Information and Instructions for

Patients Considering *an*

AMS Ambicor®

Penile Prostheses

American Medical Systems

Table of contents

1 WHAT IS ERECTILE DYSFUNCTION?

Male Erectile Dysfunction, also known as impotence, is the inability to maintain an erection that is firm enough or that lasts long enough to have successful intercourse.

Erectile dysfunction is a frustrating condition that may have either physical or psychological causes. Impotence is also common. One out of ten men is affected by continuing or chronic erectile dysfunction.

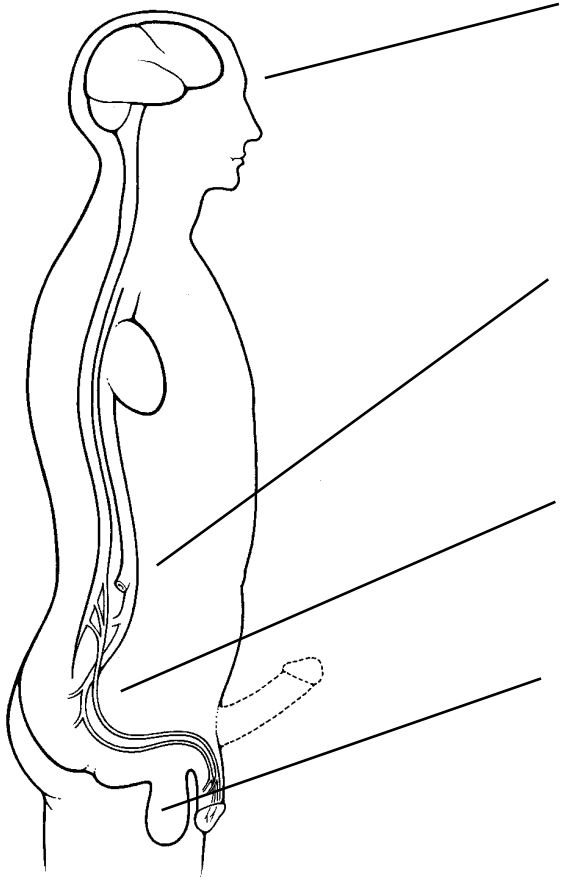
There are other types of sexual problems that are sometimes confused with erectile dysfunction. For instance, premature ejaculation is not a sign of erectile dysfunction, nor is low sex drive. The fact that you may need manual or oral stimulation to get an erection is not a sign of erectile dysfunction.

Erectile dysfunction is not caused by too much sex or by masturbation when you were younger. Erectile dysfunction is not related to infertility. Most importantly, erectile dysfunction is not "normal" at any age.

Erectile dysfunction can be devastating to those who have it. It can also be very hard to talk about. The first step is to seek professional help. A doctor that regularly treats erectile dysfunction has heard all about erectile dysfunction concerns from other patients and will not be uncomfortable with the topic.

1.1 How does an erection occur?

For an erection to occur, several parts of the body must work together. The brain sends messages to control the nerves, hormone levels, blood flow, and muscles that cause an erection. If anything interferes with one or more of these messages, or if any part of the system doesn't function correctly, an erection will not occur.



The brain controls all sexual functions, from being aroused to starting and controlling the psychological, hormonal, nerve, and blood flow changes that lead to an erection.

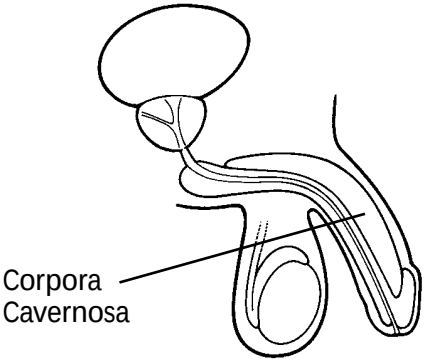
Arteries deliver the extra blood to the penis that causes it to stiffen. Veins then drain the blood out of the penis after intercourse.

Nerve impulses relay signals of arousal and sensation to and from the penis.

Hormones, including testosterone, control the male sex drive. Testosterone is secreted by the testicles.

