AMS
Acticon™
Neosphincter

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CAUTION: ***Federal Law restricts this device to sale by or on the order of a physician with appropriate training.***

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.

NOTE: Refer to the Operating Room Manual for further information on the Acticon™ Neosphincter and its implantation.

Brief Device Description

The Acticon™ Neosphincter is an implantable, fluid filled, solid silicone elastomer device used to treat severe fecal incontinence. The Acticon™ Neosphincter may be implanted in either women or men and consists of three interconnected components: an occlusive cuff, a pressure-regulating balloon and a control pump with a septum. The three components are connected with kink-resistant tubing. The Acticon™ Neosphincter simulates normal anal sphincter function by allowing the anal canal to open at the control of the patient. The occlusive cuff is implanted around a segment of the anal canal. The device maintains continence in the patient by using the pressure of the fluid-filled cuff to occlude the anal canal. To evacuate the bowel, the patient squeezes and releases the pump mechanism, located in the labium or scrotum, several times to move fluid from the cuff to the pressure-regulating balloon implanted in the abdomen. This movement of fluid empties and collapses the cuff, resulting in the release of the compressive force around the anal canal. Residual pressure within the balloon allows fluid to flow back into the cuff, automatically refilling the cuff within a few minutes. The pressure-regulating balloon maintains pressure in the occlusive cuff. This device contains solid silicone elastomer. These devices are for men or women who, after appropriate patient history and diagnostic evaluations as well as discussions with their physician about other alternative treatment methods, are determined to be suitable candidates for implantation surgery.

Indications for Use

The Acticon™ Neosphincter is an implantable, solid silicone elastomer device used to treat severe fecal incontinence in post-pubescent males and females who have failed, or are not candidates for, less invasive forms of restorative therapy. It is intended to mimic the natural process of bowel control and bowel movement.

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 an irreversibly obstructed proximal segment of bowel.

Warnings

1. Patients with urinary tract or gastrointestinal infections, diabetes, spinal cord injuries, open sores, or skin infections in the region of the surgery have an increased risk of infection associated with a prosthesis. Appropriate measures should be taken to reduce the likelihood of infection.

   Infection that fails to respond to antibiotic therapy may result in removal of the prosthesis. Infection followed by explantation of the device may result in scarring which may make subsequent reimplantation more difficult.

2. Erosion may be caused by infection, pressure on the tissue, improper cuff sizing, improper balloon selection, tissue damage, and component misplacement. The cuff may erode around the anal canal or the control pump may erode through the scrotal or labial skin. The pressure-regulating balloon can erode into the bladder. Failure to evaluate and promptly treat the erosion may result in a substantial worsening of the condition leading to infection and/or loss of tissue.

3. This device is composed of a number of materials, including solid silicone elastomers. This device does not contain silicon gel. Scientific literature has included reports of adverse events in patients with implantable silicone devices. These adverse events, as reported, suggest allergic-like reactions or autoimmune-like symptoms. No causal relationship has been established between these events and solid silicone elastomer.

4. Surgical, physical, psychological, or mechanical complications, if they occur, may necessitate revision or removal of the prosthesis. Removal of the device without timely reimplantation of a new device may complicate subsequent reimplantation. The timing of reimplantation should be determined by the treating

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physician based on the patient's medical condition and history.

5. Receptive anal intercourse may damage the occlusive cuff and is not recommended for patients implanted with this prosthesis.

Precautions

Patient Related

1. Patient selection requires thorough preoperative consultation and evaluation by the physician.

2. Patients should be counseled in order to have a realistic expectation of the physical, psychological, and functional outcome of the implantation of an Acticon™ Neosphincter. Although the prosthesis is designed to restore bowel control, some patients continue to have a degree of incontinence after this procedure.

3. Patients may experience pain when the device is activated in the postoperative period and during periods of initial use. Cases of chronic pain associated with device have been reported. Pain with a severity or duration beyond that which is expected may require medical or surgical intervention. Patients should be counseled on expected postoperative pain including severity and duration.

4. Tissue fibrosis or previous surgery in the area of the implant may preclude implantation of an occlusive cuff at the anal canal.

5. Acute pathological conditions of the bowel, e.g. diarrhea or constipation, can interfere with proper functioning of the device and may require the use of external pads or manipulations to assist defecation.

6. Any progressively degenerative disease, e.g. multiple sclerosis, may limit the future usefulness of the implanted prosthesis as a treatment of the patient's fecal incontinence.

