critical healing period.[1]

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

Efficient

- Low profile design facilitates trocar deployment and mechanical fixation
- Easily cut to customize shape and size

Effective

- Uncoated lightweight monofilament polypropylene allows for complete tissue ingrowth with a low percentage of contraction1 for a strong repair
- Hydrogel barrier minimizes tissue attachment to the visceral side of the mesh
- Lightweight polypropylene mesh may lead to decreased patient discomfort[2, 3, 4]

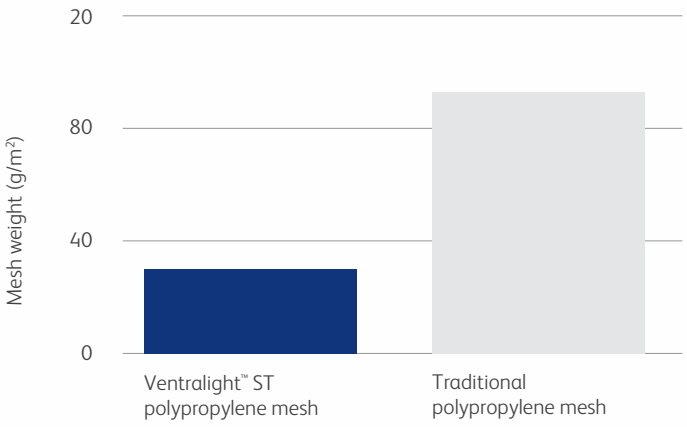
Proven

- Hydrogel barrier is based on Sepra™ Technology
- Lightweight monofilament polypropylene
- Both materials have been used in general surgery for years with demonstrated clinical success

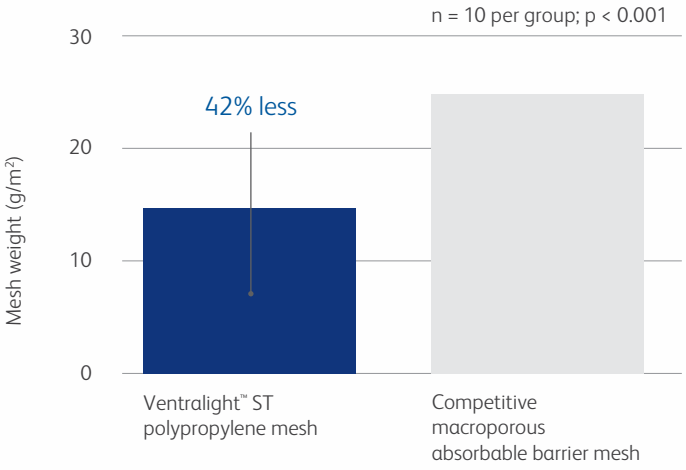
Effective

Minimal contraction shown in preclinical testing compared to a leading macroporous absorbable barrier mesh.

The Ventralight™ ST polypropylene mesh is approximately 50% lighter than traditional polypropylene mesh.



At four weeks, Ventralight™ ST Mesh demonstrated 42% less area mesh contracture than a competitive macroporous absorbable barrier mesh. Results are statistically significant.[1]

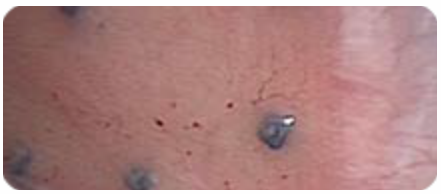


Ventralight™ ST preclinical data with SorbaFix™ Absorbable Fixation System[1]

Laparoscopic Incisional Hernia Repair with Ventralight™ ST Mesh

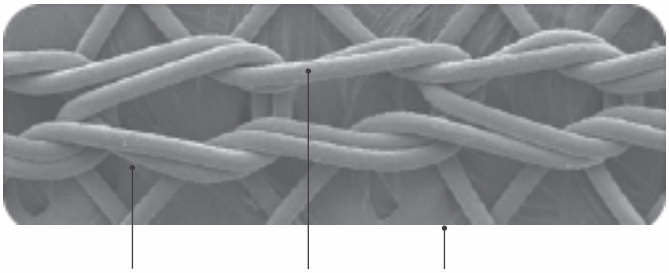
At implant

Four weeks post-op



Strong tissue incorporationsystem*

The parietal side of Ventralight™ ST Mesh (25x)



