Colorectal procedure guide
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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 IFU.
Abdominoperineal resection

A scaffold for new tissue, Biodesign® can support areas of weakness while the peritoneal defect heals, and Biodesign can reinforce the stoma site.
1. Close the anal opening by using a purse-string suture, and properly position the patient for a laparotomy and sigmoid mobilisation. Identify and separate the sigmoid colon and the rectum from supporting structures, such as the blood vessels, the peritoneum, and other attachment points. Mobilise the rectum down the total mesorectal excision (TME) plane to the level of coccyx posteriorly (seminal vesicles anteriorly in men). Take care to not injure the pelvic nerves and ureters.

2. Use a linear stapler to transect the left colon in a location that allows a healthy and well-functioning stoma.
3. Form a stoma at a premarked site. Place the Biodesign Hernia Graft according to user preference in order to reinforce the abdominal wall at the stoma site. Complete the abdominal part of the procedure by closing the abdomen and maturing the colostomy.

4. Position the patient to achieve the maximum exposure and access to the relevant anatomy. Create a teardrop-shaped or oval-shaped incision, and resect tissue in the plane just outside of the anal sphincter complex. Remove enough tissue to ensure safe margins.
5. Complete the perineal dissection. Extract the specimen through the perineal opening.

6. Ensure adequate haemostasis. To reinforce and support the surrounding tissues, place the Biodesign Hernia Graft (10 x 10 cm) in the perineal defect that was created by the perineal resection.
Anal fistula repair

Using the Biodesign plug with no button

The anal fistula plug treats difficult fistulas without causing sphincter-muscle damage that can lead to incontinence.

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

Some products or part numbers may not be available in all markets. Contact your local Cook representative or Customer Service for details.
1. Place a draining seton if any signs of sepsis or infection are present, and allow the tract to mature and stabilise 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 two minutes. 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. Fixate the plug by using 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 centre 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 track.

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4B. Direct-visualisation 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 centre 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-visualisation 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 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.
Anal fistula repair

Using the Biodesign plug with the button

The anal fistula plug treats difficult fistulas without causing sphincter-muscle damage that can lead to incontinence. The plug’s button design facilitates fixation and minimises the risk of extrusion.

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

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1. Place a draining seton if any signs of sepsis or infection are present, and allow the tract to mature and stabilise 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 two minutes. 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. Fixate the plug by using 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.
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.
Anal fistula repair

Using LIFT with Biodesign

Ligation of the Intersphincteric Fistula Tract (LIFT) with the Biodesign 4-Layer Tissue Graft can repair the fistula while keeping the sphincter intact. This procedure is a solution to painful and embarrassing symptoms.

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

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

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. Irrigate the tract again with hydrogen peroxide or a similar fluid to flush out any loose debris.

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. Create a 3 cm incision along the intersphincteric groove. Dissect 1-2 cm of the intersphincteric tissue that is proximal and lateral to the fistula tract. Once you have identified the tract, isolate it with forceps and excise it within the intersphincteric groove.

4. Within the intersphincteric plane, place an absorbable suture to close the primary opening of the fistula tract. The secondary tract should be left open, and the external opening of the fistula may be enlarged for adequate drainage.

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5. Place anchor sutures through the Biodesign graft and through the external sphincter, levator ani, or puborectalis muscle. Then perform the parachute technique to place the graft within the intersphincteric plane. To ensure adequate coverage of the repaired fistula tract, provide a minimum of 1-2 cm of overlap proximal, distal, and lateral to the repaired fistula opening. To ensure that the graft makes sufficient contact with the tissue, place multiple absorbable sutures along the edges of and in the center of the graft.

6. Use interrupted sutures to ensure partial closure of the perineal incision. Interrupted sutures will permit adequate wound drainage. Each suture bite should include the skin, internal sphincter, Biodesign graft, and external sphincter.
Parastomal hernia repair – Sugarbaker technique

The Biodesign Hernia Graft provides long-term strength while minimising the risk of erosion and infection. In the Sugarbaker technique, the Biodesign graft offsets the bowel intra-abdominally and lessens the pressure on the defect.
1. Using open or laparoscopic techniques, perform adhesiolysis, reduce the hernia contents, and identify the parastomal defect.

