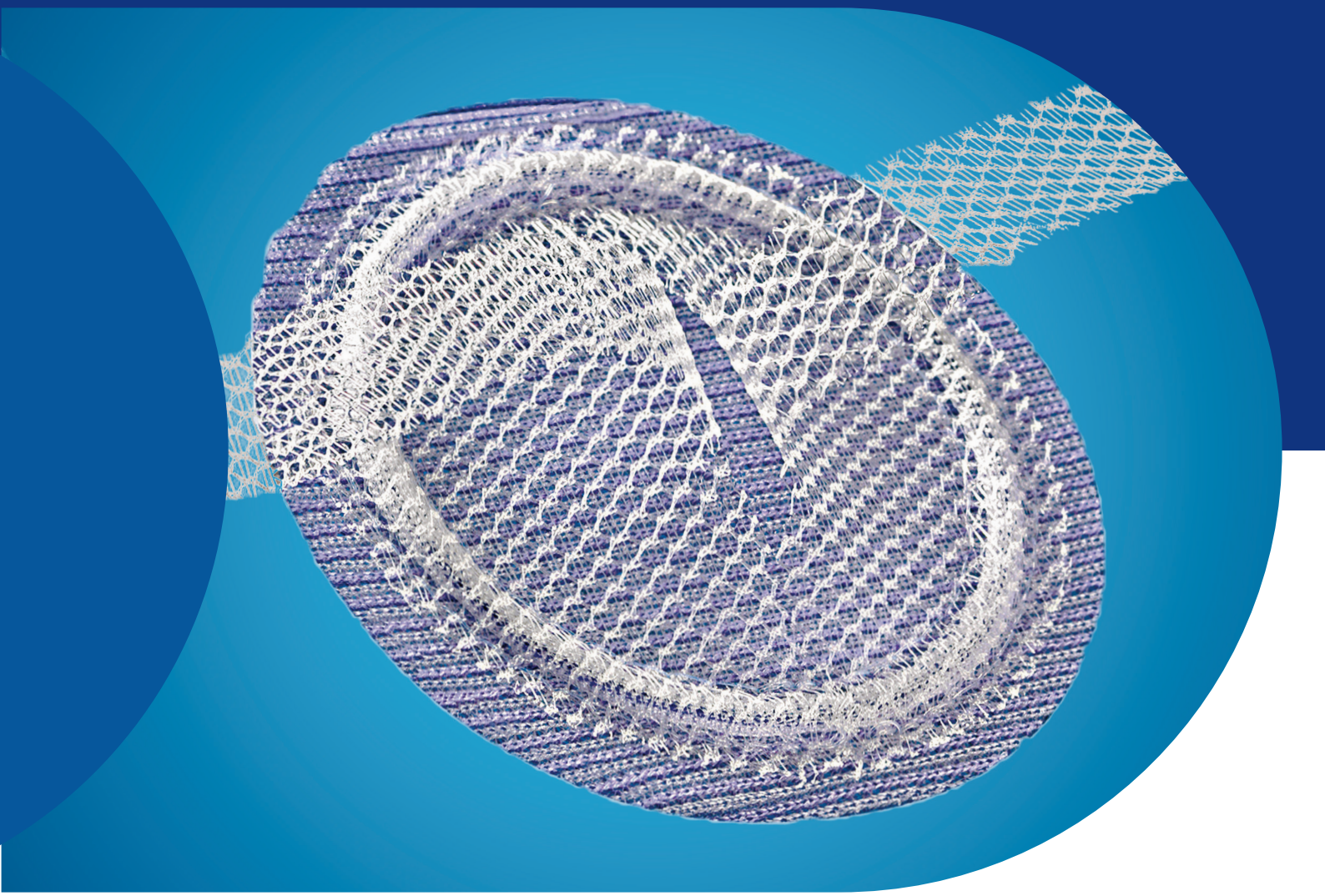


Ventralex™ ST Hernia Patch

Featuring Sepra™ Technology

BD

Proven Sepra™ Technology in a low profile, lightweight mesh

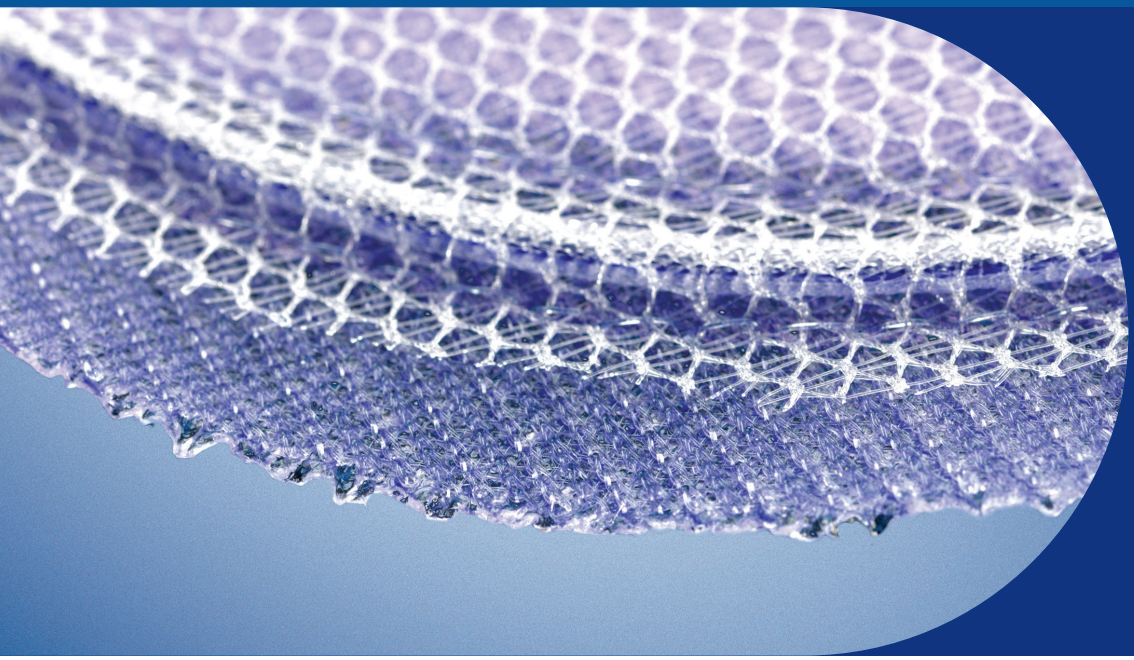
A clinically proven umbilical hernia repair solution with an absorbable barrierfeaturing Sepra™ technology

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

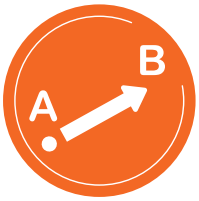
Unique hydrogel barrier swells to minimize tissue attachment to the visceral side of t.he mesh.[1]

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.



Easy

- Simple tension-free intraabdominal repair
- Minimum dissection and fixation required

