Patient Information and Instructions for the

AMS Sphincter 800™ Urinary Control System

TABLE OF CONTENTS

GLOSSARY

BPH – Stands for Benign Prostatic Hyperplasia. BPH is the noncancerous growth of normal prostate tissue. BPH occurs in all men to some degree and is thought to be a natural part of aging.

Bladder instability – Involuntary bladder contractions that produce a strong desire to urinate and make it hard to hold urine. Often, this condition can be treated successfully with bladder training and medication.

Bladder neck – The place where the urethra and bladder connect.

Bulbous urethra – The curved, wider portion of the urethra that passes through the penis.

Cuff – The cuff surrounds the urethra or bladder neck.

Deactivation button – This small button can be felt on the upper, hard part of the pump.

Edema - Edema is when the tissue next to any part of the device is swollen. It is normal for some swelling to occur in the healing period after surgery.

Erosion – Erosion is when the tissue next to any part of the device is "worn away."

Incontinence (urinary) – The inability to control the storage or release of urine. Incontinence is not a disease, it is a symptom of some underlying health problem.

Infection – Infection can happen with any surgery. It occurs when bacteria or virus enter the body through the incisions. It can happen during surgery or after surgery when the wound is healing.

Irresolvable detrursor hyperreflexia – Similar to bladder instability except that it is caused by a nervous system disorder, like a stroke or multiple sclerosis.

Migration - Migration is the movement of the cuff, pump, or pressure-regulating balloon within the body space where they were originally placed. If migration occurs, it can cause pain, psychological/medical complications, or device malfunction.

Pressure-regulating balloon –The balloon is implanted in the space next to the bladder. This balloon contains fluid that refills the cuff to prevent the flow of urine.

Pump – The pump lies in the scrotum and can be felt through the skin. The lower part of the pump is soft and squeezable. The upper part of the pump is hard and contains the deactivation button. This pump opens the cuff to allow the flow of urine.

Reduced outlet resistance – A normal sphincter blocks the bladder outlet and stops urine flow. When the sphincter fails, this block on the bladder outlet is reduced and urine flow is not completely stopped. Reduced outlet resistance is also known as intrinsic sphincter deficiency (ISD).

Solid silicone elastomers – A rubber-like material used to make the device. Solid silicone elastomers have been extensively tested for use in the human body.

Sphincter – The urinary sphincter controls the flow or urine and is located in the area of the bladder neck and urethra. It opens when the bladder is full and shuts when the bladder is empty.

Scrotum – The sack of skin below your penis that contains the testicles.

Surgical revision – A surgery to replace or remove your implant.

Urethra – Canal through which urine leaves the body. The urethra begins at the bladder neck and passes through the prostate, sphincter, and penis.

URINARY INCONTINENCE IN MEN

Urinary **incontinence*** can occur following prostate surgery. For men, a radical prostatectomy (RP) to treat cancer is the most common cause of **incontinence.**[1] In order to remove the cancer, parts or all of the tissues that help control urine flow may need to be removed. The rate of incontinence following RP surgery ranges from 3% to 60%.[2,3] **Incontinence** is less frequent following prostate surgery to treat an enlarged prostate (benign prostatic hyperplasia or BPH). Severe incontinence following prostate surgery occurs in less than 5% of patients.[4,5] Several factors can affect rates of incontinence following prostate surgery including age, general health, and the amount of prostate and surrounding tissue removed during surgery. Patients often experience incontinence immediately following surgery but the leakage usually stops within weeks or a few months. When **incontinence** persists beyond a few months, it is difficult to tell if it will stop and you should consult your doctor.

Indication for use

The AMS Sphincter 800 is used to treat urinary incontinence due to **reduced outlet resistance** (intrinsic sphincter deficiency) following prostate surgery.

