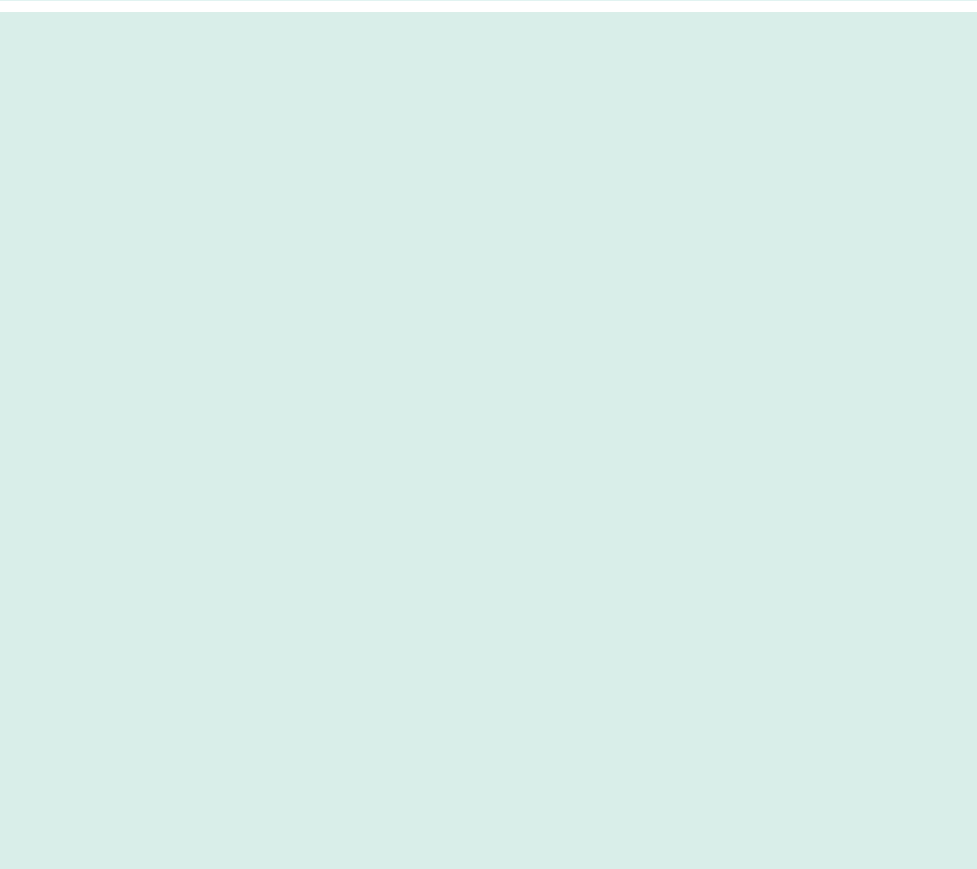


Fistula Repair



A Patient's Guide

Fistula Causes, Symptoms & Treatment Options



Patient Guide Overview

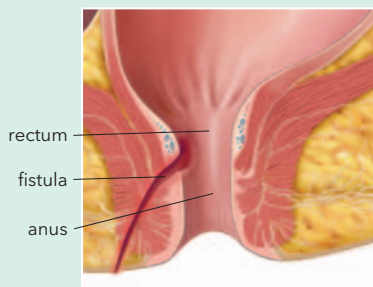
In this guide, you will learn what causes anal and recto-vaginal fistulas, and the types of patients who are susceptible to them. You will also learn how to recognize symptoms of both types of fistulas. Finally, the guide will introduce you to the available treatments, including the new, minimally invasive Surgisis® Biodesign™ fistula repair options from Cook Medical.

For your convenience, a glossary has been included to help you better understand the terms used throughout this guide. Any term that appears in boldface type can be found in the glossary.

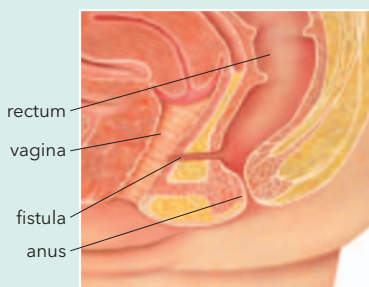
Causes

What is a fistula?

