Silicone Gel-Filled Breast Implant Surgery:

Making an Informed Decision

August 2004

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GLOSSARY

Areola	The pigmented or darker colored area of skin surrounding the nipple of the breast
Asymmetry	Lack of proportion of shape, size and position between the two breasts
Autoimmune disease	A disease in which the body mounts an "attack" response to its own tissues or cell types Normally, the body's immune mechanism is able to distinguish clearly between what is a normal substance and what is foreign In autoimmune diseases, this system becomes defective and produces antibodies against normal parts of the body, causing tissue injury Certain diseases such as rheumatoid arthritis and scleroderma are considered to be autoimmune diseases
Axillary	Pertaining to the armpit area
Bilateral	Relating to, or affecting, the right and left breast
Biopsy	The removal and examination of tissue, cells or fluid from the body
Breast augmentation	A surgical procedure that increases the size and proportions of a woman's breast
Breast reconstruction	A surgical procedure that restores the natural breast contour and mass following mastectomy, trauma, or injury
Capsular contracture	A tightening of the scar tissue surrounding an implant, resulting in firmness or hardening of the breast
Capsulectomy	Surgical removal of the capsule (scar tissue)
Capsulotomy (closed)	A breakage in the capsule (scar tissue) by massage or compression on the outside of the breast
Capsulotomy (open)	Incision or opening in the capsule (scar tissue) made by an open surgical approach
Carcinoma	A malignant (cancerous) tumor
Congenital anomaly	A deviation from a normal body part, existing at or dating from birth
Connective tissue	A disease or group of diseases affecting connective tissue The cause of these disease is unknown The diseases are grouped together on the basis of clinical signs, symptoms, and laboratory abnormalities.
Delayed reconstruction	Breast reconstruction that takes place weeks, months, or years after a mastectomy.
Displacement	Movement from the usual or proper place
Epidemiological	Relating to the incidence, distribution and control of disease in a population
Extrusion	The pressing out of the implant through the surgical wound
Fibrous tissues	Connective tissues composed mostly of fibers

Flap	A portion of tissue (which may include muscle, fat and skin) with its blood supply moved from one part of the body to another
Hematoma	A mass or swelling containing blood
Immune response	A bodily response to the presence of a foreign substance
Inframammary	Below the breast
Inframammary fold	The crease at the base of the breast and the chest wall
Inframammary incision	An incision made in the fold below the breast
In-patient surgery	A surgical procedure in which the patient is required to stay overnight in the hospital
Latissimus dorsi	Two triangular muscles running from the spinal column to the shoulder
MRI	Magnetic resonance imaging
Mammaplasty	Plastic surgery of the breast
Mammary	Pertaining to the breast
Mammography	X-ray examination of the breasts (as for early detection of cancer)
Mastectomy	The removal of breast tissue due to the presence of a cancerous or precancerous growth Subcutaneous mastectomy: surgical removal of the breast tissues, but sparing the skin, nipple, and areola Total mastectomy: surgical removal of the breast including the nipple, areola, and most of the overlying skin Modified radical mastectomy: surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the lymphatic-bearing tissue in the axilla Radical mastectomy: surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the pectoral muscles, lymphatic bearing tissue in the axilla, and various other neighboring tissue
Mastopexy	Plastic surgery to move sagging breasts into a more elevated position
Necrosis	Death of living tissue
Oncologist	A doctor specializing in the study of tumors
Out-patient surgery	A surgical procedure in which the patient is not required to stay in the hospital overnight
Palpate	To feel with the hand
Palpability	Capability of being touched or felt
Pectoralis	Major muscle of the chest
Plastic surgery	Surgery intended to repair, restore, or improve the body following trauma, injury, or illness
Prosthesis	Any artificial device used to replace or represent a body part

Ptosis	Breast sagging that is usually the result of normal aging, pregnancy, or weight loss
Rectus abdominus	A long flat muscle extending the whole length of the front of the abdomen (stomach)
Rupture	Refers to loss of silicone from a silicone-filled breast implant due to a tear or cut in the implant shell
Saline	A solution that is made up of water and a small amount of salt Approximately 70% of an adult's body weight consists of this salt-water solution
Seroma	Accumulation of fluid in tissue
Serratus	Muscle located beneath the chest's pectoralis major and minor muscles and the rib cage
Silicone elastomer	A type of silicone that has elastic properties similar to rubber
Silent rupture	Refers to rupture that is not recognized or otherwise apparent except through appropriate imaging techniques such as MRI
Subglandular placement	Placement underneath the mammary gland and on top of the chest muscle
Submuscular placement	Placement wholly or partially underneath the pectoralis major (chest) muscle
Surgical incision	A cut or wound of body tissue made during surgery
Tissue expander	An adjustable implant that can be inflated with salt water to stretch the tissue at the mastectomy site to create a new tissue flap for implantation of the breast implant
Transaxillary incision	An incision made across the long axis of the armpit
Umbilical	Relating to the navel
Unilateral	Affecting only one side

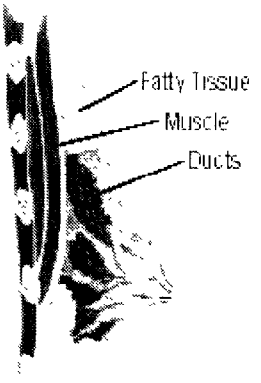
SILICONE GEL-FILLED BREAST IMPLANT SURGERY: MAKING AN INFORMED DECISION

1.0 So You're Considering Silicone Gel-Filled Breast Implant Surgery

The purpose of this brochure is to help you in making an informed decision about breast augmentation (enlargement) and breast reconstruction (restoration) surgery. This educational brochure is set up to help you talk with your surgeon, as well as provide you with general information on breast implant surgery and give you specific details about Mentor silicone gel-filled breast implants

What Gives the Breast Its Shape?

The breast consists of milk ducts and glands, surrounded by fatty tissue that provides its shape and feel. The pectoralis major muscle or chest muscle is located beneath the breast. Factors such as pregnancy (when milk glands are temporarily enlarged), rapid weight loss, and the effects of gravity as you age, combine to stretch the skin, which may cause the breast to droop or sag.



What Is a Silicone Gel-Filled Breast Implant?

A breast implant is a sac (implant shell) of silicone elastomer (rubber) filled with silicone gel, which is surgically implanted under your tissues.

Are You Eligible for Silicone Gel-Filled Breast Implants?

Implants are to be used for females for the following indications (procedures):

• **Breast Augmentation** —This procedure is done to increase the size and proportions of a woman's breasts. **A woman must be at least 18 years old for breast augmentation.**

• **Breast Reconstruction** —This procedure is done to restore a woman's breast shape after a mastectomy or injury that resulted in either partial or total loss of the breast(s), or to correct a birth defect

• **Breast Revision** —This procedure is done to correct or improve the result of previous breast surgery The revision may involve replacement of a breast implant.

What Are Important Factors for You to Consider When Deciding to Have Silicone Gel-Filled Implants?

Whether you are undergoing augmentation or reconstruction, be aware that breast implantation may not be a one-time surgery You are likely to need additional surgery and surgeon 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 breast feeding. Also, breast implants will not prevent your breasts 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.

For patients who have undergone breast implantation either as a cosmetic or a reconstructive procedure, health insurance premiums may increase, coverage may be dropped (your existing insurance coverage may not continue), and/or future coverage may be denied (you may not be able to get insurance in the future). Treatment of complications may not be covered as well You should check with your insurance company regarding these coverage issues. You should discuss the complete extent of your insurance coverage before undergoing surgery

Who Is Not Eligible for Breast Implants ?

Implants are not to be used for

- Women with existing malignant or pre-malignant cancer of her breast without adequate treatment
- Women with active infection anywhere in her body
- Augmentation in women who are currently pregnant or nursing

What are Contraindications for You to Consider?

Surgical practices that are contraindicated in breast implantation because they may damage the shell and cause rupture

- Alteration of the implant
- Stacking of implants (more than one implant per breast per breast pocket)

What are Precautions for You to Consider?

Safety and effectiveness have not been established in patients with the following conditions:

- Autoimmune diseases such as lupus and scleroderma
- Conditions that interfere with wound healing and blood clotting
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease)
- Reduced blood supply to breast tissue

Further considerations:

- **Pre-implantation Mammography** —You may wish to have a preoperative mammogram and another one 6 months to 1 year after implantation to establish a baseline.
- **Interference with Mammography** —The implant may interfere with finding breast cancer during mammography and also may make it difficult to perform

mammography. Therefore, it is essential that you tell your mammography technologist that you have an implant before the procedure. The technologist can use special techniques to reduce the possibility of rupture and to get the best possible views of the breast tissue. Because the breast is squeezed during mammography, it is possible for an implant to rupture during the procedure

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.

• **Distinguishing the implant from breast tissue during breast self-examination** —You should perform a breast self-examination monthly on your implanted breast. In order to do this effectively, you should ask your surgeon to help you tell the difference between the implant and your breast tissue. Any new lumps should be evaluated with a biopsy. If a biopsy is performed, care must be taken to avoid breaking the implant

• **Long-Term Effects** —The long-term safety and effectiveness of breast implants have not been studied; however, Mentor is monitoring the long-term (i.e., 10 year) chance of implant rupture, reoperation, implant removal, and capsular contracture (hardening of the tissues around the implant). Mentor is also conducting mechanical testing to assess the long-term likelihood of implant rupture. Mentor will update this brochure with this information as it becomes available.

• **Capsule Procedures** —You should be aware that closed capsulotomy, the practice of forcible squeezing or pressing on the fibrous capsule around the implant to break the scar capsule, is not recommended, as this may result in breakage of the implant

• **Follow-up Examinations –** After breast implantation, it is recommended that you have follow-up examinations by your doctor on an annual or biannual basis.

