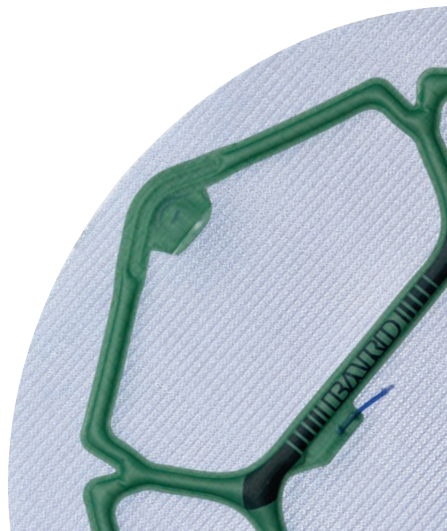


ECHO PS™ Positioning System

For Laparoscopic Ventral Hernia Repair

A Review of Preclinical Time Savings Data *and* A Surgeon Clinical Experience Survey*

Unique design.
Exceptional performance.
Significant results.



Results you can count on.

At BARD, we believe success is measured in every step of the repair. We utilize proven materials that are designed to work together, along with proven surgical techniques. Our goal is to help you achieve a strong, long-term repair for your patients while increasing effectiveness for you and your OR team.

As part of our ongoing commitment to share data, we have undertaken a preclinical porcine study to help demonstrate the advantages of the BARD ECHO PS™ Positioning System during a laparoscopic ventral hernia repair when compared to the same procedure using four transfascial positioning sutures.

BARD
DAVOL INC.

*All study participants were paid consultants for Davol Inc.

PRECLINICAL STUDY*

Davol sponsored and designed in conjunction with:

Erin M. Hanna¹, MD, Guy R. Voeller², MD, FACS, J. Scott Roth³, MD, FACS, David Iannitti¹, MD, FACS

¹ Carolinas Medical Center, Charlotte, NC; ² University of Tennessee Health Science Center, Memphis, TN; ³ University of Kentucky College of Medicine, Lexington, KY

Study Design

- 17 general surgeons
- Preclinical porcine model
- Mesh size: 8" x 10" (20cm x 25cm)

Methods

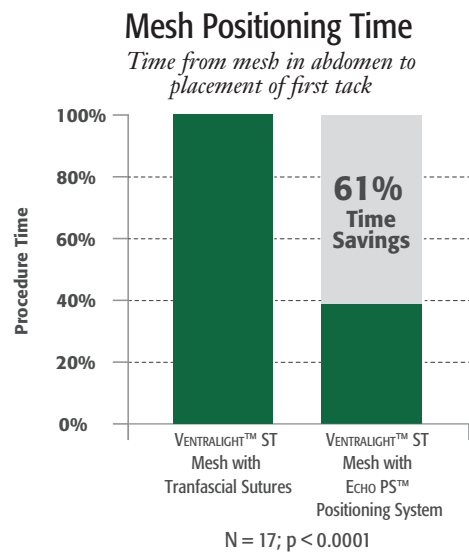
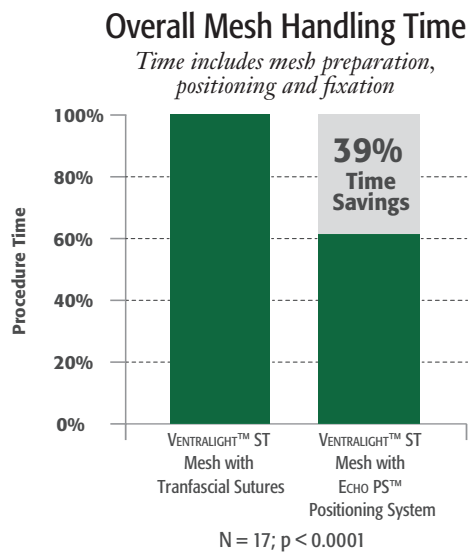
- Surgeons implanted two pieces of mesh in random order
 - VENTRALIGHT™ ST Mesh with four transfascial positioning sutures
 - VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System
- Time from mesh preparation through initial perimeter fixation with SORBAFIX™ Absorbable Fixation System was recorded

Surgeon Profile

	Average	Range
Years Post-Residency	12	2-37
Hernia Repairs / Year	143	25-400
Ventral Hernia Repairs / Year	40	20-115
Percent Repaired Laparoscopically	86	35-100
Clinical Experience (# of cases) with ECHO PS™ Positioning System	18	3-100

Collectively, ECHO PS™ Positioning System experience amongst the study participants represented over 300 clinical uses of the device.

Statistically Significant Results

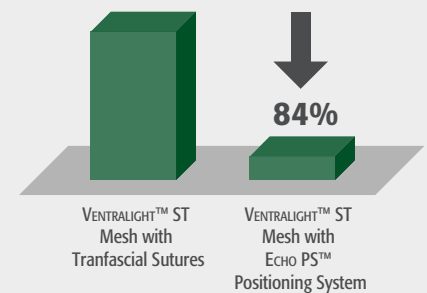


VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System demonstrated a 39% time savings vs. mesh alone, placed with four transfascial sutures. When looking at the mesh positioning portion of the procedure in particular, ECHO PS™ Positioning System demonstrated a 61% time savings.

