A Patient's Guide

Enterocutaneous Fistula Causes, Symptoms & Treatment Options

Remember, your physician is always the best source of information.

Patient Guide Overview

In this guide, you will learn what causes enterocutaneous fistulas to form. You will also learn how to recognize symptoms of this type of fistula. Finally, the guide will introduce you to an advanced new treatment option.

For your convenience, a medical glossary has been included to help you better understand the terms used throughout this guide. Whenever a term appears in bold font, it can be found in the medical glossary.

Physician Contact Information

Physician Name: _____

Procedure Date: _____

If you have any questions regarding your condition or this procedure, please contact:

Contact Name: _____

Contact Number: _____

E-mail Address: _____

Hospital: _____

Causes

What is an enterocutaneous fistula (ECF)?

A fistula is a small tunnel or tract that creates an abnormal opening in the body. Fistulas can occur at different places in the body. When a fistula occurs between the small or large bowel and the surface of the skin, commonly near the abdomen, it is called an enterocutaneous fistula (ECF).

These tracts allow enteric contents to leak through to the skin, which may lead to multiple problems discussed on page 5 in the "Symptoms" section of this patient guide. ECFs with less leakage may be better suited for repair options.[1] Your doctor can measure your output level.

What causes an ECF?

ECFs may be a result of abdominal surgeries such as laparoscopic procedures. At times, small accidental cuts are made in the intestines during surgery, and this allows contents to leak through and form an ECF.[2]

ECFs may also be caused by certain types of diseases, such as cancer (or radiation therapy associated with treatment), inflammatory bowel disease (IBD), Crohn's disease and diverticulitis. In some circumstances these diseases may irritate the bowel enough to create an ECF.

[1] Chang P, Chun JT, Bell JL. Complex enterocutaneous fistula: closure with rectus abdominis muscle flap. South Med J. 2000;93(6):599-602.

[2] Kate V. Enterocutaneous fistula. Medscape Reference Web site. http://emedicine.medscape.com/article/1372132-overview. Updated December 19, 2011. Accessed March 6, 2012.

Symptoms

What are the symptoms of an ECF?

Depending on the location of the ECF, fluid imbalances and lack of nourishment can occur. Sepsis is another concern because germs can cause infections in the exposed area.

Additionally, ongoing abdominal pain, tenderness, swelling, and leakage of bowel contents from the drain site and the main wound after surgery are symptoms of ECFs. Fever, vomiting, constipation and an abnormally rapid heartbeat are also associated with this condition.[3]

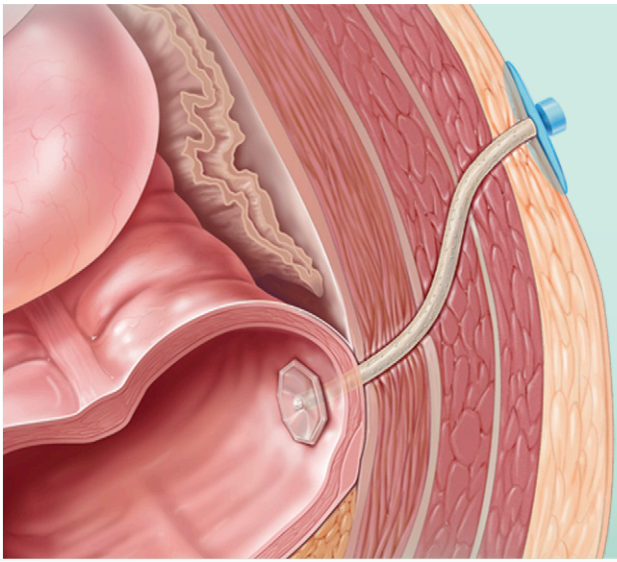
[3] Howson A. Enterocutaneous fistula. Beth Israel Deaconess Medical Center Web site. http://www.bidmc.org/YourHealth/ConditionsAZ.aspx? ChunkID=577660. Reviewed December 2011. Accessed March 6, 2012.

Diagnosis and Treatment Options

How is an ECF diagnosed?

Your physician may be able to diagnose an ECF by physically examining the affected area. Typically, ECFs can be diagnosed by several different types of physicians including gastroenterologists, colorectal surgeons and general surgeons.

