

Erectile Dysfunction (ED)

A patient guide



Coloplast

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Erectile Dysfunction (ED): It's common¹ and treatable²

Erectile dysfunction is the consistent inability to sustain an erection sufficient for sexual intercourse.¹ That can be:

- Not getting an erection at all
- Getting an erection inconsistently
- Getting an erection that doesn't stay hard enough for sex

If you have ED, you're not alone. **over 100 million men***

40%

of men over 40
are affected by ED³



50%

of patients say that
ED negatively impacts
their everyday life⁴

While erectile dysfunction is common, it is **not an inevitable part of aging**,¹ and in most cases, **it can be overcome.**

We know ED can affect your self-confidence and have a negative impact on your relationship.

Read this guide to learn more about:

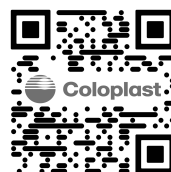
- Erectile dysfunction
- Treatment options
- **Resources** available to you including
 - How to **find a physician** specializing in Men's Health and
 - **Patient Educators** who have taken control of ED with a penile implant

Want to talk to someone who has been there?

Patient Educators are **men and their partners** who have **found a solution to their ED** with a penile implant – and they're ready to **share their experiences with you.**

Ask them questions about:

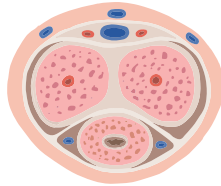
- what it's like to live with a penile implant
- what you can expect throughout your ED journey
- how they returned to feeling like themselves again



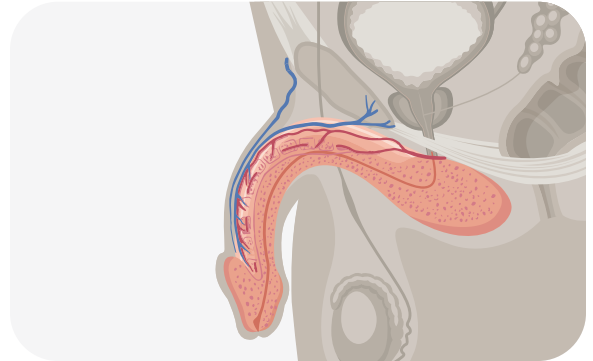
To schedule time to meet with a Coloplast Patient Educator, visit erectile-dysfunction-solutions.uk, or call our nurse Clare on 07703 477315, alternatively scan the QR code, and click on "Talk to a Patient/Nurse."

How does an erection occur?⁵

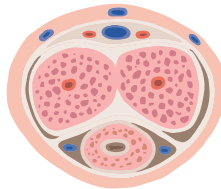
- 1 Sexual stimulation and excitement cause the brain, nerves, the heart, blood vessels and hormones to work together to produce a rapid increase in the amount of blood flowing to the penis.



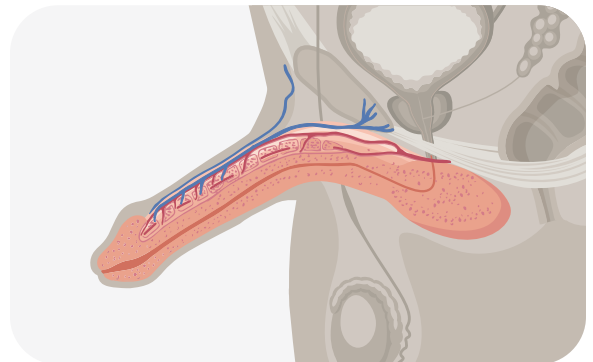
Cross-section of penis



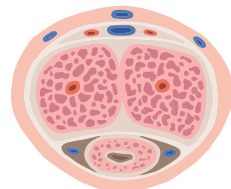
- 2 The blood becomes trapped and held in the two spongy chambers in the shaft of the penis.



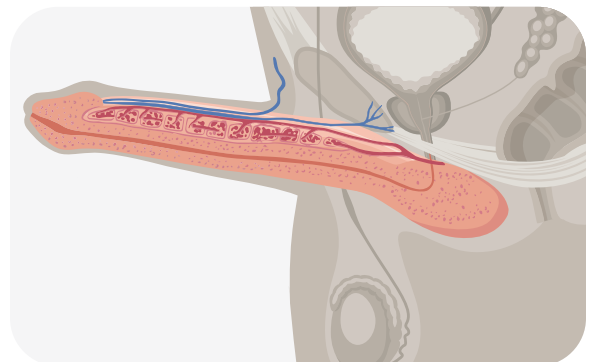
Cross-section of penis



- 3 As the chambers rapidly fill with blood, they expand, and the penis becomes firm and elongated. The result is an erection.