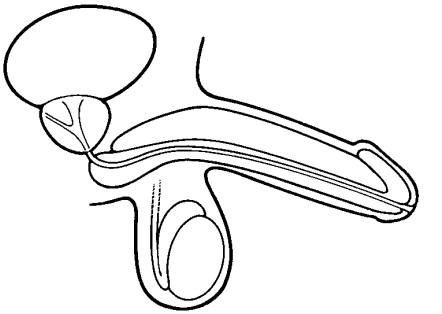
The flaccid penis

The shaft of the penis contains the corpora cavernosa, two channels which run the full length of the penis and into the pelvis. These channels are rich in special blood vessels which contain relatively little blood when the penis is flaccid (soft, relaxed, not enlarged). Without sexual stimulation, the penis remains flaccid.



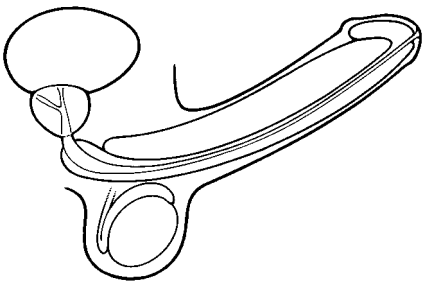
The tumescent penis

When the brain is sexually aroused, it stimulates the nervous system to enlarge the blood vessels in the corpora cavernosa, making room for extra blood. The corpora cavernosa absorb arterial blood flow like a sponge. At this point the penis is swollen, but not yet rigid (hard) enough for intercourse.



The erect penis

As the corpora cavernosa continue to absorb blood, the swelling puts pressure on the veins in the penis. This traps the blood in the corpora cavernosa, making the penis rigid (hard).



1.2 Impotence is common

Most men occasionally have difficulty getting an erection. However, about one in ten men are afflicted by chronic (continuing) impotence.

Impotence can be devastating to those affected by it. Unfortunately, it can also be very difficult to talk about. But the first step is to seek professional help. If your doctor regularly treats impotence problems, you can be sure that any question you ask will be one he has heard before from other patients.

1.3 Impotence is treatable

In more than half of all impotence cases the cause is physical – the result of diabetes, blocked arteries, a hormone problem, or other causes. In other cases, the cause could be psychological – the result of stress or depression. And in many cases, physical causes can produce psychological side effects.

Diagnosing the cause is the first step before recommending a treatment. Your doctor will require a thorough history, physical examination, and laboratory tests to determine whether the impotence has a physical or psychological cause.

The good news is that there are treatments available. And there is usually more than one option. Choices may range from sex counseling or marriage counseling, to medical and surgical treatments. Your doctor can determine which treatment alternative is appropriate for you. Most impotence problems can be treated successfully.

2 CAUSES OF IMPOTENCE

2.1 Psychological causes

Depression can cause a lack of energy and a reduced sex drive. This may result in an occasional inability to get an erection. If this happens, you may become even more depressed. This can lead to impotence. The first step is to treat the depression.

Stress can also result in an occasional inability to get an erection. Stress can be caused by your job, marital, financial, or other situations. Like depression, this inability to have an erection adds to the stress and can lead to impotence.

Performance anxiety (fear that you will fail if you try to have intercourse) happens to most men once in a while. If it keeps happening it can lead to the inability to have an erection and, ultimately, impotence.

Misinformation about sexuality and about how men should or shouldn't be able to "perform" at a certain age can lead to anxiety and stress, which can lead to impotence.

To treat a psychological cause, your doctor may recommend that you seek treatment from a qualified psychologist, psychiatrist, sex therapist, or marriage counselor. Counseling can often resolve the psychological problem causing impotence or be part of the recommended treatment. You and your partner may wish to go through counseling together.

Even if the problem is physical, there may be psychological side effects. Therefore, counseling may also be part of the recommended treatment for a physical problem.

2.2 Physical causes

Diabetes can cause damage to the nerves or blood vessels that control the flow of blood to the penis. In some cases, keeping your diet and blood sugar under control can help. But permanent damage to these nerves and vessels may result in chronic (continuing) impotence.

Cardiovascular problems, such as hardening of the arteries, can decrease the blood flowing into the penis. This makes it difficult for you to get or keep an erection. In other cases, the veins that keep the blood in the penis during an erection are damaged. If this happens, you cannot keep the erection long enough for sexual intercourse. Impotence can also occur if the nerves that control this flow of blood to the penis are damaged by lack of blood.

Trauma (injury) or **pelvic surgery,** including cancer surgery in the prostate, bladder, colon or rectal area, can cause impotence. In cancer surgery, the surgeon's most important goal is to remove all of the cancer. Nerves and blood vessels that control erections may be near the cancerous tissue. Sometimes these are damaged in an effort to remove the cancer.

