



# Adjunct Study Protocol for Mentor Silicone Gel-Filled Mammary Prosthesis



**MENTOR**

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## **INTRODUCTION**

Surgically implanted mammary prostheses have been in use for nearly thirty years. Clinical indications for mammary prostheses include aesthetic augmentation of the female breast for cosmetic purposes and for breast reconstruction following mastectomy and correction of congenital deformities. Mammary prostheses have successfully been used for these two purposes since the early 1960's and have been implanted in nearly two million women. Historical data from previous reports and studies and marketing analyzed for mammary prostheses show that approximately 80 percent of breast implant procedures have been performed for breast augmentation and approximately 20 percent have been used for breast reconstruction. Mentor Corporation began marketing mammary prostheses in April 1984 following corporate acquisition of this product line from American Heyer-Schulte who sold and distributed mammary prostheses from 1972 until the acquisition by Mentor. Since that time Mentor has manufactured, sold and distributed a number of different types of saline-filled and silicone gel-filled mammary prostheses.

## **OBJECTIVES**

Mentor is undertaking a five-year prospective clinical study designed to collect safety data associated with the implantation of its gel-filled mammary prostheses. This study is an "adjunct" study, which will encompass clinical reviews of reconstructive cases in all patients who meet clinical and regulatory criteria for breast reconstruction with gel-filled mammary prostheses. This "adjunct" study will be accomplished under a limited clinical protocol in which specific parameters will be required but with controls somewhat less stringent than those normally required in Investigational Device Exemption (IDE) Trials.

Objectives of this study are to gather safety data regarding short term, post-implant events and complications needed to support Premarket Approval (PMA) submissions for Mentor Silicone Gel-Filled Mammary Prostheses and to maintain a comprehensive record of the patient's ongoing medical history. The FDA has placed the devices in a regulatory category as a Class III device, pursuant to the Medical Device Amendments to the Federal Food and Drug Act which went into effect in May 1976. For devices in this class, FDA requires certain clinical data regarding the risks associated with mammary prostheses. Due to several issues surrounding possible risks of silicone gel-filled breast implants, the FDA has mandated specific clinical study requirements to further assess possible risks and complications of silicone devices. Clinical data collected via this study will supplement data which will be collected in more extensive "Core" studies for breast reconstruction and augmentation procedures.

### **Primary Objective - Safety Assessment**

Specifically, data collected during this study will provide risk and complication data with regard to short-term use of silicone breast implants. This safety assessment will include, but is not limited to:

- Incidence of capsular contracture
- Occurrence of complications such as infection and seroma
- Rupture rates for the implant

### **Secondary Objectives**

This study is not intended to assess rare, long-term or speculative conditions which are not proven clinically to be associated with mammary prostheses, such as their relationship to Connective Tissue Disorders, an increased risk of cancer or teratogenic effects among breast implant patients. This study is also not intended to address issues regarding the effects of breast implants on mammography interpretation and occurrence of calcium deposits in the tissue surrounding the implant. However, data on these and other complications noted in this study, should they occur, will be recorded and analyzed with regard to the objective of the study.

## **RISKS AND BENEFITS OF THE PROCEDURE AND DEVICE**

As a result of numerous previous clinical studies and published reports and articles regarding surgical techniques, complications and psychological benefits of reconstruction and augmentation mammoplasties, the overall risks and benefits of mammary prostheses are comprehensively documented and widely distributed. As with any surgical intervention, the procedure itself proposes certain inherent risks such as infection and delayed wound healing.

Other known clinical risks specific to breast implant surgery include:

### **Capsular Contracture**

The scar tissue that forms around the implant can tighten and squeeze the implant. This can occur as a natural response to having any foreign object implanted in the body. It can cause varying degrees of pain and unnatural firmness of the breast. Capsular contracture can also make the detection of breast cancer more difficult. In some cases, the scar tissue may be surgically "scored" or removed altogether during a surgical procedure. In other cases, surgeons may wish to use a technique called Closed Capsulotomy in which he/she will apply forceful external pressure to the breast(s) to "break up" the scar tissue. This is not recommended by the manufacturer because it could result in several complications, including rupture of the implant; however surgeons may feel this is the best method for correcting the firmness. If the surgeon uses this technique, several complications may occur. These include formation of a hematoma, displacement of the implant, which may result in asymmetry, and rupture of the envelope shell. The surgeon should be sure to explain all possible complications as well as alternate methods for correcting capsular contracture.

### **Calcium Deposits**

Deposits of calcium may develop in the tissue surrounding the implant. This may not occur until years after implant surgery. These calcium deposits can make evaluation more difficult and could interfere with the detection of some lesions.

### **Calcification**

Calcification of the capsule can also occur. This can contribute to hardening of the tissue and sensation of pain.

### **Rupture/Deflation of the Implant**

Breast implants may not last a lifetime. The shell of an implant can rupture or deflate due to injury, valve leaks, or normal wear over time, releasing the silicone gel filling. Two types of implants included in this study (Becker device and Combination Gel-Saline device) contain both silicone gel and saline. Deflation may also occur in saline implants causing the saline to leak into the body. Although deflation of saline implants usually requires replacement of the implant, there is no known clinical danger of the saline leaking into the body. The frequency of implants rupturing or deflating is not known. Implants that rupture usually require explantation and replacement.

Implants can rupture without any noticeable symptoms; however, saline-filled implants usually deflate quickly and the patient may notice a definite decrease in breast size. Some women have reported a burning sensation or a change in the feel or shape of the breast. Patients should be told to see their doctor if they notice these symptoms or if they think their implant may have ruptured. No reliable method to detect rupture or leakage now exists, although mammography, ultrasound and physical examination may be helpful in diagnosing rupture.

The gel released as a result of rupture may be contained within the capsule surrounding the implant or may migrate to other parts of the body. The risks from this are unknown.

### **Changes in Nipple and Breast Sensation**

There can be increased or decreased sensation of the breast and/or nipple. This change can vary in degree and may be temporary or permanent and may affect comfort while nursing and affect sexual response.

### **Interference with Mammography in Detection of Cancer**

An implant can interfere with mammography detection of early breast cancer because it may "hide" suspicious lesions in the breast during an X-ray exam. It is especially important for women who are at high risk of developing breast cancer to consider this before having implants. Since the breast is compressed during mammography, it is possible for an implant to rupture. These problems can be reduced, but not eliminated, by making sure the mammography facility is accredited by the American College of Radiology (ACR) and asking if the personnel at the facility are experienced in performing mammography on women with implants.

Before the mammography exam, women should tell the technologist that they have implants. The technologist should take special care when compressing the breast to avoid implant rupture. Also, an experienced technologist should know how to push the implant away from the breast tissue to get the best possible views of the tissue. Even when this special technique is used, some breast tissue may be missed. Also, women are subject to additional radiation and higher costs because more X-ray views are needed for women with implants.

Recently several additional questions have been raised by the FDA, consumer groups and other organizations regarding long-term, adverse biological responses hypothesized to be associated with the use of breast implants. These questions focus on the possibility of an association between mammary prostheses and autoimmune diseases such as lupus, scleroderma and rheumatoid arthritis. Additional questions focus on the possibility of a potential increase in the risk of cancer and teratogenic effects among women who have undergone breast implant surgery. These issues are primary concerns associated with gel-filled breast implants that were raised due to gel migration and leakage and the possible effects of silicone gel absorption into body tissues. These questions are primarily associated with silicone gel-filled implants. Both implants have a silicone rubber envelope but saline-filled implants contain only salt water and any risk that might be related to gel leakage would not occur with saline-filled implants. There is currently no scientific evidence that women with either silicone gel-filled or saline-filled breast implants have an increased risk of autoimmune diseases, cancer or teratogenic effect but the possibility cannot be ruled out. Continuing assessment of both known and possible risks associated with breast implant surgery is required to determine the overall safety and efficacy of mammary prostheses.

#### **DEVICE DESCRIPTION**

Mentor Gel-Filled Mammary Prostheses are comprised of a shell made of medical grade silicone elastomer. Gel-filled implant devices manufactured by Mentor will be used in this study:

- Gel-filled device which is available in smooth surface and textured surface (Siltex<sup>®</sup>)
- Becker Expander/Mammary Prosthesis which is available in both the smooth and the textured (Siltex) version
- Combination Gel-Saline Mammary Prosthesis available in both smooth and textured surface

All three of these devices were originally indicated for both augmentation and reconstruction mammoplasty procedures, however for purposes of this study, indications are for reconstruction only.

### **Mentor Becker Expander/Mammary Prosthesis**

The Mentor Becker Expander/Mammary Prosthesis is a double-lumen, silicone elastomer device that combines some of the advantages of a tissue expander with the natural feel of a gel mammary. The prosthesis has a gel-filled outer lumen and an adjustable saline-fillable inner lumen. 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, which give the prosthesis its elasticity and integrity. This prosthesis is available in both smooth-surface and textured (Siltex), which provides a disruptive surface for collagen interface. Each prosthesis is supplied with a pre-inserted fill tube and a choice of two connector systems (True-Lock and stainless steel) and two injection domes (microinjection dome and standard injection dome). The inner lumen can be gradually filled with saline over an extended period of time via the injection dome. Once the desired volume is achieved, the fill tube and injection dome are removed through a small incision under local anesthesia.

After removal of the fill tube and injection dome, the prosthesis seals via a self-sealing valve and remains in position as a breast implant. The valve is minimally palpable after removal of the fill tube.

Becker Expander/Mammary Prostheses are supplied individually sterile and pyrogen-free in a double-wrap packaging system. This prosthesis has precise filling requirements with regard to the fill tube and filling procedures; specific instructions are provided in the Product Information Data Sheets located in of this protocol.

### **Mentor Smooth Low-Bleed Gel-Filled and Siltex<sup>®</sup> Low-Bleed Gel-Filled Mammary Prostheses**

Both the smooth surface and textured surface (Siltex) implants are constructed with successive cross-linked layers of silicone elastomer, which give the prosthesis its elasticity and integrity. In the Siltex surface implant, the final outer layer is textured to provide a disruptive surface for collagen interface. These prostheses can be used in various surgical approaches. Both the smooth surface and textured surface prostheses are supplied individually sterile and pyrogen-free in a double-wrap packaging system. Other technical data relative to these prostheses is thoroughly explained in the Product Information Data Sheets located in this protocol.

### **Mentor Combination Gel-Saline Mammary Prosthesis**

The Mentor Combination Gel-Saline Mammary Prosthesis is a silicone elastomer device consisting of a detached silicone gel-filled implant within a larger saline-filled implant. Both shells are made of silicone elastomer. The prosthesis is available a textured (Siltex) and smooth-surface shell. The outer lumen is filled with saline at the time of surgery and provides some degree of volume adjustability within specified limits. This prosthesis is supplied with a fill tube and features a self-sealing Mentor Leaf Valve which is closed except when the fill tube is inserted. The Mentor Leaf Valve is located on the posterior surface of the prosthesis. It is minimally palpable and allows for various surgical approaches. These prostheses are supplied individually sterile and pyrogen-free in a double-wrap packaging system. Fill techniques and specific instructions are provided in the Product Information Data Sheets located in this protocol.

## **STUDY DESIGN**

### **Patient Selection**

All patients who are candidates for breast reconstruction that meet the inclusion/exclusion criteria for reconstruction with silicone gel-filled implants may be entered into this study. If a patient does not meet the Inclusion Criteria or has one or more of the conditions listed under the Exclusion Criteria then they are NOT ELIGIBLE for gel implants.

Note: Under no circumstances can gel-filled breast implants be used for first time, primary augmentation. Nor is a “planned,” 2-step procedure allowed (i.e. inserting saline implants in either augmentation or reconstruction patients with the patient expectation that the saline implants will be replaced with a gel-filled implant during a subsequent revision procedure.)