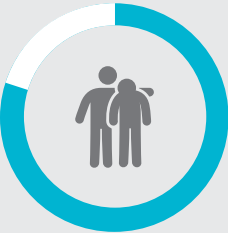


Cross-section of penis



Causes of ED

Erections may not occur as expected and erectile dysfunction may occur due to one of several medical conditions that decrease blood supply and nerve function. If a medical condition is the cause of erectile dysfunction, it means there are treatment options. **For more than 80% of men with ED, it is caused by a physical problem or disorder.**⁶ The cause can usually be identified, and proper treatment can help you and your partner return to a satisfying sex life.



80%

of the time ED is caused by a physical problem or disorder⁶



Physical causes include:⁷



Disease
(such as diabetes, high blood pressure, or high cholesterol)



Surgery
(such as prostate removal)



Medication/substance use
(such as tobacco, drugs, alcohol, and some medications)



Injury
(such as brain or spinal cord injury)

Learn more about the link between ED and the following on the next few pages:

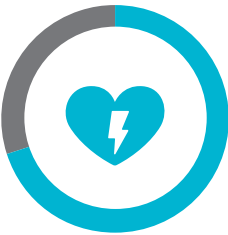
- Cardiovascular disease
- Diabetes
- Peyronie's disease
- Prostate cancer treatments

It is important to consider making lifestyle changes such as stopping smoking, losing weight, increasing physical activity and eating a healthy diet. Adopting better choices can have a positive impact on your erectile function.

Cardiovascular disease and ED

ED is common among patients with cardiovascular diseases (CVD) and can be an early warning sign of cardiovascular disease.⁸

With coronary artery disease, a buildup of plaque inside the arteries can limit the amount of blood that's able to flow through them.⁹ Because the arteries that supply blood to the penis are much smaller than the ones that feed the heart, the problem may show up earlier as having difficulty getting an erection.⁸



Almost
70%

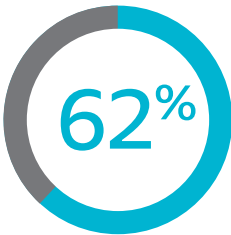
of men with ED end up having **coronary artery disease**⁸



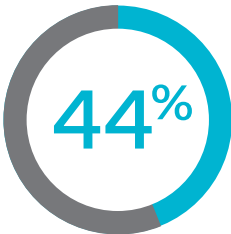
What it means for you

If you are experiencing ED, you should talk with your doctor about your potential risk for cardiovascular disease. And if you're already taking certain medications such as nitrites for your heart or alpha-blockers to manage blood pressure, your doctor will discuss whether ED medications are right for you or whether other options may be more appropriate.

In one study that followed men for an average of six years, those with ED were



more likely to have a **heart attack** and,



more likely to have a **cardiovascular event**⁸

Diabetes and ED

Diabetes can cause nerve, blood vessel, and muscle damage¹⁰ that results in problems like pain, numbing or loss of sensation in the hands and feet. These issues can also result in ED problems because nerve signals and blood flow are necessary to the process of getting an erection.



What it means for you

If you are a diabetic and experiencing ED, talk with your doctor or diabetes educator about the treatment options that may be best for you. Most cases of ED can be treated, and oral medications are often the first step. However, they have been shown to be less effective for men with diabetes, and more advanced treatment options may be needed.¹¹

Over



of men with diabetes experience ED.

ED can even be the **first symptom** of the disease, especially in younger men¹⁰

Men with diabetes are



more likely to have ED than other men, and it often affects them at a **younger age**¹⁰

Peyronie's disease and ED

An estimated

1 in 10

men in the UK have Peyronie's disease¹²

Peyronie's disease is a condition resulting from fibrous scar tissue that develops on the penis. The scar tissue can change the shape of the erect penis, causing curved erections. This can cause discomfort and make sexual intercourse difficult.¹² **Many men with Peyronie's disease also experience ED.**¹³

The cause of Peyronie's disease isn't entirely known. It is believed that repeated injury to the penis causes scar tissue to form. The injuries may be small, unrecognized events that occur during sexual intercourse, athletic activity, or from a more obvious trauma. Risk factors can include age, family history of Peyronie's disease, trauma, and diabetes.



Studies demonstrate that the prevalence of ED among patients with Peyronie's disease can reach up to

54%¹³

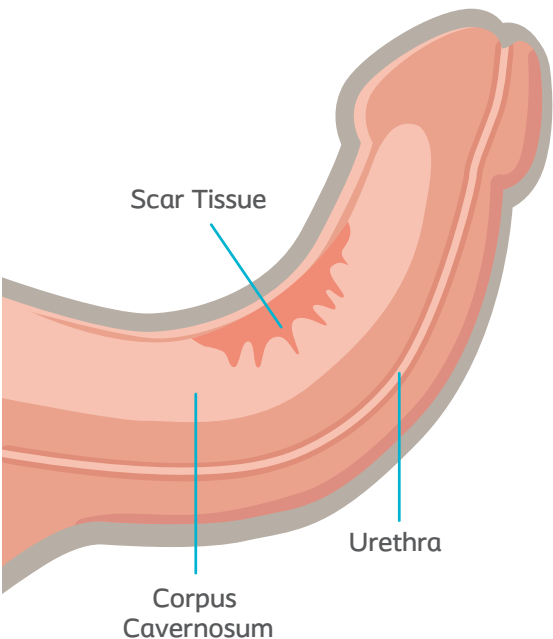
What it means for you

The Titan[®] penile implant is a treatment method for patients experiencing erectile dysfunction in the presence of Peyronie's disease. During the procedure to place the penile implant, the physician may choose to perform a straightening technique called manual modeling.

