

The Hydrophilic-Coated Inflatable Penile Prosthesis: 1-Year Experience

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ABSTRACT

Introduction: Penile prosthesis infections are a devastating complication for both patient and surgeon. Efforts to reduce the risk of infection from these elective procedures are a major focus of research and development by the major prosthesis companies. The Titan inflatable penile prosthesis is coated with polyvinylpyrrolidone (PVP), a hydrophilic substance that reduces bacterial adherence and absorbs and elutes the antibiotics the device is immersed in intraoperatively. The Titan device was introduced to the US market in September 2002. This study reports the 1-year experience in the U.S. with the Titan and compares infection rates with the noncoated Alpha-I IPP made by Mentor Corporation.

Materials and Methods: Two thousand three hundred and fifty-seven Titan prostheses were implanted in the U.S. from September 2002 to August 2003, compared with the 482 non-coated Alpha-I IPPs implanted over the same time period. Infection rates were compared, along with bacterial culture data. All data were collected from Mentor's internal database, as generated from the FDA's mandatory reporting of explanted medical devices, and available on the internet.

Results: The infection rate for the coated Titan IPP was 1.06% (25/2357). During the same time period, the infection rate for the Alpha-1 non-coated prosthesis was 2.07% (10/482). Staphylococcus species predominated in both groups (9/25 Titan, 6/10 Alpha-I).

Conclusions: At 1 year of follow-up, the data demonstrate that the hydrophilic coating on the Titan IPP confers a significant advantage in reducing the rate of infection over the non-coated device. Long-term follow-up on this first year database is needed before this innovation is accepted as the standard of care for prosthetic surgery. Nevertheless, the theoretical reduction in bacterial adhesion conferred by the hydrophilic PVP surface and the ability to choose which antibiotic the device is immersed in intraoperatively gives the implanting surgeon distinct advantages with this new product.

COLOPLAST KEY TAKEAWAYS

- Due to changing bacterial environment, choice of antibiotics offers increased protection against infection risk.
- The hydrophilic property increases the lubriciousness of the device. This aids in three ways.
 - As the device is slippery, the coating makes it easier to implant the cylinders and reservoir.
 - The hydrophilic coating aids in preventing bacterial attachment and growth on the device by resisting colonization.
 - The hydrophilic coating absorbs and elutes perioperative antibiotics, aiding further in infection prevention.
- If bacterial attachment to a device can be reduced or eliminated, the chance for biofilm formation and ultimately prosthesis infection can be reduced greatly.
- The Titan[®] hydrophilic coating is on all device components, including rear-tip extenders (RTE's) and connectors.

Indications

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

Contraindications

The Titan, Titan OTR and Titan Touch Inflatable Penile Prosthesis is contraindicated in patients with an active infection present anywhere in the body, especially urinary tract or genital infection; with a documented sensitivity to silicone; with unresolved problems affecting urination, such as an elevated residual urine volume secondary to bladder outlet obstruction or neurogenic bladder; or, 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.

Potential Complications

Potential complications include scrotal swelling, auto-inflation, discomfort, angulation/curvature, edema, device malfunction, chronic pain, difficulty with ejaculation, transient urinary retention. 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.us.

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