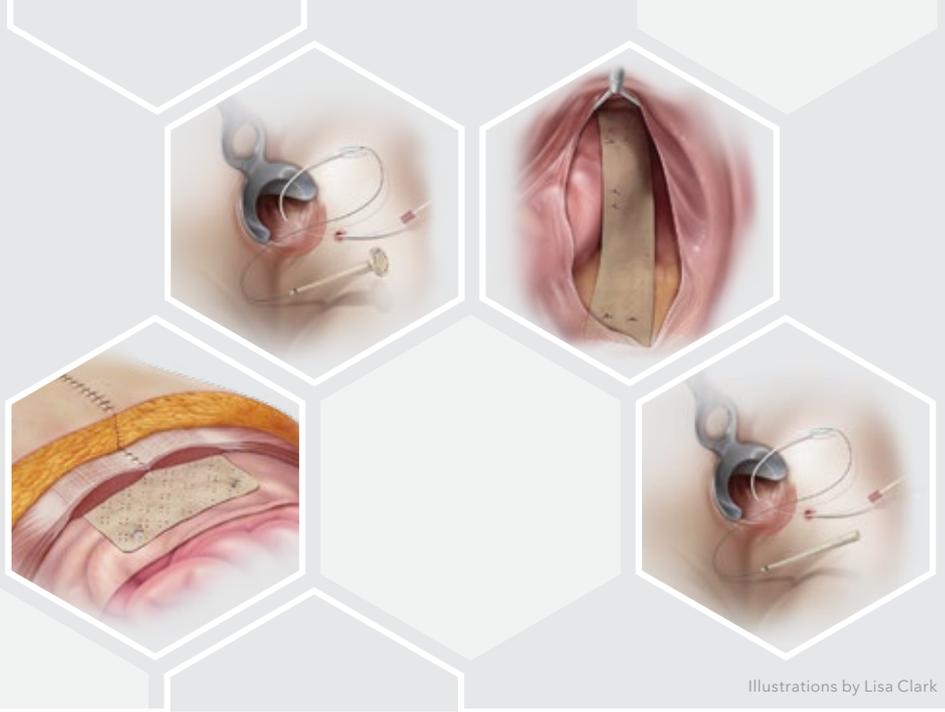


Colorectal procedure guide

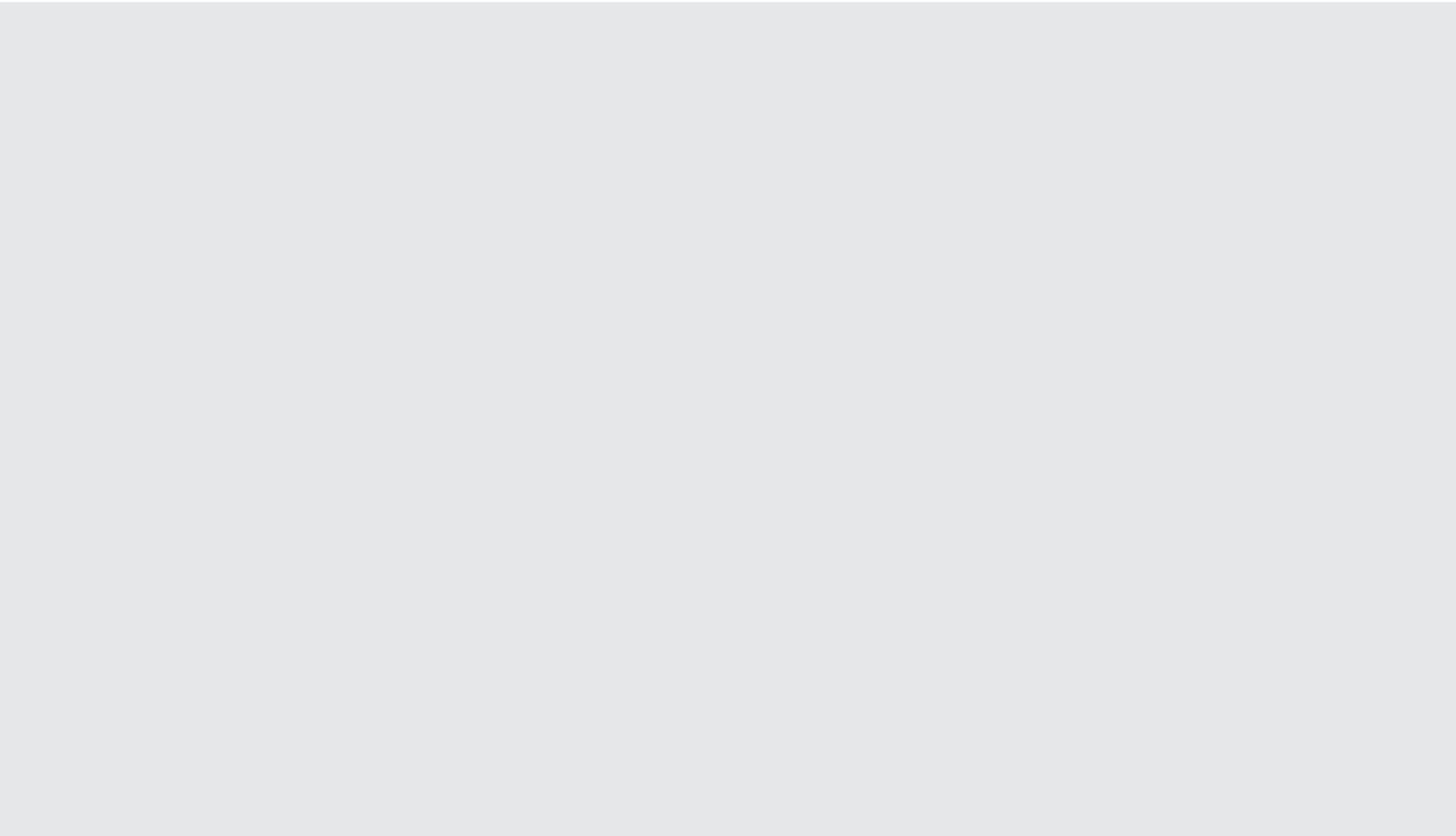


Illustrations by Lisa Clark

Biodesign[®]
ADVANCED TISSUE REPAIR



cookmedical.com



INDEX

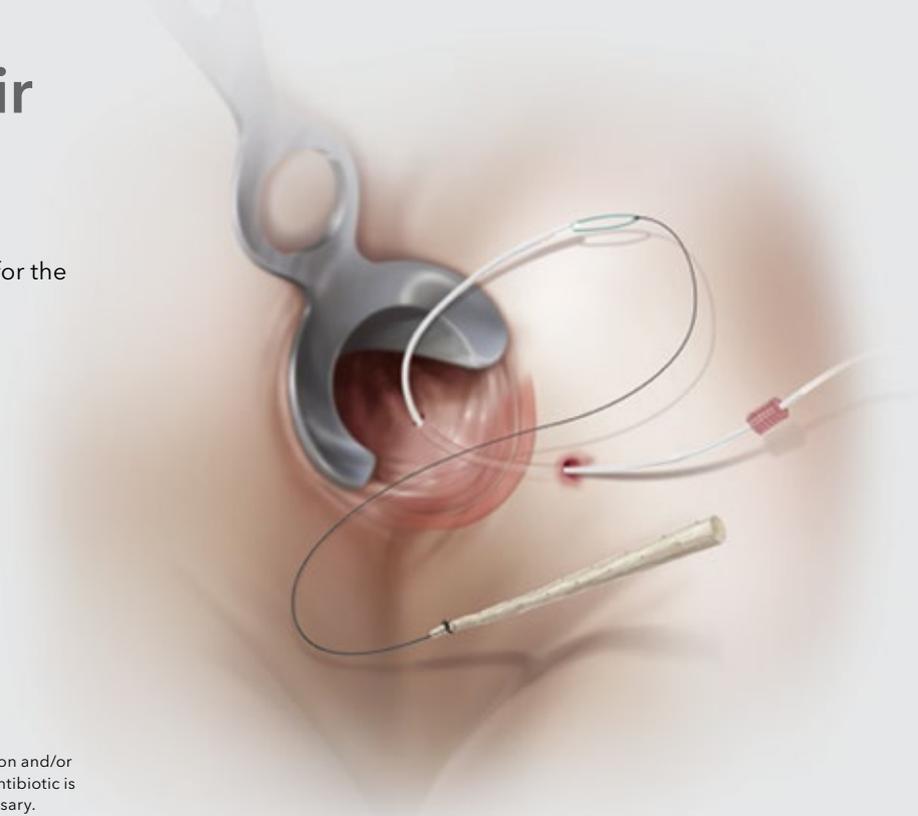
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The techniques presented in this guide are recommendations that should help you achieve optimum results, but this guide is not meant to be a substitute for the instructions for use.

