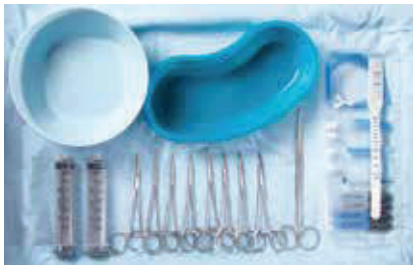
AMS 800™
Urinary Control System

Preparation Guide
AMS 800™ Urinary Control System[1]

Instrument and Supply Requirements

The following conventional sterile surgical tools and supplies are needed, at a minimum, to prepare the AMS 800™ Urinary Control System for implantation.



- Plastic-draped Mayo stand or stainless steel tray
- Approximately 1 liter of filling solution
  (AMS recommends using sterile normal saline. See the AMS 800 Urinary Control System Operating Room Manual for a complete list of approved filling solutions.)
- 15-gauge blunt tip needle
  (included in the AMS 800 Urinary Control System Accessory Kit)
- 30 cm length of blue tubing
  (included in the AMS 800 Urinary Control System Accessory Kit)
- Powder-free surgical gloves
- Kidney basin
- Sponge bowl
- 30 cc disposable syringe
- Five mosquito hemostats

CAUTION: **Do not use powdered gloves to handle the devices. Powder from the gloves could deposit inside the tubing and cause possible blockage to system fluid flow. Be certain that the components do not come into contact with paper or cloth drapes as fragments from these materials can cause obstruction of fluid flow if they enter the device.**

Prepare Hemostats

1. Completely cover all teeth of the eight hemostats by sliding the blue tubing *(included in the AMS 800 Urinary Control System Accessory Kit)* over both hemostat jaws.
2. Trim tubing at jaw tip with sharp, virgin scissors.
3. Reserve scissors for use as tubing scissors throughout procedure.

1. AMS 800™ Urinary Control System Operating Room Manual.

Preparing the AMS 800™ Urinary Control System Components

The following steps outline the procedures for preparing the AMS 800 Urinary Control System components to ensure that they are free of excess air and properly stored until needed for implantation.

Fig. A

Fig. B

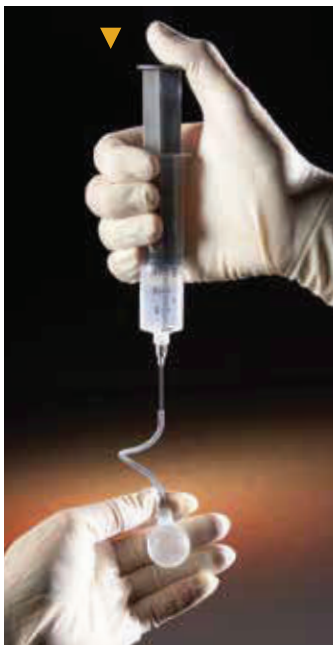


Fig. C

Prepare the Control Pump

1. Submerge the ends of the pump tubing in the sponge bowl filled with filling solution.

   Note: *It is important to keep tubing submerged during filling procedure.*

2. Hold the pump at a 45 degree angle with the black tube on top.

3. Squeeze and release the pump bulb repeatedly until all air in the pump and tubing has been displaced with fluid. **(Fig. A)**

   Note: *Continue to squeeze and release the pump bulb until all air is removed from the system. If air bubbles remain in the pump bulb, continue to squeeze and release the pump bulb to remove them; they will be evacuated through the black color-coded tubing.*

4. While keeping the ends of the pump tubing submerged, use the tubing-shod hemostats to clamp (one notch only) each tube approximately 4 cm - 5 cm from the end. **(Fig. B)**

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

5. Pump preparation is now complete. Store the prepared pump in the following manner until needed for implantation:

   - Non-InhibiZone™ Treated Pumps – Submerge the pump in the sponge bowl with filling solution.
   - InhibiZone Treated Pumps – Place the pump in a dry sterile storage container such as a kidney basin or on an empty sterile tray and cover with a drape.

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

Prepare the Pressure-Regulating Balloon (PRB)