Generally speaking, a **fistula** is a small tunnel or tract that connects one surface in the body to another. Fistulas can occur at different places in the body. When one occurs between the internal **anal canal** and the exterior skin of the body near the anus, it is called an anal fistula. When one occurs between the **rectum** and the **vagina**, it is called a recto-vaginal fistula.



Anal Fistula



Recto-Vaginal Fistula

What causes an anal fistula?

An anal fistula is usually caused by an anal **abscess**, an infection-filled cavity occurring in the underlying tissues of the anal canal. When an abscess bursts or is opened, and the pus or fluid drains from it, an anal fistula is often formed. It then remains open, even after the abscess has healed.

If you have an inflammatory bowel disease (IBD)—such as diverticulitis, colitis, or Crohn’s—you are more likely to develop an anal abscess and fistula. Individuals with diseases that reduce the body’s immunity—such as AIDS or cancer—are also at a higher risk.

Does an abscess always result in an anal fistula?

Many anal abscesses do *not* result in anal fistulas. In fact, a fistula develops in only about half of all anal abscess cases.

What causes a recto-vaginal fistula?

Most recto-vaginal fistulas result from an injury to the **perineum** (the area of tissue between the vagina and the rectum) during childbirth. However, they can also be caused by radiation treatment, inflammatory bowel diseases or vaginal or rectal surgeries.

Symptoms

What are the symptoms of an anal fistula?

Ongoing pain, swelling, and tenderness are symptoms of both anal abscess and fistulas. You may also experience drainage of pus and fluid from the abscess, which can cause irritation and itching in the skin around the anus. Other symptoms include fever, chills, fatigue or weakness.

What are the symptoms of a recto-vaginal fistula?

The most common symptom of a recto-vaginal fistula is passage of bowel contents (gas and/or stool) through the vagina. You may also experience inflammation of the vagina, which results in burning, itching and discharge; or inflammation of the bladder, which causes frequent and sometimes painful urination.

Diagnosis

How is an anal fistula diagnosed?

Your physician may be able to diagnose an anal fistula by physically examining the area surrounding the anus. However, if external signs, such as an opening in the skin, are missing, then an internal exam will be necessary. An instrument called an **anoscope** is used to inspect the anal canal and rectum for indications of an abscess or other inflammation.

How is a recto-vaginal fistula diagnosed?

To diagnose a recto-vaginal fistula, the physician usually performs a physical examination of the rectum and vagina. This is often followed by an **endoscopic** examination of the rectum and the lower part of the colon using a thin, flexible tube with a light and a camera lens.

Anal Fistula Treatment Options

How is an anal fistula treated?

An anal fistula will not heal on its own. Although antibiotics may occasionally be effective, most persistent anal fistulas require a more aggressive approach. More aggressive approaches, such as surgery, seton and Endorectal Advancement Flap, can require cutting the sphincters which can cause **incontinence**.

Surgery

The most common treatment for an anal fistula is a surgical procedure called a **fistulotomy**.

In a fistulotomy, the surgeon makes an incision in the fistula tract, opening it up and merging it with the anal canal. This allows the tissues to heal from the inside out.

For very small fistulas, a fistulotomy may be performed in a doctor's office, using only local anesthesia. Larger fistulas, however, require surgery under spinal or general anesthesia, usually performed in a hospital or surgery center. Patients typically experience mild or moderate discomfort or pain following this procedure, with a recovery time of one to four weeks.

Seton

Fistulotomies work well for fistulas that are relatively close to the skin. For deeper fistulas, however, the physician may choose to use a **seton**. A seton is a piece of suture material that is passed from the external skin opening, along the fistula tract, through the internal opening in the anal canal, exiting through

the anus. The suture material is then tied in a loop, which is gradually tightened over a period of weeks. This ultimately has the same effect as a fistulotomy—to open the fistula tract and allow it to heal.

Fibrin Glue

In some cases, an anal fistula is closed by the injection of fibrin glue—a solution of the clotting factors **fibrinogen** and **thrombin**. This glue results in the formation of a clot within the fistula, which helps promote healing of the tract.

