Biodesign®

RECTOPEXY GRAFT

FP0099-01A

COOK® MEDICAL

Manufacturer	**Attention, see instructions for use**
Temperature limit	**Keep dry**
Use-by date	STERILE EO **Sterilized using ethylene oxide**
Do not re-use	

Manufacturer

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BIODESIGN® RECTOPEXY GRAFT

DEVICE DESCRIPTION

The Biodesign® Rectopexy Graft is a dried multi-layered small intestinal submucosa (SIS) sheet. The graft is used to reinforce soft tissue for the repair of rectal prolapse. The graft can be cut to size to accommodate the patient's anatomy and is provided sterile for single use only.

INTENDED USE

The Biodesign® Rectopexy Graft is intended to reinforce soft tissue where weakness exists in the gastroenterological anatomy including transabdominal repair of colon and rectal prolapse. The device 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.

RECTOPEXY GRAFT This symbol means the following: Rectopexy Graft

CONTRAINDICATIONS

- This device 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.
- Device 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 the graft is rehydrated prior to suturing, stapling or tacking.
- Device performance has not been evaluated with suture spacing greater than 2mm.
- 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.
- 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 during delivery to the surgical site.
- Care should be taken to avoid implanting the device in an infected surgical field.

GENERAL

- Users should be familiar with surgical technique for rectal prolapse repair.
- Users should exercise good surgical practice for the management of clean-contaminated, contaminated or infected fields.

POTENTIAL COMPLICATIONS

Complications that can occur with the use of any prosthesis may include, but are not limited to: inflammation, induration, allergic reaction, migration, bowel or vaginal erosion, seroma formation, infection, fever, abscess, recurrent prolapse, nerve damage, constipation, impaction, vaginal or rectal wall perforation, bowel obstruction, periostitis, osteomyelitis, spondylodiscitis, urinary retention, de novo stress urinary incontinence, incisional herniation, adhesions, and pain. If any of the following conditions occur and cannot be resolved, device removal should be considered:

- Infection
- Acute or chronic inflammation (initial application of surgical graft materials may be associated with transient, mild, localized inflammation)
- Allergic reaction

STORAGE

This device should be stored in a clean, dry location at room temperature.

STERILIZATION

This device has been sterilized with ethylene oxide and should not be resterilized.

INSTRUCTIONS FOR USE

Required Materials

- Measuring instrument
- Sterile dish (kidney dish or other bowl)
- Sterile forceps and scissors and scalpel blade
- Rehydration fluid: room temperature, sterile saline or sterile lactated Ringer's solution
- Suitable resorbable suture, such as: 2-0 or 0 polydioxanone (PDS) or coated polyglycolic acid suture (coated PGA), tacks, and/or screws

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

PREPARATION

1. Remove the packaging containing the Rectopexy Graft from the envelope.
2. Remove the inner pouch containing the graft from the outer package using aseptic technique. Place the inner pouch into the sterile field.
3. Open the pouch and shape the graft to accommodate the patient's anatomy.
   NOTE: The recommended practice for preoperative bowel preparation in elective colorectal surgery includes mechanical bowel cleansing through the use of enemas and cathartic agents, and administration of prophylactic oral or intravenous antimicrobial agents. Insufficient cleansing or inadequate antibacterial prophylaxis may predispose the patient to infections. [1-3]

PROCEDURAL

1. Perform under regional or general anesthesia.
2. Establish access to the abdomen according to the surgeon's preference.
3. Use retraction techniques according to the surgeon's preference for retraction of the organs near the prolapsed colon or rectum.
4. Begin dissection to gain access to the prolapsed colon or rectum. Take care to avoid damage to the surrounding anatomy, specifically the nearby nerves, veins, vessels, and ureters.
5. Hydrate the shaped Biodesign Rectopexy Graft in sterile saline or sterile lactated Ringer's solution until the desired handling characteristics are achieved. The graft should not be rehydrated for longer than one minute. Be sure to utilize aseptic technique when handling the graft.
6. Return the prolapsed colon or rectum to its functional anatomy using the graft. Avoid placing the graft under excess tension.
7. Secure the graft to the surgical site under minimal tension with sutures, staples or tacks.
8. Close the previously dissected tissue and complete the surgical procedure.
9. Discard any unused portions of the graft according to institutional guidelines for medical waste.

POST-OPERATIVE CARE

To provide the best environment for tissue integration into the Biodesign Rectopexy Graft, patient activity should be minimized. Provide patients with a list of post-procedural care recommendations. The following patient guidelines should be considered:

1. Patients should avoid any strenuous physical activity beyond a gentle walk for at least 2 weeks following rectal prolapse repair.
2. Patients should avoid any heavy lifting over 10lbs (5kg) for at least 4 weeks following rectal prolapse repair.
3. Patients should use a stool softener for at least 4 weeks after surgery.
4. The patient may resume sexual activity when comfortable.

REFERENCES

1. Nichols RL, Smith JW, Garcia RY, et al. Current practices of preoperative bowel preparation among North American colorectal surgeons. Clin Infect Dis 1997; 24(4):609-19.
2. Yabata E, Okabe S, Endo M. A prospective, randomized clinical trial of preoperative bowel preparation for elective colorectal surgery-comparison among oral, systemic, and intraoperative luminal antibacterial preparations. J Med Dent Sci 1997; 44(4):75-80.
3. Mangram A, Horan TC, Pearson ML, et al. Guideline for Prevention of Surgical Site Infection, 1999. Centers for Disease Control and Prevention (CDC).