Patient Information and Instructions for the AMS Acticon™ Neosphincter

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Glossary

Anal canal – A muscular tube from the rectum to the anus that stool passes through.

Anal sphincter – A muscular portion of the anal canal that controls the flow of stool from the body.

Anesthesia – A drug or combination of drugs used to create the loss of sensation in a specific area of the body (local) or throughout the entire body (general).

Antibiotic – A drug used to prevent or treat infection.

Constipation – Constipation is difficult or incomplete removal of stool from the body.

Contraindication– Special symptoms or circumstances that increase the risks or chance of harm if you use the device.

Cuff – The cuff surrounds the anal canal and simulates the function of the anal sphincter.

Deactivation button – This small button can be felt on the upper, hard part of the pump. It is used to "turn off" the device.

Defecation – The discharge of stool from the rectum and out through the anus.

Edema - Edema is when the tissue next to any part of the device is swollen.

Erosion – Erosion is when the tissue next to any part of the device is "worn away."

Fecal impaction – Fecal impaction occurs when a large mass of hardened stool collects in the colon or anal canal and cannot be passed from the body.

Infection – Infection can happen with any surgery. It occurs when bacteria or viruses enter the body through the incisions. It can happen during surgery or after surgery when the wound is healing.

Labia (singular - **labium)** – The two folds of skin on either side of the vaginal opening.

Migration – Migration is the movement of the cuff, pump, or pressure-regulating balloon within the body space away from where they were originally placed.

Ostomy – A surgically constructed opening in the abdominal wall that permits the passage of stool from the intestines to the outside of the body.

Pressure-regulating balloon – The balloon is implanted in the space next to the bladder.

Prosthesis – A device that replaces or mimics performance of a natural body part or function.

Proximal – A medical term that means "nearest to the point of origin". For example, the proximal portion of the leg is near the hip joint, where it "originates" in the body.

Pump – The pump lies in the scrotum or labium and can be felt through the skin. The lower part of the pump is soft and squeezable. The upper part of the pump is hard and contains the deactivation button.

Revision - A surgery to reposition, replace or remove your implant.

Scrotum – The sack of skin below the penis that contains the testes.

Solid silicone elastomers – A rubber-like material used to make the device. Solid silicone elastomers have been extensively tested for use in the human body.

Stoma – Often used interchangeably with ostomy. A stoma refers to the end of the large or small bowel that can be seen protruding through the abdominal wall.

Surgical revision – see **Revision**

Fecal incontinence

Fecal incontinence is the inability to control your bowel movements. It is a medical condition that can occur when some underlying cause, such as a disease, accident, or injury, affects the normal functioning of the **anal sphincter** muscles. Normally, when the **anal sphincter** and pelvic floor muscles relax, the rectal muscles and lower bowel begin to contract slowly and rhythmically. This movement pushes the stool through the intestines and out through the anus. If nerves around the **anal sphincter** are impaired or if the **anal sphincter** is damaged, you can lose control of your bowel movements. Fecal incontinence occurs in different degrees. **Severe fecal incontinence** occurs when loss of control leads to one or more episodes of incontinence a week.

Indication for use

The Acticon Neosphincter is an implantable device used to treat **severe fecal incontinence** in men and women eighteen years and older who have failed, or are not candidates for, less invasive forms of restorative therapy.

Contraindications

1. This device is **contraindicated** in patients whom the physician determines to be poor candidates for surgical procedures and/or **anesthesia** due to physical or mental conditions.

2. This device is **contraindicated** in patients with fecal incontinence complicated by some types of permanent bowel blockages.

3. This device is contraindicated in patients with an active infection.

Ask your doctor if you have questions about the indication and contraindications for the device.

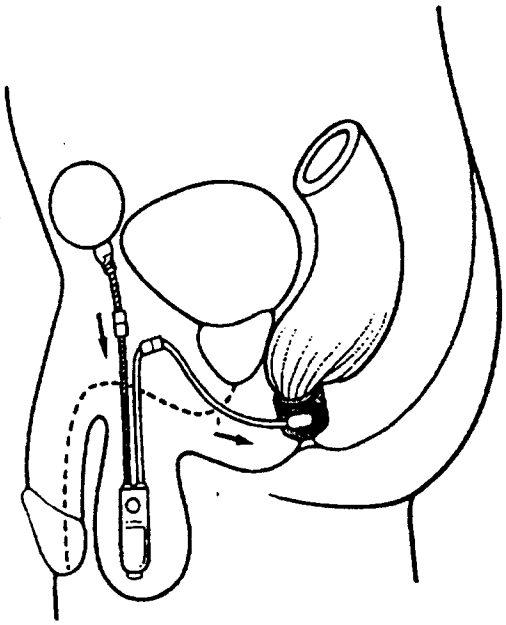
* Note: Boldface words are defined in the glossary at the front of this booklet.

