

Important Information
for **Patients**
Considering
an
Acticon™ Neosphincter

You_{and}
your

doctor have been discussing ways to treat your severe *fecal incontinence*. After talking about all of your options, you are now considering the implantation of the Acticon™ Neosphincter. Depending on your age, preference, and medical condition, some of your other options may include diet changes, pads or diapers, medications, muscle exercises with biofeedback, and surgical procedures such as sphincteroplasty, colostomy, the muscle transposition procedure, and the gracilis stimulator implant procedure.

This booklet will tell you about the Acticon *prosthesis* and how it can help you. You will learn about the risks and benefits of the prosthesis. If you have any questions about the information in this brochure or if you have any questions related to your treatment for fecal incontinence, be sure to ask your doctor.

Humanitarian Device. Authorized by Federal law for use in the treatment of severe fecal incontinence. The effectiveness of this device for this use has not been demonstrated.



General Warnings and Cautions

How safe are silicone elastomer prostheses?

The Acticon Neosphincter is composed of a number of materials including solid silicone elastomers (rubber). This device does not contain silicone gel. Solid silicone elastomers have been commonly used in a variety of biomedical devices for over 40 years.

Scientific literature has included reports of adverse events in patients with implantable silicone devices. These adverse events indicate allergic like reactions or autoimmune like symptoms. However, even though these reactions or symptoms are seen in some patients, there has been no proof that the silicone elastomer caused them.

Silicone elastomer sometimes may lose tiny particles off its surface after it has been implanted. Sometimes these particles migrate (move) to lymph nodes in other parts of the body where they can then stay. Medical journals, however, have not indicated any events adverse to the patient's health resulting from particle migration.^{1,2}

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

Will my prosthesis have to be replaced?

It is not possible to predict how long an implanted prosthesis will function in a particular patient. As with any biomedical prosthesis, this device is subject to wear and eventual failure over time and should not be considered a lifetime implant. Product wear or other mechanical problems may lead to the prosthesis not functioning as intended and may lead to additional surgery to replace the prosthesis. Clinical experience has shown that most patients with AMS implantable prostheses do not need to have their prostheses removed or replaced for at least 5 years after the original implant. Discuss any changes you notice in the function of your prosthesis with your doctor.

¹ Barret DM, O'Sullivan DC, Malizia AA, Reiman HM, and Abell-Aleff PC, 1991. Particle Shedding and Migration from Silicone Genitourinary Prosthetic Devices. *J Urol* 146: 319-322.

² Reinberg Y, Manivel JC, Gonzalez R 1993. Silicone Shedding From Artificial Urinary Sphincter in Children. *J Urol* 150: 694-696.

Can I have Magnetic Resonance Imaging (MRI) with my prosthesis?

Yes. Several studies regarding MRI and AMS solid silicone prostheses have concluded that the presence of an AMS prosthesis will not produce harmful effects during scanning.^{3,4,5,6} The studies showed no unsafe magnetic interactions when prostheses were subjected to magnetic fields similar to those produced during MRI. It is unlikely that your prosthesis will interfere with normal MRI.

Need for Manual Dexterity

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

Possibility of Malfunction

The possibility of leakage, blockage, or other mechanical malfunction exists.

Possibility of Infection

Contact your doctor immediately if there is redness, swelling, and/or heat around the incision area or drainage from the incision. This may indicate an infection.

Possibility of Erosion

Contact your doctor immediately if there is a thinning of the skin or tissue over the prosthesis. This may indicate *erosion*. Failure to treat erosion can make it worse and lead to infection and loss of tissue.

Possibility of Migration

Contact your doctor immediately if the surface or any other part of your device is visible through the skin or you cannot locate the control pump. These symptoms indicate that a part of your device may have moved within your body or may be moving to the outside of your body.

Pain

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 complication or mechanical device malfunction.

Receptive Anal Intercourse

Receptive anal intercourse may damage the occlusive cuff. Patients implanted with the Acticon prosthesis are cautioned not to engage in receptive anal intercourse.

Pregnancy

Vaginal delivery of children may interfere with proper functioning of the occlusive cuff. Discuss vaginal delivery and other options for childbirth with your physician.

³ Shellock F, 1988. MR Imaging of Metallic Implants and Materials: A Compilation of the Literature, *Am Jour Rad* October.

⁴ Shellock F, 1991. MR Imaging and Biomedical Implants, Materials and Devices: An Updated Review, *Radiology* 180: 541-550.

⁵ Shellock F, 1993. MR Procedures and Biomedical Implants, Materials and Devices: 1993 Update, *Radiology* 189: 587-599.

⁶ Shellock F, 1993. *MR Procedures and Metallic Objects: Update* 1997. Philadelphia, Lippincott-Raven, pp. 101, 110.