Manual modeling is used to straighten the penis and correct the deformity caused by Peyronie's disease.

*The Titan implant is the only penile implant FDA approved for the treatment of erectile dysfunction in the presence of Peyronie's disease.*¹⁴

Refer to page 24 for the Titan implant information.



Prostate cancer treatments and ED

Prostate cancer itself will not cause ED, but treatment options, like **radical prostatectomy** and **radiation therapy**, may affect your erections by impacting nerves or blood flow.⁷

Even though prostate removal is considered the gold standard of care for prostate cancer, **1 in 5 men are unhappy with their functional results** likely due to sexual dysfunction.¹⁵

As a prostate cancer survivor, you may have ED as a result of your treatment. You don't have to live with these side effects² and deserve to have your erectile function restored.



What it means for you

Speak with your physician about the right ED treatment options for you following prostate cancer treatments.



Radical prostatectomy

During prostate surgery or prostate removal, the nerve bundles may be damaged.

After a **prostatectomy**, approximately

47%

of patients, experience **moderate to severe ED**¹⁶



Radiation therapy

Over time, the radiation therapy may damage blood vessels to the penis, preventing blood flow.

Within 5 years of **radiation therapy**, approximately

50%

of patients, could develop **radiation-induced ED**¹⁷

ED treatment options

There are several treatment options depending on the reason for your ED. It's important to explore and learn about all alternative treatment options. **Your doctor will be able to explain all your options and help you choose the best option for you.**



Oral medication

Pills like Viagra,[™] Cialis,[™] Levitra,[™] or Spendra[™] may help achieve erections in response to stimulation. They must be taken at least half an hour to one hour before anticipated sexual activity. Potential side effects include headaches, facial blushing, upset stomach, back pain/muscle aches, and nasal congestion.¹⁸



Penile injections

For this treatment option, a needle is placed into the penis to inject medication to create an erection. This produces an erection with 5-20 minutes.¹⁹ Potential side effects include priapism (erection lasting 4 hours or more), penile pain, numbness or irritation, bruising at the injection site, and penile fibrosis (deformed penis shape).²⁰



Vacuum erection devices

Vacuum erection devices are external pumps placed over the penis to help with ED. The device, consisting of a cylinder and pump, creates a vacuum that pulls blood into the penis creating an erection and a constriction ring that helps maintain the erection. Patients that use vacuum erection devices may have a learning curve and may experience an erection that is not warm to the touch.²¹



Insertable medication

Insertable medications are another ED solution available but are not as commonly prescribed. A small pellet (suppository) is inserted into the urethra using an applicator and the pellet is released allowing for increased blood flow, creating an erection. Erections usually start within 10 minutes and last between 30-60 minutes. Side effects can include burning and aching in the penis and groin.²²



Penile implants

A penile implant offers a long-term solution for ED.²³ It is an erection assistance device that is placed inside the body during a surgical implant procedure. Read on in the following pages of this brochure for more information on penile implants. Refer to the important safety information at the end of this brochure to view potential complications.

TM* Third party brands are property of their respective owners.

Typical ED treatment pathways

Here are some typical ED treatment pathways

Oral medication:

75% of patients, start with pills as a first line ED therapy²⁴



50% of patients **discontinue treatment in the first year** due to reasons such as:

- Medication failure
- Concerns about side effects or long-term safety²⁵

77% of patients who try a second treatment **move onto another brand of pills**²⁶

It is estimated that for

40% of cases, pills are **not effective**²⁶

Penile injections:

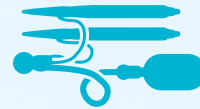
20% of patients who try a second treatment try penile injections²⁶



It is estimated that for

30% of cases, **injections fail to work** or men experience **priapism** (erection lasting 4 hours or more)²⁶

Penile implants



For some patients, when pills and injections no longer work, they move to a penile implant. For other patients, they may move to a penile implant right away.²⁷

Penile implants have been shown to be a more effective long-term ED treatment.²³



Penile implants

A penile implant is a long-term solution to ED²³ that can restore a man's confidence without the hassle of timing medication or using needles.⁴

It is an erection assistance device that is designed to help a man get an erection and is **completely hidden inside the body**. It puts the man back in **control of his body and can be used at any time**. Unlike other treatments for ED, a penile implant **restores spontaneity and allows a man to get an erection without any planning or waiting**.⁴



98% patient satisfaction
with the Titan[®] implant
for erectile dysfunction⁴

96% partner satisfaction
with the Titan implant
for erectile dysfunction²⁹

How is the device implanted?

