



Preparing AMS 700™ Penile Prosthesis with MS (Momentary Squeeze) Pump preconnected pump and cylinders

PREPARING AMS 700™ PENILE PROSTHESIS WITH MS (MOMENTARY SQUEEZE) PUMP PRECONNECTED PUMP AND CYLINDERS:

The American Medical Systems, Inc. 700 Series cylinders and pump are pre-connected.

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

REMOVING AIR FROM THE SYSTEM

CAUTION: Do not inject fluid into the black color-coded tubing (reservoir line) using a syringe as this will damage the pump.

1. Partially fill a graduate with sterile, normal saline.
2. Submerge the single, black color-coded tubing from the pump into the sterile saline being careful not to introduce debris into the saline that could plug the pump valves.

3. Hold the pump so the pump bulb is on the bottom. You will continue to hold it upright in this position throughout the prepping procedure.

NOTE: Keep the black tubing submerged when performing steps 4-9

4. Squeeze and release the deflation button one time.
5. Make an initial Hard, Quick squeeze of the pump bulb. Saline should appear in the pump bulb. DO NOT squeeze the deflation button and pump bulb at the same time. (See Fig. 1)

NOTE: This sequence may be required more than once to get the pump activated.

NOTE: If saline does not appear in the pump bulb or if the bulb does not fully re-inflate, press the deflation button 1 time and release. This will reset the pump. Repeat step 5.

6. Following the initial squeeze, continue to squeeze and release the pump bulb until the cylinders are rounded and the pump is more difficult to squeeze. Let the pump bulb completely refill between each pump.
7. Press the deflation button and hold for 2-4 seconds to allow air to be expelled from components. Gently squeeze both cylinders flat to remove remaining air and saline. (See Fig. 2)
8. Repeat steps 6 and 7 until all air is removed from the system.

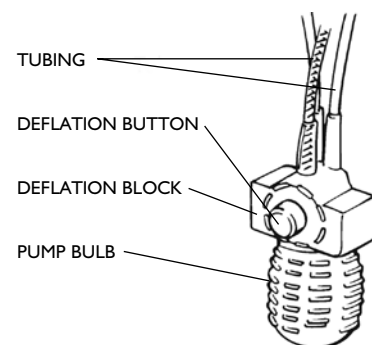


Fig. 1



Fig. 2

Note: it is important to hold the cylinders so the rear tips are pointed up while squeezing the deflation button.

See back for additional information.



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CLAMP AND PREPARE FOR IMPLANTATION

9. With the black color-coded tubing still in the saline, using a blue shod mosquito hemostat, clamp (one notch only) the black tubing one inch from the open end.

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

10. For components treated with InhibiZone™ Antibiotic Surface Treatment place the prepared 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 non-InhibiZone treated components, submerge the prepared cylinders and pump into a kidney basin of sterile, normal saline or antibiotic solution until the surgeon is ready to implant the cylinders.*

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, 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.