American Medical Systems

AMS Ambicor® Penile Prosthesis

Operating Room Manual

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General Information

Detailed Device Description

The AMS Ambicor® Penile Prosthesis is a closed fluid-filled system consisting of a pair of cylinders, which are implanted in the corpora cavernosa and a pump which is implanted in the scrotum. All components are connected by kink-resistant tubing. The device is delivered prefilled with normal saline and preconnected. The cylinders are inflated as fluid is pumped from the reservoirs, which are located in the proximal ends of the cylinders, into the main cylinder body, creating an erection. They are deflated as fluid is transferred back to the reservoirs, making the penis flaccid once again.

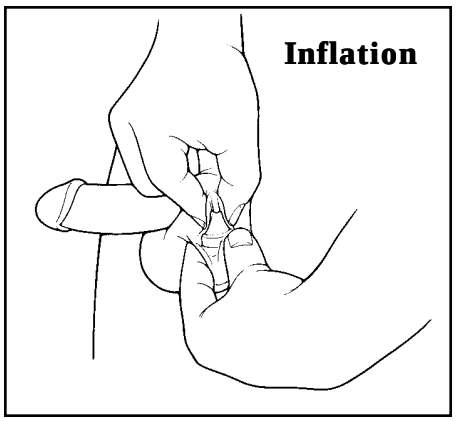
Device Characteristics

Two-piece Component

This prefilled and preconnected two-piece device eliminates the need to fill the device during surgery.

Easy to Inflate and Deflate

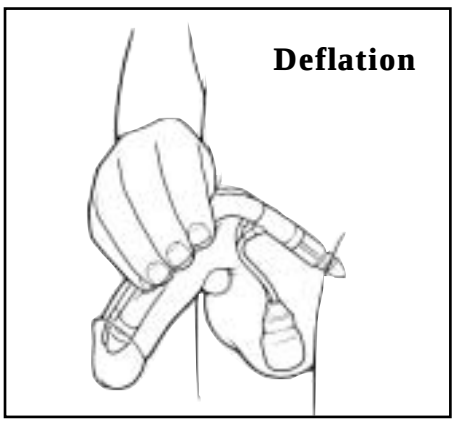
The inflation pump in the scrotum is easy for the patient to locate and requires few squeezes to inflate the device, because each squeeze displaces a large amount of fluid. To deflate the device, the patient simply bends the penis towards the scrotum, hold the position for 6-12 seconds, and releases.



Device Function

Inflation

The inflation pump is placed in the scrotum. To inflate the cylinders, the patient should stabilize the pump with one hand and use the other hand to squeeze and release the pump bulb several times to make the cylinders stiff. When the cylinders are fully inflated, the pump bulb will be hard and can no longer be compressed



Deflation

To deflate the device, the patient places the thumb of one hand under the base of the penis. Using the fingers of the same hand, he should then bend the penis down over the thumb toward the scrotum and hold the position for approximately 6-12 seconds and then release. This will open the valves which allow the fluid to flow back into the pump. If more flaccidity is desired, the shaft of the penis may be squeezed for approximately 5 seconds.

DEVICE COMPONENTS

Cylinder Sizes

The AMS Ambicor penile prosthesis is provided in the following cylinder lengths:

Sizes (diameter by length)
11mm x 14cm (measured diameter 12.5mm)
11mm x 16cm (measured diameter 12.5mm)
11mm x 18cm (measured diameter 12.5mm)
13mm x 16cm (measured diameter 14mm)
13mm x 18cm (measured diameter 14mm)
13mm x 20cm (measured diameter 14mm)
15mm x 18cm (measured diameter 15.5mm)
15mm x 20cm (measured diameter 15.5mm)
15mm x 22cm (measured diameter 15.5mm)

Each prosthesis package contains 4 sets of rear tip extenders (RTEs), one set each of 0.5cm, 1cm, 2cm and 3cm RTEs. The rear tip extenders are packaged in a protective cushion at the proximal end of the cylinders.