Anal fistula repair

Using the Biodesign plug with no button

The Biodesign Anal Fistula Plug Set is used for the repair of anorectal fistulas.



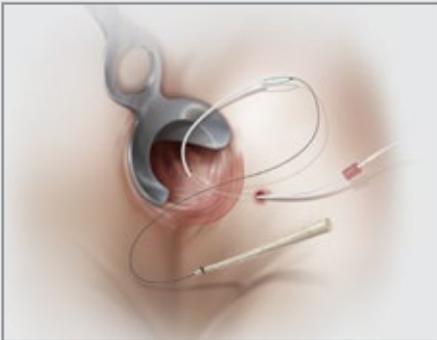
The surgeon should decide whether to perform bowel preparation and/or a small-volume enema. A single preoperative dose of systemic antibiotic is recommended. A continuous dosage of the antibiotic is unnecessary.

ANAL FISTULA REPAIR



1. Place a draining seton if any signs of sepsis or infection are present, and allow the tract to mature and stabilize for six to eight weeks before you place the plug.

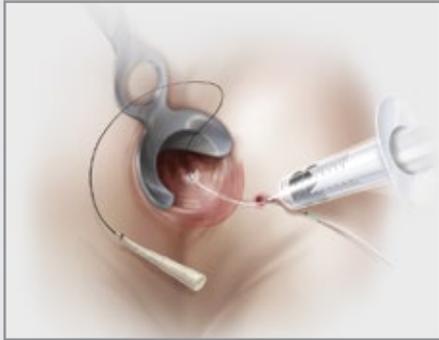
After you inspect the seton and fistula, irrigate the tract with hydrogen peroxide or a similar fluid. Cut the seton and attach a suture to the cut end.



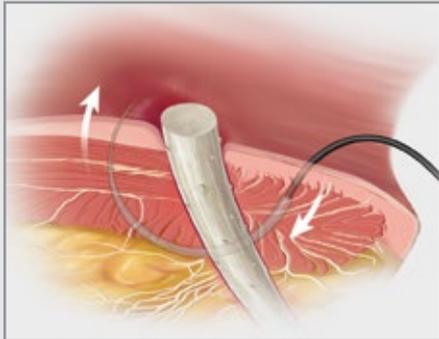
2. Tie the suture to the Cook® Fistula Brush. Pull the brush catheter into the fistula tract. Using a back-and-forth motion, clean and remove nonvascular tissue.

A small amount of blood at the tract and on the brush's bristles indicates adequate debridement.

Do not mechanically debride the fistula tract in a way that would likely make the tract wider and harder to close.



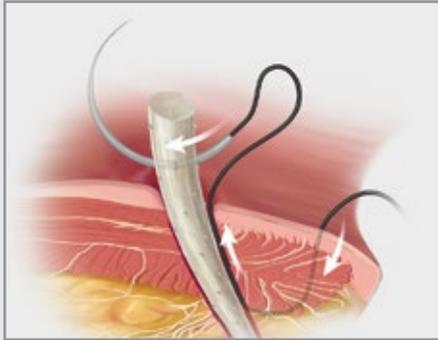
3. Hydrate the plug in sterile saline for no more than one minute. Tie the plug onto the suture. Use hydrogen peroxide or a similar fluid again to irrigate the tract and flush loose debris.