The device is implanted during a procedure through a small opening in the skin. Most men return home from the procedure the next day and are able to resume sexual activity upon his doctor's clearance, **typically after 6 weeks**.³⁰

Refer to the important safety information at the end of this brochure to view potential complications.

Titan® Inflatable Penile Implant

The Titan® inflatable penile implant was designed to **mimic the look and performance of a natural erection**.⁴ The Titan implant is made with a unique material called **Bioflex**,[®] which is a material that is safe for your body and is **stronger than silicone**.³¹ The Bioflex material was specifically engineered for penile implants to **make them stronger**³² and **more durable**³¹ than other penile implants available.

The Titan implant has three parts:

1

A reservoir
placed in the
abdomen

2

Two cylinders
placed in
the penis

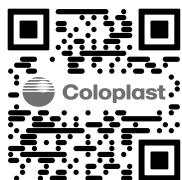
3

A pump
placed in the
scrotum

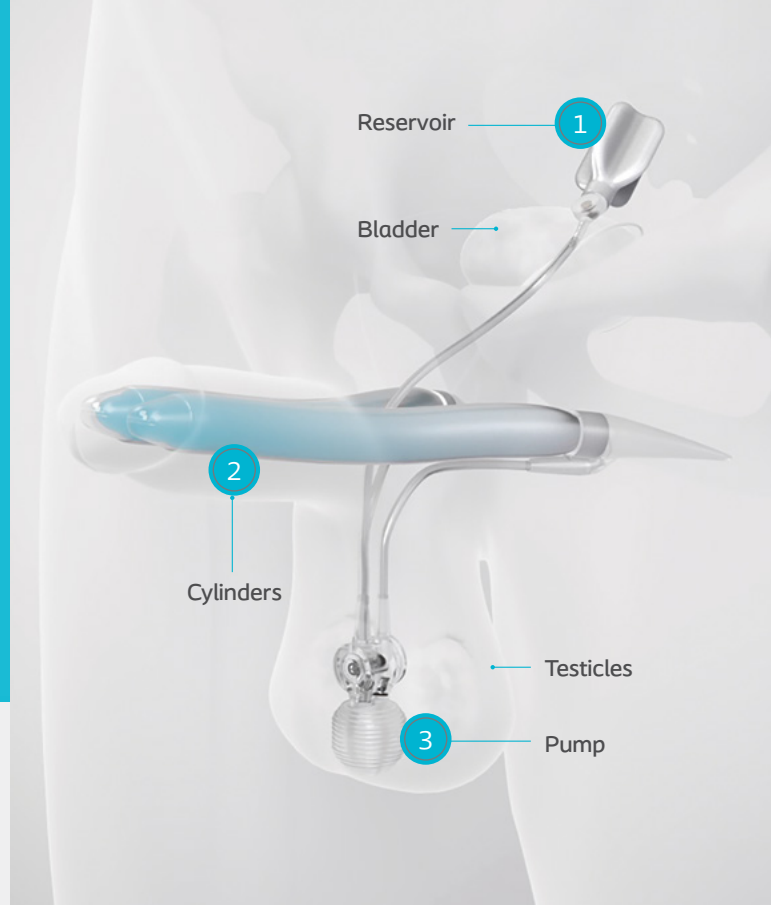
Titan inflatable penile implant features:⁴

- Easy to use and activate
- One-step deflation
- Not visibly noticeable when flaccid
- Acts and feels more like a natural erection
- Maximizes the girth and rigidity of the penis

If you'd like to talk to someone who has the Titan implant, schedule time to meet with a **Coloplast Patient Educator**.



To schedule time to meet with a **Coloplast Patient Educator**, visit [Erectile-dysfunction-solutions.uk](https://erectile-dysfunction-solutions.uk) and click on "Talk to a Patient" or scan the QR code.



How does the Titan implant work?

When you squeeze the pump in the scrotum, fluid moves from the reservoir into the cylinders in the shaft of the penis, creating an erection.

When you press the deflate button on the pump in the scrotum, the fluid moves out of the penis and back into the reservoir for a natural looking flaccid state.³³

Reasons to consider a penile implant:



A discrete treatment for ED:

A penile implant is not visibly noticeable when your penis is flaccid. Others won't be able to tell you've had an implant to treat your ED unless you tell them.⁴

98%

Patient satisfaction rates:

Patients report a 98% satisfaction rate for Titan® penile implants.⁴ Partners of those with a Titan implant are also highly satisfied with a 96% satisfaction rate.²⁹



Minimal recovery time:

Every man is different, but a typical recovery time after a penile implant procedure is four to six weeks. After you've fully recovered, you can begin enjoying sex again.³⁰



Cost-effective:

Penile implants have been shown to be the most cost-effective ED treatment over a 10-year period.²⁶



NHS coverage:

Penile implants are prescribed by your surgical team and are generally covered on the NHS in most cases of ED.



