



156001-01

PRODUCT INSERT DATA SHEET

ENGLISH

## GEL BREAST IMPLANTS

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### DESCRIPTION

MENTOR® Gel Breast Implants 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.

Mentor offers Gel Breast Implants with two types of shell surfaces: SILTEX™ and smooth surfaced. The SILTEX™ shell is textured to provide a disruptive surface for collagen interface. All MENTOR® Gel Breast Implants contain silicone gel which is cohesive. Mentor offers Gel Breast Implants with a variety of cohesivity levels of the filling material. The devices are available in a round shape with different projections and in several contour shapes with different heights and projections. The volume indicated on the product label is the fill volume of the gel.

### INDICATIONS

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

- Cosmetic augmentation. The European Parliament “recommends that implants in women under 18 years of age should be authorized only on medical grounds.”
- Immediate or delayed breast reconstruction following mastectomy.
- Reconstruction due to cancer treatments other than mastectomy.
- Revision due to complications or other undesirable results of a previous surgery for mastectomy or cancer treatments other than mastectomy.
- Post-Trauma defined as 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 surgery for patients with previous augmentation or reconstruction with silicone gel-filled or saline-filled implants.

### CONTRAINDICATIONS

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

- Pregnancy or nursing mothers.
- Lupus (e.g., SLE and DLE).
- Scleroderma (e.g., progressive systemic sclerosis).
- Currently has a condition that could compromise or complicate wound healing (except reconstruction patients).
- Infection or abscess anywhere in the body.
- Demonstrates tissue characteristics, which are clinically incompatible with implant (e.g., tissue damage resulting from radiation, inadequate tissue, or compromised vascularity).
- Possesses any condition, or is under treatment for any condition which, in the opinion of the consulting physician(s), may constitute an unwarranted surgical risk.
- Anatomic or physiologic abnormality, which could lead to significant postoperative complications.
- A history of sensitivity to foreign materials or repeated attempts and failures at breast augmentation or reconstruction.
- An unwillingness to undergo any further surgery for revision.
- Unrealistic expectations, such as inappropriate attitude or motivation, or a lack of understanding of the risks involved with the surgical procedure and implants.
- Premalignant breast disease without a subcutaneous mastectomy.
- Untreated or inappropriately treated breast malignancy, without mastectomy.

NOTE: The satisfactory use of gel-filled prostheses for tissue replacement following mastectomy or trauma 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.

### BENEFITS

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

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

### PATIENT EDUCATION AND INFORMED CONSENT

The surgical procedures associated with the use of gel breast implants are not without potential complications and risks. The use of this product is an elective procedure. The patient should be counseled prior to surgery regarding the benefits and possible risks associated with tissue reconstruction and/or breast augmentation using breast prostheses and alternative procedures. Patients should be advised that breast implants should not be considered lifetime implants and that revision surgery may be necessary including implant removal or replacement. The surgeons in the

European Community (EC) member states and Australia are required to provide each prospective patient with the Mentor patient brochure titled: "Gel-Filled Breast Implant Surgery: Making an Informed Decision." The purpose of this brochure is to assist patients in making informed decisions about breast augmentation and breast reconstruction surgery. A Patient Signature Form is provided in the back of the patient brochure. For patients in the EC member states and Australia, the patient brochure must be read, understood and the Patient Signature Form must be signed by the patient prior to surgery.

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

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

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

#### INSTRUCTIONS FOR USE

The implantation of gel-filled prostheses for breast reconstruction or augmentation involves a variety of surgical techniques; therefore, the surgeon is best advised to use the method, which his/her own practice and discretion dictate to be best for the patient. The procedures listed below are recommended by Mentor for gel-filled implants.

