# Table of Contents

## Introduction
- Overview .................................................................................. 1
- Indications for Use ................................................................... 1
- Additional Information ............................................................... 1
- System Description ................................................................... 1
- System Operation ...................................................................... 1

## Device Description
- Occlusive Cuff .......................................................................... 2
- Pressure-Regulating Balloon ...................................................... 3
- Control Pump ............................................................................ 3
- Accessory Kit ............................................................................ 4
- Quick Connect Assembly Tool (Optional) ................................. 5
- Insertion Package/Tubing Passers (Optional) .............................. 5
- Deactivation Package (Optional) ................................................ 5

## Device Sterilization and Storage
- Implantable Components ............................................................ 6
- Tool Sterilization ....................................................................... 6
- Storage ..................................................................................... 6

## Operating Room Instructions
- Surgical Team Preparation .......................................................... 7
- Patient Preparation .................................................................... 7
- Supplies and Instrument Requirements ....................................... 7
- Open Components ...................................................................... 9
- Prepare Hemostats .................................................................... 10
- Prepare System Components ...................................................... 10
- Prepare Control Pump ................................................................ 10
- Prepare Pressure-Regulating Balloon ........................................ 11

## Prepare Cuff ............................................................................. 13
- Surgical Procedures .................................................................... 14
- Surgical Team Preparation .......................................................... 14
- Patient Preparation .................................................................... 14

## Bulbous Urethra Cuff Placement - Perineal Approach .............. 15
- Implant Pressure Regulating Balloon ......................................... 16
- Implant Pump ............................................................................. 17
- Connect the Tubing .................................................................... 17
- Deactivation ............................................................................... 17

## Bulbous Urethra Cuff Placement - Transverse Scrotal Approach .. 18
  - Implant Pressure Regulating Balloon ......................................... 20
  - Implant Pump ........................................................................... 21
  - Connecting the Tubing .............................................................. 21
  - Deactivation ............................................................................ 21

## Bladder Neck Placement ............................................................ 21
  - Connecting the Tubing .............................................................. 22
  - Deactivation ............................................................................ 22

## Connect Tubing ......................................................................... 23

## Deactivate Cuff .......................................................................... 25

## Activate Cuff ............................................................................. 25
- Activate Cuff: Normal Method .................................................... 25
- Activate Cuff: Optional Methods ................................................ 26

## Bulbous Urethra Double-Cuff Placement .................................... 27
- Double Cuff Procedure Modifications ......................................... 28
- Original Double Cuff .................................................................. 28
- If Replacing Original Cuff ............................................................ 28
- If Adding New Cuff to System ....................................................... 29
  - Connecting the Tubing .............................................................. 29
  - Deactivation ............................................................................ 29

## Post Operative Care
- Immediately Postoperative ......................................................... 30
- After Release From Hospital ....................................................... 30
- Evaluating Long-Term Function and Placement ......................... 30

## Documentation
- Completing the Patient Information Form ................................ 31
- Inventory Returns and Replacement Information ....................... 31
- Document Information .............................................................. 31
- InhibiZone™ Antibiotic Surface Treatment ............................... 31

## Disclosures
- Indications For Use .................................................................... 32
- Contraindications ...................................................................... 32
- Warnings ................................................................................... 32
- Precautions ............................................................................... 33
Introduction

Overview
American Medical Systems, Inc. (AMS) has produced this operating room manual to assist the operating room staff in preparing for and performing the surgical implantation of the AMS 800™ Urinary Control System. The company does not intend that this manual be an all-encompassing reference on the prosthetic device. For more detailed information on the product and its use, please refer to the related AMS literature or contact your AMS representative.

Indications for Use
The AMS 800 is used to treat urinary incontinence due to reduced outlet resistance (intrinsic sphincter deficiency) following prostate surgery.

Additional Information
The device contraindications, warnings, precautions, and adverse events are described in the AMS 800 Urinary Control System For Male Patients Instructions for Use packaged with the device. They are also described in the Disclosures section of this Operating Room Manual.

System Description
The AMS 800 Urinary Control System (Figure 1-1) consists of three components: an occlusive cuff, a control pump, and a pressure-regulating balloon attached to each other with kink-resistant tubing. The cuff can be implanted around either the bulbous urethra or bladder neck.

System Operation
The AMS 800 Urinary Control System simulates normal sphincter function by opening and closing the urethra, under patient control. When the cuff is closed, urine stays in the bladder. (Figure 1-2a).

To void, patients simply squeeze and release the pump several times. This causes the fluid in the cuff to move into the pressure-regulating balloon. (Figure 1-2b) The depressurized cuff allows urine to pass through the urethra and for the patient to void normally. After a period of 1 to 11 minutes (dependent on both cuff and balloon size) the cuff automatically re-pressurizes and closes the urethra to restore continence. (Figure 1-2c). During voiding a patient with a slow or weak stream may find that voiding has not been completed before the cuff automatically closes and restores continence. In this case, the patient should be advised to deflate the cuff a second time to finish voiding.

The control pump, when implanted in the scrotum, is also designed to allow the clinician or patient to deactivate and activate the system without additional surgery. This deactivation feature is explained in the section titled “Deactivate Cuff”.
Device Description

This section provides a brief description of the following AMS 800 Urinary Control System components (Figure 2-1) and accessories:

- Occlusive Cuff
- Pressure-regulating Balloon
- Control Pump
- Accessory Kit (Including Connectors)
- Quick Connect Assembly Tool (Optional)
- Insert Package (Optional)
- Deactivation Package (Optional)

Cuffs and pumps are available with InhibiZone™ Antibiotic Surface Treatment, which is an antibiotic surface treatment of rifampin (rifampicin) and minocycline hydrochloride (minocycline HCl).*

**Occlusive Cuff**

The occlusive cuff closes the urethra or bladder neck by applying pressure around them. The occlusive cuff is available with InhibiZone Antibiotic Surface Treatment. The cuff is made of silicone elastomer and is available in thirteen sizes, ranging from 3.5 cm to 11.0 cm in length. All cuffs are approximately 2.0 cm wide when deflated.

The surgeon can implant the occlusive cuff at either the bulbous urethra (most common site) or the bladder neck. The occlusive cuff can be implanted at the bulbous urethra using either the perineal approach or the transverse scrotal approach. The surgeon determines the proper size to be used in the patient by measuring the circumference of the tissue around the urethra or bladder neck.

A connector links the cuff's clear tubing to the control pump's clear tubing.

---

* InhibiZone™ Antibiotic Surface Treatment is not available in all markets.
Pressure-Regulating Balloon

The pressure-regulating balloon (PRB) determines the amount of pressure applied by the occlusive cuff. The surgeon usually implants the PRB in the prevesical space. It is also made of silicone elastomer and is available in three ranges. The surgeon usually selects the lowest balloon pressure needed to maintain closure of the bulbous urethra or bladder neck. The most commonly used pressure range is 61-70 cm/H₂O (45-51 mm Hg). For patients requiring less pressure a 51-60 cm/H₂O (38-44 mm Hg) balloon may be used. For patients with a higher leak point pressure, a 71-80 cm/H₂O (52-59 mm Hg) may provide better continence.