It may also be necessary to conduct laboratory tests or imaging scans for proper diagnosis. Gastroenteric contrast studies, fistulography, ultrasonography and computed tomography (CT) are some of the possible imaging tools used for diagnosis.



How is an ECF treated?

Your doctor will likely start you on antibiotics while also providing fluids and nutritional support. Some ECFs will close by themselves. Although antibiotics are sometimes effective, persistent ECFs may require a more aggressive approach. Some aggressive approaches, such as certain types of surgery, can be very complex. They often require removal of part of the intestine.

Biodesign® enterocutaneous fistula plug

The Biodesign enterocutaneous fistula plug is an advanced tissue repair technology that is completely remodeled by the body.

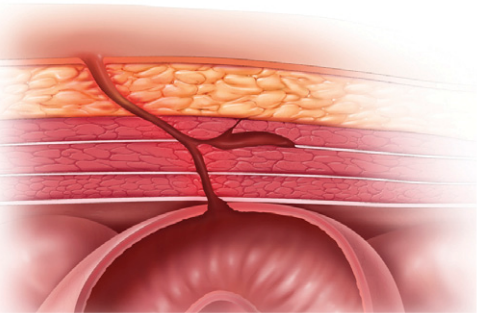
The plug is inserted during a minimally invasive procedure as an alternative to surgery.

Once the enterocutaneous fistula plug is in place, the nearby tissue grows across it, closing the ECF tract.

Ideally, the plug should remodel into strong, fully vascularized tissue.

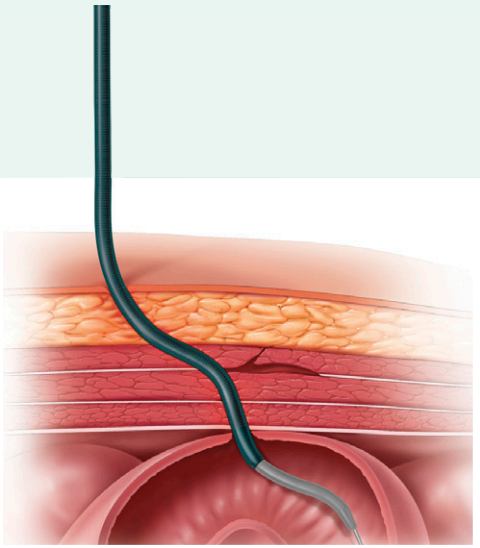
The Biodesign Enterocutaneous Fistula Plug Procedure

Once your physician diagnoses an ECF and the decision is made to treat the ECF with the Biodesign enterocutaneous fistula plug, you will be referred to an interventional radiologist for placement of the plug. The placement is a minimally invasive procedure that will be explained by your physician ahead of time and generally follows four simple steps:



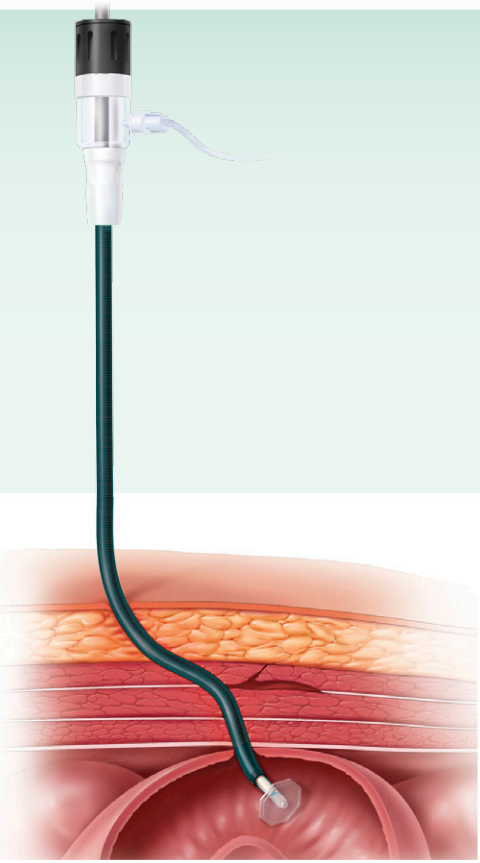
Step 1

Guided by imaging devices, the doctor locates the inside opening of the fistula.