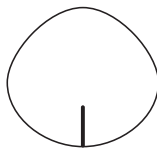
#### Implant Selection

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

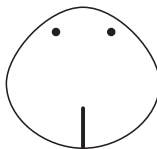
- The implant should not be too small or too large in comparison to the patient's chest-wall dimensions.
- Available tissue must provide adequate coverage of the implant.
- Submuscular placement of the implant may be preferable in patients with thin or poor quality tissue.
- A well-defined dry pocket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

#### Contour Profile only:

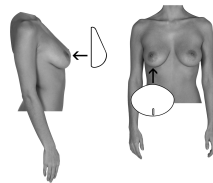
The SILTEX™ CONTOUR PROFILE™ Gel (CPG™ Gel) Breast Implant Cohesive III™ contains raised orientation marks on the anterior and posterior of the implant. These marks help the physician orient the implant and ensure proper placement during implantation.



Anterior Orientation Marks



Posterior Orientation Marks



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

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

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

#### Testing Procedure for Gel Breast 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.

#### Recording Procedure for Gel Breast 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 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.

#### MANUFACTURING

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

#### CLEANING AND STERILIZATION

MENTOR® Gel Breast Implants are supplied individually in a **sterile and non-pyrogenic double-wrap packaging system**. The double-wrap system facilitates the preferred method of sterile product transfer from the circulating area to the sterile field. Sterility cannot be guaranteed if the double-wrap packaging system has been damaged. This product has been sterilized by Dry Heat sterilization. **Do not resterilize the device.**

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All MENTOR® Gel Breast Implants are indicated for **single use only**. If a device is re-used against the manufacturer's instruction, there is a risk of infection (microbial as well as viruses and other transmissible agents) as well as immune responses. The sterility of the device can no longer be guaranteed. Furthermore, the integrity of the device can not be guaranteed due to the risk of damage to the implant. The established shelf life of the product is compromised and thus null and void if compliance with single-use only indication is not followed. Sterility, safety and efficacy cannot be assured for damaged devices. In the event the product becomes contaminated, contact your local Mentor representative (see **RETURNED GOODS AUTHORIZATION**).

#### STORAGE, HANDLING AND PACKAGING DISPOSAL INFORMATION

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

#### PRECAUTIONS

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

- Preexisting infection should be treated and resolved before implantation of the prosthesis.
- Any surgeon performing augmentation or 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 prostheses should be carefully inspected for structural integrity **prior to and during** implantation. Meticulous care must be exercised in handling and implanting the device.
- Excessive force and overmanipulation during the implantation procedure are to be avoided as this may damage the implant.
- 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 device with disposable, capacitor-type cautery instruments as damage to the outer shell of the prosthesis may result.

#### Additional Precautions for SILTEX™ Gel Breast Implants

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

#### Contour Profile

- Ensure that the pocket is not too large as this may result in excessive movement or rotation of the implant.
- Mentor recommends the surgeon consider the **firmer nature of the gel**, as well as the **size of the implant** and the **firmer nature and high profile of the SILTEX™ shell** when choosing optimal **incision size** and **surgical approach**. (See also **Implant Selection** section of this insert.)

#### WARNINGS

**It is the responsibility of the surgeon**, and Mentor relies on the surgeon, to advise the patient of all potential risks and complications associated with the proposed surgical procedure and device, including providing a comparison of the risks and complications of alternative procedures. **Patients should be advised that breast implants should not be considered lifetime implants.**