Efficient

- Pocket and strap facilitates placement, positioning and fixation
- SorbaFlex™ Memory Technology allows the patch to “spring open”, lay flat to maintain shape and then fully absorbs over time[1]

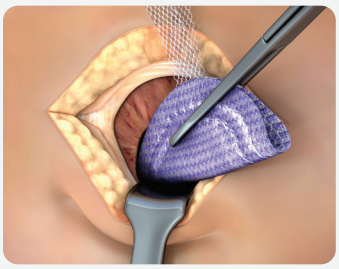
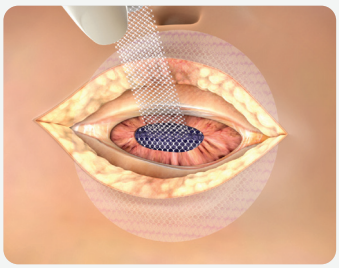
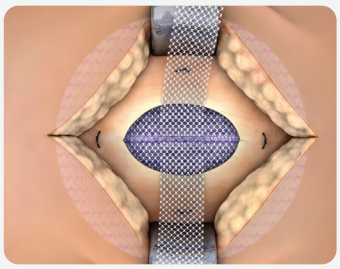
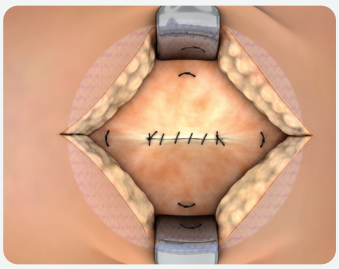
Proven

- Hydrogel barrier is based on Sepra™ Technology
- Uncoated monofilament polypropylene mesh allows for complete tissue ingrowth leading to a strong repair
- Clinically supported technique since 2002 with peer-reviewed published clinical studies

