ADVERSE REACTIONS

Any patient undergoing a surgical procedure is subject to possible unknown operative and postoperative complications. Potential reactions and complications associated with the use of the Sizer and breast implant should be discussed with and understood by the patient prior to surgery. It is the responsibility of the surgeon, and Mentor relies on the surgeon, to provide the patient with this information and to weight the benefits for each patient.

Adverse reactions which may result from the use of the Sizer and corresponding breast implant include the risks associated with the methodology and methods used in the surgical procedure as well as the patient’s degree of tolerance to any foreign material placed in the body. The MENTOR® Volume Sizer for Breast Implants is similar in materials to some saline and gel-filled breast implants; however, the Sizer is not intended as an implantable device. Prior to surgery, the surgeon should be familiar with all the information, including ADVERSE REACTIONS, contained in the Product Insert Data Sheet for the breast implant to be used.

PRODUCT EVALUATION

Mentor requests that physicians notify the company of complications which occur with the use of this device. Any complications should be brought to the immediate attention of the Product Evaluation Department at Mentor, 3041 Skyway Circle North, Irving, TX 75038; (800) 258-3487 in the USA or (972) 252-6060 outside the USA.

RETURNED GOODS AUTHORIZATION

U.S. Customers

Merchandise returned must have all manufacturer’s seals intact and the return must be within 60 days from date of invoice to be eligible for credit or replacement. Products returned more than 60 days after shipment date will be subject to restocking charges.

International Customers

Authorization for return of merchandise should be obtained from your respective Mentor distributor. Other conditions noted above also apply.

PRODUCT INFORMATION DISCLAIMER

No representation or other affirmation of fact, including but not limited to statements regarding suitability for use, or otherwise, including, but not limited to, any implied warranties of merchantability, fitness, or design. Mentor shall not be liable for any direct, incidental or consequential loss, damages or expense, direct or indirectly arising from the use of this product. No representation or other affirmation of fact, including but not limited to statements regarding suitability for use, or performance of the product shall be or be deemed to be a warranty by Mentor for any purpose. Mentor neither assumes nor grants any other or any additional liability or responsibility in connection with the device.

PRODUCT ORDER INFORMATION

U.S. Customers

For product information or to order directly in the USA, please contact the Mentor Customer Service Department, 33 Technology Drive, Irvine, CA 92618. Toll free telephone: (800) 210-5773; Fax: (949) 867-7108.

International Customers

For product information or to order directly, contact your local Mentor product distributor or the Mentor International Customer Service Department, 33 Technology Drive, Irvine, CA 92618, USA. Telephone: (800) 879-4000, Fax: (949) 867-7108.

REFERENCES

Literature references are available upon request.


SINGLE USE SALINE BREAST IMPLANT SIZER

The Round High Profile Volume Sizer is available in eight sizes with nominal fill-volumes ranging from 350 to 600 cc. The Round Moderate Plus Profile Volume Sizer is available in twenty sizes with nominal fill-volumes ranging from 190 to 630 cc. The Round High-Profile Volume Sizer is available in ten sizes with nominal fill-volumes ranging from 150 to 300 cc. The Contral Profile Volume Sizer is available in five sizes with nominal fill-volumes ranging from 275 to 650 cc.

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

NOTE: Sizers are imprinted “Single Use only.”

INDICATIONS

The Sizer is only indicated for single use for temporary insertion intraoperatively to evaluate the volume of the breast implant to be implanted. Prior to using the Sizer, the physician should be familiar with all of the literature associated with the breast implant to be implanted. This information is intended to supplement the Product Insert Data Sheets that are included with all MENTOR® Breast Implants. Additional copies are available from Mentor (see PRODUCT ORDER INFORMATION). The MENTOR® Volume Sizer for breast implants is intended strictly for the sizing of MENTOR® Breast Implants, and not for use with any other prostheses or implants.

CONTRAINDICATIONS

The use of this Sizer as a long-term breast implant or tissue expander is contraindicated. Multiple use and/or multiple sterilizations of the Sizer are contraindicated.

PATIENT EDUCATION AND INFORMED CONSENT

The surgical procedures associated with the use of the Sizer, breast implant and related devices are not without potential complications and risks. The patient should be counseled prior to surgery regarding the benefits and possible risks associated with the selected treatment option and/or breast augmentation using mammoplasty procedures and alternative procedures.

It is the responsibility of the surgeon to decide the best method by which to counsel a patient prior to surgery. Mentor relies upon the surgeon to advise the patient of all potential complications and risks associated with the use of the Sizer and breast implant. Criteria for patient selection is the responsibility of the surgeon.
Prior to using the Sizer, the physician should become familiar with all the literature associated with the breast implant to be inserted (see breast implant Product Insert Data Sheet). The fill tubing provided is of sufficient length to facilitate application in any of the three primary types of incisions: inframmary, periareolar, or transaxillary. Mentor has tested its Sizers or breast implants for implantation by endoscopic or cutaneous approach. These methods of insertion cannot be recommended by Mentor at this time. The following procedures are recommended by Mentor for the Breast Implant Sizer.

