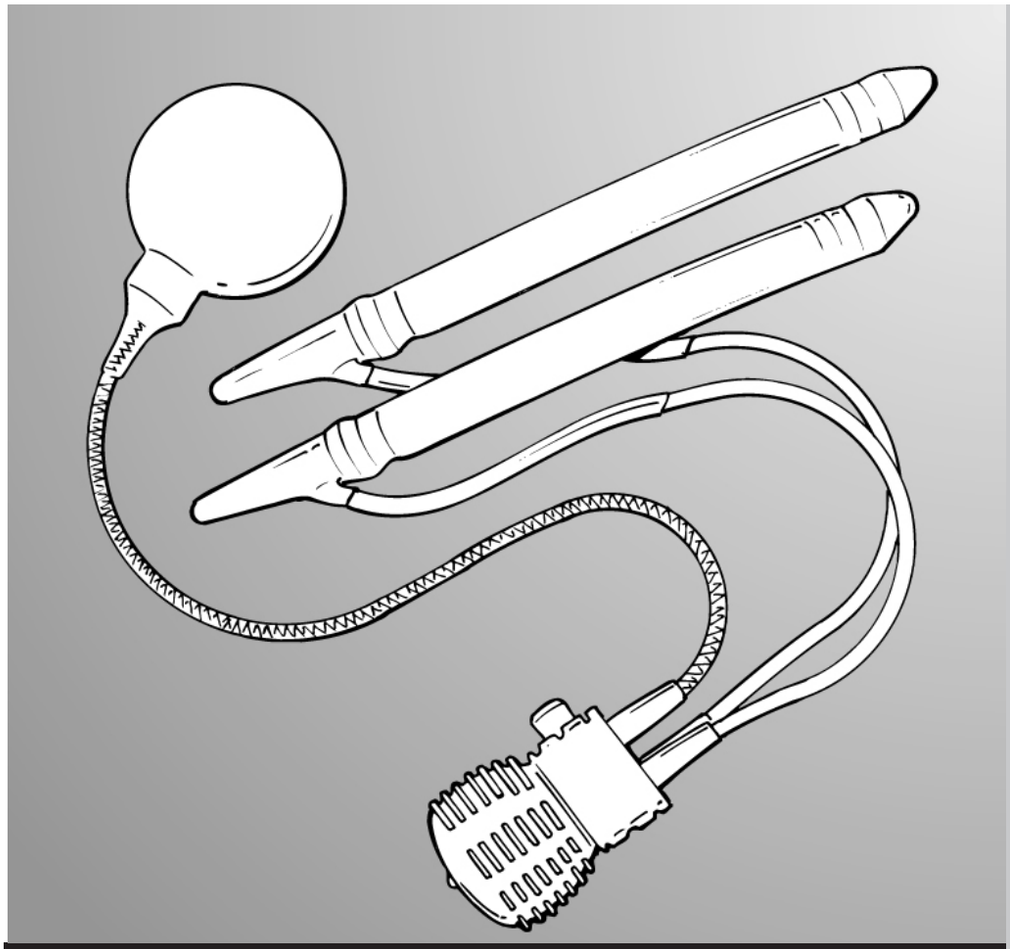
AMS™



AMS 700™ with MS Pump™

Penile Prosthesis

Operating Room Manual

English

℞ ONLY

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Introduction

Overview

The American Medical Systems (AMS) 700 Penile Prosthesis Product Line includes the following implantable prosthetic devices:

- ✓ **AMS 700™ CX with MS Pump™ Penile Prosthesis**
- ✓ **AMS 700™ CX Preconnect with MS Pump™ Penile Prosthesis**
- ✓ **AMS 700™ CXR with MS Pump™ Penile Prosthesis**
- ✓ **AMS 700™ CXR Preconnect with MS Pump™ Penile Prosthesis**
- ✓ **AMS 700 LGX™ with MS Pump™ Penile Prosthesis**
- ✓ **AMS 700 LGX™ Preconnect with MS Pump™ Penile Prosthesis**

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

The AMS 700 Penile Prostheses with MS Pump are totally implantable, closed fluid-filled system **(Figure 1-1)** consisting of:

- Two cylinders
- One pump
- One fluid reservoir

The reservoir stores the fluid that fills and expands the penile cylinders. The patient operates the pump to inflate or deflate the system. The cylinders are inflated by multiple squeezes of the pump, which transfers fluid from the reservoir. This makes the penis erect **(Figure 1-2)**. The cylinders are deflated by pressing the deflation button for 2-4 seconds. This transfers fluid back into the reservoir making the penis flaccid **(Figure 1-3)**. The penis can be made more flaccid by squeezing on the penis shaft. All components are connected by kink-resistant tubing (KRT).

For warnings, precautions and contraindications please refer to the Instructions for Use provided on the AMS website at www.amselabeling.com.

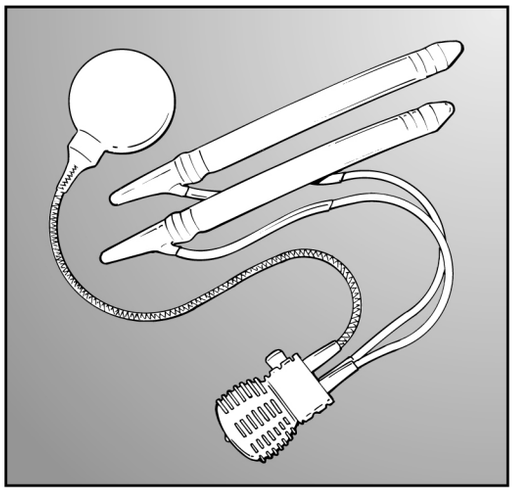


Figure 1-1. AMS Penile Prosthesis

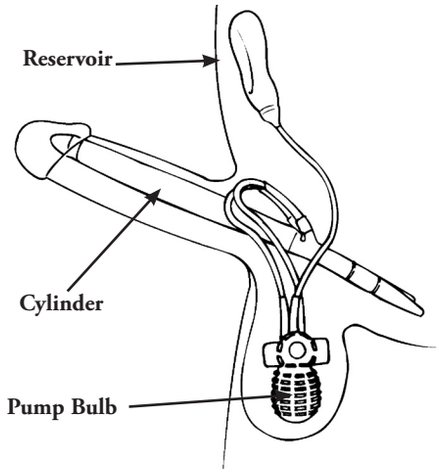


Figure 1-2. System Inflation

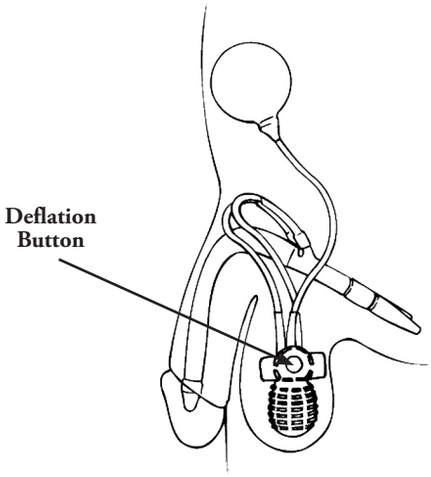


Figure 1-3. System Deflation

Device Description

Cylinders

Each cylinder kit **(Figure 1-4, Figure 1-4a)** consists of:

- Two silicone cylinders with:
  - Solid silicone elastomer inner tube with Parylene coating inside and outside (provides wear protection)
  - Woven stretch fabric cylinder (between inner/outer tubes)
  - Solid silicone elastomer outer tube with Parylene coating inside (provides wear protection)
- One silicone, kink resistant tube (KRT) per cylinder
- One protective PTFE (polytetrafluoroethylene) sleeve per cylinder
- One traction suture per cylinder

The cylinders come in various lengths and diameters, depending on the model number. Rear Tip Extenders are provided in a separate kit. Rear Tip Extenders are placed over the solid rear tip of the cylinder in a combination appropriate for the patient's anatomical length.

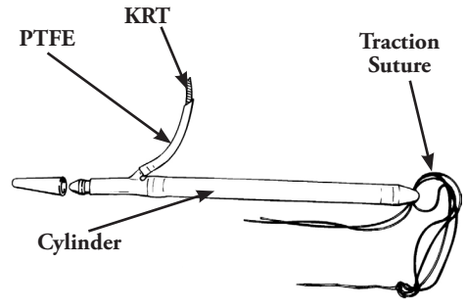


Figure 1-4.
CX, CXR, LGX Penile Prosthesis: Cylinders

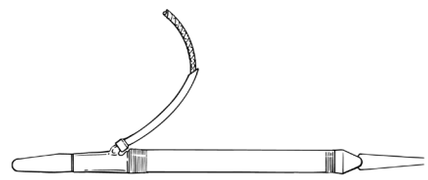


Figure 1-4a. CXR Penile Prosthesis: Cylinders

Pump

The pump **(Figure 1-5)** consists of:

- Pump bulb
- Deflation button
- Three silicone, kink resistant tubes (KRT)
- Internal lock-out valve

The MS pump is used with all types of AMS 700 Series cylinders. The single, black-striped tubing connects the pump to the reservoir. The pair of clear tubing connects the pump to the two penile cylinders. In the preconnect systems, the connections between the pump and cylinder are made at the factory.

