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# *Acticon*<sup>™</sup>

NEOSPHINCTER



## **OPERATING ROOM MANUAL**

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American Medical Systems, Inc., has produced this operating room manual to assist the operating room staff in preparing for the surgical implantation of the Acticon™ Neosphincter. The company does not intend that this manual be an all-encompassing reference on the prosthetic device.

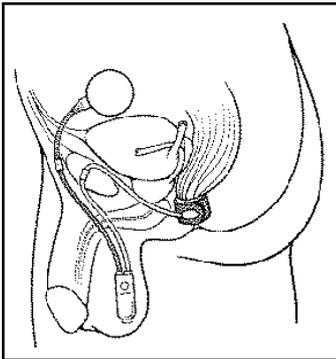
**Caution:** Federal law (USA) restricts this device to sale by or on the order of a physician.

**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.

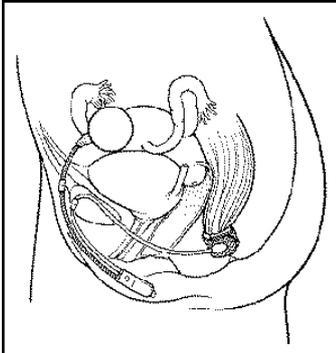
# General Information

## Indications for Use

The Acticon™ Neosphincter from American Medical Systems, Inc. is an implantable, fluid-filled, solid silicone elastomer prosthesis used to treat severe fecal incontinence. The Acticon Neosphincter prosthesis can be implanted in men and women.



**Acticon Neosphincter implanted in a male patient**



**Acticon Neosphincter implanted in a female patient**

## Device Characteristics

The Acticon prosthesis consists of three components: a cuff, a control pump with septum port, and a pressure-regulating balloon, connected to each other with kink-resistant tubing.

**Note: For Warnings, Precautions, and Contraindications, please refer to the Package Insert provided in the product packaging.**

## Device Function

The Acticon prosthesis simulates normal sphincter function by opening the anal canal at the control of the patient.

When the patient wishes to defecate, he or she squeezes and releases the pump, implanted in the scrotum or labium, several times. This causes the fluid in the cuff, implanted around a segment of the anal canal, to move from the cuff into the pressure-regulating balloon. The cuff opens to allow the stool to pass through the anal canal. The balloon then automatically repressurizes the cuff through the fluid-control valves and the cuff refills again, applying pressure to the anal canal.

The control pump is designed to allow the physician to deactivate the implanted device without additional surgery. This deactivation option is explained on page 13.

A septum port is located on the end of the pump to allow the physician to transfer fluid into the system, if necessary, without additional surgery (see *Using the Septum Port*, page 14).

## Components

### Packaging

American Medical Systems, Inc. sterilizes all of the Acticon prosthesis components prior to shipment. Each sterile component and accessory kit is packaged separately within an inner plastic tray which is sterile and sealed with a Tyvek™ lid. The inner tray lies within the sterile environment of a plastic outer tray which is also sealed by a Tyvek lid. A dustcover box protects the tray.

Adhesive labels on one end of the dustcover box and on the Tyvek lid of the outer tray identify the components, their sizes, and serial and lot numbers.

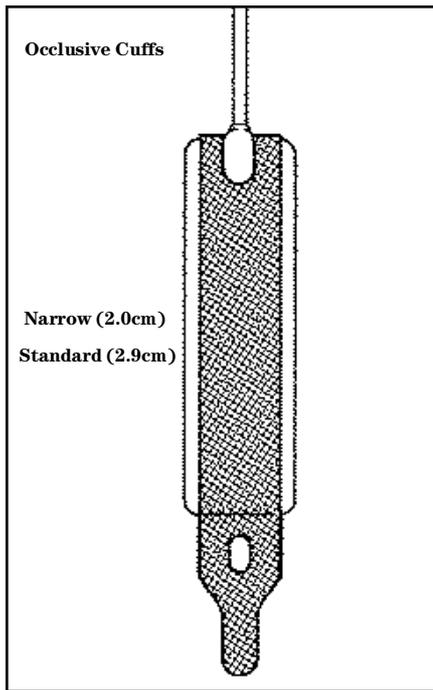
To complete one implant, the following components and tools from AMS are needed:

- an occlusive cuff
- a pressure-regulating balloon
- a control pump
- an accessory kit
- an Acticon Neosphincter tubing passer
- Acticon Neosphincter cuff sizer
- a Quick Connect™ assembly tool (optional)

**Confirm adequate inventory prior to implantation procedure.**

## Individual Components

### Occlusive Cuff



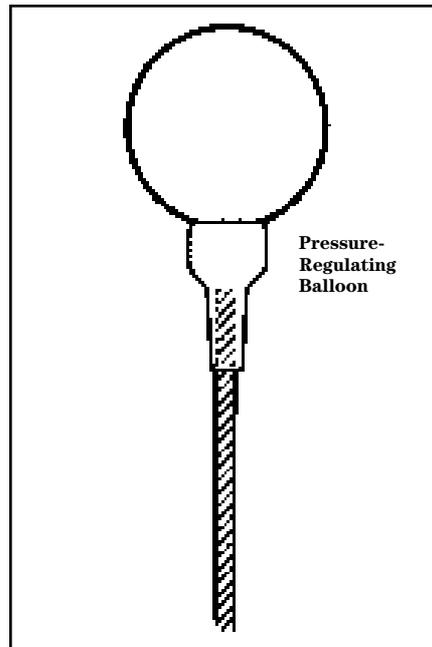
The cuff is implanted around a segment of the anal canal. When inflated, the cuff occludes the anal canal by applying pressure on the circumference of the canal. It is made of silicone elastomer and is available in twelve sizes with cuff lengths ranging from 9.0cm to 14.0cm (in 1cm increments) and two cuff widths: narrow (2.0cm; deflated), standard (2.9cm; deflated).

Narrow	Standard
9.0cm	9.0cm
10.0cm	10.0cm
11.0cm	11.0cm
12.0cm	12.0cm
13.0cm	13.0cm
14.0cm	14.0cm

The surgeon determines the approximate cuff length and width to be used in the patient by measuring the circumference and length of the anal canal, using the AMS cuff sizer intra-operatively. The cuff sizer is not a precision instrument and is for reference only. The surgeon should use his own judgement when choosing a cuff to fit the patient's anatomy.

A connector links the cuff's tubing to the tubing from the control pump. The connection is secured with 3-0 polypropylene suture ties if suture-tie connectors are used, or with AMS Quick Connect™ Sutureless Window Connectors.

### Pressure-Regulating Balloon

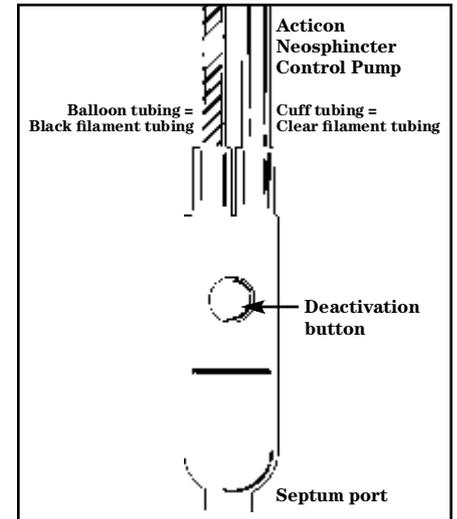


The pressure-regulating balloon, implanted in the prevesical space, controls the amount of pressure exerted on the anal canal by the occlusive cuff. It is also made of silicone elastomer and is provided in four pressure ranges.

- 81-90cm H<sub>2</sub>O
- 91-100cm H<sub>2</sub>O
- 101-110cm H<sub>2</sub>O
- 111-120cm H<sub>2</sub>O

The balloon's tubing is also linked to tubing from the control pump by a connector. The connection is secured with 3-0 polypropylene suture ties or with AMS Quick Connect Sutureless Window Connectors.