• **Rupture –** If you suspect that your implant may be ruptured, you should consult your doctor If rupture is confirmed by your doctor, it is recommended that you have your implant removed. You should monitor your breast implants for rupture when you check your breasts for lumps monthly. Examine your breast tissue by feeling for lumps. Then feel the breast implants Move the implants around while looking in the mirror Look for changes in shape, size and feel of the implants. Know, and pay attention to, how the breast implants feel on the inside and well as the outside If you notice any changes, see your plastic surgeon so that he or she can examine the implants for rupture or other changes.

What are Warnings for Your Doctor to Consider?

- **Closed Capsulotomy** – Your doctor should not treat capsular contracture by forceful external compression, which will likely result in implant damage, rupture, folds and/or hematoma
- **Reuse** – Your doctor should not reuse or resterilize breast implants.
- **Avoiding Damage During Surgery** – Your doctor should take care not to damage the implant with surgical instruments. Your doctor should not use, or attempt to repair, a damaged breast implant. Your doctor should use care during any later procedures to avoid damage to the implant shell. Your doctor should not contact the implant with disposable, capacitor-type cautery devices.
- **Microwave Diathermy** – The use of microwave diathermy (generation of heat in tissue by use of microwaves) is not recommended, as it has been reported to cause tissue necrosis, skin erosion, and extrusion of the implant.
- Your doctor should not use endoscopic placement (performed by insertion through an instrument for visualizing the interior of an organ) or the periumbilical (through the belly button) approach in placement of the implant.

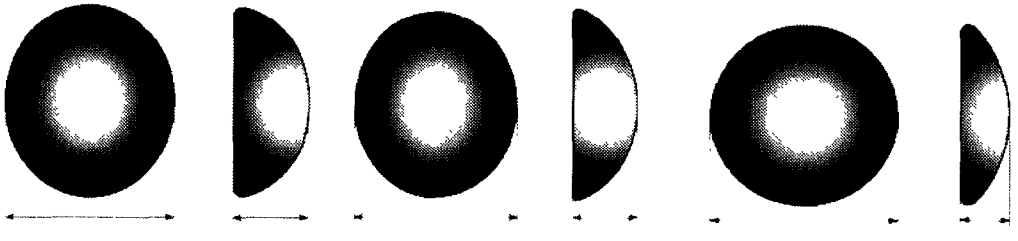
What Types of Breast Implants Are Available from Mentor?

Breast implants come in a variety of shapes, surface textures, and sizes. Breast implants are either silicone-filled, saline-filled, or a combination silicone/saline-filled. There are 2 types/families of Mentor implants filled with saline – one referred to as Saline-Filled and the other referred to as Spectrum™ Implants The Saline-Filled family of implants has a self-sealing valve located on the front (anterior) of the implant that is used for filling the device. The Spectrum™ family has a valve on the back (posterior) of the implant that allows saline to be added after surgery (postoperative adjustability) The implants are available with Siltex® textured, or smooth surface shells. All currently available Mentor silicone-filled breast implants have either a Siltex textured shell or smooth surface shell.

Below is a description of Mentor silicone gel-filled implant styles. Be sure to familiarize yourself with the different features of breast implants and to discuss the best type(s) of implants for you with your surgeon

Catalog Number	Silicone Gel-Filled Breast Implant Style	Size Range
350-7100BC/ 7800BC	Smooth, Round, Moderate Profile	100-800 cc
354-1007/8007	Siltex, Round, Moderate Profile	100-800 cc
350-1001BC/ 8001BC	Smooth, Round, Moderate Plus Profile	100-800 cc
354-1001/8001	Siltex, Round, Moderate Plus Profile	100-800 cc
350-1254BC/ 8004BC	Smooth, Round, High Profile	125-800 cc
354-1007/8007	Siltex, Round, High Profile	125-800 cc

The following diagrams illustrate the high, moderate plus, and moderate profiles.



High Profile Moderate Plus Profile Moderate Profile

2.0 What Are Potential Breast Implant Complications?

Undergoing any surgical procedure may involve the risk of complications such as the effects of anesthesia, infection, swelling, redness, bleeding, and pain. In addition, there are potential complications specific to breast implants.

These complications include.

• Rupture

Breast implants rupture when the shell develops a hole or a tear Implant rupture may or may not result in the release of silicone gel Ruptured implants may result in hard knots in the breast, uneven appearance of the breasts, pain or tenderness, tingling, swelling, numbness, burning or changes in breast sensation. There may be a loss of the size or shape of your breast. However, there may be no symptoms or loss of the size or shape of your breast ("silent rupture") Some implants rupture in the first few months after being implanted, and some rupture after several years Causes of rupture include damage by surgical instruments or other trauma during surgery, capsular contracture, closed capsulotomy, stresses such as trauma or intense physical manipulation (rough treatment with the hands or by mechanical means) after surgery, excessive compression during mammographic imaging, and unknown/unexplained reasons. You should also be aware that the breast implant may wear out over time and rupture.

A retrospective (historical) study on rupture of silicone gel-filled breast implants[1] 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 Magnetic Resonance Imaging (MRI) examination of their breasts to determine the status of their current breast implants. The 344 women who received an 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 a 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
- http://www.fda.gov/cdrh/breastimplants/studies/birupture.pdf

Robinson et al. studied 300 women who had their implants for 1 to 25 years and had them removed for a variety of reasons[2] Visible signs of rupture in 51% of the women studied were found. Severe silicone leakage (silicone outside the implant without visible tears or holes) was seen in another 20%. Robinson et al also noted that the chance of rupture increases as the implant ages. Other studies indicate that silicone may escape the capsule in 11-23% of rupture cases[3 4 5 6]

Clinical data from studies of Mentor silicone gel-filled breast implants, along with more recent medical literature, suggest that the current models of breast implants rupture less frequently than the earlier implants that were associated with the high prevalence of rupture described above.

Ruptured implants require additional surgery to remove and to possibly replace the implant. Magnetic resonance imaging with equipment specifically designed for imaging the breast may be used for evaluating patients with suspected rupture or leakage of their silicone gel-filled breast implant

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[3] Vinnik CA. Migratory silicon – 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).

[4] Duffy MJ, Woods JE. Health Risks of failed silicone gel breast implants: a 30-year clinical experience Plast Reconstr Surg 1994; 94.295-299.

[5] 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 the MR and US criteria. Radiology 1995;45-52.

[6] Goreczyca DP, Schneider E, DeBruhl ND, Foo KTF, 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.

Silicone gel, which escapes the scar tissue capsule surrounding the implant, may migrate away from the breast The free silicone may cause lumps to form in the breast or other tissues (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 with the capsule, because the silicone gel may eventually leak into surrounding tissues If you are considering removal of an implant and the implantation of another one, be sure to discuss the benefits and risks with your doctor.

• Capsular Contracture
The scar tissue or capsule that normally forms around the implant may tighten and squeeze the implant and is called capsular contracture. Capsular contracture may be more common following infection, hematoma, and seroma. It is also more common with subglandular placement (behind the mammary gland and on top of the chest muscle) Symptoms range from mild firmness and mild discomfort to severe pain, distorted shape, palpability (ability to be touched or felt) of the implant, and/or movement of the implant

Additional surgery is needed in cases where pain and/or firmness is severe. This surgery ranges from removal of the implant capsule tissue to removal and possibly replacement of the implant itself. Capsular contracture may happen again after these additional surgeries

• Pain
Pain of varying intensity and length of time may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain associated with nerve entrapment or interference with muscle motion. You should tell your surgeon about severe pain

• Additional Surgeries
You should know 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 deflation, 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. If you choose not to, you may have cosmetically unacceptable dimpling and/or puckering of the breast following removal of the implant

• Dissatisfaction with Cosmetic Results
Dissatisfying results such as wrinkling, asymmetry, implant displacement (shifting), incorrect size, unanticipated shape, implant palpability (ability to be touched or felt), scar deformity, hypertrophic (irregular, raised scar) scarring, and/or sloshing may occur Careful surgical planning and technique can minimize but not always prevent such results

• Infection
Infection can occur with any surgery Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. Infections with an implant present are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved (cleared up).

In rare instances, toxic shock syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. A doctor should be seen immediately for diagnosis and treatment for this condition.

• Hematoma/Seroma
Hematoma is a collection of blood inside a body cavity, and a seroma is a collection of the watery portion of the blood (in this case, around the implant or around the cut made during the surgery) Postoperative hematoma and seroma may contribute to infection and/or capsular contracture. Swelling, pain, and bruising may result. If a hematoma occurs, it will usually be soon after surgery. However, this can also occur at any time after injury to the breast While the body absorbs small hematomas and seromas, large ones will require the placement of surgical drains for proper healing. A small scar can result from surgical draining. Implant deflation/rupture can occur from surgical draining if damage to the implant occurs during the draining procedure

• Changes in Nipple and Breast Sensation
Feeling in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. Changes in feeling can be temporary or permanent and may affect your sexual response or your ability to nurse a baby (See the paragraph on breast feeding below.)

• Breast Feeding
At this time it is not known if a small amount of silicone may diffuse (pass through) from the breast implant silicone shell and may find its way into breast milk. If this occurs, it is not known what effect it may have on the nursing infant. Although there are no current methods for detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone-filled gel implants when compared to women without implants

With respect to the ability to successfully breast feed after breast implantation, one study reported up to 64% of women with implants who were unable to breast feed compared to 7% without implants The periareolar (located around the colored portion surrounding the nipple) incision site may significantly reduce the ability to successfully breast feed The surgical path typically associated with the periareolar incision passes directly through glandular tissue and would be expected to disrupt ductal tissue important for breast feeding. A modification of this typical periareolar approach that avoids passing directly through ductal tissue has been suggested as an alternative to reduce the likelihood of subsequent breast feeding difficulties.[7]

• Calcium Deposits in the Tissue Around the Implant
Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish calcium deposits from cancer Calcium deposits also occur in women who undergo breast reduction procedures,[8 9 10] and in the breasts of women who have not undergone any breast surgery (increasing in prevalence with age from 8 percent in women 25 to 29 years old up to 86 percent in women 75 to 79 years old)[11]

• Delayed Wound Healing
In some instances, the incision site takes longer to heal than 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.