1 Preclinical data on file at C. R. Bard. Results may not correlate to performance in humans.

Easy

The Ventralex™ ST Hernia Patch's simple technique is clinically proven for reliable umbilical hernia repairs

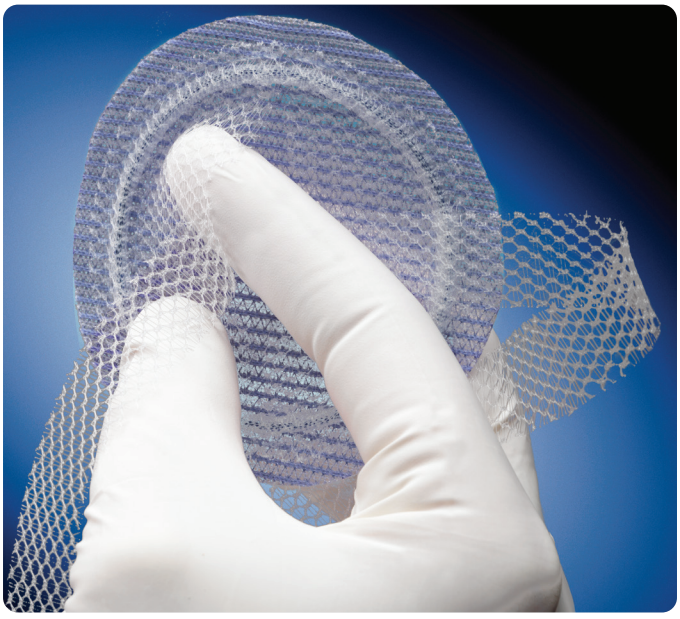
- Designed for intraabdominal repairs of umbilical and other small ventral hernias.
- Intraabdominal placement eliminates lateral dissection required for preperitoneal placement.
- Post-op pain may be reduced due to the minimal dissection required to secure the prosthesis.

Unique positioning pocket aids in proper placement, positioning and lateral fixation

- Special positioning strap and memory technology assure that the patch lays flat against the abdominal wall.
- Three sizes available.

Efficient

The Ventralex™ ST Hernia Patch's proven design aids placement, positioning and fixation