- 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 open capsulotomy, breast pocket revision, etc.). It is the responsibility of the attending physician to determine if a new implant should be inserted. **If the implant is damaged, it must be removed.**
- Silicone gel can leak or "bleed" through the semipermeable outer silicone envelope into the capsule and adjacent breast tissue. Migration into capillaries has also been reported. The long-term effects of such "bleed" are unknown. Prospective patients should be made aware of this potentiality. (See **ADVERSE REACTIONS/EVENTS** section of this insert.)
- Only one prosthesis should be implanted per breast. Mentor recommends against the stacking of implants, one upon the other. The devices have not yet been tested for this use and the integrity of the implants cannot be guaranteed as the materials may abrade and wear. Such abnormal stress may result in weakening or rupture of the prostheses.
- Do not insert or attempt to repair a damaged or altered prosthesis.
- The action of drugs (e.g., antibiotics and steroids) in contact with the prosthesis has not been tested by the manufacturer, and their use cannot be recommended. Each physician who chooses to use chemotherapeutic drugs with this prosthesis must assure compatibility of the drug with the silicone elastomer.
- 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.
- If povidone-iodine is used within the implant space, the site should be carefully rinsed with saline to remove the residual solution.
- 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.
- Mentor strongly recommends against the treatment of capsule firmness by forceful external stress (such as closed capsulotomy) and 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. Such abnormal stress or trauma to the breast and the prosthesis could result in rupture of the prosthesis.
- Mentor has not tested the in vivo effects of radiation therapy on tissues of patients who have breast implants; however, the literature suggests that radiation therapy may increase the likelihood of experiencing capsular contracture.<sup>1</sup> In addition, the literature notes the following about the effects of radiation therapy on implanted breasts: "(a) when the implanted breast was free of fibrotic changes, radiotherapy produced acceptable results, (b) whenever feasible, 45 Gy/5 weeks seemed preferable over higher doses, (c) irradiation immediately after the reconstructive surgery appeared to produce poorer cosmetic results."<sup>2</sup> The decision regarding the use of radiation therapy following breast implantation should be made by the surgeon and the radiation oncologist.
- The use of the periumbilical approach in placement of the implant has not been established and is not recommended.
- Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist, it is recommended that the device not be implanted until the bleeding is controlled.
- If a physician treats a hematoma or serous fluid accumulation by aspiration, or if a biopsy or lumpectomy is performed, care must be taken to avoid damaging the implant. These procedures present possible risk of implant puncture.
- The incidence of extrusion of the prosthesis has been shown to increase when the prosthesis has been placed in injured areas: scarred, heavily irradiated or burned tissue, crushed bone areas or where severe surgical reduction of the area has 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.
- Surgical implantation of a breast implant may interfere with the ability to breast-feed. The Institute of Medicine (IOM) concluded that there is limited evidence that implantation, especially through a peri-areolar incision, may interfere with lactation and breast-feeding. However, it should be noted that previous breast reconstruction surgery, such as mastectomy, may be the initial cause of this interference.

#### ADVERSE REACTIONS/EVENTS

Any patient undergoing a surgical procedure is subject to possible unforeseen operative and postoperative complications. Potential reactions and complications associated with the use of breast implants should be discussed with and understood by the patient prior to surgery. It is the responsibility of the surgeon, and Mentor relies on the surgeon, to provide the patient with this information and to weigh the risk/benefit potential for each patient.

#### RISKS OF THE PROCEDURE

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

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

#### RISKS SPECIFIC TO BREAST IMPLANT SURGERY

##### Capsular Contracture

Capsular contracture is the most common side effect of breast implants. To accept the implant, a surgical pocket behind the breast is made somewhat larger than the implant itself. Normally a healing scar forms an envelope around the implant, which, on occasion, will shrink sufficiently to squeeze the implant, producing varying degrees of firmness. At its worst, the implant can feel hard, be painful and/or distorted. This can occur soon after surgery or years later and may be unilateral, bilateral or asymmetric. Surgical release or excision of the scar is often successful but recurrence is not uncommon. The cause of the contracture phenomenon is poorly understood. In the past, closed disruption of the scar by squeezing the breast was common, but this is rarely practiced today. Capsular contracture is graded in severity on a scale of I to IV by Baker classification.

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

##### Rupture of the Implant

Breast implants may not last a lifetime. Although rupture can occur at any time following implantation, a number of studies examining rupture of current generation, single-lumen, CE marked, round and shaped silicone gel-filled breast implants of various manufacturers over time (using MRI evaluations) have consistently reported similar results indicating the average expected lifetime exceeds 10 years.

