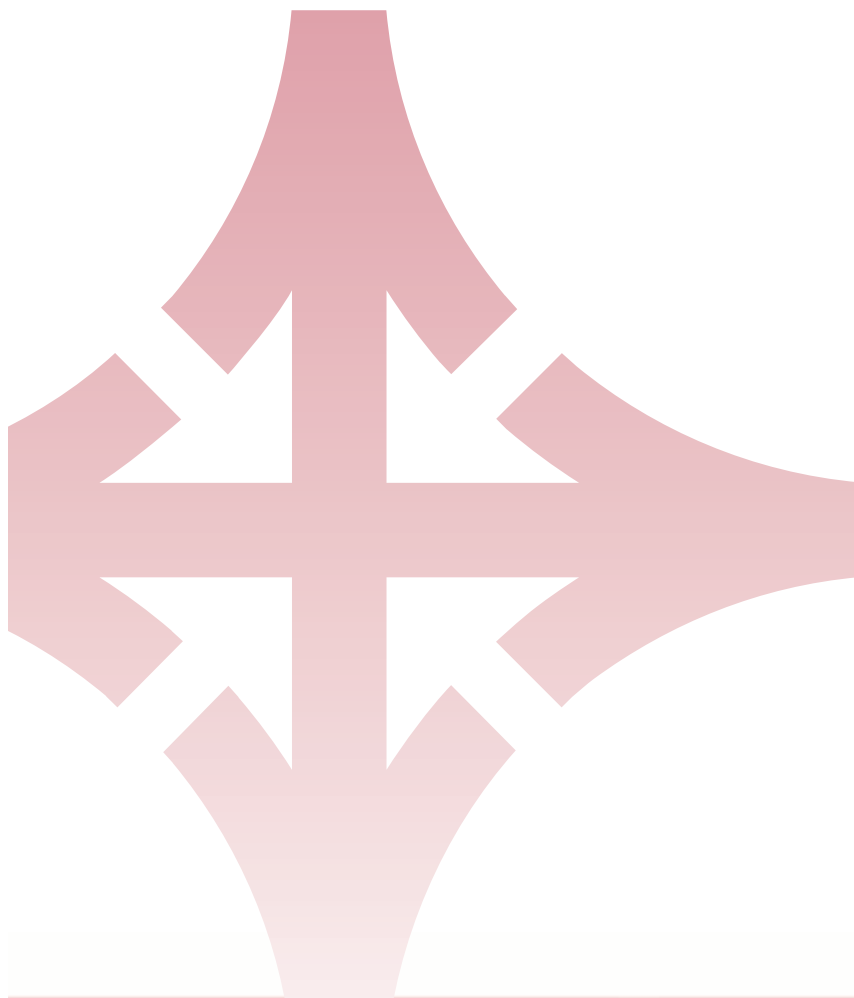


Important Information for
Reconstruction Patients about
Mentor MemoryGel™ Silicone
Gel-Filled Breast Implants



Important Information for Reconstruction Patients about Mentor MemoryGel™ Silicone Gel-Filled Breast Implants November 2006

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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/or 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 mounts an attack against normal parts of the body, causing tissue injury. Certain diseases such as rheumatoid arthritis, lupus, and scleroderma are considered to be autoimmune diseases.
Axillary	Pertaining to the armpit area.
Biocompatible	The condition of being compatible with living tissues or systems without being toxic.
Biopsy	The removal and examination of tissues, cells, or fluid from the body.
Body Esteem Scale (BES)	A questionnaire which asks about a person’s body image.
Breast augmentation	A surgical procedure to increase breast size. For this document, it refers to placement of a breast implant. The first time a breast implant is placed to increase breast size, it is called primary augmentation. All subsequent times the implant is replaced, it is called revision-augmentation.
Breast implant	An internal artificial device or implant intended to replace the breast.
Breast mass	A lump or body in the breast.

Breast reconstruction	A surgical procedure to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality.
Calcification	Process of hardening by calcium salts.
Capsule	Scar tissue that forms around the breast implant. Sometimes this capsule squeezes the implant, resulting in capsular contracture (below).
Capsular contracture	<p>A tightening of the tissue capsule surrounding an implant, resulting in firmness or hardening of the breast and in squeezing of the implant if severe. Capsular contracture is classified by Baker Grades. Baker Grades III or IV are the most severe. Baker Grade III often results in the need for additional surgery (reoperation) because of pain and possibly abnormal appearance. Baker Grade IV usually results in the need for additional surgery (reoperation) because of pain and unacceptable appearance. Capsular contracture Baker Grade II may also result in the need for additional surgery. Capsular contracture is a known risk for implant rupture. Below is a description of each Baker Grade.</p> <ul style="list-style-type: none">• Baker Grade I – Normally soft and natural appearance• Baker Grade II – A little firm, but breast looks normal• Baker Grade III – More firm than normal, and looks abnormal (change in shape)• Baker Grade IV – Hard, obvious distortion, and tenderness with pain
Capsulectomy	Surgical removal of the scar tissue capsule around the implant.

