

Tried. Tested. Trusted.

Genesis® implants deliver performance you can trust.¹

Designed for durability and long-term reliability,¹ Genesis gives you confidence in your device choice. It assembles easily with no special tools required, seamlessly integrating into your practice.¹ Genesis supports patients from those with limited dexterity to the most complex cases.²

Genesis at a glance



Hydrophilic coating allows you to choose your aqueous solution and helps with smooth insertion¹



Silver wire coil and helix prevent spring-back and buckling for superior concealability¹



Engineered for mechanical durability 8,000+ bend cycles¹



Maintains position from straight to 90° after repeated bending¹

Tailored for patients. Trusted by surgeons.

Genesis is designed to accommodate individual anatomies while maintaining excellent concealability. Available in three diameters and with trimmable lengths and interchangeable tail caps, the device offers flexible sizing options to help deliver a natural fit for each patient.¹

Available diameters: 9.5 mm, 11 mm, 13 mm¹

Anatomical tip for a natural profile and discreet appearance¹



Tail caps in standard, +0.5 cm, and +1.0 cm sizes¹

Trimmable cylinders allow precise length adjustment¹

Unique helix-constructed core prevents buckling and eliminates spring back¹

Ordering Information

Coloplast Interventional Urology Service Support **800-258-3476**

Genesis® Malleable Penile Prosthesis

Item #	Diameter (mm)	Length (min-max)
91-9509SC	9.5	14-23
91-9511SC	11	16-25
91-9513SC	13	18-27



Genesis® Malleable Penile Prosthesis Brief Statement

Indications

The Prosthesis is designed for the management of impotence stemming from a variety of causes, including: epispadias; pelvic fracture; spinal cord injury or disease; prostatectomy; cystectomy; abdominal-perineal resection; multiple sclerosis; diabetes mellitus; alcoholism; arteriosclerosis and hypertensive vascular disease; priapism; and Peyronie's disease. The Prosthesis may also be used in selected patients with psychogenic impotence.

Contraindications

Implantation procedures are not advisable if infection is present anywhere in the body, especially urinary tract or genital infection.

The Prosthesis should not be used in patients who have unresolved problems such as elevated residual urine from bladder outlet obstruction, or neurogenic bladder.

The Prosthesis should be used with caution in diabetic patients who are more susceptible to infection and the complications of infection than nondiabetic patients.

Other contraindications include unresolved urinary problems, any condition which may hamper sexual activity (such as severe angina), a history of sensitivity to foreign materials, compromised wound healing, compromised immune system, any anatomic or physiologic abnormality that could lead to significant postoperative complications, an unwillingness to undergo any further surgery for revision and psychological instability of the patient.

Warnings

Coloplast relies on the surgeon to advise the patient of all potential risks and complications associated with the proposed surgical procedure and device, including providing a comparison of the risks and complications of alternative procedures and implants. Patients should be advised that penile implants should not be considered lifetime implants due to the inherent nature of silicone implants, implant procedures and potential individual physiological reactions.

Any surgeon implanting the Prosthesis should be familiar with the currently available techniques for measuring the patient, determining the implant size, and performing the surgery.

The Prosthesis should be used with caution in patients with borderline bladder decompensation or enlargement of the prostate.

Spontaneous urethral extrusion of the Prosthesis has occurred in paraplegics with indwelling catheters at the time of operation; therefore, patients should be free of catheters prior to implantation.

Precautions

The patient should undergo a thorough diagnostic evaluation and psychiatric/sexual counseling may be considered. Patent corpora cavernosa are prerequisite for the insertion of the Prosthesis.

Potential Complications

Complications may include, but are not limited to, the following: • Foreign body response, • erosion, • perforation or extrusion, • infection, • necrosis, • device malfunction (e.g., twisting, fracture, separation), • impaired blood flow to penis, • lymphedema of the penis, • hematoma, • scarring, • pain, • malposition, • SST deformity, • incorrect sizing, • paraphimosis, • voiding difficulty, • decreased sensation, and • inflammation/irritation.

Advice to Patient

Prosthesis may differ from original erection (e.g. not of equal length or girth) compared to what was previously experienced with natural erections.

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.com.

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

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1. Data on file.

2. Chung E, Wang J. State-of-art review of current malleable penile prosthesis devices in the commercial market. *Ther Adv Urol*. 2023;15:17562872231179008. Published 2023 Jul 14.