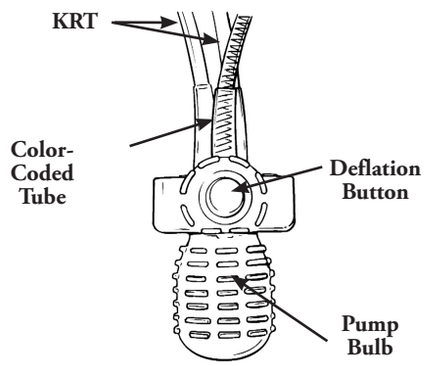


Figure 1-5. Penile Prosthesis: Pump

Reservoir

The reservoir **(Figure 1-6)** consists of:

- One silicone fluid storage reservoir, coated on the inside with Parylene (provides wear protection)
- One silicone, black-striped kink resistant tube (KRT)
- Two size options:
  - 65 ml (spherical reservoir only)
  - 100 ml (spherical reservoir and AMS Conceal™ Low Profile Reservoir)*

The single, black-striped tubing connects the reservoir to the pump.

*not available in all markets

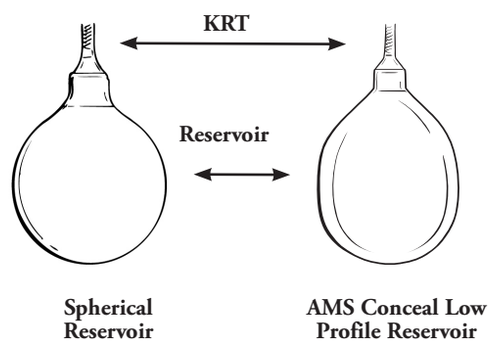


Figure 1-6. Penile Prosthesis: Reservoir

AMS 700 CX with MS Pump Prosthesis

The AMS 700 CX Preconnect with MS Pump Prosthesis components are configured as follows:

- Pump and cylinders are available pre-connected or unconnected.
- Infrapublic pre-connect configuration has 18 cm of tubing connecting pump and cylinders
- Penoscrotal package has 9 cm of tubing connecting pump and cylinders
- Reservoir: 65 ml (spherical reservoir only), 100 ml (spherical reservoir and AMS Conceal Low Profile Reservoir)
- Cylinder diameter: 12 mm-18 mm
- Cylinder lengths: 12 cm, 15 cm, 18 cm, 21 cm, 24* cm
- Rear Tip Extenders: RTE kit contains two each-0.5 cm, 1.0 cm, 1.5 cm stackable, 2.0 cm, 3.0 cm, 4.0 cm, 5.0 cm, 6.0 cm (packed in their own tray).
- Cylinders expand only in girth
- Cylinders, pump and reservoir are available with InhibiZone Antibiotic Surface Treatment

**Special Order Only. Allow 6-8 weeks for delivery.*

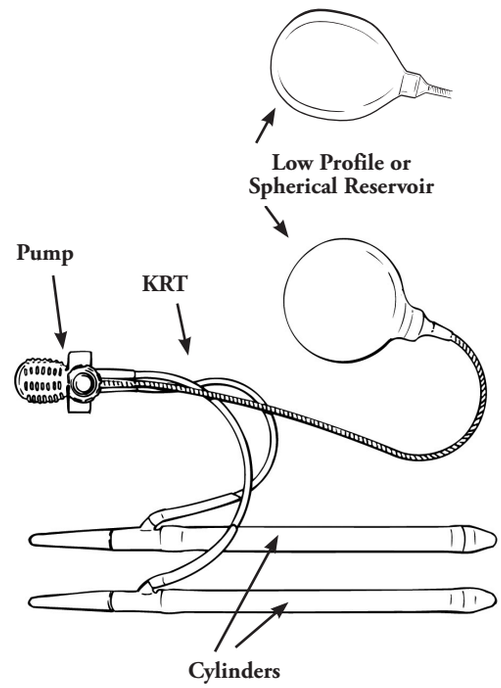


Figure 1-7. AMS 700 CX, LGX Penile Prosthesis

AMS 700 LGX with MS Pump Prosthesis

The AMS 700 LGX Preconnect with MS Pump components are configured as follows:

- Pump and cylinders are available pre-connected and unconnected
- Infrapublic pre-connected package has 18 cm tubing connecting pump and cylinders
- Penoscrotal pre-connected package has 9 cm tubing connecting pump and cylinders
- Reservoir: 65ml (spherical reservoir only), 100 ml (spherical reservoir and AMS Conceal Low Profile Reservoir)
- Cylinder diameter: 12 mm-18 mm
- Cylinder lengths: 12 cm, 15 cm, 18 cm, 21 cm
- Rear Tip Extenders:
  RTE kit contains two each-0.5 cm, 1.0 cm, 1.5 cm stackable, 2.0 cm, 3.0 cm, 4.0 cm, 5.0 cm, 6.0 cm (packed in their own tray).
- Cylinders expand in girth and length
- Cylinder, pump and reservoir are available with InhibiZone Antibiotic Surface Treatment

AMS 700 CXR with MS Pump Prosthesis

The AMS 700 CXR prosthesis is designed for a patient with an anatomy that requires shorter and narrower cylinders. It is also useful for penile prosthesis re-implantation procedures.
The AMS 700 CXR Prosthesis with MS Pump components are configured as follows:

- Pump and cylinders are available pre-connected or unconnected
- Infrapubic pre-connected package has 15 cm tubing connecting pump and cylinders
- Penoscrotal package has 9 cm tubing connecting pump and cylinders
- Reservoir: 65 ml (spherical reservoir only), 100 ml (spherical reservoir and AMS Conceal Low Profile Reservoir)
- Cylinder diameter: 9.5 mm-14.5 mm
- Cylinder lengths: 10* cm, 12 cm, 14 cm, 16 cm, 18 cm
- Rear Tip Extenders: RTE kit contains two each—0.5 cm, 1.0 cm, 1.5 cm stackable, 2.0 cm, 3.0 cm, 4.0 cm, 5.0 cm, 6.0 cm (packed in their own tray).
- Cylinders expand only in girth
- Cylinder, pump and reservoir are available with InhibiZone Antibiotic Surface Treatment

**Special Order Only. Allow 6-8 weeks for delivery.*

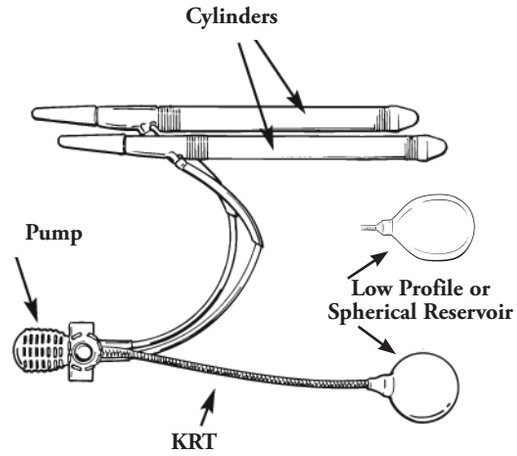


Figure 1-8. AMS 700 CXR Penile Prosthesis

Device Sterilization and Storage

Sterilization

American Medical Systems sterilizes all of the components in the AMS 700 with MS Pump Product Line.

Under normal storage conditions, the components will remain sterile until the expiration date if the sterile barriers of the packaging remain intact.

Devices with InhibiZone have a different shelf life than untreated devices.

Always check the expiration date before using products in the AMS 700 with MS Pump Product Line.

To protect the integrity of the packaging and the function of the 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 pouches within their plastic travel cases. Inspect the packaging for damage before use.

CAUTION: Do not resterilize the components of the AMS 700 with MS Pump Product Line.

CAUTION: Do not resterilize any component in the AMS Accessory Kit.

AMS Tools

American Medical Systems has surgical instruments that can be used during the surgery to help facilitate the surgeon's implantation of the penile prosthesis. For reprocessing information, refer to the instructions manual provided with the tools. The following non-sterile AMS tools can be ordered from AMS.

- AMS Tubing Passers
- AMS Closing Tool
- Furlow Insertion Tool
- AMS Quick Connect Assembly Tool
- AMS Sizer

The following tool is provided sterile in the AMS 700 Accessory Kit.

- Proximal Tool

This tool is designed to facilitate the insertion of the proximal portion of the cylinder into the corpora, and may also be used to assist in closing.

CAUTION: Do not resterilize or reuse the proximal tool. It is intended for single use only.

The following tools are provided sterile in separate packages

- AMS Cavernotome
- SKW Retractor Kit

CAUTION: Do not resterilize or reuse the AMS Cavernotome or SKW Retractor Kit. They are intended for single use only.

Storage

The versions of the AMS 700 with MS Pump 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 product with InhibiZone above 40°C (104°F).

CAUTION: Do not use product that is past its expiration date.

Figure 2-1. Proximal Tool

Operating Room Instructions

The following instructions are intended as a guide for the surgeon. Various surgical techniques can be used to implant the AMS penile prosthesis. The instructions here represent one of these techniques.

CAUTION: This device is to be used only by physicians who are knowledgeable regarding the use of inflatable penile prostheses. This manual is not intended to be a complete reference.

Preoperative Setup

Instruments

The hospital should provide those instruments normally required for a urological surgical procedure.

In addition to the AMS 700 Penile Prosthesis components, you will need the following sterile setup:

- ✓ Sterile normal saline (filling and flushing solution)
- ✓ Two 60 cc and Two 10 cc syringes (for filling and flushing prosthesis components)
- ✓ Eight mosquito hemostats (for clamping tubing when prepared with shods)
- ✓ One pair of clean, sharp scissors for trimming tubing
- ✓ Hegar dilators (7 mm-14 mm), or urethral sounds (21Fr-42Fr) (for dilating corpora cavernosa)
- ✓ Furlow Insertion Tool (for measuring and passing pulling sutures through glans)
- ✓ AMS Quick Connect Assembly Tool (only needed for sutureless window connectors)
- ✓ AMS 700 with MS Pump Accessory Kit (see description that follows)
- ✓ AMS 700 with MS Pump Rear Tip Extender Kit
- ✓ Cavernotomes (optional)
- ✓ AMS Tubing Passers (optional)
- ✓ AMS Closing Tool (optional)
- ✓ SKW Retractor System (optional)

The AMS 700 with MS Pump Accessory Kit for the AMS 700 with MS Pump Product Line contains the materials necessary for one implant procedure. It includes:

Special Purpose Needles

- ✓ Two 15-gauge disposable blunt needles (for filling components)
- ✓ Two 22-gauge disposable blunt needles (for flushing air and blood from tubing immediately before a connection is made)
- ✓ One pair Keith Needles (for transporting cylinder pulling sutures through glans)

Note: The Keith needles are "lightening bolt" shaped - the bend is normal.

