



TISSUE EXPANDER

102921-001 Rev A Effective August 2010

DESCRIPTION

The Tissue Expander is used in a variety of procedures to develop skin flaps for defect correction. The device consists of a silicone elastomer inflatable expander with a remote silicone elastomer injection dome. The round, rectangular, elliptical and crescent-shaped expanders are available with a smooth elastomer shell. The expander and remote injection dome are for **temporary** subcutaneous or submuscular implantation **and is not intended for use beyond six months**.

The devices have a remote injection dome that is attached to the expander with a length of silicone elastomer tubing. A stainless steel connector is supplied with each of these devices for use in connecting the tubing should shortening of the tubing be desired.

All tissue expanders have polyester mesh reinforced silicone elastomer bases.

All injection sites have integral stainless steel needle guards to help prevent inadvertent needle puncture.

INDICATIONS

The Tissue Expander can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures.

CONTRAINDICATIONS

The use of this expander is contraindicated in patients who have one or more of the following conditions:

- Active infection anywhere in the body.
- Recent history of breast abscess.
- Diffuse painful cystic mastitis or breast tumor.
- Clinically persistent or recurrent cancer.
- Poor vascularization of tissue in the area where the implant is to be used.
- Other conditions which provide for abnormal stresses at the site of expansion or inadequate or unsuitable tissue.
- A history of compromised wound healing.
- A compromised immune system.
- A history of sensitivity to foreign materials or repeated attempts and failures at breast augmentation or reconstruction.
- Unsuitable tissue due to radiation damage on the chest wall, tight thoracic skin grafts or radical resection of the pectoralis major muscle.
- Any anatomic or physiologic abnormality which could lead to significant postoperative complications.
- An unwillingness to undergo any further surgery for revision.
- Psychological instability such as inappropriate attitude or motivation, or a lack of understanding of the risks involved with the surgical procedure and expander.
- The expander is contraindicated for long-term implantation.

PATIENT EDUCATION AND INFORMED CONSENT

The surgical procedures associated with the use of tissue expanders are not without potential complications and risks. The use of this product is an elective procedure. The patient should be counseled prior to surgery regarding the benefits and risks associated with tissue reconstruction utilizing both tissue expanders and alternative procedures.

It is the responsibility of the individual surgeon to decide the best method by which to counsel a patient prior to surgery. Mentor relies upon the surgeon to advise the patient of all potential complications and risks associated with the use of tissue expanders.

INSTRUCTIONS FOR USE

The Tissue Expander may be used in a variety of surgical techniques. Therefore, the surgeon is best advised to use the method which his/her own practice and discretion dictate to be best for the patient. Prior to use, test the device for structural integrity by submerging the air-filled device in nonpyrogenic, sterile fluid (water or saline). Apply gentle pressure and check for possible punctures or leakage.

Do not implant a device that shows evidence of leakage or lack of patency.

The physician may, if desired trim the tubing leading to the remote injection dome and then reconnect it using the stainless steel connector supplied with the product.

Nonabsorbable sutures should be tied around the tubing and connector (as shown in Figure 1) to secure the joint.

CAUTION: Extreme care should be taken when reconnecting the fill tube with the stainless steel connector. The tubing is easily damaged with surgical instrumentation (e.g., forceps contact). Their use should be avoided.

Incremental inflations of the device and time intervals involved should be determined by the surgeon in the best interest of the patient. Mentor recommends that injections of 10% of the maximum recommended inflation volume of the device be made at intervals of three to five days until an adequate amount of tissue is available for reconstruction. **Once expansion has been completed, the expander should be removed and is not intended for use beyond six months.** If left in place for more than six months, the formation of tissue adhesions may make it difficult to remove. **This expander is intended for short-term use only.**

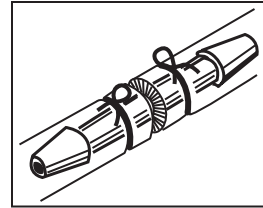


Figure 1

The following general guidelines, developed for the use of the Tissue Expander, are provided for information purposes:

When used for breast reconstruction, the device is inserted into a space centrally located in the area to be expanded, generally below the muscle fasci and below the remaining tissue. A pocket is surgically prepared adjacent to the device (generally below the axilla) into which the remote injection dome is placed.

