Directions for Use

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Sterile Intraoperative Sizer

FOR NATRELLE® SALINE-FILLED BREAST IMPLANTS

Distributed by

ALLERGAN

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

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Device Description

The Allergan Saline Sizer is constructed of restricted grade medical silicone elastomer. The device consists of a shell and silicone tubing used for filling the sizer. The Allergan Sizer is supplied with an integral fill tube with a Luer adapter, and a tubing clamp to facilitate filling. Each saline breast implant sizer is provided sterile and is intended for single use.

Indications

- The Allergan Saline 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 volume.

Prior to using the Allergan Saline Sizer, the physician should be familiar with all of the literature associated with the breast prosthesis to be implanted. This Allergan Saline 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
- Use as a Tissue Expander
- Multiple Use
- Multiple Sterlizations

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 Allergan Saline Sizer.

Warnings

1. Temporary Implantation Only

The Allergan Saline Sizer MUST NOT be used as a long-term breast implant or tissue expander. This device is designed for temporary intra-operative insertion as a breast implant sizer only. DO NOT place this device in patient for more than 1 hour.

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 single temporary intra-operative sizing use only.

3. Alteration

DO NOT alter the Allergan Saline 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.

5. Fill

DO NOT fill device to a volume less than or greater than specified (see product label). Underfilling the device could result in buckling, folding or wrinkling, causing sizing errors. Overfilling the device may also cause implant sizing errors or shell rupture.

Precautions

The following **precautions** apply to the use of this Allergan Saline 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 Allergan Saline 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 Allergan Saline Sizer.

3. Avoiding Damage During Surgery

Care should be taken to avoid damaging the Allergan Saline Sizer with sharp instruments during surgery. Such contact may result in sizer deflation. Each device 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.

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

Sterile back-up Allergan Saline 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 leaks or nicks prior to use. DO NOT attempt to repair damaged products.

Avoid too small an incision. A larger incision than is normally used for a permanent mammary prosthesis and/or some form of lubrication may be required to facilitate insertion and to avoid damage to the sizer. Allergan recommends the surgeon consider the size, shape, firmness and profile of the breast implant to be implanted when choosing optimum incision size and surgical approach.

4. Single-Use Only

The Allergan Saline Sizer is designed for single 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/or fill tube and eventual leakage and/or 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 Allergan Saline Sizers of various sizes should be readily available at the time of surgery in the event of a different size is desired.

6. Fill Tube

Extreme care should be taken when handling the fill tube. The tube is easily damaged with surgical instruments (e.g., forceps contact), and their use should be avoided. Kinking of the fill tube or separation of the components may result in the failure of the sizer to inflate.

Adverse Reactions & Complications

The Allergan Saline 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 mammary prosthesis to be used. The following **adverse reactions** apply to the use of this temporary Allergan Saline Sizer only.

Adverse reactions which may result from the use of this Allergan Saline 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 Allergan Saline Sizer is supplied **sterile**, and must not be resterilized.

Instructions for Use

Prior to using the Allergan Saline Sizer, the physician should also become familiar with all the literature associated with, and provided by the manufacturer of the mammary prosthesis to be implanted.

The 12" fill tubing provided is of sufficient length to facilitate application in any of the three primary types of incisions: inframmary, periareolar, or transaxiliary. Allergan has not tested its Sizers for implantation by endoscopic insertion of umbilical approach. These methods of insertion cannot be recommended by Allergan.

Sizer Selection

- The base diameter of the Saline 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 Saline Sizer.
- A well-defined, dry pocket of adequate size and symmetry must be created to provide a smooth surface that allows the Saline Sizer to be placed flat.

Note: It is recommended that more than one size Saline 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.

Testing the Sizer

The Sizer should be tested for patency and shell integrity immediately prior to use. This can be accomplished by the following steps:

1. Partially inflate the Sizer with air through the fill tube, taking care not to damage the tube.
2. Occlude fill tube with tubing clamp.
3. Submerge the air-filled Sizer in sterile, pyrogen-free testing fluid (water or saline).
4. Apply mild pressure and check for possible punctures or leakage.

Filling Procedure

Deflation and Insertion of Sizer

Prior to inserting the Allergan Sizer into the surgically prepared pocket, remove luer lock plug from tubing luer connector, be sure tubing clamp is in the unclamped position and deflate the device completely. Attach an empty, sterile syringe to the Luer-lock adapter attached to the end of the fill tube and draw out as much air as possible. Fold the Sizer and insert it into the pocket (some surgeons prefer to partially fill the device prior to placement).

Filling the Sizer

Use a new sterile and packaged syringe filled with pyrogen-free, sterile, Sodium Chloride U.S.P. Solution for Injection to fill the Sizer to the recommended volume (see specifications noted on product label).

Only sterile, pyrogen-free Sodium Chloride U.S.P. Solution for Injection drawn from its original container should be used. Because bacterial infections may result from contaminated saline and syringes; it is recommended that a new sterile saline container and sterile syringe be used with each surgery and Sizer use.

The Sizer should not be filled to a volume less than or greater than specified (see product label) as this could cause discrepancies in implant volume sizing. Underfilled devices may buckle, fold or wrinkle causing sizing errors. Additionally, inflation beyond the maximum recommended volume may also cause implant sizing errors or shell rupture.

If excessive resistance to filling is encountered prior to reaching the minimum indicated fill volume, discontinue filling to prevent possible tissue damage. Drain the saline solution by removing the syringe and completely deflate the Sizer and remove from mammary pocket. Repeat the filling procedure using a smaller Sizer.

Note: Should adjustment of volume become necessary, use the filling syringe to withdraw or add fluid as needed.

Caution: The use of forceps or hemostats is specifically contraindicated as fill-tube or Sizer shell damage may lead to deflation of the Sizer.

Deflation and Removal

When the correct desired prosthesis size is determined, drain the Sizer by removing the syringe and tubing clamp. Completely deflate the Sizer and remove from mammary pocket.

Sterile Product

The Allergan Sizer is supplied individually sterile, with an integral fill tube, attached Luer adapter and tubing clamp and may not be resterilized.

Returned Goods Policy

Product returns should be handled through an Allergan Breast Aesthetics Business Development Manager or through the Allergan 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.

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 Breast Aesthetics Business Development Manager or the Allergan Customer Care Department at 800.766.0171.

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SYMBOLOGY

SBIS = Sterile Breast Implant Sizer

LP = For McGhan Style 68 Low Profile

HP = For McGhan Style 68 High Profile

MP = For McGhan Style 68/168 Moderate Profile

SP = For McGhan Style 468 Shaped Profile

LOT = Manufacturing Lot Number

REF = Catalog Number

= Do Not Resterilize – Single Use Only

STERILE R = Sterilized by Irradiation


= Not Returnable if Opened


= Use by:


= Do Not Reuse


= Attention: See Instructions For Use

QTY = Quantity Enclosed

VOL = Recommended Volume


= Product not designed for long-term implantation.


= SSP cannot be responsible for the transfer of biological contaminants in the event of reuse.

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