Hemostat Shods

- ✓ Four 13 cm lengths of tubing (for covering tips of hemostats used to prepare components—tubing-shod hemostats help protect prosthesis from tubing damage)

Tubing Connection Accessories

- ✓ Four straight AMS Quick Connect Sutureless Window Connectors
- ✓ Three right angle AMS Quick Connect Sutureless Window Connectors
- ✓ One locking ring holder with eight collets
- ✓ Three straight suture-tie connectors
- ✓ Two right angle suture-tie connectors
- ✓ One tubing plug (to prevent fluid from entering or leaving the prosthesis during revision surgeries)

Documentation

- ✓ One Quick Connect instructions for use brochure
- ✓ One Patient Information Form (PIF)
- ✓ One mailing envelope (for returning the completed PIF to AMS)
- ✓ One patient ID card

AMS Proximal Tool

The AMS Quick Connect Assembly Tool must be ordered separately. It is a reusable stainless steel instrument used to assemble the connectors.

The AMS Quick Connect system may be used for new systems or when all previously implanted components are removed and replaced with new components.

Equipment Preparation

Unpacking the AMS Accessory Kit

1. Remove the tray from the dust cover box in the operating room
2. Have the scrub nurse remove the inner tray from outer tray, using appropriate sterile technique, and place inner tray on a sterile, lint free Mayo stand.
3. Open the inner tray and place it on the sterile, lint free Mayo stand.

Note: The circulating nurse should record the part and serial lot/numbers of the Accessory Kit on the PIF. 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. This information is also listed on the Tyvek™ lid of the outer tray.

Prepare Hemostats

Use the following procedure to cover the hemostats with the blue tubing provided in the accessory kit:

1. Place blue tubing on both jaws of hemostats to completely cover serrated surfaces.
2. Clamp jaws together until the first click to prevent excessive pressure on tubing.
3. Trim the tubing at jaw tip with sharp, clean scissors.
4. Reserve one pair of scissors as “clean” tubing scissors throughout procedure. These will be used throughout the surgery for trimming tubing prior to connecting. These should be straight scissors.

Surgical Procedures

Prepare Patient

Before the surgery, the surgeon should take adequate steps to limit the risk of post-operative infection.

CAUTION: Using a device with InhibiZone Antibiotic Surface Treatment does not change the need to follow normal hospital protocols for prophylactic antibiotic administration.

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

Establish the sterile field, drape, and prepare the patient according to the physician's instructions. Throughout the procedure, the surgical site should be flushed with copious amounts of broad-spectrum antibiotic. Position the patient according to the physician's preferred surgical approach: infrapubic or penoscrotal.

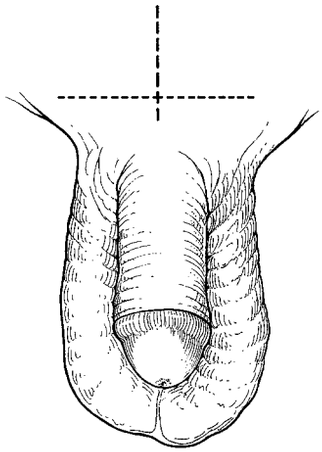


Figure 4-1. Infrapubic: Identify Incision Site

Surgical Approaches

The following descriptions are an overview of the infrapubic and penoscrotal surgical approaches; the physician will make the final choice of surgical approach and technique.

Infrapubic Approach

All of the prostheses in the AMS 700 with MS Pump product line can be implanted through an infrapubic incision. If the prosthesis is preconnected, be certain that the cylinder/pump package is labeled infrapubic.

Penoscrotal Approach

It is also possible to implant all of the prostheses in the AMS 700 with MS Pump product line through a penoscrotal incision. If the prosthesis is preconnected, be certain the cylinder/pump package is labeled **penoscrotal**.

Make Incision and Dissect

1. Place a Foley catheter to facilitate urethra identification. The Foley catheter will help decompress the bladder and help avoid bladder injury during reservoir placement.
2. Make the appropriate incision for the surgical approach chosen.

   Penoscrotal: Make a 2 to 3 cm incision through the median raphe of the scrotum at the penoscrotal angle.

   - When using the SKW retractor, place the ring retractor on the patient with the large ring toward the patient's head (cephalad) and the smaller ring towards the patient's feet (caudal). **(Figure 4-2)**.
   - After orienting the retractor, place the sharp blue hook in the meatus, then draw the penile strap tight, like a bowstring. Attach the penile strap at the 3 o'clock and 9 o'clock positions on the ring retractor.
   - Make a high scrotal incision, move the incision onto the penis and do not let go.
   - While holding the incision on the penis, place hooks at 1, 5, 7, 11, 3 & 9 o'clock (**Figure 4-2**).

   Infrapubic: Make a 4 to 5 cm longitudinal, or transverse incision, at symphysis pubis (**Figure 4-1**). Avoid the midline neurovascular bundle.
3. For the penoscrotal approach, laterally retract the corpus spongiosum to avoid damaging the urethra (**Figure 4-3).**
4. Dissect through Dartos fascia and Bucks fascia to expose the tunicae albuginea.
5. Place stay sutures.
6. Make an incision into one of the corpora cavernosa **(Figure 4-4).**

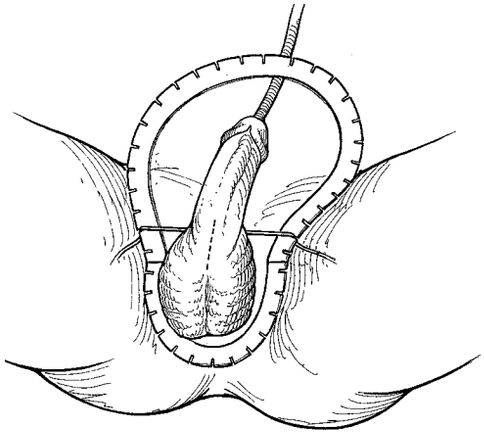


Figure 4-2. Penoscrotal: Identify Incision Site

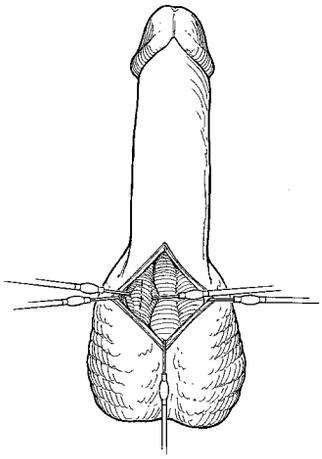


Figure 4-3. Penoscrotal: Retract Corpus Spongiosum

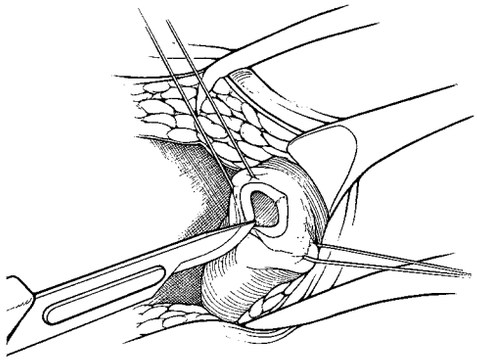


Figure 4-4. Make Corporotomy

Dilate and Measure

1. Using a series of dilation tools, dilate the proximal corpus cavernosum (towards the crus) at least to 11 mm if the cylinder tubing will exit directly from the corporotomy, larger if the tubing will be inside the proximal corpus cavernosum and the distal corpus cavernosum to at least 12 mm to create a space for inserting a penile cylinder. After dilating one corpus cavernosum, incise and dilate the adjacent corpus cavernosum following the same procedure.

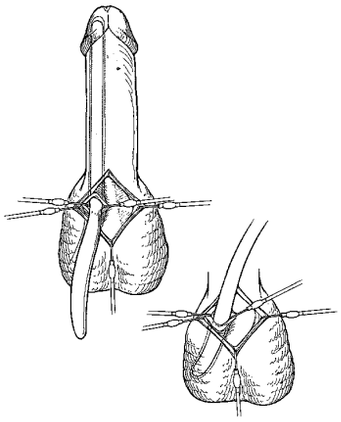


Figure 4-5a. Penoscrotal: Dilate

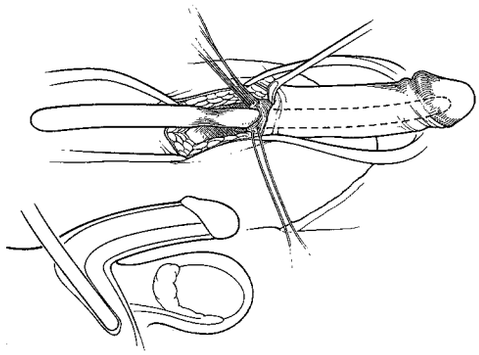


Figure 4-5b. Infrapubic: Dilate

2. Measure each corpus proximally and distally using the Furlow Insertion Tool or AMS Measuring Tool slightly stretching the penis during this process. These measurements help the physician select cylinders and rear tip extenders that fit the patient's anatomy.

   Note: Measuring both directions from one of the stay sutures provides consistency. However, when using LGX devices, some physicians choose to measure distally from the distal edge of a 2 cm corporotomy and proximally from the proximal end of a 2 cm corporotomy for a more optimal sizing of the device.

