



156000-01

PRODUCT INSERT DATA SHEET

ENGLISH

SILTEX™ BECKER™ EXPANDER/BREAST IMPLANTS

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DESCRIPTION

Each implant in the MENTOR® SILTEX™ BECKER™ Expander/Breast Implant family of devices has a low-bleed, gel-filled outer lumen and an adjustable saline-fillable inner lumen. The resulting devices combine the advantages of tissue expanders with the feel of a gel breast implant. In order to provide a prosthesis with elasticity and integrity, the outer and inner shells are made with successive cross-linked layers of silicone elastomer. The textured SILTEX™ shell provides a disruptive service for collagen interface. The silicone elastomer fill tube is pre-inserted into the dual self-sealing valve system at the time of manufacture and is joined to the injection dome by the connector system at the time of surgery. Two types of connector systems and injection domes are provided with each BECKER™ product and either may be used. The inner lumen can be gradually filled with saline over an extended period of time via the fill tube and injection dome. Once expanded to the desired volume, the fill tube and injection dome are removed through a small incision under local anesthetic, and the prosthesis remains in position as a breast implant.

The saline-filled inner lumen of the SILTEX™ BECKER™ Expander/Breast Implant provides the physician with the ability to control, within specified limits, the amount of expansion desired.

Options Included

Each prosthesis is supplied with a choice of two connector systems and a choice of two injection domes.

1. Connector Systems:
 - The MENTOR® TRUE-LOCK™ Connector does not require a suture tie. (See the "TRUE-LOCK™ Connector" section provided in the connector and dome package.)
 - The stainless steel connector does require suture material tied around tube and connector to secure the connection. (See **INSTRUCTIONS FOR USE** section of this insert.)
2. Injection Domes (used for temporary subcutaneous implantation):
 - The **micro injection dome** may be used when diminished palpability is desirable. This dome is designed to withstand up to 10 total injections. It is suggested that the dome be placed in a relatively superficial location to allow ease of identification and access during subsequent filling procedures. Inflation is accomplished by using sterile isotonic saline. Use a 23-gauge (or finer) standard or butterfly 12° bevel needle. **Extreme care should be taken to puncture only the center of the top surface of the micro injection dome** (Figure 1).
 - The **standard injection dome** is larger in diameter and height than the micro injection dome and can withstand up to 20 total injections.

See figure 1.

Options Available

SILTEX™ Round BECKER™ 25 Expander/ Breast Implant Cohesive I™	SILTEX™ Round BECKER™ 50 Expander/ Breast Implant Cohesive I™	SILTEX™ CONTOUR PROFILE™ BECKER™ 35 Expander/ Breast Implant Cohesive II™
Gel volume 25 percent nominal implant size. Cohesive I™ (standard) gel filling material. Indicated for temporary overexpansion. (see Table 1)	Gel volume 50 percent nominal implant size. Cohesive I™ (standard) gel filling material. Not indicated for temporary overexpansion. The maximum Temporary Volume is identical to the Maximum Final Volume. (see Table 2)	Gel volume 35 percent nominal implant size. Cohesive II™ (moderate) gel filling material. Indicated for temporary overexpansion. (see Table 3)

INDICATIONS

This prosthesis may be used in the case of one or more of the following indications:

- Cosmetic augmentation. The European Parliament "recommends that implants in women under 18 years of age should be authorized only on medical grounds."
- Immediate or delayed breast reconstruction following mastectomy.
- Reconstruction due to cancer treatments other than mastectomy.
- Revision due to complications or other undesirable results of a previous surgery for mastectomy or cancer treatments other than mastectomy.
- Post-Trauma defined as a total or partial removal of the breast(s) through surgery (for any reason) or as a result of the trauma itself.
- Congenital deformities: Pectus Excavatum defined as congenital concave chest-wall deformity with abnormalities of the sternum and anterior ribs; Pectus Carinatum defined as congenital convex chest-wall deformity with abnormalities of the sternum and anterior ribs; and severe asymmetry defined as congenital or acquired substantial discrepancy in breast sizes such as to represent a significant physical deformity (e.g., Poland's syndrome).
- Severe ptosis defined as requiring a specific reconstruction procedure (e.g., mastopexy).
- Patients who require revision for implant replacement for severe deformity caused by medical or surgical complications, regardless of original indication for implantation or type of device originally implanted.
- Patients who require augmentation mammoplasty in the unaffected breast as a result of the surgery, due to one of the above indications, in the affected breast (e.g., unilateral mastectomy with augmentation to opposite breast to provide symmetry).
- Replacement or revision for patients whose prior surgery was not a result of treatment for cancer and for whom saline implants are unsuitable (e.g., skin too thin, insufficient tissue, etc.) as deemed by the surgeon.

- Determined by a physician not to be a candidate for saline-filled breast implants, due to skin being too thin, insufficient tissue, etc.

CONTRAINDICATIONS

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

- An active infection anywhere in the body.
- Recent history of breast abscess.
- Diffuse painful cystic mastitis or breast tumor.
- A history of compromised wound healing.
- A compromised immune system.
- Persistent or recurrent breast cancer.
- Pregnancy or nursing mothers.
- Lupus (e.g., SLE and DLE).
- Scleroderma (e.g., progressive systemic sclerosis).
- Uncontrolled diabetes or other disease which impacts healing.
- Unsuitable tissue due to radiation damage on the chest wall, tight thoracic skin grafts, or radical resection of the pectoralis major muscle.
- Compromised vascularity.
- A history of sensitivity to foreign materials or repeated attempts and failures at breast augmentation or reconstruction.
- 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 prosthesis.

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

BENEFITS

Breast Augmentation is a surgical procedure that allows the size of the breasts to be increased for aesthetic reasons.

Breast Reconstruction is a surgical procedure to replace breast tissue that has been removed because of cancer or injury, or to replace breast tissue that has failed to develop properly because of a severe breast abnormality.

PATIENT EDUCATION AND INFORMED CONSENT

The surgical procedures associated with the use of tissue expanders and breast implants 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 possible risks associated with tissue reconstruction and/or breast augmentation using tissue expanders, breast prostheses and alternative procedures. Patients should be advised that breast implants should not be considered lifetime implants and that revision surgery may be necessary including implant removal or replacement. The surgeons in the European Community (EC) member states and Australia are required to provide each prospective patient with the Mentor patient brochure titled: "Gel-Filled Breast Implant Surgery: Making an Informed Decision." The purpose of this brochure is to assist patients in making informed decisions about breast augmentation and breast reconstructive surgery. A Patient Signature Form is provided in the back of the patient brochure for this product. For patients in the EC member states and Australia, the patient brochure must be read, understood and the Patient Signature Form must be signed by the patient prior to surgery.

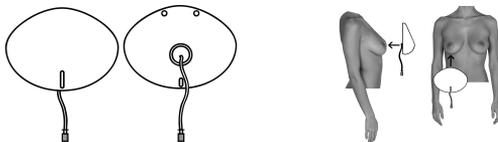
It is the responsibility of the individual surgeon to decide the best method by which to counsel a patient prior to surgery. Mentor relies upon the surgeon to advise the patient of all potential complications and risks associated with the use of breast implants.

After surgery, surgeons in the EC member states and Australia are to provide the patient with the Patient ID Card with information on the implant(s) used. Labels are supplied with the implant to be applied to the Patient ID Card. Patients should be advised to carry the patient card to facilitate medical care in case of emergency.

