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Boston Scientific

AMS 700™ Inflatable Penile Prosthesis with TENACIO™ Pump

Patient Guide

BSC (Custom Template 11.25 x 8), Patient Guide, Tenacio, en, 51558343-01B

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Perforation

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300 Boston Scientific Way
Marlborough, MA 01752 USA
USA Customer Service +1-888-272-1001

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2023-08

51558343-01

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Place AMS 700 Cylinder or preconnected system label here.

Place AMS 700 TENACIO Pump label here, if a preconnected system was not used.

Boston Scientific Corporation
300 Boston Scientific Way
Marlborough, MA 01752 USA
USA Customer Service +1-888-272-1001

MRI safety information:
This person has an AMS 700 Inflatable Penile Prosthesis and 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 Instructions for Use, which can be obtained at www.IFU-BSCI.com or by calling +1-888-272-1001

This device is MR Conditional to 3.0 Tesla

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

To request a new card:
Please contact the Patient Liaison at:
U.S. Toll Free: +1-800-328-3881, Option 2

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Implanting Surgeon: _____

Surgeon Telephone: _____

Hospital: _____

_____

_____

_____

For additional information see IFU on website: www.IFU-BSCI.com

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Boston Scientific

Implant Card

AMS 700™ with TENACIO™ Pump Inflatable Penile Prosthesis

Important Physician Information

This person has an AMS 700 with TENACIO Pump Inflatable Penile Prosthesis implanted to treat erectile dysfunction.

Patient Name: _____

Patient Telephone: _____

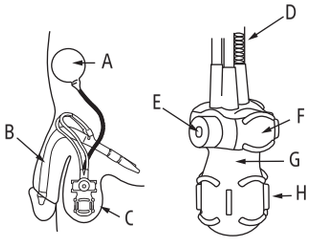
Implant Date: _____

Guide Outside Cover

Design: The AMS 700 is a fluid-filled system. It consists of three components: a reservoir, a pair of cylinders, and a pump, as shown in Figure 1. Kink resistant tubing connects the components. All components contain silicone.

To inflate: While avoiding the deflation button, grasp opposing sides of the valve block with one hand. Using the other hand, give the pump bulb a firm squeeze and then release to allow the pump bulb to refill. Continue to 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. Squeeze the bulb lower down and further from the neck to reduce the force needed to squeeze.

To deflate: Grasp opposing sides of the valve block with one hand. Using the other hand, place the thumb and forefinger on opposite sides of the valve block. Depress the deflation button and then release it.



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

Figure 1

Place patient AMS 700 Reservoir label here.

Place patient Rear Tip Extender label here, if used.

Place AMS 700 Accessory Kit label here.

AMS 700™ Inflatable Penile Prosthesis with TENACIO™ Pump

Patient Guide

Introduction

The AMS 700 with TENACIO Pump Inflatable Penile Prosthesis is used to treat chronic, organic, male erectile dysfunction (impotence). The AMS 700 is designed to provide the patient with control over the erect and flaccid states of their penis.

Once implanted, the AMS 700 with TENACIO Pump is not visible. The device consists of three components connected by tubing, as shown in Figure 1: a reservoir, two cylinders, and the TENACIO pump. The AMS 700 is available with an antibiotic treatment of rifampin and minocycline HCl, named InhibiZone. The reservoir, implanted in the pelvic area near the bladder, holds fluid until the patient decides to inflate the cylinders. Two cylinders reside side-by-side in the shaft of the penis. The pump, implanted in the scrotum, consists of a pump bulb and a deflation button as shown in Figures 2, 3 and 4. The pump inflates and deflates the cylinders by moving fluid from the reservoir to the cylinders. When the cylinders fill with fluid, the penis becomes erect.

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, as shown in Figure 2.

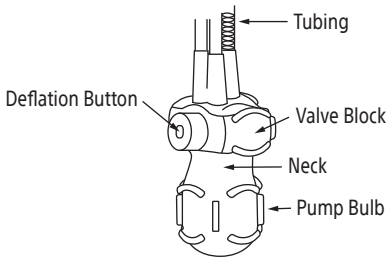


Figure 2: AMS 700 TENACIO Pump.

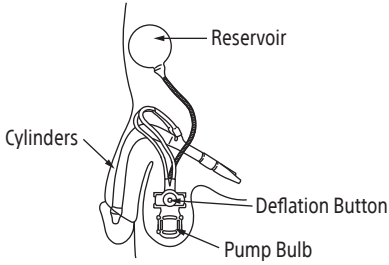


Figure 3: AMS 700 with TENACIO Pump: Deflated.

Indications for use

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

Contraindications

- The use of this device is contraindicated in patients who have active urinary tract, genital or skin infections in the region of surgery.
- The use of the InhibiZone version of this device is contraindicated in patients with known allergy or sensitivity to rifampin, minocycline HCl, or other tetracyclines.
- The use of products with InhibiZone is contraindicated in patients with lupus because minocycline HCl has been reported to aggravate this condition.

