

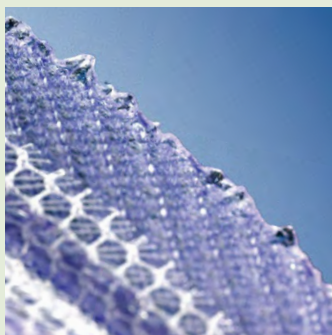
VENTRIO™ ST Hernia Patch

featuring Sepra® Technology

BAIRD
DAVOL INC.

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



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



Easy:

- Provides the benefits of a laparoscopic repair through the ease of a smaller incision.
- SORBAFLEX™ Memory Technology allows the patch to “spring open,” lay flat to maintain shape and then fully absorbs over time.¹
- Simplifies placement and positioning of the patch throughout the ventral hernia repair.

Efficient:

- Unique pocket aids in the proper placement and positioning of the patch.
- Designed to facilitate the use of mechanical fixation devices and/or sutures.
- Available in a variety of shapes and sizes to accommodate defect sizes and locations.

Proven:

- Hydrogel barrier is based on Sepra® Technology.
- Uncoated monofilament polypropylene mesh allows for complete tissue ingrowth leading to a strong repair.
- Materials have been used in general surgery for years with demonstrated clinical success.²

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

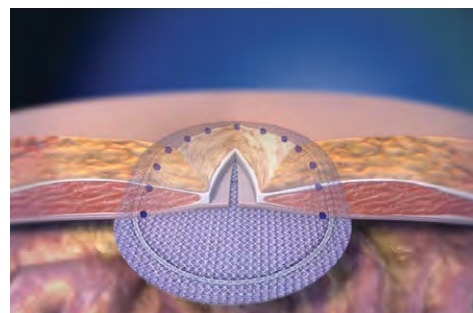
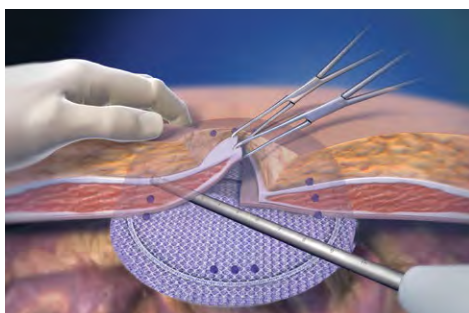
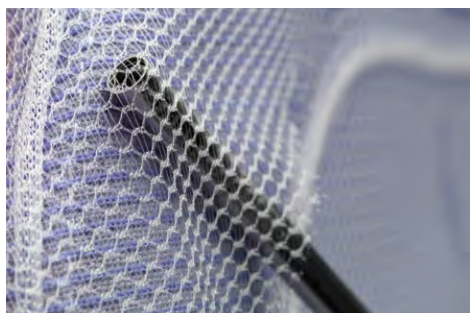
² Iannitti, D. et al. “Technique and Outcomes of Abdominal Incisional Hernia Repair Using a Synthetic Composite Mesh: A Report of 455 cases.” *Journal of the American College of Surgeons*. 2008 Jan; 206 (1):83-8.

SOFT TISSUE REPAIR

Right Procedure. Right Product. Right Outcome.

Efficient

The unique positioning pocket aids in proper placement and positioning, while also allowing the use of mechanical fixation, for a quick efficient repair. The monofilament polypropylene results in strong tissue incorporation within a short period of time, providing the long-term strength of the repair.

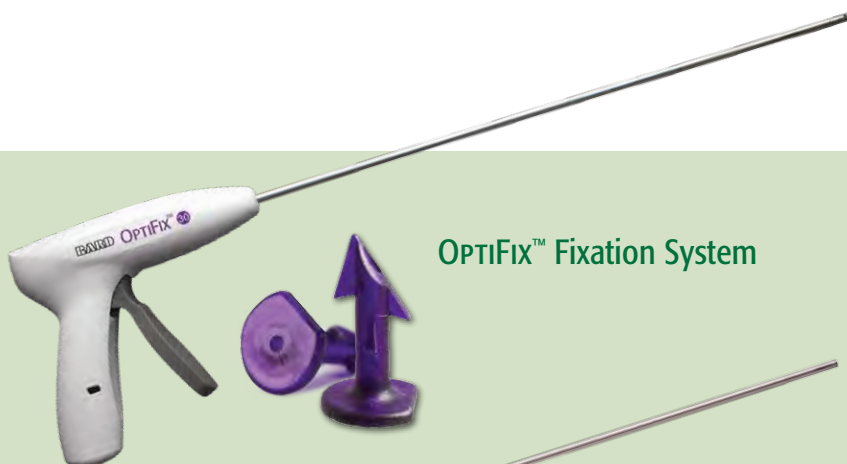


Variety of Sizes Available

VENTRIO™ ST Hernia Patch is available in a variety of shapes and sizes to meet your surgical needs dependent on defect size and location. A unique mid-line oval shaped patch designed for multiple defects is also available.

