

## SEPRAMESH™ IP Composite

is just one in a complete Sepra® Technology suite of products for ventral hernia repair:

VENTRALIGHT™ ST Mesh

VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System

VENTRALEX™ ST Hernia Patch

VENTRIO™ ST Hernia Patch

SEPRAMESH™ IP Composite

## Use our fixation products for a complete repair:

SORBAFIX™ Absorbable Fixation System

PERMAFIX™ Permanent Fixation System

PERMASORB™ Disposable Fixation Device

# A SINGLE-ARM, SINGLE-CENTER, RETROSPECTIVE STUDY WITH PROSPECTIVE FOLLOW-UP OF LAPAROSCOPIC 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.*

Possible complications include seroma, adhesions, hematomas, inflammation, extrusion, fistula formation, infection, allergic reaction, and recurrence of the hernia or soft tissue defect.

Bard, Davol, Echo PS, PermaFix, Permasorb, SorbaFix, Ventralex, Ventralight, 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. All other trademarks are the property of their respective owners.

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

© Copyright 2012, C. R. Bard, Inc. All Rights Reserved.

MMSTPOS



Davol Inc. • Subsidiary of C. R. Bard, Inc.  
100 Crossings Boulevard • Warwick, RI 02886  
1.800.556.6275 • [www.davol.com](http://www.davol.com)

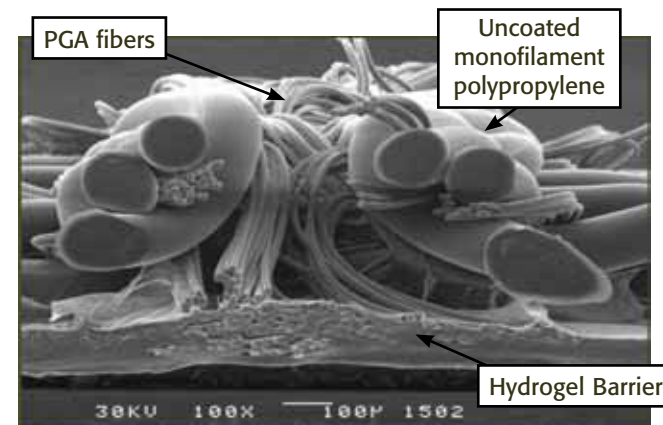
# A Single-Arm, Single-Center, Retrospective Study with Prospective Follow-Up of Laparoscopic Ventral Hernia Repair Utilizing the Bard Sepramesh™ IP Composite.

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

## Introduction

Laparoscopic ventral hernia repairs have been shown to offer benefits when compared to open repairs, including reduced complication and recurrence rates. Choice of mesh plays a significant role with respect to outcomes.<sup>1</sup> The authors have used Sepramesh™ IP Composite (C. R. Bard, NJ) for seven years with positive clinical outcomes, however upon reviewing published literature, we found no published clinical studies with Sepramesh™ IP Composite to date.

Figure 1: Sepramesh™ IP Composite Cross Section



Sepramesh™ IP Composite has uncoated monofilament polypropylene mesh on the anterior surface and a unique hydrogel barrier, composed of hyaluronate (HA) and carboxymethylcellulose (CMC) on its posterior surface. Bioresorbable PGA fibers bind the hydrogel barrier to the polypropylene mesh.

This is the first human study with Sepramesh™ IP Composite to report recurrence rate and incidence of complications.

## Methods

This study is a retrospective single center review with prospective follow-up concerning the incidence of recurrence and reported complications with laparoscopic ventral hernia repairs using Sepramesh™ IP Composite in 90 patients. Endpoints include the incidence of recurrence, reported complications and procedural time.

Table 1: Patient Demographics

Average Age	56 ± 12.2
Age Range	31 - 89
Average Weight (kg)	98.5 ± 23.9
Average BMI (kg/m <sup>2</sup> )	33.9 ± 7.36
BMI Range	16.4 - 51.5
Prior History of Hernia	24.4%
Current Smokers	17 (18.9%)

Standard laparoscopic hernia repair technique was used and mesh was sized so that a 3-4 cm overlap around the defect was achieved. The mesh was secured to the anterior abdominal wall using either a 5mm SorbaFix™ (C. R. Bard, N.J.) or ProTack™ (Covidien, MA) laparoscopic fixation device in a double crown manner. No transfascial fixation sutures were used during these procedures. Mean follow-up was 3 years.

Table 2: Clinical Hernia Characteristics

Incisional	42 (46.7%)
Umbilical	43 (47.8%)
Incisional and Umbilical	5 (5.6%)
Primary	81 (90%)
Recurrent	9 (10%)
Mean Defect Size (cm <sup>2</sup> )	29.0 ± 44.36
Mean Mesh Size (cm <sup>2</sup> )	182.9 ± 107.03
Mean Follow-Up Time (months)	35.3 ± 14.06

## Results

One of the 90 patients (1.1%) experienced a recurrence approximately 14 months following the repair. This recurrence may be explained by the patient's multiple comorbidities including immunosuppressive therapy before, during and after surgery as well as underlying hepatic disease.

Two complications were reported (2.2%), including the recurrent incisional hernia referenced above. Another patient had a postoperative subxiphoid hernia at the trocar site of the surgical procedure approximately six months following the initial procedure.

Table 3: Results

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.

Figure 2: 47 Year Old Male with Sepramesh™ IP Composite 4 Months after Surgery



## Conclusion

Animal studies have demonstrated favorable performance of Sepramesh™ IP Composite when compared to other mesh types with respect to tissue ingrowth and adhesion formation.<sup>2,3</sup>

This retrospective analysis with prospective three year (avg) follow-up shows that the authors experience with Sepramesh™ IP Composite in laparoscopic ventral hernia repairs results in a low rate of recurrence (1.1%), as well as low rates of short-term and long-term complications.

Further studies should be conducted to confirm the benefits of using Sepramesh™ IP Composite in laparoscopic ventral hernia repairs.

## References

- Eriksen, JR, Gögenur, I, Rosenberg, J. Choice of mesh for laparoscopic ventral hernia repair. *Hernia* (2007). 11:481-492.
- Gaertner, WB, Bonsack, ME, Delaney, JP. Visceral adhesions to hernia prostheses. *Hernia* (2010) 14:375-381.
- Deeken, CR, Matthews, BD. Comparison of contracture, adhesion, tissue ingrowth, and histologic response characteristics of permanent and absorbable barrier meshes in a porcine model of laparoscopic ventral hernia repair. [published online ahead of print July 12 2011. *Hernia* (2011) <http://dx.doi.org/10.1007/s10029-011-0854-5>. Accessed August 22 2011.

## Acknowledgements

This study was sponsored by C. R. Bard. Dr. Archer is a paid consultant for C. R. Bard.

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

Davol, Bard are trademarks and/or registered trademarks of C.R. Bard, Inc. or an affiliate. Sepramesh is a registered trademark of Genzyme Corporation licensed to C.R. Bard, Inc. All other trademarks are the property of their respective owners.