Neurological disorders such as spinal cord injuries can cause impotence. The spinal cord is the relay center for nerve impulses, brain messages, and blood flow. When the spinal cord is damaged in certain locations, messages can't get through to the nerves of the penis, causing impotence.

Medications may cause impotence by interfering with the nerve impulses or blood flow to the penis. These medications include some prescriptions for high blood pressure, depression and a number of other conditions. Sometimes a change in the medication or the dosage will decrease the risk of impotence.

Caution: Medications should never be changed without the doctor's permission.

Alcoholism changes hormone levels and can lead to permanent nerve damage, causing impotence. This type of impotence may be reversible, depending on the severity of the nerve damage.

Hormone problems are rarely the cause of impotence, but certain diseases can change the balance of hormones which control erections. Kidney failure and liver disease are among these conditions.

3 AM I IMPOTENT?

If, after reading this, you are still questioning whether or not you are impotent and what the cause may be, the following questions may indicate whether you should consult a urologist, a doctor who specializes in treating problems associated with the urinary tract. In general, if you answer "yes" to any of the first six questions, you should see a urologist who specializes in the treatment of impotence.

If your current doctor does not regularly treat impotence problems, you might ask for a referral to a urologist who specializes in the diagnosis and treatment of impotence.

When you see the urologist, share the answers from the following self-test. This information will be valuable to the doctor as he or she determines a diagnosis.

Most importantly, you should know that continuing impotence is not a problem that you should have to live with, or that will just go away. It's important to make a medical appointment as soon as the problem becomes apparent. It is important so that you can help avoid the psychological problems that may make it worse. Remember that impotence can be treated in almost every case.

3.1 Impotence self-test*

Current Sexual Performance

1. Have you had any difficulty recently in achieving erections?
2. Does this problem occur at least three out of every four times that you attempt intercourse?

Sexual Performance Trends

3. Have you been having difficulty for longer than one month in achieving erections regularly?
4. Are morning and spontaneous erections becoming less common?
5. Does it take much longer to achieve an erection than in the past?
6. Has it become more difficult to have intercourse in certain sexual positions?

Medical History

7. Have you ever been told you have any form of heart disease, especially hardening of the arteries, peripheral arterial disease (PAD), or hypertension?
8. Have you ever had an operation for heart disease or some other cardiovascular problem?
9. Have you ever been told you have an elevated cholesterol level?
10. Do you ever experience serious pain in the legs when walking?
11. Are you taking any form of drug for a cardiovascular problem, especially hypertension?

Caution: Medications should never be changed without the doctor's permission.

12. Do you have any known glandular disorder, especially diabetes?
13. Do you have any neurological disorder, such as multiple sclerosis or epilepsy?
14. Have you ever had major surgery in the pelvic area, especially surgery involving the prostate gland or colon?
15. Have you ever had an injury involving the pelvic area, back, spinal cord, or head?
16. Have you ever been treated with radiation therapy for a problem in the pelvic area?
17. Have you ever had an episode of priapism (an erection which lasts for longer than usual and becomes painful)?

Lifestyle

18. Do you now smoke or did you once smoke for a long period of time?
19. Are you a heavy drinker or a diagnosed alcoholic?
20. Have you used illegal drugs, especially cocaine?
21. Are you a frequent user of drugs you can buy at the drugstore without a doctor's prescription?
22. Are you excessively overweight?

If it is determined that you are impotent, and that your impotence is caused by a physical problem, your doctor can offer several options for treatment. These may include hormone therapy, injections, vacuum devices, penile implants, or vascular surgery.

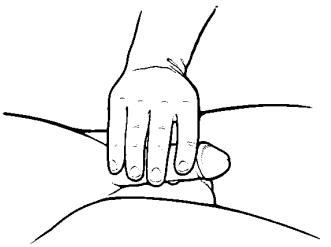
* Self-test questions are reprinted and edited with permission from Love Again, Live Again by Steven Morganstern, MD, and Allen Abrahams, PhD.

4 WHAT TO EXPECT AT YOUR EXAMINATION

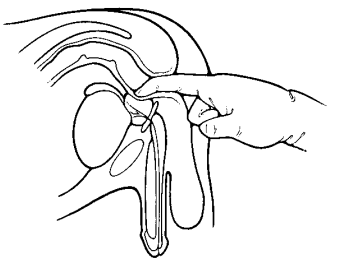
4.1 Physical examination

Your doctor will ask you several questions in order to understand when and under what circumstances you experience signs of impotence. Then your doctor will give you a complete physical exam. This exam is to determine if the blood vessels, nerves, and tissues of your penis are working normally.

