DAILY USE:
While the cuff is closed, urine stays inside the bladder. To urinate, open the cuff as follows: Feel for the control pump in your scrotum. Stabilize the control pump in the proper place by grasping the tubing above the control pump.
Use the other hand to squeeze and release the lower, softer part of the pump several times. Repeat this step until the pump is flat. Once flat, this indicates that the cuff is deflated. The urethra is now open and you can urinate.

**MR Conditional: 3.0 Tesla**
DEACTIVATING:
Squeeze and release the lower part of the control pump several times to empty the cuff. (The cuff is empty when the pump remains flat). Then, allow the pump bulb to partially refill for about 30-60 seconds. After allowing the pump bulb to partially refill, firmly press the deactivation button found at the top of the pump.
When the device is deactivated, a slight indentation will be felt at the center of the soft part of the pump.

**MR Conditional: 3.0 Tesla**
ACTIVATING:
Begin by stabilizing the control pump in the proper place by grasping the tubing above the control pump. Use your other hand to firmly squeeze the sides of the upper, hard part of the pump for several minutes.
Continue stabilizing the control pump by holding the tubing. Give the lower part of the pump a hard, forceful squeeze. This step may need to be repeated if you’re not successful the first time. The system should now function normally.

MR Conditional: 3.0 Tesla

Rx Only

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The AMS 800™ Urinary Control System is intended for use in the treatment of male urinary incontinence. This device is not for patients who are determined by their doctor to be poor surgical candidates, have permanent blockage of the lower urinary tract or who have uncontrollable contraction of the bladder. Some AMS 800™ Urinary Control devices may contain an antibiotic (InhibiZone™).

The AMS 800™ Urinary Control System consists of three main components: an occlusive cuff, a control pump, and a pressure-regulating balloon (Figure 1). These are connected by tubing and are filled with a sterile solution. The cuff works much like a normal sphincter, gently squeezing the urethra (urinary canal) closed to keep urine in the bladder.

The device may not be suited for patients who are allergic to the antibiotics contained within the device (rifampin, minocycline or other tetracycline’s). Patients with urinary tract infections, diabetes, spinal cord injuries, or skin infections may have an increased risk of infection.
Using the AMS 800™
Urinary Control System

While cuff is closed, urine stays inside of the bladder.

To urinate, the cuff is opened as follows:

1. Feel for the control pump in your scrotum (Figure 2).

2. Stabilize the control pump in the proper place by gently grasping the tubing above the control pump (Figure 3).
3. Use the other hand to squeeze and release the lower, softer part of the control pump (*Figure 4*). Do this several times until the control pump is flat.

![Figure 4](image)

4. When the lower part of the control pump is flat, it indicates that the fluid that filled the cuff has moved to the pressure-regulating balloon (PRB), deflating the cuff (*Figure 5*). The urethra opens and you can urinate.

![Figure 5](image)
That is the all the manipulation required to urinate. The fluid automatically returns from the PRB to refill the cuff. Once full, the cuff again squeezes the urethra closed. It usually takes several minutes for the cuff to be filled by the fluid (urethra to be re-closed), but each person is different. After using your AMS 800™ Urinary Control System a few times, you will know how long it takes for your cuff to refill.

If you feel that you did not empty your bladder completely before the cuff refilled, give the soft part of the control pump a few more squeezes to re-open the urethra.

It is a good idea to get into the habit of emptying your bladder on a regular basis, such as every two to three hours.

**It is important to let someone else, such as your spouse, know how to operate the AMS 800™ Urinary Control System to assist you if needed.**
Deactivating the AMS 800™ Urinary Control System

The AMS 800™ Urinary Control System has a deactivation button which stops the flow of the fluid from one component to another. Your doctor may deactivate your device at various times, such as while you are healing following your surgery or before inserting a catheter or other instrument into your urethra.

Special precautions to take with your AMS 800™ Urinary Control System before undergoing a medical procedure

It is important for healthcare providers to know that you have an AMS 800™ Urinary Control System before you undergo any medical procedure. This is especially true of any procedures which require the insertion of a catheter or any other instrument into the urethra. Such procedures can only be safely performed after your AMS 800™ Urinary Control System has been deactivated (see the following section for deactivation instructions). Failure to deactivate the AMS 800™ Urinary Control System before inserting a catheter or other instrument into the urethra can result in damage to the device and/or your urethra. It is possible that such damage could require removal of the device.
To deactivate the AMS 800™ Urinary Control System:

1. Squeeze and release the lower part of the control pump several times, just as you would do to urinate.

2. After completely emptying the cuff (the cuff is empty when the pump remains flat), allow the pump bulb to partially refill (about 30-60 seconds). When the control pump is partially refilled, firmly press the deactivation button on the top of the control pump. After pressing the deactivation button, you will still feel the button on the upper part of the pump. Pressing the deactivation button locks out the flow of fluid through the control pump. When the device is properly deactivated, a slight indentation will be felt at the center of the soft part of the pump. The cuff will now remain open (Figure 6).

When the AMS 800™ Urinary Control System is deactivated, the cuff around your urethra will not stop the flow of urine. You should use pads while the AMS 800™ Urinary Control System is deactivated.

What happens if the deactivation button is squeezed accidentally? The device will deactivate and two problems could occur.
Fluid may not refill the cuff, so you will keep leaking urine, or fluid may lock in the cuff so you cannot urinate. If either problem occurs, you will notice that the pump feels different from its normal status. You can activate the device to solve these problems.

Activating the AMS 800™ Urinary Control System

It is important that the AMS 800™ Urinary Control System remain open while you are healing following your surgery. Closely follow your doctor’s instructions about the amount of time before activating the device.

To activate the AMS 800™ Urinary Control System:

1. Use one hand to grasp the tubing above the control pump to hold the control pump in an appropriate place (Figure 7).

2. Use the other hand to squeeze the sides of the upper, hard part of the control pump, on the side opposite the deactivation button. Be sure to use steady, firm pressure for several minutes. This will cause the lower part of the control pump to become hard and filled with fluid.

Figure 7
3. Continue stabilizing the control pump by holding the tubing (DO NOT STABILIZE THE PUMP BY HOLDING THE UPPER, HARDER PART OF THE PUMP DURING THIS STEP. DOING SO WILL MAKE PROPER ACTIVATION EXTREMELY DIFFICULT). Give the lower part of the pump a quick, forceful squeeze (Figure 8). This step may need to be repeated if you’re not successful the first time. Because greater pressure is required for activation than for normal operation, you may experience some discomfort while activating the device.

The system should now function normally.

Figure 8
When should I contact my doctor?

Contact your doctor if you notice any of the following:

- Fever
- Swelling near the incision
- Redness near the incision
- Any other signs of infection
- If the surgical area does not heal
- Prolonged pain or discomfort
- If the device can be seen or felt outside of the skin
- Return of leakage
- If the device is not working correctly
Where can I get more information about the AMS 800™ Urinary Control System?
Your doctor is the best source for getting more information on the AMS 800™ Urinary Control System. Your doctor is most familiar with your medical situation and can work with you to make sure you get the best possible results from the AMS 800™ Urinary Control System. Contact your doctor if you have questions or would like to receive additional information.

You can also call the AMS patient liaison at 1-800-328-3881, extension 6261, or visit our website at www.AmericanMedicalSystems.com.