Control Pump

The control pump (Figure 2-2) is implanted in the soft tissue of the scrotum. The control pump is available with InhibiZone Antibiotic Surface Treatment. It is approximately 1.2 cm wide and 3.3 cm long. The upper part of the control pump contains the resistor and valves needed to transfer fluid between the components. The bottom half of the control pump is a bulb that the patient squeezes and releases to transfer fluid in order to void.

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 open:
- During the postoperative healing period
- For transurethral procedures

The AMS 800 prosthesis has color-coded tubing to help surgeons make the correct connections between the components:
- Clear tubing connects to cuff
- Black tubing connects to balloon

The connections are made with AMS straight or curved Quick Connect Sutureless Window Connectors. They may also be made with straight or curved suture connectors, secured with 3-0 polypropylene (non-absorbable) ties.
Accessory Kit
The Accessory Kit for the AMS 800 Urinary Control System contains accessory materials necessary for one implant procedure. The Accessory Kit includes the following disposable items:

Cuff Sizer
- One disposable cuff sizer

Special Purpose Needles
- Two 15-gauge blunt needles (for filling components)
- Two 22-gauge blunt needles (for flushing tubing)

Hemostat Shods
- Two 30 cm lengths of silicone tubing (for covering tips of hemostats used to prepare components - tubing shods help protect prosthesis from tubing damage)

Tubing Connection Accessories
- Three straight suture-tie connectors
- Two right angle suture-tie connectors
- One 3-way suture tie connector (Y-connector for double cuff)
- Three straight quick-connect window connectors
- Two right angle quick-connect window connectors
- One 3-way quick-connect window connector (Y-connector for double cuff)
- One Locking ring holder with eight collets

Documentation
- One Quick-Connect Instructions For Use
- One AMS 800 Instructions For Use
- One Patient Information Form (PIF)
- One Patient ID card
- One Mailing envelope
Quick Connect Assembly Tool (Optional)

There are two systems for connecting components and tubing for the AMS 800 Urinary Control System.

- Quick-connectors (Figure 2-3a)
- Suture-tie connectors (Figure 2-3b)

In order to use the quick-connectors in the Accessory Kit, you must order the AMS Quick Connect Assembly Tool. (Figure 2-4) This is a reusable stainless steel instrument used to close the connectors. The Quick Connect Assembly Tool is shipped non-sterile and may be re-sterilized. Quick-connectors should not be used on revision surgeries, except when all previously implanted components are removed and replaced with new components.

**CAUTION:** Sterilize the AMS Quick Connect Assembly Tool before use.

**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 suture-tie connectors in the Accessory Kit are used to connect the tubing using permanent suture ties (3-0 polypropylene). Suture-tie connectors should be used in revision surgeries involving previously implanted components.

Insertion Package/Tubing Passers (Optional)

The Insertion Package (Figure 2-5) consists of two curved tubing passers 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.

**CAUTION:** Sterilize tubing passers before use.

Deactivation Package (Optional)

The Deactivation Package (Figure 2-6) 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.
Device Sterilization and Storage

Implantable Components
American Medical Systems sterilizes all implantable components and all accessories kit components of the AMS 800 Urinary Control System.

CAUTION: Do not re-sterilize any of the implantable components or accessory kit components.

Each sterile component and the accessory kit are packaged separately within an inner plastic tray that 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 dust cover box and on the Tyvek lid of the outer tray identify the components, their sizes, and serial/lot numbers.

To protect the integrity of the packaging and function of the AMS 800 Urinary Control System, 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 dust cover boxes.

Under normal storage conditions, with the sterile barriers of the packaging intact, the components will remain sterile for the period indicated on the dust cover box. Devices with InhibiZone have a different shelf life than untreated devices.

Tool Sterilization
Only these two stainless steel instruments used in conjunction with the AMS 800 prosthesis are shipped non-sterile and may be resterilized:
- AMS Tubing Passers (Insertion Package)
- AMS Quick Connect Assembly Tool

CAUTION: Sterilize the AMS Quick Connect Assembly Tool and the AMS Tubing Passer before use.

Before using, sterilize these stainless steel instruments by steam autoclave. For reprocessing information, refer to the instructions manual provided with the tools.

Storage
The versions of the AMS 800 components with InhibiZone Antibiotic Surface Treatment are light and temperature sensitive. Care should be taken to store the products according to the instructions on the package.

CAUTION: Do not store products with InhibiZone above 40°C (104°F).

CAUTION: Do not use this product past its expiration date.
Surgical Team Preparation
Before beginning an AMS 800 Urinary Control System implant procedure, the surgeon and the OR staff should:

• Know system components
• Have required supplies and instruments
• Understand surgical steps

American Medical Systems provides instructional information about the AMS 800 Urinary Control System and an overview of the implant procedure in a surgical procedure video. American Medical Systems recommends that the surgeon and OR staff watch the video prior to the surgery.

We also recommend that the surgeon and the OR staff review the information in this manual prior to surgery. In addition, there should be a copy of this manual in the operating room during the surgery as a quick reference.

It is helpful for the surgeon and/or the OR staff to observe an implant surgery. This will allow them to become familiar with the OR set-up and the procedure. A surgical observation can usually be arranged through your AMS Representative.

Patient Preparation
Before the surgery, many surgeons prescribe prophylactic antibiotics for the patient. This helps to reduce the risk of infection.

It is also important that the surgeon tell the patient about the possibility of an allergic reaction to the materials in 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. There is no latex used in any system component or accessory. However, during the manufacturing process employees may wear latex gloves similar to those worn by surgeons.

Supplies and Instrument Requirements
A number of conventional surgical tools and supplies are needed for implantation of the AMS 800 Urinary Control System. Each surgeon may also have a preference about what should be available.

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

- Sterile stainless steel tray
- Sterile normal saline (recommended filling solution)
- 1000 cc graduated container
- 500 cc graduated container
- Sponge bowl
- Medicine cup
- Emesis basin
- Two 30 cc disposable syringe
- One 10 cc disposable syringe
- Eight mosquito hemostats
- Straight “virgin” scissors
- Hegar dilators
- Babcock clamps
- Asepto syringe
- Antibiotic solution
- Urinary catheter
- Penrose drain (optional)
- Rectal tube (optional)
- Centimeter ruler (optional)
- Scott retractor (transverse scrotal approach)

Use a plastic-draped Mayo stand or a stainless steel tray as a station for handling and filling the components of the prosthesis.

CAUTION: Be certain that the components do not come into contact with paper or cloth drapes. Fragments of these can cause possible obstruction of fluid flow if they enter the device.
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.

