



Dual Magnetic
Port Locator
Instructions For Use

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OPUS™

The Dual Magnetic Port Locator is provided NON-STERILE and is intended to be used only with the **Sientra OPUS AlloX2 Breast Tissue Expander** in a non-sterile environment.

Refer to “*AlloX and AlloX2 Breast Tissue Expander Instructions for Use*” document for a complete description of general indications, general contraindications, warnings, precautions, adverse reactions, and other information general to the use of the AlloX2 Breast Tissue Expanders.

Link: [AlloX and AlloX2 Breast Tissue Expander Instructions for Use](#)

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

Indications For Use

AlloX2 Breast 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 reconstruction following mastectomy, to aid in the treatment of underdeveloped breasts and to aid in treatment of soft tissue deformities. Additionally, the AlloX2 Breast Tissue Expander contains 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.

Device Description of Dual Magnetic Port Locator For Use With The AlloX2 Breast Tissue Expander

The Dual Magnetic Port Locator is for use with the AlloX2 Breast Tissue Expander. The single housing locator has clearly labeled “Fill” and “Drain” magnets for locating the respective AlloX2 fill and drain ports.

The Dual Magnetic Port Locator is supplied non-sterile in a reclosable, poly bag.

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 of the AlloX2. Verify the correct port prior to injecting or draining the AlloX2 by confirming the Dual Magnetic Port Locator attracts accurately to both ports, with the “Fill” magnet on the locator attracted to the fill port of the expander and the “Drain” magnet on the locator attracted to the drain port of the expander. 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 of the AlloX2.

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 Dual Magnetic Port 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 AlloX2 Breast Tissue Expander

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 or 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 AlloX2 expander flat and correctly-oriented with the drain manifold in the inferior location of the pocket. **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 ("FILL" port is to the **right** as you face the patient) and the magnetic drain port ("DRAIN" port is to the **left** as you face the patient), as described below in the section "Magnetic Injection and Drain Port Location."

WARNING: Unaspirated fluids may cause the device to flip such that the integral 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.

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

Magnetic Injection and Drain Port Location

To assist with magnetic injection and drain site location, use the Dual Magnetic Port Locator. While the injection port can be generally identified by palpation, always verify the location and orientation of the injection port with the Dual Magnetic Port Locator, as described below, before each filling.

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

- A. Prepare the patient injection site by using an antiseptic swab, and also wipe down the Dual Magnetic Port Locator with an isopropyl alcohol swab or antibacterial soap and water prior to use.

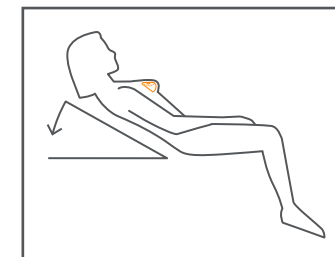


Diagram (A)

- B. Position the patient in an orientation where the patient's skin overlaying the tissue expander ports is horizontal. (see Diagram A)

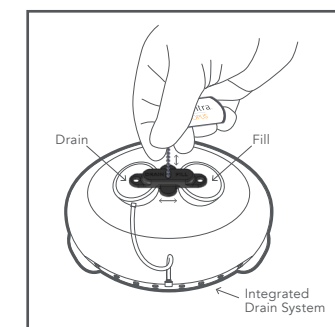


Diagram (B)

- C. Hold the Dual Magnetic Port Locator in the middle of the chain between your forefinger and thumb. Suspend the Dual Magnetic Port Locator above the expander ports as close to the patient's skin as possible. (see Diagram B)

Note: the integrated fill port is to the right of the drainport.

- D. The relationship between the locator magnets and the patient tissue should be parallel. Move the locator to the right, left and up and down over the tissue until a parallel relationship is achieved. Then, slowly lower the Dual Magnetic Port Locator to the patient tissue.

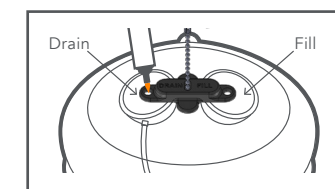


Diagram (C)

- E. The Dual Magnetic Port Locator lateral holes should be used to identify the center of the respective fill and drain ports. If the locator moves, repeat steps C and D, above. (See Diagram C)

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

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 expansion 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.

Use of Drain System

Follow the instructions for Dual Magnetic Port Locator above. **Note: the drain port is located to the left of the filling port as you are looking at**

the patient of the device. Always use the “Drain” magnet on the locator to locate the drain port.

NOTE: Due to the compact design of the drain 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.

After correct drain port location is marked:

- A. Insert a new, sterile 21 gauge (or smaller) standard 12 degree bevel hypodermic needle into drain port. The needle should enter perpendicular to the top of the drain port (see Diagram D).
- B. Penetrate the drain port until the needle is stopped by the port base (see Diagram E). **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.
- 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.

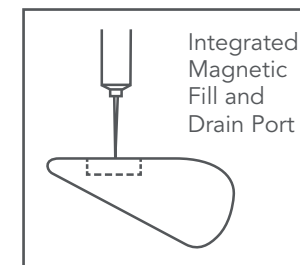


Diagram D

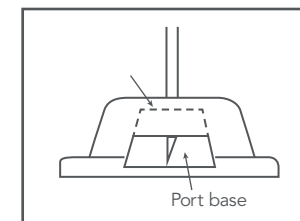


Diagram E

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.**

Dual Magnetic Port Locator

The Dual 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 prior to use. Wiping down the locator with an isopropyl alcohol swab or antibacterial soap and water is recommended.

