Biodesign®

ENTEROCUTANEOUS FISTULA PLUG

FP0069-01K

COOK® MEDICAL

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

Manufacturer
COOK BIOTECH
INCORPORATED
1425 Innovation Place
West Lafayette, IN 47906 U.S.A.

www.cookmedical.com

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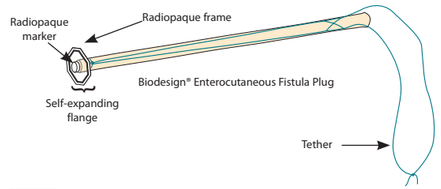
BIODESIGN® ENTEROCUTANEOUS FISTULA PLUG

INTENDED USE

The Biodesign Enterocutaneous Fistula Plug is for implantation to reinforce soft tissue for repair of enterocutaneous fistulas. 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

This product is intended for use by medical professionals trained in the use of this device and in surgical techniques for enterocutaneous fistula repair.

CONTRAINDICATIONS

- The plug is derived from a porcine source and should not be used for patients sensitive to porcine materials.
- **Not for vascular use.**

WARNINGS

- **Plug implantation in areas of weakened bowel tissue integrity as a result of comorbidities, cancer, or irradiation treatment raises the risk of severe complications such as bowel rupture, plug dislodgement into the abdominal cavity, or abscess.** Emergent reoperation may be needed to correct these complications and prevent further patient morbidity.[1]
- This device contains nitinol, an alloy of nickel and titanium. Patients with allergic reactions to these metals may suffer an allergic reaction to the plug. Prior to implantation, patients should be counseled on the materials contained in the plug, as well as potential for allergy/hypersensitivity to these materials.

GENERAL PRECAUTIONS

- Optimize patient nutrition prior to implanting the plug.
- The plug is designed for single use only. Attempts to reprocess, resterilize, and/or reuse may lead to failure and/or transmission of disease.
- **Do not resterilize.** Discard all unused portions of the device.
- The device is sterile if the package is dry, unopened and undamaged. Do not use if the package seal is broken.
- Discard the device if mishandling has caused possible damage or contamination or if the device is past its expiration date.
- Do not implant the plug in a grossly infected, abscessed or inflamed fistula tract.
- Do not implant the plug in a bowel fistula that exceeds 7 mm in diameter.
- Do not implant the plug in a bowel fistula that is less than 2 cm in length.
- Use caution if implanting the plug in a recently irradiated field.
- Use caution if implanting the plug adjacent to cancerous tumors.
- Use caution if implanting the plug into a bowel that is currently diverted (e.g. ileostomy, colostomy) as bowel motility may be compromised.
- Use with caution in patients with inflammatory bowel or friable tissues.

PROCEDURAL PRECAUTIONS

- Users should exercise good surgical practice for the management of clean-contaminated, contaminated or infected fields.
- The use of prophylactic antibiotics and cleaning of the fistula tract may decrease the potential for infection of the plug material following implant.
- Ensure that the plug is hydrated before cutting or suturing.
- Ensure that the gastrointestinal tract is free of obstruction distal to the fistula prior to placement of the plug. (See BOWEL PREPARATION)
- Do not flush the plug or delivery sheath with fluids before deploying the self-expanding flange into the bowel. Advance the dry plug through the delivery system and hydrate after the self-expanding flange is confirmed to be fully expanded in the bowel.
- **Use caution when advancing the delivery sheath and dilator into diseased bowel.**
- Once the plug is loaded into the transfer tube, do not separate the plug from the transfer tube until the device is transferred into the delivery sheath.
- Use fluoroscopic confirmation to ensure that the flange of the plug is flush against the bowel wall to restrict ingress of intestinal contents back into the fistula.
- Use fluoroscopic confirmation to ensure that all bowel communications within the fistula tract are sealed.
- The fistula opening at the dermal surface should maintain an open pathway for drainage.
- If the flange is retained in the patient beyond eight weeks, the patient should be monitored for bowel obstruction, erosion, perforation, or flange migration.
- Ensure that the patient is provided with the Patient Pamphlet to guide them through the post-operative care period (See POST OPERATIVE CARE).