Spontaneity:

Penile implants give patients the ability to have an erection instantly and spontaneously, any time.⁴

Why does the Bioflex® material make a difference?

The Titan Inflatable Penile Implant is made of the exclusive Bioflex® material, which gives the cylinders enhanced durability, rigidity and girth compared to the competitive penile implant.

3x

More durable³¹

than competitor penile implant

The Titan penile implant may enhance penetration performance for greater confidence in a variety of sexual positions so patients can feel uninhibited.^{31,32,35}

17%

More girth

than competitor penile implant³⁶

The maximized girth of the Titan implant may lead to increased partner stimulation and satisfaction.³⁷

3x

More rigid

than competitor penile implant³²

Increased rigidity may enhance penetration performance during sexual intercourse with your partner.³²

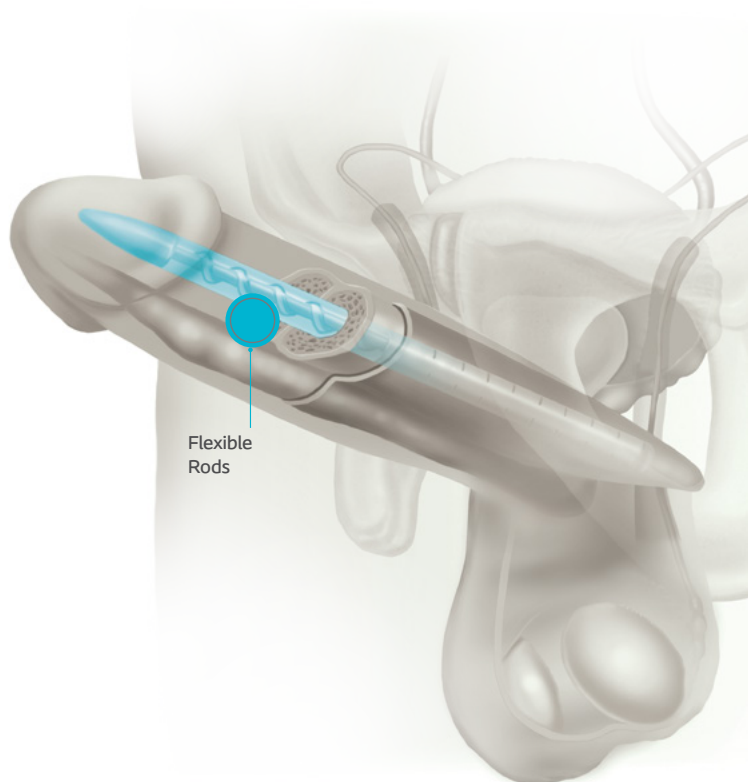
Refer to the important safety information at the end of this brochure to view potential complications.

What are malleable penile implants?

The Genesis® malleable penile implant consists of two firm but flexible rods that are placed into the shaft of the penis. There are no other parts to this implant. To have an erection, you simply hold the penis and move it into the desired position. When you are finished, you bend it back down to conceal it. The malleable penile implant can be a good option for men with limited dexterity.³⁸

Genesis implant features:³⁸

- Easy for you or your partner
- Good option for men with limited dexterity
- Because it stays firm when not erect, may be more difficult to conceal in clothing



Both the Titan® and Genesis® penile implants are totally concealed in the body and give a man with ED the ability to have an erection – **instantly, whenever the time is right, for however long he and his partner want.**⁴

It helps put the man back in control and back to a normal life.

Speak with a doctor to determine if a penile implant is right for you.

Are you a partner of someone with ED?

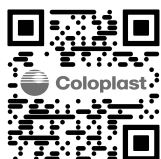
Erectile dysfunction (ED) is often called the couple's disease. It can impact your **self-esteem and relationship by limiting the intimate moments** you have with your partner.³⁹

As a partner, you may feel guilty or rejected³⁹ if your partner cannot get an erection. However, for more than 80% of men, the cause of their Erectile Dysfunction is from a physical problem or disorder.⁶ **Don't blame yourself.**

It is important to **open the lines of communication with your partner and emphasize why talking about ED is important to you.**³⁹ Do not approach the conversation with negative emotions. Men with ED can often experience deep feelings of shame, loneliness, anxiety, and depression. He may often say the ability to have an erection makes him feel like less of a man.⁴⁰

Learn about ED and potential treatment options. Speaking with a urologist who specializes in men's sexual health can allow you and your partner to **understand the right treatment options for both of you.**

Learn more about how to support a partner through their ED journey and download a guide on how to talk to your partner about ED:



Visit [Erectile-dysfunction-solutions.uk](https://erectile-dysfunction-solutions.uk) or scan the QR code.



