

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 and 2)

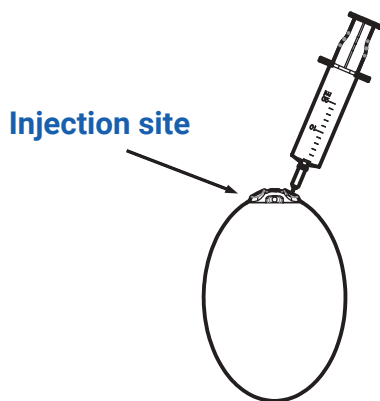


Figure 1

Figure 2

View from top

*Supplies are not provided by Rigicon



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.

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.



Caution: Federal Law (U.S.) restricts this device to sale by or on the order of a physician.

Prior to use, please review the Instructions for Use for a complete listing of indications, contraindications, warnings, precautions and potential adverse events.

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