

MENTOR® MemoryShape™ RESTERILIZABLE GEL BREAST IMPLANT SIZER STERILE

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

102998-001 Rev A Effective April 2015
LAB100300459v1

DESCRIPTION

MENTOR® MemoryShape™ Resterilizable Gel Breast Implant Sizer (Gel Sizer) is a sizing device designed for temporary intraoperative placement to assist in evaluating the appropriate breast implant size and shape for each patient prior to implantation of a MENTOR® MemoryShape™ 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 Mentor’s proprietary formulation for 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 STERILE** for the first use, and must be resterilized prior to each subsequent use. The Gel Sizer can be resterilized up to nine (9) times after the first use for a total of ten (10) uses, after which you must discard the device.

MemoryShape™ sizers are offered in various styles and sizes to match the corresponding MemoryShape™ breast implants. These Gel Sizers contain raised orientation marks on the anterior and posterior of the device. These marks help the physician orient the sizer and ensure proper placement during intraoperative insertion (Figure 1).

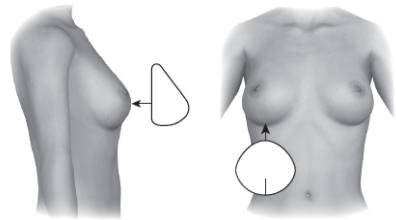
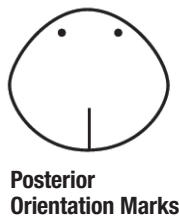
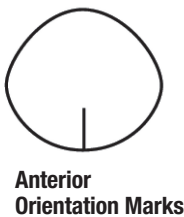


Figure 1. Orientation Marks on MemoryShape™ Sizers

INDICATIONS

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

Prior to using the Gel Sizer, the physician should be familiar with all of the literature associated with MemoryShape™ Breast Implants.

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. Forceps or hemostats should not be used.

DO NOT resterilize in packaging system provided.

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

Do not sterilize the device more than nine (9) times.

Do not use the sizer until it has cooled completely.

DO NOT use alternate methods of sterilization or physical parameters.

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

PRECAUTIONS

Mentor recommends that the surgeon consider the size and firmness of the MemoryShape™ Breast Implant to be implanted when choosing the optimum incision size and surgical approach. Certain surgical approaches may cause higher stresses on the sizer. The incision will be longer for MemoryShape™ implants than the one typically made for round MemoryGel® Breast Implants. Reference the corresponding Mentor breast implant Product Insert Data Sheet (PIDS) for detailed warnings, precautions, implant selection and incision information.

HOW SUPPLIED

The Gel Sizer is supplied individually in a sterile and non-pyrogenic, double-thermoform packaging system. This product has been sterilized by Dry Heat Sterilization. Sterility cannot be guaranteed if the double-sealed packaging system has been damaged.

INSTRUCTIONS FOR USE

The Gel Sizer is provided sterile. Cleaning and sterilization is not necessary prior to first use.

The Gel Sizer must be cleaned and sterilized prior to each subsequent use. The Gel Sizer should not be resterilized more than nine (9) times.

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 size and shape in permanent breast implant selection.

NOTE: It is advisable to have more than one size 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, such as drape and sponge lint, dust, talc, surgical glove powder, 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 that 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.

The silicone elastomer shell may easily be cut by scalpel or ruptured by excessive stress, manipulation with blunt instruments or penetration by a needle. Forceps or hemostats should not be used.

Reprocessing Instructions

Warnings

Follow instructions and warnings as issued by the manufacturers of any decontaminants or cleaning agents.

When handling soiled or contaminated medical devices, always handle with care, wearing protective clothing, gloves and eyewear in accordance with local Health and Safety procedures and OSHA Standard 29 CFR 1910.030, Occupational Exposure to Bloodborne Pathogens.

Limitations on Reprocessing

The Gel Sizer should not be sterilized more than nine (9) times.

