

Study finds lower rates of post-operative diastasis and hernia recurrence with porcine small intestinal submucosa (SIS)* when compared to AlloDerm®¹

COMPARATIVE STUDY

Seventy-four patients underwent ventral hernia repair using natural tissue. Of these, 41 procedures were performed using Surgisis® Gold* derived from porcine small intestinal submucosa (SIS). The remaining 33 patients had ventral hernia repair using human dermis (AlloDerm).

Biodesign arm - No hernia recurrences. Mean follow up 29 months.

AlloDerm arm - Eight hernia recurrences. An additional 15 AlloDerm patients (15/33) developed a diastasis or bulging at the repair site. Mean follow up 18 months with all complications reported in the first 14 months.

The study validates the use of biologic grafts in potentially contaminated fields.

Of note with AlloDerm: The manufacturer indicates that there may be as much as a 50% increase in the size of the implanted material.

Of note with Surgisis Gold: Initial Surgisis design led to seroma complications early in this study. Continuous process improvement resulted in fewer incidents of seromas later in this study. This process of continuous improvement resulted in the launch of the Biodesign Hernia Graft in 2008.

0 recurrences
with porcine SIS

74 patients

Graft	Number of patients	Recurrences	Mean follow-up
Porcine SIS	41	0	29 months
AlloDerm	33	8	18 months

Clinical cases are unique and individual results may vary.

RISK INFORMATION: BIODESIGN HERNIA GRAFT

INTENDED USE

The Biodesign® Hernia Graft is intended for implantation to reinforce soft tissues where weakness exists. Indications for use include the repair of a hernia or body wall defect. The graft is supplied sterile and is intended for one-time use.

This graft is intended for use by trained medical professionals.

CONTRAINDICATIONS

This graft is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.

PRECAUTIONS

• The graft is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to graft failure and/or transmission of disease. • **Do not resterilize.** • Ensure that the graft is hydrated prior to cutting, suturing, stapling, tacking or loading the graft laparoscopically. • Ensure that all layers of the graft are secured when suturing, stapling, or tacking. •

Place the graft in maximum possible contact with healthy, well-vascularized tissue to encourage cell ingrowth and tissue remodeling. • Suturing, stapling, or tacking more than one graft together may decrease graft performance. • If wound is left open, keep graft moist to prevent dryness.

POTENTIAL COMPLICATIONS

Possible adverse reactions with the use of any prosthesis may include, but are not limited to: • adhesion • bowel erosion • fistula formation • hematoma • infection • inflammation • premature degradation • recurrence of tissue defect • seroma formation

Complications, such as delayed wound infection, premature degradation, hernia recurrence, bowel erosion, and the need for re-operation, should be reasonably expected in patients who are critically ill or who have severely contaminated abdomens.

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REFERENCE

1. Gupta A, Zahriya K, Mullens PL, Salmassi S, Keshishian A. Ventral herniorrhaphy: experience with two different biosynthetic mesh materials, Surgisis and AlloDerm. *Hernia*. 2006;10:419-425.

***Note:** The device used in this study was a predecessor design of the current Biodesign Hernia Graft device.

Biodesign grafts are manufactured by Cook Biotech Incorporated.

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Distributed by:

Evergen

1425 Innovation Place

West Lafayette, IN 47906 USA

T 855.201.6914

evergenbio.com

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