Instructions For Use
AlloX® and AlloX2®
Tissue Expanders

sientra

OPUS®

Description

Sientra Tissue Expanders are intended for temporary subcutaneous or submuscular implantation to develop surgical flaps and additional tissue coverage and are not intended for use beyond 6 months. All Tissue Expanders require periodic, incremental inflation with sterile saline for injection until the desired amount of tissue is developed.

The Sientra Tissue Expanders are constructed from silicone elastomer and consist of an expansion envelope with a smooth or textured surface with an integrated Magnetic Injection Port system for incremental expander filling. The AlloX and AlloX2 tissue expanders have an incorporated drainage system accessed either by a magnetic drain port or a remote drain port (refer to product labeling). The incorporated drain system allows for aspiration of fluids that may present during the expansion process.

The AlloX and AlloX2 expanders are manufactured with mid-height and full height base options and base ranges from 11cm-16cm to meet diverse patient needs and to achieve individualized aesthetic results. Each expander is supplied sterile. A Magnetic Port Locating Device and a sterile winged needle infusion set are supplied sterile, individually packaged inside the product box.

Sientra warrants that reasonable care was used in the selection of materials and manufacture of the device. Sientra disclaims any additional warranties concerning the safety or efficacy of the device in any medical procedure, including, but not limited to suitability for the intended use. Sientra makes no representation concerning the useful life of the device. Final approval of the device and its use in any medical procedure are solely the responsibilities of the surgeon.

CAUTION: Federal (USA) law restricts these devices to sale by or on the order of a licensed physician.

For more information, please contact Sientra Customer Experience at 1.888.708.0808 or at customer.experience@sientra.com.

AlloX and AlloX2 Tissue Expanders

The Sientra AlloX and AlloX2 Tissue Expanders contain rare earth, permanent magnets for location of injection and drain systems. When the Magnetic Site Locator is suspended and slowly passed over the surface of the tissue being expanded as described in Instructions for Use, its permanent magnet indicates the location of the magnetic injection port and the magnetic drain port.

CAUTION: DO NOT use the magnetic injection port expanders in patients who already have implanted devices that would be affected by a magnetic field (e.g. pacemakers, drug infusion devices, and artificial sensing devices.) Do not perform diagnostic testing with Magnetic Resonance Imaging (MRI) in patients with magnetic injection port expanders in place. See Magnetic Field under WARNINGS for more information.

Indications For Use

AlloX and AlloX2 Tissue Expanders are intended for temporary (less than six months) subcutaneous or submuscular implantation to develop surgical flaps and additional tissue coverage required in a wide variety of applications, particularly to aid in reconstructions following mastectomy, to aid in the treatment of underdeveloped breasts and to aid in treatment of soft tissue deformities. Additionally, the AlloX and AlloX2 Tissue Expanders contain a silicone drain component which allows access to and drainage of latent fluids from the periprosthetic space. The drain component does not replace short-term, immediate, intraoperatively placed drains.

General Indications

- Breast reconstruction following mastectomy.
- Correction of underdeveloped breasts.
- Treatment of soft tissue deformities.
- Access to and drainage of latent fluids from the periprosthetic space.

General Contraindications

It is the responsibility of the surgeon to advise the prospective patient(s) or their representative, prior to surgery, of the contraindications with the use of this product.

- Magnetic injection port expanders should not be used in patients who already have implanted devices that would be affected by a magnetic field.
- Tissue covering determined unsuitable by the surgeon. To varying degrees, radiation damage, ulceration, compromised vascularity, or history of compromised wound healing may affect tissue covering suitability.
- Active infection in the body.
- Existing carcinoma at the intended expansion site.
- Adjuvant radiotherapy without filling delay or myocutaneous flap as necessary to avoid unsuitable donor tissue.
- Physiological condition determined by the surgeon to pose unduly high surgical risk of surgical and/or postoperative complications. To varying degrees, sensitive over or underlying anatomy, obesity, smoking, diabetes, autoimmune disease, hypertension, chronic lung or severe cardiovascular disease or osteogenesis imperfecta may affect patient suitability for tissue expander surgery.
- Use of drugs that might result in high surgical risk and/or significant postoperative complications, including any drug that would interfere with blood clotting or affect tissue viability.
- Psychologically unsuitable patient.