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[7] Brody, G.S 1998. Safety and effectiveness of breast implants. In. *Surgery of the Breast Principals and Art*, Ed: Spears, S.: Philadelphia: Lippincott-Raven.
[8] Abboud, M., J. Vadoud-Seyedi, A. De Mey, M. Cukierfajn, and M Lejour 1995. Incidence of calcification in the breast after surgical reduction and liposuction. *Plast Reconstr Surg.* 96:620-626.
[9] Mitnick, J.S., D.F. Roses, M.N. Harris, and S R. Colen. 1990. Calcifications of the breast after reduction mammoplasty. *Surg Gynecol. Obstet* 171.409-412.
[10] Brown, F.E , S.K. Sargent, S.R. Cohen, and W.D. Morain. 1987. Mammographic changes following reduction mammaplasty *Plast Reconstr. Surg.* 80:691-698.
[11] Stomper, P.C., D.J. D'Souza, P.A. DiNitto, and M A. Arredondo. 1996. Analysis of parenchymal density on mammograms in 1353 women 25-79 years old *Am. J Roentgenol* 167.1261-1265.

Rarer Complications
In addition to these common complications, there have been concerns with rarer diseases, of which you should be aware

• Connective Tissue Disease
Concern over the association of breast implants to the development of autoimmune or connective tissue diseases and symptoms, such as lupus, scleroderma, or rheumatoid arthritis, was raised because of cases reported in the literature of small numbers of women with implants A review of recent long-term epidemiological studies of women with and without implants,[12] together with the review of a number of previously conducted epidemiological studies,[13] indicates that these diseases and symptoms are no more common in women with implants than those in women without implants. However, a lot of women with breast implants believe that their implants caused a connective tissue disease.

• Cancer
Published medical literature[14] indicates that:
1 Patients with breast implants are not a greater risk than those without breast implants for developing breast cancer;
2 Early detection of hidden breast cancer is possible in women with breast implants,
3. Submuscular placement of breast implants allows for greater visualization of breast tissue during mammography;
4. Mammography exams should be performed and interpreted by radiologists experienced in the evaluation of women with breast implants and should include additional views (i.e., Eklund views using displacement techniques); and
5. The current recommendations for getting screening/preoperative mammograms are no different for women with breast implants than for those without implants.
6. A recently published review of four large scale incidence studies that included more than 10,000 women with cosmetic implants followed for up to 29 years concluded that, based on these studies, there is no significant excess of brain cancer incidence among women with cosmetic breast implants[15]

• Neurological
Some women with breast implants have reported that they have neurological symptoms (such as difficulties with vision, sensation, muscle strength, walking, balance, thinking or remembering things) or diseases (such as multiple sclerosis) related to their implants. Several studies have indicated that women with implants are not at an increased risk of being hospitalized with neurological disease compared to other women. The IOM report found no basis for thinking that women with implants were more likely to have neurological diseases or symptoms

• Second Generation Effects
There have been concerns raised regarding potential damaging effects on children born of mothers with implants. Two large, well-controlled, population-based epidemiological studies (one from Sweden[16] and one from Denmark[17]) have found no evidence to support an association of maternal

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[3] Bondurant, S., V L. Ernster and R. Herdman, Eds 2000. *Safety of silicone breast implants.* Committee on the Safety of Silicone Breast Implants, Division of Health Promotion and Disease Prevention, Institute of Medicine. Washington, D.C. National Academy Press.
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silicone breast implants and adverse health outcomes in offspring A review of the published literature on this issue suggests that the information may be insufficient to draw definitive conclusions

3.0 Mentor's Clinical Studies

Although you will experience your own risks (complications) and benefits following breast implant surgery, this section describes the specific complications and benefits of Mentor's gel-filled breast implants. Mentor's clinical studies indicate, for example, that while most women can expect to experience at least one complication at some point through 2 years after implant surgery, most women were satisfied with their implants The studies also indicate that the chance of additional surgery is 1 in 8 for augmentation patients (with capsulectomy as the most common type of additional surgery) and 1 in 4 for reconstruction patients (with the most common type of additional surgery being implant size change). The information below provides more details about the complications and benefits you may experience.

The long-term safety and effectiveness of breast implants have not been studied; however, Mentor is monitoring the long-term (i.e., 10 year) chance of implant rupture, reoperation, implant removal, and capsular contracture (hardening of the tissues around the implant) Mentor is also conducting mechanical testing to assess the long-term likelihood of implant rupture Mentor will update this brochure with this information as it becomes available.

Description of Studies

Mentor Corporation conducted clinical studies of its silicone gel-filled implants to determine the short term and most common complications as well as the benefits of their implants. These were assessed in the following clinical studies: the Core Study and the Adjunct Study.

The Core Study was designed as a 10 year study to assess safety and effectiveness in augmentation, reconstruction and revision patients Patient follow-up was at 6 months, 12 months, 24 months, and annually through 10 years, and is currently on-going. Complications as well as patient satisfaction, breast size change, and measures of body esteem/self esteem/body image were assessed The Core Study consisted of 551 augmentation patients, 251 eligible reconstruction patients, and 205 revision patients

The Adjunct Study was designed to assess safety outcomes for a large number of reconstruction patients at 1, 3 and 5 years, and is on-going. The safety assessment was based on the reported incidence of capsular contracture, seroma, infection and rupture The secondary objective of the study was to provide data concerning potential complications in addition to those reported in the safety assessment The Adjunct Study enrolled 48,307 patients (includes primary patients and patients who were re-implanted with study devices).

4.0 Results from Adjunct Study

What Were Follow-up Rates from the Adjunct Study?

The follow-up rates from the Adjunct Study are shown in the table below

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INDICATION	NUMBER ENROLLED	YEAR 1 FOLLOW-UP	YEAR 3 FOLLOW-UP	YEAR 5 FOLLOW-UP
Reconstruction	13,288	3,614 (34%)	1,301 (19%)	394 (11%)
Revision	34,205	9,665 (35%)	3,772 (18%)	1,336 (10%)

What Were the 5-Year Complication Rates from the Adjunct Study?

The table below shows the 5 year complication rates for reconstruction patients and revision patients. The rates reflect the number of patients out of 100 who experienced the listed complication. For example, 16% or 16 out of 100 reconstruction patients experienced capsular contracture at some time within 5 years after implantation. However, this does not mean that 16% of the reconstruction patients still have capsular contracture at 5 years

Adjunct Study 5-Year Complication Risk Rates

Complication	**Revision**	**Reconstruction**
	N=1,363	**N=394**
Asymmetry	27%	42%
Wrinkling	27%	26%
Breast Pain	19%	19%
Capsular Contracture III /IV	18%	16%
Explantation	13%	11%
Reoperation	10%	18%
Hypertrophic Scarring	6%	9%
Irritation/Inflammation	4%	3%
Infection	2%	3%
Seroma	2%	1%
Hematoma	2%	1%
Rupture	2%	1%
Lymphadenopathy	2%	2%
Calcification	2%	1%
Delayed Wound Healing	1%	3%
Necrosis	1%	2%
Extrusion	1%	2%

5.0 Augmentation Results from Core Study

What Were the Follow-up Rates from the Core Study for Augmentation Patients?

Of those patients available to be seen at the 3 year follow-up visit, data are available for 94% of the augmentation patients.

What Were the 3-Year Complication Rates from the Core Study for Augmentation Patients?

The 3-year complication rates are shown from the most common to the least common in the table below The rates reflect the number of augmentation patients out of 100 who experienced the listed complication at least once within the first 3 years after implantation Some complications occurred more than once for some patients The two most common complications experienced within the first 3 years of implantation were reoperation (15% or 15 patients out of 100) and nipple sensation changes (11% or 11 patients out of 100)

COMPLICATIONS*	3-Year Complication Rate N=551 Patients
Reoperation	15%
Nipple Sensation Changes	11%
Capsular Contracture III/IV	8%
Hypertrophic Scarring	6%
Hematoma	3%
Breast Mass	2%
Ptosis	2%
Breast Pain	2%
Breast Sensation Changes	2%
Wrinkling	1%
Miscarriage	1%
Seroma	1%
Infection	1%
External Injury Not Related to Breast Implants	1%
Placement Damage	1%
Rash	1%
Suture Reaction	1%
Rupture	<1%
Asymmetry	<1%
Inflammation	<1%
Granuloma	<1%
Implant Malposition/Displacement	<1%
Lymphadenopathy	<1%
Lactation Difficulties	<1%
Necrosis	<1%
New Diagnosis of Rheumatic Disease	<1%
Other (Non-cosmetic)	3%

*Excludes mild occurrences of asymmetry, breast pain, calcification, position change, nipple sensation changes, breast sensation, nipple complications and wrinkling

What Were the Types of Additional Surgical Procedures Performed for Augmentation Patients?

The following table provides a breakdown of the types of additional surgical procedures that were performed through the 3 years after the initial implantation There were 160 additional surgical procedures performed in 134 reoperations involving 79 augmentation patients and 115 implants The most common type of additional surgical procedure was capsulectomy (36% of the 160 procedures)

TYPE OF ADDITIONAL SURGICAL PROCEDURE	PERCENTAGE N=160 Procedures
Capsulectomy	36 (23%)
Implant Removal with Replacement	24 (15%)
Implant Removal without Replacement	21 (13%)
Scar Revision	18 (11%)
Capsulotomy	17 (11%)
Incision and Drainage	12 (8%)
Skin Adjustment	8 (5%)
Mastopexy	4 (3%)
Biopsy	4 (3%)
Capsulorrhaphy	4 (3%)
Implant Reposition	4 (3%)
Revision of Wound Closure	3 (2%)
Implant Pocket Revision	2 (1%)
Excise Breast Mass	2 (1%)
Nipple Related Procedure (unplanned)	1 (1%)

What Were the Reasons for Implant Removal for Augmentation Patients?