Some surgeons prefer submuscular placement of the device for breast reconstruction. The decision to use this device submuscularly is left to the discretion of the surgeon.

Mentor recommends that the patient be wrapped superiorly with an elastic (Ace) bandage, taped laterally, and wear a surgical bra 24 hours a day to help prevent shifting of the expander.

When the device is used to develop a skin flap, it should be placed in an area near the defect to be corrected.

EXPANSION

The device may be partially inflated prior to complete closure of the wound site or may be filled after closure is accomplished. It is suggested that the injection site location be outlined on the skin for ease of identification during subsequent filling procedures.

Inflation is accomplished by using sterile, nonpyrogenic, isotonic saline, preparing the skin, and inserting a 21 gauge (or smaller) standard bevel or Huber-tip needle into the top of the injection site, perpendicular $\pm 30^\circ$ to the base (see Figure 2). A 21 gauge butterfly needle may also be used.

The injection site has a slightly raised palpation ring. Injections must be made into the area enclosed within this palpation ring. If injections are made on or outside this palpation ring, leakage can occur.

Fill slowly until the overlying tissue is expanded to the appropriate volume. Care must be taken not to overexpand the tissue beyond the recommended guidelines. Subsequent inflations should be conducted at convenient intervals (generally once every three to five days) until an adequate amount of tissue is available for reconstruction. The patient must be monitored during the expansion period to guard against such complications as sloughing, necrosis, and wound dehiscence. If, at any time, the overlying tissue exhibits any of these symptoms, the device should be reduced in volume by reversing the filling procedures to withdraw saline. If signs persist, the device must be removed.

Once the flap is developed and the defect area is prepared for grafting, the device is removed and the flap is sutured in place. A postoperative care routine must be established by the surgeon to ensure viability of the product.

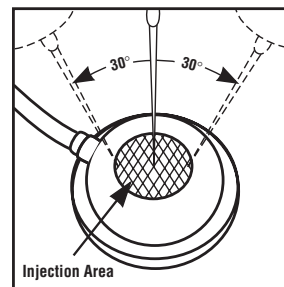


Figure 2

RECORDING PROCEDURE FOR TISSUE EXPANDERS

Each device is supplied with a patient record label showing the catalog number, style, size and lot number for the unit. This pressure-sensitive label should be attached directly to the patient's chart. The date of placement, expansion data (date and volume), and date of explant should be indicated on the label.

HOW SUPPLIED

Tissue Expanders are sterilized by Gamma Radiation. The implants are supplied individually in a **sterile and nonpyrogenic double-wrap packaging system**. The double-wrap system facilitates the preferred method of sterile product transfer from the circulating area to the sterile field. Sterility cannot be guaranteed if the double-wrap packaging system has been damaged.

This product is for **single use only**.

PRECAUTIONS

- It is the responsibility of the surgeon to advise prospective patients or their representatives, prior to surgery, of the possible complications associated with the use of this product.
- Pre-existing infection should be treated and resolved before implantation of the expander.
- Mentor is aware that a small percentage of saline-filled expanders will leak over an undefined period of time and long-term results cannot be guaranteed. Prospective patients should be made aware of the possibility of deflation. (See **ADVERSE REACTIONS** section of this insert.)
- Lint, dust, talc, surgical glove powder, drape and sponge lint, fingerprints, skin oils and other surface contaminants deposited on an expander by improper handling may cause foreign body reactions. Strict adherence to clean, aseptic techniques should be maintained to prevent contamination of the expander and possible complications. Surgical instruments and gloves should be rinsed clean of any impurities before handling the expander.
- 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. This device should not be implanted following any modifications to its original design. An expander which has been damaged, or on which repairs or modifications have been attempted, should not be implanted. **A standby expander should be available at the time of surgery.**
- The silicone elastomer shell, fill tube and injection dome or site may be easily cut by a scalpel or ruptured by excessive stress, manipulation with blunt instruments or incorrect penetration by a needle. Subsequent deflation will result. For these reasons, meticulous care must be exercised in handling, connecting and placing the device.
- Any subsequent surgical procedures in the area of the expander should be undertaken with extreme caution as damage to the expander could occur. In the event that an expander is damaged, it must be removed.
- Do not use disposable, capacitor-type cautery devices as damage to the outer shell of the expander may result.
- The tube which connects the expander to the remote injection dome should be carefully sized to avoid kinks. Careful attachment of the fill tube to the stainless steel connector is important to prevent separation. Failure of the device to inflate may be due to kinking of the tube, leakage, separation of the components or injections which do not penetrate the injection dome.
- Surgeons should ensure themselves of the position of the injection dome prior to adding or withdrawing fluid.
- Potential for contamination exists when fluid is added to or removed from the device. Use aseptic technique in the introduction of solution into the expander; a single-use, sterile saline container is recommended.