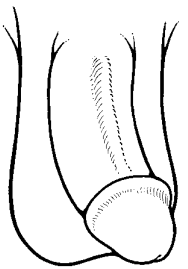
Your doctor may begin by feeling for the pulse in your penis and surrounding pelvic area. This will give an indication if the blood supply to your penis is adequate.



Your doctor must also perform a rectal examination to check for prostatitis (a swollen prostate gland). Problems with your prostate can decrease blood flow and feeling in the penis. Prostatitis can also make intercourse uncomfortable.



Your doctor will also check for physical abnormalities such as Peyronie's disease (a curved and painful erection caused by scar tissue within the penis). He will also check your history for previous injuries or surgery in the pelvic area which may have caused nerve damage.



4.2 Tests you may be asked to take

To confirm your diagnosis, other tests can detect hormonal abnormalities, determine blood flow problems, and may help to rule out psychological problems.

Blood tests and urine analysis

These tests are used to measure your hormone levels, cholesterol, and triglycerides (to detect hardening of the arteries), and liver and kidney function. To detect diabetes mellitus, a blood glucose test may also be requested.

Penile blood flow studies

Additional tests may be done to see how effectively blood flows into the penis. One test involves an injection with a drug that increases the blood flow to the penis directly, without stimulating the nerves in the penis. If the blood vessels of your penis are healthy, this injection will produce an erection.

Sleep monitoring

Most men experience at least 3 to 4 erections each night when they are dreaming. If you don't have nighttime erections, perhaps the nerve or blood supply to your penis is inadequate for erections. Your doctor may ask you to measure nighttime erections at home with a simple test that he or she will provide.

5 TREATMENT OPTIONS FOR PHYSICAL CAUSES OF IMPOTENCE

Depending on your diagnosis, your recommended treatment may be medical or surgical. Medical treatments range from simply changing your prescription drugs, to hormone replacement therapy, antidepressant therapy, and devices or self-injection therapy to produce erections. Surgical treatments include vascular surgery or implants. Your doctor will discuss options that may be appropriate in treating your impotence, as well as the risks and benefits of each option.

5.1 Medication

Changing prescription medications or their dosages may change the side effects, which may be causing your impotence. Caution: Medications should never be changed without the doctor's permission. Hormone replacement therapy may be recommended if you have a hormone deficiency. Antidepressant drugs may be the first course of treatment if you've been diagnosed with severe clinical depression. Drugs that increase the flow of blood to the penis to help cause an erection are also available.

Caution: Medications should never be changed without the doctor's permission.

5.2 Vacuum erection devices

These devices are placed around the outside of the penis and draw blood into the penis by creating a vacuum. Then you or your partner place a constriction band (rubber band) around the base of the penis to keep the blood inside the penis until sexual intercourse is completed.

5.3 Injections

Injecting medication directly into the penis prior to intercourse can also produce an erection. If you and your doctor choose this option, you will be taught how to administer the injections yourself.

5.4 Vascular surgery

For a few men, vascular surgery may be indicated to improve blood flow into the penis. Leaking veins may also be surgically repaired. In cases where arterial blockage is reducing blood flow to the penis, an arterial bypass around the blockage may be recommended.

5.5 Surgical implants

Penile implants, or prostheses, may be a choice that lasts longer for a number of impotent men, especially those who've tried psychological and other medical treatments without success. Implants have helped over 250,000 men return to an active sex life. Many studies show most patients and their partners are highly satisfied with the results.

Implants are concealed entirely within the body. They require manipulation by you or your partner before intercourse to make the penis firm enough for sexual intercourse. Manipulation is also needed afterwards to return the implant to a relaxed state (make it flaccid).

There are several types of implants to choose from. Differences include manner of operation, naturalness of the erection, and the number of components implanted. In choosing a penile prosthesis you should consider the manual dexterity that is needed to operate each type of device. The best choice of penile prosthesis for you will depend upon your medical condition, your lifestyle and, possibly, the cost of each prosthesis.
Before deciding on a penile prosthesis, you should consult with your doctor about the physical, psychological, cosmetic, and functional outcome of the implantation surgery. You should be sure that you understand the risks and benefits of the surgery.