Mechanical Fixation

The VENTRIO™ ST Hernia Patch is compatible in both open and laparoscopic ventral procedures with the OPTIFix™ Absorbable Fixation System and the CAPSURE™ Permanent Fixation System.



OPTIFix™ Fixation System

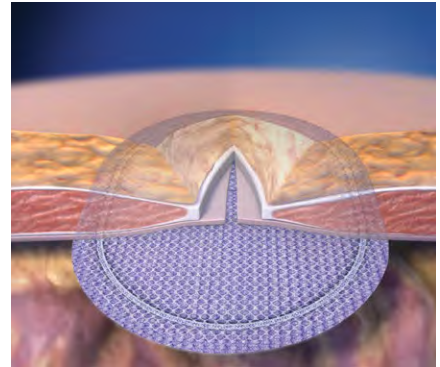
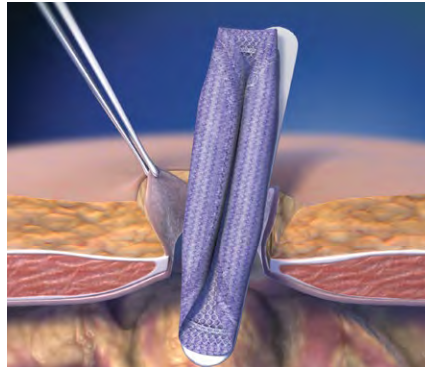


CAPSURE™ Fixation System

VENTRIO™ ST Hernia Patch

Easy

The VENTRIO™ ST Hernia Patch's unique design provides the benefit of laparoscopic repair through the ease of a smaller incision.



Intraabdominal Placement Through a Small Open Incision³

- No preperitoneal lateral dissection may reduce surgical time and lead to quick patient recovery.
- Minimized dissection may reduce the chance of infection and seroma as well as the need for drains.
- The unique SORBAFLEX™ Memory Technology permits rolling of the patch for easy insertion, allowing the patch to “spring open,” lay flat to maintain shape and then fully absorbs over time.

Established Technique Supported by Published Clinical Data

- The design of the VENTRIO™ ST Hernia Patch allows the use of the familiar CK™/VENTRIO™ Hernia Patch technique for open ventral hernia repair.
 - Technique is peer reviewed and supported by published clinical data.⁴

³ Please see the “Patch Technique” section in the Instructions for Use.

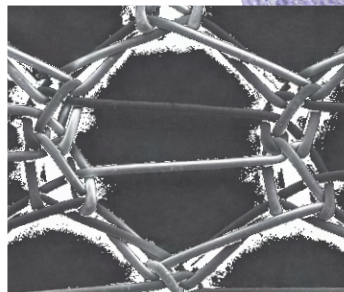
⁴ Iannitti, D. et al. “Technique and Outcomes of Abdominal Incisional Hernia Repair Using a Synthetic Composite Mesh: A Report of 455 cases.” *Journal of the American College of Surgeons*. 2008 Jan; 206 (1):83-8.