- 4A. *Blind-pass technique:* Pull the plug, narrow end first, into the fistula tract until you feel slight resistance. Affix the plug by using a 2-0 long-term absorbable suture on a UR6 or comparable needle.

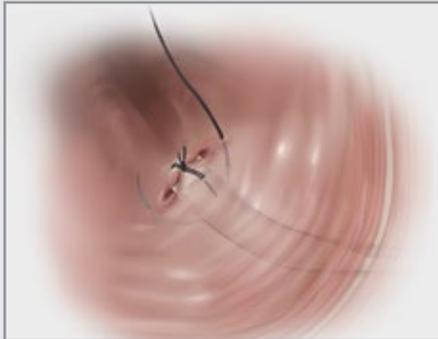
Adjacent to the internal opening, pass a stitch deep into the sphincter muscles and directly through the center of the plug, exiting on the opposite side. Gently pull the plug partially out of the internal opening to verify that the stitch went directly through the plug.

Pull the plug back to its original position. Remove any slack from the sutures in the fistula tract.



- 4B. *Direct-visualization technique:* Place the plug as described in step 4A, then pull the plug partially out of the internal opening. Adjacent to the internal opening, pass a stitch deep into the sphincter muscles without piercing the plug. Continue the stitch by passing the needle directly through the center of the plug.

Continue the stitch by passing the needle down alongside the plug, deep into the sphincter muscles.



5. Repeat the previous step (4A or 4B depending on which technique you chose), and make a stitch perpendicular to your first stitch. Note: If you are using the direct-visualization technique, then at the end of this step, pull the plug back to its original position.

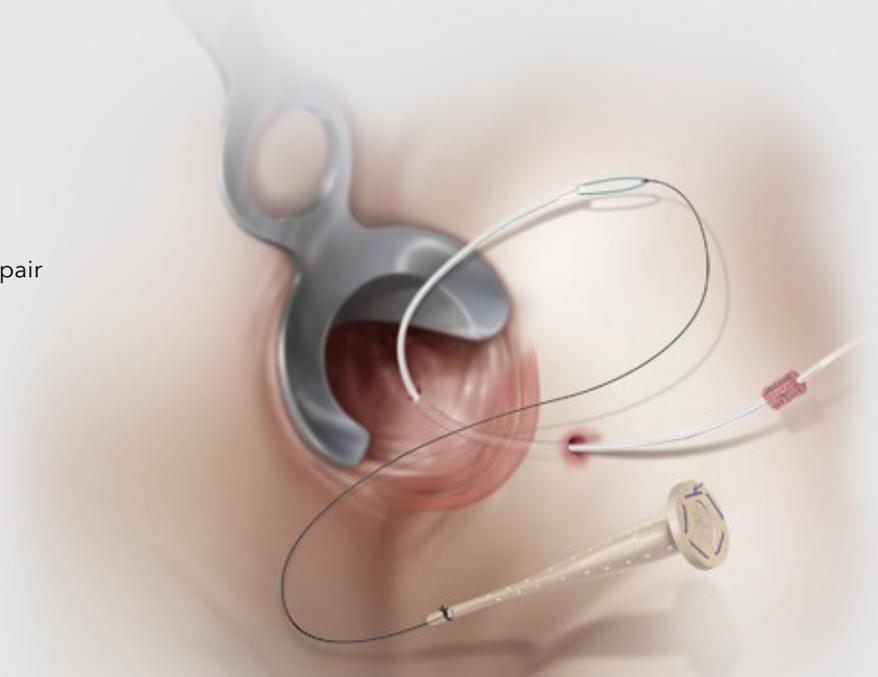
6. Tie off the sutures over the top of the plug, effectively pulling the mucosal layer over the top of the plug. No part of the plug should be visible at the internal opening.

Trim any external portion of the plug flush with the skin. Slightly enlarge the external opening to facilitate drainage. Drainage is expected for a minimum of 2 weeks and can continue for up to 12 weeks. Provide the patient with the postoperative patient guide. The patient's compliance with the guide directly affects the success of the plug.