There are certain instances when you and your physician may decide that a surgical implant is not an appropriate choice for you if:

- the risks associated with surgery are too high because of your medical condition
- your medical history includes previous surgery which make an implant impossible
- you are satisfied with one of the less invasive treatment options discussed in Chapter 6
- you choose not to be implanted with a silicone elastomer device
- you want to preserve the internal physical structure of your penis in case someday you may again experience a normal erection

In addition to discussions with your doctor, you may want to discuss the various options with your partner.

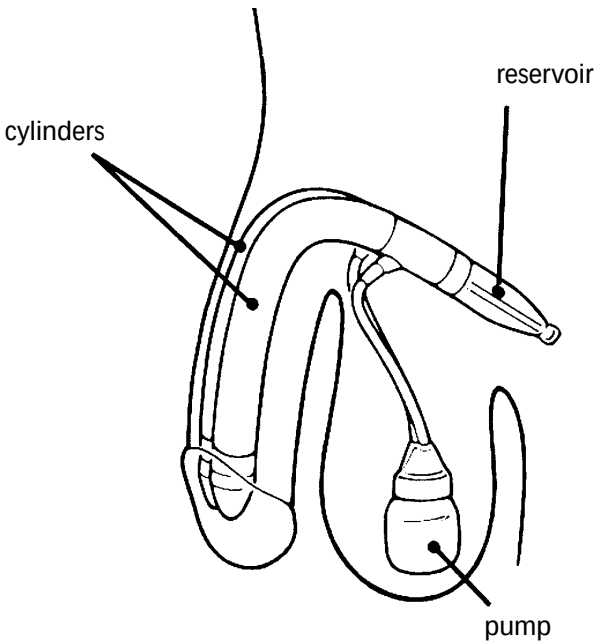
6 DESCRIPTION OF THE AMS AMBICOR® PENILE PROSTHESIS

The Ambicor® prosthesis consists of two cylinders and a pump bulb.

The two **cylinders** are inserted side by side into the corpora cavernosa of the penis.

The **pump bulb** is placed in the scrotum.

Caution: Implantation of a penile prosthesis may cause the penis to become shorter, curve, or become scarred.



7 GENERAL WARNINGS AND CAUTIONS

7.1 How safe are silicone elastomer prostheses?

The AMS Ambicor® Penile Prosthesis is made of solid silicone elastomers (a type of rubber). Penile prostheses, or solid silicone elastomers, do not contain silicone gels. Silicone elastomers have been commonly used in many different types of biomedical devices for over 40 years.

Solid silicone elastomers are also used to compare against 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.) However, 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.[1,2]

[1] Barrett DM, O'Sullivan DC, Malizia AA, Reiman HM and Abell-Aleff PC. "Particle Shedding and Migration from Silicone Genitourinary Prosthetic Devices," J. Urol. 146: 319-322. (1991)

[2] Reinberg Y, J. Urol. 150: 694-696. (1993)

7.2 Will my prosthesis have to be replaced?

It is not possible to predict how long an implanted penile prosthesis will function in a particular patient. As with any biomedical device, penile prostheses are subject to wear and eventual failure over time, and therefore should not be considered to be lifetime implants. Other causes can lead to malfunctions of the prosthesis which occur more quickly. Discuss any changes you notice in the function of the prosthesis with your doctor.

Product wear or other mechanical problems, such as unintended inflation or deflation, or difficulty or inability to inflate or deflate may lead to additional surgery to remove or replace the device.

7.3 Need for manual dexterity

The Ambicor® prosthesis requires some manual dexterity to inflate and deflate.

7.4 Possibility of malfunction

The possibility of leakage, blockage, or device malfunction exists.

7.5 Possibility of changes in the penis or scrotum

Implantation of a penile prosthesis may cause the penis to become shorter, curve, or be scarred. Scrotal deformity (pump bulge in the scrotum) may also occur.

7.6 Destruction of any latent natural erection

Implanting a penile prosthesis is likely to damage or destroy any remaining natural ability to have an erection.

7.7 Different erection

Your erection with the prosthesis may be different from your original, natural erection. Differences may include a shorter penis, less firmness, less width, and reduced sensation in the penis. Also, because the prosthesis will not extend to the tip of your penis (the glans), this part of your penis may be floppy.

7.8 Less softness when deflated

When your prosthesis is deflated, your penis may not be as soft (flaccid) as it was naturally.

7.9 Possibility of infection

Contact your doctor immediately if there is redness, swelling, and/or heat around the incision area or drainage from the incision. This may indicate an infection.