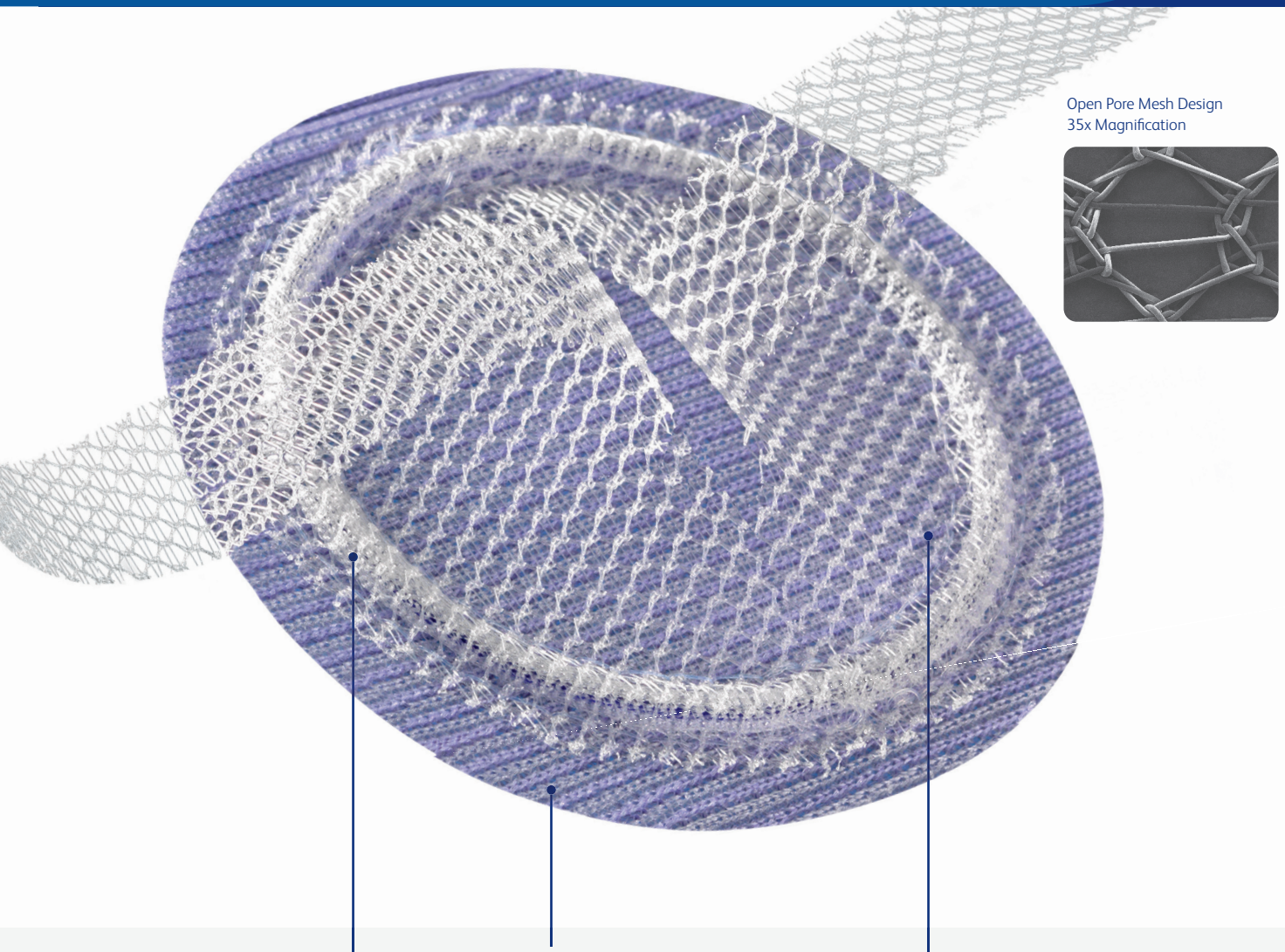



Unique positioning pocket aids in proper placement, positioning and lateral fixation

- Special positioning strap and memory technology assure that the patch lays flat against the abdominal wall.
- Three sizes available.

Proven Material

The Ventralex™ ST Hernia Patch combines materials used in general surgery for many years to deliver proven benefits to you and your patients



Open Pore Mesh Design
35x Magnification

SorbaFlex™ Memory Technology

- Polydioxanone (PDO) monofilament is commonly used in other well-known surgical products (e.g. suture)
- Unique in its flexibility and tensile strength, it facilitates patch insertion and proper placement
- Absorption via hydrolysis is essentially complete in 24-32 weeks[7]

Sepramesh™ IP Composite

Hydrogel barrier is based on the Sepra™ technology which has more than 10 publications and used clinically since 2007

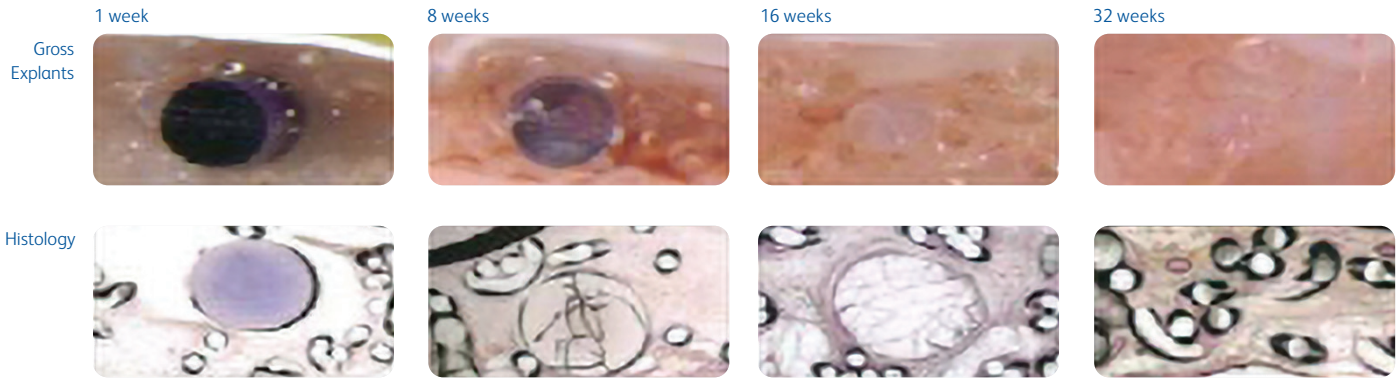
- Unique hydrogel barrier swells to minimize tissue attachment to the visceral side of the mesh[7]
- Resorbs within 30 days providing visceral protection during the critical healing process

