DESCRIPTION
Each implant in the Becker Expander/Mammary Prosthesis family of devices has a low-bleed, gel-filled outer lumen and an adjustable saline-fillable inner lumen. The resulting devices combine some of the advantages of tissue expanders with the feel of a gel mammory. 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 surface 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 adjoined 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 Becker Expander/Mammary Prosthesis 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.

Options Available
1. Smooth and Siltex Becker 25 Expander/Mammary Prosthesis
   • Gel volume 25 percent nominal implant size.
   • Indicated for temporary overexpansion. (see Table 1)
2. Smooth and Siltex Becker 50 Expander/Mammary Prosthesis
   • Gel volume 50 percent nominal implant size.
   • Not indicated for temporary overexpansion.
   • The Maximum Temporary Volume is identical to the Maximum Final Volume. (see Table 2)
INCLUSION CRITERIA

- One or more of the following indications:
  - 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 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.
  - Special circumstances for implantation will be considered on a case-by-case basis per written FDA authorization.
- Determined by a physician not to be a candidate for saline-filled mammary implants, due to skin being too thin, insufficient tissue, etc.
- Patient must be willing to follow the Reconstruction Adjunct Study requirements.

EXCLUSION CRITERIA

When used in the Reconstruction Adjunct Study, the use of this prosthesis is contraindicated in patients who have any of the following conditions:

- An active infection or abscess anywhere in the body.
- Pregnancy or nursing mothers.
- Lupus (e.g., SLE and DLE).
- Scleroderma (e.g., progressive systemic sclerosis).
- Uncontrolled diabetes or other disease which impacts healing.
- Tissue characteristics which are clinically incompatible with mammoplasty (e.g., tissue damage resulting from radiation, inadequate tissue, compromised vascularity or ulceration).
- History of sensitivity to foreign materials or repeated attempts and failures at breast reconstruction or augmentation.
- Possess any condition or currently be under treatment for any condition which, in the plastic surgeon's and/or consulting physician's opinion, may constitute an unwarranted surgical risk.
- An unwillingness to undergo any further surgery for revision.
- Psychological characteristics such as inappropriate attitude or motivation which, in the surgeon's opinion, are incompatible with the surgical procedure and prosthesis.
- Augmentation mammoplasty and the failure to have at least one of the diagnoses identified in the INCLUSION CRITERIA.

NOTE: The satisfactory use of this prosthesis for tissue replacement following mastectomy may require special reconstructive procedures, particularly in the presence of radiation damage on the chest-wall, tight thoracic skin, thoracic skin grafts or radical resection of the pectoralis major muscle.
PATIENT EDUCATION AND INFORMED CONSENT

The surgical procedures associated with the use of tissue expanders and mammary prostheses 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 using tissue expanders, breast prostheses and alternative procedures. Patients should be advised that breast implants should not be considered lifetime implants due to the inherent nature of silicone implants, implant procedures and potential physiological reactions. An Informed Consent document is provided for this product. This must be read, understood and 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 mammary prostheses.

INSTRUCTIONS FOR USE

The implantation of gel-filled prostheses or tissue expanders for breast reconstruction 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. The procedures listed below are recommended by Mentor for breast prostheses or tissue expanders.

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 Becker/Expander Mammary Prosthesis 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.

Testing Procedure for Becker Expander/Mammary 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 corruption of the outer shell, using firm hand manipulation. Remove any air from the device prior to filling.

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 tube 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.

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 Becker 25 Expander/Mammary Prosthesis as a reconstructive implant have been provided by Dr. Hilton Becker for informational purposes only. (Instructions for the Becker 50 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 upon 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 system. The injection dome is then 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 100cc 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 Becker 50 Expander/Mammary Prosthesis has been provided by Dr. John Gibney for informational purposes only:

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 re-establish the origin of the muscle or to close the muscle.
- Blunt dissection is used to approximately 1 cm greater than the size of the implant.
- The fibers of the origin of the pectoralis major 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 insertion of the prosthesis. In the interest of inframammary fullness, or ptosis, it is necessary to create a submuscular pocket and an inferior fascial/fat 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 superiority 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, pyrogen-free 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 ± 30° to the top surface (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 pyrogen-free, sodium chloride USP solution for injection to inflate the prosthesis to the recommended volume. Only sterile, pyrogen-free, 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 of the injection dome. It is important to grasp beyond the connector and remove the tube before taking out the injection dome. This prevents the tube from dislodging and retracting back into the pocket. Trace amounts of gel may appear on the tube during its removal from the device. Do not pull on the connector while removing the tube as it may disconnect and subsequent deflation could occur. Use a slow and steady traction to remove the fill tube and thus prevent damage to the prosthesis or its self-sealing valve. (See PRECAUTIONS and WARNINGS sections of this insert.)