### **Inclusion Criteria (Patients Must Meet All Four of the Inclusion Criteria)**

- 1) Must be female (genotypical females only), and
- 2) The patient must be willing to follow the study requirements to include:
  - a) Sign the Informed Consent Document before surgery is performed. (If the patient is under the age of consent, the parent or guardian must sign. It is the responsibility of the doctor to determine the state’s age of majority.)
  - b) Agree to complete all required follow-up visits.
  - c) For those patients who wish to participate in the Patient Registry: agree to conditions of the Implant Registry and follow the requirements of the Registry program.
  - d) Agree to follow Mentor Standard Operating Procedures for explant analysis in which case the patient may be asked to authorize the sponsor to complete analysis on any study device(s) that may require removal throughout the duration of the study.
  - e) Must be determined by the Investigator and other medical specialists (as required) to be an acceptable candidate for reconstructive breast surgery. General medical condition and history, as well as psychological appropriateness should be considered before surgical intervention. AND
- 3) In the medical opinion of the surgeon conditions must be such that saline implants are deemed unsuitable for the patient. (Patient preference for gel implants is NOT considered a medical condition.) Examples of saline unsuitability are:
  - a) Severe wrinkling of an existing saline implant to the extent that it would be considered a severe deformity (implant must have been in place longer than 6 months)
  - b) Unilateral replacement (opposite breast is gel)
  - c) Tissue or skin is too thin to support a saline implant
  - d) Previously dissected pocket is incompatible with saline implant, AND

- 4) The patient must have one or more of the following breast conditions:
  - a) Post-unilateral or bilateral mastectomy (immediate or delayed) as a result of cancer or other disease process.
  - b) Require reconstruction due to cancer treatments other than mastectomy.
  - c) Require a revision due to complications or other undesirable results of a previous surgery for the above reasons.
  - d) 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.
  - e) Congenital deformities defined as:
    - i) Pectus Excavatum defined as congenital concave chest wall deformity with abnormalities of the sternum and anterior ribs.
    - ii) Pectus Carinatum defined as convex chest wall deformity with abnormalities of the sternum and anterior ribs.
    - iii) Severe asymmetry defined as congenital or acquired substantial discrepancy in breast sizes such as to represent a significant physical deformity or abnormality (e.g., Poland's syndrome).
  - f) Severe ptosis defined as requiring a reconstruction procedure such as a mastopexy (tissue and/or skin must be removed from the breast to qualify as a mastopexy procedure).
  - g) Patients who require revision with implant replacement for severe deformity caused by medical or surgical complications, regardless of original indication for implantation or type of device originally implanted.
  - h) 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. (Please read "NOTE" under introductory "PATIENT SELECTION" paragraph)
  - i) Size changes (larger or smaller) are only allowed if the Investigator determines that a revision or replacement is required for medical reasons. In a case where a change of size is the only indication for surgery, and no medical necessity exists, the protocol will not allow replacement.
  - j) 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 (i.e., unilateral mastectomy with augmentation to opposite breast to provide symmetry).
  - k) Special circumstances for implantation will be considered on a case by case basis per written FDA authorization.

### **Exclusion Criteria**

In addition to general conditions which, in the opinion of the surgeon and/or consulting physicians may exclude a patient from enrollment as a study subject, patients must be excluded if they meet any one of the following conditions. These patients may be considered for enrollment into a "Core" study at a later date.

- 1) Augmentation mammoplasty and the failure to have at least one of the diagnoses identified in the inclusion criteria.
- 2) Have an abscess or infection anywhere in their body at the time of study entry.
- 3) Be currently pregnant or nursing.

- 4) Be diagnosed as having lupus defined as Systemic Lupus Erythematosus or Discoid Lupus, or scleroderma defined as Progressive Systemic Sclerosis.
- 5) Currently have uncontrolled diabetes or any diseases which are clinically known to impact wound healing ability.
- 6) Demonstrate tissue characteristics which are clinically incompatible with mammoplasty (e.g., tissue damage resulting from radiation, inadequate tissue, compromised vascularity or ulceration).
- 7) Possess any condition or currently be under treatment for any condition, which in the opinion of the Investigator and/or consulting physician(s), may constitute an unwarranted surgical risk.
- 8) Demonstrate psychological characteristics such as inappropriate attitude or motivation, which, in the opinion of the Investigator are incompatible with the risks, involved with the surgical procedure and the prosthesis.
- 9) Unwillingness to undergo any further surgery for revision (if required).

#### **Duration of Study**

This is a five-year study, in which patients will be followed a minimum of 1 year, 3 years, and 5 years postoperatively. Specific clinical assessments and recording of data will be accomplished at each of these visits.

#### **Study Sites/Investigator Selection**

No specific limit or selection criteria apply to study sites. All Investigators who meet the following inclusion criteria are eligible for participation.

- Surgeons must be in good standing within the medical community with a current unrestricted medical license and unrestricted operating privileges at a JCAHO or equivalent accredited medical facility.
- Must agree to follow this study protocol by execution of an Investigator's Agreement between the Sponsor and the Investigator.
- Must have IRB approval.

#### **INSTITUTIONAL REVIEW BOARD (IRB) AND INVESTIGATOR ENROLLMENT**

Institutional Review Board (IRB) approval must be obtained prior to beginning this study or implanting any devices in patients to be used as study subjects.

#### **Local/Institutional IRBs**

Investigators who practice in institutions which have an established IRB responsible for reviewing clinical studies, may utilize that institution's IRB to review this clinical study. Investigators have the responsibility to submit this protocol and all supporting documentation to their IRB and must follow any additional requirements established by the IRB. Investigators will submit applications required/provided by the individual facility to which he/she is applying for IRB approval.

Investigators will provide Mentor with a written copy of the IRB approval letter, signed by the IRB Chairperson, prior to beginning this study or implanting any devices in a study subject participating in this clinical study. At a minimum, approval letter(s) will contain the information:

- Name of Investigator(s)
- Address of institution(s) where Investigator(s) are approved to perform the surgery.
- Title and date of Study (from Protocol)
- Duration of approval period (NOTE: FDA regulations allow an IRB to approve a study for a maximum of one year. Continuing approval for each year, thereafter will be required prior to the expiration of the approval period to ensure uninterrupted continuity of the study.)

Additionally, if the IRB modifies the patient informed consent, a copy of the consent must be included with the approval documents.

Investigators will notify Mentor immediately, if at any time, their IRB withdraws approval for continuing with the clinical study.

#### **National IRB/Non-Local IRB**

Mentor has arranged a National IRB and Non-Local IRB service (“independent IRB”) for Investigators who do not practice in an institution or clinical setting which has an IRB. These independent IRBs will be responsible for the administrative review of this study and will provide the Investigators with an Investigator Application package. All documentation requested must be completed in a timely manner and returned directly to the IRB. Investigators will initially be contacted individually by the independent IRB and periodically, throughout the duration of the study. Investigators agree to comply with the terms of the Investigator Application and any additional condition established by the independent IRB. The independent IRB will be responsible for:

- Initial approval of the study protocol and continuing review and approval of the study.
- Investigator approval.
- Establishing a direct relationship with the Investigators and maintaining communication with Investigators, the sponsor and the FDA, as required.
- Maintaining adequate documentation of IRB activities relative to the study.
- Maintaining confidentiality of all records and reports relative to the study, to the extent possible.
- Reviewing serious or unanticipated adverse events involving study subjects which may occur throughout the duration of the study.
- Ensuring that the clinical study is carried out in full compliance with the FDA regulations 21 CFR 50 and 56 and with generally accepted ethical principles.

### Approval Procedures

- 1) Mentor completes and submits the national IRB application, along with the Investigator's current Curriculum Vitae (CV).
- 2) If the Investigator practices in an institution/facility which has an IRB, notification must also be included which waives that institution/facility's review of the study.
- 3) The independent IRB will then review the Investigator's application, CV and "waiver" letter (if applicable) and will notify the Investigator, in writing, (within 10 days) of the IRB's decision.
- 4) The independent IRB will provide an original approval letter to the Investigator and a copy of the approval to Mentor.

To apply to the National IRB, or a Non-Local IRB, please contact Mentor Adjunct Study Coordinator at (800) 258-3494 and request a list of approved IRBs.

### **INVESTIGATOR RESPONSIBILITIES**

Each Investigator must complete an Investigator Agreement and comply with all provisions of the agreement and all terms specified in this protocol and any additional terms established by the IRB.

- The Investigator will make known to the patient, all aspects of this clinical study via an Informed Consent document. Information provided to the patient will include, at a minimum
  - Nature and purpose of the study
  - Expected duration
  - Follow-up evaluation requirements
  - All potential risks and complications of the procedure
  - Available alternative therapy to the procedure.
- The Investigator will ensure that the patient signs the Informed Consent and provide a copy to the patient and a copy to the sponsor.
- The Investigator will objectively complete all clinical assessments, record all data as required by this protocol and maintain complete, current and accurate records.

## **CLINICAL AND ADMINISTRATIVE PROCEDURES**

### **Enrollment/Preoperative (Accomplished prior to procedure)**

#### Preoperative History and Physical

Routine history and physical will be performed and information recorded on the Preoperative Patient History Record. The surgeon may use his/her customary history and physical procedures; however all data specified on the Preoperative Patient History Record must be recorded on the form. Exclusion Criteria for admission into the study is also included on the form. Entries checked "Yes" will exclude patients from admission into the "Adjunct" study. The patient's Social Security Number (SSN) should be entered as the Patient Study Number on this and all other Case Report Forms.<sup>1</sup>

#### Prophylactic Tissue Removal

Surgeons who are considering performing breast reconstruction following prophylactic tissue removal must certify that the procedure is being performed due to medical reasons. This statement is included on the Preoperative Patient History form and must be checked when applicable.

#### Connective Tissue Disorder History

All patients must receive a Connective Tissue Disorder History screening prior to entry into the study. This screening may be performed by the attending surgeon using the Rheumatology Screening Questionnaire. Patients who exhibit symptoms of immunologic/rheumatology/ connective tissue disorders should be carefully evaluated by the surgeon to determine if the symptoms are severe enough for the patient to be referred to a specialist (e.g., rheumatologist) for a rheumatology workup prior to entry into the study. Patients who are diagnosed with lupus (e.g., Systemic Lupus Erythematosus, Discoid Lupus) or Scleroderma (e.g., Progressive Systemic Sclerosis) will be excluded.

#### "Patient Registry" Enrollment

All patients entered into this study will be asked to enroll into Mentor Patient Registry Program<sup>2</sup> and will follow the conditions of the program. Patients who elect not to enroll in the Registry may indicate so on the enrollment form and the consent form. The surgeon however, must develop alternative procedures to maintain contact with the patient.

#### Informed Consent Document

Informed Consent Document approved for use by the FDA and the IRB must be used on all patients. Patients must be provided a copy of the Informed Consent prior to surgery.

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<sup>1</sup> Disclosure of SSN is optional. Patients who do not wish to disclose their SSN will be assigned an alternate identifier. Mentor will provide instructions on using alternate identifiers.

<sup>2</sup> Enrollment into the Patient Registry is at the discretion of the patient.

**Operative (At time of surgical procedure)**

The form must be mailed to the sponsor within 10 working days after the procedure is performed. Surgical incision, implant placement, approach and technique will be carried out according to the surgeon's usual customary practice consistent with the Product Information Data Sheets and/or unique requirements of this protocol.

Operative procedures will be recorded on the Operative Report. All operative information contained on the Operative Report must be completed.

**Postoperative Follow-Up**

Postoperative evaluations and treatment will be performed using the surgeon's customary practice techniques, unless otherwise noted. All postoperative evaluations will be recorded on the Postoperative Report. The same form is used during all follow-up visits required for this study. All information as specified on the form must be completed. Specific assessments which may not be required at a particular visit should be marked NOT APPLICABLE if the assessment was not done at a particular visit. All Postoperative Case Report Forms will be forwarded to the sponsor within 10 days following each postoperative visit.

Postoperative Evaluations will be accomplished 1 year, 3 years and 5 years postoperatively. All assessments will be accomplished and documented during each visit (unless otherwise indicated).

Clinical complications such as infection, seroma, implant rupture, etc., will be recorded during all postoperative follow-up visits, should they occur. Capsular contracture assessment will be accomplished during the 1 year, 3 year and 5 year postoperative visits. The Baker Scale will be used for all assessments. (See Attachment 1). Although Closed Capsulotomy is not recommended by the manufacturer, the Investigator may feel this is the best method for correcting the firmness. If the Investigator uses this technique, several complications may occur. These include formation of a hematoma, displacement of the implant which may result in asymmetry, and rupture of the envelope shell. The Investigator should explain these possible complications as well as alternate methods for correcting capsular contracture to the patient.

Implant Ruptures will be evaluated during all postoperative visits. Patients should also be instructed on the techniques for performing routine breast self-examinations and methods to detect implant ruptures. Surgeons who suspect or detect implant ruptures should refer the patient for mammography, ultrasound, etc. The surgeon should then indicate on the Postoperative Report Form the method used to detect the rupture.

Rheumatological assessment is required during the 3 year and 5 year postoperative follow-up visits. Patients who exhibited symptoms of rheumatologic/immunologic or connective tissue disorders upon their initial assessment preoperatively should be carefully evaluated by the surgeon to determine if the symptoms are severe enough for the patient to be referred to a specialist (e.g., Rheumatologist/Internist) for further evaluation.

All postoperative Case Report Forms will be forwarded to Mentor within ten days following each postoperative visit.

### **ADDITIONAL DOCUMENTATION REQUIREMENTS**

All clinical support documentation (e.g., lab reports, mammographic interpretations, pathology reports, consultation reports, etc.) must be maintained at the site throughout the study. These will be provided to the sponsor upon request at any time during or after the study's conclusion. All documentation is subject to auditing/verification by the sponsor, IRB, and/or the FDA. Copies of all Case Report Forms and supporting documentation must be maintained at the site for the duration of this clinical study. Upon conclusion of the study all documentation will be maintained according to disposition instructions provided by the FDA.

All documentation (e.g., Case Report Forms, etc.) as specified above will be mailed to Mentor the in the supplied addressed and stamped envelope or mailed to the address below:

Mentor  
Attn: Adjunct Study Coordinator  
201 Mentor Drive  
Santa Barbara, CA 93111 USA  
Phone: (805) 879-6000  
FAX: (805) 879-6095

All documentation is subject to auditing/verification by the Mentor, the responsible IRB, and the FDA. Copies of all Case Report Forms and supporting documentation must be maintained at the site for the duration of this clinical study.