7.10 Delay intercourse until your doctor gives the OK

If you attempt intercourse before your incision has healed completely, you risk the possibility of infection, pain, or surgical complication.

7.11 Erosion

Contact your doctor immediately if there is thinning of skin or tissue over the prosthesis. This may indicate erosion. Failure to treat erosion can make it worse and lead to infection and loss of tissue.

7.12 Pain

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 complication or mechanical device malfunction.

7.13 Migration

Contact your doctor if the surface of any part of your device is visible through your skin or if you cannot locate the inflate/deflate pump in your scrotum. These symptoms may indicate that a part of your device may have moved within your body or may be moving to the outside of your body.

8 WHAT TO EXPECT DURING AND AFTER IMPLANT SURGERY

Implantation of a penile prosthesis involves a surgical procedure usually lasting from 30 minutes to 2 hours. The length of your hospital stay depends on your physical condition and the type of prosthesis chosen. You will be able to return to work and everyday activities at the discretion or direction of your physician. (Everyday activities include any type of activity you were able to perform before your implant surgery, for example, exercise, working, bathing.)

8.1 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.

Depending on your physical condition and your doctor's preference, you will either be given a local anesthetic (it numbs only the area where the surgery occurs) or a general anesthesia (which puts you to sleep for the surgery). If you are to be given a general anesthetic, you will be asked to abstain from food or drink for 12 hours before surgery.

The prosthesis will be implanted through a type of incision call a **penoscrotal incision.** An incision will be made through the skin between your penis and scrotum. Your doctor will usually implant the cylinders and the pump bulb through this one incision.

To implant the cylinders, your doctor will first dilate (widen) the corpora cavernosa (the two channels in the shaft of your penis which fill with blood when you get a natural erection). Then your doctor will measure this area to choose which size cylinder will best fit your anatomy.

After the cylinders are in place, your doctor will make a space in your scrotum in which to place the pump bulb. He will place the pump so that it is easy for you to reach.

Finally, before closing the incision in your skin, your doctor will inflate and deflate the prosthesis to make sure it is working properly.

8.2 After your surgery

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 physician. (Everyday activities include any type of activity you were able to perform preoperatively, for example, exercise, working, bathing.)

After you leave the hospital, you will be encouraged to avoid wearing tight-fitting underwear. This helps to prevent any curvature in your penis that could occur during healing. After urinating you should carefully retape your penis to the abdomen in the same straight position that it was in prior to untaping it to void.

You may experience pain at the operative site during the early time after surgery and when you first use your prosthesis. In most cases the pain goes away within a few weeks of surgery; however, cases of chronic (continuing) pain have been reported.

Many doctors recommend that you wait four to six weeks after surgery before having intercourse using the prosthesis. This time allows your incision site to heal.

You will probably have an appointment with your doctor during this time to be sure you are healing properly. Be sure to discuss these possibilities with your doctor and ask how long after your surgery you should wait before having intercourse.

Caution: If you attempt intercourse before the incision has healed completely, you risk the possibility of infection, pain, or surgical complications.

You will also have several postoperative visits and annual or semi-annual follow-up visits with your doctor after the surgery. During this recovery time, and after it, take care to avoid trauma to the pelvic area. Always keep in mind that you have had a surgical implant and choose your activities wisely. Things that may cause pelvic area trauma may include seat belt jolts from a car accident, being tackled in contact sports, or slipping and falling on ice. Trauma like these may damage the prosthesis or surrounding tissues.

Caution: Take precautions to avoid trauma to your pelvic area.

8.3 Problems that may develop

Implant surgery carries the same types of risks that every surgical procedure involves, including infection and risks associated with anesthesia. In addition, the outcome of your implant surgery may be unsuccessful. For example, the device may not function as intended. If this happens, you may need another surgery to remove or replace the prosthesis. If the prosthesis must be removed, reimplantation of a new prosthesis may be complicated by the amount of time between the two surgeries. Discuss these possibilities with your doctor.

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

Approximately 2% of patients in the clinical trial reported having an infection.

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.

If you get an infection that cannot be treated successfully with antibiotics, your doctor may have to remove the prosthesis. If your prosthesis is removed due to an infection, the infection may leave scars inside your penis. This can make replacing your prosthesis hard or impossible.

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
- tissue damage
- misplacement of the cylinders or pump bulb

Erosion involving the cylinders most often involves:

- the glans (the tip of the penis)
- the urethra (the tube inside the penis that carries urine out of the body)
- the skin of the penis

It is also possible for pump bulb to erode through the skin of the scrotum.

