Biodesign®

INGUINAL HERNIA GRAFT

FP0109-01B

COOK® BIOTECH

LOT	Batch code
REF	Catalogue number
	Consult instructions for use
BIO	Contains biological material of animal origin
US	Country of manufacture
	Date of manufacture
STERILIZE	Do not resterilize
	Do not re-use
	Do not use if package is damaged and consult instructions for use
	Keep dry
MR	Magnetic resonance safe
	Manufacturer
MD	Medical device
	Double sterile barrier system
STERILE EO	Sterilized using ethylene oxide
UDI	Unique device identifier
	Use-by date

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BIODESIGN® INGUINAL HERNIA GRAFT

INTENDED USE

Biodesign® Inguinal Hernia Graft is intended to reinforce soft tissues where weakness exists, including the repair of inguinal hernias. 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.

INGUINAL HERNIA GRAFT This symbol means the following: Inguinal Hernia Graft

This product 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.

COMPOSITION

Biodesign® is an extracellular membrane derived from the small intestinal submucosa (SIS) of pigs from qualified animal production facilities.

WARNING

- Higher recurrence rates but lower pain scores have been observed in the Biodesign® Inguinal Hernia Graft (BIHG) group when compared to the Polypropylene (PP) group in a recent U.S. clinical trial for tensionless Lichtenstein hernia repair. Detailed discussion of the results from clinical trials can be found in the Clinical Considerations section of this IFU.
- Special surgical considerations aimed to reduce the risk of recurrence are outlined in the Instructions for Use section (Step 6) of this IFU. See step 6 for special instructions concerning positioning the graft around the spermatic cord.
- As with all tensionless inguinal hernia repairs in obese patients, a higher risk of recurrence may exist. Therefore, alternative repair techniques may be considered when using this graft.
- Whenever possible, avoid bridging of large hernia defects.
- During the period of graft incorporation and new collagen formation, the repair has not reached its maximum strength. Allow 6 months required for graft resorption before resuming strenuous physical activity or weightlifting.

PRECAUTIONS

- The graft 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 the graft if mishandling has caused possible damage or contamination, or if the graft is past its expiration date.
- Ensure that graft is hydrated prior to cutting, suturing, stapling, tacking, or loading of the graft laparoscopically.
- Care should be taken to avoid damaging the graft when loading laparoscopically. Loading the graft through a 10 mm or larger port is recommended.
- Ensure that all layers of the graft are secured when suturing, stapling, or tacking.
- 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.
- Place the graft in maximum possible contact with healthy, well-vascularized tissue to encourage cell ingrowth and tissue remodeling.

POTENTIAL COMPLICATIONS

Possible adverse reactions with the use of any prosthesis may include, but are not limited to:

- Adhesion
- Fistula formation
- Hematoma
- Infection
- Inflammation
- Pain
- Recurrence of tissue defect
- Seroma formation

Complications, such as delayed wound infection, hernia recurrence, and the need for re-operation, should be reasonably expected in patients who are critically ill or who have severely contaminated wounds or strangulated hernias. Patients with significant co-morbidities and/or family history of inguinal hernia formation are more prone to hernia recurrence.

CLINICAL CONSIDERATIONS

The Biodesign® Inguinal Hernia Graft (BIHG) was implanted in 95 patients in 3 separate clinical studies and the results were published in 3 peer reviewed articles. The results address the durability of repair with resorbable Biodesign® Inguinal Hernia Graft as used for open, tensionless repairs of inguinal hernias. One of the studies was a recent U.S. randomized clinical trial comparing the use of Biodesign® Inguinal Hernia Graft (BIHG) to PP mesh (PP) using the Lichtenstein hernia repair procedure. This repair included bridging the defect. Results showed hernia recurrence rates of 6.7% (3/45 patients) and 0% (0/50 patients) at 1 year follow-up in the treatment (BIHG) versus control groups. A difference in hernia recurrence rate was also seen at 3 years with 15.6% (7/45 patients) and 4.0% (2/50 patients) for the BIHG and PP groups, respectively*[1]. In addition, post-operative pain was assessed with a 1 year follow-up. Persistent pain trended higher in the PP group (6% vs. 4%). Authors of the U.S. study note that factors other than device performance could influence hernia recurrence outcomes, e.g., surgical approach, surgical experience, etc.

Two OUS prospectively randomized clinical investigations were conducted comparing BIHG to PP using the Lichtenstein Repair. These studies found no hernia recurrences for BIHG-treated patients at 1 and 3 years, (0/15, 1 year)[2] and 0% (0/35, 3 years)[3], respectively. Recurrence rates for the PP-treated group found hernia recurrences of 0% (0/15, 1 year)[2] and 2.9% (1/35, 3 years)[3]. Both studies found lower post-operative pain and discomfort in the BIHG patients at 30 days[2,3]. The reported differences regarding hernia recurrence between the OUS and U.S. clinical investications may be reflective of many factors, chief among these being the probable difference in surgical procedures.