The open pore design of the uncoated monofilament polypropylene in Ventralight™ ST Mesh allows for:

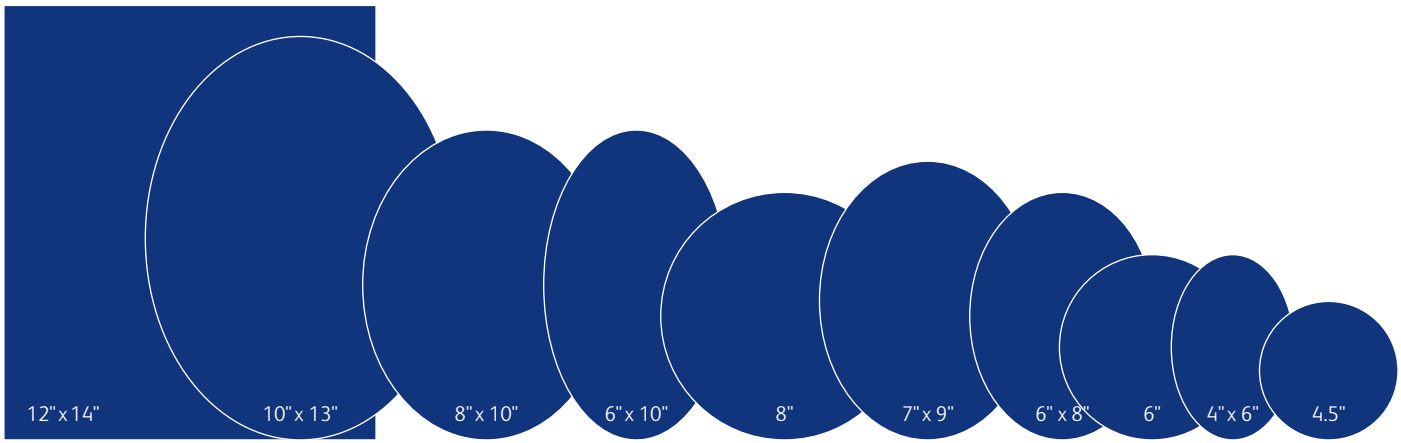
- Fast tissue ingrowth
- Strong tissue incorporation into the abdominal wall
- A strong repair long-term repair

Uncoated polypropylene allows for the majority of tissue ingrowth and strength to occur in the first two weeks after placement of a composite hernia prosthesis.[5,6]

Efficient

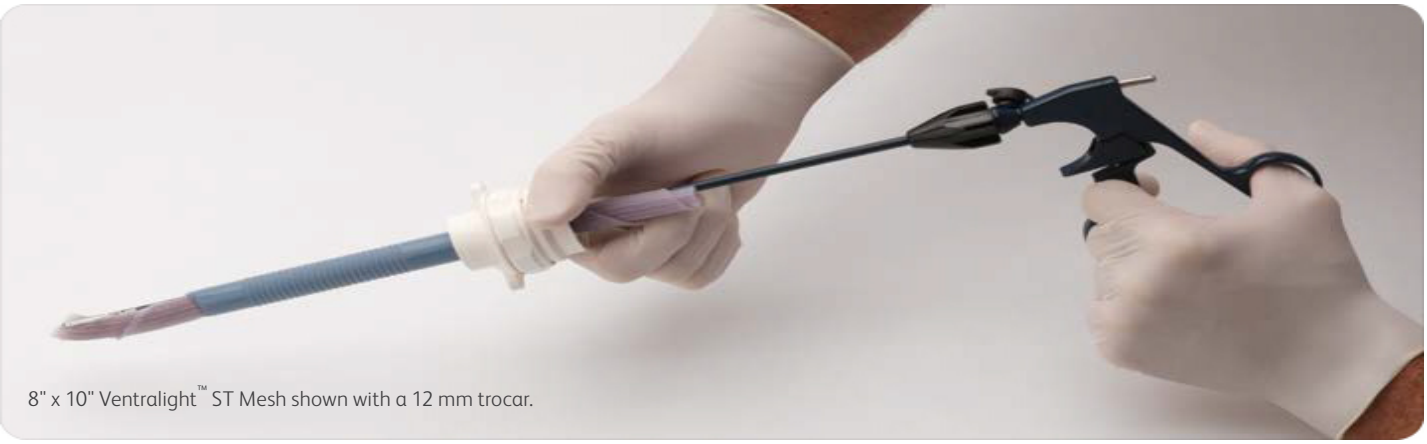
Designed to fit:

- Multiple shapes (circle, oval, ellipse, rectangle)
- Sizes ranging from a 4.5” circle to 12” x 14” rectangle
- Customizable; the unique hydrogel barrier covers the edge of the mesh even after trimming



Easy trocar deployment

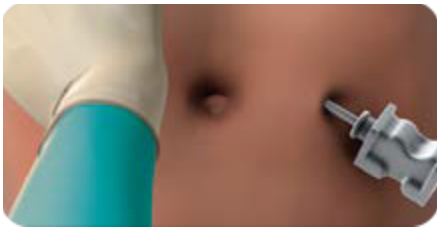
Low profile, lightweight design facilitates trocar deployment.

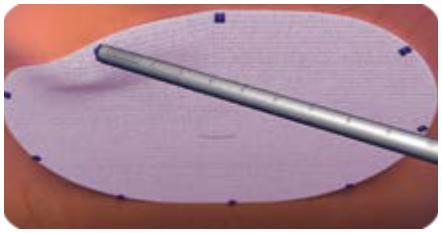


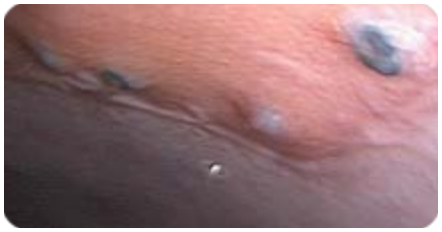
8" x 10" Ventralight™ ST Mesh shown with a 12 mm trocar.

Secure fixation

The SorbaFix™ Absorbable Fixation System provides secure fixation with Ventralight™ ST Mesh. Threaded hollow core allows for tissue ingrowth through interior of fastener.