Each box also contains:

- 2 Keith needles
- Patient Information Form
- Patient ID Card

Packaging

The prosthesis is delivered prefilled and sterile inside a fluid filled pouch. The pouch is contained inside a sterile TyvekTM pouch, which is packaged within a dustcover box.

NOTE: For warnings, precautions and contraindications please refer to the Instruction for Use (package insert) provided in the product packaging.

STERILIZATION

Sterilization of Components

American Medical Systems presterilizes the Ambicor Penile Prosthesis. Under normal storage conditions, the devices will remain sterile until the expiration date provided the sterile barriers of the packaging remain intact.
To protect the integrity of the packaging and the function of the prosthesis, store the presterilized devices on a protected shelf or in a cabinet. The environment should be clean, dry, and near room temperature. For maximum protection during storage, leave the component trays within their dustcover boxes. Inspect the packaging for damage before use.

CAUTION: Do not resterilize the AMS Ambicor® Penile Prosthesis.

Sterilization of AMS Tools

American Medical Systems does not sterilize the AMS Closing Tool, or Furlow Insertion Tool prior to shipping. These instruments are shipped in steam sterilization packages ready for hospital sterilization. For sterilization information see instructions provided with tools.

OPERATING ROOM INSTRUCTIONS

CAUTION: This device is to be used only by physicians who have received appropriate training regarding the use of inflatable penile prostheses. This Manual is not intended to be a complete reference.

Preoperative Set-up Materials

The hospital should provide those instruments normally required for a surgical urological procedure. In addition to the AMS Ambicor penile prosthesis, you will need the following sterile setup:

- 2 Keith needles
- Furlow Insertion Tool or Dilamezinsert
- Hegar dilators (7mm-16mm) or urethral sounds (21Fr-42Fr)
- Patient information form
- 1 plastic draped Mayo stand or a stainless steel tray
- 1 kidney basin of sterile normal saline
- antibiotic solution for irrigation (optional)
- AMS Closing Tool (optional)

Patient Preparation

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

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

The patient should be positioned so that a penoscrotal incision can be made.

Unpacking the Device

NOTE: The adhesive label at one end of the dustcover box and the small, pealable labels on the side of the plastic trays show the part and serial/lot numbers and the size of the components. This information is also listed on the Tyvek lid of the outer tray, and on the Tyvek pouches. Record this information on the Patient Information Form (PIF).

Keep the sterile trays or pouches in the dustcover boxes until the components are in the operating room. Remove the trays from the dustcover boxes in the operating room by opening the unlabeled end of each dustcover box.

To Open an Ambicor

NOTE: Do not unpackage the prosthesis until after the surgeon dilates and measures both corpora cavernosa intraoperatively.

1. Remove the fluid-filled foil pouch from the Tyvek pouch.

CAUTION: To avoid the possibility of cutting the silicone tubing, do not cut pack open with scissors.

2. Place the sterile, fluid-filled foil pouch onto a sterile, lint free Mayo stand.

CAUTION: Cloth towels placed on Mayo stand may transfer lint to the AMS components.

3. Hold the foil pouch over a kidney basin containing sterile normal saline. Carefully tear the foil pouch at the side notch. Empty the device and the fluid into the kidney basin. There should be enough fluid from the pouch and additional sterile normal saline to cover the components in the kidney basin.

NOTE: Do NOT leave the prosthesis exposed to air. Submerge the prosthesis in the fluid from the foil pouch or in sterile normal saline immediately after removing it from package. Keep the prosthesis submerged until implantation in order to prevent air from entering the device.

4. Remove the rear tip extenders from the protective end cushion.

5. Discard the end cushion.

Note: Do not discard the protective end cushion until all rear tip extenders have been removed.

6. Leave device in the basin until ready to implant.

Intraoperative Procedures

Surgical Procedures

Assemble the necessary equipment and position the patient for a penoscrotal surgical approach. The penoscrotal approach leaves the incision well hidden and provides convenient access to the corpora cavernosa.

Establish the sterile field, drape and prepare the patient according to the physician's instruction. Throughout the procedure the surgical site may be flushed with copious amounts of broad-spectrum antibiotic.

