Score & Fold

Boston Scientific

AMS 800™
Artificial Urinary Sphincter (AUS)
Patient Guide for Male Patients

BSC (Patient Guide with Card, Custom Template 11.25in x 8in), Patient Guide, MB, AMS 800 Male, en, 51381641-01A

Score & Fold

Perforation

EC REP Boston Scientific Limited
Ballybrit Business Park
Galway IRELAND

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

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

CH REP Boston Scientific AG
Ritterquai 8
4500 Solothurn
Switzerland

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

www.IFU-BSCI.com

www.bostonscientific.com

CE 2797

2025-02

51381641-01

Score & Fold

Place deactivation package label here.

Place accessory kit label here.

MRI Safety Information:

MR Conditional up to 3.0 Tesla

This person is implanted with an AMS 800 AUS and can safely undergo an MRI exam only under very specific conditions. Scanning under different conditions may result in injury or device malfunction. MRI safety information is available in the AMS 800 AUS IFU, which can be obtained at www.IFU-BSCI.com or by calling +1-888-272-1001.

Security Screening:

The metal in your device may be detectable.

Consult urologist prior to urethral catheterization or other transurethral procedures to avoid damaging the AUS or surrounding tissues. This will require deactivating the device.

Score & Fold

Implanting Surgeon: _____

Surgeon Telephone: _____

Hospital: _____

To request a new Implant Card:

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

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

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

Score & Fold

Boston Scientific

Implant Card

AMS 800™
Artificial Urinary Sphincter (AUS)

Important Physician Information

This person has an AMS 800 Artificial Urinary Sphincter (AUS) implanted to treat urinary incontinence.

Patient Name: _____

Patient Telephone: _____

Implant Date: _____

Guide Outside Cover

Drawing 51381641

Black (K) ΔE ≤5.0 / CMYK Image

Design: The implant acts like the muscle that allows us to urinate. It has three parts – a cuff, a balloon, and a control pump **(Figure 1)**.

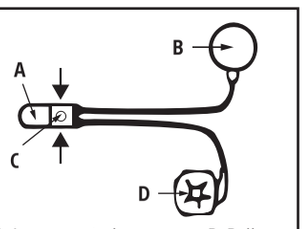
Location: Your cuff is implanted:
- ☐ at the bladder neck, OR
- ☐ at the bulbous urethra.

The cuff (D) encircles and gently compresses the urethra or bladder neck. The balloon (B) lies beneath the rectus muscle and the control pump (A and C) is implanted in the scrotum.

To urinate: Squeeze and release the lower pump area (A) until it feels flat. This deflates (opens) the cuff by transferring fluid from the cuff to the balloon. The bladder can now empty. When you stop squeezing the pump, the cuff refills with fluid. It takes several minutes before the cuff fully inflates, allowing time for the bladder to empty.

Caution: Before urethral catheterization or other transurethral procedures, deactivate (open) the cuff using the following procedure:

1. Squeeze the lower pump area 3-4 times until flat.
2. Allow the lower pump area to partially refill with fluid (about 30-60 seconds).
3. Firmly press the deactivation button (C) on the upper area of the control pump. A slight indentation will be felt at the center of the lower pump area.
4. To restore continence, grasp the pump tubing with one hand and use the other hand to push the deactivation button a few times (C). Then give the lower pump area (A) a quick, forceful squeeze while still holding the tubing. This will take several minutes.



A. Lower control pump area B. Balloon
C. Deactivation button D. Cuff

Figure 1. AMS 800 AUS

Place patient balloon label here.

Place patient cuff label here.

Place patient pump label here.

AMS 800™
Artificial Urinary Sphincter (AUS)

Patient Guide for Male Patients

Device Information

The AMS 800 Artificial Urinary Sphincter (AUS) is intended for use in the treatment of male urinary incontinence. Some AMS 800 AUS devices may contain anti-infection properties (device may be treated with InhibiZone (IZ) which is a combination of the drugs rifampin and minocycline HCl).