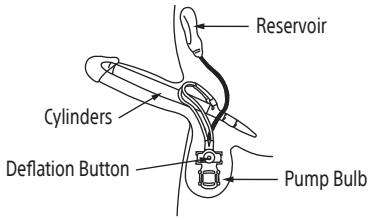


Figure 4: AMS 700 with TENACIO Pump: Inflated.

What to expect after surgery

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.

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 Prosthesis 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.

After you have healed, continue to have yearly contact with your doctor to evaluate the device. The AMS 700 is not a lifetime implant. The device will be subject to wear through normal daily use, which will vary by patient. It is possible that parts of the system may require replacement or removal over time. The AMS 700 has been tested after 1,000 inflations and 1,000 deflations, which is based on 2 uses of the device per week for 10 years.

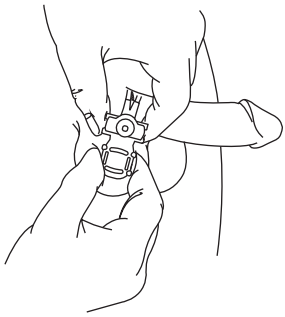


Figure 5: View of the TENACIO Pump in the scrotum during inflation.

How to use my AMS 700

Inflation

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 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 5.

Continue to squeeze the pump bulb and release, to allow it to fully refill 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.

Deflation

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 your 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 6 and 7.
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.

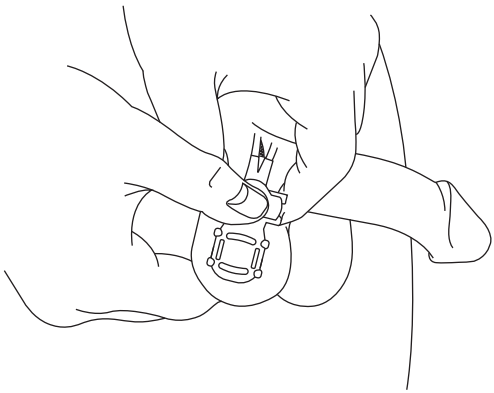


Figure 6: View of the TENACIO Pump in the scrotum during deflation.

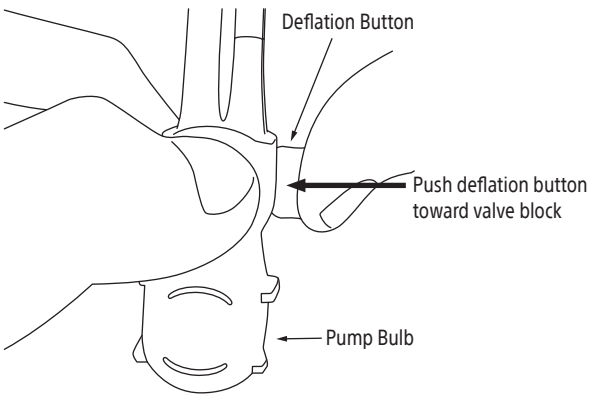


Figure 7: The deflation button is pushed in, and, toward the valve block.

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

Adverse events

Patients reported the following adverse events during a clinical study (conducted from January 31, 1995 to October 24, 2002) for the AMS 700 without InhibiZone:

- Blood in urine (Hematuria)
- Bruising at or near the urinary and genital organs (Urogenital ecchymosis)
- Collection of blood outside of blood vessel (Urogenital hematoma)
- Cylinder bulge (Cylinder aneurysm)
- Decreased penile sensation
- Dizziness
- Dry Mouth
- Device in an inappropriate position (Device malposition)
- Device inflates on its own (Auto-inflation)
- Device malfunction, such as leaks, incomplete inflation or deflation
- Device moved from original location (Device migration)
- Infection
- Inflammatory disease affecting joints (Rheumatoid Arthritis)
- Joint pain
- Low grade fever
- Pain or discomfort during urination (Dysuria)
- Patient dissatisfaction
- Pelvic pain
- Penile curvature
- Problems with ejaculation
- Problems with healing at an incision area
- Problems with memory function
- Problems with sexual function
- Problems with skin sensation such as prickling, numbness, feeling of pins and needles (Paresthesia)
- Problems with urination
- Scar tissue around the reservoir (Reservoir encapsulation)
- Scrotal tissue attached to the pump
- Skin redness (Urogenital erythema)
- Swelling or stiffness
- Swelling, redness or raised tissue, at or near the urinary or genital organs (Urogenital edema)
- Urinating more than usual (Urinary frequency)
- Weakness

- Wearing down of tissue around the device (Erosion/Extrusion)
- Other*

*Patients reported the following "Other" adverse events during the clinical study, and each occurred in less than 0.5 % of patients:

- A headache, often accompanied by nausea and sensitivity to light and sound (Migraine)
- An infection in any part of the urinary system, the kidneys, bladder, or urethra (Urinary tract infection)
- Back pain
- Decreased sexual desire
- Depression
- Downward angle of the penile head (Glans hypermobile - dorsally)
- Extreme sensitivity to light (Photosensitivity reaction)
- Eye disorder
- Eye pain
- Feeling off balance (Vertigo)
- Hair loss (Alopecia)
- Inability to control bowel movements (Fecal incontinence)
- Inability to pull back the penile foreskin (Phimosis)
- Kidney stone (Kidney calculus)
- Pain in the upper abdomen and just below the ribs (Epigastric pain)
- Poor control of glucose levels in the blood (Diabetes mellitus)
- Scar tissue (Fibrosis)
- Skin infection (Cellulitis)
- Sudden and urgent need to urinate (Urinary urgency)
- Thickening of the skin
- Tissue death (Necrosis)

Patients reported the following adverse events during the clinical study, which may be associated with the use of this product:

- Bleeding
- Blood clot in a blood vessel (Thrombosis)
- Blood vessel problem (Vascular compromise)
- Curved or bent penis during erection (Ventral chordee)
- Decreased blood flow to an organ or tissue that may cause a change in skin color (Ischemia)
- Exposure to harmful material (Biohazard)
- Formation of a sore (Ulceration)
- Inflammatory disease affecting joints (Non-Rheumatoid Arthritis)
- Injury of the bladder, penis, nerve, or urine pathway from the bladder
- Injury to a blood vessel (Vessel trauma)
- Pain that does not go away or is severe
- Penile cylinder crossing over from one side of the penis to the other (Cavernosal Crossover)
- Prolonged surgery due to device issue
- Small area of inflamed tissue (Granuloma formation)
- Small piece of the device found in the body
- Swelling (Seroma)

Risks associated with the implantation of the AMS 700

Warnings

- Not quickly treating erosion may cause it to worsen, leading to infection and further injury.
- If an allergic reaction develops to an AMS 700 treated with InhibiZone, a doctor should remove the device and start appropriate treatment.
- Implantation of a penile prosthesis may result in a curved or scarred penis.
- Men with diabetes, spinal cord injuries, or open sores may have an increased risk of infection associated with a prosthesis.
- Pre-existing abdominal or penile scarring or tissue tightening may make surgical implantation more complicated or impractical.
- The implantation of a penile prosthesis will make natural or spontaneous erections impossible.
- The implantation of a penile prosthesis may make some erectile dysfunction treatment options impossible.
- Carefully consider with a doctor the risks and benefits of the device regarding sensitivity to silicone.

Precautions

- Occasionally, parts of the device move in the body, such as a cylinder, pump, or reservoir.
- Removal of a device without quick replacement may complicate a future implant surgery.
- For proper inflation and deflation, the patient will need adequate manual dexterity and strength.
- Certain psychological conditions or abnormal brain function, such as dementia or memory loss, may prevent the patient's successful operation of the device.
- Physical injury to the pelvic or abdominal areas may may result in damage to the device and surrounding tissue which may require device replacement or another type of surgery.
- Use of injection therapy will damage the device.
- InhibiZone does not replace normal antibiotic protocols. Continue to use medications prescribed by a doctor.
- Patients should tell their doctor if they are taking methoxyflurane to carefully monitor kidney function, because when combined with InhibiZone it can increase the potential for kidney damage.
- Patients should tell their doctor if they are taking warfarin because an ingredient in InhibiZone can slow blood clotting time.
- Patients should tell their doctor if they are taking thionamides, isoniazid, or halothane because when combined with an ingredient in InhibiZone it can increase the potential for liver damage.

Materials

The AMS 700, with and without InhibiZone, utilizes the same materials with the same surface areas. AMS 700 with InhibiZone (including reservoir, pump, and two cylinders), regardless of configuration, contains ≤ 33 mg Rifampin (CAS # 13292-46-1) and ≤12 mg Minocycline HCl (CAS # 10118-90-8). This represents less than 2 % of an oral dose exposure for a complete course of Rifampin or Minocycline HCl with the maximum

dose calculated for the most common device configuration's average content plus one standard deviation.

This device is composed of a number of materials, including solid silicone elastomers and a fluorosilicone lubricant. The tubing plug and Keith needles are composed of stainless steel and therefore may contain cobalt.

The following tables describe the materials that have long-term contact with patient tissue as part of the implanted device. The physician may use either Quick Connect Window Connectors or Suture-Tie Connectors to connect the device. Table 1 describes device materials if the physician uses Quick Connect window connectors; Table 2 describes device materials if the physician uses Suture-Tie connectors.

