

# VENTRALEX™ ST Hernia Patch

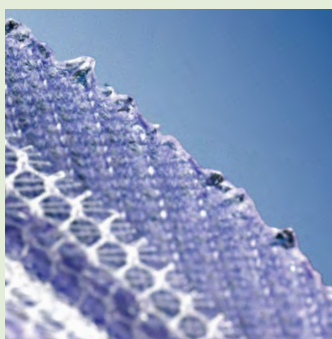
featuring Sepra® Technology

**BAIRD**  
DAVOL INC.

Proven Sepra® Technology in a Low Profile, Lightweight Mesh

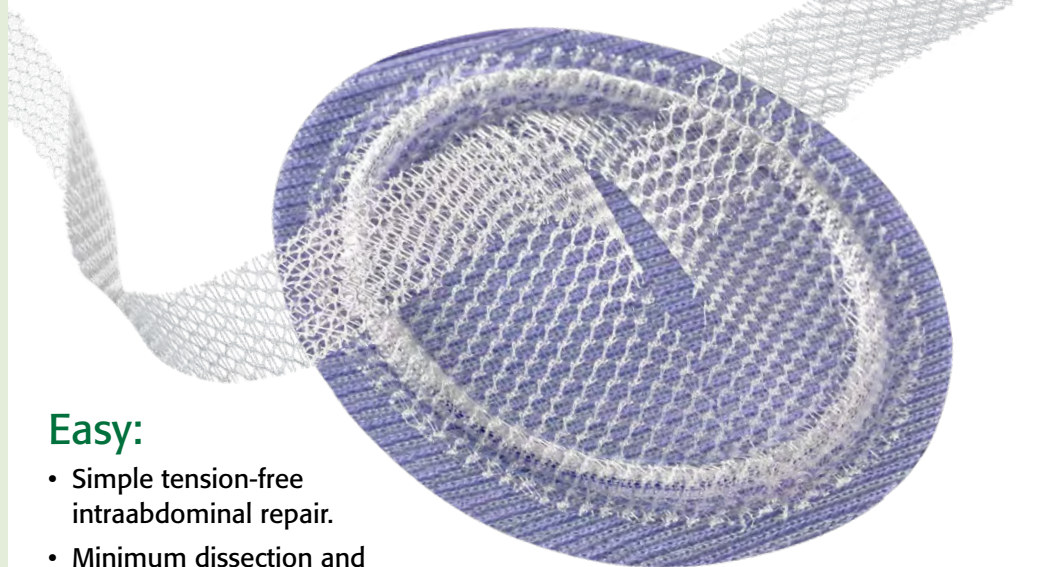
## Sepra® Technology

- 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 the mesh.<sup>1</sup>
- 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.<sup>1</sup>



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

## A clinically proven umbilical hernia repair solution with an absorbable barrier featuring Sepra® technology



## 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.<sup>1</sup>
- Three sizes available for coverage of larger defects to smaller trocar site closures.

## 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.

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

**SOFT TISSUE REPAIR**

Right Procedure. Right Product. Right Outcome.

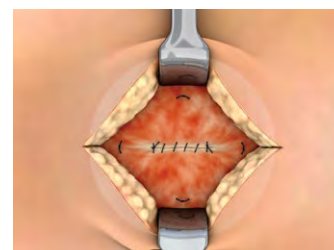
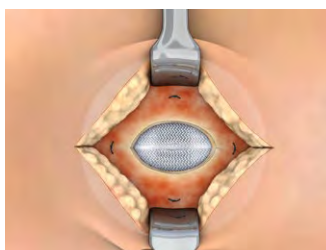
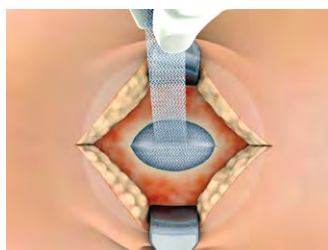
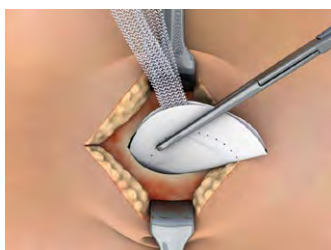
# Proven Technique

## Clinical Summary<sup>2</sup>

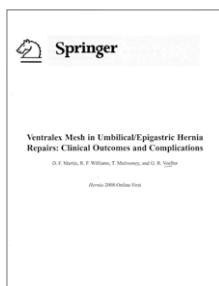
**“VENTRALEX Mesh in Umbilical/Epigastric Hernia Repairs: Clinical Outcomes and Complications” (Hernia/2008)** D.F. Martin, R. F. Williams, T. Mulrooney, and G. R. Voeller<sup>3</sup>

## 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<sup>4</sup>



Initial implant



2 weeks

<sup>2</sup> VENTRALEX™ clinical results may not directly correlate to VENTRALEX™ ST performance.

