

CUI[™] BRAND
SALINE FILL
TISSUE EXPANDER



THE SCIENCE OF REJUVENATION[™]

CAUTION: U.S. Federal law restricts this device to sale by or on the order of a licensed physician.

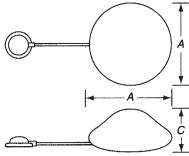
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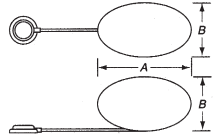
EXPANDER STYLES

STANDARD TISSUE EXPANDERS

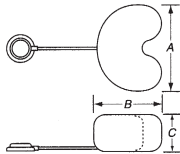
**ROUND
SFS**



**SMALL OVAL
SOE**

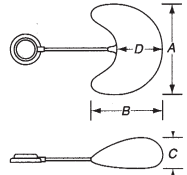


**CRESCENT
SCS**

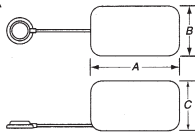


VERSAFIL TISSUE EXPANDERS

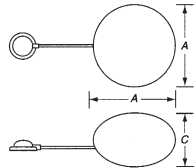
**CROISSANT
CZV / CRS**



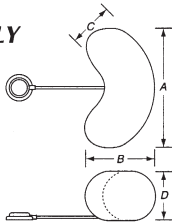
**RECTANGULAR
SRS**



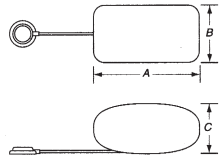
**ROUND
FZV / SFV**



**LONGITUDINALLY
CURVED
SLS**



**RECTANGULAR
RZV / SRV**



DESCRIPTION

The CUI™ Tissue Expander has been designed for temporary implantation to develop a skin flap. The device is used for reconstructive correction of a defect or to provide cover for a prosthetic implant. The CUI™ Tissue Expander consists of a silicone elastomer envelope and a remote injection port. Most expanders also have a patented fill valve for rapid interoperative inflation. The implanted expander is incrementally inflated with sterile normal saline solution at periodic intervals until the desired amount of tissue is developed.

INDICATIONS

The CUI™ Saline Fill Tissue Expander is indicated for increasing tissue area to provide for:

- Post mastectomy reconstruction.
- Scar revision procedures.
- A variety of procedures to develop an adjacent skin flap for correction of a defect.

CONTRAINDICATIONS

- Open cuts or sores at the implant site.
- Poor general patient health.
- Systemic disorders such as diabetes.
- Cardiovascular disease.
- Physiological and anatomical anomalies.
- Previous repeated contour correction failures.
- Inadequate tissue coverage.
- Tissue covering determined unsuitable by the surgeon. To varying degree, radiation damage, ulceration, compromised vascularity, or history of compromised wound healing may affect tissue covering suitability.
- Physiological condition determined by the surgeon to pose unduly high risk of surgical and /or postoperative complications. To varying degree, obesity, smoking, diabetes, autoimmune disease, coagulopathy, chronic lung or severe cardiovascular disease may affect patient suitability for surgical implantation.
- Use of drugs that may result in high surgical risk and/or significant postoperative complications, including any drug that would interfere with blood clotting.
- Psychologically unsuitable patient, including negativism or lack of understanding, motivation, or cooperation. Sensitive over or underlying anatomy.

NOTE: The above indications and contraindications are generalized. Each patient must be individually evaluated for surgery based on the medical judgement of the physician.

INFORMATION THAT SHOULD BE PROVIDED TO THE PATIENT

Tissue expansion surgery is known to provide psychological satisfaction to patients. Nevertheless, it is not without potential risks. Tissue expansion surgery is an elective procedure and the patient should be well counseled on the risk-benefit relationship.

Before the decision to proceed with surgery, Allergan relies upon the surgeon to inform the patient of the general warnings, precautions, and adverse reactions listed in this package insert, as well as any complications specific to the implant device and intended use. The surgeon should advise the patient that medical management of serious adverse reactions may include explantation.

POSSIBLE COMPLICATIONS AND WARNINGS

Possible complications associated with tissue expansion surgery are listed below. Possible complications, risks, and alternative procedures should be discussed with the patient prior to the decision to proceed with surgery. Other potential complications such as infection, poor reaction to medication/surgical procedure, hematoma, nerve damage or irritation, thrombosis of blood vessels, hypertrophic scarring, inappropriate scar location, and those other risks associated with all surgical procedures, including temporary or permanent anesthesia or hyperesthesia, are not addressed here but should be discussed with the patient.