WARNINGS

It is the responsibility of the surgeon, and Mentor relies on the surgeon, to advise the patient of all potential risks and complications associated with the proposed surgical procedure and the expander, including providing a comparison of the risks and complications of alternative procedures.

- At the time of incision closure, care should be taken not to damage the device with surgical instruments. Such contact may result in immediate or delayed deflation.
- **This is a single-use product and should not be reused.**
- **This device is a temporary expander and is not intended for use beyond six months.** Wrinkling, folding and bunching of the shell are inherent characteristics of the device during the expansion process. Creases, abrasion and weakening of the shell, with subsequent deflation, can occur. Extended time intervals between injections during the serial expansion process will increase the likelihood of the above occurring. For this reason, Mentor recommends timely expansion of the device. The device should be removed upon completion of expansion and achievement of the desired result.
- Do not insert or attempt to repair a damaged or altered expander.
- The action of drugs (examples: antibiotics and steroids) in contact with the device has not been tested by the manufacturer and their use cannot be recommended. Each physician who chooses to use chemotherapeutic drugs with this expander must assure compatibility of the drug with the silicone elastomer.
- Do not introduce or make injections of drugs or other substances into the expander. Injections through the expander shell will compromise the product's integrity, causing it to leak fluid and eventually deflate.
- Surgeons should ensure themselves of the position of the injection site prior to adding or withdrawing fluid.
- Mentor relies on the surgeon to select the optimum incision and pocket size for the chosen expander design and projected volume.

- Preoperative evaluation of the expander design and expander site should include allowances for adequate tissue coverage. Pressure, force, tension and other stresses to which the expander site will be susceptible must be considered.
- The injection site should not be penetrated with a needle larger than 21 gauge as it may not reseal. **Injections should be made only into the top of the injection site or dome, perpendicular to $\pm 30^\circ$ to the base and within the raised palpation ring (see Figure 2).**
- Excessive inflation of the device may result in tissue necrosis/thrombosis.
- Sepsis, hemorrhage or thrombosis may result from the placement of any foreign object in the body.
- 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.
- Failure of the device to inflate may be due to leakage, injections which do not penetrate the injection dome, or (when included) kinking of the tubing or separation of the components.
- Any subsequent surgical procedures in the area of placement should be taken with extreme caution as damage to the device could occur. In the event the device is damaged, it must be removed.
- Leakage from the injection site can result from the use of an improper size of injection needle, injections outside of the palpation ring or excessive pressure on the overlying tissue at the expander site, resulting in back pressure directed to the injection site.
- Extreme care should be taken reconnecting the fill tube with the connector. The tubing is easily damaged with surgical instrumentation (e.g., forceps contact). Their use should be avoided. Securing ligatures must not be placed so snugly around the connector tubing junctions as to damage the tubing.
- Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist, it is recommended that the device not be used until the bleeding is controlled.
- If a physician treats a hematoma or serous fluid accumulation by aspiration, or if a biopsy or lumpectomy is performed, care must be taken to avoid damaging the expander. These procedures present possible risk of expander puncture.
- The incidence of extrusion of the expander 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.
- Excessive fibrous capsular formation or contracture may occur around any expander placed in contact with soft tissues. The incidence and severity of this occurrence may increase if postoperative local hematoma or infection occurs.
- The physician should use personal discretion when deciding to use these expanders regarding patients who exhibit psychological instability.
- It is possible for a granuloma to form around a tiny amount of silicone. Although these lumps are noncancerous, they can be difficult to distinguish from cancerous lumps without being removed (biopsied) and examined.
- The FDA believes there is currently inadequate research on the relationship, if one exists, between birth defects and silicone devices. Manufacturers will be conducting further studies on this issue to submit for FDA review.
- Surgical implantation of the expander in the breast region may interfere with the ability to breast feed. However, it should be noted that previous breast reconstruction surgery, such as mastectomy, may be the initial cause of this interference.