Endorectal Advancement Flap

An endorectal advancement flap is a surgical procedure typically reserved for more complex fistulas. This surgery is often more involved and invasive than the other procedures described earlier. In the operating room, the doctor uses surgical instruments to dissect and lift a portion, or flap, of the rectal wall adjacent to the internal opening. The doctor pulls the flap down over that opening and sutures it into place to close the opening, allowing the fistula to heal.

Surgisis Biodesign Anal Fistula Plug

The Surgisis Biodesign Anal Fistula Plug is a unique, minimally invasive alternative to traditional fistula surgery. It's a conical-shaped device made from an advanced tissue repair graft that communicates with your body, signaling surrounding tissue to grow across and into the plug, allowing your body to restore itself. Incontinence is unlikely, since the placement of the Anal Fistula Plug does not require cutting the sphincters.

Recto-Vaginal Fistula Treatment Options

How is a recto-vaginal fistula treated?

Often, fistulas resulting from childbirth or surgery heal on their own within a period of 6-12 weeks. Those that do not heal within this time frame, however, may require some form of repair. More aggressive approaches, such as Transanal Advancement Flap and surgery, can require cutting the sphincters which can cause incontinence.

Transanal Advancement Flap

In this approach, the doctor dissects and lifts a portion, or flap, of the rectal wall adjacent to the fistula opening. The doctor then pulls the flap down over that opening and sutures it into place to close the opening, allowing the fistula to heal. The fistula opening on the vaginal side is left open for drainage. This procedure is sometimes called a "local repair," because it is performed directly at the fistula site.

Surgery

Some fistulas that are located high in the rectum/vagina are not candidates for a local repair. In these cases a **transabdominal** repair may be chosen. The surgeon makes an incision in the abdomen to gain access to the fistula. He or she then makes an incision that divides the fistula tract. When the incision heals, the tissues grow together, eliminating the fistula.

Fibrin Glue

In some cases, a recto-vaginal fistula is closed by the injection of fibrin glue—a solution of the clotting factors **fibrinogen** and **thrombin**. This glue results in the formation of a clot within the fistula, which helps promote healing of the tract.

Surgisis Biodesign Recto-Vaginal Fistula Plug

The Surgisis Biodesign Recto-Vaginal Fistula Plug is a unique, minimally invasive alternative to traditional fistula surgery. It's a conical-shaped device made from an advanced tissue repair graft that communicates with your body, signaling surrounding tissue to grow across and into the plug, allowing your body to restore itself. Incontinence is unlikely, since the placement of the Recto-Vaginal Fistula Plug does not require cutting the sphincters.

Surgisis Biodesign Fistula Plugs

How do the Surgisis Biodesign fistula plugs work?

Surgisis Biodesign fistula plugs communicate with your body, signaling surrounding tissue to grow across and into the plug. This action supports your body's own healing process by attracting cells and nutrients to the area and allowing your tissue to restore itself. It also allows your body's immune system to protect the plug from potential infection.

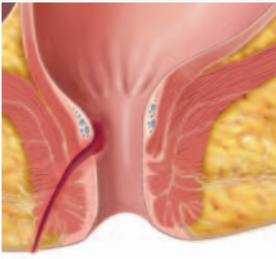
What happens to the plug after the fistula is healed?

During the healing process, the plug provides mechanical strength for tissue support while acting as a scaffold for rapid, guided tissue ingrowth. Eventually, the Surgisis Biodesign fistula plug completely remodels into strong, healthy tissue. Once the healing process is finished, the plug is completely incorporated into your own tissue, leaving a permanent repair without a permanent implant.

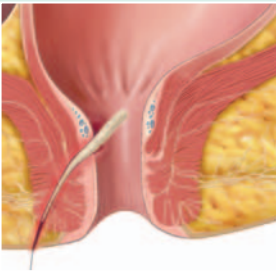
How are Surgisis Biodesign fistula plugs specially designed?

The Surgisis Biodesign fistula plugs are specially designed using an advanced tissue repair graft to treat anal and recto-vaginal fistulas. Several steps in the manufacturing of the Surgisis Biodesign fistula plugs ensure their safety as an implant. All Surgisis Biodesign material undergoes thorough cleaning and disinfection using certified medical device manufacturing procedures.