1. TEMPORARY DEVICE:

The CUI™ Tissue Expander is a temporary device and is not intended for long term or permanent implantation. The tissue expander should be removed once adequate tissue has been developed as extended periods of implantation increase the likelihood of spontaneous deflation. Tissue expanders are typically implanted for less than 90 days.

2. CAPSULAR CONTRACTURE:

Formation of a fibrous tissue capsule surrounding the device is a normal physiological response to a foreign body. Contracture of the fibrous capsular tissue surrounding the device may result in firmness, discomfort or pain, distortion, palpability, and/or displacement of the device.

It has been suggested that postoperative hematoma can increase the probability of capsular contracture. Meticulous attention to hemostasis is recommended. In addition, it has been suggested that the presence of infection may initiate contracture.

3. DEFLATION OF TISSUE EXPANDERS:

Deflation of the expansion envelope is possible at any time and the containment of the saline cannot be guaranteed by Allergan. If leakage is suspected, the device should be removed. The patient should be informed of the deflation potential of the device prior to the decision to proceed with surgery.

Wrinkling and/or creasing of the expansion envelope is inherent to the intended use of this device and may result in weakening and deflation of the expansion envelope, especially when left underfilled for a prolonged period of time. Openings in the envelope along crease lines have been observed.

Saline leakage through the valve has been observed. Strict adherence to our INSTRUCTIONS FOR USE will help minimize such occurrences. For devices with posterior fill valves, do not store expander with fill tube in place as fill tube may form a track within the valve channel. Leakage can also occur through the injection port or connecting tubing. Leakage of unknown etiology has also been reported.

Nicking of devices during handling or in surgery can cause early or late deflation. Envelopes which have been weakened by nicking can rupture at the nick point post-operatively.

The patient should be advised that excessive manipulation or trauma could rupture the expansion envelope and cause deflation.

Though the expansion envelope is easily stretched, expansion beyond the recommended volume increases the probability of deflation.

4. BREAKAGE AT SURGERY:

Extreme care must be taken in handling to prevent damage to the device and to insure aseptic presentation. The structural integrity of the device must be verified before implantation (see PRODUCT EXAMINATION AND HANDLING). Do not implant a damaged or contaminated device.

All tissue expanders have been produced by established manufacturing techniques and under strict quality control standards. However, it is expected that there will be some breakage of devices during handling or in surgery. Utmost care must be taken to avoid contact with sharp objects. Damaged products should not be implanted.

A backup tissue expander should be available at the time of surgery in the event of damage to or contamination of the device.

5. EXTRUSION AND NECROSIS:

Stretching of skin and tissue can cause inhibition of blood supply, venous thrombosis, and tissue thinning such that skin and tissue breakdown, necrosis, sloughing, extrusion of the device or the remote fill port, and wound dehiscence can occur. Skin breakdown has been reported with the use of steroid drugs and irradiated tissue.

6. CONTAMINATION OF DEVICES:

Care must be taken to prevent possible surface contaminants such as talc, dust, and skin oils from coming into contact with the device. The expansion envelope and injection port should be inspected for contamination prior to implantation. Contaminated products must not be used.

7. ASEPTIC TECHNIQUE:

Fungal colonization in the saline fill contents of an explanted silicone tissue expander has been reported. Meticulous attention to the use of aseptic technique with regard to handling of saline solution prior to and during inflation is recommended.

8. SILICONE TO SILICONE ADHERENCE:

Reports of apparent silicone adherence upon removal of the device from its packaging have been received. This anomaly can be characteristic of silicone materials and may be resolved by gently pulling the surfaces apart. A wash of sterile saline solution over the adhered surfaces may help lubricate silicone and aid in separation.

9. REUSE OF DEVICES:

A tissue expander is a single use device. Explanted devices should not be reused. Biological residues such as blood, tissue, and other matter which could retain resistant pathogens, may not be removed by cleaning and sterilization.

10. ALTERATION OF DEVICES:

Do not attempt to repair damaged products. Alterations to the original design/fabrication should not be attempted. Unauthorized alteration of any part of the device voids all warranties, express or implied.

11. FLUID USE:

The Remote Injection Port provided with the CUI™ Tissue Expander is designed for passage of sterile normal saline. No fluid other than sterile normal saline may be injected through the Remote Injection Port.

