

AMS 800[®]

Urinary Control System

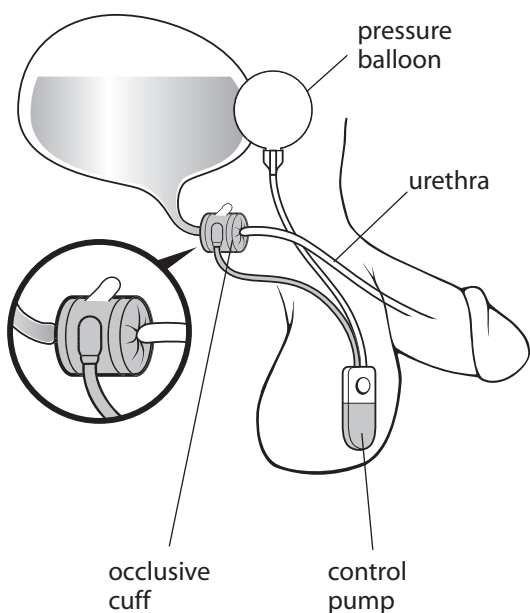
User's Guide

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The AMS 800 Urinary Control System

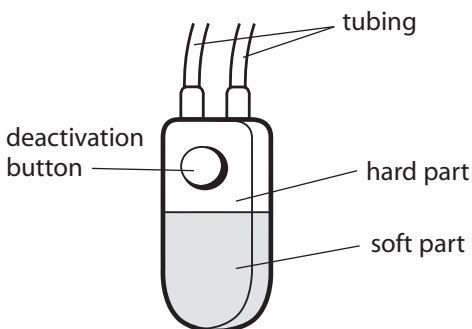
The 800 consists of three main components: urethral cuff, pressure balloon and control pump. These are connected by tubing and are filled with a sterile solution. The cuff works much like a natural, healthy sphincter, gently squeezing the urethra (urinary canal) closed to keep urine in the bladder.



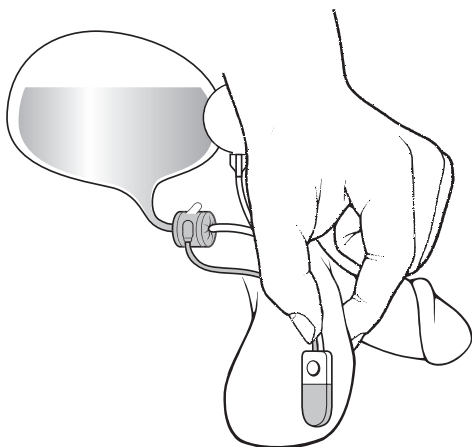
Using the AMS 800 Urinary Control System

To urinate, the cuff is opened as follows:

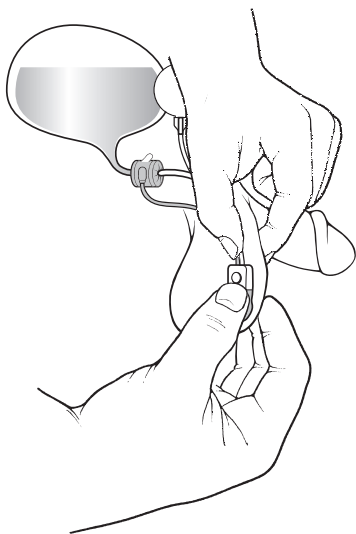
1. Feel for the control pump in your scrotum.



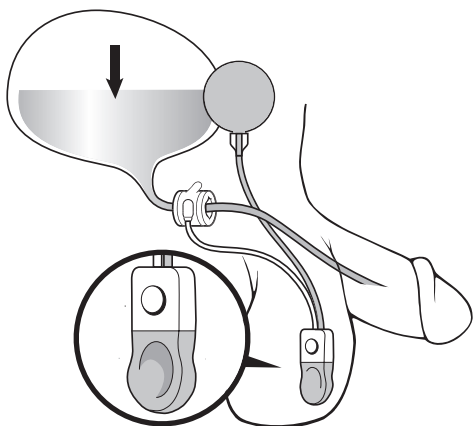
2. Stabilize the control pump by gently grasping the tubing above the control pump.



- Use the other hand to squeeze and release the lower, softer part of the control pump. Do this several times until the control pump is flat.



- When the lower part of the control pump is flat, the cuff should be open and you should be able to urinate.



That's it! You do not need to do anything after you urinate. The fluid automatically returns from the pressure balloon to refill the cuff. Once full, the cuff again squeezes the urethra closed. This usually takes several minutes, but each person is different. After using your 800 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 control pump a few more squeezes to re-open the cuff so that you can completely empty your bladder.

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.

