

*It's great that you've used this brochure to begin answering some of your questions. Next...*

**Watch the enclosed DVD**

It will help answer some of the more personal questions you may have.

**Talk with your doctor**

Your doctor can give you the details you need so you can confidently take the next step.

ERECTILE DYSFUNCTION

**1.** Erectile dysfunction. [http://kidney.niddk.nih.gov/KUDiseases/pubs/ED/ErectileDysfunction\\_508.pdf](http://kidney.niddk.nih.gov/KUDiseases/pubs/ED/ErectileDysfunction_508.pdf). National Kidney and Urologic Diseases Information Clearinghouse Web site. Downloaded January 21, 2013. **2.** Selvin E, Burnett A, Platz E. Prevalence and risk factors for erectile dysfunction in the U.S. *Am J Med.* 2007;(120):151-157. **3.** Erectile dysfunction (ED). [www.auanet.org/content/education-and-meetings/med-stu-curriculum/ed.pdf](http://www.auanet.org/content/education-and-meetings/med-stu-curriculum/ed.pdf). American Urological Association Web site. Downloaded January 21, 2013. **4.** DiMeo PJ. Psychosocial and relationship issues in men with erectile dysfunction. *Urol Nurs.* 2006;26(6):442-453. **5.** Viagra® Prescribing Information, Pfizer Inc. Revised January 2010. **6.** Cialis® Prescribing Information, Lilly USA, LLC. Revised October 2011. **7.** Levitra® Prescribing Information, Bayer HealthCare Pharmaceuticals. Revised November 2011. **8.** Scott FB, Bradley WE, Timm GW. Management of erectile impotence: use of implantable inflatable prosthesis. *Urology.* 1973;2(1):80-82. **9.** Penile prosthesis. <http://www.essm.org/society/esha/malesd/oraltreatments/penileprosthesis.html>. European Society for Sexual Medicine (ESSM) Web site. Downloaded January 1, 2013. **10.** AMS 700™ Patient Manual. Information and Instructions for Patients Considering an Inflatable Penile Prosthesis. American Medical Systems. 2012. **11.** Rajpurkar A, Dhabuwala C. Comparison of satisfaction rates and erectile function. *J Urol.* 2003;170:159-163. **12.** Montorsi F, Rigatti P, Carmignani G, et al. AMS three-piece inflatable implants for erectile dysfunction: a long-term multi-institution study in 200 consecutive patients. *Eur Urol.* 2000;37:50-55. **13.** Dymedex Consulting. Assessment of the market potential for Penile Prosthetic Implants (PPI), November, 2010. **14.** AMS 700™ Penile Prosthesis Operating Room Manual. American Medical Systems. 2012. **15.** AMS 700™ Penile Prosthesis Product Line Instructions for Use. American Medical Systems. 2012.

Viagra® is a registered trademark of Pfizer, Inc.  
MUSE® is a registered trademark of Meda AB.

**Rx Only**

™ The denoted marks are trademarks or registered trademarks of American Medical Systems, LLC.  
© 2015 American Medical Systems, LLC. All Rights Reserved. Minnetonka, MN 55343

AMSUS/ED-00320(1)/April 2013 [www.AmericanMedicalSystems.com](http://www.AmericanMedicalSystems.com) 1-800-328-3881

AU, CA, NZ and US Use Only



ERECTILE DYSFUNCTION

# Answers for Men

*Understanding Your Treatment Options*



*Brought to you by American Medical Systems, Inc.*



## Answers for Men

### What Is Erectile Dysfunction (ED)?

ED is defined as the persistent inability to achieve or maintain an erection that is firm enough to have sexual intercourse.<sup>1</sup>

### How Common Is ED?

ED is a common problem and it's important to know you're not alone:

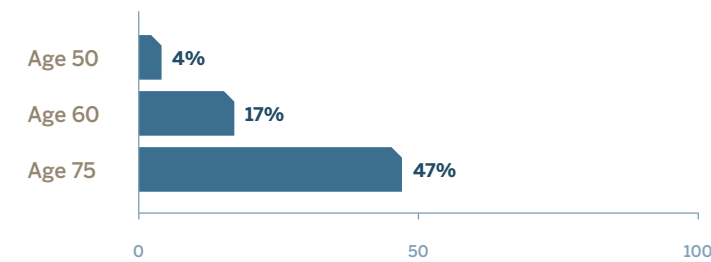


Approximately 1 in 5 American men aged 20 and older suffers from some degree of ED.<sup>2</sup>

In the United States, this adds up to as many as

**30 million men.**<sup>1,13</sup>

### Age breakdown of men with total inability to achieve an erection<sup>1</sup>



## What Causes ED?<sup>1,3</sup>

There's no single cause of ED. There are real physical and psychological reasons for ED.