### **ADVERSE REACTION REPORTING**

Clinical Investigators must report any serious adverse reaction, injury or effect, device malfunction, death or life-threatening occurrence that may be reasonably suspected of being associated with Mentor Silicone Gel-Filled Implants immediately to Mentor and the applicable IRB. All other complications, device related or otherwise, occurring to any patient in the course of this investigation must be recorded on the appropriate case report form.

### **Reportable Adverse Reactions**

Adverse reactions that must be reported include:

- Device leaks, tears, ruptures in which the silicone and/or saline leaks into the patient and all instances of surgical removal of the implant due to leaks, tears and ruptures.
- Severe infections which do not respond to antibiotic therapy and consequently require removal of the implant.
- All capsular contractures which result in surgical intervention.
- Any other adverse occurrence, side effect, injury, toxicity, or sensitivity reaction that reasonably suggests complications from the implant which involve life threatening conditions or permanent impairment of body function. These include any of the Rheumatic Diseases or Rheumatic Syndromes listed on the Rheumatology Screening Questionnaire.

### **Reporting Procedures**

Immediate notification (within 72 hours) must be made to the Mentor Product Evaluation Department by telephone or by facsimile using the Adverse Reaction Report provided to the surgeon. This information includes the time the reaction occurred or was first observed, a complete description of the event, the severity, and probable cause, patient's condition and actions taken by the surgeon. If immediate notification is made by phone, written follow-up notification must be made within 10 calendar days from the date of telephone notification. Product Evaluation personnel will ensure all adverse reactions are reported in accordance with Medical Device Reporting (MDR) rule, 21 CFR, part 803.

Adverse reactions which are reported to Mentor by the Investigators must also be reported to the IRB responsible for reviewing the clinical study. Copies of the Adverse Reaction Report should be submitted to the IRB. Written responses received from Mentor Product Evaluation Department regarding each device evaluation will also be submitted to the IRB for review.

### **Explant Analysis**

If the adverse reaction requires removal of an implanted prosthesis, the device must be returned to Mentor for investigation and analyses by the Product Evaluation Department.<sup>3</sup> For return of explanted devices, a Returned Device Questionnaire must be completed. In addition, the patient (or the Investigator, upon verbal authorization of the patient) may be asked to sign the appropriate section of the Adverse Reaction Report authorizing Mentor to alter the condition of the device to facilitate evaluation.

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<sup>3</sup> Return of explanted devices is a requirement of this study. Investigation and analyses of explanted devices will provide the Sponsor with valuable research data on device failures and is an important aspect of Mentor Quality Assurance. Investigators should explain this to the patient in the event explant is required.

A thorough investigation and evaluation of the device(s) will be performed by the Product Evaluation Department as specified in the Product Complaint Standard Operating Procedures. Both the FDA and the Investigator will be provided a written response of the findings of the device evaluation with a copy of the response forwarded to the Clinical Monitor. The Investigator will then discuss these findings with the patient. These documents will be maintained as study case documentation and will be used in the summary analyses of the study.

## **Attachment 1**

### **Baker Clinical Grading Scale**

<b>Grade</b>	<b>Description</b>
Class I	The breast feels as soft as an unoperated one.
Class II	The breast is less soft; the implant can be palpated but is not visible.
Class III	The breast is more firm; the implant can easily be palpated and it (or distortion from it) can be seen.
Class IV	The breast is hard, tender, painful, cold and distortion is often marked.

## Attachment 2 Case Report Form Completion Schedule

Data to be Captured	Timeframe				
	Baseline	Operative	1 year	3 year	5 Year
Subject Informed Consent	X				
Inclusion/Exclusion Criteria	X				
Rheumatology Screening Questionnaire	X				
Physical Exam	X				
Demographics	X				
Medical History	X				
Cancer Treatment History	X				
Rheumatology Assessment	X				
Operative Report		X			
Registry Enrollment		X			
Capsular Contracture Assessment			X	X	X
Mammography Results			X	X	X
Pregnancy/Lactation Complications			X	X	X
Complications			X	X	X
Secondary Procedures <sup>A</sup>			X	X	X
Rheumatology Questionnaire			X	X	X
Adverse Events <sup>B</sup>			X	X	X
Discontinuation/End of Study <sup>C</sup>			X	X	X
<sup>A</sup> Document upon occurrence. Document <b>all</b> postoperative procedures. If procedure does not involve device removal, document on Postoperative Report. If patient reimplanted, document on Secondary Procedures Report. <sup>B</sup> Document upon occurrence, whether at scheduled or interim visit, by completing an Adverse Event Report <sup>C</sup> Completed when patient finishes 5 year follow-up visit, elects to drop, misses two consecutive visits, and/or is discontinued for other reasons					

**Attachment 3**  
**Investigator Agreement**

## Adjunct Study Investigator's Agreement

Sponsor: Mentor, 201 Mentor Drive, Santa Barbara, CA 93111 USA

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INVESTIGATOR: \_\_\_\_\_  
Print Name

1. The above named physician, herein after referred to as the Investigator, agrees that the information on this clinical study provided by Mentor, herein after referred to as the Sponsor, or developed by the Investigator in pursuit of this investigation, will be kept confidential and will not be disclosed to any third parties during the term of this agreement, except for information which is or comes into public domain; information which the Investigator had prior to the Sponsor's disclosure; or information which comes from an independent third party not under confidential obligation to the Sponsor. The Investigator's signature of this form is regarded as agreement to the assurances stated herein.
2. The Investigator understands and agrees to the following conditions:
  - a. **The Investigator certifies that he/she will inform any patient that the device is being used in a clinical study, and will obtain written Informed Consent from the subject using the Informed Consent included in this protocol and he/she will provide the subject with a copy of the Informed Consent. He/she further understands the device will not be implanted until the written Informed Consent document is executed. The Investigator agrees to supply the patient with a completed copy of the Breast Implant Identification Form.**
  - b. The Investigator is required to maintain adequate records of the disposition of all receipts of the device, including dates, quantity, and use by subject and by lot number, and serial number as available.
  - c. The Investigator agrees to arrange a rheumatology consultation for those patients exhibiting symptoms of immunologic/rheumatology/connective tissue disorders if required.
  - d. The Investigator agrees to arrange for continuity of care and monitoring with another Investigator who is in this clinical study, for any patient in which he/she originally enrolls into the study and performs reconstruction augmentation, should the patient/subject no longer be able to complete scheduled follow-up visits at the facility where originally entered into the study, due to relocation, etc. This applies only if the patient wishes to continue in the study but cannot continue at the original site where enrolled.
  - e. The Investigator is required to prepare and maintain adequate case histories designed to record all observations and other data pertinent to the study. Adequate case histories, for purposes of this clinical study, includes **all Case Report Forms as specified in the protocol; originals or photocopies of laboratory slips, radiographic interpretations, pathology reports, oncology reports, additional specialty consultation reports and other clinical support data** generated on patients enrolled as study subjects in this clinical study.

## **Adjunct Study Investigator's Agreement**

Sponsor: Mentor, 201 Mentor Drive, Santa Barbara, CA 93111 USA

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- f. The Investigator is required to furnish his/her reports to the Sponsor in a timely manner. Specifically, documentation will be submitted as specified in the protocol. Documentation not specifically listed in the protocol (i.e., clinical support documentation as specified) will be maintained in subject case files and submitted to the Sponsor when requested.
- g. Any death, serious injury or malfunction, which could lead to a death or serious injury, must be reported immediately to the Sponsor and IRB. Such reports are required routinely for all medical devices as part of Mentor's Product Evaluation Unit and the Medical Device Reporting (MDR) federal regulation, and are not unique to this study. Adverse events occurring within this study are defined as capsular contracture which requires medical intervention; implant explantation because of leaks, tears, ruptures or deflations; life-threatening or permanent impairment conditions including rheumatologic conditions. The Investigator agrees that the devices used in this study will be implanted only in patients enrolled as study subjects and only under his/her personal supervision or under the supervision of specifically designated physicians responsible to him/her and that the devices will not be supplied to any other Investigator or clinic.
- h. The Investigator agrees not to allow any transfer of study devices to any person or entity not fully approved for this Adjunct study without the express consent of the Mentor Corporation.
- i. The Investigator agrees that all unused devices in his/her possession shall immediately be returned to the Mentor Corporation at fair market value should the Investigator's participation in the Adjunct Study be terminated.
- j. The Investigator agrees to provide the sponsor with a current copy of his/her curriculum vitae to be accompanied with this agreement.
- k. The Investigator understands that Institutional Review Board (IRB) approval will be obtained and agrees to follow any additional terms which may be required by the IRB responsible for monitoring the study. The Investigator agrees that devices will not be implanted in study subjects until written IRB approval has been obtained.
- l. The Investigator understands that this clinical study is subject to audit by the Food and Drug Administration (FDA) and agrees to allow access to his/her patient files and documentation accumulated during this study to FDA officials.
- m. The Investigator shall permit a representative of the Sponsor to make regular site visits during the course of the study. The Investigator shall also permit the Sponsor to inspect all Case Report Forms and corresponding portions of the study subject's medical records and source documents at regular intervals during the course of the study. The Investigator shall be available to meet with the Sponsor to discuss study progress, document and sign off on corrections, respond to questions and attest to completeness and accuracy of Case Report Forms and other requested information.

## Adjunct Study Investigator's Agreement

Sponsor: Mentor, 201 Mentor Drive, Santa Barbara, CA 93111 USA

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- n. The Investigator agrees to conduct this study in accordance with this agreement, and to follow all terms and conditions as delineated in the clinical study protocol with which, he/she has been provided a copy and which he/she fully understands.
- o. The Investigator agrees to facilitate the return of explanted devices to Mentor for analysis for subjects who agree to explant analysis.
- p. The Investigator understands that the success of this study and his/her involvement in the study is contingent upon the Investigator's maintenance of patient follow-up as indicated for the duration of the study.
- q. The Investigator agrees to follow all procedural instruction in the Product Insert Data Sheet, especially as noted in the "INCLUSION CRITERIA", "EXCLUSION CRITERIA" AND "WARNINGS" sections of the insert.
- r. The Investigator agrees to protect the confidentiality of the study subjects, to the extent possible and to ensure that case study documentation is kept secure at all times. The Investigator further agrees that he/she will promptly report any compromise in confidentiality to the sponsor and to the IRB.
- s. The Investigator understands that failure to follow established Adjunct Study guidelines shall result in the imposition of the following sanctions that will restrict device shipment and ultimately terminate participation in the Adjunct Study for the enumerated protocol violations:
  - Adjunct Study surgery performed at a site without IRB approval.
  - Surgery performed on a patient failing to meet inclusion / exclusion criteria.
  - Failure to respond to requests for Adjunct Study data after a warning letter.
  - Investigational site fails to permit a scheduled monitoring visit by the Sponsor or the FDA.
  - Failure to complete case report forms at specified time points.
    1. **First Violation:** Suspension of product shipment for 10 working days.
    2. **Second Violation:** Suspension of product shipment for 30 working days.
    3. **Third Violation:** Permanent suspension. The FDA and the affected IRB shall be notified of the Investigator's suspension. (Note: The Sponsor will petition the IRB for IRB suspension of the named Investigator. The Investigator may not be reinstated without the approval of the Medical Director of Clinical Programs.)
    4. **Permanent Termination:** A single instance of the following Adjunct Study Protocol violations shall result in **permanent expulsion**, without the possibility of future reinstatement.
      - a. A surgery utilizing an Adjunct Study device that is for cosmetic purposes.
      - b. The Investigator fails to return the patient's signed Informed Consent.

**Adjunct Study  
Investigator's Agreement**

Sponsor: Mentor, 201 Mentor Drive, Santa Barbara, CA 93111 USA

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The Investigator represents and warrants that he/she is not under any preexisting obligations inconsistent with the provisions of this agreement.

INVESTIGATOR:

\_\_\_\_\_  
Investigator Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Investigator Name Printed

\_\_\_\_\_  
Street Address

\_\_\_\_\_  
City

\_\_\_\_\_  
State

\_\_\_\_\_  
Zip

Telephone (     ) \_\_\_\_\_

MENTOR:

\_\_\_\_\_  
Mentor Representative Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Mentor Representative Name Printed

**NOTE - SIGN AND RETURN THE FOLLOWING TO MENTOR:**

- A Signed Copy Of This Investigator's Agreement
- A Current Copy Of Your Curriculum Vitae
- A copy of your current medical license

**Attachment 4**  
**Informed Consent**

Revised November 2000

**CONSENT TO BE A SUBJECT IN THE MENTOR ADJUNCT STUDY FOR SILICONE GEL-FILLED MAMMARY PROSTHESIS**

INVESTIGATOR:

CITY:

STATE:

PATIENT'S STUDY NO. (SS#):

**1) PURPOSE AND BACKGROUND OF THE STUDY**

You are being asked to participate in the Mentor Silicone Gel-Filled Mammary Prosthesis Clinical Study. This Informed Consent gives you information about your breast implant procedure and your participation in this study and verifies that you have received it.

To be eligible for participation in this clinical study; you must complete a basic screening by your surgeon; be a candidate for breast reconstruction in which saline-filled implants are not suitable; and must not have specific connective tissue disorders. In addition, you must sign this document indicating that you have been provided with the required information. You should ask your surgeon to clarify any terms which you do not understand. Additionally, your surgeon must provide you with a copy of this document.

