

# How to Use Your Implant



**Caution:** U.S. Federal law restricts this device to sale by or on the order of a physician.

Your doctor is your best source for information on the risks and benefits of the AMS 800™ Urinary Control System. Talk to your doctor for a complete listing of risks, warnings and important safety information.

The AMS 800 Urinary Control System is intended for use in the treatment of male stress urinary incontinence (intrinsic sphincter deficiency) following prostate surgery.

Men with diabetes, spinal cord injuries or skin infections may have an increased risk of infection. Some AMS 800 devices contain an antibiotic (InhibiZone™ Antibiotic Surface Treatment). The device may not be suited for patients who are allergic to the antibiotics contained within the device (rifampin, minocycline or other tetracyclines) or have systemic lupus.

Potential risks may include: device malfunction/failure leading to additional surgery, wearing away/loss of tissue (device/tissue erosion), inability to urinate (urinary retention), infection, and pain/soreness. MH-545611-AA

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MH-554040-AA JUN 2018

**AMS 800™ URINARY CONTROL SYSTEM**

# The AMS 800™ Urinary Control System

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.

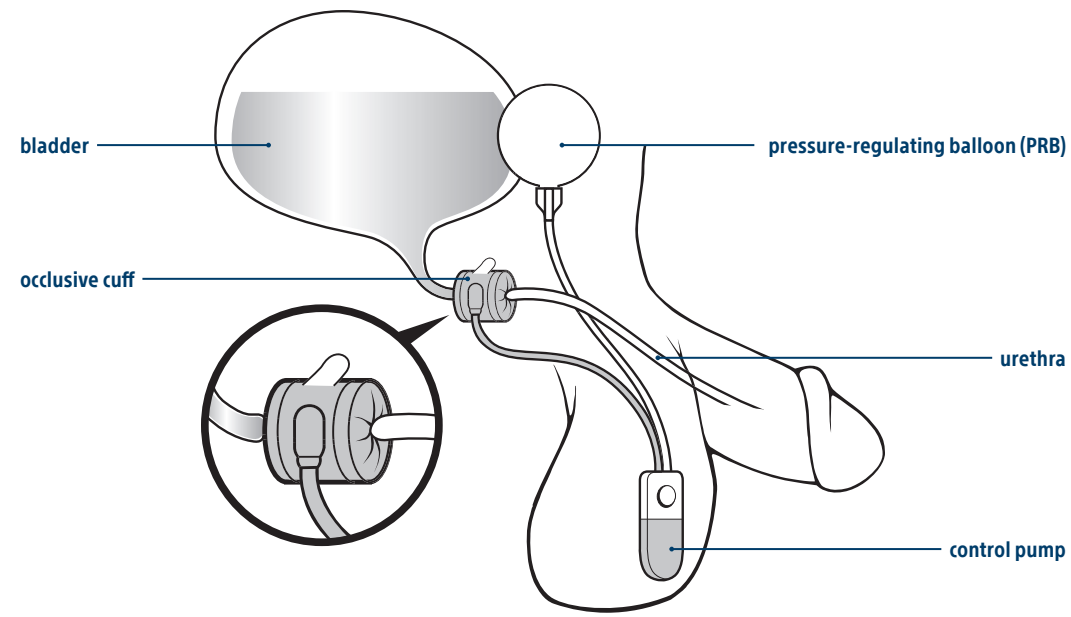


Figure 1

## Using (activating) 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 (soft part) is flat.
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.
5. The fluid automatically returns from the PRB to refill the cuff. Once full, the cuff again squeezes the urethra closed. 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.

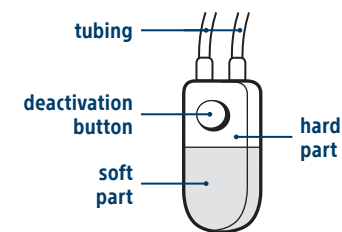


Figure 2

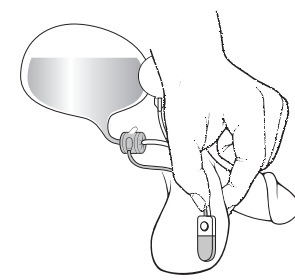


Figure 3

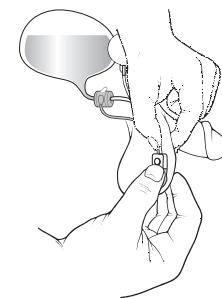


Figure 4

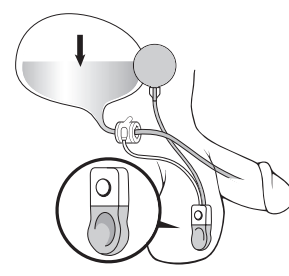


Figure 5

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

**To deactivate 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.

1. Squeeze and release the soft 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 control pump 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).
3. 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.

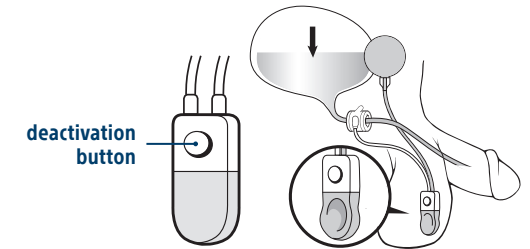


Figure 6

**What happens if the deactivation button is squeezed accidentally? The device will deactivate and two problems could occur.**

1. 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.
2. You can activate the device to solve these problems by following the same steps for using/activating the device (above).

## 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 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.

## 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 Boston Scientific patient liaison at 1-800-328-3881, option 2, or visit our website at [www.bostonscientific.com](http://www.bostonscientific.com).

## Order Your AMS 800 Urinary Control System Medical I.D. Bracelet

At no charge to you, at your request Boston Scientific will ship you a medical I.D. bracelet that can be worn to alert any medical professional treating you to consult a urologist before urethra catheterization. Request online at [www.AUSmedicalID.com](http://www.AUSmedicalID.com), or by phone at 844.433.2873. Two styles to choose from.



Silicone band



Metal band