Information That Should Be Provided To The Patient

Tissue expansion can be a beneficial surgical alternative for many pediatric and adult patients. At the surgeon's discretion, the use of a tissue expander may contribute to the benefit of the treatment. Nevertheless, tissue

expansion is not appropriate for every patient, because it is a time and labor intensive process that may cause temporary discomfort and distortion. The surgeon is responsible for selecting appropriate candidates and counseling those patients on the risk/benefit relationship. Before expander placement, patients should fully understand the elective nature of the procedure and the nature of the device being used. Patients should be willing to comply with expansion process requirements to minimize the risk of complications.

Available on-line at sientra.com/resources is an Information and Informed Patient Consent Form that may be used to facilitate awareness and acceptance of the risks associated with silicone tissue expander surgery. It is recommended that the patient read and sign this form. It is also recommended that the patient and the surgeon each keep a copy of this signed form.

Warnings, Precautions, Adverse Reactions

Before the decision to proceed with the surgery, the surgeon should inform the patient of the general warnings, precautions, and adverse reactions listed in this package insert, as well as any complications specific to the tissue expander and its intended use. The surgeon should advise the patient that adverse reactions may interfere with the original surgical plan and that medical management may include premature explantation.

Warnings

MAGNETIC FIELD **DO NOT** use magnetic injection/drain port expanders in patients who already have implanted devices that would be affected by a magnetic field (e.g., pacemakers, drug infusion devices, artificial sensing devices), because the magnetic injection/drain port **contains a strong rare earth, permanent magnet**.

Diagnostic testing with Magnetic Resonance Imaging (MRI) is contraindicated in patients with magnetic injection/drain port expanders in place. The MRI equipment could cause movement of the magnetic injection/drain port and/or expander, and result in not only patient discomfort, but also expander displacement, requiring revision surgery. In addition, the magnet could interfere with MRI detection capabilities.

Sientra has not tested the *in vivo* effects of radiation therapy with the magnetic injection/drain port expander, and cannot warrant the safety of such use. Magnetic injection/drain port expanders must be explanted before radiation therapy is initiated.

USE OF DRAIN SYSTEM The drain system will only remove fluid that is located at the location of the drain manifold hole. **DO NOT push fluid through the drain system**. Follow Instructions for Integrated Drain Port Use or Instructions for Remote Drain Port Use as applicable to the device selected for use. Sientra has not tested this device for the use of injecting anesthetic, steroids or antibiotic solutions. As a result, this use cannot be supported by Sientra.

This device is not intended to take the place of additional drains that may be used immediately post-operatively. This device is intended to provide access to and drainage of latent fluids from the periprosthetic space without the necessity of inserting a needle adjacent to the device. Thus, reducing the potential for device failure as a result of needle puncture when draining fluids from this space.

ALTERATION **DO NOT** alter the expander. Alteration to the original design and fabrication voids all warranties, express or implied, except as provided for alteration of the connector tube in Techniques For Using the Remote Drain Port.

ADULTERATED FILL **DO NOT** use adulterated fill. Expanders are to be filled only with sterile saline for injection, and only as described in the Instructions for Use. Sientra can neither predict nor warrant the safety of intralumenal introduction of any adulterated fill, including but not limited to, anesthetic, steroid, and antibiotic solutions.

REUSE Expanders are intended for single use only. Do not reuse or resterilize.