Following surgery, the surgeon should inform the patient of necessary postoperative office visits and the need to continue to consult a physician for routine examinations to detect for breast cancer. Patients should be advised to inform a physician or surgeon of the presence of an implant if any surgery of the breast area is scheduled, and to consult a physician or pharmacist before the use of topical medicines such as steroids in the breast area. In addition, the patient should be instructed to contact her surgeon should she experience any problem related to her breast implants.

INSTRUCTIONS FOR USE

The implantation of gel-filled prostheses or tissue expanders for breast reconstruction or augmentation involves 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.



156000-01

Implant Selection

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

- The implant 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 implant.
- Submuscular placement of the implant 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.

NOTE: It is advisable to have more than one size mammary implant in the operating room at the time of surgery to allow for flexibility in determining the appropriate size implant to be used. A backup implant should also be available.

Reports in the medical literature suggest that prophylactic antibiotic treatment may be indicated during subsequent dental or other surgical procedures for patients with some type of silicone implants.

Patients should be specifically questioned regarding a medical history involving any type of allergic reactions to any of the implant materials or filling agents.

Testing Procedure for SILTEX™ BECKER™ Expander/Breast Implants

The device should be tested for patency and shell integrity immediately prior to use. Partially inflate the device with air or saline through the fill tube, taking care not to damage the tube. Visually inspect the device for leakage and for any compromise of the outer shell, using firm hand manipulation. Remove any air from the device prior to filling.

See figure 2.

Filling and Connection Procedure

1. Prior to inserting the prosthesis into the surgically prepared pocket, deflate the device completely via the two-way check valve. The two-way check valve opens when a syringe is attached, and closes when the syringe is removed. The luer adapter and check valve are used to facilitate intraoperative filling of the device, and **must not be implanted** (see Figure 2).
2. Before connecting the fill tube to the injection dome, trim the device and discard the luer adapter and check valve. Connect the fill tube to the desired injection dome using one of the connectors supplied. Care should be taken to tailor the length of the tube so that it will not kink or shorten as the implant expands.

NOTE: If using the **stainless steel connector**, nonabsorbable suture material should be tied around the tube and connector (Figure 3) to secure the connection. It is important to **securely tie the fill tube both distally and proximally to the connector** so the entire fill tube assembly will be removed when the injection dome is removed from the patient. Care must be taken to secure the tube to the connector with ligatures in such a manner as to avoid cutting or occluding the tube or connector.

Caution: The use of forceps or hemostats to aid in the connection and suture tying process is specifically contraindicated as tube or connector damage may lead to deflation and/or rupture of the device.

See figure 3.

Instructions for use of the TRUE-LOCK™ Connector are included in the connector and dome package. Read these instructions carefully before using this connection system. It is important to securely assemble both sides of the fill tube to the connector so that the entire fill tube assembly will be removed when the injection dome is removed from the patient. (See **PRECAUTIONS** section of this insert.)

3. The following instructions for implanting the **SILTEX™ Round BECKER™ 25 Expander/Breast Implant** as a reconstructive implant have been provided by Dr. Hilton Becker for informational purposes only.¹ Instructions for the SILTEX™ Round BECKER™ 50 Breast Implant follow:
 - An incision is made through the serratus anterior muscle at the level of the 6th to 7th rib. A large pocket is dissected in the submuscular space behind the pectoralis major muscle and is extended beneath the insertion of the rectus abdominus muscle.
 - The deflated implant is placed in the submuscular space and saline is injected through the fill tube by a syringe to the point where the implant takes up the slack skin. This usually does not exceed one-third of the total designated fill volume of the implant, depending on the amount of skin available and the circulation to the skin. If the circulation appears to be compromised, no additional saline should be added at this stage.
 - The injection dome is then attached to the fill tube using the TRUE-LOCK™ Connector. The injection dome is secured in a subcutaneous pocket adjacent to the device (generally below the axilla). Care must be taken to tailor the tube length to the patient so that it will not kink or shorten as the implant expands. The skin flaps are approximated and sutured in layers.
Caution: Postoperative filling of the implant is started as soon as viability of the skin flaps is assured, usually within the first few days postoperatively. If the skin flaps appear to be compromised, saline should be removed from the implant.

Expansion

Up to 100 cc of saline are added twice weekly by percutaneous injection into the injection dome. One of three types of needles may be used to inflate the implant: a 21-gauge (or smaller) standard needle, a butterfly 12° bevel needle, or a huber-tip needle. The needle must be inserted into the top of the injection dome (see Figure 4). The butterfly needle, however, is inserted at a 90° angle, staying within the top portion of the dome. Care should be taken not to puncture the dome's radius or tube flange, as leakage may result. (Refer to the directions for use of the micro injection dome in the **Options Included** section of this insert when a smaller dome is indicated.) Expansion continues until the desired size is obtained. Care must be taken not to inflate the device beyond its specified limits.

4. The following surgical procedure for using the **SILTEX™ Round BECKER™ 50 Expander/Breast Implant** has been provided by Dr. John Gibney for informational purposes only.²

Delayed Breast Reconstruction

- An inframammary incision is used for delayed breast reconstruction. This allows better dissection under the pectoralis major muscle and establishes an anchor at the inframammary fold. The scar acts as a fulcrum and prevents the implant from sliding down onto the rectus fascia.
- An incision is made in the pectoralis major muscle underneath the existing mastectomy scar. In the inferior portion of the muscle, no attempt is made to reestablish the origin of the muscle or to close the muscle.
- Blunt dissection is used to approximately 1 cm bigger than the size of the implant.

- The fibers of the origin of the pectoralis muscle are released from the lateral sternal margin. This allows medial movement of the implant, resulting in better cleavage.
- No attempt is made to elevate the serratus anterior laterally. Normally the abdominal portion of the flap is thick enough so that protection by the muscle is not necessary laterally.
- Sutures are placed in the deep anterior fascia. Sutures should be placed prior to placement of the implant to help avoid inadvertent puncturing of the implant.
- The lateral aspect of the mastectomy scar is opened and a separate subcutaneous pocket is created for the injection dome.

Immediate Breast Reconstruction

- For immediate breast reconstruction, the mastectomy incision is used for the insertion of the prosthesis. In the interest of inframammary fullness, or ptosis, it is necessary to create a submuscular pocket and an inferior fascial/flat flap (toward the muscle).
 - Undermining of the inferior flap extends to the level of the previous inframammary fold, both above the fascial flap (toward the skin) and below the fascial flap (toward the muscle).
 - An incision is made through the pectoralis major at the level of the 5th rib. The submuscular pocket is dissected.
 - The origin of the pectoralis major is released from the sternal margin at the 4th to 6th rib.
 - The fascial flap is attached to the muscle. Thus, placement of the implant is primarily submuscular with the inferior approximately one-fourth placed subfascially. This placement ensures that the implant will not ride up superiorly in the pocket and allows easier expansion of the tissue.
 - The injection dome is placed subcutaneously over the 4th rib at the midaxillary line.
5. It is suggested that the injection dome and tube be placed high in the subcutaneous tissue adjacent to the device to allow easy identification and access during subsequent filling. The dome should be placed no less than three inches from the prosthesis to avoid damage to the device during postoperative filling. Inflation is accomplished by using sterile, non-pyrogenic, sodium chloride USP solution for injection. Use a 23-gauge (or finer) standard or butterfly needle. **Extreme care should be taken to puncture only the center of the top surface of the injection dome at an angle perpendicular $\pm 30^\circ$ to the top surface** (Figure 4).
See figure 4.
6. Before closing the surgical incisions, confirm that the device is patent. This can be accomplished by inserting the 23-gauge butterfly needle with syringe attached into the injection dome, infusing or withdrawing solution and observing for proper inflation/deflation of the prosthesis.
7. Entrapped air may be removed by using the attached filling syringe. Any remaining air will eventually diffuse out and be absorbed by tissue.
Caution: At the time of wound closure, extreme care should be taken not to damage the prosthesis with surgical instruments. Preplacement of deep sutures may help to avoid inadvertent product contact with suture needles and subsequent product damage.

