

Anti-Infection Dip Suggestions for the Coloplast Titan[®] Inflatable Penile Prosthesis in the Era of the Infection Retardant Coated Implant

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ABSTRACT

Introduction: Infection is the worst complication seen with inflatable penile prosthesis (IPP). Both the American Medical Systems (AMS) and Coloplast IPP have infection retardant coatings. AMS is coated at the factory with rifampicin and minocycline (InhibiZone). The Coloplast IPP has a hydrophilic coating covalently bonded to its components that will absorb any aqueous solution before implantation and provides increased surface lubricity to decrease bacterial adherence.

Objective: We tested several antibiotic dips comparing zones of inhibition (ZOI) against five commonly infecting bacteria with coated Coloplast implants. Results were compared with those ZOI created with strips of an AMS IPP pre-coated with InhibiZone.

Methods: Pieces of sterile Coloplast Titan IPP were dipped in (i) trimethoprim/polymixin B ophthalmic solution; (ii) trimethoprim/sulfamethoxazole infusion solution; (iii) bacitracin; (iv) rifampicin/minocycline; and (v) rifampin/trimethoprim/sulfamethoxazole. ZOI for the Titan strips and for AMS InhibiZone coated strips were tested against *Staphylococcus epidermidis*, *Staphylococcus lugdunensis*, *Staphylococcus aureus*, *Pseudomonas*, and *Enterococcus*.

Main Outcome Measure: ZOIs of the Coloplast Titan for each of the medicated solutions were compared with ZOI created by undipped strips of a sterile InhibiZone coated IPP placed on plates of the identical bacteria.

Results: All dips except bacitracin showed ZOI greater than or equal to InhibiZone ($P =$ greater than or equal to 0.005) for most organisms. Because of broad spectrum effectiveness, ease of handling, and cost, infusion vial of trimethoprim/sulfamethoxazole seemed optimal at this time. If trimethoprim/sulfamethoxazole is unavailable; the ZOI with Polytrim ophthalmic solution zones were almost as good.

Conclusions: The Coloplast strips when dipped in several solutions showed equal or significantly larger ZOI against commonly infecting organisms than the InhibiZone coated strips. At the present time using off the shelf trimethoprim/sulfamethoxazole infusion solution seems optimum. The flexibility of choosing the drug eluting from the Coloplast device seems promising in the changing bacterial environment.

COLOPLAST KEY TAKEAWAYS

- Trimethoprim/sulfamethoxazole showed the best zone of inhibition (ZOI) against all bacteria and larger ZOI than InhibiZone strips against all bacteria ($P < 0.01$) including activity against *Pseudomonas*.
- ZOI on the Titan prosthesis against the more pathogenic infecting organisms like *S. aureus*, *Pseudomonas*, and *Enterococcus* were statistically significantly better than InhibiZone.
- Hydrophilic-coated Coloplast strips dipped in bacitracin did not generate significant bacterial death.
- 'If we are to impact the remaining more pathogenic infections, we must consider structuring the implant to elute antibiotics aimed at these organisms while still preserving activity for the weaker skin organisms.'
 - The authors conclude that the advantage of the hydrophilic coating is that the dip can be tailored to the changing local pattern of microbial pathogens and to the state of the current knowledge of implant infections.

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.