

Titan® and Titan® Touch Inflatable Penile Prosthesis Brief Statement

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: Patients with an active infection present anywhere in the body, especially urinary tract or genital infection. Patients with a documented sensitivity to silicone. Patients with unresolved problems affecting urination, such as an elevated residual urine volume secondary to bladder outlet obstruction or neurogenic bladder. 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. Failure to evaluate and promptly treat erosion may result in a substantial worsening of the condition, leading to infection and loss of tissue. Implantation of a penile prosthesis may result in penile shortening, curvature or scarring. Pre-existing abdominal or penile scarring or contracture may make surgical implantation more complicated or impractical.

Precautions

Surgeons implanting penile prostheses should be familiar with the currently available techniques for measuring the patient, determining implant size, and performing the surgery. Removal of an implanted prosthesis without timely reimplantation of a new prosthesis may complicate subsequent reimplantation or may make it impossible. A thorough preoperative consultation should include a discussion between the patient and physician of all available treatment options and their risks and benefits. The prosthesis should not be implanted in patients who lack the manual dexterity or strength necessary to operate the device. The device may be used in the presence of Peyronie's Disease. If the manual modeling technique is to be utilized, see the Surgical Protocol for more information.

Potential Complications

Scrotal swelling, auto-inflation, discomfort, angulation/curvature, edema, device malfunction, chronic pain, difficulty with ejaculation, transient urinary retention, fever, migration, patient dissatisfaction, site infection, deflation, hematoma/seroma, wound leakage, bleeding, delayed wound healing, phimosis, sensory loss, cylinder aneurysm, fibrous capsule formation, over/under inflation, erosion, scrotal erythema, genital change, wound infection, and inguinal hernia.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to the product's Instructions for Use. Alternatively, you may contact a Coloplast representative at 1-800-258-3476 and/or visit the company website at www.coloplast.com.

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