MENTOR®

Product Insert
Data Sheet

ENGLISH

MENTOR® RESTERILIZABLE GEL BREAST IMPLANT SIZER

112023-001 Rev A Effective September 2017
LAB100056987v5

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.

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® or MemoryGel® Xtra 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® or MemoryGel® Xtra 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® and MemoryGel® Xtra Breast Implants to be implanted.

CONTRAINDICATIONS

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

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** regarding the Gel Sizer are intended to supplement the **WARNINGS** listed in the **Product Insert Data Sheet** for the breast implant to be used.

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

DO NOT resterilize the device more than ten (10) times.

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.

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.

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 temporary intraoperative insertion as a breast implant 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.

PRECAUTIONS

Mentor recommends that the surgeon consider the size, shape, firmness and profile of the MemoryGel® or MemoryGel® Xtra 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.

GENERAL ADVERSE EVENTS ASSOCIATED WITH USE OF SIZERS

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 Sizers 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 Sizers 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.

Potential adverse events that may occur with the use of the Sizers during breast implant surgery include: blood borne pathogen transmission/infection, failure of treatment or failure of aesthetic outcome (reoperation). Below is a description of these adverse events.

Blood Borne Pathogen Transmission/Infection
Blood borne pathogens, such as bacteria and viruses, are present in blood and body fluids and can be transmitted between users when improper handling or cleaning of sizers occurs. Signs of acute infection reported in association with breast implants include erythema, tenderness, fluid accumulation, pain, and fever. In rare instances, as with other invasive surgeries, Toxic Shock Syndrome (TSS) has been noted in women after breast implant surgery. It is a life-threatening condition. Symptoms of TSS occur suddenly and include a high fever (102°F, 38.8°C or higher), vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches, and drops in blood pressure, which may cause fainting. Patients should be instructed to contact a doctor immediately for diagnosis and treatment if they have these symptoms.

Failure of Treatment/Failure of Aesthetic Outcome (Reoperation)
Patients should be informed that dissatisfaction with cosmetic results related to such things as incorrect size, scar deformity, hypertrophic scarring, asymmetry, wrinkling, implant displacement/migration, and implant palpability/visibility might occur. Careful surgical planning or technique can minimize, but not preclude, the risk of such results. Pre-existing asymmetry may not be entirely correctable. Revision surgery may be indicated to maintain patient satisfaction but carries additional considerations and risks.

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 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 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 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. (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 (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.

Note: Water (type and temperature) used in the preparation of cleaning solutions should be in accordance with the manufacturer's recommendations. Warm (99-109°F/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°F (121°C) and 15 psi.** Minimum dry time is 45 minutes.
- Optional Gravity-Displacement Cycle: **20 minutes at 270°F (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 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 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, 33 Technology Drive, Irvine, CA 92618. Toll free telephone (800) 235-5731;
FAX (805) 967-7108, or via our website, www.mentorwwllc.com or www.mentordirect.com.

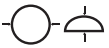
SYMBOLS GLOSSARY

ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied

Title 21 Code of Federal Regulations Parts 801.109

Not made with natural rubber latex

Not returnable if opened



Diameter, Projection

Serial number
ISO 15223-1 Reference 5.1.7

Date of manufacture
ISO 15223-1 Reference 5.1.3

Caution
ISO 15223-1 Reference 5.4.4

See instructions for use
ISO 15223-1 Reference 5.4.3

Sterilized using steam or dry heat
ISO 15223-1 Reference 5.2.5

Non-pyrogenic
ISO 15223-1 Reference 5.6.3

Catalogue number
ISO 15223-1 Reference 5.1.6

Use-by date
ISO 15223-1 Reference 5.1.4

Batch code
ISO 15223-1 Reference 5.1.5

Manufacturer
ISO 15223-1 Reference 5.1.1

CAUTION: Federal (USA) law restricts this device to sale by or on the order of a licensed healthcare practitioner.
Title 21 Code of Federal Regulations Parts 801.109

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Released: 15 Jun 2017
CO: 100544080
Release Level: 7 - Production

MENTOR®

For customer service, please call (800) 235-5731 in USA
www.mentorwwllc.com • www.mentordirect.com