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

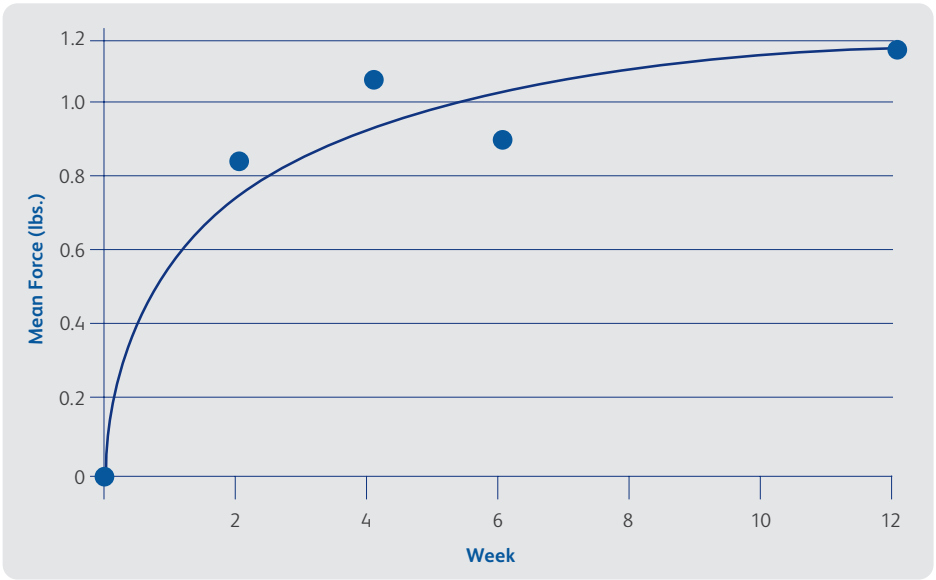
Uncoated monofilament polypropylene mesh

- Over 40 years of proven results in hernia repair
- Allows a fast fibrotic response for a strong repair
- Provides a long-term repair with minimized recurrence

These images are from a porcine study using the Ventrio™ Hernia Patch which contains the same SorbaFlex™ Memory Technology[7]

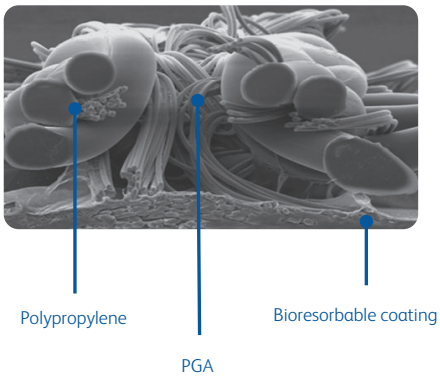


Strength of tissue ingrowth in a preclinical study[5]



Logarithmic regression curve of mean force of lap-shear strength as a function of time. **74% of the 12-week strength is achieved by 2 weeks postoperatively.[5,6]**

Cross section view



Sepramesh™ IP Composite: A preclinical study[8]

"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.[9] Surgical Innovation 2009 Mar; 16(1): 46-54.

Table 1 – Adhesion Properties and Mesh Contraction

Mesh Type	N	Adhesion Grade (1–4)	Adhesion Coverage (%)	Mesh Contraction (%)
Sepramesh™ IP Composite	**6**	**1.0 ± 0.0**	**0.0 ± 0.0**	**6.4 ± 8.4**
Ultra lightweight Polypropylene	12	1.7 ± 1.1	10.7 ± 19.8	9.1 ± 8.3
Polypropylene mesh 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
ePTFE material	10	1.3 ± 0.9	1.4 ± 4.4	39.0 ± 6.0
Multifiliment Polyester mesh	6	1.2 ± 0.4	0.8 ± 2.0	14.7 ± 5.0
Polypropylene mesh, ORC fabric and PDS film	6	2.8 ± 1.0	28.8 ± 16.1	29.7 ± 12.5