**CAUTION:** Do not use powdered gloves to handle the devices. Powder from the gloves could deposit inside the tubing and cause possible blockage to system fluid flow.

Position the splash basins so that the surgeons can conveniently clean their gloves during the surgical implantation procedure; especially before they make the tubing connections.

Antibiotics

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

Filling Solutions

The fluid used to fill the prosthesis must be sterile and completely free of particulate matter. The presence of any foreign materials in the fluid can affect the operation of the prosthesis. The solution must also be isotonic to minimize the transfer of fluid across the silicone membrane, which is semi-permeable. Normal saline is the recommended isotonic solution to use when filling the prosthesis.

However, if contrast media is preferred, one of the tested solutions in the table below may be used for filling. If you do not use the contrast media in the mixture proportions, you may alter the isotonicity of the mixtures and promote the formation of particulate matter.

*Note: The products listed below are some of the radiographic solutions tested by American Medical Systems for use in AMS devices, only sterile water should be used for dilution. For a complete list contact American Medical Systems.*

**CAUTION:** Do not use sterile saline or lactated Ringer’s solution to dilute the contrast solutions.

**WARNING:** Contrast media are contraindicated if the patient has an iodine allergy.

<table>
<thead>
<tr>
<th>CONTRAST MEDIA</th>
<th>DILUTION</th>
<th>MANUFACTURER</th>
<th>VALIDATED FOR INHIBIZONE USE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Conray 43</td>
<td>30 cc Conray 43</td>
<td>+ 60 cc sterile H₂O</td>
<td>Mallinckrodt Yes</td>
</tr>
<tr>
<td>Cysto Conray II</td>
<td>60 cc Cysto Conray II</td>
<td>+ 15 cc sterile H₂O</td>
<td>Mallinckrodt Yes</td>
</tr>
<tr>
<td>Hypaque-Cysto</td>
<td>60 cc Hypaque-Cysto</td>
<td>+ 58 cc sterile H₂O</td>
<td>Nycomed No</td>
</tr>
<tr>
<td>Isovue 200</td>
<td>60 cc Isovue 200</td>
<td>+ 23 cc sterile H₂O</td>
<td>Bracco No</td>
</tr>
<tr>
<td>Isovue 300</td>
<td>57 cc Isovue 300</td>
<td>+ 60 cc sterile H₂O</td>
<td>Bracco No</td>
</tr>
<tr>
<td>Isovue 370</td>
<td>38 cc Isovue 370</td>
<td>+ 60 cc sterile H₂O</td>
<td>Bracco No</td>
</tr>
<tr>
<td>Omnipaque 180</td>
<td>60 cc Omnipaque 180</td>
<td>+ 14 cc sterile H₂O</td>
<td>Nycomed No</td>
</tr>
<tr>
<td>Omnipaque 240</td>
<td>60 cc Omnipaque 240</td>
<td>+ 38 cc sterile H₂O</td>
<td>Nycomed No</td>
</tr>
<tr>
<td>Omnipaque 300</td>
<td>57 cc Omnipaque 300</td>
<td>+ 60 cc sterile H₂O</td>
<td>Nycomed Yes</td>
</tr>
<tr>
<td>Omnipaque 350</td>
<td>48 cc Omnipaque 350</td>
<td>+ 60 cc sterile H₂O</td>
<td>Nycomed No</td>
</tr>
<tr>
<td>Telebrix 12</td>
<td>53 cc Telebrix 12</td>
<td>+ 47 cc sterile H₂O</td>
<td>Laboratoire Guerbel Yes</td>
</tr>
</tbody>
</table>

Use an equivalent ratio dye with sterile water for a larger total volume.
Open Components

Always keep the sterile trays in their dust cover boxes when moving the components from storage to the operating room. The components should only be opened in the operating room when the surgeon directs the surgical team to do so.

*Note:* The AMS 800 Urinary Control System Accessories must always be opened first in order to prepare the hemostats and syringes used for preparing and filling components.

1. To open the components in the operating room, follow this procedure:

2. Remove trays from dust covers by opening the boxes at the security tab.

   *Note:* The circulating nurse should record the part and serial/lot numbers as well as the size of the components on the AMS Patient Information Form (PIF). Use the labels provided with the device.

   *Note:* The adhesive label at one end of the dust cover box and the small, removable labels on the side of the plastic trays contain the part and serial/lot numbers as well as the size of the components. This information is also listed on the lid of the outer tray.

3. Remove inner tray from outer tray using the following method:
   - Peel back lid completely from tray in one motion. Continue to hold outer tray without touching sterile inner tray.
   - Have scrub nurse use his or her index finger (not thumb) to carefully lift inner tray up and out of outer tray.
   - Scrub nurse should place inner tray on a plastic-draped Mayo stand in the sterile field.

4. Open inner tray just before preparing components using the following method:
   - Remove components from inner trays by peeling back lids of sterile inner trays.
   - Carefully remove components from tray.
   - Place them in their appropriate positions on plastic-draped Mayo stand.
Prepare Hemostats

To protect component tubing from being damaged by the mosquito hemostat jaws (Figure 3-1), cover the jaws with the silicone tubing provided in the Accessory Kit. Complete the following instructions to cover the jaws:

1. Place tubing on both jaws of hemostats up to box lock. Completely cover all teeth on both jaws of six hemostats.
2. Trim tubing at jaw tip with sharp, virgin scissors.
3. Reserve scissors for use as tubing scissors throughout procedure.
4. When using the hemostats, clamp jaws together to only first click to prevent excessive pressure on tubing.

Prepare System Components

The following paragraphs outline the procedures for preparing the system components to ensure that they are free of excess air and properly submerged in the filling solution. The components are submerged in a storage basin of filling solution to prevent contact between the component and foreign materials. This also helps reduce the possible transfer of air into the prosthesis through its semi-permeable silicone. Those components that are labeled as being treated with InhibiZone Antibiotic Surface Treatment should not be submerged in sterile normal saline.

CAUTION: Soaking antibiotic impregnated devices in saline will cause the antibiotics to diffuse off the device into the solution. This will cause the solution to turn orange and will reduce the concentration of antibiotics on the device.

Prepare Control Pump

Complete the following instructions to prepare the control pump. A syringe is not necessary to fill the control pump.

1. Place end of each tubing in a basin with the appropriate filling solution. (Figure 3-2a)
2. Hold the pump at a 45 degree angle with the black tube on top.
3. Squeeze and release pump bulb repeatedly until all air in the pump and tubing has been displaced with fluid.

   Note: It is important to keep tubing submerged during filling procedure. If air bubbles remain in pump bulb, continue to squeeze and release pump bulb to remove them; they will be evacuated through black color-coded tubing.

4. While keeping tubing submerged, use tubing-shod hemostats to clamp (one notch only) each tube 4 cm or 5 cm from the end. (Figure 3-2b)
Operating Room Instructions (continued)

CAUTION: Do not advance the hemostat’s ratchet more than one notch. Excessive pressure will permanently damage tubing.