Capsulorrhaphy	Surgical stitching of a tear in the scar tissue capsule around the implant.
Capsulotomy (closed)	An attempt to break the scar tissue capsule around the implant by pressing or pushing on the outside of the breast. This method does not require surgery but is a known risk for rupture of the implant and is contraindicated.
Capsulotomy (open)	Surgical incision into the scar tissue capsule around the implant.
Congenital anomaly	An abnormal development in part of the body.
Connective tissue disease/disorder (CTD)	A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc. and/or the immune system. Connective tissue diseases (“CTDs”) that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma.
Contraindication	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.
Contralateral	Opposite side.
Core Study	The primary clinical study of augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients that supported the approval of the premarket approval (PMA) application. Safety and effectiveness data are collected yearly through 10 years, with the follow-up from years 4 through 10 being performed as part of a postapproval Core Study.
Delayed reconstruction	Breast reconstruction that takes place weeks, months, or years after a mastectomy.

Delayed wound healing	Delayed progress in the healing of an opened wound.
Displacement	Movement of the implant from the usual or proper place.
Epidemiological	Relating to the science of explaining the relationships of factors that determine disease frequency and distribution.
Extracapsular rupture	A type of rupture in which the silicone gel is outside of the scar tissue capsule surrounding the implant.
Extrusion	Skin breakdown with the pressing out of the implant through the surgical wound or skin.
Fibromyalgia	A disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue.
Fibrous tissues	Connective tissues composed mostly of fibers.
Flap	A portion of tissue (which may include muscle, fat, and skin) moved from one part of the body to another. The tissue flap may or may not have its blood supply attached.
Follicular cyst	Any closed sac, usually containing liquid, resulting from the blocking of a duct or small gland.
Functional Living Index-Cancer (FLIC)	The Functional Living Index-Cancer (FLIC) is a questionnaire used to evaluate day-to-day functioning in patients who have cancer.
Granuloma	A lump or mass made of inflammatory cells surrounding a foreign substance due to longstanding inflammation.
Hematoma	A collection of blood within a space.

Hypertrophic scarring	An enlarged scar remaining after the healing of a wound.
Immune response	A bodily response to the presence of a foreign substance.
Infection	Invasion with microorganisms (for example, bacteria, viruses). An infection usually results in fever, swelling, redness, and/or pain.
Inflammation	The response of the body to infection or injury that is characterized by redness, swelling, warmth, pain, and/or loss of function.
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.
Inpatient surgery	A surgical procedure in which the patient is required to stay overnight in the hospital.
Intracapsular rupture	A type of rupture in which the silicone gel remains inside the scar tissue capsule surrounding the implant.
Lactation	The production and secretion of milk by the breast glands.
Latissimus dorsi	Two triangular muscles running from the spinal column to the shoulder.
Low molecular weight silicones	Components of silicone of smaller molecular weight that may bleed out of silicone gel.
Lumpectomy	Removal of a small amount of breast tissue.
Lymphadenopathy	Enlargement of the lymph node(s).
Malposition	Implant malposition or displacement is when the implant is not in the correct

spot in the breast. This could have been due to incorrect placement of the implant during the surgery or due to shifting of the implant position over time.

MRI

Magnetic resonance imaging. A radiographic examination that currently has the best ability to detect rupture of silicone gel-filled breast implants.

Mammary

Pertaining to the breast.

Mammography

A type of X-ray examination of the breasts used for detection of cancer.

Mammoplasty

Plastic surgery of the breast.

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.

Metastatic Disease

Spreading of cancer cells from the original site to other parts of the body.