Contraindications

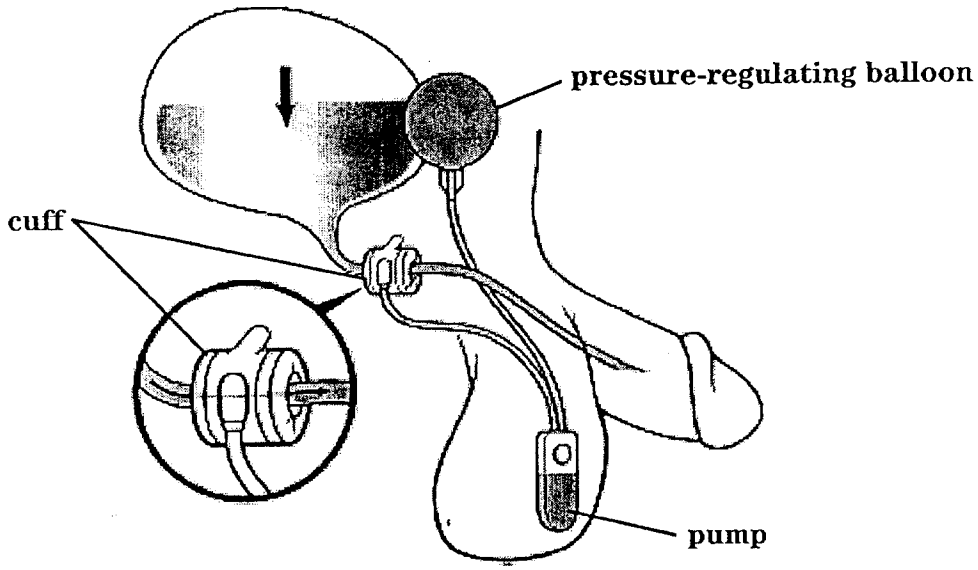
1. This device is contraindicated if your doctor determines you are a poor candidate for surgical procedures and/or anesthesia due to physical or mental conditions.
2. This device is contraindicated if your urinary **incontinence** is due to or complicated by an irreversibly blocked lower urinary tract.
3. This device is contraindicated if you have irresolvable detrusor hyperreflexia or **bladder instability.**
4. This device is contraindicated for individuals with certain pre-existing medical conditions.

Ask your doctor if you have questions about the indication and contraindications for the device.

* Note: Boldface words are defined in the glossary at the front of this booklet.

DESCRIPTION OF THE AMS SPHINCTER 800™

The AMS Sphincter 800 Urinary Control System is a small fluid-filled device that is implanted entirely within the body. The device is used in men who have urinary **incontinence** because of prostate surgery. It is designed to restore the natural process of urinary control. The device simulates normal **sphincter** function by opening and closing the **urethra** at the control of the patient. This device is made from **solid silicone elastomer** and consists of three parts connected by tubing: a **cuff**, a **pump**, and a **pressure-regulating balloon.**



The **cuff** is implanted at either the **bladder neck** or the **bulbous urethra.** The pump is placed in the scrotum. The soft and rounded lower part of the pump is the deflation site. When the patient wishes to urinate, he gently squeezes the soft and rounded lower part of the **pump**. The hard and rectangular shaped upper part of the **pump** is the deactivation site.

The **pressure-regulating balloon** is implanted in the lower abdomen, under the muscle layer, and is filled with sterile saline solution or a sterile solution that will be visible when x-rayed.

GENERAL WARNINGS AND CAUTIONS

Solid silicone elastomer safety

The AMS Sphincter 800 is made of **solid silicone elastomer** (a type of rubber). The AMS Sphincter 800 does not contain silicone gels. Silicone elastomers have been commonly used in many different types of biomedical devices for over 40 years.

Solid silicone elastomers also are used for comparison when a new material is being considered for use in a biomedical device. The new material is tested to see if it is as biocompatible (causes as few problems in living tissue) as silicone elastomers.

Scientific literature has included reports of adverse events in some patients with implantable silicone devices. These adverse events indicate allergic-like reactions or autoimmune-like symptoms. In an autoimmune reaction, the body's own immune cells may attack some or many of the body's own tissues by mistake. Even though these reactions or symptoms were seen in some patients, there has been no proof that the silicone elastomer caused them.