Description of the AMS Acticon™ Neosphincter

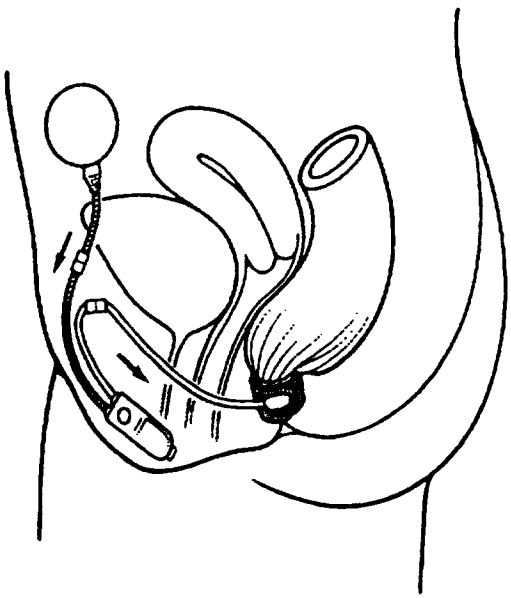
The AMS Acticon Neosphincter is a small fluid-filled device (**prosthesis**) that is implanted entirely within the body. The device is used in men or women who have **severe fecal incontinence**. It is designed to restore the natural process of bowel control. The device simulates normal **sphincter** function by opening and closing the **anal canal** at the control of the patient. This device is made from **solid silicone elastomer,** and it consists of three parts connected by tubing: a **cuff,** a **pump,** and a **pressure-regulating balloon.**

Location of the device in your body

The **cuff** is implanted around the **anal canal.** The **pump** is placed in the



Male



Female

labium or **scrotum**. The soft and rounded lower part of the **pump** is the deflation site, which is squeezed to **defecate**. The hard and rectangular shaped upper part of the **pump** is the deactivation site.

The **pressure-regulating balloon** is implanted in the lower abdomen, under the muscle layer, and is filled with sterile saline solution or a sterile solution that will be visible when x-rayed.

How the device works

The **cuff** is filled with fluid and when it is closed it gently squeezes shut the **anal canal**. To have a bowel movement (defecate), you open the **cuff** by squeezing and releasing the lower, soft part of the **pump** several times. This moves fluid out of the **cuff** and into the **balloon**. Because the empty **cuff** no longer squeezes the **anal canal**, stool can now pass through the **anal canal** and out of your body. Pressure created by the **balloon** automatically pushes fluid back into the **cuff**. It takes several minutes for the cuff to refill. When the **cuff** has refilled, it once again gently squeezes shut the **anal canal**.

General warnings and cautions

Solid silicone elastomer safety

The AMS Acticon Neosphincter is made of **solid silicone elastomer** (a type of rubber). The AMS Acticon Neosphincter does not contain silicone gels. Silicone elastomers have been commonly used in many different types of biomedical devices for over 40 years.

Solid silicone elastomers also are used for comparison when a new material is being considered for use in a biomedical device. The new material is tested to see if it causes as few problems in living tissue as silicone elastomers.

Scientific literature has included reports of adverse events in some patients with implantable silicone devices. These adverse events indicate allergic-like reactions or autoimmune-like symptoms. In an autoimmune reaction, the body's own immune cells may attack some or many of the body's own tissues by mistake. Even though these reactions or symptoms were seen in some patients, there has been no conclusive data that the silicone elastomer caused

them. No autoimmune-like symptoms have been reported in the literature for patients with Acticon Neosphincters.

Silicone elastomer may sometimes lose tiny particles off its surface after it has been implanted. Sometimes these particles move to lymph nodes in other parts of the body where the particles then stay. (Your lymph nodes are a normal part of your body's defense system against **infection**.) Medical journals, however, have indicated that particle migration has not resulted in any adverse effects to a patient's health [1,2].

Fluorosilicone (a silicone fluid) is used as a lubricant in the device to reduce wear in the **cuff**. Silicone fluids have a large history of use in medical devices, such as lubricating hypodermic syringes.

Device replacement

It is not possible to predict how long an implanted neosphincter will work in a particular patient. As with any biomedical device, implanted neosphincters are subject to wear and eventual malfunction over time. Therefore, do not consider your device a lifetime implant. Your implant surgery may not be as successful as you would like. For example, the device may fail to work or you may have a surgical complication. Carefully review the section, **Problems that may develop** (pages 15-20) so you understand possible outcomes from your implant surgery. Discuss with your doctor any questions you have about problems that may develop after your implant surgery. Additional surgery is required to correct some problems that occur after implant surgery.

Future pregnancy

Very limited information is available on patients who become pregnant after having a neosphincter implanted. The device may need to be deactivated due to pregnancy. If you become pregnant, your doctor may recommend a caesarian delivery. If you plan on future pregnancies or if you become pregnant, it is important that you discuss the presence of the neosphincter with your doctor.