Postoperative Expansion Procedure

1. Use a syringe filled with non-pyrogenic, sodium chloride USP solution for injection to inflate the prosthesis to the recommended volume. Only sterile, non-pyrogenic, sodium chloride USP solution for injection drawn from its original container should be used.
2. Once expansion is completed, the injection dome and fill tube are removed. Make a small incision at the location dome.

Fill-tube Removal:

The fill tube in the SILTEX™ BECKER™ Expander/Breast Implant is pre-inserted in the device and should be handled carefully.

- a. Once expansion is completed, the injection dome and fill tube are removed. Make a small incision at the location of the dome.

NOTE: The tubing should be removed before taking out the injection dome.

- b. **It is important to grasp the tubing beyond the connector and as close to the implant as possible.** Avoid instrument damage to the fill tube which may result in tube breakage, retraction of the tube into the pocket and subsequent deflation and/or rupture of the device.
- c. Place the opposite hand on the expander/implant to secure it in place while pulling the fill tube.
- d. Exert a slow, steady, even force when withdrawing the fill tube. **If the fill tube turns white, relax the tube and re-grasp the fill tube closer to the implant.** Again, exert a slow, steady, even force to withdraw the tube.
- e. Gentle massage of the expander/implant and valve while withdrawing the tube may help facilitate removal.
- f. Refer to the additional instructions under **INSTRUCTIONS FOR USE, PRECAUTIONS** and **WARNINGS**. (See **PRECAUTIONS** and **WARNINGS** sections of this insert.)

Caution: The Final Expansion Volume should not be less than the Minimum Recommended Volume or bigger than the Maximum Recommended Volume (see Table 1, 2 or 3). Underfilled prostheses may buckle, fold or wrinkle causing crease/fold failure of the device and subsequent deflation and/or rupture can occur. Inflation beyond the Maximum Recommended Volume may also cause crease/fold failure or shell rupture.

3. The patient must be monitored during the volume adjustment period to guard against sloughing, necrosis, wound dehiscence and other complications associated with tissue expansion. If at any time the overlying tissue exhibits any of these symptoms, the device should be reduced in volume by reversing the filling procedures and withdrawing fluid from the prosthesis. **If signs persist, the device must be removed.**

NOTE: It is recommended that the duration of expansion not exceed six months as tissue adhesions may make it difficult to easily remove the fill tube or compromise valve integrity. Damage to the implant may result. Mentor recommends timely volume adjustment of the device. Upon achievement of the desired expansion result, the fill tube and injection dome must be removed.

For expansion guidelines see:

Table 1: SILTEX™ Round BECKER™ 25 Expander/Breast Implant Cohesive I™

Table 2: SILTEX™ Round BECKER™ 50 Expander/Breast Implant Cohesive I™

Table 3: SILTEX™ CONTOUR PROFILE™ BECKER™ 35 Expander/Breast Implant Cohesive II™

Recording Procedure for SILTEX™ BECKER™ Expander/Breast Implants

156000-01

Each prosthesis is supplied with two Patient Record Labels showing the catalog number, lot number and serial number (if applicable) for that unit. One of these pressure-sensitive labels should be attached to the patient's chart. The implanted position (left or right side) of each prosthesis and date of surgery should be indicated on the label. The fill volume of each prosthesis should be recorded on the label also.

MANUFACTURING

The device is not manufactured using phthalate components/materials. Furthermore, the device does not contain latex nor has it been in contact with latex-containing products during manufacturing. In addition, the device is not manufactured utilizing tissues of animal origin (Commission Directive 2003/32/EC).

CLEANING AND STERILIZATION

The SILTEX™ BECKER™ Expander/Breast Implants and accessories are supplied individually in a **sterile and non-pyrogenic 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. The SILTEX™ BECKER™ Expander/Breast Implant has been sterilized by Dry Heat, the stainless steel and TRUE-LOCK™ Connector and the Injection Dome have been sterilized by gamma irradiation, and the Safsite check valve and Butterfly Infusion Set have been sterilized by ethylene oxide. **Do not resterilize the device.** All MENTOR® Breast Implants are indicated for **single use only**. If a device is re-used against the manufacturer's instruction, there is a risk of infection (microbial as well as viruses and other transmissible agents) as well as immune responses. The sterility of the device can no longer be guaranteed. Furthermore, the integrity of the device cannot be guaranteed due to the risk of damage to the implant. The established shelf life of the products is compromised and thus null and void if compliance with the single-use only indication is not followed. Sterility, safety and efficacy cannot be assured for damaged devices. In the event the product becomes contaminated, contact your local Mentor representative (see **RETURNED GOODS AUTHORIZATION**).

STORAGE, HANDLING AND PACKAGING DISPOSAL INFORMATION

There are no special storage conditions for this product. The product has been tested after exposure to temperature and humidity extremes during accelerated aging. Follow local governing ordinances and recycling plans regarding disposal or recycling of the device packaging materials.

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.

- Preexisting infection should be treated and resolved before implantation of the prosthesis.
- It is possible that bubbles may form in the silicone gel as a result of the manufacturing or sterilization process. These bubbles will not detract from the safety or efficacy of the prosthesis, and will diffuse and dissipate of their own accord.
- Any surgeon performing augmentation or reconstructive mammoplasty with implants should be familiar with the currently available techniques for measuring the patient, determining implant size and performing surgery. (See **INSTRUCTIONS FOR USE** section of this insert.)
- Lint, dust, talc, surgical glove powder, drape and sponge lint, fingerprints, skin oils and other surface contaminants deposited on an implant by improper handling may cause foreign body reactions. Strict adherence to clean, aseptic techniques should be maintained to prevent contamination of the implant and possible complications. Surgical instruments and gloves should be rinsed clean of any impurities before handling the implant.
- The dual self-sealing valve of the SILTEX™ BECKER™ Expander/Breast Implant family of prostheses is unique and may be unfamiliar to the surgeon. The fill tube is inserted into the prosthesis at the time of manufacture and should be handled carefully to avoid accidental dislodgment from its prepositioned location. **Do not hold the device by its fill tube.**
- The silicone elastomer shell, fill tube and injection dome may be easily 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**.
- Meticulous care must be exercised in handling, connecting and implanting the device.
- Any subsequent surgical procedures in the area of the implant should be undertaken with extreme caution as damage to the implant could occur. In the event that an implant 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. This prosthesis should not be implanted following any modifications to its original design. A prosthesis which has been damaged, or on which repairs or modifications have been attempted, should not be implanted. **A standby prosthesis should be available at the time of surgery.**
- When removing the fill tube and injection dome, the fill tube should be removed first. **Grasp the fill tube beyond the connector to prevent separation of the injection dome from the fill tube. Do not exert sudden or undue tension on the fill tube during removal.** Avoid instrument damage to the fill tube which may result in tube breakage, retraction of tube into the pocket and subsequent deflation and/or rupture of the device.
- Tissue ingrowth can occur when using the TRUE-LOCK™ Connector. Surgeons should anticipate the need to dissect the capsule prior to removing the fill tube and injection dome. Grasp beyond the connector and remove the fill tube before taking out the injection dome.
- Do not contact the device with disposable, capacitor-type cautery instruments as damage to the outer shell of the prosthesis may result.
- The fill tube which connects the implant to the injection dome should be carefully sized to avoid kinks. Careful attachment of the fill tube to the connector is important to prevent separation. Failure of the device to inflate may be due to kinking of the fill tube, leakage, separation of the components or injections which do not penetrate the injection dome.
- Extreme care should be taken when connecting the fill tube to the connector. The tube is easily damaged with surgical instrumentation (e.g., forceps contact), and their use should be avoided.
- 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 saline into the implant; a single-use, sterile saline container is recommended.