The following description is an overview of the penoscrotal surgical approach.

Penoscrotal Approach

1. To begin, place a Foley catheter to facilitate identification of the urethra.

2. Some physicians place a retractor around the penis and place the penis on "stretch". It is important to have the IV tubing on the retractor. This elevates the base of the penis and allows exposure of the corpora.

3. Make a 2cm to 3cm incision through the median raphe of the scrotum at the penoscrotal angle. Some physicians may prefer a high scrotal incision for better proximal corporal access. Then laterally retract the corpus spongiosum to avoid damaging the urethra.

4. Dissect through to Buck's fascia to expose the tunica albuginea. Place stay sutures to use as a reference point when measuring the corpora. Then make an incision into one of the corpora cavernosa.

5. Dilate the proximal corpus (crus) and the distal corpus to create a space for inserting a penile cylinder. Dilate the corpus cavernosum to 7-13mm. After dilating one corpus cavernosum, incise and dilate the adjacent corpus cavernosum following the same procedure.

6. To select the cylinders and rear tip extenders that will fit the patient's anatomy, measure each corpus proximally and distally using the Furlow Insertion Tool or the Dilamezinsert. (See page 2 for choosing cylinder size.) As a general rule, the corporotomy is best placed when two thirds of the total corporal measurement is distal to the incision and one third is proximal. This facilitates the placement of the cylinders, and may avoid the need to extend the corporotomy during the procedure.

7. Select the appropriate size cylinders, apply rear tip extenders (if necessary) and use the insertion tool to introduce the cylinders into the corpora cavernosa, as follows:

   a. When inserting the cylinder distally, use the Furlow Insertion Tool to put the penis on mild stretch. The tool should be palpable beneath the glans.

   b. First thread the pulling suture at the front of the cylinder through a Keith needle, then place the Keith needle in the insertion tool.

   c. Insert the insertion tool distally into the corpora cavernosa and pass the needle through the glans.

   d. Inflate the cylinders fully, then insert the proximal end of the cylinder.

   e. Deflate the cylinder by bending the device and holding it for 6-12 seconds.

   f. Position the distal end of the cylinder by pulling the front of the suture.

   During insertion, be sure that the Furlow Insertion Tool is in the ipsilateral corpora at the distal penis. Because the intracavernosal septum may be inconsistent distally, it is easy to cross over to the contralateral side. If you think you may have crossed over, place a dilator into the other side. If the cylinder does cross over, no repair is necessary. Simply remove the cylinder and place it correctly.

NOTE: The corporal incision may need to be extended to ensure the input tube exits directly from the corporotomy.

Once both cylinders are implanted close the tunica albuginea. Place the AMS Closing Tool (or other suitable instruments) over the cylinder to protect it from

inadvertant needle injury, so that the corporal body can be closed. This should be done with meticulous attention to hemostasis.

8. Use blunt dissection to form a pocket in the most lateral and dependent portion of the scrotum.

9. Insert the pump into the scrotal pocket. The tubing between the pump and cylinders should not be palpable to the patient.

10. After both the cylinders and pump are implanted, check the function of the prosthesis by inflating and deflating the device.

11. Some physicians close the dartos in two layers with running 2-0 chromic catgut suture. Close the skin.

12. Apply a wound dressing. Leave the device partially inflated and tape penis to abdomen overnight. In addition, a drain may be placed for 12 to 24 hours.

For postoperative instructions see the section entitle Postoperative Procedures.

Sizing

Below is the recommended method of selecting cylinder sizes for the AMS Ambicor penile prostheses.

Method

This method allows the tubing to exit directly from the corporotomy. 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.

1. Calculate the Total Corporal Length (distal + Proximal)
   Example

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

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

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

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

Adjusted Measurement	17cm
Selected Cylinder Length	16cm

4. 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	19cm
Selected Cylinder Length	-16cm
Rear Tip Extender Length	3cm

Inflate/Deflate Test

After all components implanted, inflate the device to check the quality of the erection and deflate to evaluate flaccidity. The penis should lie down close to the body when deflated. There may be some swelling that precludes a good flaccid result.