POTENTIAL COMPLICATIONS

Complications that can occur with this device include, but are not limited to: abcess, bowel obstruction, bowel perforation, delayed or failed incorporation of the plug, erosion, extrusion, fistula recurrence, induration, infection, inflammation, migration, and seroma formation. If any of the following conditions occur and cannot be resolved, surgical intervention should be considered:

- Abnormal bleeding
- Abscess
- Allergic reaction
- Bowel obstruction or impaction
- Bowel perforation
- Device erosion through bowel tissue
- Flange migration into the abdominal cavity
- Infection
- Inflammation

STORAGE: Store the device in a clean, dry location at a temperature that does not exceed 30°C.

STERILIZATION: This device has been sterilized with ethylene oxide.

INSTRUCTIONS FOR USE

Required Materials

- Cytology, or comparable brush
- 20 mL, sterile, luer lock syringe
- Hydration fluid: at least 40 mL of room temperature sterile saline or sterile lactated Ringer's solution
- Resorbable suture such as 2-0 polydioxanone (PDO or PDS)
- Contrast media
- Wire guides, sheaths, and instruments standard to radiological procedures

Bowel Preparation

The recommended practice for preoperative bowel preparation in elective enteric surgery includes bowel cleansing through the use of enemas and cathartic agents and administration of prophylactic enteric or intravenous antimicrobial agents. Insufficient cleansing or inadequate antibacterial prophylaxis can predispose the patient to infection. [2-4]

NOTE: A pictorial insert is included within the product box to provide illustrations of the Suggested Instructions for Use. See Part 1 of the insert for assessment and preparation of the fistula tract. See Part 2 for implantation of the Enterocutaneous Fistula Plug.

Procedure

NOTE: Handle device using aseptic technique

1. Perform under local, regional, or general anesthesia.
2. Prepare the treatment site using standard interventional techniques and instruments appropriate for enterocutaneous fistula access.
3. Use fluoroscopy to assist in the insertion and advancement of all wire guides, catheters, the plug, and associated instruments.
4. Insert a 0.035 inch or smaller wire guide into the skin-surface opening of the fistula tract. The wire guide may be introduced into the fistula through an existing drainage catheter if it is present.
5. Advance the wire guide down the fistula tract to the abscess cavity. **Do not advance the wire guide into the bowel at this time.**
6. Introduce a sideport injection sheath containing a radiopaque tip over the wire guide and advance it into the abscess cavity. **Do not advance the injection catheter into the bowel fistula opening at this time.**
7. USING SMALL "PUFFS" AT VERY LOW PRESSURE, inject a small bolus of contrast through the injection catheter into the abscess cavity to assess its size and identify any communication(s) with the bowel.

NOTE: If the abscess cavity is not sufficiently drained of abscess and contracted down to a size close to that of the catheter, or if the abscess cavity is immediately adjacent to the internal fistula opening, do not implant the plug.

8. If the fistula tract is mature and only a minimal abscess cavity exists, advance the wire guide through the bowel opening of the fistula. If the initial fistula assessment indicated a narrowed or tortuous tract communication with the bowel, a steering wire guide may be required. Advance the wire guide at least 15 cm into the bowel lumen. Use caution to avoid perforating the bowel.
9. Use the injection sheath to exchange the wire guide for a stiffer 0.035 inch (or comparable) wire guide. This may straighten the tract. Advance this wire guide at least 15 cm into the bowel lumen.
10. Advance the sideport injection sheath with radiopaque tip to the portion of fistula tract communicating with the bowel. **Do not advance the sheath into the bowel.**
11. Inject contrast at the bowel fistula opening to assess the fistula size. The opening may have been stretched to a larger size by the catheter.
12. Referencing the radiopaque sheath tip, determine the diameter of the fistula at the bowel fistula opening. Select the properly sized Enterocutaneous Fistula Plug kit according to the sizing chart below.