Table 1: Implantable Materials in AMS 700 IPP System plus AMS 700 IPP Accessory Kit (if using Quick Connect window connectors)

Implantable Material	Patient Contacting Surface Area (sq cm)	% Patient Contacting Surface Area Implant Material / Total Implantable Patient Contacting Surface Area
Silicone	612.00	92.85
Expanded PTFE	33.50	5.08
Polyamide	0.03	Trace
316 Stainless Steel[1]	0.52	0.08
Polyacetal	13.06	1.98
Total Implantable	**659.11**	**100**

[1]Implantable stainless steel is attributable to the tubing plug included in the AMS 700 IPP Accessory Kit. The tubing plug is used to plug component kink resistant tubing in the event of revision surgery when the physician decides to preserve and maintain that component.

Table 2: Implantable Materials in AMS 700 IPP System plus AMS 700 IPP Accessory Kit (if using Suture-Tie connectors)

Implantable Material	Patient Contacting Surface Area (sq cm)	% Patient Contacting Surface Area Implant Material / Total Implantable Patient Contacting Surface Area
Silicone	612.00	94.54
Expanded PTFE	33.50	5.18
Polyamide	0.03	Trace
316 Stainless Steel[1]	0.52	0.08
Polysulfone	1.27	0.20
Total Implantable	**647.32**	**100**

[1]Implantable stainless steel is attributable to the tubing plug included in the AMS 700 IPP Accessory Kit. The tubing plug is used to plug component kink resistant tubing in the event of revision surgery when the physician decides to preserve and maintain that component.

Frequently asked questions

Below are answers to some of the more frequent questions about a penile prosthesis. 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 doctor that you have an AMS 700 to prevent damage to the device or injury to the surrounding areas.

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 an Implant Card, please ask your doctor or visit our website at: https://www.bostonscientific.com/en-US/patients/health-conditions/mens-urology-resources/pru-reply-card.html

What should 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 AMS 700?

Your first resource is your doctor. Your doctor is most familiar with your medical situation and can work with you to achieve optimal results from the AMS 700. You can also call Boston Scientific at +1-800-328-3881, or visit our website at www.bostonscientific.com

MRI Safety Information

Table 3 provides the MRI parameters for patients with an AMS 700 IPP with TENACIO Pump. The patient may be safely scanned under these conditions regardless of cylinder type/size, reservoir type/size, RTEs, connector type, or if there is a tubing plug implemented. Failure to follow these conditions may result in injury.

Table 3. MRI parameters for patients with an AMS 700 IPP with TENACIO Pump.

Static Magnetic Field Strength (B_0)	1.5 T or 3.0 T
MR Scanner Type	Cylindrical
B_0 Field Orientation	Horizontal
Maximum Spatial Field Gradient	40 T/m (4,000 gauss/cm)
RF Excitation	Circularly Polarized (CP)
RF Transmit Coil Type	There are no Transmit Coil restrictions
RF Receive Coil Type	Any
Operating Mode	Normal Operating Mode

Maximum Whole-Body SAR	2 W/kg (Normal Operating Mode)
Scan Duration	2 W/kg whole-body average SAR for 60 minutes of continuous RF (a sequence or back-to-back series/scan without breaks)
MR Image Artifact	The presence of this implant may produce an image artifact that extends approximately 33 mm from the device

If information about a specific parameter is not included, there are no conditions associated with that parameter.

Report any serious incident that occurs in relation to this device to Boston Scientific and to the relevant local regulatory authority for medical devices in your country. For customers in Australia, report any serious incident that occurs in relation to this device to Boston Scientific and to the Therapeutic Goods Administration (https://www.tga.gov.au)

The Instructions for Use, which this Patient Guide relates to, is: 51558342.

Symbol Definitions

	Catalog Number
	Indicates the date the device must be implanted by.
	Lot Number
	Unique Device Identifier
	Magnetic Resonance Conditional
	Legal Manufacturer

REF This document is applicable to the following products:

720182-01	72404172	72404293	72404406	72404450	72404467
720185-01	72404173	72404294	72404407	72404451	72404468
72400095	72404174	72404320	72404408	72404452	72404469
72403872	72404175	72404321	72404420	72404453	72404480
72404010	72404241	72404322	72404429	72404455	72404481
72404011	72404242	72404323	72404430	72404456	72404482
72404012	72404243	72404324	72404431	72404457	72404483
72404013	72404244	72404325	72404432	72404458	72404484
72404014	72404271	72404326	72404433	72404460	72404485
72404043	72404272	72404330	72404434	72404461	72404486
72404155	72404273	72404400	72404435	72404462	72404487
72404156	72404274	72404401	72404436	72404463	72404488
72404161	72404275	72404402	72404437	72404464	72404489
72404162	72404291	72404403	72404438	72404465	72404850
72404171	72404292	72404405	72404439	72404466	