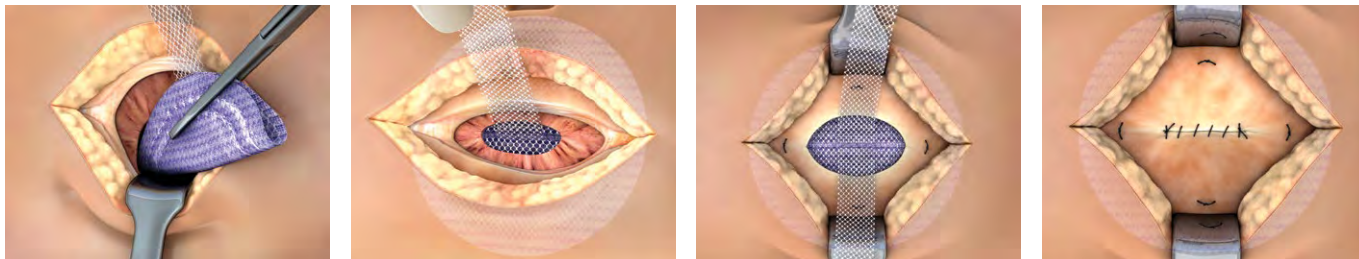
<sup>3</sup> Dr. Guy Voeller is a paid consultant to Davol, Inc.

<sup>4</sup> Preclinical data on file at C. R. Bard. Results may not correlate to performance in humans.

# VENTRALEX™ ST Hernia Patch

## Easy

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



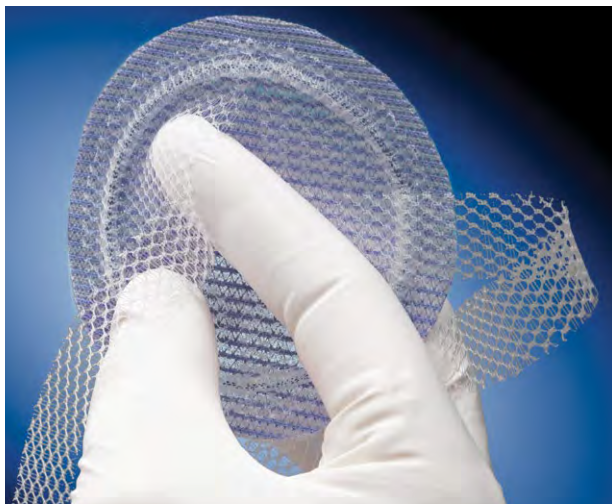
- Designed for intraabdominal repairs of umbilical and other small ventral hernias.
- Intraabdominal placement eliminates lateral dissection required for preperitoneal placement.
- Post-op pain may be reduced due to the minimal dissection required to secure the prosthesis.

## Ideal for trocar site closures.

Herniation into a trocar site, along with Richter's hernias, may occur even if the anterior fascia above the defect has been closed. The smallest VENTRALEX™ ST Hernia Patch allows for an intraabdominal, tension-free repair with no transfascial suturing.

## 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.**

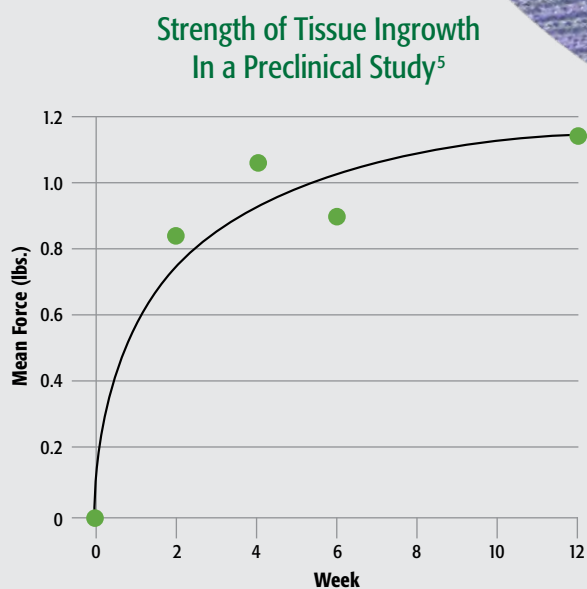
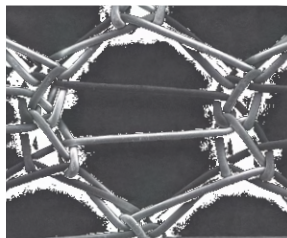
- Special positioning strap and memory technology assure that the patch lays flat against the abdominal wall.
- Three sizes available for coverage of larger defects to smaller trocar site closures.