Alternative treatment options for incontinence

People with fecal incontinence can manage accidental stool loss by using a number of different options including diet, medications, absorbent products, biofeedback, surgery, or **ostomy**. Discuss the details of these or any other alternative treatments for incontinence with your doctor.

Diet

Fecal incontinence often occurs as a result of a decreased ability of **the anal sphincter** to handle large amounts of liquid stool. The first step, then, is to try to make your stool more solid and easier to hold. Simple changes in your diet may help.

Medications

Mild incontinence can be managed with medication. Medicine used for diarrhea makes the stool harder and increases the tone of the rectal muscle. Other medications that may be used include those that decrease intestinal secretions and bowel motility, those that increase intestinal tone, and those that slow the movement of stool through the bowel. Medications that reduce the water content in the stools or protect the intestinal lining from irritation can also be used to manage fecal incontinence.

Absorbent products

Absorbent pads, diapers and protective undergarments can help you manage bowel control problems.

Biofeedback

You can use biofeedback to help you gain awareness and control of your **anal canal** and pelvic floor muscles. You can improve your continence with better control of your overall muscle activity. The principle of biofeedback is simple: a variety of instruments are used to record the small electrical signals that are

given off when specific muscles are squeezed to defecate. Biofeedback can help you can better activate your weak muscles on demand, relax your overly tense muscles, and coordinate your overall muscle activity.

Surgery

Sometimes it takes surgery to repair a defect in the **anal sphincter** or pelvic floor to correct fecal incontinence. This type of surgery focuses on repairing damage to muscles in the **anal sphincters** or pelvic floor. Different techniques are used depending on the type or extent of damage. Sphincteroplasty is a technique that attempts to repair damage to **anal sphincter** muscles. Postanal pelvic floor repair is another technique that attempts to repair damage to the sphincter muscles and pelvic floor. Overlapping muscle transposition is a technique of transferring a muscle from another part of the body and wrapping it around the **anal canal** to act like a sphincter. Surgery also can be used to repair rectal prolapse or a birth defect that causes fecal incontinence.

Ostomy

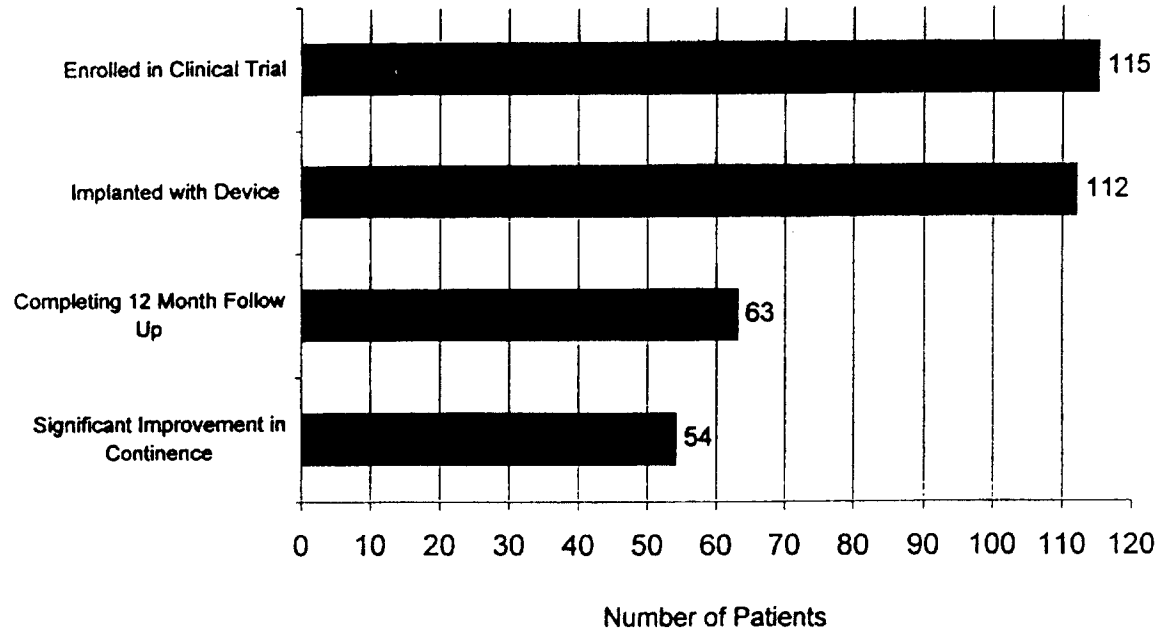
The terms **ostomy** and **stoma** are general descriptive terms that are often used interchangeably though they have different meanings. An **ostomy** is the surgically constructed opening in the abdominal wall that permits the passage of stool from the intestines to the outside of the body. A **stoma** is the actual end of the small or large bowel that can be seen protruding through the abdominal wall. The most common ostomies are colostomy and ileostomy. A colostomy is a surgical procedure of the large intestine (colon), which results in a **stoma**. An ileostomy is a surgical procedure of the small intestine (ileum), which results in a **stoma**. The Acticon Neosphincter is an alternative treatment for patients who have not responded to more conservative therapies and who are considering an **ostomy**. You can learn more about ostomies at the website of The United Ostomy Association (www.uoa.org). The UOA is a volunteer-based health organization dedicated to providing education, information, support and advocacy for people who have had or will have intestinal or urinary diversions.