TISSUE DAMAGE **DO NOT** expand if the pressure will compromise wound healing. **DO NOT** expand beyond patient or tissue tolerance. Excessively rapid tissue expansion may compromise the vasculature of the overlying tissue. Stop filling immediately if any signs of tissue damage, wound dehiscence, abnormal skin pallor, erythema, edema, pain, or tenderness are observed. In the absence of other signs, some temporary erythema may occur as a recognized normal tissue response to expansion.

Tissue viability may be adversely affected by radiotherapy steroid use in the surgical pocket, excessive heat or cold therapy, and smoking.

INFECTION Infection anywhere in the body must be treated and resolved before surgical placement of any expander. Untreated preexisting infection increases the risk of periprosthetic infections. **DO NOT** expose the expander or injection needles to contaminants, which increase the risk of infection. Patients who present with wound dehiscence, tissue erosion, ischemia, or necrosis run an increased risk of periprosthetic infection. Measures to protect such areas from infection should be taken.

Signs of acute infection reported in association with tissue expanders include erythema, tenderness, fluid accumulation, pain and fever. Infection may compromise the expansion process. Postoperative infections should be treated aggressively according to standard medical practices to avoid more serious complications. Infection that is unresponsive to treatment or necrotizing infection may require premature expander removal.

Precautions

SURGICAL PLANNING Sientra tissue expanders have many useful applications in diverse clinical situations. Sientra relies on the surgeon to know and follow proper surgical procedures specific to the type of expansion and desired physical outcome, expander dimensions, incision placement, pocket dissection, expander filling, and final flap dimensions, using current accepted techniques and individual experience.

AVOIDING CONTAMINATION AT SURGERY To avoid contamination, aseptic technique is essential. **DO NOT** expose the expander to lint, talc, sponge, towels, skin oils, and other surface contaminants. Contamination at the time of surgery increases the risk of periprosthetic infection, which could require premature explantation of the expander.

To minimize the risk of contamination, follow recommended procedures under "Avoiding Contamination at Surgery".

AVOIDING DAMAGE DURING SURGERY Extreme care should be taken to avoid damage to the expander during surgery. Possible sources of damage include sharp surgical instruments such as scalpels and needles used during the initial surgery, subsequent filling, or hematoma/fluid evacuation.

Products must be carefully inspected for leaks or nicks prior to use. **DO NOT** attempt to repair damaged products.

To minimize the risk of damage, follow recommended procedures for expander handling, examination, placement, and filling.

MAINTAINING HEMOSTASIS/AVOIDING FLUID ACCUMULATION Postoperative hematoma and seroma may be minimized by meticulous attention to hemostasis during surgery, and possibly by postoperative use of closed drains. Persistent, excessive bleeding must be controlled before the expander is placed. If the incision is remote from the site of expansion, the expander may be filled to tissue tolerance at the time of surgery to help minimize serous fluid accumulation in the surrounding pocket. If wound stability is a concern, inflate only slightly to fill the pocket space without applying tension to the tissue.

Any postoperative evacuation of hematoma or other fluid accumulation must be conducted with care to avoid introduction of contaminants and/or damage to the expander from needles or other sharp instruments.

AVOIDING TISSUE DAMAGE DURING EXPANSION If the incision site is not remote from and radial to the site of expansion, the wound should be stable before tissue expansion begins. However, a slight amount of inflation to fill the pocket space without tension to the tissue may be initially possible.

Expansion should proceed in moderate increments, never beyond patient or tissue tolerance.

The patient should be carefully monitored during each session. If any signs of tissue damage, abnormal skin pallor, erythema, edema, pain, or tenderness are observed, filling should immediately stop until the problem is resolved.

See also Tissue Damage under WARNINGS and ADVERSE REACTIONS.

AVOIDING EXPANDER DAMAGE DURING EXPANSION Extreme care should be taken to avoid needle puncture or other damage to the expander tubing or the injection/drain port during the expansion process.

To minimize the risk of expander damage during expansion, fill the expander only with sterile saline for injection and use the appropriate location methods and instruments, as described in the Port Location and Expander Filling instructions.

