Patient Educational Brochure

AUGMENTATION

Breast Augmentation with MENTOR® MemoryGel™ and MENTOR® MemoryGel™ Xtra Silicone Gel Breast Implants

The sale and distribution of this device is restricted to users and/or user facilities that provide information to patients about the risks and benefits of this device in the form and manner specified in the approved labeling provided by Mentor Worldwide LLC.

WARNING:

- Breast implants are not considered lifetime devices. The longer people have them, the greater the chances are that they will develop complications, some of which will require more surgery.
- Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL.
- Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

MENTOR®

PATIENT EDUCATIONAL BROCHURE

AUGMENTATION

BREAST AUGMENTATION WITH MENTOR® MEMORYGEL™ AND MENTOR® MEMORYGEL™ XTRA SILICONE GEL BREAST IMPLANTS

MENTOR®

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GLOSSARY

Abdomen	The part of the body between the upper chest (breasts) and the pelvis (hips); often called the stomach.
Areola	The pigmented or darker colored area of skin surrounding the nipple.
Asymmetry	Uneven appearance between a woman's left and right breasts in terms of their size, shape or breast level.
Atrophy	Thinning or diminishing of tissue or muscle.
Autoimmune Disease	An autoimmune disease is a disease in which the body's immune system attacks its own cells or tissues by mistake, causing damage and dysfunction. Autoimmune diseases can affect connective tissue in the body (the tissue that binds together body tissues and organs). Autoimmune diseases can affect many parts of the body, like nerves, muscles, glands and the digestive system.
Axillary	Under the arm.
Biocompatible	The ability to exist along with living tissues or systems without causing harm.
Biopsy	The removal and examination of tissue, cells, or fluid from a living body.
Body Dysmorphic Disorder (BDD)	A psychological condition characterized by excessive worry about an imagined or minor physical flaw to the point that it can interfere with normal daily activities.
Body Esteem Scale	A series of questions asking about a person's feelings about his or her body.
Breast Augmentation	A surgical procedure to increase breast size and to treat such conditions as sagging or drooping of the breast (ptosis) or breasts of different size, shape, or placement (asymmetry). The first time a breast implant is placed to increase breast size or treat such conditions as ptosis or asymmetry, it is referred to as "primary augmentation." Any time there is another surgery to replace the implant, it is referred to as "revision-augmentation."
Breast Evaluation	A series of questions that ask about a person's breast.
Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)	BIA-ALCL is not breast cancer; it is a rare type of non-Hodgkin's lymphoma (cancer of the immune system).

Breast Implant	Any surgically implanted artificial device intended to replace missing breast tissue or to enhance a breast.
Breast Mass	A lump in the breast.
Breast Reconstruction	A surgical procedure to replace breast tissue or reconstruct a breast after tissue was taken out because of cancer or injury. Breast reconstruction also includes the surgical correction of a breast that has failed to develop properly due to a severe abnormality or congenital defect. The first time a breast implant is placed to replace breast tissue is referred to as "primary reconstruction." Any time there is another surgery to replace the implant, it is referred to as "revision-reconstruction."
Calcification/ Calcium Deposits	The process of soft tissue hardening when the mineral calcium builds up in a certain place.
Capsular Contracture	Tightening of the scar tissue (also called a capsule) that normally forms around the breast implant during the healing process after surgery. In some women, the scar tissue (capsule) squeezes the implant. When this occurs, it is called capsular contracture. This results in firmness or hardening of the breast. Capsular contracture is classified by the Baker Grade Scale.
Capsule	Scar tissue that forms around the breast 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 may rupture the implant and is contraindicated (meaning that the procedure is improper and should not be performed).
Capsulotomy (Open)	A surgery to create an incision or opening in the capsule (scar tissue).
Chest Wall	The system of structures outside the lungs that move as a part of breathing, including bones (the rib cage) and muscles (diaphragm and abdomen).
Congenital Anomaly	An abnormal body part that existed at birth. Also called a congenital malformation or congenital deformity.
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.
Delayed Wound Healing	Unusually slow progress in the healing of a wound; surgical incision site fails to heal normally or takes longer to heal.
Displacement	Movement (shifting) of the implant from the usual or proper place.
Extracapsular Rupture	A type of rupture in which the silicone gel is outside of the scar capsule surrounding the breast implant (see Rupture).
Extracapsular Silicone	Silicone material outside the breast implant capsule.
Extrusion	Skin breakdown with the implant pressing through the skin or surgical incision.
Fibrocystic Breast Disease	Common, benign (noncancerous) changes in the tissues of the breast. The term "disease" is misleading, and many doctors prefer the term "change." The condition is so commonly found in breasts, it is believed to be a variation of normal. Other related terms include "mammary dysplasia," "benign breast disease," and "diffuse cystic mastopathy."
Fibromyalgia	A chronic condition characterized by widespread pain in muscles and joints. It may include fatigue, difficulty sleeping, and morning stiffness.
Fibrous Tissues	Connective tissue composed mostly of fibers (for example, tendons).
Gel Bleed/Gel Diffusion	When silicone gel leaks or "bleeds" or "diffuses" through the implant shell.
Granuloma	Noncancerous lumps that can form around foreign material, such as silicone. Like any lump, it should be evaluated to distinguish it from a lump that might be cancerous.
Groin	The fold where the lower abdomen meets the inner part of the thigh.
Hematoma	A collection of blood inside the body, for example in skin tissue or other body space.
Hypertrophic Scarring	An enlarged scar that remains after a wound heals.
Infection	The growth in the human body of microorganisms such as bacteria, viruses or fungi. An infection can occur as a result of any surgery.

Inflammation/Irritation	The response of the body to infection or injury resulting in swelling, redness, warmth and/or pain.
Inframammary Fold	The crease under the breast where the breast and chest meet.
Inframammary Incision	An incision made in the fold below the breast.
Intracapsular Rupture	A type of rupture in which the silicone gel remains inside the scar tissue capsule surrounding the breast implant (see Rupture).
Lactation	The production and secretion of milk by the breast glands.
Local Complications	Complications that occur in the breast or chest area.
Lymph Nodes	Lymph nodes are glands that play an important part in the body's defense against infection. They produce lymph, which travels throughout the body in the lymph system, and filters impurities from the body. Common areas where the lymph nodes can be felt with the fingers include: groin, armpit, neck, under the jaw and chin, behind the ears, and on the back of the head.
Lymphadenopathy	Enlarged lymph node(s).
Malposition	When the implant is placed incorrectly during the initial surgery or when the implant has moved/shifted from its original position. Shifting can be caused by many factors, such as gravity, trauma, poor initial placement, and capsular contracture.
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.
Mastopexy	Surgical procedure to raise and reshape sagging breasts.
MemoryGel™ Core Study	A Core study is the clinical study that supports the approval of a medical product (such as breast implants). For Mentor's breast implants, the MemoryGel™ Core Study includes augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients. Information on the safety and effectiveness of the implants are collected every year for 10 years after study participants get their implants.