The AMS 800 AUS consists of three main parts: an occlusive cuff, a control pump, and a pressure-regulating balloon (PRB) **(Figure 1)**. These are connected by Kink Resistant Tubing (KRT) and are filled with fluid. The cuff works much like the muscle that helps us urinate, gently squeezing the urethra (urinary canal) closed to keep urine in the bladder.

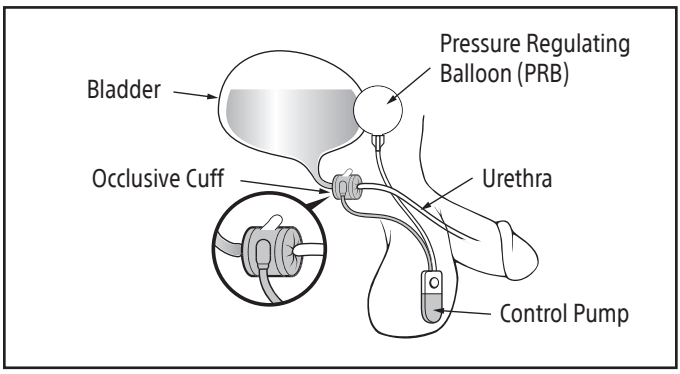


Figure 1. AMS 800 AUS implanted device parts

Indications for use

Indications for Use for Patients in the United States and Related Geographies Only

The AMS 800 AUS is used to treat urinary incontinence due to reduced outlet resistance (intrinsic sphincter deficiency) following prostate surgery.[1]

Indications for use for Patients Outside of the United States

The AMS 800 AUS is used to treat urinary incontinence due to reduced urethral/bladder outlet resistance (intrinsic sphincter deficiency) in adult males.

[1] Consult with your doctor if you have questions about your device as it relates to your treatment.

Contraindications

- This device is contraindicated in patients whom the physician determines to be poor candidates for surgical procedures and/or anesthesia due to physical or mental conditions.
- This device is contraindicated in patients with urinary incontinence due to or complicated by an irreversibly obstructed lower urinary tract.
- This device is contraindicated in patients with irresolvable detrusor hyperreflexia or bladder instability.
- The implantation of the InhibiZone version of this device is contraindicated in patients with known allergy or sensitivity to rifampin or to minocycline hydrochloride (HCl) or other tetracyclines.
- The implantation of products with InhibiZone is contraindicated in patients with systemic lupus erythematosus because minocycline HCl has been reported to aggravate this condition.

Patient contacting materials

The AMS 800 AUS, with and without InhibiZone, utilizes the same materials with the same surface areas. AMS 800 AUS with InhibiZone (including PRB, pump and cuff), regardless of configuration, contains ≤ 6.5 mg rifampin (CAS # 13292-46-1) and ≤8 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.

The following tables describe the materials that have long-term contact with patient tissue as part of the implanted device. Check with your doctor for which table applies to you.

Table 1: Configuration 1: AMS 800 AUS Device Assembly Using Quick Connect Window Connectors and Collets-Material Table

Implantable Material	Largest Surface Area (sq cm) Based on Device	% Patient Contacting Surface Area Implant Material / Total Implantable Patient Contacting Surface Area
Silicone Elastomer	286.4	94.5% - 96.7%
Adhesive Silicone	2.4	0.2% - 0.8%
Polyester	0.6	0.1% - 0.2%
Polyacetal	13.3	3.0% - 4.5%
Total Implantable	**296.2**	**100%**

Table 2. Configuration 2: AMS 800 AUS Device Assembly Using Suture Tie Connectors-Material Table

Implantable Material	Largest Surface Area (sq cm) Based on Device	% Patient Contacting Surface Area Implant Material / Total Implantable Patient Contacting Surface Area
Silicone Elastomer	282.7	98.6% - 99.5%
Adhesive Silicone	2.3	0.2% - 0.8%
Polyester	0.6	0.1% - 0.2%
Polysulfone	1.1	0.1% - 0.4%
Total Implantable	**284.1**	**100%**

Table 3. AMS 800 AUS Deactivation Package Plug Material

Tubing Plug Material	Area
Stainless Steel[2]	100%

[2]Implantable stainless steel is attributable to the tubing plug included in the Deactivation Package. The tubing plug is used to plug component kink resistant tubing in the event of revision (corrective) surgery when the physician decides to preserve and maintain that component.