42% of women feel their partner's ED is their fault⁴¹

94% of men with ED felt their partner's support was important³⁹



Partners report a **96% satisfaction rate** with penile implants²⁹

There was a romance, a spark that was put back that we didn't know went out.

- STAN

After the operation, I noticed a change in my husband in terms of his self-esteem. It's something that's made him feel comfortable and happy; he feels like a different man.

- ANABEL



Frequently asked questions

Q. Can I have an orgasm and ejaculate with a penile implant?

A. You should be able to have an orgasm and ejaculate with a penile implant if you were able to ejaculate and orgasm before the implant.⁴² Consult your physician about your expected outcome.

Q. Will a penile implant cause me to lose sensation in my penis?

A. If you had sensation in your penis before receiving the implant, you should have the similar sensation in your penis after the implant.⁴³ The implant and associated surgery is not supposed to change your penis sensation since typically the surgery does not have any negative effects on the nerves in the head of the penis that cause sensations. If you are considering moving forward with penile implant surgery, it is important to find a urologist that has adequate training in men's sexual health and the penile implant procedure and further discuss the risks and benefits of the penile implant procedure.

Q. What is the recovery time?

A. Everyone is different and recovery time varies, but typically it's 6 weeks until you can resume sexual activity.³⁰ Your surgical team will determine what you can and can't do during this time. It is important to follow all recommendations from your physician for the best outcome.

Q. Will I lose any length after getting a penile implant?

A. Each penile implant is custom fit to your anatomy.⁴³ Like any body part that goes unused for a long time, the muscles and fibers of that body part begin to break down. If it has been a long time since you've achieved a good erection, you may experience some atrophy and perceived penis shortening. Discuss this in greater detail with your physician.

Q. Will anyone notice that I have an implant?

A. The Titan® implant is completely placed inside your body and is not visibly noticeable. The penis appears relaxed and normal when in the flaccid state,⁴ and it is not obvious by looking at a man that he has an implant. The Genesis® malleable implant stays firm when not in the erect position, and it may "show" through clothes.

Q. How long does the penile implant last?

A. A study showed that estimated overall device survival rates are: 87.2% at 5 years, 76.8% at 10 years, and 63.7% at 15 years.²³

Frequently asked questions

Q. Will I be able to have spontaneous erections with a penile implant?

A: Both the Titan® and the Genesis® implants give you the ability to have an erection instantly and spontaneously, any time you want one.⁴ However, the implant surgery makes it impossible to ever have a “latent” or natural erection that’s not dependent on the device.³³ Therefore, you should consider carefully whether or not an implant is the right choice for you.

Q. What is the difference between the Genesis and the Titan implants?

A: Both help give you the ability to have an erection satisfactory for intercourse. The main difference is that the Genesis is a flexible (malleable) implant that consists of two firm but bendable rods that are placed into the shaft of the penis (corpora cavernosa). There are no other parts to this implant. To have an erection, you simply hold the penis and move it into the desired position. When you are finished, you return the penis to its tucked-down position. With the Titan implant, you inflate the cylinders by squeezing the pump located in your scrotum to achieve an erection, and deflate by pressing the release valve to return the fluid from the cylinders into the reservoir to return to flaccid state.

Q: Is a penile implant available on the NHS?

A: Most patients will be entitled to erectile dysfunction treatment on the National Health Service (NHS). This includes penile implants although your urologist may recommend trying less invasive ED treatments further. Speak to your GP about a referral to a urologist who specializes in Erectile dysfunction treatment.

Q. Will the Titan implant interfere with other equipment (e.g., MRI)?

A: The Titan implant contains metal that can be safely scanned by airport security. The Titan implant is MR-Conditional meaning it can be scanned by a magnetic resonance imaging (MRI) machine when it is used according to MR-Conditional specifications. After surgery you will receive a Patient Implant Card to carry at all times. This card identifies your device as MR-Conditional and provides the specific manufacturing details of your penile implant.⁴

Q: Can I go through airport security with the Titan implant?

A: Yes, the Titan penile implant is safe for standard airport security.

Q: What can I expect after the penile implant procedure?

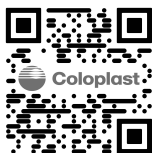
A: After the penile implant procedure, mild swelling, pain, and discomfort can occur.⁴⁴ Your doctor will advise on when to return to normal activities. Most men can resume strenuous physical activity and sexual activity about 4-6 weeks after the procedure. Sexual activity should not be resumed until approval is received from the implanting physician.⁴⁵

Q: What are the risks of the penile implant?

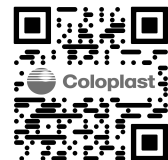
A: Review the Important Safety Information on pages 42-45 for a full list of risks and potential complications.

Where can you go from here?