Migration/Gel Migration	Movement of silicone material outside the breast implant to other areas of the body.
MRI (Magnetic Resonance Imaging)	MRI uses a magnetic field to create a 3-dimensional picture of a body part or organ. MRI is the imaging method that currently has the best ability to detect rupture of silicone gel breast implants.
Necrosis	Death of cells or tissues.
Palpability/Visibility	Palpability is when the implant can be felt through the skin. Visibility is when the implant can be seen through the skin.
Pectoralis	Major muscle of the chest.
Periareolar	The areola is the pigmented or darker colored area of skin surrounding the nipple. Periareolar refers to the area just around the areola.
Periumbilical	Around the belly button.
Plastic Surgery	Surgery intended to enhance or improve the appearance of the body.
Platinum	A metallic element used to help make both silicone elastomer (the rubbery material of the breast implant shell) and silicone gel.
Postoperative	After surgery.
Precautions	Information that warns the reader of a potentially hazardous situation that, if not avoided, may result in minor or moderate injury.
Primary Breast Augmentation	The first time a breast implant is placed for the purpose of breast augmentation.
Prosthesis	Any artificial device used to replace or represent a body part.
Ptosis	Sagging or drooping of the breast.
Quality of Life (QoL) Measures	Assessments that may contribute to the evaluation of benefit (effectiveness), including the Rosenberg Self Esteem Scale (measures self-worth or self-acceptance), the Body Esteem Scale (measures a person's body image), and the SF-36 (measures physical, mental, and social health).
Redness/Bruising	Bleeding at the surgical site that causes discoloration and varies in degree and length of time. This is expected following breast implant surgery or other breast procedures.

Removal	Removal of the implant, with or without replacement using another implant.
Reoperation	Any additional surgery performed to the breast or chest area after the first breast implantation.
Revision-Augmentation	Refers to the correction or improvement of a primary augmentation. In the context of this document, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast augmentation.
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.
Risks	The chance or likelihood that an undesirable effect will occur
Rosenberg Self-Esteem Scale	A questionnaire that measures overall self-esteem.
Rupture	A hole or tear in the shell of the implant that allows silicone gel filler material to leak from the shell.
Saline	Saltwater (a solution made of water and a small amount of salt).
Scar Revision	A surgical procedure to improve the appearance of a scar.
Scarring	Formation of tissue at an incision site; all wounds heal by the formation of a scar.
Seroma	Similar to a bruise, a seroma occurs when the watery portion of the blood collects around a surgical incision or around a breast implant.
SF-36 Scale	The Short Form 36 Health Scale; a questionnaire intended to measure physical, mental, and social health.
Silent Rupture	A breast implant rupture without symptoms or a visible change. Silent rupture cannot be felt by the woman or detected by a doctor through physical examination. Silent rupture can only be discovered through appropriate imaging techniques such as MRI.
Silicone	Silicone is a man-made material that can be found in several forms such as oil, gel, or rubber (elastomer). The exact make-up of silicone will be different depending on its use.

Silicone Elastomer	A type of silicone that has elastic properties similar to rubber.
Silicones – Low Molecular Weight (LMW)	Small silicone molecules that may be present in gel bleed/gel diffusion.
Subglandular Placement	When the implant is placed under the breast glands (breast tissue) but on top of the chest muscles.
Submuscular Placement	When the implant is placed underneath the chest muscles.
Surgical Incision	A cut made to body tissue during surgery.
Suspected or Confirmed Rupture	The sum of all ruptures that were either suspected due to MRI imaging or actually confirmed as ruptured after explantation.
Symptom	Any perceptible change in the body or its functions that indicates disease or a phase of a disease.
Symptomatic	Experiencing symptoms; any evidence or sign of disease or disorder.
Symptomatic Rupture	A breast implant rupture that is associated with symptoms (such as lumps, persistent pain, swelling, hardening, or change in implant shape).
Systemic	Pertaining to or affecting the body as a whole.
Tennessee Self Concept Scale (TSCS)	A questionnaire that evaluates how the patient sees herself and what she does, likes, and feels. The scale is intended to summarize an individual's feeling of self-worth, the degree to which the self-image is realistic, and whether or not that self-image is normal. It also measures the following aspects of how the patient feels about herself: moral-ethical, social, personal, physical, and family, identity, behavior, and self-satisfaction.
Toxic Shock Syndrome (TSS)	A rare, but life-threatening bacterial infection that may occur after surgery. Symptoms of TSS occur suddenly: a high fever, vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches, and/or drops in blood pressure, which may cause fainting. A doctor should be seen immediately for diagnosis and treatment if TSS is suspected.
Warnings	A statement that alerts the reader about a situation that, if not avoided, could result in serious injury or death.
Wound Dehiscence (Wound Opening)	Opening of a wound.
Wrinkling/Rippling	Wrinkling of the implant that can be felt or seen through the skin.

1. HOW TO USE THIS EDUCATIONAL BROCHURE

Mentor, the company that sells MemoryGel™ Breast Implants and MemoryGel™ Xtra Breast Implants, has designed this educational brochure to help you understand breast augmentation and to help you talk with your doctor(s) about breast augmentation. Mentor sponsored a large clinical study of these breast implants (also referred to in this brochure as the "MemoryGel™ Core Study") that gathered data about these breast implants. A total of 1,008 patients participated in the MemoryGel™ Core Study. A total of 552 patients had primary augmentation, 145 patients had revision-augmentation, 251 patients had primary reconstruction, and 60 patients had revision-reconstruction with MENTOR® MemoryGel™ Breast Implants. Results from this study are presented in Section 9 of this brochure.

After you receive this information, give yourself time to read and think about the information. Because breast implants will require monitoring and care for the rest of your life, you should wait 1-2 weeks after reviewing and considering this information before deciding whether to have the surgery. If you are having revision-augmentation surgery, your surgeon may advise you to have the surgery sooner.

At the end of this brochure, Mentor has included a **Patient Decision Checklist** that summarizes the risks associated with breast implants and breast implant surgery. The checklist also includes other important information, like insurance coverage, for you to consider. Please take time and review each section of the checklist. Please place your initials at the end of each section if you understand the information presented or, if there are sections that you are unsure about, write down your questions and discuss them with your surgeon before deciding to have breast implant surgery.

When you place your signature at the end of the checklist, you are confirming that you have reviewed each section, have had your questions addressed and understand all the information presented. Additionally, to help ensure the material is reviewed, the checklist allows for patients and physicians to affirmatively acknowledge (e.g., via initials and/or signatures) that specific information was read and discussed.

It is important to remember that the lifetime of breast implants varies by person and cannot be predicted. That means everyone with breast implants may need additional surgeries, but no one can predict when. The longer your implants are implanted, the greater the chances are that you will develop complications, some of which will require more surgery.

2. SAFETY INFORMATION AVAILABLE ON WEBSITE:

Mentor's website, **breastimplantsbymentor.com**, includes important safety information as well as links to the latest version of Mentor's Patient Educational Brochures. You should check this website periodically to stay up to date on any new safety information posted.

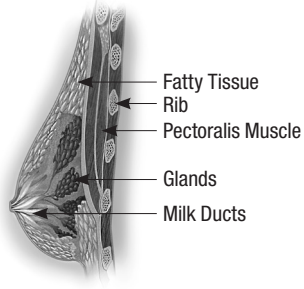
3. GENERAL INFORMATION ABOUT BREAST AUGMENTATION WITH BREAST IMPLANTS

The information in this section provides some general information about breast augmentation with breast implants.

3.1 What Gives the Breast Its Shape?

As shown in Figure 1, your breast consists of milk ducts, glands, blood vessels, and nerves that are surrounded by fatty tissue. Glandular tissue is firm and gives the breast its shape. The fatty tissue gives the breast its soft feel.

Figure 1.
Anatomy of the Breast



The chest muscle (the pectoralis major muscle) is located underneath all this breast tissue but does not have much effect on the shape or feel of the breast.

