What you should know about anal fistulas.
<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>You’ve been diagnosed with an anal fistula</td>
<td>3</td>
</tr>
<tr>
<td>What is an anal fistula?</td>
<td>4</td>
</tr>
<tr>
<td>What are your treatment options?</td>
<td>8</td>
</tr>
<tr>
<td>What happens next?</td>
<td>12</td>
</tr>
<tr>
<td>Helpful resources</td>
<td>18</td>
</tr>
</tbody>
</table>
You’ve been diagnosed with an anal fistula.

Now what?

Chances are, if you have been diagnosed with an anal fistula, you have been experiencing considerable pain, discomfort and possibly even discharge. It is only natural to be concerned about your condition.

However, making informed decisions — and having realistic expectations about what lies ahead — are the best ways to overcome your anxiety and fear.

This brochure was created to help provide the information you’ll need in the days and weeks ahead. We hope that you will read it — and share it with family members and friends.

Remember, a proper clinical diagnosis is key. Now that you know the cause of your discomfort, you and your physician can calmly discuss the specifics of your case, as well as the treatment he or she recommends.

By consulting with your physician, you have already taken the important first steps toward treatment and recovery.
What is an anal fistula?

• Definition
• Five types of anal fistulas
• What causes an anal fistula?
• What are the symptoms?
• Will it heal by itself?
**Definition**

An anal fistula is an abnormal connection between two organs or vessels that normally do not connect. In most cases, anal fistulas develop after an abscess in an otherwise healthy patient.

An anal fistula represents the chronic stage of an anorectal abscess in the area around the genitals and the anus. When a portion of the abscess cavity and drainage tract persists, an anal fistula is created. This abnormal passageway starts at the primary (internal) opening in the anorectum and continues to the secondary (external) opening in perianal skin.

Think of an anal fistula as a small tunnel that connects a previously infected anal gland to the skin on the buttocks on the outside of the anus.

Anal fistulas may also be associated with Crohn’s disease, trauma, malignant disease, human immunodeficiency virus infection or radiation therapy.
Types of anal fistulas

The following classifications of anal fistulas describe the location and amount of sphincter muscle involved.

**Intersphincteric fistulas** – are generally confined to the internal sphincter and may extend downward to the perianal skin, extend in an upwards (blind) tract or open into the rectum.

**Transsphincteric fistulas** – are known to pass through the internal and external sphincter into the area between the anal canal and perianal skin.

**Suprasphincteric fistulas** – are known to cross the internal sphincter and pass upward around the external sphincter above the puborectalis muscle. The anal fistula then tracts downward into the ischioanal fossa and out to the skin.

**Extrasphincteric fistulas** – while this type represents only two percent of all anal fistulas, it is also among the most challenging to treat. Although this fistulous tract bypasses the anal canal and sphincter, it passes through the ischiorectal fossa and levator ani muscle and exits into the rectum.

**Superficial fistulas** – do not cross the internal or external sphincters. These anal fistulas may be due to Crohn’s disease or anorectal procedures that include hemorrhoidectomies or sphincterotomies.
What causes an anal fistula?

Anal fistula (fistula-in-ano) is usually caused by a previous anorectal abscess, characterized by chronic drainage of pus or stool from an opening in the skin. Other causes include Crohn’s disease, inflammatory bowel disease, cancer, diverticular disease, radiotherapy, tuberculosis, other infections or trauma.

What are the symptoms?

Typical symptoms include ongoing pain and discomfort, tenderness, abscesses and drainage of pus or blood.

Will it heal by itself?

Rarely does an anal fistula heal by itself. Occasionally, antibiotics are effective in treating anal fistulas: however, most anal fistulas require more aggressive procedures.

In the next section of this brochure, we will take a closer look at the ways in which anal fistulas can be repaired.
What are your treatment options?

• The GORE® BIO-A® Fistula Plug
• Advancement flap
• Seton
• Fistulotomy
• LIFT technique
• Protein-based fibrin glue
Endorectal / endoanal advancement flap

This procedure involves cleaning / debridement of the anal fistula tract, mobilization of a well-vascularized rectal mucosal or anodermal flap, and covering of the internal opening of the tract with or without closure of the tract. With this procedure, incontinence can be as high as 35%*.

GORE® BIO-A® Fistula Plug

The GORE® BIO-A® Fistula Plug is designed to provide a less invasive approach compared to surgery. It is designed to minimize the disadvantages associated with other sphincter preserving approaches, such as extrusions that could lead to non-healing.

The GORE® BIO-A® Fistula Plug is engineered to conform to the tract and reduce the potential for failure due to fall-out.

