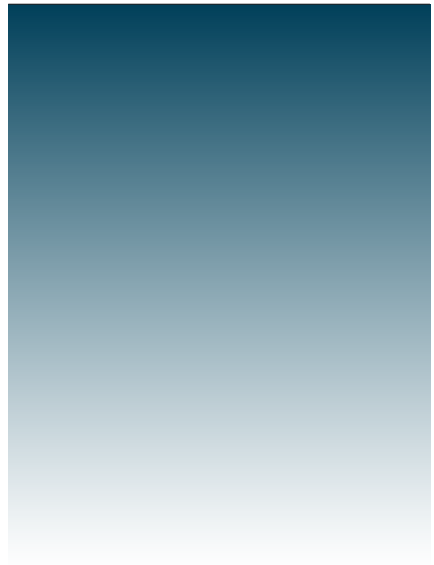
Directions for Use

NATRELLE™ Silicone-Filled Breast Implant Sizer



ALLERGAN

THE SCIENCE OF REJUVENATION™

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

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Device Description

The NATRELLE™ silicone filled breast implant sizers are designed to provide a volumetric tool to assist with final implant size and shape selection. Filled with lightly pigmented silicone gel to avoid confusion with the actual breast implant, the NATRELLE™ silicone sizer has a white patch which is permanently marked with the sizer volume. Each sizer ships STERILE and is designed for single patient use only.

Indications

- The NATRELLE™ silicone sizer is indicated for single use only for temporary intra-operative insertion in the surgical pocket to evaluate and assist in determining the final breast implant size.

Prior to using the NATRELLE™ silicone sizer, the physician should be familiar with all of the literature associated with the breast prosthesis to be implanted. This NATRELLE™ silicone sizer should be used in conjunction with the surgeons judgment and expertise to best determine the volume only and not necessarily the shape of the prosthesis to be implanted.

Contraindications

- Use as a Long-term Breast Implant
- Multiple Patient Use
- Multiple Sterilizations

Information that Should be Provided to the Patient

Allergan relies on the surgeon to advise the patient and/or the patient's representative of all warnings, precautions, and potential adverse reactions associated with the use of this device as well as the surgical procedure(s). The surgeon is responsible for selecting appropriate candidates for the use of this device.

The patient should be advised prior to surgery of the benefits and possible risks associated with elective tissue reconstruction and/or breast augmentation using breast implants, sizers and alternative procedures.

The following **warnings, precautions and adverse reactions** apply only to the use of this NATRELLE™ silicone breast implant sizer.

Warnings

1. Temporary Implantation Only

The NATRELLE™ silicone sizer MUST NOT be used as a long-term breast implant. This device is designed for temporary intra-operative insertion as a breast implant sizer only.

2. Reuse

DO NOT reuse explanted product. Biological contaminants may be difficult to remove from sizer surface and could be transferred from patient to patient. Breast implant sizers are intended for temporary intra-operative sizing use only.

3. Alteration

DO NOT alter the NATRELLE™ silicone sizer. Alteration to the original design or fabrication voids all warranties, express or implied.

4. Damage

DO NOT insert or attempt to repair a damaged sizer.

Precautions

The following **precautions** apply to the use of this NATRELLE™ silicone sizer only.

1. Surgical Planning

Allergan relies on the surgeon to know and follow proper surgical procedures specific to the type of procedure performed to minimize the occurrence of adverse reactions. The surgeon must carefully evaluate patient suitability.

2. Avoiding Contamination at Surgery

To avoid contamination, aseptic technique is essential. DO NOT expose the NATRELLE™ silicone sizer to surgical glove powder, lint, dust, talc, drape and sponge lint, fingerprints, skin oils and other surface contaminants. Contamination at the time of surgery 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 NATRELLE™ silicone sizer.

3. Avoiding Damage During Surgery

Care should be taken to avoid damaging the NATRELLE™ silicone sizer with sharp instruments during surgery. Such contact may result in sizer rupture. Each device should be continuously monitored throughout the procedure to ensure the structural integrity of the device is not compromised in any way.

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

Sterile back-up NATRELLE™ silicone sizers of various sizes should be readily available at the time of surgery in the event that damage occurs. Products must be carefully inspected for damage prior to use. DO NOT attempt to repair damaged products.

