Directions for Use

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NATRELLE®
Re-Sterilizable
Breast Implant
Sizers

ALLERGAN

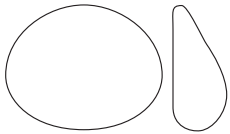
THE SCIENCE OF REJUVENATION™

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed physician.

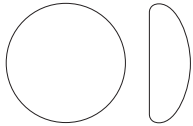
RE-STERILIZABLE BREAST IMPLANT SIZERS

STYLES INCLUDED

***NATRELLE*® 410 RE-STERILIZABLE BREAST IMPLANT SIZER**
***NATRELLE*®** 410 Smooth Silicone Gel-Filled Re-sterilizable Sizer.



***NATRELLE*® ROUND RE-STERILIZABLE BREAST IMPLANT SIZER**
***NATRELLE*®** Smooth Silicone Gel-Filled Re-sterilizable Sizer.



DESCRIPTION
***NATRELLE*®** Re-sterilizable Breast Implant Sizers are designed for temporary intraoperative placement, to assist in determining the desired breast implant volume. They are used during breast augmentation or reconstruction procedures. The ***NATRELLE*®** Round Re-sterilizable Sizers are constructed from a smooth silicone elastomer shell and are filled with responsive gel. The ***NATRELLE*®** 410 Re-sterilizable Breast Implant Sizers are constructed from a smooth silicone shell and are filled with a gel that maintains the shape. The ***NATRELLE*®** 410 and Round Re-sterilizable Sizers have been designed to match the ***NATRELLE*®** Style 410 breast implants and the ***NATRELLE*®** Round Silicone breast implants, respectively.

NOTE: ***NATRELLE*®** Re-sterilizable Breast Implant Sizers are supplied sterile and intended for a maximum of ten additional reuses following cleaning, disinfection and sterilization after each use. They are designed for temporary use and should not be permanently implanted.

SIZER DESIGN FEATURES
- ***NATRELLE*®** Re-sterilizable Sizers are supplied sterile and can be re-sterilized a maximum of ten times.
- ***NATRELLE*®** 410 Re-sterilizable Sizers contain Soft Touch gel and include orientation marks. (see Figure 1)

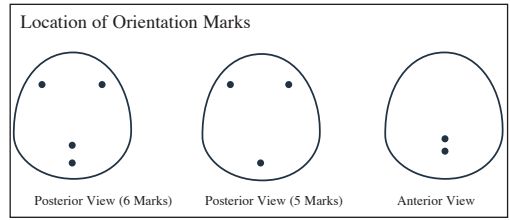


FIGURE 1

INDICATIONS
***NATRELLE*®** Re-sterilizable Round Silicone Breast Implant Sizers are used during breast augmentation or reconstruction procedures to assist the surgeon in determining the appropriate size of a breast implant to use. Prior to using the ***NATRELLE*®** Re-sterilizable Sizer, the physician should be familiar with all of the literature associated with the breast prosthesis to be implanted.

CONTRAINDICATIONS
Refer to the Round Silicone Breast Implant Directions for Use for information on contraindications.

WARNINGS
Re-sterilizable Breast Implant Sizers are intended to be used only by a qualified surgeon. Before proceeding with surgery, the surgeon should inform the patient of the following warnings.

1. **Rupture**
   Patients should be advised that the Sizer may rupture, releasing silicone gel into the surrounding cavity.

   Causes of rupture include:
   - Damage by surgical instruments, such as nicks, slices, or puncture;
   - Other trauma during surgery, such as improper handling or manipulation.

   Do not insert or attempt to repair a damaged sizer.

2. **Infection, Necrosis, Hematoma/Seroma & Pain**
   Infection, necrosis, hematoma/seroma and pain, are complications which may occur following any type of surgery and may require further investigation and treatment.

3. **Gel Diffusion**
   Minute quantities of silicone may diffuse through the elastomer envelope of the Sizer. ***NATRELLE*®** Breast Implant Sizer shells feature a patented barrier coat between two layers of silicone elastomer to minimize gel diffusion.

4. **Alteration**
   DO NOT alter the Re-sterilizable Sizer. Alteration to the original design and fabrication voids all warranties, express or implied.

5. **Temporary Device**
   NATRELLE® Re-sterilizable Sizers are temporary devices, and are not intended to be used as a permanent implant. They should only be used for temporary intra-operative placement, to assist the surgeon in permanent implant size selection.

