

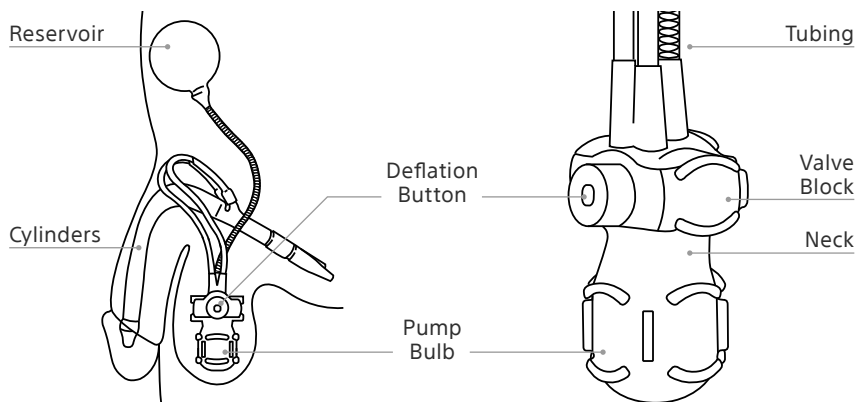


AMS 700™ with TENACIO™ Pump Inflatable Penile Implant

Post-op patient resources

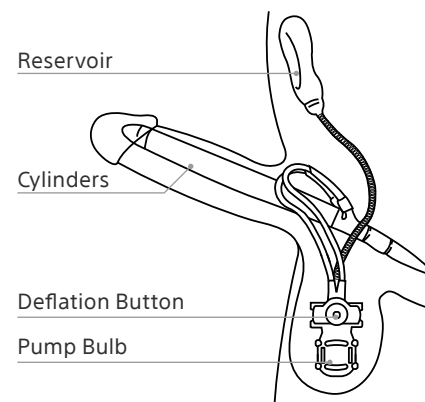
This information is intended to supplement the information found in the patient guide. Read the patient guide in its entirety before using the device.

The AMS 700 Inflatable Penile Implant with TENACIO 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, a valve block, the neck, tubing, 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 round and is at the bottom of the pump. The deflation button is above the pump bulb on the rectangular valve block (**Figure 1B**).



(A) AMS 700 with TENACIO Pump: Deflated.

(B) TENACIO Pump.



AMS 700 with TENACIO Pump: Inflated.

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 TENACIO Pump in your scrotum.
2. Determine the location of the deflation button, to avoid pressing it during inflation.
3. Grasp the tubing above the deflation block with one hand, to hold the pump in place.
4. With the other hand, grasp the bulb toward the bottom of the pump and away from the pump neck.
5. For the first pump, give the pump bulb a firm squeeze and then release to allow the pump bulb to fully refill.

Continue to squeeze the pump bulb and release, to allow it to refill fully with fluid. Quickly alternate between squeezing and releasing until the cylinders fill and the penis becomes erect. A full erection will take multiple squeezes of the pump bulb to reach the desired firmness. Be sure to talk to your doctor to determine the right number of squeezes for your device.

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

[Click here to watch an animated demonstration of the TENACIO pump.](#)

➤ 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 post-operative instructions.
- You will be able to return to work and daily activities at the discretion or direction from your doctor.

Deflating the implant

When you squeeze the deflation button your penis starts to soften.

1. Feel for the TENACIO Pump in your scrotum.
2. With one hand, determine the location of the deflation button.
3. With the other hand, grasp the sides of the valve block, to hold the pump in place.
4. Press the deflation button in toward the valve block with your thumb and forefinger on opposite sides of the valve block.
5. Release the deflation button. The cylinders will continue to deflate and your penis will become soft.
6. After the cylinders have begun to deflate, you may squeeze your penis to make it more flaccid.

Device usage training

Next steps for device usage:

- After your doctor says you can begin using your AMS 700 Inflatable Penile Implant with TENACIO 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 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 implants. 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. Bend and squeeze your penis to evacuate any residual fluids left behind in the cylinders.
3. Give the pump bulb a firm squeeze and then release to allow the pump bulb to refill.
4. Inflate the device normally.

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

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

It is important to tell your health care providers that you have a penile implant to prevent damage to the device or injury to the surrounding areas.

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 device may set off a metal detector. 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 surgery, there is the possibility that complications may develop. 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
- Problems with urination
- Fever
- Pus coming from the incision or head of the penis
- Hives or rash
- 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 is intended for use in the treatment of male erectile dysfunction (impotence).

With all medical procedures, there are risks associated with the procedure and the use of the device.

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 the tissue
- 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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