



**Erectile
Dysfunction (ED)**
Patient Information
Guide



What is Erectile Dysfunction?

Erectile Dysfunction (ED) also known as impotence. ED is the inability to get or keep an erection firm enough for sexual intercourse.

Symptoms of ED include:

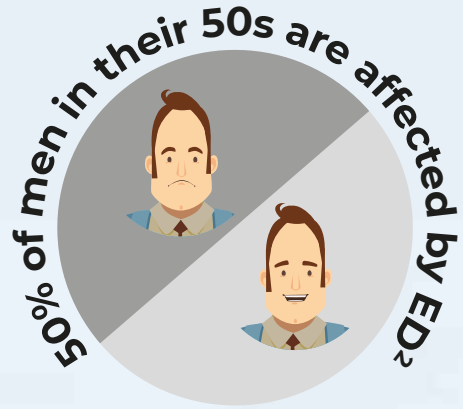
- Erections that are too soft for sex
- Erections that do not last long enough for sex
- An inability to get an erection

How Common is ED?

"ED is estimated to affect approximately 52% of men in age of 40 to 70 years.

ED affects about 10% of men per decade of life. For example, 50% of men in their 50s are affected by ED.

It is projected in 2025, the worldwide ED prevalence of about 322 million."²



What are Erections and how do they occur?

An erection is the result of increased blood flow into the penis. Blood flow is usually stimulated by either sexual thoughts or direct contact with the penis.

When a man is sexually excited, muscles in the penis relax. This allows for increased blood flow through the penile arteries, filling two chambers inside the penis. As the chambers fill with blood, the penis grows firm and elongated.

An erection ends when the muscles contract and the accumulated blood can flow out through the penile veins.

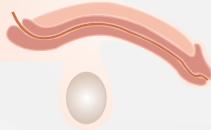
Stage 1



Initial Filling

With psychological or sexual stimulation, neurotransmitters cause penile smooth muscles to relax which increases blood flow to the body of the penis.

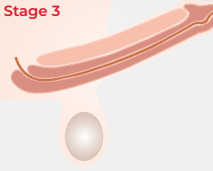
Stage 2



Partial Erection

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

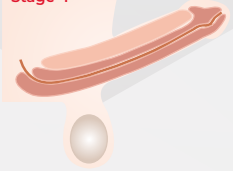
Stage 3



Full Erection

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

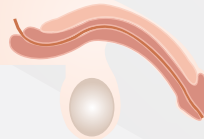
Stage 4



Rigid Erection

Maximum rigidity is attained. The body and the tip of the penis enlarge until the penile veins are forcefully compressed. This increases engorgement and maintains maximum penile rigidity which will later be followed by ejaculation.

Stage 5



Return to Flaccidity

Muscle contractions result in increased blood outflow from the penis, thus decreasing its length and girth, and then returning to its flaccid state.

Treatment Options for ED

There are many treatment options for ED. A urologist experienced in this field can discuss the various treatment options that may be the most appropriate, along with the risks and benefits of such treatments.

Treatment options include:

- Lifestyle changes (diet, exercise, quit smoking)
- Oral Medication (Viagra®, Cialis®, Levitra®)
- Vacuum Erection Devices
- Injection Therapy to inject medication directly into the penis
- Intraurethral Suppositories
- Penile Prosthesis

Rigicon Penile Prosthesis

Penile prostheses have been in use for more than 40 years. Thanks to the extensive technical developments and a large number of clinical research in this field, the penile prosthesis has become an effective and long-term ED treatment option for patients who cannot get satisfactory results with other treatment options.

A penile prosthesis is a medical device that is surgically implanted into the erection chambers of the penis. Penile prosthesis implantation offers a permanent solution where other treatment options may fail. It remains the gold standard for the treatment of patients with ED. Research shows that patients are more satisfied with the results of penile prosthesis implantation compared to other treatment options.

The penile prosthesis is available in two types: malleable prosthesis and inflatable prosthesis. The malleable prosthesis utilizes a pair of malleable rods whereas the inflatable prosthesis utilizes two cylinders, which are filled with saline solution, and are operated by squeezing a pump

implanted into the scrotum. Penile prostheses require surgical procedures usually with an overnight stay. Your urologist can discuss the details of the procedure, recovery process and how to use the prosthesis.

Consulting with a specialized urologist is important while deciding on which implant would be more suitable for you. Before a decision is made to go on with the procedure, patients must undergo proper counselling and education with their urologist and discuss all the implications and risks of surgery. It is advised to involve partners in the discussion.