12. INFLATION OF THE ENVELOPE:

Meticulous preparation of the skin over the injection port must be completed each time the injection port is penetrated. The physician must verify the location and proper orientation of the injection port prior to each insertion of the filling needle. Failure to do so may lead to puncture of the expansion envelope, damage to the injection port and/or subject the patient to undue trauma.

Inflation of the expansion envelope beyond the suggested fill volume should be undertaken with extreme care and increased attention to avoid trauma to the device or surrounding tissue.

Following each inflation injection, the patient should be observed for possible complications. The withdrawal of normal saline may be required if symptoms of the inhibition of blood supply to the covering tissue are detected.

Failure of the expansion envelope to inflate may result from improper placement of the filling needle into the injection port or from damage to the expansion envelope.

13. PLACEMENT OF THE DEVICE:

Care must be taken in the placement of the device in reference to the placement of the remote access port as the expansion envelope may be accidentally penetrated by needle if port is too close to the device.

14. USE OF DRUGS:

If antibiotic or steroid drug therapy is indicated, it is the individual surgeon's responsibility to insure that the drugs are compatible and efficacious when in contact with the device. Therapy which relies on the diffusion of drugs through the device wall is not endorsed by Allergan.

15. CHEST-WALL DEFORMITY:

Chest-wall flattening (deformity) has been reported with the use of tissue expanders and silicone breast implants. Pressure from expanders may cause deformation or resorption of underlying bone.

16. DISSATISFACTION WITH COSMETIC RESULTS:

Patient should be informed that dissatisfying cosmetic results such as scar deformity, hypertrophic scarring, asymmetry, and unanticipated contour may occur. Careful surgical planning and technique can minimize, but not preclude the risk of such results. Preexisting asymmetry may not be entirely correctable.

Physiological and behavioral differences among patients and variations in surgical techniques and medical treatments account for a wide variety of responses to tissue expansion surgery. Revision surgery may be indicated to maintain patient satisfaction, but carries additional considerations and risks, and should be kept to a minimum. Revision surgery may be complicated by scarring, tissue deficit, and decreased vascularity from previous surgery.

EXPANDER FEATURES

Tubing Connector

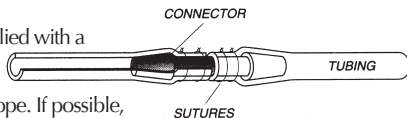
Tissue expanders with a remote injection port are supplied with a tube connector. The connector is used if the physician desires to shorten the length of the tubing connecting the remote fill port to the expander envelope. If possible, the connector should be placed an equal distance from the envelope and the remote fill port along the length of the tubing.

After cutting the tubing to the desired length, insert the connector into the tubing attached to the injection port. Do the same with the tubing attached to the envelope. Make sure that the two ends of the tubing meet in the center of the tubing connector. Sterile isotonic saline may be used as a lubricant. As a safeguard, the connection should be secured by tying non-absorbable sutures over the tubing as indicated in Figure 1.

Posterior Flat Fill Valve

Most CUI™ Tissue Expanders are supplied with a patented posterior flat fill valve for rapid filling at the time of surgery. The valve is also convenient for removing air from the expander during surgery.

FIGURE 1



A. INSERTING THE FILL TUBE INTO THE FILL VALVE

1. Gently insert the fill tube cannula into the valve by entering at the small opening in the center of the valve (See Figure 2). The valve is lubricated with a small amount of silicone lubricant to aid in the insertion of the cannula.
2. Gently push the cannula down through the valve channel until:
 - a. The tip of the cannula protrudes through the small round end of the valve within the expander; and
 - b. The tapered portion of the cannula, up to the retaining flange, is inserted into the opening of the valve. This is important as it helps to seal the valve and retain the cannula in the valve.

Caution: Care must be exercised not to damage the expander envelope or valve with the tip of the cannula during insertion.

REPEATED INSERTION OF THE FILL TUBE OR STORAGE WITH THE FILL TUBE IN PLACE MAY IMPAIR THE VALVE SEALING CAPABILITIES.

B. FILLING THROUGH THE VALVE

1. Attach a syringe filled with sterile normal saline to the Luer lock connector at the end of the fill tube.
2. Fill the expander to the desired volume.

NOTE: It is important that no fluid other than sterile normal saline be introduced into the expander through the fill tube.