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While the silicone material itself has not been shown to biodegrade, the shell may rupture due to wear and tear, or direct injury. If the implant shell is ruptured, the escaping gel is usually contained by the scar envelope in the surgical pocket (intracapsular) and may be undetectable except by MRI (silent rupture), which is about 85% effective in detecting rupture. If the scar envelope is torn, the gel can be driven into the local tissue planes and breast tissue (extracapsular). Most of the escaped gel remains in the immediate environment of the breast but on rare occasions it has been reported to migrate down the arm, into nerve sheaths or into the abdominal wall. Ultrasound, mammography and physical examination may also diagnose these ruptures, which have escaped the scar envelope. Most of the reported cases occurred in the more fragile, thinner shell devices implanted in the late 1970s.

Rupture should be suspected if there is a change in character of the device such as a new, persistent unilateral burning sensation or a change in softness, texture or shape of the implant. Because of the silent nature of most ruptures and the difficulty of diagnosis without surgical exploration, the true incidence is unknown. Current products have thicker and stronger shells and more cohesive gel contents. Caution should be used when comparing expected or actual rupture rates of current devices to historical incidences, especially when, as is often the case, the brand, vintage and type of device is unknown. Explanation and/or replacement may be indicated if the implant fails, especially if it is seen in the breast parenchyma as it could be confused with or mask a tumor.

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

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

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

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

#### **Interference with Mammography in Detection of Cancer/Calcium Deposits**

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

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

#### **Extrusion of the Implant/Interruption of Wound Healing**

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

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

#### **Wrinkling of the Implant/Dissatisfaction with Cosmetic Results/Asymmetry**

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

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

#### **Possible Reactions to Silicone**

This text contains a brief summary of information from the medical literature. Mentor recognizes that the information contained within this text is highly technical. However, medical ethics and practice dictate that the physician must be an intervening party between the manufacturer of prescriptive medical devices and the patient. The issue of the possible relationship between silicone (and other implantable materials) and various diseases has been the subject of significant scientific debate. Concerns include immunological and neurological disorders, carcinogenicity and connective tissue disorders.

Despite numerous anecdotal reports of established and newly described connective tissue diseases attributed to the device, multiple epidemiological studies have very consistently shown no significant association between silicone breast implants and any established or new connective tissue or other immunological diseases. Four prestigious multispecialty scientific expert panels have reviewed the published literature on this topic, specifically as it relates to silicone breast implants, and have issued lengthy reports on their findings. These expert panels include the Independent Review Group (commissioned by the Chief Medical Officer of the U.K.), the National Science Panel (appointed by Judge Pointer for MDL 926), the IOM and the Scientific and Technical Options

Assessment (STOA) Programme (commissioned by the European Parliament). These four panels have uniformly concluded that there was no discernible evidence of causal association or positive risk ratio between exposure to silicone breast implants and recognized or new autoimmune or connective tissue diseases.

Coincident neurological problems such as multiple sclerosis and amyotrophic lateral sclerosis (ALS) have occurred in a small number of breast implant patients. Subsequent studies have not demonstrated a relationship between any neurological disease and breast implants.

Several studies have been conducted to determine the carcinogenic risk of breast implants and no evidence of increased risk of cancer has been demonstrated. Continuing assessment of both known and possible risks associated with breast implant surgery is ongoing.

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

Although any breast surgery, including breast implantation, could theoretically interfere with the adequacy of a woman's milk supply, many women with breast implants have nursed their babies successfully. It is known that any breast surgery such as breast biopsy can affect the quantity of milk produced. In recent years, the question has been raised regarding the potential transfer of silicone into the breast milk of women with silicone breast prostheses and possible effects on the health of the breast-fed children. However, more recent studies have provided strong evidence of the lack of association between silicone breast implants and adverse effects in breast-fed children. The American Academy of Pediatrics has stated that there is no reason why a woman with implants should refrain from nursing. The European Committee on Quality Assurance and Medical Devices in Plastic Surgery (EQUAM) concluded in 2000 that silicone gel-filled breast implants do not adversely affect pregnancy, fetal development, breast-feeding, nor the health of breast-fed offspring.

