Titan[®]

Inflatable Penile Prosthesis Patient Information Leaflet en



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What is Titan?

Titan is a surgically implanted mechanical inflatable penile prosthesis intended for the treatment of erectile dysfunction in men. Titan is a 3-piece fluid-filled system made of silicone and Bioflex®, (soft, strong synthetic material), voluntarily operated to produce and sustain an erection for sexual intercourse.

Is Titan right for me?

There are a number of options available to treat erectile dysfunction, each with unique benefits and risks. Discuss the benefits and risks of each treatment with your doctor to consider which option is best for you based on your medical history, current health and lifestyle.

Titan cannot be implanted if you:

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

Surgery may be more difficult or impossible if you have abdominal or penile scarring or permanent shortening of the penis. Erections achieved with an inflatable penile prosthesis can be shorter in length and curving or scarring of the penis can occur. With a prosthesis, it is not possible to achieve a natural erection or use some other forms of treatment for erectile dysfunction. Patients with difficulty grasping objects or limited hand strength may require additional assistance or training to operate the device. Resurgery is possible if you experience a surgical complication, device malfunction or damage the device. Titan is considered a permanent implant, however, as a mechanical device the lifetime of performance is dependent on the use of the device. Replacement may be required. Testing demonstrates that Titan withstands inflation and deflation of the device simulating performance over 60 years with average use.

You will receive instructions for surgery and post-operative care and your doctor will explain what to expect during normal post-operative healing. Complications or difficulty operating the device should be reported immediately. Failure to report or treat complications may result in worsening of the condition, infection and loss of tissue.

It is important to attend routine follow-up visits to monitor your health and ensure your device is operating properly. In-office training and written instructions for the proper operation of the Titan penile prosthesis will be provided by the doctor.

What are the risks?

There may be increased risks of infection or slow healing with a penile prosthesis if you have a compromised immune system, difficulty healing, diabetes, or spinal cord injury.

Complications may occur following penile prosthesis surgery.

These risks can include:

- Allergic reaction or sensitivity
- · Bleeding/excessive bleeding
- · Blockage or slowing of urine or blood
- Collection of blood or fluid outside of tissue or vessels
- · Delayed, difficult or abnormal wound healing
- · Device malfunction
 - Cylinder or tubing buckle, bulge or hole
 - Difficult or unintended cylinder inflation or deflation
- Difficult or painful sexual intercourse
- Difficulty emptying bladder or voluntarily controlling urination
- · Discomfort or pain
- Hernia
- Improper positioning of the reservoir, pump or cylinders
- Infection
- Injury to tissue or organs resulting in damage or loss of tissue
- Numbness, irritation or decreased sensation
- Opening or tunnel between tissue or organs
- Scarring
- Swelling of arms or legs
- · Swelling, redness or hardening of tissue
- · Tightening, shortening or curvature of penis
- · Urinary tract infection

Will Titan interfere with other equipment?

Titan contains metal that can be safely scanned by standard airport security. Titan 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 an 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 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 Titan prosthesis, you or your doctor should also notify Coloplast A/S, the company that makes Titan, 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, or TGA. Report the problem online at www.tga.gov.au. or by calling the Adverse Medicine Events Line at 1300 134 237.

Titan with TOUCH Pump

For Erection:

Find the pump in your scrotum. Place the bulb portion of the pump between your thumb and finger and squeeze the bulb.
Using two hands may be helpful. Repeat this action until you have reached your desired erection. You may feel a slight vibration of fluid moving through the pump into the cylinders. The first pump and final pumps may require more pressure. Do not hold down the release button.



Titan with Classic Pump

For Erection:

Find the pump in your scrotum. Place the bulb portion of the pump between your thumb and finger and squeeze the bulb.
Using two hands may be helpful. Repeat this action until you have reached your desired erection. You may feel a slight vibration of fluid moving through the pump into the cylinders. The first pump and final pumps may require more pressure. Do not hold down the release bars.



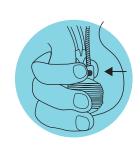
For Flaccid:

Find the release button located on the pump in your scrotum. You should be able to feel an indentation where the release button is located. Squeeze the Touch release button located on the side of the pump using your thumb and first two fingers for approximately 1-2 seconds. This allows fluid to return to the reservoir.



For Flaccid:

Follow the pump upwards with your hand as it narrows until you feel the flat release bars. Place thumb on one side of the bar and a finger on the opposite side of the bar. Squeeze the release bars with firm and steady pressure. The bars must be squeezed continuously until the cylinders are deflated.



For a faster return to flaccid, gently squeeze the shaft of the penis after squeezing the release button.



For a faster return to flaccid, gently squeeze the shaft of the penis while squeezing the release bars.