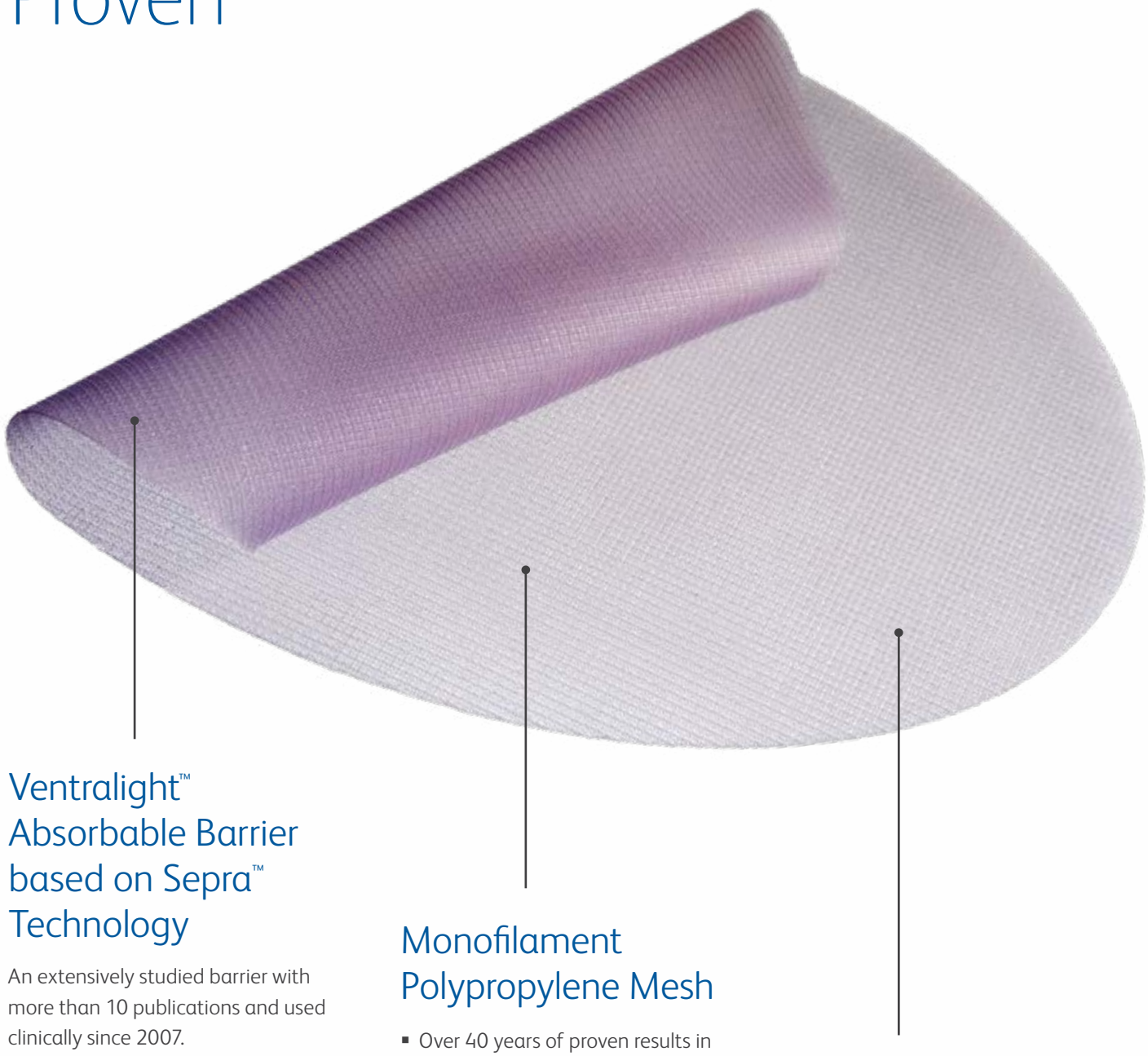






New peritoneal layer completely covers mesh fixation points at four weeks.[1]

Proven



Ventralight™ Absorbable Barrier based on Sepra™ Technology

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

- Unique hydrogel barrier swells to minimize tissue attachment to the visceral side of the mesh.[1]
- Bioresorbable PGA fibers reinforce the integrity of the hydrogel barrier by binding it to the polypropylene mesh.
- The hydrogel barrier resorbs within 30 days providing visceral protection during the critical healing period.[1]

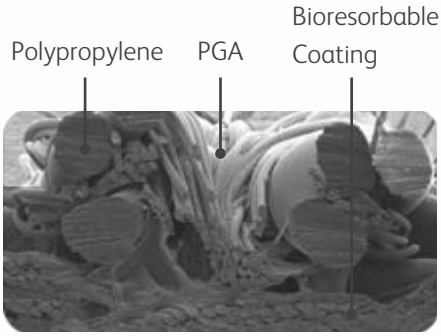
Monofilament Polypropylene Mesh

- Over 40 years of proven results in hernia repair.
- "It is completely inert, resists infection and sinus tract formation, has rapid fibrinous fixation, becomes completely incorporated into the host tissue."[7]

PGA Fibers

- Bioresorbable PGA fibers reinforce the integrity of the hydrogel barrier by binding it to the polypropylene mesh.

