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Instructions for use

SIENTRA SILICONE GEL BREAST IMPLANT SIZER

sientra®

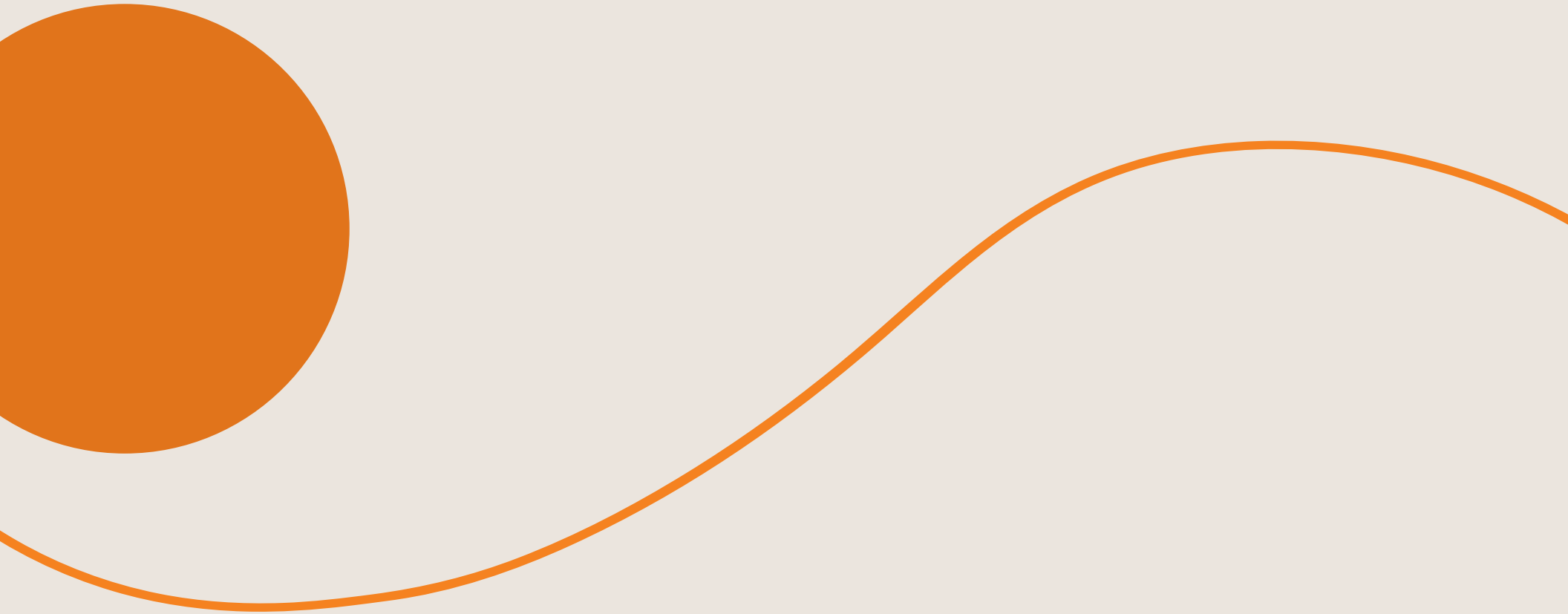

TABLE OF CONTENTS

DEVICE DESCRIPTION 5

INDICATIONS FOR USE 6

CONTRAINDICATIONS 6

WARNINGS 6

PRECAUTIONS 7

ADVERSE REACTIONS AND COMPLICATIONS 7

HOW SUPPLIED 8

INSTRUCTION FOR USE 8

- Sizer Selection 9
- How to Open Sterile Product Package 9
- Method for Removing Ruptured Silicone from the Surgical Pocket 9

STERILE PRODUCT 10

RETURNED GOODS POLICY 10

LIMITED WARRANTY 10

PRODUCT ORDERING 11

DEVICE DESCRIPTION

The Sientra® Silicone Gel Breast Implant Sizer ("Gel Sizer") is a single-use sizing device designed for temporary intraoperative placement to assist the surgeon in determining the appropriate breast implant volume and shape during breast augmentation or reconstruction procedures prior to final selection and implantation of a Sientra Silicone Gel Breast Implant ("Breast Implant"). The Sientra Gel Sizer is designed to match the portfolio of Sientra Breast Implants and is therefore available in the same range of diameters, projections and volumes as Sientra Breast Implants.

The Sientra Gel Sizer is a single-use device and is composed of a silicone elastomer shell, which is thin and soft, and a filler made of clear high-strength cohesive (HSC) silicone gel. The silicone elastomer used in the Sientra Gel Sizer shell is composed of a compound of dimethyl polysiloxane and a dimethyl fluoro silicone copolymer, catalyzed by a platinum compound. The Sientra Gel Sizer is sterilized by dry heat sterilization. The Sientra Gel Sizer shell is clearly marked, "SIZER", "SINGLE USE ONLY", and "DO NOT IMPLANT". The Sientra Gel Sizer is for single patient use only. The Sientra Gel Sizer is not intended for long-term implantation or re-sterilization.

