

Testi10™ Testicular Prosthesis

Safety Information

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/tumor,
- Testicular torsion,
- Testicular atrophy,
- Testicular agenesis (unilateral or bilateral congenital absence of the testicles),
- Orchitis,
- Trauma, disease or other abnormalities,
- Transsexual surgery,

Contraindications

The implantation of this prosthesis is contraindicated in patients who have active urogenital infections or active skin infections in the region of the surgery. The use of testicular prosthesis 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
- Others (psychologically suitable 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 prosthesis 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 in children are only recommended for cosmetic 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 of 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 a 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 being guaranteed.

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