Continue to learn more about ED and treatment options by scheduling time with the following resources:



Schedule time with a **Patient Educator.**



Schedule time with a **Physician** who specializes in ED and Men's Sexual Health.

- 1 Visit **Erectile-dysfunction-solutions.uk** to listen to patient stories, see how a penile implant works, or to schedule time with a patient educator or urologist who specializes in ED and men's sexual health
- 2 Take the **Sexual Health Inventory for Men (SHIM)** on the next page and bring it in to your doctor's appointment.
- 3 Speak to a **Men's Health Nurse Specialist** on 07703 477315 or via email **GBCLAK@Coloplast.com** to discuss ED, penile implants, and find a solution that is best for you.
- 4 Set up an **appointment** with your urologist or specialist nurse to learn more about erectile dysfunction and penile implants. Click "Find a Physician" on **Erectile-dysfunction-solutions.uk** or use the QR code on the page to the left to schedule time.



Sexual Health Inventory for Men (SHIM)⁴⁶

The SHIM is an ED questionnaire to help patients and physicians in the diagnosis of erectile dysfunction. Bring your answers to this survey to an appointment with your physician to assist in the diagnosis of ED.

Over the past 6 months:

1. How do you rate your confidence that you could keep an erection?

- ☐ 1 – Very Low
- ☐ 2 – Low
- ☐ 3 – Moderate
- ☐ 4 – High
- ☐ 5 – Very High

2. When you had erections with sexual stimulation, how often were your erections hard enough for penetration (entering your partner)?

- ☐ 1 – Almost never or never
- ☐ 2 – A few times (much less than half the time)
- ☐ 3 – Sometimes (about half the time)
- ☐ 4 – Most times (much more than half the time)
- ☐ 5 – Almost always or always

3. During sexual intercourse, how often were you able to maintain your erection after you had penetrated (entered your partner)?

- ☐ 1 – Almost never or never
- ☐ 2 – A few times (much less than half the time)
- ☐ 3 – Sometimes (about half the time)
- ☐ 4 – Most times (much more than half the time)
- ☐ 5 – Almost always or always

4. During sexual intercourse, how difficult was it to maintain your erection to completion of intercourse?

- ☐ 1 – Extremely difficult
- ☐ 2 – Very Difficult
- ☐ 3 – Difficult
- ☐ 4 – Slightly Difficult
- ☐ 5 – Not Difficult

5. When you attempted sexual intercourse, how often was it satisfactory for you?

- ☐ 1 – Almost never or never
- ☐ 2 – A few times (much less than half the time)
- ☐ 3 – Sometimes (about half the time)
- ☐ 4 – Most times (much more than half the time)
- ☐ 5 – Almost always or always



Do you prefer take the SHIM online?

Visit ColoplastMensHealth.com or scan the QR code.

Add the numbers corresponding to questions 1-5.

TOTAL: _____

The Sexual Health Inventory for Men (SHIM) 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
- 22-25:** No significant ED

Important Safety Information

Titan® and Titan® Touch Inflatable Penile Prosthesis – Important Safety Information

A penile implant, also called a penile prosthesis, is concealed entirely within the body to address erectile dysfunction (impotence). The implant requires some degree of manipulation before and after intercourse to make the penis erect or flaccid.

Indications

The Titan and Titan Touch Inflatable Penile Prosthesis is indicated for male patients suffering from erectile dysfunction (impotence) who are considered to be candidates for implantation of a penile prosthesis.

Contraindications

The Titan and Titan Touch Inflatable Penile Prosthesis is contraindicated in patients who have one or more of the following: (1) Patients with an active infection present anywhere in the body, especially urinary tract or genital infection. (2) Patients with a documented sensitivity to silicone. (3) Patients with unresolved problems affecting urination, such as an elevated residual urine volume secondary to bladder outlet obstruction or neurogenic bladder. (4) Patients unwilling to undergo any further surgery for device revision.

Warnings

Implantation of the device may make latent natural erections, as well as other interventional treatment options, impossible. Men with diabetes or spinal cord injuries, as well as immunocompromised patients, may have an increased risk of infection associated with a prosthesis. Implantation of a penile prosthesis may result in penile shortening, curvature or scarring.

Precautions

Removal of an implanted prosthesis without timely reimplantation of a new prosthesis may complicate subsequent reimplantation or may make it impossible. MRI quality may be compromised if the area of interest is in the exact same area or relatively close to the position of the Titan, and Titan Touch IPP. Be sure to consult with your physician. Patients

should discuss all available treatment options and their risks and benefits with their physician. Health conditions which hamper sexual activity, such as severe chest pain (angina), may prevent successful use of this device. The prosthesis should not be implanted in patients who lack the manual dexterity or strength necessary to operate the device. Trauma to the pelvic or abdominal areas, such as impact injuries associated with sports (e.g., bicycle riding), can result in damage of the implanted device and/or surrounding tissues. This damage may result in the malfunction of the device and may necessitate surgical correction, including replacement of the device. The device may be used in the presence of Peyronie's disease.

