

## CPX3 CONTOUR PROFILE® TISSUE EXPANDER WITH SUTURING TABS

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

102924-001 Rev. A Effective August 2010

### DESCRIPTION

The CONTOUR PROFILE® Tissue Expander with suturing tabs (CPX3) is used for breast reconstruction following mastectomy. In order to provide a Tissue Expander with elasticity and integrity, the shell is made with successive cross-linked layers of silicone elastomer. Superior and anterior reinforcement allows for directional expansion in the lower pole of the device. The device has an integral, silicone elastomer, magnetically detected, injection site, and incorporates a BUFFERZONE® area with self-sealing technology (containing silicone oil) to the front patch of the device in order to minimize and/or prevent device leakage in the event of an accidental needle puncture. The SILTEX® Textured shell provides a disruptive surface for collagen interface. The suturing tabs allow the surgeon the option to attach the device to surrounding tissue to enhance device stability. The tabs can be sutured on any part of the surface or the suturing hole can be utilized for added convenience. The expander is intended for **temporary** subcutaneous or submuscular implantation **and is not intended for use beyond six months.**

Identification of the injection port site can be accomplished by use of either the CENTERSCOPE® Magnetic Detection Device provided with the Tissue Expander, The Detector™, or by palpation of the raised outer ring of the injection port. To use the CENTERSCOPE® Magnetic Detection Device or The Detector™, follow the instructions provided with the specific port detection device. Injections must be made using sterile, pyrogen-free Sodium Chloride U.S.P. Solution for Injection and into the area enclosed within the palpation ring. If injections are made on or outside this palpation ring, leakage can occur.

### INDICATIONS

It is the responsibility of the surgeon to advise the prospective patients or their representatives, prior to surgery, of the indications associated with the use of this product.

The CONTOUR PROFILE® Tissue Expander can be utilized for breast reconstruction after mastectomy, correction of an underdeveloped breast, scar revision and tissue defect procedures. The device is intended for temporary subcutaneous or submuscular implantation and is not intended for use beyond six months.

### CONTRAINDICATIONS

It is the responsibility of the surgeon to advise the prospective patients or their representatives, prior to surgery, of the contraindications associated with the use of this product.

Patient Groups in which the product is contraindicated:

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

- Implanted devices such as pacemakers, drug infusion devices, artificial sensing devices, etc., that would be affected by a magnetic field.
- Active infection anywhere in the body.
- Existing malignant or pre-malignant breast cancer without adequate treatment

*Surgical practices in which product use is contraindicated due to compromise of product integrity:*

- Do not alter the expander shell or valve.
- Do not place drugs or substances inside the implant other than sterile saline for injection.
- Do not allow the device to come into contact with Betadine®

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NOTE: The satisfactory use of this Tissue Expander for tissue replacement following mastectomy or trauma may require special reconstructive procedures.

## **WARNINGS**

It is the responsibility of the surgeon to advise the prospective patients or their representatives, prior to surgery, of the possible warnings associated with the use of this product.

1. *Magnetic Fields*

- DO NOT use the CONTOUR PROFILE® Tissue Expander in patients that have a previously implanted device that could be affected by a magnetic field. MRI is not to be used on a patient implanted with this device because movement of the device could occur causing patient pain or lead to displacement of the tissue expander which could require revision surgery.

2. *Radiation Therapy*

- Mentor has not tested the in-vivo effects of radiation therapy with the device and cannot warrant the safety of such use. The decision regarding the use of the device in patients about to undergo radiation therapy should be made by the surgeon and the radiation oncologist.

3. *Extrusion of the Device*

- The incidence of extrusion of 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.

4. *This device is a temporary expander.*

- The expander is not intended for use beyond six months.

5. *Reuse*

- Tissue Expanders are for single use only. Do not resterilize.

6. *Avoid Damage During Surgery*

- Care should be taken to prevent damaging the device with surgical instruments.
- Do not insert or repair a damaged expander.
- Use care in subsequent procedures such as tissue expansion, open capsulotomy, breast pocket revision, hematoma seroma aspiration, and biopsy/lumpectomy to avoid damage to the implant shell or valve.
- Do not contact the implant with disposable, capacitor-type cautery devices.