3.2 What Is a Silicone Gel Breast Implant?

A silicone gel breast implant is a sac (implant shell) made of silicone elastomer (rubber), which is filled with clear silicone gel. Mentor uses medical grade silicone elastomer and gel to manufacture its breast implants. Mentor's silicone gel breast implants are designed to resemble the human breast in shape, weight, and feel.

MENTOR® MemoryGel™ Breast Implants and MENTOR® MemoryGel™ Xtra Breast Implants are round devices with shells constructed from medical grade silicone elastomer. The shell is filled with MemoryGel™, Mentor's proprietary formulation of medical grade silicone gel, and is constructed of successive cross-linked layers of silicone elastomer. There are two styles of shell: smooth and textured. In general, MENTOR® MemoryGel™ Xtra Breast Implants have a higher fill than MENTOR® MemoryGel™ Breast Implants. More information on the types of MemoryGel™ and MemoryGel™ Xtra Breast Implants can be found in Section 7.3 *(Choosing the Right Implant for You)*.

3.3 How Do Breast Implants Work in Breast Augmentation?

Breast implants are used to make the breasts larger or to restore or replace breast tissue. They are surgically implanted beneath your breast tissue, either on top of the chest muscle (subglandular placement) or underneath part or all of the chest muscle (submuscular placement).

4. DECIDING WHETHER TO HAVE BREAST AUGMENTATION SURGERY WITH IMPLANTS

The answers to the questions in this section will help you to decide whether breast augmentation surgery with implants is right for you.

4.1 Am I Eligible for Augmentation with Silicone Gel Breast Implants?

Breast implants have been approved for use in augmentation in two cases:

- **Primary augmentation** to increase the size and proportions of the breast(s) in women at least 22 years old.
- **Revision-augmentation** to correct or improve the result of primary augmentation. Revision-augmentation includes replacing an existing breast implant.

Women who have lost breast tissue to cancer or injury or want to correct a congenital anomaly may also use MemoryGel™ Breast Implants or MemoryGel™ Xtra Breast Implants. This is considered breast reconstruction with implants.

A different educational brochure that describes breast reconstruction with MemoryGel™ Breast Implants or MemoryGel™ Xtra Breast Implants is available for you to read if appropriate to your situation.

4.2 Contraindications

A contraindication is a condition or circumstance that, if present, means a procedure should not be done. Contraindications for breast implant surgery are discussed in this section.

MemoryGel™ Breast Implants and MemoryGel™ Xtra Breast Implants are contraindicated in the following circumstances because the risk of undergoing breast augmentation with implants outweighs the benefits:

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

Surgery in general is not recommended in patients with an active infection, existing cancer or pre-cancer and existing pregnancy (unless the surgery is to treat the infection, cancer or

pregnancy as recommended by your doctor), as it may interfere with the treatment of the infection or the cancer and safety of the pregnancy/nursing. In addition, these conditions may interfere with the healing after surgery.

Adequate studies have not been performed to demonstrate the safety of breast implant surgery in women with these conditions or under these circumstances; therefore, if you have any of the above conditions or circumstances, breast augmentation surgery with implants should not be performed at this time. Failure to take into consideration these contraindications may increase the risks involved with the surgery and could cause harm.

4.3 Precautions

CAUTION: Notify your doctor if you have any of the following conditions as the risks of breast implant surgery may be higher if you have any of these conditions.

- An autoimmune disease
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease)
- Planned chemotherapy following breast implant placement
- Planned radiation therapy to the breast following breast implant placement
- Conditions that interfere with wound healing and/or blood clotting
- Reduced blood supply to breast tissue
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. If you have been diagnosed with or treated for depression, an anxiety disorder, or another mental health condition, you should wait until your condition has resolved or stabilized before having breast implant surgery. Discuss any history of mental health disorders with your doctor(s) prior to surgery.

Before you have surgery, you should have a detailed conversation with all of your doctors (primary care doctor, surgeon, and any specialists you see) about breast implant surgery in light of your medical history.

CAUTION: In order to avoid possible injury or damage to your incision site(s), you should avoid the following for the first month after your surgery:

- Sun exposure,
- Jerky movements or activities that stretch the skin at your incision site(s),
- Participating in sports or other activities that raise your pulse or blood pressure, and
- Unnecessary physical or emotional stress.

4.4 Warnings

There is a boxed warning on all breast implants (See Cover Page).

Read this entire brochure before having breast implant surgery so that you will understand the risks and benefits and have realistic expectations of the outcome of your surgery. Breast implants are associated with many short-term and long-term risks.

WARNING – Smoking can make it harder for your body to heal. If you smoke, your doctor will probably have told you to stop before your surgery. Do not smoke while you are recovering from breast implant surgery.

WARNING – The following is a list of possible complications associated with breast implant surgery. Make sure you read and understand these before deciding whether to have breast implant surgery. Please refer to the following sections in this brochure for more detail on these factors: Section 5 - *RISKS ASSOCIATED WITH BREAST IMPLANTS*, Section 8 - *CARING FOR YOURSELF AFTER BREAST IMPLANT SURGERY* and Section 9 - *MENTOR'S CLINICAL STUDY RESULTS*.

- Breast implants are not expected to last for the rest of your life, and breast implantation may not be a one-time surgery. It is likely that you will need other surgery

related to your breast implants over the course of your life. These additional surgeries can include implant removal with or without replacement, or they can include other surgical procedures.

- Many of the changes to your breast that may occur as a result of breast implant surgery will be permanent and cannot be undone. If you have your implants removed, your skin may be permanently dimpled, puckered, or wrinkled.
- Breast implants may interfere with your ability to produce milk (lactate) for breastfeeding. If you are planning to breastfeed your infant, be prepared to use formula and bottle-feed your baby in the event you have difficulty breastfeeding.
- Mammography for detecting breast cancer (or cancer recurrence) may be more difficult with breast implants in place. You will need more views captured than during a routine mammogram. Therefore, the procedure will take more time and you will be exposed to more radiation than during a standard routine screening mammogram. However, the benefits of mammograms outweigh this risk. You must tell the technologist that you have silicone gel breast implants before the procedure. The technologist can then use special techniques to get the best possible views of your breast tissue.
- Your implants could rupture without you feeling the rupture or noticing any change in your breasts. In some of these instances even your doctor might not be able to tell that a rupture has occurred. A rupture that has no symptoms is called a "silent" rupture. The best way to diagnose a silent rupture is with a Magnetic Resonance Imaging (MRI) examination. An MRI is similar to using x-ray imaging but an MRI machine uses magnetism and not x-ray radiation. It is recommended that you have periodic imaging (e.g., MRI, ultrasound) of your silicone gel-filled implants to screen for implant rupture regardless of whether your implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on your medical history or circumstances (i.e., screening mammography for breast cancer). Even if you have no symptoms, you should have your first ultrasound or MRI at 5-6 years after your initial implant surgery and then every 2-3 years thereafter. If you have symptoms at any time or uncertain ultrasound results for breast implant rupture, an MRI is recommended.
- Routine self-examination of your breasts may be more difficult with implants. However, you should still perform an examination of your breasts every month for cancer screening. 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, swelling, hardening, or change in implant shape, which may be signs of rupture of the implant. Report any of these symptoms or persistent pain to your doctor. Your surgeon may recommend an evaluation via MRI to check for rupture.
- After undergoing breast augmentation surgery, you may experience changes in your healthcare insurance. Your health insurance premiums may increase; your coverage may be dropped or discontinued; you may not be able to get health insurance coverage in the future; and/or insurance may not cover treatment of complications associated with your breast implants. Be sure to check with your insurance company about these potential issues and understand the complete extent of your health coverage before having breast augmentation with implants.
- Capsular contracture is not to be treated by closed capsulotomy or forceful external compression, which will likely result in implant damage, rupture, folds, and/or hematoma.