Silicone elastomer may sometimes lose tiny particles off its surface after it has been implanted. Sometimes these particles migrate (move) to lymph nodes in other parts of the body where the particles then stay. (Your lymph nodes are a normal part of your body's defense system against infection.) Medical journals, however, have indicated that particle migration has not resulted in any adverse effects to a patient's health [6,7].

Fluorosilicone (a silicone fluid) is also used as a lubricant in the device to reduce wear in the cuff. Silicone fluids have a large history of use in medical devices, such as lubricating hypodermic syringes.

Device replacement

It is not possible to predict how long an implanted urinary device will function in a particular patient. As with any biomedical device, implanted urinary devices are subject to wear and eventual malfunction over time. Therefore, they should not be considered lifetime implants. The outcome of your implant surgery may be unsuccessful. For example, the device may fail to function or a surgical complication may occur. Carefully review the section *Problems that may Develop* (page 11) so you understand possible outcomes from your implant surgery. Discuss with your doctor any questions you have regarding problems that may develop following your implant surgery.

ALTERNATIVE TREATMENT OPTIONS FOR INCONTINENCE

People with **incontinence** can manage accidental urination by using a number of different options.

Absorbent products

Absorbent pads, diapers and garments can help individuals to deal with bladder control problems. However, absorbent products should not be employed for long-term bladder control unless a physician has evaluated the patient's incontinence. In particular, early reliance on absorbent pads may be a stumbling block for bladder control. The wearer may develop a sense of security and acceptance of the condition, which could lessen the desire to seek adequate diagnosis and treatment.

Internal collection devices

An internal collection device, such as a catheter (a hollow plastic tube), may be recommended for certain individuals to ensure that the bladder is emptied on a regular schedule and does not overfill. Intermittent catheterization (the periodic insertion of a catheter into the urethra and into the bladder) is performed at regular intervals each day (usually every 3 to 6 hours).

External devices

External collection devices, such as external catheters, are urine storage products that may be useful for short-term incontinence treatment in men. They are attached to the shaft of the penis by adhesive, latex or foam strap devices, and a tube to a urine-collecting bag connects them.

For men, external occluding (closing) devices can be used to block the flow of urine by squeezing the **urethra** shut or plugging the **urethra.** Mechanical devices include penile clamps (e.g., the Cunningham clamp) and compression rings. The penile clamp is a V-shaped casing with a foam cushion that fits over and under the penis. When closed, the penile clamp should stop the flow of urine without causing discomfort. Compression devices are adjustable rings that surround the penis and, when inflated with air, pinch off the urine flow. Improper use of penile clamps and compression devices can result in penile and urethral erosion, penile edema (swelling), pain and obstruction.

Biofeedback/Electrical stimulation

Biofeedback/electrical stimulation is practiced to help people gain awareness and control of their urinary tract muscles. The principle of biofeedback is simple: a variety of instruments are used to record small electrical signals that are given off when specific muscles are squeezed to urinate. These muscle squeezings are converted into audio (hearing) and/or visual (seeing) signs that patients can recognize and learn in order to control muscular activity. With biofeedback, weak muscles can be better activated on demand, overly tense muscles can be relaxed, and overall muscle activity can be coordinated.

PATIENT EXPECTATIONS

Patients should be counseled in order to have a realistic expectation of the physical, psychological, and functional outcome of the implantation. The risks, benefits and potential adverse events of all available treatment options should be discussed with the patient and considered by the physician and patient when choosing a treatment option.

After receiving an AMS Sphincter 800, you can expect an improvement in your continence status and an improvement in your quality of life. In two recent clinical studies conducted by AMS to support FDA marketing approval, 85% to 97% of patients with severe incontinence following prostate surgery reported being dry or little leakage (1-3 pads a day) after implant with the Sphincter 800. The results from the two studies are consistent with results reported in medical journals. These reports showed that continence improved for 74% to 94% of patients treated with the device.[8,9,10] The two clinical studies also showed that the Sphincter 800 had a positive impact on the quality of life for most men treated with the device. The results from the clinical studies matched results reported in medical journals that show quality of life improved for about 80% of men who received the Sphincter 800.