**Sizer/Implant Selection**

Some of the important surgical and implant sizing variables that have been identified include the following:

- The implant should not be too small or too large in comparison to the patient’s chest wall width.
- Available tissue must provide adequate coverage of the implant; submuscular placement of the implant may be preferable in patients with thin or poor quality tissue, and
- A well-defined, firm pocket of adequate size and symmetry must be created to provide a smooth surface that allows the implant to be placed flat.

Mentor recommends the surgeon considers the size of the implant and the firmness and quality of implantation with test sizes when selecting optimum incision size and surgical approach. Certain surgical approaches and techniques may cause higher stresses on the device during implantation.

Avoid too small an incision when using an endoscopically placed breast implant. A larger incision than is normally used for other smooth surface implants may be required to facilitate insertion and to avoid damage to the device. A Sizer which is damaged during insertion will result in a suboptimal outcome.

**NOTE:**

If excessive resistance to filling is encountered prior to reaching the minimum indicated fill volume, discontinue filling to prevent possible tissue damage. Drain the saline solution by removing the syringe and check valve, completely deflate the Sizer, and remove from manufacturer’s packaging. Repeated filling procedures using a smaller volume may increase the risk of leakage.

**NOTE:**

Should adjustment of volume be necessary, use the attached filling syringe to withdraw or add fluid as needed. Caution: the use of forceps or hemostats is specifically contraindicated as fill tube or shell may damage leading to deflation of the device.

**Deflation and Removal**

When the correct implant size is determined, drain the Sizer by removing the check valve and completely deflate the Sizer and remove from manufacturer pocket.

**PRECAUTIONS**

It is the responsibility of the surgeon to advise prospective patients or their representatives, prior to surgery, of the possible complications associated with the use of this product.

Prior to surgery, the surgeon should be familiar with all the information contained in the Product Insert Data Sheet concerning the breast implant to be used. The following Section PRECAUTIONS are intended to supplement the PRECAUTIONS listed in the Product Insert Data Sheet for the breast implant to be used.

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

- **The Sizer is designed for single use only.** Stresses from multiple sterilizations, surgeries and surgical technique will likely cause abrasion of the shell and fill tube of the implant. Any surgeon performing augmentation or reconstruction mammopexy with implants should be familiar with the current techniques for measuring the patient, determining the implant size and performing surgery. (See how to measure the patient, how to select the implant, and their use should be avoided.)

**Filling Procedure**

Prior to deflation, insertion, and adding fluid to the Sizer, the enclosed two-way check valve should be attached to the Laser implant adapter of the fill tube. This two-way check valve opens when the syringe is attached and closes when the syringe is removed.

**WARNING**

Extreme care should be taken when handling the fill tube. The tube is easily damaged with surgical instruments (e.g., finger contact), and should not be used. Potential for external contamination exists if adding or removing it from the Sizer. Use of aseptic techniques in the introduction of Sodium Chloride U.S.P. Solution for injection into the device, a single-dose, sterile saline container is recommended. 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 following any modifications to its original design. A Sizer which has been damaged, or on which repairs or modifications have been attempted, should not be used. Standard size of different shells should be available at the time of the surgery.

The silicone elastomer shell and fill tube may be easily cut or ruptured by excessive stress, manipulations with blunt instruments or penetration by a needle. Subsequent deflation will result. All products should be carefully inspected for structural integrity prior to and during surgery.

Fill tube of the Sizer may be easily cut or ruptured by excessive stress, manipulations with blunt instruments or penetration by a needle. Subsequent deflation will result. All products should be carefully inspected for structural integrity prior to and during surgery.

Careful hemostasis is important to prevent post-operative hematoma formation. Should excessive bleeding persist, it is recommend that the Sizer not be used until the bleeding is controlled.

This product is designed for single use for temporary infrapectoral insertion as a breast implant implant. Verify the Sizer does not retain air prior to use and the filling is not blocked.

- **The Sizer must not be used as a long-term breast implant or tissue expander.**
SINGLE USE SALINE BREAST IMPLANT SIZER

TITLE: SINGLE USE SALINE BREAST IMPLANT SIZER
DESCRIPTION:...
LAB NUMBER: LAB100053189v3
SPECIAL INSTRUCTIONS/COMMENTS:...
BINDING:...
COLORS: Black
STOCK: 50# White Offset

FLAT SIZE: 18.75" x 7.5" 476.25 mm x 190.5 mm
FOLDED SIZE: 6.25" x 7.5" 158.75 mm x 190.5 mm
BLEED SIZE:...

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