

Acticon®

Neosphincter

Information Guide

treatment for fecal incontinence



Getting
Back
to Life



American Medical
Systems

Introduction

If you suffer from loss of bowel control, you are not alone. Did you know that over 2% of the worldwide population and people of all ages suffer from this condition known as fecal incontinence? This condition can be emotionally and physically devastating, causing many people to drastically restrict their activities and lifestyles.

The good news is that you do not have to suffer in silence. Fecal incontinence can be effectively treated so you can return to a normal life. Since 1996, over 2,500 patients with fecal incontinence have regained bowel control by using the Acticon® Neosphincter.

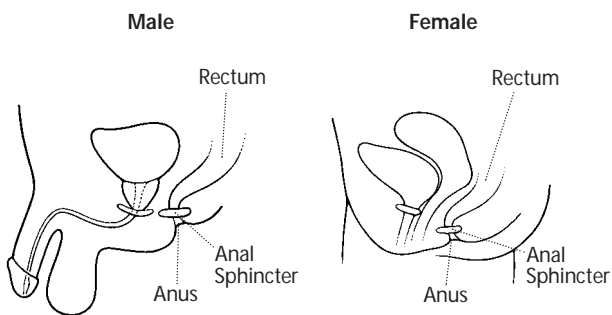
Getting an Acticon is an exciting, life-changing decision. By helping you control your incontinence, the Acticon Neosphincter can get you back to life.

What is bowel control?

We often talk about "bowel control" but, in reality, the bowel does not control the release of stool. The function of the bowel is to collect and store stool.

A circular muscle called the sphincter controls the release of stool. In men and women, this muscle wraps around the anal canal, a small tunnel between the rectum and the anus.

A healthy sphincter naturally stays tightly closed most of the time. This muscle squeezes the anal canal and prevents stool from leaking out of the bowel. When the sphincter relaxes, the anal canal opens and allows stool to be carried through the anal canal, out the rectum.



What is fecal incontinence and what causes it?

Fecal incontinence is the condition whereby you cannot control excretion of bowel contents or stool from your body. Severe fecal incontinence, defined as the accidental loss of solid or liquid stool at least weekly, is an especially debilitating problem.

Continence depends on the consistency of the stool, the ability of the rectum to hold stool, the ability of nerves to send signals when the rectum is full and the ability of the anal sphincter to hold the anal canal closed. If any of these do not function properly, incontinence may occur.

What can be done to treat fecal incontinence?

Depending on the origin of the incontinence you have, your age, and medical condition, your doctor may propose one or several treatments listed below. You and your doctor should work together to determine the best treatment option for you.

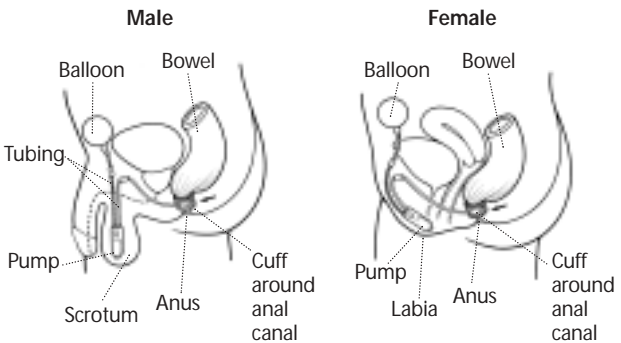
- **Change in Diet:** You may be asked to avoid certain foods that produce gas, or to increase the intake of "constipating" foods such as bananas or rice.
- **Drug Therapy:** Certain types of drugs may be effective if you have abnormal stool consistency or irritable bowel syndrome.

- **Muscle Exercises with Biofeedback:** These exercises may help to strengthen weak sphincter and perineal muscles. With biofeedback, instruments measure the strength of your sphincter contractions and give you immediate feedback about the effectiveness and strength of your muscle-conditioning exercises.
- **Sphincter Repair Procedures:** Surgery may be performed to repair physical damage of the sphincter or perineal muscles. The Sphincteroplasty is the most commonly performed surgical repair of the sphincter and provides satisfying results in most cases. However, if the extent of the anatomic defect is too great or if the origins of the incontinence are multiple, surgical repair may fail and other alternatives will be proposed to you.
- **Neosphincter Procedures:** Placement of a Neosphincter may be proposed if other conservative or surgical therapies have failed or if your doctor feels they may not offer a satisfactory result. A Neosphincter is a small implant that simulates the function of the natural sphincter muscle and, in most cases, restores bowel control.
- **Ostomy:** In several cases where other treatments haven't worked or are contraindicated, an ostomy may be performed. Part of the colon is rerouted out of the body to an opening in the lower abdomen. An ostomy does not control the flow of the stool, but simply allows outflow of waste into a collection bag worn outside the body.

What is the Acticon Neosphincter?

Acticon has been used successfully for over eight years in over 2,500 patients to provide simple and discreet bowel control. It is a small implant that is placed completely inside your body. No parts are visible once the Acticon Neosphincter is in place meaning that nobody can tell that you have this implant.

The Acticon Neosphincter is a small prosthesis placed within the body that functions like a healthy sphincter and is designed to mimic the natural process of your bowel sphincter, restoring control to bowel movements. The Acticon Neosphincter is comprised of three components: the cuff, a pump, and a small balloon. When you choose to have a bowel movement, you squeeze the pump and the cuff opens as the fluid shifts to the balloon. Afterwards the cuff refills with fluid, thus closing the anal canal.



How is the Acticon Neosphincter placed inside my body?

