Rigicon®

Innovative Urological Solutions

Instructions for Use

Testi10™

Testicular Prosthesis

℞ ONLY

Symbols on Label

	Manufacturer Information
	The authorized representative in the European Community
	Date of Manufacture
	Use by YYYY-MM-DD
	LOT Number
	Do Not Reuse
	Do Not Resterilize
	Sterilized Using Ethylene Oxide
	Consult Instructions for Use
	Caution: Federal law (U.S.) restricts this device to sale by or on the order of a physician
	Caution
	Do not use if package is damaged
	Temperature limit
	Keep dry
	Keep away from sunlight
CE 2764	CE Mark

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DEVICE DESCRIPTION

Testi10™ Testicular Prosthesis is a silicone elastomer prosthesis designed to simulate the shape and feel of a testicle in the male scrotum.

The prosthesis is provided as sterile. It is manufactured in white and/or transparent color.

Testi10™ Testicular Prosthesis prevents psychogenesis sequelae and is advisable for patients who are diagnosed with testicular agenesis or patients whose testicle or testicles were surgically removed due to several pathologies.

MODELS AND SIZES

There are three models of the Testi10™ Testicular Prosthesis; firm, saline-filled and saline testicular prostheses. The firm testicular prosthesis is made of medical-grade silicone elastomer and has a mesh for easy fixation in the scrotum.

The saline-filled testicular prosthesis is manufactured empty and is filled with sterile saline during the operation.

The saline testicular prosthesis is manufactured as full. The saline is filled into the prosthesis during manufacturing.

All models are provided sterile and are available in 5 different sizes.

Testi10™ Firm Testicular Prosthesis					
Product Code	TestiF-XS	TestiF-S	TestiF-M	TestiF-L	TestiF-XL
Dimensions	21 x 27 mm	26 x 32 mm	29 x 41 mm	32 x 47 mm	32 x 51 mm

Testi10™ Saline Testicular Prosthesis					
Product Code	TestiS-XS	TestiS-S	TestiS-M	TestiS-L	TestiS-XL
Dimensions	21 x 27 mm	26 x 32 mm	29 x 41 mm	32 x 47 mm	32 x 51 mm

Testi10™ Saline-filled Testicular Prosthesis					
Product Code	TestiSF-XS	TestiSF-S	TestiSF-M	TestiSF-L	TestiSF-XL
Dimensions	21 x 27 mm	26 x 32 mm	29 x 41 mm	32 x 47 mm	32 x 51 mm

Testi10™ Firm

Testi10™ Saline

Testi10™ Saline-filled

INDICATIONS

The device is indicated for patients diagnosed with testicular agenesis, or patients whose testicle or testicles were surgically removed due to several pathologies. The prosthesis is also indicated for replacement. Testicular prosthesis implantation is carried out for patients with removed testicles or for patients who have lost their testicle/testicles due to several causes. These causes might be:

- Ectopic testicle,
- Genitourinary cancer / Metastatic prostate cancer,
- Testicular bulk / tumour,
- Testicular torsion,
- Testicular atrophy,
- Testicular agenesis,
- Orchitis,
- Trauma, disease or other abnormalities,
- Sex reassignment surgery.

CONTRAINDICATIONS

Implantation of this prosthesis is contraindicated in patients who have active urogenital infections or active skin infections in the region of surgery. The use of testicular implants is also contraindicated in patients who have one or more of the following conditions:

- Insufficient tissue,
- Existing local or metastatic carcinoma,

- Deficient vascularization of tissue in local area,
- Irradiated tissue (in selected patients),
- A history of sensitivity to silicone materials,
- Physiologically and or psychologically unsuitable patients.

WARNINGS

This prosthesis contains silicone elastomer. The risks and benefits of implanting this prosthesis in patients with documented sensitivity to silicone should be carefully considered.

Patients who undergo surgical operations are liable to complications during and after the surgery. Surgeries associated with the use of testicular prostheses entail risks or potential complications. Thus, prior to surgery, physicians should inform patients about possible complications related to the use of this prosthesis.

This product has been designed for single use.

Testicular prosthesis implantation in children is only recommended for cosmetic purposes.

Patients must be educated on how to distinguish the implanted prosthesis from the natural testicle through self-examination.

Removal of the prosthesis is advisable in the case of surgical, physical or psychological problems.

PRECAUTIONS

Migration of the prosthesis may occur if the prosthesis is not sutured in place.

Use of an oversized prosthesis for the existing scrotal pocket may result in necrosis and subsequent extrusion.

The implantation of this prosthesis should only be considered in patients who the physician determines as adequate surgical candidates.

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

Careful patient selection is essential, as well as a thorough diagnostic study before the surgery.

The prosthesis must be checked prior to and during the surgery to monitor the structural integrity of the prosthesis.

The prosthesis should be handled carefully, avoiding pointed, toothed, or sharp instruments, as any nick or damage may be the cause for subsequent complications of the implant.

Dirt, fingerprints, talc or any other substance that can contaminate the surface of the prosthesis may cause reactions to foreign bodies. Extreme preventive measures must be taken to avoid contamination.