7. Adequate manual dexterity, strength, and motivation are required for proper use of the device.

8. Trauma or injury to the pelvic, perineal or abdominal areas, such as impact injuries associated with sports,

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can result in damage to the implanted device and/or surrounding tissues. This damage may result in the malfunction of the device and may necessitate surgical correction including replacement of the prosthesis. The physician should advise patients of these possibilities and warn them to avoid trauma to these areas.

9. If a radiopaque solution is used instead of sterile isotonic saline to fill the device, ensure the patient is not allergic to the radiopaque solution.

10. Vaginal delivery of children may interfere with future proper functioning of the occlusive cuff.

Surgery Related

1. Improper cuff sizing, improper balloon selection, or other causes may result in tissue erosion, migration of components, or continued incontinence.

2. Component migration can occur if the cuff is sized improperly, if the pump or balloon are not positioned correctly, or if the tubing lengths are incorrect. Migration can result in pain, complications, device malfunction and surgical revision.

3. Unsuccessful outcomes may result from improper surgical technique, anatomical misplacement of components, improper sizing and/or filling of components.

4. Although reinforced tubing has been designed to be more resistant to tubing kinks, tubing kinks may still result from tailoring the connecting tubing to an improper length during the implant procedure.

Device Related

1. The Acticon™ Neosphincter prosthesis is intended as a prosthetic device which is designed to restore to the patient an important physiological function. As with any biomedical prosthesis this device is subject to wear and eventual failure over time. It is not feasible to predict how long the implanted prosthesis will function in a particular patient.

2. If the deactivation valve is closed when the cuff is inflated, fluid cannot transfer from the cuff to the balloon and sustained fecal obstruction may arise as a result:

   In the event of large pressures within the bowel, automatic pressure relief that normally occurs with

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the device would be prevented. The fecal obstruction can be relieved by cycling the device.

Cycling the device may be difficult if deactivation occurs when the pump bulb is deflated. If unable to cycle the prosthesis, squeezing the sides adjacent to the deactivation button will allow fluid to fill the pump bulb and then the pump can be cycled normally.

Release of the deactivation valve may require greater pressure than that used to cycle the device.

3. Use caution when passing any instrument through the anal canal. For certain procedures, e.g. anal ultrasound or colonoscopy, first deflate the cuff then deactivate the device prior to passing any instrument through the anal canal.

4. System pressure changes may occur over time.

Clinical Studies

A prospective clinical trial was undertaken to evaluate the safety and effectiveness of parameters specifically studied. The Acticon™ Neosphincter can be surgically implanted without serious adverse sequelae and the prosthesis provided an acceptable level of continence. The clinical trial reported adverse events associated with the implantation and use of these devices. Safety data related to adverse events, revision surgery, diagnoses and health status evaluations were captured on case report forms. Patient self-evaluations related to quality of life and health status were measured on two validated outcome instruments.

Adverse Events

A prospective clinical trial to demonstrate safety and effectiveness of the device is underway. Table 1 presents the adverse device effects reported during the clinical trial.

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Table 1
AMS Acticon Neosphincter Adverse Device Effects (n=50)

ADE	# Events
Infection	18
Pain	14
Constipation	11
Impaction	8
Erosion	7
Surgical Perforation	4
Wound Dehiscence (separation)	4
Erythema	4
Difficult Evacuation	3
Fecal Incontinence	3
Difficult Activation	2
Malposition	2
Fever	2
Hematoma	2
Wound Drainage	1
Seroma	1
Edema	1
Other[1]	15

[1] Other events include: Report of fullness with difficulty sitting, slight discomfort at night, patient reports needs to "pump" 60 times to open system, vaginal tear (5mm), insufficient cuff pressure, few episodes of stool leakage, unable to pump device, excessive bleeding during implant, urinary retention, discomfort cycling pump, perianal itching, ecchymosis, drainage from posterior perineal area, patient cannot access pump secondary to arthritis in finger, and report of red incision.

One hundred and two device related events occurred in 38 patients. Sixty-six of these 102 events either required no intervention or required only non-invasive intervention. The remaining 36 events required some form of surgical intervention. Table 2 summarizes the types of events and methods of resolution.

