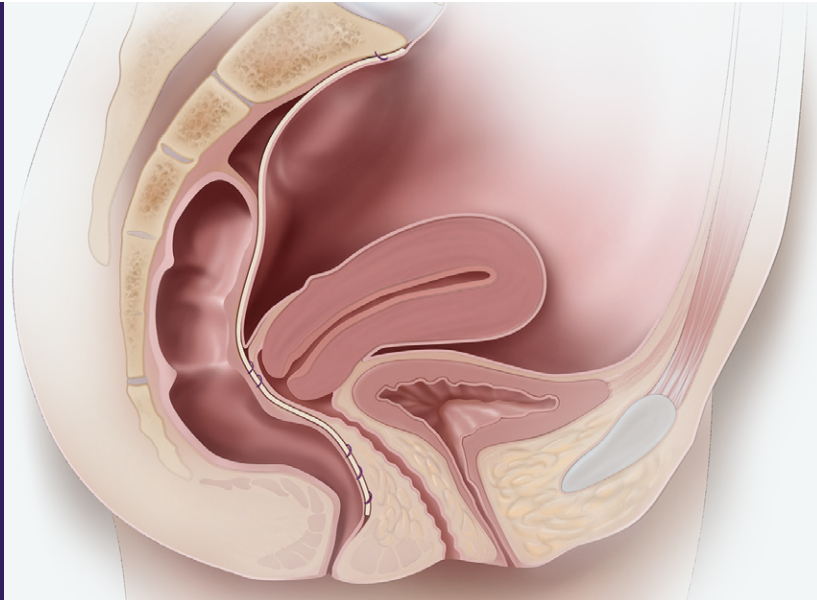


The Biodesign Rectopexy Graft is intended to reinforce soft tissue where weakness exists in the gastroenterological anatomy including transabdominal repair of colon and rectal prolapse.



- 1 Place the patient in the modified lithotomy or Lloyd Davies position. Secure the patient's arms. Establish access to the pneumoperitoneum. Retract the uterus, sigmoid colon, and vagina.

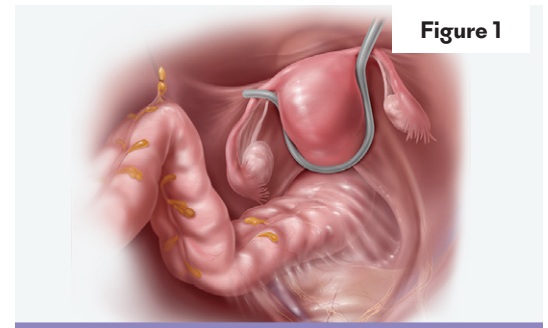


Figure 1

- 2 Begin dissection at the sacral promontory on the right side of the colon/rectum, being careful to avoid damage to the hypogastric nerves, iliac vessels, and ureters.

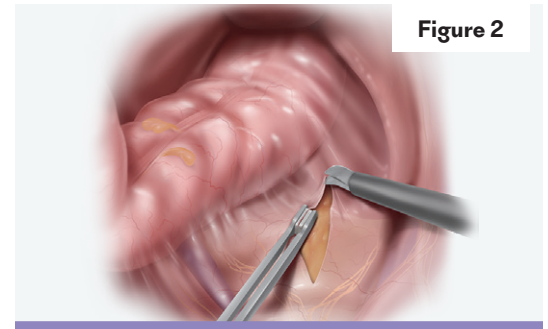


Figure 2

- 3 Incise the peritoneum superficially from the sacral promontory down to the pouch of Douglas. Incise the pouch of Douglas to develop a plane from the rectovaginal septum to the pelvic floor. Dissect laterally as necessary.

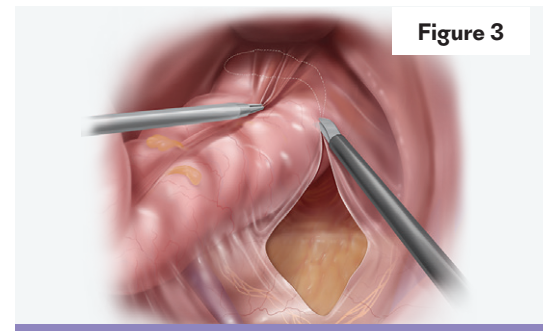


Figure 3

- 4** Shape the graft to fit the patient's anatomy and hydrate in sterile saline or sterile lactated Ringer's solution for 1 minute / less.



Figure 4

- 5** Position the graft so that the distal portion touches the anterior rectum and the proximal portion touches the sacral promontory. Secure the graft to the anterolateral rectum with absorbable, interrupted deep muscle sutures on each side of the graft. Place additional sutures on the left side of the intraperitoneal rectum. Secure the graft to the sacral promontory in a way that keeps the graft under minimal tension.



Figure 5

- 6** To help the body remodel the graft, ensure maximum contact between the graft and the tissue and ensure that the graft lays flat against the adjacent tissue. Close the exposed peritoneal edges with a continuous suture over the graft. Release the sigmoid colon and pelvic structures from retraction and close the port sites.

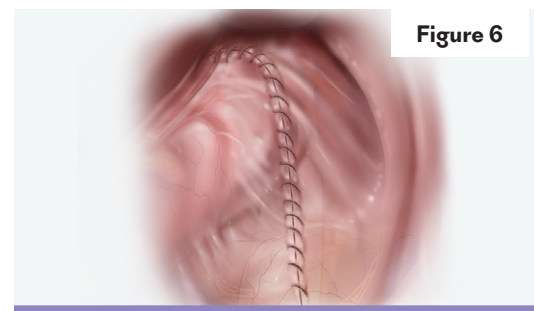


Figure 6

RISK INFORMATION: BIODESIGN RECTOPEXY GRAFT

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.

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.** • 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. • Suturing, stapling, or tacking more than one graft

together may decrease graft performance. • Care should be taken to avoid implanting the graft in an infected surgical field.

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 • Periostitis • Recurrent prolapse • Seroma • Spondylodiscitis • Urinary retention • Vaginal or rectal wall perforation

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

ERI_FP0099-01B

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Distributed by:
Evergen
1425 Innovation Place
West Lafayette, IN 47906 USA
T 855.201.6914
evergenbio.com

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