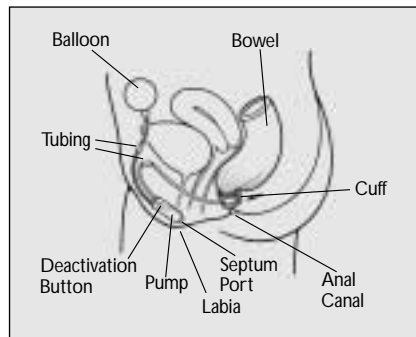
What is Fecal Incontinence?

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. Fecal incontinence occurs when some underlying condition, such as a disease, accident, or injury, affects the normal functioning of the anal canal and sphincter muscles.

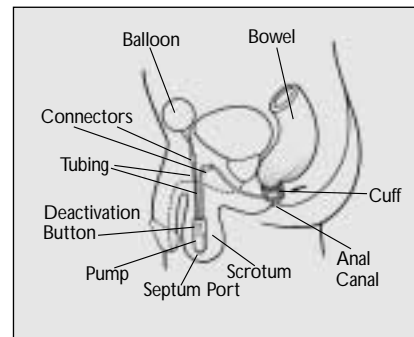
About the Acticon™ Neosphincter



The Acticon prosthesis is used in men and women to treat severe fecal incontinence (the loss of liquid or solid stool at least weekly). It is a small, fluid-filled device that is completely implanted within your body. It is composed of a number of materials, including solid silicone elastomer (an elastic substance resembling rubber). The prosthesis is designed to mimic the natural function of the sphincter muscle, giving you control over your bowel movements.



Female



Male

The prosthesis consists of three components: a **balloon** that is placed in the abdomen, a circular **cuff** that is implanted around a segment of the *anal canal*, and a **pump** that is placed in either the scrotum or labium.

How the Prosthesis Works



Female



Male

The cuff is filled with fluid and gently squeezes the anal canal closed. When you want to have a bowel movement, you open the cuff by squeezing and releasing the lower, soft part of the pump 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 now pass through the anal canal and out of your body. You may have to empty the cuff a second time to complete *defecation*.



Female



Male

The fluid automatically flows from the balloon back to the cuff. When the cuff is full, it again squeezes the anal canal closed.

About the Surgical Procedure

Your doctor will give you general *anesthesia* so you remain asleep during the surgery. Additionally, your doctor will prescribe *antibiotics* for you to take before the surgery to help reduce the risk of infection. The procedure to implant the Acticon prosthesis 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 the anus to allow room for the cuff around your anal canal. Another incision is made in your lower abdominal area to implant the balloon and pump. Through this incision, the balloon is implanted next to your bladder, and the control pump is implanted in the scrotum or labium. The components are then connected with kink-resistant tubing, allowing the fluid to move within the Acticon prosthesis.

To help you heal and reduce the risk of infection after the surgery, the wound must be kept as clean as possible. Your doctor may create a temporary *stoma* during implant surgery to help keep the cuff incision site clean. However, not all patients require this procedure.

Surgical Risks

Implant surgery carries the same types of risks that every surgical procedure involves, including that of infection and those associated with anesthesia. In addition, the outcome of your implant surgery may be unsuccessful due to improper surgical technique, anatomical misplacement of components, improper sizing and filling of components, failure of the device to function as intended, psychological problems, and/or simply be associated with patient dissatisfaction. If any of these happen, you may need additional surgery to remove or replace the prosthesis. If the prosthesis must be removed, reimplantation of a new prosthesis may be complicated by the amount of time between the two 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. 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.

Because the tissues where the cuff was implanted need time to heal, your doctor will not activate your Acticon prosthesis 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 the prosthesis. If a temporary stoma was created during surgery, it will be closed at this time. You should then be back to your normal activities within a few weeks.



Problems that may Develop

Each of these problems has been reported during clinical use of the Acticon prosthesis. Please ask your doctor for an explanation of any of the problems that you do not understand.

Infection. As with any surgical procedure, an infection may develop. If the infection cannot be treated with antibiotics, it may be necessary to remove the prosthesis. In many cases another prosthesis can be implanted after the infection is treated. If your prosthesis must be removed due to infection, the infection can cause scarring that may make implanting a new prosthesis difficult.

Warning: Contact your doctor immediately if you notice any redness, swelling, and/or heat around the incision areas or drainage from the incisions. These symptoms may indicate an infection.

Erosion. A breakdown of the tissue next to an implanted component is called erosion. Erosion can be caused by infection, pressure on the tissue, improper component sizing or component misplacement. In any case of erosion, your doctor must evaluate whether to replace or remove the component when doing the repair.

