















Biodesign®

RECTOPEXY GRAFT

FP0099-01B

COOK®

BIOTECH

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

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 graft is derived from a porcine source and should not be used in patients with known sensitivity to porcine material.

PRECAUTIONS

- This 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 the graft is hydrated prior to suturing, stapling or tacking.
- Graft performance has not been evaluated with suture spacing greater than 2 mm.
- 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 hydration 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 graft in an infected surgical field.

GENERAL

- Users should be familiar with surgical technique for rectal prolapse repair, specifically the ventral rectopexy procedure.
- 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:

- Abscess
- Adhesions
- Allergic reaction
- Bowel obstruction
- Bowel or vaginal erosion
- Constipation
- De novo stress urinary incontinence
- Fever
- Impaction
- Incisional herniation
- Induration
- Infection
- Inflammation
- Migration
- Nerve damage
- Osteomyelitis
- Pain
- Peritonitis
- Recurrent prolapse
- Seroma
- Spondylodiscitis
- Urinary retention
- Vaginal or rectal wall perforation

If any of the following conditions occur and cannot be resolved, graft removal should be considered.

STORAGE

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

STERILIZATION

The graft has been sterilized with ethylene oxide and should not be resterilized.

INSTRUCTIONS FOR USE

Required Materials

- Sterile ruler
- Sterile basin
- Sterile smooth forceps
- Hydration 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: Handle the graft using aseptic technique, minimizing contact with latex gloves.

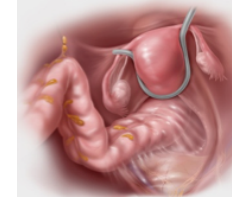
Preparation

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. Open the pouch and shape the graft to accommodate the patient's anatomy.

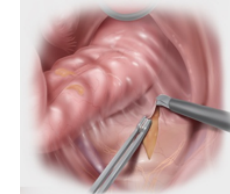
NOTE: The recommended practice for preoperative bowel preparation in elective colorectal surgery includes mechanical bowel cleansing through the use of enemas and cathartic agents, and administration of prophylactic oral or intravenous antimicrobial agents. Insufficient cleansing or inadequate antibacterial prophylaxis may predispose the patient to infections.¹⁻³

Procedure

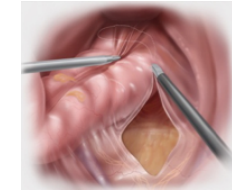
1. Perform under regional or general anesthesia.
2. Position the patient in the modified lithotomy or Lloyd Davies position with both arms secured on either side.
3. If performing the procedure laparoscopically, place the ports according to the surgeon's preference.
4. If present, retract the uterus, sigmoid colon, and/or vagina.



5. Begin dissection at the sacral promontory. Take care to avoid damage to the left hypogastric nerve and left iliac vein.



6. Continue dissection distally to the right side of the mesorectum to the pouch of Douglas. Take care to avoid damage to the right iliac vessels and ureter.



7. Incise the pouch of Douglas to develop a plane from the rectovaginal septum to the pelvic floor.
8. In males, limit the ventral dissection in the rectovesical pouch to the apex of the prostate and avoid lateral dissection around the seminal vesicles.
9. Hydrate the graft in sterile saline or sterile lactated Ringer's solution until the desired handling characteristics are achieved. A hydration time of greater than 1 minute is not required.


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10. Deliver the distal end of the graft to the ventral rectum. Secure the graft to the anterolateral rectum with interrupted deep muscle sutures on each side of the graft. Absorbable sutures, such as 2-0 PDS, are recommended.



NOTE: Avoid full thickness suturing of the rectum.

11. Place additional sutures on the left side of the intraperitoneal rectum.
12. Secure the graft to the sacral promontory under minimal tension with sutures, tacks, or screws.
13. Close the peritoneal tissue over the graft. Ensure maximum contact between the graft and tissue to produce better surgical outcomes.



14. Following confirmation of hemostasis, release the sigmoid colon and pelvic structures from retraction, and close the port sites.
15. Discard any unused portion of the graft according to institutional guidelines for medical waste.

Post-Operative Care

To provide the best environment for tissue integration into the 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 10 lbs (5 kg) 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. Berrios-Torres SI, Umscheid CA, Bratzler DW, et al. Centers for Disease Control and Prevention guideline for the prevention of surgical site infection, 2017. *JAMA Surg.* 2017;152(8):784-791.