Note: The clear pump tubing will connect to the clear cuff tubing, and black tubing will connected to black balloon tubing.

5. For a non InhibiZone treated pump, submerge the filled pump in a storage basin containing filling solution until implantation.

6. For a pump treated with InhibiZone Antibiotic Surface Treatment, place the pump onto an empty sterile tray or kidney basin and cover with a sterile drape. Prior to implanting, the pump should be inspected for entrapped air.

CAUTION: Soaking antibiotic impregnated devices in saline will cause the antibiotics to diffuse off the device into the solution. This will cause the solution to turn orange and will reduce the concentration of antibiotics in the device.

Prepare Pressure-Regulating Balloon

Complete the following instructions to prepare the Pressure-Regulating Balloon (PRB):

1. Attach a 15-gauge blunt tip needle to a 30 cc syringe.
2. Fill syringe with 25 cc of filling solution.
3. Hold air-filled balloon with one hand and squeeze it until it is deflated.
4. Insert needle into end of balloon tubing.
5. Aspirate any air left in balloon until you feel resistance on syringe plunger. (Figure 3-3a)

Note: Always hold syringe upright: that is, needle pointing down, plunger pointing up.

6. Fill balloon with 20 cc of recommended filling solution. (Figure 3-3b)

7. Rotate balloon until all air bubbles are gathered into one bubble. (Figures 3-3c and 3-3d)

8. Hold balloon by tubing to draw air bubble into tubing adapter area.

9. Aspirate air first, and then all fluid with syringe held upright until all air has been removed from balloon. Check that no air remains in balloon or tubing.
CAUTION: Do not over-aspirate pressure-regulating balloon because air can be drawn into system through the semi-permeable silicone membrane. (Figure 3-3c)

10. Hold plunger upright to maintain pressure.
11. Clamp tubing (one notch only) with tubing-shod hemostat 3 cm below the needle. (Figure 3-3e)

CAUTION: Do not advance the hemostat’s ratchet more than one notch. Excessive pressure will permanently damage the tubing.

12. Submerge empty balloon in a storage basin containing filling solution until implantation.

CAUTION: Do not place any hemostats on top of the balloon. Any instruments on the balloon can damage it.
Prepare Cuff

Complete the following instructions to prepare the occlusive cuff:

1. Attach 15-gauge blunt tip needle to 30 cc syringe.
2. Fill syringe with 10 cc of filling solution.
3. Hold air-filled cuff with one hand and squeeze it until it is deflated.
4. Insert needle into end of cuff tubing.
5. Aspirate any air left in cuff until you feel a slight resistance on the plunger. (Figure 3-4a)
6. Fill the cuff with 1 cc to 5 cc of recommended filling solution, depending on cuff size. (Figure 3-4b)
   **CAUTION: Do not over fill the cuff.** (Figures 3-4c) Excessive fluid can stretch cuff material.
   
   Note: The amount of fluid that is needed to fill cuff will vary depending on cuff size – larger cuffs require more fluid than smaller cuffs.
7. Place syringe onto Mayo stand and hold both ends of cuff. Collect all small air bubbles into one large air bubble.
8. Roll end of cuff with your thumb to squeeze large air bubble into tubing adapter. (Figure 3-4d)
9. Hold syringe upright again (needle pointing down and plunger pointing up). Maintain pressure on cuff while pulling back on plunger to first aspirate remaining air bubble from cuff and then fluid.
10. If air remains in either cuff or tubing, repeat above steps.
11. With the air and fluid removed and cuff completely empty, use two tubing-shod mosquito hemostats to double-clamp cuff tubing (one notch only) 3 cm below needle and again 3 cm below first hemostat.

---

**Figure 3-4a. Aspirate Air**

**Figure 3-4b. Insert Needle Into Tube**

**Figure 3-4c. Do Not Overfill Cuff**

**Figure 3-4d. Roll End of Cuff**
12. For a cuff treated with InhibiZone Antibiotic Surface Treatment, place the cuff onto an empty sterile tray or kidney basin and cover with a sterile drape. Prior to implanting, the cuff should be inspected for entrapped air.

13. For a non InhibiZone treated cuff, submerge the cuff into a kidney basin of sterile normal saline until the surgeon is ready to implant the cuff.

Caution: Soaking antibiotic impregnated devices in saline will cause the antibiotics to diffuse off the device into the solution. This will cause the solution to turn orange and will reduce the concentration of antibiotics on the device.

**Surgical Procedures**

There are a number of possible surgical approaches to implantation of the AMS 800 Urinary Control System. The following instruction outlines three possible surgical approaches. More detailed information regarding implantation techniques is available from American Medical Systems.

**Surgical Team Preparation**

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

**Patient Preparation**

Once the patient is in the operating room, shave the abdominal and genital area. Following the shave, scrub the area with povidone-iodine soap for ten minutes, or use the approved hospital preoperative scrub procedure.

For bulbous urethra cuff placement (Figure 3-5a) using the perineal approach, place the patient in the lithotomy position. Prepare and drape for both a perineal and an abdominal incision.

For bulbous urethra cuff placement using the transverse scrotal approach, place the patient in a supine position. Prepare and drape for a scrotal incision.

For bladder-neck cuff placement (Figure 3-5b), the approach requires a set-up similar to that used for suprapubic prostatectomy. Place the patient in a supine position. Prepare and drape for an abdominal incision. Be sure to maintain access to the perineum.

Caution: Using a device with InhibiZone Antibiotic Surface Treatment does not change the need to follow normal hospital protocols for prophylactic antibiotic administration.
Bulbous Urethra Cuff Placement - Perineal Approach

Complete the following steps to place the cuff at the bulbous urethra:

1. Place a Foley catheter or a 20Fr sound into urethra to help identify it during dissection.
2. Make a midline perineal incision and bluntly dissect bulbocavernosus muscle from around the bulbous urethra. (Figure 3-6)
   
   Note: Use blunt dissection.
3. Place cuff sizer (or Penrose drain) around urethra where cuff is to be implanted. It should fit snugly without constricting urethra. (Figure 3-7)
   
   Note: If catheter or sound is in urethra, remove it before measuring the urethra.
   
   Note: Do not stretch cuff sizer before use.
   
   Note: Surgeon should use his or her judgment in choosing an appropriate cuff size; the measuring tape only provides approximate measurement of bulbous urethra circumference. The inside circumference of cuff is somewhat smaller than the outside circumference of cuff.
4. Select cuff size that corresponds to measured length.
   
   Note: A cuff length of 3.5 cm to 4.5 cm is typically required for bulbous urethra placement.
   
   Note: Cuff length is outside circumference of cuff when it encircles urethra.
5. Prepare cuff for implantation as described in the section titled “Prepare Cuff”.
6. Position cuff at implant site with mesh toward outside and “pillow” side toward urethra.
7. Pass prepared cuff, tab first, under urethra.
   