The main reasons for implant removal among augmentation patients in the Core Study over the 3 years are shown in the table below There were 45 implants removed in 26 patients Of these 45 implants, 24 (53%) were replaced The most common reason for implant removal was patient request (60% of the 45 implants removed)

MAIN REASON FOR IMPLANT REMOVAL	PERCENTAGE N=45 Implants Removed
Patient Request	27 (60%)
Capsular Contracture (III and IV)	5 (11%)
Breast Pain	2 (4%)
Infection	2 (4%)
Necrosis	2 (4%)
False Positive MRI for Rupture	1 (2%)
Wrinkling	1 (2%)
Right Implant Removed so Left Implant Removed Also	1 (2%)
Reason Missing	4 (9%)

What Were the Breast Disease and CTD Events in Augmentation Patients?

Breast disease and connective tissue disease (CTD) were reported in some patients through 3 years after implantation in the Core Study Although there were 551 augmentation patients enrolled in the Core Study, not every patient returned for each follow-up visit Therefore, the percentage of patients with these events cannot be determined Only the number of events can be provided No new cases of breast cancer were reported in augmentation patients

The table below shows the number of reports of CTD through 3 years after implantation Some patients may have reported more than one CTD Confirmed reports were based on a diagnosis by a doctor

Rheumatic Disease	Augmentation Patients
Hashimoto Thyroiditis	1
Rheumatoid Arthritis	1
Hypothyroiditis	1
TOTAL	3

Without a comparison group of women with similar characteristics (age, race, etc) and without breast implants, no conclusions can be made about the relationship between breast implants and these breast disease and CTD events

What Were the Benefits from the Core Study for Augmentation Patients?

The Core Study measured a variety of outcomes that assessed the benefits of the implants For augmentation, these outcomes included circumferential chest size (the distance around the chest), breast size change, as well as satisfaction and comfort with appearance These outcomes were assessed before implantation and at 3 years after surgery for those patients who still had their original implants

For augmentation patients, the average increase in circumferential chest size was 7 1 cm 370 of the 551 patients at 3 years were included in the analysis of cup size Of these 370 patients, 34% experienced an increase of one bra cup size, 50% experienced an increase of two bra cup sizes, and 13% experienced an increase of three bra cup sizes

Ninety seven (97)% of augmentation patients indicated they would have the breast implant surgery again

Among augmentation patients, there was no significant change over two years in the Tennessee Self-Concept Scale and Body Esteem Scale There was a statistically significant increase in the Rosenberg Self-Esteem Scale, indicating an improvement in self esteem

On the SF-36 Health Survey, at baseline, the overall population scored significantly higher than did the general United States female population on all eight subcategories The study patients also scored significantly higher than the United States female population on the Mental Component Score (MCS) and Physical Component Score (PCS) The results for some of the subscales showed scores that decreased slightly, but statistically significantly, from preoperative to postoperatively, indicating a slight worsening in physical and mental health However, the magnitude of these changes was slight, and postoperatively the study patients continued to score statistically higher for all eight subcategories and the MCS and PCS as compared to the United States female population

6.0 Breast Augmentation Considerations

Special Considerations for Breast Augmentation

What Are the Alternatives to Breast Augmentation?

- Accept your breasts as they are
- Wear a padded bra or external prostheses

You are advised to wait a week after reviewing and considering the information in this brochure before deciding whether to have augmentation surgery

What Questions Do You Ask Your Surgeon about Breast Augmentation?

The following list of questions may help to remind you of topics to discuss with your surgeon:

1 What are the risks and complications associated with having breast implants?
2 How many additional operations on my implanted breast(s) can I expect over my lifetime?
3 How will my breasts look if I decide to have the implants removed without replacement?
4 What shape, size, surface texturing, incision site, and placement site are recommended for me?
5 How will my ability to breast feed be affected?
6 How can I expect my implanted breasts to look over time?
7 How can I expect my implanted breasts to look after pregnancy? After breast feeding?
8 What are my options if I am dissatisfied with the cosmetic outcome of my implanted breasts?
9 What alternate procedures or products are available if I choose not to have breast implants?
10 Do you have before- and -after photos I can look at for each procedure, and what results are reasonable for me?

Other Factors to Consider In Breast Augmentation

- ***Choosing a Surgeon***

When choosing a surgeon who is experienced with breast augmentation, you should know the answers to the following questions

1 How many breast augmentation implantation procedures does he/she perform per year?
2 How many years has he/she performed breast augmentation procedures?
3 Is he/she board certified, and if so, with which board?
4 In which states is he/she licensed to practice surgery? Note that some states provide information on disciplinary action and malpractice claims/settlements to prospective patients either by request or on the World Wide Web
5 What is the most common complication he/she encounters with breast augmentation?
6 What is his/her reoperation rate with breast augmentation and what is the most common type of reoperation he/she performs?

Familiarize yourself with the following options in breast implant surgery and be prepared to discuss with your surgeon the following issues

- ***Implant Shape and Size***

Depending on the desired shape you wish to achieve, you and your surgeon may choose a round or contoured implant shape Generally, the larger you want your cup size, the larger the breast implant the surgeon will consider (measured in cubic centimeters, or cc's) You should be aware that contoured implants that are placed submuscularly (under your chest muscle) may assume a round shape after implantation

Your surgeon will also evaluate your existing tissue to determine if you have enough to cover the breast implant If you desire a breast implant size too large for your tissue, the surgeon may warn you that breast implant edges may be apparent or visible postoperatively You may even risk surgical complications Also, excessively large breast implants may speed up the effects of gravity and result in earlier droop or sag.

- ***Surface Texturing***

Textured-surface implants were designed to reduce the chance of capsular contracture Some information in the literature on small numbers of patients suggests that surface texturing reduces the chance of severe capsular contracture, but clinical information from studies of a large number of women with Mentor implants

show no difference in the likelihood of developing capsular contracture with textured implants compared to smooth-surfaced implants

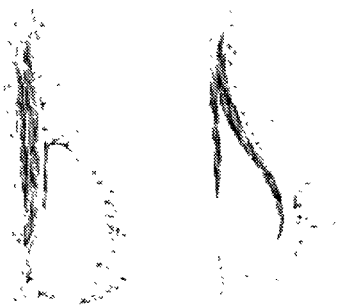
• ***Palpability***

The following may cause implants to be more palpable (more easily felt): textured implants, larger implants, subglandular placement, and the amount of skin/tissue available to cover the implant

• ***Implant Placement***

The breast implant can be placed either partially under the pectoralis major muscle (submuscular) or on top of the muscle and under the breast glands (subglandular) You should discuss with your surgeon the pros and cons of the implant placement selected for you

The **submuscular placement** may make surgery last longer, may make recovery longer, may be more painful, and may make it more difficult to have some reoperation procedures than the subglandular placement The possible benefits of this placement are that it may result in less palpable implants, less capsular contracture, and easier imaging of the breast with mammography



The **subglandular placement** may make surgery and recovery shorter, may be less painful, and may be easier to access for reoperation than the submuscular placement However, this placement may result in more palpable implants, more capsular contracture, and more difficult imaging of the breast with mammography

• ***Incision Sites***

You should discuss with your surgeon the pros and cons for the incision site specifically recommended for you, depending on whether you will be having augmentation or reconstruction

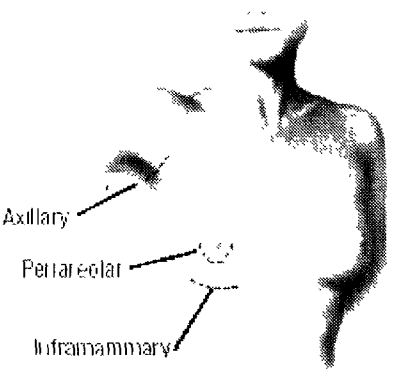
There are 3 common incision sites under the arm (axillary), around the nipple (periareolar), or within the breast fold (inframammary) If the incision is made under the arm, the surgeon may use a probe fitted with a miniature camera, along with minimally invasive (very small) instruments, to create a "pocket" for the breast implant

• Periareolar - This incision is the most concealed, but is associated with a higher likelihood of inability to successfully breast feed, as compared to the other incision sites

• Inframammary - This incision is less concealed than periareolar and associated with less difficulty than the periareolar incision site when breast feeding.

• Axillary - This incision is less concealed than periareolar and associated with less difficulty than the periareolar incision site when breast feeding

• Umbilical/endoscopic - This incision site has not been studied and is not recommended



• ***Surgical Setting and Anesthesia***
Augmentation surgery is usually performed on an outpatient basis, either in a hospital operating room, surgery center, or

surgical suite in the surgeon's office General anesthesia is commonly used, and local anesthesia is also an option The surgery usually lasts 1 to 2 hours Your surgeon will make an incision and create a pocket for the breast implant Then the breast implant will be placed in the pocket and positioned Finally, the incision will be closed, usually with stitches, and possibly taped

• *Postoperative Care*
You will probably feel somewhat tired and sore for several days following the operation, and your breasts may remain swollen and sensitive to physical contact for a month or longer You may also experience a feeling of tightness in the breast area as your skin adjusts to your new breast size

Postoperative care may involve the use of a postoperative bra, compression bandage, or jog bra for extra support and positioning while you heal At your surgeon's recommendation, you will most likely be able to return to work within a few days, although for at least a couple of weeks you should avoid any strenuous activities that could raise your pulse and blood pressure. Your surgeon may also recommend breast massage exercises

Note· If you experience fever, or noticeable swelling and/or redness in your implanted breast(s), you should contact your surgeon immediately

7.0 Reconstruction Results from Core Study

What Were the Follow-up Rates from the Core Study for Reconstruction Patients?