1. Attach a 15-gauge blunt tip needle to a 30 cc syringe.

2. Fill the syringe with 25 cc of filling solution.

3. Squeeze the balloon portion of the PRB to remove the excess air.

4. Insert the 15-gauge needle into the end of the PRB tubing.

5. Aspirate any air left in the PRB until you feel resistance on the syringe plunger.

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


Fig. D


Fig. E

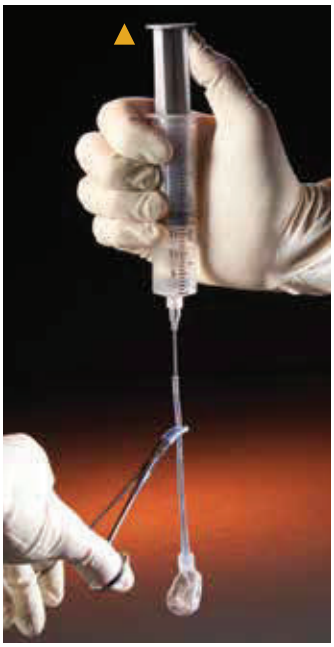


Fig. F

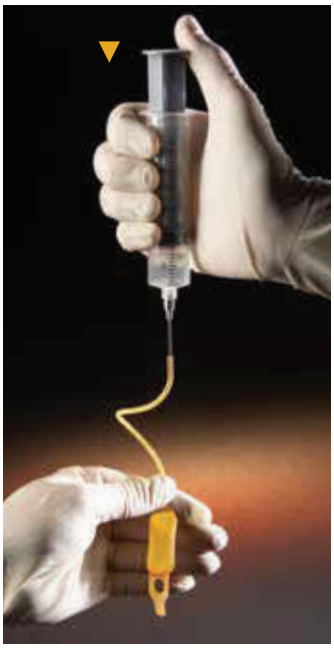


Fig. G

6. Fill the PRB with 20 cc of filling solution. **(Fig. C)**
7. Rotate the balloon portion of the PRB until all air bubbles are gathered into one large bubble. **(Fig. D)**
8. Hold the PRB by the tubing to draw the air bubble into the tubing adapter area.
9. Aspirate the remaining air first, and then all fluid so the PRB is completely void of fluid and air. **(Fig. E)** Check that no air remains in the PRB or tubing.

   CAUTION: **Do not over-aspirate the PRB because air can be drawn into the system through the semi-permeable silicone membrane.**
10. While maintaining upright pressure on the syringe plunger, clamp the PRB tubing (one notch only) with tubing-shod hemostat approximately 3 cm below the needle. **(Fig. F)**

    CAUTION: **Do not advance the hemostat's ratchet more than one notch as excessive pressure will permanently damage the PRB tubing.**
11. PRB preparation is now complete. Store the prepared PRB in the following manner until needed for implantation:
    - Non-InhibiZone Treated PBR – Submerge the PRB in the sponge bowl filled with filling solution.

    Note: *The PRB is only available in non-InhibiZone treated configurations.*

    CAUTION: **Do not place any hemostats on top of the PRB as this can result in damage to the PRB.**

Prepare the Occlusive Cuff

1. Attach a 15-gauge blunt tip needle to 30 cc syringe.
2. Fill the syringe with 10 cc of filling solution.
3. Squeeze the cuff to remove the excess air.
4. Insert the 15-gauge blunt needle into the end of the cuff tubing.
5. Aspirate any air left in the cuff until you feel resistance on the syringe plunger.

   Note: *Always hold syringe upright, that is, needle pointing down, plunger pointing up.*
6. Fill the cuff with 1 cc to 5 cc of filling solution, depending on cuff size. **(Fig. G)**

   Note: *The amount of fluid that is needed to fill cuff will vary depending on cuff size; larger cuffs require more fluid than smaller cuffs.*

   CAUTION: **Do not over fill the cuff as excessive fluid can stretch the cuff material.**

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Fig. H

Fig. I

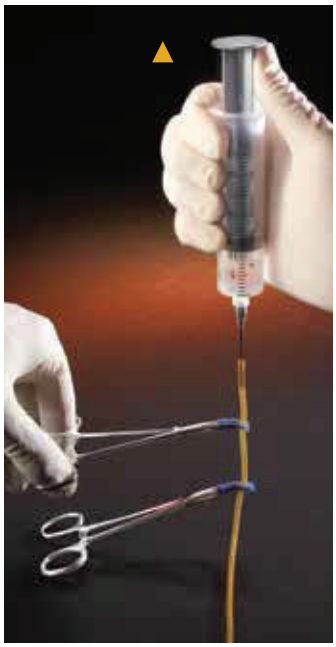

Fig. J

Prepare the Occlusive Cuff *continued*

7. Rotate the cuff until all air bubbles are gathered into one large bubble. **(Fig. H)**

8. Roll end of the cuff with your thumb to force the large air bubble into the tubing adapter. **(Fig. I)**

9. While squeezing the cuff, aspirate the remaining air first and then all the fluid so the cuff is completely empty.

10. While maintaining upright pressure on the syringe plunger, clamp the cuff tubing (one notch only) with two tubing-shod mosquito hemostats approximately 3 cm below the needle and again approximately 3 cm below the first hemostat. **(Fig. J)**

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

11. Cuff preparation is now complete. Store the prepared cuff in the following manner until needed for implantation:

- Non-InhibiZone™ Treated Cuffs – Submerge the cuff in the sponge bowl filled with filling solution.
- InhibiZone Treated Cuffs – Place the cuff in a dry sterile storage container such as a kidney basin or on an empty sterile tray and cover with a sterile drape.

CAUTION: **Soaking InhibiZone-impregnated devices in filling solution 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 additional information, please consult the AMS 800 Urinary Control System Operating Room Manual, which can be found at www.amselabeling.com.

AMS 800™ Urinary Control System Brief Summary

The AMS 800™ Urinary Control System (or Artificial Urinary Sphincter) is intended to treat urinary incontinence due to reduced outlet resistance (Intrinsic Sphincter Deficiency) following prostate surgery. The device is contraindicated in patients who are determined to be poor surgical candidates, have an irreversibly blocked lower urinary tract, have irresolvable detrusor hyperreflexia or bladder instability, or (for the AMS 800 with InhibiZone™ have a known sensitivity or allergy to rifampin, minocycline or other tetracyclines). Patients with urinary tract infections, diabetes, spinal cord injuries, open sores or regional skin infections may have increased infection risk. Device-tissue erosion may occur. Proper patient evaluation, selection and counseling of realistic expectations should occur. Possible adverse events include, but are not limited to, compromised device function, pain/discomfort, delayed wound healing, migration and recurrent incontinence. Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events.

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