Some common causes are:

- Diabetes
- Cardiovascular problems (high blood pressure, heart disease)
- Prostate cancer treatment
- Surgery (prostate, bladder, colon, rectal)
- Medications (blood pressure, antidepressants)
- Lifestyle choices (smoking, excessive alcohol, obesity, lack of exercise)
- Spinal cord injuries
- Hormone problems

ED is not just a medical issue; it can also deeply affect relationships.<sup>4</sup>



### How did ED affect your relationship?

*"The intimacy that we used to have went away. All of a sudden, it was like we were completely separated. There was no connection."*

—Tom



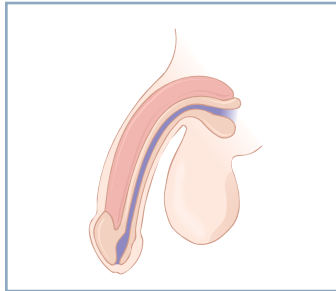
Watch the enclosed DVD to see Frieda and Tom talk about getting their groove back.



## Erections and How They Work<sup>3</sup>

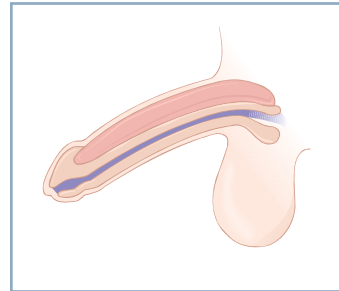
To learn more about ED, it is important to understand how the penis normally works. The erection process includes the following 5 stages:

### 1. Initial Filling



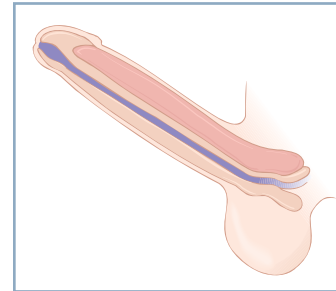
With psychological or sexual stimulation, neurotransmitters cause penile smooth muscles to relax, increasing blood flow to the corporal bodies (the 2 chambers within the shaft of the penis).

### 2. Partial Erection



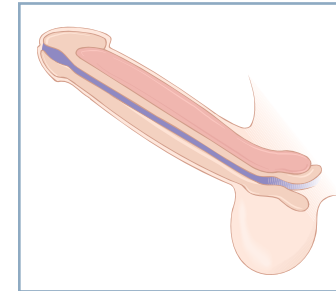
Penile arteries expand to accommodate the increased blood flow needed to elongate and expand the penis.

### 3. Full Erection



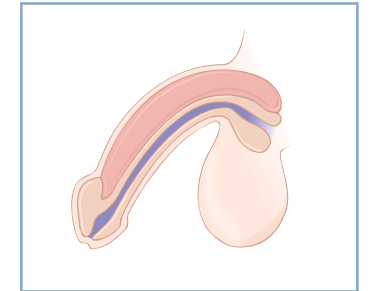
The increased volume of blood within the penis is prevented from draining, thus expanding the penis to full erection.

### 4. Rigid Erection



Maximum rigidity is attained. The glans and spongiosum (tip of the penis and penis body) enlarge until penile veins are forcefully compressed. This increases engorgement and maintains maximum penile rigidity. Release of semen (ejaculation) occurs.

### 5. Return to Flaccidity



Muscle contractions result in increased blood outflow from the penis, thus decreasing penile length and girth until flaccid.