Fistula Plug Sizing Chart:

Fistula Diameter	Biodesign® Plug
1 - 4 mm	4 mm
>4 - 7 mm	7 mm

NOTE: The plug should not be implanted if the bowel fistula opening exceeds a diameter of 7 mm. A drainage catheter should be placed within the tract and a waiting period should ensue to allow the fistula to drain and contract (mature).

13. While removing the sheath, perform a sterile saline flush of the fistula tract to remove residual contrast. Leave the wire guide positioned at least 15 cm into the bowel lumen. Alternatively, the injection sheath can be left in place and a second wire guide can be placed along side of it. Leave this wire guide positioned at least 15 cm into the bowel lumen.
14. Insert a cytology brush or comparable instrument over the wire guide and advance it through the fistula tract. Gently move the brush back and forth starting at the bowel opening of the fistula and working back to the cutaneous opening. The entire fistula tract should be gently abraded to remove granulation tissue. Take care that fistula tract abrasion does not disrupt the bowel-to-fistula connection.

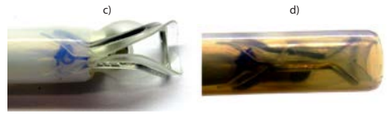
NOTE: Plug incorporation into surrounding tissue may be inhibited if granulation tissue lines the fistula tract. Abrading the tract gently may improve device incorporation and lead to a better healing response.

15. Remove the fistula brush from the tract and flush the tract with hydrogen peroxide or sterile saline to purge debris from the fistula. Tract flushing should be performed with light pressure to prevent ingress of debris into the microvasculature.
16. Dilate the tract to appropriate size to accommodate the larger 16 or 22 Fr delivery sheath.
17. Remove the plug's outer foil package and Flexor delivery system (sheath, dilator, pusher, and Molnar disk) from the box.
18. Using aseptic technique, remove the inner pouch containing the plug from the outer foil package. Place the inner pouch onto the sterile field.
19. Using sterile gloved hands, open the inner pouch and remove the tray containing the plug.
20. Remove the plug and transfer tube from the tray. The plug is contained within the transfer tube. **Do not separate.**
21. Uncoil the tether to allow the plug to be loaded into the transfer tube.
22. To prepare the plug for delivery, the self-expanding flange must first be loaded into the transfer tube. Compress the flange for loading by first tipping it 90° so that one side of the octagon flange is touching the side of the plug and the flange is aligned along the length of the plug with the suture knot on the opposite side (see image "a"). Then, wrap the flange around the body of the plug so that the flange rolls around the plug to form a tube (see image "b").

a) b)

23. Slide the transfer tube toward the rolled flange while holding the flange in a tightly wrapped configuration. Push the rolled flange into the transfer tube until a majority of the flange is contained within the transfer tube (see image "c"). Pull on the plug from the opposite end of the transfer tube to draw any exposed flange into the transfer tube (see image "d"). This will complete the flange loading process.

c) d)