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 Tissue Expanders 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 risk/benefit potential for each patient.

DEFLATION Patients should be advised that the expanders may deflate, and require replacement surgery. Deflation occurs when saline leaks through a damaged injection site, disconnected or damaged remote injection site connection tube, or a damaged expander envelope.

See also Avoiding Damage during Surgery and Avoiding Expander Damage during Expansion, under PRECAUTIONS.

TISSUE DAMAGE Improper patient selection, tissue expander selection, placement and inflation may result in tissue damage and require premature explantation of the expander. Signs of tissue damage include abnormal skin pallor, erythema, edema, pain, or tenderness, and should be promptly investigated. In the absence of other signs, some temporary erythema may occur and is recognized as a normal tissue response to expansion.

The stresses of the expanding device may induce pressure ischemia and necrosis, especially in tight or thin-skinned areas. Folds in a partially filled expander may also result in thinning and erosion of adjacent tissue. Excessively rapid tissue expansion may compromise the vascularity of the overlying tissue.

Radiotherapy, steroid use or other drug therapy in the surgical pocket, excessive heat or cold therapy, and smoking may adversely affect tissue viability.

See also Avoiding Tissue Damage during Expansion, under PRECAUTIONS.

INFECTION Preexisting infections not resolved before tissue expander placement increase the risk of periprosthetic infection.

Infection is an inherent risk following any type of invasive surgery and may occur during the tissue expansion process. Remote drain site expanders are associated with greater risk of infection around the drain site and potentially around the expander. Patients who present with wound dehiscence, tissue erosion, ischemia or necrosis, and patients undergoing immediate breast reconstruction run an increased risk of periprosthetic infection. Signs of acute infection reported in association with tissue expanders include erythema, tenderness, fluid accumulation, pain and fever.

Toxic Shock Syndrome has been reported as a complication of both augmentation and reconstructive mammoplasty.

Erythema may also occur as a normal response to expansion. Aspiration to differentiate between this type of erythema and erythema as a sign of early infection is a recognized precaution.

Research identifies Staphylococcus and Pseudomonas organisms in association with infection around tissue expanders. Escherichia and Streptococcus organisms have also been noted in association with tissue expanders in the lower extremities. Infection may occur at any time after surgery, and may compromise the expansion process. Postoperative infections should be treated aggressively according to standard medical practices to avoid more serious complications. Infection that is unresponsive to treatment or necrotizing infection may require premature expander removal.

EXTRUSION Tissue damage may compromise tissue covering and/or wound healing, result in extrusion, and require premature expander removal. See also Tissue Damage, above.

HEMATOMA/SEROMA Postoperative hematoma and seroma may contribute to infection. Postoperative hematoma and seroma may be minimized by meticulous attention to hemostasis during surgery and possibly by postoperative use of closed drains. Persistent, excessive bleeding must be controlled before the device is implanted.

CAPSULAR CONTRACTURE Formation of a fibrous tissue capsule around an implanted device is a normal physiological response, although not all capsules contract. Contracture of the fibrous capsular tissue surrounding the expander may cause a range of symptoms including firmness, discomfort, pain, distortion, palpability, and/or displacement. Contracture may make expansion difficult and painful. Lower rates of contracture are associated with expansion begun soon after placement and continued regularly.

PREMATURE EXPLANTATION Adverse reactions may require premature explantation, which may affect desired flap size.

DISPLACEMENT The expander may become displaced, especially if the surgical pocket is too large. Expander displacement may make the integrated valve location difficult or impossible to locate without surgical correction. Remote drain port displacement may occur, causing kinking of tubing

and/or drain port location difficulty, necessitating device removal or correction should you wish to use the drain component.

EFFECTS ON BONE Chest wall compression has been reported in association with the use of tissue expanders for breast reconstruction. The presence of a thick capsule, causing greater resistance to expansion may be a contributing factor. The medical literature indicates that following expander removal, effects on bone caused by the pressure of expansion are often completely reversed.

