
MENTOR® RESTERILIZABLE GEL BREAST IMPLANT SIZER

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician. 102925-001 Rev. A Effective August 2010

DESCRIPTION

The MENTOR® Resterilizable Gel Breast Implant Sizer (Gel Sizer) is a sizing device designed for temporary intraoperative placement to assist in evaluating the appropriate breast implant shape and size for each patient prior to implantation of a MENTOR® MemoryGel® Breast Implant.

The Gel Sizer is not intended as an implantable device. The Gel Sizers are specifically labeled “Not for Implant”.

The smooth-surface of the Gel Sizer shell is made with a silicone elastomer shell filled with silicone gel. The device is designed 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 Gel Sizer is provided non-sterile and must be sterilized prior to use. The Gel Sizer should not be sterilized more than ten (10) times.**

INDICATIONS

The Gel Sizer is indicated for use **for temporary insertion** intraoperatively to evaluate the shape and size of the MemoryGel® Breast Implant to be implanted.

Prior to using the Gel Sizer, the physician should be familiar with all of the literature associated with the MemoryGel® Breast Implants to be implanted.

CONTRAINDICATIONS

The use of this Gel Sizer as a long-term breast implant is contraindicated.

WARNINGS

DO NOT insert or attempt to repair a damaged Gel Sizer.

The Gel Sizer may rupture during surgery, releasing gel into the surgical pocket. Causes of ruptures can include damage by surgical instruments, improper handling and manipulation.

The Gel Sizer must not be used as a long-term breast implant.

PRECAUTIONS

Mentor recommends that the surgeon consider the size, shape, firmness and profile of the MemoryGel® Breast Implant to be implanted when choosing the optimum incision size and surgical approach. Certain surgical approaches may cause higher stresses on the sizer.

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

HOW SUPPLIED

The Gel Sizer is supplied non-sterile in a single wrap package. The Gel Sizer must be cleaned and sterilized prior to use. The Gel Sizer should not be sterilized more than ten (10) times.

INSTRUCTIONS FOR USE

Any surgeon performing breast augmentation or reconstruction with breast implants should be familiar with the currently available techniques for measuring the patient, determining the implant size, and performing surgery.

The Gel Sizer is designed for temporary intraoperative insertion as a tool to assist the surgeon in determining the shape and size in permanent breast implant selection.

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

Lint, dust, talc, surgical glove powder, drape and sponge lint, fingerprints, skin oils and other surface contaminants deposited on the Gel 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 Gel Sizer.

Each Gel Sizer 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 modification to its original design. A Gel 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 may easily be cut by scalpel or ruptured by excessive stress, manipulation with blunt instruments or penetration by a needle. The sizer should be carefully inspected for structural integrity prior to and during surgery.

Testing the Gel Sizer

The Gel Sizer should be tested for patency and shell integrity immediately prior to each use. This can be accomplished by gently manipulating the device with hand and fingers, while carefully examining for leakage sites.

Caution: The use of forceps or hemostats is specifically contraindicated as shell damage may lead to rupture of the Gel Sizer.

Removal

When the correct implant size is determined, remove the Gel Sizer from the mammary pocket.

The following cleaning and sterilization techniques for Gel Sizers have been found effective for test devices and are provided as a guide.

Cleaning the Gel Sizer

For any reprocessing method to be effective, **the reusable device must be thoroughly cleaned before it is subjected to the sterilization process.** Hand wash soiled Gel Sizers for a minimum of 3 minutes in a solution of mild surgical soap or a 1% anionic, alkaline, or enzymatic detergent. Water used in the preparation of cleaning solutions should be warm (86°F-104°F / 30°C-40°C) or hot (any temperature above 104°F / 40°C) depending upon the degree of soiling. Ambient temperature may be acceptable, especially for presoak. Rinse the product copiously in non-pyrogenic purified or distilled water. Discard the cleaning solution after use. Dry the cleaned device with lint-free toweling or allow to air dry before packaging for sterilization.