## ED Treatment Options<sup>3</sup>

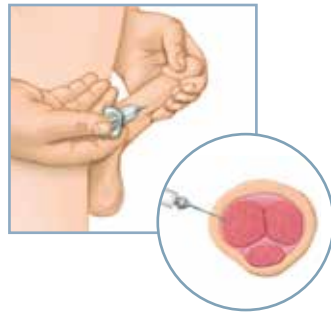
The good news is that there are treatment options for ED, and there are multiple options available. For some men, oral medications don't work, so it's important to know all of your options.<sup>5-7</sup> Your doctor will discuss options that may be appropriate for you, along with the potential risks and benefits.

### Oral Medications

There are a number of prescription medications available that may improve blood flow to the penis. Combined with sexual stimulation, this can produce an erection.

### Injections

With injection therapy, a needle is used to inject medication directly into the penis. The medication allows blood to flow into the penis, creating an erection.



### Penile Implants

A medical device is implanted into the penis that allows men with ED to achieve an erection. This device is entirely contained within the body. To operate, one squeezes and releases the pump in the scrotum to achieve an erection.



### Vacuum Erection Devices

A plastic cylinder is placed over the penis, and a pump (either manual or battery operated) creates a vacuum suction within the cylinder, drawing blood into the penis to create an erection. A stretchable tension band is placed at the base of the penis to help maintain the erection.



### Intraurethral Suppositories

An applicator containing a small pellet (suppository) is inserted into the urethra and the pellet is released. The pellet dissolves and increases blood flow to the penis, creating an erection.





## What is a Penile Implant?

A penile implant is a medical device that is implanted into a man's body. The surgery is typically performed as an outpatient procedure<sup>14</sup>

Penile implants have been in clinical use for over 40 years<sup>8</sup> and have helped over 300,000 men return to an active and satisfying sex life.<sup>9</sup> Implants provide an option for men who have tried other treatments without success. Many studies show most patients and their partners are highly satisfied with the results.<sup>10</sup>

Finding a treatment option for ED can be a life-changing event for many men and their partners. Choosing the penile implant that is best for you is a very personal decision. Because each type of implant offers unique features, you will want to discuss the risks and benefits of each with your doctor to help you choose the option that is right for you.

### Features of a Penile Implant:

- Entirely contained in the body<sup>10</sup>
- May offer a long-term treatment option to ED<sup>15</sup>
- Once activated, you can maintain an erection as long as you desire<sup>15</sup>
- Spontaneous – have sex when the mood strikes<sup>15</sup>
- Typically does not interfere with ejaculation or orgasm<sup>15</sup>
- Designed to feel natural during intercourse<sup>15</sup>

### Risks of a Penile Implant<sup>10</sup>:

- Will make natural or spontaneous erections as well as other interventional treatment options impossible
- If an infection occurs, the implant may have to be removed
- May cause the penis to become shorter, curved, or scarred
- Pain (typically associated with the healing process)
- There may be mechanical failure of the implant

The journey can be a long one.



How long was your journey before you considered an implant?

*"I had had heart problems... so I couldn't take Viagra® or any of those drugs because they can't be combined. I really didn't consider the vacuum erection device. Next was the little suppositories, the MUSE®, which I tried...and sometimes it didn't work.... So we kept on going down the list. I'm one of those guys who really doesn't like the idea of giving myself a shot in the penis, so I said, 'Well, let's skip over that one.' So the last one was the implant."*

—David



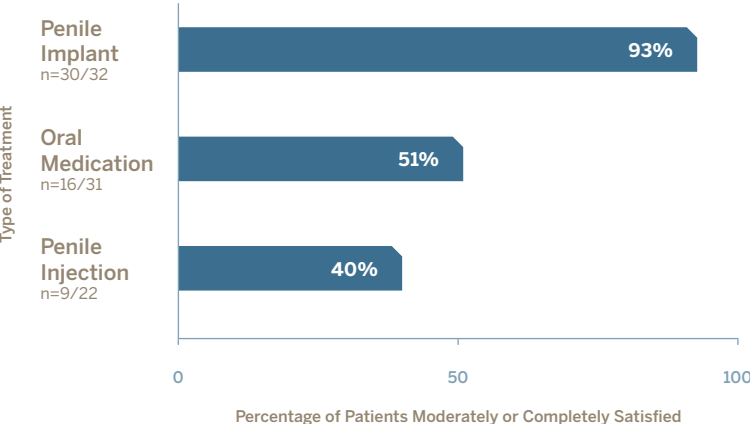
# Patient and Partner Satisfaction

ED can limit your intimacy, affect your self-esteem, and impact your most important relationships.<sup>4</sup>