4.5 What Are the Alternatives to Implantation with Silicone Gel Breast Implants?

If this is your first (primary) breast augmentation surgery your alternatives may include:

- Electing to have no surgery,
- Wearing a padded bra or external prosthesis,

- Having a breast lift surgery (mastopexy) without implant(s),
- Having breast augmentation with saline-filled implants, or
- Having fat injection(s).

If you are considering a revision surgery, your alternatives may include:

- No revision surgery,
- Removing your implants without replacing them,
- Wearing a padded bra or external prosthesis,
- Having revision breast augmentation with saline-filled implants, or
- Having fat injection(s).

5. RISKS ASSOCIATED WITH BREAST IMPLANTS

Undergoing any type of surgery involves risks. There are a number of local complications (problems at or near the breast/surgical incision site) that may occur after you have silicone gel breast implant surgery. The following addresses both general, surgery-related complications and implant-related complications.

Table 1 below presents the potential risks associated with breast implant surgery, the likelihood of the risks based on the results from Mentor's MemoryGel™ Core Study through 10 years, as well as the possible effects of the events for primary and revision-augmentation patients.

Table 1
Potential Risks Associated with Breast Augmentation[1]

	Likelihood of the Event Occurring Through 10 Years		
Event	**Primary Augmentation Patients N=552**	**Revision-Augmentation Patients N=145**	**Possible Resulting Effects of the Event**
Key Complications			
Any Reoperation	25 out of 100 patients (25%)	44 out of 100 patients (44%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result

Table 1 *Continued on next page*

Table 1
Potential Risks Associated with Primary Breast Augmentation[1] (continued)

Event		Likelihood of the Event Occurring Through 10 Years: Primary Augmentation Patients N=552	Likelihood of the Event Occurring Through 10 Years: Revision-Augmentation Patients N=145	Possible Resulting Effects of the Event
Other Risks Occurring in 1% or More of Patients				
Implant Removal with or without Replacement		12 out of 100 patients (12%)	24 out of 100 patients (24%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Capsular Contracture Baker Grade III/IV		12 out of 100 patients (12%)	24 out of 100 patients (24%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Rupture[2]	Initial MRI Cohort[3]	24 out of 100 patients (24%)	24 out of 100 patients (24%)	• Implant removal • Silicone migration • Pain • Discomfort • Change in breast shape and size
	Supplemental MRI Cohort[3]	21 out of 100 patients (21%)	8 out of 100 patients (8%)	
Capsular Contracture Baker Grade III		11 out of 100 patients (11%)	24 out of 100 patients (24%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant Removal
Nipple Sensation Changes		8 out of 100 patients (8%)	8 out of 100 patients (8%)	• Increased or decreased nipple sensitivity • Breast-feeding difficulties • May affect sexual response
Capsular Contracture Baker Grade IV		4 out of 100 patients (4%)	8 out of 100 patients (8%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Ptosis (sagging)		4 out of 100 patients (4%)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Wrinkling/Rippling • Reoperation • Implant removal
Breast Pain		3 out of 100 patients (3%)	3 out of 100 patients (3%)	• Resulting effects are contingent on underlying cause(s)

Table 1 *Continued on next page*

Table 1
Potential Risks Associated with Primary Breast Augmentation[1] (continued)

Event	Likelihood of the Event Occurring Through 10 Years		Possible Resulting Effects of the Event
	Primary Augmentation Patients N=552	Revision-Augmentation Patients N=145	
Other Risks Occurring in 1% or More of Patients			
Breast Sensation Changes	3 out of 100 patients (3%)	2 out of 100 patients (2%)	• Increased or decreased breast sensitivity
Hypertrophic Scarring (irregular, raised scar)	3 out of 100 patients (3%)	4 out of 100 patients (4%)	• Scar revision procedure (reoperation) • Undesirable cosmetic result
Capsular Contracture Baker Grade II with Surgical Intervention	2 out of 100 patients (2%)	5 out of 100 patients (5%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Lactation Difficulties	2 out of 100 patients (2%)	1 out of 100 patients (1%)	• Painful breast-feeding • Inability to successfully breast-feed
New Diagnosis of Rheumatic Disease	2 out of 100 patients (2%)	4 out of 100 patients (4%)	• Pain or discomfort
Asymmetry	1 out of 100 patients (1%)	0 out of 100 patients (0%)	• Undesirable cosmetic result • Reoperation • Implant removal
Hematoma	1 out of 100 patients (1%)	3 out of 100 patients (3%)	• Swelling and bruising • Pain or discomfort • Infection • Incision and drainage (reoperation) • Implant removal
Implant Malposition/ Displacement	1 out of 100 patients (1%)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Asymmetry • Visibility • Reoperation • Implant removal
Infection	1 out of 100 patients (1%)	1 out of 100 patients (1%)	• Redness or rash • Pain or tenderness • Swelling • Fever • Reoperation • Implant removal
New Diagnosis of Breast Cancer	1 out of 100 patients (1%)	2 out of 100 patients (2%)	• Reoperation or other procedures

Table 1 *Continued on next page*

Table 1
Potential Risks Associated with Primary Breast Augmentation[1] (continued)

Event	Likelihood of the Event Occurring Through 10 Years		Possible Resulting Effects of the Event
	Primary Augmentation Patients N=552	Revision-Augmentation Patients N=145	
Other Risks Occurring in 1% or More of Patients			
Wrinkling	1 out of 100 patients (1%)	3 out of 100 patients (3%)	• Discomfort • Undesirable cosmetic result • Reoperation • Implant removal
Seroma	<1 out of 100 patients (<1%)	2 out of 100 patients (2%)	• Swelling and bruising • Pain or discomfort • Infection • Incision and drainage (reoperation) • Implant removal
Delayed Wound Healing	<1 out of 100 patients (<1%)	2 out of 100 patients (2%)	• Pain or discomfort • Scarring • Implant extrusion • Necrosis • Reoperation • Implant removal
Granuloma	<1 out of 100 patients (<1%)	1 out of 100 patients (1%)	• Pain or discomfort • Reoperation or other procedures
Extrusion	0 out of 100 patients (0%)	1 out of 100 patients (1%)	• Pain or discomfort • Scarring • Reoperation • Implant removal
Calcification	<1 out of 100 patients (<1%)	2 out of 100 patients (2%)	• Pain or discomfort
Other complications[4]	15 out of 100 patients (15%)	19 out of 100 patients (19%)	• Resulting effects are contingent on underlying cause(s)

[1] Based on the results of the MENTOR® MemoryGel™ Core Study.

[2] These estimated rates were determined through use of Kaplan-Meier methodology, which attempts to take loss of patients to follow-up over time into account by calculating a rate based on the available patient data for any given timepoint.

[3] Two groups of patients underwent MRI screening for rupture. One group of patients, identified as the Initial MRI Cohort, was scheduled to receive MRI exams at 1, 2, 4, 6, 8 and 10 years post implantation. The second group, identified as the Supplemental MRI Cohort, was scheduled to receive MRI exams at 8 and 10 years post implantation. A small portion of the patients in the Supplemental MRI Cohort who had not yet reached their 6-year follow up visit also had an MRI exam at the 6-year post implantation timepoint.