Of those patients available to be seen at the 3 year follow-up visit, data are available for 95% of the reconstruction patients.

What Were the 3-Year Complication Rates from the Core Study for Reconstruction Patients?

The 3-year complication rates (including all levels of severity, from mild to severe) are shown from the most common to the least common in the table below The rates reflect the number of reconstruction patients out of 100 who experienced the listed complication at least once within the first 3 years after implantation Some complications occurred more than once for some patients. The two most common complications experienced within the first 3 years of implantation were reoperation (26% or 26 patients out of 100) and capsular contracture (9% or 9 patients out of 100)

COMPLICATION*	3 Year Complication Rate N=251
Reoperation	26%
Capsular Contracture III/IV	9%
Asymmetry	7%
Ptosis	7%
Hypertrophic Scarring	6%
Infection	5%
Seroma	5%
Breast Mass	4%
Wrinkling	3%
Nipple Sensation Changes	3%
Breast Pain	2%
Metastatic Disease	2%
Lymphadenopathy	2%
Implant Malposition/Displacement	2%
Recurrent Breast Cancer	2%
Hematoma	2%
Necrosis	1%
Rupture	1%
Extrusion	1%
Miscarriage	1%
Breast Sensation Changes	1%
Rash	<1%
New Diagnosis of Rheumatic Disease	<1%
External Injury Not Related to Breast Implants	<1%
Delayed Wound Healing	<1%
Other (Non-cosmetic)	8%

*Excludes mild occurrences of asymmetry, breast pain, calcification, position change, nipple sensation changes, breast sensation, nipple complications and wrinkling

What Were the Types of Additional Surgical Procedures Performed for Reconstruction Patients?

The following table provides a breakdown of the types of additional surgical procedures that were performed through the 3 years after the initial implantation There were 139 additional surgical procedures performed in 95 reoperations involving 64 reconstruction patients and 82 implants The most common type of additional surgical procedure was implant removal with replacement (17% of the 139 procedures)

TYPE OF ADDITIONAL SURGICAL PROCEDURE	PERCENTAGE N=139 Procedures
Implant Removal (With Replacement)	23 (17%)
Implant Reposition	17 (12%)
Implant Removal (without Replacement)	17 (12%)
Capsulotomy	14 (10%)
Skin Adjustment	14 (10%)
Capsulectomy	10 (7%)
Biopsy	10 (7%)
Scar Revision	7 (5%)
Implant Pocket Revision	6 (4%)
Mastopexy	4 (3%)
Incision and Drainage	4 (3%)
Nipple Related Procedure (unplanned)	2 (1%)
Removal of Nodule on Chest Wall	2 (1%)
Capsulorrhaphy	2 (1%)
Create Inframammary Fold	2 (1%)
Revision of Breast/External to Pocket	2 (1%)
Revision of Wound Closure	1 (1%)
Flap Coverage of Expander	1 (1%)
Breast Mass Excision	1 (1%)

What Were the Reasons for Implant Removal for Reconstruction Patients?

The main reasons for implant removal among reconstruction patients in the Core Study over the 3 years are shown in the table below There were 40 implants removed in 31 patients Of the 40 implants removed among reconstruction patients, 23 (58%) were replaced The most common reason for implant removal was patient request (33% of the 40 implants removed)

MAIN REASON FOR IMPLANT REMOVAL	PERCENTAGE N=40 Implants Removed
Patient Request	13 (33%)
Asymmetry	10 (25%)
Capsular Contracture III/IV	4 (10%)
Implant Reposition	3 (8%)
Implant too Large	2 (5%)
Infection	2 (5%)
Extrusion	2 (5%)
Hematoma	1 (3%)
Lack of Projection	1 (3%)
Muscle Spasm	1 (3%)
Recurrent Breast Cancer	1 (3%)

What Were the Breast Disease and CTD Events in Reconstruction Patients?

Breast disease and connective tissue disease (CTD) were reported in some patients through 3 years after implantation in the Core Study Although there were 251 reconstruction patients enrolled in the Core Study, not every patient returned for each follow-up visit Therefore, the percentage of patients with these events cannot be determined Only the number of events can be provided There was a new diagnosis of breast cancer in one reconstruction patient

The table below shows the number of reports of CTD through 3 years after implantation Some patients may have reported more than one CTD Confirmed reports were based on a diagnosis by a doctor

Rheumatic Disease	Reconstruction Patients
Fibromyalgia	1
TOTAL	1

Without a comparison group of women with similar characteristics (age, race, etc) and without breast implants, no conclusions can be made about the relationship between breast implants and these CTD events

What Were the Benefits of the Core Study for Reconstruction Patients?

The Core Study measured a variety of outcomes that assessed the benefits of the implants For reconstruction, these outcomes included circumferential chest size, as well as satisfaction and comfort with appearance These outcomes were assessed before implantation and at 3 years after surgery for those patients who still had their original implants

For reconstruction patients (includes delayed post-mastectomy patients only) the average increase in circumferential chest size was 3.3 cm

Ninety eight (98)% of reconstruction patients indicated they would have the breast implant surgery again

Among reconstruction patients, there was no significant change over two years in the Tennessee Self-Concept Scale, Rosenberg Self Esteem Scale and Body Esteem Scale

On the SF-36 Health Survey, at baseline, the overall population scored significantly higher than did the general United States female population on all eight subcategories The study patients also scored significantly higher than the United States female population on the Mental Component Score (MCS) and Physical Component Score (PCS) The results for some of the subscales showed scores that decreased slightly, but statistically significantly, from preoperative to postoperatively, indicating a slight worsening in physical and mental health However, the magnitude of these changes was slight, and postoperatively the study patients continued to score statistically higher for all eight subcategories and the MCS and PCS as compared to the United States female population

8.0 Breast Reconstruction Considerations

Special Considerations for Breast Reconstruction

Should You Have Breast Reconstruction?

Whether you decide to have breast reconstruction depends on your own individual case, medical condition, general health, lifestyle, emotional state, and breast size and shape. You may consider consulting your family, friends, breast implant support groups, and breast cancer support groups to help you in making this decision.

If you are considering breast reconstruction and do not have a plastic surgeon, ask your general surgeon for a referral for the names of experienced, board-certified plastic surgeons in your area. Your general surgeon, plastic surgeon, and oncologist should work together to plan your mastectomy and reconstruction procedure to give you the best possible result.

What Are the Alternatives to Breast Reconstruction?

You may choose not to undergo breast reconstruction. In this case, you may or may not decide to wear an external breast form (prosthesis) inside your bra. Breast forms are available in a variety of shapes, sizes, and materials such as foam, cotton, and silicone. Custom prostheses are also available to match the size and shape of your breast.

What Are the Choices in Reconstructive Procedures?

The type of breast reconstruction procedure available to you depends on your medical situation, breast shape and size, general health, lifestyle, and goals. Women with small or medium-sized breasts are the best candidates for breast reconstruction.

Breast reconstruction can be accomplished by the use of a prosthesis (a breast implant, either silicone gel or saline-filled), your own tissues (a tissue flap), or a combination of the two. A tissue flap is a section of skin, fat, and/or muscle which is moved from your stomach, back, or other area of your body to the chest area, and shaped into a new breast.

Whether or not you have reconstruction with or without breast implants, you will probably undergo additional surgeries to improve symmetry and appearance. For example, because the nipple and areola are usually removed with the breast tissue in mastectomy, the nipple is usually reconstructed by using a skin graft from another area of the body or the opposite breast in addition to tattooing the area. Nipple reconstruction is usually done as a separate outpatient procedure after the initial reconstruction surgery is complete.

Breast Reconstruction with Breast Implants

Your surgeon will decide whether your health and medical condition make you an appropriate candidate for breast implant reconstruction. Women with larger breasts may require reconstruction with a combination of a tissue flap and an implant. Your surgeon may recommend breast implantation of the opposite, uninvolved breast in order to make them more alike (maximize symmetry) or he/she may suggest breast reduction (reduction mammoplasty) or a breast lift (mastopexy) to improve symmetry. Mastopexy involves removing a strip of skin from under the breast or around the nipple and using it to lift and tighten the skin over the breast. Reduction mammoplasty involves removal of breast tissue and skin. If it is important to you not to alter the unaffected breast, you should discuss this with your surgeon, as it may affect the breast reconstruction methods considered for your case.

Reconstruction Incision Sites

Most implants in breast reconstruction use the mastectomy scar either immediately (during the tissue expansion procedure) or after tissue expansion.

Surgical Settings and Anesthesia

Reconstruction surgery is usually performed on an inpatient basis in an operating room. General anesthesia is most often used.

The Timing of Your Breast Implant Reconstruction

The following description applies to reconstruction following mastectomy, but similar considerations apply to reconstruction following breast trauma or reconstruction for congenital defects. The breast reconstruction

process may begin at the time of your mastectomy (immediate reconstruction) or weeks to years afterwards (delayed reconstruction) Immediate reconstruction may involve placement of a breast implant, but typically involves placement of a tissue expander, which will eventually be replaced with a breast implant It is important to know that any type of surgical breast reconstruction may take several steps to complete

Two potential advantages to immediate reconstruction are that your breast reconstruction starts at the time of your mastectomy and that there may be cost savings in combining the mastectomy procedure with the first stage of the reconstruction However, there may be a higher risk of complications such as deflation with immediate reconstruction, and your initial operative time and recuperative time may be longer

A potential advantage to delayed reconstruction is that you can delay your reconstruction decision and surgery until other treatments, such as radiation therapy and chemotherapy, are completed Delayed reconstruction may be advisable if your surgeon anticipates healing problems with your mastectomy, or if you just need more time to consider your options

There are medical, financial, and emotional considerations to choosing immediate versus delayed reconstruction You should discuss with your surgeon, plastic surgeon, and oncologist the pros and cons of the options available in your individual case

Surgical Considerations to Discuss with Your Surgeon

Discuss the advantages and disadvantages of the following options with your surgeon and your oncologist·

• Immediate Reconstruction·

One-stage immediate reconstruction with a breast implant (implant only)

Two-stage immediate reconstruction with a tissue expander, followed by delayed reconstruction several months later with a breast implant

• Delayed Reconstruction·

Two-stage delayed reconstruction with a tissue expander, followed several months later by replacement with a breast implant

What Is the Breast Implant Reconstruction Procedure?