INSTRUCTIONS FOR USE

SURGICAL PROCEDURE

Allergan relies on the surgeon to know and follow the proper surgical procedures with Silicone Gel-Filled Sizers. The surgeon can use the Sizer to evaluate the correct implant size for each implantation. Planning should include clear delineation of aesthetic goals to ensure mutual understanding between surgeon and patient. The surgeon should observe current and accepted techniques to minimize the risk of adverse, and potentially disfiguring reactions.

NOTE: Additional sizers of various sizes should be available to assist the surgeon in determining the appropriate size.

PRODUCT IDENTIFICATION

Product labels are supplied within the internal product packaging of each ***NATRELLE***® Re-sterilizable Sizer. The product labels provide specific information, which allows product identification. In addition to the product labels, a Sizer Re-sterilization Record Card is also provided with the product for the recording of details of subsequent re-sterilization cycles carried out on the sizer.

REPEAT USE

These products are intended for ten (10) additional uses after initial use and only after adequate cleaning, disinfecting and re-sterilization by validated techniques.

DO NOT reuse Re-sterilizable Sizers more than ten (10) times after initial use.

DO NOT use disinfectant on the Re-sterilizable Sizer.

Please ensure that a record of the reprocessing details of the Sizer is documented to ensure product identification and device traceability.

STERILE PRODUCT

Each Sizer is supplied sterile in a sealed, double package. Sterility of the Sizer is maintained only if the packages, including the package seals, are intact. Avoid prolonged exposure to extreme storage conditions. We recommend that these devices are stored at ambient room temperatures, at atmospheric pressure and in dry conditions away from direct sunlight.

DO NOT use the product if the packages or seals have been damaged.

DO NOT reprocess product under a non-validated procedure.

NEVER, under any circumstances attempt to re-sterilize using ethylene oxide, which is known to cause adverse tissue reaction if not completely removed from the device.

HOW TO OPEN STERILE PRODUCT PACKAGE

Remove the Sizer from its packages in an aseptic environment and using talc-free gloved hands.

DO NOT expose the Sizer to lint, talc, sponge, towel, skin oils or other surface contaminants.

1. Peel open the outer package.
2. Invert the outer package over the sterile field, allowing the sealed inner package to gently fall into the field.
3. Peel open the inner package.
4. Gently retrieve the Sizer.

Prior to use, keep the Sizer covered in the inner package, to prevent contact with airborne and surgical field particulate contaminants.

IMPORTANT: Please ensure that the serial number, lot number, and catalogue number of device are recorded in all patient documentation and in the Sizer Re-sterilization Record to ensure product identification and device traceability. The serial number is located on the outer package label.

PRODUCT EXAMINATION PRIOR TO USE

Prior to use, examine the Re-sterilizable Sizer for any evidence of damage or particulate contamination.

DO NOT use any Re-sterilizable Sizer that may appear to have leaks, nicks or rupture.

DO NOT use damaged or contaminated Re-sterilizable Sizers.

DO NOT use Re-sterilizable Sizers that have been damaged or deformed during previous surgical operations.

SIZER PLACEMENT

Ensure incision is sufficiently large to facilitate insertion and avoid damage to the device. The Sizer can be inserted/removed several times to assist with size selection of the permanent implant.

DO NOT damage the Re-sterilizable Sizer with sharp surgical instruments such as needles and scalpels, blunt instruments such as clamps and forceps, or by overhandling and manipulation during introduction into the surgical pocket.

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

DO NOT use excessive force during placement of the Re-sterilizable Sizer, especially with 410 Soft Touch gel-filled shaped Re-sterilizable Sizers. Silicone gel may be deformed due to over manipulation, resulting in deformation of the anatomical shape.

NOTE: Sizers are for sizing purposes only and are not for permanent implantation.

METHOD FOR REMOVING RUPTURED GEL FROM THE SURGICAL POCKET

In the event of Re-sterilizable Sizer rupture, the following technique is useful for removal of the gel mass. Wearing double talc-free surgical gloves on one hand, use the index finger to penetrate the gel mass.