[4] Other complications include abnormal mammogram, acute swelling, breast mass, breast trauma external cause, bruise on breast, contracted scar on breast, contralateral explant, deep vein thrombosis, ectopic pregnancy, Epstein-Barr virus infection, erythema of breast, excessive bruising, superior pole fullness, excessive implant movements, fibroadenoma, fibrocystic breast changes, fluid accumulation, granuloma, implant removal-patient request, inflammation of breast, inframammary fold dissatisfaction, irritation on breast, lack of projection, low projection, lymphoma, mammogram evidence of free silicone outside capsule, metastatic disease, milky appearance of implant, miscarriage, muscle spasm, nipple complications, nipple discharge, occasional burning discomfort of skin, palpability--implant, patient desired to switch to saline, patient dissatisfaction, patient request for new implants,

patient would not have surgery again, pre-eclampsia, premature delivery, rash, recurrent breast cancer, recurrent breast cancer metastasis, red drainage from incision, rupture per physical examination contrary to medical opinion of principal investigator, scar dissatisfaction, scarring, severe allergic reaction, silicone bleed, silicone in lymph node, skin lesion, stillborn delivery, suicide, suspected new cancer, suspected rupture-not ruptured, symmastia.

Using information from Mentor's MemoryGel™ Core Study, the risk of a patient experiencing any complication (excluding rupture) at some point through 10 years after implant surgery was calculated. Through 10 years, this risk was 46% for primary augmentation patients and 62% for revision-augmentation patients. This means that 46 out of 100 primary augmentation patients and 62 out of 100 revision-augmentation patients may experience a complication (of some kind) within 10 years after receiving implants. For additional information on events reported in the MemoryGel™ Core Study, please read the section of this brochure on the MemoryGel™ Core Study (Section 9).

5.1 What Are the Potential Complications?

• Infection

Infection is a possible consequence of any kind of surgery. It most often happens within days to weeks after the surgery, but you could develop an infection in your breast(s) at any time. Breast and nipple piercing procedures may increase the possibility of infection. Signs that you have an infection include: redness or rash, tenderness or pain, fluid accumulation in or around the breast(s), and fever. If you experience any of these symptoms, call your doctor right away. It is harder to treat an infection with an implant present. If antibiotics do not cure your infection, it is possible that your implant(s) may have to be removed to treat the infection.

In rare cases, Toxic Shock Syndrome (TSS) has been noted in women after surgery, including breast implant surgery. TSS is a life-threatening condition. Symptoms of TSS occur suddenly: a high fever, vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches, and/or drops in blood pressure, which may cause fainting. If you feel any of these symptoms, contact a doctor immediately.

• Hematoma or Seroma

You may experience a hematoma or a seroma following your surgery. A hematoma is similar to a bruise; hematomas related to breast implants are the collection of blood within the space around the implant. A seroma is a buildup of fluid around the implant.

Symptoms from a hematoma or seroma may include swelling, pain, and bruising. Having a hematoma and/or seroma following surgery may result in infection and/or capsular contracture later on. If a hematoma or seroma occurs, it will usually be soon after surgery. However, other injuries to the breast can cause hematomas and/or seromas in your breast.

The body can absorb small hematomas and seromas on its own, but some will require surgery. When surgery is needed, it often involves draining the blood or fluid and sometimes involves placing a surgical drain in the wound temporarily for proper healing. A small scar can result from surgical draining. Implants may rupture if they are damaged by surgical instruments during the draining procedure.

• Capsular Contracture

After your breast implant surgery, your breasts will begin to heal and to adapt to the presence of the breast implants. A regular part of this process is that the breast tissue typically forms an internal scar immediately surrounding the implant. In many cases, this tissue forms a capsule that helps hold the implant in place. However, in some women, the scar tissue around the implant tightens and squeezes the implant. When scar tissue squeezes an implant, it is called capsular contracture.

Capsular contracture causes the breast to feel abnormally firm or hard and can cause pain. There is a scale for describing the severity of the contracture. It is called the Baker Grading Scale. The grades are:

- Grade I – contracture is observed, but the breast feels and looks normal (it is soft)
- Grade II – the breast is a little firm, but looks normal
- Grade III – the breast is firm and looks abnormal
- Grade IV – the breast is hard, painful, and looks abnormal

Capsular contracture may be more common if you have had a breast infection or hematoma/seroma. The chances of having contracture typically increase the longer you have your implants. Capsular contracture is a risk factor for implant rupture,[9] and it is one of the most common reasons for reoperation. It also seems that women who have additional surgery to replace their implants (revision surgery) are more likely to have capsular contracture than women having their first augmentation or reconstruction. However, whether or not a woman experiences capsular contracture at all and with what degree of severity varies from woman to woman.

If you feel severe pain and/or firmness (usually Grades III and IV contracture), you may need surgery to correct the problem. This could mean that the surgeon has to remove the part of your breast tissue that has contracted around the implant (the scar tissue capsule), and you could lose some breast tissue during such a surgery. During such surgery, it is possible that your implant(s) would need to be replaced. Even after having surgery to fix contracture problems once, contracture may happen again.

The capsular contracture Baker Grade III/IV rates in Mentor's MemoryGel™ Core Study through 2, 4, 6, 8, and 10 years are presented in Table 2. The MemoryGel™ Core Study reported a 12% risk of experiencing Baker Grade III or IV capsular contracture for primary augmentation patients through 10 years after receiving implants. For revision-augmentation patients, the risk was 24% through 10 years. This means that 12 out of 100 primary augmentation patients and 24 out of 100 revision-augmentation patients may experience Baker Grade III or IV capsular contracture within 10 years after receiving implants.

Table 2
Capsular Contracture Baker Grade III/IV Rates by Patient Cohort

Cohort	2 Year	4 Year	6 Year	8 Year	10 Year
Primary Augmentation, N=552	7.8%	8.8%	9.6%	10.8%	12.1%
Revision-Augmentation, N=145	18.2%	19.6%	21.9%	23.6%	24.4%

More details on capsular contracture results from the MemoryGel™ Core Study are found in Section 9.4.

• Rupture

Breast implants are considered to have ruptured when the implant shell develops a tear or hole. Sometimes silicone gel can minimally leak or "bleed/diffuse" through the implant shell even if there is no obvious tear in the shell. This is called "gel bleed" or "gel diffusion."

Implants could rupture any time after your implant surgery, but the longer the implants are in place, the higher the possibility that the implants will rupture or the gel will leak. Breast implants may rupture or leak because of any of these reasons:

- Damage by surgical instruments at the time of implantation or during any subsequent surgical procedure,
- Stress to the implant during implant surgery that weakens it,
- Folding or wrinkling of the implant shell,
- Excessive force to the chest (for example, during closed capsulotomy, which is a procedure that should not be used),
- Trauma (such as being in a car accident),
- Compression during a mammogram,
- Severe capsular contracture, or
- Normal use over time.

Sometimes there are symptoms associated with gel implant rupture that you or your doctor can notice. Sometimes your implants could rupture without you feeling the rupture or noticing any changes in your breasts. In some of these instances even your doctor might not be able to tell that a rupture has occurred. A rupture that has no symptoms is called a "silent" rupture.

Mentor has done studies to better understand what causes breast implants to rupture or leak gel. These studies might not have identified all the causes of rupture and these studies are continuing.

