

Biodesign® Hernia Graft

Study demonstrates safety and efficacy of Biodesign in treatment of complex hernias¹

RETROSPECTIVE CLINICAL STUDY

Twenty-three patients who underwent abdominal wall reconstruction with a mesh or graft were retrospectively analyzed. Of these, 14 patients received a Biodesign graft, 6 received synthetic mesh, and 3 received Permacol®.

All procedures were performed using components separation with a mesh or graft to approximate the midline.

Median patient age was 57 (age range: 20-76).

All hernia procedures were Grade III or Grade IV cases in patients with various complications. Of the 23, 15 had stomas, and 8 had enterocutaneous fistulas.

Median follow-up was 17 months (range: 2-48 months).

At follow-up, reported complications included seromas (n = 5), recurrence (n = 3), infection (n = 3), wound dehiscence (n = 5), and ischemic stoma (n = 2). The surgeons concluded that drains must be used to prevent seromas and that the ischemic stomas resulted from a too-tight repair around the stoma.

Midline closure was achieved in 87% of the cases, which surgeons determined was critical to prevent recurrences.

Grade III-IV hernias
can be treated successfully with
the Biodesign Hernia Graft.

23 patients

Graft	Number of patients	Recurrences
Biodesign	14	7%
Synthetic mesh	6	17%
Permacol®*	3	33%

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. Nockolds CL, Hodde JP, Rooney PS. Abdominal wall reconstruction with components separation and mesh reinforcement in complex hernia repair. *BMC Surg.* 2014;14:25.

*Permacol is a trademark of Covidien AG Corporation.

Biodesign grafts are manufactured by Cook Biotech Incorporated.

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