Additional Precautions for SILTEX™ BECKER™ Expander/Breast Implants

- **Avoid too small an incision.** A larger incision than is normally used for smooth-shelled implants may be required to facilitate insertion and to avoid damage to the device. A device which is damaged during insertion may result in inadvertent deflation and/or rupture.
- Mentor recommends the surgeon consider the **size of the implant** and the **firmer nature and higher profile of the SILTEX™ shell** when choosing optimum **incision size and surgical approach**. Certain surgical approaches may cause higher stresses on the device during implantation. (See also **Implant Selection** section of this insert.)

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 device, including providing a comparison of the risks and complications of alternative procedures. **Patients should be advised that breast implants should not be considered lifetime implants.**

- At the time of incision closure, extreme care should be taken not to damage the prosthesis with surgical instruments. Such contact may result in immediate or delayed shelf deflation and/or rupture. Preplacement of deep sutures may help to avoid inadvertent product contact with suture needles and subsequent product damage.
- This product is for **single use only**. The possibility of damage to the implant and infection exists if a subsequent procedure is performed, such as open capsulotomy, breast pocket revision, etc. It is the responsibility of the attending physician to determine if a new implant should be inserted. **If the implant is damaged, it must be removed.**
- Silicone gel can leak or "bleed" through the semipermeable outer silicone envelope into the capsule and adjacent breast tissue. Migration into capillaries has also been reported. The long-term effects of such "bleed" are unknown. Prospective patients should be made aware of this potentiality. (See **ADVERSE REACTIONS/EVENTS** section of this insert.)
- Only one prosthesis should be implanted per breast. Mentor recommends against the stacking of implants, one upon the other. The devices have not yet been tested for this use and the integrity of the implants cannot be guaranteed as the materials may abrade and wear. Such abnormal stress may result in weakening or deflation/rupture of the prostheses.
- Do not insert or attempt to repair a damaged or altered prosthesis.
- The action of drugs (examples: antibiotics and steroids) in contact with the prosthesis has not been tested by the manufacturer and their use cannot be recommended. Each physician who chooses to use chemotherapeutic drugs with this prosthesis must assure compatibility of the drug with the silicone elastomer.
- In vitro testing has demonstrated that even low concentrations of povidone-iodine solution placed within the breast implant will compromise implant integrity in the long term. Therefore, we recommend that no povidone-iodine solution or other antibacterial, antiseptic or cleaning agent be added to the injection media. If a cleaning solution is to be used within the implant space, the site should be carefully rinsed to remove the residual solution.
- Do not introduce or make injections of drugs or other substances into the implant. Injections through the implant shell will compromise the product's integrity, causing it to leak while in use and eventually deflate and/or rupture.
- Preoperative evaluation of the implant design, size, and implant site should include allowances for adequate tissue coverage. Pressure, force, tension and other stresses to which the implant site will be susceptible must be considered.
- Excessive inflation of the device may result in tissue necrosis/thrombosis.
- Final Expansion Volume should not be less than the Minimum Recommended Volume or more than the Maximum Recommended Volume (see Table 1, 2 or 3). Underfilled prostheses may buckle, fold or wrinkle causing crease/fold failure of the device and subsequent deflation and/or rupture can occur. Inflation beyond the Maximum Recommended Volume may also cause crease/fold failure or shell rupture.
- Sepsis, hemorrhage or thrombosis may result from the placement of any foreign object in the body.
- The use of microwave diathermy in patients with breast implants has been reported to cause tissue necrosis, skin erosion and extrusion of the implant. Its use in patients with breast implants is not recommended.
- The patient should be made aware that any abnormal stress or trauma to the breast could result in rupture of the prosthesis. Women should be advised to see their physician immediately if they suspect that their implant has ruptured.
- Mentor strongly recommends against the use of forceful external stress (such as closed capsulotomy) to treat capsule firmness. Mentor is not responsible for the structural integrity of the implant should the surgeon elect to perform such a procedure. If the physician uses this technique, several complications may occur: hematoma, displacement of the implant and/or shell rupture. The physician should inform the patient of these potential complications and of alternatives to the procedure. Capsule firmness must not be treated by overexpansion of the device. Such abnormal stress or trauma to the breast and the prosthesis could result in rupture of the prosthesis.
- The American College of Radiology has stated that mammography may be less effective on implanted breasts and may interfere with early detection of breast cancer. The mammographer should be trained and experienced with the most current radiologic techniques and equipment. This may increase cost and radiation exposure to the patient. Patients should inform the mammographer that they have breast implants and should also be instructed how to distinguish the prosthesis from normal or abnormal breast tissue during self-examinations for breast cancer.
- Mentor has not tested the in vivo effects of radiation therapy on tissues of patients who have breast implants; however, the literature suggests that radiation therapy may increase the likelihood of experiencing capsular contracture.² In addition, the literature notes the following about the effects of radiation therapy on implanted breasts: "(a) when the implanted breast was free of fibrotic changes, radiotherapy produced acceptable results, (b) whenever feasible, 45 Gy/5 weeks seemed preferable over higher doses, (c) irradiation immediately after the reconstructive surgery appeared to produce poorer cosmetic results."⁴ The decision regarding the use of radiation therapy following breast implantation should be made by the surgeon and the radiation oncologist.
- The use of the periumbilical approach in placement of the implant has not been established and is not recommended.
- Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist, it is recommended that the device not be implanted 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 implant. These procedures present possible risk of implant puncture.
- The incidence of extrusion of the prosthesis has been shown to increase when the prosthesis has been placed in injured areas: scarred, heavily irradiated or burned tissue, crushed bone areas or where severe surgical reduction of the area has been previously performed.

156000-01

- Excessive fibrous capsular formation or contracture may occur around any implant placed in contact with soft tissues. The incidence and severity of this occurrence may increase if postoperative local hematoma or injection occurs.
- The physician should use personal discretion when deciding to use these prostheses in patients who exhibit psychological instability.
- Surgical implantation of a breast implant may interfere with the ability to breast-feed. The Institute of Medicine concluded that there is limited evidence that implantation, especially through a peri-areolar incision, may interfere with lactation and breast-feeding. However, it should be noted that previous breast reconstruction surgery, such as mastectomy, may be the initial cause of this interference.

ADVERSE REACTIONS/EVENTS

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 breast implants 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.