In clinical studies in which BIHG was used to repair an inguinal hernia, the mean BMI in patients undergoing inguinal herniorraphy was 26 kg/m^2. Recurrence rates may be higher in obese patients (BMI>30) when using BIHG in a tensionless inguinal hernia repair. A synopsis of each study is presented in the following tables.

*Three year follow-up data not yet validated or published.

Table 1: Bochicchio GV, *et al.*, Biologic vs Synthetic Inguinal Hernia Repair: 1-Year Results of a Randomized Double-Blinded Trial. *J Am Coll Surg* 2014; 218:751-759.

Number of centers	*One center; Baltimore VA Hospital; 7 investigators including 4 surgeons*
Number of patients	*100 male patients randomized in a 1:1 fashion to open Lichtenstein repair of the test groups, Biodesign® Inguinal Hernia Graft (BIHG) and control Polypropylene (PP) mesh: 50:50 patients* **Note:** *In BIHG group, 5 patients were withdrawn prior to surgery due to emergency surgery or traumatic event resulting in 45:50 patients*
Study inclusion/ exclusion criteria	*Exclusion Criteria: life expectancy<3 years, ASA class IV and V, bowel obstruction, strangulation, peritonitis, bowel perforation, local or systemic infection, history of inguinal hernia repair with mesh* *Inclusion Criteria: 18 years of age or older, unilateral hernia, able to provide informed consent*
Patient Age, BMI and Hernia Types	*All male patients* *Mean Age: 64 (24-85) BIHG and 59 (25-97) PP* *BMI: 26 (18-39) BIHG; 25 (19-37) PP* *Hernia Type:* *Direct 20 (44% BIHG) 2 (42% PP)* *Indirect 26 (58% BIHG) 29 (58% PP)* *Sliding 24 (53% BIHG) 19 (38% PP)* *Non-sliding 26 (58% BIHG) 31 (62% PP)*
Operative procedure specifics - anesthesia, duration of procedure	*Lichtenstein open repair* *Anesthesia:* *Spinal: 4 (9% BIHG) 6 (12% PP)* *General: 42 (93% BIHG) 44 (88% PP)* *Procedure time (Minutes): 134 (BIHG) 115 (PP)*
Patient duration of follow-up outcomes/adverse events	*All patients were followed up for 12 months* *Recurrences:* *• 3 hernia recurrences all in the BIHG group incidence 6.7% vs 0% in PP group* *• All recurrences occurred in patients who originally had direct inguinal hernias (recurrence rate in subset of patients with direct hernias: 3/20 or 15% at 1 year)* *• Unpublished 3 year data recurrence rates: 15.6% (7/45) BIHG vs 4% (2/50) PP* *Post-operative pain:* *At 2 weeks : 9 (20% BIHG) vs 8 (16% PP)* *At 1 year : 2 (4% BIHG) vs 3 (6% PP)* *Adverse events:* *Hematoma: 6 (13% BIHG) vs 1 (2% PP)* *Incisional pain: 2 (4% BIHG) vs 4 (8% PP)* *Surgical site reaction : 3 (7% BIHG) vs 0 (0% PP)* *Seroma : 5 (11% BIHG) vs 0 (0% PP)* *Neuralgia: 4 (9% BIHG) vs 6 (12% PP)* *Infection: 0 (0% BIHG) vs 0 (0% PP)* *Testicular Problems: 5 (11% BIHG) vs 4 (8% PP)* *Urinary retention: 6 (13% BIHG) vs 3 (6% PP)* *Spermatic cord injury: 0 (0% BIHG) vs 1 (2% PP)* **One death in BIHG group due to myocardial infarction.*

Table 2: Ansaloni L, *et al*. Inguinal hernia repair with porcine small intestine submucosa: 3-year follow-up results of a randomized controlled trial of Lichtenstein's repair with Polypropylene mesh versus Biodesign® Inguinal Hernia Repair Graft. *Am J Surg* 2009; 198:303-312.

Number of centers	*1 OUS Center / 2 investigators*
Number of patients	*70 patients randomized to:* *• Polypropylene (PP)* • Biodesign® Inguinal Hernia Graft *(BIHG)*
Study inclusion/ exclusion criteria	*Excluded patients with recurrent hernia, any condition preventing a correct evaluation of pain, hypersensitivity to drugs used in study, intraoperative findings of pathology other than inguinal hernia*
Patient Age, BMI and Hernia Types	*Mean age: 61.3 years for PP (SD 17.7 years)* *56.2 years for BIHG (SD 18.0 years)* *Mean BMI: 26* *Mix of direct and indirect inguinal hernias in each group*
Operative procedure specifics - anesthesia, duration of procedure	*Operative time: BIHG 68.6 Minutes / PP 66.0 Minutes* *Preoperative antibiotics* *General or Spinal anesthesia (patient's choice/ anesthetist's preference)*
Patient duration of follow-up outcomes/adverse events	*36 month follow-up* *• Hernia recurrence: 0% BIHG / 2.9% PP* *• Chronic pain:* *6 months 11% BIHG / 31% PP* *12 months 8% BIHG / 23% PP* *36 months 3% BIHG / 14% PP* *• Surgical site occurrence at 1 week post-surgery:* *Hematoma: 5.7% BIHG / 5.7% PP* *Seroma: 5.7% BIHG / 17.1% PP*

Table 3: Puccio F, *et al*. Comparison of three different mesh materials in tension-free hernia repair: Prolene versus Vypro versus Surgisis. *Int Surg* 2005:90:S21-S23.