Caution: The Final Expansion Volume should not be less than the Minimum Recommended Volume or greater than the Maximum Recommended Volume (see Table 1, 2). 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: Becker 25 Expander/Mammary Prosthesis
Table 2: Becker 50 Expander/Mammary Prosthesis

Fill-tube Removal:
The fill tube in the Becker Expander/Mammary Prostheses is pre-inserted in the device and should be handled carefully.

Note: The tubing should be removed from the implant prior to disconnecting the injection dome.
1. Once expansion is completed, the injection dome and fill tube are removed. Make a small incision at the location of the dome.
2. 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.
3. Place the opposite hand on the expander/implant to secure it in place while pulling the fill-tube.
4. 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.
5. Gentle massage of the expander/implant and valve while withdrawing the tube may help facilitate removal.
6. Please review the Product Insert Data Sheet for additional Instructions, Precautions and Warnings.

Recording Procedure for Becker Expander/Mammary Prostheses
Each prosthesis is supplied with a Patient Record Label showing the catalog number, lot number and serial number (if applicable) for that unit. One of these pressure-sensitive labels should be attached directly to the Patient Registry Enrollment Form, and one 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 indicated on the label also.

HOW SUPPLIED
Becker Expander/Mammary Prostheses and accessories 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 recommended for single use only.

PRECAUTIONS
- Pre-existing 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 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 Becker Expander/Mammary 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 products 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 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 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 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 Becker Expander/Mammary Prostheses:**

• **Avoid too small an incision.** A larger incision than is normally used for smooth-shelled expander/mammary implants may be required to facilitate insertion and to avoid damage to the device. A device which is damaged during insertion may result in postoperative deflation and/or rupture.

• Mentor recommends the surgeon consider the size of 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.

**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** due to the inherent nature of silicone implants, implant procedures and potential physiological reactions.

• 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 shell 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 an 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 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.

• In vitro testing has demonstrated that even low concentrations of Betadine® solution placed within the breast implant will compromise implant integrity in the long term. Therefore, we recommend that no Betadine 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 surgical 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 fluid 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). 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. The gel portion of this product is vulcanized to retard the migration of gel should a rupture occur in the silicone envelope. However, should the silicone envelope be ruptured, Mentor cannot guarantee reliable gel containment and the prosthesis must be immediately removed. The long-term biological effects of silicone gel are currently unknown. A burning sensation and change or loss of breast shape may be symptoms of implant rupture; however, implants can rupture without symptoms. Women should be advised to see their physician immediately if they suspect that their implant has ruptured.

• Mentor strongly recommends against the use of 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 over-expansion 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.

*Betadine® is a registered trademark of the Purdue Frederic Company.
• 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 previously been performed.

• 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 infection occurs.

• The physician should use personal discretion when deciding to use these prostheses regarding patients who exhibit psychological instability.

• Granulomas are non-cancerous lumps that can form when certain body cells surround foreign material, such as silicone. Like any lump, it should be further evaluated to distinguish it from a lump that might be cancerous and may require a biopsy.

• Preliminary animal studies show no evidence that birth defects are caused by breast implants. However, to rule out that possibility for humans, further scientific studies are necessary to show whether or not breast implants are associated with birth defects.

• Surgical implantation of a mammary prosthesis 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 Becker Expander/Mammary Prostheses 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 a mammary prosthesis is a normal physiologic response to the implantation of a foreign object in soft tissues. 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 breast firmness, misshapen breast, deflation and/or rupture, increased palpability, wrinkling and/or displacement of the prosthesis may occur and may require surgical intervention. In some patients, breast firmness may recur subsequent to corrective surgical procedures. Mentor strongly recommends against the use of closed capsulotomy to treat capsule firmness.