Stainless steel contains cobalt: CAS No. 7440-48-4; EC No. 231-158-0. Defined as a 1B carcinogen and reproductive toxicant according to the European Commission in concentration above 0.1% weight by weight.

Based on animal studies, the European Commission has classified cobalt as a substance that may cause cancer, or interfere with normal reproduction. However, research shows that metal alloys containing cobalt used in medical devices do not cause an increased risk of these effects in humans. Talk to your doctor if you have questions about your device.

Expected lifetime and follow-up

The AMS 800 AUS is not intended to be a lifetime implant. As with any mechanical implant, the device is subject to wear through normal daily use. It is possible the system parts or the entire system may require replacement, deactivation, or removal over time.

The system reliability of the AMS 800 AUS, with and without InhibiZone, has been verified to be at least 29,220 cycles, which equates to 8 urinations per day over the course of 10 years. Results may vary based on your use.

Follow up with your doctor on a yearly basis to evaluate the function of the device. If you notice any changes in device function between annual visits, inform your doctor promptly.

What to expect after the procedure

You may have pain or discomfort at the surgery site(s) right after your operation. 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 talk to you about when you will be able to use your device.

It is important that the AMS 800 AUS cuff remain empty/deflated while you are healing following your surgery. Closely follow your doctor's instructions about the amount of time before activating the device. Contact your doctor if pain persists beyond the expected severity or duration as explained by your doctor. Pain with a severity or duration beyond what is expected may require surgical intervention.

Your doctor will discuss when you will be able to use your device. Most doctors recommend that you wait four to six weeks before using your device. This allows your incision site to heal and helps 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. Your doctor may want additional visits or follow-up after your 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 a surgical implant and choose your activities wisely. Trauma, such as falling or impact sports, may damage the device or the 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.

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

After the healing period, you should continue to have contact with your doctor at least on an annual basis to evaluate the function of the device and to check for signs of infection or erosion (breakdown of the tissue next to the implant).

Implant Card

Your doctor should provide you with an Implant Card that identifies your particular implant, and should be carried with you at all times. Your Implant Card should be presented to all your health care providers (doctors, dentists, technicians) so they know that you have an implanted 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. You may also contact the Patient Liaison at: U.S. Toll Free: +1-800-328-3881, Option 2.

Special precautions to take with your device before undergoing a medical procedure

It is important for healthcare providers to know that you have an AMS 800 AUS before you undergo any future medical procedure. This is especially true of any procedures which require the insertion of a catheter or any other instrument into the urethra. Such procedures can only be safely performed after your AMS 800 AUS has been deactivated (see the **Deactivating the AMS 800 AUS** section for instructions). Failure to deactivate the AMS 800 AUS before inserting a catheter or other instrument into the urethra can result in damage to the device and/or your urethra. It is possible that such damage could require removal of the device.

How to use my device

While cuff is closed, urine stays inside of the bladder **(Figure 2)**.

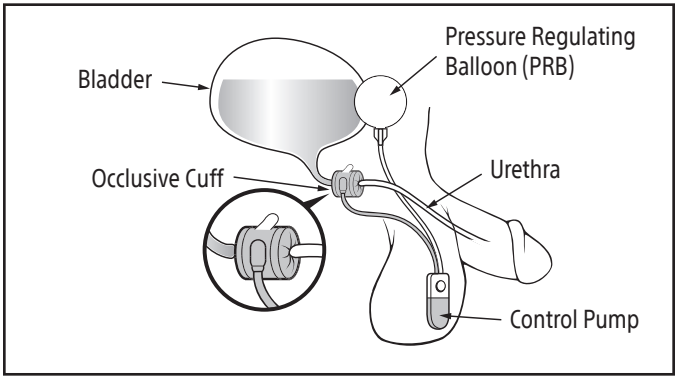


Figure 2. Fluid-filled cuff closes urethra

To urinate, the cuff is opened as follows:

1. Feel for the control pump **(Figure 3)** in your scrotum **(Figure 4)**.
2. With one hand, keep the control pump in place by gently grasping the tubing above the control pump **(Figure 4)**.

