

AMS 700™ with MS Pump™
Inflatable Penile Prosthesis
Patient Guide

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Perforation

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CE 2797

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2024-04

Place AMS 700 Cylinder or
preconnected system
label here.

Implanting
Surgeon: _____
Surgeon
Telephone: _____
Emergency
Contact: _____
Contact
Telephone: _____

USA Customer Service 888-272-1001
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MRI safety information:

This implant is
MR Conditional to 3.0 Tesla



The person with this implant can
safely undergo an MR exam only
under very specific conditions.
Scanning under different conditions
may result in injury or device
malfunction. Full MRI safety
information is available in the
Physician IFU, which can be obtained
at www.IFU-BSCL.com
or by calling +1-888-272-1001.

Security Screening: The metal in your
implant may be detectable.

To request a new card:

Please contact the Patient Liaison at:
U.S. Toll Free: 1-800-328-3881, Option 2

Patient ID Card

AMS 700™ with MS Pump™
Inflatable Penile Prosthesis

Important Physician Information

This person has an AMS 700
with MS Pump Series Three-Piece
Inflatable Penile Prosthesis implanted
to treat erectile dysfunction.

Patient
Name: _____
Patient
Telephone: _____
Implant
Date: _____

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Guide Outside Cover

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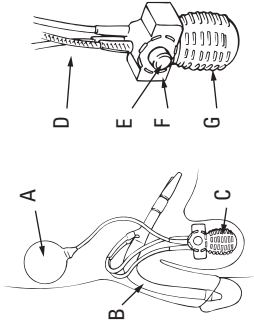
Perforation

Design: The implant is a closed, fluid-filled system consisting of three components: a reservoir, a pair of cylinders implanted in the shaft of the penis, and a pump implanted in the scrotum (Figure 1). Kink resistant tubing connects the components, which are made from silicone elastomer.

To inflate: Grasp the tubing above the deflation block with one hand. Using the other hand, squeeze and release the pump bulb quickly and firmly. Then squeeze and release the bulb several times until the cylinders fill with fluid and become erect. Do not squeeze the deflation button while squeezing the bulb.

To deflate: Grasp the tubing above the deflation block with one hand. Using the other hand, place the thumb and forefinger on opposite sides of the

deflation block. Squeeze the deflation button for about 4 seconds, and then release it.



- A. Reservoir
- B. Cylinders
- C. Pump
- D. Tubing
- E. Deflation Button
- F. Deflation Block
- G. Pump Bulb

Figure 1

Place patient AMS 700™
Reservoir label here.

Place patient Rear Tip
Extender label here if used.

Place AMS 700 MS Pump™
label here if a preconnected
system was not used.

AMS 700™ with MS Pump™ Inflatable Penile Prosthesis

Patient Guide

Introduction

The AMS 700 with MS Pump Inflatable Penile Prosthesis 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 1): a reservoir, two cylinders, and an inflate/deflate pump. Some AMS 700 devices contain anti-infection properties. 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.

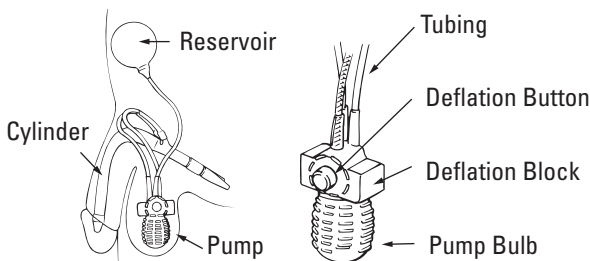


Figure 1

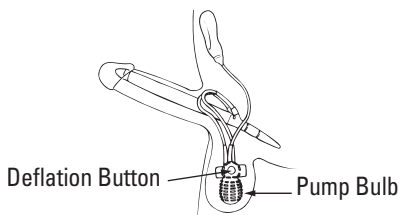


Figure 2

What to expect after the procedure

Your doctor will provide guidance on positioning your penis and the type of undergarment to use during your healing period. After voiding you should carefully reposition your penis per your doctor's guidance.