Sterilizing the Gel Sizer

The Gel Sizer is supplied individually in a non-sterile single wrap packaging system. **Do not sterilize in the packaging system provided.** Remove the Gel Sizer from the packaging provided and wrap the Gel Sizer in suitable material intended for autoclave use (e.g., woven fabrics, non-woven materials, lint-free blue sterilization wrap, autoclavable peel pouches of plastic and/or paper, etc.). Packaging systems should be permeable to allow steam penetration and direct contact with the device. If using a sterilization wrap, wrap loosely to allow expansion of the device during sterilization. Place the packaged device in the autoclave, or on an open clean autoclaving tray if used, and autoclave with one

of the following gravity displacement methods in accordance with ANSI/AAMI ST8, “Hospital Steam Sterilizers”, and ANSI/AAMI ST46, “Steam Sterilization and Sterility Assurance in Health Care Facilities”:

Standard Cycle: **30 minutes at 250° (121°C)** and 15 psi. Minimum dry time is 45 minutes

Optional Cycle: **20 minutes at 270° (132°C)** and 30 psi. Minimum dry time is 45 minutes

The method of sterilization and the stated parameters outlined herein are the only method and parameters that have been qualified to deliver a sterile product while maintaining product integrity up to ten (10) times sterilization. **Do not use alternate methods of sterilization or physical parameters.**

Caution: Do not use a pre-vacuum high temperature autoclave cycle, ethylene oxide (EO), STERRAD, or chemical sterilization methods. **The use of a “flash” sterilization autoclave cycle is contraindicated.** Do not dry the device using a vacuum cycle.

Standard operating protocol for autoclaving of reusable devices/instrumentation in individual healthcare facilities should be followed. Double wrapping/pouching of the Gel Sizer is an acceptable packaging configuration to facilitate sterile transfer of product into the surgical setting. Flash sterilization cycles should not be used in accordance with AORN Recommended Practice IV for Sterilization in the Perioperative Practice Setting.

To dry the wrapped Sizer after the autoclave cycle is complete, the autoclave door may be opened slightly to allow excess steam to escape, then closed while allowing the Sizer to remain in the autoclave until the packaging material is entirely dry. Alternately, a programmed dry cycle of not less than 45 minutes may be used for a Gravity-Displacement Sterilization cycle. Also, air bubbles may appear in the gel following sterilization. These bubbles are expected and do not affect the integrity or purpose of the Gel Sizer.

The Sizer may rupture while still hot from the autoclave, and could require up to 45 minutes to cool based on Sizer volume. Care must be used during handling to avoid damage while hot.

After each sterilization cycle record the date of cleaning and sterilization and who performed the sterilization on the Sterilization Record card. The device and the card should be kept together to insure keeping accurate sterilization records.

Because packaging methods and packaging materials may vary from one healthcare facility to another, Mentor cannot determine the shelf-life for devices sterilized outside of our manufacturing facility. The

shelf-life of a packaged sterile item is event related. An event must occur to compromise package content sterility. Refer to current AORN Standards, Recommended Practices, and Guidelines for the selection and use of packaging systems. Sterile packaged devices should not be stacked, and should be stored under environmentally controlled conditions for temperature and humidity. Provided the packaging instructions are followed, the device will remain sterile to the date determined by individual policies and procedures for event-related sterility in perioperative settings.

The Gel Sizer can be resterilized up to ten (10) times. **Do not resterilize the device more than 10 times.**

The product is for **ten (10) times use only. Sterility, safety and efficacy cannot be assured for damaged devices.**

After the Gel Sizer has been sterilized and inserted ten (10) times, discard device.

Dispose of material in accordance with all federal, state, and local regulations. Responsibility for proper waste disposal is with the owner of the waste.

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 your local Mentor representative, who will be responsible for informing the Product Evaluation Department at Mentor Texas.

RETURNED GOODS AUTHORIZATION

Authorization for return of merchandise should be obtained from your local Mentor representative prior to return of merchandise. Merchandise returned must have all manufacturer's seals intact.















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, 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, 201 Mentor Drive, Santa Barbara, CA 93111. Toll free telephone (800) 235-5731; FAX (805) 967-7108.

 NOM. DIM.	Nominal Dimensions	 R <input type="checkbox"/> <input type="checkbox"/> L	Breast; Right (or) Left	 MIN. VOL.	Minimum Volume final (cc)
 MIN. DIM.	Minimum Dimensions		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).
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For customer service, please call (800) 235-5731 in USA; or outside of USA, call (805) 879-6000, or contact your local representative.

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