Breast implants have been used in nearly two million women since the early 1960s. There are known risks and potential complications from having breast implants. Since 1992 the Food and Drug Administration (FDA) has allowed limited silicone gel implants for clinical studies of breast reconstruction after mastectomy for cancer correction of deformities, or replacement of damaged implants. The FDA has not formally approved these gel-filled implants as safe and effective because additional scientific evidence needs to be collected. Your participation will help answer the remaining questions.

**2) DEVICE DESCRIPTION**

The manufacturer of the implants you and your doctor have chosen is Mentor. You may receive one of two different types of silicone gel-filled implants. One implant contains silicone-gel and saline solution and the second contains only silicone. Your plastic surgeon will discuss the various types of implants with you and explain why a particular device may be best suited for you.

**3) SECOND OPINIONS**

If any problems occur during the study, you may be asked or wish to obtain second opinions. You have the right to consult a physician of your choice.

#### **4) STUDY PROCEDURES**

You will talk about your procedure and participation in this study with your surgeon in advance and you should take sufficient time to think about participating. You should check with your insurance company prior to the operation, as the surgery may affect your insurance coverage. For patients who have undergone breast implantation either as a reconstructive procedure, health insurance premiums may increase, coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. Check with your insurance company regarding insurance coverage.

- a) If you agree to be in this study, you will first have to be examined to determine if you are a good candidate and if you are eligible. This screening may involve referral to other physicians. Follow-up visits to other physicians may also be required.
- b) **Description of Operation:** The operation you will have will be performed by a surgeon using accepted standards of practice. The operation may be performed in the physician's office, or in a hospital operating room or in an outpatient surgical center. Hospitalization may or may not be required. Your surgeon will explain the particular type of implant that will be used, how and where it will be placed and the type of anesthesia to be used. He/she will also give you an overall description of the operation. This may not be a one time operation. Further procedures involving expansion/inflation of your implant or management of complications may be needed.
- c) **Surgical Consent:** In addition to this Consent Form, you may have signed, or will be asked to sign a surgical consent form which addresses specific risks of the surgical procedure and risks of anesthesia.
- d) **Additional Follow-Up Visits/Extra Appointments with your Surgeon:** In addition to normal visits/appointments with your surgeon (e.g., 1-2 weeks, 1 month, 6 months), additional appointments are required as part of the research. Your participation in the research will be for 5 years. The study schedule requires follow-up visits 12 months, 36 months and 60 months after your surgery. Each visit will take about 30-60 minutes. You are making a commitment to continue in the study for the duration. It is important that you come back for all postoperative (follow-up) visits. If you move within 5 years, arrangements will be made with your surgeon for follow up with someone in your area.

#### **5) IMPLANT REGISTRY**

You will additionally be asked to enroll in a breast implant registry which will allow Mentor to notify you, if necessary, of important safety information about your silicone gel-filled breast implant(s). Every effort will be made to keep the information in the registry confidential and will only be provided to the FDA, upon their request. However, under certain circumstances, Congress has the right to get clinical data from the FDA or a court could order disclosure of certain information that could include your clinical study records.

## 6) BENEFITS OF BREAST IMPLANTS

Women with breast cancer have reported that breast reconstruction with mammary implants has aided in their recovery from breast cancer and has reduced emotional stress by helping to return their body to a more natural appearance.

You may benefit other women by providing information about possible health problems associated with breast implants and to help demonstrate the safety of the device. There are no direct additional benefits to you beyond receiving this implant.

## 7) RISKS AND DISCOMFORTS OF THE OPERATION

Breast surgery requires an incision. As with any surgical procedure, there are risks such as:

**Infection:** (severe infection on rare occasions results in Toxic Shock Syndrome or TSS). An infection can result from any surgery and produce swelling, tenderness, pain and fever. Almost all infections appear within a few days of the operation but may appear at any time after your surgery. If you get a serious infection, which doesn't go away with antibiotics, your implant may have to be removed.

**Hematoma Formation:** A collection of blood in the surgical area.

**Seroma:** (fluid accumulation around the implant that may or may not require removal). Your body will absorb both areas of fluid accumulation (seromas) and small hematomas, but large ones may have to be drained surgically to permit proper healing. Surgical techniques, under most circumstances, can minimize though not eliminate them.

**Scarring:** Any incision in the skin will leave a scar that is permanent. While your surgeon will use plastic surgical techniques to make this as inconspicuous as possible, some patients have a skin quality that results in more conspicuous scars no matter how the incision is repaired.

**Anesthetics:** There are risks from anesthetics as well.

## 8) RISKS AND DISCOMFORTS OF BREAST IMPLANTS

Breast implants have certain specific risks and complications, which may include:

**Capsular Contracture:** The normal healing scar membrane that forms around the implant can, in some women, tighten and squeeze the implant. This can cause the implant to feel firm. This firmness can range from slight to quite hard and the firmest ones can cause varying degrees of discomfort or pain. In addition to the firmness capsular contracture can result in a misshapen breast, visible surface wrinkling and/or displacement of the implant. Detection of breast cancer by mammography may also be more difficult.

If you wish to have this contracture softened, the scar tissue can be released or removed by making an incision into the breast during a surgical procedure called an Open Capsulotomy.

Your surgeon may recommend a technique called Closed Capsulotomy in which he/she will apply forceful external pressure to the breast(s) to “break up” the scar tissue. Mentor does not recommend this technique because it could result in several complications, such as breakage of the implant, bleeding, and displacement of the implant resulting in asymmetry or distortion.

Your surgeon will explain the possible complications, as well as helping you determine your choice for correcting capsular contracture.

Calcification of the capsule surrounding the implant can also occur. This can contribute to the hardening of the tissue and may be painful. Sometimes it may be necessary to remove the implant and/or the calcified capsule.

**Deflation/Rupture/Leakage:**

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 (“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, armpit, 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.<sup>1</sup> 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.<sup>2</sup> 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 silicone may escape the capsule in 11-23% of rupture cases.<sup>3,4 5 6</sup>

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<sup>1</sup> Brown SL, Middleton MS, Berg WA, Soo MS, Pennello G. Prevalence of rupture of silicone gel breast implants in a population of women in Birmingham, Alabama. *American Journal of Roentgenology* 2000; 175:1-8.

<sup>2</sup>Robinson OG, Bradley EL, Wilson DS. Analysis of explanted silicone implants: a report of 300 patients. *Ann Plast Surg.* 1995; 34:1-7.

<sup>3</sup>Vinnik CA. Migratory silicone – clinical aspects. *Silicone in Medical Devices -- Conference Proceedings.* 1991 February 1-2; Baltimore, MD: U.S. Department of Health and Human Services, FDA Publication No. 92-4249 (p.59-67)

<sup>4</sup>Duffy MJ, Woods JE. Health risks of failed silicone gel breast implants: a 30-year clinical experience. *Plast Reconstr Surg* 1994;94:295-299.

<sup>5</sup>Berg WA, Caskey CI, Hamper UM, Kuhlman JE, Anderson ND, Chang BW, Sheth S, Zerhouni EA. Single- and double-lumen silicone breast implant integrity. Prospective evaluation of MR and US criteria. *Radiology* 1995;197 45-52.

<sup>6</sup>Gorczyca DP, Schneider E, DeBruhl ND, Foo TKF, Ahn CY, Sayre JW, Shaw WW, Bassett LW. Silicone breast implant rupture: Comparison between three-point Dixon and fast spin-echo MR imaging. *AJR* 1994;162:305-310

**Gel Bleed:** Silicone gel is made up of a sponge like mesh filled with silicone in oil form. This oil is used in many medical products such as syringes, pills and anti-gas medications such as Mylanta. It is known that some very small amounts of the oil part of the gel “bleeds” through the implant’s covering or envelope. Although most of this stays in the implant pocket or is trapped in the surrounding scar, minute amounts of this silicone could possibly travel (migrate) to different parts of the body.

Silicone oil has not been demonstrated to cause cancer or other illnesses.

**Changes in Nipple and Breast Sensation/Breast Pain:** Any surgery on the breast, including a biopsy or breast implant surgery, can result in the breast and/or nipple being oversensitive or undersensitive on one or both sides. . This change can vary in degree and may be temporary or permanent. It may affect comfort while nursing or sexual response.

Most women undergoing augmentation or reconstruction with a mammary prosthesis 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:** An implant can interfere with the detection of early breast cancer because it may “hide” suspicious lesions in the breast during an X-ray exam. It is especially important for women who are at high risk of developing breast cancer to consider this before having implants. The earlier cancer is detected, the better the chance for a cure.

Regular self-examination is very important for all women but especially if you have implants. You are urged to contact the American Cancer Society for literature and instructions on the early detection of cancer.

Since the breast is compressed during mammography, it is possible, but rare for an implant to rupture. These problems can be reduced, but not eliminated, by asking if the personnel at the facility are experienced in performing mammography on women with implants.

Before the mammography exam, you should tell the technologist that you have implants. The technologist should take special care when compressing the breast to avoid rupture. Also, an experienced technologist should know how to push the implant away from the breast tissue to get the best possible views of the tissue. Even when this special technique is used, some breast tissue may be missed in the x-ray. More x-ray views are necessary with these special techniques; therefore, women with breast implants will receive more radiation. However, the benefit of the mammogram in finding cancer outweighs the risk of the additional x-rays.

**Calcium Deposits:** Small spots of calcium in the breast are often found in any breast and can be seen on x-rays (mammography). These deposits may not occur in breasts with implants and may not appear for years after the implant surgery. They are benign (noncancerous) and cause no problems but must be differentiated from the calcium that is often seen in breast cancers. An expert radiologist can usually tell a benign (noncancerous) calcium spot from a malignant one but occasionally a biopsy may be necessary to make this distinction. 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.

**Delayed Wound Healing:** In some cases, the incision site fails to heal normally.

**Extrusion:** Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion, which is when the breast implant comes through the skin.

**Necrosis:** Necrosis is the formation of dead tissue around the implant. This may prevent wound healing and require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis. Factors associated with increased necrosis include infection, use of steroids in the surgical pocket, smoking, chemotherapy / radiation, and excessive heat or cold therapy.

**Breast Tissue Atrophy/Chest Wall Deformity:** The pressure of the breast implant may cause the breast tissue to thin and shrink. This can occur while implants are still in place or following implant removal without replacement.

**Dissatisfaction with Cosmetic Results:** You may not be satisfied with the appearance of your breasts after implants. The surgeon has only limited control over the final shape which is finally determined how your chest, your breast and the implant all fit together. Incorrect implant size, excessive scarring and misplacement of implants may interfere with a satisfactory appearance. Asymmetry (unequal breast size or shape) may not be totally corrected even by different sized implants. The implanted breast may sag or droop (ptosis) over time, much like a natural breast.

In addition, breast implants will not prevent your breasts from sagging after pregnancy. Very rarely the implant may change position or break through the skin, particularly if you have very thin breast tissue covering it. You may be able to feel or see wrinkles in the implant through your skin.

**Granulomas:** These 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.

**Resurgery:** You should understand that there is a high chance that you will need to have additional surgery at some point to replace or remove the implant. Also, problems such as rupture, capsular contracture, infection, shifting, and calcium deposits can require removal of the implants. Many women decide to have the implants replaced, but some women do not. Those who do may have cosmetically unacceptable dimpling and/or puckering of the breast following removal of the implant.

## 9) UNKNOWN RISKS:

The long-term biological effects of silicone compounds in women have received a great deal of attention over the last 25 years. Both rupture and gel bleed may result in silicone going to other parts of the body. Concerns have included connective tissue disease, immunological and neurological disorders, and the risk of cancer.

**Connective Tissue Disorders:** There have been reports describing an association between certain silicone-based products and certain connective tissue disorders. These are a group of disorders in which the body reacts to its own tissue as though it was foreign material. These disorders can cause long-term, serious, disabling health problems. Symptoms may include pain and swelling of the joints, tightness, redness or swelling of the skin, swollen glands or lymph nodes, unusual and unexplained fatigue, swelling of the hands and feet, and unusual hair loss. Generally, people who have these relatively rare connective tissue disorders experience a combination of these and other symptoms.

Some cases of these disorders have been reported in women with breast implants. Some of these women have reported a reduction in symptoms after their implants were removed.

**Neurological Symptoms:** There have been some reports of patients experiencing neurological symptoms at variable times after breast implant surgery. Some of the complainants have involved difficulties with vision, sensation, muscle strength, walking, and balance.

**Cancer:** There is presently no scientific evidence that links either silicone gel-filled or saline-filled breast implants with cancer. However, the possibility cannot be ruled out.

**Birth Defects:** Preliminary animal studies and a study in humans show no evidence that birth defects are caused by silicone 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.

**Breast-Feeding:** Many women with breast implants have nursed their babies successfully. Any breast surgery, such as breast biopsy or partial mastectomy, that removes a great deal of breast tissue, or even breast implant surgery, could theoretically interfere with your ability to nurse your baby or the amount of milk available.

