CLINICAL ABSTRACT SUMMARY

# Comparison of AMS 700 CX and Coloplast Titan Inflatable Penile Prosthesis Cylinders Subjected to In-Vitro Cyclic Buckling

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## ABSTRACT

**Background:** Parylene coating has been proven to increase the durability of AMS 700 series penile prosthesis cylinders. However, aneurysmal failures in parylene-coated AMS 700 cylinders during "woman on top" intercourse have been reported.

**Objective**: We attempt to compare the resistance of AMS 700 and Coloplast Titan cylinders to this type of aneurysmal failure.

**Methods:** Five (1 non-parylene-coated and 4 parylene-coated) 18cm AMS700 CX and two 18cm Coloplast Titan cylinders were compared. Each cylinder was fixed proximally and distally, with the distal tip placed in a 10 degree angled fixture to simulate the vaginal canal angle. The cylinders were inflated to 15PSI and placed in a 98.6˚F saline bath. Axial loading was created using an Instron electodynamic test system, resulting in buckling of the cylinder. Cylinders were examined every 100,000 cycles for aneurysms and degradation.

**Results:** In the non-parylene coated AMS 700 cylinder, no aneurysm formed, but the outer silicone layer failed at 600,000 cycles. The 4 parylene-coated cylinders developed aneurysmal defects between 1.1 and 2.05 million cycles, 2 also with catastrophic failures. The aneurysms occurred in areas of separation of the fibers in the fabric layer. The 2 Titan cylinders have been cycled 3.5 and 6.5 million times without signs of compromise in the integrity of the cylinder wall.

**Conclusion:** The durability of AMS 700 cylinders has been improved by the addition of parylene, but they may be prone to aneurysm formation due to buckling of the cylinders. Initial in-vitro studies suggest that Coloplast cylinders are inherently more resistant to this type of failure. Further testing will be required to fully define these differences and their clinical significance.

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## COLOPLAST KEY TAKEAWAYS

- In the non-parylene coated AMS 700 cylinder, no aneurysm formed, but the outer silicone layer failed at 600,000 cycles.
- The 4 parylene-coated cylinders developed aneurysmal defects between 1.1 and 2.05 million cycles, 2 also with catastrophic failures. The aneurysms occurred in areas of separation of the fibers in the fabric layer.
- The 2 Titan cylinders have been cycled 3.5 and 6.5 million times without signs of compromise in the integrity of the cylinder wall.
- Initial in-vitro studies suggest that Coloplast cylinders are inherently more resistant to this type of aneurysmal failure.

**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.



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