



Erectile Dysfunction Media Fact Sheet

What is Erectile Dysfunction?

Erectile dysfunction (ED) is a common condition defined by an inability to achieve or maintain an erection that is firm enough to have sexual intercourse.¹ ED can happen when blood flow to the penis is limited or nerves are damaged, but is associated with many risk factors. In other words, the penis doesn't get hard enough to allow for sex. It may begin in the bedroom, but it can have a profound effect on self-esteem and relationships with a partner.²



One study projects that around **322 million men** worldwide will have ED by 2025.³



Approximately **1 in 5 American men** aged 20 and older, suffers from some degree of ED.⁴

Signs and Symptoms of ED

Ability to get an erection sometimes, but not every time.⁵

Ability to get an erection, but not maintaining it long enough for sex.⁵

Inability to get an erection at any time.⁵

One Condition, Many Causes

There is no single cause of ED, and it may happen for a range of physical and psychological reasons.⁵

Risk factors of ED include diabetes, vascular disease, prostate cancer treatment, depression, anxiety and the side effects of some medications.⁵

Stress, smoking and excess drinking can also affect sexual performance.⁵

ED affects people of every ethnicity, age and lifestyle.⁶

Treatment Options for Erectile Dysfunction

ED is treatable at any age. Treating the underlying cause of ED is a good place to start, such as making lifestyle adjustments, quitting smoking and reducing stress. When these adjustments are not effective, there are several options available:

Oral Medications

Many people with ED start with pills, which may improve blood flow to the penis and help enable an erection.⁷



Penile Injections

Penile injections are administered directly into the penis, which may improve blood flow to the penis and help enable an erection.⁷



Vacuum Erection Devices (VEDs)

Vacuum erection devices use a mechanical pump designed to pull blood into the penis to cause an erection. Once an erection is achieved, an elastic tension ring is placed at the base of the penis to help maintain the erection.⁷



Penile Implants

A penile implant is a surgically implanted device which allows for direct control of both timing and duration of an erection.⁸



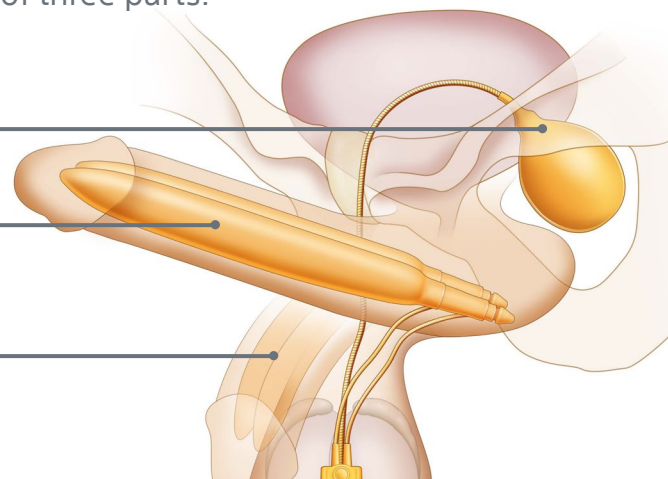
About the AMS 700™ Inflatable Penile Implant

How does the AMS 700 Inflatable Penile Implant work?⁹

The AMS 700 Inflatable Penile Implant is made up of three parts:

- 1 A pair of cylinders implanted in the penis.
- 2 A pump placed inside the scrotum.
- 3 A reservoir filled with saline placed in the lower abdomen.

- Reservoir
- Cylinder inflated
- Cylinder deflated
- Pump



Squeezing and releasing the pump is designed to create an erection and pressing the deflation button returns the penis to a natural-looking state.

What is the procedure and where is it performed?

The procedure, typically performed under outpatient care, done under anesthesia, involves a small incision in the scrotum or above the pubic bone for inserting all components. Most people return home within a day of the penile implant surgery and are back to normal activities within a week. They are typically able to activate the implant around four to six weeks post-surgery.⁹

Is the implant detectable?

The implant is undetectable and concealed in the body, so no one knows it's there. It is designed to look natural when erect and when flaccid.

Are patients satisfied with AMS 700 Penile Implant? How long does it last?

- In one study, 95% of 194 patients with an AMS 700 Penile Implant reported satisfaction with sexual intercourse.¹⁰
- In a study of 80 patients who received the AMS 700 Penile Implant, 97% would recommend a penile implant to a friend.¹¹
- A study of over 55,000 patients who received the AMS 700 Penile Implant showed that the 7-year mechanical survival rate is 94%.¹²

Potential Risks

As with any medical procedure, complications can occur. Side effects include, but are not limited to:⁹

- Natural or spontaneous erections as well as other interventional treatment options (such as oral medications, penile injections and VEDs) will no longer be possible.
- Infection, in which case the implant may have to be removed. To help reduce the risk of infection, the AMS 700 Penile Implant is the only implant available with antibiotic treatment already built in.¹³⁻¹⁸
- Pain, typically associated with the healing process.
- Mechanical failure of the implant.

All treatment options have varying degrees of success depending on the cause of the ED. An ED specialist can help determine which treatment options are appropriate for an individual's condition and lifestyle. For more information, visit EDCure.org.

Caution: U.S. Federal law restricts this device to sale by or on the order of a physician.

Results from case studies are not necessarily predictive of results in other cases. Results in other cases may vary.

IMPORTANT INFORMATION:

These materials are intended to describe common clinical considerations and procedural steps for the use of referenced technologies but may not be appropriate for every patient or case. Decisions surrounding patient care depend on the physician's professional judgment in consideration of all available information for the individual case.

Boston Scientific (BSC) does not promote or encourage the use of its devices outside their approved labeling. Case studies are not necessarily representative of clinical outcomes in all cases as individual results may vary.

AMS 700™ Inflatable Penile Prosthesis Brief Summary

Your doctor is your best source for information on the risks and benefits of the AMS 700™ Inflatable Penile Prosthesis. Talk to your doctor for a complete listing of risks, warnings and important safety information.

The AMS 700™ Inflatable Penile Prosthesis is intended for use in the treatment of male erectile dysfunction (impotence). Implanting a penile prosthesis will damage or destroy any remaining ability to have a natural erection, as well as make other treatment options (oral medications, vacuum devices or injections) impossible.

Men with diabetes, spinal cord injuries or skin infections may have an increased risk of infection. Implantation may result in penile curvature or scarring. Some AMS 700 devices contain an antibiotic (InhibiZone™ Antibiotic Surface Treatment). The device is not suitable for patients who are allergic to the antibiotics contained within the device (rifampin, minocycline HCl or other tetracyclines) or those who have systemic lupus, these patients should use one of the devices that do not contain InhibiZone antibiotic surface treatment.

Potential risks may include: device malfunction/failure leading to additional surgery, device migration potentially leading to exposure through the tissue, wearing away/loss of tissue (device/tissue erosion) infection, unintended-inflation of the device and pain/soreness.

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