PAIN As expected following any invasive surgical procedure, pain of varying intensity and duration may occur following expander placement. In addition, the expansion process may cause some discomfort but should not cause excessive pain. Pain may indicate expansion beyond tissue tolerance, which could result in ischemia and necrosis. Pain may also accompany other adverse reactions. Unexplained pain must be promptly investigated. Further expansion should be discontinued until the pain is resolved.

SENSATION The possibility of temporary or permanent dysesthesia exists following any invasive surgical procedure. Surgical technique and expansion must be performed carefully to avoid neurological impairment. Nerve traction and compression have been reported in rare cases in association with tissue expansion. Immediate partial deflation should be standard precaution if nerve impingement is suspected and filling should not resume until the problem is resolved.

CANCER Published studies indicate that breast cancer is no more common in women with implants than those without implants. To the extent that such research applies to the safety of silicone for implantation, it is relevant to tissue expanders in general.

DISTORTION Tissue expansion is a time and labor intensive process that may cause temporary discomfort and distortion. Patients should be psychologically suitable, well-informed, and motivated to complete the expansion process. Patient response to the distortion of body image may vary. Negative reactions may include depression and withdrawal.

INADEQUATE TISSUE FLAP Inadequate tissue flap following expansion may occur and may require additional surgery and expansion. In cases with limited viable donor site tissue, such sequential expansion may be included as part of the original surgical plan. See also Surgical Planning, under PRECAUTIONS.

INFLAMMATORY REACTION Studies evaluating the capsules around textured expanders have reported what were possibly silicone particles within giant cells, indicative of a local foreign body reaction and silicone granuloma formation. Another study suggests that certain types of capsule cells, including some perceived as giant cells, may actually be secretory cells that form in response to the frictional forces of the expander, providing lubrication at the capsule-expander interface.

CONNECTIVE TISSUE DISEASE Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma or rheumatoid arthritis, has been raised because of cases reported in the literature with small numbers of women with implants. A review of several large epidemiological studies of women with and without implants indicates that these diseases are no more common in women with implants than those in women without implants. To the extent that such research applies to the safety of silicone in general for implantation, it is relevant to tissue expanders.

Surgical Procedure

Sientra relies on the surgeons to know and follow the appropriate surgical procedures for the type of expansion performed and expander used. The surgeon must carefully evaluate patient suitability for expansion and desired physical outcome, expander dimensions, incision placement, pocket dissection, expander filling and final flap dimensions using current, accepted techniques and individual experience.

Product Identification

A patient record label accompanies each device within the internal product packaging. The patient record label provides product-specific information. The patient record label may be attached to the patient's chart for product identification purposes.

Product Accessories

Sientra AlloX2 Tissue Expanders with an Integrated Magnetic Drain Port are supplied with an AlloX2 Magnetic Site Locator. Sientra AlloX Tissue Expanders with a Remote Drain Port are supplied with extra silicone tubing and stainless steel tubing connectors to vary the length of the remote connector tube and a Precision Point™ Magnetic Injection Port Locator. All AlloX and AlloX2 Tissue Expanders are provided with a sterile winged needle infusion set. All accessories are provided sterile.

Single Use Sterile Product

Each AlloX and AlloX2 Expander is supplied sterile in a sealed, double primary package. Sterile products are processed by a strictly controlled sterilization cycle. Sterility of the expander is maintained only if the outer pouch is intact.

DO NOT use the product if the packages or seals have been damaged. Do not reuse or resterilize.

How To Open Sterile Product Package

Remove the expander and product accessories from their sterile packages in an aseptic environment using talc-free gloved hands.

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

1. Peel open the outer peel pouch using the corner peel edge.
2. Invert the outer peel pouch over the sterile field, allowing the sealed inner peel pouch to gently fall into the field.
3. Peel open the inner/primary peel pouch package using the corner peel edge.
4. Gently retrieve the expander.