### Control Pump



The control pump is implanted in the soft tissue of the scrotum or labium and is approximately 1.2cm wide and 3.6cm long. The upper part of the control pump contains the resistor and valves needed to transfer fluid to and from the cuff. It also contains the deactivation button.

The bottom half of the control pump is a bulb which the patient squeezes and releases to transfer fluid within the device. There is also a septum port located at the bottom of the control pump bulb. The septum port is designed to be used post surgically in the event that a small amount of fluid needs to be transferred into the Acticon prosthesis system. The control pump comes in one size that accommodates all cuff and balloon sizes.

The Acticon prosthesis has color-coded tubing to help surgeons make the appropriate tubing connections. The control pump tubing that connects to the cuff tubing has clear nylon filament inside. The control pump tubing that connects to the balloon tubing has black nylon filament inside.

These connections may be made with a straight or right angle connector and are secured with 3-0 polypropylene ties. The connections may also be made with AMS Quick Connect Sutureless Window Connectors.

## Accessory Kit

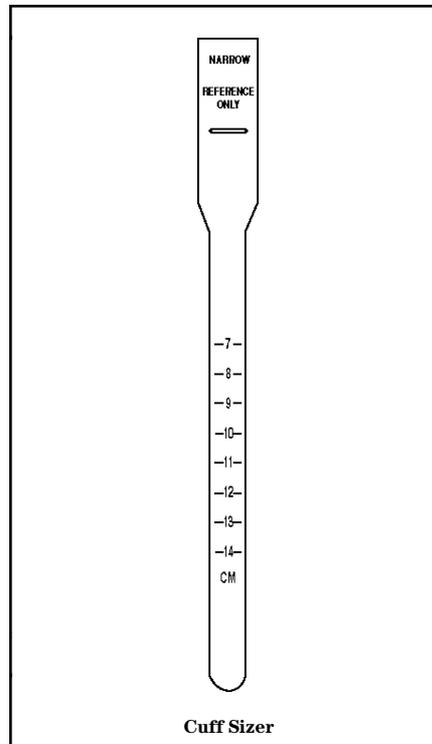
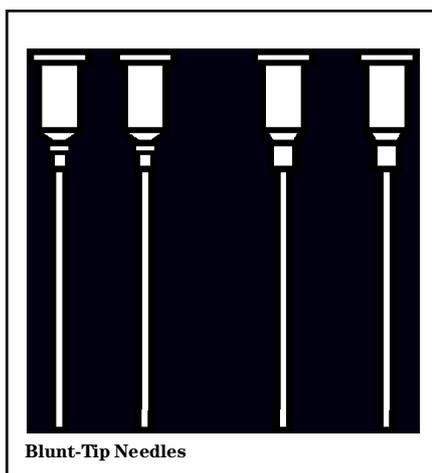
The Accessory Kit for the Acticon prosthesis contains accessory materials necessary for one implant procedure.

The Accessory Kit includes:

- 2 15-gauge disposable blunt needles
- 2 22-gauge disposable blunt needles
- 1 Disposable cuff sizer\*
- 2 30cm lengths of silicone tubing
- 3 Straight AMS Quick Connect Sutureless Window Connectors
- 2 Right angle AMS Quick Connect Sutureless Window Connectors
- 1 Locking ring holder with 8 collets
- 3 Straight Suture-Tie Connectors
- 2 Right angle Suture-Tie Connectors
- 1 Quick Connect Instruction Brochure
- 1 Package Insert
- 1 Patient Information Form
- 1 Warranty Brochure
- 1 Patient ID Card
- 1 Mailing envelope
- 1 Medic Alert Brochure

\*Cuff sizer is packaged separately.

Use the 15-gauge needles to prepare the components. They fit snugly into the tubing lumen to prevent fluid from leaking during preparation. The 22-gauge needles are used to flush away air and blood from the tubing before a connection is made.



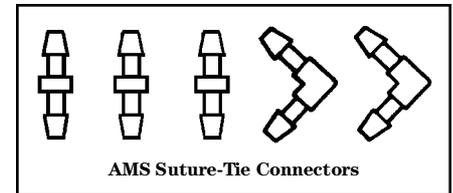
The cuff sizer, which should not be stretched before use, is made of silicone elastomer. The cuff sizer is used by the surgeon to get an approximate measurement of the circumference and the appropriate length of the anal canal at the site where the occlusive cuff is to be implanted. The cuff sizer is for reference only and the surgeon should use his own judgement in choosing an appropriate cuff size.

Place the silicone tubing from the Accessory Kit over the tips of the hemostats used for clamping tubing or handling device components (see *Preparing Mosquito Hemostats* ).

## Connectors

There are two systems available for connecting components and tubing of the Acticon prosthesis.

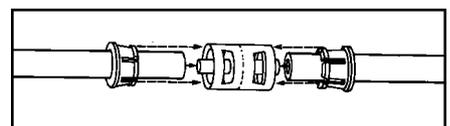
The Accessory Kit contains three straight and two right angle AMS Suture-Tie Connectors. These connectors are attached with permanent suture ties (3-0 polypropylene).



The Accessory Kit also contains three straight and two right angle AMS Quick Connect Sutureless Window Connectors, eight collets (or locking rings) and one collet holder. If you plan to use the AMS Quick Connect Sutureless Window Connectors, you will need to order the AMS Quick Connect Assembly Tool, a reusable stainless steel instrument used to assemble the connectors. **Caution: AMS Quick Connect Sutureless Window Connectors should not be used in revision procedures involving previously implanted component tubing. Changes in the tubing over time may cause the Quick Connect Sutureless Window Connectors to be less effective.** The Quick Connect system may be used when all previously implanted components are removed and replaced with new components.



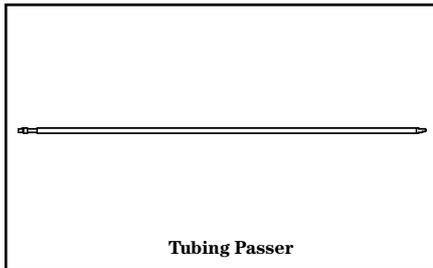
AMS Quick Connect™ Sutureless Window Connectors



## Tubing Passer

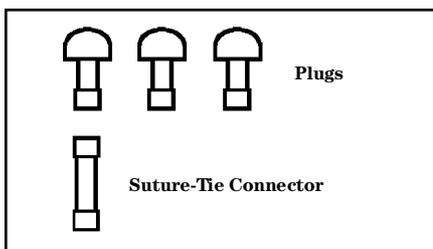
The tubing passer is made of stainless steel and is used to route the tubing of the components through the appropriate tissue planes.

The machined end of the passer provides a snug fit in the tubing lumen. The lumen of each component's tubing is placed over the machined end of the tubing passer. This allows the device tubing to be routed to the appropriate position for proper connection between the device components.



## Deactivation Package

The Deactivation Package is an optional package not normally required for an initial implant. It contains three stainless steel plugs and one suture-tie connector. The three plugs are often useful during revision surgical procedures when components may be separated to create a non-functioning device during periods of tissue healing.



The three plugs may also be used during implantation of the occlusive cuff and control pump. The plugs may be temporarily placed in the tubing of the cuff and pump at the time of component preparation. Use of these plugs will allow temporary removal of the mosquito hemostats from the tubing during implantation.

# Implantation

## Preoperative

### *Surgical Team Preparation*

Before beginning an Acticon prosthesis implant procedure, the surgeon and the OR staff should be familiar with the device and the equipment needed as well as the steps in the procedure.

AMS provides this Operating Room Manual as an informative guide to the implant procedure. Both the surgeon and the OR staff should review the information in this manual prior to surgery. In addition, there should be an OR Manual in the operating room during the surgery as a quick reference.