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

#### **Anaplastic Large Cell Lymphoma**

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

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

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

#### **Gel Bleed**

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

#### **Granulomas**

It is possible for a granuloma to form around a tiny amount of silicone. Although these lumps are noncancerous, they can be difficult to distinguish from cancerous lumps without being removed (biopsied) and examined. Granulomas, if large or suspicious for malignancy, may need to be biopsied or surgically removed and examined.

#### **Other Possible Reactions**

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

#### **Instructions and Precautions for Implant Removal**

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

#### **PRODUCT EVALUATION**

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

#### **RETURNED GOODS AUTHORIZATION**

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

156001-01

**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 additional liability or responsibility in connection with this product.

**PRODUCT ORDER INFORMATION**

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

**REFERENCES**

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

**DEFINITIONS OF SYMBOLS ON LABELING**

Left Breast	Left Breast is the location of the implanted breast implant	Surgeon Name	Surgeon Name
Right Breast	Right Breast is the location of the implanted breast implant	Address	Surgeon's Address
Date of Implant	Date of the implant surgery	Phone	Surgeon's Telephone Number
Patient Name	Patient Name		



Quantity One



Use By



Catalogue Number



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



Lot Number (Batch Code)



Single-Use Device; Do Not Reuse



Sterilized by Dry Heat (and Date of Sterilization)

<b>LP</b>	Smooth Round Low Profile Gel Breast Implant Cohesive I™		
<b>MP</b>	Smooth Round Moderate Profile Gel Breast Implant Cohesive I™ SILTEX™ Round Moderate Profile Gel Breast Implant Cohesive I™	<b>MP</b>	SILTEX™ Round Moderate Profile Gel Breast Implant Cohesive II™
<b>M+</b>	Smooth Round Moderate Plus Profile Gel Breast Implant Cohesive I™ SILTEX™ Round Moderate Plus Profile Gel Breast Implant Cohesive I™	<b>M+</b>	SILTEX™ Round Moderate Plus Profile Gel Breast Implant Cohesive II™
<b>HP</b>	Smooth Round High Profile Gel Breast Implant Cohesive I™ SILTEX™ Round High Profile Gel Breast Implant Cohesive I™	<b>HP</b>	SILTEX™ Round High Profile Gel Breast Implant Cohesive II™
<b>UHP</b>	Smooth Round Ultra High Profile Gel Breast Implant Cohesive I™ SILTEX™ Round Ultra High Profile Gel Breast Implant Cohesive I™		





