MENTOR® RESTERILIZABLE GEL BREAST IMPLANT SIZER

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 STERILE for the first use, and must be resterilized prior to each subsequent use. The Gel Sizer can be resterilized up to ten (10) times after the first use for a total of eleven (11) uses, after which discard the device.**

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.

DO NOT resterilize in packaging system provided.

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

Do not resterilize the device more than ten (10) times.
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 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 ten (10) 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 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 and shell integrity immediately prior to each use. This can be
accomplished by gently manipulating the device with gloved hand and fingers, while carefully examining
for leakage sites. It is important to continuously monitor the structural integrity of the device throughout the
procedure to ensure 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. Therefore the use of forceps or hemostats is specifically contraindicated as shell damage may lead to rupture of the Gel Sizer.

**Reprocessing Instructions**

**Warnings**

*Follow instructions and warnings as issued by the manufacturer’s 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 resterilized more than ten (10) times.

**From Point of 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 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. (see note below)

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 (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.

*Note: Water (type and temperature) used in the preparation of cleaning solutions should be in accordance with the manufacturer’s recommendations. Warm (37-43°C) tap water has been demonstrated effective when used according to procedures stated above.*
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, wrap the Gel Sizer in a suitable material intended for autoclave use (e.g., pack, sterilization wrapper, bag, or accessories). Packaging systems should be permeable to allow steam penetration and direct contact with the device; 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 available, and autoclave with one of the following gravity displacement methods in accordance with ANSI/AAMI ST8, “Hospital Steam Sterilizers,” and ANSI/AAMI ST79, “Comprehensive Guide to Steam Sterilization and Sterility Assurance in Health Care Facilities.”

- Displacement Cycle: 30 minutes at 250° (121°C) and 15 psi. Minimum dry time is 45 minutes.
- Optional Gravity-Displacement 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 resterilization. **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, 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 Center 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 resterilized up to ten (10) times after the first use for a total of eleven (11) uses, after which discard the 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.

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 the Product Evaluation Department at Mentor, 3041 Skyway Circle North, Irving, Texas.

Note: Returned used devices must be decontaminated and sterilized, and be accompanied with the relevant documented evidence.

RETURNED GOODS AUTHORIZATION
Authorization for the 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 AND OTHER INQUIRIES

US 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, or via our website, www.mentorwwllc.com or www.mentordirect.com.

- Nominal Dimensions
- Sterilized using steam or dry heat
- Quantity
- Sterile and Non-Pyrogenic
- Latex free
- Catalogue number
- Not returnable if opened
- Use by
- Serial number
- Batch code
- Date of manufacture
- CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.
- Attention, see instructions for use
- For customer service or to return product, please call (800) 235-5731 in USA.
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