• Capsular contracture can also make the detection of breast cancer more difficult.

• Cases of calcification of the fibrous capsule have occurred, necessitating removal of the implant and/or the fibrotic calcareous capsule.

• Any surgery or injury to the breast can produce small spots of calcium in the breast tissue which can be seen on X-rays. These deposits may not occur until years after implant surgery. They are benign and cause no problems but must be differentiated from the calcium that is often seen in breast cancers. An expert radiologist can usually determine if a calcium spot is benign or malignant, but occasionally a biopsy may be necessary. 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.

Rupture/Deflation of the Implant
Breast implants are not lifetime devices and cannot be expected to last forever. Some implants deflate or rupture in the first few months after being implanted and some deflate after several years; others are intact 10 or more years after the surgery.
Silicone Gel-Filled Breast Implants – When silicone gel-filled implants rupture, some women may notice decreased breast size, nodules (hard knots), uneven appearance of the breasts, pain or tenderness, tingling, swelling, numbness, burning, or changes in sensation. Other women may unknowingly experience a rupture without any symptoms (i.e., “silent rupture”). Magnetic resonance imaging (MRI) with equipment specifically designed for imaging the breast may be used for evaluating patients with suspected rupture or leakage of their silicone gel-filled implant.

Silicone gel which escapes the fibrotic capsule surrounding the implant may migrate away from the breast. The free silicone may cause lumps called granulomas to form in the breast or other tissues where the silicone has migrated, such as the chest wall, arm pit, arm, or abdomen.

Plastic surgeons usually recommend removal of the implant if it has ruptured, even if the silicone is still enclosed within the scar tissue capsule, because the silicone gel may eventually leak into surrounding tissues. If you are considering the removal of an implant and the implantation of another one, be sure to discuss the benefits and risks with your doctor.

FDA completed a retrospective study on rupture of silicone gel-filled breast implants.1 This study was performed in Birmingham, Alabama and included women who had their first breast implant before 1988. Women with silicone gel-filled breast implants had a MRI examination of their breasts to determine the status of their current breast implants.

The 344 women who received a MRI examination had a total of 687 implants. Of the 687 implants in the study, at least two of the three study radiologists agreed that 378 implants were ruptured (55%). This means that 69% of the 344 women had at least one ruptured breast implant. Of the 344 women, 73 (21%) had extracapsular silicone gel in one or both breasts. Factors that were associated with rupture included increasing age of the implant, the implant manufacturer, and submuscular rather than subglandular location of the implant. A summary of the findings of this study is also available on FDA’s website at http://www.fda.gov/cdrh/breastimplants/studies/biinterview.pdf and http://www.fda.gov/cdrh/breastimplants/studies/birupture.pdf.

Robinson et al. studied 300 women who had their implants for 1 to 25 years and had them removed for a variety of reasons.2 Visible signs of rupture in 51% of the women studied were found. Severe silicone leakage (silicone outside the implant without visible tears or holes) was seen in another 20%. Robinson et al. also noted that the chance of rupture increases as the implant ages.

Other studies indicate that saline may escape the capsule in 11-23% of rupture cases.3,4,5

To evaluate the risk to the patient of prosthesis rupture, patients must be monitored for a minimum of 10 years. The manufacturer of this prosthesis is currently collecting information on the incidence of rupture of this device. Implants that rupture usually require explantation and replacement; however, implants can rupture without noticeable symptoms. Causes of rupture and/or deflation of implants include, but are not limited, to the following events:

- Damage from surgical instruments.
- Intraoperative or postoperative trauma.
- Excessive stresses or manipulations as may occur during daily routines such as vigorous exercise, athletics, routine manual massage and intimate physical contact.
- Mechanical damage prior to or during surgery.
- Valve malfunctions or tissue ingrowth into the valve.

• Leakage from the tube or fill dome.
• Underfilling or overfilling the device (see product label and Table 1 or 2).
• Damage during fill tube removal.
• Damage during the injection/filling stage.
• Closed capsulotomy.
• Capsular contracture.
• Origins which are unknown.

NOTE: More frequent intraoperative rupture is reported to occur with the use of too small an incision for introduction of the prosthesis.

