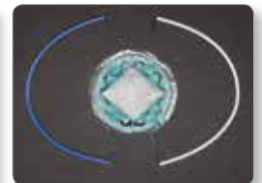


VENTRALEX™ ST Hernia Patch

featuring Sepra® Technology

The BARD® Advantage

BARD® VENTRALEX™ ST
Hernia Patch



	VENTRALEX™ ST Hernia Patch	Parietex™ Ventral Patch
#1 umbilical patch sold in the market today ¹	✓	
Uncoated monofilament polypropylene for rapid tissue ingrowth	✓	
SORBAFLEX™ Memory Technology – Absorbable Recoil Ring (PDO)	✓	
Recoil Ring encased in monofilament polypropylene	✓	
Hydrogel barrier with over 14 years of history	✓	
Proven technique supported by multiple published, peer reviewed clinical papers	✓	
Designed to fit down a trocar	✓	
Indicated for repair of trocar site deficiencies	✓	
Average ball burst strength (n=10) ²	105 lbs of force	36 lbs of force

BARD

DAVOL INC.

¹ Based on Q2 2013 IMS data.

² 3/8" burst probe. Bench data on file at C. R. Bard, Inc. Results may not correlate to performance in humans.

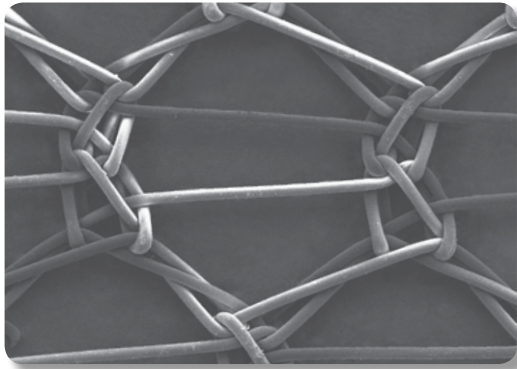
VENTRALEX™ ST Hernia Patch

featuring Sepra® Technology

Anterior Layer

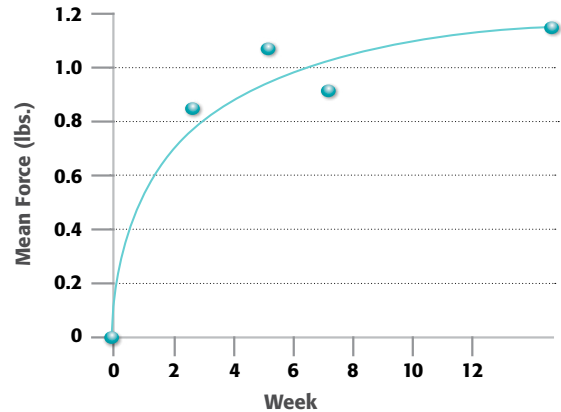
Uncoated Mesh

Monofilament polypropylene mesh allows a prompt fibroblastic response through the open interstices of the mesh.



Open Pore Mesh Design 25x Magnification

Strength of Tissue Ingrowth in a Preclinical Model^{3,4}



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 post-operatively.³

Posterior Layer

SEPRAMESH™ IP Composite

Unique hydrogel barrier, based on the Sepra® Technology, swells to minimize tissue attachment to the visceral side of the mesh and resorbs within 30 days providing visceral protection during the critical healing process.⁵



SEPRAMESH™ IP Composite Preclinical Study⁵

"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."

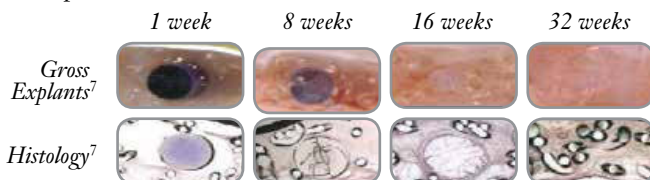
Table 1 - Adhesion Properties and Mesh Contraction

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
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

Design

SORBAFLEX™ Memory Technology

Polydioxanone (PDO) monofilament is unique in its flexibility and tensile strength, facilitating patch insertion and placement. Absorption via hydrolysis is essentially complete in 6-8 months.⁶



Unique Pocket and Strap Design

Pocket and strap facilitate placement, positioning and lateral fixation. SORBAFLEX™ Memory Technology is contained within a knitted polypropylene mesh tube.



³ Majercik, S. et al. "Strength of tissue attachment to mesh after ventral hernia repair with synthetic composite mesh in a porcine model." *Surg Endos.* (2006) 20: 1671-1674.

⁴ Results may not correlate to performance in humans.

⁵ Pierce, Richard A. MD, PhD, et al. *Surgical Innovation.* March 2009; 16, 1:45-54.

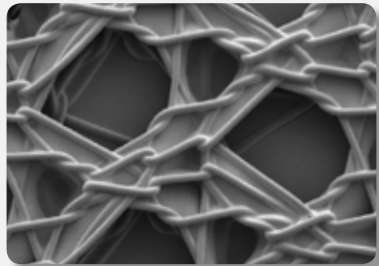
⁶ Preclinical data on file at C. R. Bard. Results may not correlate to performance in humans.