Symptoms of erosion into the scrotum or penis may include (after having been symptom free) pain, redness of skin, tenderness over the involved part, changes in skin texture, drainage, and/or being able to see the prosthesis through the skin. Less than 1% of patients in the clinical trial experienced erosion of any part of the device.

Warning: Contact your doctor immediately if you notice any pain, tenderness over the involved part, change in skin texture, drainage, or if you can see the prosthesis 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 prosthesis 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 penis or scrotum. 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 when walking on ice to prevent slipping and falling

Pain. It is normal to have some pain in your penis and scrotum immediately after surgery and when you are first using the device. Nearly 17% of the patients in the clinical trial reported pain to their doctors after surgery.

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 been reported to 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. These cases occur rarely.

Migration. Migration is the movement of one or both cylinders or the pump bulb 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 cylinders
- improper positioning of the pump bulb

About 1% of the patients in the clinical trial had device parts which migrated.

Warning: Contact your doctor if you cannot locate the inflate/deflate pump in your scrotum.

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

Mechanical problems may include inflation or deflation of the device. Unintentional inflation or deflation means that the device inflates or deflates with no manipulation on your part. Difficulty or inability to inflate or deflate the device can also be due to a mechanical problem.

If problems occur with your prosthesis, first check the user instructions to be sure you are operating the device correctly. If you still have the same problem, contact your doctor.

About 10% of patients experienced mechanical problems in the clinical trial. These cases included unintended inflation of the device that occurred when patients were straining the lower abdomen area and difficulty in inflating the prosthesis, as well as unintended deflation of the device and inability to correctly deflate the device.

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 5% of the patients in the clinical trial reported having swelling.

Bruising or discoloration of the penis. It is normal to have some bruising after surgery. About 3% of the patients in the clinical trial reported bruising to their doctors. In these patients, the bruising normally went away in about 14 days.

Obvious redness in penis or scrotum. It is normal to have some redness of the skin around the implant. However, extreme redness should be reported to your doctor. In the clinical trial, about 1% of the patients reported obvious redness to their doctors. The redness went away in an average of 13 days.

Other. Problems which occurred in less than 4% of patients in the clinical trial were: problems with passing urine, hematoma, ejaculation problems, inability to urinate, problems with the surgical incision, device parts "sticking" to the tissue inside the penis or scrotum, and pain or burning when urinating, abscess (collection of pus beneath skin), kidney failure, and abnormal sexual function, foot sores related to diabetes, chest pain, degenerative arthritis, pneumonia and would healing problems

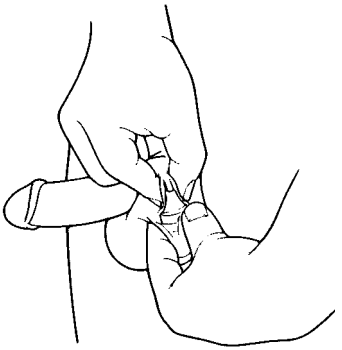
Please ask your doctor for explanation on any of the problems that you do not understand.

9 OPERATING INSTRUCTIONS

The prosthesis works by moving sterile fluid from the reservoir area of each cylinder into the main body of the cylinder. Squeezing and releasing the pump bulb moves fluid from the reservoir into the inflation chamber. Repeating the squeeze and release action on the pump bulb allows the cylinders to completely inflate. This should make your penis hard.

9.1 Inflation

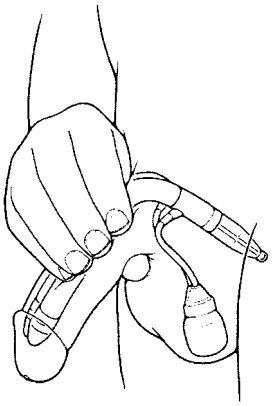
1. Feel for the pump in your scrotum.
2. With one hand, gently grasp your scrotum around the bottom of the pump to hold the pump in place.
3. Use the thumb and forefinger of your other hand to locate the pump. Squeeze and release the pump bulb several times. This transfers sterile fluid from the reservoir into the inflatable chambers of the cylinders, making your penis firm.



9.2 Deflation

The cylinders must be fully inflated before you try to deflate them.

