Anatomical Controlled™ Tissue Expansion Matrix

sientra®

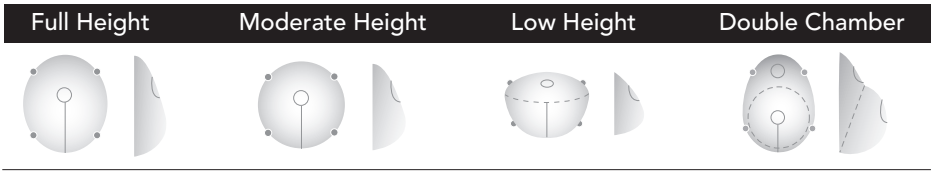
DIRECTIONS FOR USE

Contents

PRODUCT NAME

ACX™, Anatomical Controlled™ Tissue Expander

EXPANDER STYLES



DESCRIPTION

The ACX™, Sientra's Anatomical Controlled™ Tissue Expander, is a breast Tissue Expander that allows for controlled and individualized expansion of breast tissue. The expander features a large integrated magnetic injection port designed for easy location and injection. The expander is made of a single, textured shell that has a reinforced base, suture tabs and an orientation mark.

The injection port site can be located by using the magnet finder provided. To use the magnet finder please follow the instructions included in the Sientra Injection Port Location section of this document.

INDICATIONS

Sientra's Anatomical Controlled™ Tissue Expansion Matrix is indicated for increasing tissue area for:

- Post-mastectomy reconstruction.
- Scar revision.
- Other reconstructive procedures to correct hypoplasia and tissue defects.

CONTRAINDICATIONS

The use of this expander is contraindicated in patients who have any of the following conditions:

- Implanted devices that could be affected by a magnetic field. Examples of such devices include: pacemakers, and drug infusion devices or artificial sensing devices.
- Active infection anywhere in the body.
- Existing breast cancer or pre-malignancy without adequate treatment.

- Inadequate tissue coverage or tissue deemed unsuitable by the surgeon, for example, due to radiation damage, ulceration, compromised vascularity or history of compromised wound healing.
- History of severe allergies or foreign body reactions.
- Use of drugs that may result in high surgical risk and/or postoperative complications, including any drug that interferes with blood coagulation.
- Any condition or behavior determined by the surgeon to pose an unduly high risk of surgical and/or postoperative complication, such as obesity, smoking, diabetes, autoimmune disease, coagulopathy, chronic pulmonary disease, severe cardiovascular disease, or psychological problems.

INFORMATION THAT SHOULD BE PROVIDED TO THE PATIENT

Sientra relies upon the surgeon to inform the patient, prior to any decision to proceed with surgery, of the general warnings, precautions and adverse reactions identified in these directions for use. The surgeon should also advise the patients about any potential complications that are specific to the intended use of the device for the particular patient's situation. The surgeon should advise the patient that medical management of serious adverse reactions may include explantation.

The patient should be advised that vigorous body movement (e.g., physical exercise) or excessive manipulation or trauma in the region of the expander may cause stress to the device and result in subsequent deflation.

WARNINGS

1. *Magnetic Fields*

- DO NOT use the ACX™, Anatomical Controlled™ Tissue Expander in patients who have been previously implanted with a device that could be affected by a magnetic field.
- MRI is not to be used on patients implanted with this device because movement of the device could occur. This could potentially cause patient pain or lead to displacement of the Tissue Expander, which may require revision surgery.

2. *Radiation Therapy*

- The potential effects of radiation therapy in conjunction with the device have not been tested and Sientra cannot warrant the safety of such use. The decision regarding the use of the device in patients about to undergo radiation therapy should be made by the surgeon and the radiation oncologist.

3. *Extrusion of the Device*
- The incidence of extrusion of Tissue Expanders has been shown to increase when the expander has been placed in injured areas: scarred, heavily irradiated or burned tissue, crushed bone areas or where severe surgical reduction of the area has previously been performed.

4. *This Device is a Temporary Expander and is Not Intended For Long-term or Permanent Implantation*
- Tissue Expanders are typically implanted for less than 90 days.