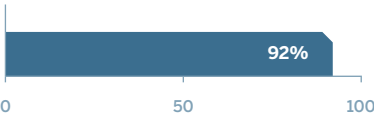
Many studies show that penile implants may offer the satisfying results that so many couples seek. Consult your doctor to determine which type of implant is best suited for your condition and lifestyle.

In one study of 106 ED patients, 32 received a penile implant. Of these patients, 93% were satisfied with their implant.<sup>11</sup>

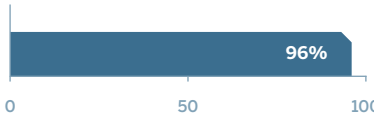
## Overall Patient Satisfaction with ED Treatments<sup>11</sup>



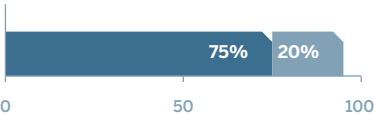
Often patients wonder if their sexual activity will be the same and if they will be able to experience orgasms and sensation. In one study of 200 patients and 120 partners, both men and their partners found the AMS 700™ penile implant to be satisfying<sup>12</sup>:



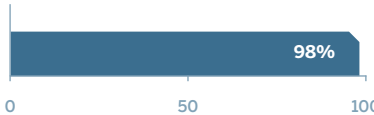
**92% of patients reported** sexual activity with the implant to be excellent or satisfactory



**96% of their partners reported** sexual activity with the implant to be excellent or satisfactory



**75% of patients reported** no change in their orgasm, and **20% reported** better orgasms, following the surgery



**98% of patients reported** their erections to be excellent or satisfactory following surgery

Satisfaction achieved.



How did an implant address your worries about performance?

*“The penile implant changed my life in such a way that confidence is abundant. I do not have to worry about whether or not I’m going to be able to satisfy my partner because I know without a shadow of a doubt that I will be able to give her total sexual satisfaction. And, as a man, in feeling that we must be able to sexually satisfy our partner, it brings about a great deal of satisfaction.”*

—Herschel



## AMS 700™ Penile Prosthesis

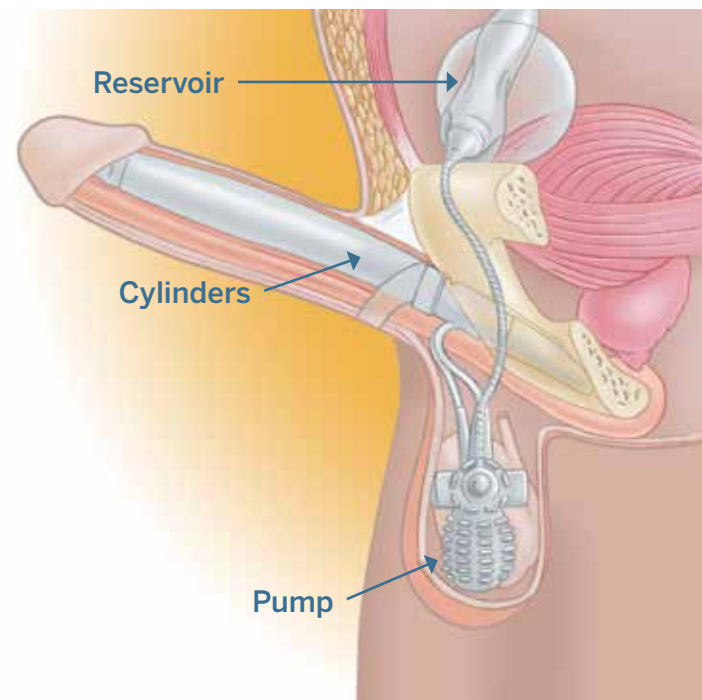
### Three-Piece Inflatable Penile Implant

The 3-piece, fluid-filled, inflatable penile implant consists of a pair of cylinders that are implanted into the penis, a pump that is implanted in the scrotum, and a reservoir that is implanted into the lower abdomen. To get an erection, squeeze and release the pump several times. When the fluid is pumped into the cylinders, it creates an erection that is suitable for intercourse. Once both you and your partner are satisfied, you can deflate the device by pressing the deactivation button located on the pump.