Open pore mesh design, post absorption (25x)



Clinical success

Sepramesh™ IP Composite – a preclinical study†

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

Pierce, R., Perrone, J., Abdelrahman, N., Sexton, J., Walcutt, J., Frisella, M., Matthews, B. *Surgical Innovation.* 2009 Mar; 16(1): 46-54.[8]

Key Findings

Sepramesh™ IP Composite resulted in 0% adhesion coverage, the lowest of all mesh products studied. (Table 1)

Table 1 – Adhesion Properties and Mesh Contraction

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

Ventralight™ ST Mesh has the same absorbable barrier as Sepramesh™ IP Composite, but with a lightweight polypropylene mesh.

Sepramesh™ IP Composite – a clinical study‡

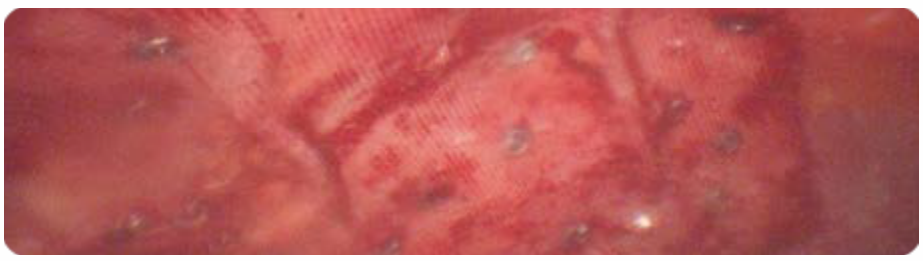
A single-arm, single-center, retrospective study with prospective follow-up of laparscopic ventral hernia repair utilizing the Bard Sepramesh™ IP Composite.

Andrew Archer, DO, Stephen Fleischer, DO, Rhett Lohman, DO, Edward Caldwell, DO. Grandview Medical Center, Dept. of Surgery, Dayton, OH.

Results – 90 patients, three year follow up

Hernia recurrence	1 *(1.1%)*
Postoperative subxiphoid hernia	1 *(1.1%)*
Mean procedure time (min)	41.4 ± 20.6

Two additional adverse events (seroma and abdominal pain) were also reported.



47 year old male with Sepramesh™ IP Composite four months after surgery

† Results may not correlate to performance in humans.
‡ Study was sponsored by BD. Dr. Archer is a paid consultant for BD.

Ordering information

Product code	Qty.	Shape	Dimensions	
5954450G	1/cs	Circle	4.5" (11.4 cm)	☐
5954460G	1/cs	Ellipse	4" x 6" (10.2 cm x 15.2 cm)	☐
5954600G	1/cs	Circle	6" (15.2 cm)	☐
5954680G	1/cs	Ellipse	6" x 8" (15.2 cm x 20.3 cm)	☐
5954610G	1/cs	Oval	6" x 10" (15.2 cm x 25.4 cm)	☐
5954790G	1/cs	Ellipse	7" x 9" (17.8 cm x 22.9 cm)	☐
5954800G	1/cs	Circle	8" (20.3 cm)	☐
5954810G	1/cs	Ellipse	8" x 10" (20.3 cm x 25.4 cm)	☐
5954113G	1/cs	Ellipse	10" x 13" (25.4 cm x 33 cm)	☐
5954124G	1/cs	Rectangle	12" x 14" (30.5 cm x 35.6 cm)	☐

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. The use of this mesh has not been studied in breastfeeding or pregnant women. 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. 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.) 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 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. 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. **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.