Prior to use, keep the expander in the inner/primary peel pouch covered to prevent contact with airborne and surgical field particulate contaminants.

Preliminary Product Examination

Prior to use, examine the expander for leakage by partially filling with sterile saline for injection and gently compressing. The Injection Site for incremental filling is located on the right anterior shell surface for the AlloX2 with Integrated Magnetic Drain Port device or in the center anterior shell surface for the AlloX with Remote Drain Port device. Verify the correct port prior to injecting by confirming the locator with the yellow housing attracts to the port. To avoid missing any leaks due to hand position, reposition the expander several times and repeat the inspection. If satisfactory, aspirate all sterile saline and air from the inspected expander.

Prior to use, verify the drainage system is clear from obstructions by withdrawing sterile saline or air through the Drain System. The Drain Port is the site located on the left anterior shell surface for the AlloX2 with Integrated Magnetic Drain Port device. Verify the correct integrated drain port prior to drainage by confirming the locator with the blue housing attracts to the port.

Upon completion of preliminary product examination, return the expander to the inner/primary peel pouch and keep it covered until implanted to prevent contact with airborne contaminants.

DO NOT implant any device that appears to have particulate contamination, nicks, leaks, obstructed saline or air flow, or if the locator does not locate the magnetic integrated injection or drain port as noted above.

DO NOT attempt to repair damaged products.

Techniques For Using The AlloX Tissue Expanders

DO NOT use force during any of the steps in the following procedures.

DO NOT damage the expander with sharp surgical instruments such as needles and scalpels, or by excessive handling and manipulation during introduction into the surgical pocket.

Placement of Tissue Expander

Plan and dissect the surgical pocket for placement of the expander using current and accepted surgical techniques. If the pocket is too small, the expander may not have adequate room to unfold, increasing the risk of tissue erosion. If the pocket is too large, the expander may not remain in proper position for filling and expansion.

Place the expander flat and correctly-oriented with the drain manifold in the inferior location of the pocket. For those devices with a remote drain port, place the drain port flat and correctly-oriented in a separate subcutaneous pocket ensuring its palpability. Ensure that the drain port connector tube lies flat and securely connects the drain site to the expander through a subcutaneous tunnel. **The magnetic port(s) must be situated anteriorly, adjacent to the skin surface. Attempting to inject into, or drain fluids from, the injection/drain ports from the bottom of the device will result in device failure.**

Prior to wound closure, verify the magnetic injection port is to the right, and the magnetic drain port is to the left (as you face the patient) by suspending the magnetic site locator over the ports as described below under "Magnetic Injection and Drain Port Location".

WARNING: Unaspirated fluids may cause the device to flip such that the intregral injection and drain ports of the AlloX2 device are in the posterior position, not adjacent to the skin, potentially resulting in an inadvertent puncture of the device when attempting to perform subsequent filling or drainage of fluids. It is important to monitor and aspirate any accumulation of fluids while the device is implanted in the patient to prevent the device from flipping within the periprosthetic pocket.

OPTIONAL: A sterile accessory set including silicone tubing and stainless steel tubing connectors is packaged with the device for varying the length of the remote connector tube. Using aseptic technique, cut the tubing, and attach the pieces to opposite ends of the connector so that the tubing meets tightly in the middle, suture tubing ends together as shown in Diagram 1 (a & b).

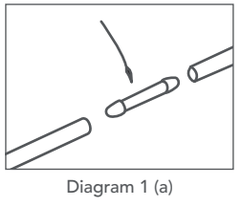

Diagram 1 (a)

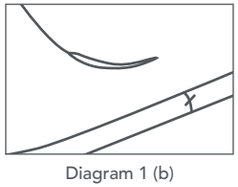

Diagram 1 (b)

DO NOT use lubricants, which create the risk of pocket contamination. Lubricants may also affect tissue adherence.