4. Single-Use Only

The NATRELLE™ silicone sizer is designed for single patient use only. Biological contaminants may be difficult to remove from the sizer surface and could be transferred from patient to patient. Stresses from multiple sterilizations, surgeries and surgical technique will likely cause abrasion of the shell and eventual rupture of the device.

5. Sizing

Any surgeon performing augmentation or reconstructive mammaplasty with implants should be familiar with the currently available techniques for measuring the patient, determining the implant size and performing surgery (See INSTRUCTIONS FOR USE section of this insert.)

Sterile back-up NATRELLE™ silicone sizers of various sizes should be readily available at the time of surgery in the event of a different size is desired.

Adverse Reactions & Complications

The NATRELLE™ silicone sizer is not intended as an implantable device. Prior to surgery, the surgeon should be familiar with all information provided by the manufacturer of the breast implant to be used. The following ADVERSE REACTIONS apply to the use of this temporary NATRELLE™ silicone sizer only.

Adverse reactions which may result from the use of this silicone sizer 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. Adverse reactions and/or complications may include, but are not limited to the following:

1. Sepsis, Hemorrhage or Thrombosis

Sepsis, hemorrhage or thrombosis may result from the placement of any foreign object in the body.

2. Bleeding

Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist it is recommended that the sizer not be used until bleeding is controlled.

3. Infection

Infection is a possible serious complication which could be associated with use of this device and is most frequently caused by skin contaminants. Aseptic technique during surgery is essential.

How Supplied

The NATRELLE™ silicone sizer is supplied sterile, and must not be resterilized.

Instructions for Use

Prior to using the NATRELLE™ silicone sizer, the physician should also become familiar with all the literature associated with, and provided by the manufacturer of the breast implant to be implanted.

Sizer Selection

- The base diameter of the NATRELLE™ silicone sizer should not be too small or too large in comparison to the patient's chest wall dimensions.
- Available tissue must provide adequate coverage of the silicone sizer.
- A well-defined, dry pocket of adequate size and symmetry must be created to provide a smooth surface that allows the silicone sizer to be placed flat.

Note: It is recommended that more than one size NATRELLE™ silicone sizer be available in the operating room at the time of surgery to allow the surgeon flexibility in determining the appropriate size implant to be used.

Caution: The use of forceps or hemostats is specifically contraindicated as silicone sizer shell damage may lead to rupture.

How to Open Sterile Product Package

Each NATRELLE™ sterile silicone filled breast implant sizer is supplied in a sealed, double primary package. Sterility of the implant is maintained only if the thermoform package, including the package seal, is intact.

DO NOT use the product if the thermoform package or seal has been damaged.

DO NOT resterilize any product.

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

How to Open Sterile Product Package

Remove the sterile silicone filled breast implant sizer from its package in an aseptic environment and using talc-free gloved hands.

DO NOT expose the breast implant to lint, talc, sponge, towel, and other contaminants.

1. Carefully peel open the lid of the outer thermoform package.

2. Invert the outer thermoform package over the sterile field, allowing the sealed inner thermoform package to gently fall into the field.

3. Peel open the lid of the inner thermoform package using the pull tab.

4. Gently retrieve the silicone sizer.

Method for Removing Ruptured Silicone From the Surgical Pocket

In the event of silicone sizer rupture, the following technique is useful for removal of the silicone mass. Wearing double talc-free surgical gloves on one hand, use the index finger to penetrate the silicone mass. With the other hand, exert pressure on the breast to facilitate manipulation of the silicone mass into the double-gloved hand. Once the silicone is in hand, pull the outer glove over the silicone mass and remove. To remove any residual silicone, blot the surgical pocket with gauze sponges. Avoid contact between surgical instruments and the silicone. If contact occurs, use isopropyl alcohol to remove the silicone from the instruments. Ruptured silicone sizers must be reported and should be returned to Allergan. In the event of silicone sizer rupture, contact Allergan's Product Support Department at 800.624.4261.

Sterile Product

The NATRELLE™ silicone sizer is supplied individually **sterile**, and may not be resterilized.

Returned Goods Policy

Product returns should be handled through an Allergan Sales Representative or through the Customer Care Department at 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. Certain products are non-returnable, including ZYDERM® dermal filler and ZYPLAST® dermal filler.

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. 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 not limited to, any implied warranties of merchantability or fitness for use.

Product Ordering

To order directly in the U.S.A or for product information, please contact your local Allergan Sales Representative or the Allergan's Customer Care Department at 800.766.0171.

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