With the other hand, exert pressure on the breast to facilitate manipulation of the gel mass into the double-glove hand. Once the gel is in hand, pull the outer glove over the gel mass and remove. To remove any residual gel, blot the surgical pocket with gauze sponges. Avoid contact between surgical instruments and the gel. If contact occurs, use isopropyl alcohol to remove the gel from the instruments. Ruptured Sizers must be reported and returned to Allergan. In the event of Re-sterilizable Sizer rupture, contact Allergan's Product Surveillance Department at 1.800.624.4261

INSTRUCTIONS FOR REPROCESSING

Re-sterilizable Sizers are intended for a maximum ten (10) additional uses after initial use following validated procedures for cleaning, disinfecting and re-sterilization. Complete Sizer Sterilization Record Card provided with the device after each re-sterilization process. The name of person performing the re-sterilization and date of re-sterilization should be recorded on the card. Translations of the text on the Sterilization Record Card are provided on the reverse side of the card. The Sizer Sterilization Record Card should accompany the device at all times.

CLEANING AND DISINFECTION

Manual Cleaning

Directly after use, place the device into a basin, cover with purified water (DI, RO, or WFI) and transport to central processing. Hand wash silicone-filled Re-sterilizable Sizer for a minimum of fifteen (15) minutes with an anionic-enzymatic type detergent, equivalent to a 2% Multi-Terge™ solution, which should be discarded after each use. Rinse with warm (between 37°C and 43°C) running deionized water for a minimum of one (1) minute to remove detergent residuals.

Manual Disinfection

After cleaning, disinfect using a glutaraldehyde solution with a working concentration of 2 – 3.4% (i.e. Cidex®, Cidex-Plus®, or equivalent). Immerse the device in the solution for at least 60 minutes. Discard disinfection solution after each use. Rinse in flowing deionized water for at least one (1) minute. Dry with a clean smooth absorbent cloth. Place the disinfected device in a sealed clean container until ready for autoclaving. *Alternatively*, the device may be disinfected using 7% peracetic acid. Immerse the device in this solution for 1-10 minutes. Discard the solution after each use. Rinse in flowing tap water for at least (1) one minute. Dry with a clean smooth absorbent cloth and place the disinfected device in a sealed clean container until ready for autoclaving.

Automated Washer and Disinfector

Alternatively, process the devices in an automated washer-disinfector (Miele Model #G7835) using a cycle program such as the Miele G7835 "Intense Cycle" for cleaning & rinsing:

- Pre-wash with hot tap water at > 55°C for 1 minute
- Wash cycle for 3 minutes at > 85°C using NeoDisher FA or equivalent caustic detergent.
- Neutralize for 1 minute at > 10°C with NeoDisher Z (neutralizer solution)
- Rinse two times with DI water at > 10°C (1 minute and then 2 minutes)
- Rinse one time with DI water at > 80°C for one minute

The devices are to be placed directly on each shelf (a maximum of 4 largest size RSS per shelf). The devices can be cleaned with any basic detergent similar to NeoDisher® FA (at any concentration). Use of this detergent in this automated washer will result in detergent residues below detection limits.

VISUAL INSPECTION

Visually inspect the devices for any signs of gel leakage or tears in the device shell. This can be done without the aid of any magnification equipment. If there are no signs of physical damage, the device may then be wrapped and sterilized as noted below.

STERILIZATION PROCEDURE (INCLUDING PRION PROCESS)

Double wrap Re-sterilizable Sizer in suitable autoclave wrapping material loosely enough to allow for expansion during autoclaving, such as CSR sterilization wrap (e.g. Kimgaurd KC series or DuraBlue®), place in autoclave and process under the following validated autoclave cycle before subsequent re-use:

1. Gravity-Displacement Cycle:

Temperature:	134 +2/-0°C
Time:	Eighteen (18) minutes minimum
Pressure:	30-32 psig
Dry Time:	30 minutes minimum*

2. Pulse Vacuum or Prevacuum Cycle:

Temperature:	134 +2/-0°C
Pulse Vacuums:	4 at a maximum of 75 mBar
Time:	Eighteen (18) minutes minimum
Pressure:	30-32 psig
Dry Time:	30 minutes minimum*

** Dry times vary with load composition (more wrapped goods will increase the drying time) and exhaust efficiency of the sterilizer. The user should verify this time with their specific equipment and loads.*

The Sizer must be destroyed and not re-used after use if the patient is suspected of having Creuzfeld-Jakob Disease (CJD), or a risk factor such as previous treatment with Human Growth Hormone, neurological surgery, or genetic history (familial CJD).

