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AMS 700™

Inflatable Penile Prosthesis with MS (Momentary Squeeze) Pump™

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

Please consult the AMS 700 Penile Prosthesis with MS Pump Operating Room Manual for complete instructions prior to the initiation of a case. Once the surgeon has determined the proximal and distal lengths of the corpora cavernosa, choose the appropriate preconnect cylinder and pump from inventory.

Remove air from the system

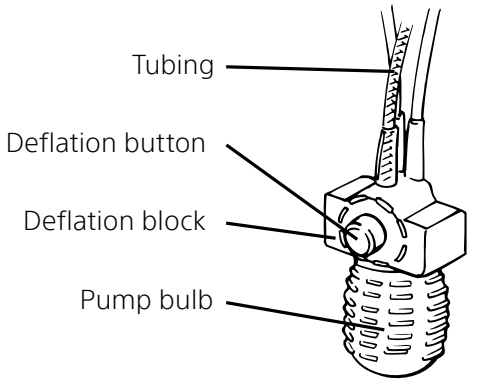
CAUTION: Do not inject fluid into the black colour-coded tubing (reservoir line) using a syringe as this will damage the pump.

1. Partially fill a graduate with sterile, normal saline.
2. Submerge the single, black colour-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 deflate mechanism (button and block) is on top and the pump bulb is on the bottom. 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, FAST 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 Figure 1)

   NOTE: 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 more difficult to squeeze. Let the pump bulb completely refill between each pump.

   CAUTION: Do not inject fluid into the black colour-coded tubing (reservoir line) using a syringe as this will damage the 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 Figure 2)
8. Repeat steps 6 and 7 until all air is removed from the system and no bubbles are noted in the graduate during deflation.



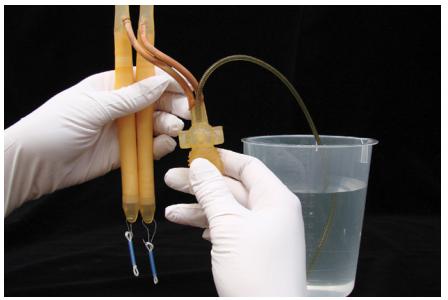


Figure 1

Clamp and prepare for implantation

9. With the black colour-coded tubing still in the saline, using a blue shod mosquito hemostat, clamp (one notch only) the black tubing 1 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 empty cylinders and filled 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 Treatment components, submerge the prepared 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.

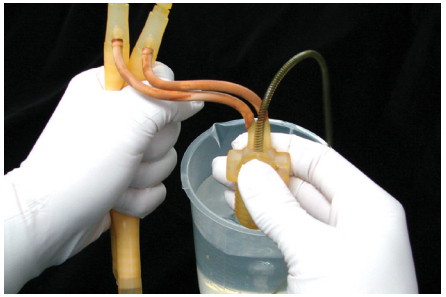


Figure 2

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

CAUTION: The law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings, and instructions for use can be found in the product labelling supplied with each device or at www.IFU-BSCI.com. Products shown for INFORMATION purposes only and may not be approved or for sale in certain countries. This material not intended for use in France.

Prior to use, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events.

Indications for Use: The AMS 700™ Inflatable Penile Prosthesis product line is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence).

Contraindications: The AMS 700 Inflatable Penile Prostheses are contraindicated in the patients that have active urogenital infections or active skin infections in the region of surgery or (for the AMS 700 prosthesis with InhibiZone™ Antibiotic Surface Treatment) have a known sensitivity or allergy to rifampin, minocycline HCl or other tetracyclines, or patients with lupus erythematosus because minocycline HCl has been reported to aggravate this condition.

Warnings: Implantation of the device 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 associated with the implantation of a prosthesis. Failure to evaluate and promptly treat erosion may result in a substantial worsening of the condition leading to infection and loss of tissue. Implantation may result in penile curvature, or scarring. Pre-existing abdominal or penile scarring or contracture may make surgical implantation more complicated or impractical. If a hypersensitivity reaction develops to a device treated with InhibiZone, the penile prosthesis should be removed and the patient treated appropriately.

Precautions: Migration of the device components can occur if the cylinders are improperly sized, if the pump or the reservoir is not positioned properly, or if the tubing lengths are incorrect.

Potential Adverse Events: May include device malfunction/failure leading to additional surgery, device migration potentially leading to exposure through the tissue, device/tissue erosion, infection, unintended-inflation of the device and pain/soreness.

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