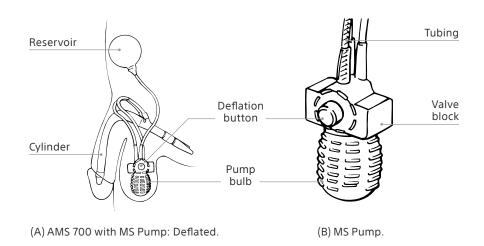




Post-op patient resources

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 700 Inflatable Penile Implant with MS Pump is a fluid-filled device that is implanted entirely within the body and is not visible. The implant consists of three components connected by tubing (**Figure 1A**): a reservoir, two cylinders, and an inflate/deflate pump. The fluid-filled reservoir is implanted in the pelvic area near the bladder or location chosen by the doctor. The reservoir holds the fluid until the patient decides to inflate the cylinders. The two cylinders are inserted side by side in the shaft of the penis. The pump, consisting of a pump bulb and a deflation button, is placed in the scrotum (**Figures 1 and 2**). The pump is used to inflate and deflate the cylinders by transferring fluid from the reservoir to the cylinders. The pump bulb is the rounded part at the bottom of the pump. The deflation button is above the bulb on the firm, rectangular shape of the pump (valve block) (**Figure 1B**).



AMS 700 with MS Pump: Inflated.

Reservoir

Cylinders

Deflation button

Pump bulb

Figure 1 Figure 2

How to use the device

Inflating the implant

When you squeeze and release the pump bulb, the fluid moves from the reservoir, through the pump and into the cylinders. When the cylinders fill with fluid, the penis becomes erect.

- 1. Feel for the pump in your scrotum.
- 2. Grasp the tubing above the valve block with one hand, to hold the pump in place.
- 3. Initially, squeeze the pump bulb **quickly** and **firmly**, and then release it to activate the pump (**Figure 3**).

The remaining pump bulb squeezes can be slower. Releasing allows the inflation bulb to refill with fluid. Continue to alternate squeezing and releasing until the cylinders fill with fluid and become erect. Full erection may take multiple squeezes of the pump bulb. Be sure to talk to your doctor for the optimal number of squeezes.

Note: Do not squeeze the deflation button while squeezing the pump bulb.

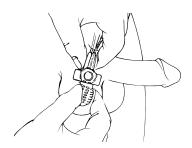


Figure 3

Deflating the implant

When you squeeze the deflation button for about four seconds, the fluid begins to leave the cylinders and return to the reservoir. After about four seconds, release the deflation button and the cylinders will return to their deflated position. The penis becomes soft (flaccid).

- 1. Feel for the pump in your scrotum.
- 2. Grasp the tubing above the valve block with one hand, to hold the pump in place.
- 3. With your other hand, locate the raised deflation button on the valve block.
- 4. To effectively squeeze the deflation button, you must place a thumb and forefinger on opposite sides of the valve block (**Figure 4**).
- 5. Squeeze the deflation button for about four seconds and then release. The cylinders will continue to deflate and your penis will become soft (flaccid).
- 6. After the cylinders have deflated, you may squeeze your penis to make it more flaccid.

Note: Do not squeeze the deflation button while squeezing the pump bulb.



Figure 4

What to expect after the procedure

Post-operative instructions

- Your doctor will provide specific instructions on how to position your penis and care for it during your healing process.
- Carefully position your penis after using the restroom, according to your doctor's instruction.

Pain and discomfort:

- You may experience pain and/or discomfort at the surgical area after your surgery and when you first use your device.
- In most cases, the pain goes away within a few weeks of surgery. Some patients have reported lasting pain.
- Contact your doctor if the pain persists longer than expected or is severe, as this may require further treatment.

Recovery timeline:

- Recovery times vary between patients.
- It is important to follow your doctor's postoperative instructions.
- You will be able to return to work and daily activities at the discretion or direction from your doctor.

Device usage and training

Next steps for device usage:

- After your doctor says you can begin using your AMS 700 Inflatable Penile Implant with MS Pump, follow the operating instructions carefully.
- Avoid trauma to the pelvic or abdominal area during and after recovery and as it may damage the device or surrounding areas.