# 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



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.<sup>5</sup>

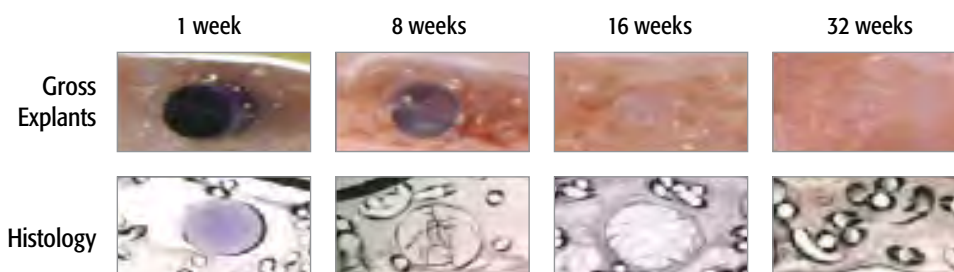
## Uncoated Monofilament Polypropylene Mesh

- 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.

<sup>5</sup> Majercik, S. et al. "Strength of tissue attachment to mesh after ventral hernia repair with synthetic composite mesh in a porcine model." *Surg Endoscopy* (2006) 20: 1671-1674. Results may not correlate to performance in humans.

## 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.<sup>7</sup>



These images are from a porcine study using the VENTRIO™ Hernia Patch which contains the same SORBAFLEX™ Memory Technology.<sup>7</sup>

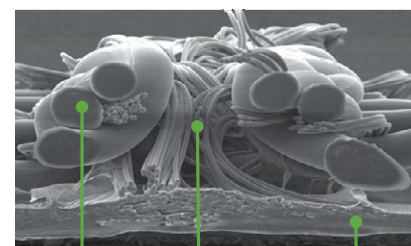
## SEPRAMESH™ IP Composite

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.<sup>7</sup>
- 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.

### Cross Section View



Polypropylene

Bioresorbable coating

PGA

## SEPRAMESH™ IP Composite: A Preclinical Study<sup>8</sup>

“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.<sup>9</sup> *Surgical Innovation* 2009 Mar; 16(1): 46-54.

### 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
ProLite Ultra	12	1.7 ± 1.1	10.7 ± 19.8	9.1 ± 8.3
C-Qur	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
Dualmesh	10	1.3 ± 0.9	1.4 ± 4.4	39.0 ± 6.0
Parietex	6	1.2 ± 0.4	0.8 ± 2.0	14.7 ± 5.0
Proceed	6	2.8 ± 1.0	28.8 ± 16.1	29.7 ± 12.5

<sup>7</sup> Preclinical data on file at C. R. Bard. Results may not correlate to performance in humans.

<sup>8</sup> Preclinical results may not correlate to performance in humans.

<sup>9</sup> Dr. Matthews is a paid consultant for Davol. Financial support for the study was supplied by Atrium Medical Corporation.

# VENTRALEX™ ST Hernia Patch



## Ordering Information

Catalog Number	Quantity	Shape	Size	
5950007	1/cs.	Small Circle with Strap	1.7" x 1.7" (4.3 cm x 4.3 cm)	<input type="checkbox"/>
5950008	1/cs.	Medium Circle with Strap	2.5" x 2.5" (6.4 cm x 6.4 cm)	<input type="checkbox"/>
5950009	1/cs.	Large Circle with Strap	3.2" x 3.2" (8.0 cm x 8.0 cm)	<input type="checkbox"/>

## Order Form

- ☐ Please add these marked products to my preference card.
- ☐ I would like to have these marked products in stock.  
(Reference catalog numbers checked)
- ☐ I would like to trial these marked products.

Purchase Order Number

Date

Catalog Number(s)

Quantity

Surgeon's Signature

## VENTRALEX™ ST Hernia Patch

### Indications

The VENTRALEX™ ST Hernia Patch is indicated for use in the reinforcement of soft tissue, where weakness exists, in procedures involving soft tissue repair, including repair of hernias and deficiencies caused by trocars.

### Contraindications

Do not use the VENTRALEX™ ST Hernia Patch in infants or children, whereby future growth will be compromised by the use of such mesh material. Do not use the VENTRALEX™ ST Hernia Patch for the reconstruction of cardiovascular defects. Literature reports that there may be a possibility for adhesion formation when the polypropylene is placed in contact with the bowel or viscera.

### Warnings

Do not cut or reshape the VENTRALEX™ ST Hernia Patch, as this could impact its effectiveness, except for the polypropylene positioning strap. 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 bowel or skin perforation and infection. Follow proper folding techniques for all patches as described in these Instructions for Use as other folding techniques may compromise the SORBAFLEX™ PDO monofilament. Ensure proper orientation; the bioresorbable coated side of the prosthesis should be oriented against the bowel or sensitive organs. Do not place the polypropylene mesh 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.

### Adverse Reactions

Possible complications include seroma, adhesions, hematomas, inflammation, extrusion, fistula formation, infection, 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.

To learn more, contact your local BARD Representative  
or call 1.800.556.6275.

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

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