Just prior to surgery, the surgical team should scrub for ten minutes using povidone-iodine soap or the approved hospital scrub procedure.

### *Patient Preparation*

A standard mechanical bowel preparation should be performed before the surgery. The physician should prescribe prophylactic antibiotics active against both anaerobic and aerobic bacteria. This helps to reduce the risk of infection. The evening before the procedure the patient should be instructed to do a Phisohex scrub.

The physician should discuss all Warnings, Precautions and Contraindications with the patient prior to surgery, including those in the Package Insert and those dictated by his own training and experience.

It is also important that the surgeon discuss with the patient the possibility of an allergic reaction to the materials in the device or the filling solution for the device. 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 causal relationship has been established between these events and silicone elastomer.

Once the patient is in the operating room, the anal and genital area may be shaved. Following the shave, the area should be scrubbed with povidone-iodine soap for ten minutes or the approved hospital preoperative scrub procedure.

The patient is placed in the lithotomy position, prepped and draped for both a perianal and an abdominal incision. A proctoscopic exam and use of Betadine/saline irrigation is recommended to clear the rectum of any residual stool.

## Equipment Needed

A number of conventional surgical instruments and supplies are needed for implantation of the Acticon prosthesis. Each physician also may have a preference about what should be available.

The following equipment, among other standard operating room materials, should be available:

- Sterile stainless steel tray
- 100cc graduate container
- 500cc graduate container
- Sponge bowl
- Medicine cup
- Emesis basin
- 60cc disposable syringe
- 2 10cc disposable syringes
- 6 silicone-shod mosquito hemostats
- Straight "virgin" scissors
- Hegar dilators
- Statinsky clamp
- Babcock clamps
- Centimeter ruler
- Asepto™ syringe
- Antibiotic solution
- Foley catheter
- Vaginal pack
- Sterile saline for rinsing gloves
- Umbilical tape
- 2 5/8 inch Penrose drains
- Betadine solution
- Sterile water

Use a plastic-draped **Mayo stand** or a stainless steel tray as a station for handling and preparing the components of the prosthesis. Be certain that the components do not come into contact with paper or cloth drapes.

Submerge the prepared components of the prosthesis in a **storage basin** containing sterile water, normal saline, or a separate container of filling solution until they are implanted.

Position **splash basins** so that the surgeons can conveniently clean their gloves during the surgical implantation procedure, especially before they make the tubing connections. It is important to change gloves frequently.

## Sterilization

American Medical Systems sterilizes all of the components of the Acticon prosthesis. Sterilization of the prosthesis saves time, assures sterility of the components upon delivery to the hospital, and reduces handling of the components.

**Caution: Do not resterilize Acticon Neosphincter components.**

**Caution: Do not resterilize the AMS Suture-Tie Connectors or the AMS Sutureless Window Connectors.**

### ***Shelf Life of Sterilized Components***

Refer to the label on the package of the component or the outside carton label for shelf life.

### ***Care and Storage of Sterilized Components***

To protect the integrity of the packaging and function of the Acticon prosthesis, store the sterilized components on a protected shelf or in a cabinet. The environment should be clean, dry, and near room temperature. For maximum protection during storage, leave the component trays within their dustcover boxes.

### ***How to Sterilize AMS Instruments***

**Note:** *The AMS Quick Connect Assembly Tool and Acticon Tubing Passer are shipped nonsterile.*

American Medical Systems does not sterilize the Acticon Tubing Passer or the AMS Assembly Tool. These instruments are shipped in steam sterilization packages ready for hospital sterilization. For sterilization information see instructions packaged with the tools.

## Equipment Preparation

### ***Preparing Mosquito Hemostats***

To protect component tubing from being damaged by the mosquito hemostat jaws, cover the jaws with the silicone tubing provided in the Accessory Kit.

1. Place tubing on both jaws of the mosquito hemostats up to the box lock. Completely cover all of the teeth on both jaws of each hemostat.
2. Clamp jaws together to only the first click to prevent excessive pressure on the tubing. Trim the tubing at the jaw tip with sharp, virgin scissors. Reserve the scissors as the tubing scissors throughout the procedure.

### ***Antibiotics***

The surgical set-up should include a broad-spectrum antibiotic solution for irrigation. The antibiotic solution and the filling solution must be kept separate from each other.

### ***Surgical Gloves***

Because silicone components actively attract dust and lint, all surgical gloves must be rinsed free of powder. Glove powder that enters tubing may block the pump valves.

## Unpacking the Components

As the circulating nurse transports the components from storage to the operating room, he or she should keep the sterile trays in the dustcover boxes.

To unpack the components in the operating room, follow this procedure:

1. Remove the trays from the dustcovers by opening the boxes.
2. Remove the inner tray from the outer tray using the following method: Peel back the Tyvek lid completely from the outer tray in one motion and continue to hold the outer tray without touching the sterile inner tray. Ask the scrub nurse to use his or her index finger (not thumb) to carefully lift the inner tray up and out of the outer tray. The scrub nurse should then place the inner tray on a plastic-draped Mayo stand in the sterile field.
3. When the scrub nurse is ready to prepare the components, he or she should remove the components from the inner trays by peeling back the lids of the sterile inner trays and carefully picking out the components. Place them in their appropriate positions on the plastic draped Mayo stand.

**Note:** *The adhesive labels at one end of the dustcover box and the small peelable labels on the side of the plastic trays show the serial number, lot number and the size of the components. Because you will need to record this information on the patient information form, keep the dustcover boxes or the peelable labels in the operating room. This information is also on the Tyvek lid of the outer tray.*

## Preparing the Components

The filling solution must remain free of debris that can block components. Currently used filling solutions are:

CONTRAST MEDIA	DILUTION		MANUFACTURER	
Conray 43	30cc Conray 43	+	60cc sterile H <sub>2</sub> O	Mallinckrodt
Conray FL	58cc Conray FL	+	42cc sterile H <sub>2</sub> O	Not Applicable
Cysto Conray II	60cc Cysto Conray II	+	15cc sterile H <sub>2</sub> O	Mallinckrodt
Cystografin 14%	62cc Cystografin 14%	+	59cc sterile H <sub>2</sub> O	Squibb
Cystografin Dilute	60cc Cystografin Dilute	+	12cc sterile H <sub>2</sub> O	Squibb
Dip Conray 30%	47cc Dip Conray 30%	+	50cc sterile H <sub>2</sub> O	Daiichi
Hypaque 25%	50cc Hypaque 25%	+	60cc sterile H <sub>2</sub> O	Winthrop-Breon Labs
Hypaque-Cysto	60cc Hypaque-Cysto	+	58cc sterile H <sub>2</sub> O	Winthrop Pharmaceuticals
Hypaque-Meglumine 30%	60cc Hypaque-Meglumine	+	56cc sterile H <sub>2</sub> O	Winthrop Pharmaceuticals
Imeron 250	49cc Imeron 250	+	21cc sterile H <sub>2</sub> O	Byk
Imeron 300	49cc Imeron 300	+	35cc sterile H <sub>2</sub> O	Byk
Iopamiro 200	60cc Iopamiro 200	+	23cc sterile H <sub>2</sub> O	Bracco
Iopamiro 300	57cc Iopamiro 300	+	60cc sterile H <sub>2</sub> O	Bracco
Iopamiro 370	38cc Iopamiro 370	+	60cc sterile H <sub>2</sub> O	Bracco
Isopaque-Cysto	60cc Isopaque-Cysto	+	27cc sterile H <sub>2</sub> O	Not Applicable
Omnipaque 180	60cc Omnipaque 180	+	14cc sterile H <sub>2</sub> O	Nyegaard
Omnipaque 240	60cc Omnipaque 240	+	38cc sterile H <sub>2</sub> O	Schering
Omnipaque 300	57cc Omnipaque 300	+	60cc sterile H <sub>2</sub> O	Winthrop-Breon Labs
Omnipaque 350	48cc Omnipaque 350	+	60cc sterile H <sub>2</sub> O	Winthrop-Breon Labs
Solutrast 200	60cc Solutrast 200	+	22cc sterile H <sub>2</sub> O	Byk
Solutrast 300	53cc Solutrast 300	+	47cc sterile H <sub>2</sub> O	Byk
Telebrix 12	53cc Telebrix 12	+	47cc sterile H <sub>2</sub> O	Laboratoire Guerbei
Ultravist-150	57cc Ultravist-150	+	3cc sterile H <sub>2</sub> O	Schering
Urografin 30%	49cc Urografin 30%	+	51cc sterile H <sub>2</sub> O	Schering
Urovist Cysto	51cc Urovist Cysto	+	50cc sterile H <sub>2</sub> O	Berlex

*Or an equivalent ratio dye with sterile water for a larger total volume.*

If you do not use the recommended solutions and the recommended mixture proportions, particulate matter will form and the isotonicity of the mixtures will be altered. The presence of particulate matter in the fluid can affect the operation of the prosthesis. The solution must also be isotonic with intracellular fluid to minimize the transfer of fluid across the semi-permeable silicone membrane.