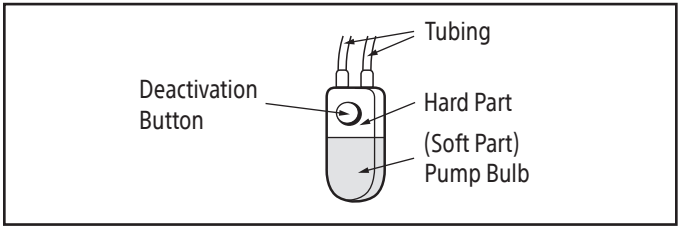


Figure 3. Parts of the control pump

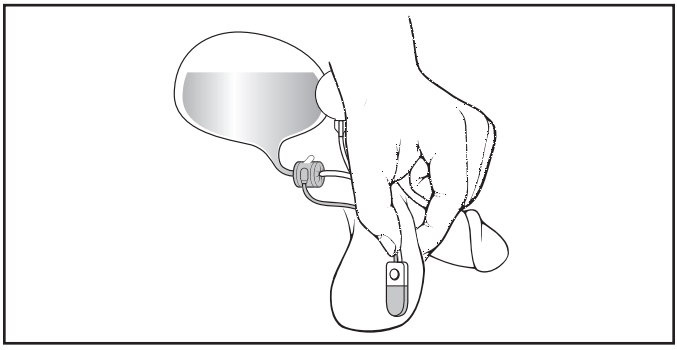


Figure 4. Locate control pump in scrotum and grasp tubing

3. Use the other hand to squeeze and release the lower, softer part of the control pump **(Figure 5)**. Do this several times until the control pump is flat.

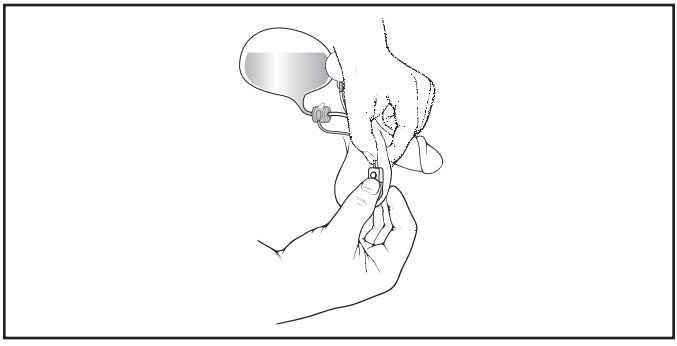


Figure 5. Squeeze pump bulb to urinate

When the lower part of the control pump is flat, it indicates that the fluid that filled the cuff has moved to the pressure-regulating balloon (PRB), deflating the cuff **(Figure 6)**. Once the cuff is deflated the urethra opens. If you have some control of the muscle that allows you to urinate, you may still have some level of control for urination once the cuff is deflated.

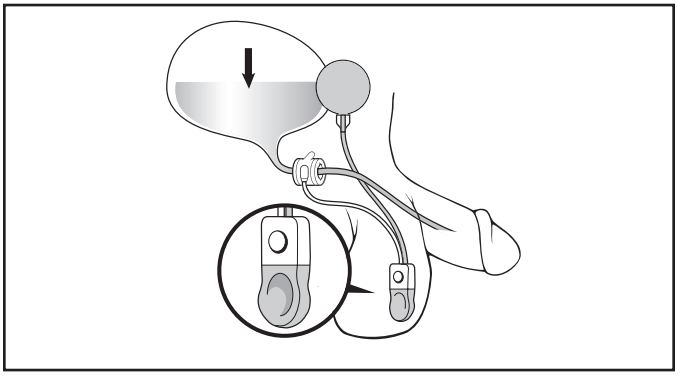


Figure 6. Empty cuff opens urethra

The pressure from the PRB pushes fluid back into the cuff. Once full, the cuff again squeezes the urethra closed. It usually takes several minutes for the cuff to be filled by the fluid (urethra to be re-closed), but each person is different. After using your AMS 800 AUS a few times, you will know how long it takes for your cuff to refill.