RISKS OF THE PROCEDURE

All surgical procedures have a small risk of complication inherent to the surgery itself and to anesthesia. These risks include:

- Infection, as manifested by heat, swelling, tenderness, redness, and fever may appear in the immediate postoperative period or at any time after insertion of the device in the absence of classic symptoms. Infections may result in Toxic Shock Syndrome (TSS). Symptoms of TSS include, but are not limited to sudden fever, vomiting, diarrhea, fainting, dizziness and/or a sunburn-like rash. Treatment for infection can range from administration of antibiotics orally or intravenously up to surgical removal of the device.
- Hematoma formation, which is manifested by enlargement, tenderness, and discoloration of tissue, which may or may not require surgical evacuation. Careful hemostasis is important to prevent postoperative hematoma formation.
- Seroma formation is a rare occurrence manifested by swelling of the breast from a collection of serum within the implant pocket which may or may not require surgical evacuation. This can occur soon after surgery or years later and the etiology is obscure.
- There are risks from the anesthetics as well.

RISKS TO SPECIFIC BREAST IMPLANT SURGERY

Capsular Contracture

Capsular contracture is the most common side effect of breast implants. To accept the implant, a surgical pocket behind the breast is made somewhat larger than the implant itself. Normally a healing scar forms an envelope around the implant, which, on occasion, will shrink sufficiently to squeeze the implant, producing varying degrees of firmness.

At its worst, the implant can feel hard, be painful and/or distorted. This can occur soon after surgery or years later and may be unilateral, bilateral or asymmetric. Surgical release or excision of the scar is often successful but recurrence is not uncommon. The cause of the contracture phenomenon is poorly understood. In the past, closed disruption of the scar by squeezing the breast was common, but this is rarely practiced today. Capsular contracture is graded in severity on a scale of I to IV by Baker classification.

Calcification of the capsule can also occur. Calcification is a phenomenon that is occasionally seen with long-term scarring especially if there is irritation such as tight burn scars that cross joints. Calcified capsules may require removal if the patient wishes relief from her contracture but otherwise seem to be harmless. Small foci of calcification are commonly seen anywhere in the breast parenchyma. They can usually be identified as benign by the radiologist but on occasion may require biopsy to rule out a malignancy.

Rupture/Deflation of the Implant

Breast implants may not last a lifetime. Although rupture can occur at any time following implantation, a number of studies examining rupture of current generation, single-lumen, CE marked, round and shaped silicone gel-filled breast implants of various manufacturers over time (using MRI evaluations) have consistently reported similar results indicating the average expected lifetime exceeds 10 years. The cumulative incidence of rupture at 5 years (identified by physician exam rather than MRI) for MENTOR® SILTEX™ BECKER™ Expander/Breast Implants (double-lumen breast implants) was 6% among 1,428 primary reconstruction patients, 9% among 490 revision reconstruction patients, and 11% among 60 revision augmentation patients (all with follow-up at 5 years).

While the silicone material itself has not been shown to biodegrade, the shell may rupture due to wear and tear, or direct injury. If the implant shell is ruptured, the escaping gel is usually contained by the scar envelope in the surgical pocket (intracapsular) and may be undetectable except by MRI (silent rupture) which is about 85% effective in detecting rupture. If the scar envelope is torn, the gel can be driven into the local tissue planes and breast tissue (extracapsular). Most of the escaped gel remains in the immediate environment of the breast but on rare occasions it has been reported to migrate down the arm, into nerve sheaths or into the abdominal wall. Ultrasound, mammography and physical examination may also diagnose these ruptures which have escaped the scar envelope. Most of the reported cases occurred in the more fragile, thinner shell devices implanted in the late 1970's. Rupture should be suspected if there is a change in character of the device such as a new, persistent unilateral burning sensation or a change in softness, texture or shape of the implant. Because of the silent nature of most ruptures and the difficulty of diagnosis without surgical exploration, the true incidence is unknown. Current products have thicker and stronger shells and more cohesive gel contents. Caution should be used when comparing expected or actual rupture rates of current devices to historical incidences, especially when, as is often the case, the brand, vintage and type of device is unknown. Explantation and/or replacement may be indicated if the implant fails, especially if it is seen in the breast parenchyma as it could be confused with or mask a tumor.

Causes of implant rupture/deflation include but are not limited to: damage from surgical instruments, intraoperative or postoperative trauma, excessive stresses or manipulations as may occur during daily routines such as vigorous exercise, contact athletics, routine manual massage, intimate physical contact and from compression required during mammography.

Complications of Tissue Expansion

- Tissue thinning.
- Sloughing of poorly vascularized tissue.
- Closed, 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.

Changes in Nipple and Breast Sensation/Breast Pain

Any surgery of the breast can result in undersensitive or oversensitive nipple-areolar complexes and/or undermined areas of breast skin. These changes can vary in degree and may be temporary or permanent. Changes in nipple/breast sensation may, on occasion, affect sexual response or comfort while nursing. These changes are believed to be a result of nerve damage or stretching of the nerves from the surgery. There is no specific treatment for this condition.

Most women undergoing augmentation or reconstruction with a breast implant will experience some breast and/or chest pain postoperatively. While this pain normally subsides in most women as they heal after surgery, it can become a chronic problem in other women. Chronic pain can be associated with hematoma, migration, infection, and implants that are too large or capsular contracture. Sudden severe pain may be associated with implant rupture.

Interference With Mammography in Detection of Cancer/Calcium Deposits

As silicone is opaque to x-rays, an implant may theoretically interfere with the early detection of cancer by mammography as it may obscure part of the breast. Newer techniques of breast compression improve the amount of breast that can be visualized. Alternatively, most surgeons feel that the device may improve the detection of tumors by palpation. While of considerable theoretical concern, delayed detection due strictly to the presence of an implant has not been reported. Women at high risk of developing breast cancer should consider getting implants with caution. Since the breast is compressed during mammography, it is possible for the implant to rupture, but this is rare and should not deter a woman from regular, routine mammographic screening. Before the mammography exam, women should inform the technologist that they have implants.

Calcium deposits are seen occasionally in old scars anywhere in the body and this is true of the implant capsule. This usually does not occur until years after implant surgery. Benign calcifications are also commonly seen on mammography in otherwise normal breast parenchyma even in breasts that have never been operated on. These benign calcium deposits usually have a different x-ray appearance than the calcifications that signal a malignancy. An expert radiologist can usually determine if a calcium spot is benign or malignant but occasionally a biopsy may be necessary to rule out malignancy. There is no evidence that these deposits occur more or less frequently in women with implants than those who have not received implants. After many years, some patients may develop a thin layer of calcium in the scar capsule that surrounds the implant. This is almost always associated with capsular contracture but otherwise causes no known problem.

Extrusion of the Implant/Interruption of Wound Healing

Skin necrosis and/or sloughing resulting in implant exposure may occur from undue tension of the tissues overlying the implant, the overdosage of steroids placed in the implant pocket or surgical or external trauma.

This is quite rare in the augmentation patient but occurs occasionally in the more challenging tissue environment of reconstruction after mastectomy, local tissue injury and/or radiation. The areas of the scar, especially after radiation to that area, seem to be the most vulnerable to disruption. Extruded implants may need to be surgically removed.