POSTOPERATIVE PROCEDURES

Immediately Postoperative

After the surgery, some physicians partially inflate the cylinders for the first 24 hours. This will aid hemostatis. 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 and completely deflate the cylinders. 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-fours 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 the physician. Some physicians have their patients position the pump daily.

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

1. Locate the pump in the scrotum.

2. 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.

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:

1. 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.

2. Ask the patient about pain when cycling the device and observe the patient inflating and deflating the device.

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.

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.

Procedure Illustrations

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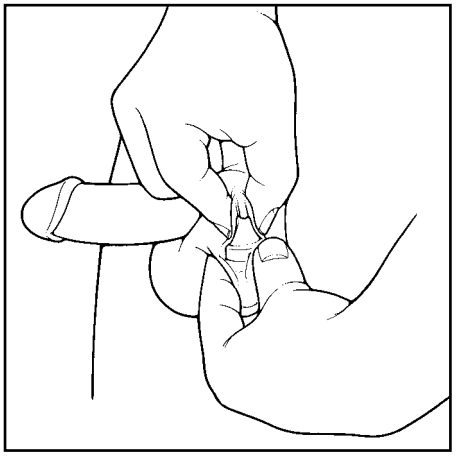

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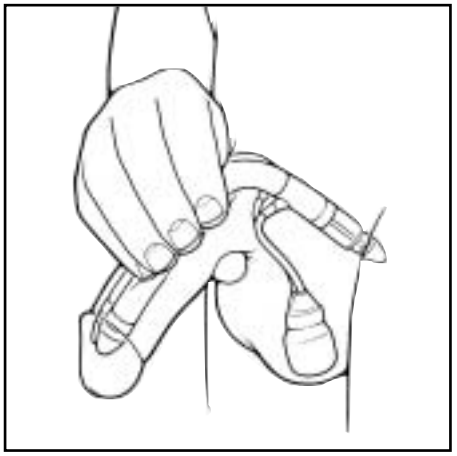

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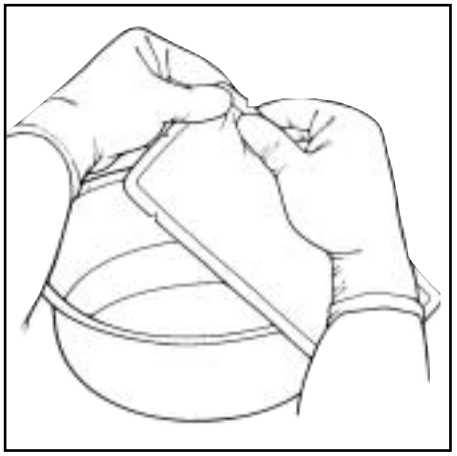

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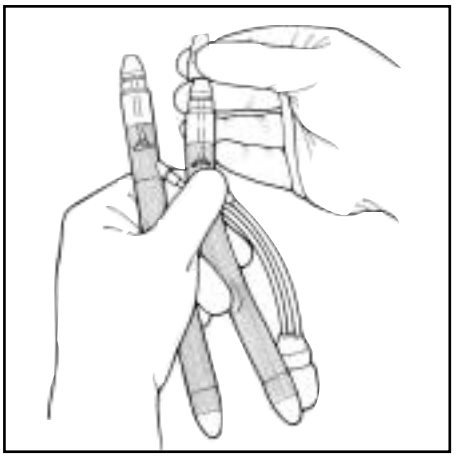

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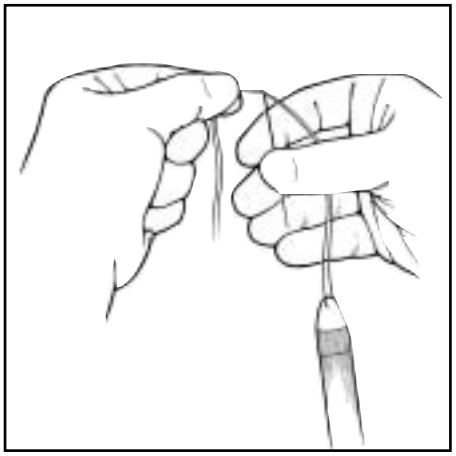

