

Study finds use of porcine small intestinal submucosa (SIS)* results in minimal recurrence in 5+ year follow-up¹

RETROSPECTIVE CLINICAL STUDY

Method

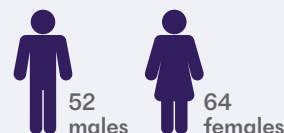
All procedures were conducted laparoscopically using either the intraperitoneal onlay mesh (IPOM) technique (n = 130) or the two-layered “sandwich” repair (n = 3). As a general rule, the hernia was reduced and the borders cleared of adhesions per sharp dissection (5cm circumferential margin). The hernia defect was closed with permanent suture and the SIS graft placed in an onlay position with a ≥ 3 cm overlap in all directions, preferably 5cm when practical. Fixation of the graft to the abdominal wall was maintained by transfascial sutures or staples.

Additional complications, out of 116 patients, including mild pain (n = 10; 8.6%), seroma (n = 11; 9.5%), and wound infection (n = 1; 0.9%), were reported.

5.3% recurrence rate

7 out of 133 procedures

116 patients



Hernia type	Number of procedures
Incisional	57
Umbilical	38
Inguinal	29
Femoral	3
Spigelian	4
Parastomal	2
Total procedures	133

Surgical fields	
Contaminated	39
Potentially contaminated	94

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.

ERI_FP0036-02P

REFERENCE

1. Franklin ME Jr, Treviño JM, Portillo G, Vela I, Glass JL, González JJ. The use of porcine small intestinal submucosa as a prosthetic material for laparoscopic hernia repair in infected and potentially contaminated fields: Long-term follow-up. *Surg Endosc*. 2008;22:1941-1946.

***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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