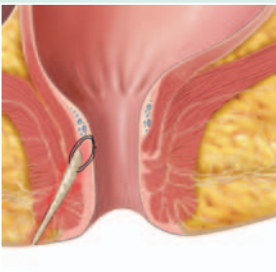
The Surgisis Biodesign Fistula Plug Procedure



- 1** The doctor locates the inside opening of the fistula using a fistula probe and irrigates the tract.



- 2** The plug is pulled into the inside opening. The doctor notes where the plug enters the primary opening and cuts the plug to size.



- 3** The inside opening is closed by suturing the top tissue layers over the plug's head. The exterior opening is not closed to allow for drainage. The tip of the plug is trimmed at skin level.

The Surgisis Biodesign Recto-Vaginal Fistula Plug Procedure



- 1** The doctor locates the opening of the fistula using a fistula probe and irrigates the tract.



- 2** The plug is pulled into the rectal opening. The doctor notes where the plug exits the fistula tract on the vaginal side and cuts the plug to size.



- 3** The rectal opening is closed by suturing the button on the end of the plug to the top tissue layers.

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 after your procedure may include those listed below.

- Maintain a liquid diet for two days after the procedure (e.g., soup, Jell-O, etc.)
- Begin eating a high-fiber diet after two days
- Use stool softeners for two weeks
- Use the bathroom at least once a day
- Take over-the-counter pain medicine as needed
- Do not use topical steroids such as Preparation H
- Do not lift anything over 10 lbs for two weeks (six weeks for Recto-Vaginal Fistula).
- Avoid any exercise more strenuous than a gentle walk for two weeks (six weeks for Recto-Vaginal Fistula).
- Abstain from sexual intercourse and other forms of vaginal/rectal insertion (i.e., tampons) for at least two weeks if you have received the Anal Fistula Plug and for six weeks if you have received the Recto-Vaginal Fistula Plug.
- Shower standing up and bathe the area with water to soothe and keep it clean.
- Expect some drainage for two to four weeks. Drainage can continue for up to 12 weeks after the procedure as the plug is incorporated and the fistula tract is closed.

FAQs

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

Once the plug is implanted, your body's cells, tissues and blood vessels will grow into it. Eventually, the plug will be incorporated into your body and completely replaced by your own tissue.

Is there a risk of incontinence after my procedure?

Incontinence is typically caused by surgeries that damage the sphincter muscles. Since the placement of a Surgisis Biodesign fistula plug does not require cutting the sphincters, incontinence would be unlikely.

What happens if the plug falls out?

If the Surgisis Biodesign fistula plug falls out, it simply means that the suture holding it in place has broken or dissolved. You will need to return to your physician and discuss the situation. He or she may decide to put another Surgisis Biodesign fistula plug in place.

How long will drainage continue after my procedure?

It is not uncommon to have some drainage for two to four weeks after the fistula plug has been placed. Drainage may even continue for up to 12 weeks as the plug incorporates and the fistula tract heals.

Will my fistula heal on its own?

Anal and recto-vaginal fistulas rarely heal on their own. Getting them to close will require some type of treatment.

Will the Surgisis Biodesign fistula plug work if I have Crohn's, colitis or other IBD-related diseases?

There is no 100% guarantee that the plug will work in any patient. However, clinical experience to date indicates that it can be an effective option for patients with Crohn's, colitis or an IBD-related disease.

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

The Surgisis Biodesign fistula plugs are approved for use in North and South America and in Europe.

Glossary

Abscess

A localized collection of pus in part of the body.

Anal canal

The final portion of the digestive tract, ending in the anal opening.

Anoscope

A small viewing scope used to examine the anal canal and lower rectum.

Endoscopic

Procedure in which the inside of the body is viewed through an instrument called an endoscope.

Fibrinogen

A protein found in blood plasma that is essential in the clotting process.

Fistula

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

Incontinence

The loss of voluntary control over the sphincters permitting involuntary passage of feces and gas.

Perineum

The area of tissue between the vagina and the rectum.

Fistulotomy

An incision of a fistula.

Rectum

The lowest 6-8 inches of the large intestine, ending in the anal opening.

Recto-vaginal septum

A layer of tissue that separates the vagina and the lower part of the rectum.

Seton

A piece of suture material that is threaded through the anal fistula and gradually tightened to open the fistula tract.

Thrombin

A protein found in blood that facilitates clotting.

Transabdominal

Across or through the wall of the abdomen.



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