7. *Proper Filling*

- Surgeons should ensure themselves of the position of the fill dome prior to adding or withdrawing fluid. Needle punctures on or outside the palpation ring of the device may penetrate the shell causing deflation or compromise the fill dome and necessitate replacement of the device. Although the device has a self-sealing BUFFERZONE® area around the injection dome, DO NOT ATTEMPT TO INJECT INTO THE AREA AROUND THE DOME, as damage to the device may occur.
- Mentor relies on the surgeon to select the optimum incision and pocket size for the chosen expander design and projected volume.

## 8. *Suturing Safety*

- Take care when suturing the device into place. Avoid puncturing the tissue expander's shell during implantation and placement. If the tissue expander's shell should become compromised, remove the implant and replace it with a new one.
- The injection dome 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 dome, perpendicular to  $\pm 30^\circ$  to the base and within the raised palpation ring.
- Excessive inflation of the device may result in tissue necrosis/thrombosis.
- Failure of the device to inflate may be due to leakage or injections which do not penetrate the injection dome.
- Leakage from the injection dome 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 backpressure directed to the injection site.

### *Instructions to Patient*

- 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.

## **PRECAUTIONS**

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

## **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 procedures 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:

### **Additional Surgeries**

- Additional surgery will be required to either replace a deflated tissue expander and/or to complete the breast reconstruction procedure.

### **Cancer**

- Published studies indicate that breast cancer is no more common in women with implants than those without implants.

### **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.

### **Complications of Tissue Expansion**

- Tissue thinning or necrosis.
- Sloughing of poorly vascularized tissue.
- Gross postoperative hematoma, manifested by enlargement, tenderness and discoloration leading, if untreated, to extrusion of the device.
- Undue pressure on the tissue located over the device or trauma to surrounding tissues which may lead to venous thrombosis, the breakdown of skin over the device and subsequent extrusion. Deflation or removal of the device may be necessary for tissue repair.

### **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, was 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.

### **Deflation/Rupture/Leakage**

- Saline-filled tissue expanders deflate when saline solution leaks through an unsealed or damaged valve or through a break in the implant shell. Implant deflation can occur immediately or progressively over a period of days and is noticed by loss of size or shape of the implant. Additional surgery is needed to remove deflated implants.

**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.

**Extrusion of Expander/Interruption of Wound Healing**

- Skin necrosis and/or sloughing may result from undue tension on 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 is 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.

**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.

**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.

**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 Tissue Expander is indicated.
- Toxic Shock Syndrome has been reported as a complication of both augmentation and reconstructive mammoplasty.

**Pain**

- Pain may be felt of varying severity (degrees) and duration (length of time) during the tissue expansion process.

**Wrinkling of the Tissue Expander**

- Surgeons have reported that in some patients, visible or palpable wrinkling of the envelope, usually associated with textured prostheses, has occurred. Folds in the envelope can be visible beneath the overlying skin. This is reported to occur more frequently with: thin-skinned patients with little or no subcutaneous fat; subglandular rather than submuscular placement; a Tissue Expander that is too large relative to the pocket size or frame of the patient; overlying tissue that is minimal or of poor quality; or where there is contracture and/or insufficient fill volume.

## **RECORDING PROCEDURE FOR TISSUE EXPANDERS**

Each device is supplied with a patient record label showing the catalog number and lot number for that unit. One of these pressure sensitive labels 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.

### **Sterilization**

Tissue expanders are provided sterile. The product is dry heat sterilized and is for single use only. Do not resterilize.

### **Implant Selection**

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

- The expander should not be too small or too large in comparison to the patient's chest wall dimensions.
- Available tissue must provide adequate coverage of the device.
- Submuscular placement of the expander may be preferable in patients with thin or poor quality tissue.
- A well-defined, dry pocket of adequate size and symmetry must be created to allow the implant to be placed flat on a smooth surface.
- Avoid too small of an incision.

## **TESTING PROCEDURE FOR TISSUE EXPANDERS**

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

1. Using a 21 gauge or smaller needle, partially inflate the device with air through the injection port.
2. Submerge the air-filled prosthesis in sterile, pyrogen-free testing fluid (water or saline).
3. Apply mild pressure and check for possible punctures or leaks.

