

Titan[®]

Bioflex[®] is the Difference

The Coloplast Titan[®] Inflatable Penile Prosthesis (IPP) features unique Bioflex[®] material that delivers greater cylinder girth and rigidity than competitor's products.



	Coloplast	Competitor
Material Composition IPPs are manufactured from two types of raw materials	Bioflex[®] Unique and proprietary material engineered specifically for penile implant cylinders	Silicone Generic material used for other prosthetic devices, not specifically developed for IPPs
Durability Titan is built for outstanding fatigue resistance	6.5 Million+ Cycles (inflation and deflation) to material failure ¹ 3x more durable ¹	1.5-2 Million Cycles (inflation and deflation) to material failure ¹
Strength Bioflex withstands higher pressure	Tensile strength of 7,500 psi² 8x more strength ²	Tensile strength of 900 psi²
Girth Titan can expand to the maximum size of the corpora	Maximum Girth Expansion 21mm of each cylinder ³ 17% more girth ³	Limits girth to 18mm per cylinder ⁴

A recent study compared the kink resistance of the Coloplast Titan with that of the AMS 700 LGX™ penile prosthesis cylinders during longitudinal load testing.⁵

Rigidity

Better ability to withstand the longitudinal compressive forces

Average Kinking Load

	Titan 18 cm	AMS 700 LGX 18 cm	The Titan® Difference
10 psi	2.2490 lbs	0.6650 lbs	+238%
15 psi	2.2645 lbs	1.0605 lbs	+114%
20 psi	2.4945 lbs	1.4485 lbs	+72%

Pressure Sensitivity

Less dependent on device filling pressures

Percent of Max Rigidity*

	Titan 18 cm	AMS 700 LGX 18 cm	The Titan® Difference
10 psi	90%	46%	+96%
15 psi	91%	73%	+25%
20 psi	100%	100%	

*Max rigidity defined as the highest average kinking load (20psi in all cases tested)

1. Pritchard C., et al. Comparison of AMS 700 CX and Coloplast Titan Inflatable Penile Prosthesis Cylinders Subjected To In Vitro Cyclic Buckling
2. Coloplast Test Data: Bioflex Monograph
3. Coloplast Document: VV-0048540
4. AMS 700™ with MS Pump™ Penile Prosthesis Operating Room Manual; American Medical Systems, Inc., August 2016
5. Scovell J., et al. Longitudinal and Horizontal Load Testing of Inflatable Penile Implant Cylinders of Two Manufacturers: An Ex Vivo Demonstration of Inflated Rigidity. JSM 2016 10(13):567-70.

TITAN BRIEF STATEMENT

Indications: The Titan family of 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 device is contraindicated in patients who have one or more of the following conditions: Patients with an active infection present anywhere in the body, especially urinary tract or genital infection. 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 eliminates natural erections, as well as other related 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. The risks and benefits of implanting this device in patients with lupus, scleroderma, myasthenia gravis, or documented sensitivity to silicone should be carefully considered.

Precautions: A thorough preoperative consultation should include a discussion between the patient and physician of all available treatment options and their risks and benefits.

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

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.

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