**Caution: Never use sterile saline or lactated Ringer's solution to dilute the recommended contrast**

**solutions. If one of the recommended contrast solutions is not available, or if you do not choose to use a radiopaque filling solution, normal or isotonic saline alone is the only acceptable alternative.**

**Caution: Contrast media are contraindicated if the patient has an iodine allergy. Failure to follow these recommendations may affect device performance.**

When prepared, each component should be submerged in a storage

basin of sterile water, normal saline or filling solution to prevent contact between the component and foreign materials.

In the event that debris is seen in the filling solution, discard the filling solution and container and begin the filling procedure again with a clean container and solution. If debris is seen in the Acticon prosthesis system, the contaminated components should not be implanted. Replace the contaminated components with new components.

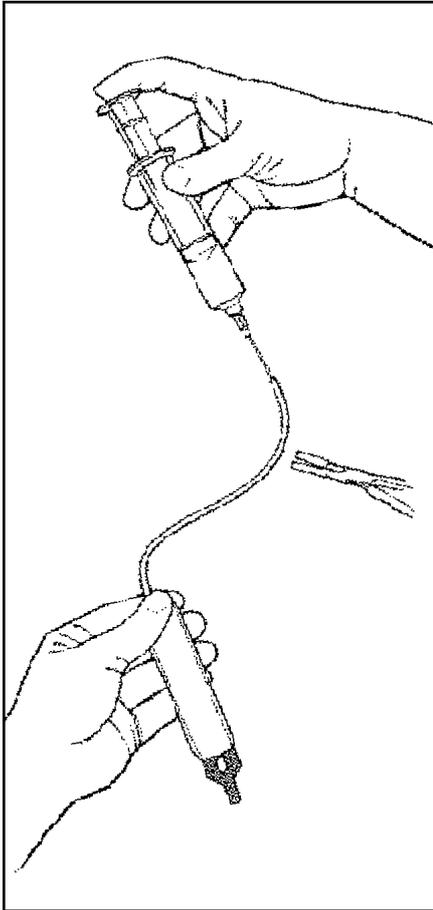
### ***Preparing the Occlusive Cuff***

Using a syringe with a 15-gauge needle, aspirate the air from the selected cuff, and then inject the cuff with filling solution, being careful not to overdistend the cuff.

Aspirate the air. When all of the air has been displaced, evacuate the fluid from the cuff.

Clamp the cuff tubing 3cm from the end with a silicone-shod mosquito hemostat (one notch only), and remove the 15-gauge needle. Submerge the cuff in a storage basin of sterile water or normal saline or a separate container of filling solution, until implantation.

**It is important that the mosquito hemostat not be clamped down more than one click to prevent excessive compression of the tubing. Excessive pressure will damage the tubing permanently.**

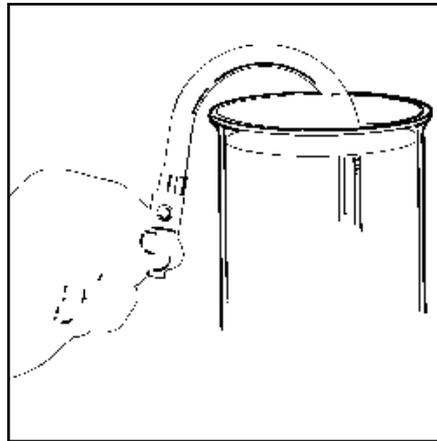


### ***Preparing the Control Pump***

Do not use the 15-gauge blunt needle and syringe when filling the control pump.

During filling of the control pump, it may be helpful to deactivate and activate the pump once or twice. To fill the control pump, place the end of each tubing in a basin of the appropriate filling solution. With the pump held in an upright position and below the level of the basin, gently squeeze the pump bulb repeatedly, until all of the air has been displaced with fluid.

Clamp each tubing 3cm from the end with a silicone-shod mosquito hemostat (one notch only). Submerge the filled control pump in a storage basin of sterile water or normal saline or a separate container of filling solution, until implantation.

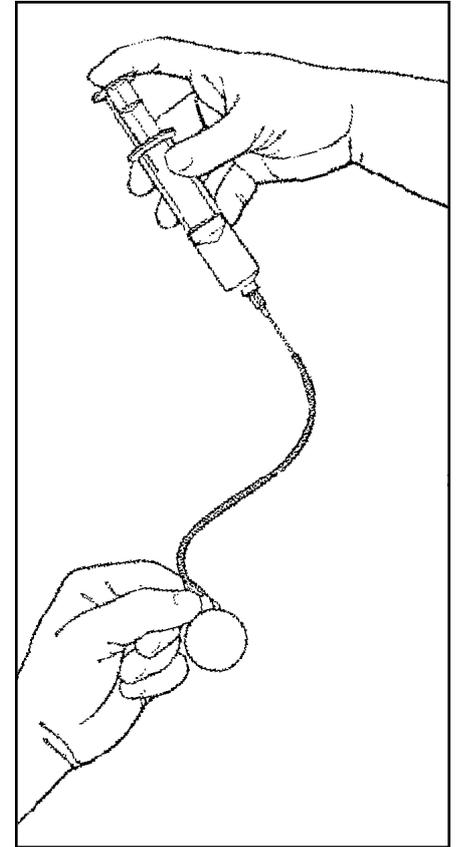


### ***Preparing the Pressure-Regulating Balloon***

Use a syringe with a 15-gauge blunt needle to aspirate the air from the balloon and then fill it with approximately 40cc of the appropriate filling solution.

Hold the balloon down to aspirate all of the air, and then evacuate the fluid. Clamp the tubing 3cm from the end with a silicone-shod mosquito hemostat (one notch only) and remove the 15-gauge needle. Submerge the balloon in a storage basin of sterile water or normal saline or a separate container of filling solution, until implantation.

Remember that silicone elastomer is semi-permeable. Be careful not to over aspirate the pressure regulating balloon because air can be drawn into the system.

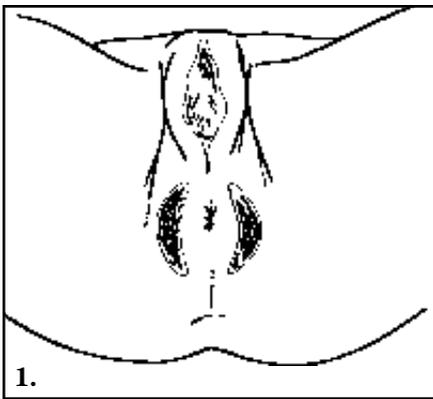


# Intraoperative Surgical Procedures

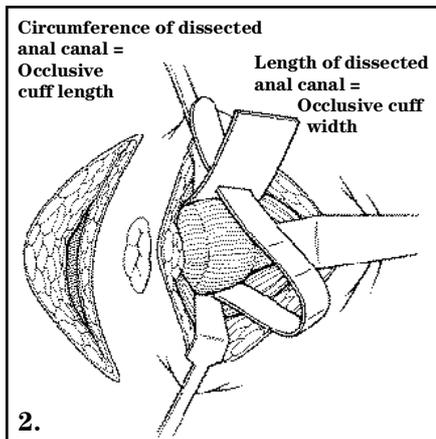
## Anal Canal Placement

This procedure requires a set-up similar to that used for anal surgery. The patient is placed in the lithotomy position, prepped, and draped for both a perianal and an abdominal incision.