## **MAINTAINING HEMOSTASIS/AVOIDING FLUID ACCUMULATION**

Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist, the implantation of the device should be delayed until bleeding is controlled. Postoperative evacuation of hematoma or seroma must be conducted with care to avoid expander contamination, or damage from sharp instruments.

## **MENTOR INJECTION PORT DETECTOR**

### **Instructions For Use**

Using sterile technique, remove the CENTERSCOPE® port detector from the sterile pouch. Grip The Detector™ with either hand, ensuring that the free-swinging magnetic arm is pointing away from the hand holding it. Place the base of the unit (the flat side) on the patient. Move the unit in a circular motion until the magnetic arm detects (points towards) the location of the injection dome. Follow the direction that the arm points towards until the arm is pointing straight towards the hole in the base of The Detector™ (the target). When the arm is centered perfectly in the target, the injection site has been located.

To mark the site for injection, follow one of these three options:

**Option 1:** With the magnetic arm centered in the target, make a mark with an ink pen in each of the three notches around the anterior perimeter of the base. Next, make a fourth mark in the hole located behind the magnetic arm that runs through the center base of The Detector™. After all four marks have been made, lift the device from the patient. Using the same pen, carefully connect the opposing dots with a line, creating an injection 'crosshair'. Then, make a clear mark at the point where the two perpendicular lines intersect. This point is your injection site.

**Option 2:** With the magnetic arm centered in the target, gently but firmly press the device against the patient. Hold for several seconds. Lift the device from the patient. The raised 'X' on the bottom of The Detector™ will leave a clearly imprinted 'crosshair' mark on the patient's skin. Mark the center of the crosshair with a pen. This point is your injection site.

**Option 3:** Utilize a combination of options 1 and 2 for further confirmation of the best point for injection.

### **TISSUE EXPANDER FILLING PROCEDURE**

To inflate the tissue expander;

1. Identify the injection port site using either the CENTERSCOPE® Magnetic Detection Device included with the expander, Detector™, or by palpating the raised outer ring of the injection port.
2. Once the center of the port has been identified, a skin marker can be used to identify the area of injection.
3. Inflation is accomplished by premarking the skin, 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 (a 21 gauge butterfly needle may also be used), and filling the device using sterile, pyrogen-free Sodium Chloride U.S.P. Solution for Injection.
4. Injections must be made into the area enclosed within the palpation ring. If injections are made on or outside the palpation ring, leakage can occur. Although the device has a self sealing feature around the area of the injection dome, DO NOT ATTEMPT TO INJECT OUTSIDE THE DOME AS LEAKAGE MAY OCCUR.

### **SUTURE**

Mentor does not recommend any specific type of suturing material for placement of the device. This is left to the surgeon to decide what is appropriate with his/her technique and for the patient.

### **POSTOPERATIVE CARE**

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 implant.

### **DEVICE RETRIEVAL EFFORTS**

Mentor requests that any explanted devices be sent to Mentor, Product Evaluation Department, 3041 Skyway Circle North, Irving, TX 75038 USA for examination and analysis.

### **PRODUCT EVALUATION**

Mentor requires that any complications or explantation 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 USA.

## 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 local Mentor representative. Other conditions noted above also apply.

## PRODUCT ORDER INFORMATION

To order directly in the USA, please contact the Mentor 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 representative.

















## REFERENCES

Literature references are available upon request from:

Mentor Marketing Services, Literature Department

201 Mentor Drive

Santa Barbara, CA 93111 USA

 <b>NOM. DIM.</b>	Nominal Dimensions		Do not resterilize	 <b>MIN. VOL.</b>	Minimum Volume final (cc)
 <b>MIN. DIM.</b>	Minimum Dimensions		Latex free	 <b>MAX. VOL.</b>	Maximum Volume final (cc)
 <b>QTY 1</b>	Quantity		Not returnable if opened	 <b>STERILE &amp; NONPYRO</b>	The enclosed device is sterile and nonpyrogenic (unless the package has been opened or damaged).
 <b>S</b>	Style		Fluid added		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.
 <b>S</b>	Style: nnnn Round		Date		Warning: Use only a 21 gauge or smaller needle when adding or withdrawing fluid through the reservoir.
<b>R</b>  <b>L</b>	Breast; Right (or) Left				



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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