If you feel that you did not empty your bladder completely before the cuff refilled, give the soft part of the control pump a few more squeezes to re-open the urethra. It is a good idea to get into the habit of emptying your bladder on a regular basis, such as every two to three hours.

It is important to show someone else, such as your spouse, how to operate the AMS 800 AUS to assist you if needed.

Deactivating the AMS 800 AUS

The AMS 800 AUS has a deactivation button which stops the flow of the fluid from one device part to another. Your doctor may deactivate your device at various times, such as while you are healing following your surgery or before inserting a catheter or other instrument into your urethra.

To deactivate the AMS 800 AUS:

1. Squeeze and release the lower part of the control pump several times, just as you would do to urinate.

2. Allow the control pump bulb to partially refill (about 30-60 seconds).
3. When the control pump is partially refilled, firmly press the deactivation button on the top of the control pump. After pressing the deactivation button, you will still feel the button on the upper part of the pump.

Pressing the deactivation button locks out the flow of fluid through the control pump. When the device is properly deactivated, a slight indentation will be felt at the center of the soft part of the pump. The cuff will now remain open **(Figure 7)**.

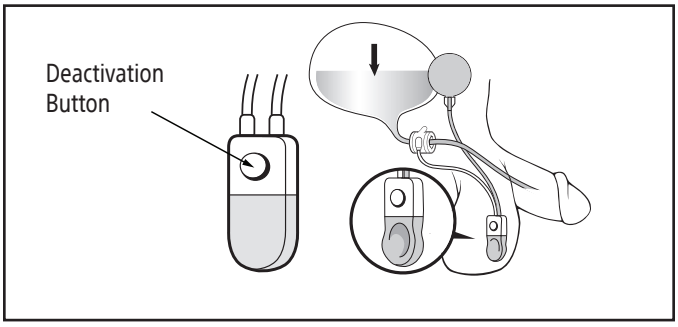


Figure 7. Deactivation button

When the AMS 800 AUS is deactivated, the cuff around your urethra will not stop the flow of urine. You should use pads while the AMS 800 AUS is deactivated.

Activating the AMS 800 AUS

To activate the AMS 800 AUS:

1. Grasp the pump tubing with one hand **(Figure 8)**.
2. Use the other hand to push the deactivation button a few times **(Figure 7)**.
3. Give the lower part of the control pump a quick, forceful squeeze while still holding the tubing **(Figure 8)**. This step may need to be repeated until the bulb is depressed in. Since greater pressure is required for activation than for normal operation, you may experience some discomfort while activating the device. This will allow the control pump to fill, and feel firm without an indentation. The system should now function normally.

Note: Do not stabilize the control pump by holding the deactivation button on the upper, harder part of the control pump during this step. Doing so will make proper activation very difficult.

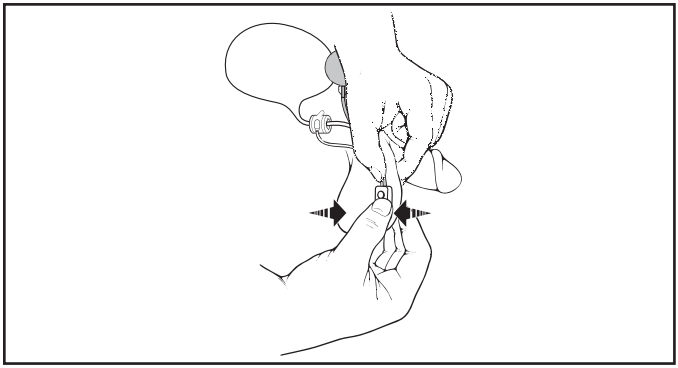


Figure 8. Forcefully squeeze pump bulb

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, swelling or rash near the incision
- Pus coming from the incision
- Fever
- Any problems with urination
- Any part of the device is visible through skin
- Unable to locate control pump
- Bleeding

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

Information on safe use

As a reference for you, some of the side effects, potential complications, and risks associated with surgical correction of urinary incontinence using an artificial urinary sphincter are listed below. You should consult your doctor for a complete understanding of this information.