3. To remove air, tilt the expander so the valve end is in pocket and aspirate the air.

C. WITHDRAWING THE CANNULA AND SEALING THE VALVE

1. Grasp the cannula near the valve opening and gently pull the cannula from the valve.
2. Firmly compress and flatten the full length of the valve channel to aid in sealing the valve. Any excess silicone lubricant may be removed from the valve opening.

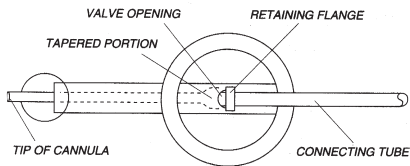
INJECTION PORTS

CUI™ Tissue Expanders are provided with one of several different injection ports, depending on the size and style of expander ordered. All dome ports are designed for self-sealing when punctured with 12 degree standard bevel needles.

A. DOME TYPE PORTS

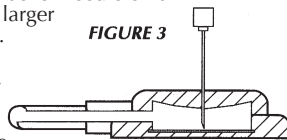
1. Use only a new 23-gauge (or smaller) 12 degree standard bevel needle on all sizes of domed injection ports. Other types of needles or larger needles may damage the injection port and prevent resealing.
2. Always try to penetrate the central port (See Figure 3).
3. With the needle perpendicular to the top surface of the port, drive the needle through the self-sealing dome until the needle stop is encountered.
4. It is recommended that no more than ten injections be made into the dome type ports. Additional punctures may reduce the sealing ability of the port.
5. The dome type ports are normally supplied with holes around the periphery of the dome for suture fixation. No other part of the port should be penetrated by needle for purposes of fixation.

FIGURE 2



FILL TUBE CANNULA IN FILL VALVE

FIGURE 3



HOW SUPPLIED

SINGLE USE

This product is for single use only

DO NOT reuse explanted products

STERILE DEVICES

Each sterile device is supplied in a sealed double primary package. See product outer box label for manufacturer method and date of sterilization. Sterility of the device is maintained only if the package seal is intact. **DO NOT** use product if the package seal has been damaged. **DO NOT** attempt to resterilize using ethylene oxide which is known to cause adverse tissue reaction if not completely removed from the implant.

PRODUCT IDENTIFICATION/PATIENT RECORD LABEL

Patient record labels accompany each device within the internal product packaging. The patient record label provides product specific information and is pressure sensitive so that the backing may be removed and the label attached directly to the chart.

INSTRUCTIONS FOR USE

SURGICAL PROCEDURE

Proper surgical procedures and techniques are the responsibility of the medical profession. Each surgeon must evaluate the suitability of the patient based upon current accepted techniques, individual judgment, and experience. Only those who intimately understand the physiology and mechanics of tissue expansion should inflate the device. The surgeon must carefully evaluate the expander size and contour, incision placement, pocket dissection, and implant placement criteria with respect to the patient's anatomy and desired physical outcome. The surgeon should observe current and accepted techniques to minimize the risk of adverse, and potentially disfiguring, reactions.

A backup expander should be available during surgery

HOW TO OPEN STERILE PRODUCT PACKAGE

Remove the expander from its package in an aseptic environment and 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 pouch.
2. Invert the outer pouch over the sterile field, allowing the sealed inner pouch to fall gently into the sterile field
3. Peel open the inner pouch.
4. Invert the inner pouch over the sterile field, allowing the expander to fall gently into the sterile field.

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

PRELIMINARY PRODUCT EXAMINATION

1. The product should be visually examined for evidence of particulate contamination or damage (see POSSIBLE COMPLICATIONS AND WARNINGS).
2. The product should be tested for leakage by filling the expander with air and immersing the entire expander in sterile normal saline. Apply gentle pressure to the main envelope and watch for any sign of continuous release of air bubbles.
3. The patency of the injection port and its connecting tube should be ascertained by placing an appropriate size needle into the injection port and introducing a small amount of sterile saline into the main envelope.
4. Do not use if there is any evidence of leakage, lack of patency, damage or contamination.

INTRAOPERATIVE FILLING

At this point in the procedure, some surgeons prefer to partially fill the product prior to placement. A small amount of fluid in the expander acts as a lubricant and aids in initial placement and expansion. The expander should have very little air in it. To remove air, tilt device so the air can be removed through the fill tube cannula or through the injection port. Any residual air will produce a sloshing sound but will ultimately diffuse through the wall of the expander.