Migration	Movement of silicone materials outside the breast implant.
Necrosis	Death of cells or tissues.
Oncologist	A doctor who studies, identifies, and treats cancer.
Outpatient surgery	A surgical procedure in which the patient is not required to stay in the hospital overnight.
Palpate	To feel with the hand.
Palpability	The ability to feel the implant.
Pectoralis	Major muscle of the chest.
Periareolar	Around the darkened or pigmented area surrounding the nipple of the breast.
Plastic surgery	Surgery intended for the improvement of appearance of the body.
Postoperatively	After surgery.
Primary breast reconstruction	The first time a breast implant is placed for the purpose of breast reconstruction.
Ptoxis	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).
Reoperation	An additional surgery after your first breast implantation.
Revision-Reconstruction	Refers to the correction or improvement of a primary reconstruction. In the context of this document, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast reconstruction.
Rheumatological Disease/Disorder	A variety of diseases involving connective tissue structures of the body, especially the joints and fibrous tissue. These diseases are often associated with pain,

	inflammation, stiffness, and/or limitation of motion of the affected parts. Can include autoimmune diseases. Fibromyalgia is a rheumatological disorder.
Rosenberg Self Esteem Scale	A questionnaire that measures self esteem.
Rupture	A tear or hole in the implant shell. Silicone implant ruptures may be silent or symptomatic. Ruptures can be intracapsular or extracapsular.
Saline	A solution that is made up of water and a small amount of salt.
Scar revision	A surgical procedure to improve the appearance of a scar.
Seroma	A build-up of the watery portion of the blood in a tissue location.
SF-36 Scale	A questionnaire intended to measure health-related quality of life. It includes questions that measure physical, mental, and social health.
Silicone elastomer	A type of silicone that has elastic properties similar to rubber.
Silent rupture	A breast implant rupture without symptoms and which is not apparent except through appropriate imaging techniques such as MRI. Most silicone breast implant ruptures are silent. (see symptomatic rupture below)
Subglandular placement	Placement of a breast implant underneath and within the breast glands but on top of the chest muscle.
Submuscular placement	Placement of a breast implant wholly or partially underneath the chest muscle.
Surgical incision	A cut made to body tissue during surgery.

Symmastia	Joining together of implants in the middle of the chest resulting in loss of cleavage.
Symptom	Any perceptible change in the body or its functions that indicates disease or a phase of a disease.
Symptomatic	Any evidence or sign of disease or disorder reported by the patient.
Symptomatic rupture	A breast implant rupture that is associated with symptoms (such as lumps, persistent pain, swelling, hardening, or change in implant shape). Some silicone breast implant ruptures are symptomatic, but most are silent.
Systemic	Pertaining to or affecting the body as a whole.
Tennessee Self Concept Scale	A questionnaire that evaluates how the patient sees herself and what she does, likes, and feels.
Tissue expander	An adjustable implant that can be inflated with saline to stretch the tissue at the mastectomy site to create a new tissue flap for implantation of the breast implant.

Important Information for Reconstruction Patients about Mentor MemoryGel™ Silicone Gel-Filled Implants

1. Considerations for Silicone Gel-Filled Breast Implant Reconstruction

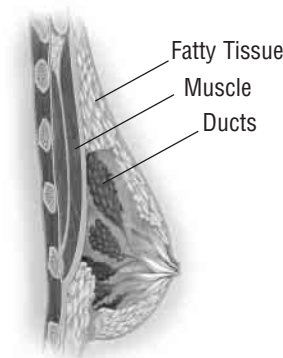
The purpose of this brochure is to help you in making an informed decision about having breast implants for reconstruction (restoration) or breast revision-reconstruction (replacement) surgery. This brochure is not intended to replace consultation with your surgeon. This educational brochure is set up to provide you information about risks and benefits of Mentor silicone gel-filled (MemoryGel™) breast implants.

Please read this entire brochure carefully, and if you have any questions or there are things you do not understand, please discuss them with your surgeon before making any decisions. As part of your decision, both you and your surgeon will be required to sign the last page of this brochure to confirm your understanding of what you have read.

You should wait at least 1-2 weeks after reviewing and considering this information before deciding whether to have primary breast reconstruction or replacement (revision-reconstruction) surgery, unless an earlier surgery is deemed medically necessary by your surgeon.

1.1. 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 chest muscle (pectoralis major 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.



Breast cancer surgery can significantly change the shape of the breast, to a greater or lesser degree, depending on how much breast tissue is removed in a partial or complete mastectomy; how much skin is removed at the time of surgery; and how much tissue reaction or scarring there is

in the remaining breast and skin in response to chemotherapy or radiation therapy.

1.2. 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 breast tissue or under your chest muscle.



1.3. Are You Eligible for Silicone Gel-Filled Breast Implants?

Mentor MemoryGel Silicone Gel-Filled Breast Implants are indicated for females for the following uses (procedures):

- **Breast augmentation for women at least 22 years old.** Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery. (A separate patient brochure is available and should be read for breast augmentation.)
- **Breast reconstruction.** Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the result of a primary breast reconstruction surgery.

Contraindications

Breast implant surgery should not be performed in:

- Women with existing cancer or pre-cancer of their breast who have not received adequate treatment for those conditions
- Women with active infection anywhere in their body
- Women who are currently pregnant or nursing.