Wrinkling of the Implant/Dissatisfaction With Cosmetic Results/Asymmetry

Visible and/or palpable wrinkles in an implant are related to the thinness of the overlying tissue cover, the degree of capsular contracture and the texturing of the implant shell surface. Traditional smooth walled gel devices rarely demonstrate wrinkles. Some have described camouflaging of wrinkling with autologous fat transfer superficial to the implant. Surgical error, preexisting asymmetry or deformity, keloid formation of the incisional scar, vagaries of time, weight gain or loss, pregnancy and nursing can all contribute to an immediate or late poor aesthetic result. With time most breasts, with or without implants, become ptotic to some degree. Asymmetry is usually related to the inability to totally correct for preexisting disparity between the two breasts. It can also be attributed to surgical error, asymmetric contracture, or rupture of the implant.

Excessive buildup of collagen at the incision site during the healing process causes some patients to develop scars of cosmetic concern. Keloid scars, which do not respond well to treatment, often extend beyond the edges of the original scars and can continue to enlarge over time. Hypertrophic scars are generally confined to the original site and respond well to scar revision treatment, which may include steroid injections to break down the collagen or surgery to revise the position, direction or line of the scar.

POSSIBLE REACTIONS TO SILICONE

This text contains a brief summary of information from the medical literature. 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. The issue of the possible relationship between silicone (and other implantable materials) and various diseases has been the subject of significant scientific debate. Concerns include immunological and neurological disorders, carcinogenicity and connective tissue disorders.

Despite numerous anecdotal reports of established and newly described connective tissue diseases attributed to the device, multiple epidemiological studies have very consistently shown no significant association between silicone breast implants and any established or new connective tissue or other immunological diseases. Four prestigious multispecialty scientific expert panels have reviewed the published literature on this topic, specifically as it relates to silicone breast implants, and have issued lengthy reports of their findings. These expert panels include the Independent Review Group (commissioned by the Chief Medical Officer of the U.K.), the National Science Panel (appointed by Judge Pointer for MDL 926), the Institute of Medicine (IOM) and the Scientific and Technical Options Assessment (STOA) Programme (commissioned by the European Parliament). These four panels have uniformly concluded that there was no discernible evidence of causal association or positive risk ratio between exposure to silicone breast implants and recognized or new autoimmune or connective tissue diseases.

Coincident neurological problems such as multiple sclerosis and amyotrophic lateral sclerosis (ALS) have occurred in a small number of breast implant patients.

Subsequent studies have not demonstrated a relationship between any neurological disease and breast implants.

Several studies have been conducted to determine the carcinogenic risk of breast implants and no evidence of increased risk of cancer has been demonstrated.

Continuing assessment of both known and possible risks associated with breast implant surgery is ongoing.

No credible reports on birth defects or other reproductive effects in humans associated with implantation of silicone breast implants of any type have been identified in literature. Recent studies sponsored by Mentor provide further evidence that silicone materials used in breast implants do not cause adverse reproductive effects in experimental animals.

Although any breast surgery, including breast implantation, could theoretically interfere with the adequacy of a woman's milk supply, many women with breast implants have nursed their babies successfully. It is known that any breast surgery such as breast biopsy can affect the quantity of milk produced. In recent years, the question has been raised regarding the potential transfer of silicone into the breast milk of women with silicone breast prostheses and possible effects on the health of the breast fed children. However, more recent studies have provided strong evidence of the lack of association between silicone breast implants and adverse effects in breast fed children. The American Academy of Pediatrics has stated that there is no reason why a woman with

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implants should refrain from nursing. The European Committee on Quality Assurance and Medical Devices in Plastic Surgery (EQUAM) concluded in 2000 that silicone gel-filled breast implants do not adversely affect pregnancy, fetal development, breast-feeding, nor the health of breast fed offspring.

The report sponsored by the IOM, "Safety of Silicone Breast Implants," released in July 1999 states that women with silicone breast implants are no more likely than the rest of the population to develop cancer, immunologic diseases, or neurological problems. The committee also concluded that there is no evidence that mothers with implants pass silicone on to infants when breast-feeding.

Anaplastic Large Cell Lymphoma

Based on information reported to the FDA and found in medical literature, a possible association has been identified between breast implants and the rare development of anaplastic large cell lymphoma (ALCL), a type of non-Hodgkin's lymphoma.³ Women with breast implants may have a very small but increased risk of developing ALCL in the fluid or scar capsule adjacent to the implant. ALCL has been reported globally in patients with an implant history that includes Mentor's and other manufacturer's breast implants.

You should consider the possibility of ALCL when you have a patient with late onset, persistent peri-implant seroma. In some cases, patients presented with capsular contracture or masses adjacent to the breast implant. When testing for ALCL, collect fresh seroma fluid and representative portions of the capsule, and send for pathology tests to rule out ALCL. If your patient is diagnosed with peri-implant ALCL, develop an individualized treatment plan in coordination with a multidisciplinary care team. Because of the small number of cases worldwide, there is no defined consensus treatment regimen for peri-implant ALCL.

For more complete and up-to-date information on the FDA's analysis and review of the ALCL in patients with breast implants, please visit:
<http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm>.

Gel Bleed

The gel in an implant consists of huge three-dimensional mesh-like single molecules that constitute about 20% of the total volume. The spaces within these molecules are filled with medical grade silicone, viscous fluid. This viscous fluid is similar to the materials available in many products including antiflatulence medication, available without prescription for infants and adults. A small amount of this material can diffuse or bleed through the shell of the implant. The major portion of this material stays on the implant wall. A smaller amount moves into the scar capsule where it is gradually picked up by a certain "scavenger" cells of the body's immune system, called macrophages. Normally, these cells try to destroy foreign material such as bacteria. However, if the material (such as silicone) cannot be destroyed, it is carried to the lymph glands by the macrophages. As noted in the section on **POSSIBLE REACTIONS TO SILICONE**, the STOA report published in 2000 concluded: "Studies do not point to an association between silicone implants and serious health risks, such as cancer and connective tissue diseases."

Granulomas

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. Granulomas if large or suspicious for malignancy may need to be biopsied or surgically removed and examined.

Other Possible Reactions

- Thrombosed veins, resembling large cords, have temporarily developed in the area of the prosthesis 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.**
- Hypertrophic scarring has been reported.
- The prosthesis may become difficult to explain if the degree of tissue adhesion is significant.

Instructions and Precautions for Implant Removal

Standard surgical approaches and practices should be used should implant removal be necessary. The entirety of the device needs to be removed. In the case of a ruptured gel-containing implant, all of the gel should be removed as far as possible.

PRODUCT EVALUATION

Mentor requires that any complications and/or explantation resulting from the use of this device be brought to the immediate attention of your local Mentor representative, who will be responsible for informing Mentor Medical Systems B.V., Zernikedreef 2, 2333 CL Leiden, The Netherlands; (+31) 71 7513600. If explantation is necessary, analysis will be performed on the explanted device and the patient and the physician may be asked to allow tests to be performed which might alter the condition of the device.

RETURNED GOODS AUTHORIZATION

Authorization for return of merchandise should be obtained from your local Mentor representative prior to the return of merchandise, or contact Mentor Medical Systems B.V., Zernikedreef 2, 2333 CL Leiden, The Netherlands; (+31) 71 7513600. Merchandise must have all manufacturer's seals intact to be eligible for credit or replacement. Returned products may be subject to a restocking charge.

PRODUCT INFORMATION DISCLOSURE

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PRODUCT ORDER INFORMATION

For product information or to order directly, contact your local Mentor representative.

