**PRODUCT ORDER INFORMATION**

**PRODUCT EVALUATION**

Mentor requests that physicians notify the company of complications which occur with the use of this device.

**ADVERSE REACTIONS**

Adverse reactions which may result from the use of the Sizer and corresponding breast implant include the risks associated with the medication and methods used in the surgical procedure as well as the patient’s degree of tolerance to any foreign object placed in the body.

**REFERENCES**

Literature references are available upon request.

**PRODUCT ORDER INFORMATION**

- **US Customers** – call customer service or order online at www.MentorDirect.com.
- **International Customers** – contact customer service.

**DESCRIPTION**

The **MENTOR® Breast Implant Sizer** is a silicone elastomer device designed for temporary intraoperative placement in the surgically prepared mammary pocket. The Sizer is used to evaluate the appropriate breast-implant volume for each patient prior to implantation of a breast implant. The Sizer is inflated to its optimal volume with saline after it is placed within the pocket, and then deflated prior to its removal.

The smooth-surface Sizer is made with successive cross-linked layers of silicone elastomer, each cross-linking layer uniting with the last to provide the device with elasticity and integrity. The Sizer is supplied with an integral fill-tube valve and a two-way check valve to facilitate filling. The Sizer is provided sterile and is for single use only.

The smooth check valve is supplied sterile separately.

The Round High Profile Volume Sizer is available in ten sizes with nominal fill-volumes ranging from 190 to 630 cc.

The Round Moderate Profile Volume Sizer is available in sizes with nominal fill-volumes ranging from 125 to 450 cc.

The Round Low Profile Volume Sizer is available in sizes with nominal fill-volumes ranging from 75 to 150 cc.

The Contour Profile Volume Sizer is available in sizes with nominal fill-volumes ranging from 70 to 150 cc.

Sizes should be used to assist in determining only the volume, not shape, of the saline breast implant to be implanted.

**INDICATIONS**

The **MENTOR® Breast Implant Sizer** (Sizer) is a silicone elastomer device designed for temporary intraoperative placement in the surgically prepared mammary pocket. The Sizer is used to evaluate the appropriate breast-implant volume for each patient prior to implantation of a breast implant. The Sizer is inflated to its optimal volume with saline after it is placed within the pocket, and then deflated prior to its removal.

The smooth-surface Sizer is made with successive cross-linked layers of silicone elastomer, each cross-linking layer uniting with the last to provide the device with elasticity and integrity. The Sizer is supplied with an integral fill-tube valve and a two-way check valve to facilitate filling. The Sizer is provided sterile and is for single use only.

The smooth check valve is supplied sterile separately.

The Round High Profile Volume Sizer is available in ten sizes with nominal fill-volumes ranging from 190 to 630 cc.

The Round Moderate Profile Volume Sizer is available in sizes with nominal fill-volumes ranging from 125 to 450 cc.

The Round Low Profile Volume Sizer is available in sizes with nominal fill-volumes ranging from 75 to 150 cc.

The Contour Profile Volume Sizer is available in sizes with nominal fill-volumes ranging from 70 to 150 cc.

Sizes should be used to assist in determining only the volume, not shape, of the saline breast implant to be implanted.

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

4. Apply mild pressure and check for possible punctures or leakage.

3. Submerge the air-filled Sizer in sterile, pyrogen-free testing fluid (water or saline).

The filling of the Sizer

Use a new sterile and packaged syringe and fingernail hygiene, saline, Sterile Chloride U.S.P. Solution for Injection to fill the Sizer to the recommended volume (see specifications noted on product label).

Drinking saline from the Sizer is not recommended. If drinking saline solution from the original container is unavoidable because the syringe/mill must result in contaminated saline and syringe, it is recommended that a new sterile saline container and sterile syringe be used with each surgery.

Testing the Sizer

When the correct implant size is determined, drain the Sizer by removing the syringe and check valve. Completely deflate the implant to its original design. A Sizer which has been damaged, or on which repairs or modifications have been attempted, should not be used.

The enclosed Sizer and two-way check valve must not be resterilized.

Each device should be checked for patency prior to use and continuously monitored throughout the procedure to ensure the structural integrity of the device is not compromised in any way. This device should not be used in patients with a known allergy to any component of the device.

Preoperative evaluation of the eventual implant type and implant site with the Sizer should include allowances for adequate tissue coverage. Such contact may result in Sizer deflation. Careful hemostasis is important to prevent post-operative hematoma formation. Should excessive bleeding persist, it is recommended that the Sizer not be used until the bleeding is controlled.

Care should be taken not to damage the Sizer with surgical instruments (e.g., forceps contact), and their use should be avoided.

Potential for contamination exists when added for removal from the Sizer. Use of sterile technique is the responsibility of the surgeon. A Sizer which has been damaged, or on which repairs or modifications have been attempted, should not be used.

The Sizer must not be used as a long-term breast implant or tissue expander.
<table>
<thead>
<tr>
<th>TITLE</th>
<th>DESCRIPTION</th>
<th>LAB NUMBER</th>
<th>SPECIAL INSTRUCTIONS/COMMENTS</th>
<th>BINDING</th>
<th>STOCK</th>
<th>DRAWING IS NOT TO SCALE: DRAWINGS REFLECT INFORMATION FOR PRODUCTION OF PRINTED PIECES AND DO NOT CONTAIN ACTUAL ARTWORK. This document or data herein or herewith is not to be reproduced, used or disclosed in whole or part without the permission of Ethicon, Inc.</th>
</tr>
</thead>
<tbody>
<tr>
<td>SINGLE USE SALINE BREAST IMPLANT SIZER</td>
<td>PIDS (English)</td>
<td>LAB1000053189v3</td>
<td>N/A</td>
<td>N/A</td>
<td>50# White Offset</td>
<td></td>
</tr>
<tr>
<td>Flat Size</td>
<td>18.75&quot; x 7.5&quot; 476.25 mm x 190.5 mm</td>
<td>FOLDED SIZE 6.25&quot; x 7.5&quot; 158.75 mm x 190.5 mm</td>
<td>PAGE COUNT 6</td>
<td>N/A</td>
<td>X</td>
<td></td>
</tr>
<tr>
<td>BLEED SIZE</td>
<td>NONE BLEED ALL SIDES BLEED TOP BLEED RIGHT BLEED LEFT BLEED BOTTOM</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>N/A</td>
</tr>
<tr>
<td>STOCK</td>
<td>50# White Offset</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STOCK</td>
<td>50# White Offset</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STOCK</td>
<td>50# White Offset</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STOCK</td>
<td>50# White Offset</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>STOCK</td>
<td>50# White Offset</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>