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.