Like with most surgery, you may experience pain or discomfort at the operative site(s) immediately following your surgery and when you first use your implant. In most cases the pain goes away within a few weeks of surgery; however, cases of chronic (continuing) pain have been reported.

Recovery times vary from patient to patient. You will be able to return to work and everyday activities at the discretion or direction of your doctor. After three to six weeks your doctor may instruct you to cycle the device for the first time.

Your doctor will discuss when you will be able to use your device. Most doctors recommend that you wait four to six weeks before having intercourse. This time allows your incision site to heal and help your body adapt to your implant. 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 additional visits or follow-ups from this procedure.

After your doctor says you can begin using the device, 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 choose your activities wisely. Examples of such trauma may include a seat belt jolt from a car accident, being tackled in contact sports, or slipping and falling on ice. Trauma may damage the implant or surrounding tissues. Use of injection therapy in the pelvic or abdominal area, or additional treatment in that area, may also damage the implant. Always talk to your doctor about medical procedures you may undergo in the future.

Additionally, your doctor may ask you to take antibiotics before and after any dental or surgical procedure as a precautionary measure to prevent infection.

How to use my 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 deflation 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.

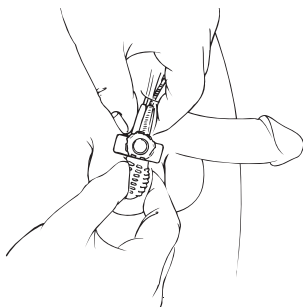


Figure 3

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 deflation block with one hand, to hold the pump in place.
3. With your other hand, locate the raised deflation button on the deflation block.
4. To effectively squeeze the deflation button, you must place a thumb and forefinger on opposite sides of the deflation block (Figure 4).

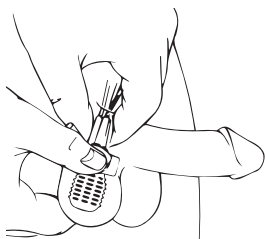


Figure 4

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).

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

6. After the cylinders have deflated, you may squeeze your penis to make it more flaccid.

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.

- Unusual or prolonged pain
- Redness or rash near the incision or scrotum
- Swelling near the incision, scrotum or penis
- Pus coming from the incision or head of the penis
- Hives
- Fever
- Any problems with urination

You should contact your doctor immediately if any of these symptoms occur.

Reservoir Location Information

Medical journal articles were reviewed in 2022 to evaluate the surgical placement of the AMS 700 reservoir in either the pelvic area near the bladder or in another location chosen by the doctor (known as ectopic reservoir placement). Seventy articles described reservoir location from more than 9,000 patients and from that total, over 6,000 patients had a reservoir placed in another location (ectopic reservoir placement). Levels of satisfaction and the number of complications were similar, no matter the reservoir location.

The medical journal article review identified the following possible adverse events (AEs) for either reservoir location:

- Device inflates on its own (Auto-inflation)
- Wearing down of tissue around the device (Erosion)
- Device moved from original location (Migration or herniation)
- Infection
- Reservoir malfunctions such as leaks, incomplete inflation or deflation
- Pain
- Feeling the reservoir under the skin (Palpability)
- Reservoir in an inappropriate position (Reservoir malposition)
- A second surgery may be required to reposition or remove the reservoir (Reservoir revision or removal)

Ectopic reservoir placement may not have regulatory approval in all markets.

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.

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. Since most inflatable penile implants have minimal metal parts, they 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 the Men's Health patient liaison at 1-800-328-3881, option 2.

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. 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 deflation 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 deflation block while squeezing the pump bulb at the same time.

Where can I get more information about my device?

Your best resource is your doctor. Your doctor is most familiar with your medical situation and can work with you to make sure you get the best possible results from the penile implant. You can also call the Men's Health patient liaison at 1-800-328-3881, option 2, or visit our website at www.bostonscientific.com.