Table 2
Methods of Intervention (n=50)

Event Type	Number of Patients[1]	Number of Events[2]	Methods of Intervention[3]			
			None Required	Medication	Surgery	Other[4]
Infection	14	18		7	15	3
Pain	10	14	1	7	2	7
Constipation	6	11		11		2
Impaction	8	8	1	1	1	3
Erosion	7	7		2	7	1
Surgical Perforation	4	4			4	
Wound Dehiscence (separation)	4	4	2	1		1
Erythema	3	4	1	3		1
Difficult Evacuation	3	3	1	2		1
Fecal Incontinence	2	3			3	
Difficult Activation	2	2				2
Malposition	2	2			2	
Fever	2	2		2		
Hematoma	2	2	1			1
Wound Drainage	1	1				1
Seroma	1	1				1
Edema	1	1	1			
Other[5]	9	15	1	2	2	9

[1] Patients may have had more than one type of event.

[2] Patients may have had more than one event of the same type.

[3] There may have been more than one type of intervention for each event, and patients may have multiple events that are treated with the same intervention.

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* Examples of other interventions reported are: enemas, wound packing/cleaning, and observation.

* Other events include: Report of fullness with difficulty sitting, slight discomfort at night, patient reports needs to "pump" 60 times to open system, vaginal tear (5mm), insufficient cuff pressure, few episodes of stool leakage, unable to pump device, excessive bleeding during implant, urinary retention, discomfort cycling pump, perianal itching, ecchymosis, drainage from posterior perineal area, patient cannot access pump secondary to arthritis in finger, and report of red incision.

The following risks of implantable bowel sphincters or their materials have been reported in the medical literature but did not occur during the prospective study: tubing kink, tubing leak, cuff tab tearing, scrotal adhesion. No deaths, life-threatening conditions or unanticipated adverse device effects were reported in the study.

Revision Surgery

Revisions were reported in the clinical trial. No long-term adverse sequelae was reported in association with revision surgery in the clinical trial. A revision is considered any surgical intervention that is related to the function, placement or site reaction to the implanted device. Revisions were due to Infection, Erosion, Malposition, Pain, Recurring Incontinence, and Surgical Perforation.

Patient Evaluation of Quality of Life, Psychological Well-Bing, and Health Status

No decline in the overall patient quality of life, psychological well-being, and health status was demonstrated during the clinical trial. The Fecal Incontinence Quality of Life Questionnaire was designed to assess the impact of fecal incontinence on a variety of activities and feelings. The majority of patients at six months (12/13) and all patients at 12 month follow-up (n=6) demonstrated marked improvement or resolution of their fecal incontinence. As a result, these patients experienced less restriction of their daily activities. They expressed little or no fear of going out for activities such as a movie. Patients also reported reductions in the mental stress experienced due to fecal incontinence. Following implantation, a majority of patients reported no longer feeling depressed or ashamed due to accidental bowel leakage. Patients reported being able to hold their bowel movement long enough to reach a bathroom most or all of the time. As a result of improved bowel control, the use of pads was reduced and use of diapers was eliminated.

Following implantation of the Acticon™ Neosphincter, patients reported improvements in their quality of life. Many patients reported less restriction of their activities and they spent less time worrying about fecal incontinence. With bowel control restored, patients

were less distressed and more able to enjoy life.

The overall health status, as measured by Health Status Questionnaire (HSQ 2.0), showed changes in a positive direction on seven out of eight scales. The HSQ is analyzed to determine scores for eight scales of health status, function, limitations and perceptions. Social Functioning showed a statistically significant improvement from Baseline to 12 Month Follow-up. Of the seven other scales which did not show statistically significant differences, six had changes in a positive direction.

Supplementary Clinical Information

Although it is not feasible to predict exactly how long an implanted prosthesis will function in a particular patient, American Medical Systems, Inc. has assembled a set of data on device removals and revisions to help gain insight into the product performance over time.

Since 1996, the AMS Acticon™ Neosphincter has been used clinically in the European Union and South America. The following table provides an estimate of the rate of device removals and revisions based on this experience. The data set comes from Patient Information Forms (PIFs) submitted to AMS by physicians using the Acticon™ Neosphincter. The PIF form is voluntarily submitted for surgical procedures requiring parts replacement under AMS warranty. Because surgeries may not be reported to AMS, the number of patients implanted and the incidence of removals and revisions may actually be higher. AMS considers the vast majority of its device revisions and removals to be non life-threatening and therefore do not represent significant safety issues.