Any dent or mark in the prosthesis is a possible cause of failure, since it may serve as a surface to host materials that may cause reactions to foreign bodies or infections in the patient.

ADVERSE EFFECTS

Possible complications associated with the use of this prosthesis must be discussed with the patient prior to surgery.

Complications which may result from the use of this prosthesis include the risks associated with the medication and methods utilized in the surgical procedure, as well as the patient's degree of intolerance to any foreign body. Some complications may demand prosthesis removal.

Pain or fever indicating infection may appear after the implantation.

Infections that do not respond to antibiotic therapy demand prosthesis removal.

Dermic necrosis or wound opening may appear as a result of; an inadequate tension of the skin covering the implant, a trauma of skin surface during surgery or an inadequate circulating inhibition of the tissue. Subsequent extrusion of the implant may be necessary after this.

Post-surgical hematoma, manifested as swelling and tissue color change, may cause extrusion of the device, if not treated appropriately.

Excessive fluid accumulation around the prosthesis may occur after surgery, as a result of traumas.

Prosthesis size, wrong placing or migration may cause unsatisfactory visual results.

The post-surgical formation of a fibrous tissue capsule surrounding the testicular prosthesis is a normal physiological reaction to the implantation of a foreign body.

If the patient feels discomfort, pain, throbbing of heart or prosthesis movement, the implant must be removed.

SURGICAL PROCEDURE

When the patient is taken into the operation room, the patient must be prepared according to operational procedures of the hospital.

This procedure is carried out either under general anesthesia (where you are asleep during the procedure) or spinal anesthesia (where you are awake but unable to feel anything from the waist down).

The patient must be positioned according to the incision type that is preferred by physicians (urologists, plastic surgeons or pediatric surgeons).

For each operation the physician should evaluate the suitability of the procedure based on accepted techniques, individual conditions and experience.

The testicular prosthesis is inserted into the scrotum through a small incision in the groin. The neck of the scrotum is then closed with stitches to prevent the prosthesis from moving back up to the groin.

An incision is made in the groin through the old orchiectomy incision if present and a self-retaining retractor is inserted. The external oblique is then exposed and incised, identifying the neck and previous tunnel to the scrotum that usually commences at the external ring, or the spermatic cord if this is still present. A finger identifies the scrotal neck, beginning the entry tunnel into the scrotum.

A pair of standard sponge-holding forceps are then gently advanced through the identified neck or passed alongside the cord, into the scrotum. The fulcrum of the forceps is positioned to align with the scrotal neck so the neck is not stretched.

The dense adhesions or existing prosthesis capsule are divided and fractured, by opening and closing the forceps in a gentle spreading motion that may be directed to all parts of the scrotum.

The length of the forceps enables adhesions to be broken all the way to the most dependent region of the hemiscrotum. When closed, the forceps tips approximate the position of the prosthesis, indicating if further dissection is necessary. An anatomical pouch is created where a pseudo-capsule will eventually develop as healing occurs.

The wound is then irrigated with iodine-based antiseptic. After a glove replacement, the chosen prosthesis is placed into the scrotum where, if necessary, it is gently 'milked down' from the outside of the scrotal skin, to

confirm satisfactory placement in the pouch previously created.

The wound is closed in layers. If prostheses are sutured, narrow tissue forceps may be used to invert the scrotal skin into the inguinal canal, then a suture is placed in the scrotum and tied to the prosthesis before placement.

After surgery, the patients are encouraged to 'milk down' the prosthesis to maintain it in the pouch region until healed and a peri-prosthetic fibrous pseudo-capsule has developed.

TESTI10™ SALINE-FILLED PROSTHESIS FILLING INSTRUCTIONS

Appropriate fill volume for the prosthesis shall be determined by the physician (urologists, plastic and pediatric surgeons) according to the patient's anatomy.

Rigicon, Inc. does not supply the needle used during the filling of the prosthesis with saline. The physician can use 27 G needles and 2 cc or 5 cc syringes.

The syringe is filled out with the appropriate volume of sterile saline. Then, the needle is inserted through the injection ports located on the top of the prosthesis. Physicians must be careful during the insertion of the needle not to puncture the prosthesis from the inside. The saline in the syringe is emptied slowly into the prosthesis.

STORAGE

Store the device in a clean, dry, dark area at room temperature (0-25°C).

PACKAGING

The device is supplied to the market in a sealed, double pouch and inside a protective carton box. The package should be checked in terms of damaging, tearing and puncture. Do not use damaged, teared or punctured packages.

Before unpacking, the expiry date of the product should be checked. Do not use the products which have passed the expiration date. Sterilization of the products which have passed the expiration date is not guaranteed.

Prostheses removed from patients should be disposed as medical waste in accordance with hospital, administrative and/or local government policy.

DISCLAIMER

The manufacturer Rigicon, Inc. reserves the right to make technical or design changes as part of the device's continual improvement process.

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Warranty & Product Replacement:

To activate the warranty of the prosthesis, Patient Surgery Form must be filled and filed with Rigicon, Inc.

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Customers outside the United States and Canada should contact their local Rigicon Representative.

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