1. To begin the procedure the surgeon makes a perianal incision and dissects around the anal canal. There are several possible approaches to this procedure:
  - a) a single anterior transverse incision;
  - b) bilateral vertical incisions as shown here or
  - c) pre- and retroanal incisions.



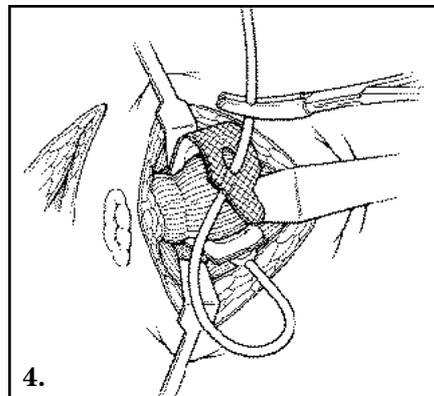
2. To determine the approximate cuff length needed, measure the *circumference* of the anal canal with the AMS cuff sizer. Place the cuff sizer around the anal canal at the site where the cuff is to be implanted. It has to fit snugly without constricting the anal canal. This *anal canal circumference* will determine the *cuff length* to be used. The physician may insert a finger at this time to determine adequate anal canal tone.



*The length of the anal canal corresponds to the width of the cuff.* The width of the cuff sizer corresponds to the narrow (2.0cm) cuff width. The surgeon should use his/her judgement to determine if the dissection is adequate to accommodate a standard cuff width.

The cuff sizer may be left in place around the anal canal during cuff preparation to maintain the plane and facilitate cuff placement. Remember, the cuff sizer is for reference only.

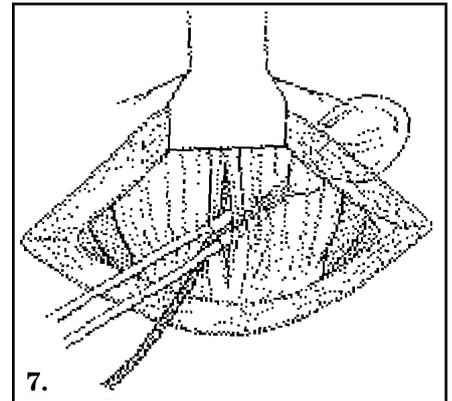
3. Prepare the selected cuff for implantation (see instructions for *Preparing the Occlusive Cuff* on page 7).
4. To implant the cuff, pass the cuff, tab first, around the anal canal. If the pump and balloon are to be placed on the patient's left side, grasp the cuff tab and insert the cuff counter-clockwise around the anal canal. If the pump and balloon are to be placed on the patient's right side, grasp the cuff tab and insert the cuff clockwise. To avoid damage to the cuff, grasp the cuff tab with a silicone shod mosquito hemostat and grab the tab only.



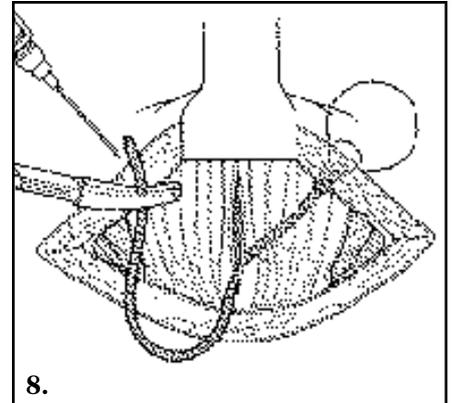
5. The criteria used to determine which balloon size to select for implantation are dependent on, but not limited to a combination of: cuff fit, tissue quality, patient's stool consistency, and patient's activity level. For example, if a patient consistently leaks liquid stool, they may benefit from a higher pressure balloon which would cause a greater force to be exerted on the anal canal by the cuff and provide a higher level of continence. Alternatively, a

patient who has had several previous surgical procedures may need a lower pressure balloon which would exert less force on the compromised tissue.

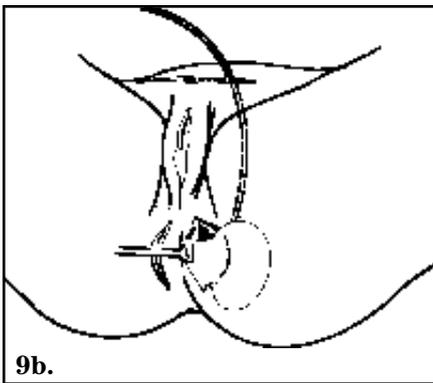
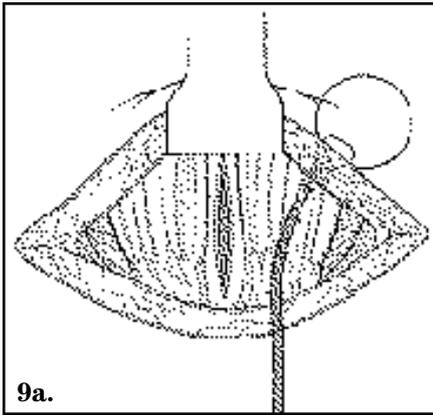
6. Make a suprapubic incision, divide the rectus fascia transversely, and use a spreading motion to separate the linea alba to reach the prevesical space.
7. Use blunt dissection to create a space for the balloon and position the balloon in the prevesical space.



8. Fill the balloon with 55cc of the appropriate filling solution and clamp the tubing (one notch only) with a silicone-shod mosquito hemostat.

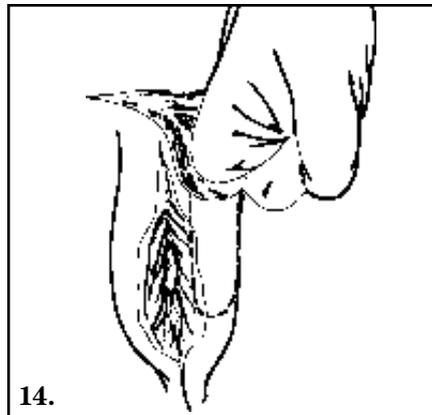


9. Route the balloon tubing through the rectus muscle and fascia to the abdominal incision. Then route the cuff tubing to this area using the Acticon Tubing Passer.

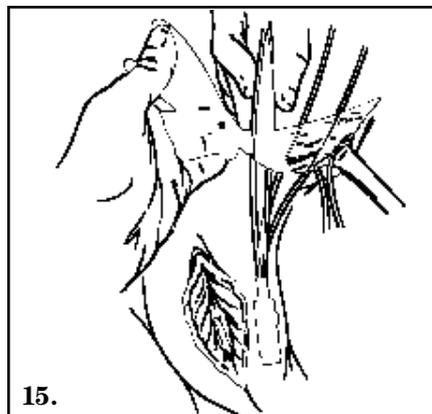


10. Next, the cuff **must** be pressurized. This is a critical step in the procedure as it ensures that the proper volume is in the system. To pressurize the cuff, the cuff tubing and the balloon tubing are temporarily connected using a straight connector. Remove the tubing clamps and wait 60 seconds for the cuff to pressurize. The physician may insert a finger into the anus to determine if adequate anal canal compression is achieved. This will also help to determine if the correct cuff size was implanted.
11. If the cuff does not provide adequate anal canal compression or is too tight around the anal canal, remove the implanted cuff and replace it with a more appropriate size cuff as needed. If the anal canal compression is still inadequate after cuff replacement, it may be necessary to replace the balloon component to achieve optimal fit of the device.