Its scaffold facilitates new tissue generation to fill the anal fistula tract completely, while the versatility of its disk-and-tubes design allows tailoring of the device to the particular size, shape, and dimensions of the anal fistula.
For patients with an infected anal fistula, a loose seton is typically used — especially for those who are scheduled for an anal fistula plug implant. In such cases, the seton is placed as a drain to control infection and inflammation. A loose seton alone may heal an anal fistula, though this is rare.

**Seton placement**

The entire anal fistula tract from the internal to the external opening is laid open. Fistulotomies remain the standard approach for simple anal fistulas, which can be treated with minimal risk to continence. For high transsphincteric or other complex anal fistulas, there may be risk of incontinence due to the cutting of the sphincter muscles.

**Fistulotomy**

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Ligation of intersphincteric fistula tract (LIFT)

The LIFT procedure begins with a small incision below where the anal fistula tract crosses from the internal to the external sphincter. The space is opened and the tract is identified and ligated with suture. Although the LIFT procedure is sphincter sparing, it can involve significant tissue dissection.

Fibrin glue

Fibrin glue is a soluble mixture which is injected into an anal fistula tract to seal the tract as the glue sets. Some advantages of fibrin glue are that it is simple, relatively inexpensive and noninvasive, which allows earlier return to normal activity compared with surgery.

However, fibrin glue does not preclude subsequent use of another procedure to address a recurrent anal fistula. While fibrin glue therapy has not been reported to affect the patient’s level of continence, many studies have found that fibrin glue has a low rate of success in healing anal fistulas.*
What happens next?

• Pre-procedure
• Procedure using the GORE® BIO-A® Fistula Plug
• Post-procedure
• Understanding the healing process: managing your expectations
• Can this happen to you again?
• Will your lifestyle change?
Pre-procedure

How do you prepare?
Your physician will review the next steps to prepare you for your operation. If you smoke you will be asked to stop, as smoking increases your risk of infection which could impede your recovery. To help empty your bowels, you may be asked to take laxatives and fiber supplements a few days before your operation. In addition, you will be asked to follow fasting instructions. Typically you must not eat or drink for about six hours before a general anesthetic is administered.

Does this procedure require anesthesia?
In some cases, anal fistula surgery requires general anesthesia, which means that you will be asleep during the procedure. Upon arrival, a nurse will check your heart rate and blood pressure, and test your urine. An enema may be necessary.

Will I need to sign a consent?
Your physician will most likely ask you to sign a consent form to confirm that you fully understand any risks, benefits and possible alternatives to the procedure and have given your permission to go forward with the procedure.

Procedure using the GORE® BIO-A® Fistula Plug

This procedure involves plugging the anal fistula with a device — in this case, the GORE® BIO-A® Fistula Plug.

The anal fistula plug is fixed into position from the inside of the anus. The GORE® BIO-A® Fistula Plug is gradually absorbed by the body.

How long will the procedure last?
Implanting the GORE® BIO-A® Fistula Plug takes approximately fifteen minutes. The entire procedure may take anywhere from one to two hours, depending upon preparation and recovery.

How long before I can go home?
While procedures will vary, many may be performed on an outpatient basis. If your procedure is being performed as outpatient, be sure to make arrangements for someone to drive you home from the outpatient clinic or the hospital. You won’t feel up to driving a car right after your surgery.
Post-procedure

What happens after surgery?

Your physician will provide you with a specific post-operative treatment routine which may include laxatives, stool softeners and pain medication. You may also want to discuss sitz baths as an option.

Will I need to rest?

It is always recommended that you rest until the effects of the anesthetic have worn off. It is not uncommon to need pain relief to ease any discomfort as the anesthetic wears off. You can begin drinking clear fluids when you feel you are ready.

Will my diet change?

Eat a regular diet with lots of fruits and vegetables. Avoid spicy foods and excess alcohol. Drink at least eight glasses of water each day.

Will I continue to have regular bowel movements?

You should have one to two bulky bowel movements per day, beginning on the day after your operation. To accomplish this, your physician may have you take a fiber supplement. If you do not have a bowel movement one day, take two stool softening tablets that night. Also, take prescription pain medications and other medications, if prescribed, as directed on the label.

Will my physical activity be restricted?

You should significantly restrict your physical activity for the first two weeks following your operation as too much activity may result in failure of the operation. That means no heavy lifting, no sports, no lengthy auto rides, no anoreceptive sex. Walking and climbing stairs is permitted.
When will my sutures be removed?

Suture material used in rectal surgery is of the dissolving kind; therefore, it does not require removal. It is normal to continue to have drainage from the anal fistula site on your buttocks for several weeks after the operation. Wear a pad or gauze to keep your undergarments clean.

How long will the healing process take?

Follow-up visits with your physician are essential for good results. You will need to be seen at various intervals during your recovery, based on your individual progress.
Understanding the healing process: managing your expectations

What if I notice drainage or bleeding?