24. Using aseptic technique, remove the inner pouches containing the delivery system sheath, dilatory, pusher, and Molnar disk from the Tyvek pouch. Place the inner pouches onto the sterile field.
25. Remove the Flexor sheath and dilator from their inner pouches. **Do not flush the Flexor sheath or dilator with fluids at this time. The plug contacting parts of the delivery system should remain dry for proper plug delivery.**
26. Prepare the delivery system for use by reversing the direction of the dilator in the Flexor sheath so that the tapered end of the dilator exits the delivery end of the sheath.
27. Advance the Flexor delivery system (dilator and sheath) over the wire guide through the fistula tract until the Flexor sheath tip extends approximately 1 to 2 cm into the bowel lumen.
28. Remove the wire guide and, if needed, perform a contrast injection through the dilator to confirm that the radiopaque sheath tip and dilator tip are both in the bowel. Alternatively, contrast can be injected through the injection sheath if it was left within the tract.
29. Completely remove the dilator from the delivery system sheath, while leaving the Flexor delivery sheath in place. If the injection sheath is present in the fistula tract do not remove it.
30. If bowel fluids are observed flowing into the clear chamber of the delivery sheath, connect a syringe to the side-port stopcock that is attached to this chamber and aspirate as much of the fluid as possible.
31. Locate and open the Captor valve on the end of the delivery sheath. Insert the transfer tube into the Captor valve, flange end first, and advance it into the delivery sheath until it will not advance further. Rotate the Captor valve clockwise approximately one-half turn around the transfer tube to prevent the transfer tube from backing out of the sheath.
32. Place a finger directly on the exposed back end of the plug. Push directly on the back end with a finger to advance the plug forward until it is flush with the end of the transfer tube.
33. Hold the tether to one side and insert the pusher into the transfer tube. Advance the plug out of the transfer tube and into the delivery sheath until the plug is confirmed fluoroscopically to be positioned at the tip of the sheath. **At this point stop any further advancement.**
34. Reconfirm the position of the Flexor sheath tip in the bowel lumen with fluoroscopy.
35. When the Flexor sheath tip is confirmed to be approximately 1 to 2 cm in the lumen of the bowel, continue advancing the pusher until the flange deploys into the bowel lumen. Complete expansion of the octagon frame should be observed under fluoroscopic imaging to confirm full deployment of the flange. If complete expansion is not observed, continue to advance the pusher until full deployment is observed.

NOTE: If the pusher reaches the end of its traveling length and the flange does not deploy, completely remove the pusher by pulling it from the sheath, then open the Captor valve and remove the transfer tube. Reinsert the pusher and proceed to advance it until full deployment of the flange is observed.

36. Open the Captor valve and remove the transfer tube and pusher from the delivery sheath. The tether should remain exposed out of the back of the Captor valve.
37. Completely close the Captor valve. Draw sterile saline or lactated Ringer's solution into a sterile syringe. Attach the syringe to the side port of the delivery sheath and slowly push all of the solution to flood the sheath. Grip the tether during injection to prevent possible further advancement of the plug. To achieve adequate hydration, 40 mL or more of hydration fluid may be required.
38. Release the tether, completely open the Captor valve, and carefully pull back on the Flexor delivery sheath. Completely unsheath the plug device and withdraw the Flexor delivery sheath from the tract. If the injection sheath is still present within the tract, draw it back into the tract far enough so that it does not obstruct the internal fistula opening. Do not completely remove it.
39. Grip either the tether or the exposed plug and carefully apply tension, as needed, to retract the plug's flange against the bowel wall. This will exclude the fistula from the bowel lumen. Seating of the flange against the bowel wall should be confirmed by observing a small (1 to 2 mm) out-of-plane separation in the oblique view between the radiopaque octagon frame and radiopaque marker at the tip of the plug. Do not apply more tension than is needed to seal the fistula opening.
40. When the plug is properly positioned, trim away the knot at the tip of the exposed tether and unthread the tether from the exposed end of the plug. This will separate the tether and plug at the exposed end.
41. Remove the Molnar disk from the inner pouch and place it around the exposed plug at the skin surface.
42. Hold the Molnar disk on the skin surface and temporarily secure the tether around it with tension applied to maintain the seal around the flange at the internal opening. If the injection sheath is still present within the tract, perform a contrast injection at the base of the plug to verify that the flange position is correct and that the internal opening has been sealed.
43. Wait 10 minutes after temporarily securing the tether to the Molnar disk and then confirm with fluoro that the flange has maintained the desired geometry as described in step 39. Re-apply tension, if needed, to obtain the proper flange geometry at the internal opening. If the injection sheath is still present within the tract, a contrast injection at the base of the plug may be repeated.
44. Tie the tether around the Molnar disk under tension to maintain the seal around the flange at the internal opening. Trim away and discard any loose tether. If the injection sheath is present within the tract, remove it at this time.
45. Lay the exposed plug onto the skin surface and suture the plug to the skin or to the Molnar disk at the site of the external fistula opening using a heavy gauge resorbable suture. In order to allow drainage to occur, do not sew the external opening of the fistula closed.
46. Trim away and discard any remaining portion of the plug that is not implanted within the fistula tract or contained within the Molnar disk. Discard the unused portions of the plug according to institutional guidelines for medical waste.