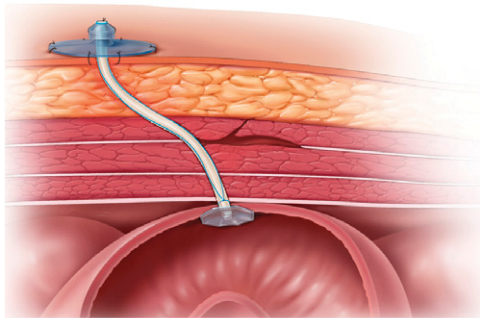
Step 2

The outer sheath is introduced into the fistula tract and guided to the position where the plug needs to be placed.



Step 3

Once the sheath is in the proper location, the enterocutaneous fistula plug is introduced through the sheath and into the ECF tract.



Step 4

The sheath is removed, and the plug is secured to the skin to prevent dislodgment.

Following the procedure, you will receive follow-up care as coordinated by your physician and interventional radiologist.

Biodesign Enterocutaneous Fistula Plug

How does the Biodesign enterocutaneous fistula plug work?

The body reacts to Biodesign by sending nutrients and cells to the affected area to restore the tissue. Once the remodeling process is complete, no Biodesign material is left behind. The new fully vascularized tissue holds its strength over time.

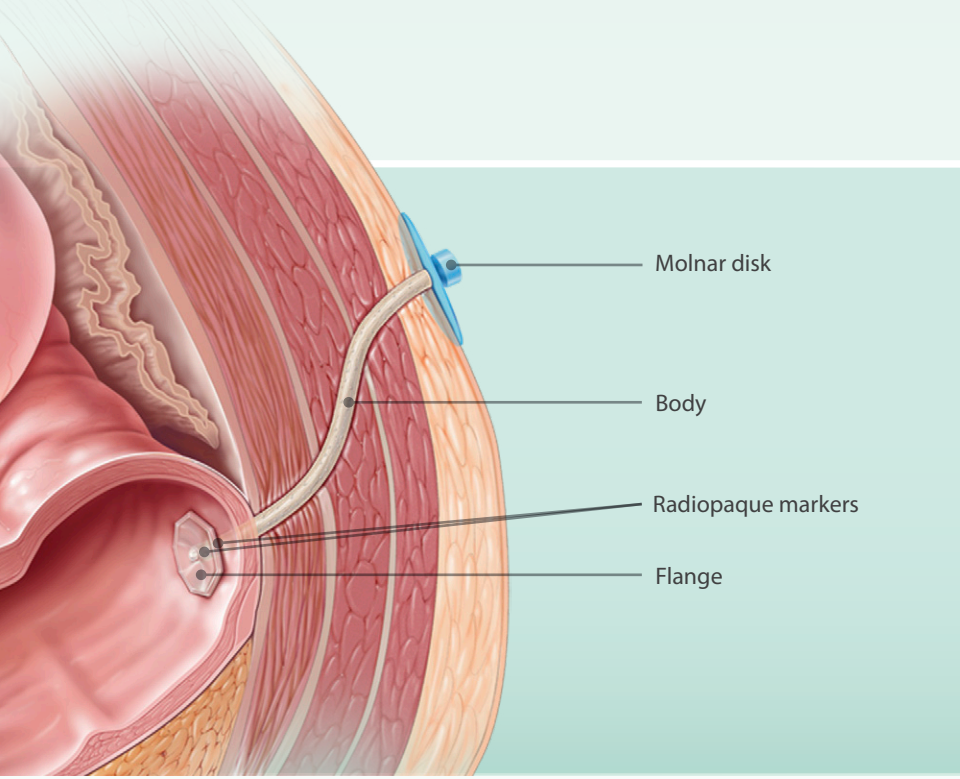
How is the Biodesign enterocutaneous fistula plug specially designed?

The Biodesign enterocutaneous fistula plug is specially designed using a porcine source. Several steps in the manufacturing of the enterocutaneous fistula plug ensure its safety as an implant. All Biodesign products are made using certified medical device manufacturing processes to ensure quality and sterility.

The Biodesign enterocutaneous fistula plug's body features a polyurethane flange with radiopaque markers attached to one end. The flange has two jobs. It is made to create a seal that helps stop enteric fluids from entering the fistula tract, and also allows the doctor to clearly see the plug under fluoroscopic x-ray.

What happens to the plug after the ECF is healed?