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1. Becker, Hilton, M.D., Personal Communication.
2. Gibney, John, M.D., Personal Communication.
3. Halpern, J., McNeese, M.D., Kroll, S.S. and Ellerbroek, N. Irradiation of Prosthetically Augmented Breasts: A Retrospective Study of Toxicity and Cosmetic Results. *Int. Jour. Radiat. Oncol. Biol. Phys.* 18: 189, 1990.
4. Spear, S.L. and Onyewu, C. Staged Breast Reconstruction with Saline-Filled Implants in the Irradiated Breast: Recent Trends and Therapeutic Implications. *Plast. Reconstr. Surg.* 105: 930, 2000.
5. de Jong, D. et al. 2008. Anaplastic Large-Cell Lymphoma in Women With Breast Implants. *JAMA.* 300: 2030-2035, 2008.
6. ISO 14607: 2009, Non-active surgical implants - Mammary Implants - Particular Requirements

DEFINITIONS OF SYMBOLS ON LABELING

Left Breast	Left Breast is the location of the implanted breast implant	Final Volumes	Final Volumes
Right Breast	Right Breast is the location of the implanted breast implant	Nominal Implant Size	Nominal Implant Size
Date of Implant	Date of the implant surgery	Nominal Saline Volume	Nominal fill volume of the saline
Patient Name	Patient Name	Gel Volume	Nominal fill volume of the gel
Surgeon Name	Surgeon Name	Maximum Saline	Maximum fill volume of the saline
Address	Surgeon's Address	Total Gel-Saline	Total range of fill volume of the gel plus the fill volume of the saline
Phone	Surgeon's Telephone Number	Total Saline	Total range of fill volume of the saline
Nominal Total Volume	Nominal fill volume of the gel plus the nominal fill volume of the saline	Table	Table
Temporary Overexpansion Volumes	Temporary Overexpansion Volumes	*Not to exceed six months.	*Not to exceed six months.



Quantity One



Use By



Catalogue Number



CAUTION! There are specific warnings or precautions associated with the device.



Lot Number (Batch Code)



Single-Use Device; Do Not Reuse



Sterilized by Dry Heat (and Date of Sterilization)

Table 1

SILTEX™ Round BECKER™ 25 Expander/Breast Implant Cohesive I™

REF	Nominal Implant Size	Nominal Saline Volume	Gel Volume	Temporary Overexpansion Volumes*		Final Volumes	
				Maximum Saline	Total Gel-Saline	Total Saline	Total Gel-Saline
354-1500	150 ccm	110 ccm	40 ccm	185 ccm	225 ccm	85–150 ccm	125–190 ccm
354-2000	200 ccm	150 ccm	50 ccm	250 ccm	300 ccm	125–200 ccm	175–250 ccm
354-2500	250 ccm	190 ccm	60 ccm	315 ccm	375 ccm	165–255 ccm	225–315 ccm
354-3000	300 ccm	225 ccm	75 ccm	375 ccm	450 ccm	200–300 ccm	275–375 ccm
354-3500	350 ccm	260 ccm	90 ccm	435 ccm	525 ccm	235–350 ccm	325–440 ccm
354-4000	400 ccm	300 ccm	100 ccm	500 ccm	600 ccm	275–400 ccm	375–500 ccm
354-5000	500 ccm	375 ccm	125 ccm	625 ccm	750 ccm	350–500 ccm	475–625 ccm
354-6000	600 ccm	450 ccm	150 ccm	750 ccm	900 ccm	425–600 ccm	575–750 ccm
354-7000	700 ccm	525 ccm	175 ccm	875 ccm	1050 ccm	500–700 ccm	675–875 ccm
354-8000	800 ccm	600 ccm	200 ccm	1000 ccm	1200 ccm	575–800 ccm	775–1000 ccm

*Not to exceed six months.

Table 2

SILTEX™ Round BECKER™ 50 Expander/Breast Implant Cohesive I™

REF	Nominal Implant Size	Nominal Saline Volume	Gel Volume	Final Volumes	
				Total Saline	Total Gel-Saline
354-1515	300 ccm	150 ccm	150 ccm	150–200 ccm	300–350 ccm
354-2020	400 ccm	200 ccm	200 ccm	200–300 ccm	400–500 ccm
354-2525	500 ccm	250 ccm	250 ccm	250–350 ccm	500–600 ccm
354-3030	600 ccm	300 ccm	300 ccm	300–425 ccm	600–725 ccm
354-3535	700 ccm	350 ccm	350 ccm	350–500 ccm	700–850 ccm

PPE Specification
 Labeling Specification
 156000-01 PID SILTEX BECKER EXPANDER / BREAST IMPLANTS

100069597 | Rev:3
 Released: 13 Nov 2013
 CO: 100163851
 Release Level: 4. Production

156000-01

Table 3

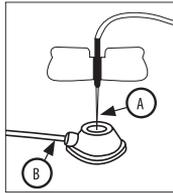
SILTEX™ CONTOUR PROFILE™ BECKER™ 35 Expander/Breast Implant Cohesive II™

REF	Nominal Implant Size	Nominal Saline Volume	Gel Volume	Temporary Overexpansion Volumes*		Final Volumes	
				Maximum Saline	Total Gel-Saline	Total Saline	Total Gel-Saline
324-0955	145 ccm	95 ccm	50 ccm	120 ccm	170 ccm	85–95 ccm	135–145 ccm
324-1055	195 ccm	125 ccm	70 ccm	155 ccm	225 ccm	110–125 ccm	180–195 ccm
324-1155	255 ccm	165 ccm	90 ccm	205 ccm	295 ccm	145–165 ccm	235–255 ccm
324-1205	290 ccm	190 ccm	100 ccm	235 ccm	335 ccm	170–190 ccm	270–290 ccm
324-1255	325 ccm	215 ccm	110 ccm	270 ccm	380 ccm	190–215 ccm	300–325 ccm
324-1305	365 ccm	240 ccm	125 ccm	300 ccm	425 ccm	215–240 ccm	340–365 ccm
324-1355	400 ccm	270 ccm	130 ccm	335 ccm	465 ccm	240–270 ccm	370–400 ccm
324-1405	460 ccm	300 ccm	160 ccm	375 ccm	535 ccm	270–300 ccm	430–460 ccm
324-1505	565 ccm	370 ccm	195 ccm	460 ccm	655 ccm	330–370 ccm	525–565 ccm
324-1605	685 ccm	445 ccm	240 ccm	555 ccm	795 ccm	440–445 ccm	640–685 ccm

*Not to exceed six months.

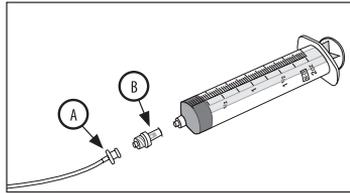
Covered by one or more of the following U.S. patents: 4, 455, 691; 4, 890, 866; 4, 643, 733; 4,944, 749; 4, 960, 425; 5, 019, 101; 5, 022, 942 and their foreign counterparts.