When silicone gel breast implants rupture, most of the silicone gel usually stays in the implant, and if any silicone does escape through a tear or hole, most of the gel stays within the scar tissue (capsule) around the implant.[1,2] Sometimes, the gel does not stay there and may move to other areas around the body (gel migration). There have been rare reports of gel moving to nearby tissues such as the chest wall, armpit, or upper abdominal wall, and to more distant locations down the arm or into the groin. One group of researchers found silicone in the livers of women with silicone gel breast implants.[3]

Sometimes silicone travels into the lymph nodes. When silicone gel moves into the lymph nodes, they may become enlarged. When silicone gel moves into lymph nodes or other parts of the body, small hardened lumps of silicone (called silicone granulomas) may be felt. These lumps are NOT cancer, but it can be hard to tell them from cancerous lumps just by feeling them. If you feel any lumps in your breasts, around your breasts, in your armpits or anywhere in your body, your doctor should examine them. Based on your presentation and history, your surgeon may elect to observe you for a period of time or they may begin a work up to find out why the lymph nodes are enlarged. Reasons for enlargement are varied and it may be a result of infection, silicone migration to the lymph node, certain types of cancer, or other causes. Your doctor may have to remove a small amount of tissue from the lump(s) (called taking a biopsy) to find out if the lump is cancer. It is important that you discuss your implant history with your surgeon as well as the details of your lymph node enlargement.

Studies have been done to find out what, if any, effects migrated silicone gel has on the body.[3,4,5,6,7] In most cases, no serious problems were reported. Several studies report that some women with migrated silicone gel experienced breast hardness, numbness and/or tingling in their extremities, and some seemed more sensitive to sunlight.[3,6,8] In a few cases, migrated gel has caused nerve damage, hard silicone nodules (granulomas) in the body, and/or breakdown of the body tissues around the gel.[7]

Studies on breast implants that women have had for a long time suggest that gel bleed may play a role in capsular contracture.[9] However, complication rates for silicone gel breast implants are similar to or lower than those for saline-filled breast implants (which do not have silicone gel and, therefore, do not have gel bleed).

There were two groups of patients in Mentor's MemoryGel™ Core Study who underwent scheduled MRI screenings for the detection of rupture. The first of these groups, identified as the *Initial MRI Cohort*, was a subset of randomly selected patients that underwent scheduled MRI screenings at the 1, 2, 4, 6, 8, and 10-year post-implantation visits. In November 2006, FDA required that the remaining patients in the Core Study not included in the Initial MRI Cohort undergo regular MRI evaluations for the remainder of the study. These patients made up the *Supplemental MRI Cohort*. Most patients in the Supplemental MRI Cohort were beyond their 6-year post implantation visit and therefore were only able to undergo MRI screening at the 8-year and 10-year post-implantation time points. However, a portion of the patients in the Supplemental MRI Cohort had not yet reached their 6 years post-implantation visit and underwent 6, 8 and 10-year MRI screenings. Rupture status identified by MRI evaluation includes both *suspected ruptures* which are those ruptures identified by MRI, but not confirmed by removal (explantation) and examination of the implant and *confirmed ruptures* which are those ruptures that are confirmed by evaluation of the explanted implant. Table 3 below provides the Kaplan-Meier estimated cumulative incidence rates through 10-years for

suspected or confirmed ruptures (combined) and for confirmed ruptures. The Kaplan-Meier methodology attempts to take in to account the loss of patients in the study over time by calculating a rate based on the available patient data for any given timepoint.

Table 3
Estimated Cumulative Incidence of Rupture by Kaplan-Meier Analysis Through 10 Years

Initial MRI Cohort		
	Primary Augmentation	**Revision-Augmentation**
Suspected or Confirmed		
By Patient:	24.2%	23.7%
By Implant:	14.9%	16.5%
Confirmed		
By Patient:	9.8%	13.9%
By Implant:	7.4%	9.9%
Supplemental MRI Cohort		
	Primary Augmentation	**Revision-Augmentation**
Suspected or Confirmed		
By Patient:	21.4%	7.5%
By Implant:	12.5%	6.3%
Confirmed		
By Patient:	7.6%	2.6%
By Implant:	4.6%	7.9%

Rupture rate information on Mentor's MemoryGel™ Breast Implants was also provided during the FDA's 2005 Panel Meeting, regarding MRI and Explantation Investigation of silicone gel implants, from the European study known as the U.K. Sharpe and Collis Study.[2,80] Silent rupture was assessed by MRI on 101 patients implanted with textured MemoryGel™ Breast Implants. The average age of the implants was approximately 10 years. The results suggest that by 12 years approximately 15% (95% CI, 5.6 – 24.5%) of implants will have ruptured. All ruptures were confirmed to be intracapsular. For more information on MemoryGel™ Breast Implants, refer to the MENTOR'S CLINICAL STUDY RESULTS, section 9 of this brochure.

- **Reoperation**

It is likely that you will need additional surgery (a reoperation) at some point after your first breast implant surgery, either to correct a problem with or replace your breast implants. Patients may decide to change the size or type of their breast implants, requiring additional surgery. Problems such as rupture, capsular contracture, asymmetry (lack of proportion of shape, size, and/or position between the two breasts), hypertrophic scarring (irregular, raised scar), infection, and shifting can require additional surgery. Some changes to your breast(s) after having breast implants are irreversible (cannot be changed or fixed). These may include dimpling, puckering, wrinkling, or the appearance that the breast is empty or deflated.

The MemoryGel™ Core Study reported a 25% risk of experiencing reoperation for primary augmentation patients through 10 years after receiving implants. This means that 25 out of 100 primary augmentation patients may experience reoperation within 10 years after receiving implants. The most common reasons for reoperation were capsular contracture Baker Grade III/IV and breast mass. For revision-augmentation patients, the risk was 44% through 10 years. This means that 44 out of 100 revision-augmentation patients may experience reoperation within 10 years after receiving implants. The most common reasons for reoperation were capsular contracture Baker Grade III/IV and breast mass. More details on reoperation from the MemoryGel™ Core Study are found in Section 9.5.

- **Implant Removal**

Your breast implants may be removed (with or without being replaced) at some point during the course of your life. You and your doctor may decide to remove an implant or implants because of a complication or to improve the cosmetic result.

Because these are not lifetime devices, the longer you have your breast implants, the more likely it will be for you to have them removed for any reason, either because of dissatisfaction, an unacceptable cosmetic result, or a complication such as severe capsular contracture.

Women who have their breast implants removed often have them replaced with new implants, but some women do not. If you choose not to replace your implants, you may have cosmetically unacceptable dimpling, puckering, wrinkling, and/or other potentially permanent cosmetic changes of the breast following removal of the implant. Even if you have your implants replaced, implant removal may result in loss of breast tissue. Also, implant replacement increases your risks of future complications. For example, the risks of severe capsular contracture and reoperation increase for patients with implant replacement compared to first time placement. You should consider the possibility of having your implants replaced and its consequences when making your decision to have implants.

The MemoryGel™ Core Study reported a 12% risk of implant removal (including removal with replacement for a size exchange) for primary augmentation patients through 10 years. For revision-augmentation patients, the risk was 24% through 10 years. This means that 12 out of 100 primary augmentation patients may experience implant removal within 10 years after receiving implants, and 24 out of 100 revision-augmentation patients may experience implant removal within 10 years after receiving implants. More details on implant removal from the MemoryGel™ Core Study are found in Section 9.6.