   Note: Tubing should be on the pump side.
   
   CAUTION: To avoid damage to the cuff, grasp the cuff tab with a tubing-shod hemostat.
8. Pass tubing through tab hole by:
   • Pass the end of the cuff tubing through the hole until the hemostat meets the hole. Clamp a second hemostat onto the cuff tubing on the opposite side of the hole, and then release the first
Operating Room Instructions (continued)

hemostat, so air does not enter the cuff.

• Pull the remainder of the tubing through the hole and close the
cuff by pulling the tab over the tubing adapter (button). Ensure
that the edges of the hole fit into the slot of the adapter.
• Rotate the cuff so the adapter is lateral to the urethral midline and
position the tubing to avoid contact with the cuff.

Implant Pressure Regulating Balloon

1. Select appropriate size pressure-regulating balloon.
2. Make a suprapubic incision, divide rectus fascia transversely, and use
a spreading motion to separate the linea alba to reach prevesical space.
(Figure 3-8)
3. Use blunt dissection to create a space for balloon.
4. Position the balloon in prevesical space.
5. Flush balloon tubing end using 22-gauge needle on 10 cc syringe
filled with filling solution.
6. Connect 15-gauge needle on 30 cc syringe filled with filling solution
to balloon and unclamp tubing.
7. Fill the balloon with 22 cc of the chosen filling solution.

Note: Larger cuff sizes may require more filling solution. Refer to step 9
for Cuff Pressurization Option.
8. Clamp (one notch only) the tubing approximately 3 cm from the end
with a tubing-shod hemostat. (Figure 3-9)

CAUTION: Do not advance the hemostat’s ratchet more than one
notch. Excessive pressure will permanently damage tubing.
9. Cuff Pressurization Option: Larger cuff sizes may require more filling
solution, which can be provided by pressurizing the cuff as follows:

• Flush balloon and cuff tubing.
• Make temporary connection between balloon and cuff.
• Unclamp; wait one minute; then reclamp (one notch only).
• Disconnect balloon and cuff.
• Flush balloon tubing, unclamp and aspirate filling solution.
• Refill with 20 cc of filling solution and clamp.
**Implant Pump**

1. Use blunt dissection to create a dependent subdartos pouch in the scrotum. *(Figure 3-10)*

   *Note: Control pump should be placed on same side as the pressure-regulating balloon.*

2. Place pump into scrotal pouch with deactivation button facing outward so that it is palpable. *(Figure 3-11)*

3. Route the tubing to abdominal incision.

4. Note: The pump tubing should be above rectus muscle and fascia in abdominal incision.

**Connect the Tubing**

Follow the instructions in the section titled “Connect Tubing”. Cycle the device to test the connections.

**Deactivation**

The device system must be left in the deactivated mode for four to six weeks following implantation. Deactivate the device by following the instructions in the section titled “Deactivate Cuff”.

---

*Figure 3-10. Create Pouch*

*Figure 3-11. Place Pump Into Pouch*
Bulbous Urethra Cuff Placement - Transverse Scrotal Approach

Complete the following steps to place the cuff at the scrotum:

1. Place the patient supine with his legs gently abducted on arm boards or other spreaders. Knees and hips are not flexed. This avoids placing the urethra on a stretch as occurs in the lithotomy position. Place a urethral catheter to drain the bladder to avoid injury during placement of the pressure regulating balloon. (Figure 3-12)

2. Make an upper transverse scrotal incision and deepen it through the subcutaneous tissue. Move the incision up onto the penis and stabilize with a Scott retractor and blunt stay hooks at the 1, 3, 5, 7, 9 and 11 o’clock positions. These stay hooks secure the scrotal incision and help prevent unnecessary dissection in the scrotum. The scrotal incision allows excellent access to the proximal bulbourethra the retropubic and dartos spaces, and leaves the bulbocavernosus muscle intact. (Figure 3-13)

3. Expose the tunica albuginea of both corpora cavernosa using sharp dissection. Pass the Metzenbaum scissors proximally along the ventral surface of the tunica to the proximal corpora. (Figure 3-14)
4. When deep exposure of the proximal corpora is secured, place a 
Deaver retractor on the side of the urethra for caudal retraction. 
(Figure 3-15)

5. Repeat on the contralateral side exposing the scrotal septum. 
(Figure 3-16)

6. Sharply dissect the scrotal septum off of the bulbar urethra. 
(Figure 3-17)

7. Mobilize the urethra by sharply dissecting webs of Buck’s fascia 
binding the diverging corpora cavernosum to the corpora 
 spongiosum. 
(Figure 3-18)
8. Because the patient is in the supine position, the urethra is mobile and a right angle clamp can be used to conduct the posterior dissection of the urethra almost under direct vision. Spread the right-angle clamp to create sufficient space for the placement of the occlusive cuff. (Figure 3-19)

9. a. Using the cuff sizer, measure the circumference of the urethra and place the proper size occlusive cuff around the urethra. (Figure 3-20b)

   Note: If a catheter has been placed in the urethra, it must be removed before measuring the urethral circumference.

   b. A cuff that was implanted through a perineal incision five years earlier is shown for reference. (Figure 3-20b)

**Implant Pressure Regulating Balloon**

There are two ways to place the pressure regulating balloon (PRB), described in steps 10a and 10b.

10 a. Empty the bladder remove the Scott retractor stays and displace the scrotal incision to the side of the penis. Place the PRB in the retro-pubic space in a similar fashion to a penile implant reservoir by locating the inguinal ring and piercing the transversalis fascia. (Figure 3-21b) After PRB implantation, narrow the opening by placing an absorbable suture.

10 b. Displace the scrotal incision over the inguinal area and locate the inguinal ring. Use finger dissection to develop a pouch beneath the rectus but anterior to the transversalis fascia (cephalad to the inguinal ring). This avoids the necessity of piercing the fascia in patients with scarred retroperitoneum from radiation or radical surgery. After PRB implantation, narrow the opening by placing an absorbable suture.
Implant Pump
Evaluate the inferior aspect of the scrotal incision and develop a space underneath the scrotal skin and dartos muscle to serve as a pouch for the pump. Begin the development of the tunnel about 2 cm from the skin edge in order to facilitate eventual tubing and connector concealment. Loosely tie a purse string suture around the opening of the tunnel to secure the pump position. (Figure 3-22)

Connecting the Tubing
Follow the instructions in the section titled “Connect Tubing”. Cycle the device to test the connections.

Deactivation
The device system must be left in the deactivated mode for four to six weeks following implantation. Deactivate the device by following the instructions in the section titled “Deactivate Cuff”.

Bladder Neck Placement
Complete the following steps to place the cuff onto the bladder neck:
1. To begin the procedure, make a suprapubic incision and dissect around the bladder neck. (Figure 3-23)
2. Place cuff sizer around bladder neck (Figure 3-24) at the site where the cuff is to be implanted.
   