Some patients may become dissatisfied by the presence of the device in their body. This issue should be discussed with your doctor prior to the surgery. Patient dissatisfaction may lead to device removal. Patients should also be aware that the AMS Sphincter 800 is not a lifetime implant and the possibility of device malfunction exists. Your doctor will advise you regarding treatment for these situations.

Not all patients become completely dry following surgery. Some patients may have some degree of incontinence following surgery. Discuss this possibility with your doctor as well as methods of managing this leaking should it occur.

WHAT TO EXPECT DURING AND AFTER IMPLANT SURGERY

Your doctor will give you a general or spinal anesthesia. You will be asked to abstain from food or drink for 12 hours before the surgery. Additionally, your doctor will prescribe antibiotics for you to take before the surgery to help reduce the risk of infection. The procedure to implant the AMS Sphincter 800 usually lasts 30 to 90 minutes. The hospital stay lasts 1 to 2 days following surgery. Full recovery from surgery takes from 4 to 6 weeks. You will be able to resume most daily activities within 2 to 3 weeks after leaving the hospital.

The surgical method

Your doctor should be able to give you a thorough explanation of what will happen during the surgery and the rest of your hospital stay. In general, the procedure begins with some preoperative tests, which may include blood tests, urine analysis, and delivery of antibiotics.

The **cuff** can be placed in one of two areas. Depending on your physical condition, your doctor may choose to place the **cuff** around your **bladder neck** or **bulbous urethra.** If the **cuff** will be placed at the **bulbous urethra,** your doctor will make an incision in your perineum (this is the area between your scrotum and anus). If the **cuff** will be placed at the **bladder neck,** your doctor will make an incision in the lower abdomen. After the incision is made, your doctor will then locate the **urethra** and measure its circumference to choose the correct cuff size for you

Next, your doctor will place the **pressure-regulating balloon** through a small incision in the lower abdomen.

Finally, before closing the incisions, the control **pump** will be placed in the scrotum and all the components will be filled and connected.

Device deactivation

Your doctor will "lock" the device with the **cuff** in an open condition (deactivated) during the healing phase following the surgery. Your doctor will instruct you or assist you regarding the method of activation after healing.

AFTER YOUR SURGERY

After the surgery, your doctor may insert a catheter into the **urethra** before the incision is closed. The length of time the catheter is left in place is up to the discretion of your doctor. Your doctor may also ask for ice packs to be placed in the region of the pump to reduce any swelling. Your doctor may ask you to use absorbent pads or a condom catheter until the device is activated in 4 to 6 weeks after the surgery. This time allows your incision to heal. You will probably have an appointment with your doctor during this time to be sure you are healing properly.

After you are released from the hospital, you may be advised to avoid putting any pressure around the incision area during your recovery from surgery.

Recovery times vary from patient to patient. You can begin walking and eating your normal diet before leaving the hospital. You will be able to return to work and everyday activities (exercise, showering, driving) at the direction of your doctor. You should avoid heavy lifting for six weeks following surgery. Your doctor will talk to you about when you can start using your device, typically 4 to 6 weeks following surgery. You will have an appointment with your doctor to activate the device for the first time. During this recovery time and after, take care to avoid trauma (injury) to the pelvic or abdominal area. Always keep in mind that you have a surgical implant and choose your activities wisely. Examples of such trauma may include a seat belt jolt from a car accident, a tackle in a contact sport, or a slip and fall. Trauma may damage the device or surrounding tissues.

Infection - Infection can happen after any kind of surgery. Your doctor will try to lower your risk by giving you antibiotics before and after your operation and by flushing (washing out) the surgical site with antibiotics during surgery. Some conditions increase the risk of getting an infection:

- diabetes
- a spinal cord injury
- open sores
- an existing skin infection near the incision site
- an existing urinary tract infection

Infection in the prospective clinical study (Study 1) was 7%, with 4.7% of infections leading to revision over a period of 24 months. Infection leading to revision in the retrospective clinical study (Study 3) was 6.7% over a period up to ten years. If you get an infection that cannot be treated successfully with antibiotics, your doctor may have to remove the device. It may not be possible to implant a new one.