In recent years there has been some question as to whether small amounts of silicone that “bleeds” from gel-filled breast implants can find its way into breast milk, and, if this were to occur, could that affect the child. If you are considering breast-feeding, you are urged to check with your doctor or the FDA’s Breast Implant Information line at (800) MENTOR8 for the most current information. The American Academy of Pediatrics has stated that “there is no reason why a woman with implants should refrain from nursing.”

#### **10) ALTERNATIVE PROCEDURES TO PARTICIPATION IN THIS STUDY**

You may choose not to participate in this study. There are several alternative procedures to breast reconstruction with silicone gel-filled breast implants. These include having nothing done or wearing an external prosthesis inside your bra. Breasts can be made by transferring fatty tissues from other parts of the body such as the stomach, buttock or back (flap procedure). For many women, saline-filled breast implants are also an alternative.

You may also choose to have your silicone gel breast implant procedure using another physician who is participating in a study using another brand of implant. If you choose to not participate in the study, you may not be provided with silicone gel implants by the manufacturer. Your surgeon should discuss these alternatives with you. Your doctor will discuss these and other procedures and their relative risks and benefits.

#### **11) IMPORTANT FACTORS TO CONSIDER WHEN DECIDING TO HAVE GEL-FILLED IMPLANTS**

Be aware that breast implantation may not be a one time surgery. You are likely to need additional surgery and doctor visits over the course of your life.

Breast implants are not considered lifetime devices. You will likely undergo implant removal with or without replacement over the course of your life.

Many of the changes to your breast following implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast. Breast implants may affect your ability to produce milk for breastfeeding. Also, breast implants will not prevent your breast from sagging after pregnancy.

With breast implants, routine screening mammography will be more difficult, and you will need to have additional views, which means more time and radiation.

Your health insurance premiums may increase, coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. You should check with your insurance company regarding coverage issues.

Reconstruction – Most insurance covers the first breast reconstruction operation. Insurance coverage for reoperation procedures or additional doctor’s visits following reconstruction may not be covered, depending on the policy.

## **12) COMPENSATION FOR INJURY**

Compensation for physical injuries, complications or medical treatment from your participation in this study is not available from Mentor other than outlined in the attached Mentor Warranty. If your complication is related to rupture, you will be reimbursed under the warranty policy. If a problem occurs, medical treatment will continue to be available. Your doctor will let you know what to do if you experience any complications while you are in this study.

## **13) CONFIDENTIALITY**

Your confidentiality will be protected as much as possible throughout this study. Records generated during this study which identify you by name will be maintained as confidential, with the exception that those records, as well as your medical records, may be reviewed by authorized representatives from your doctor's office and from Mentor. In addition, authorized representatives from the U.S. Food and Drug Administration may inspect the records. Results of data collected will be reported as numbers only, no names. Under certain circumstances, Congress or a court order could obtain your clinical records. While every effort will be taken to keep this information confidential, under these special circumstances, this could mean public disclosure of your surgery and loss of your privacy.

## **14) LEGAL RISK AND ANALYSIS OF REMOVED IMPLANT**

If your implant needs to be removed, Mentor requests the implant be returned to Product Evaluation to be analyzed. This could have implications in any legal action involving your implant. Mentor will ask your permission to analyze it, a process that may alter or destroy it. You will be contacted first through your doctor and asked whether you wish to give permission for such an evaluation. Results of the analysis will be made available to you, your doctor and/or the FDA upon request. Mentor and the FDA believe there is scientific benefit to testing an explanted implant.

**15) QUESTIONS**

During the course of the study, you will be informed by your physician regarding any new information about Mentor breast implants which may become known during the study. You also have the right to ask questions and have them answered. For questions about your procedure, you should contact your surgeon,

Dr. \_\_\_\_\_ at ( \_\_\_\_\_ ) \_\_\_\_\_

For questions regarding your participation in the study and your rights as a research subject please contact the local, national, or non-local independent reviewer of the research listed below, which your physician will provide you:

**16) VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM STUDY**

Your participation in this study is voluntary and your decision not to participate will not result in loss of benefits to which you are otherwise entitled; however, you will not receive Mentor silicone gel-filled implants without being in this study. You may drop out at any time and you will still receive all necessary medical care.

**17) ACKNOWLEDGMENT**

I was provided this consent form and met with my surgeon. All my questions have been answered to my satisfaction and I have been provided a copy of this form and Experimental Subject’s Bill of Rights (in California only).

\_\_\_\_\_  
Patient’s Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Patient’s Printed Name

\_\_\_\_\_  
Investigator’s Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Witness Signature

\_\_\_\_\_  
Date

If the patient/subject is under 18 (or the legal age of majority in this state), she has given her assent above. I am being asked, based on all the above information, to give my permission to allow her participation in this study and I do so by my signature.

\_\_\_\_\_  
Parent or Guardian Signature

\_\_\_\_\_  
Date

\_\_\_\_\_  
Parent or Guardian’s Typed/Printed Name

Note: Complete, make 2 photocopies:

- Keep original copy of Informed Consent in the patient's chart
- Give one photocopy to the patient
- Return the other photocopy to:
  - Attn: Adjunct Study Coordinator
  - Mentor
  - 201 Mentor Drive
  - Santa Barbara, CA 93111

## **MENTOR BREAST IMPLANT WARRANTY SUMMARY**

### **What Does the Warranty Cover?**

The warranty covers patients' uninsured, out-of-pocket costs that are directly related to breast implant revision surgery. When the warranty applies, Mentor provides the following:

- **Free Lifetime Replacement:**  
Throughout a patient's lifetime Mentor will replace, at no cost, the same or a similar type of Mentor breast implant when implant replacement is required. If a more expensive product is requested, Mentor will invoice the surgeon for the price difference.
- **Financial Assistance:**  
For the first five years following a breast implant procedure, Mentor will provide financial assistance up to \$1,200, per revision surgery to help cover operating room expenses and anesthesia expenses not covered by insurance.

### **What Products are Covered?**

The Mentor breast implant warranty automatically applies to all Mentor saline and silicone-gel filled mammary implants that are sold and implanted in the United States and Canada after October 1, 1998, provided these implants have been:

- Implanted in accordance with Mentor literature, current to the date of implantation, and other notifications or instructions published by Mentor.
- Used by appropriately qualified, licensed surgeons, in accordance with accepted surgical procedures.

### **What Events are Covered?**

The Mentor breast implant warranty applies to the following:

- Deflation due to crease fold failure, patient trauma or unknown cause.
- Loss of valve integrity.
- Rupture of any Mentor gel or Becker prosthesis.

Other loss-of-shell-integrity events also may be covered by this warranty. A physician retained by Mentor will determine if specific, additional events should be covered. However, events listed in the "What Events are Not Covered?" section of this brochure will not be covered.

### **What Events are Not Covered?**

The Mentor breast implant warranty does not cover the following:

- Removal of intact implants due to capsular contracture, wrinkling or rippling.
- Loss of implant shell integrity resulting from reoperative procedures, open capsulotomy, or closed compression capsulotomy procedures.
- Removal of intact implants for size alteration.

**How are Claims Filed?**

To file a warranty claim for covered events; the surgeon must contact Mentor's Consumer Affairs Department. When all necessary materials from the surgeon are received and confirmed by Mentor, replacement product(s) and/or a check will be issued to the appropriate party in accordance with Mentor's warranty.

Prior to reimbursement for revision surgery, the surgeon must complete all forms and requested documentation about medical treatments and expenses.

This is a summary of the Mentor Medical Inc. Product Replacement Policy and Limited Warranty. It is an overview only and not a complete statement of the warranty. You may obtain a copy of the complete Limited Warranty for Mentor breast implants by writing to:

Attn: Consumer Affairs Department  
Mentor  
201 Mentor Drive  
Santa Barbara, CA 93111 USA

**Attachment 5**  
**CRFs**



**MENTOR**

**ADJUNCT STUDY  
Gel Mammary  
Prostheses**

**Registry Enrollment Form**

Please type or legibly print all requested information.

CRF PAGE

**1-1**

**I. REGISTRANT INFORMATION**

Social Security No. [ ]-[ ]-[ ] Date of Birth [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]  
month day year

Patient Name \_\_\_\_\_  
Last First MI

Address \_\_\_\_\_  
Street Address (and Apt # if any) City

Address [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] - [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] Phone No. [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] - [ ] [ ] [ ] [ ] [ ] [ ]  
State Zip/Mail Code Area Code

**II. IMPLANTING SURGEON INFORMATION**

Date of Surgery [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]  
month day year

Surgeon's Name \_\_\_\_\_  
Last First MI

Address \_\_\_\_\_  
Street Address (and Suite # if any) City

Address [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] - [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] Phone No. [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] - [ ] [ ] [ ] [ ] [ ] [ ]  
State Zip/Mail Code Area Code

Name of Facility (location of surgery) \_\_\_\_\_

Address \_\_\_\_\_  
Street Address City

Address [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ] - [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]  
State Zip/Mail Code

**III. IMPLANTED DEVICE(S) INFORMATION** Place Patient Record Label(s) on both NCR copies or legibly print information.

**LEFT BREAST**  Not Implanted

Product Name \_\_\_\_\_

Serial No \_\_\_\_\_  
(if applicable)

Cat. No \_\_\_\_\_

Lot No \_\_\_\_\_

Date of Surgery [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]  
month day year

**RIGHT BREAST**  Not Implanted

Product Name \_\_\_\_\_

Serial No \_\_\_\_\_  
(if applicable)

Cat. No \_\_\_\_\_

Lot No \_\_\_\_\_

Date of Surgery [ ] [ ] [ ] [ ] [ ] [ ] [ ] [ ]  
month day year

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**MENTOR**

**ADJUNCT STUDY  
Gel Mammary Prosthesis**

**Preoperative Patient History Record**

CRF PAGE

**2-1**

PATIENT NAME last first m		PATIENT STUDY NO (SOCIAL SECURITY NO)	INVESTIGATOR
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Date of Surgery: month day year	Patient's Date of Birth: month day year
Date of Exam: month day year	

INCLUSION CRITERIA	EXCLUSION CRITERIA
<i>If any answer to questions 1-4 is NO, the patient must be excluded from the study.</i>	<i>Any YES response excludes patient from the study.</i>
<p>1 Patient must be female (genotypical only), and <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>2 Patient willing to follow study requirements, and <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>3 The patient <b>must</b> have one or more of the following indications. (please check the appropriate reason) <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>I Post Mastectomy and Other Cancer Treatments</p> <p><input type="checkbox"/> Post mastectomy (check one):</p> <p><input type="checkbox"/> Immediate reconstruction</p> <p><input type="checkbox"/> Delayed reconstruction</p> <p><input type="checkbox"/> Other cancer treatments requiring reconstruction</p> <p>II. Severe Deformity</p> <p><input type="checkbox"/> Post Trauma</p> <p><input type="checkbox"/> Congenital/Developmental (check one)</p> <p><input type="checkbox"/> Pectus Excavatum/Carinatum</p> <p><input type="checkbox"/> Tubular Breasts</p> <p><input type="checkbox"/> Severe Asymmetry/Unilateral Absence of Breast (e.g. Poland's Syndrome)</p> <p><input type="checkbox"/> Severe Ptosis Correctable by Mastopexy (with tissue removal)</p> <p>III. Replacement/Revision</p> <p><input type="checkbox"/> Reconstruction</p> <p><input type="checkbox"/> Augmentation</p> <p>Reason for replacement/revision surgery _____</p>	<p>1. Has abscess or infection anywhere in body <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>2. Pregnant or nursing <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>3. Diagnosed with lupus or scleroderma <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>4. Uncontrolled diabetes or other disease which impacts healing <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>5. Incompatible tissue characteristics (i.e. radiation damage) <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>6. Unwarranted surgical risk <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p>7. Psychological reasons (see protocol for further details) <input type="checkbox"/> YES <input type="checkbox"/> NO</p>
<p>4 In the medical opinion of the surgeon, conditions must be such that saline implants are deemed unsuitable for one or more of the following reasons, and (please check the appropriate reason) <input type="checkbox"/> YES <input type="checkbox"/> NO</p> <p><input type="checkbox"/> Skin is too thin</p> <p><input type="checkbox"/> Insufficient tissue</p> <p><input type="checkbox"/> Severe wrinkling</p> <p><input type="checkbox"/> Other, specify _____</p>	<p><b>BREAST HISTORY</b></p> <p><b>Previous Breast Surgery?</b> (include mastectomies and previous implant surgeries)</p> <p><input type="checkbox"/> No <input type="checkbox"/> Yes</p> <p>Date: month year Type: _____</p> <p>_____</p> <p>_____</p> <p>_____</p> <p><b>Certification of Prophylactic Mastectomy</b> (check if appropriate)</p> <p>I certify that this patient required prophylactic mastectomy resulting in removal of breast tissue for the following medical reason(s)</p> <p><input type="checkbox"/> History of Breast Cancer</p> <p><input type="checkbox"/> Family History of Breast Cancer: Relationship. _____</p> <p><input type="checkbox"/> Severe Fibrocystic Disease</p> <p><input type="checkbox"/> Chronic Mastitis</p> <p><input type="checkbox"/> Other _____</p>

**Certification of Eligibility for Enrollment in Adjunct Study**

I certify that this patient meets all criteria for inclusion in the Adjunct Study as listed in the Study protocol.