   Note: It has to fit snugly without constricting the urethra. If a catheter has been placed in the urethra, it must be removed before measuring the bladder neck.
3. Select cuff size that corresponds to measured length.
4. Prepare selected cuff for implantation (see instructions in the section titled “Prepare Cuff”).
5. To implant prepared cuff, pass cuff, tab first, under bladder neck.
   
   Note: To avoid damage to cuff, grasp it with tubing-shod hemostat and grab tab only.
6. Select appropriate pressure-regulating balloon.
7. Use blunt dissection to create a space for balloon in the prevesical space.
8. Position balloon in the prevesical space. (Figure 3-25)
9. Fill balloon with 22 cc of appropriate filling solution. Clamp tubing 3 cm from end with a silicone-shod hemostat (one notch only).

   **CAUTION:** Route balloon tubing and cuff tubing to inguinal area. (Figure 3-26)

10. To pressurize the cuff, cuff tubing and balloon tubing are temporarily connected using a straight connector.

11. If a catheter has been placed in urethra, make sure it is removed before pressurization. Remove tubing clamps and wait 10 to 30 seconds for cuff to pressurize.

12. Clamp cuff tubing and balloon tubing approximately 3 cm from end with silicone-shod hemostats and remove connector.

13. Insert a syringe with a 15-gauge needle into balloon tubing. Remove hemostat, and aspirate all of remaining fluid from balloon.

14. Refill it with 20 cc of filling solution, clamp tubing with a silicone-shod hemostat, and remove syringe.

15. To implant the control pump in the scrotum, use blunt dissection to create a dependent subdartos pouch.

   *Note: The control pump should be placed on the same side where the pressure-regulating balloon was placed.*

16. Place pump in pouch (Figure 3-27) making sure that deactivation button faces outward and is palpable.

17. Route the pump tubing to inguinal area.

**Connecting the tubing**

Follow the instructions in the section titled “Connect Tubing”. Cycle the device to test the connections.

**Deactivation**

The device system must be left in the deactivated mode for six to eight weeks following implantation. Deactivate the device by following the instructions in the section titled “Deactivate Cuff”.

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**Operating Room Instructions (continued)**
Connect Tubing

AMS Suture-Tie Connectors or AMS Quick Connect Sutureless Window Connectors may be used to connect the tubing. In most cases, use the straight connectors. Right angle connectors should always be used when the tubing makes a sharp curve at the point of connection.

CAUTION: Do not use AMS Quick Connect Sutureless Window Connectors 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.

Figures 3-28 through 3-33a illustrate the tubing connections required for the perineal cuff placement approach. The same principles for tubing connections apply to the transverse scrotal approach.

Using AMS Quick Connect Sutureless Window Connectors

1. Using virgin scissors, trim tubing lengths squarely to fit patient’s anatomy. (Figure 3-28)

2. Slide collet ring onto tubing, making sure collet ring teeth face toward tubing end. (Figure 3-29)

3. Use a 22-gauge needle and a 10 cc syringe filled with filling solution to flush connector and tubing to remove particulate matter and air. (Figure 3-30)

4. Insert tubing end into connector. (Figure 3-31)
   • Firmly push one side of tubing to middle wall of connector.
   • Check placement through connector window.
   • Flush both connector and tubing before final connection.

5. Insert the other tubing end into connector. (Figure 3-31)
   • Firmly push one side of tubing to middle wall of connector.
   • Check that both tubing ends touch middle.

6. Place straight connector ends into assembly tool jaws.
7. Squeeze tool handles until closure stop touches opposite handle.  
(Figure 3-32)

**CAUTION:** Check tubing before you close assembly tool. Do not trap tubing between assembly tool jaw and connector. Tubing must exit straight from ends of connector, through slots in assembly tool.

**CAUTION:** After using assembly tool, tubing should bulge through connector. This indicates that tubing is firmly against middle of connector wall.

8. If using right angle connector: Use tool twice, once on each end  
(Figure 3-33)  
*Note: Squeeze tool handles until closure stops touching opposite handle.*

9. When using a 3-way connector, the assembly tool must be used 3 times – once on each end of the connector.  
(Figure 3-33a) The assembly tool must be engaged from the side of each connector end. Advance the tubing into each connector end until the tubing touches the inner connector wall as seen through the connector window.

**CAUTION:** The long branch of the 3-way connector must be connected to the control pump.

10. After all connections have been made, cycle the device to confirm function, and deactivate device (see instructions in “Deactivate Cuff”).

**Using AMS Suture-Tie Connectors**

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

1. Cut tubing to fit patient’s anatomy.

2. Use a 22-gauge blunt tip needle to flush tubing ends with filling solution to remove particulate matter and air before connecting.

3. Push connector ends over tubing so they meet at connector’s center hub; use 22-gauge blunt tip needle to flush connector before completing connection.

   *Note: Be certain that the tubing is on the connector straight.*

4. Use a double-throw overhand surgeon’s knot followed by two single throws to attach the tubing to the connector.

   *Note: 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.

6. After all connections have been made, cycle the device to confirm function, and deactivate device (see instructions in “Deactivate Cuff”).
**Operating Room Instructions (continued)**

**Deactivate Cuff**

To deactivate the device, complete the following instructions:

1. Squeeze and release the pump bulb several times to remove all fluid from cuff. *(Figure 3-34)*
   
   *Note: The cuff will be empty when the pump remains flat.*

2. Allow pump bulb to partially refill (approximately 30 seconds to one minute).
   
   *Note: It is recommended that time needed to fill pump or number of pumps needed to empty pump be recorded. This information is helpful postoperatively.*

3. When slight indentation in pump bulb is felt, press the deactivation button. *(Figure 3-35)*

4. Note: It is important to leave a slight indentation in pump bulb to ensure there is enough fluid in pump to activate device later.

   *Note: You will always feel the deactivation button, even when the device is deactivated.*

5. After you press the deactivation button, the pump bulb may feel more firm than usual.

   *Note: The indentation in the pump bulb will remain partially filled until activated. When the device is deactivated, the cuff will not be inflated and your patient will be incontinent. No fluid will move into the cuff or pump when it's deactivated.*

**Activate Cuff**

**Activate Cuff: Normal Method**

To activate the device, complete the following instructions:

Push deactivation button a few times to loosen the poppet. *(Figure 3-36)*

Then give the pump bulb a quick, forceful squeeze.

*Note: This will move deactivation poppet back to activated position. After device is activated, pump will fill first and then cuff will refill. *(Figure 3-37)*

It will take a few minutes for device to refill and for cuff to close off urethra or bladder neck. When system is activated, the pump may become less firm.

*Note: If you have difficulty activating device, there may not be enough fluid remaining in pump to push deactivation button to its activated position. Use the optional method if this happens.*
Activate Cuff: Optional Methods

If the normal activation method does not work, use one of the following optional methods.