After Initial Use

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

For best results, reprocess immediately after use. Remove excess body fluids and tissue with a disposable, non-shedding wipe and cover device with a damp cloth.

Containment/Transportation

Devices should be placed in a basket or other containment device prior to transport to decontamination area.

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

1. Rinse soiled Gel Sizers under cold (approximately 68°F/20°C) tap water for a minimum of 3 minutes.
2. Soak Gel Sizers in a solution of alkaline, enzymatic or 1% anionic detergent for a minimum of 6 minutes. Water (type and temperature) used in the preparation of cleaning solutions should be in accordance with the manufacturer's recommendations.
3. Hand wash Gel Sizers for a minimum of 4 minutes, while submerged under the cleaning solution. Discard the cleaning solution after use.
4. Rinse Gel Sizers with warm (99-109°F/37-43°C) distilled water for a minimum of 3 minutes. Dry the cleaned device with a clean, lint-free towel or allow to air dry before packaging for sterilization.

Inspection

After cleaning, visually inspect the Gel Sizer for complete removal of soil or fluids. If any soil or fluid is still visible, repeat the previous cleaning steps.

Visually inspect and check all devices for damage.

Reste­ri­lizing the Gel Sizer

After cleaning the sizer, package the Gel Sizer in a suitable material intended for autoclave use (e.g., pack, sterilization wrapper, bag, or accessories); package loosely to allow expansion of the device during sterilization. Container systems should be permeable to allow steam penetration and direct contact with the device. Place the packaged device in the autoclave, or on an open clean autoclaving tray if available, and autoclave with one of the following gravity-displacement methods:

- Displacement Cycle: **50 minutes at 250°F (121°C)** and 15 psi. Minimum dry time of 45 minutes is recommended.
- Optional Gravity-Displacement Cycle: **20 minutes at 270°F (132°C)** and 30 psi. Minimum dry time of 45 minutes is recommended.

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 nine (9) times sterilization. **Do not use alternate methods of sterilization or physical parameters.**

Caution: Do not use a pre-vacuum high temperature autoclave cycle, immediate-use or “flash” sterilization autoclave cycle, ethylene oxide (EO), STERRAD® Sterilization System, or chemical sterilization methods. 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.

Immediate-use or “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 Gel 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 Gel 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 Gel 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 ensure 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 resterilized 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. For the selection and use of packaging systems, refer to a list of FDA-cleared packaging systems available and applicable healthcare standards and practices. Examples of standards and practices can be found with the Association for the Advancement of Medical Instrumentation (AAMI), the Association of periOperative Registered Nurses (AORN) and the Centers for Disease Control and Prevention—Healthcare Infection Control Practices Advisory Committees (CDC-HICPAC). 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 sterilized up to nine (9) times, after which the device must be discarded.

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

Sterility, safety and efficacy cannot be assured for damaged devices.

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, 3041 Skyway Circle North, Irving, TX 75038-3540.

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, 301 Mentor Drive, Santa Barbara, CA 93111. Toll-free telephone (800) 235-5731; FAX (805) 967-7108. Or visit www.MentorDirect.com.



Low Height,
Moderate Plus Profile



Not made with
natural rubber
latex



CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.



Medium Height,
Moderate Profile



Manufacturer



Sterilized using steam or dry heat



Medium Height,
High Profile



Date of
manufacturer



See instructions for use



Medium Height,
Moderate Plus Profile



Serial number



Caution



Tall Height,
Moderate Plus Profile



Catalogue
number



Not returnable if opened



Nominal Dimensions



Batch number



For customer service or to return product, please call (800) 235-5731 or contact your local representative.



Quantity



Use by

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MENTOR[®]

For customer service, please call (800) 235-5731 in USA; or outside of USA,
call +1 (805) 879-6000, or contact your local representative.