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.
• Toxic Shock Syndrome has been reported as a complication of both augmentation and reconstructive mammaplasty. (See Possible Reactions to Silicone and Thermoplastic Elastomer.)

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.

Extrusion of Implant/Interruption of Wound Healing
• Skin necrosis and/or sloughing may result from undue tension of the skin overlying the implant, trauma to the skin flap during surgical procedures or inadequate flap thickness inhibiting circulation. Subsequent exposure and/or extrusion of the implant may occur.
• Displacement, twisting, fracture or extrusion may occur from improper implant sizing and/or placement, i.e., when the implant is too large or the pocket too small or when there has been inadequate preoperative assessment of stresses causing movement to the prosthesis.
• 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 or crushed bone areas; where severe surgical reduction of the area has been performed; and where steroids are used in the breast pocket.

Hematoma
• Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist, it is recommended that the device not be implanted 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 implant as a result of trauma and after vigorous exercise has been reported. Fluid accumulation appears to occur more frequently with textured implants.

Dissatisfaction With Cosmetic Results
• Incorrect implant size, inappropriate scar location or appearance and misplacement or migration of implants may interfere with a satisfactory cosmetic result. These complications are generally associated with the surgical procedure and technique.
• Some patients may find valve palpability aesthetically undesirable.

Wrinkling of the Implant
• Some surgeons report that in certain patients, visible or palpable wrinkling of the envelope occurs. Folds in the envelope can be visible beneath the overlying skin. This is reported to occur more frequently with thin-skinned patients; patients with little or no subcutaneous fat; subglandular rather than submuscular placement; an implant that is too large relative to the pocket size or frame of the patient; overlying tissue that is minimal or of poor quality; and/or when contracture is present.

Asymmetry/Ptosis
• The implanted breast may become ptotic over time, much like a natural breast.
• In some instances, an excessively globular contour may give an unacceptable cosmetic result.
• Failure to evacuate all the air from the prosthesis at the time of surgery may result in asymmetry of the breast and in the patient experiencing a sloshing or squishing effect.
• Asymmetry may also be attributed to incorrect choice of implant shape or size, surgical technique, contracture of the fibrous capsule, seroma or hematoma, development of postoperative breast dysplasia, unilateral discrepancy in muscle development or deflation of the implant.

Change in Nipple and Breast Sensation
• Neural complications associated with breast implants have been reported. They include temporary or permanent anesthesia or hyperesthesia of a segment of the breast's surface, particularly the nipple or areola.

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 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.
• Kinking or separation of tube can occur.
• Hypertrophic scarring has been reported.
• The prostheses may become difficult to explant if the degree of tissue adhesion is significant.
• Tissue ingrowth and adhesions may result in greater resistance to removal of the fill tube, and damage to the implant may result.

PRODUCT EVALUATION
Mentor requests that any complications and/or explantation related to 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. If explantation is necessary, Mentor will analyze the explanted device(s) and the patient and physician may be asked to allow Mentor to perform tests that might alter the condition of the device.

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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.

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PRODUCT ORDER INFORMATION
U.S. Customers
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 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.
### Table 1
**BECKER 25 EXPANDER/MAMMARY PROSTHESIS SPECIFICATIONS**

<table>
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<th>Smooth Catalog Number</th>
<th>Siltex® Catalog Number</th>
<th>Nominal Implant Size</th>
<th>Gel Volume</th>
<th>Maximum Saline</th>
<th>Total Gel-Saline</th>
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*Not to exceed six months*

### Table 2
**BECKER 50 EXPANDER/MAMMARY PROSTHESIS SPECIFICATIONS**

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<th>Smooth Catalog Number</th>
<th>Siltex® Catalog Number</th>
<th>Nominal Implant Size</th>
<th>Gel Volume</th>
<th>Total Saline</th>
<th>Total Gel-Saline</th>
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REFERENCES
Literature references are available upon request from:
Mentor
Marketing Services, Literature Department
201 Mentor Drive
Santa Barbara, CA 93111 USA

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   2617 N. Flagler Drive, Suite 504
   West Palm Beach, FL 33407 USA
2. Dr. John Gibney
   3271 N. Civic Center Place
   Scottsdale, AZ 85251 USA

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Mentor Medical Systems B.V.
Zernikdreef 2
2333 CL, Leiden
The Netherlands

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