

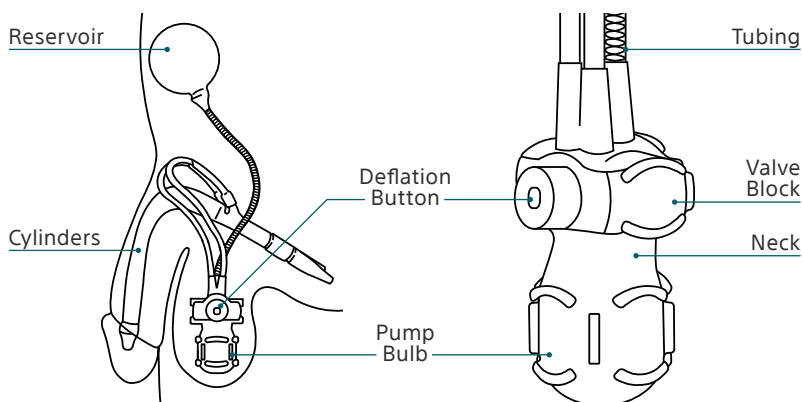
AMS 700™ with TENACIO™ Pump Inflatable Penile Implant

Digital Patient Guide

Abridged

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 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**).

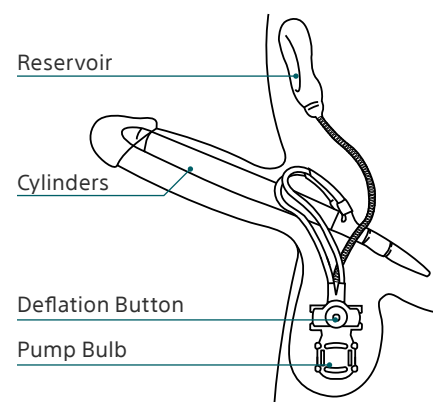
Figure 1



(A) AMS 700 with TENACIO Pump: Deflated.

(B) TENACIO Pump.

Figure 2



AMS 700 with TENACIO Pump: Inflated.

What to expect after the procedure

Your doctor will give you instructions on positioning your penis and the required care during your healing period. After using the restroom, carefully position your penis, per your doctor's instruction.

You may experience pain 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. However, some patients have reported lasting pain. Contact your doctor if pain lasts longer than expected or is severe, as this may require either surgical or non-surgical treatment.

Recovery times vary from patient to patient. It is important to follow post-operative instructions from your doctor. You will be able to return to work and everyday activities at the discretion or direction from your doctor. Up to six weeks after your procedure, your doctor may show you how to inflate and deflate your device and talk with you about when you can start using it.

How to use your device

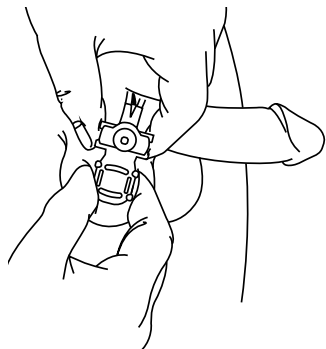
Inflating the implant

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 sides of the valve 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, as shown in **Figure 3**.

Continue to squeeze the pump bulb and release, to allow it to refill fully with fluid. Continue to alternate 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 of the patient and partner. 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.

Figure 3



Most doctors recommend that you wait up to six weeks before having sex. This time allows your incision site to heal and helps your body to adapt to your device. You will probably have an appointment with your doctor during the recovery period to be sure you are healing properly. At your doctor's discretion, you may have follow-up visits after the surgery. After your doctor says you can begin using your AMS 700 Inflatable Penile Implant with TENACIO Pump, follow the operating instructions.

During the recovery time and after, take care to avoid trauma to the pelvic or abdominal area. Always keep in mind that you have had a surgical implant and carefully choose your activities. Trauma, such as falling or sports, may damage the device or the nearby area. Use of injection therapy in the pelvic or abdominal area, or additional treatment in that area, may also damage the device. Always inform your doctor and dentist about your device before any medical procedures, so they can take appropriate precautions.

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, as shown in **Figures 4 and 5**.
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.

Figure 4

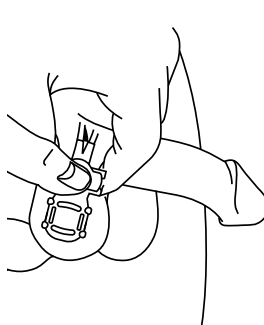
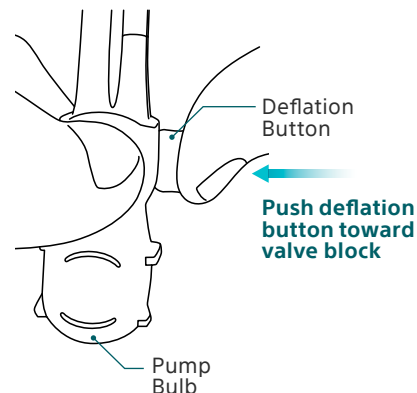


Figure 5



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
- 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

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.

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 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. Since the AMS 700 has minimal metal, it should not set off a metal detector. However, if detected, report that you have a medical device. Carry the Implant Card for the AMS 700 because it identifies you as a recipient of a medical device.

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

Reset the pump by following these steps:

1. Squeeze the deflation button to refill the pump bulb.
2. Give the pump bulb a firm squeeze and then release to allow the pump bulb to refill.
3. Inflate the device normally.

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

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 make sure you get the best possible results from the penile implant. For additional assistance, call **1-844-433-2873**.

Boston Scientific offers additional videos and information about your device, including a downloadable copy of the Patient Identification Card. Visit the [Boston Scientific website](https://www.bostonscientific.com/en-US/patients/about-your-device/penile-implants/resources.html) (www.bostonscientific.com/en-US/patients/about-your-device/penile-implants/resources.html).

AMS 700™ Inflatable Penile 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 700™ Inflatable Penile Prosthesis. Talk to your doctor for a complete listing of risks, warnings and important safety information.

The AMS 700™ with Inflatable Penile Prosthesis is intended for use in the treatment of male erectile dysfunction (impotence). 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. Some AMS 700 devices contain an antibiotic (InhibiZone™ Antibiotic Surface Treatment). The device is not suitable for patients who are allergic to the antibiotics contained within the device (rifampin, minocycline or other tetracyclines) or those who have systemic lupus, these patients should use one of the devices that do not contain InhibiZone antibiotic surface treatment.

Potential risks may include: 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 and pain/soresness. MH-545411-AB

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URO-1745813-AA FEB 2024