You may want to have someone else, such as a spouse, know how to operate the 800 to assist you if need be.



Special precautions to take with your 800 before undergoing a medical procedure

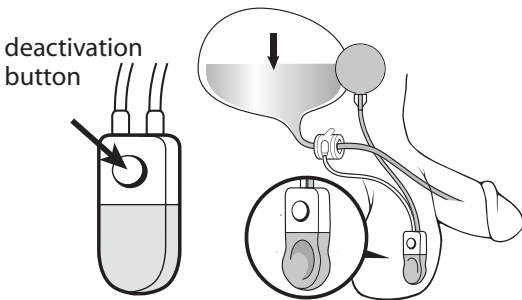
It is important for healthcare providers to know that you have a 800 before you undergo any medical procedure. This is especially true of any procedures which require the insertion of a catheter or any other instrument into the urethra. Such procedures can only be safely performed after your 800 has been deactivated (see below). Failure to deactivate the 800 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.

Deactivating your 800

Your 800 has a deactivation button which allows it to be "turned off". 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.

To deactivate your 800:

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 20 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. The lower part of the control pump will feel like a Lifesaver® candy when the device is properly deactivated. The cuff will now remain open.



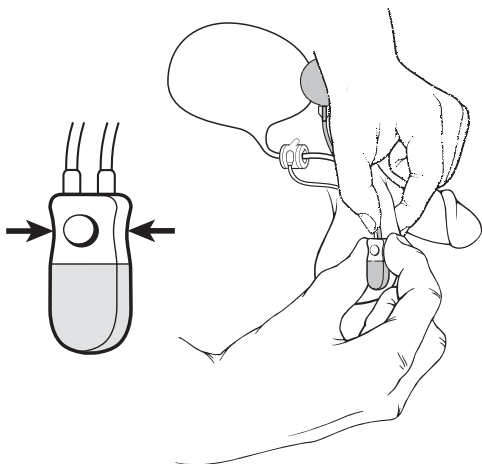
When your 800 is deactivated, the cuff around your urethra will not stop the flow of urine. You should use pads while your 800 is deactivated.

Activating your 800

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

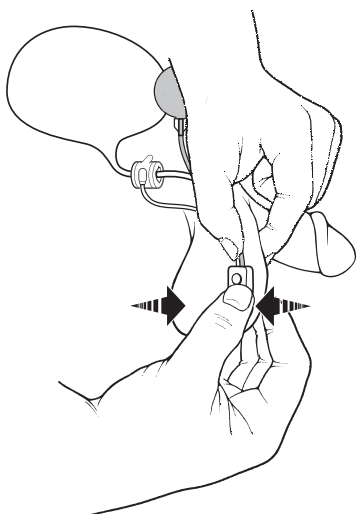
To activate your 800:

1. Use one hand to grasp the tubing above the control pump to hold the control pump in place.
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.



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. 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.



What symptoms may indicate that I have a problem with my 800?

As with any medical device, there is always a possibility of complications, infections or side effects. Contact your doctor right away if you notice any of the following symptoms:

- Unusual or prolonged pain
- Redness, swelling or rash near the incision or scrotum
- Pus coming from the surgical incision
- Fever
- Any problems with urination
- Any part of the device is visible through the skin
- Unable to locate control pump

Symptom: The lower portion of the control pump is harder than usual and difficult to squeeze or is squeezed flat and doesn't refill.

Possible cause: Accidental de-activation of the 800.

What to do: Follow the steps for activating your 800 on page 7. Contact your doctor if these attempts fail.

Symptom: Pain.

Problem: Pain is fairly typical in first 4-6 weeks after surgery. If pain is persistent and severe, the cause may be infection or another problem.

What to do: If not severe, take prescribed pain medication or analgesic. If severe, contact your doctor.

Commonly Asked Questions

Below are answers to some commonly asked questions about the 800. Talk with your doctor about any additional questions you have about your 800, and your specific medical situation.

Can I ride a bicycle?

Check with your doctor before bicycling after your surgery. Whether you use a regular or stationary bicycle, AMS recommends using a split seat. Consult your local bike shop for a recommendation.

Will the 800 affect sexual activity?

The 800 should not have a negative effect on sexual activity. In fact, many men report that achieving continence with the 800 actually enhances their sexual activity. It is a good idea for your partner to have an understanding of the device, including where the control pump is located and how it works.

What about activities that put added pressure on the body?

It is a good idea to discuss all sports and other activities with your doctor before participating in them. Activities that involve pressure changes such as flying or scuba diving should not affect the normal function of the 800.

Can I have magnetic resonance imaging (MRI) or go through airport security?

Yes. The 800 is MRI compatible, and the small amount of stainless steel in the control pump will not set off airport security alarms.

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