NOTE: The plug tension can be adjusted, as needed, postoperatively to maintain the seal around the flange at the internal opening.

IMPORTANT: The bowel fistula opening is the higher-pressure zone of the fistula, as well as the site of ingress of enteric contents into the fistula tract. The plug's flange must therefore be flush against the bowel wall to restrict ingress of intestinal contents into the fistula. The flange is designed to detach from the plug after a few weeks. This is part of the natural progress of healing the fistula tract. The flange should pass during a bowel movement or possibly during regular, physical activity.

47. If the fistula tract is longer than 18 cm and the entire plug is used to fill the tract (e.g. no part of the plug is exposed), apply the required tension to the tether and tie it around the Molnar disk on the skin surface as described in steps 42, 43 and 44. The tether is made of polydiaxanone (PDS) and will dissolve over time.

NOTE: To allow drainage of the fistula tract, place a sterile gauze between the skin and Molnar disk, and do not close the cutaneous opening when suturing the plug in place. Complete obstruction of the cutaneous opening may result in accumulation of fluid, infection, abscess and/or failure to close the tract.

48. Clean the area of skin around the fistula plug and apply a dry sterile dressing.

POST OPERATIVE CARE

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

1. Patients should refrain from strenuous physical activity beyond a gentle walk for at least 6 weeks after procedure.
2. Patients should not lift items weighing over 10 pounds for at least 6 weeks after procedure.
3. Patients should use stool softeners for 3 weeks after the procedure.
4. The patient's dietary restrictions after the procedure should include a liquid diet for the first 48 hours, followed by a high fiber diet.
5. Patients should expect some drainage for up to 16 weeks after the procedure.
6. Patients should use over-the-counter pain medicine as needed.
7. The use of an abdominal binder after the procedure is recommended.
8. MRI conditionality/safety (See section on MRI information)

Failure to counsel patients on the information above may result in additional patient exposure to potential risks. These may include but are not limited to early release of the flange, plug migration out of the fistula, fluid accumulation, infection, abscess, and failure of the fistula to heal.

MRI INFORMATION

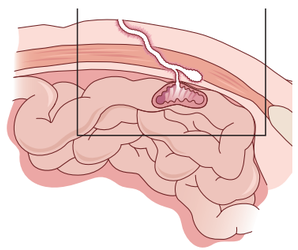
A patient with the Cook Biotech Biodesign Enterocutaneous Fistula Plug may be safely scanned under the following conditions.[5] Failure to follow these conditions may result in injury to the patient.

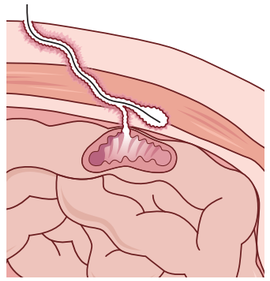
Name/identification of device	Biodesign Enterocutaneous Fistula Plug
Nominal values of static magnetic field (T)	1.5 T and 3.0 T
Maximum spatial field gradient (T/m) and (Gauss/cm)	7.2 T/m (720 Gauss/cm)
RF excitation	Circularly polarized (CP)
RF transmit coil type	Whole body transmit coil; Head RF transmit-receive coil
Maximum whole body SAR (W/kg)	2.0 W/kg (Normal Operating Mode)
Limits on scan duration	2.0 W/kg whole body average SAR for 15 minutes of continuous RF (a sequence or back to back series/scan without breaks)
MR image artifact	The presence of this implant may produce an image artifact of 29 mm.
If information about a specific parameter is not included, there are no conditions associated with that parameter.	