Warning: Contact your doctor immediately if you notice any redness, swelling, and/or heat around the incision area or drainage from the incision. These symptoms may indicate an infection.

Erosion - Erosion is when the tissue next to any part of the device is "worn away." Conditions that can cause erosion include:

- infection
- pressure on the tissue, cutting off the blood supply
- improper sizing
- prior tissue damage
- misplacement of the cuff, pressure regulating balloon, or pump

The **pump** may erode through the skin of the scrotum. **The pressure-regulating balloon** can erode into the bladder or bowel.

Symptoms of erosion into the **scrotum** may include pain, redness of skin, tenderness over the involved part, changes in skin texture, drainage, and/or being able to see the device through the skin after having been symptom free. Erosion into the bladder may result in pain, tenderness in bladder area, a change in your ability to urinate or a change in the color of urine. In Study 1, 3.5% of patients had erosion that led to more surgery. Erosion leading to more surgery Study 3 was 16.2% over a period up to ten years.

Warning: Contact your doctor immediately if you notice any pain, tenderness over part of the device, change in skin texture, drainage, or if you can see the device through your skin. These symptoms may indicate erosion. Failure to treat the erosion can make it worse and lead to infection and loss of tissue.

Your doctor must evaluate any possible erosion. Sometimes the tissue can be repaired and only part of the device replaced. Other times the entire device must be removed.

Trauma - Trauma (injury) to the hip or stomach area can cause damage to either the device or the surrounding tissue in your scrotum or abdomen. This can cause the device to malfunction and could require surgery to replace it. Some things you can do to decrease possible damage are:

- avoid contact sports where you might be tackled
- take extra precautions to prevent slipping and falling

Pain - It is normal to have some pain in your **scrotum** or abdomen immediately after surgery and when you first start using the device. Pain following surgery usually lasts no more than four to seven days, and can be controlled with pain medications recommended or prescribed by your doctor.

Warning: Contact your doctor if you have pain that is very severe or if it lasts longer than expected. Such pain may be a symptom of a medical condition or mechanical device malfunction.

Some patients have had chronic (continuing) pain with no known medical cause. Sometimes these patients have chosen to have the device removed because the pain would not go away. About 15% of patients in Study 1 reported pain. Less than 1.5% of these patients had pain that lead, at least in part, to more surgery up to two years following implant. Pain leading to more surgery in Study 3 was 1.4% over a period up to ten years.

Migration - Migration is the movement of the **cuff, pump,** or **pressure-regulating balloon** within the body space where they were originally placed. If migration occurs, it can cause pain, psychological/medical complications, or device malfunction. Migration may need to be corrected with surgery. Causes of migration include:

- improperly-sized cuff
- improper positioning of the pump or pressure regulating balloon
- incorrect tubing length

Warning: Contact your doctor if any part of the device is visible through your skin or if you cannot locate the pump in your scrotum.

Migration in Study 1 was 3.4%, with 1.2% of the events leading to more surgery. Migration leading to more surgery in Study 3 was 1.2% over a period up to ten years.

Mechanical problems - Product wear (the use of the device over a period of time) or other mechanical problems may occur over time. Surgery may be required to correct the problem. Mechanical problems may include a leak in any of the components.

Mechanical problems in Study 1 occurred in 7.0% of patients, with 4.7% of the events leading to more surgery. Mechanical problems leading to more surgery in Study 3 were reported in 10.6% of patients over a period up to ten years.

Recurrent incontinence – Most patients see a noticeable improvement in continence after receiving the device. In some cases, leakage slowly returns over time. This may be due to changes in the size of the urethra, a mechanical problem, or damage to the device due to trauma or improper medical intervention. In most cases, recurrent **incontinence** signals that an underlying problem exists. Contact your doctor if your **incontinence** gets worse after the device was implanted. Recurrent **incontinence** in Study 1 occurred in 8.2% of patients, with 4.7% of the reports associated with more surgery. Recurrent **incontinence** associated with more surgery in Study 3 was 27% over a period up to ten years.

