Filling Procedure
For the Torosa Saline-Filled Testicular Prostheses
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 adaptor
- Sterile, isotonic, pyrogen-free Sodium Chloride U.S.P. solution
- One 20 cc or larger syringe

Overfilling:
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.

<table>
<thead>
<tr>
<th>Catalog Number</th>
<th>Testicular Size</th>
<th>Over-Fill Volume Range</th>
<th>Final-Fill Volume Range</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Lower Limit</td>
<td>Upper Limit</td>
</tr>
<tr>
<td>450-1323</td>
<td>Extra Small</td>
<td>7 cc</td>
<td>9 cc</td>
</tr>
<tr>
<td>450-1325</td>
<td>Small</td>
<td>10 cc</td>
<td>12 cc</td>
</tr>
<tr>
<td>450-1327</td>
<td>Medium</td>
<td>13 cc</td>
<td>15 cc</td>
</tr>
<tr>
<td>450-1329</td>
<td>Large</td>
<td>17 cc</td>
<td>19 cc</td>
</tr>
</tbody>
</table>

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.
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.

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).
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.
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.

Caution: Do not attempt to adjust the fill volume of this device postoperatively.

Suture Tab
A suture tab is provided on the end of the implant opposite the injection port for suturing the prosthesis into position if desired. If a suture is used, it must only be tied through the punched hole in the suture tab.

Caution: The suture must be placed through the pre-punched hole in the suture tab. Suture placement in any area other than the pre-punched hole will result in damage to the device.

CAUTION: Federal law restricts this device to sale to or on the order of a physician or properly licensed practitioner. Please refer to the Product Insert Data Sheet provided with each implant for the latest information on Saline-Filled Testicular Prostheses.

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