12. Clamp the cuff tubing and the balloon tubing with silicone-shod mosquito hemostats and remove the connector.
13. Insert a 15-gauge needle into the balloon tubing. Remove the mosquito hemostat and aspirate all of the remaining fluid from the balloon. Refill it with 40cc of filling solution, clamp the tubing with a silicone-shod mosquito hemostat.
14. To implant the control pump in the scrotum or labium, use blunt dissection to create a dependent pouch. Most surgeons prefer implanting the control pump via the abdominal incision. The control pump should be placed on the same side where the pressure-regulating balloon was placed.



15. It is important to discuss pump placement with the patient prior to implant. The patient may choose to have the pump placed on either the right or the left side depending upon their manual dexterity. Place the pump in the pouch making sure that the deactivation button faces anteriorly and is palpable. The pump tubing should be above the rectus muscle and fascia in the abdominal incision.



16. After the components are placed, connect the tubing using either AMS Suture-Tie Connectors or AMS Quick Connect Sutureless Window Connectors. (See instructions for *Connecting the Tubing* on page 10.) Tubing connectors lie above the rectus muscle and fascia in the abdominal incision.
17. Deactivate the device. (See *Deactivation/Activation* instructions on page 13.)

## Connecting the Tubing

AMS Suture-Tie Connectors or AMS Quick Connect Sutureless Window Connectors may be used to connect the tubing. For either connection system, the choice to use straight connectors or right angle connectors is determined by the surgical technique and the anatomical characteristics of the patient. In most cases, straight connectors will be used. Right angle connectors should always be used when the tubing makes a sharp curve at the point of connection.

**Caution:** *AMS Quick Connect Sutureless Window Connectors should not be used in revision procedures involving previously implanted component tubing. Changes in the tubing over time may cause the Quick Connect Sutureless Window Connectors to be less effective. The Quick Connect System may be used when all previously implanted components are removed and replaced with new components.*

## AMS Suture-Tie Connectors

All connections using AMS Suture-Tie Connectors are tied with 3-0 non-absorbable polypropylene sutures.

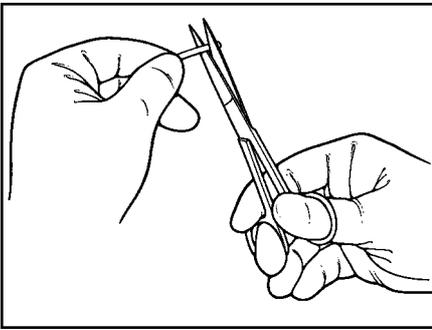
1. Cut the tubing to fit the patient's anatomy. Be careful to cut the tubing at a right angle so the tubing will seat tightly all the way around the connectors. Use a 22-gauge blunt tip needle to flush the tubing ends with sterile normal saline or appropriate filling solution to remove particulate matter and air before connecting.
2. Use the 22-gauge blunt tip needle to flush the connector ends. Push the tubing over the ends of the connector so that they meet at the center hub of the connector. Be certain that the tubing is on the connector straight.
3. Use a double-throw overhand surgeon's knot followed by two single throws to attach the tubing to the connector.
4. The suture should crimp, but not cut the tubing.
5. Pass the suture to the opposite side of the connector and use the same tying technique.

## AMS Quick Connect™ Sutureless Window Connectors

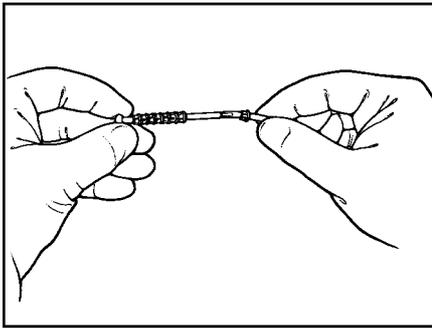
The AMS Quick Connect System cannot be resterilized. Conventional hospital sterilization will damage the connector components. However, the AMS Assembly Tool may be resterilized.



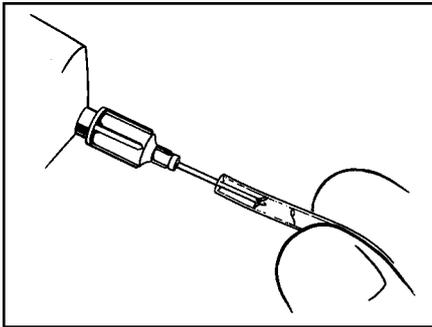
Assembly Tool



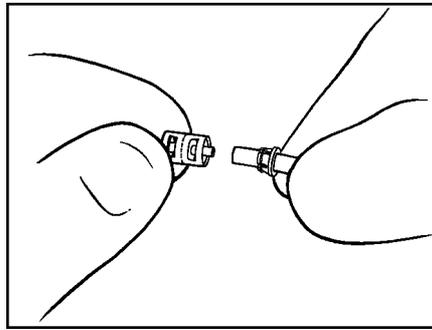
1. Trim the tubing lengths to fit the patient's anatomy. Cut squarely.



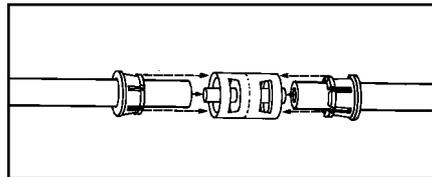
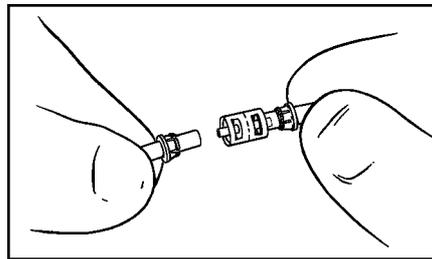
2. Slide the collet ring onto the tubing, making sure that the teeth of the collet ring face toward the tubing end. Repeat with other tubing.



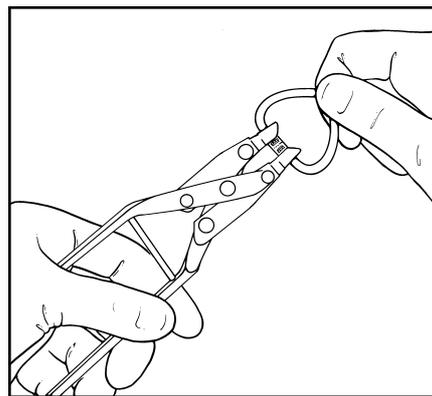
3. Flush the end of the connector and the tubing with sterile normal saline or appropriate filling solution to remove particulate matter and air using a 22-gauge blunt tip needle.



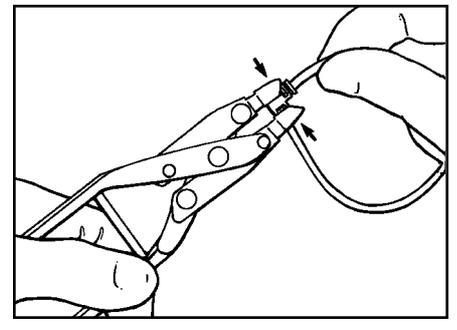
4. Insert the tubing ends onto the connector. Firmly push one side of the tubing to the middle wall of the connector and check tubing placement through the connector window. Flush both the connector and tubing end before the final connection.



