Biodesign® Hernia Graft

Study finds lower rates of post-operative diastasis and hernia recurrence with Biodesign when compared to Alloderm®[1]

Comparative study

74 patients

Product	Number of patients	Recurrences	Mean follow-up
Biodesign	**41**	**0**	**29 months**
Alloderm	**33**	**8**	**18 months**

0
RECURRENCES
with Biodesign material

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. The remaining 33 patients had ventral hernia repair using 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 complications reported in the first 12 months.

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.

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.

Note: The name of our product has changed from Surgisis to Biodesign since this trial was published.

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.

BIODESIGN® HERNIA GRAFT

INTENDED USE

The Cook® 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.

Rx ONLY This symbol means the following:

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician.

HERNIA GRAFT This symbol means the following: Hernia Graft

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**. Discard all open and unused portions of the graft. • The graft is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken. • Discard the graft if mishandling has caused possible damage or contamination, or if the graft is past its expiration date. • 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. • No studies have been conducted to evaluate the reproductive impact of the clinical use of the graft. • Extended hydration or excessive handling could lead to partial delamination of superficial layers of the graft. • Care should be taken to avoid damage to the graft when loading laparoscopically. Loading the graft through a 10 mm or larger port is recommended. • 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.

See package insert for full product information.

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COOK® BIOTECH

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