Procedure time variability in the ECHO PS™ Positioning System group was reduced by 84%

A 2007 article in *OR Manager* suggests that more consistent procedure times may lead to greater operating efficiencies in addition to reduced start time tardiness, fewer excess staffing costs, and better results on patient satisfaction surveys.⁴

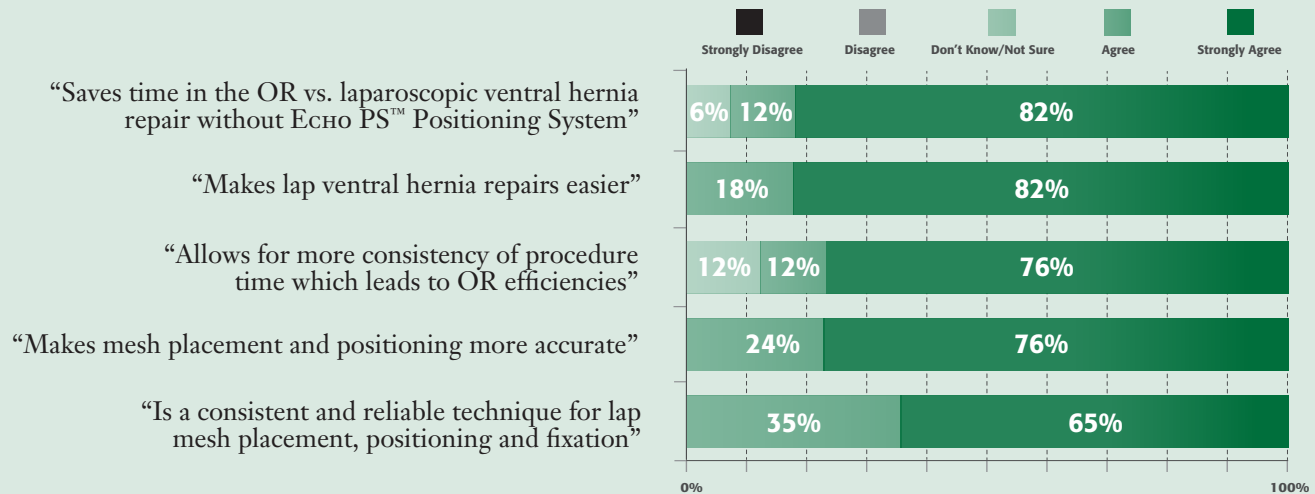
Procedure Time Variability



*Preclinical results may not correlate to performance in humans.

SURGEON CLINICAL EXPERIENCE SURVEY

We asked participating surgeons about their clinical experience with ECHO PS™ Positioning System:



16 out of 17 surgeons surveyed agreed that less time under anesthesia could be a patient benefit of doing a hernia repair with the ECHO PS™ Positioning System.

Literature suggests that shorter anesthesia durations may be associated with:

- Reduced postoperative infection rates⁶
- Reduced postoperative nausea and vomiting⁷
- Reduced length of stay⁶
- Reduced pulmonary complications⁸

Collectively, ECHO PS™ Positioning System experience amongst the survey participants represented over 300 clinical uses of the device.

ECHO PS™ Positioning System: Potential Economic Benefits

Time Savings

Survey Question: “How much OR time on average does ECHO PS™ Positioning System save you?”

Average = 25 min. savings (10-60 min. savings)

Value

- If ECHO PS™ Positioning System saves an average of 25 minutes, at an average OR cost of \$66/min⁵, it could save a hospital \$1,650 per patient
- In cases where ECHO PS™ Positioning System saves 60 minutes, the OR cost savings may be approximately \$4,000

If a hospital averages three large ventral hernia repairs each month, it could save approximately \$60,000 annually using the ECHO PS™ Positioning System



For more information, visit www.davol.com/echo

VENTRALIGHT™ ST Mesh with ECHO PS™ Positioning System is a low profile, bioresorbable, coated, permanent mesh, with a pre-attached removable positioning system, designed for the reconstruction of soft tissue deficiencies during laparoscopic ventral hernia repair.

Indications

VENTRALIGHT™ ST Mesh is indicated for use in the reconstruction of soft tissue deficiencies, such as for the repair of hernias. The ECHO PS™ Positioning System is intended to be used to facilitate the delivery of soft tissue prostheses during laparoscopic hernia repair.

Contraindications

Literature reports there is a possibility for adhesion formation when the polypropylene is placed in direct contact with the bowel or viscera.

Warnings

VENTRALIGHT™ ST Mesh is the only permanent implant component of the device. The inflation adapter and syringe are to be kept external to the patient and discarded after use. The ECHO PS™ Positioning System (including the balloon, all connectors, and inflation tube) is to be removed from the patient and appropriately discarded as it is not part of the permanent implant.

The ECHO PS™ Positioning System should not be used with any other hernia prosthesis aside from those with which it comes pre-attached/ packaged.

Precautions

Do not trim the mesh. This will affect the interface between the mesh and positioning system.

Adverse Reactions

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

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

¹⁻³ Surgeons were paid consultants for Davol Inc.

⁴ "Are your operating rooms `efficient'?" OR Manager. December 2007; Vol.23, No 12.

⁵ Shippert, R.D. "A Study of the Time-Dependent Operating Room Fees and How to Save \$100,000 by Using Time-Saving Products." The American Journal of Cosmetic Surgery. 2005; Vol. 22, No.1.

⁶ Procter, L.D., et al. "General Surgical Operative Duration is Associated with Increased Risk-Adjusted Infectious Complication Rates and Length of Hospital Stay." JACS. January 2010; Vol. 210 No. 1.

⁷ Rusch, D., et al. "Nausea and Vomiting After Surgery Under General Anesthesia." Deutsches Arzteblatt International. 2010; 107(42): 733-41.

⁸ Mitchell, C.K., et al. "Multivariate Analysis of Factors Associated with Postoperative Pulmonary Complications Following General Elective Surgery." Arch Surg. Feb 1998; Vol. 133.

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