For more information, please contact Sientra Customer Experience at 1.888.478.5782 or at info@sientra.ca.

INDICATIONS FOR USE

The Sientra Silicone Gel Breast Implant Sizer is a single-use, sterile, intraoperative device indicated for temporary placement during breast augmentation or reconstruction procedures to assist the surgeon in determining the appropriate size of the long-term Sientra Breast Implant to be implanted.

CONTRAINDICATIONS

- Long Term Implantation
- Multiple Patient Use
- Multiple Sterilizations

WARNINGS

It is the responsibility of the surgeon to advise the patient (or their representative) of all the potential risks and complications associated with the proposed surgical procedure 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 the Sientra Gel Sizer only.

The Sientra Gel Sizer is designed for temporary intraoperative use as a Sizer only.

- **DO NOT** use the Sientra Gel Sizer as a long-term breast implant
- **DO NOT** re-sterilize
- **DO NOT** reuse
- **DO NOT** alter
- **DO NOT** insert or attempt to repair a damaged Sientra Gel Sizer

PRECAUTIONS

The following precautions apply to the use of the Sientra Gel Sizer.

1. 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. To avoid contamination, aseptic technique is essential. **DO NOT** expose the Sientra Gel 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.
3. Care should be taken to avoid damaging the Sientra Gel Sizer with sharp instruments during surgery. Such contact may result in shell rupture.
4. Do not contact the Sientra Gel Sizer with disposable, capacitor-type cautery devices as damage to the shell of the Sientra Gel Sizer may result.
5. The Sientra Gel Sizer is for single patient use only.

ADVERSE REACTIONS AND COMPLICATIONS

The Sientra Gel Sizer is an intraoperative, single-use device and is not intended as a permanent implantable device. The following ADVERSE REACTIONS apply to the use of this temporary single-use Sientra Gel Sizer.

Adverse reactions which may result from the use of the Sientra Gel Sizer and corresponding breast implant 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.

Potential adverse reactions may include, but are not limited to the following:

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

3. Bleeding
4. 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.
5. Infection
6. 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 Sientra Gel Sizer is supplied individually in a sterile, double-thermoform packaging system. This product has been sterilized by dry heat sterilization. Sterility cannot be guaranteed if the double-sealed packaging system has been damaged.

INSTRUCTION FOR USE

Prior to use, the physician should be familiar with all the literature associated with and provided by the manufacturer of the breast implant to be implanted. The surgeon should be familiar with the currently available techniques for measuring the patient and determining the implant size, prior to performing surgery. The Sientra Gel Sizer is designed for temporary intraoperative insertion as a tool to assist the surgeon in determining the shape and size in long-term breast implant selection. It is important to continuously monitor the structural integrity of the Gel Sizer throughout the procedure to ensure the device is not compromised in any way. Do not use if any damage or alteration is identified.

Sizer Selection

1. The base diameter of the Sientra Gel Sizer should not be too small or too large in comparison to the patient's chest wall dimensions.
2. Available tissue must provide adequate coverage of the Sientra Gel Sizer.
3. 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 Sientra Gel 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 damage to the shell of the Sientra Gel Sizer may lead to rupture.

How to Open Sterile Product Package

1. Examine the Sientra Gel Sizer's sealed outer box before entering the surgical area to verify package integrity. Do not utilize any Sientra Gel Sizer with packaging that appears to be damaged in any way.
2. Open the outer box and remove the interior double blister packaging.
3. Open the outer blister package to gain access to the inner sterile blister packaging, taking care not to contaminate the inner sterile blister packaging by touching it to the outside of the outer blister.
4. Open the sterile inner blister package being careful to avoid contact with dust, lint and talc, and place the Sizer onto the surgical tray.

Method for Removing Ruptured Silicone from the Surgical Pocket

In the event the Sientra Gel Sizer ruptures during use, 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. 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.

STERILE PRODUCT

The Sientra Gel Sizer is supplied sterile and may not be re-sterilized. Sterility of the product is maintained only if the package is intact and undamaged. If the package has been opened or damaged the product must not be used.

RETURNED GOODS POLICY

For product returns please contact your local Sientra Plastic Surgery Consultant or the Sientra Customer Experience Team at 1.888.478.5782. All package seals must be intact to be eligible for return.

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

Sientra warrants that reasonable care was used in the manufacture and production of this product. Because Sientra 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, Sientra does not warrant either a good effect or against an ill effect following its use. Sientra 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

For product information please contact your local Sientra Plastic Surgery Consultant or the Sientra Customer Experience Team at 1.888.478.5782.

Symbology

Rx Only

 = Consult instructions for use

 = Sterilized using dry heat

 = Do not reuse

 = Do not resterilize

 = Made in USA

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Sientra, Inc. | Toll Free: 1.888.478.5782 | sientra.ca
Manufactured by Sientra, Inc. | Franklin, WI 53132 USA
Sientra Corporate Office | 3333 Michelson Dr., Suite 650, Irvine, CA 92612

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