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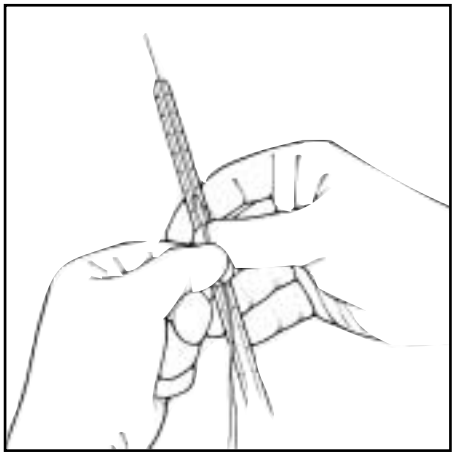

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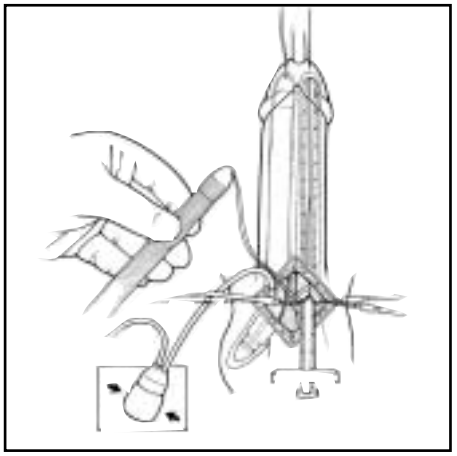

PROCEDURE ILLUSTRATIONS (CONTINUED)

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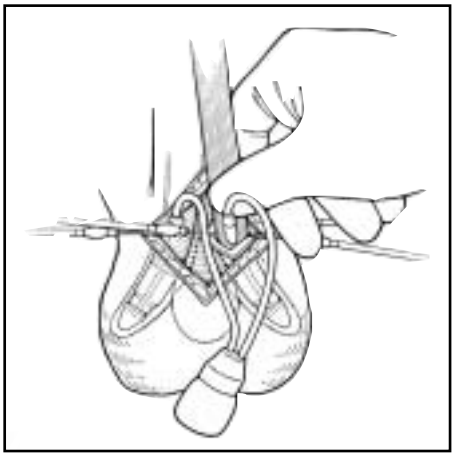

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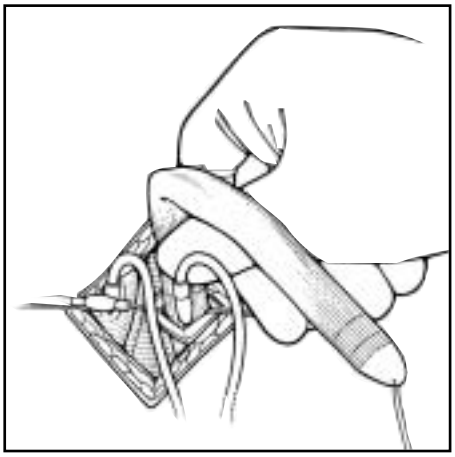

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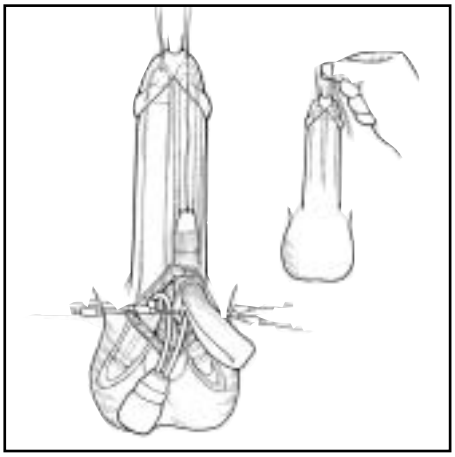