Investigator's Signature \_\_\_\_\_ Date \_\_\_\_\_

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**MENTOR**

**ADJUNCT STUDY  
Gel Mammary Prostheses**

**Preoperative Patient History Record**

CRF PAGE

**2-2**

PATIENT STUDY NO  
(SOCIAL SECURITY NO)

month

DATE OF SURGERY  
day

year

INVESTIGATOR

**PHYSICAL EXAMINATION RESULTS**

Date of Exam

month day year

Height

ft in

Weight

lb

**DEMOGRAPHICS**

Marital Status

- Single
- Married
- Widowed
- Divorced
- Separated

Annual Household Income

- Less than \$20,000
- \$20,000 - \$40,000
- \$40,000 - \$60,000
- \$60,000 - \$80,000
- Over \$80,000

Race

- Caucasian
- Black
- Hispanic
- Asian
- Indian
- Other

Educational Level

- Less than 12 years
- High School Graduate
- Some College
- College Graduate
- Post Graduate

**MEDICAL HISTORY**

Mammogram Done?

- No
- Yes, Date:

month day year

Results

- Normal
- Abnormal, specify: \_\_\_\_\_

Tissue Characteristics

- Not Evaluated
- Normal
- Abnormal, specify: \_\_\_\_\_

Number of Pregnancies: \_\_\_\_\_ (if none, enter "0")

Number of Live Births: \_\_\_\_\_ (if none, enter "0")

Complications During Pregnancy?

- No
- Yes, specify: \_\_\_\_\_

Breastfed Children?  No  Yes

Number of Breastfed Children: \_\_\_\_\_ (if none, enter "0")

**MEDICAL HISTORY (continued)**

Smoking History?

- No
- Yes, Quantity \_\_\_\_\_ Duration: \_\_\_\_\_

Alcohol Use

- None
- Light
- Moderate
- Heavy

History of Disease

- None
- Yes, check all that apply:

- Diabetes
- Fibrocystic Disease
- Tuberculosis
- Blood Disease
- Epilepsy (Seizure Disorder)
- Heart Disease
- Other: \_\_\_\_\_
- Hypertension
- Lung Disease
- Asthma
- Stroke
- Multiple Sclerosis
- Kidney Disease

**CANCER TREATMENT HISTORY**

Type of Adjunctive Therapy:

- Radiation:  No  Yes, check all that apply:

Date initiated: \_\_\_\_\_ month day year

	LEFT	RIGHT
Beam Radiation	<input type="checkbox"/>	<input type="checkbox"/>
Radioisotopes	<input type="checkbox"/>	<input type="checkbox"/>
Radiation, not specified	<input type="checkbox"/>	<input type="checkbox"/>
Radiation with surgery	<input type="checkbox"/>	<input type="checkbox"/>

- Administered:  Before surgery  After surgery  Before and after surgery
- Recommended, unknown if administered

Chemotherapy  No  Yes, check all that apply:

Date initiated: \_\_\_\_\_ month day year

- Chemotherapy, not specified
- Single agent
- Multiple agents
- Recommended, unknown if administered

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**MENTOR**

**ADJUNCT STUDY  
Gel Mammary Prostheses**

**Preoperative Patient History Record**

CRF PAGE

**2-3**

PATIENT STUDY NO  
(SOCIAL SECURITY NO )

month

DATE OF SURGERY  
day year

INVESTIGATOR

**RHEUMATOLOGY QUESTIONNAIRE**

Date of Exam

month	day	year
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Has the patient been **DIAGNOSED BY A RHEUMATOLOGIST** for any of the following?  
*If "YES" for discoid lupus, scleroderma or systemic lupus erythematosus, then patient is excluded from study.*

RHEUMATIC DISEASE/SYNDROME:	YES	NO	Year of Onset (if known) or N/A	Has disease been diagnosed in a blood relative?		
				YES	NO	UNKNOWN
Ankylosing spondylitis	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Chronic fatigue syndrome	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Discoid lupus</b>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Fibromyalgia (Fibrositis)	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Lyme disease	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Osteoarthritis	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Polymyositis	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Psoriatic arthritis	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Raynaud's phenomenon	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Reiter's syndrome	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Rheumatoid arthritis	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Scleroderma</b> (progressive systemic sclerosis)	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<b>Systemic lupus erythematosus</b>	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Vasculitis	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other, specify	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other, specify	<input type="checkbox"/>	<input type="checkbox"/>		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

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**MENTOR****ADJUNCT STUDY  
Gel Mammary Prostheses****Operative Report**

CRF PAGE

**3-1**

PATIENT NAME last first m		PATIENT STUDY NO (SOCIAL SECURITY NO)	INVESTIGATOR
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**SURGICAL INFORMATION**

Date of Surgery. month day year	Procedure performed in: <input type="checkbox"/> Physician's Office <input type="checkbox"/> Hospital Inpatient/Outpatient <input type="checkbox"/> Outpatient Surgicenter	Type of Anesthesia (check all that apply): <input type="checkbox"/> General <input type="checkbox"/> Local with Sedation <input type="checkbox"/> Local <input type="checkbox"/> Other: _____
------------------------------------	-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	-----------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

<b>Indications</b> (check all that apply)	<b>Left</b>	<b>Right</b>	<b>Postoperative Recommendations for Patient</b> (check all that apply).
Reconstruction	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Antibiotics
Immediate/Post-Mastectomy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Restricted Activities
Delayed/Post-Mastectomy	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Recommend Massage
Severe Deformity	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Other, specify _____
Contralateral Breast	<input type="checkbox"/>	<input type="checkbox"/>	
Revision/Replacement	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Surgical Approach</b> (check all that apply):	<b>Left</b>	<b>Right</b>	<b>Pocket Irrigation:</b>
Periareolar	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Steroid
Inframammary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Antibiotics
Transaxillary	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Betadine
Mastectomy Scar	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Other, specify: _____
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>	

<b>Placement</b> (check all that apply):	<b>Left</b>	<b>Right</b>	<b>Type of Dressing:</b>
Submuscular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Surgical Bra
Subglandular	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Gauze
Other, specify: _____	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/> Pressure

<b>Size of Incision</b> (check all that apply):	<b>Left</b>	<b>Right</b>
0-3 cm	<input type="checkbox"/>	<input type="checkbox"/>
3-6 cm	<input type="checkbox"/>	<input type="checkbox"/>
6-9 cm	<input type="checkbox"/>	<input type="checkbox"/>

<b>LEFT BREAST</b> <input type="checkbox"/> Not Implanted	<b>RIGHT BREAST</b> <input type="checkbox"/> Not Implanted
Serial No (if applicable) _____	Serial No (if applicable) _____
Cat No _____	Cat. No _____
Lot No _____	Lot No.: _____

Investigator's Signature _____	Date _____
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**MENTOR**

**ADJUNCT STUDY  
Gel Mammary Prosthesis**

**Postoperative Report/  
Subject Discontinuation Report**  
(to be completed at 12, 36, and 60 months)

CRF PAGE

**4-1**

PATIENT NAME last first middle			PATIENT STUDY NO (SOCIAL SECURITY NO)		INVESTIGATOR
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**PHYSICAL EXAMINATION RESULTS**

Date of Original Surgery:  month  day  year

Date of Exam:  month  day  year

Type of Visit (check one)

- 12 Months
- 36 Months
- 60 Months
- Other, specify \_\_\_\_\_

**CAPSULAR CONTRACTURE ASSESSMENT**

Check one box for each side:

**Left Right**

- Baker Class I    
*(Normally soft and natural in appearance)*
- Baker Class II    
*(A natural appearance despite palpable firmness)*
- Baker Class III    
*(Firm with visible distortion)*
- Baker Class IV    
*(Obvious spherical distortion)*

**MAMMOGRAPHY RESULTS**

- Not Done
- Normal
- Abnormal, specify: \_\_\_\_\_

**PREGNANCY/LACTATION COMPLICATIONS**

Pregnancy complications since implantation as part of study?

- No
- Yes, specify: \_\_\_\_\_

Lactation complications since implantation as part of study?

- No
- Yes, specify: \_\_\_\_\_

**COMPLICATIONS**

No New Complications

Check one box per line if complication is device- or procedure-related

	SIDE	SEVERITY			DATE OF OCCURRENCE
		Mild 1	Moderate 2	Severe 3	
Asymmetry	Left	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Right	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Breast Pain	Left	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Right	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Calcification	Left	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Right	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Delayed Wound Healing	Left	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Right	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Extrusion	Left	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Right	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Hematoma	Left	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Right	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Hypertrophic Scarring	Left	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Right	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Infection, without Explant	Left	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Right	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Irritation/Inflammation	Left	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Right	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Lymphadenopathy	Left	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Right	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Necrosis	Left	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Right	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Seroma	Left	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Right	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Wrinkling	Left	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Right	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Other, specify _____	Left	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Right	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

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**MENTOR**

**ADJUNCT STUDY  
Gel Mammary Protheses**

**Postoperative Report/  
Subject Discontinuation Report**

CRF PAGE

**4-2**

PATIENT STUDY NO  
(SOCIAL SECURITY NO)

DATE OF ORIGINAL SURGERY  
month day year

INVESTIGATOR

Date of Exam

month day year

**Procedures performed since last exam?**

- None
- Yes, check all that apply:

	Left	Right	Date of Procedure
Port Removal	<input type="checkbox"/>	<input type="checkbox"/>	_____
Nipple Tattoo	<input type="checkbox"/>	<input type="checkbox"/>	_____
Nipple Reconstruction	<input type="checkbox"/>	<input type="checkbox"/>	_____
Capsulotomy, closed	<input type="checkbox"/>	<input type="checkbox"/>	_____
Capsulectomy, without explant	<input type="checkbox"/>	<input type="checkbox"/>	_____

**The following is to be completed at the 36 and 60 month follow-up visits only.**

**RHEUMATOLOGY QUESTIONNAIRE**

Has the patient been **DIAGNOSED BY A RHEUMATOLOGIST** for any of the following since implant surgery?

	Yes	No	Date of Diagnosis
Ankylosing spondylitis	<input type="checkbox"/>	<input type="checkbox"/>	_____
Chronic fatigue syndrome	<input type="checkbox"/>	<input type="checkbox"/>	_____
Discoid lupus	<input type="checkbox"/>	<input type="checkbox"/>	_____
Fibromyalgia (Fibrositis)	<input type="checkbox"/>	<input type="checkbox"/>	_____
Lyme disease	<input type="checkbox"/>	<input type="checkbox"/>	_____
Osteoarthritis	<input type="checkbox"/>	<input type="checkbox"/>	_____
Polymyositis	<input type="checkbox"/>	<input type="checkbox"/>	_____
Psoriatic arthritis	<input type="checkbox"/>	<input type="checkbox"/>	_____
Raynaud's phenomenon	<input type="checkbox"/>	<input type="checkbox"/>	_____
Reiter's syndrome	<input type="checkbox"/>	<input type="checkbox"/>	_____
Rheumatoid arthritis	<input type="checkbox"/>	<input type="checkbox"/>	_____
Scleroderma (progressive)	<input type="checkbox"/>	<input type="checkbox"/>	_____
Systemic lupus erythematosus	<input type="checkbox"/>	<input type="checkbox"/>	_____
Vasculitis	<input type="checkbox"/>	<input type="checkbox"/>	_____
Other, specify	<input type="checkbox"/>	<input type="checkbox"/>	_____
Other, specify	<input type="checkbox"/>	<input type="checkbox"/>	_____

**SUBJECT DISCONTINUATION REPORT**

Date of Discontinuation: month day year

Reason for Discontinuation (check one box):

**Unable to Locate**

List Contact Attempts:

1. month day year  Phone  Letter

2. month day year  Phone  Letter

If patient is being seen by another physician for follow-up, please indicate.

Physician's Name: \_\_\_\_\_

City/State \_\_\_\_\_

**Deceased:**

Date of Death. month day year

Cause: \_\_\_\_\_

**Explanted:**

Date device explanted: month day year

Reason: \_\_\_\_\_

**Other reason for discontinuation:** \_\_\_\_\_

Investigator's Signature

month day year

FORM-CP-0102-004A

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**MENTOR****ADJUNCT STUDY  
Gel Mammary Prostheses****Adverse Event Report**

CRF PAGE

**5-1**

PATIENT NAME last first m			PATIENT STUDY NO (SOCIAL SECURITY NO)	INVESTIGATOR
------------------------------	--	--	------------------------------------------	--------------

**Reminder:** This form should be completed for all Adverse Events listed under Reportable Adverse Reactions that are device-related. (Please see protocol for details.)

**Immediately submit the pink copy of this form to your local or national Institutional Review Board.**

Investigator's Address: \_\_\_\_\_

Contact Name: \_\_\_\_\_ Phone Number: (\_\_\_\_) \_\_\_\_\_

**Event Information:**

Type of Adverse Event

- Device Failure (check all that apply)
  - Leaks
  - Tears
  - Ruptures, detected by (check all that apply):
    - Mammogram
    - Ultrasound
    - MRI
    - Other, specify: \_\_\_\_\_
- Severe Infection (resulting in explant)
- Capsular Contracture (requiring surgical intervention)
- Other: \_\_\_\_\_

Date of occurrence:    month    day    year

Date of resolution    month    day    year

**Treatment/Resolution:**

Date patient seen by physician for this Adverse Event:

\_\_\_\_\_ month    \_\_\_\_\_ day    \_\_\_\_\_ year

Treatment (check all that apply).