Potential Complications

Penile implants are surgical solutions requiring a healing period that have risks associated with surgery such as scrotal swelling, auto-inflation, discomfort, angulation/curvature, swelling (edema), device malfunction, chronic pain, difficulty with ejaculation, transient urinary retention, fever, migration, patient dissatisfaction, infection at surgical site or wound, deflation, swelling of clotted blood or clear fluid (hematoma/seroma), wound leakage, bleeding, delayed wound healing, narrowing of the opening of the foreskin (phimosis), sensory loss, cylinder malfunction, formation of thick tissue (fibrous capsule formation), over/under inflation, erosion, scrotal reddening (erythema), genital change, and inguinal hernia.

This treatment is prescribed by your physician. Discuss the treatment options with your physician to understand the risks and benefits of the various options to determine if a penile implant is right for you.

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

Genesis® Malleable Penile Prosthesis - Important Safety Information

A penile implant, also called a penile prosthesis, is concealed entirely within the body to address erectile dysfunction (impotence). The device is manually positioned to simulate an erect or flaccid penis.

Intended Purpose

The Genesis Malleable Penile Prosthesis is a flexible silicone elastomer device designed to be implanted into the penis for the management of erectile dysfunction (commonly known as impotence).

Indications

The prosthesis is designed for the management of erectile dysfunction (impotence) stemming from a variety of causes, including: epispadias (a rare birth defect located at the opening of the urethra), pelvic fracture; spinal cord injury or disease; prostatectomy; cystectomy; abdominal-perineal resection (surgical removal of the anus, rectum, and sigmoid colon); multiple sclerosis; diabetes mellitus; alcoholism; arteriosclerosis and hypertensive vascular disease; priapism (prolonged and painful erection of the penis); and Peyronie's disease (curvature of the penis). The Prosthesis may also be used in selected patients with psychogenic impotence.

Contraindications

The Genesis Malleable Penile Prosthesis should not be used in: patients with an active infection present anywhere in the body, especially urinary tract or genital infection; patients with a documented sensitivity to silicone; and, patients with unresolved urinary problems, such as an elevated residual urine volume secondary to bladder outlet obstruction or neurogenic bladder.

Warnings

Implantation of a penile Prosthesis may make natural erections difficult to achieve. It may make some other interventional treatment options not possible. Implantation of a penile Prosthesis may result in penile shortening, curvature or scarring. Men with diabetes as well as immunocompromised patients, may have an increased risk of infection which could result in permanent damage to tissue/organs.

Consult with your physician if you are experiencing a change in rigidity or appearance of the erect penis. Replacement of the prosthesis may be necessary. If you have borderline bladder decompensation, an indwelling catheter, or enlargement of the prostate talk to your doctor.

Precautions

Patients should be informed that erections achieved with a malleable penile Prosthesis may differ from original erection (e.g. not of equal length or girth) compared to what was previously experienced with natural erections. Talk with your physician regarding realistic expectations. Health conditions which hamper sexual activity (e.g. severe angina) may prevent successful use of this device. Penile implants are not considered lifetime implants due to the inherent nature of mechanical devices. Trauma to the pelvic area, such as impact injuries associated with sports, can result in damage of the implanted device and/or surrounding tissues. This damage may result in the malfunction of the device and may necessitate surgical correction, including replacement of the device.

Potential Complications

Adverse events are known to occur with penile protheses procedures and implants; some may require revision surgery or removal of the implant. Adverse events following penile protheses implantation may be new (de novo), persistent, worsening, lasting for a short time (transient), or permanent.

Penile implants are surgical solutions requiring a healing period that have risks associated with surgery such as deformity, delayed / impaired / abnormal wound healing, injury to tissue or organs (erosion / extrusion / migration) resulting in damage or loss of tissue (necrosis), opening or tunnel between tissue or organs (fistula), allergic reaction or sensitivity to device, collection of blood or fluid outside of tissue or vessels (hematoma, seroma), bleeding or excessive bleeding (hemorrhage), infection, redness or swelling of tissue, irritation, penile implant moves (migration), penile tissue dying off (necrosis), pain/discomfort, inability to pull the foreskin forward over the tip of an uncircumcised penis (paraphimosis), inability to pull the foreskin back from the tip of an uncircumcised penis (acquired phimosis), perforation or injury of soft tissue (e.g., muscles, nerves, vessels), penile structures, or organs (e.g., urethra), scarring, difficulty during sexual activity, numbness or decreased sensation in penis, blockage or slowing of urine (urethral obstruction / occlusion), urinary tract infection, and difficulty emptying bladder.

The occurrence of these events may require one or more subsequent surgeries which may or may not always fully correct the complication.

This treatment is prescribed by your physician. Discuss the treatment options with your physician to understand the risks and benefits of the various options to determine if a penile implant is right for you.

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

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