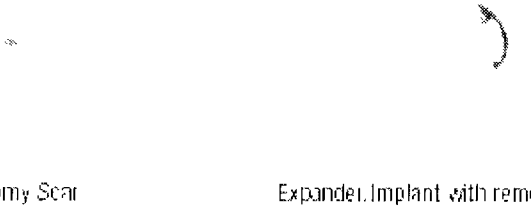
• One-Stage Immediate Breast Implant Reconstruction

Immediate one-stage breast reconstruction may be done at the time of your mastectomy After the general surgeon removes your breast tissue, the plastic surgeon will then implant a breast implant that completes the one-stage reconstruction In reconstruction following mastectomy, a breast implant is most often placed submuscularly

• Two-Stage (Immediate or Delayed) Breast Implant Reconstruction

Breast reconstruction usually occurs as a two-stage procedure, starting with the placement of a breast tissue expander, which is replaced several months later with a breast implant The tissue expander placement may be done immediately, at the time of your mastectomy, or be delayed until months or years later

Stage 1 Tissue Expansion



Mastectomy Scar Expander/Implant with remote injection dome

During a mastectomy, the general surgeon removes skin as well as breast tissue, leaving the chest tissues flat and tight. To create a breast-shaped space for the breast implant, a tissue expander is placed under the remaining chest tissues

The tissue expander is a balloon-like device made from elastic silicone rubber It is inserted unfilled, and over time, sterile saline fluid is added by inserting a small needle through the skin to the filling port of the device The filling port or injection dome can be integral (part of the tissue expander itself) or remote (separate from the tissue expander) As the tissue expander fills, the tissues over the expander begin to stretch, similar to the gradual expansion of a woman's abdomen during pregnancy The tissue expander creates a new breast-shaped pocket for a breast implant

Tissue expander with integral injection dome

Final result with implant

Tissue expander placement usually occurs under general anesthesia in an operating room. Operative time is generally 1 to 2 hours The procedure may require a brief hospital stay, or be done on an outpatient basis Typically, you can resume normal daily activity after 2 to 3 weeks

Because the chest skin is usually numb from the mastectomy surgery, it is possible that you may not experience pain from the placement of the tissue expander. However, you may experience feelings of pressure, tightness, and discomfort after each filling of the expander, which subsides as the tissue expands but may last for a week or more Tissue expansion typically lasts 4 to 6 months

Stage 2 Placing the Breast Implant

After the tissue expander is removed, the unfilled breast implant is placed in the pocket, and then filled with sterile saline fluid In reconstruction following mastectomy, a breast implant is most often placed submuscularly The surgery to replace the tissue expander with a breast implant (implant exchange) is usually done under general anesthesia in an operating room. It may require a brief hospital stay or be done on an outpatient basis

Breast Reconstruction Without Implants: Tissue Flap Procedures

The breast can be reconstructed by surgically moving a section of skin, fat, and muscle from one area of your body to another The section of tissue may be taken from such areas as your abdomen, upper back, upper hip, or buttocks

The tissue flap may be left attached to the blood supply and moved to the breast area through a tunnel under the skin (a pedicled flap), or it may be removed completely and reattached to the breast area by microsurgical techniques (a free flap) Operating time is generally longer with free flaps because of the microsurgical requirements

Flap surgery requires a hospital stay of several days and generally a longer recovery time than implant reconstruction Flap surgery also creates scars at the site where the flap was taken and on the reconstructed breast However, flap surgery has the advantage of being able to replace tissue in the chest area This may be useful when the chest tissues have been damaged and are not suitable for tissue expansion Another advantage of flap procedures over implantation is that alteration of the unaffected breast is generally not needed to improve symmetry.

The most common types of tissue flaps are the TRAM (transverse rectus abdominus musculocutaneous flap) (which uses tissue from the abdomen) and the Latissimus Dorsi flap (which uses tissue from the upper back)

It is important for you to be aware that flap surgery particularly the TRAM flap, is a major operation, and more extensive than your mastectomy operation It requires good general health and strong emotional motivation If you are very overweight, smoke cigarettes, have had previous surgery at the flap site, or have any circulatory problems, you may not be a good candidate for a tissue flap procedure Also, if you are very thin, you may not have enough tissue in your abdomen or back to create a breast mound with this method

The TRAM Flap (Pedicle or Free)

Step 1 Mastectomy is performed and the donor site is marked

Step 2 The flap of rectus muscle and tissue is tunneled to the breast

Step 3 Final Result

During a TRAM flap procedure, the surgeon removes a section of tissue from your abdomen and moves it to your chest to reconstruct the breast The TRAM flap is sometimes referred to as a "tummy tuck" reconstruction, because it may leave the stomach area flatter

A pedicle TRAM flap procedure typically takes 3 to 6 hours of surgery under general anesthesia, a free TRAM flap procedure generally takes longer. The TRAM procedure may require a blood transfusion Typically, the hospital stay is 2 to 5 days You can resume normal daily activity after 6 to 8 weeks Some women, however, report that it takes up to 1 year to resume a normal lifestyle You may have temporary or permanent muscle weakness in the abdominal area If you are considering pregnancy after your reconstruction, you should discuss this with your surgeon You will have a large scar on your abdomen and may also have additional scars on your reconstructed breast

The Latissimus Dorsi Flap With or Without Breast Implants

Step 1 A skin flap and muscle are taken from donor site in the back.

Step 2 The tissue is tunneled to the mastectomy and used to create a breast mound

Step 3 An implant can also be used to create the breast mound.

During a Latissimus Dorsi flap procedure, the surgeon moves a section of tissue from your back to your chest to reconstruct the breast Because the Latissimus Dorsi flap is usually thinner and smaller than the TRAM flap, this procedure may be more appropriate for reconstructing a smaller breast

The Latissimus Dorsi flap procedure typically takes 2 to 4 hours of surgery under general anesthesia Typically, the hospital stay is 2 to 3 days You can resume daily activity after 2 to 3 weeks You may have some temporary or permanent muscle weakness and difficulty with movement in your back and shoulder You will have a scar on your back, which can usually be hidden in the bra line You may also have additional scars on your reconstructed breast

• Postoperative Care

Depending on the type of surgery you have (i e , immediate or delayed), the postoperative recovery period will vary

Note If you experience fever, or noticeable swelling and/or redness in your implanted breast(s), you should contact your surgeon immediately

What Questions Do You Ask Your Surgeon about Breast Reconstruction?

The following list of questions may help to remind you of topics to discuss with your surgeon·

1. What are all my options for breast reconstruction?
2 What are the risks and complications of each type of breast reconstruction surgery, and how common are they?
3 What if my cancer recurs or occurs in the other breast?
4 Will reconstruction interfere with my cancer treatment?
5 How many steps are there in each procedure, and what are they?
6 How long will it take to complete my reconstruction?
7 How much experience do you have with each procedure?
8 Do you have before- and- after photos I can look at for each procedure, and what results are reasonable for me?
9 What will my scars look like?
10 What kind of changes in my implanted breast can I expect over time?
11 What kind of changes in my implanted breast can I expect with pregnancy?
12 What are my options if I am dissatisfied with the cosmetic outcome of my implanted breast?
13 Can I talk with other patients about their experiences?
14 For staged reconstruction, what is the estimated total cost of each procedure?
15 How much will my health insurance carrier cover, especially any complication that may require surgery?

16 How much pain or discomfort will I feel, and for how long?
17 How long will I be in the hospital?
18 Will I need blood transfusions, and can I donate my own blood?
19 When will I be able to resume my normal activity (sexual activity or athletic activity)?

Other Factors to Consider In Breast Reconstruction

• *Choosing a Surgeon*

When choosing a surgeon who is experienced with breast reconstruction, you should know the answers to the following questions:

1 How many breast reconstruction implantation procedures does he/she perform per year?
2 How many years has he/she performed breast reconstruction procedures?
3 Is he/she board certified, and if so, with which board?
4 In which states is he/she licensed to practice surgery? Note that some states provide information on disciplinary action and malpractice claims/settlements to prospective patients either by request or on the World Wide Web
5 What is the most common complication he/she encounters with breast reconstruction?
6 What is his/her reoperation rate with breast reconstruction and what is the most common type of reoperation he/she performs?

Familiarize yourself with the following options in breast implant surgery and be prepared to discuss with your surgeon the following issues:

• *Implant Shape and Size*

Depending on the desired shape you wish to achieve, you and your surgeon may choose a round or contoured implant shape Generally, the larger you want your cup size, the larger the breast implant the surgeon will consider (measured in cubic centimeters, or cc's)

Your surgeon will also evaluate your existing tissue to determine if you have enough to cover the breast implant If you desire a breast implant size too large for your tissue, the surgeon may warn you that breast implant edges may be apparent or visible postoperatively. You may even risk surgical complications Also, excessively large breast implants may speed up the effects of gravity and result in earlier droop or sag.

