

Patient Information Leaflet

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What is Genesis Malleable Penile Prosthesis?

Genesis Malleable Penile Prosthesis is a surgically implanted penile prosthetic device intended for the management of erectile dysfunction (impotence) in men. Genesis is a set of semi-rigid, bendable, silicone rods with hydrophilic (water absorbing) coating implanted in the penis to produce an erection for sexual intercourse. An erection is created by grasping the penis and bending it into the desired position for intercourse, and following intercourse, the penis is bent back to its previous position concealing the device.

Is Genesis the right option for me?

There are a number of surgical and non-surgical options available to treat erectile dysfunction, each with unique benefits and risks. Discuss the benefits and risks of each treatment with your doctor to determine the best option for you based on your expectations, medical history, pre-existing conditions, current health and lifestyle.

Genesis cannot be implanted if you have one or more of the following conditions:

- Are sensitive or allergic to silicone
- Have ongoing difficulty urinating or emptying the bladder
- Have an active infection, particularly urinary tract or genital infection

Implantation with a malleable penile prosthesis can make a natural erection impossible and some other forms of treatment may not be used. Erections achieved with a malleable penile prosthesis can be shorter in length and curvature or scarring of the penis can occur. Resurgery is possible if you experience a surgical complication, device malfunction, or the device is damaged (e.g., impact injury from sports). Surgery may be more difficult or impractical if you have penile scarring or permanent shortening of the penis.

Genesis is considered a permanent implant, but as a mechanical device, the lifetime performance is dependent on device use and replacement of the device may be required. Testing demonstrates successful extension and flexion of the device simulating performance over 60 years with average use.

The doctor will provide instructions for surgery, post-operative care, and Genesis operation. The doctor will advise when it is safe to use the device and return to strenuous activity. It is important to attend routine follow-up visits with the doctor to monitor your health and ensure your device is operating properly.

Immediately report complications, difficulty operating the device, or changes in the appearance or rigidity of the penis to the doctor. Failure to report or treat complications may result in worsening of the condition, infection and loss of tissue. Should surgical, physical, psychological, or mechanical problems occur, removal of the device may be needed.

What are the risks?

There may be an increased risk of infection or slow healing with a malleable penile prosthesis for men with a compromised immune system, difficulty healing or diabetes. Caution should be used in patients with conditions related to bladder decompensation (e.g., frequent urinary tract infections, urinary incontinence), enlarged prostate, or patients with an indwelling catheter.

Health conditions which hamper sexual activity (e.g., severe angina) may prevent successful use of the device.

Complications may occur following penile prosthesis surgery. These risks can include:

- Allergic reaction or sensitivity to device
- Bleeding / excessive bleeding (hemorrhage)
- Blockage or slowing of urine (urethral obstruction / occlusion)
- Collection of blood or fluid outside of tissue or vessels (hematoma, seroma)
- Delayed, difficult or abnormal wound healing
- Device migration
- Difficult or painful sexual intercourse
- Difficulty emptying bladder
- Discomfort or pain
- Inability to pull the foreskin back from the tip of an uncircumcised penis (acquired phimosis)
- Inability to pull the foreskin forward over the tip of an uncircumcised penis (paraphimosis)
- Infection
- Injury to tissue or organs (erosion / extrusion / migration) resulting in damage or loss of tissue (necrosis)
- Numbness or decreased sensation in penis
- Opening or tunnel between tissue or organs (fistula)
- Penile shortening, tightening or deformity
- Redness or swelling of tissue
- Scarring
- Urinary tract infection

Will Genesis interfere with other equipment?

Genesis contains metal that can be safely scanned by standard airport security equipment. Genesis is MR-Conditional meaning it can be scanned by a magnetic resonance imaging (MRI) machine when 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 identification details of your malleable penile prosthesis

How do I report a serious complication?

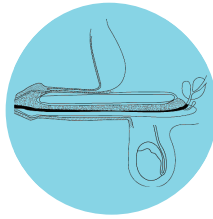
You should report all complications to your doctor right away. If the complications are serious and you or your doctor think they are related to your Genesis prosthesis, you or your doctor should notify Coloplast A/S, the company that makes Genesis, and the appropriate national authority. You can find contact information for Coloplast A/S on your Patient Implant Card.

If you live in Australia and experience a serious complication, you should report the problem to Coloplast A/S and your national authority, the Therapeutic Goods Administration (TGA). Report the problem online at www.tga.gov.au. or by calling the Adverse Medicine Events Line at 1300 134 237.

Instructions

To Simulate an Erection:

When an erection is desired, position the penile implant into an erect position.



To Return to Concealment State:

Move the penile implant to a lowered position under clothing.