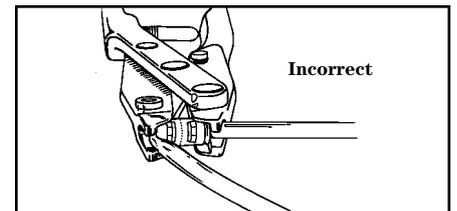
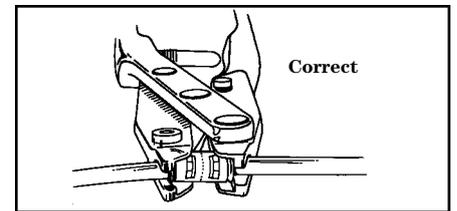
5. Firmly push the other tubing to the middle wall. Check the connector window to make certain both tubing ends are still touching the middle wall.



6. Place the connector ends in the assembly tool jaw. Squeeze the tool handles until the closure stop touches the opposite handle.



7. When using a right angle connector, the assembly tool must be used twice, once on each end of the connector. Again, make certain the tubing is touching the middle wall on both sides of the connector. The closure stop of the assembly tool must touch the opposite handle each time a connection is made.



**Caution:** Check the tubing before you close the assembly tool. The tubing must not be trapped between the assembly tool jaw and the connector. The tubing must exit straight from the ends of the connector, through the slots in the assembly tool. After using the AMS Quick Connect Assembly Tool, the tubing should bulge through the connector window. This indicates that the tubing is still firmly against the middle wall of the connector.

After all of the connections have been made, cycle the device to confirm function, then deactivate the device.

**Note:** Make sure the pump bulb has refilled with some fluid before pressing the deactivation button; otherwise it will be difficult at a future date to activate the device.

# Intraoperative Troubleshooting

## *Total Device*

<b>Problem</b>	<b>What to Do</b>
The device fails to cycle	<ul style="list-style-type: none"><li>• Check connections between components. If they are correct, change the entire device.</li></ul>

<b>Problem</b>	<b>What to Do</b>
Leak in any of the components	<ul style="list-style-type: none"><li>• Determine affected component and replace.</li><li>• Do not mechanically flush the pump which could cause blockage of the delay-fill resistor.</li><li>• Replace the control pump.</li><li>• Because it is difficult to adequately flush an implanted cuff, replace the cuff.</li><li>• Flush the pressure-regulating balloon.</li></ul>

## *Occlusive Cuff*

<b>Problem</b>	<b>What to Do</b>
Too tight or too loose around the anal canal	<ul style="list-style-type: none"><li>• Remove improperly sized cuff. Remeasure with cuff sizer and implant proper size. Increase or decrease as needed.</li></ul>

<b>Problem</b>	<b>What to Do</b>
Punctured or damaged	<ul style="list-style-type: none"><li>• Remove and replace with new cuff.</li></ul>

## *Pressure-Regulating Balloon*

<b>Problem</b>	<b>What to Do</b>
Punctured during closing	<ul style="list-style-type: none"><li>• Remove and replace with new pressure-regulating balloon.</li></ul>

## *Control Pump*

<b>Problem</b>	<b>What to Do</b>
Difficulty activating the device	<ul style="list-style-type: none"><li>• Squeeze the sides of the control pump adjacent to the deactivation button to allow fluid to fill the pump bulb. When enough fluid has returned to the pump bulb, give it a quick, forceful squeeze.</li></ul>

## **Postoperative Care**

### *Immediately Postoperative*

After 24 hours, the nursing staff may place ice packs in the region of the pump to reduce postoperative edema. At the discretion of the implanting physician antibiotics may be prescribed. The patient should be advised on the use of absorbent pads until the device is activated approximately six to eight weeks after the surgery. The patient should be advised to avoid undue compression of the cuff area.

### *After the Patient is Released from the Hospital*

The patient is usually discharged within 5-10 days after surgery. After leaving the hospital, the patient should take antibiotics as prescribed by the physician.

The patient must return to the physician's office to activate the device prior to use of the Acticon prosthesis. The device is normally activated six to eight weeks post-operatively. At that time, instruct the patient that it is possible to begin using the prosthesis.

To determine that the patient is ready to use the device, check the incision site to be sure that it has healed properly. There should be no redness, swelling, or drainage. Any of these things may indicate that an infection is present and the infection should be treated appropriately.

Ask the patient about tenderness and/or discomfort when cycling the device. It is possible that the patient may experience some mild discomfort the first few times the prosthesis is used.

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

The physician may want to observe the patient for a period of time in the office to determine if sufficient continence is achieved with the device activated.

Provide patient re-education on how to use the Acticon prosthesis.

It is recommended that the patient order and wear a "Medic Alert" bracelet to inform others of the device in case of emergency.

### *Evaluating Long-Term Function and Placement*

After the postoperative healing period, the surgeon should continue to have contact with the patient at least on an annual basis to evaluate the function of the device. During the evaluation, the surgeon should ask the patient about how the device is functioning and if he or she has noticed any changes in the function of the device.

If the patient is having mechanical difficulty with the device, or there is infection or erosion present, revision or removal surgery may be necessary. In the event of a revision surgery, follow the same preparation and implantation techniques outlined elsewhere in this manual. Suture-tie connectors must be used in any revision surgery where the total device is not explanted.

### *Imaging of the Prosthesis*

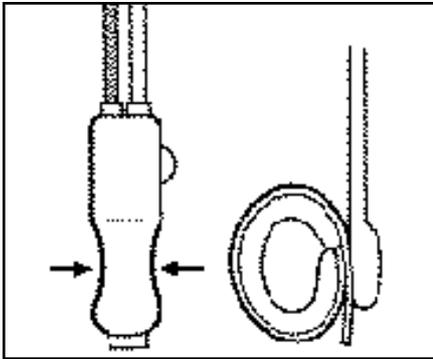
The Acticon prosthesis may be imaged using ultrasound, magnetic resonance imaging (MRI) and plain film Xray.

## Deactivation/Activation

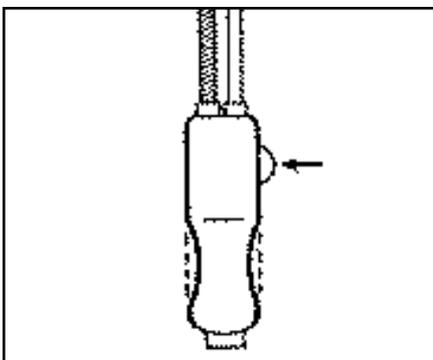
The Acticon prosthesis has a unique deactivation feature. The deactivation button is located in the upper portion of the control pump. When the deactivation button is pressed, it stops fluid from being transferred between the components. This feature allows the physician to leave the cuff that surrounds the anal canal open during the postoperative healing period to facilitate the healing process or for transrectal procedures.

### To deactivate the device:

1. Squeeze and release the pump bulb several times to remove all of the fluid from the cuff. The cuff will be empty when the pump remains flat.



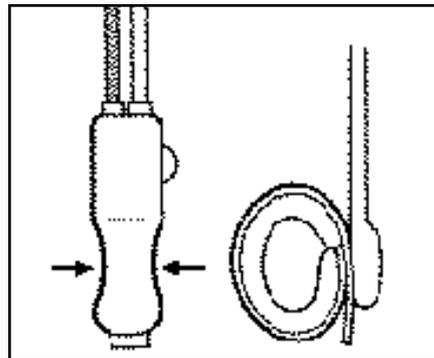
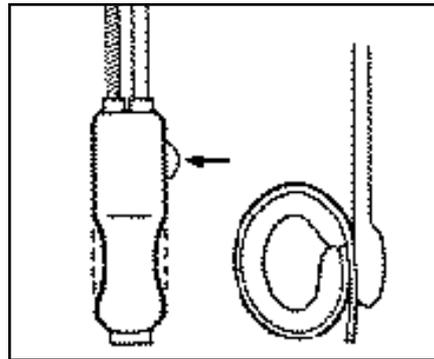
2. Allow the pump bulb to partially refill (approximately 30 seconds to one minute). When there is a **slight indentation** in the pump bulb, press the deactivation button. It is important to leave a slight indentation in the pump bulb to ensure that there is enough fluid in the pump to activate the device later. After the device is deactivated you will still be able to feel the deactivation button.