SorbaFix™ Absorbable Fixation System

Indications. The SorbaFix™ Absorbable Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during 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 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 in-growth of tissue into the mesh over time, which could result in inadequate fixation once the fastener is resorbed. 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 SorbaFix™ Absorbable Fixation System in the close vicinity of such underlying structures is contraindicated. For reference, the length of the fastener is 6.0 mm, the fastener head is another 0.7 mm (total 6.7 mm). **Warnings.**1. The SorbaFix™ Absorbable Fixation System is intended for Single Use Only – DO NOT RESTERILIZE. Reuse, reprocessing, re-sterilization, 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, re-sterilization, 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. This product is supplied sterile. Inspect the packaging to be sure it is intact and undamaged prior to use. 2. Do not use beyond the expiration date on the package. 3. Do not use if the center of the temperature indicator is black. 4. As with any implant material the presence of bacterial contamination may enhance bacterial infectivity. Accepted surgical practices 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 SorbaFix™ 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. Prosthetics should be evaluated for compatibility prior to use. 7. To prevent patient injury from the piloting tip, stay clear of vessels, nerves, bowel, and iscera when entering the surgical site, manipulating tissue, and fixating mesh. After use, the SorbaFix™ Absorbable Fixation System may be a potential biohazard. This device has a piloting tip, which should be considered a sharp even when the device is not actuated. Handle and dispose of in accordance with any local and federal laws regarding medical waste and sharps disposal requirements to prevent sharps injuries.

Precautions.1. Please read all instructions before using the SorbaFix™ 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 SorbaFix™ 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 SorbaFix™ Absorbable Fixation System should enter and exit the trocar easily without excessive force. The use of too much force could damage the instrument. 4. Counter pressure should be applied on the target area. Avoid placing hand/finger directly over the area where the fastener is being deployed to prevent injury. 5. Insertion of fasteners into some collagenous structures such as ligaments and tendons is possible but is NOT possible directly into bone or cartilage. This may damage the device.6. Avoid excessive trigger force as this may damage the device. 7. If the device locks, remove the device from the patient and lightly tap the trigger forward toward the tip to release. 8. If the device locks and cannot be separated from a fastener that has been deployed into tissue, you may rotate the device counterclockwise to free the device. The locked 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 air to ensure proper fastener deployment. Once proper fastener deployment is confirmed, the device may be reinserted into the patient. 10. The safety and effectiveness of SorbaFix™ Absorbable Fixation System have not been evaluated or established in pregnant or breast feeding women. 11. 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 SorbaFix™ 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; septicemia/infection; hernia recurrence/wound dehiscence.

1 Preclinical data on file at BD. Results may not correlate to performance in humans. 2 Novitsky YW, Harrell AG, Hope WW, Kercher KW, Heniford BT. Meshes in hernia repair. Surg Technol Int. 2007;16:123-7. 3 Cobb WS, Kercher KW, Heniford BT. The argument for lightweight polypropylene mesh in hernia repair. Surg Innov. 2005 Mar;12(1):63-9.9. 4 Agarwal BB, Agarwal KA, Mahajan KC. Prospective double-blind randomized controlled study comparing heavy- and lightweight polypropylene mesh in totally extra-peritoneal repair of inguinal hernia: early results. Surg Endosc. 2009 Feb;23(2):242-7. 5 Based on a preclinical study of a composite polypropylene/ePTFE hernia repair mesh. 6 Majercik S, Tsikitis V, Iannitti DA. Strength of tissue attachment to mesh after ventral hernia repair with synthetic composite mesh in a porcine model. Surg Endosc. 2006 Nov;20(11):1671-4. 7 Amid PK, Shulman Aenstein IL, Hakakha M. Biomaterials for abdominal wall hernia surgery and principles of their applications. Langenbecks Arch Chir. 1994;379(3):168-71. 8 Dr. Matthews is a paid consultant for Davol. Financial support for the study was supplied by Atrium Medical Corporation.

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

BD Switzerland Sarl
Terre Bonne Park – A4, Route De Crassier, 17, 1262 Eysins, Vaud, Switzerland
T: + 41 21 556 3000

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