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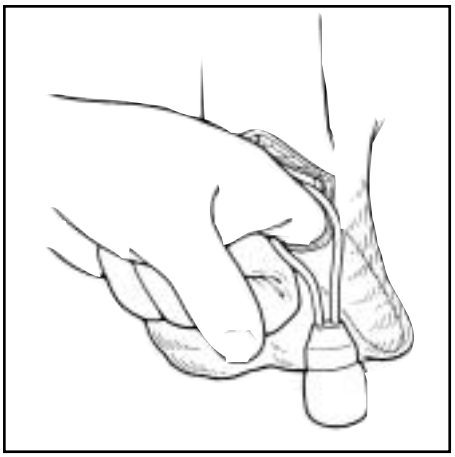

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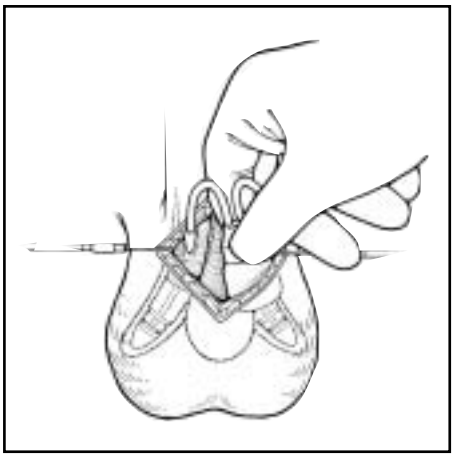

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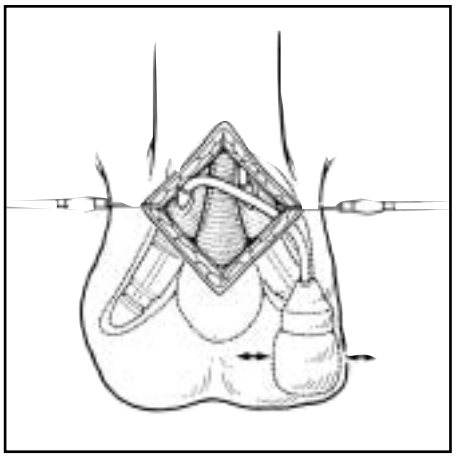

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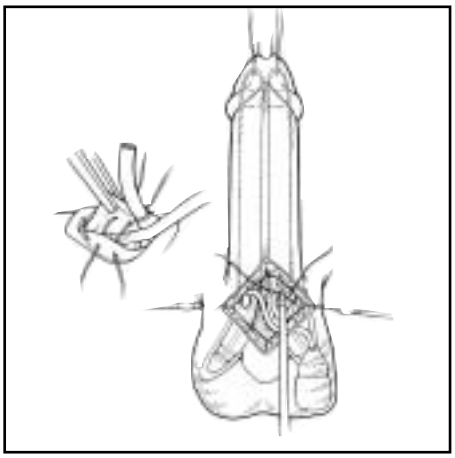

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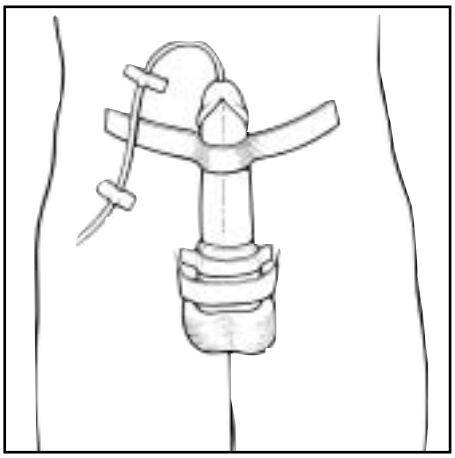

Solutions for Life™ American Medical Systems is a world leader in medical devices and procedures that treat: incontinence, excessive menstrual bleeding, erectile dysfunction (ED) and benign prostate hyperplasia (BPH). Any one of these conditions can profoundly diminish a patient's quality of life and significantly impact relationships. Our products provide a cure or reduce the incapacitating effects of these diseases, often through minimally invasive surgery.

American Medical Systems

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