Instructions for Use

Sterile Intraoperative Sizer

For Sientra OPUS™ Round and Shaped Breast Implants

sientra®

OPUS™

PRODUCT ORDERING

To order or for product information, please contact Sientra's Customer Experience Team at (888) 708-0808.

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

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SIENTRA ROUND AND SHAPED BREAST IMPLANT SIZERS

DESCRIPTION

Sientra Round and Shaped Breast Implant Sizers are designed to be used during plastic and reconstructive surgery when it is desirable to determine the correct volume and/or symmetry of breast implants prior to implantation.

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

The Sizers are available in a range of sizes.

Sizers should be used to assist in determining only the volume, not shape, of the breast implant to be implanted.

INDICATIONS

This Sizer is only indicated for **single use for temporary insertion** intraoperatively to evaluate the volume of the breast implant to be implanted.

Prior to using the Sizer, the physician should be familiar with all of the literature associated with the breast implant to be implanted. This sizer should be used in conjunction with the surgeon's judgement and expertise to best determine the volume only and not the shape of the breast implant to be implanted.

INFORMATION THAT SHOULD BE PROVIDED TO THE PATIENT

Sientra 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.

CONTRAINDICATIONS

- Do not use as a Long-term or Permanent Breast Implant
- Do not use as a Tissue Expander
- Do not re-use the Sizer
- Do not re-sterilize

WARNINGS

It is the responsibility of the surgeon to advise prospective patients or their representatives, prior to surgery, of the possible complications associated with the use of this product.

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 permanently implanted. The following **WARNINGS, PRECAUTIONS AND ADVERSE REACTIONS** apply to the use of this Sizer only.

1. **Temporary Implantation Only**
   The Sizer MUST NOT be used as a long-term breast implant or tissue expander. This device is designed for temporary intraoperative insertion as a sizer only. DO NOT place this device in the patient for more than one (1) hour.

2. **Reuse**
   DO NOT reuse product. Biological contaminants may be difficult to remove from sizer surface and could be transferred from patient to patient. Sizers are intended for single temporary intraoperative sizing use only.

3. **Alteration**
   DO NOT alter the Sizer. Alteration to the original design or fabrication voids all warranties, express or implied.

4. **Damage**
   DO NOT insert into a patient or attempt to repair a damaged Sizer.

5. **Fill**
   DO NOT fill device to a volume less than or greater than specified on the 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 Sizer only.

1. **Surgical Planning**
   Sientra 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 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 Sizer.

3. **Avoiding Damage During Surgery**
   Care should be taken to avoid damaging the 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 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.

It is recommended 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 Sizer is designed for single use only. Biological contaminants may be difficult to remove from 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 Sizers of various sizes should be readily available at the time of surgery in the event 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 AND COMPLICATIONS

This Sizer is **not intended as an implantable device.** Prior to surgery, the surgeon should refer to the information provided with the breast implant to be used. The following **ADVERSE REACTIONS** apply to the use of this temporary Sizer only.

Adverse reactions which may result from the use of this 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

Sientra Round and Shaped Breast Implant Sizers are supplied **sterile,** and must not be resterilized.

INSTRUCTIONS FOR USE

Prior to using this Sizer, the physician should also become familiar with all the literature associated with the breast implant to be implanted.

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

The following procedures are recommended for the Sizer.

Sizer Selection

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

  NOTE: It is recommended that more than one size 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 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 specified on the 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 on the 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 implant size is determined, drain the Sizer by removing the syringe and tubing clamp. Completely deflate the Sizer and remove from mammary pocket.

STERILIZATION

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

DEVICE RETURNS AND REPORTING

Devices associated with a product complaint must be returned to Sientra and the reason for the return must be provided. These devices must be returned in a Sientra Explant Return Kit. Please contact the Sientra Customer Experience Team at (888) 708-0808 for a Sientra Explant Return Kit and instructions.

RETURNED MERCHANDISE POLICY

Product returns should be processed through a Sientra Plastic Surgery Consultant or through the Sientra Customer Experience Team at (888) 708-0808. All package seals must be intact to be eligible for return.

LIMITED WARRANTY, LIMITATION OF LIABILITY AND DISCLAIMER OF OTHER WARRANTIES

Specialty Surgical Products, Inc. "SSP" warrants that reasonable care was used in the manufacture and production of this product. Because Sientra and SSP have no control over the conditions of use, patient selection, surgical procedure, post-surgical stresses, or handling of the device after it leaves our possession, Sientra and SSP do not warrant either a good effect or against an ill effect following its use. Sientra and SSP 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.

SYMBOLOGY

 = Manufacturer

SN = Manufacturing Lot - Serial Number

REF = Catalog Number

 = Do not resterilize—Single Use Only

STERILE R = Sterilized by Irradiation

 = Not Returnable if Opened

 = Use by: YYYY-MM-DD

 = Do Not Reuse

 = Attention: See Instructions For Use

QTY = Quantity Enclosed

VOL = Recommended Volume

 = Product not designed for long-term implantation.

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

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

 = Do not use if package is damaged

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