Patient expectations

You should discuss the AMS Acticon Neosphincter and the surgery needed to implant the device with your doctor in order to have a realistic expectation of the physical, psychological, and functional outcome of the implantation. You should consider and discuss with your doctor the risks, benefits, and potential adverse events of all available treatment options before you choose one.

If you select treatment with an AMS Acticon Neosphincter, clinical study results show that if your device remains implanted you can expect an improvement in your continence status and an improvement in your quality of life. In a 115-patient clinical study conducted by AMS to support FDA marketing approval, 112 patients were implanted with the Neosphincter. Sixty-three (63) of these patients were able to keep the device in place for 12 months and completed the required follow-up. Of these patients, 54 (86%) showed significant improvements in their continence.

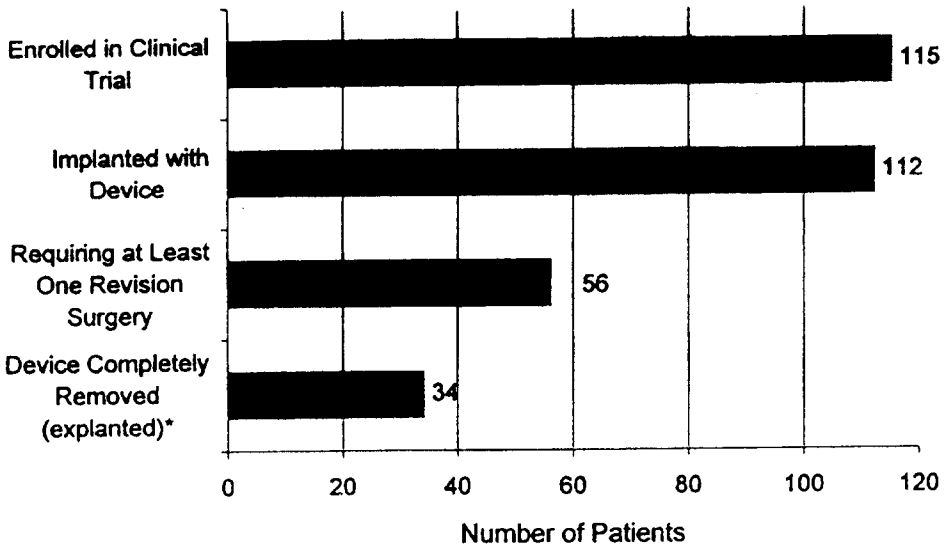
Figure 1: Clinical Study Effectiveness Summary



One-half (50%) of all the patients who were implanted with the Acticon Neosphincter (56 patients) required additional surgery to adjust or remove the device (**revision surgery**) after it was originally implanted. Some of the

patients (18) required more than one revision surgery. Thirty-four (34) patients who received implants (30%) had their devices completely removed (explanted) prior to the end of the 12-month study. Seven patients were later reimplanted with the device. When all patients who enrolled in the study are considered, 51% had significant improvements in their continence 12 months after receiving the device.

Figure 2: Device Revisions



* NOTE: These patients are a subset of patients who had a revision surgery

You may become dissatisfied by the presence of the neosphincter in your body for a number of reasons, such as a smaller improvement in continence than you expected or an inability to adjust to the feel of the device in your body. You may become so unhappy with it that you may want it removed. You should discuss this issue with your doctor before your surgery. You should also know that the AMS Acticon Neosphincter is not a lifetime implant and it may stop working correctly after a time. Be sure you discuss these issues with your doctor and learn what to expect from your implant.

You may not become completely continent following your surgery. Discuss this possibility with your doctor as well as methods of managing this leaking, should it occur. The average patient who was able to complete the study improved

from daily incontinence of liquid and/or solid stool to daily minor seepage or soiling at the 12-month follow-up.

About the surgical procedure

One to two days before surgery, your doctor will tell you to change your diet and give you medicine to help prepare your bowels for surgery. Before the surgery, your doctor will give you some type of **anesthesia** so you either remain asleep or do not feel pain during the surgery. Your doctor will prescribe **antibiotics** for you to take before the surgery to help reduce the risk of **infection**. The procedure to implant the AMS Acticon Neosphincter usually lasts about two hours.

The components of the **prosthesis** are filled with fluid and then implanted through two incision sites. Your doctor makes incisions around your anus to allow room for the **cuff** around your **anal canal**. Another incision is made in your lower abdominal area to implant the **pressure-regulating balloon** and **pump**. Through this incision, the balloon is implanted next to your bladder, and the control **pump** is implanted in your **scrotum** or **labium**. The components are then connected with kink-resistant tubing, allowing the fluid to move within the device. Figure 1 on page 7 shows an Acticon device where it will be in your body.