Proven Technique

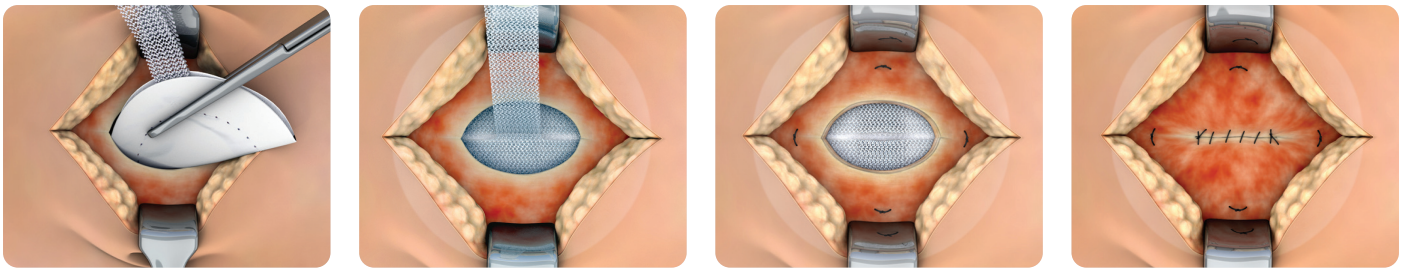
Clinical summary[2]

"Ventralex Mesh in Umbilical/Epigastric Hernia Repairs: Clinical Outcomes and Complications" (Hernia/2008)

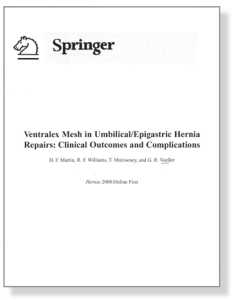
D.F. Martin, R. F. Williams, T. Mulrooney, and G. R. Voeller[3]

Overview

- 88 patients (69 male, 19 female) were evaluated from 2003–2006 and 89 Ventralex™ Hernia Patches were placed
- 0 hernia recurrences



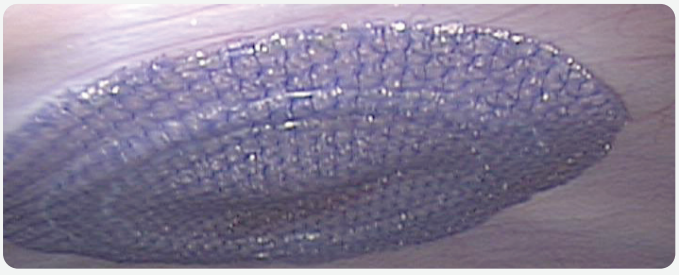
Highlights



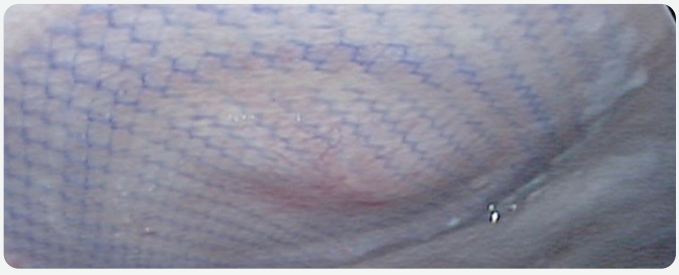
"Interrupted nonabsorbable 2-0 Prolene U-stitches are used at the 12 and 6 o'clock position for the 4.3 cm patch and at the 12, 3, 6 and 9 o'clock position for the 6.4 cm patch, attaching only the polypropylene part of the patch to the fascia."

"We believe our attention to meticulous technique, securing the patch to good healthy fascia at least 2 cm beyond the defect, placement of the patch behind the defect, and re-approximating the fascia over the patch are essential to our low complication and recurrence rate."

Ventralex™ ST Hernia Patch preclinical results[4]



Initial implant



2 weeks

2 Ventralex™ clinical results may not directly correlate to Ventralex™ ST performance.
3 Dr. Guy Voeller is a paid consultant to Davol, Inc.
4 Preclinical data on file at C. R. Bard. Results may not correlate to performance in humans.

Ordering information

Product code	Qty.	Shape	Dimensions	
5950007G	1/cs	Small Circle with Strap	1.7" x 1.7" (4.3 cm x 4.3 cm)	☐
5950008G	1/cs	Medium Circle with Strap	2.5" x 2.5" (6.4 cm x 6.4 cm)	☐
5950009G	1/cs	Large Circle with Strap	3.2" x 3.2" (8.0 cm x 8.0 cm)	☐

Indications. The Ventralex™ 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 Ventralex™ 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 Ventralex™ 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.

Please consult package insert for more detailed safety information and instructions for use.

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BD Switzerland Sarl, Terre Bonne Park – A4, Route De Crassier, 17, 1262 Eysins, Vaud. Switzerland.

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