



How to Use Your Implant



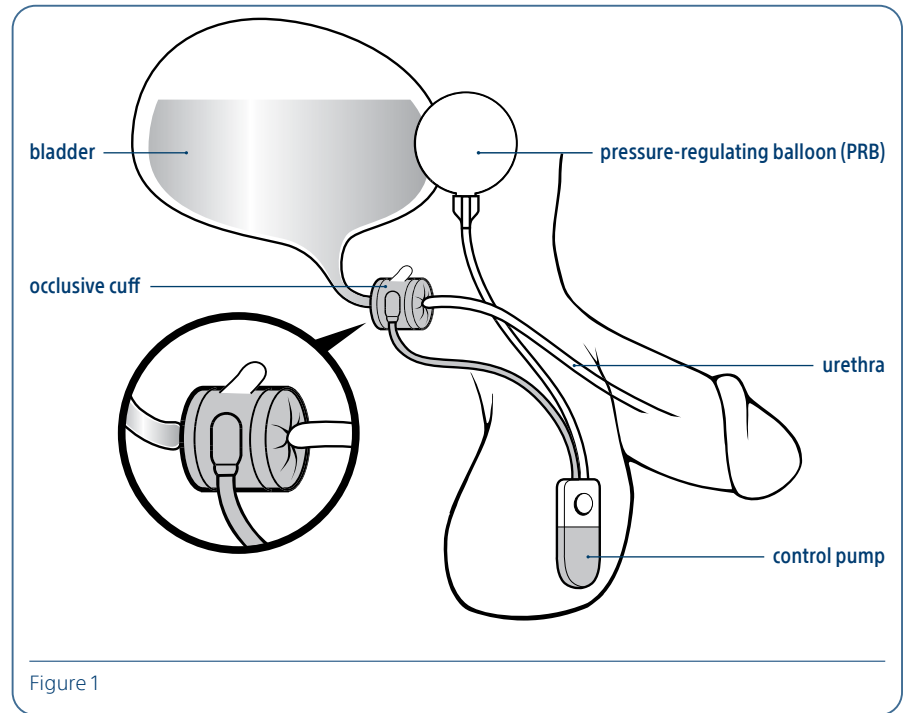
AMS 800™ ARTIFICIAL URINARY SPHINCTER

The AMS 800™

Artificial Urinary Sphincter

This information is intended to supplement the information found in the patient guide. Read the patient guide in its entirety before using the device.

The AMS 800™ Artificial Urinary Sphincter 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.



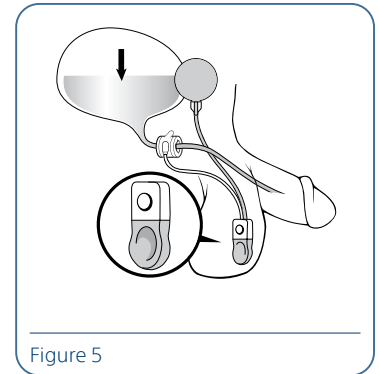
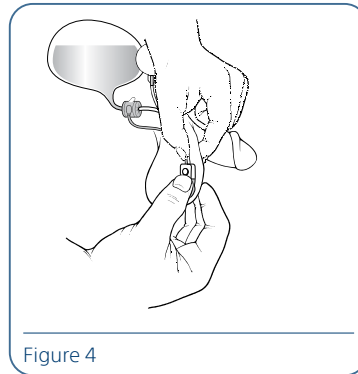
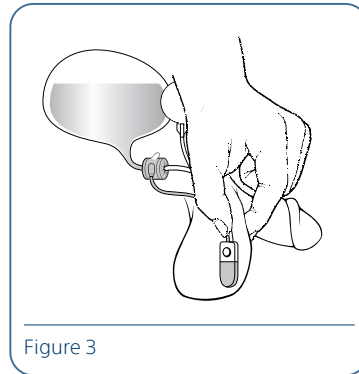
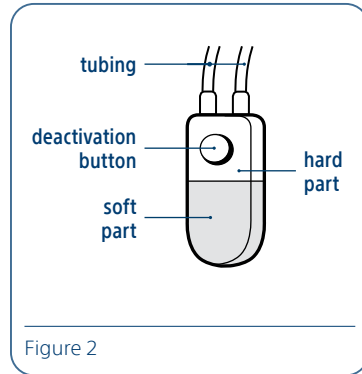
Using the AMS 800™ Artificial Urinary Sphincter

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. Stabilise 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.

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



Deactivating the AMS 800™ Artificial Urinary Sphincter

To deactivate the AMS 800™ Artificial Urinary Sphincter:

The AMS 800™ Artificial Urinary Sphincter 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 (there is a slight indentation in the soft part of the control pump), 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).



Want to know more?

Visit our website and download the Patient Guide to find additional support and guidance and important safety information.

3. When the AMS 800™ Artificial Urinary Sphincter is deactivated, the cuff around your urethra will not stop the flow of urine. You should use pads while the AMS 800™ Artificial Urinary Sphincter 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 by following the same steps for using/activating the device (above).

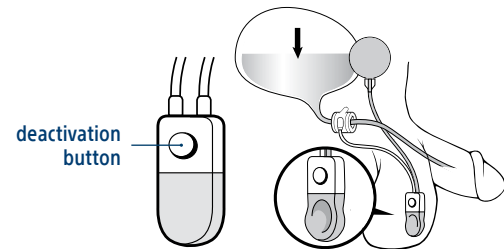


Figure 6

Special precautions to take with your AMS 800™ Artificial Urinary Sphincter before undergoing a medical procedure

It is important for healthcare providers to know that you have an AMS 800™ Artificial Urinary Sphincter 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™ Artificial Urinary Sphincter has been deactivated (see the deactivation instructions).

Failure to deactivate the AMS 800™ Artificial Urinary Sphincter 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.



Your doctor is the best source for getting more information on the AMS 800™ Artificial Urinary Sphincter. Your doctor is most familiar with your medical situation and can advise you on the risks and benefits of all available treatment options for urinary incontinence.

Important Safety Information

The AMS 800 AUS is used to treat urinary incontinence due to reduced outlet resistance (intrinsic sphincter deficiency) following prostate surgery. With all medical procedures, there are risks associated with the procedure and the use of the device. Patients with urinary tract infections, diabetes, spinal cord injuries, open sores, or skin infections in the region of the surgery have an increased risk of infection. The device is not suitable for patients with active urinary tract, genital or skin infections in the region of surgery. Some AMS 800 devices contain an antibiotic (InhibiZone™ Antibiotic Surface Treatment). AMS 800 with InhibiZone is not suitable for patients who are allergic to the antibiotics contained within the device (rifampin and minocycline HCl) or other tetracyclines, or for patients with systemic lupus, so devices that do not contain InhibiZone should be considered for these patients. The risks include but are not limited to: allergic reaction, erosion (wearing away or a state of being worn away, as by friction or pressure resulting in a breakdown of tissue), limited urethral coaptation (limited closing of the urethra) which may be due to device leak, sizing, malfunction placement, or other causes, device malfunction/failure leading to additional surgery, malposition of parts (parts placed in an inappropriate position), device migration of a component (device moving to another part of the body), any problems with urination.

Be sure to talk with your doctor so that you thoroughly understand all of the risks and benefits associated with the use of the device.

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.

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