- **Pain**

You will probably have some pain after your surgery. The intensity of the pain and the length of time it lasts vary from patient to patient. The pain may persist long after you have healed from surgery. In addition, improper implant size, placement, surgical technique, or capsular contracture may result in pain. Tell your surgeon if you have a lot of pain or if your pain does not go away.

- **Changes in Nipple and Breast Sensation**

Feeling in the nipple and breast can change after implant surgery. Nipples may become more or less sensitive. They may be painfully sensitive or feel nothing at all. These changes are temporary for many women, but for some, sensation may never be what it was before implant surgery. They may affect a woman's sexual response or ability to breastfeed. (See the paragraph on breastfeeding below.)

- **Cosmetic Changes**

You may not be satisfied with the way your breasts look or feel after your surgery. Unsatisfactory results such as scarring or asymmetry (note: asymmetry that exists before breast implant surgery may not be entirely correctable), wrinkling of the skin, implant displacement/migration, incorrect size, unanticipated shape and/or implant palpability/visibility may occur.

A surgeon can minimize the chances of these things happening by planning the surgery carefully and using good surgical techniques. You should understand the possible cosmetic results and discuss them carefully with your doctor before the surgery. Your surgeon cannot promise that after implant surgery your breast(s) will look exactly as you wanted them to look. Revision surgery may be the only way to improve a result you do not like.

- **Breastfeeding**

Breast implant surgery might interfere with your ability to successfully breastfeed. It is possible that you will produce less milk or not be able to produce milk at all. Some women with breast implants have also reported painful breastfeeding.[9,10] If your surgeon uses an incision around the colored portion surrounding the nipple (periareolar surgical approach), it may further increase the chance of breastfeeding difficulties.

The Institute of Medicine (IOM) and The American College of Obstetricians and Gynecologists (ACOG) encourage women with breast implants to try breastfeeding. The IOM concluded, "Breastfeeding should be encouraged in all mothers when possible, including those with silicone breast implants. There is evidence that breast implantation may increase the risk of insufficient lactation,[11] but no evidence that this poses a hazard to the infant beyond the loss of breastfeeding itself. The evidence for the advantages of breastfeeding to infant and mother is conclusive".[9,12] The MemoryGel™ Core Study collected information from patients who had babies after augmentation with MemoryGel™ Breast Implants. Fifteen of the 83 primary augmentation patients who attempted to breastfeed following breast implant surgery experienced difficulty with breastfeeding through 10 years in Mentor's MemoryGel™ Core Study. Two of the 11 revision-augmentation patients who attempted to breastfeed after receiving breast implants had difficulty. Lactation experiences from the MemoryGel™ Core Study are also discussed more in Section 9.7.

- **Implant Extrusion**

Extrusion is when the breast implant comes through the skin. This can happen if your surgical wound has not healed properly or if the skin over your breast weakens. Radiation therapy has been reported to increase the chances of implant extrusion. Additional surgery is needed to fix implant extrusion. This can result in more scarring or loss of breast tissue. An extruding implant may have to be removed and not replaced.

- **Necrosis/Delayed Wound Healing**

Necrosis means that of most or all of the cells in a certain part of your body have died. In the case of implanted breasts, it means dead or dying breast tissue or skin. This can mean that the implant may extrude. Necrotic tissue must be surgically removed. The additional surgery may cause more scarring or loss of breast tissue. Your implant may have to be removed with or without being replaced.

Some patients may take a long time to heal after breast implant surgery. The longer it takes for your surgical wound to close and heal, the greater the risk for infection, implant extrusion, or necrosis. The normal time for wound healing is different for every patient. Infection, radiation, chemotherapy, smoking, taking steroids, and excessive heat or cold therapy can cause necrosis and delayed wound healing. Be sure to ask your surgeon how long he or she expects healing to take for you. If you do not heal in that timeframe, talk to your surgeon immediately.

- **Breast Atrophy/Chest Wall Deformity**

The breast implant pressing on the breast tissue may cause the tissue to become thinner. When this happens, you may be able to see and/or feel the breast implant through the skin. This tissue thinning can occur while implants are still in place or following implant removal without replacement.

The presence of breast implants can cause deformity that is noticeable, especially in very thin women.

Additional surgery may be needed to correct either of these conditions, which may mean more scarring, and removal with or without replacement of your breast implant(s).

• Calcium Deposits

Calcium deposits (hard lumps of calcium) may form in your breast(s) and may be painful. Calcium deposits form in women who have not had any breast surgery and in women who have had breast surgeries. They also become more common as women get older.

Calcium deposits do not mean you are ill, but they can be mistaken for cancer. It may be difficult to tell if they are calcium deposits or cancer just by feeling them. They can show up on mammograms as possible cancer lumps. If you have hard lumps, your doctor may have to operate in order to perform a biopsy (remove a small piece of the lump for testing) or to remove the lump(s). Tell your doctor about any lumps you feel in or around the breast or anywhere on your body.

• Enlarged Lymph Nodes

There are a large number of lymph glands in the body, but it is the lymph nodes in the armpit that drain the breast area of fluid. Some patients with breast implants have been found to have enlarged lymph nodes in the armpit. This is referred to as lymphadenopathy. It has been reported to occur in women with both ruptured and intact silicone gel breast implants. If an enlarged lymph node becomes painful, it may need to be surgically removed. You should report any painful or enlarged lymph nodes to your doctor.

Literature reports associate lymphadenopathy with both intact and ruptured silicone gel-filled breast implants. One study reported that armpit lymph nodes from women with both intact and ruptured silicone gel-filled implants had abnormal tissue reactions, granulomas, and the presence of silicone.[7] These reports were in women who had implants from a variety of manufacturers and implant models.

5.2 What Are Other Reported Conditions?

Patients receiving breast implants have reported a variety of systemic symptoms such as joint pain, muscle aches, confusion, chronic fatigue, autoimmune diseases and others. Individual patient risk for developing these symptoms has not been well established. Some patients report complete resolution of symptoms when the implants are removed without replacement.

Furthermore, it is possible that there are risks that are not known and could be associated with breast implants in the future.

The information discussed in this section is based on studies published in the medical literature reviews through 2016[79] that include women with many different types, brands, and models of breast implants for augmentation and/or reconstruction.

Cancer

• Breast Cancer

Patients with breast implants do not seem to have greater risk of developing breast cancer (based on literature published from 2000-2016).[18,19,20,21,22,23,24,25,26,27,28,79]

The Institute of Medicine (IOM) report (a comprehensive review of studies that looked at the safety of silicone gel breast implants since they were introduced in 1962) showed that breast cancer is no more common in women with implants than those without implants.

Some studies have suggested that breast implants may interfere with or delay breast cancer detection by mammography and/or biopsy. However, other studies reported that breast implants neither delayed breast cancer detection nor affected cancer survival (based on literature published from 2000-2006).[20,28,29,30,31]

- **Brain Cancer**

Most studies of brain cancer in women with silicone gel breast implants have found no increased risk (based on literature published from 2000-2007).[19,21,23,26,27,28,32] One study from the same time period reported a higher rate of brain cancer in women with breast implants, compared to the general population.[29,33] However, rates of brain cancer were not significantly higher in women with breast implants when compared to women who had other non-breast implant plastic surgeries.

- **Lympho-Hematopoietic Cancers**

Lympho-hematopoietic cancers are cancers that develop in the lymph nodes or certain blood cells. Lymph nodes and the affected cells are part of the body's immune system to fight infection. These kinds of cancers include non-Hodgkin's lymphoma, Hodgkin's disease, multiple myeloma, and leukemia.