According to the PIF data, 152 patients have received Acticon™ Neosphincter implants through December 31, 1998. The 16 adverse device effects involved 11 patients and resulted in 15 surgical procedures. The procedures included 9 revision surgeries, 2 replacement surgeries, and 4 removal surgeries. The adverse device effects are summarized in Table 3.

Table 3
Adverse Device Effects based on PIF data

Adverse Device Effect	Frequency
Infection	2
Erosion	3
Migration	0
Malposition	0
Mechanical	5
Pain	1
Recurring incontinence	3
Patient dissatisfaction	0
Other	9

When analyzed using a denominator of n = 152 , 9.8% of original implants were revised, removed, or replaced for reported adverse device effects.

Patient Counseling Information

Patients should be counseled in order to have a realistic expectation of the physical, psychological and functional outcome of the implantation. The risks, benefits and potential adverse events of all available treatment options should be discussed with the patient and considered by the physician and patient when choosing a treatment option.

An appropriate patient history, including history of personality disorders, and diagnostic work-up should be a part of the patient decision making process.

Some patients may become dissatisfied by the presence of the prosthetic device in their body. This issue should be discussed with the patient prior to the surgery. Patient dissatisfaction may lead to device removal. Patients should also be aware that the Acticon™ Neosphincter is not considered to be a lifetime implant.

It is also important that the physician discusses with the patient the possibility of an allergic reaction to the materials in the device (See Silicone Information).

Silicone Information

This device is composed of a number of materials, including solid silicone elastomers and a fluorosilicone lubricant. Silicone gel is not a component in the materials of this device. Solid silicone elastomers have been commonly used in a variety of biomedical devices for over 40 years. Silicone fluids have an extensive history of use in medical devices.

Scientific literature has included reports of adverse events and other observations in patients with implantable silicone devices. As reported, these events/observations indicate "allergic-like" symptoms and in other cases a symptom complex associated with immunological disorders. No casual relationship has been established between these events and silicone elastomer or fluorosilicone lubricant.

There are reports of malignant tumor formation in laboratory animals only associated with implants of relatively large size. Many different materials are associated with this effect in animals, silicone elastomers among them. No such effect has been described in humans.

Extensive testing has been conducted on all materials in the AMS Acticon™ Neosphincter. This testing has indicated no toxicological response attributable to the materials. However, some of the materials caused minor irritation when implanted in animals.

Silicone elastomer particulate shedding and particulate migrations to regional lymph nodes have been reported in the literature on penile implants. There are no known clinical sequelae to this phenomenon.

Magnetic Resonance Imaging (MRI) Information

Several studies regarding MRI and AMS prostheses have concluded that the presence of an AMS prosthesis will not produce harmful effects during scanning. These studies were conducted by Robert C. Lange, Ph.D., Yale University and Frank G. Shellock, Ph.D., Cedars-Sinai Medical Center, Los Angeles. Dr. Lange produced his study for American Medical Systems and Dr. Shellock produced his studies independently for publication in the *American Journal of Roentgenology* (AJR) and *Radiology*.[1,2,3,4]

In these studies, the metallic components in AMS prostheses were subjected to magnetic field strengths up to 1.5 Tesla and showed no unsafe magnetic interaction. The small stainless steel components in AMS prostheses may distort the uniform magnetic field in the vicinity of the implant, although it is unlikely that these components will interfere with normal MRI. However, the complete compatibility profile of these products within a MRI field has not been established.

[1] Shellock F, *MR Imaging of Metallic Implants and Materials:* A Compilation of the Literature, AJR, October 1988.

[2] Shellock F, *MR Imaging and Biomedical Implants, Materials and Devices: An Updated Review*, Radiology, 1991, Vol 180, pp. 541-550.

[3] Shellock F, *MR Procedures and Biomedical Implants, Materials and Devices:* 1993 Update, Radiology, 1993, Vol. 189, pp. 587-599

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

Inventory Returns and Product Replacement Information

Before returning any components, whether explanted or unused (sterile or nonsterile), customers must fill out the Return Goods Form located on the last page of the Patient Information Form.

Follow **all** of the instructions on the form carefully, and be sure that the components have been thoroughly cleaned before returning them to AMS.

In all cases, obtaining credit or percentage of credit for a returned component is subject to approval under the terms of the AMS Return Goods Policy and the AMS Product Replacement Policy. For complete information regarding these policies, contact the AMS Customer Service Department.