Proven

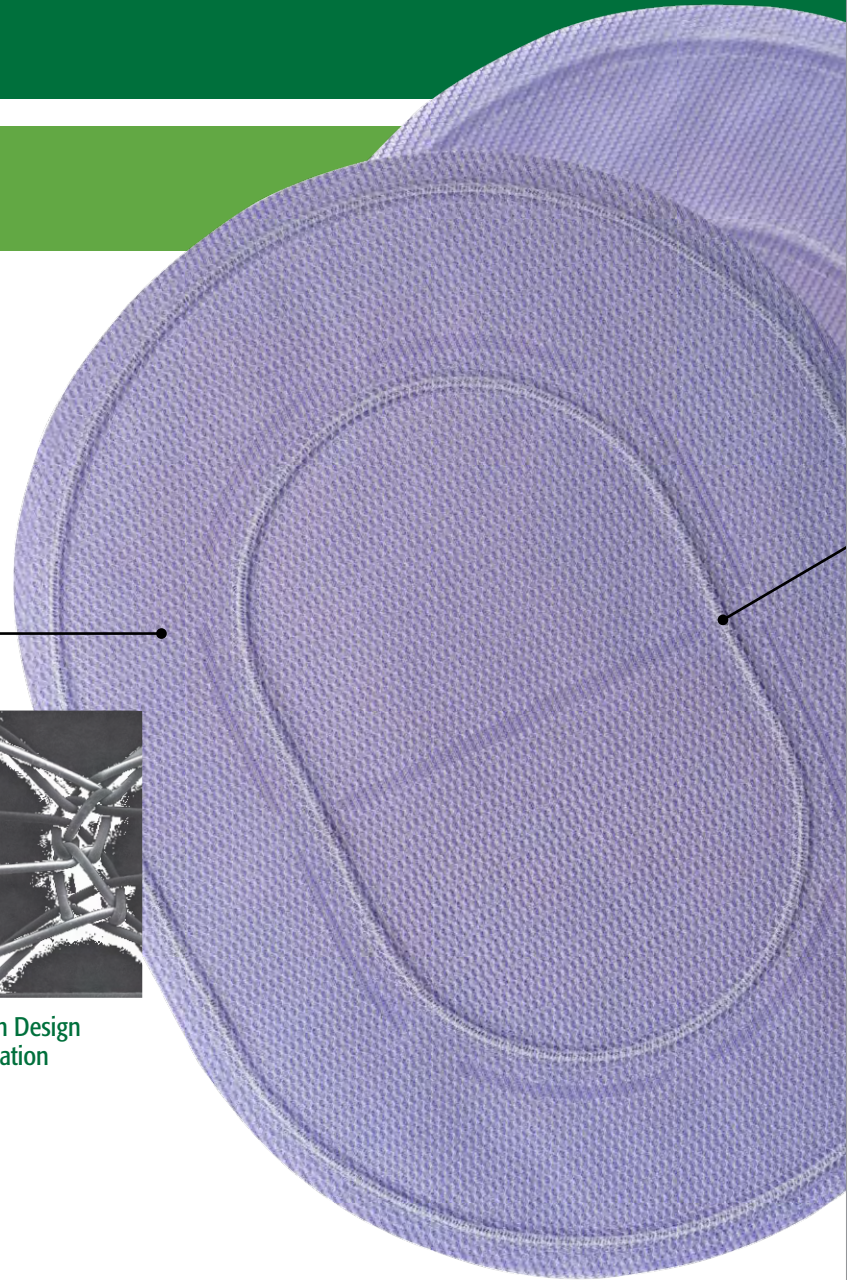
The VENTRIO™ ST Hernia Patch combines materials used in general surgery for many years to deliver proven benefits to you and your patients.

Uncoated Monofilament Polypropylene Mesh

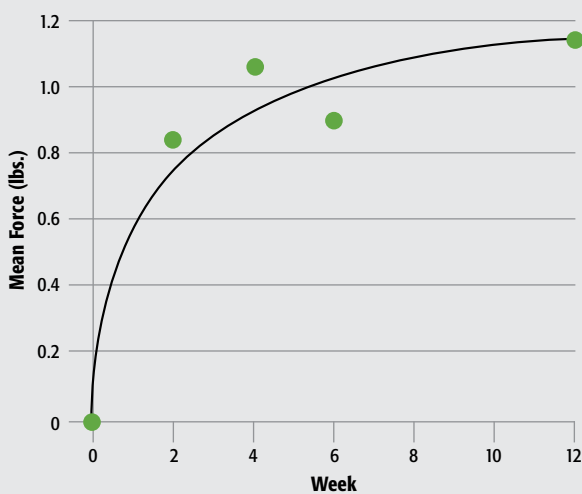
- Over 40 years of proven results in hernia repair.
- Allows a fast fibrotic response for a strong repair.
- Provides a long-term repair with minimized recurrence.



Open Pore Mesh Design
35x Magnification



Strength of Tissue Ingrowth In a Preclinical Study⁵



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}

VENTRIO™ ST Hernia Patch Preclinical Results⁷



Initial Implant



2 weeks

⁵ 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.

⁶ Results may not correlate to performance in humans.

⁷ Images are from a porcine study using the VENTRIO™ ST Hernia Patch. Data on file.

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.⁸

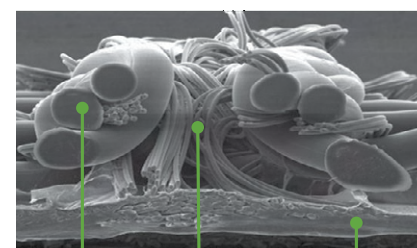


These images are from a porcine study using the VENTRIO™ Hernia Patch which contains the same SORBAFLEX™ Memory Technology.⁸

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.⁸
- 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 Study⁹

“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.¹⁰ *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

⁸ Preclinical data on file at C. R. Bard. Results may not correlate to performance in humans.

⁹ Preclinical results may not correlate to performance in humans.

¹⁰ Dr. Matthews is a paid consultant for Davol. Financial support for the study was supplied by Atrium Medical Corporation.