Expanders with Lateral Extensions (i.e., suture tabs)

Reinforced lateral extensions located on some expander designs may be sutured once the device is placed in the desired location. Extreme care should be taken to move the expander shell away from the tabs to avoid accidental shell puncture during suturing operations. Tabs may be trimmed if desired. Extreme care should be taken during trimming operations to avoid shell damage with sharp instrument.

Remote Drain Port Location

Always verify the location and orientation of the drain port by palpation prior to removal of fluids.

- Ensure that the base of the drain port is properly oriented for needle entry.
- Prepare the drain site for removal of fluids using antiseptic swabs.

Magnetic Injection and Drain Port Location

To assist with magnetic injection and drain site location, a magnetic site locating device is included in a double peel pouch, **sterile** package inside the secondary packaging of each product. While the injection port can be generally identified by palpation, always verify the location and orientation of the injection port with the magnetic injection port locator, as described below, before each filling.

Devices with the integrated drain port have an AlloX2 Magnetic Site Locator which includes a locator for both the fill port and the drain port. **Always use the locator magnetic with the Blue Housing to locate the drain port which should be located on the left side as you are facing the patient.**

DO NOT store or use the Magnetic Site Locator near any loose metal particles as they may attach themselves to the magnet.

a. Suspend the magnetic port locator above the tissue overlaying the implanted magnetic injection/drain port expander. **Note:** the integrated fill port is to the right of the drain port.

b. Slowly lower the magnetic injection port locator over the tissue surface in a slow sweeping motion. When the magnet on the magnetic injection port locator locates the magnetic injection port in an absolutely perpendicular manner (Diagram 2 (a)), gently tilt the locator in order to mark the tissue with a surgical marker (Diagram 2 (b)).

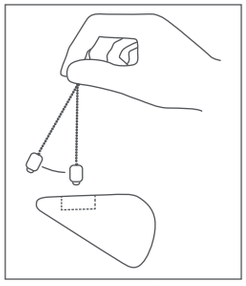

Diagram 2 (a)

WARNING: If you observe the blue magnet housing chain bending, or otherwise rotating around the left port (to which it should correspond) or alternatively the yellow magnet locator bending, or otherwise rotating around the right port (to which it should correspond) during the above process (Diagram 3), this means the tissue expander injection port may be rotated. Stop this process and verify the tissue expander is properly oriented so the magnetic ports are located anteriorly, adjacent to the skin.

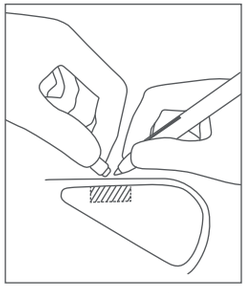

Diagram 2 (b)

Notice: Attempting to inject into the injection port from the bottom of the device will result in device failure.

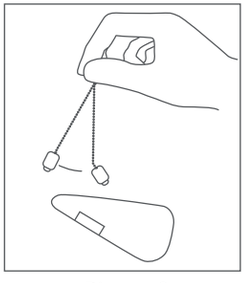

Diagram 3

c. Prepare the injection site for filling using an appropriate antiseptic swab.

Expander Filling

If the incision site is remote from and radial to the site of expansion, the expander may be filled to tissue tolerance at the time of surgery. Not only will this help to maintain proper expander placement, but it will also help to minimize fluid accumulation, expander folds, and the formation of a thick, resistant, capsule.

If the incision site is not remote from and radial to the site of expansion, the wound should be stable before tissue expansion begins. However, a slight amount of inflation to fill the pocket space without tension to the tissue may be initially possible.

DO NOT unnecessarily delay expansion after placement. The longer the delay, the more likely the formation of a resistant capsule making expansion difficult.

NOTE: Due to the compact design of the injection ports, clearance for the needle in the ports is minimal. The ports are designed for use with a 21 gauge or smaller needle. Use of larger needles may damage port sealing capability or result in marginal port entry and subsequent difficulty in filling the device.

NEVER proceed with filling beyond patient or tissue tolerance.