Surgical risks

Implant surgery carries the same types of risks as every other surgical procedure, including risks of bleeding, procedural errors, **infection** and those risks associated with **anesthesia**. A risk of any type of bowel surgery is bowel perforation (a small hole or tear in the bowel). Other risks of surgeries involving device implantation include possible misplacement of components or implantation of components that are not the correct size.

If any of these happens, you may need additional surgery to replace, revise or remove the device. It is possible that correct device placement may not be

possible in later procedures due to the prior surgeries or if there is a long time between the surgeries. Discuss these possibilities with your doctor.

What to expect after the surgical procedure

After surgery, you will be kept in the hospital for a recovery period. Your doctor will monitor you carefully for any complications, such as bleeding, acute pain, and **infection**. To help you heal and reduce the risk of **infection** after the surgery, your wounds must be kept as clean as possible. You will be given **antibiotics** and may be put on a special diet. Your nurses will monitor your bowel habits and stool consistency while you are in the hospital. You will stay in the hospital for approximately five days.

Because the tissues where your doctor implanted your **cuff** need time to heal, your doctor will not activate your AMS Acticon Neosphincter for six to eight weeks. This means that you will still be incontinent when you leave the hospital and you may need to use absorbent pads. After the six to eight week recovery period, your doctor will activate your device during a visit to his or her office.

Problems that may develop

If you have certain pre-existing medical conditions, you may not be a candidate for treatment with the AMS Neosphincter. Discuss the **contraindications** for this device with your doctor. **Contraindications** for the device are listed on page 6.

Surgical revision - You may not be happy with the outcome of implant surgery. Your device may not work as you hoped it would, or its presence in your body may make you uncomfortable or depressed. If this happens, you may need a **surgical revision** to remove or replace the device. If a doctor must remove your device, it may not be possible to re-implant the device because of previous surgeries or if there is a long time between the surgeries. Discuss these possibilities with your doctor.

During the clinical trial, 50% of the patients required **revision surgery** following their original implant surgeries. Sixteen percent (16%) of the

patients required more than one revision surgery. Table 1 lists the reasons why patients had revision surgery during the clinical trial. A patient may have had more than one reason for a revision surgery. A patient also may have had the same complication more than once.

Table 1: Reasons for Revisions

Reasons for revision	No. of patients who had revision	Percent of all patients (%)
Infection	28	25.0
Erosion	24	21.4
Malfunction	11	9.8
Recurring Incontinence	10	8.9
Migration	6	5.4
Pain	6	5.4
Patient Dissatisfaction	4	3.6
Malposition	3	2.7
Other	13	11.6

Revision surgery can lead to similar types of problems as your original implant surgery. In the clinical study, 62% of the patients who had revision surgery reported some type of complication after the revision surgery.

Pain - It is normal to have some pain in your **scrotum** or **labium** or abdomen immediately after surgery and when you first start using the device. Pain following surgery usually lasts no more than four to seven days. Thirty-two out of every 100 patients (32%) in the clinical study reported some pain following surgery.

> **IMPORTANT:** Contact your doctor if you have pain that is very severe or if it lasts longer than expected. Such pain may be a symptom of a medical condition or mechanical device malfunction.

Some patients had continuing (chronic) pain with no known medical cause. Sometimes these patients chose to have the device removed because the pain

would not go away. About 5% of patients in the clinical study reported pain as one reason for **revision**.

Infection - Infection can happen after any kind of surgery. Your doctor will try to lower your risk by giving you **antibiotics** before and after your operation and by washing out the surgical site with **antibiotic** fluid during surgery. If you have any of the following conditions, you have a greater risk of getting an **infection** than someone who does not have the conditions:

- diabetes
- a spinal cord injury
- open sores
- an existing skin **infection** near the incision site
- musculoskeletal abnormality
- pre-existing **stoma**
- history of allergies
- weakened immune system

Infection was reported in 31 out of every 100 (31%) patients in the clinical trial. Some patients with **infections** were treated with **antibiotics** only. If you get an **infection** that cannot be treated successfully with **antibiotics**, your doctor may have to revise or remove the device.

> **IMPORTANT:** Contact your doctor immediately if you notice any redness, swelling, and/or heat around the incision area or drainage from the incision. These signs and symptoms may indicate an **infection** and your urgent need for treatment.

In the clinical study, 25% of patients had a revision surgery to remove or revise the device because of **infection**. If your device is removed, it may not be possible to implant a new one.