Edema - Edema is when the tissue next to any part of the device is swollen. It is normal for some swelling to occur in the healing period after surgery. About 6% of patients in Study 1 and 9.5% of patients in Study 3 reported swelling.

Bruising or discoloration of the skin - It is normal to have some bruising after surgery. About 1% of patients in both studies 1 and 3 reported bruising to their doctors.

Obvious redness of the scrotum - It is normal to have some redness of the skin around the implant after the surgery. However, extreme redness should be reported to your doctor.

Please ask your doctor for an explanation of any problems that you do not understand.

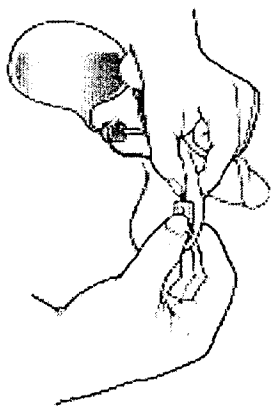
OPERATING INSTRUCTIONS

Opening the cuff to urinate

The AMS Sphincter 800 requires some manual dexterity and strength to operate the pump, which controls the device.

To urinate, open the cuff by squeezing and releasing the soft rounded pump bulb several times. This moves the fluid out of the cuff and into the balloon. Because the empty cuff does not press the urethra closed, urine can flow from the bladder.

1. Feel for the pump in your scrotum.
2. With one hand, gently grasp the tubing above the pump to hold the pump in place.
3. With the other hand, squeeze and release the lower, soft part of the pump several times until it remains flat.



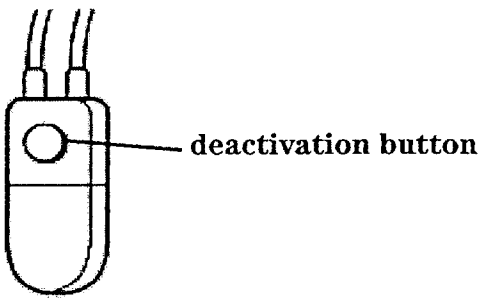
When the lower part of the pump is flat, the cuff is open, and you are able to urinate.

Closing the cuff to keep urine in the bladder

You do not need to do anything to refill the cuff after you urinate. The fluid will automatically return from the balloon to the cuff within several minutes, and the cuff will squeeze the **bladder neck** or urethra closed.

Activating and deactivating your Sphincter 800

Activating the device means turning on the Sphincter 800; deactivating means turning it off. Your Sphincter 800 can easily be deactivated by pushing the deactivation button located on the upper, hard part of the pump, NOT the soft, squeezable lower part.



If the deactivation button is pushed after squeezing the pump and draining the fluid from the cuff, fluid will be locked out of the cuff and the cuff will not refill.

This means you will be unable to control the flow of urine, since the cuff will not be pressing on the urethra and stopping the flow of urine from your bladder. You can use pads for your incontinence while the Sphincter 800 is deactivated.

When should my Sphincter 800 be deactivated?

Your doctor may deactivate your device at various times, such as while you are healing from surgery. Your doctor may also instruct you to deactivate your device at night, to give your urethra a rest from the pressure of the cuff.

It is extremely important to let other healthcare professionals know that you have a Sphincter 800 so they can take precautions when treating you. If you ever need to have a catheter inserted into the bladder, the Sphincter 800 *must be deactivated before placing the catheter.* If not, you risk an injury to your urethra and damage to your device.

What should I do if I accidentally deactivate my Sphincter 800?

You could accidentally press the deactivation button and deactivate your Sphincter 800. As a result, one of two things could happen:

1. Fluid will completely drain from the cuff and urine will leak out. In this case, the pump will feel hard.
2. Fluid will get trapped in the cuff, so you could not urinate. In this case, the pump will feel flat.