References

1. Kaufman C, Adkison G, Smith T, Jenkins L, Cizman Z. Single institution outcome of minimally invasive enterocutaneous fistula management utilizing the Biodesign® fistula plug. *Cardiovasc Intervent Radiol.* 2022;45(6):846-851.
2. 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):609-619.
3. 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.
4. 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.
5. Data on File, Cook Biotech Incorporated.

⚠ Part 1





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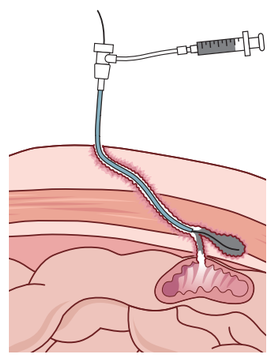

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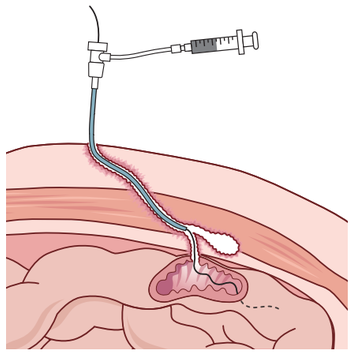

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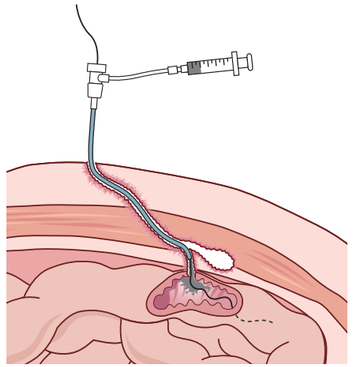

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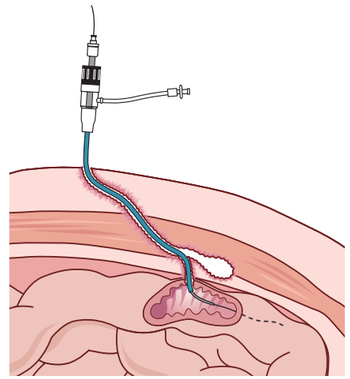

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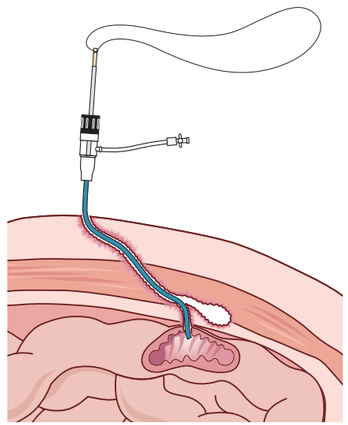

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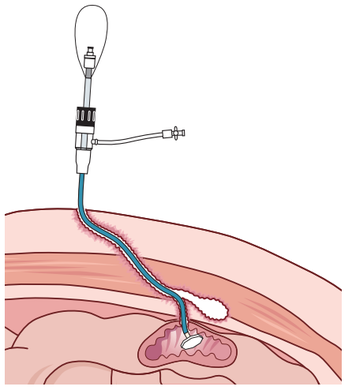

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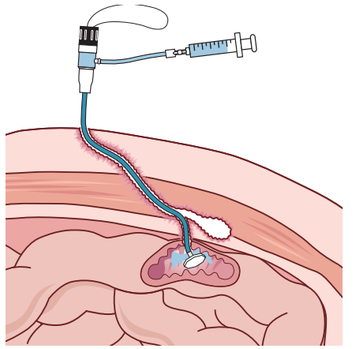

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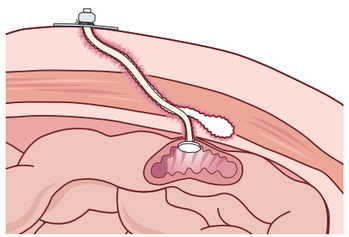

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