## CLINICAL ARTICLE SUMMARY

## Inflatable Penile Prosthesis Placement in Men with Peyronie's Disease and Drug-resistant Erectile Dysfunction: A Single-Center Study

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## **ABSTRACT**

**Introduction**: Erectile dysfunction (ED) frequently accompanies Peyronie's disease (PD) and changes the therapeutic approach.

**Aim:** To evaluate a single-center experience with inflatable penile prostheses (IPP) in men with medication refractory ED and PD.

**Methods:** Ninety men underwent placement of an IPP with straightening maneuvers as necessary to address their deformity and ED.

**Outcomes:** Preoperative assessment included International Index of Erectile Function-erectile function domain (IIEF-EF) and duplex ultrasound to confirm ED and measure erect deformity. Postoperative assessment included a modified Erectile Dysfunction Index of Treatment Satisfaction (EDITS) questionnaire, as well as office visits at 1, 6, and every 12 months thereafter.

Results: Complete chart review was performed with mean follow-up of 49 months. Mean preoperative IIEF-EF score was 11. Full rigidity was not obtained in any patient during duplex ultrasound. Mean curvature at maximum erection was 53°. There were seven mechanical failures requiring device replacement, two revision surgeries for pump or reservoir malposition, one infected device, and two corporoplasties for distal tunica erosion. Postoperative office assessment revealed a functionally straight (i.e., <20°) erect penis and a properly positioned as well as operational device in all patients. The modified EDITS questionnaire was returned by 56 (62%). Overall, 84% of patients were satisfied with their outcome, yet only 73% were satisfied with their straightness. Patient perceived postoperative curvature correction stabilized quickly and was complete by 3 months in 84% of patients. Satisfaction with ease of inflation, deflation, and concealability was 84%, 71%, and 91%, respectively. Coital activity was reported by 91% of men in this group.

**Conclusion:** In men with PD and ED, IPP placement allowed reliable and satisfactory coitus for the great majority of men. Mechanical failure was 7%. Men with PD undergoing IPP placement should be counseled regarding potential penile length loss and residual curvature, neither of which appeared to interfere with coitus but may reduce satisfaction.

## **COLOPLAST KEY TAKEAWAYS**

- Inflatable penile prosthesis (IPP) implantation with additional straightening maneuvers is a successful, reliable, and appropriate treatment option for the man with medication resistant ED and PD.
- 79% of patients achieved functionally straight erections of less than 20° curvature by their first post-op office visit.
- The mean time when the patients felt that their penis had reached maximum straightness postoperatively was 1.9 months.
- Subjective patient satisfaction rates with IPP device were 100% for the Alpha-1 Mentor (now Coloplast), 86% for Coloplast Titan, 86% with AMS Ambicor, and 77% with AMS 700 CX.
- There were no documented mechanical failures with either the Coloplast Titan or Mentor Alpha-1 (now Coloplast) while there were 4 mechanical device failures with the AMS 700 and 3 mechanical device failures with the AMS Ambicor.

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. See the device manual for detailed information regarding the implant procedure, contraindications, warnings, precautions, and potential complications/adverse events.

For further information, call Coloplast Corp at 1-800-258-3476 and/or consult the company website at www.coloplast.us.

