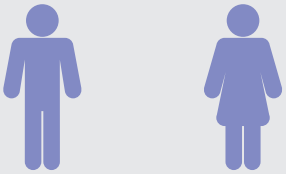
Biodesign® Hernia Graft

Study finds use of Biodesign Hernia Graft results in minimal recurrence in 5+ year follow-up[1]

Retrospective clinical study

116 patients



52 males

64 females

5.3%

RECURRENCE RATE

7 out of 133 procedures

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

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 (5 cm 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 5 cm 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.

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

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.

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: • This device is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to device 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 graft if mishandling has caused possible damage or contamination, or if the graft is past its expiration date. • Ensure that graft is rehydrated prior to cutting, suturing, stapling, tacking or loading of the graft laparoscopically. • Ensure that all layers of the graft are secured when suturing, stapling, or tacking. • Place 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 rehydration 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. It is recommended to load through a 10 mm or larger port. • 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: • infection • inflammation • adhesion • fistula formation • seroma formation • hematoma • bowel erosion • recurrence of tissue defect • premature degradation. 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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