ADVERSE REACTIONS

Any patient undergoing a surgical procedure is subject to possible unforeseen 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 weigh the risk/benefit for each patient.

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.

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 be returned 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

Mentor expressly disclaims all warranties, whether written or oral, statutory, express or implied by the operation of law 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, directly 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 authorizes any other or additional liability or responsibility in connection with this 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) 235-5731; FAX (805) 967-7108.

International Customers

For product information or to order directly, contact your local Mentor products distributor or the Mentor International Customer Service Department, 33 Technology Drive, Irvine, CA 92618, USA. Telephone (805) 879-6000; FAX (805) 967-7108.

REFERENCES

Literature references are available upon request:
US Customers – call customer service or order online at www.MentorDirect.com.
International Customers – contact customer service.

NOM. DIM.	Nominal Dimensions	2 STERILIZE	Do not resterilize	MIN. VOL.	Minimum Volume final (cc)
MIN. DIM.	Minimum Dimensions	LATEX	Latex free	MAX. VOL.	Maximum Volume final (cc)
QTY 1	Quantity		Not returnable if opened	STERILE & NONPYRO	The enclosed device is sterile and nonpyrogenic (unless the package has been opened or damaged).
S	Style		Fluid added		For customer service or to return product, please call (800) 235-5731 in USA; or outside of USA, call (805) 879-6000, or contact your local representative.
S	Style: nnnn Round		Date		
R L	Breast; Right (or) Left		Date of manufacture		

MENTOR®

For customer service, call Mentor, a unit of Johnson & Johnson Medical Products, a division of Johnson & Johnson Inc., at 1-800-668-6069 or contact your local Mentor representative.
www.mentorwwllc.com • www.mentordirect.com

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EC REP **European Representative**
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CE
0086

100053189 | Rev:3
Released: 08 Feb 2017
CO: 100495245
Release Level: 4. Production

MENTOR®

Product Insert
Data Sheet

ENGLISH

SINGLE USE SALINE BREAST IMPLANT SIZER

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

102922-001 Rev C Effective November 2016
LAB100053189v3

DESCRIPTION

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 shell 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 with a Luer adapter, and a two-way check valve to facilitate filling. **The Sizer is provided sterile and is for single use only**. The twoway check valve is supplied sterile separately.

The Round Moderate Profile Volume Sizer is available in eight sizes with nominal fill-volumes ranging from 125 to 475 cc.
The Round Moderate Plus Profile Volume Sizer is available in twenty sizes with nominal fill-volumes ranging from 175 to 800 cc.
The Round High Profile Volume Sizer is available in ten sizes with nominal fill-volumes ranging from 190 to 630 cc.
The Contour 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 elective tissue reconstruction and/or breast augmentation using mammary prostheses 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.

HOW SUPPLIED
The Sizer is supplied sterile. The product is sterilized by gamma radiation. Do not resterilize the device.

INSTRUCTIONS FOR USE
The implantation of breast implants – for routine cosmetic augmentation, breast reconstruction or body defect correction involves a variety of surgical techniques; therefore the surgeon is best advised to use the method which his/her own practice and discretion dictate to be best for the patient.

Prior to using the Sizer, the physician should become familiar with all the literature associated with the breast implant to be implanted (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: inframammary, periareolar, or transaxillary. Mentor has not tested its Sizers or breast implants for implantation by endoscopic insertion or umbilical 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 dimensions;
- 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, dry 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 consider the size of the implant and the firmer nature and higher profile of implants with textured shells when choosing 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 implant with a textured shell. 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 may result in intraoperative deflation.

NOTE: It is advisable to have more than one size Breast Implant Sizer in the operating room at the time of surgery to allow the surgeon flexibility in determining the appropriate size implant to be used.

Testing the Sizer
The Sizer should be tested for patency and shell integrity immediately prior to use. This can be accomplished by the following steps:

1. Attach the two-way check valve to the Luer adapter.
2. Partially inflate the Sizer with air through the fill tube, taking care not to damage the tube.
3. Submerge the air-filled Sizer in sterile, pyrogen-free testing fluid (water or saline).
4. Apply mild pressure and check for possible punctures or leakage.

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

Deflation and Insertion of Sizer
Prior to inserting the Sizer into the surgically prepared pocket, deflate the device completely. Attach an empty, sterile syringe to the Luer-lock adapter of the fill tube and draw out as much air as possible. Fold the Sizer and insert it into the pocket (some surgeons prefer to partially fill the device prior to placement).

Filling the Sizer
Use a new sterile and packaged syringe filled with pyrogen-free, sterile, Sodium Chloride U.S.P. Solution for Injection to fill the Sizer to the recommended volume (see specifications noted on product label).

Only sterile, pyrogen-free Sodium Chloride U.S.P. Solution for Injection drawn from its original container should be used. Because bacterial infections may result from contaminated saline and syringes, it is recommended that a new sterile saline container and sterile syringe be used with each surgery and Sizer use.

The Sizer should not be filled to a volume less than or greater than specified (see product label) as this could cause discrepancies in implant volume sizing. Underfilled devices may buckle, fold or wrinkle causing sizing errors. Additionally, inflation beyond the maximum recommended volume may also cause implant sizing errors or shell rupture.

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 mammary pocket. Repeat the filling procedure using a smaller Sizer.

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 damage may lead to deflation of the Sizer.

Deflation and Removal
When the correct implant size is determined, drain the Sizer by removing the syringe and check valve. Completely deflate the Sizer and remove from mammary 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 information contained in the **Product Insert Data Sheet** concerning the breast implant to be used. The following Sizer **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/or fill tube and eventual leakage and/or rupture of the device.