Anal fistula repair

Using the Biodesign plug with the button

The Biodesign Fistula Plug Set is used for the repair of rectovaginal and anorectal fistulas.



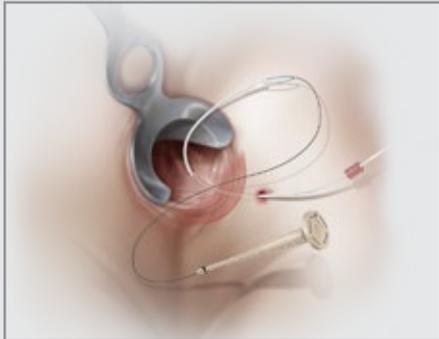
The surgeon should decide whether to perform bowel preparation and/or a small-volume enema. A single preoperative dose of systemic antibiotic is recommended. A continuous dosage of the antibiotic is unnecessary.

ANAL FISTULA REPAIR



1. Place a draining seton if any signs of sepsis or infection are present, and allow the tract to mature and stabilize for six to eight weeks before you place the plug.

After you inspect the seton and fistula, irrigate the tract with hydrogen peroxide or a similar fluid. Cut the seton and attach a suture to the cut end.

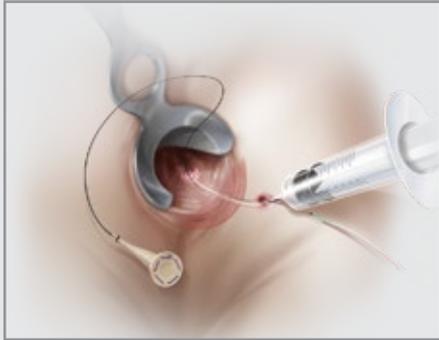


2. Tie the suture to the Cook® Fistula Brush. Pull the brush catheter into the fistula tract. Using a back-and-forth motion, clean and remove nonvascular tissue.

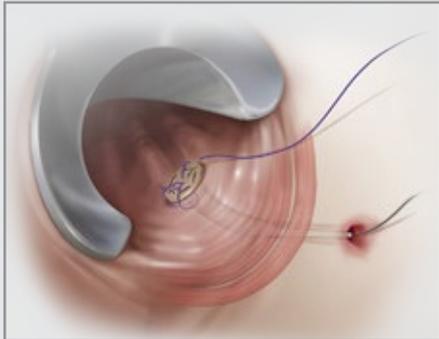
A small amount of blood at the tract and on the brush's bristles indicates adequate debridement.

Do not mechanically debride the fistula tract in a way that would likely make the tract wider and harder to close.

ANAL FISTULA REPAIR

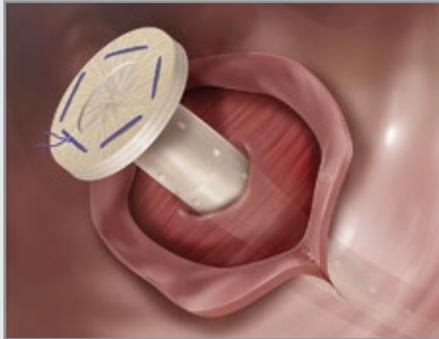


3. Hydrate the plug in sterile saline for no more than one minute. Tie the plug onto the suture. Use hydrogen peroxide or a similar fluid again to irrigate the tract and flush loose debris.

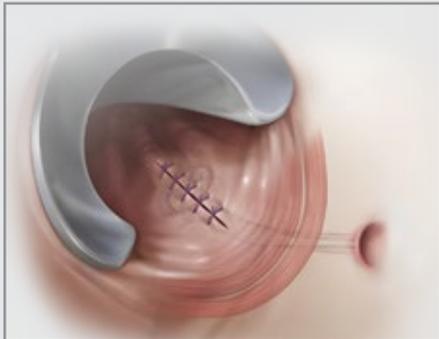


- 4A. *Superficial placement:* Pull the plug, narrow end first, into the fistula tract until the button is flush against the mucosa. Affix the plug by using a 2-0 long-term absorbable suture on a UR6 or comparable needle. Place four sutures through the center of the plug, deep into the sphincter muscles.