Fill volumes during each session, intervals between filling sessions, and total expansion time may vary because they are highly patient and procedure dependent. Filling is typically performed at weekly intervals. A Patient Fill Volume Record card is provided with each expander for recording fill volumes and monitoring the expansion process.

NOTE: The suggested fill volume is located on the product labeling. The patient should be carefully monitored during each session for any signs of adverse reactions. If any signs of tissue damage, abnormal skin pallor, erythema, edema, pain or tenderness are observed, filling should immediately stop until the etiology is determined and the problem resolved.

The **FILL** port is designed for use with a 21 gauge or smaller needle. Use of larger needles may damage port sealing capability.

Use of Drain System

If the Drain Port is integrated, follow the instructions for Magnetic Injection/ Drain Port Location. **Note: the drain port is located to the left of the filling port on the device as you are looking at the patient. Always use the locator magnetic with the Blue Housing to locate the drain port.**

If the Drain Port is remote from the expander, locate the port by palpation.

NOTE: Due to the compact design of the drain ports, clearance for the needle in the ports is minimal.

The **DRAIN** port is designed for use with an 18 gauge or smaller needle. Use of larger needles on either port may damage port sealing capability.

After correct **drain port** location is marked:

a. Insert a new, sterile 18 gauge (or smaller) standard 12 degree bevel hypodermic needle into drain port. Ideally, the needle should enter perpendicular to the top of the drain port (see Diagram 4 (a) and (b) as applicable.

b. Penetrate the drain port until the needle is stopped by the port base (see Diagram 4 (a) and (b).

   NOTE: The surgeon should feel the needle making gentle contact with the port base. Contact must be made with the base to ensure flow through the drain system. **DO NOT** force the needle against the port base which may bend or burr the needle and result in port damage.

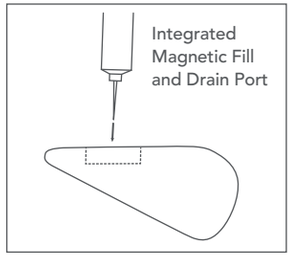

Diagram 4 (a) (integrated port)

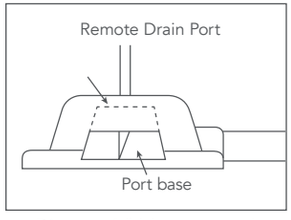

Diagram 4 (b) (remote port)

c. Syringe is now capable of fluidic communication with the drain system. Gently pull syringe to move fluid from the surgical pocket through the drain system.

   NOTE: The drain system will only remove fluid that is located at the location of the drain manifold holes. **DO NOT push fluid through the drain system.**

Magnetic Port Locator

The magnetic port locator is not intended to come into contact with patient bodily fluids. Prior to reuse of the locator for subsequent filling or drainage, it must be cleaned and disinfected. Wiping down the locator with an isopropyl alcohol swab or antibacterial soap and water is recommended.

Returned Goods Policy

Tissue expander return value is based on time limits and the condition of the returned product packaging. For more information, please contact Sientra Customer Experience toll free at 1.888.708.0808 or your local Sientra Plastic Surgery Consultant.

Reporting And Return Of Explanted Devices

Explanted devices associated with a complaint or serious injury should be reported and returned to Sientra. In the event of such an explantation, please contact the Sientra Customer Experience toll free at 1.888.708.0808 for instructions on proper return procedures.

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, postsurgical 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 of fitness for use.

Product Ordering

To order directly in the US or for product information, please contact Sientra Customer Experience toll free at 1.888.708.0808. International orders may also be placed directly with your local representative.

Symbology

QTY = Quantity enclosed

SN = Serial number

REF = Catalog number

STERILE R = Sterilized by Irradiation

STERILE EO = Sterilized by Ethylene Oxide

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

STERILE = Sterilized using dry heat

 = Consult instructions for use

 = Do not reuse

 = MR Unsafe

 = Do not resterilize

 = Made in USA

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