1. Both cylinders can be deflated at the same time. Using either hand, place your thumb under the shaft of your penis.
2. Place your other fingers on top of the shaft of your penis.
3. Bend your penis down over your thumb (at about a 55 to 65 degree angle).
4. Hold the penis in this position for 6 to 12 seconds, then release. This will return the sterile fluid to the reservoirs and the penis will relax.



10 TROUBLESHOOTING

Signs and Symptoms That May Develop After Surgery		
Symptom	**Problem**	**What to do***
Pain. Discharge from incision. Redness, swelling.	Infection.	Contact your doctor.
Cylinder surface can be seen through the skin.	Erosion of cylinders (associated with infection).	Contact your doctor.
Pump surface can be seen through scrotal wall. Pain.	Erosion of pump (associated with infection).	Contact your doctor.
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.
Inability to inflate.	Mechanical problem or improper understanding.	Review patient instruction materials. If still unable to inflate, contact your doctor.
Inability to deflate.	Mechanical problem or improper understanding.	Review patient instruction materials. If still unable to deflate, contact your doctor.
Spontaneous inflation.		Deflate the device. If it continues, contact your doctor.

10 TROUBLESHOOTING (CONTINUED)

Signs and Symptoms That May Develop After Surgery		
Symptom	**Problem**	**What to do***
Spontaneous deflation.		Review patient instruction materials to be sure that the device is being fully inflated. If it continues, contact your doctor.
Penile curving.		Contact your doctor.
Gradual loss of rigidity.		May mean our device may have lost fluid. Contact your doctor.
Inability to pump.		Review patient instruction materials. If still unable to pump, contact your doctor.
Inability to locate pump.	Migration.	Review patient instruction materials. If still unable to locate, contact your doctor.
Any part of the device visible through your skin.	Erosion	Contact your doctor.
Pain, skin disruption (opening), leaking of body fluids, bruising.	Trauma.	Contact your doctor.

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

11 SUMMARY

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

Your inflatable penile prosthesis requires some manual dexterity to inflate and deflate.

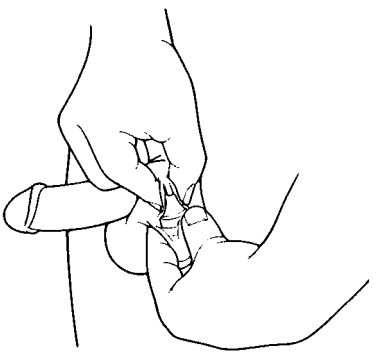
The possibility of leakage, blockage, or device malfunction exists. Discuss any changes you notice in the function of your prosthesis with your doctor.

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 inflate/deflate pump in your scrotum

To inflate:

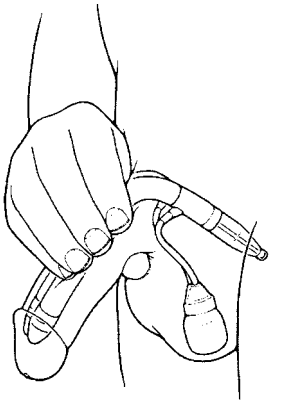
1. Feel for the pump in your scrotum.
2. With one hand, gently grasp your scrotum around the bottom of the pump bulb to hold the pump bulb in place.
3. Use the thumb and forefinger of your other hand to squeeze and release the pump bulb several times. This transfers sterile fluid from the reservoir portion of each cylinder into the inflatable chambers of the cylinders, making your penis firm.



To deflate:

The cylinders must be fully inflated before you try to deflate them.

1. Both cylinders can be deflated at the same time. Using either hand, place your thumb under the shaft of your penis.
2. Place your other fingers on top of the shaft of your penis.
3. Bend your penis down over your thumb (at about a 55 to 65 degree angle).
4. Hold the penis in this position for 6 to 12 seconds, then release. This will return the sterile fluid to the reservoirs of each cylinder and the penis will relax.



12 INDEX

Solutions for Life™ American Medical Systems is a world leader in medical devices and procedures that treat three major diseases: incontinence, erectile dysfunction (ED) and benign prostate hyperplasia (BPH). Any one of these conditions can profoundly diminish a patient's quality of life and significantly impact relationships. Our products provide a cure or reduce the incapacitating effects of these diseases, often through minimally invasive surgery.

American Medical Systems

American Medical Systems, Inc.
10700 Bren Road West
Minnetonka, MN 55343 USA

Toll Free: (800) 328-3881
Phone: (952) 933-4666
Fax: (952) 930-6157
www.AmericanMedicalSystems.com

Order Number: 23600005E.web (03/03)