- No Treatment
- Medication
- Secondary Procedure
- Hospitalization
- Other, specify: \_\_\_\_\_

Was device explanted?

- No
- Yes, complete Secondary Surgeries Report or Subject Discontinuation Report

Reason for explant: (check all that apply).

- Rupture
- Capsular Contracture
- Infection
- Other, specify: \_\_\_\_\_

Date of explant    month    day    year

**Device(s) experiencing Adverse Event/Explant:**     Left     Right     Bilateral

Left Catalog Number: \_\_\_\_\_

Right Catalog Number: \_\_\_\_\_

Left Lot Number: \_\_\_\_\_

Right Lot Number: \_\_\_\_\_

**Device Information:** Date of original surgery    month    day    year

Investigator's Signature \_\_\_\_\_

Date \_\_\_\_\_

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**MENTOR****ADJUNCT STUDY  
Gel Mammary Prosthesis****Secondary Surgeries Report  
(if re-implanted)**CRF PAGE  
**6-1**

PATIENT NAME last first mi			PATIENT STUDY NO (SOCIAL SECURITY NO)	INVESTIGATOR
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**SURGICAL INFORMATION**

Date of Original Surgery: month day year	Date of Secondary Surgery: month day year	Type of Anesthesia (check all that apply) <input type="checkbox"/> General <input type="checkbox"/> Local with Sedation <input type="checkbox"/> Local <input type="checkbox"/> Other: _____
<b>Reason:</b> <i>Please complete CRF page 5-1 (Adverse Event Report) if the reason for surgery is considered an Adverse Event (see CRF 5-1)</i>	<b>LEFT</b> <input type="checkbox"/> Not Implanted	<b>RIGHT</b> <input type="checkbox"/> Not Implanted
	<input type="checkbox"/> Staged Reconstruction <input type="checkbox"/> Rupture <input type="checkbox"/> Capsular Contracture <input type="checkbox"/> Infection <input type="checkbox"/> Other: _____	<input type="checkbox"/> Staged Reconstruction <input type="checkbox"/> Rupture <input type="checkbox"/> Capsular Contracture <input type="checkbox"/> Infection <input type="checkbox"/> Other: _____
	<b>Device Placement:</b>	
	<input type="checkbox"/> Submuscular <input type="checkbox"/> Subglandular <input type="checkbox"/> Other: _____	<input type="checkbox"/> Submuscular <input type="checkbox"/> Subglandular <input type="checkbox"/> Other: _____
	<b>Size of Incision:</b>	
<input type="checkbox"/> 0-3 cm <input type="checkbox"/> 3-6 cm <input type="checkbox"/> 6-9 cm	<input type="checkbox"/> 0-3 cm <input type="checkbox"/> 3-6 cm <input type="checkbox"/> 6-9 cm	
<b>Pocket Irrigation:</b>		
<input type="checkbox"/> Steroid <input type="checkbox"/> Antibiotics <input type="checkbox"/> Betadine <input type="checkbox"/> Other: _____	<input type="checkbox"/> Steroid <input type="checkbox"/> Antibiotics <input type="checkbox"/> Betadine <input type="checkbox"/> Other: _____	

**FACILITY WHERE SURGERY TOOK PLACE**

Facility Name: \_\_\_\_\_

Facility Address: \_\_\_\_\_

Street Address

City: \_\_\_\_\_ State: \_\_\_\_\_ Zip/Mail Code: \_\_\_\_\_

**IMPLANTED DEVICE(S) INFORMATION** Place Patient Record Label(s) on both NCR copies or **legibly** print information.

<b>LEFT BREAST</b> <input type="checkbox"/> Not Implanted <hr/> Product Name: _____ Serial No. (if applicable): _____ Cat No: _____ Lot No: _____ Date of Surgery: month day year	<b>RIGHT BREAST</b> <input type="checkbox"/> Not Implanted <hr/> Product Name: _____ Serial No. (if applicable): _____ Cat No: _____ Lot No: _____ Date of Surgery: month day year
--------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------	---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------

Investigator's Signature \_\_\_\_\_

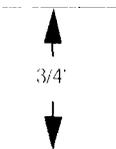
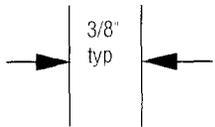
Date \_\_\_\_\_

FORM: CP-0102-006A

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**Attachment 6**  
**Product Information Sheet (PIDS)**



Product Insert  
Data Sheet



## SILTEX<sup>®</sup> AND SMOOTH-SURFACE LOW-BLEED GEL-FILLED MAMMARY PROSTHESES (RECONSTRUCTION ADJUNCT STUDY)

102748-001 Rev. D Effective Jan 2001

### DESCRIPTION

The Mentor Siltex<sup>®</sup> \* and Smooth-Surface Low-Bleed Gel-Filled Mammary Prostheses are silicone elastomer mammary devices. The gel-filled shell is constructed of successive cross-linked layers of silicone elastomer, which give the prosthesis its elasticity and integrity. The Siltex shell is textured to provide a disruptive surface for collagen interface.

### 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 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 these prostheses are contraindicated in patients who have one or more of the following conditions:

- An active infection or abscess anywhere in the body
- Pregnancy or nursing mothers
- Lupus (e.g., SLE and DLE)

\* Registered in the U.S. Patent and Trademark Office and other countries around the world

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Title: PIDS: Adjunct Study—Low-Bleed

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- 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 gel-filled prostheses 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 gel-filled 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 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 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 gel-filled implants.

**Implant Selection**

Some of the important 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 flexibility in determining the appropriate size implant to be used. A backup implant should also be available.

**Caution:** Implant size and the firmer nature and higher profile of the Siltex shell should be a consideration when choosing optimum incision size and surgical approach. Avoid too small an incision, a larger incision than is normally used for other smooth-surface gel-filled implants may be required to facilitate insertion and to avoid damage to the device.

**Testing Procedure for Gel-Filled Implants**

The device should be tested for patency and shell integrity immediately prior to use. This can be accomplished by gently manipulating the prosthesis with hand and fingers, while carefully examining for leakage sites.

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### Recording Procedure For Gel-Filled Implants

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 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.

### HOW SUPPLIED

Siltex and Smooth-Surface Low-Bleed Gel-Filled Mammary Prostheses 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**. Sterility, safety and efficacy cannot be assured for damaged devices.

### 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 the 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 silicone elastomer shell may be easily cut by a scalpel or ruptured by excessive stress, manipulation with blunt instruments or penetration by a needle. Subsequent rupture will result. All products should be carefully inspected for structural integrity prior to and during implantation.
- Meticulous care must be exercised in handling 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.**
- Do not contact the prosthesis with disposable, capacitor-type cautery instruments as damage to the outer shell of the prosthesis may result.

#### Additional PRECAUTIONS for Siltex Gel-Filled Low-Bleed Mammary Prostheses:

- Mentor recommends the surgeon consider the **size of implant** and **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.)
- **Avoid too small an incision.** A larger incision than is normally used for other smooth-shelled gel-filled 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 rupture.

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**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 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 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 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 device has not been tested by the manufacturer, and their use cannot be recommended.
- *In vitro* testing has demonstrated that even low concentrations of Betadine<sup>®</sup> 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 device. Injections through the implant shell will compromise the product's integrity, causing it to leak while in use and eventually 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.
- 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 a physician uses this technique, several complications may occur: hematoma, displacement of implant and/or shell rupture. The physician should inform the patient of these potential complications and of alternatives to the procedure. Such abnormal stress or trauma to the breast and the prosthesis could result in rupture of the prosthesis.

\*Betadine is a registered trademark of the Purdue Frederic Company

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- 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.
- 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 noncancerous 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 Siltex and Smooth-Surface Low-Bleed Gel-Filled 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 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, 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 calcified capsule.

	
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- 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 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, armpit, 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.<sup>1</sup> 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/binterview.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.<sup>2</sup> 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.<sup>3,4,5</sup>

<sup>1</sup> Brown SL, Middleton MS, Berg WA, Soo MS, Pennello G. Prevalence of rupture of silicone gel breast implants in a population of women in Birmingham, Alabama. *American Journal of Roentgenology* 2000; 175:1-8.

<sup>2</sup> Robinson OG, Bradley EL, Wilson DS. Analysis of explanted silicone implants: a report of 300 patients. *Ann Plast Surg* 1995; 34:1-7.  
Vinnik CA. Migratory silicone – clinical aspects. *Silicone in Medical Devices – Conference Proceedings*, 1991 February 1-2, Baltimore, MD. U.S. Department of Health and Human Services, FDA Publication No. 92-4249 (p. 59-67).

<sup>3</sup> Duffy MJ, Woods JE. Health risks of failed silicone gel breast implants: a 30-year clinical experience. *Plast Reconstr Surg* 1994; 94:295-299.

<sup>4</sup> Berg WA, Caskey CI, Hamper UM, Kuhlman JE, Anderson ND, Chang BW, Sheth S, Zerhouni EA. Single- and double-lumen silicone breast implant integrity: Prospective evaluation of MR and US criteria. *Radiology* 1995; 197:45-52.

<sup>5</sup> Gorczyca DP, Schneider E, DeBruhl ND, Foo TKF, Ahn CY, Sayre JW, Shaw WW, Bassett LW. Silicone breast implant rupture: Comparison between three-point Dixon and fast spin-echo MR imaging. *AJR* 1994; 162:305-310.



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Implants that rupture usually require explantation and replacement however, implants can rupture without noticeable symptoms. 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. Causes of rupture 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
- 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 device.

#### **Infection**

- Infection, manifested by swelling, tenderness, pain and fever may appear in the immediate postoperative period or at any time after insertion of the device. In the absence of classic symptoms, subacute or chronic infections may be difficult to diagnose. If infection does not subside promptly with the appropriate treatment, removal of the device is indicated.
- Toxic Shock Syndrome has been reported as a complication of both augmentation and reconstructive mammoplasty. (See **Possible Reactions to Silicone Elastomer**)

#### **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.



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**Wrinkling of the Implant**

- Some surgeons report that in some 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 where there is contracture.

**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.
- 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 rupture 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.

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**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.

**TUMORGENICITY/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.
- Hypertrophic scarring has been reported.
- The prosthesis may become difficult to explant if the degree of tissue adhesion is significant.

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**PRODUCT EVALUATION**

Mentor requests that any complications and/or explanation 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 explanation 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.

**RETURNED GOODS AUTHORIZATION**

**U.S. Customers**

Authorization must be received from Mentor prior to return of merchandise. Merchandise returned must have all manufacturer's seals intact and be returned within 30 days from date of invoice to be eligible for credit or replacement. Please contact the Mentor Customer Service Department for details. To obtain a Return Authorization Number call (800) 235-5731, FAX (805) 967-7108. 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.**

**REFERENCES**

Literature references are available upon request from: Mentor  
Marketing Services Literature Department  
201 Mentor Drive  
Santa Barbara, CA 93111 USA

Covered by one or more of the following U.S. Patents: 4,455,691; 4,472,226; 4,960,425; 5,022,942



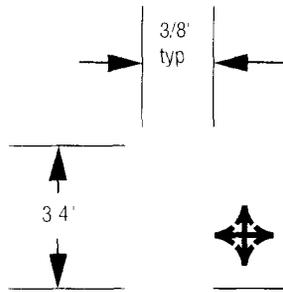
For customer service or to return product, please call (800) 235-5731 in USA; outside of USA call (805) 879-6000.

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**European Representative**  
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## BECKER EXPANDER/MAMMARY PROSTHESES (RECONSTRUCTION ADJUNCT STUDY)

102757-001 Rev. E Effective July 2002

### 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 mammary. 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)

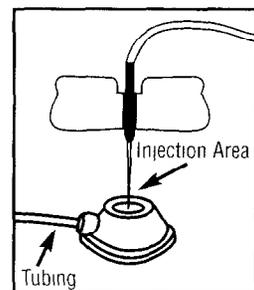
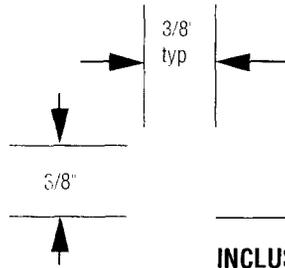


Figure 1

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**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

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## 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.

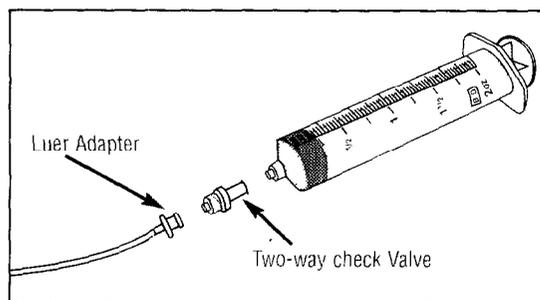


Figure 2

**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.

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**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.)

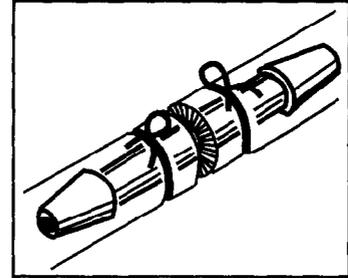


Figure 3

- 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<sup>1</sup> (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.