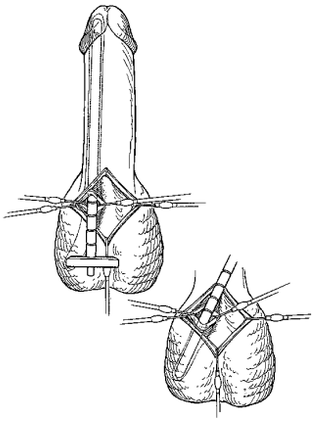


Figure 4-6a. Penoscrotal: Measure

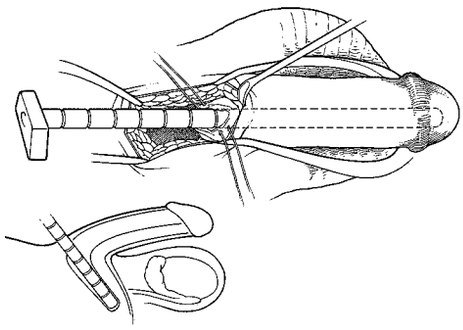


Figure 4-6b. Infrapubic: Measure

Select Appropriate Size Cylinder

Select the appropriate size cylinders and if applicable, apply rear tip extenders.

Sizing

- **AMS 700 CXR with MS Pump**
- The proximal portion of the CXR cylinder is approximately 1.5 cm longer than the CX and LGX cylinder. Sizing using Method A is recommended and will result in tubing exiting from the corporotomy. Except for the 1.5 cm rear tip extender, the RTEs for the AMS 700 CXR cannot be stacked. They have an internal interlocking design. Select the appropriate rear tip length and attach to the cylinder, twisting the RTE onto the cylinder to provide tactile indication of proper connection.
- **CAUTION: Do not stack CXR Rear Tip Extenders other than the 1.5 cm RTE. If other sizes of RTE are stacked, then the locking mechanism will not engage and rear tip extenders may not stay connected to each other.**

- **AMS 700 CX with MS Pump and LGX with MS Pump**
- **CAUTION: Do not stack CX/LGX Rear Tip Extenders other than the 1.5cm RTE. If other sizes of RTE are stacked, then the locking mechanism will not engage and rear tip extenders may not stay connected to each other.**
- There are two methods of selecting cylinder sizes for the AMS 700 CX and LGX prostheses. Each surgeon's own implanting experience will determine which technique is used.

Method A reduces the length of the solid proximal portion of the cylinders in the shaft of the penis and allows the tubing sleeve to contact a portion of the expandable shafts of the cylinders. **(Figure 4-7a)**. As the tubing is partially buried in the corpora, using Method A has the potential to increase the likelihood of tubing compression or kinking, which may reduce fluid flow. If you believe the tubing is kinked, attempt to gently straighten it.

Calculate the Total Corporal Length (distal + proximal)
Example

Distal Corporal Length	12 cm
Proximal Corporal Length	+7 cm
Total Corporal Length	19 cm

Select the closest cylinder size that is shorter than or equal to the Total Corporal Length. Add rear tip extenders, if necessary, to fit the patient's anatomy.
Example

Total Corporal Length	19 cm
Selected Cylinder Length	-18 cm
Rear Tip Extender Length	1 cm

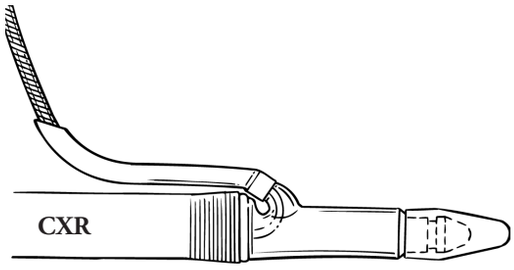


Figure 4-7a. Method A

Method B allows the tubing to exit directly from the corporotomy (**Figure 4-7b)**. Follow the formula described below to select the appropriate cylinder length and number of rear tip extenders. If necessary, extend the length of the corporotomy.

Calculate the Total Corporal Length (distal + proximal)
Example

Distal Corporal Length	12 cm
Proximal Corporal Length	+7 cm
Total Corporal Length	19 cm

Subtract 2 cm from the Total Corporal Length to obtain an Adjusted Measurement.
Example

Total Corporal Length	19 cm
	-2 cm
Adjusted Measurement	17 cm

Select the closest cylinder size that is shorter than or equal to the Adjusted Measurement.
Example

Adjusted Measurement	17 cm
Selected Cylinder Length	15 cm

Subtract the Selected Cylinder Length from the Total Corporal Length to determine the length of rear tip extenders required to fit the patient.
Example

Total Corporal Length	19 cm
Selected Cylinder Length	-15 cm
Rear Tip Extender Length	4 cm

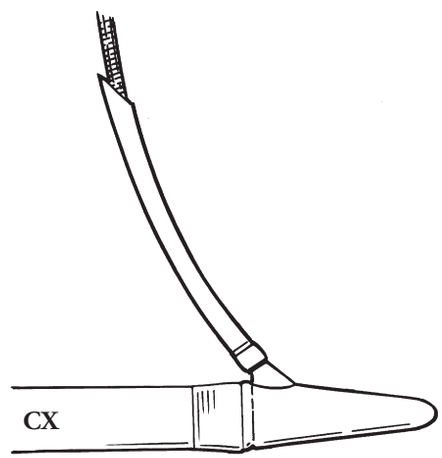


Figure 4-7b. Method B

Note: Do not open any component packages until cylinder length is confirmed.

Unpack Components

The AMS 700 with MS Pump Penile Prosthesis components are packaged in sterile pouches, except the RTE's, which are packaged in sterile trays.
Keep the sterile products in their plastic travel cases until they are in the operating room.

Open Packs, Including Devices with Inhibizone Antibiotic Surface Treatment

1. Remove the product from the outer travel box in the operating room.
2. Have scrub nurse remove sterile inner pouch and place it on a sterile, lint free Mayo stand.
   CAUTION: Do not place cloth towels on Mayo stand. They may transfer lint to the AMS components.
3. When ready to prepare AMS components, open inner pouch and place them onto sterile, lint free Mayo stand.
   Note: The circulating nurse should record the part and serial/lot numbers as well as the size of the components of the PIF.
   Note: The small, removable adhesive labels contain the part and serial/lot numbers as well as the size of the components.

Prepare Components

AMS recommends that all components of the AMS 700 with MS Pump Product Line be prepared with sterile normal saline. The sterile normal saline must remain free of debris that can block fluid flow through components.

Note: The circulating nurse should record the part and serial/lot numbers as well as the size of the components on the PIF. The part and serial/lot numbers as well as the size of the components are listed on the product pouch.

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 an orange and will reduce the concentration of antibiotics on the device.

Prepare Non-connected AMS 700 MS Pump

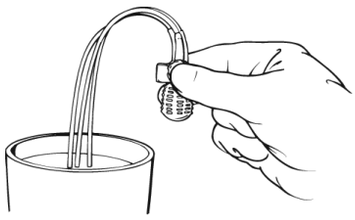


Figure 4-8

1. Partially fill a graduate with sterile, normal saline.
2. Submerge pump's three tubing ends into sterile normal saline. (**Figure 4-8**)
3. Hold the pump so the deflate mechanism is on top.
4. Squeeze the deflation button 1 time and release.
5. Make an initial hard, quick squeeze of the pump bulb. Saline should appear in the pump bulb.
   Note: This step is important to lubricate the valves of the pump for further prepping.
   Note: If saline does not appear in the pump bulb or if the bulb does not fully reinflate, press the deflation button 1 time and release. This will reset the pump. Repeat Step 5. This sequence may be required more than once to get the pump activated.
6. Following the initial squeeze, continue to squeeze and release the pump bulb 2-3 more times to allow the air to be expelled from the components; no air bubbles in the graduate (these squeezes can be softer). Let the pump bulb completely refill before each squeeze.
   CAUTION: Do not squeeze the deflation button and the pump bulb at the same time.
7. Using 3 blue shod mosquito hemostats, clamp (1 notch only) each of the 3 tubes 1 inch from the end.

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

8. For a pump treated with InhibiZone Antibiotic Surface Treatment, place the pump onto an empty sterile tray, empty kidney basin or sterile Mayo stand- the pump should not be submerged in 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.

9. For a non-InhibiZone treated pump, submerge the filled pump into a kidney basin of sterile normal saline or antibiotic solution until the surgeon is ready to implant the pump.

Prepare Preconnected MS Pump and Cylinders

The AMS 700 CX Preconnect, CXR Preconnect and LGX Preconnect Penile Prosthesis cylinders and respective pumps are provided already connected. The only connection required of the surgeon is between the pump and reservoir.

Once the surgeon has determined the proximal and distal lengths of the corpora cavernosa, choose the appropriate preconnect cylinder and pump from inventory.

The following instructions outline the preparation of the device to ensure that the air is removed from the cylinders and pump before the surgeon connects the reservoir.

1. Partially fill a graduate with sterile, normal saline.
2. Submerge the single, black color-coded tubing from the pump into sterile normal saline.
3. Hold the pump so the deflate mechanism is on top.
4. Squeeze the deflation button 1 time and release.
5. Make an initial hard, quick squeeze of the pump bulb. Saline should appear in the pump bulb.

   Note: This step is important to lubricate the valves of the pump for further prepping.

   Note: If saline does not appear in the pump bulb or if the bulb does not fully reinflate, press the deflation button 1 time and release. This will reset the pump. Repeat Step 5. This sequence may be required more than once to get the pump activated.