Warning: Contact your doctor immediately if you notice any pain or tenderness over the involved part of the prosthesis 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.

Migration. Migration is the movement of or displacement of components within the space in which they were implanted. It can result in surgical revision, pain, psychological or medical complications, or device malfunction. Component migration can occur if the cuff is sized improperly, if the pump or balloon is not positioned correctly, or if the tubing lengths are incorrect.

Warning: Contact your doctor if any part of the device is visible through your skin or if you cannot locate the control pump in your labium or scrotum.

Pain. It is normal to have some pain at the incision and implant sites immediately following surgery. You also may experience some pain at the implant sites when you are first using the prosthesis. Cases have been reported of chronic pain associated with prosthesis

implantation. Severe pain that lasts beyond a reasonably expected time may indicate a medical complication or mechanical prosthesis malfunction which may lead to a medical or surgical treatment.

Warning: 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.

Trauma. Trauma or injury to the hip, stomach, or perineal areas, such as impact injuries associated with sports, can result in damage to the implanted prosthesis and/or surrounding tissues. This damage may result in the malfunction of the prosthesis and could require surgery to replace it. Some things that you can do to decrease possible damage are:

- ◆ Avoid contact sports where you might be tackled
- ◆ Take extra care when walking on ice to prevent slipping and falling
- ◆ Discuss bicycle riding with your doctor. Bicycle seats designed to reduce pressure on the area of the implanted cuff are available from a bicycle dealer.

Mechanical Problems. As with any biomedical prosthesis, the Acticon prosthesis is subject to wear and eventual failure over a period of time. Surgery is usually required to correct the problem. You may be experiencing mechanical problems with your prosthesis if you are leaking a significant amount of stool or if you squeeze and release the pump but are still unable to have a bowel movement. Pump failure, fluid leaks, and tubing kinks are all possible mechanical problems.

If these problems occur, first check the user instructions to be sure you are operating the device correctly. If you still have the same problem, contact your doctor.

Patient Expectations. After implantation of the Acticon Neosphincter your stool control may not be perfect. This will depend on the location of the device, the amount of gas, liquid stool or solid stool, your diet, bowel habits, and your activity level. You may need to use pads or diapers if your level of bowel control is not acceptable. You may have to use laxatives, enemas, or use certain foods to promote soft stool, in order to properly empty your bowel.

Troubleshooting Guide

<i>Symptom</i>	<i>Problem</i>	<i>What to Do</i>
Discharge from incision. Redness, swelling. Pain.	Infection.	Contact your doctor.
Cuff surface can be seen through the perineal skin.	Erosion of cuff.	Contact your doctor.
Pump surface can be seen through the scrotum or labium.	Erosion of pump.	Contact your doctor.
Balloon surface can be seen through abdomen.	Erosion of balloon.	Contact your doctor.
Pain.	Pain is fairly typical in the 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 medication or analgesic. If severe, contact your doctor.
Inability to pump.	Possible accidental deactivation.	Review patient instruction materials. If still unable to pump, contact your doctor.
Inability to locate pump.	Migration.	Review patient instruction materials. If still unable to locate pump, contact your doctor.
Any part of device visible through your skin.	Erosion.	Contact your doctor.
Pain, skin disruption (opening), leaking of body fluids, bruising.	Trauma.	Contact your doctor.
Unable to have bowel movement.	Constipation or fecal impaction.	If not severe, take prescribed laxative or medication. If severe, contact your doctor.



Benefits of the Acticon™ Prosthesis

Improved Control of Bowel Movements

Designed to mimic the natural function of the anal sphincter muscle, the Acticon prosthesis can help give you control over your bowel movements.

All Components are Internal

All of the components of the Acticon prosthesis are implanted within your body. The prosthesis cannot be seen as you carry out your day to day activities.

Easy to Use

After the prosthesis is activated, you will be able to control your bowel movements by simply squeezing and releasing the lower, soft part of the control pump several times when you want to defecate.



Glossary of Terms

Anal Canal: The tube near the anus through which stool passes.

Anal Sphincter: The muscle surrounding the anal canal that holds stool within the body.

Anesthesia: The loss of all sensation in a specific area of the body (local anesthesia) or throughout the entire body (general anesthesia).

Antibiotic: A medication used to prevent or treat infection.

Defecation: The passing of stool from the bowels.

Erosion: A breakdown of the tissue next to an implanted component.

Fecal Incontinence: The inability to control bowel movements.

Migration: The movement or displacement of components from within the space where they were implanted.

Prosthesis: A device that replaces or mimics performance of a natural bodily function.

Stoma: A surgically constructed opening in the abdominal wall that permits the passage of waste from the intestines to the outside of the body.





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