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Service for details.



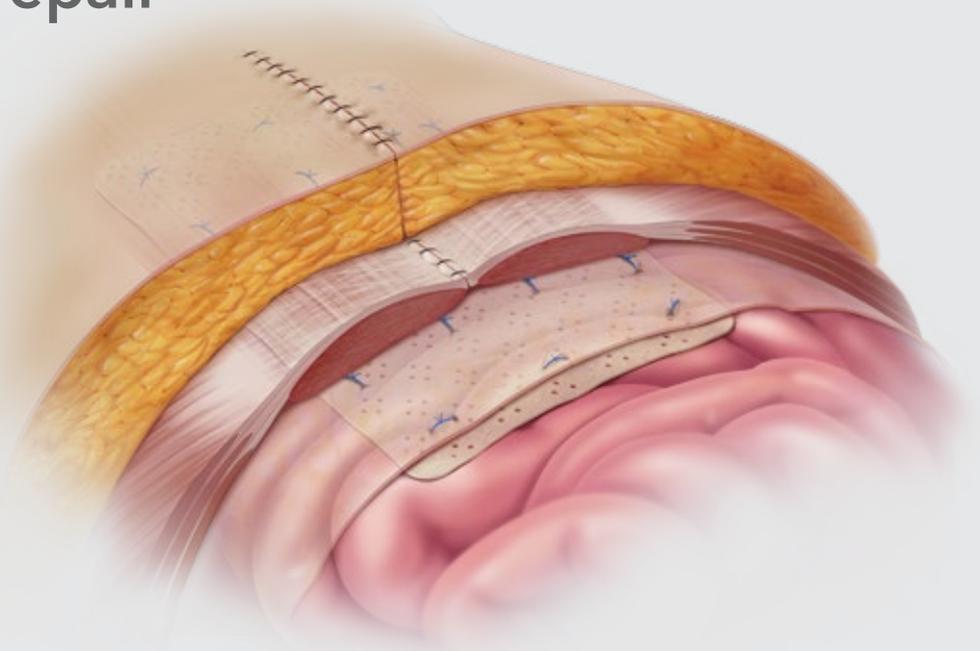
- 4B. *Submucosal placement*: Create small mucosal flaps or undermine the mucosa circumferentially to create a small pocket that can accommodate the button portion of the plug. Place the plug as described in step 4A; the button portion should be flush with the internal sphincter. Then reapproximate the mucosal edges, and completely cover the button.



5. Trim any external portion of the plug flush with the skin. Slightly enlarge the external opening to facilitate drainage. Drainage is expected for a minimum of 2 weeks and can continue up to 12 weeks. Provide the patient with the post-operative patient guide. The patient's compliance with the guide directly affects the success of the plug.

Ventral hernia repair

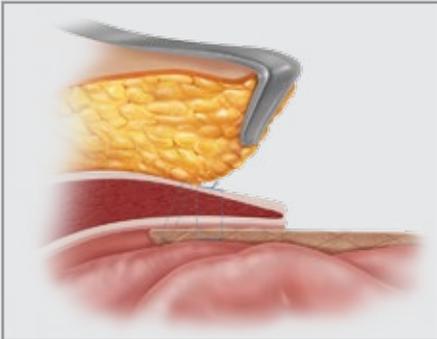
The Biodesign Hernia Graft is used to reinforce soft tissue where weakness exists, including a hernia or body wall defect.



VENTRAL HERNIA REPAIR

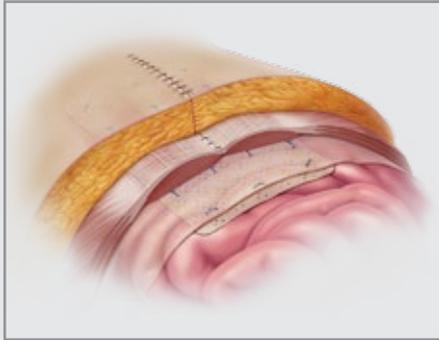


1. Hydrate the graft for no longer than one minute in a room-temperature, sterile, lactated Ringer's solution or sterile saline.

