



(New York, USA)

# Testicular Prostheses

## Testi10™

Designed using high quality silicone, to help patients experience a complete and natural feeling.

Testi10™ is specifically used for the replacement of one, or two testicles due to monorchism, orchiectomy, congenital anorchism or similar procedures.

(FDA APPROVED)



# 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)

# Testi10™ Testicular Prosthesis

There are two models of Testicular Prosthesis

## ⦿ Saline-filled

Testi10™ Saline-filled offers More Natural Feeling Design

## ⦿ Firm

Testi10™ Firm offers simple implantation



# Testi10™ Saline-filled Testicular Prostheses

Saline-filled model is supplied as empty and gives the surgeon the opportunity to create a more natural feel to the implant

- More Natural Feeling Design
- Aims For Higher Patient Satisfaction
- Size Options
- Soft Texture and shape designed for natural testicle feeling



The surgeon fills the prosthesis with sterile saline during the surgery via the injection ports.



### **Easy to Fill**

Dedicated injection ports for easy filling of the device during the surgery



### **Diverse Sizes**

Available in 5 sizes between XS to XL to offer the best fit to patient's anatomy.



### **Mimics the Natural**

Mimics the Natural The prosthesis is designed to replicate the structure and feel of the natural testicle.

# Testi10S™ At A Glance

## Dedicated Injection Port

Dedicated injection ports for easy filling of the device during the surgery.



## Diverse Sizes

Available in 5 sizes between XS to XL to offer the best fit to patient's anatomy.



# Warnings

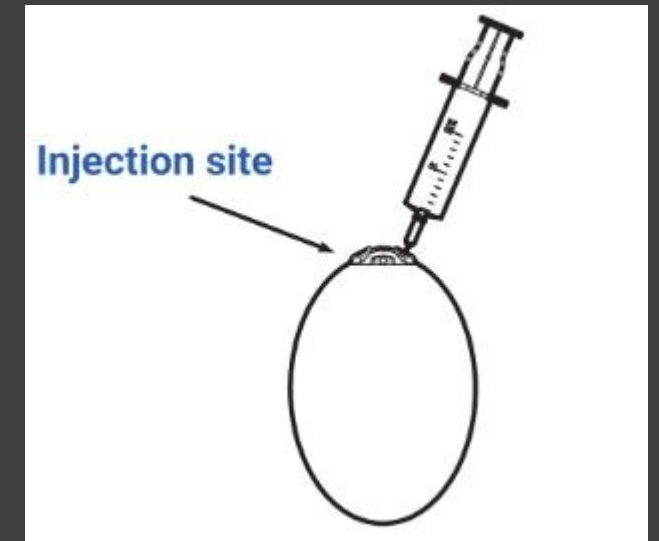
- This prosthesis contains a silicone elastomer. The risks and benefits of implanting this prosthesis in patients with documented sensitivity to silicone should be carefully considered.
- Patients who undergo surgical operations are liable to complications during and after the surgery.
- Surgeries associated 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.



# TESTI10™ SALINE-FILLED TESTICULAR PROSTHESIS FILLING INSTRUCTIONS

- Testi10™ Saline-filled Testicular Prosthesis is supplied in a sealed, double-pouch and inside a protective carton box.
- Supplies needed for filling\*
  - Sterile, isotonic, pyrogen-free Sodium Chloride U.S.P. solution
  - 27 Gauge Needle
  - One 2 cc or 5 cc syringe
- Filling Instructions
  - Step 1. Fill a 20 cc (or larger) syringe with sterile, isotonic, pyrogen-free Sodium Chloride U.S.P. solution
  - Step 2. Insert the needle into the injection site of the prosthesis (the circle around the suture tab)

(See Figure 1)



(Figure 1)

# WARNINGS AND CAUTIONS:

- Use only a sterile 27 Gauge needle.
- Insert the needle carefully through the injection site (where the suture tab is) as close to the center.
- Make sure that the needle is inserted into the injection site in a gentle manner to eliminate the risk of puncturing the inner walls of the prosthesis.
- Also, inserting the needle from any different location other than the injection site will puncture the prosthesis and will result in fluid leakage.
- Do not use the prosthesis if it is punctured in any location other than the injection site.
- Do not squeeze the prosthesis while the needle is inserted and do not try to evacuate air from the prosthesis.
- Step 3. Hold the testicular prosthesis with the injection site (the circle around the suture tab) at the top and position the syringe in a manner to enable the air inside the prosthesis will travel into the syringe.
- Step 4. Start injecting sterile saline into the prosthesis. While injecting saline, release the syringe plunger at intervals to allow air to be drawn into the syringe.
- Repeat this cycle until remaining air travels into the syringe.

# WARNINGS AND CAUTIONS:

- Step 5. Stop injecting sterile-saline when the desired firmness is achieved. A fill volume chart is presented below for the physician's reference. The physician can stay under or go up to %10 of the recommend fill volumes.

SIZE	FILL VOLUME
TESTISF-XS	6 CC
TESTISF-S	12 CC
TESTISF-M	18 CC
TESTISF-L	22 CC
TESTISF-XL	26 CC

# Suture Tab

- If desired the physician can suture the prosthesis with the help of the suture tab located on the prosthesis. The prosthesis must be tied only through the hole in the suture tab. Suturing the prosthesis in any area other than the suture tab will damage the prosthesis and result in fluid leakage.





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