Number of centers	*1 OUS Center / 5 investigators*
Number of patients	*45 patients with unilateral primary inguinal hernia receiving Lichtenstein repair randomized to:* *• Polypropylene (PP)* *• Polyglactin and PP* • Biodesign® Inguinal Hernia Graft (BIHG)
Study inclusion/ exclusion criteria	*Excluded patients with history of major surgery in lower abdomen other than cancer or immune deficiency*
Patient Age, BMI and Hernia Types	*Mean age: 54 (range 26-74 years)* *Mean BMI: 26* *Mix of direct and indirect inguinal hernias in each group*
Operative procedure specifics - anesthesia, duration of procedure	*Operative time for all patients: 45 minutes (range 35-80 min)* *Preoperative antibiotics* *Local anesthesia*
Patient duration of follow-up outcomes/adverse events	*12 mo (1-16 mo)* *All patients received 3 month follow-up, using ultrasound U/S - no evidence of prosthesis in SIS group, prosthesis visible in other groups* *• PP - early complications (<30 days): 1 hematoma, 1 seroma, 1 delayed wound healing, 8 discomfort; late complication (>30 days) 1 hyperesthesia; hernia recurrence 0* *• Polyglactin and PP - early complications: 2 hematoma, 1 prolonged pain, 1 sensory loss, 7 discomfort; long term: 1 hyperesthesia, 1 prolonged pain, 1 sensory loss, hernia recurrence 0* *• Porcine small intestinal submucosa (Surgisis) - early: 1 seroma, 2 discomfort; late - none, hernia recurrence 0*

STORAGE

Store in a clean place at room temperature. Do not place in freezer. Avoid excessive heat. Keep dry.

STERILIZATION

This graft has been sterilized with ethylene oxide.

INSTRUCTIONS FOR USE

Required Materials

- Sterile basin
- Hydration fluid: room temperature, sterile saline or lactated Ringer's solution

Procedure

NOTE: Always handle the graft using aseptic technique, minimizing contact with latex gloves.

1. Remove the packaging containing the graft from the envelope.
2. Using aseptic technique, open the outer pouch and pass the inner pouch containing the graft onto the sterile field.
3. Place the graft into the sterile basin on the sterile field.
4. Place enough hydration fluid in the basin to completely cover the graft.
5. Allow the graft to hydrate for five minutes or until the desired handling characteristics are achieved.
6. Prepare the graft site using standard surgical techniques.
7. If necessary, trim the graft to the patient's anatomy, providing a small allowance for overlap with adjacent tissues

NOTE: It is recommended to minimize the bridging of defects to improve outcomes.

8. Affix the graft into place, avoiding excess tension.

NOTE: Imbricating the floor of the inguinal canal to flatten a saccular direct inguinal hernia may maximize graft exposure to better vascularized tissue.

NOTE: Approximating the graft around the cord such that the gap between the neo-internal ring and the cord can only accept the tip of a hemostat or DeBakey Pickup may help minimize the recurrence of a medial direct inguinal hernia or indirect hernia.

9. Complete the standard surgical procedure.
10. Discard any unused portions of the graft according to institutional guidelines for disposal of medical waste.
11. Patients should be advised to avoid strenuous physical activity and weight lifting for at least 6 months post-surgery. Activities requiring torso twisting such as golf, bowling, raking leaves, and shoveling snow should also be avoided during this period.

REFERENCES

1 Bochicchio GV, Jain A, McGonigal K, et al. Biologic vs synthetic inguinal hernia repair: 1-year results of a randomized double-blinded trial. *J. Am. Coll. Surg.* 2014;218(4):751-757.

2 Puccio F, Solazzo M, Marciano P. Comparison of three different mesh materials in tension-free inguinal hernia repair: prolene versus Vypro versus surgisis. *Int. Surg.* 2005;90(3 Suppl):S21-23.

3 Ansaloni L, Catena F, Coccolini F, Gazzotti F, D'Alessandro L, Pinna AD. Inguinal hernia repair with porcine small intestine submucosa: 3-year follow-up results of a randomized controlled trial of Lichtenstein's repair with polypropylene mesh versus Surgisis Inguinal Hernia Matrix. *The American journal of surgery.* 2009;198(3):303-312.