The 3-piece penile implant is entirely contained in the body and is designed to produce a natural erection.

Another feature of the 3-piece penile implant is that it expands in girth (all AMS 700™ cylinders) and length (AMS 700 LGX™ cylinders).

### AMS 700™ Penile Prosthesis



### Additional Implant Options

AMS offers 2 additional types of penile implants, the Ambicor™ 2-Piece Inflatable Penile Prosthesis and the Spectra™ 1-Piece Concealable (Bendable) Penile Prosthesis. Please talk to your doctor to determine which implant is right for you.

Don't wait another day to get your questions answered.



How did you feel about solving your ED issues?

*"I thank God for giving man the technology to manufacture such a device. It is a blessing."*

—Rev. Peterson



Watch the enclosed DVD to see implant patients give their heartfelt reactions to ED.



## What Is It Like to Use an Implant?



### Natural feel

*"Everything is the same as it was, I want to say, when I was 18. All the sensation you experienced during orgasm is still there."*

—Thurman



### Easy to use

*"It's very spontaneous. It takes a few pumps to pump it up, and I'm ready to go."*

—Bill

*The stories throughout this brochure recount the experiences of people who are using AMS therapies related to erectile dysfunction. AMS invited these people to share their stories candidly. As you review them, please bear in mind that the experiences are specific to these particular people. As with all medical treatment, not every response is the same—results vary.*



### Pleasing for your partner

*"For me, it's very exciting. Once he has an ejaculation, the erection is still there. We can be intimate for as long as I want, which is very satisfying for me."*

—Linda



### After the recovery period

*"We pretty much hurried home. That was a pretty good day. That was a wonderful day. That really was."*

—Frieda and Tom

Couples can rediscover a sense of positive anticipation.



After his surgery, were you both eager to try it out?

*"The only difficult part was they said that for 6 weeks you couldn't... 'do anything.' After the 6 weeks, all I can say is it was well worth it."*

—Sarah



Watch the enclosed DVD to see Sarah explain why it was worth the wait.



## *With So Much to Know, What Haven't I Thought of?*

### **Insurance Coverage**

Most insurers cover the diagnosis and medically necessary treatment of ED. Medicare has a national coverage policy for ED, which includes penile implants—however coverage may depend on where you live. Work with your doctor's office and insurance carrier to check coverage levels prior to receiving treatment.

### **Surgery**

The implant procedure is typically done on an outpatient basis. Patients generally check in the morning of the procedure and are discharged within 24 hours. Patients receive anesthesia during the surgery. Your doctor can tell you more about the surgical procedure.

### **Healing**

You may experience pain and soreness at the surgical site. Typically, it takes a few days to return to your regular daily routine of light activity. The full healing time before using your device is usually about 6 weeks.



## *Sexual Health Inventory for Men (SHIM)<sup>3</sup>*

This quiz is often used to help doctors determine a patient's degree of erectile dysfunction (ED).

### **Discuss your answers with your doctor today.**

After you take the quiz make a list of your questions and concerns, clip out your completed quiz, and return to the urologist's office for a more in-depth conversation about possible next steps.

