

AMS Ambicor™ Inflatable Penile Prosthesis

Patient Guide

Introduction..... 1

What to expect after the procedure 2

How to use my device 3

What symptoms may indicate that I should contact my doctor?..... 5

Frequently asked questions 5

Where can I get more information about my device? 6

Score & Fold

Perforation

EC REP EU Authorized Representative

Boston Scientific Limited
Ballybrit Business Park
Galway
IRELAND

AUS Australian Sponsor Address

Boston Scientific (Australia) Pty Ltd
PO Box 332
BOTANY
NSW 1455
Australia
Free Phone 1800 676 133
Free Fax 1800 836 666

ARG Argentina Local Contact

Para obtener información de contacto de Boston Scientific Argentina SA, por favor, acceda al link www.bostonscientific.com/arg

Legal Manufacturer

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752
USA
USA Customer Service 888-272-1001

CE 2797

© 2019 Boston Scientific Corporation or its affiliates. All rights reserved.



50698479-01

2019-11

Place patient AMS Ambicor label here.

Place patient Rear Tip Extender label here if used.

MRI safety information:
This implant is M/R Conditional to 3.0 Tesla

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

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

USA Customer Service 888-272-1001
©2018 Boston Scientific Corporation or its affiliates. All rights reserved.



Patient ID Card

**AMS Ambicor™
Inflatable Penile Prosthesis**

Important Physician Information

This person has an AMS Ambicor Inflatable Penile Prosthesis implanted to treat erectile dysfunction.

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

Score & Fold

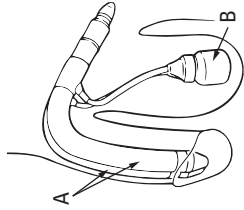
Score & Fold

Guide Outside Cover

Score & Fold

Perforation

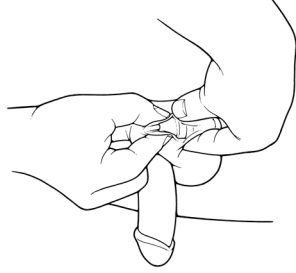
Design: The implant is a closed, fluid-filled system consisting of two components: a pair of cylinders implanted in the shaft of the penis, and a pump implanted in the scrotum (Figure 1). Kink resistant tubing connects the components, which are made from silicone elastomer.



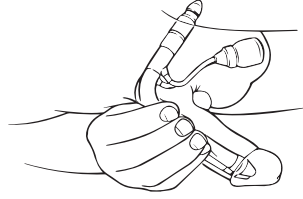
A. Cylinders B. Pump Bulb

Figure 1

To inflate: Squeeze and release the pump bulb several times. This transfers fluid from the reservoirs located at the proximal end of the cylinders to the main portion of the cylinders, creating an erection (Figure 2).

**Figure 2**

To deflate: Bending the penis to an angle of approximately 65°, holding it there for 10-12 seconds, and then returning the penis to a horizontal position will return the fluid to the reservoirs and the penis will relax (Figure 3).

**Figure 3**

AMS Ambicor™ Inflatable Penile Prosthesis

Patient Guide

Introduction

The AMS Ambicor Inflatable Penile Prosthesis is a fluid-filled device that is implanted entirely within the body and is not visible. The implant consists of two cylinders and a pump bulb. The two cylinders are inserted side by side into the shaft of the penis. The pump is placed in the scrotum. The pump is used to inflate the cylinders by transferring fluid from the reservoir to the cylinders.

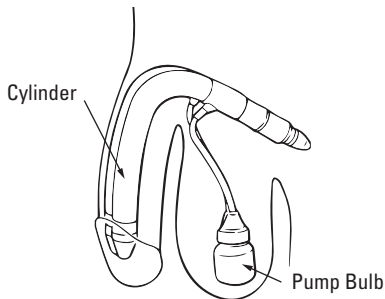


Figure 1

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.

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 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. With one hand, gently grasp your scrotum to locate and hold the tubing above the pump to keep the pump in place.
2. Use the other hand to locate the pump.
3. Squeeze the pump completely and then release it. Continue to alternate squeezing and releasing until the cylinders fill with the fluid and your penis becomes firm (Figure 2).

Full erection may take multiple squeezes of the pump. Be sure to talk to your doctor for the optimal number of squeezes.



Figure 2

Deflating the implant

The cylinders must be fully inflated before you try to deflate them. When you simultaneously bend and maintain a continuous squeeze on the cylinders, the fluid moves from the cylinders and returns to the reservoir. The cylinders return to their flaccid position.

1. Both cylinders can be deflated at the same time.
2. Using either hand, place your thumb under the shaft of your penis. Place your other fingers on the top of the shaft of your penis.
3. Bend your penis down over your thumb at an angle of approximately 65 degrees.
4. Hold the penis in this position for ten to twelve seconds. This will return the fluid to the reservoir and the penis will become flaccid (Figure 3).

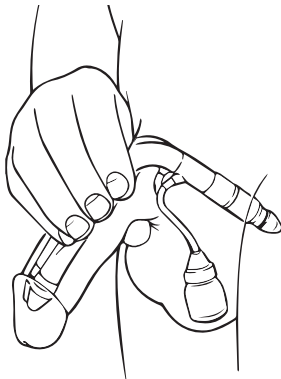


Figure 3

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.

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.

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.