5. *Single Use Device*
- Tissue Expanders are for single use only.
- DO NOT resterilize Tissue Expanders.
- DO NOT reuse explanted expanders.

6. *Avoid Damage During Surgery*
- Care should be taken to prevent damaging the device with surgical instruments or cautery devices.
- Do not implant or repair a damaged expander.
- Following implantation with the device, use care in subsequent procedures such as tissue expansion, open capsulotomy, breast pocket revision, hematoma/seroma aspiration, and biopsy/lumpectomy to avoid damage to the implant shell or port.

7. *Proper Filling*
- Surgeons should locate the exact position of the fill port prior to adding or withdrawing fluid (sterile saline solution). Needle punctures on or outside the device's integrated port may penetrate the shell causing deflation or may compromise the port and necessitate replacement of the device.
- The injection port should be penetrated only with 21 gauge (or smaller) needles. Do not use needles larger than 21 gauge because the port may not reseal.
- Injections should be made only inside the injection site, perpendicular to the base.
- Failure of the device to inflate may be due to leakage.
- Failure of the device may be due to injections that do not penetrate the integrated port.
- Leakage from the port can result from the use of an improper size of injection needle, from injections made outside of the port or from excessive pressure on the overlying tissue at the expander site, resulting in backpressure directed to the injection site.

- Only fill with sterile normal saline solution. Never use any other liquids or solutions. Never use solutions containing iodine to fill the device.
- Sientra relies on the surgeon to select the optimum incision and pocket size for the chosen expander design and projected volume.
- Excessive inflation of the device may result in tissue necrosis/thrombosis.

PRECAUTIONS

- Pre-existing infection should be treated and resolved before implantation of the Tissue Expander.
- Any surgeon performing reconstructive mammoplasty with Tissue Expanders should be familiar with the currently available techniques for measuring the patient, determining the Tissue Expander size and performing the surgery.
- Lint, dust, talc, surgical glove powder, drape and sponge lint, fingerprints, skin oils and other surface contaminants deposited on a Tissue Expander by improper handling may cause foreign body reactions. Strict adherence to clean, aseptic techniques should be maintained to prevent contamination of the Tissue Expander and possible complications.
- Surgical instruments and gloves should be rinsed clean of any impurities before handling the Tissue Expander.
- The silicone elastomer shell may easily be cut by a scalpel or ruptured by excessive stress, manipulation with blunt instruments or penetration by a needle. Subsequent deflation and/or rupture will result. All prostheses should be carefully inspected for structural integrity prior to and during implantation.
- Any subsequent surgical procedures in the area of the Tissue Expander should be undertaken with extreme caution as damage to the Tissue Expander could occur. In the event that the Tissue Expander is damaged, it must be removed.
- Each device should be checked for patency prior to surgery and continuously monitored throughout the surgical procedure to ensure the structural integrity of the device is not compromised in any way.
- Potential for contamination exists when fluid is added or removed from the device. Use aseptic technique in the introduction of saline into the Tissue Expander; a single-use, sterile saline container is recommended.
- A backup expander should be available during surgery.

ADVERSE REACTIONS

Any patient undergoing a surgical procedure is subject to possible unforeseen operative and postoperative complications. Potential reactions and complications associated with the use of the Tissue Expander should be discussed with, and understood by, the patient prior to surgery. It is the responsibility of the surgeon, and Sientra relies on the surgeon, to provide the patient with this information and to weigh the potential risks and benefits for each patient.

Potential complications include, but are not limited to, tissue thinning, skin necrosis, erosion, extrusion, capsule formation and contracture, seroma, hematoma, infection, displacement of the expander, loss of skin sensation, irritation/inflammation and deflation or leakage.

RECORDING PROCEDURE FOR TISSUE EXPANDERS

Each expander is supplied with Patient Record Labels showing the reference number and serial number for that expander. One of these pressure-sensitive labels should be attached directly to the ACX Fill Volume Tracking Card; the implanted position (left or right side), the date of placement, expansion data (date and volume) should be indicated on the card and retained in the patient's file.

