Biodesign® Hernia Graft

Study demonstrates safety and efficacy of Biodesign in treatment of complex hernias[1]

Retrospective clinical study

23 patients

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

GRADE III-IV HERNIAS

can be treated successfully with the Biodesign Hernia Graft.

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 eight 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 present seromas and that the ischemic stomas resulted from a too-tight repair around the stoma.

Midline closure was achieved in 80% of the cases, which surgeons determined was critical to prevent recurrences.

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® 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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