POST-OPERATIVE PERCUTANEOUS FILLING OF DEVICE

1. Locate injection port by gentle palpation. If port location proves difficult, fluoroscopy can be used as the port is x-ray detectable.
2. Using aseptic technique, prepare skin surface in a meticulous manner over and around injection site.
3. Insert the appropriate size needle until it encounters the needle stop (See Figure 3).
4. The CUI™ Tissue Expander should be filled only with sterile normal saline. The filling is accomplished by a standard syringe filled with sterile normal saline attached to the injection needle. (Leaving the needle in place in the injection port while refilling the syringe will help to optimize the life of the device by minimizing the number of punctures to the injection port.)
5. The amount of tissue expanded, time intervals between expansions, and total duration of time is solely the responsibility of the operating surgeon.
6. Avoid overfilling more than the recommended volume.

GENERAL GUIDELINES FOR THE USE OF TISSUE EXPANDERS

1. For optimal expansion, the pocket created should be larger than the base of the device. Typically, inflations start after a period of wound healing.
2. Care must be taken to place the remote fill port the optimal distance (the length of the tubing) from the envelope to minimize accidental needle penetration of the envelope. Care should be taken not to place the injection port inferior to the expansion envelope as gravity may tend to migrate the device in that direction. To avoid a twisting action upon expansion, the base of the remote fill port should be placed on the same plane as the base of the expansion envelope.
3. Since the tissue expander is meant to be only a temporary device, removal will occur at the discretion of the surgeon and after the desired expansion has occurred.

TROUBLESHOOTING

If problems arise in the use of a CUI™ Tissue Expander, consult the following list for possible causes.

A. Cannot Locate Injection Port

If port cannot be located by palpation, fluoroscopy can be used as the port is radiopaque. Note: It may be helpful to out-line the port on the skin to aid in subsequent insufflations.

B. Cannot Inject Fluid Into The Injection Port

1. The port may have rotated so that the needle is not entering perpendicular to the center of the anterior surface. Try to correct the port orientation and reinsert needle completely to needle stop. (See Figure 3).
2. The connecting tubing may be bent or kinked so that fluid will not pass through it. Attempt to relieve tension from the tubing.
3. Material in the needle tip may be occluding the needle. Some hypodermic needles may tend to “core” the sealing material of the port. Coring occurs when the sharp edges of the needle tip slice out a small piece of the silicone seal as the needle passes through it. Such a small piece, or core, may become lodged in the needle lumen, thus restricting flow. Any material should be removed or a new needle used.

C. Cannot Fill Expander Although Fluid Is Being Injected

1. The needle may have missed the injection port. Reinsert needle until needle stop is encountered.
2. If the tubing connector was used, it is possible that there is a leak at the connector. It is recommended that the tubing connections be secured with a suture.
3. The expander envelope may be compromised thus necessitating its removal.

REPORTING AND RETURN OF EXPLANTED DEVICES

Explanted devices associated with a complaint or serious injury should be reported and returned to Allergan. In the event of such an explantation, please contact the Allergan Customer care Department at 800.766.0171 for a Return Kit and explant return information.

RETURN GOODS POLICY

Product returns should be handled through an Allergan Breast Aesthetics Business Development Manager or through the Allergan Customer care Department at 800.766.0171. Return value is based on time limitations. All package seals must be intact to be eligible for return. Returned products may be subject to a restocking charge. Certain products are non-returnable, including custom products.

LIMITED WARRANTY, LIMITATION OF LIABILITY AND DISCLAIMER OF OTHER WARRANTIES

Allergan warrants that reasonable care was used in the manufacture and production of this product. Because Allergan 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, Allergan does not warrant either a good effect or against an ill effect following its use. Allergan shall not be responsible for any incidental or consequential loss, damage or expenses directly or indirectly arising from use of this product. Allergan's sole responsibility, in the event that Allergan determines that the product was defective when shipped by Allergan, shall be replacement of the 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.

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

PRODUCT ORDERING

To order directly in the U.S.A. or for product information, please contact your Allergan Breast Aesthetics Business Development manager or the Allergan Customer care Department at 800.766.0171.

SYMBOLOLOGY

The following symbology may be used on the product label:



Attention! See Instruction for Use



Do not Reuse



YYYY-MM

Method of Sterilization: Dry Heat
Date of Sterilization: Year and Month

LOT

Batch Code (Manufacturing lot)

SN

Serial Number

REF

Product Catalog Number

QTY

Content of Product Box

STYLE

Device Style

Patented. See: www.allergan.com/products/patent_notices

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THE SCIENCE OF REJUVENATION™

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