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 Mentor relies on the surgeon, to provide the patient with this information and to weigh the risk/benefit potential for each patient.

Complications which may result from the use of this product include the risks associated with the medication and methods used in the surgical procedure as well as the patient's degree of intolerance to any foreign object placed in the body. The complications may include, but are not limited to, the following:

Capsule Formation and Contracture

- Postoperative formation of a fibrous tissue capsule around an implanted device is a normal physiologic response to the implantation of a foreign object. Capsule formation occurs in all patients in varying degrees. Capsules range from thin to heavily-thickened.

- Contracture of the fibrous capsule may occur, independent of its thickness. Discomfort, pain, excessive tissue firmness and misshapen expanded tissue, deflation, increased palpability and wrinkling and/or displacement of the expander may occur and may require surgical intervention. In some patients, tissue firmness may recur subsequent to corrective surgical procedures.

Deflation of the Expander

Mentor is aware that a small percentage of tissue expanders will deflate because of leakage over an indefinite period of time (see **PRECAUTIONS** section of this insert). Causes of deflation of saline-filled expanders include, but are not limited to, the following events:

- Crease fold flaw.
- Intraoperative or postoperative trauma.
- Excessive stresses or manipulations as may occur during normal, daily routines such as vigorous exercise, athletics, routine manual massage and intimate physical contact.
- Mechanical damage prior to or during surgery.
- Leakage from the fill tube or injection dome.
- Overfilling the device. The filling specifications must be followed.
- Damage from surgical instruments.
- Use of too small an incision for introduction of the device.
- Damage to the expander during the injection/filling stage.
- Closed capsulotomy.
- Shell abrasion.
- Capsular contracture.
- Origins which are simply unknown.

NOTE:

The usual correction is a replacement procedure. Patients should be informed prior to surgery of the potential for deflation.

Infection

- Infection, manifested by swelling, tenderness, pain and fever, may appear in the immediate postoperative period or at any time after insertion of the device. In the absence of classic symptoms, subacute or chronic infections may be difficult to diagnose. If infection does not subside promptly with the appropriate treatment, removal of the device is indicated.

Extrusion of Expander/Interruption of Wound Healing

- Skin necrosis and/or sloughing may result from undue tension of the skin overlying the expander, trauma to the skin during surgical procedures or inadequate tissue thickness inhibiting circulation. Subsequent exposure and/or extrusion of the expander may occur.
- Displacement, twisting, fracture or extrusion may occur from improper expander sizing and/or placement, e.g., when the expander is too large or the pocket too small or when there has been inadequate preoperative assessment of stresses causing movement of the expander.
- The incidence of extrusion of the expander has been shown to increase when the expander has been placed in injured areas: scarred, heavily irradiated or burned tissue or crushed bone areas; where severe surgical reduction of the area has been performed; and where steroids are used in the surgical pocket.

Hematoma

- Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist, it is recommended that the device not be used until bleeding is controlled.
- Gross postoperative hematoma, manifested by enlargement, tenderness and discoloration of tissue may, if untreated, lead to extrusion of the device.

Fluid Accumulation

- Excessive postoperative fluid accumulation and transient reaccumulation of fluid around the expander as a result of trauma and after vigorous exercise have been reported.

Dissatisfaction With Cosmetic Results

- Incorrect expander size, inappropriate scar location or appearance and misplacement or migration of expanders may interfere with a satisfactory cosmetic result. These complications are generally associated with the surgical procedure and technique.