Fig. 1



EN	A. Injection Area	B. Tubing
DE	A. Injektionsbereich	B. Schlauchvorrichtung
FR	A. Zone d'injection	B. Tube
IT	A. Area di iniezione	B. Tubo
ES	A. Zona de inyección	B. Tubo
MX	A. Zona de inyección	B. Sonda
PT	A. Área de injeção	B. Tubo
BR	A. Área de injeção	B. Equipo
NL	A. Injectiegebied	B. Slangen
SV	A. Injektionsområde	B. Slang
DA	A. Injektionsområde	B. Slange
PL	A. Obszar iniekcji	B. Dren
EL	A. Περιοχή ένεσης	B. Σωλήνωση
TR	A. Enjeksiyon alanı	B. Tüp
RU	A. Область инъекции	B. Трубка
JA	A. 注入部位	B. チューブ
ZH	A. 注射部位	B. 填充管

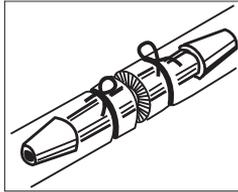
Fig. 2



EN	A. Luer Adapter	B. Two-way check valve
DE	A. Luer-Adapter	B. Zweizeige-Rückflusssperre
FR	A. Embout Luer	B. Valve de contrôle bidirectionnelle
IT	A. Adattatore Luer	B. Valvola di ritengo a due vie
ES	A. Adaptador Luer	B. Válvula antirretorno de dos vías
MX	A. Adaptador Luer	B. Válvula de retención de dos vías
PT	A. Adaptador Luer	B. Válvula de controlo de duas vias
BR	A. Adaptador Luer	B. Válvula de controle de duas vias
NL	A. Lueradapter	B. Tweewegregelklep
SV	A. Lueradapter	B. Tvåvägs-backventil
DA	A. Luer-adapter	B. Tøvejs kontrolventil
PL	A. łącznik typu Luer	B. Dwukierunkowy zawór kontrolny
EL	A. Προσαρμογέας Luer	B. Διπλή βαλβίδα αντεπιστροφής
TR	A. Luer adaptör	B. İki yönlü kontrol valfi
RU	A. Адаптер с насадкой Люэра	B. Двусторонний обратный клапан
JA	A. ルエアアダプター	B. 双方向チェックバルブ
ZH	A. 鲁尔接头	B. 双向阀

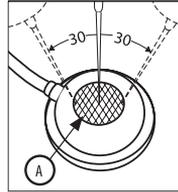
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Fig. 3



- EN Connector
- DE Konnektor
- FR Connecteur
- IT Connettore
- ES Conector
- MX Conector
- PT Conector
- BR Conector
- NL Connector
- SV Koppling
- DA Konnektor
- PL łącznik
- EL Συνδέτης
- TR Konektör
- RU Соединитель
- JA コネクター
- ZH 连接器

Fig. 4



- EN A. Injection Area
- DE A. Injektionsbereich
- FR A. Zone d'injection
- IT A. Area di iniezione
- ES A. Zona de inyección
- MX A. Zona de inyección
- PT A. Área de injeção
- BR A. Área de injeção
- NL A. Injectiegebied
- SV A. Injektionsområde
- DA A. Injektionsområde
- PL A. Obszar iniekcji
- EL A. Περιοχή ένεσης
- TR A. Enjeksiyon alanı
- RU A. Область инъекции
- JA A. 注入部位
- ZH A. 注射部位



For customer service or to return product, please call (+31) 71 7513600 or your local representative.



Manufacturer

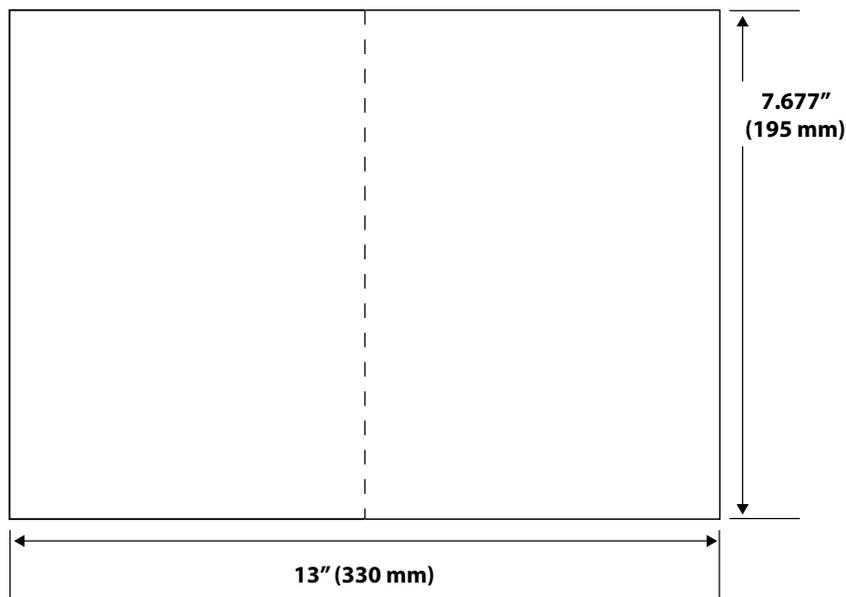
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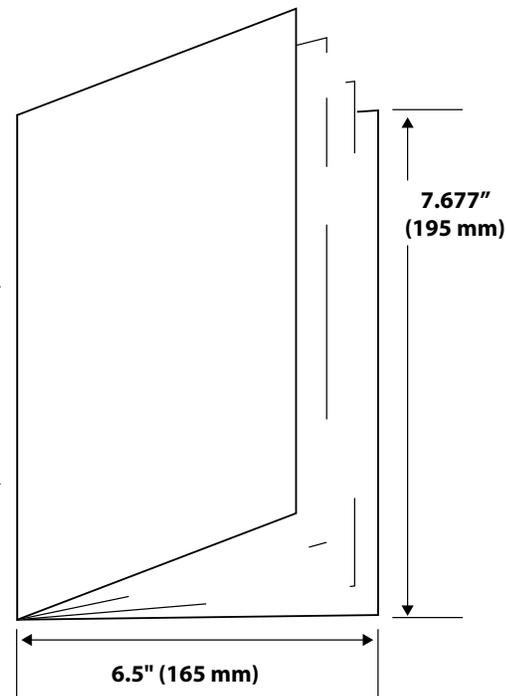
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TITLE Siltex™ Becker™ Expander/ Breast Implants		DESCRIPTION PIDS		LAB NUMBER LAB100069597v3	SPECIAL INSTRUCTIONS/COMMENTS NA			BINDING Glued	COLORS Black		
FLAT SIZE 13" x 7.677" 330 mm x 195 mm	FOLDED SIZE 6.5" x 7.677" 165 mm x 195 mm	RMC NUMBER 156000-01	PAGE COUNT 188	LANGUAGES DA, DE, EL, EN, ES-EU, ES-MX, FR, IT, JP, NL, PL, PT-BR, PT-EU, RU, SV, TR, ZH-CN				SELF COVER <input checked="" type="checkbox"/>	PLUS COVER <input type="checkbox"/>	SEALING METHOD NA	WAFER SEAL <input type="checkbox"/>
BLEED SIZE .5" (12.7 mm) <input type="checkbox"/> .125" (3.175 mm) <input checked="" type="checkbox"/>		NONE <input type="checkbox"/>	BLEED ALL SIDES <input type="checkbox"/>	BLEED TOP <input type="checkbox"/>	BLEED RIGHT <input checked="" type="checkbox"/>	BLEED LEFT <input checked="" type="checkbox"/>	BLEED BOTTOM <input type="checkbox"/>	DRAWING IS NOT TO SCALE: DRAWINGS REFLECT INFORMATION FOR PRODUCTION OF PRINTED PIECES AND DO NOT CONTAIN ACTUAL ARTWORK. This document or data herein or herewith is not to be reproduced, used or disclosed in whole or part without the permission of Ethicon, Inc.			
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