Neither situation is serious, and you can fix the problem by calling your doctor or by reactivating your Sphincter 800 by yourself. To reactivate your Sphincter 800, follow these simple steps.

First, determine what the problem is by deciding whether the pump feels harder than usual or flat. Then, follow the appropriate steps for the problem.

If the lower, soft part of the pump feels harder than usual:

- With one hand, grasp the tubing above the pump to hold the pump in place.
- With the other hand, give the lower part of the pump a quick, forceful squeeze.
- Squeeze the pump several times as you normally would to urinate.
- You may experience pain while activating the device.
- Contact your doctor right away if you cannot activate the device.

If the lower, soft part of the pump is squeezed flat and doesn't refill as it normally does:

- With one hand, grasp the tubing above the pump to hold the pump in place.
- With your other hand, squeeze the sides of the upper, hard part of the pump, opposite the button. Use hard, steady pressure.
- When the lower part of the pump is hard and filled with fluid, give the lower part of the pump a quick, forceful squeeze.
- This step may need to be repeated if not successful the first time.
- You may experience pain while activating the device.
- Contact your doctor right away if you cannot activate the device.

TROUBLESHOOTING

Signs and Symptoms That May Develop After Surgery		
Symptom	**Problem**	**What to do***
Pain.	Pain is fairly typical in first 4-6 weeks after surgery. If pain is persistent and severe, the cause may be infection or another problem.	If not severe, take prescribed pain medication or analgesic. If severe, contact your doctor.
Pain. Discharge from incision. Redness, swelling.	Infection.	Contact your doctor.
Any part of device visible through skin.	Erosion.	Contact your doctor.
Cuff surface can be seen through the skin.	Erosion of the cuff.	Contact your doctor.
Pump surface can be seen through scrotum.	Erosion of pump.	Contact your doctor.
Balloon surface can be seen.	Erosion of balloon.	Contact your doctor.
Unable to locate pump.	Migration.	Contact your doctor.
Unable to pump.	Possible accidental deactivation.	Review device activation instructions on page 17. If still unable to pump, contact your doctor.
Unable to urinate.	Pump problem.	Contact your doctor.
Pain. Skin disruption (opening). Leaking of body fluids. Bruising.	Trauma.	Contact your doctor.

*These suggestions always are subject to your doctor's instructions.

SUMMARY

The entire manual should be read before operating your device. This summary is for reference and is not meant to replace the complete instructions found in this manual.

Opening the cuff

Your implanted urinary device requires some manual dexterity and strength to operate the pump.

1. Feel for the pump in your scrotum
2. With one hand, gently grasp the tubing above the pump to hold the pump in place.
3. With the other hand, squeeze and release the lower, soft part of the pump several times until it remains flat.

Closing the cuff

You do not need to do anything to close the cuff after you urinate. The fluid will automatically return from the balloon to fill the cuff within several minutes, and the cuff will squeeze the **bladder neck** or urethra closed.

Problems that may develop

The possibility of leakage, blockage, or device problem exists. Discuss any changes you notice in the function of your device with your doctor.

Contact your doctor immediately if there is:

- redness
- swelling
- heat around the incision area or drainage from the incision (symptoms of erosion)
- if your pain is very severe or lasts longer than expected
- if any part of your device is visible through your skin or
- if you cannot locate the pump in your scrotum

INDEX

REFERENCES

[1] Blaivas JG. Conquering Bladder and Prostate Problems. New York: Plenum Publishing Corporation, p. 208.

[2] Litwin MS et al. Quality of life Outcomes in Men Treated for Localized Prostate Cancer. *Journal of American Medical Association* 1995; 273:129.

[3] Herr HW. Quality of Life of Incontinent Men after Radical Prostatectomy. *Journal of Urology* 1994; 151:652.

[4] Krane RJ. Urinary Incontinence after Treatment for Localized Prostate Cancer. *Molecular Urology* 2000; volume 4, 3:279-286.

[5] Mulcahy JJ. Tips for Successful Placement of the Artificial Urinary Sphincter. *Contemporary Urology* Sept. 1999; 46-51.