- Drainage may occur following anal fistula surgery. While not everyone will experience drainage, it is normal and should not be cause for alarm. As the anal fistula heals, the drainage you may have experienced initially should begin to subside.

- Some bleeding may also be visible after surgery. This is typically a result of the surgery itself and not a part of the healing process.

Will I experience pain?

- Pain following any rectal surgery is to be expected; however, the pain should subside progressively in the weeks following your operation. You may need to take pain medications at set intervals for the first week to two. Keep in mind that pain medications work best when they are taken before pain levels build.

Use this chart to monitor your pain and drainage during the healing process

Helpful Hints: track the dates and levels of pain and drainage and share these results with your surgeon at each follow-up appointment.

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<thead>
<tr>
<th></th>
<th>MONTH 1</th>
<th>MONTH 2</th>
<th>MONTH 3</th>
<th>MONTH 4</th>
<th>MONTH 5</th>
<th>MONTH 6</th>
</tr>
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<tbody>
<tr>
<td>Pain</td>
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<tr>
<td>None</td>
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<td>Light to moderate</td>
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<td>Intense</td>
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<tr>
<td>Drainage</td>
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<tr>
<td>None</td>
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<tr>
<td>Light spotting</td>
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<td>Persistent</td>
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Can this happen to me again?

Unfortunately, no procedure guarantees that the anal fistula will not recur. For that reason, an anal fistula must be taken seriously and dealt with expeditiously. Special care must be taken to minimize the risk of infection in the future.

Further consultation with your physician can also help to address the likeliness of an anal fistula return.

Will my lifestyle change?

With the approval of your physician, after the initial four to six-week recovery period, you should be able to resume your regular activities and return to a normal lifestyle.

Speak with your doctor before returning to work or returning to any strenuous activities including exercise, sexual activities and lifting.

Any surgery should be treated with a measure of caution and awareness. While each person is different, it is likely that most – if not all – of your pre-surgery activities can resume. Once again, your physician will be your best resource for guidance.

Is there a risk of incontinence or other complications after the procedure?

As with any procedure, there is a risk of post-procedural complications. With most anal fistula procedures, you should expect some pain, minor discomfort, bleeding and possible scarring. The possibility of incontinence occurs when there is surgical damage to the sphincter muscles. Not all procedures involve these potential risks.

Complications that have been known to occur as a result of an anal fistula procedure include difficulty passing urine, involuntarily passing wind, loose stool and bowel incontinence. Be sure to follow up with your physician, as he or she will determine the best procedure for you, based on the specifics of your case.
Helpful resources

- Glossary
- Appointments
- Notes
Fistula Glossary of Terms

Abscess
A localized collection of pus and fluid that forms in the body.

Advancement Flap
An advancement flap is a piece of native tissue that is removed from your rectum or from the skin around the anus, used to facilitate anal fistula repair.

Anal Canal
The end of the anal tract (anal opening), the final portion of the digestive tract.

Anal Fistula
A small, unnatural tunnel or tract that connects one surface in the body to another.

Anal Fistula Plug
A device engineered to facilitate the operative success of sphincter-preserving anal fistula repairs.

Anoscope
A small medical scope utilized to examine the anal canal, sphincter and lower rectum.

Endoscope
A medical examination instrument used to view the intestinal system within the body.

Endoscopic
The terminology used to define a procedure in which the intestinal system is viewed through an endoscope.

Fibrogen
A highly important protein found in blood plasma, essential to the clotting process.

Incontinence
Loss of voluntary control over the sphincter muscles that can result in the involuntary passage of feces and gas.

Fistulectomy
A surgical procedure to treat an anal fistula by surgical removal.

Fistulotomy
An anal fistula repair procedure requiring the incision (or laying open) of an anal fistula.

Rectum
The final six to eight inches of the large intestine which leads to the anal opening.

Seton
A piece of material placed within the anal fistula, used to either facilitate drainage or to cut the anal fistula tract as a definitive procedure.

Thrombin
A common blood protein, known to facilitate clotting.
Appointments

Keep your appointments – they’re important!

To give yourself the best possible outcome on the path to healing and recovery, please take your pre and post-operative appointments seriously.

Your next appointment is on: _________________________________
At: __________________________ o’clock
With: ______________________________
Located at: ______________________________
Instructions: ______________________________

Your next appointment is on: _________________________________
At: __________________________ o’clock
With: ______________________________
Located at: ______________________________
Instructions: ______________________________

Your next appointment is on: _________________________________
At: __________________________ o’clock
With: ______________________________
Located at: ______________________________
Instructions: ______________________________
For more information, please visit goremedical.com/fistulaplug
or scan this QR Code with your iPhone®, DROID® and most
BLACKBERRY® Smartphones and follow the prompts.
Refer to the Instructions for Use for a complete description of all warnings, precautions, and contraindications.

Products listed may not be available in all markets. *Data on file.

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