Precautions

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

- Autoimmune diseases (for example, lupus and scleroderma).
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease).

- Conditions that interfere with wound healing and blood clotting.
- Reduced blood supply to breast tissue.
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders with your surgeon prior to surgery. Patients with a diagnosis of depression, or other mental health disorders, should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery.

1.4. Important Factors You Should Consider When Choosing Silicone Gel-Filled Implants.

- You should be aware that there are many factors that will affect the outcome and timing of your reconstruction with breast implants, such as the stage of your disease, the type and extent of cancer removal surgery you have had, the amount of skin and soft tissue available for the reconstruction, and additional treatments such as chemotherapy and radiation, which you may require.
- Breast implants are not lifetime devices, and breast implantation is likely not a one-time surgery. You will likely need additional unplanned surgeries on your reconstructed and/or contralateral augmented breasts because of complications or unacceptable cosmetic outcomes. These additional surgeries can include implant removal with or without replacement, or they can include other surgical procedures. When you have your implants replaced (revision-reconstruction), your risk of future complications increases compared to first time (primary) reconstruction surgery, so you should review the complication rates for revision-reconstruction patients to see what future risks you may experience.
- Many of the changes to your breast and chest wall following preparation and implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed and not replaced, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast.
- If you undergo a mastectomy, removal of the breast tissue eliminates the ability to breast feed with the removed breast. In addition, contralateral breast augmentation may affect your ability to breast feed, either by reducing or eliminating milk production.
- Rupture of a silicone gel-filled breast implant is most often silent. This means that neither you nor your surgeon will know that your implants have a rupture most of the time. In fact, the

ability of a physical examination by a plastic surgeon who is familiar with breast implants to detect silicone breast implant rupture is 30%¹ compared to 89% for MRI.² You will need to have regular screening MRI examinations over your lifetime in order to determine if silent rupture is present. You should have your first MRI at 3 years after your initial implant surgery and then every 2 years, thereafter. The cost of MRI screening may exceed the cost of your initial surgery over your lifetime. This cost, which may not be covered by your insurance, should be considered in making your decision.

- If implant rupture is noted on by MRI, you should have the implant removed, with or without replacement.
- With breast implants, routine screening mammography for breast cancer will be more difficult. You should continue to undergo routine mammography screening as recommended by your primary care physician. The implant may interfere with finding breast cancer during mammography. Because the breast and implant are squeezed during mammography, an implant may rupture during the procedure. More x-ray views are necessary for women with breast implants; therefore, you will receive more exposure to radiation. However, the benefit of having the mammogram to find cancer outweighs the risk of the additional x-rays. Be sure to inform the mammography technologist that you have implants.
- You should perform an examination of your breasts every month for cancer screening; however, this may be more difficult with implants. You should ask your surgeon to help you distinguish the implant from your breast tissue.
- You should perform an examination of your breasts for the presence of lumps, persistent pain, swelling, hardening, or change in implant shape, which may be signs of symptomatic rupture of the implant. These should be reported to your surgeon and possibly evaluated with an MRI to screen for rupture.
- The timing for any revision following reconstruction surgery should be discussed with your surgeon so that all issues such as the potential effects of radiation, chemotherapy, and additional cancer surgery or treatments can be fully discussed.
- After undergoing cancer treatment and/or reconstructive breast surgery (either primary or revision), your health insurance premiums may increase, your insurance coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. You should discuss

the complete extent of your insurance coverage with your insurance company before undergoing reconstructive surgery with breast implants.

- You should inform any other doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.
- Mentor will continue its ongoing Core Study through 10 years to further evaluate the long-term safety and effectiveness of these products. In addition, Mentor has initiated a separate, 10-year postapproval study to address specific issues for which the Mentor Core Study was not designed to fully answer, as well as to provide a real-world assessment of some endpoints. The endpoints in the large postapproval study include long-term local complications, connective tissue disease (CTD), CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI compliance and results. Mentor will update its labeling as appropriate with the results of these two studies. You should also ask your surgeon if he/she has any available updated clinical information.
- It is important that you read this entire brochure because you need to understand the risks and benefits and to have realistic expectations of the outcome of your surgery.

2. Potential Breast Implant Complications

Undergoing any type of surgical procedure involves risks (some serious) such as the effects of anesthesia, infection, swelling, redness, bleeding, pain, and even death, which need to be balanced against the benefits of the breast reconstruction surgery. There are potential complications specific to breast implant surgery and breast implants, as described below. It should also be noted that the cited references include data from augmentation and/or reconstruction patients, as well as from a variety of manufacturers and implant models.