The sterilization cycle above has been demonstrated effective when the Re-sterilizable Sizer mass to autoclave chamber volume ratio does not exceed 7100g/m^3. Examples of mass to autoclave volume are:

Maximum Total Mass of Sizers	Volume of Autoclave Sterilizer
3600g	0.51m^3 (18.0ft^3)
2700g	0.41m^3 (14.5ft^3)
1800g	0.31m^3 (10.9ft^3)

Allow Sizer device to dry in the autoclave until outer wrap is entirely dry. Do not use a vacuum assisted drying cycle. The wrapped device should be placed in a covered container to minimize collection of air-borne contaminants. Allow for complete cooling of Re-sterilizable Sizer after sterilization and before subsequent re-use.

After autoclaving, discolouration of the gel may occur and/or air bubbles might appear in the gel. These changes do not affect the integrity or purpose of the Gel Sizer.

STORAGE

Store the wrapped and autoclaved device in a sealed clean container until ready for use. Re-use the sizer within 30 days after autoclaving.

DISPOSAL OF USED RSS

After the RSS has been sterilized a maximum of 10 times, it must be disposed of. Disposal is the responsibility of the owner, and must be performed according to local, state, and federal regulations.

RETURNED GOODS POLICY

Product returns and exchanges must be authorized through your Allergan representative. For more information, please contact your Allergan representative.

REPORTING COMPLAINTS AND RETURN OF RE-STERILIZABLE SIZERS

Re-sterilizable Sizers associated with a complaint or injury must be reported and returned to Allergan. Please contact Allergan's Product Surveillance Department at 800.624.4261 for return instructions. The Re-sterilizable Sizer if used, must be decontaminated and properly packaged before return.

Preparation of the Device for Decontamination

1. Carefully place the Sizer into an autoclavable bag/pouch with an indicator to indicate completion of the sterilization cycle.
2. Place this pouch containing the Sizer into an outer autoclavable bag/pouch.

Decontamination Instructions

Decontaminate by one of the following gravity displacement autoclave cycles:

1. Minimum of 40 minutes at 270°F, 30 psi (132°C, 2kg/cm^2)
2. Minimum of 70 minutes at 250°F, 15 psi (121°C, 1kg/cm^2).

After decontamination the Re-sterilizable Sizer should be prepared for shipping, by carefully packaging the autoclavable bag/pouch containing the Sizer in such a way to prevent damaging the device during transportation.

Note: Do not use a prevacuum autoclave or orthylene oxide decontamination.

The decontamination instructions provided are to be used only as a guide. The autoclave must be set on the "slow exhaust" or on "liquids" setting. Open the door slowly following decontamination cycle to allow the pressure to equalize.

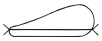
LIMITED WARRANTY, LIMITATION OF LIABILITY, AND DISCLAIMER OF OTHER WARRANTIES

Allergan warrants that reasonable care was used in the manufacture and production of this product. Because Allergan has no control over the conditions of use, patient selection, surgical procedure, post-surgical stresses, or handling of the device after it leaves our possession, Allergan does not warrant either a good effect or against an ill effect following its use. Allergan shall not be responsible for any incidental or consequential loss, damage or expenses directly or indirectly arising from use of this product. Allergan's sole responsibility in the event that Allergan determines the product was defective when shipped by Allergan, shall be replacement of the product. This warranty is in lieu of and excludes all other warranties not expressly set forth herein, whether express or implied by operation of law, or otherwise, including, but nor limited to, any implied warranties of merchantability or fitness of use.

PRODUCT ORDERING

To order directly or for product information, please contact your local Allergan representative or the Allergan Customer Care Department at 1.800.766.0171.

GRAPHICAL SYMBOLS

STYLE	DEVICE STYLE
L	CHECK FOR LEFT BREAST USE
R	CHECK FOR RIGHT BREAST USE
SN	SERIAL NUMBER
QTY	QUANTITY INCLUDED
LOT	LOT NUMBER
REF	CATALOGUE NUMBER
STERILE YYYY-XX	STERILE, DRY HEAT STERILIZED, DATE OF STERILIZATION, YEAR & MONTH
YYYY-XX	USE BY, YEAR & MONTH
	ATTENTION, SEE INSTRUCTIONS FOR USE
	ROUND DIAMETER OF SIZER
	ROUND SIZER PROJECTION
	ANATOMICAL SIZER HEIGHT
	ANATOMICAL SIZER WIDTH
	ANATOMICAL SIZER PROJECTION
	MANUFACTURER
	DO NOT USE IF PACKAGE IS DAMAGED

THE SCIENCE OF REJUVENATION™

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