Potential complications:

Potential complications that may occur related to the implantation and use of the AMS 800 AUS device include:

Adhesion (formation of fibrous band which binds surfaces together), Allergic reaction, Contracture (shortening of muscle), Deep vein thrombosis (formation of blood clots in deep veins), Dehiscence

(rupture of the wound), Dysuria (discomfort/pain when urinating), Edema (swelling), Erosion (wearing away or a state of being worn away, as by friction or pressure resulting in a breakdown of tissue), Exposure to biohazardous material, Fibrosis (scarring), Fistula (abnormal connection of two body cavities and/or parts), Foreign body/unretrieved device fragment (device and/or device fragments left inside body), Hematoma (localized collection of blood outside of blood vessel), Hematuria (blood in urine), Hemorrhage/bleeding, Herniation of the device through tissue (protrusion or movement of device through weak tissue or abnormal opening), Infection, Limited urethral coaptation (limited closing of the urethra) which may be due to device leak, sizing, malfunction, placement, or other causes, Malfunction (device failure), Malposition of parts (parts placed in an inappropriate position), Mechanical malfunction or mechanical difficulty, Migration of a component (device moving to another part of the body), Overactive bladder (loss of urine), Pain/discomfort, Prolonged procedure (device-related delay in the procedure), Unintended surgical damage (perforation or injury to the bladder, urethra, nerves, vessels, or other local structures), Urethral atrophy (wasting away of the urethra), Urethral stricture (narrowing of the urethra), Urinary retention, and Urinary urgency (sudden, uncontrollable need to void).

The following complications have been reported:

Impaired device function, Pain/discomfort, Delayed wound healing, Bladder spasms (bladder muscle contractions), Difficult activation, Migration (device moving to another area of the body from where it was initially implanted), Tissue erosion (wearing away or a state of being worn away, as by friction or pressure resulting in a breakdown of tissue), Difficult deactivation, Infection, Recurrent incontinence (recurrent involuntary leakage of urine), Fistula formation (abnormal connection of two body cavities and/or parts), Hematoma (localized collection of blood outside of blood vessel), Swelling, Hydrocele (swelling of the scrotum), Patient dissatisfaction, Positional incontinence (urine leakage when you sit or stand), Wound infection, and Urinary retention (inability to relieve yourself).

Risks associated with the AMS 800 AUS implant

Warnings

- Patients with urinary tract infections, diabetes, spinal cord injuries, open sores, or skin infections in the region of the surgery have an increased risk of infection associated with a prosthesis. Appropriate measures should be taken to reduce the likelihood of infection.
- Infection that fails to respond to antibiotic therapy may result in removal of the prosthesis.

- It is important for healthcare providers to know that you have an AMS 800 AUS before you undergo any future medical procedure. This is especially true of any procedures which require the insertion of a catheter or any other instrument into the urethra. Such procedures can only be safely performed after your AMS 800 AUS has been deactivated (see the **Deactivating the AMS 800 AUS** section). Failure to deactivate the AMS 800 AUS before inserting a catheter or other instrument into the urethra can result in damage to the device and/or your urethra. It is possible that such damage could require removal of the device.
- Infection followed by explantation of the device may result in scarring which may make subsequent reimplantation more difficult.
- Adequate manual dexterity, strength, motivation, and mental sharpness are required for proper use of the device. Surgical complications, or physical or psychological complications (such as any progressively degenerative disease), if they occur, may affect the use of the system. Continued improper use may lead to revision or removal of the device.
- Notify your doctor or surgeon if you have any changes in manual dexterity, strength, motivation, or mental sharpness.
- If you think you may be having an allergic reaction, notify your doctor or surgeon. These signs may include: redness, swelling, itching, rash, fever, shortness of breath, and wheezing.
- Removal of the device without timely implantation of a new device may complicate subsequent reimplantation. The timing of reimplantation should be determined by your doctor based on your medical condition and history.
- Any mechanical malfunction that does not permit the transfer of the fluid from the cuff to the balloon may result in an inability to urinate. Mechanical events should be evaluated carefully by your doctor, and you should be informed of the risks and benefits of treatment options, including removal or revision surgery.