PACKAGING AND STERILIZATION

- Tissue expanders are provided sterile in a sealed, double packaging system. The expanders are dry-heat sterilized and are for single use only. Sterility is maintained only if the package seal is intact.
- DO NOT use product if the package seal has been damaged.
- DO NOT reuse explanted products.
- DO NOT resterilize.
- The magnetic finder is sterilized by Gamma Ray.

EXPANDER SELECTION

Some of the important surgical and sizing variables that have been identified include the following:

- The expander 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 device.

- Submuscular placement of the expander may be preferable in patients with thin or poor quality tissue.
- A well-defined, dry pocket of adequate size and symmetry must be created to allow the implant to be placed flat on a smooth surface.
- Avoid too small of an incision.
- A backup expander should be available during surgery.

HANDLING INSTRUCTIONS

Remove the expander from its package in an aseptic environment using talc-free gloved hands and follow these steps:

1. Peel open the outer blister packaging.
2. Invert the outer blister packaging over the sterile field, allowing the sealed inner blister packaging to fall gently into the field.
3. Peel open the inner blister packaging.
4. Invert the inner blister packaging over the sterile field, allowing the expander to fall gently into the sterile field.

DO NOT expose the expander to lint, talc, sponge, towel, skin oil and other surface contaminants.

Prior to use, keep the Tissue Expander in the inner blister to prevent contact with potential airborne and particulate contaminants.

TESTING PROCEDURE FOR TISSUE EXPANDERS

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

1. Using a 21 gauge needle or smaller, partially inflate the device with air through the injection port.
2. Submerge the air-filled prosthesis in sterile, pyrogen-free testing fluid (water or saline).
3. Apply mild pressure and check for air bubbles signifying possible punctures or leaks.
4. Do not use if there is any evidence of leakage, lack of patency, damage or contamination.

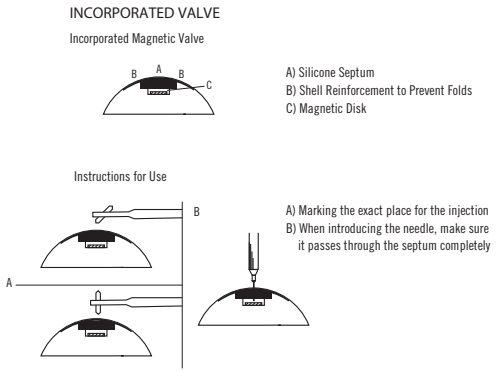
SIENTRA INJECTION PORT LOCATION

Using sterile technique, remove the magnet finder from the sterile pouch. Make sure the magnet inside the magnet finder device moves freely without obstruction. Hold the magnet finder above the area overlying the implanted integrated injection port. Slowly pass the magnet finder over the tissue surface. The magnet inside the magnet finder will indicate the location of the injection site. The integrated injection port is located when the magnet on the magnet finder is perpendicular to the injection site.

POSTOPERATIVE PERCUTANEOUS FILLING (EXPANSION PROCESS)

To inflate the Tissue Expander:

1. Locate the injection port using the Sientra magnetic injection-port finder included with the expander. Once the center of the port has been located, a skin marker can be used to mark the area for injection.
2. Inflation is accomplished by inserting a 21 gauge (or smaller) standard bevel or Huber-tip needle into the top of the injection site, perpendicular to the base and filling the device with sterile normal saline solution for injection.



3. Injections must be made into the area enclosed within the port. If injections are made on or outside the port, leakage can occur.

RETURNED MERCHANDISE POLICY

A Returned Merchandise Authorization (RMA) is required for product returns. All package seals must be intact to be eligible for return. Please contact Sientra Customer Service at (888) 708-0808 for an RMA and product return instructions. Products returned without a prior authorization may be refused.

EXPLANTED DEVICE RETURNS AND REPORTING

Explanted devices must be returned to Sientra and the reason for explantation must be provided. All explanted devices must be returned in a Sientra Explant Return Kit. Please contact Sientra Customer Service at (888) 708-0808 for a Sientra Explant Return Kit and instructions.

PRODUCT ORDERING

To order directly in the U.S.A. or for product information, please contact Sientra Customer Service at (888) 708-0808.

CAUTION Federal Law (U.S.A.) restricts these devices to sale by or on the order of a licensed physician.

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SILIMED

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