Erosion - Erosion is when the tissue next to any part of the device is "worn away." If you have any of the following conditions, your risk of having **erosion** is greater than the risk for someone who does not have these conditions:

- **infection**
- history of radiation
- improper sizing
- prior tissue damage
- misplacement of the **cuff, pressure regulating balloon,** or **pump**

The **cuff** may erode into the **anal canal** or through the skin into the area between your legs. The **pump** may erode through the skin of the **scrotum** or **labium**. The **pressure-regulating balloon** can erode into the bladder or bowel. Symptoms of **erosion** through the skin may include pain, redness of skin, tenderness over the involved part, changes in skin texture, drainage, and/or being able to see the device through the skin after having been symptom free.

> **IMPORTANT:** Contact your doctor immediately if you notice any pain, tenderness over part of the device, change in skin texture, drainage, or if you can see the device through your skin. These symptoms may indicate erosion. Failure to treat the erosion can make it worse and lead to infection and loss of tissue.

Erosion into the bladder or bowel may result in pain and tenderness in the bladder or bowel area. A change in your ability to urinate, a change in the color of your urine, a change in your ability to defecate, or bleeding from your rectum may indicate a possible **erosion**. Your doctor must evaluate any possible **erosion**. Your doctor may be able to repair your eroded tissue or replace only part of the device. It is possible that the **erosion** will be so severe that your doctor may have to remove the entire device. In the clinical study, 21 out of every 100 (21%) patients had a **revision** due to **erosion**.

Migration - Migration is the movement of the **cuff, pump,** or **pressure-regulating balloon** within your body space away from where your doctor put them. If your device migrates, it can cause pain, psychological/medical complications such as depression, or device malfunction. You may have to have surgery to put the device back where it belongs. Causes of migration include:

- improper cuff selection
- improper pump or pressure regulating balloon placement
- improper tubing length

Migration in the clinical study was 6%, with 5% of the patients requiring more surgery.

> **IMPORTANT:** Contact your doctor if any part of the device is visible through your skin or if you cannot locate the **pump** in your **labium** or **scrotum**. Failure to treat the **migration** can make it worse and lead to tissue damage or malfunction of the device.

Mechanical problems - Product wear (due to the use of the device over a period of time) or other mechanical problems may occur over time. You may have to have surgery to correct the problem. Mechanical problems may include a leak in any of the components. There were mechanical problems with the device in about 10 out of every 100 (10%) patients in the clinical study. Ninety-two percent (92%) of the patients who had mechanical problems with their device needed more surgery to fix the problem.

Recurrent incontinence – After an initial improvement in continence, some patients in the clinical trial experienced a slow return of some fecal leakage. This may have been due to changes in the size of the **anal canal**, a mechanical problem, or damage to the device due to trauma or improper medical intervention. In most cases, if you have incontinence after the device is implanted, you probably have an underlying problem. Contact your doctor if your incontinence gets worse after the device is implanted. In the clinical study,

recurrent incontinence occurred in 19 out of every 100 (19%) patients, with 9% of the patients needing more surgery.

Constipation – **Constipation** is difficult or incomplete removal of stool from the body. In the clinical study, 19% of patients experienced **constipation** after the Acticon was implanted. **Constipation** may be due to anal trauma or to long term dietary changes. Approximately 94% of these events were resolved without the need for further surgery.

Fecal impaction – Fecal impaction occurs when a large mass of hardened stool collects in the colon or **anal canal** and cannot be passed from the body. **Fecal impaction** was reported by about 18% of the patients in the clinical study. In most cases (89%) this problem was solved without further surgery.

Edema - Edema is when the tissue next to any part of the device is swollen. It is normal for some swelling to occur in the healing period after surgery. About 8% of patients in the clinical study reported swelling that was not normal.

Bruising or discoloration of the skin - It is normal to have some bruising after surgery. Less than 1% of patients in the clinical study reported bruising to their doctors.

Trauma - Trauma (injury) to the hip, pelvis, or stomach area can cause damage to either the device or the surrounding tissue in your **scrotum, labium**, or abdomen. This can cause the device to malfunction and could require surgery to replace it. Some things you can do to decrease possible damage are:

- avoid contact sports or activities where you might be tackled or fall
- take extra precautions when walking on ice to prevent slipping and falling

Please ask your doctor for an explanation of any problems that you do not understand.

Would you like more information about the Acticon?

American Medical Systems' website (www.visitams.com) contains more information on the Acticon Neosphincter. Visit the AMS website to learn more about treatment options for fecal incontinence and to learn more about how the Acticon works. The Patient Library on the website contains reports on the Acticon Neosphincter published in medical journals from around the world. If you would like to contact AMS directly, use the contact information on the website or on the back of this brochure.

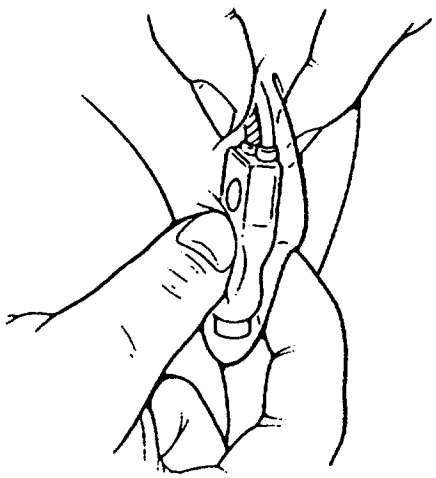
Operating instructions

Opening the cuff

The AMS Acticon Neosphincter requires some manual dexterity and strength to operate the **pump**, which controls the device.