Precautions

- The risk, if any, from temporary exposure to the InhibiZone antibiotics on the fertility of men of childbearing potential is unknown. If you are of childbearing age, you should weigh the benefit of using an InhibiZone-treated device (compared to using a non-InhibiZone device) to reduce the risk of infection during surgery.
- If you are taking methoxyflurane and have received a device with InhibiZone, consult your doctor to be carefully monitored for signs of renal toxicity.
- If you receive a device with InhibiZone and are also taking warfarin, you should have your prothrombin time monitored because

tetracyclines (e.g., minocycline, included in InhibiZone) have been reported to slow coagulation (clotting of blood).

- Always keep in mind that you have had a surgical implant and choose your activities wisely. Trauma or injury to the pelvic, groin, or abdominal areas, such as impact injuries associated with sports, can result in damage to the implanted device and/or surrounding tissues. This damage may result in the malfunction of the device and may necessitate surgical correction including replacement of the device.
- If the deactivation button is depressed when the cuff is inflated, fluid will stay in the cuff and you will not be able to urinate. If the deactivation button is depressed when the cuff is deflated, you will keep leaking urine. If either problem occurs, you will notice that the pump feels different from its normal status. You can activate the device to solve these problems. Please see the **Activating the AMS 800 AUS** section.

Frequently asked questions

Below are answers to some commonly asked questions about artificial urinary sphincters. Talk to your doctor about any additional questions you may have.

How long does it take to stop urine leakage after the procedure?

Most patients achieve stoppage of urine leaking once the device is activated. This typically occurs 4-6 weeks after the surgery, per your doctor's evaluation. Once the AMS 800 AUS is activated, your doctor will teach you how to use it to control your urination.

What happens if the deactivation button is squeezed accidentally?

The device will deactivate and two problems could occur. Fluid may not refill the cuff, so you will keep leaking urine, or fluid may lock in the cuff so you cannot urinate. If either problem occurs, you will notice that the pump feels different from its normal status. You can activate the device to solve these problems. Please see the **Activating the AMS 800 AUS** section.

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

It is important that your doctor knows that you have an AMS 800 AUS to prevent damage to the device and/or your urethra.

Can I go through security screening?

When you walk through security screening, your implant may be detectable by a metal detector or body scanner. If detected, tell the Security Officer that you have an implanted medical device. It is recommended that you show your Implant Card.

Magnetic Resonance Imaging (MRI) 

Safety Information

If you do not have an Implant Card, or if you have questions about your device as it relates to MRI or security screening, please ask your doctor or visit our website at www.bostonscientific.com.

MRI safety information – MR Conditional

Table 4 provides the MRI parameters for patients with the AMS 800 Artificial Urinary Sphincter (AUS), for both InhibiZone-treated and non InhibiZone-treated devices. Patients may be safely scanned using the information in the table below. If you require an MRI scan, inform your doctor or medical professional that you have the AMS 800 AUS implanted and the device is MR Conditional. Also show your Implant Card. **Failure to follow these conditions may result in injury.**

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

Table 4. AMS 800 AUS (IZ-treated and non-treated) MR Conditional Parameters

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 36 mm from the device.

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 AMS 800 AUS. You can also call Boston Scientific at +1-800-328-3881, Option 2, or visit our website at www.bostonscientific.com.

Reporting serious incidents

Report any serious incident that occurs in relation to this device to your healthcare provider, 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).

Related professional use documents: 51266568, 51266569.

Symbol definitions

The following symbols are used for patient information:

	Use-by date		Catalog number
	Lot Number		Unique Device Identifier
	MR Conditional		Manufacturer
	Contains hazardous substance		Date
	Patient identification		Health care center or doctor

REF

This document is applicable to the following products:

72400023	72400168	72404136
72400024	72400170	72404137
72400025	72400172	72404138
72400098	72400174	72404140
72400160	720133-01	72404142
72400161	72404127	72404144
72400162	72404130	720157-01
72400163	72404131	72400095
72400164	72404132	72401685
72400165	72404133	720066-01
72400166	72404134	
72400167	72404135	