VENTRIO™ ST Hernia Patch

Ordering Information

Catalog Number	Quantity	Shape	Mesh Size	
5950030	1/cs.	Small Oval	3.1" x 4.7" (8.0 cm x 12.0 cm)	<input type="checkbox"/>
5950040	1/cs.	Medium Oval	4.3" x 5.5" (11.0 cm x 14.0 cm)	<input type="checkbox"/>
5950050	1/cs.	Large Oval	5.4" x 7.0" (13.8 cm x 17.8 cm)	<input type="checkbox"/>
5950010	1/cs.	Small Circle	3.0" (7.6 cm) diameter	<input type="checkbox"/>
5950020	1/cs.	Large Circle	4.5" (11.4 cm) diameter	<input type="checkbox"/>
5950070	1/cs.	Extra Large Oval	7.7" x 9.7" (19.6 cm x 24.6 cm)	<input type="checkbox"/>
5950080	1/cs.	Extra Large Oval	8.7" x 10.7" (22.1 cm x 27.1 cm)	<input type="checkbox"/>
5950090	1/cs.	Extra Large Oval	10.8" x 13.7" (27.4 cm x 34.9 cm)	<input type="checkbox"/>
5950060	1/cs.	Midline	6.1" x 10.1" (15.5 cm x 25.7 cm)	<input type="checkbox"/>

CAPSURE™ Permanent Fixation System

Indications

The CAPSURE™ Permanent Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

Contraindications

Carefully inspect the area in the vicinity of the tissue being fastened to avoid inadvertent penetration of underlying structures such as bone, nerves, vessels, and viscera. Use of the CAPSURE™ Permanent Fixation System in the close vicinity of such underlying structures is contraindicated. For reference, the length of the fastener below the fastener head is 3.2 mm, the fastener head is another 1 mm (total 4.2 mm).

Precautions

Adequate counterpressure should be applied on the target area. Avoid placing hand or finger directly over the area where fastener is being deployed to prevent injury.

Use caution when applying the CAPSURE™ fastener over or in proximity to underlying bone, vessels, nerves, or viscera. The intended fixation site should be assessed to ensure that while the tissue is compressed the total distance from the surface of the tissue to any underlying structures is greater than the length of the CAPSURE™ fastener.

Adverse Reactions

Adverse reactions and potential complications associated with fixation devices such as the CAPSURE™ Permanent Fixation System may include, but are not limited to the following: hemorrhage, pain, edema and erythema at wound site; septicemia/infection; hernia recurrence/wound dehiscence, erosion and allergic response in patients with known sensitivities to PEEK and metals contained in 316L stainless steel, including chromium, nickel, copper, and iron.

OPTIFIX™ Absorbable Fixation System

Indications

The OPTIFIX™ Absorbable Fixation System is indicated for the approximation of soft tissue and fixation of surgical mesh to tissues during open or laparoscopic surgical procedures, such as hernia repair.

Contraindications

Contraindications associated with laparoscopic and open 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 ingrowth of tissue into the mesh over time, which could result in inadequate fixation once the fastener is absorbed.

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 OPTIFIX™ Absorbable Fixation System in the close vicinity of such underlying structures is contraindicated. For reference, the length of the fastener below the fastener head is 6.1 mm, the fastener head is another 0.6 mm (total 6.7 mm).

Warnings

The device may not fixate through prosthetics derived from biologic material such as xenografts and allografts. Prosthetic should be evaluated for compatibility prior to use. After use, the OPTIFIX™ Absorbable Fixation System may be a potential biohazard. Handle and dispose of in accordance with any local and federal laws regarding medical waste.

Adverse Reactions

Adverse reactions and potential complications associated with fixation devices such as the OPTIFIX™ 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; infection/septicemia; hernia recurrence/wound dehiscence.

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

Quantity

Catalog Number(s)

Date

Surgeon's Signature

VENTRIO™ ST Hernia Patch

Indications

The VENTRIO™ ST Hernia Patch is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias.

Contraindications

Do not use the VENTRIO™ ST Hernia Patch in infants or children, whereby future growth will be compromised by the use of such mesh material. Do not use the VENTRIO™ 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 VENTRIO™ ST Hernia Patch, as this could impact its effectiveness. 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.

Bard, Davol, CapSure, OptiFix, and Ventrío are trademarks and/or registered trademarks of C. R. Bard, Inc. Sepra and Sepramesh are registered trademarks of Genzyme Corporation licensed to C. R. Bard, Inc.

© Copyright 2016, C. R. Bard, Inc. All Rights Reserved.

Davol Inc. • Subsidiary of C. R. Bard, Inc.
100 Crossings Boulevard • Warwick, RI 02886
1.800.556.6275 • www.davol.com
Medical Services & Support 1.800.562.0027
DAV/VNST/0814/0003(2)

BARD
DAVOL INC.