To defecate, open the **cuff** by squeezing and releasing the soft rounded **pump** bulb several times. This moves the fluid out of the **cuff** and into the balloon. Because the empty **cuff** does not press the **anal canal** closed, stool can flow from the bowel.

1. Feel for the **pump** in your **labium** or **scrotum**.
2. With one hand, gently grasp the tubing above the **pump** to hold the **pump** in place.
3. With the other hand, squeeze and release the lower, soft part of the **pump** several times until it remains flat.



To open the cuff, squeeze and release lower soft part of pump

When the lower part of the **pump** is flat, the **cuff** is open, and you are able to defecate. You may need to open the **cuff** more than once to finish your bowel movement.

Closing the cuff

You do not need to do anything to refill the **cuff** after you defecate. The fluid will automatically return from the balloon to the **cuff** within several minutes, and the **cuff** will squeeze the **anal canal** closed.

Activating and deactivating your Acticon Neosphincter

Activating the device means turning on the Acticon Neosphincter; deactivating means turning it off. Your device can easily be deactivated by pushing the **deactivation button** located on the upper, hard part of the **pump**, NOT the soft, squeezable lower part. If the **deactivation button** is pushed after squeezing the **pump** and draining the fluid from the **cuff**, fluid will be locked out of the **cuff**. The **cuff** will not automatically refill. This means you will be unable to control your bowels, since the **cuff** will not be pressing on the **anal canal** and stopping the flow of stool from your bowel. You can use pads for your incontinence while your Acticon Neosphincter is deactivated.

When should my Acticon Neosphincter be deactivated?

Your doctor will deactivate your device at various times, such as while you are healing from surgery.

Deactivate your Acticon Neosphincter before inserting any medical instrument into the **anal canal**. It is extremely important to tell other healthcare professionals that you have an Acticon Neosphincter so they can take precautions when treating you. If you ever need to have a medical instrument (for anal ultrasound, colonoscopy, sigmoidoscopy, etc.) inserted into your **anal canal**, before the procedure tell your healthcare professional that you have an **anal sphincter** implant. If the Acticon is not deactivated before inserting a medical instrument into the **anal canal**, you risk an injury and damage to your device.

What should I do if I accidentally deactivate my Acticon Neosphincter?

You could accidentally press the **deactivation button** and deactivate your Acticon Neosphincter. As a result, one of two things will happen:

1. Fluid will completely drain from the **cuff**, the **cuff** will not refill, and you will be incontinent. In this case, the **pump** will feel hard.
2. Fluid will get trapped in the **cuff**, so you could not defecate. In this case, the **pump** will feel flat.

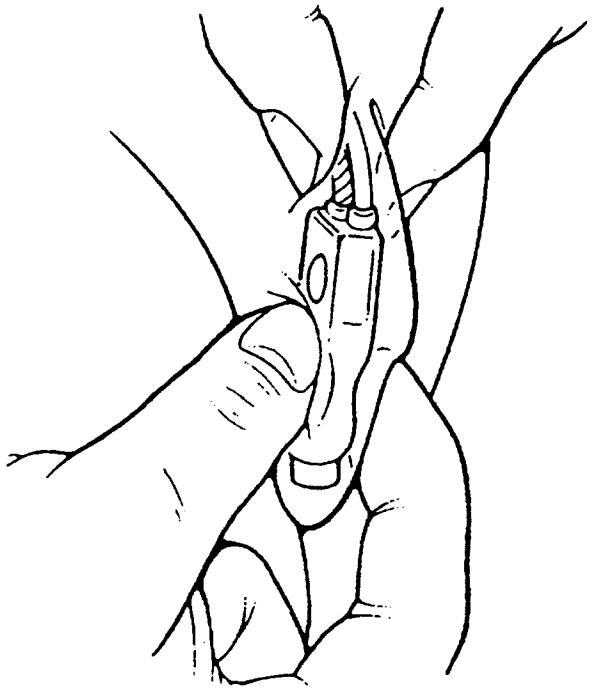
Neither situation is serious and you can fix the problem by calling your doctor or by activating the Acticon Neosphincter by yourself.

To activate your Acticon Neosphincter, follow these simple steps. First, determine what the problem is by deciding whether the **pump** feels harder than usual or flat. Then, follow the appropriate steps to fix the problem.

If the lower, soft part of the pump feels harder than usual:

1. With one hand, grasp the tubing above the **pump** to hold the **pump** in place.
2. With the other hand, give the lower part of the **pump** a quick, forceful squeeze.
3. Squeeze the **pump** several times as you normally would to defecate.
4. You may experience pain while activating the device.

