DIRECTIONS FOR USE

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# *NATRELLE* INSPIRA®
# Single Use Sizers

Allergan™

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

# *NATRELLE* INSPIRA® Single Use Sizers

## DEVICE DESCRIPTION

*NATRELLE* INSPIRA® Single Use 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.

*NATRELLE* INSPIRA® Single Use Sizers are constructed of a smooth silicone elastomer shell and are filled with responsive gel that contains the colorant cobalt aluminate blue spinel at a concentration of 0.01%. They have been designed to match the dimensions of the *NATRELLE* INSPIRA® breast implants.

*NATRELLE* INSPIRA® Single Use Sizers are supplied sterile and are for single patient use, one sizer per breast.

## INTENDED USE AND INDICATIONS FOR USE

*NATRELLE* INSPIRA® Single Use Sizers are used during breast augmentation or reconstruction procedures to assist the surgeon in determining the appropriate size breast implant.

## CONTRAINDICATIONS

*NATRELLE* INSPIRA® Single Use Sizers should not be used in women contraindicated for breast implant surgery, which includes:

- Women with active infection anywhere in their body
- Women with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions
- Women who are currently pregnant or nursing

## WARNINGS

*NATRELLE* INSPIRA® Single Use 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 during surgery.

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

**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* INSPIRA® Single Use Sizer shells feature a patented barrier coat between two layers of silicone elastomer to minimize gel diffusion during surgery.

**4. Alteration**
Do not alter the sizer. Alteration to the original design and fabrication voids all warranties, express or implied.

Do not insert or attempt to repair a damaged sizer.

**5. Temporary Device**
*NATRELLE* INSPIRA® Single Use 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.

**6. Single Use Device**
*NATRELLE* INSPIRA® Single Use Sizers are single patient use only. Do not resterilize or reuse.

## INSTRUCTIONS FOR USE

**SURGICAL PROCEDURE**
Allergan relies on the surgeon to know and follow the proper surgical procedures with *NATRELLE* INSPIRA® Single Use Sizers, including use of proper aseptic techniques.

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* INSPIRA® Single Use Sizer. The product labels provide specific information to identify the product including, catalog number, lot number, serial number and unique device identifier (UDI).

**REPEAT USE**

*NATRELLE* INSPIRA® Single Use Sizers are single patient use, one sizer per breast, only. Do not resterilize or reuse.

**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 thermoform packages or seals have been damaged.

DO NOT resterilize the product.

Avoid unnecessary exposure of the breast implant to lint, talc, sponges, towels, skin oils, and other contaminants.

Prior to use, keep the breast implant in the inner thermoform and covered to prevent contact with airborne and surgical field particulate contaminants

**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 the device are recorded in all patient documentation to ensure product identification and device traceability. The serial number is located on the outer package label, inner package label and patient chart labels.

**PRODUCT EXAMINATION PRIOR TO USE**

Prior to use, examine the product for any evidence of damage or particulate contamination.

DO NOT use any sizer that may appear to have leaks, nicks or be ruptured.

DO NOT use damaged or contaminated sizers.

**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 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 sizer. Silicone gel may be deformed due to over manipulation, resulting in deformation of the sizer shape.

**METHOD FOR REMOVING RUPTURED GEL FROM THE SURGICAL POCKET**

In the event of rupture to the sizer, 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 sizer rupture, contact Allergan's Product Surveillance Department at 1.800.624.4261.

**PRODUCT DISPOSAL**

Unless product is damaged, the sizer should disposed of according to local requirements for medical waste. Damaged product should be returned to Allergan; contact Allergan's Product Surveillance Department at 1.800.624.4261.

**RETURNED GOODS POLICY**

Product returns should be handled through your Hospital or Surgical Sales Representative or the Allergan Aesthetics Customer Care Department at 1.800.766.0171. Return value is based on time limitations. All package seals must be intact to be eligible for return. Returned products may be subject to a restocking charge.

**PRODUCT ORDERING**

To order directly in the U.S.A. or for product information, please contact your local Allergan Aesthetics Hospital or Surgical Sales Representative or the Allergan Aesthetics Customer Care Department at 1.800.766.0171.

**REPORTING PROBLEMS**

The U.S. Food and Drug Administration (FDA) requires healthcare providers to report serious injuries involving medical devices (defined as those that need medical or surgical intervention to prevent permanent damage) to the manufacturer and/or to FDA. In addition, injuries or complications can be voluntarily reported directly by the patient to FDA's MedWatch program.

If you have a patient who has experienced one or more serious problems related to the *NATRELLE* INSPIRA® Single Use Sizers, you are encouraged to report the serious problem(s) to the FDA through the MedWatch voluntary reporting system for her. Examples of serious problems include disability, hospitalization, harm to offspring, and medical or surgical intervention to prevent lasting damage.

You are also required to report any product problem or serious adverse event to Allergan. Deaths must be reported to Allergan and FDA. You can report by telephone to 1-800-FDA-1088; by FAX, use Form 3500 to 1-800-FDA-0178; electronically at https://www.accessdata.fda.gov/scripts/medwatch/index.cfm; or by mail to MedWatch Food and Drug Administration, 5600 Fishers Lane Rockville, MD 20852-9787. Keep a copy of the completed MedWatch form for your records. This information reported to MedWatch is entered into databases to be used to follow safety trends (patterns) of a device and to determine whether further follow-up of any potential safety issues related to the device is needed.

## GRAPHICAL SYMBOLS

The following symbols appear in the package labels for *NATRELLE* INSPIRA® Single Use Sizers.

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|  | Prior to using this device refer to the Directions for Use (DFU) Document at www.allerganlabeling.com or request a copy by calling 1-888-474-5665 |
|   | Dry Heat Sterilized |
|  | For Single Use Only |
|  | Expiration Date (YYYY-MM-DD) |
|   | Lot |
|   | Catalog Number |
|   | Serial Number |
|   | Not Made With Natural Rubber Latex |

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