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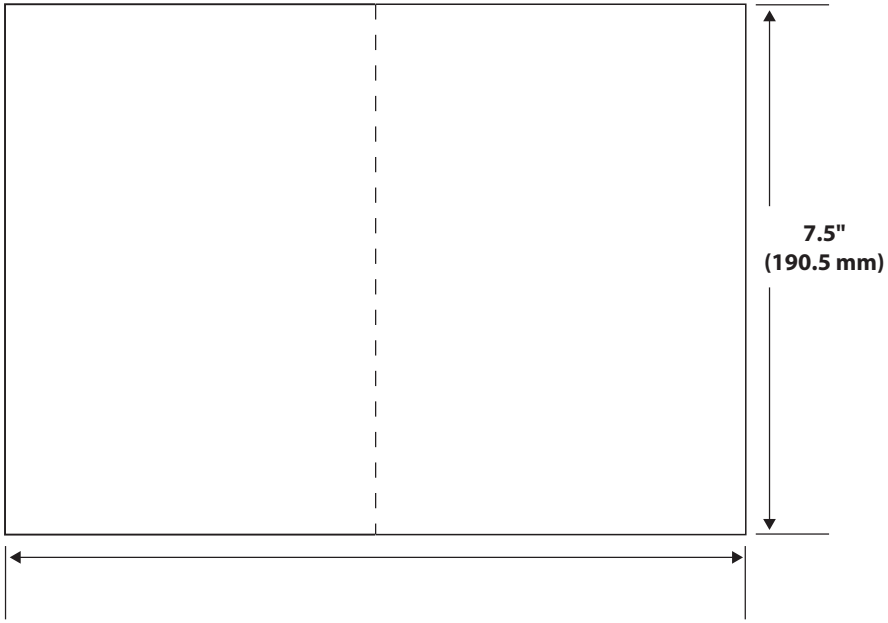
IFU PRINTING SPECIFICATION SHEET

PAGE LAYOUT



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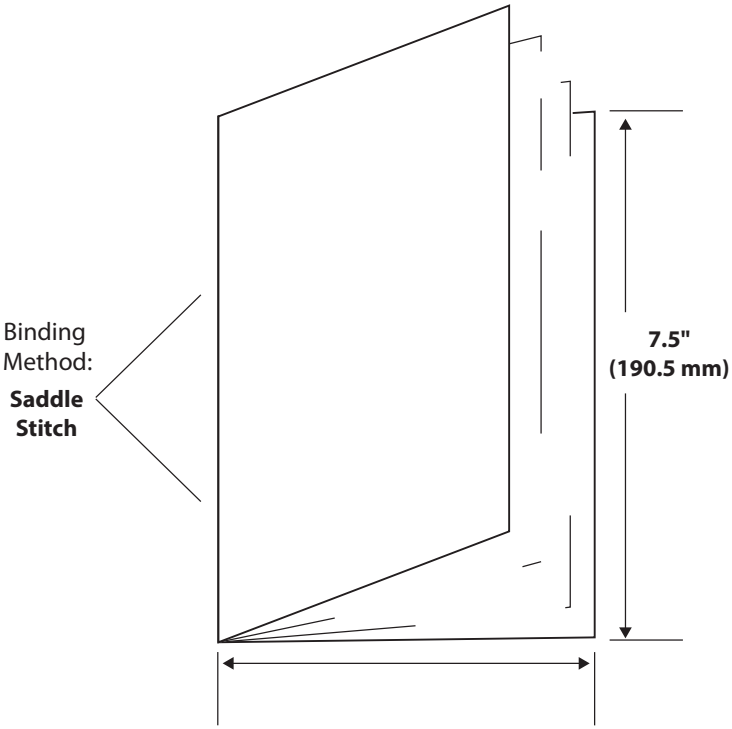
FOLD PATTERN



Folded Size
6.25" (158.75 mm)

TITLE	DESCRIPTION	LAB NUMBER	SPECIAL INSTRUCTIONS/COMMENTS	BINDING	COLORS
Resterilizable Gel Breast Implant Sizer	**Non CE PIDS**	**LAB100056987v5**	**NA**	**Saddle Stitch**	**Black**

FLAT SIZE	FOLDED SIZE	RMC NUMBER	PAGE COUNT	LANGUAGES	SELF COVER	PLUS COVER	SEALING METHOD	WAFER SEAL
12.5"x 7.5" **317.5 mm x 190.5 mm**	**6.25" x 7.5"** **158.75 mm x 190.5 mm**	**112023-001 Rev A**	**80**	**EN**	[X]	☐	**NA**	☐

BLEED SIZE .5" (12.7 mm)	BLEED SIZE .125" (3.175 mm)	NONE	BLEED ALL SIDES	BLEED TOP	BLEED RIGHT	BLEED LEFT	BLEED BOTTOM
☐	[X]	☐	☐	☐	[X]	☐	☐

DRAWING IS NOT TO SCALE: DRAWINGS REFLECT INFORMATION FOR PRODUCTION OF PRINTED PIECES AND DO NOT CONTAIN ACTUAL ARTWORK.

STOCK
50 lb. White Offset

ETHICON