

Filling Procedure

The **only** FDA-approved testicular implant

The prosthesis is initially overfilled with saline (over-fill volume range). Air and saline are then evacuated to reduce the saline fill volume in the prosthesis to within its final-fill-volume range. Please consult the Saline Fill-Volume Chart for the acceptance range of over-fill-and final-fill-volumes for each size prosthesis.

Step 1: Fill a 20 cc (or larger) syringe with the appropriate Over-Fill Volume Range of sterile, pyrogen-free Sodium Chloride U.S.P. Solution for Injection, based on the Saline Fill-Volume Chart.

Step 2: Connect the Luer hub of the infusion line to the syringe. Place the needle stop on the butterfly infusion needle. Insert the butterfly needle into the center of the injection port, which is located on the end of the prosthesis opposite the suture tab site. It can be easily located as a lightly depressed area encircled by the Coloplast name and serial number.

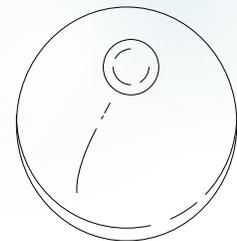
Caution: Use only a sterile 21 gauge butterfly needle (not supplied by Coloplast) and the needle stop (provided with the prosthesis) for the filling procedure. The needle must only penetrate the injection port, preferably as close to the center as possible and must not contact any other part of the prosthesis. Puncture of the prosthesis through any location other than the injection port will damage the device and result in fluid leakage. Discard any device that is punctured in any location other than the injection port.

Step 3: Do not evacuate air from the prosthesis. Position the testicular prosthesis with the injection port at the top. Position the syringe so that air released from the prosthesis will travel into the syringe (see figure 1).

Step 4: Overfill the prosthesis by injecting saline into the prosthesis according to the Over-Fill-Volume Chart. Release the syringe plunger, allowing the compressed air in the prosthesis to be drawn into the syringe.

Step 5: If all the air is not evacuated from the prosthesis, repeat Step 4 (fill prosthesis again, and release the syringe plunger to allow the remaining air and excess saline to vent to the syringe). After the air and excess saline have vented to the syringe, the device should contain the Final-Fill-Volume Range listed in the Saline Fill-Volume Chart. Remove needle slowly to aspirate any remaining air bubble.

Caution: The injection port may be pierced no more than five (5) times within the port area, permitting adjustment of the fluid volume if desired. All filling and expulsion of air must be done before implantation. Discard any device pierced more than 5 times in the port area.



Injection port

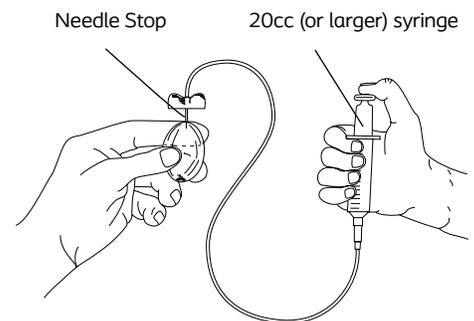


Figure 1

Position of the testicular prosthesis with injection port at top, and position of the syringe ready to fill the prosthesis

How Supplied:

The Torosa® Saline-Filled Testicular Prosthesis is supplied individually in a sterile double-wrap packaging system. The double-wrap system facilitates the preferred method of sterile-product transfer from the circulating area to the sterile field. The prosthesis is supplied with two sterile pre-packaged needle stops.

Supplies needed but not supplied by Coloplast:

- One sterile 21 gauge butterfly needle connected to a Luer lock adapter
- Sterile, isotonic, pyrogen-free Sodium Chloride U.S.P. solution
- One 20 cc or larger syringe

Ordering Information

Coloplast Interventional Urology Surgical Support **800-258-3476**

Saline Fill-Volume Chart

Order Number	Size	Over-Fill Volume Range		Final Fill Volume Range	
		Lower Limit	Upper Limit	Lower Limit	Upper Limit
450-1323	Extra Small	7 cc	9 cc	5 cc	6 cc
450-1325	Small	10 cc	12 cc	8 cc	9 cc
450-1327	Medium	13 cc	15 cc	11 cc	12 cc
450-1329	Large	17 cc	19 cc	15 cc	16 cc

For additional Torosa resources including educational videos, coding guide and additional ordering information, visit ColoplastMD.com or scan the QR Code.



TOROSA® Saline-Filled Testicular Prosthesis Brief Statement

Indications: The Coloplast TOROSA Saline-Filled Testicular Prosthesis is intended for use when cosmetic testicular replacement is indicated i.e., in the case of agenesis or following the surgical removal of a testicle.

Contraindications: The implantation of testicular prostheses is contraindicated in the presence of infection or untreated neoplasm.

Warnings: This device contains solid silicone elastomer. The risks and benefits of implanting this device in patients with lupus (e.g., SLE or DLE), scleroderma (e.g., progressive systemic sclerosis), myasthenia gravis, or documented sensitivity to silicone should be carefully considered. The issue of the possible relationship between silicone and various diseases has been and continues to be the subject of scientific and medical debate.

Sepsis or hemorrhage may result from the placement of any foreign object in the body.

Excessive fibrous capsular formation or contracture may occur around any implant placed in contact with soft tissues.

Precautions: Each prosthesis should be checked for patency prior to surgery and continuously monitored throughout the surgical procedure to ensure that the structural integrity of the implant is not compromised in any way.

The action of drugs (such as antimicrobials, chemotherapy agents or steroids) in contact with the prosthesis has not been tested by the manufacturer, and their use cannot be recommended. Each physician who chooses to use drugs in combination with this prosthesis must assure compatibility of the drug with silicone elastomer.

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

Implantation of the TOROSA Saline-Filled Testicular Prosthesis may be difficult or impossible in patients with inadequate scrotal tissue to cover the prosthesis, patients who have undergone prior pelvic radiation therapy, or patients whose wound healing abilities are compromised (e.g., uncontrolled diabetes, poor circulation).

Potential Complications: Potential complications include pain and discomfort.

The information provided is not comprehensive with regard to product risks. For a comprehensive listing of indications, contraindications, warnings, precautions, and adverse events refer to this product's Instructions for Use. Alternatively, you may contact a Coloplast Representative at 1-800-258-3476 and/or visit the company website at www.coloplast.us

Caution: Federal law (USA) restricts this device to sale by or on the order of a physician.