



13157-00

Product Insert Data Sheet

ENGLISH

MENTOR STERILE RESTERILIZABLE GEL BREAST IMPLANT SIZER

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13157-00

DESCRIPTION

The Mentor Sterile 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. It can be used as a "single use" Gel Sizer or resterilized for multiple uses.

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. Prior to reuse, the Gel Sizer must be thoroughly cleaned, disinfected and sterilized. The Gel Sizer should not be re-sterilized more than ten (10) times.**

INDICATIONS

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.

CONTRAINDICATIONS

The Gel Sizer is not intended as a long term implantable device. The Gel Sizers are specifically labeled "Not for Implant".

PRECAUTIONS

- Mentor recommends that the surgeon consider the size, shape, firmness and profile of the Gel Sizer when choosing the optimum incision size and surgical approach.
- 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 shell may easily be cut by scalpel or ruptured by excessive stress, manipulation with blunt instruments or penetration by a needle. The Gel Sizer should be carefully inspected for structural integrity prior to and during surgery.
- 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. Stand by Gel Sizers of different sizes should be available at the time of surgery.
- The Gel Sizer may be ruptured while still hot from the autoclave. Care must be used during handling to avoid damage.
- After autoclaving, air bubbles might appear in the gel. These bubbles do not affect the integrity or purpose of the Gel Sizer.
- Use aseptic technique to handle the Gel Sizer following the sterilization. Leave the sterile unit covered until insertion, to avoid air-borne contaminants which may collect on the surface.
- The Gel Sizer can be resterilized up to ten (10) times.
- After the Gel Sizer has been sterilized ten (10) times, discard device.
- Sterility, safety and efficacy cannot be assured for damaged devices.

WARNINGS

- Pre-clean the Gel Sizer under running cold tap water **immediately** after each surgical use.
- The Gel Sizer should not be sterilized more than ten (10) times.
- Do not use an ethylene oxide (EtO) sterilization cycle.
- 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.
- **NOTE:** In case there is a suspicion of contamination by prions or viruses, the Gel Sizer should be discarded.

INSTRUCTIONS FOR USE

The application of the Gel Sizer involves a variety of surgical techniques. Prior to using the Gel Sizer, the physician should be familiar with all of the information provided associated with the MemoryGel breast implants to be implanted.

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.

The Gel Sizer is supplied individually in a sterile and non-pyrogenic double-wrap packaging system. The double-wrap system facilitates the preferred method of sterile product transfer from the circulating area to the sterile field. Sterility cannot be guaranteed if the double-wrap packaging system has been damaged. This product has been sterilized by Dry Heat Sterilization.

CLEANING, DISINFECTING AND STERILIZATION OF THE GEL SIZER

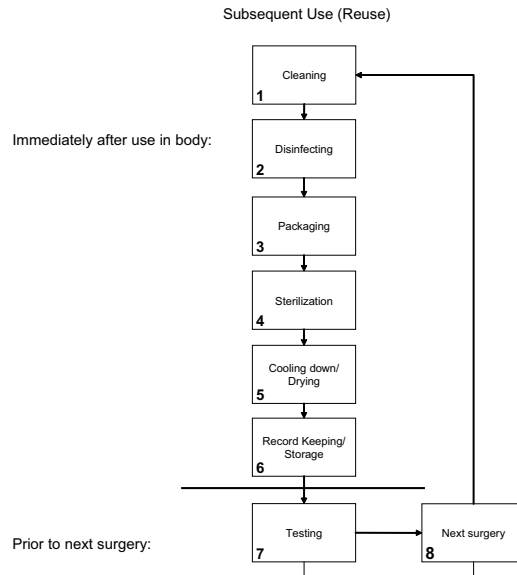
First Time Use of the Gel Sizer

The Gel Sizer is supplied sterile. Therefore, the device does not have to be cleaned, disinfected and sterilized prior to first time use.

Subsequent Use of Gel Sizer (Re-use)

When re-using the Gel Sizer, the device must be cleaned, disinfected and sterilized (autoclave) as indicated by the flow chart below:

NOTE: In the instructions for the manual and automatic cleaning/disinfecting processes, the same numbers as shown in the flow chart are indicated for reference.



(1) CLEANING / (2) DISINFECTING

MANUAL

Cleaning steps:

- Use surgical gloves during all procedures.
- Pre-clean: After removing excess soil, immerse the Gel Sizer into cold tap water for 5 minutes.
- Clean the Sizer under running tap water with a soft brush until all visible residues are removed.
- Clean the device by hand for a minimum of 3 minutes in a solution of water and Neodisher US detergent (or equivalent) for enzymatic cleaning at a temperature between 25°C and 32°C (or 77°F and 90°F).
- Wipe the Gel Sizer with a cloth to remove all residues until it is visibly clean.
- After the cleaning, the Gel Sizer must be soaked in the detergent solution for 10 minutes.
- Rinse the Gel Sizer copiously (at least 3 times) with demineralised water to make sure all detergent is removed.
- Inspect the Gel Sizer thoroughly for cleanliness.
- If necessary, repeat the cleaning process again until the Gel Sizer is visibly clean.