After a few weeks, when Biodesign has begun to be replaced by your body's own tissue, the flange is designed to detach from the unit. This is part of the natural progress of healing the ECF. The flange should pass during a bowel movement.



Fistula Repair

What care is needed before and after the procedure?

It is important for you and your doctor to discuss the appropriate care needed before and after your procedure. Your doctor will have specific recommendations for you to follow. Some of your doctor's recommendations for care may include those listed below.

- Use stool softeners for a three-week period after your procedure to ease bowel movements and reduce pressure on the fistula.
- Follow a liquid diet for the first two days after your procedure because the affected area may not immediately be ready for normal food intake.
- Begin a high-fiber diet two days after surgery. Fiber softens stool and decreases the amount of pressure in the digestive system.
- Take over-the-counter pain medicine as recommended by your physician.
- Do not lift anything over 8 lbs. for six weeks (not even a gallon of milk). Too much strain may lead to difficulties with the fistula repair.

- Avoid exercise more strenuous than a gentle walk for 6 weeks.
- Expect some drainage for 2-4 weeks. Drainage may continue for up to 16 weeks after the procedure.

Contact your physician if you have any questions or concerns.

FAQs

What happens to the Biodesign enterocutaneous fistula plug after my procedure?

Once the plug is implanted, your body's cells, tissue and blood vessels will grow into the plug material and remodel it into strong, fully vascularized tissue. If your physician used a Molnar disk to secure the plug, it should naturally detach as healing progresses.

Is there a chance that an ECF will heal on its own?

An ECF may close by itself.[3] For those that don't close, your physician may consider treatment options.

[3] Chang P, Chun JT, Bell JL. Complex enterocutaneous fistula: closure with rectus abdominis muscle flap. South Med J. 2000;93(6) 599-602.

Will the Biodesign enterocutaneous fistula plug work if I have Crohn's or other inflammatory bowel diseases (IBDs)?

There is no guarantee that the plug will result in complete closure of the fistula in any patient. However, it can be an option for patients with Crohn's, colitis or an IBD-related disease.

Are there any physicians in my area who provide the Biodesign enterocutaneous fistula plug as a treatment option?

The enterocutaneous fistula plug may or may not be available in your area. Please ask your physician to contact his or her local Cook Medical representative for further information.

Glossary

Abdomen

Part of the body between the pelvis and thorax commonly known as the stomach area.

Computed Tomography

Imaging process that uses multiple x-ray images to produce a three-dimensional image of internal organs. Also known as a CT scan.

Contrast studies

Imaging procedure in which a special liquid dye is introduced into the body during imaging (CT scan, ultrasonography, x-ray, etc.) to differentiate between different types of tissue.

Crohn's disease

Inflammatory disease of the intestines that can cause abdominal pain, diarrhea, vomiting and weight loss.

Diverticulitis

Inflammation of pouch formations in the digestive system, particularly in the large intestine.

Enteric

Of or relating to the intestines.

Enterocutaneous fistula

Formation of a fistula between the small or large bowel and the surface of the skin around the abdomen.

Fistula

A small tunnel or tract that connects one surface in the body to another.

Fistulography

X-ray imaging of a fistula after contrast has been injected.

Fluoroscopic

Of or related to x-ray imaging techniques commonly used by physicians to obtain live, moving images of the internal structures of a patient.

Gastroenteric

Of or relating to the stomach and the intestines.

Inflammatory bowel disease (IBD)

A group of inflammatory conditions of the colon and small intestine; Crohn's disease and diverticulitis are types of IBD.

Interventional radiologist

A doctor who uses image guidance methods to gain access to vessels and organs in the body and provide treatment.

Glossary

Laparoscopic

Of or relating to a visual examination of the inside of the abdomen by means of a laparoscope, a medical tool inserted through an incision in the abdominal wall.

Porcine

Of or related to pigs.

Radiopaque

Able to be seen in x-ray photographs.

Sepsis

Potentially deadly medical condition characterized by a whole-body inflammatory state and presence of a known or suspected infection.

Ultrasonography

Use of sound waves to produce images of internal organs of the body.

Vascularized

Provided with blood vessels.

AORTIC INTERVENTION

CRITICAL CARE

ENDOSCOPY

INTERVENTIONAL RADIOLOGY

LEAD MANAGEMENT

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SURGERY

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