The Acticon Neosphincter implantation procedure typically lasts about two hours, and a general anesthetic is used. Small incisions are made to place the implant. One or two incisions are made in the perianal region to place the cuff around your anal canal. Another incision is made on the abdomen to place the balloon close to your bladder and the pump in your scrotum or labia.

What can I expect after surgery?

Your Acticon Neosphincter will not be functional or activated for six to eight weeks after the surgery to give your incisions time to heal. During this recovery time, you will continue to use pads for your incontinence.

You may feel some pain in your scrotum or labia immediately after surgery and when your Acticon Neosphincter is first activated. Some slight pain after surgery is normal and can usually be treated with oral pain medications.

After the recovery period, your doctor will activate the Acticon Neosphincter by a simple manipulation, and you will return to normal activities as soon as you feel comfortable. After that, you will be able to control your stool by squeezing the pump whenever you need to have a bowel movement.

Ask your doctor for a list of warnings, complications and precautions for an Acticon Neosphincter implant or if you have any concerns about the procedure.

What have studies shown about the effectiveness of the Acticon Neosphincter?

Since 1996, over 2,500 Acticon Neosphincter implants have been placed in men and women throughout the world. Clinical studies show that the Acticon Neosphincter is an effective treatment for severe fecal incontinence. A clinical study¹ showed that among patients who had a functioning Acticon Neosphincter in place:

- 100% were continent to solid stool
- 79% were continent to liquid stool
- 63% were continent to gas

What else can I expect?

Below are answers to some of the more frequently asked questions about the Acticon Neosphincter. Talk to your doctor about your specific medical questions.

Will anyone know that I have an Acticon Neosphincter?

Your Acticon Neosphincter is placed entirely inside your body, so no one will be able to see it. You will receive a medical identification card after your Acticon Neosphincter is placed. For this reason, we recommend that you carry this card with you to let medical personnel know that you have an Acticon Neosphincter implanted.

¹ Michot F, et al. Artificial anal sphincter in severe fecal incontinence outcome of a prospective experience in one institution. *Annals of surgery*, 2003. 237,1:52-56.

Can I ride a bicycle?

Biking is a great way to stay in shape if your doctor has given permission to participate in this activity. Check with your doctor before resuming your bike routine after surgery. Whether you use a regular or stationary bicycle, AMS recommends using a split seat.

How does having the Acticon Neosphincter affect sexual activity?

The Acticon Neosphincter should have no negative effect on sexual activity. In fact, many people report that achieving continence with the Acticon Neosphincter gives them more confidence with sexual activity. However, anal intercourse is not recommended and may damage your implant. It is a good idea for your partner to have an understanding of the device, including where the pump is located.

Can I have magnetic resonance imaging (MRI) or go through airport security?

Yes. The Acticon Neosphincter is MRI compatible, and the small amount of stainless steel in the pump will not set off airport security alarms.

How long can I expect the Acticon Neosphincter to last?

It is not possible to predict how long your Acticon Neosphincter will last. As with any biomedical device, implanted neosphincters are subject to wear and eventual malfunction over time. Surgical complications such as an infection may require additional surgery. The best way to prolong the life of your Acticon Neosphincter is to follow the precautions from your doctor and take good care of the device.

I see that the Acticon Neosphincter is partially composed of silicone. How safe is this?

The Acticon Neosphincter is composed of a number of materials, including solid silicone elastomers. These elastomers have been used in a variety of similar devices for over 40 years, and have been proven safe. Fluorosilicone, a silicone fluid, is also used as a lubricant within the cuff to reduce rubbing and wear. Silicone fluids have a long history of use in medical devices and have been proven to be safe. The Acticon Neosphincter does not contain silicone gel.

Getting back to life

You do not need to live with fecal incontinence and the limitations it causes. Join other men and women who have an Acticon Neosphincter and once again get back to life.

Glossary

Acticon® Neosphincter – a device from American Medical Systems that is used to treat fecal incontinence by mimicking the action of a healthy, natural anal sphincter

Anal canal – a canal, surrounded by the sphincter, that carries stool from the bowel out of the body

Biocompatible – harmless to the body

Bowel – a tube where stool is collected and stored

Defecation – to release stool from the bowel

Fecal Incontinence – the inability to control release of stool or gas from the bowel

Perineum – area between the scrotum or vagina and the anus

Saline – a fluid composed of salt and water

Sphincter – a circular muscle that squeezes the anal canal closed and keeps stool in the bowel

Stool – waste products from digested food carried out of the body

Solutions for Life™ American Medical Systems is a world leader in medical devices and procedures that treat incontinence, excessive menstrual bleeding, erectile dysfunction (ED), and benign prostate hyperplasia (BPH). Any one of these conditions can profoundly diminish a patient's quality of life and significantly impact relationships. Our products provide a cure or reduce the incapacitating effects of these diseases, often through minimally invasive surgery.



"Now my life is so much easier. I can go for 2-5 mile walks. I can go out to eat. I am wearing white today, which I never would have done before."

— Michelle, after receiving an Acticon® Neosphincter



"I just feel wonderful. I can go places and do shopping. I can do things for the grandkids that I haven't been able to do. I can go out to dinner with my husband. Also, I can eat things that I never ate before, and not have to run to the bathroom. I have complete control now. I am a lot happier person."

— Pam, after receiving an Acticon® Neosphincter



 American Medical Systems

American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, MN 55343 USA

U.S. Toll Free: (800) 328-3881
Phone: (952) 930-6000
Fax: (952) 930-6157

www.AmericanMedicalSystems.com