POSSIBLE REACTIONS TO SILICONE AND THERMOPLASTIC ELASTOMER**Introduction**

This text contains a brief summary of information from the medical literature. The following information is mainly derived from literature and studies based on mammary implants but may also be relevant to other implants, prostheses and devices composed of like materials.

Mentor recognizes that the information contained within this text is highly technical. However, medical ethics and practice dictate that the physician must be an intervening party between the manufacturer of prescriptive medical devices and the patient. In light of the foregoing, Mentor provides this text as an overview of current information to assist the physician in obtaining informed consent from the patient.

The issue of the possible relationship between silicone (and other implantable materials) and various diseases has been and continues to be the subject of great scientific and medical debate.

Articles continue to be published on a regular basis on this subject. Because of the dynamic nature of this issue, and because product information supplied by Mentor can only reflect a summary of information as of a specific point in time, Mentor reminds the surgeons of their independent responsibility to keep abreast of scientific developments relating to devices they are prescribing and to provide prospective patients with the most up-to-date information.

The association between silicone and other thermoplastic elastomers (hereafter "silicone") and the following complications has not been verified by controlled scientific studies. However, there have been case reports in the medical literature associating these complications with silicone implants and devices. Toxicity studies are currently in progress by various research facilities, universities, government agencies, the medical community and the medical device industry. Some of these studies are conducted in animal models to determine potential immunotoxicity and autoimmune issues related to silicone materials. There is a potential that in the animal models being studied, immunotoxicity may result. The clinical significance of some of these studies has not been determined.

IMMUNOLOGICAL AND NEUROLOGICAL RESPONSE

The medical literature has raised the possibility that there may be an association between certain immunological-based diseases and silicone implants. The diseases most commonly mentioned include scleroderma, rheumatoid arthritis and syndromes which mimic systemic lupus erythematosus. Available information does not permit precise quantification of risk. Neurological problems have been reported in a small number of breast implant patients who also exhibit immunological symptoms. These reports do not prove a link between the implants and immunological or neurological problems.

NOTE: If an immunological response is suspected, the physician must evaluate the necessity of removing the implant. Limited observations suggest that removal of silicone breast implants may alleviate symptoms in some patients who have developed rheumatic disease; however, this is not predictable (American College of Rheumatology 3/91.) The long-term effects of silicone in terms of immunological responses are currently unknown.

Connective Tissue Disorders

The term, Connective Tissue Disorders, has been used to describe a variety of symptoms thought to be related to silicone breast implants. Symptoms include, but are not limited to: skin lesions, alopecia, pyrexia, rash, swelling of joints, weight loss, chronic arthropathy, morphea, arthritis, general malaise and keratoconjunctivitis. Some cases of these disorders have been reported in women with breast implants, and some of these women have reported a reduction in symptoms after their implants were removed. Manufacturers are sponsoring large-scale scientific studies to explore whether a possible link exists between silicone breast implants and connective tissue disorders; however, to date there is no evidence to suggest that the prevalence of these disorders is greater among women who have received silicone implants than among the general age-matched female population.

BIOCOMPATIBILITY

Reports in the medical literature suggest that host biocompatibility responses may be affected by different biomedical polymers by altering fibroblast production and function, and selectively modulating monocyte/macrophage activity and induction of Interleukin 1 (IL1).

DEGRADATION/TOXICITY

The medical literature suggests that in vivo degradation and particle shedding of silicone elastomers may occur in the fibrous capsule and draining lymph nodes. Further research is being undertaken to determine the effects of enzymatic degradation and the possibility of extract toxicity.

TUMOROGENICITY/CARCINOGENICITY

Case reports in the medical literature have associated tumors with the presence of silicone mammary implants. During the past two decades of clinical use, the medical literature generally indicates silicone mammary prostheses are not carcinogenic. However, the long-term biological effects of silicone are currently unknown.

REPRODUCTIVE AND TERATOGENIC EFFECTS

Preliminary animal studies show no evidence that birth defects are caused by silicone implants. Further scientific studies are necessary to show an association in humans between silicone implants and birth defects.