6. Following the initial squeeze, continue to squeeze and release the pump bulb until the cylinders are rounded and the pump bulb is hard to squeeze. Let the pump bulb completely refill before each squeeze.
7. Squeeze the deflation button for 2-4 seconds to allow the air to be expelled from the components; Note: no air bubbles in graduate.
8. Repeat steps 6 and 7 until all the air is removed from the system—that is, no bubbles are noted in the graduate during deflation.
9. Squeeze the cylinders to remove the remaining saline from the cylinders.

   CAUTION: Do not squeeze the deflation button and the pump bulb at the same time.

10. Using a blue shod mosquito hemostat, clamp (1 notch only) the black tubing 1 inch from the end.

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

11. For components treated with InhibiZone Antibiotic Surface Treatment place the empty (air removed and no fluid) cylinders and pump onto an empty, non-covered sterile tray, empty kidney basin or sterile Mayo stand—components should not be submerged in 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.

For a non-InhibiZone treated components, submerge the empty cylinders and filled pump into a kidney basin of sterile normal saline or antibiotic solution until the surgeon is ready to implant the cylinders.

Prepare Non-Connected Cylinders

Once the surgeon has determined the proximal and distal lengths of the corpora cavernosa, choose a pair of appropriate length cylinders from inventory. Prepare the cylinders with sterile normal saline using a 15-gauge blunt tip needle and a 60 cc syringe by completing the following steps:

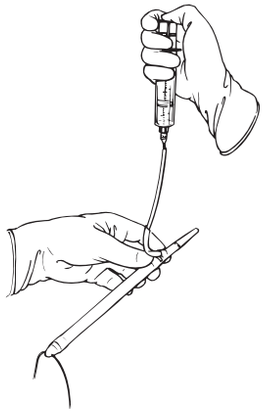


Figure 4-9

1. Hold cylinder in non-dominant hand and squeeze out air.
2. Attach 15-gauge blunt tip needle to the 60 cc syringe partially filled with sterile normal saline.
3. Use partially filled syringe to aspirate all air from the cylinder, and then slowly fill cylinder with sterile normal saline (approximately 20-30 cc) without injecting air bubble.
   - Hold the cylinder from the rear with the front tip down to allow distal portion of cylinder to fill first (**Figure 4-9**).
   - Inject fluid into cylinder until it is rounded out.
   - Aspirate all air from cylinder with syringe.
4. You may repeat this process once if desired.
5. Aspirate all sterile normal saline and air from the cylinder until it is flat, or until the syringe plunger meets resistance.

   CAUTION: Do not over aspirate to prevent air from being drawn into cylinder through its semi-permeable silicone elastomer.
6. Holding the syringe plunger up with your thumb, clamp tubing (1 notch only) 1 inch from needle top using the blue shod mosquito hemostat. Then remove the 15-gauge needle and syringe.

   CAUTION: Do not advance the hemostat's ratchet more than one notch. Excessive pressure may damage the tubing permanently.
7. For a cylinder treated with InhibiZone Antibiotic Surface Treatment, place the cylinder onto an empty, non-covered, sterile tray, empty kidney basin, or sterile Mayo stand; cylinders should not be submerged in 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 an orange and will reduce the concentration of antibiotics on the device.
8. For a non-InhibiZone treated cylinder, submerge cylinder in a kidney basin of sterile normal saline or normal saline mixed with antibiotic solution, until the surgeon is ready to implant it.
9. Prepare the other cylinder in same manner.

Prepare Reservoirs

Use two 60 cc syringes with 1 cc gradations when filling the 65 ml or 100 ml reservoir.

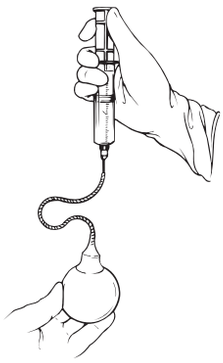


Figure 4-10

1. Begin with reservoir in non-dominant hand and squeeze air out of reservoir.
2. Holding the reservoir, attach 15-gauge blunt tip needle and a 60 cc syringe that is partially filled with sterile normal saline to the reservoir (**Figure 4-10**).
3. Use partially filled syringe to aspirate all air from reservoir.
4. After air has been removed, inject sterile normal saline (approximately 20-30 cc) without injecting an air bubble.
5. Using your thumb press in on side of reservoir to form it into a bowl shape.
6. Aspirate all remaining saline and air out of reservoir and into syringe, stopping when syringe plunger encounters resistance and/or reservoir makes a flattened bowl shape. Leave in the flattened bowl shape.

CAUTION: Do not over aspirate to prevent air from being drawn into reservoir through its semi-permeable silicone elastomer.

7. Holding syringe plunger up with thumb, clamp tubing (one notch only) 1 inch from the blunt needle tip using blue shod mosquito hemostat, and remove the 15-gauge needle and syringe.

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

8. For a reservoir treated with InhibiZone Antibiotic Surface Treatment place the reservoir onto an empty non-covered sterile tray, empty kidney basin, or sterile Mayo stand — the reservoir should not be submerged in 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.

9. For a non-InhibiZone treated reservoir, submerge the reservoir into a kidney basin of sterile normal saline or of normal saline mixed with antibiotic solution until the surgeon is ready to implant it.

Insert Cylinders

AMS has preplaced a traction suture through the distal tip of each cylinder. Depending on surgeon preference, either after or before inserting the cylinder into the crus, complete the following steps:

1. Use the Furlow Insertion Tool **(Figure 4-11)** and Keith Needle to help introduce cylinders into the corpora cavernosa.
2. Check function of Furlow Insertion Tool by withdrawing obturator to locking groove, for the "retracted" position and then fully insert obturator until tip appears at end.

   Note: Lightning Bolt Keith Needles are included in the AMS 700 Accessory Kit.
3. Withdraw obturator to "retracted" or "locked" position. Pass both ends of cylinders traction suture (approximately 10 cm) through the eye of a Lightning Bolt Keith Needle **(Figure 4-12)**.
4. Load the blunt end of this needle into the Furlow Insertion Tool **(Figure 4-13)** and place suture into into slot of the tool.
5. Completely retract suture into slot and fully draw needle into barrel of tool.
6. Hold the four strands of suture against the tool and insert tool into distal portion of corporal body until front tip is beneath glans.

   Note: It is imperative that patient's penis is aligned symmetrically with his body and that location of puncture through glans is satisfactorily identified before pushing needle through glans. The Furlow Insertion Tool should be in the ipsilateral corpora at the distal tip.

   Note: If you cross over through the intro-cavernosal septum to contralateral side, remove, place dilator into contralateral side and reposition cylinder on ipsilateral side. No repair is necessary.
7. Place the penis on a mild stretch; push needle through glans by fully inserting obturator into barrel.
8. Grasp needle with a needle holder or mosquito hemostat, and pull it completely through glans.
9. Detach the needle from suture, and remove it from the area to prevent any accidental puncture of cylinders.
10. Attach a tubing-covered hemostat to the traction sutures to prevent inadvertent retraction through glans.
11. Insert front tip of cylinder into the corporotomy.
12. Gently push cylinder distally into place from the corporotomy.

    Note: Use the traction suture to guide the cylinder until the front tip is placed well under the glans. Take care not to twist cylinder as it is being placed.
13. Carefully assess front tip position of cylinder beneath glans to verify proper cylinder placement.

    Note: Take care to leave the traction suture in place through the glans to allow the cylinder to be repositioned. If repositioning or more dilation is required, the cylinder should simply be pulled out of corporal body.

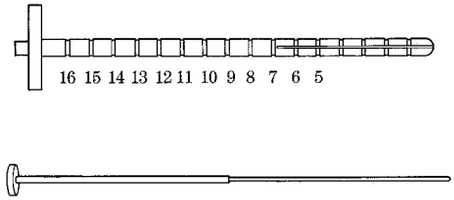


Figure 4-11. Furlow Insertion Tool

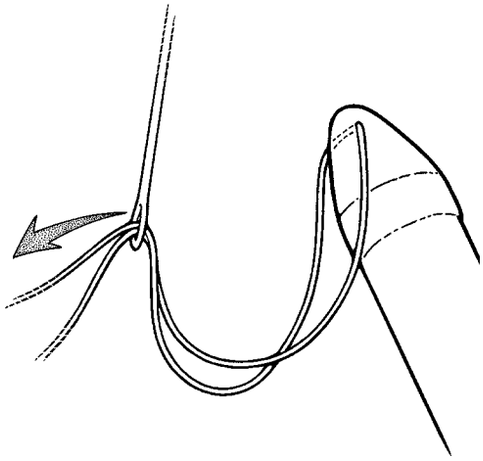


Figure 4-12. Insert Traction Suture into Keith Needle

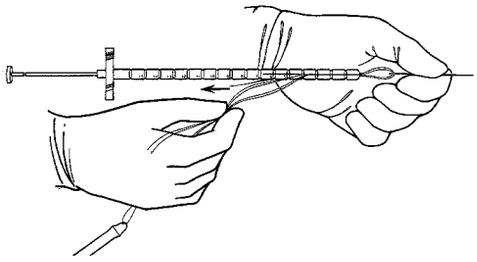


Figure 4-13. Load Keith Needle

14. Before placing proximal end of cylinder, slightly retract the distal tip of cylinder (under glans) several centimeters in proximal direction.
15. Fold cylinder back on itself, then push proximal end of cylinder into the crus while gently stretching the distal penis **(Figure 4-14a, Figure 4-14b)**. Alternatively, place the "U" shaped portion of the proximal tool at the junction between the output tube and cylinder and use the tool to push the proximal end of the cylinder into the crus while gently stretching the distal penis. The flatter side of the tool should face toward the cylinder.
16. Once the proximal portion of the cylinder is in place, reposition the distal portion under the glans by gently pulling on the traction suture.
17. Assess the cylinder length for satisfactory fit within corpora cavernosa by ensuring that the distal tip is snugly under glans, the cylinder lies within the corporotomy, and the proximal end is firmly against the crus. If not satisfactory, remove cylinder, adjust length as needed, re-implant.
18. Repeat the procedure to insert the remaining cylinder into the other corporal body.