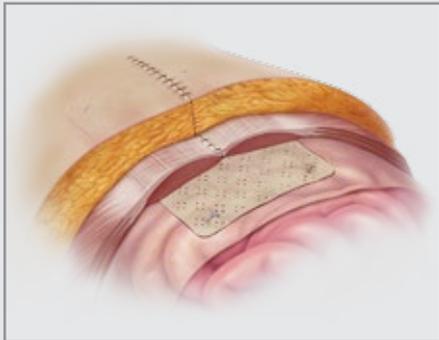


2. If you use an open procedure to place the graft, preperitoneal, retrorectus, or intraperitoneal placement is recommended. For a laparoscopic procedure, intraperitoneal placement is recommended.

VENTRAL HERNIA REPAIR



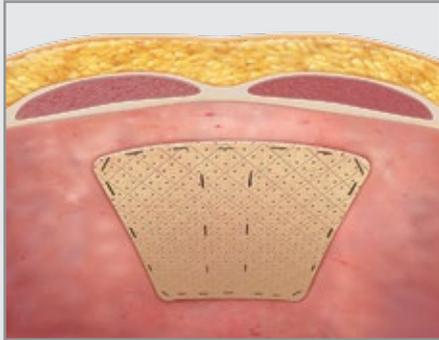
3. Trim the graft to fit the site, providing an allowance for overlap. Fundamental surgical principles suggest recurrence can be minimized if the mesh overlaps the surrounding tissue by 4-5 cm in all directions¹. When 5 cm of overlap is not attainable, overlap as much tissue as possible.



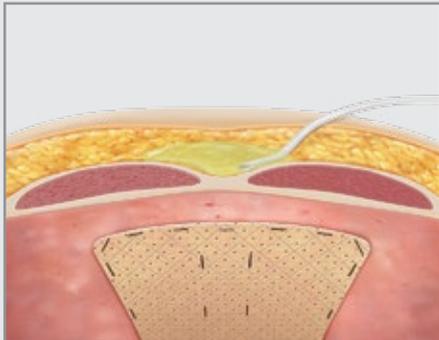
4. Bridging the hernia with only the graft is not recommended. To attain primary closure of the defects, use relaxing incisions, perform component separation, or perform retrorectus placement. If bridging is unavoidable, follow the best practices described in the IFU.

1. Klinge U, Conze J, Krones, C, et al. Incisional Hernia: Open Techniques. *World J Surg.* 2005;29(8):1066-1072.

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Service for details.



5. Use permanent or long-term absorbable sutures and tacks. The horizontal mattress suture technique is recommended. Place sutures ≤ 3 cm apart and with a bite depth of 1 cm.