Any surgeon performing augmentation or reconstruction mammaplasty with implants should be familiar with the currently available techniques for measuring the patient, determining the implant size and performing surgery. (See **INSTRUCTIONS FOR USE** section of this insert.)

Lint, dust, talc, surgical glove powder, drape and sponge lint, fingerprints, skin oils and other surface contaminants deposited on the Sizer by improper handling may cause foreign body reactions. Strict adherence to clean, aseptic techniques should be maintained to prevent contamination of the device and possible complications. Surgical instruments and gloves should be rinsed clean of impurities before handling the Sizer.

Extreme care should be taken when handling the fill tube. The tube is easily damaged with surgical instruments (e.g., forcep contact), and their use should be avoided.

Potential for contamination exists when fluid is added to or removed 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. Standby Sizers of different sizes should be available at the time of surgery.

The silicone elastomer shell and fill tube may be easily cut by scalpel or ruptured by excessive stress, manipulation 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.

Failure of the Sizer to inflate may be due to kinking of the fill tube, leakage or separation of the components.

Avoid too small an incision. A larger incision than is normally used for other saline-filled implants and/or some form of lubrication may be required to facilitate insertion and to avoid damage to the Sizer. A Sizer which is damaged during insertion may result in deflation.

Mentor recommends the surgeon consider the size, shape, firmness and profile breast implant to be implanted when choosing optimum incision size and surgical approach. Certain surgical approaches may cause higher stresses on the breast implant during implantation.

Do not contact the Sizer with disposable, capacitor-type cautery devices as damage to the outer shell of the Sizer may result.

WARNINGS
It is the exclusive responsibility of the surgeon, and Mentor relies on the surgeon, to advise the patient of all potential risks and complications associated with the proposed surgical procedure and device, including providing a comparison of the risks and complications of alternative procedures. **Prior to surgery, the surgeon should also be familiar with all WARNINGS**, **PRECAUTIONS, and ADVERSE REACTIONS associated with the use of the breast implant to be implanted**. The following **WARNINGS** are intended to supplement the **WARNINGS** listed in the **Product Insert Data Sheet** for the breast implant to be used.

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.

This product is designed for single use for temporary intraoperative insertion as a breast implant Sizer.

Do not insert or attempt to repair a damaged Sizer.

Preoperative evaluation of the eventual implant type and implant site with the Sizer should include allowances for adequate tissue coverage. Pressure, force, tension and other stresses to which the implant site will be susceptible must be considered.

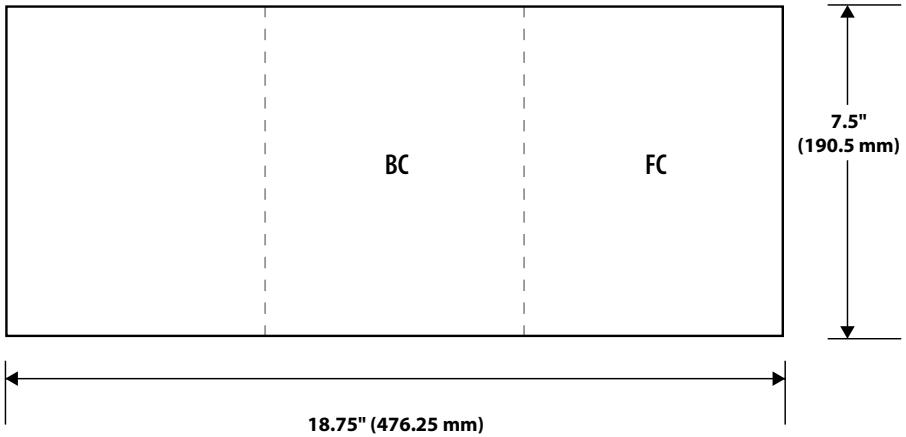
The Sizer should not be filled to a volume less than or greater than specified (see product label) as this could cause discrepancies in implant volume sizing. Under filled devices may buckle, fold or wrinkle, causing sizing errors. Additionally, inflation beyond the maximum recommended volume may also cause implant sizing errors or shell rupture.

Care should be taken not to damage the Sizer with surgical instruments. Such contact may result in Sizer deflation.

Caution: The Sizer must not be used as a long-term breast implant or tissue expander.

IFU PRINTING SPECIFICATION SHEET

PAGE LAYOUT



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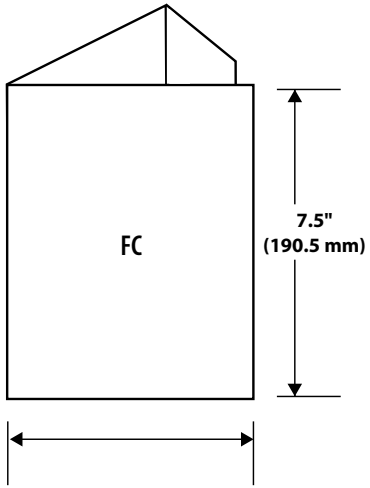
FOLD PATTERN



Folded Size

TITLE **SINGLE USE SALINE BREAST IMPLANT SIZER**	DESCRIPTION **PIDS (English)**		LAB NUMBER **LAB100053189v3**	SPECIAL INSTRUCTIONS/COMMENTS **N/A**		BINDING **N/A**	COLORS **Black**		
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**	RMC NUMBER **102922-001 Rev C**	PAGE COUNT **6**	LANGUAGES **EN**		SELF COVER [X]	PLUS COVER [ ]	SEALING METHOD **n/a**	WAFER SEAL [ ]
BLEED SIZE .5" (12.7 mm) [ ] .125" (3.175 mm) [X]	NONE [ ] BLEED ALL SIDES [ ]	BLEED TOP [ ]	BLEED RIGHT [X]	BLEED LEFT [ ]	BLEED BOTTOM [ ]	**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.			
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