Sexual activity:

 Most doctors recommend waiting until you receive your doctor's approval before engaging in sexual activity to allow your incision site to heal and your body to adjust to the device.

Follow-up appointments:

- You will have a follow-up around 4-6 weeks after your procedure with your doctor where you will be trained on how to use your pump.
- You may have an appointment with your doctor during the first few weeks of the recovery period to check that you are healing properly.
- Additional follow-up visits may be scheduled at your doctor's discretion.

Frequently asked questions

Below are answers to some of the more frequently asked questions about penile prostheses. Talk to your doctor about any additional questions you may have.

What do I do if the cylinders are difficult to inflate, or if they won't inflate?

Reset the pump by following these steps:

- 1. Press down for several seconds on the deflation button to refill the pump bulb.
- 2. Reactivate the pump with a **HARD**, **QUICK** squeeze of the pump bulb.
- 3. Inflate the device normally.

If this doesn't resolve the problem,

- 1. Squeeze the sides of the valve block to refill the pump bulb.
- 2. Squeeze the deflation button for 2-4 seconds to reset the lock-out mechanism.
- 3. Reactivate the pump with a **HARD, QUICK** squeeze of the pump bulb.
- 4. Inflate the device normally.

DO NOT squeeze the deflation button and pump bulb at the same time.

DO NOT squeeze the ends of the valve block while squeezing the pump bulb at the same time.

Will I have to take any precautions before undergoing future medical procedures?

It is important to tell your healthcare provider that you have a penile implant to prevent damage or injury.

Can I have magnetic resonance imaging (MRI)?

The device is MR Conditional, meaning that you can be MRI scanned safely within certain limits. Talk to your doctor before undergoing MRI scanning.

Can I go through security screening?

When you walk through security screening, the metal in your implant may be detectable. Inflatable penile implants should not set off a metal detector; however, if detected, tell the Security Officer that you have an implanted medical device. It is recommended that individuals with an implanted medical device carry a Patient Identification Card that identifies them as a medical device patient.

If you do not have a Patient Identification Card or if you have questions about your device as it relates to MRI or security screening, please ask your doctor or contact Boston Scientific at **1-844-433-2873**.

What symptoms may indicate that I should contact my doctor?

As with any medical procedure, there is the possibility that complications may develop after the procedure. You should contact your doctor immediately if any of these symptoms occur:

- Change in skin color, such as redness, near an incision or implant area
- Fever
- · Hives or rash

- Problems with urination
- Pus coming from the incision or head of the penis
- Severe or lasting pain
- Swelling near an incision, the scrotum or the penis

Where can I get more information about my device?

We understand there may be a learning curve as you get to know your new device. Your best resource is your doctor. They are most familiar with your medical situation and can work with you to address questions about the penile implant. For additional assistance, call **1-844-433-2873** or email **patient.services@bsci.com**.

Boston Scientific offers additional videos and information about your device, including a downloadable copy of the Patient Identification Card. Visit the **Boston Scientific website**.

Important Safety Information

The AMS 700™ Inflatable Penile Prosthesis (IPP) is intended for use in the treatment of chronic, organic male erectile dysfunction (impotence).

With all medical procedures, there are risks associated with the procedure and the use of the device, including long-term implantation.

Implanting a penile prosthesis will damage or destroy any remaining ability to have a natural erection, as well as make other treatment options (oral medications, vacuum devices or injections) impossible. Men with diabetes, spinal cord injuries or skin infections may have an increased risk of infection. Implantation may result in penile curvature or scarring. The device is not suitable for patients with active urinary tract, genital or skin infections in the region of surgery. Some AMS 700 devices contain an antibiotic (InhibiZone™ Antibiotic Surface Treatment). AMS 700 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: device malfunction/failure leading to additional surgery, device migration potentially leading to exposure through tissues, wearing away/loss of tissue (device/tissue erosion), infection, unintended-inflation of the device, pain/soreness, redness or rash near the incision or scrotum, swelling near the incision, scrotum or penis, hives, fever, problems with urination, device in an inappropriate position (device malposition), a second surgery may be required to reposition or remove the reservoir (reservoir revision or removal).

The device can be MRI scanned under specific conditions. Scanning under other conditions may result in injury or device malfunction. Be sure to talk to your doctor before undergoing MRI scanning.

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.



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