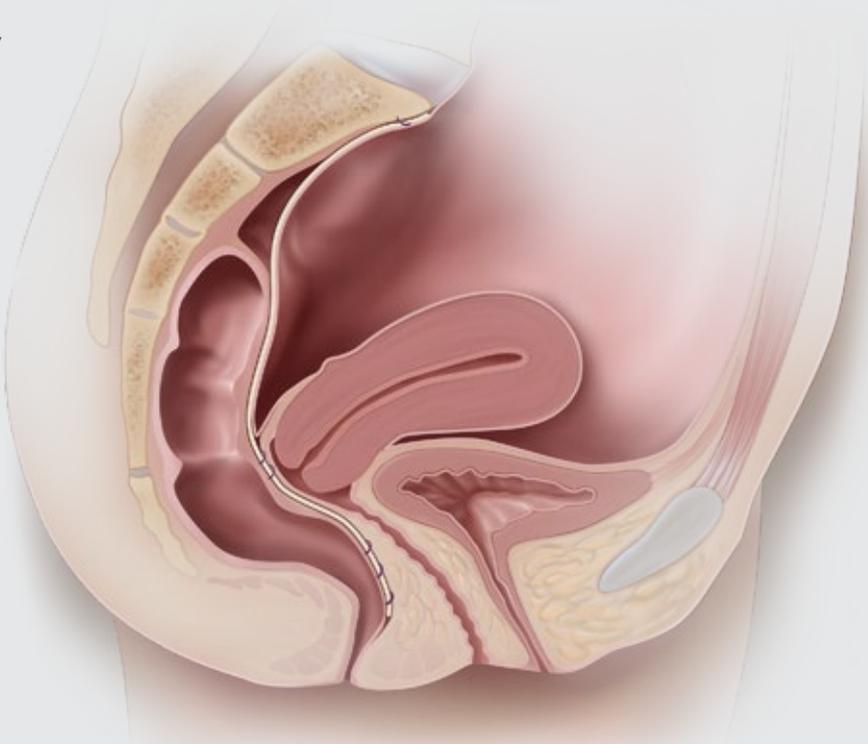


6. Place closed suction drains, and leave them in place for two to six weeks. Remove the drains when their output is < 20 mL per 24 hours for at least two consecutive days or until the drains are dry.

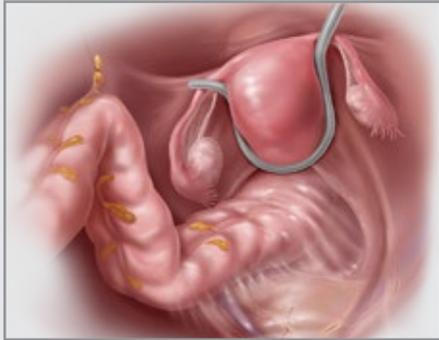
Ventral rectopexy

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

Ventral rectopexy is one option for repairing rectal prolapse. Surgeons should use their own judgement to decide which procedure fits each patient.



VENTRAL RECTOPEXY

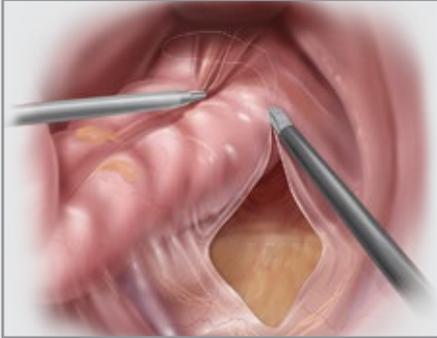


1. Put your patient in the modified Lloyd Davies position. Secure the patient's arms. Establish access to the pneumoperitoneum and the laparoscopic port.



2. Perform a technique of your preference to retract the sigmoid colon and uterus.

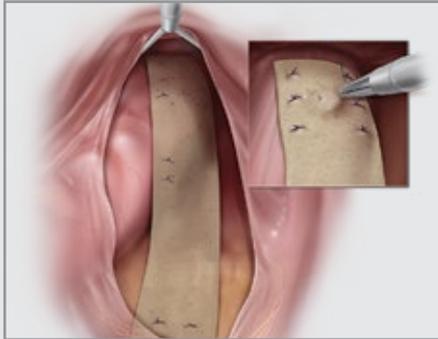
VENTRAL RECTOPEXY



3. Incise the peritoneum superficially from the sacral promontory down to the pouch of Douglas. Excise the pouch of Douglas, and continue to dissect the rectovaginal plane to the anal canal. Dissect laterally as necessary.



4. Shape the Biodesign graft according to your preference, and hydrate in sterile lactated Ringer's solution or in sterile saline for less than one minute.



5. Position the Biodesign graft so that the distal portion touches the anterior rectum and the proximal portion touches the sacral promontory. Suture the distal portion to the anterior rectum with approximately six interrupted, long-term absorbable sutures. Trim excess graft material as required. Use either tacks or sutures to secure the graft to the sacral promontory in a way that keeps the graft under minimal tension.

An additional suture in the posterior vaginal wall can secure the rectovaginal plane closure. Additional sutures can secure the surrounding tissues to the graft.



6. To help the body remodel Biodesign, ensure maximum contact between the graft and the tissue, and ensure that the graft is under minimal tension. Close the exposed peritoneal edges with a continuous suture over the Biodesign graft. Confirm hemostasis. Release the sigmoid colon and pelvic structures, and close the port sites.

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