2. Using a suturing device, approximate the defect to allow closure of the hernia and re-establishment of the desired stoma anatomy.
3. Lateralise the bowel to determine the necessary size of the Biodesign Hernia Graft. Keep in mind that sufficient overlap of healthy tissue facilitates better tissue incorporation and minimises the chances that the hernia will recur. The hernia graft should extend ≥ 5 cm beyond the edge of the closed defect.

4. Hydrate the graft in room-temperature, sterile, lactated Ringer’s solution or in sterile saline for no more than one minute. Place the graft into the abdomen through a large trocar or through the abdominal incision.
5. Using a suturing device, with permanent or long-term absorbable sutures, anchor the graft on either side of the bowel. Ensure that the graft makes maximum contact with the bowel and closed defect. Then place sutures at 5 cm intervals and with a bite depth of 1 cm. Ensure that the graft makes maximum contact with the tissue.

6. Using permanent or long-term absorbable sutures or tacks, secure the graft at multiple attachment points. When you are finished, the device should be affixed to the abdominal wall, should have minimal wrinkles or folds, and should have maximum contact with the tissue.
Rectovaginal fistula repair

Using the Biodesign plug with the button

The Biodesign Fistula Plug treats difficult fistulas without causing sphincter-muscle damage that can lead to incontinence. The plug’s button design facilitates fixation and minimises the risk of extrusion.

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

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

5. Trim away any remaining portion of the plug that is not implanted within the fistula tract. Leave at least 2 mm of material between the end of the trimmed plug and the suture to provide the appropriate suture retention strength. 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 postoperative patient guide. The patient’s compliance with the guide directly affects the success of the plug.
Rectovaginal fistula repair

Using LIFT with Biodesign

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4. Within the intersphincteric plane, place an absorbable suture to close the primary opening of the fistula tract. The secondary opening should be closed to prevent further drainage into the vagina.
5. Place anchor sutures through the Biodesign graft and through the external sphincter, lavator ani, or puborectalis muscle. Then perform the parachute technique to place the graft within the intersphincteric plane. To ensure adequate coverage of the repaired fistula tract, provide a minimum of 1-2 cm of overlap proximal, distal, and lateral to the repaired fistula opening. To ensure that the graft makes sufficient contact with the tissue, place multiple absorbable sutures along the edges of and in the center of the graft.

6. Use interrupted sutures to ensure partial closure of the perineal incision. Interrupted sutures will permit adequate wound drainage. Each suture bite should include the skin, internal sphincter, Biodesign graft, and external sphincter.
Ventral hernia

The Biodesign Hernia Graft provides long-term strength to areas of weakened tissue. Biodesign is non-dermis and is associated with minimal stretching and risk of infection or encapsulation. This graft can be used in either laparoscopic or open surgery.
VENTRAL HERNIA

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.
3. Sufficient overlap of healthy tissue allows mesh contraction, facilitates better tissue incorporation, and reduces recurrence. 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.
5. Use permanent or long-term absorbable sutures and tacks. The horizontal mattress suture technique is recommended. Place sutures $\leq 3$ 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

Biodesign grafts provide minimally invasive restoration and support without the use of synthetic material that can lead to erosion and encapsulation.
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.
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 and correct the rectovaginal prolapse. Additional sutures can secure the vaginal vault or remnants of the uterosacral ligaments 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 haemostasis. Release the sigmoid colon and pelvic structures, and close the port sites.

Illustrations by Lisa Clark
Asia Pacific Customer Service

Australia: +61 734346000, cau.custserv@cookmedical.com
China: +86 2154519599, chinacssupport@cookmedical.com
Hong Kong: +852 34721688, cs.cahk@cookmedical.com
India: +91 4426271144, india.orders@cookmedical.com
Japan: +81 368539470, jp.orders@cookmedical.com
Korea: +822 62923500, kr.orders@cookmedical.com
Malaysia: +603 79621688, my.orders@cookmedical.com
Singapore: +65 62877888, sg.orders@cookmedical.com
Taiwan: +886 266281880, tw.orders@cookmedical.com
Thailand: +662 1688630, th.orders@cookmedical.com

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