• *Surface Texturing*

Textured-surface implants were designed to reduce the chance of capsular contracture Some information in the literature on small numbers of patients suggests that surface texturing reduces the chance of severe capsular contracture, but clinical information from studies of a large number of women with Mentor implants shows no difference in the likelihood of developing capsular contracture with textured implants compared to smooth-surfaced implants

• *Palpability*

The following may cause implants to be more palpable (more easily felt). textured implants, larger implants, subglandular placement, and the amount of skin/tissue available to cover the implant

• *Insurance*

Most insurance covers the first breast reconstruction operation Insurance coverage for reoperation procedures or additional surgeon's visits following reconstruction may not be covered, depending on the policy

9.0 Revision Results from Core Study

What Were the Follow-up Rates from the Core Study for Revision Patients?

Of those patients available to be seen at the 3 year follow-up visit, data are available for 93% of the revision patients.

What Were the 3-Year Complication Rates from the Core Study for Revision Patients?

The 3-year complication rates are shown from the most common to the least common in the table below The rates reflect the number of revision patients out of 100 who experienced the listed complication at least once within the first 3 years after implantation. Some complications occurred more than once for some patients The two most common complications experienced within the first 3 years of implantation were reoperation (26% or 26 patients out of 100) and capsular contracture (17% or 17 patients out of 100)

COMPLICATION*	PERCENTAGE N=205
Reoperation	26%
Capsular Contracture III/IV	17%
Nipple Sensation Changes	9%
Hypertrophic Scarring	6%
Breast Mass	6%
Asymmetry	3%
Implant Malposition/Displacement	3%
Hematoma	3%
Rupture	2%
Wrinkling	2%
Ptosis	2%
Delayed Wound Healing	2%
Breast Pain	2%
Breast Sensation Changes	2%
Seroma	2%
Inflammation	1%
External Injury Not Related to Breast Implants	1%
Extrusion	1%
Infection	1%
Lactation Difficulties	1%
Inflammation	1%
New Diagnosis of Breast Cancer	1%
New Diagnosis of Rheumatic Disease	1%
Granuloma	1%
Recurrent Breast Cancer	1%
Other (Non-cosmetic)	6%

*Excludes mild occurrences of asymmetry, breast pain, calcification, position change, nipple sensitivity (unacceptably low), breast sensitivity (unacceptably low and unacceptably high), nipple complications and wrinkling

What Were the Types of Additional Surgical Procedures Performed for Revision Patients?

The following table provides a breakdown of the types of additional surgical procedures that were performed through the 3 years after the initial implantation There were 141 additional surgical operations performed in 100 reoperations involving 51 revision patients and 78 implants The most common type of additional surgical procedure was implant removal with replacement (15% of the 100 procedures)

TYPE OF ADDITIONAL SURGICAL PROCEDURE	PERCENTAGE N=141 procedures
Implant Removal (With Replacement)	21 (15%)
Capsulectomy	18 (13%)
Implant Removal (Without Replacement)	18 (13%)
Capsulotomy	17 (12%)
Skin Adjustment	12 (9%)
Biopsy	10 (7%)
Implant Reposition	10 (7%)
Scar Revision	9 (6%)
Incision and Drainage	7 (5%)
Capsulorraphy	6 (4%)
Mastopexy	5 (4%)
Revision of Wound Closure	2 (1%)
Excision of Skin Lesion	2 (1%)
Nipple Related Procedure (unplanned)	1 (1%)
Exploration of Right Breast and Evacuation of Hematoma	1 (1%)
Needle Aspiration	1 (1%)
Open Incision to Rule Our Implant Rupture	1 (1%)

What Were the Reasons for Implant Removal for Revision Patients?

The main reasons for implant removal among revision patients in the Core Study over the 3 years are shown in the table below There were 39 implants removed in 25 patients Of these 39 implants, 21 (54%) were replaced The most common reason for implant removal was patient request (36% of the 39 implants removed)

MAIN REASON FOR IMPLANT REMOVAL	PERCENTAGE N=39 Implants Removed
Patient Request	14 (36%)
Capsular Contracture (III and IV)	11 (28%)
Asymmetry	3 (8%)
Extrusion	2 (5%)
Symmastia	2 (5%)
Hypertrophic Scarring	1 (3%)
Infection	1 (3%)
Abnormal Mammogram	1 (3%)
Pocket Tear	1 (3%)
Suspected Rupture	1 (3%)
Reason Missing	2 (5%)

What Were the Breast Disease and CTD Events in Revision Patients?

Breast disease and connective tissue disease (CTD) were reported in some patients through 3 years after implantation in the Core Study. Although there were 205 revision patients enrolled in the Core Study, not every patient returned for each follow-up visit Therefore, the percentage of patients with these events cannot be determined Only the number of events can be provided A new diagnosis of breast cancer was reported in one revision patient

The table below shows the number of reports of CTD through 3 years after implantation Some patients may have reported more than one CTD Confirmed reports were based on a diagnosis by a doctor

Rheumatic Disease	Revision Patients
Fibromyalgia	1
Pyoderma Gangrenosum (bacterial skin inflammation)	1
TOTAL	2

Without a comparison group of women with similar characteristics (age, race, etc) and without breast implants, no conclusions can be made about the relationship between breast implants and these breast disease and CTD events

What Were the Benefits from the Core Study for Revision Patients?

The Core Study measured a variety of outcomes that assessed the benefits of the implants For augmentation, these outcomes included circumferential chest size, breast size change, as well as satisfaction and comfort with appearance These outcomes were assessed before implantation and at 3 years after surgery for those patients who still had their original implants

For revision patients, the average increase in circumferential chest size was 1 9 cm
Ninety six (96)% of revision patients indicated they would have the breast implant surgery again

Among revision patients, there was no significant change in body esteem over two years in the Body Esteem Scale The results of the Tennessee Self-Concept Scale (which measures self-concept) showed that there was a decrease across follow-up visits, indicating a lowering of their overall self-esteem The Rosenberg Self-Esteem Scale showed no changes among revision patients

On the SF-36 Health Survey, at baseline, the overall population scored significantly higher than did the general United States female population on all eight subcategories The study patients also scored significantly higher than the United States female population on the Mental Component Score (MCS) and Physical Component Score (PCS) The results for some of the subscales showed scores that decreased slightly, but statistically significantly, from preoperative to postoperatively, indicating a slight worsening in physical and mental health However, the magnitude of these changes was slight, and postoperatively the study patients continued to score statistically higher for all eight subcategories and the MCS and PCS as compared to the United States female population

10.0 Breast Revision Considerations

Special Considerations for Breast Revision

Additional surgery may be considered at anytime following original breast augmentation or breast reconstruction for correction of implant -related complications such as rupture or capsular contracture, treatment of surgical complications such as infection, hematoma (bleeding) or seroma or to improve the aesthetic outcome such as implant size/style change or pocket modification

What Are the Alternatives to Surgical Revision?

- Surgical complications may require timely surgical revision to prevent a localized complication such as infection from progressing to a systemic health concern Suspected implant rupture should also be addressed with timely surgical intervention
- Conservative treatment may be tried to improve implant- related concerns such as implant massage to slow progressive capsular contracture or the use of special garments (bras, bandeaus etc) to improve implant placement

- Aesthetic outcomes can be accepted as is or improved with undergarment choices including the use of supplementary padding to correct volume asymmetries

With the exception of treating surgical complications or implant rupture, most surgeons advise *waiting at least six months from the original surgery* before considering revisional surgery This allows time for the incision to heal, reabsorption of any seroma or edema related fluid in the pocket and tissue, scar formation and stabilization, and gradual skin and muscle relaxation to accommodate the implant volume following the original surgical procedure

What Are The Most Frequently Performed Surgical Revisions?

A short summary of the most common revisions includes:

- Treatment of grade III-IV capsular contracture by capsulotomy and/or capsulectomy
- Replacement of a suspected implant rupture
- Treatment of surgical complications such as infection or hematoma by temporary implant removal and drain insertion
- Implant size and/or style (i.e contour shape) change
- Implant placement change such as changing a subglandular placement to a submuscular placement to improve visible wrinkling , implant palpability and/or accuracy of mammography
- Implant pocket revision including adjustment of the mammary fold or expansion of pocket toward midline (cleavage)
- Correction of ptosis (drooping or sagging breast mound) by mastopexy
- Scar revisions

What Questions Do You Ask Your Surgeon about Breast Revision?

The following list of questions may help to remind you of topics to discuss with your surgeon:

1 What are the risks and complications associated with having breast implant revision surgery?
2 How many additional operations on my implanted breast(s) can I expect over my lifetime?
3 How will my breasts look if I decide to have the implants removed without replacement?
4 What shape, size, surface texturing, incision site, and placement site do you recommended for me?
5 How will my ability to breast feed be affected?
6 How can I expect my implanted breasts to look over time?
7 How can I expect my implanted breasts to look after pregnancy? After breast feeding?
8 What are my options if I am dissatisfied with the cosmetic outcome of my implanted breasts after revision surgery?
9 What conservative alternatives are available other than surgical revision?
10 Is this outpatient surgery and can it be accomplished with local anesthesia?
11 Will there be any additional scars?
12 Will I need drains placed?
13 Will my pain and recovery time be the same as experienced with my original implant surgery?
14 Is there anything I can do following this revision surgery to reduce my risk of implant complications in the future?
15 Will you be marking my chest in a sitting up position before surgery so that we both agree to planned changes?
16 *Will you be replacing my implant even if it seems intact (for capsulotomy and pocket adjustment procedures)?
17 Do you have before- and -after photos I can look at for each procedure, and what results are reasonable for me?
18 Will your office facilitate any device warranty discussions with the manufacturer of my current implants?

