

Answers for Men

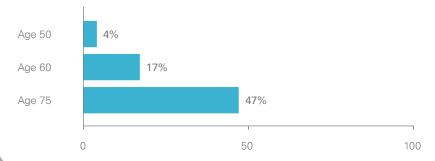
What Is Erectile Dysfunction (ED)?

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

How Common Is ED?

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

Age breakdown of men with total inability to achieve an erection¹





What Causes ED?^{1,3}

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.⁴



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

Erections and How They Work³



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).



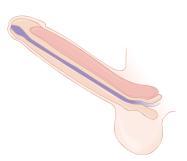
2. Partial Erection

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



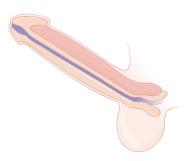
3. Full Erection

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 tip of the penis and penis body enlarge until penile veins are forcefully compressed. This increases engorgement and maintains maximum penile rigidity.



5. Return to Flaccidity

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



ED Treatment Options³



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.⁵⁻⁷ 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.



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.



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.

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 inpatient procedure.¹⁴

Penile implants have been in clinical use for over 40 years⁸ and have helped over 300,000 men return to an active and satisfying sex life.⁹ 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 ¹⁰

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 body¹⁰
- May offer a long-term treatment option to ED¹⁵
- Once activated, you can maintain an erection as long as you desire¹⁵
- Spontaneous have sex when the mood strikes¹⁵
- Typically does not interfere with ejaculation or orgasm¹⁵
- Designed to feel natural during intercourse¹⁵

Risks of a Penile Implant¹⁰:

- 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

Patient and Partner Satisfaction

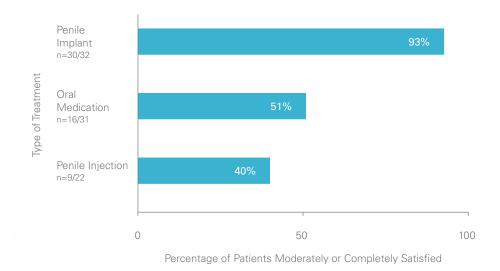


ED can limit your intimacy, affect your self-esteem, and impact your most important relationships.⁴

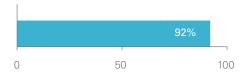
Many studies show that penile implants may offer the satisfying results that so many couples seek. Consult your doctor to determine which type of implant is best suited for your condition and lifestyle.

In one study of 106 erectile dysfunction patients, 32 received a penile implant. Of these patients, 93% were satisfied with their implant.¹¹

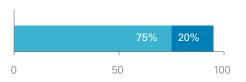
Overall Patient Satisfaction with erectile dysfunction Treatments¹¹



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

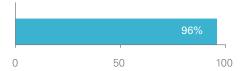


92% of patients reported sexual activity with the implant to be excellent or satisfactory

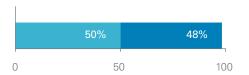


75% of patients reported no change in their orgasm, and **20% reported** better orgasms, following the surgery

patients and 120 partners, both men and their partners found the AMS 700TM penile implant to be satisfying ¹²:



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



50% of patients reported their erections as satisfactory, and48% reported excellent erections, following the surgery

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.

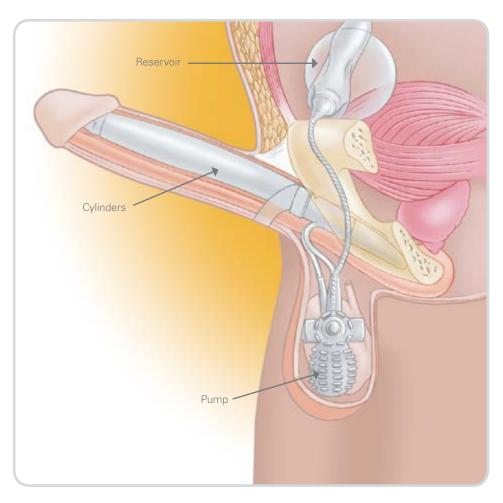
Another feature of the 3-piece penile implant is that it expands in girth (all AMS 700™ cylinders) and length (AMS 700 LGX™ cylinders).