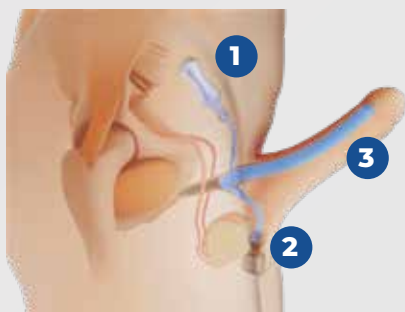
Benefits of Penile Prosthesis Implantation

- Offers a long-term solution to erectile dysfunction
- Provides the ability to have an erection anytime on-demand
- Allows for greater spontaneity – have sex when the mood strikes
- Enables you to maintain an erection as long as you desire
- Eliminates the need for costly pills or shots
- Feels natural during intercourse
- Does not interfere with ejaculation or your ability to orgasm

It is important to work with your doctor so that they can rule out or treat any underlying medical conditions.

Rigicon Infla10® Inflatable Penile Prosthesis

The Rigicon Infla10® three-piece inflatable penile prosthesis consists of a pair of cylinders implanted in the penis, a pump implanted in the scrotum, and a reservoir implanted in the lower abdomen. The Infla10® is a self-contained fluid filled (usually saline) system made from silicone. When the fluid within the reservoir is pumped manually into the cylinders by rapidly pressing and releasing the pump, the inflation creates an erection that provides rigidity.



- 1 Reservoir, placed in the abdomen**
- 2 Pump, placed in the scrotum**
- 3 Two cylinders, placed in the shaft of the penis**

Features of the Infla10® Inflatable Penile Prosthesis

- Entirely concealed within the body
- No adverse pharmacologic or hormonal effects one might experience with oral medications for ED
- Provides a natural-like erection
- The device is inflated to provide rigidity and deflated for concealment

Rigicon offers 3 models of Infla10® inflatable penile prostheses:



Infla10® X offers girth expansion, providing satisfactory axial rigidity while providing natural flaccidity.



Infla10® AX offers anatomical girth and length expansion, addressing concerns regarding post-operative penile shortening. The Infla10® AX offers up to 25% length expansion depending on patient anatomy.¹



Infla10® NarrowBody™ suitable for compromised or smaller anatomies.

Instructions for Use Infla10® Inflatable Penile Prosthesis

To Inflate

Fluid is transferred into the penile cylinders from the reservoir by squeezing and releasing the pump bulb in the scrotum repeatedly. As the fluid fills the cylinders, they inflate and result in an erection.

To Deflate

A flaccid state can be achieved by pressing the deflation button located on the pump and allowing fluid from the cylinders to transfer back to the reservoir.

To Inflate



To Deflate



Rigicon Rigi10™ Malleable Penile Prosthesis

The Rigicon Rigi10™ malleable prosthesis is the most effortless type of penile prosthesis. The prosthesis consists of a pair of malleable rods that are surgically inserted into the penis. The prosthesis is manually positioned up for sexual intercourse, or down for concealment during daily activities.



1 Two malleable rods, placed in the shaft of the penis

Instructions for Use Rigi10™ Malleable Penile Prosthesis

To obtain an erection, simply bend the penis in the direction desired. When you are finished, bend it back down to conceal it.

Erect State



Flaccid State



Features of the Rigi10™ Malleable Penile Prosthesis

- Easier to use
- Requires less manual dexterity
- Simpler surgical implantation procedure
- Lower risk of mechanical failure
- Entirely concealed within the body
- No adverse pharmacologic or hormonal effects one might experience with oral medications for ED treatment

When compared to the inflatable penile prosthesis

Rigicon Infla10® Inflatable Penile Prosthesis

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

The Rigicon Infla10® 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 impossible.

Men with diabetes, spinal cord injuries or skin infections may have an increased risk of infection. Implantation may result in penile shortening, curvature or scarring.

Potential risks may include: device malfunction/failure leading to additional surgery, device migration potentially leading to exposure through the tissue, device/tissue erosion, infection, unintended-inflation of the device, pain/soreness, patient dissatisfaction, allergic reaction, urinary obstruction, post-operative bleeding, hematoma, penile oedema, penile necrosis, perforation of the corpora or the urethra, inability to adequately dilate the corpora, incorrect sizing of the implant, and tearing or ripping of the device during or after implantation. Speak with your urologist for your individual situation.

Rigicon Rigi10™ Malleable Penile Prosthesis

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www.rigicon.com

 rigicon  rigiconurology  rigiconurology  rigiconurology

Rigicon, Inc.

2805 Veterans Memorial Hwy STE 5, Ronkonkoma, NY 11779
United States of America +1 (888) 202-9790
www.rigicon.com



References:

1 Data on file.

2 Feldman HA, Goldstein I, Hatzichristou DG, et al.
Impotence and its medical and psychosocial correlates:
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Continued Safety Monitoring
Report any serious device incidents to Rigicon on
operations@rigicon.com