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



Manufacturer

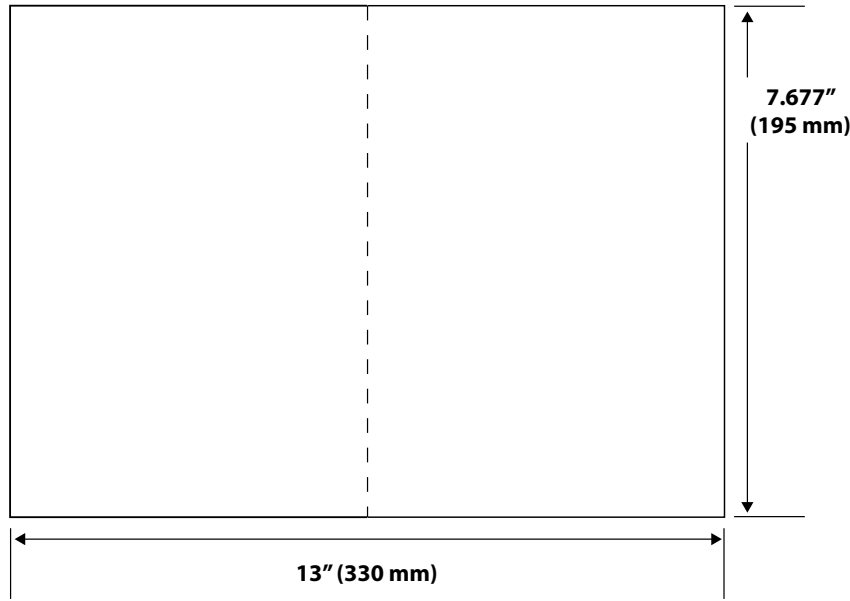
Mentor Medical Systems B.V.  
Zernikedreef 2,  
2333 CL Leiden  
The Netherlands  
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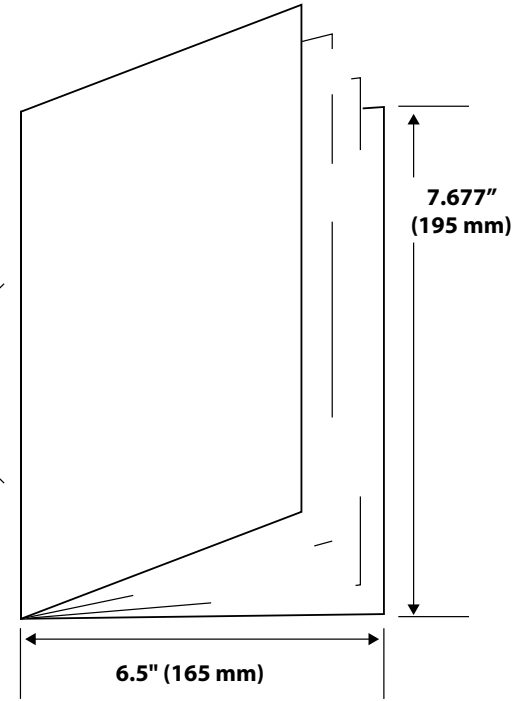
**IFU PRINTING SPECIFICATION SHEET**

PAGE LAYOUT



Flat Size

FOLD PATTERN



Folded Size

Binding Method:

Glued

TITLE <b>Gel Breast Implants</b>		DESCRIPTION <b>PIDS</b>		LAB NUMBER <b>LAB100069598v3</b>	SPECIAL INSTRUCTIONS/COMMENTS <b>NA</b>			BINDING <b>Glued</b>	COLORS <b>Black</b>		
FLAT SIZE <b>13" x 7.677"</b> <b>330 mm x 195 mm</b>	FOLDED SIZE <b>6.5" x 7.677"</b> <b>165 mm x 195 mm</b>	RMC NUMBER <b>156001-01</b>	PAGE COUNT <b>140</b>	LANGUAGES <b>DA, DE, EL, EN, ES-EU, FR, IT, KO, NL, PL, PT-BR, PT-EU, RU, SV, TH, TR, ZH-CN</b>				SELF COVER <input checked="" type="checkbox"/>	PLUS COVER <input type="checkbox"/>	SEALING METHOD <b>NA</b>	WAFER SEAL <input type="checkbox"/>
BLEED SIZE .5" (12.7 mm) <input type="checkbox"/> .125" (3.175 mm) <input checked="" type="checkbox"/>		NONE <input type="checkbox"/>	BLEED ALL SIDES <input type="checkbox"/>	BLEED TOP <input type="checkbox"/>	BLEED RIGHT <input checked="" type="checkbox"/>	BLEED LEFT <input checked="" type="checkbox"/>	BLEED BOTTOM <input type="checkbox"/>	<b>DRAWING IS NOT TO SCALE: DRAWINGS REFLECT INFORMATION FOR PRODUCTION OF PRINTED PIECES AND DO NOT CONTAIN ACTUAL ARTWORK.</b> This document or data herein or herewith is not to be reproduced, used or disclosed in whole or part without the permission of Ethicon, Inc.			
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