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.

AMS 700™ Penile Prosthesis



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

Surgery

The implant procedure is typically done on an inpatient 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.

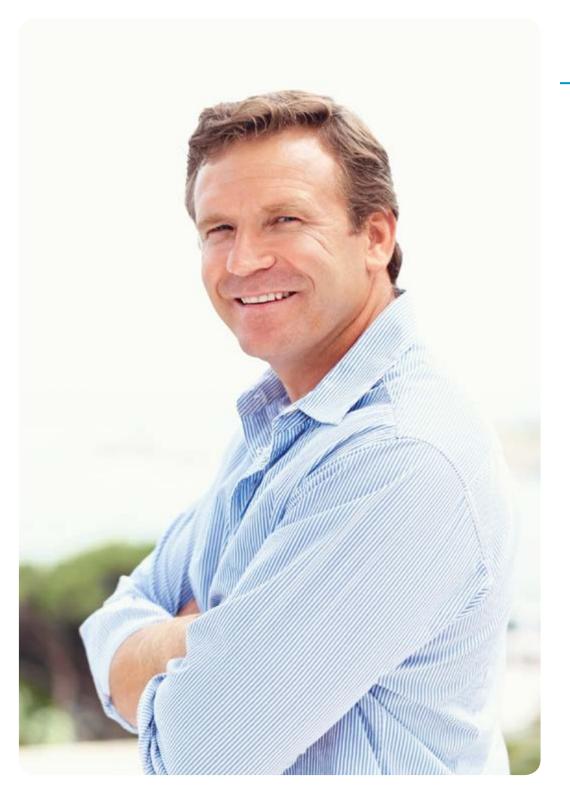


Sexual Health Inventory for Men (SHIM)³

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

How do you rate your confidence that you		Very Low	Low	Moderate	High	Very High
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 3	Slightly Difficult	Not Difficult 5
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

Erectile Dysfunction: Answers for Men 17

Questions and Concerns



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 InhibiZoneTM) 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, nonpyrogenic, 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.

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

Next...

Talk with your doctor

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

References

- Erectile dysfunction. http://kidney.niddk.nih.gov/ KUDiseases/pubs/ED/ErectileDysfunction_508.pdf. National Kidney and Urologic Diseases Information Clearinghouse Web site. Downloaded January 21, 2013.
- Selvin E, Burnett A, Platz E. Prevalence and risk factors for erectile dysfunction in the U.S. Am J Med. 2007;(120):151-157.
- Erectile dysfunction (ED). www.auanet.org/content/ education-and-meetings/med-stu-curriculum/ed.pdf. American Urological Association Web site. Downloaded January 21, 2013.
- DiMeo PJ. Psychosocial and relationship issues in men with erectile dysfunction. Urol Nurs. 2006;26(6):442-453.
- Viagra® Prescribing Information, Pfizer Inc. Revised January 2010.
- Cialis® Prescribing Information, Lilly USA, LLC. Revised October 2011.
- 7. Levitra® Prescribing Information, Bayer HealthCare Pharmaceuticals. Revised November 2011.
- Scott FB, Bradley WE, Timm GW. Management of erectile impotence: use of implantable inflatable prosthesis. Urology. 1973;2(1):80-82.

- Penile prosthesis. http://www.essm.org/society/esha/ malesd/oraltreatments/penileprosthesis.html. European Society for Sexual Medicine (ESSM) Web site. Downloaded January 1, 2013.
- AMS 700™ Patient Manual. Information and Instructions for Patients Considering an Inflatable Penile Prostheses. American Medical Systems. 2012.
- Rajpurkar A, Dhabuwala C. Comparison of satisfaction rates and erectile function. J Urol. 2003;170:159-163.
- 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.
- 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.



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CAUTION: Law restricts these devices to sale by or on the order of a physician. Indications, contraindications, warnings and instructions for use can be found in the product labelling supplied with each device. Information for the use only in countries with applicable health authority product registrations.