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Manufacturer

MENTOR

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Irving, TX 75038-3540

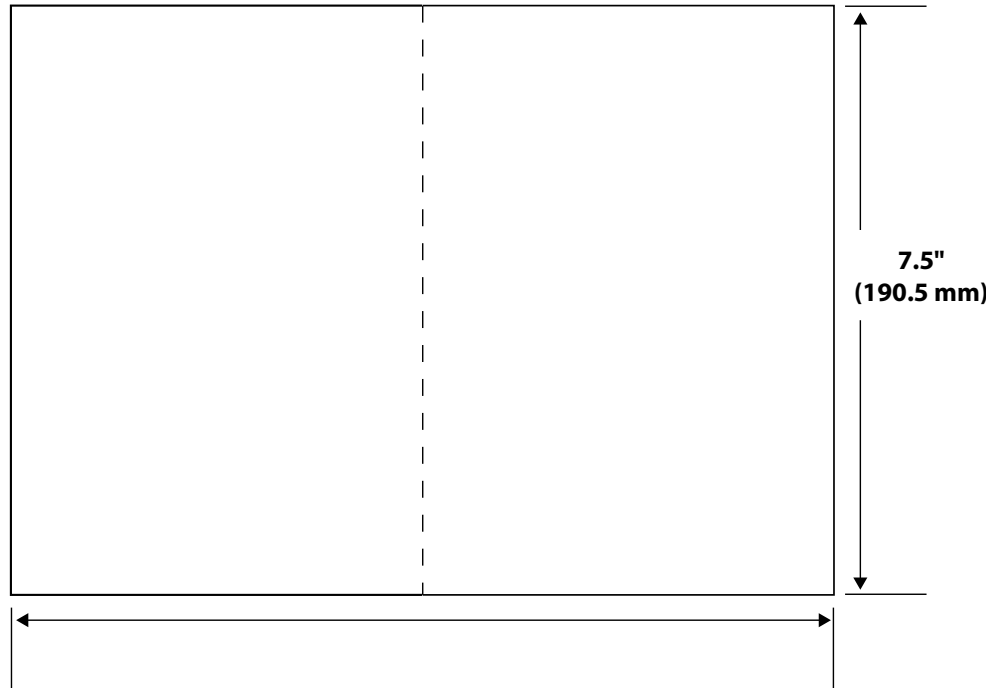
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IFU PRINTING SPECIFICATION SHEET

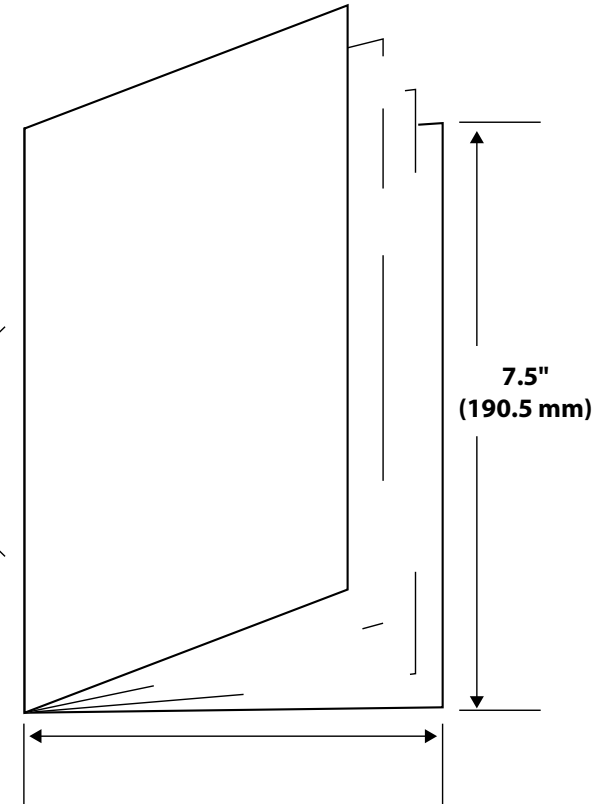
PAGE LAYOUT

FOLD PATTERN



Flat Size
12.5" (317.5 mm)

Binding Method:
**Saddle
Stitch**



Folded Size
6.25" (158.75 mm)

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