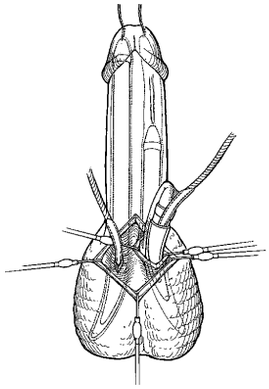


Figure 4-14a. Penoscrotal: Insert Cylinders

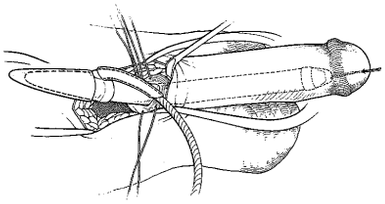


Figure 4-14b. Infrapubic: Insert Cylinders

Implant Reservoir

Reservoir Size

Select the appropriate reservoir size based on cylinder length. Refer to table in the Product Line Matrix section of this manual to determine reservoir size.

Infrapubic Implantation

1. Create a defect in rectus fascia and a pocket in prevesical space under the rectus muscle to insert the reservoir.

   Note: The reservoir tubing may be routed through the rectus fascia using the AMS Tubing Passer. When using AMS Tubing Passers, tubing should be placed on knobbed end of passer and passed through fascia. As an alternative, route tubing directly through midline between rectus muscles.

Penoscrotal Implantation

1. Create a defect in transversalis fascia through the external inguinal ring **(Figure 4-15a)**. This defect provides access to the prevesical space. You may find access to the inguinal ring and pre-vesicle space easier using the baby deaver provided in the SKW Retractor Kit. The deaver is placed in the inguinal ring and pulled toward the head, revealing the inguinal ring. Once the pocket is created in the prevesical space, use your finger to place the reservoir into the space.

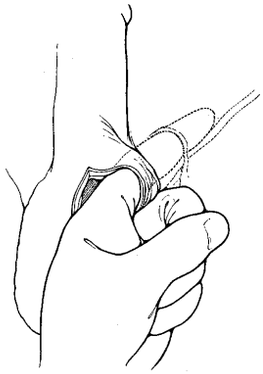


Figure 4-15a. Create Defect

Note: Alternatively, the prepared reservoir may be placed in the prevesical space through a small inguinal incision. Make a defect in prevesical space under rectus muscle large enough to accommodate reservoir without putting pressure on it. Then insert the reservoir.

Fill Reservoir

2. After implantation, flush the reservoir tubing with normal saline using a 22-gauge blunt needle on the 10 cc syringe.

3. Using the 60 cc syringe and 15-gauge blunt needle, fill the reservoir with the appropriate amount of sterile, normal saline. Generally, the amount of fluid should be equivalent to the label of the reservoir (65 cc or 100 cc). However, the 100 ml AMS Conceal Low Profile Reservoir can be filled up to 100 ml to accomodate all cylinder sizes.

4. Using the blue shod mosquito hemostat, re-clamp the reservoir tubing 1" from tip of needle (one notch only).

   Note: Do not allow excess tubing to lie on the reservoir.

Implant Pump

1. Use blunt dissection to form a pocket in the most dependent portion of the scrotum **(Figures 4-16a and 4-16b**).

2. Insert the pump into the scrotal pocket.

3. Apply Allis or Babcock clamps to pump tubing through scrotal skin to hold pump in place **(Figure 4-17)** during remainder of procedure.

4. If using a non-connected system, make connection between cylinder and pump. Refer to the instructions on making connections in this manual.

   Note: Extra tubing between the pump and cylinders may be tucked within surrounding tissues on the AMS 700 LGX Preconnect, AMS 700 CX Preconnect.

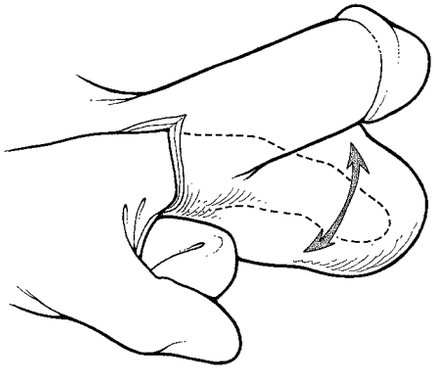


Figure 4-16a. Infrapubic: Bluntly Dissect

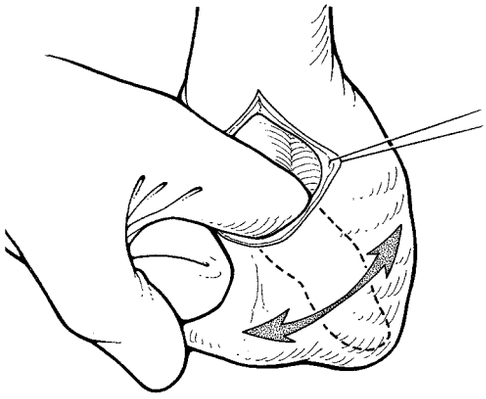


Figure 4-16b. Penoscrotal: Bluntly Dissect

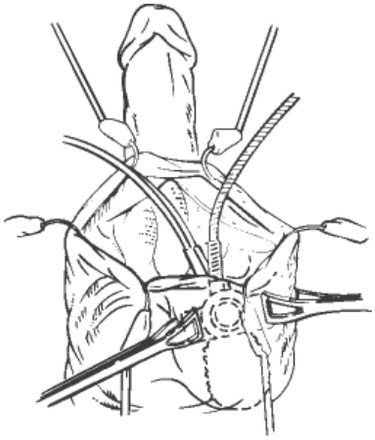


Figure 4-17. Insert Pump (Penoscrotal shown here)

Complete Inflate/Deflate Test

Close corporotomy

1. Close the tunicae albuginea with either a running horizontal mattress stitch or preplaced sutures, with meticulous attention to hemostasis.

   Note: If using mattress stitch, you may place the winged end of the AMS Reusable Closing Tool or the foot of the disposable Proximal Tool over the cylinder to protect it while suturing. Move the tool along incisions with each stitch to protect cylinder.

Perform the first inflate/deflate test

2. Flush cylinder tubing **(Figure 4-18).**
3. Attach the 60 cc syringe filled with 55 cc filling solution to each cylinder.
4. Inflate cylinders to evaluate erection quality.

   Note: Check for placement of the cylinder tip, any cylinder uckling, kinking, or disruption of the suture line, or fluid leakage from the cylinder.

5. Deflate to evaluate flaccidity.

   CAUTION: When using AMS 700 LGX Preconnect with MS Pump, AMS 700 CX Preconnect with MS Pump or AMS 700 CXR Preconnect with MS Pump, to avoid damaging the pump, don't inject fluid into the reservoir line of the pump using a syringe.

6. If each cylinder is the correct length and position, cut one end of traction suture approximately 2 cm from the glans; pull it out slowly to minimize trauma to the glans and the front tip of the cylinder.

   Note: Do not remove traction sutures from cylinders until the completion of surgery in case the cylinders need to be repositioned.

   Note: The suture is non-absorbable and must be removed from the glans.

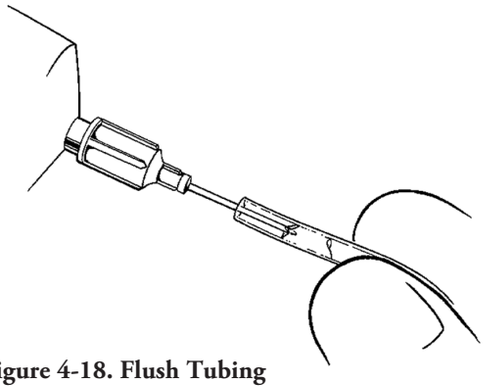


Figure 4-18. Flush Tubing

Complete Surrogate Reservoir Test

Before connecting tubing between the pump and reservoir, perform surrogate reservoir test to ensure that the pump and cylinders work well together.

CAUTION: To avoid damaging the pump, don't inject the fluid into the reservoir line of the pump using a syringe.

1. Place hemostat with blue shod on reservoir tubing.
2. Submerge tubing into basin with at least 55mL of filling solution.
3. Remove hemostat from tubing and squeeze inflation bulb to inflate cylinders and make penis erect.
4. Confirm cosmetic result is satisfactory. Cylinders should be rigid without bending or buckling.
5. Deflate cylinders by pressing the pump's deflate button for 4 seconds.
6. All of the fluid should be removed from the cylinders, therefore gently squeeze penis/cylinders to return fluid to basin.
7. Reclamp reservoir tubing with shodded hemostat.

Connect Cylinders And Reservoir

After successfully completing the surrogate reservoir test, connect the cylinders and the reservoir. Refer to the instructions on making connections in this manual.

Connecting Tubing

1. Connect the component tubing using AMS Suture-Tie Connectors or AMS Quick Connect Sutureless Window Connectors, after the cylinders, reservoir, and pump are implanted and the testing described earlier in this manual has been completed.

   CAUTION: AMS Quick Connect Sutureless Window Connectors should not be used in revision procedures involving previously implanted component tubing.

   Note: Use either straight connectors or right angle connectors, depending on surgeon's technique and patient anatomy.

2. If desired, the protective white sleeve on cylinder tubing may be peeled if it interfaces with a connection.
3. Gently grasp sleeve at tab and peel sleeve away from tubing.
4. Once sleeve has been peeled to length desired, excess sleeve may be cut.

   CAUTION: Do not remove so much white sleeve material that bare input tubing touches the expandable shaft of the cylinder.