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

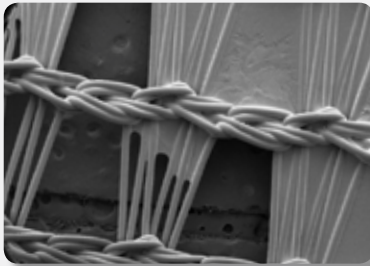
Covidien Parietex™ Composite Ventral Patch

Anterior Layer

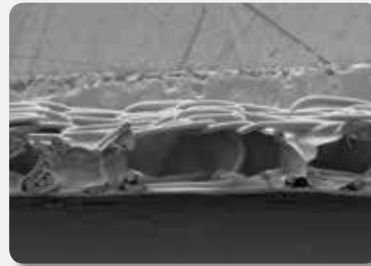
Polyester



Parietex™ Ventral Patch
Anterior Side,
Three Dimensional Polyester,
White Mesh with Collagen Coating 25x⁸



Parietex™ Ventral Patch
Anterior Side,
Two Dimensional Polyester,
Green Mesh Flaps with Collagen Coating 25x⁸

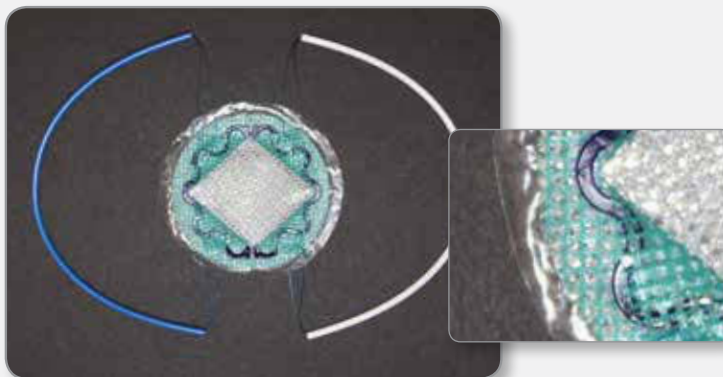


Parietex™ Ventral Patch
Cross Section,
Three Dimensional Polyester,
White Mesh with Collagen Coating 25x⁸

Posterior Layer

Bioabsorbable Hydrophilic Collagen Film

- Porcine based
- Absorbs in 21 days⁹
- Sepra® Technology swells over 60% more than Parietex™ Composite barrier¹⁰

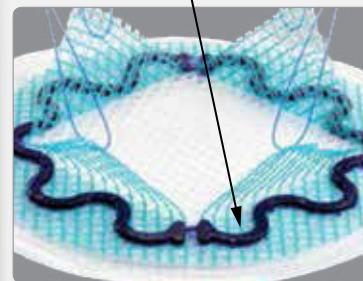


Design

- Two removal handles composed of colored tubes and yarns¹¹
- Four flaps (one at each corner of the device) made up of bidimensional monofilament polyester¹¹
- Two dyed PGLA poly (glycolide-co-L-lactide) expanders¹¹
- PGLA component is completely absorbed prior to one year¹¹



Temporary Stiffeners
PGLA expander not enclosed in any material



⁸ Images on file at C. R. Bard.

⁹ H G Doctor, Evaluation of Various Prosthetic Meshes and New Meshes for Hernia Repair, *Journal of Minimal Access Surgery*. 2006 September; 2(3): 110-6.

¹⁰ Data on file at C. R. Bard.

¹¹ Parietex Composite Ventral Patch IFU.

The BARD® VENTRALEX™ ST Hernia Patch Advantage

Easy

Minimum dissection and fixation required.

Efficient

Proprietary pocket and strap design facilitates placement, positioning and lateral fixation.

Proven

Clinically supported technique since 2002 with over 800,000 implants worldwide and peer-reviewed published clinical studies.

Five Published VENTRALEX™ Studies

Study Author(s)	Patients	Recurrence Rate
Tinella A et al "Post-laparoscopic mesh in post-meno pausal umbilical hernia repair: a case series." ¹²	51	0.0%
Inversen E et al "Abdominal wall hernia repair with a composite ePTFE/polypropylene mesh: clinical outcome and quality of life in 152 patients." ¹³	152	2.6%
Vychnevskaja K et al. "Intraperitoneal mesh repair of small ventral abdominal wall hernias with a Ventralex hernia patch." ¹⁴	101	2.2%
Martin/Voeller et al. "Ventralex Mesh in Umbilical/Epigastric Hernia Repairs: Clinical Outcomes and Complications." ¹⁵	88	0%
Hadi H et al "Intraperitoneal Tension-Free Repair of Small Midline Ventral Abdominal Wall Hernias With a Ventralex Hernia Patch: Initial Experience in 51 Patients." ¹⁶	51	1.2%

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

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.

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

¹² Tinella A, Malvasi A, Manca C, Alemanno G, Bettocchi S, Benhidjeb T. "Post-laparoscopic mesh in post-menopausal umbilical hernia repair: a case series." *Minim Invasive Ther Allied Technol.* 2011 Sep; 20(5):290-5.

¹³ Inversen E, Lykke A, Hensler M, Jorgensen LN. "Abdominal wall hernia repair with a composite ePTFE/polypropylene mesh: clinical outcome and quality of life in 152 patients." *Hernia.* 2010 Dec;14(6): 555-60.

¹⁴ Vychnevskaja K, Mucci-Hennekinne S, Casa C, et al. "Intraperitoneal mesh repair of small ventral abdominal wall hernias with a Ventralex hernia patch." *Dig Surg.* 2010; 27(5): 433-5.

¹⁵ D.F. Martin, R.F. Williams, T. Mulrooney, and G.R. Voeller. "Ventralex Mesh in Umbilical/Epigastric Hernia Repairs: Clinical Outcomes and Complications." *Hernia.* 2008 Aug 12(4) 379-83.

¹⁶ H.I.A. Hadi, A. Maw, S. Sarmah, P. Kumar. "Intraperitoneal Tension-Free Repair of Small Midline Ventral Abdominal Wall Hernias With a Ventralex Hernia Patch: Initial Experience in 51 Patients." *Hernia.* 2006: 10:409-413.

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