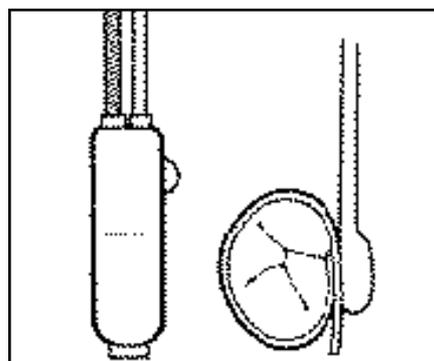
3. After the deactivation button has been pressed, the pump bulb may feel firmer than usual. The indentation in the pump bulb will remain.
4. When the device is deactivated, the cuff will not be inflated and your patient will be incontinent.

### To activate the device:

1. Push on the deactivation button a few times to loosen the poppet. Then give the pump bulb a quick, forceful squeeze. This will move the deactivation poppet back to the activated position.

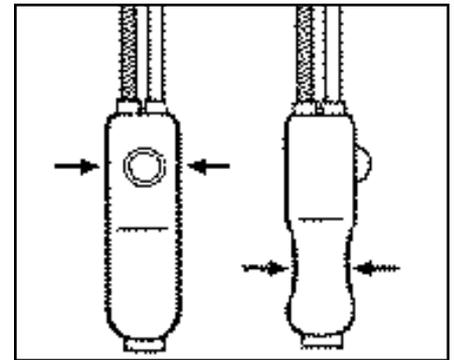


2. After the device is activated, the pump will refill first and then the cuff will refill. It will take several minutes for the device to refill and for the cuff to close off the anal canal.



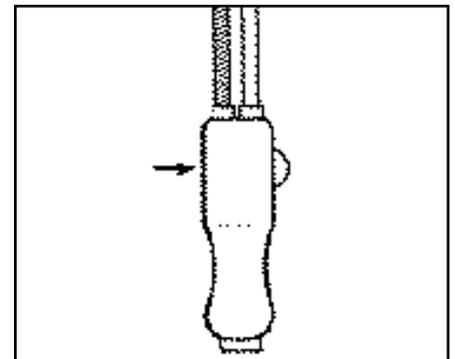
3. When the device is activated, the pump may become less firm.

4. If you have difficulty activating the device, there may not be enough fluid remaining in the pump to push the deactivation poppet to its activated position.
  - Squeeze the sides of the control pump adjacent to the deactivation button to allow fluid to fill the pump bulb. It may take several minutes for the pump to refill. When enough fluid has returned to the pump bulb, give it a quick, forceful squeeze.



OR:

- Feel the control pump to find the deactivation button. Take a cotton tip swab and apply pressure to the area of the control unit directly behind the deactivation button. This will unseat the poppet and allow fluid to fill the pump and then the cuff.



OR:

- Locate the control pump and place your index finger above the deactivation button (toward the tubing). Place the tip of your thumb below the deactivation button on the opposite side. Place the index finger of your other hand on the firm portion of the pump in front of the deactivation button (toward the pump bulb). Firmly bend the pump end down to activate. Release after bending. Squeeze and release the pump several times to transfer fluid.

## Using the Septum Port

Over time it may become necessary to add fluid to the system. Although this situation may occur infrequently, the Acticon Neosphincter control pump has a septum port located on the end of the pump through which fluid can be transferred into the system. This can be accomplished without additional surgery.

### Equipment Needed for Use of Septum Port

- 3 iodine swab sticks
- 3 alcohol swab sticks
- Sterile gloves
- Huber, non-coring 25-gauge needle, (0.5 or 0.75 inches)
- 60cc syringe with Luer lock
- **Same filling solution (radio-paque or isotonic saline solution) as was initially placed in the system.**

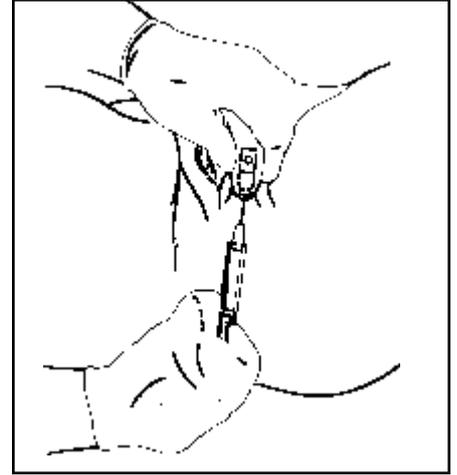
### Technique

1. Expose the cutaneous area over the section of the control pump with the septum port.
2. Identify the septum on the end of the control pump by palpating the outer perimeter. Stretch the skin taut over the septum port.



3. Using sterile technique, scrub the skin in a circular fashion using iodine swab sticks. Extend the prepped area beyond the perimeter of the pump. Use alcohol swab sticks and repeat.
4. Place fenestrated drape over the prepped septum site.
5. Attach the Luer-lock syringe with 60cc of the correct filling solution to the Huber needle. Flush air from the needle.

6. Insert the needle through the skin into the septum port at a perpendicular angle to the skin. Advance the needle approximately 0.5 inches into the septum port. A 0.5 inch needle will not be able to be inserted too far. However, if the skin is unusually thick, use a 0.75 inch needle. Needle placement in the septum port is confirmed after the initial resistance of the needle against the septum port has been relieved.



7. Inject filling solution into the prosthesis. Squeeze the pump with each 0.5cc instilled. Allow the pump to draw in fluid with only gentle pressure on the syringe. The physician should insert a finger into the anus to evaluate any increase in anal canal compression.
8. When finished, gently withdraw the needle from the septum port. Apply an adhesive bandage.

**Caution:** AMS recommends that, if necessary, the septum port be pierced a maximum of three times only over the life of the device.

## Completing the Patient Information Form

In order to meet the conditions of the American Medical Systems Limited Warranty Policy and for purposes of patient tracking regulatory requirements, American Medical Systems requires that a Patient Information Form (PIF) be completed and returned for each implantation procedure.

**For a complete description of the American Medical Systems Limited Warranty Policy, contact American Medical Systems' Customer Service Department or your local AMS Representative.**

The top portion of the form concerns the patient and the procedure. The primary etiology should be specified in detail, and the component information – cuff size, balloon pressure, and serial/lot numbers – should be as complete as possible.

Adhesive labels are packaged with each component identifying the component, size, serial and lot number. These labels should be placed in the appropriate boxes on the PIF.

Promptly return the original top copy of the Patient Information Form to American Medical Systems and keep the second copy for your files. The last page of the Patient Information Form contains the Product Return Form.

## Returning Inventory

On occasion it may be necessary for the surgeon to replace any or all of the implanted components. Any implanted components that have been removed from the patient should be returned to American Medical Systems.

**Before returning any components, whether explanted, or unused and sterile, customers in the United States must fill out the Product Return Form located on the last page of the Patient Information Form. Outside of the United States, contact your AMS Representative.**

In all cases, obtaining a credit or percentage of credit for a returned component is subject to approval under the terms of the American Medical Systems Limited Warranty Policy or the American Medical Systems Return Goods Policy. Explanations of the policies are available from your AMS Representative or American Medical Systems' Customer Service Department.

## Return Component Instructions

Please obtain an Explant Return Kit part number 84412402 to safely return a tried, not used or explanted component. The explant kits are available in the AMS Loaner Kits or you can call Customer Service at 1-800-328-3881 to obtain a kit free of charge. Outside of the U.S. contact your AMS Representative.

Shipping undisinfecting explanted components (potentially biohazardous materials) is a violation of US Postal Service regulations. Our Explant Return Kit meets those requirements.

## For More Information and Ordering Procedures

In the United States, please contact American Medical Systems Customer Service Department for more information or to place an order by calling 1-800-328-3881, extension 6469.

Outside of the United States, contact your AMS Representative.