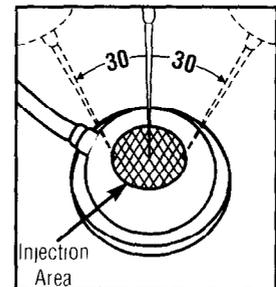


Figure 4

- 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<sup>2</sup>

#### 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.

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- 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 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, 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  $\pm 30^\circ$  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 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.

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- 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.

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- 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.

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- 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



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- 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.

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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, armpit, 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<sup>1</sup>. 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/buninterview.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. 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.<sup>2,3,4</sup>

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

<sup>1</sup>Brown SL, Middleton MS, Berg WA, Soo MS, Pennello G. Prevalence of rupture of silicone gel breast implants in a population of women in Birmingham, Alabama. *American Journal of Roentgenology* 2000; 175:1-8.

Robinson OG, Bradley EL, Wilson DS. Analysis of explanted silicone implants: a report of 300 patients. *Ann Plast Surg* 1995; 34:1-7.

Vinnik CA. Migratory silicone – clinical aspects. *Silicone in Medical Devices – Conference Proceedings* 1991 February 1-2; Baltimore, MD.

U.S. Department of Health and Human Services. FDA Publication No. 92-4249 (p. 59-67).

Duffy MJ, Woods JE. Health risks of failed silicone gel breast implants: a 30-year clinical experience. *Plast Reconstr Surg* 1994; 94:295-299.

Berg WA, Caskey CI, Hamper UM, Kuhlman JE, Anderson ND, Chang BW, Sheth S, Zerhouni EA. Single- and double-lumen silicone breast implant integrity: Prospective evaluation of MR and US criteria. *Radiology* 1995; 197:45-52.

<sup>2</sup>Gorczyca DP, Schneider E, DeBruhl ND, Foo TKF, Ahn CY, Sayre JW, Shaw WW, Bassett LW. Silicone breast implant rupture: Comparison between three-point Dixon and fast spin-echo MR imaging. *AJR* 1994; 162:305-310.



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- 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 mammoplasty (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.



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- 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/Ptoisis**

- 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.

	
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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.

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- 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.

### RETURNED GOODS AUTHORIZATION

#### U.S. Customers

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

#### International Customers

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

### PRODUCT INFORMATION DISCLOSURE

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

### PRODUCT ORDER INFORMATION

#### U.S. Customers

To order directly in the USA, 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.**

TITLE		 <b>MENTOR</b>	
PIDS.			
ARTWORK/DWG NO		E.C.O. NO	
102757-001		REV	
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BECKER EXPAND/MAMMI PROSTH (Recon Adjunct Study)			

**Table 1**  
**BECKER 25 EXPANDER/MAMMARY PROSTHESIS SPECIFICATIONS**

Smooth Catalog Number	Siltex® Catalog Number	Nominal Implant Size	Gel Volume	Temporary Overexpansion volumes*		Final Volumes	
				Maximum Saline	Total Gel-Saline	Total Saline	Total Gel-Saline
350-0150	354-1500	150cc	40cc	185cc	<b>225cc</b>	85-150cc	<b>125-190cc</b>
350-0200	354-2000	200cc	50cc	250cc	<b>300cc</b>	125-200cc	<b>175-250cc</b>
350-0250	354-2500	250cc	60cc	315cc	<b>375cc</b>	165-255cc	<b>225-315cc</b>
350-0300	354-3000	300cc	75cc	375cc	<b>450cc</b>	200-300cc	<b>275-375cc</b>
350-0350	354-3500	350cc	90cc	435cc	<b>525cc</b>	235-350cc	<b>325-440cc</b>
350-0400	354-4000	400cc	100cc	500cc	<b>600cc</b>	275-400cc	<b>375-500cc</b>
350-0500	354-5000	500cc	125cc	625cc	<b>750cc</b>	350-500cc	<b>475-625cc</b>
350-0600	354-6000	600cc	150cc	750cc	<b>900cc</b>	425-600cc	<b>575-750cc</b>
350-0700	354-7000	700cc	175cc	875cc	<b>1050cc</b>	500-700cc	<b>675-875cc</b>
350-0800	354-8000	800cc	200cc	1000cc	<b>1200cc</b>	575-800cc	<b>775-1000cc</b>

\*Not to exceed six months

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

Smooth Catalog Number	Siltex® Catalog Number	Nominal Implant Size	Gel Volume	Final Volumes	
				Total Saline	Total Gel-Saline
350-1515	354-1515	<b>300cc</b>	<b>150cc</b>	150-200cc	300-350cc
350-2020	354-2020	<b>400cc</b>	<b>200cc</b>	200-300cc	400-500cc
350-2525	354-2525	<b>500cc</b>	<b>250cc</b>	250-350cc	500-600cc
350-3030	354-3030	<b>600cc</b>	<b>300cc</b>	300-425cc	600-725cc
350-3535	354-3535	<b>700cc</b>	<b>350cc</b>	350-500cc	700-850cc



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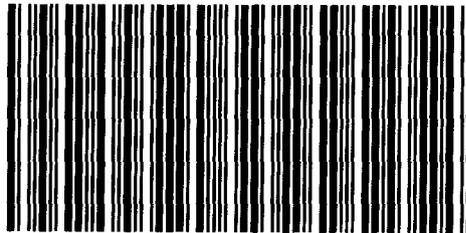
**REFERENCES**

Literature references are available upon request from  
Mentor  
Marketing Services, Literature Department  
201 Mentor Drive  
Santa Barbara, CA 93111 USA

**FOOTNOTES**

- 1 Dr Hilton Becker  
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- 2 Dr John Gibney  
3271 N Civic Center Place  
Scottsdale, AZ 85251 USA

102757-001E



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

[www.mentorcorp.com](http://www.mentorcorp.com) • [www.mentordirect.com](http://www.mentordirect.com)

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Zernikedreef 2  
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The Netherlands



TITLE PIDS:

BECKER EXPAND/MAMM PROSTH (Recon Adjunct Study)

ARTWORK DWG NO

102757-001

E.C.O. NO

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## **Attachment 7**

### **Monitoring Procedures for Physicians Enrolled in Mentor's Adjunct Study**

The sponsor will ensure that the following monitoring procedures are accomplished.

**1) An Annual Progress Report which will contain the following data:**

- a) Names and addresses of physicians participating in the study.
- b) For each physician, patient data which includes:
  - i) Total number of patients enrolled in study.
  - ii) Number of new patients enrolled during prior 12 months and their indications.
  - iii) Number of patients returning for follow-up visits during prior 12 months with associated study points per Postoperative Report:
    - (1) Capsular contracture assessment results
    - (2) Mammography results
    - (3) Complications by type.
  - iv) Number of implant removals.
    - (1) Number/summary of implants analyzed through routine product complaints.
    - (2) Number/summary of implants analyzed through destructive testing process.
  - v) Number and type of Reported Adverse Events.
  - vi) Number of implants sold and number of returns.
- c) Cumulative patient data which includes:
  - i) Total number of patients enrolled in study.
  - ii) Number of new patients enrolled during prior 12 months and their indications.
  - iii) Number of patients returning for follow-up visits during prior 12 months and the associated study points:
    - (1) Capsular contracture assessment results
    - (2) Mammography results
    - (3) Complications by type.
  - iv) Number of implant removals
  - v) Number and type of Reported Adverse Events.

- vi) Number of implants sold and number of implant returns.
  - d) List of centers removed from the study due to noncompliance with study protocol.
- 2) Verification of received Investigator's Agreement prior to sending devices to any physician.**
- 3) Verification of IRB Approval prior to sending devices to any physician enrolled in the study.**
- 4) Biannual audits of our records of physicians to determine:**
- a) Return of all appropriate forms for each patient
    - i) Patient Informed Consent
    - ii) Patient Registry Form
    - iii) Preoperative Report
    - iv) Operative Report
    - v) Postoperative Reports
  - b) Accountability of all devices sent to each physician
    - i) Number of devices implanted
    - ii) Number of devices returned
    - iii) Number of devices remaining at the study site per phone call to study site
- 5) Additional reporting requirements of the IRBs will be accomplished.**

## Attachment 8

### Study Definitions

1. **Abscess:** A localized collection of pus usually caused by bacterial infection, in or around the breast tissue.
2. **Adverse Events:** An adverse event is defined as any undesirable clinical occurrence in a subject whether it is considered to be device related or not (Clinical Investigation of Medical Devices for Human Subjects - EN 540:1993).

Including, but not limited to:

- Device leaks, tears, or ruptures and all instances of surgical removal of implant for those reasons
  - Removal of the implant for any reason
  - Baker III or Baker IV capsular contracture, hematoma, seroma, delayed wound healing, necrosis, breast pain, new diagnosis of breast cancer, lactation difficulties, ptosis, irritation/inflammation, asymmetry, hypertrophic scarring, lymphadenopathy, extrusion, wrinkling, calcification, nipple/breast sensitivity change, silicone granuloma, fluid accumulation, infection and any secondary surgical procedures
  - Any secondary surgical procedure. Examples of secondary procedures that would not be considered adverse events are nipple tattoo, staged reconstruction or port removal
3. **ALS (amyotrophic lateral sclerosis):** Syndrome marked by muscular weakness and atrophy due to degeneration of motor neurons of the spinal cord, medulla, and cortex.
  4. **Asymmetry as an Adverse Event:** If one side is not meeting cosmetic satisfaction, the side out of symmetry should be reported to have asymmetry. If both sides are not meeting cosmetic satisfaction and are both asymmetric, both sides should be reported to have asymmetry.
  5. **Asymmetry as an indication** is one or more of the following conditions:
    - One cup size difference in breast size
    - Need to differentially pad one cup to fill bra to match the opposite breast size
    - Asymmetry due to chest wall deformity such as scoliosis or other deformities of the thoracic cage and/or associated visible differences in shoulder height
  6. **Cancer:** A malignant tumor or neoplasm.
  7. **Calcification:** Grossly visible calcification on the capsule walls.

8. **Congenital Deformity:** defined as:
  - i) Pectus Excavatum defined as congenital concave chest wall deformity with abnormalities of the sternum and anterior ribs.
  - ii) Pectus Carinatum defined as convex chest wall deformity with abnormalities of the sternum and anterior ribs.
  - iii) Severe asymmetry defined as congenital or acquired substantial discrepancy in breast sizes such as to represent a significant physical deformity or abnormality (e.g., Poland's syndrome).
9. **Capsular Contracture:** Formation of scar tissue around the implant that tightens or squeezes the implant which can result in excessive firmness of the implanted breast.
10. **Capsulotomy, Open:** Technique used to correct or reduce capsular contracture through surgical intervention by incision into the breast; usually performed when the contracture is moderate; generally limited to replacement of the implant without surgical dissection of the capsule.
11. **Capsulectomy:** Technique used to correct or reduce capsular contracture, through surgical intervention, by incision into the breast; usually performed as a result of a firm, thick capsule marked contracture; generally requires surgical dissection of the capsule prior to replacement of the implant.
12. **Delayed wound healing:** Any incision that shows wound separation.
13. **Hypertrophic Scarring:** Any scar that is not flattened and mature at 18 months or that requires treatment with steroid injections or silicone pads, etc.
14. **Extrusion:** Any exposure of the implant.
15. **Granuloma:** Any foreign body (silicone) that is palpable or visible or seen at surgery.
16. **Hematoma:** Any blood collection large enough to require removal.
17. **Hypoplastic:** Characterized by incomplete or underdevelopment of the breast.
18. **Iatrogenic Rupture:** Implant damaged during surgery: ruptured, nicked, torn, etc.
19. **Immediate Breast Reconstruction:** Implant inserted no later than to 1-week post mastectomy.
20. **Indication:** Reason subject is having breast implant surgery. Study subjects are one of two indications: Reconstruction or Revision.
21. **Infection:** Any bacterial invasion that has systemic or regional signs and symptoms that require antibiotics for treatment (not prophylaxis).

- 22. Migration:** Movement of the implant from desired position within or outside the original pocket.
- 23. Multiple Sclerosis:** A chronic, slowly progressive disease of the central nervous system characterized by development of disseminated demyelinated glial patches called plaques.
- 24. Necrosis:** Tissue death.
- 25. Pectus Carinatum:** Congenital convex chest wall deformity with abnormalities of the sternum and anterior ribs.
- 26. Pectus Excavatum:** Congenital concave chest wall deformity with abnormalities of the sternum and anterior ribs.
- 27. Ptosis:** Standard grading of ptosis by nipple level.
- 28. Secondary Procedure:** Any surgery on the breast taking place after the initial implant surgery. All subsequent surgeries on the breast are considered adverse events EXCEPT: staged reconstruction, port removal, and nipple tattoo. Examples of secondary procedures considered to be adverse events are: surgical capsular contracture intervention or explants.
- 29. Seroma (fluid accumulation):** Sufficient peri-prosthetic fluid to cause a noticeable volume change or be considered abnormal when detected by breast imaging.
- 30. Wrinkling:** Any detectable implant wrinkle, either visually or palpably.