[6] Barrett DM, O'Sullivan DC, Malizia AA, Reiman HM and Abell-Aleff PC. Particle Shedding and Migration from Silicone Genitourinary Prosthetic Devices. *Journal of Urology* 1991; 146: 319-322.

[7] Reinberg Y. Silicone Shedding from Artificial Urinary Sphincter in Children. *Journal of Urology* 1993; 150:694-696.

[8] Elliott DS, Barrett DM. Mayo Clinic Long-term Analysis of the Functional Durability of the AMS 800 Artificial Urinary Sphincter: A Review of 323 Cases. *Journal of Urology* 1998; 159:1206-1208

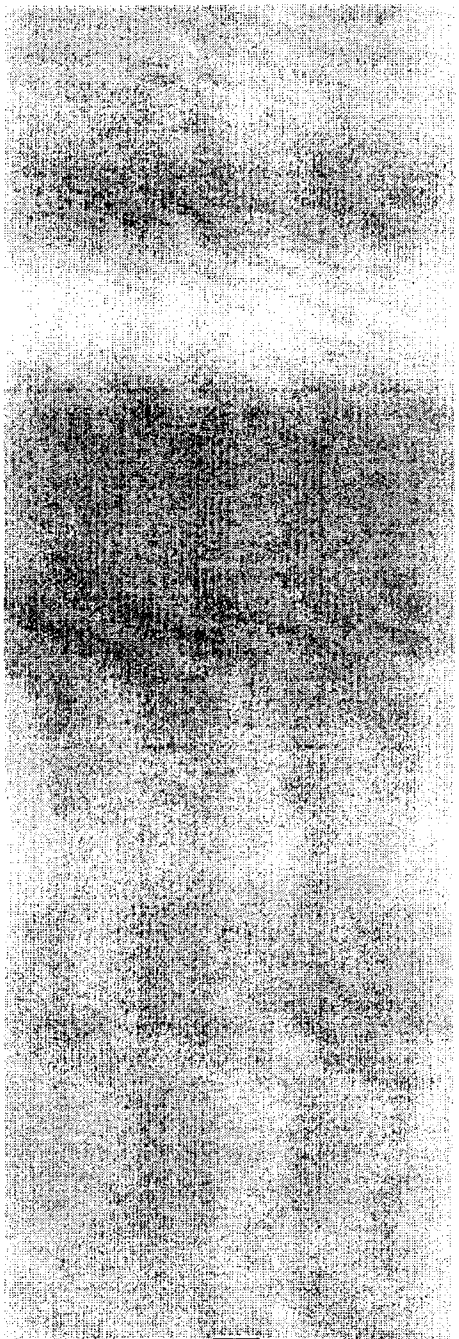
[9] Gouse AE, et al. Artificial urinary sphincter for the treatment of post radical prostatectomy urinary incontinence: long-term outcome results. *Journal of Urology* May 1996; 155(5):582

[10] Marks JL, Light JK. Management of Urinary Incontinence after Prostatectomy with the Artificial Urinary Sphincter. *Journal of Urology* 1989; 142(8):302-304.

[11] Haab F, Trockman BA, Zimmern PE, Leach GE. Continence and Quality of Life after the Artificial Urinary Sphincter: Minimum 3.5 years follow-up. *Journal of Urology* 1997; 158:435-439.

[12] Litwiller SE, Kim KB, Fone PD, DeVere White RW, Stone AR. Post-Prostatectomy Incontinence and the Artificial Urinary Sphincter: A Long-term Study of Patient Satisfaction and Criteria for Success. *Journal of Urology,* 1996; 156:1975-80.

9/



AMERICAN
MEDICAL
SYSTEMS

10700 Bren Road West
Minnetonka, MN 55343
Tel: 952.933.4666
Toll Free: 800.328.3881
Fax: 952.930.6157
www.visitAMS.com
A Publicly Traded Company
(NASDAQ:AMMD)

Order Number: 23600013D (09/01)