Contact your doctor right away if you cannot activate the device.

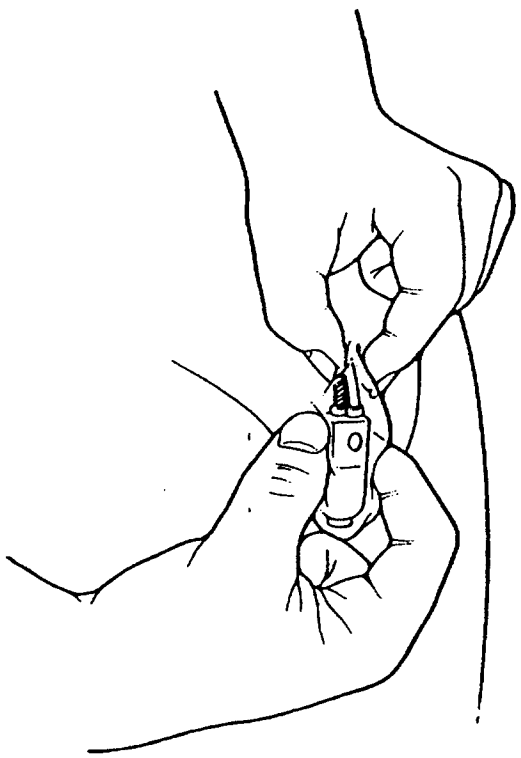


Give the lower part of the pump a quick, firm squeeze.

If the lower, soft part of the pump is squeezed flat and doesn't refill as it normally does:

1. With one hand, grasp the tubing above the **pump** to hold the **pump** in place.
2. With your other hand, squeeze the sides of the upper, hard part of the **pump**, opposite the button. Use hard, steady pressure.
3. When the lower part of the **pump** is hard and filled with fluid, give the lower part of the **pump** a quick, forceful squeeze.
4. Repeat step 3 if it does not work the first time.

You may experience pain while activating the device.
Contact your doctor right away if you cannot activate the device.



Squeeze the sides of the upper, hard part of the pump, then give a quick, firm squeeze on the lower part of the pump.

Troubleshooting

Signs and Symptoms That May Develop After Surgery		
Symptom	**Problem**	**What to do***
Pain.	Pain is fairly typical in first 4-6 weeks after surgery. If pain is persistent and severe, the cause may be infection or another problem.	If not severe, take prescribed pain medication or analgesic. If severe, contact your doctor.
Pain. Discharge from incision. Redness, swelling.	Infection.	Contact your doctor.
Cuff surface can be seen through the skin.	Erosion of the cuff.	Contact your doctor.
Pump surface can be seen through scrotum.	Erosion of pump.	Contact your doctor.
Balloon surface can be seen through abdomen.	Erosion of balloon.	Contact your doctor.
Unable to pump.	Possible accidental deactivation.	Review device activation instructions on pages 19-21. If still unable to pump, contact your doctor.
Unable to locate pump.	Migration.	Contact your doctor.
Unable to defecate.	Pump problem.	Contact your doctor.
Pain. Skin disruption (opening). Leaking of body fluids. Bruising.	Trauma.	Contact your doctor.

*These suggestions always are subject to your doctor's instructions.

Summary

This entire manual should be read before operating your device. This summary is for reference and is not meant to replace the complete instructions found in this manual.

Problems that may develop

The possibility of leakage, blockage, or device problem exists. Discuss any changes you notice in the function of your device with your doctor.

Contact your doctor immediately if there is:

- redness
- swelling
- heat around the incision area or drainage from the incision (symptoms of **erosion**)
- if your pain is very severe or lasts longer than expected
- if any part of your device is visible through your skin, or
- if you cannot locate the **pump** in your **labium** or **scrotum**.

Opening the cuff

Your device requires some manual dexterity and strength to operate the **pump**.

1. Feel for the **pump** in your **labium** or **scrotum**
2. With one hand, gently grasp the tubing above the **pump** to hold the **pump** in place.
3. With the other hand, squeeze and release the lower, soft part of the **pump** several times until it remains flat.

Closing the cuff

You do not need to do anything to close the **cuff** after you defecate. The fluid will automatically return from the balloon to fill the **cuff** within several minutes, and the **cuff** will squeeze the **anal canal** closed.

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References

[1] Barrett DM, O'Sullivan DC, Malizia AA, Reiman HM and Abell-Aleff PC. Particle Shedding and Migration from Silicone Genitourinary Prosthetic Devices. *Journal of Urology* 1991; 146: 319-322.
[2] Reinberg Y. Silicone Shedding from Artificial Urinary Sphincter in Children. *Journal of Urology* 1993; 150:694-696.

American Medical Systems
10700 Bren Rd. W
Minnetonka, MN 55343-9679
(800) 328-3881