Rigicon®

American Urological Solutions

TESTICULAR PROSTHESIS

INSTRUCTION FOR USE

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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
	Do not use if package is damaged
	Temperature limit
	Keep dry
	Keep away from sunlight
CE 2292	

DEVICE DESCRIPTION

Rigicon Inc. - Testicular Prosthesis consists of a silicone elastomer designed in a shape to simulate the testicle within the male scrotum.

They are provided as sterile. It is manufactured as white and/or transparent color.

Testicular Prosthesis prevents psychogenesis sequelae and is advisable for those patients who had suffered from testicular agenesis, or when the testicle has been removed through surgery due to several pathologies.

Firm Testicular Prosthesis

Saline Filled Testicular Prosthesis

MODELS and SIZES

There are two models for testicular prosthesis; one of them is firm and other one is saline-filled testicular prosthesis.

The firm testicular prosthesis which is made of long term medical grade silicone has a mesh to implant it easily by using suture.

The saline-filled testicular prosthesis is produced as empty and is filled out with saline during operation.

They are also sterile and are available in different sizes.

Dimensions *(diameter*leng*	***Model***			
	Product Code	**Firm Testicular Prosthesis**	**Product Code**	**Saline-Filled Testicular Prosthesis**
	TestiF-XS	21*27	TestiSF-XS	21*27
	TestiF-S	26*32	TestiSF-S	26*32
	TestiF-M	29*41	TestiSF-M	29*41
	TestiF-L	32*47	TestiSF-L	32*47
	TestiF-XL	32*51	TestiSF-XL	32*51

**TestiF is manufactures as full silicon elastomer; TestiSF is manufactures as empty and is filled out saline during operation.*

INDICATIONS

The device is indicated for those patients who had suffered from testicular agenesis, or when the testicle has been removed through surgery due to several pathologies and also designed for replacement. Testicular prosthesis is carried out for patients who had been removed testicles and, had been lost testicle because of different causes. These causes are:

- Ectopic testicle,
- Genitourinary cancer / Metastatic prostate cancer,
- Testicular bulk/tumour,
- Testicular torsion,
- Testicular atrophy,
- Testicular agenesis (unilateral or bilateral congenital absence of the testicles),
- Orchitis,
- Trauma, disease or other abnormalities,
- Transsexual surgery,
- Others (psychologically suitable patient)

CONTRAINDICATIONS

The 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 contra- indicated 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 / psychologically,
- Unsuitable patient

WARNINGS

This prosthesis contains a 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 implants 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 implants in children is only recommended for cosmetics purposes.

Patients must be taught to distinguish the 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 whom the physician determines are adequate surgical candidates.

A thorough preoperative consultation should include a discussion between patient and 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, so as to monitor the structural integrity of the implant.

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 substances that can contaminate the surface of the prosthesis may be the cause of reactions to foreign objects. Extreme preventive measures must be taken to avoid contamination.

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

The device is presented in double pouch package and inside a protective carton box. The package should be checked in terms of damaging, tearing and puncture. Do not use the damaged, teared and 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 be guaranteed.

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

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, seen as a swelling and tissue color fading, may cause extrusion of the device, if it not treated appropriately.

Excessive fluid accumulation around the implant may be produced 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 come into operation room, the patient must be prepared according to operational procedure of hospital.

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

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

Each operation shall 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 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 has now been created about which 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 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.

Saline Filling Instruction

Appropriate size and quantity of saline shall be determined for the individual patient by the physicians (*urologists, plastic and pediatric surgeons*).

The company does not supply needle for filling saline. During operation, the physician can use insulin needles (4-6 mm diameter) and injector (29-30-31G and 4-5mm lengths) for filling.

The needle fills out with appropriate quantity of saline. Then, it inserts into the silicone tab and all saline in the syringe is emptied into the testicular prosthesis.

PACKAGING

The sterile product is supplied to the market in a sealed, double pouch and inside a protective carton box. Each variant of the product is presented in this package. The package should be checked in terms of damaging, tearing and puncture. Do not use the damaged, teared and 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 be guaranteed.

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

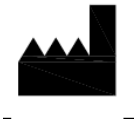
Warranty & Product Replacement

For to activate the warranty of the implant, Patient Infromation Form must be filled and filed to Rigicon,Inc.

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

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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