Other Factors to Consider In Breast Revision

Both Mentor and the scientific literature suggests that any implant revision surgery requiring temporary removal of an intact implant to accomplish capsulotomy, or pocket adjustments or the use of surgical instruments in close proximity to the originally implanted device, includes removal and replacement of the

originally implanted device with a replacement implant Mentor mammary prostheses are labeled "for single use only" Implant shell integrity can be inadvertently compromised during revisional surgery

For breast reconstruction patients, occasionally temporary removal of the implant may be suggested by the oncologist to facilitate ongoing surveillance for breast cancer recurrence or additional chemotherapeutic or radiation treatment regimens Effective and sometimes aggressive disease treatment modalities always are a first priority for the patient and their healthcare team Once the suggested treatment regimen is completed, surgical reconstruction revision including implant replacement can be safely considered

11.0 Mentor's Laboratory Testing

The information below describes some of Mentor s laboratory testing

Device Gel Bleed Testing

Gel bleed testing of sterile Smooth Moderate Profile Silicone Gel-Filled Breast Implants was performed using the suggested test method in ASTM F703-96, Appendix X2 This method provides a worst case estimate of the amount of silicone gel diffusion through a shell The results of such testing can be used for "comparison of gel bleed diffusion rates of various product configurations in a laboratory setting" (ASTM F703-96) ASTM standard clearly states, that "The results of this bleed test method can not be correlated with the actual physiological performance of an implant since the chemical gradient is not replicated "

All PMA models use the same materials and design for the shell and gel-filler; as a result, the gel bleed rate measured from one smooth device is indicative of the bleed rate of the other smooth device styles as well. The data obtained in this test demonstrate a relatively low bleed rate (starting at 0 0035 g/cm2/week and decreasing to 0 0011 g/cm2/week at week 15) that became relatively constant after approximately five weeks

An in vitro bleed test was also performed to quantitatively and qualitatively analyze the silicone compounds and platinum which bleeds into a physiological fluid An intact 125cc Smooth Round Moderate Profile device was immersed in porcine serum (at 370C) for 120 days Porcine serum was chosen to simulate the composition, including lipid content, of the extracellular fluid within the fibrous capsule that is in direct contact with the implant in the patient Aliquots of the serum were analyzed at different time points for low molecular weight (LMW) siloxane compounds (<1500 molecular weight) by gas chromatography/mass spectroscopy and for platinum by inductively coupled plasma/mass spectrometry The results indicate that only the LMW siloxanes D4, D5, and D6 and platinum diffused into the serum in measurable quantities Of all the detectable LMW siloxanes in serum D5 was the highest at 2 8 µg In total, only 4 3 µg of the three siloxanes was detected (all at about background levels) Platinum levels followed an increasing trend in the serum peaking at 4 1 µg by sixty days and then remained constant thereafter These bleed data suggest that the amount of gel-filled mammary bleed under physiological conditions is much less than that seen in the standard test suggested in ASTM F703-96

Damage During Surgery

Iatrogenic events, inadvertently induced by a physician or surgeon or by medical treatment or diagnostic procedures, may contribute to premature implant failure A study has been completed to evaluate iatrogenic events and subsequent effect on fatigue lifetime. This included surgical insertion procedure, mammography and sharp instrument damage caused by scalpel or suture needle Smooth Round Moderate Profile Gel-filled Mammary Implants were subjected to cyclic fatigue analysis following induced iatrogenic events Surgical insertion and mammography procedures showed no effect on implant fatigue lifetime Sharp instrument damage induced with scalpel and suture needle showed a significant reduction of fatigue lifetime

12.0 If You Experience a Problem, Should You Report It?

If you believe that you have experienced a serious problem(s) related to your breast implants, you should have your health professional report the problem(s) to the FDA You are encouraged to report any adverse events through their health professionals

Although reporting by physicians or other health professionals is preferred, women may also report any serious problem directly through the MedWatch voluntary reporting system An adverse event is serious and should be reported when it results in an initial or prolonged hospitalization, disability, congenital anomaly (birth defect), or medical or surgical intervention

This information reported to MedWatch is entered into databases to be used to follow safety trends (patterns) of a device and to determine whether further follow-up of any potential safety issues related to the device is needed

To report, use MedWatch form 3500, which may be obtained through the FDA's website at **http://www.fda.gov/medwatch/index.html** You may also call 1-888-463-INFOFDA (1-888-463-6332) from 10:00 a m - 4:00 p m. Eastern Time, Monday through Friday, to receive an additional FDA MedWatch package **Keep a copy of the MedWatch form completed by your doctor for your records.**

13.0 Warranty

The following is a description of the assistance available from the Mentor Advantage Limited Warrranty

The Mentor Standard Advantage is free of charge to all patients who are implanted with Mentor gel-filled breast implants. 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 provide, at no cost, the same or similar 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 $1200 per revision surgery to help cover operating room expenses and anesthesia expenses not covered by insurance. You will need to sign a Release Form to qualify for financial assistance

Products Covered

The Mentor Standard Advantage coverage applies to all Mentor gel-filled breast implants that are implanted in the United States provided they have been.

- Implanted in accordance with the Mentor package insert 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

Events Covered

The Mentor Standard Advantage coverage applies to the following:

- Rupture of the gel implant shell

Other loss-of-shell integrity events may also be covered by this program A physician retained by Mentor will determine if specific, additional events should be covered.

Events Not Covered

The Mentor Standard Advantage coverage does not apply to 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

Filing for Financial Assistance

To file a Mentor Advantage claim for product replacement and/or financial assistance, the surgeon must contact the Mentor Product Evaluation Department prior to replacement surgery

For financial assistance claims, a patient specific Release Form will be generated that the patient must sign and return For either replacement or financial assistance claims, the surgeon must send the explanted, decontaminated Mentor breast implant(s) within six months of the date of explantation to

Mentor Product Evaluation
3041 Skyway Circle North
Irving, Texas 75038-3540

Upon receipt, review and approval of the completed claim, including receipt of the explanted product and patient completion of a full general release, financial assistance will be issued

This is a summary of Mentor's Standard Advantage Limited Warranty coverage It is an overview only and not a complete statement of the program You may obtain a copy of the complete Mentor Advantage Limited Warranty for Gel-Filled Breast Implants by writing or calling

Consumer Affairs Department
Mentor Corporation
201 Mentor Drive
Santa Barbara, CA 93111
1-800-525-0245

You may also obtain a copy of the complete program from your physician or by going to www mentorcorp com

14.0 What Are Other Sources of Additional Information?

General Resources about Implants:
Upon request, you will be provided with a copy of the package insert (Directions for Use) You can request a copy from your surgeon or from Mentor The package insert has many undefined medical and technical terms since it contains information directed only to the surgeon

For more detailed information on the preclinical and clinical studies conducted by Mentor, you are referred to the Summary of Safety and Effectiveness Data for this product at http //www fda gov/cdrh/pdf/TBD pdf

If you should decide to get breast implants, you will be given a device identification card with the style and serial number of your breast implant(s) This will be given to you right after your surgery

For additional information or questions about Mentor breast implants, please call 1-800-MENTOR8

Mentor Corporation
1-800-MENTOR8
www mentorcorp com

Institute of Medicine Report on the Safety of Silicone Implants
www.nap edu/catalog/9618 html

Food and Drug Administration
1-888-INFO-FDA or 301-827-3990
http://www.fda.gov/cdrh/breastimplants/
You can find important information in the FDA breast implant consumer handbook, which is available through the phone number or website provided above

Breast Reconstruction Resources
The following list of resources may help you to find more information and support for your breast reconstruction decision

National Cancer Institute
1-800-4-CANCER
cancernet.nci.nih.gov

American Cancer Society
(Reach to Recovery)
1-800-ACS-2345
www cancer org

Y-ME National Organization for Breast Cancer Information and Support
1-800-221-2141
www y-me org

201 Mentor Drive
Santa Barbara
CA 93111 USA
(800) MENTOR-8
www mentorcorp com

Adjunct Study

19. Please provide revised Adjunct Study data as follows:

a. **Your Adjunct Study proposes 4 indications rather than 2. FDA believes that your indication groups can be combined. Therefore, please combine all primary reconstruction and severe deformity data into a single Reconstruction group. In addition, please combine revision augmentation and revision reconstruction data into a single Revision group.**

19a Response:

The Adjunct study report in Attachment 23 has been modified to report two indications: Reconstruction and Revision. As requested the indications were combined.

b. **For the Kaplan-Meier risk rates, types of additional surgical procedures, and reasons for removal data, you did not consistently use original + re-enrolled patients. While you should provide a detailed description that provides the number of patients and devices originally enrolled in the study and those re-enrolled, we do not believe it is appropriate to pool these patients. As with the Core Study, please stratify out all patients who were re-enrolled into the Adjunct Study and present their data separately. For those patients re-enrolled (i.e., reimplantation with Adjunct Study devices), please present their KM data separately.**

19b Response:

Separate Kaplan Meier data for original patients and devices and patients who were re-enrolled are presented in Appendix F and G of the Adjunct study Report located in Attachment 23.

c. **For the Kaplan-Meier risk rates, types of additional surgical procedures, and reasons for removal data, please make the same types of revisions to the individual complications as requested for the Core Study data (e.g., recategorization).**

19c Response:

Recategorization of additional surgical procedures, complications and reasons for removal was completed and included in Tables 6.3.1, 6.3.6, and 6.3.8. The revised report is located in Attachment 23.

d. **Please use the following hierarchy to determine the primary reasons for removal: rupture; infection; capsular contracture; extrusion; necrosis; hematoma/seroma; delayed wound healing; breast pain; implant**

malposition/displacement; wrinkling; palpability/visibility; asymmetry; ptosis; nipple related; scarring; device injury/damage; breast cancer/mass; biopsy; and patient request/other.

19d Response:

The above hierarchy for reasons for removal was utilized and the data are reflected in Table 6.3.6 in the Adjunct Report located in Attachment 23.

e. **Along with your summary tables of the Adjunct Study data, please provide raw tables for the Kaplan-Meier data, as you provided for the Core Study.**

19e Response:

The raw tables for the Kaplan Meier data are provided in Appendix F and G of the Adjunct Report located in Attachment 23.