Side Squeeze Method

Squeeze sides of control pump adjacent to deactivation button to allow fluid to fill the pump bulb. (Figure 3-38)

Note: 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.

Q-Tip Method

1. Feel control pump to locate deactivation button.
2. Take a cotton tip swab and apply pressure to area directly behind deactivation button. (Figure 3-39)

Note: This should unseat the poppet and allow fluid to fill pump and then cuff.

Fulcrum Method

1. Feel control pump, locate deactivation button, and place your index finger above it. (Figure 3-40)
2. Place tip of your thumb below deactivation button on the opposite side.
3. Place index finger of your other hand on firm portion of pump in front of deactivation button (toward the pump bulb).
4. Firmly bend pump end down to activate.
5. Release after bending.
6. Squeeze and release pump bulb several times to transfer fluid.
Bulbous Urethra Double-Cuff Placement

Clinical literature reports that some patients with severe stress incontinence may continue to report some degree of incontinence even after the placement of an artificial urinary sphincter. In such cases, two cuffs may be implanted around the bulbous urethra. The second cuff is connected to the device system through the use of a 3-way connector included in the accessory kit. If the patient is experiencing incontinence secondary to urethral atrophy at the site of the first cuff, the first cuff may also require replacement with a smaller cuff or cuff may need to be repositioned.

Table 1-1. Double Cuff Combinations

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*Indicates cuff combinations that may be used.*
Double Cuff Procedure Modifications

Original Double Cuff
When following the Bulbous Urethra Cuff Placement Procedure, please note the following changes:

- More filling solution must be added to system to account for additional cuff.
- To account for the second cuff, fill the balloon with 24 - 26 cc.

CAUTION: The long branch of the 3-way quick connector must be connected to the control pump.

If Replacing Original Cuff
With both new cuffs in place and clamped:

1. Flush tubing and secure 3-way connector to both tubing cuffs with 3-0 nonabsorbable polypropylene suture.
2. Flush the 3-way connector.
3. Connect pressure regulating balloon which has previously been filled with 24 cc filling solution.
4. Remove clamps from cuff and balloon tubing.
5. Allow 60 seconds for cuffs to pressurize, and then re-clamp each cuff tube below 3-way connector.
6. Disconnect balloon, aspirate fluid from balloon and refill it with 20 cc.
7. When ready to connect the pump tubing, first flush the 3-way connector to remove air and particulate matter.
8. Follow the instructions in the section titled “Connect Tubing” for connecting tubing and tying with suture.

CAUTION: Do not use AMS Quick Connect Sutureless Window Connectors 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.
If Adding New Cuff to System
1. First, deactivate artificial urinary sphincter.
2. Insert a Foley catheter to facilitate urethral palpation.
3. Make an abdominal incision to locate the white/clear tubing leading from existing cuff to pump.
4. Note: As written, these steps describe how to add a new cuff when the perineal approach was used to implant the prosthesis initially. If the transverse scrotal approach is used initially, all connectors would be located in the scrotum.
5. Clamp tubing on each side of current connector.
6. Cut the tubing at connector.
7. Follow intraoperative steps 2-8 in the section titled “Bulbous Urethra Cuff Placement - Perineal Approach”.
   Note: when placing the second cuff either proximal or distal to the first cuff, allow a 1 to 2 cm gap between two cuffs to prevent them from rubbing against each other and to maintain vascularization. (Figure 3-41)
8. With new cuff in place, trim tubing to the desired length, and flush the end.
9. Connect a syringe filled with 10 cc of filling solution and a 15-gauge blunt tip needle attached to the new cuff tubing.
10. Remove the clamp, and add 1 cc of filling solution to the new cuff.
11. Re-clamp the tubing, and remove the syringe.
12. Flush the tubing, attach the 3-way connector to the new cuff and suture tie with a 3-0 non-absorbable polypropylene suture.
13. Flush the 3-way connector and pump tubing, and suture tie the connector to the pump tubing.

Connecting the Tubing
Follow the instructions in the section titled “Connect Tubing”. Cycle the device to test the connections.

Deactivation
The device system must be left in the deactivated mode for four to six weeks following implantation. Deactivate the device by following the instructions in the section titled “Deactivate Cuff”.

Once the device is ready to be cycled, it will take about twice as long for both cuffs to fill as it does for one cuff to fill from a single balloon.
Some surgeons use a prophylactic antibiotic prior to surgery and intravenous antibiotics immediately postoperatively. Most choose to send their implanted patients home with a five to ten day course of antibiotics. The following paragraphs provide additional details on postoperative care.

**Immediately Postoperative**

After the surgery, **deactivate the cuff** and introduce a catheter into the urethra prior to closing. The length of time the catheter is left in place is at the discretion of the physician.

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 or condom catheters, until the device is activated four to six weeks after the surgery. The patient should be advised to avoid undue compression of the cuff area.

**After Release From Hospital**

The patient is usually discharged within one to four 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 AMS 800 Urinary Control System. The device is normally activated four to six weeks postoperatively. At that time instruct the patient that it is possible to begin using the prosthesis to urinate.

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. Refer to the activation/deactivation instructions in the sections titled “**Deactivate Cuff**” and “**Activate Cuff**”.

The patient may experience some mild discomfort the first few times the prosthesis is being used. 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.

The physician may want to observe the patient for up to an hour in the office to determine if sufficient continence is achieved with the device activated.

Provide patient education with regard to the sphincter operation. Patients will receive a patient ID card to inform others of the device in case of emergency and to prevent catheterization without device deactivation.

**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 annual evaluation, the surgeon should ask the patient about how the device is functioning and if he has noticed any changes in the function.

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.
Completing the Patient Information Form

American Medical Systems requires that a Patient Information Form be completed and returned for each implantation procedure. This is necessary to comply with the AMS Limited Warranty Policy and for the patient to receive an ID card.

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, using self-adhesive labels included within the packaging.

Promptly return the first copy of the Patient Information Form to American Medical Systems.
Retain the remaining copies for the files of the hospital, surgeon, or patient (if needed). Complete the Return Goods Form on the last page of the Patient Information Form if components were explanted.

Inventory Returns and Replacement Information

A Patient Information Form (PIF) must be filled out and filed with American Medical Systems at the time of implant to activate the product warranty. 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 American Medical Systems. Request an AMS Product Return Kit from the AMS Customer Service Department to return any explanted components to American Medical Systems.

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 Limited Warranty Policy. For complete information regarding these policies, contact the AMS Customer Service Department.

Document Information

This document is written for professional medical audiences. Contact American Medical Systems for lay publications.

American Medical Systems periodically updates product literature. If you have questions about the currency of this information, contact American Medical Systems.