5. Separate tubing and connectors to prevent wear.

AMS Quick Connect Sutureless Window Connectors

1. Trim tubing length to fit patient's anatomy, making sure cut end is square – straight scissors or a knife blade should be used.
2. Clamp tubing using tubing blue shod mosquito hemostats.
3. Insert small diameter portion of collet holder into tubing.
4. Slide collet ring onto tubing (**Figure 4-19a**), making sure that teeth of collet ring face toward tubing end.

   Note: The AMS Quick Connect System cannot be resterilized. Conventional hospital sterilization will damage the connector components. However, the AMS Quick Connect Assembly Tool may be resterilized according to the AMS tool resterilization instructions.

5. Repeat with end of other tubing.
6. Flush end of connector and tubing with sterile normal saline to remove particulate matter and air using a 22-gauge blunt tip needle.
7. Insert tubing ends onto connector (**Figure 4-19b**).
8. Firmly push one side of tubing to middle wall of connector and check tubing placement through connector window.
9. Firmly push other tubing to middle wall. Check connector window to make certain both tubing ends are still touching middle walls of the connector.
10. Place connector ends in tool jaw (**Figure 4-20**).
11. Squeeze tool handles until closure stop touches opposite handle.

    CAUTION: Check tubing before you close assembly tool. The tubing must not be trapped between assembly tool jaw and connector. The tubing must exit straight from ends of the connector, through the slots in assembly tool. After using AMS Quick Connect Assembly Tool, tubing should bulge through connector window. This indicates that tubing is still firmly against the middle wall of the connector. The end of the collet outside of the connector should be parallel to and almost flush with the end of the connector. (Figure 4-20) This indicates collet has been inserted completely into and attached to connector. Give a firm pull on tubing on both ends of connector to confirm a good connection has been made.

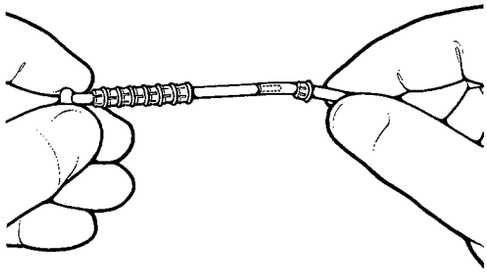


Figure 4-19a. Slide Collet Ring Onto Tubing

Figure 4-19b. Insert Tubing Ends

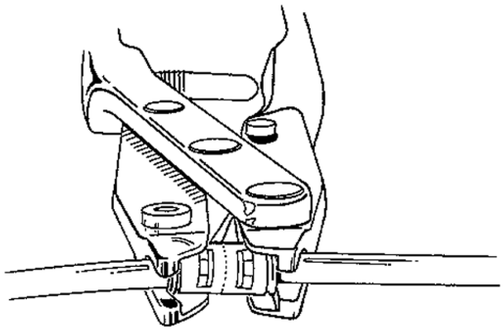


Figure 4-20. Place Connector Into Assembly Tool

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

Suture Tie Connectors

1. Cut the tubing **(Figure 4-21)** to fit the patient's anatomy.
2. All connections using AMS Suture-Tie Connectors are tied with 3-0 nonabsorbable polypropylene. Clamp the component tubing with blue shod mosquito tubing covered hemostats.
3. Use a 22-gauge blunt tip needle to flush tubing ends **(Figure 4-22)** with normal saline to remove particulate matter and air before connecting.
4. Push tubing over ends of connector so that they meet at center hub of connector.

   Note: Make sure the tubing is on the connector straight.
5. Use a double-throw overhand surgeon's knot followed by a minimum of two single throws to attach tubing to connector **(Figure 4-23).**

   Note: The suture should crimp, but not cut the tubing.
6. Pass suture 180º and use same tying technique on opposite side of the connector. Then use another suture and repeat on the opposite end of the connector.

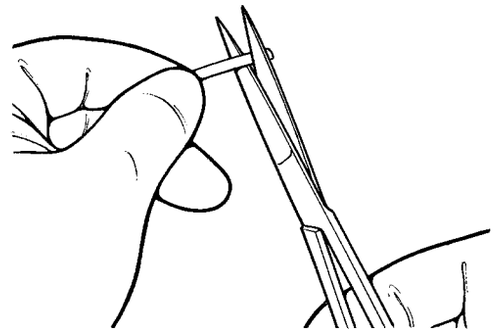


Figure 4-21. Cut Tubing

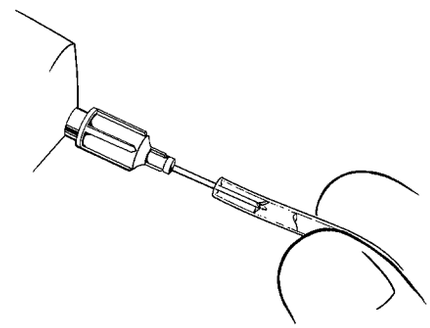


Figure 4-22. Flush Tubing

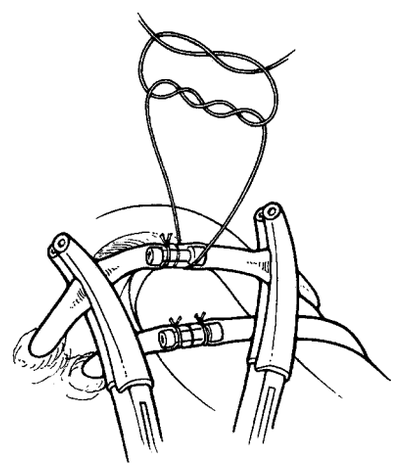


Figure 4-23. Suture Connector

Complete Final Inflate/Deflate Test

1. After all components are connected, completely inflate and deflate the cylinders at least once to ensure the device is functioning properly; to check the quality of the erection; and to evaluate flaccidity.

   Note: The erect penis should present a satisfactory cosmetic result.

   Note: The flaccid penis should lie close to body when deflated. There may be some swelling that precludes a good flaccid result.

   Note: If erect or flaccid results are not acceptable, check the amount of fluid in reservoir and adjust the volume if necessary.

2. Before ending the procedure, squeeze the deflation button to allow the cylinders to partially deflate so that some fluid still remains in the cylinders postoperatively. This will ensure the cylinder capsules are large enough to prevent resistance to inflation.

   To prevent autoinflation, squeeze the deflation button as the last action before closing the incision.

3. Close the incision.

   Note: Some physicians close the dartos in two layers with running 2-0 chromic catgut suture then close the skin.

4. Apply a wound dressing and leave partially inflated.
5. Tape penis to abdomen **(Figure 4-24).**
6. Optionally, a drain may be placed for 12-24 hours

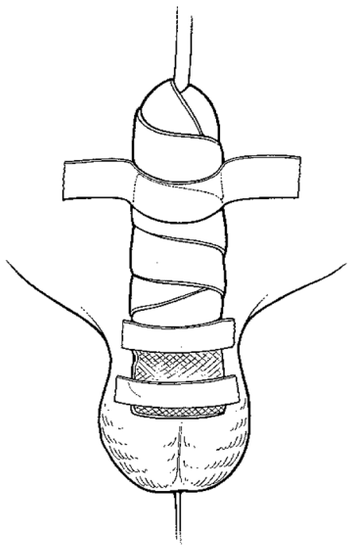


Figure 4-24. Tape Penis to Abdomen

Postoperative Procedures

Immediately Postoperative

The physician may place a closed system drain in the abdomen to drain excess fluid from the incision site.

After 24 hours, remove the dressing. Support the penis on the abdomen for four to six weeks to obtain a straight erection.

After the Patient is Released from the Hospital

The patient is usually discharged in twelve to twenty-four hours.

After the patient has returned home and the swelling from the surgery has subsided, the physician may ask the patient to pull down on the pump located in the scrotum to properly position it. Positioning the pump makes it easier for the patient to locate the pump.

The frequency of positioning the pump is up to the physician. Some physicians have their patients position the pump daily.

To position the pump in the scrotum, a patient should be told to:

- Locate the pump in the scrotum.
- Grasp the pump firmly and carefully pull the pump down in the scrotum. The patient should gently pull the pump into a position close to the outer scrotal wall.

After three to six weeks, the physician may instruct the patient to begin cycling the device for the first time. To cycle the device, the patient inflates and deflates the prosthesis several times. It may be painful for the patient the first few times that he inflates and deflates the device. However, after the postoperative healing period, the pain should subside. Instruct the patient to inflate and deflate the prosthesis several times daily. This will encourage maximum pseudocapsule development and reservoir capacity.

Four to six weeks postoperatively, instruct the patient that it is possible to begin using the prosthesis to have intercourse. To determine if 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 promptly with antibiotics.
- Ask the patient about pain when cycling the device and observe the patient inflating and deflating the device.
- If the patient is unable to inflate the device and you believe the tubing may be kinked, AMS recommends trying the pull-stretch technique: the patient's penis is pulled-stretched out, up, down and side to side 2-3 times, which may allow the cylinders to be inflated. This technique may resolve the issue by slightly modifying tubing placement to optimize fluid flow.

After determining that the patient knows how to operate the device and that the device is functioning correctly, inform the patient that it is possible to have intercourse

If the patient is familiar with injection therapies for erectile dysfunction, remind the patient that such therapies can cause damage to the penile prosthesis, and thus should not be used.

The pump contains a valve that resists elevated reservoir pressure. However, there is the possibility that the device will automatically inflate during the immediate postoperative period and the patient may have to return to the office for deflation. Autoinflation may occur for a variety of reasons.

If this occurs, verify that the patient is squeezing the deflation button for 4 seconds and that the patient does not squeeze pump bulb after this. Instruct the patient to inflate and deflate the prosthesis several times daily. This will encourage maximum pseudocapsule formation and reservoir capacity.