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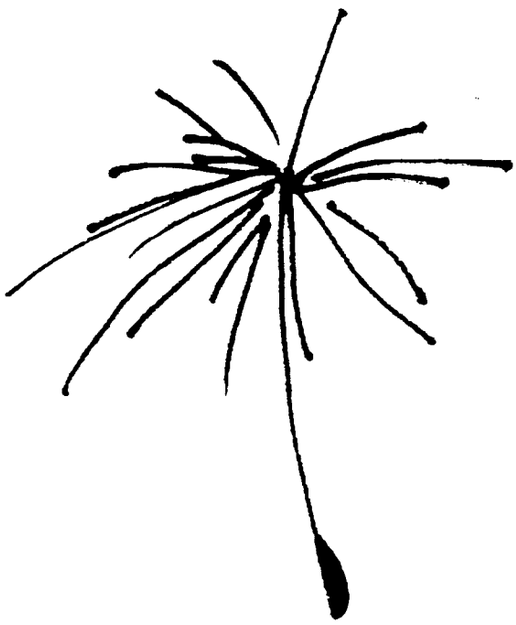


Important Information for Patients Considering an Acticon™ Neosphincter

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]

Flurosilicone (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 that 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.

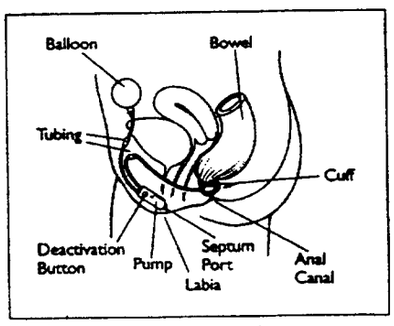
[3] Shellock F. 1988. MR Imaging of Metallic Implants and Materials: A Compilation of the Literature. *Am Jour Rad* October.
[4] Shellock F. 1991. MR Imaging and Biomedical Implants, Materials and Devices: An Updated Review. *Radiology* 180: 541-550.
[5] Shellock F. 1993. MR Procedures and Biomedical 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?

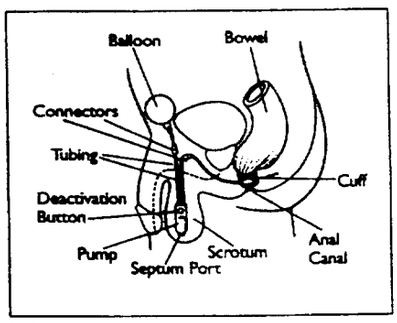
Normally, when the *anal sphincter* and pelvic floor muscles relax, the rectal muscles and lower bowel begin to contract slowly and rhythmically. This movement pushes the stool through the intestines and out through the anus. Fecal incontinence occurs when some underlying condition, such as a disease, 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.

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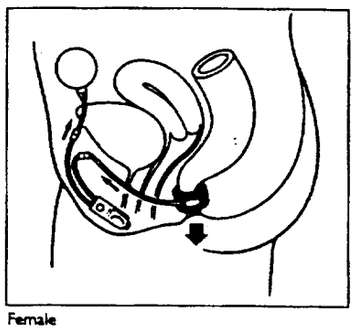
How the Prosthesis Works



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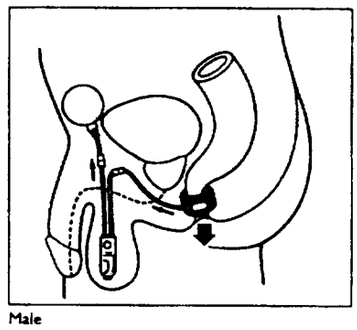
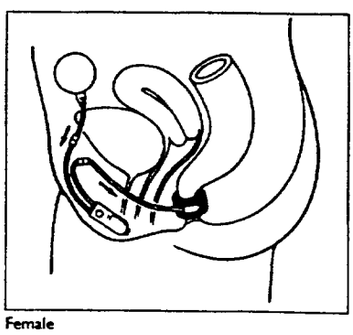
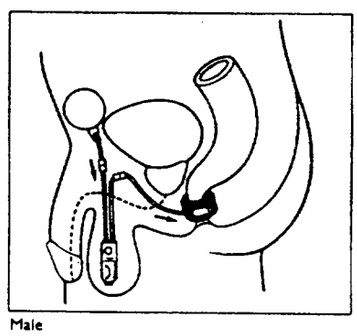


Male

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.

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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

Symptom	*Problem*	*What to Do*
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.

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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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