InhibiZone™ Antibiotic Surface Treatment

American Medical Systems has a proprietary process to impregnate antibiotics into the tissue-contacting surfaces of the urinary control system. This InhibiZone Antibiotic Surface Treatment innovation is intended to elute the antibiotics from the device surface when exposed to a warm, moist environment. In in vitro testing using susceptible organisms, this elution provided antibiotic action both on the surface and in a zone surrounding the treated device.

Existing prophylactic antibiotic protocols should be maintained as determined by the physician and or institution.

The AMS patented antibiotic surface treatment process uses a formulation of minocycline hydrochloride and rifampin (rifampicin). The AMS 800 components are treated with very low levels of antibiotics. AMS provides numerous completed configurations of the AMS 800 to individualize treatment, however, while the AMS 800 PRB component is not InhibiZone treated, a complete device (PRB, pump, and one or two cuffs) regardless of configuration, contains ≤ 6.5 mg rifampin and ≤ 8 mg minocycline HCl. This represents less than 2% of an oral dose exposure for a complete course of rifampin or minocycline HCl, with the maximum dose calculated from the means and 95% tolerance interval.

In vitro studies with the antibiotic treated device material and susceptible strains of Staphylococcus epidermidis and Staphylococcus aureus show a microbial “zone of inhibition” around the test material. The clinical significance of these in vitro data is unknown. A limited animal model study suggests that this surface treatment may reduce the potential for bacterial colonization of the treated device.

No clinical studies have been performed to evaluate the effect of the antibiotic surface treatment reducing the incidence of sphincter implantation infections.
Disclosures

This section lists the following disclosures:

- Indications For Use
- Contraindications
- Warnings
- Precautions

Indications For Use

The AMS 800 is used to treat urinary incontinence due to reduced outlet resistance (intrinsic sphincter deficiency) following prostate surgery.

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 urinary incontinence due to or complicated by an irreversibly obstructed lower urinary tract.
3. This device is contraindicated in patients with irreversible detrusor hyperreflexia or bladder instability.
4. The implantation of the InhibiZone version of this device is contraindicated in patients with known allergy or sensitivity to rifampin or to minocycline HCl or other tetracyclines.
5. The implantation of products with InhibiZone is contraindicated in patients with systemic lupus erythematosus because minocycline HCl has been reported to aggravate this condition.

Warnings

1. Patients with urinary tract 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 urethra or bladder neck. The control pump may erode through the scrotum. The pressure-regulating balloon may erode into the bladder. Acute urinary tract infection can interfere with proper functioning of the device and may lead to erosion of the urethra in the cuff area. 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. Poor bladder compliance or a small fibrotic bladder may require some measure of intervention including, in some cases, augmentation cystoplasty before implanting the prosthesis.
4. Patients with urge incontinence, overflow incontinence, detrusor hyperreflexia or bladder instability should have these conditions treated and controlled (or resolved) prior to implantation of the device.
5. Do not pass a catheter or any other instrument through the urethra without first deflating the cuff and deactivating the device to prevent potential damage to the urethra or the AMS 800.
6. This device contains solid silicone elastomers. This device does not contain silicone gel. The risks and benefits of implanting this device in patients with documented sensitivity to silicone should be carefully considered.
7. 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 physician based on the patient’s medical condition and history.
8. Product wear, component disconnection or other mechanical problems may lead to surgical intervention. Mechanical complications may include malfunctioning of the components and leakage of fluid. Any mechanical malfunction that does not permit the transfer of fluid from the cuff to the balloon may result in outflow obstruction. Mechanical events should be evaluated carefully by the treating physician and the patient should
consider risks and benefits of treatment options, including revision surgery.

9. Previous patient history of adverse reaction(s) to radiopaque solution precludes its use as a filling medium for the prosthesis. Instead, saline should be used to fill the device.

10. The implanter should check that there is an adequate amount of spongiosum muscle to surround and support a bulbous urethral cuff implant. Thinner spongiosum typically occurs toward the distal end of the bulbous urethra, and implantation of the cuff where the spongiosum is thin increases the chance of erosion and other complications. This warning is especially important for double cuff implants, where the second cuff is placed distal to the first implanted cuff.

11. If a hypersensitivity reaction develops to a device coated with InhibiZone, the cuff and pump should be removed and the patient treated appropriately.

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 AMS 800. Although the prosthesis is designed to restore urinary 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 what is expected may require medical or surgical intervention. Patients should be counseled on expected postoperative pain including severity and duration.

4. Tissue fibrosis, previous surgery, or previous radiation therapy in the area of the implant may preclude implantation of a cuff at the bulbous urethra or bladder neck.

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

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

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

8. Consideration should be given to the diameter of the implanted occlusive cuff relative to catheters or other trans-urethral devices. When fully deflated, the inside diameter of the smallest occlusive cuff (3.5cm) generally exceeds 28F. Additional clearance is required to accommodate the patient’s urethral tissue between the trans-urethral device and the occlusive cuff. Urethral tissue thickness is patient specific and requires a physician’s assessment to determine its impact on sizing.

InhibiZone-Related

1. Use of products with InhibiZone should be carefully considered in patients with hepatic or renal disease, as use of rifampin and minocycline HCl can cause additional stress on the hepatic and renal systems.

2. Patients who receive a device with InhibiZone and are also taking methoxyflourane should be carefully monitored for signs of renal toxicity.

3. Patients who receive a device with InhibiZone and are also taking warfarin should have their prothrombin time monitored because tetracyclines have been reported to slow coagulation.

4. Use of products with InhibiZone should be carefully considered in patients using thionamides, isoniazid and halothane, due to potential hepatic side effects that have been reported in patients using these drugs and higher doses of rifampin.

5. Devices with InhibiZone should not come into contact with ethyl alcohol, isopropyl alcohol or other alcohols, acetone or other non-polar solvents. These solvents may remove the antibiotics from the device.
6. InhibiZone components should not be soaked in saline or other solutions prior to implantation. The components may be briefly rinsed or dipped into a sterile solution, immediately prior to implant, if desired.

7. InhibiZone does not replace your normal antibiotic protocols. Continue using any prophylactic protocols normally used for urological surgical procedures.

8. Because products with InhibiZone are impregnated with a combination of rifampin and minocycline HCl (a derivate of tetracycline), the contraindications, warnings and precautions regarding the use of these antimicrobial agents apply and should be adhered to for the use of this device, although systemic levels of minocycline HCl and rifampin in patients receiving this device are unlikely to be detected.

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 is 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, improper sterile 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. If the deactivation valve is closed when the cuff is inflated, fluid cannot transfer from the cuff to the balloon and sustained outflow obstruction may arise as a result:
   a. In the event of large pressures within the bladder, automatic pressure relief that normally occurs with the device would be prevented. Cycling the device can relieve the outflow obstruction.

b. 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.

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

2. System pressure changes may occur over time if you fill the balloon with radiopaque solution of incorrect concentration. Follow the instructions in the Operating Room Manual to prepare the radiopaque solution with the correct concentration.