Evaluating Long-term Function and Placement

After the postoperative healing period, the physician 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, ask the patient about how the device is functioning and if he has noticed any changes in the function, for example, cylinders losing rigidity. Also check the patient for signs of infection or erosion.

If the patient is having mechanical difficulty with the device, or there is infection or erosion present, revision surgery may be necessary.

Combining Components of Different Models

Combining AMS 700 Components

It is possible to combine components from different prostheses in the AMS 700 Product Line if necessary to meet patient requirements during both primary and secondary surgeries. (See Product Line Matrix section of this manual for reservoir recommendations).

Reservoirs

Although the 100 ml spherical and AMS Conceal Low Profile Reservoirs are suitable for all AMS 700 LGX MS Pump cylinder sizes, you may choose to use the 65 ml spherical reservoir with the 12 cm and 15 cm AMS 700 LGX MS Pump cylinder sizes if an inflate/deflate test indicates that 55 cc or less of fluid is necessary to inflate both cylinders. However, the 100 ml spherical and AMS Conceal Low Profile Reservoirs should always be used with the 18 cm and 21 cm AMS 700 LGX MS Pump cylinder sizes.

Follow the applicable instructions for preparing the reservoir from the Component Preparation section of this manual. Implant and fill the reservoir.

Pump

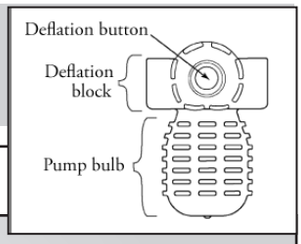
If the pump for the AMS 700 LGX with MS Pump Preconnect, AMS 700 CXR with MS Pump Preconnect or AMS 700 CX with MS Pump Preconnect is damaged during surgery, and if the cylinders have already been implanted, a separate AMS Pump may be substituted. This method can also be used if a AMS 700 with MS Pump is desired for a device that is preconnected to a standard 700 pump.

1. Clamp (one click only) each of the clear tubing between the pump and the cylinders with a tubing covered hemostat.
2. Use clean, sharp scissors to cut the pump tubing and remove the pump. These should be straight scissors.
3. Implant the pump and reconnect the new pump to the cylinders using either AMS Suture-Tie Connectors or AMS Quick Connect Sutureless Window Connectors.

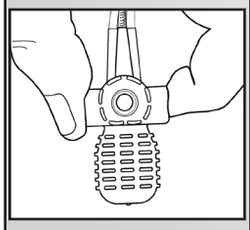
Cylinders

If the cylinders of the AMS 700 LGX Preconnect, AMS 700 CXR Preconnect or AMS 700 CX Preconnect become damaged during the primary surgery the entire pump and cylinders component should be replaced.

Troubleshooting



Cylinders

Problem	What to Do
Sized incorrectly	• Redilate and remeasure. Remove cylinder and add or subtract rear tip extenders to adjust length. If unable to adjust length with rear tip extenders, remove cylinder and replace with cylinder of the appropriate size.
Difficult to inflate	• Squeeze the deflation button to "reset" the lockout valve. Make the first pump bulb squeeze quick and firm to activate the pump (you should feel a pop). The remaining pump bulb squeezes can be slower.
Punctured	• Remove damaged cylinder and replace.
Won't inflate	• Determine that the tubing is not kinked. If it is kinked, gently straighten it. • Be sure that the cylinder has not buckled. If the cylinder has buckled, be sure that it has been inserted properly. • If the cylinders still won't inflate, remove them and replace. • Be sure all rubber shod hemostats are off the tubing.
Won't deflate 	• Be sure the pump is being deflated correctly. • Determine that the tubing is not kinked. If it is kinked, gently straighten it. • Be sure that the tubing between the pump and the cylinders is clear of debris. If there is debris in the tubing, clamp the tubing with tubing covered hemostats, remove the connector, flush the system, and reconnect the system. • Be sure that the cylinders are properly sized and are positioned without kinks. • If cylinder still won't deflate, remove them and replace. • Be sure all rubber shod hemostats are off the tubing. • Be sure the pump is being deflated correctly. The deflation button and the pump bulb might have been squeezed at the same time. Try to resolve this issue by squeezing the sides of the deflation block. Then, squeeze the deflation button for at least 5 seconds. This should allow the cylinders to deflate normally. • If cylinders still won't deflate, replace with a new pump.

Reservoirs

Problem	What to Do
Can't fill	• Be sure the reservoir adaptor is not rolled over onto the reservoir. The reservoir adaptor should follow the tubing exit path through the fascia layer. • If this does not address problem remove and replace with a new reservoir. • Make sure there is adequate space for the reservoir (i.e., not in scar tissue).
Punctured	• Remove damaged reservoir and replace.

Pump

Problem	What to Do
Pump bulb dimpled or collapsed	• Squeeze the deflation button to refill the pump bulb. Move fingers away from the deflation button. Reactivate with a firm pump bulb squeeze. Inflate normally. • If this does not resolve the problem, squeeze the sides of the deflation block to refill the pump bulb. Then, squeeze the deflation button for 2-4 seconds to reset the lock-out mechanism prior to attempting inflation. Reactivate with a firm pump bulb squeeze. Inflate normally. • Do not squeeze the deflation button and the pump bulb at the same time.
Won't inflate or deflate cylinders	• Remove the pump from the scrotum and try to inflate or deflate it outside of the body in a basin of sterile normal saline. • If pump still won't inflate or deflate, replace with new pump.

Product Line Matrix

AMS 700 With MS Pump Penile Prosthesis Product Line							
		Reservoir Recommendations			Included RTE Selection	Available preconnect	Available with InhibiZone
		Spherical reservoir		AMS Conceal Low Profile Reservoir*			
		65 ml	100 ml	100 ml			
AMS 700 CX **Inflates in girth**	12 cm	✓		✓	Rear Tip Extender package contains 2 each of: 0.5 cm, 1.0 cm, 1.5 cm (stackable), 2.0 cm, 3.0 cm, 4.0 cm, 5.0 cm, and 6.0 cm.	✓	✓
	15 cm	✓		✓		✓	✓
	18 cm	✓		✓		✓	✓
	21 cm		✓	✓		✓	✓
AMS 700 LGX **Inflates in length and girth**	12 cm	✓		✓		✓	✓
	15 cm	✓		✓		✓	✓
	18 cm		✓	✓		✓	✓
	21 cm		✓	✓		✓	✓
AMS 700 CXR **Inflates in girth**	12 cm	✓		✓		✓	✓
	14 cm	✓		✓		✓	✓
	16 cm	✓		✓		✓	✓
	18 cm	✓		✓		✓	✓

*The 100 ml AMS Conceal Low Profile Reservoir can be filled up to 100 ml to accommodate all cylinder sizes.

Appendix

InhibiZone Antibiotic Surface Treatment

AMS has a proprietary process to impregnate antibiotics into the tissue-contacting surfaces of the penile prosthesis. 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 HCl and rifampin (rifampicin). The AMS 700 components are treated with very low-levels of antibiotics. AMS provides numerous completed configurations of the AMS 700 to individualize treatment; however, a complete device (reservoir, pump and two cylinders), regardless of configuration, contains ≤33 mg rifampin and ≤12 mg minocycline HCl which represents less than 2% of oral dose exposure for a complete course of rifampin or minocycline HCl with the maximum dose calculated for the most common device configuration's average concentration plus (1) standard deviation.

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. A limited animal model study suggests that this surface treatment may reduce the potential for bacterial colonization of the treated device.

Clinical evidence of the InhibiZone (IZ) effectiveness is provided by a post marketing study, which included a comprehensive review of more than 43,000 patients in the AMS Patient Information Form (PIF) database. This study shows a significant improvement in the rate of revisions due to infection for patients with original or revision AMS 700 IZ implants (as well as patients with diabetes who received original AMS 700 IZ implants) compared to those who received AMS 700 devices without the IZ treatment.

- InhibiZone is contraindicated for patients:
  - Sensitive to rifampin (rifampicin) or tetracyclines
  - With lupus erythematosus
- InhibiZone should be carefully considered for patients:
  - With renal disease
  - Taking warfarin, thonamides, isoniazid and halothane

Note: For complete list of indications, contraindictions, warnings and precautions, refer to the Instructions for Use for the AMS 700 with MS Pump Penile Prostheses with InhibiZone and for the drugs rifampin (rifampicin) and minocycline HCl.

Parylene Coating

Parylene coating is a medical grade polymer designed to reduce wear occurrences on a variety of surface and texture materials. On the AMS 700 Product Line Penile Prostheses cylinders, an innovative micro-thin Parylene coating is applied to both sides of the internal cylinder surfaces and to the internal surface of the outer cylinder.

The coating is 60 millionths of an inch thick. This has added millions of twist cycles in laboratory bench testing before wear is detected.

Brief Summary

The AMS 700 Series Inflatable Penile Prosthesis is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence). These devices are contraindicated in patients who have active urogenital infections or active skin infections in the region of surgery or (for the AMS 700 with Inhibizone) have a known sensitivity or allergy to rifampin, minocycline HCl, or other tetracyclines. Implantation will make latent natural or spontaneous erections, as well as other interventional treatment options, impossible. Men with diabetes, spinal cord injuries or open sores may have an increased risk of infection. Failure to evaluate and treat device erosion may result in infection and loss of tissue. Implantation may result in penile shortening, curvature, or scarring. Possible adverse events include, but are not limited to, urogenital pain (usually associated with healing), urogenital edema, urogenital ecchymosis, urogenital erythema, reservoir encapsulation, patient dissatisfaction, auto-inflation, mechanical malfunction, and impaired urination.

Prior to using these devices, please review the Instructions for Use for a complete listing of

indications, contraindications, warnings, precautions and potential adverse events. Rx Only.

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