Breast Feeding

Although any breast surgery, including breast implants, could theoretically interfere with a woman's ability to nurse, many women with breast implants have nursed their babies successfully. It is not known if silicone from gel-filled implants or other sources, such as certain medications, can infiltrate breast milk or affect a child. Further studies will provide more information about these risks.

TOXIC SHOCK SYNDROME

Toxic Shock Syndrome (TSS) has been reported as a complication of tissue expansion and of both augmentation and reconstructive mammoplasty and may be associated with other types of silicone implants. Symptoms of TSS include, but are not limited to: sudden fever, vomiting, diarrhea, fainting, dizziness and/or a sunburn-like rash.

Mentor relies on the surgeon to advise the patient of all potential risks and complications associated with a proposed surgical procedure and device, including a comparison of the risks and complications of alternative procedures and implants.

OTHER

- Thrombosed veins, resembling large cords, have temporarily developed in the area of the device and have resolved without surgical or medical therapy.
- Pain from an improperly sized and/or placed implant, such as from compression of nerves or interference with muscle movement, may occur.
- Kinking or separation of tube can occur.
- Hypertrophic scarring has been reported.
- The expander may become difficult to explant if the degree of tissue adhesion is significant.

PRODUCT EVALUATION

Mentor requests that any complications and/or explantations resulting from the use of this device be brought to the immediate attention of the Product Evaluation Department at Mentor, 3041 Skyway Circle North, Irving, TX 75038. If explantation is necessary, Mentor will analyze the explanted device, and the patient and physician will be asked to allow Mentor to perform tests that might alter the condition of the device.

RETURNED GOODS AUTHORIZATION**U.S. Customers**

Merchandise returned must have all manufacturer's seals intact and be returned within 60 days from date of invoice to be eligible for credit or replacement. Please contact the Mentor Customer Service Department for details. Returned products may be subject to restocking charges.

International Customers

Authorization for return of merchandise should be obtained from your respective dealer. Other conditions noted above also apply.

PRODUCT INFORMATION DISCLOSURE

Mentor expressly disclaims all warranties, whether written or oral, statutory, express or implied, by operation of law or otherwise, including, but not limited to, any implied warranties of merchantability, fitness or design. Mentor shall not be liable for any direct, incidental or consequential loss, damage or expense, directly or indirectly arising from the use of this product. No representation or other affirmation of fact, including but not limited to statements regarding suitability for use, or performance of the product shall be or be deemed to be a warranty by Mentor for any purpose. Mentor neither assumes nor authorizes any other or additional liability or responsibility in connection with this product.

PRODUCT ORDER INFORMATION**U.S. Customers**

To order directly in the USA or for information on Special Order Devices, please contact the Customer Service Department at Mentor, 201 Mentor Drive, Santa Barbara, CA 93111. Toll-free telephone (800) 235-5731. FAX (805) 967-7108.

International Customers






For product information or to order directly, contact your local Mentor products distributor or the International Customer Service Department at Mentor, 201 Mentor Drive, Santa Barbara, CA 93111, USA. Telephone (805) 879-6000. FAX (805) 967-7108.





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






REFERENCES

Literature references are available upon request from:

Mentor • Marketing Services, Literature Department • 3041 Skyway Circle North • Irving, TX 75038 USA

	Nominal Dimensions
	Minimum Dimensions
	Quantity
	Style
	Style: nnnn Round
R <input type="checkbox"/> <input type="checkbox"/> L	Breast: Right (or) Left

	Do not resterilize
	Latex free
	Not returnable if opened
	Fluid added
	Date

	Minimum Volume final (cc)
	Maximum Volume final (cc)
	The enclosed device is sterile and nonpyrogenic (unless the package has been opened or damaged).
	For customer service or to return product, please call (800) 235-5731 in USA; or outside of USA, call (805) 879-6000, or contact your local representative.
	Warning: Use only a 21 gauge or smaller needle when adding or withdrawing fluid through the reservoir.



For customer service, please call (800) 235-5731 in USA; or outside of USA, call (805) 879-6000, or contact your local representative.

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