## Over the Past 6 Months

1. How do you rate your confidence that you could get and keep an erection?	0	1	2	3	4	5
2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration (entering your partner)?	No Sexual Activity	Almost Never or Never	A Few Times (Much Less Than Half the Time)	Sometimes (About Half the Time)	Most Times (Much More Than Half the Time)	Almost Always or Always
3. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered) your partner?	Did Not Attempt Intercourse	Almost Never or Never	A Few Times (Much Less Than Half the Time)	Sometimes (About Half the Time)	Most Times (Much More Than Half the Time)	Almost Always or Always
4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?	Did Not Attempt Intercourse	Extremely Difficult	Very Difficult	Difficult	Slightly Difficult	Not Difficult
5. When you attempted sexual intercourse, how often was it satisfactory for you?	Did Not Attempt Intercourse	Almost Never or Never	A Few Times (Much Less Than Half the Time)	Sometimes (About Half the Time)	Most Times (Much More Than Half the Time)	Almost Always or Always

**Add the numbers corresponding to questions 1-5. Total: \_\_\_\_\_**

The Sexual Health Inventory for Men further classifies ED severity with the following breakpoints: **1-7** Severe ED **8-11** Moderate ED **12-16** Mild to Moderate ED **17-21** Mild ED

## Questions and Concerns

[illegible]

Cut Here to Return to Doctor



Cut Here to Return to Doctor



Cut Here to Return to Doctor



Cut Here to Return to Doctor



### **AMS 700™ Series Inflatable Penile Prosthesis Brief Summary**

The AMS 700™ Series Inflatable Penile Prosthesis is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence). These devices are contraindicated in patients who have active urogenital infections or active skin infections in the region of surgery or (for the AMS 700 with InhibiZone™) have a known sensitivity or allergy to rifampin, minocycline, or other tetracyclines. Implantation will make latent natural or spontaneous erections, as well as other interventional treatment options, impossible. Men with diabetes, spinal cord injuries or open sores may have an increased risk of infection. Failure to evaluate and treat device erosion may result in infection and loss of tissue. Implantation may result in penile shortening, curvature, or scarring. Possible adverse events include, but are not limited to, urogenital pain (usually associated with healing), urogenital edema, urogenital ecchymosis, urogenital erythema, reservoir encapsulation, patient dissatisfaction, auto-inflation, mechanical malfunction, and impaired urination.

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, and potential adverse events.

### **Ambicor™ Penile Prosthesis Brief Summary**

The AMS Ambicor™ Penile Prosthesis is intended for use in the treatment of chronic, organic, male erectile dysfunction (impotence). These devices are contraindicated in patients who have active urogenital infections or active skin infections in the region of surgery. Implantation will make latent natural or spontaneous erections, as well as other interventional treatment options, impossible. Men with diabetes, spinal cord injuries, or open sores may have an increased risk of infection. Failure to evaluate and treat device erosion may result in infection and loss of tissue. Implantation may result in penile shortening, curvature, or scarring. Possible adverse events include, but are not limited to, urogenital pain (usually associated with healing), patient dissatisfaction, mechanical malfunction, auto-inflation, penile curvature or sensation change, urogenital hematoma, urogenital edema, and infection.

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, and potential adverse events.

## **Spectra™ Concealable Penile Prosthesis Brief Summary**

The AMS Spectra™ Concealable Penile Prosthesis is a sterile, non-pyrogenic, single-use implant that is intended for use in the treatment of chronic, organic, erectile dysfunction (impotence) in men who are determined to be suitable candidates for implantation surgery. These devices are contraindicated in patients who have active urogenital infections or active skin infections in the region of surgery; patients whose proximal corporal length measurement is less than the proximal rigid section of the Spectra cylinders, or whose total intracorporal length is not within the range of 12 cm to 27.5 cm; patients who require repeated endoscopic procedures; or patients who have compromised tissue and as a result cannot withstand constant pressure. Implantation will make latent natural or spontaneous erections, as well as other interventional treatment options, impossible. Men with diabetes, spinal cord injuries or open sores may have an increased risk of infection. Failure to evaluate and treat device erosion may result in infection and loss of tissue. Implantation may result in penile shortening, curvature, or scarring. Possible adverse events include, but are not limited to: infection, erosion, migration, extrusion, mechanical malfunction, patient dissatisfaction, adverse tissue reaction, allergic reaction, pain, urinary obstruction, and silicone particle migration.

Prior to using these devices, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions, and potential adverse events.

## **Patient Testimonials**

The stories throughout this brochure recount the experiences of people who are using AMS therapies related to erectile dysfunction. AMS invited these people to share their stories candidly. As you review them, please bear in mind that the experiences are specific to these particular people. As with all medical treatment, not every response is the same—results vary.