Disinfecting and drying steps:

- After completion of the washing steps, the Gel Sizer must be wiped with alcohol (Iso Propyl Alcohol 70%) for proper disinfection.
- Dry the Gel Sizer using a lint free towel.

AUTOMATIC**Cleaning steps:**

Put the Gel Sizer on a instrument rack (Miele E 327-06, or equivalent) in the washer disinfector machine (Miele 7735 CD, or equivalent) and start the cycle:

- 2 minutes pre-cleaning with cold water
- Draining cycle
- 5 minutes cleaning at 55°C with 0.5% alkaline detergent (Neodisher FA, or equivalent)
- Draining cycle
- 3 minutes neutralizing with warm water (>40°C) and neutralizer (Neodisher Z, or equivalent)
- Draining cycle
- 2 minutes rinsing with warm water (>40°C)
- Draining cycle

Any special instructions of the manufacturer of the automated washing machine have to be followed.

Automated disinfecting and drying steps:

- Apply the automated Thermal Disinfection procedure for the washer/disinfector in regards to applicable regional or national A0 -Value requirements (see ISO15883-1, ISO/TS 15883-5). Dry the Gel Sizer by using the drying cycle of washer/ disinfector machine. If needed, additional manual drying can be performed using lint free towel.
- Visually inspect the Gel Sizer for cleanliness. If necessary, perform the cleaning and disinfecting process again until the Gel Sizer is visibly clean.

(3) PACKAGING:

Double wrap the Gel Sizer in surgical sterilization wrap intended for autoclave use. Note: it is imperative to use sterilization wrap and not a pouch to accommodate the flow of the steam during the sterilization process.

See ISO 11607-1 Annex A. Packaging for terminally sterilized medical devices..

(4) STERILIZATION

Sterilization of the Gel Sizer is performed by applying a fractionated pre-vacuum process (according to ISO-13060/ISO 17665) by considering the respective country requirements.

Place the unit in an open, clean autoclaving tray and autoclave with a validated **Steam Sterilization** method that fits into the following range:

- Parameters for the pre-vacuum cycle: 3 pre-vacuum phases with at least 75 millibar.
- Heat up to a sterilization temperature of a minimum of 134°C and a maximum of 136°C.
- Select a minimum of 3 minutes and a maximum of 40 minutes holding.
- Select a minimum drying time of 10 minutes.

Alternatively one of the following sterilization cycles can be used:

- **Alternate Steam Sterilization** cycles:
 - Standard Cycle: 20 minutes at 121°C (250°F)
 - Optional cycle: 18 minutes at 134°C (273°F)
- **Gravity Displacement Sterilization** cycles:
 - Standard Cycle: 30 minutes at 121°C (250°F) and 15 psi
 - Optional Cycle: 20 minutes at 132°C (270°C) and 30 psi

If the cycle available for the autoclave is not one of the Steam Sterilization or Gravity Displacement Sterilization cycles described above, please contact your autoclave manufacturer to program and validate one of these sterilization cycles.

(5) COOLING DOWN/DRYING:

After autoclaving, allow the device to completely cool prior to use to avoid possible tissue damage from residual heat release. Do not dry the device using a vacuum cycle. Dry the wrapped Gel Sizer after the autoclave cycle is completed by opening the autoclave door to allow excess steam to escape, then close the door and allow the Gel Sizer to remain in the autoclave until the wrapping is entirely dry. Let the Gel Sizer cool down for at least 2 hours before sterilizing it again.

(6) RECORD KEEPING/STORAGE

Record the following information on the Sterilization Record card:

- (i) Date of cleaning and sterilization.
- (ii) Name of the person who performed the sterilization.

NOTE: The device and the card should be kept together to ensure keeping accurate sterilization records

(7) TESTING:

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.

(8) NEXT SURGERY:

Make sure that the Gel Sizer is cleaned and disinfected immediately after use in the body.

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 Medical Systems B.V., Zernikedreef 2, 2333 CL Leiden, The Netherlands, +31-71-5249600.

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



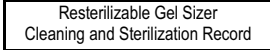
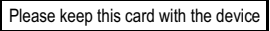



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PRODUCT ORDER INFORMATION**International Customers**

For product information or to order directly, contact your local Mentor representative or the Mentor International Customer Service Department, 201 Mentor Drive, Santa Barbara, CA 93111, USA. Telephone (805) 879-6000; FAX (805) 967-7108.

Mentor Medical Systems B.V.
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DEFINITIONS OF SYMBOLS ON LABELING:

	Quantity One
	Manufacturer
	Title of Sterilization Record Card
	Instruction on Sterilization Record Card to keep card with the device.
	Process to sterilize the Gel Sizer (Steam Sterilization)
	Date Gel Sizer was sterilized
	Name of person conducting the sterilization process