• Rupture

Breast implants are not lifetime devices. Breast implants rupture when the shell develops a tear or hole. Rupture can occur at any time after implantation, but they are more likely to occur the longer the implant is implanted. The following things may cause your implant to rupture: damage by surgical instruments; stressing the implant during implantation and weakening it; folding or wrinkling

of the implant shell; excessive force to the chest (for example, during closed capsulotomy, which is contraindicated); trauma; compression during mammographic imaging; and severe capsular contracture. Breast implants may also simply wear out over time. Laboratory studies have identified some of the types of rupture for Mentor's product; however, it is not known whether these tests have identified all causes of rupture. These laboratory studies will continue postapproval.

Silicone gel-filled implant ruptures are most often silent. (MRI examination is currently the best method to screen for silent rupture.) This means that most of the time neither you nor your plastic surgeon will know if the implant has a tear or hole in the shell. This is why MRI is recommended at 3 years and then every 2 years, thereafter, to screen for rupture. However, sometimes there are symptoms associated with gel implant rupture. These symptoms include hard knots or lumps surrounding the implant or in the armpit, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast.

When MRI findings of rupture are found, or if your surgeon determines you have signs or symptoms of rupture, you should have the implant and any gel removed, with or without replacement of the implant. It also may be necessary to remove the tissue capsule as well as the implant, which will involve additional surgery, with associated costs. If you have symptoms such as breast hardness, a change in breast shape or size, and/or breast pain, you should have an MRI to determine whether rupture is present.^{3,4}

There are also consequences of rupture. If rupture occurs, silicone gel may either remain within the scar tissue capsule surrounding the implant (intracapsular rupture), move outside the capsule (extracapsular rupture), or gel may move beyond the breast (migrated gel). There is also a possibility that rupture may progress from intracapsular to extracapsular and beyond. There have also been health consequences reported in the literature. See below for details.

Rupture Information on Mentor Implants

In Mentor's Core Study, rupture was assessed for patients who had scheduled MRIs to screen for rupture (i.e., part of the MRI cohort) and those who were not assessed for rupture by MRI (i.e., part of the non-MRI cohort). For primary reconstruction patients in the MRI cohort, the rupture rate was approximately 1% through 3 years. This means that through 3 years, 1 of every 100 primary reconstruction women had at least one ruptured breast implant. There was one primary reconstruction patient in the Mentor Core

Study with a suspected implant rupture that was silent and only detected with MRI. Rupture has not been confirmed with examination of the implant following removal. For revision-reconstruction patients in the MRI cohort, the rupture rate was 0% through 3 years. There were no ruptures reported in the non-MRI cohorts for either the primary reconstruction or revision-reconstruction patients through 3 years. Across all patients in the Mentor Core Study, of the 8 implants reported as ruptured, 4 showed intracapsular gel and 4 showed extracapsular gel on MRI (3 implants with extracapsular gel were in 2 revision-augmentation patients and 1 was in a primary reconstruction patients). For one of these implants with extracapsular gel, this was a confirmed case in which the device was explanted and the intracapsular gel rupture progressed into an extracapsular gel rupture as shown by MRIs at approximately 10 months and approximately 2 years. There were no cases of migrated gel.

Further rupture rate information on Mentor implants in augmentation patients is provided from an unpublished European study known as the U.K. Sharpe and Collis Study. Silent rupture was assessed by a single MRI on 101 augmentation patients implanted with textured Mentor implants by one surgeon. The average age of the implants was approximately 9 years. Silent rupture was found in approximately 10% of these augmentation patients, which includes one patient for which the device was not explanted to confirm rupture. There were no cases of extracapsular rupture or migrated gel.

Additional information on rupture will be collected through Mentor's postapproval Core Study and large postapproval study.

Additional Information on Consequences of Rupture from Literature
Studies of Danish women evaluated with MRI involving a variety of manufacturers and implant models showed that about three-fourths of implant ruptures are intracapsular and the remaining one-fourth are extracapsular.⁵ Additional studies of Danish women indicate that over a 2-year period, about 10% of the implants with intracapsular rupture progressed to extracapsular rupture as detected by MRI.⁶ This means that for women with silicone gel rupture within the scar tissue capsule detected via MRI after 2 years, 1 in 10 of these women had progression of the gel outside the scar tissue capsule. Approximately half of the women whose ruptures had progressed from intracapsular to extracapsular reported that they experienced trauma to the affected breast during this time period or had undergone mammography. In the other half, no cause was given. In the women with extracapsular rupture, after 2 years, the amount of silicone seepage outside the scar tissue capsule increased for about 14% of the women. This