Most studies (based on literature published from 1999-2007) have found no increased risk of these cancers for women with silicone gel breast implants[14,15,16,17,19,21,23,26,27,28]

Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)[34]. This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL. Please review additional information on BIA-ALCL below.

- **Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)[34]**

If you have breast implants, you have a very small, but increased risk of developing breast implant associated anaplastic large cell lymphoma, or BIA-ALCL. BIA-ALCL is not breast cancer—it is a rare type of non-Hodgkin's lymphoma (cancer of the immune system). In most cases, BIA-ALCL is found in the scar tissue and fluid near the implant, but in some cases, it can spread throughout the body. In the cases that have spread beyond the scar tissue and fluid near the implant, rare cases of death have been reported.

Most patients were diagnosed with BIA-ALCL when they sought medical treatment for implant-related symptoms such as swelling, pain, lumps, or asymmetry that developed after their initial surgical sites were fully healed. In the cases known to FDA to date (as of the August 20, 2020 FDA report), the earliest report of BIA-ALCL was diagnosed less than one year after implant placement and the latest was 34 years after the implant surgery. About half the cases occurred within the first 8 years after implant. BIA-ALCL was most often diagnosed in women who had textured implants. The textured implant may have been placed at the most recent surgery or at any other prior breast implant operation. Several journal articles explore the risk factors for BIA-ALCL, including the methods used to create surface texture of the implant and the role of biofilm in causing disease, among others.

If you develop swelling or pain around your breast implants, be sure to talk to your health care provider. Your health care provider should consider the possibility of BIA-ALCL if after you have recovered from your breast implant operation, you later notice changes in the way your breast looks or feels—including swelling or pain around the implant. If your health care provider suspects BIA-ALCL, they will refer you to an appropriate specialist for evaluation which may involve obtaining fluid and tissue samples from around your breast implant. If a diagnosis of BIA-ALCL is confirmed, the doctor will develop an individualized treatment plan for you. Because of the small number of cases worldwide and the variety of available treatment options, there is no single defined treatment. However, if you are diagnosed with BIA-ALCL, the National Comprehensive Cancer Network (NCCN) recommends removing the implant and the surrounding tissue.

If you have breast implants, you should monitor them and follow your routine medical care. You do not need to take any additional steps. It is not necessary to remove your breast implants if you have no symptoms and you have not been diagnosed with BIA-ALCL.

If you are diagnosed with BIA-ALCL, you can help the FDA understand the disease and the effectiveness of treatment.

You or your doctor should report all confirmed cases of BIA-ALCL to the FDA (https://www.fda.gov/Safety/MedWatch/). In some cases, the FDA may contact you for additional information. The FDA will keep the identities of the reporter and the patient confidential.

In addition, if you are diagnosed with BIA-ALCL, talk to your doctor about reporting it to the PROFILE Registry (https://www.thepsf.org/research/clinical-impact/profile.htm). Every case of BIA-ALCL should be reported to the PROFILE Registry because this helps provide a better understanding of the disease.

If you are considering breast implant surgery, you should discuss the risks and benefits with your health care provider. You may also visit the FDA's Breast Implants website for additional information **https://www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants .**

For additional information on FDA's analysis and review of BIA-ALCL, please visit: **https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma**

- **Respiratory/Lung Cancer**

Several studies have found that women with silicone gel breast implants are not at greater risk for lung cancer (based on literature published from 2000-2007).[19,21,23,26,27,28] One study from the same time period found an increased risk of respiratory/lung cancer in women with breast implants[29,33] compared to women who had other kinds of plastic surgery (non-breast implant). However, the risk of lung cancer was not higher than national lung cancer rates for the general population. Other studies of women in Sweden and Denmark have found that women who get breast implants are more likely to be current smokers than women who get breast reduction surgery or other types of cosmetic surgery[35,36,37]; this may increase their risk for lung cancer (based on literature published from 1997-2003). A published systematic review from 2016 reported there is limited or suggestive evidence of an association between breast implants and lung cancer.[79]

- **Reproductive System Cancer**

Reproductive system cancers in women are cancers of the cervix, ovaries, uterus, vulva, vagina, and other female genital organs. Most studies[19,21,23,26,27,28] found that women with silicone gel breast implants have no greater risk of these cancers than women without implants (based on literature published from 2000-2007). One study from the same time period reported an increased incidence of cervical/vulvar cancer in women with breast implants.[29,33]

- **Other Cancers**

Studies have examined other types of cancer including eye, urinary tract (related to the bladder and urethra), connective tissue (fibrous tissues like tendons, cartilage, and bone that provide structure and support throughout the body), and endocrine system (the parts of the body that make hormones). Studies show that women with silicone gel breast implants have no greater risk of these types of cancers compared to the general population (based on literature published from 2000-2007).[6,19,21,23,26,27,33,38]

- **Connective Tissue Disease (CTD) and Disorders of the Immune System**

The body's immune system protects the body from infection. It is a complicated system and includes a variety of different organs and cell types such as white blood cells and antibodies. Disorders of the body's immune system (also called autoimmune diseases) can cause CTDs when the patient's immune system mistakenly attacks parts of its own body, including the connective tissues of the body, like fibrous tissues (tendons), cartilage, and bones.

Autoimmune diseases include lupus (inflammation and tissue damage in different body parts and organs), rheumatoid arthritis (inflamed and deteriorating joints), polymyositis (inflamed, weakened muscles), dermatomyositis (inflamed, weakened muscles and skin); and progressive systemic sclerosis or scleroderma (damaged skin or organs because of excess collagen, the main protein in connective tissue).

Other CTDs include:

- Fibromyalgia (ongoing fatigue, widespread pain in muscles and joints, difficulty sleeping, and morning stiffness), and
- Chronic fatigue syndrome (ongoing mental and physical exhaustion, often with muscle and/or joint pain).

Some women with breast implants have experienced signs and symptoms that could be related to the immune system but that do not fit into a definable disease, like those listed above. These signs and symptoms include: painful or swollen joints, tightness, tingling, numbness, reddened swollen skin, swollen glands or lymph nodes, unusual or unexplained fatigue, swollen hands and feet, excessive hair loss, memory problems, headaches, and muscle weakness, pain, cramping and/or burning. Individual patient risk for developing these symptoms has not been well established. Some scientific expert panels and literature reports have found no evidence of a consistent pattern of signs and symptoms in women with silicone gel-filled breast implants (based on literature published from 2000-2004).[4,5,9,38,39,40]

Some scientific evidence supports the conclusion that there is no increased risk of CTDs or autoimmune disorders for women with silicone gel breast implants (based on literature published from 1996-2011).[4,5,9,38,41,42,43,44,45,46,47,48,49,50,51,52,53,54] Some independent scientific panels and review groups have also concluded that the weight of the evidence shows no relationship between breast implants and CTDs, or at least if a risk cannot be absolutely excluded, it is too small to be measured (based on literature published from 1998-2001).[9,55,56] A published systematic review from 2016 reported there is limited or suggestive evidence of an association between breast implants and rheumatoid arthritis.[79]

Some patients have reported resolution of symptoms when the implants are removed without replacement. Patients in Mentor breast implant Core Studies were asked to complete an annual questionnaire which included a number of potential rheumatologic or neurologic symptoms. These symptoms were collected for patients at baseline and post-implantation at each annual visit throughout the study. Data were examined to investigate whether rates of reporting new systemic symptoms increased over 10 years with longer exposure to the implanted device, as might be expected if the implant was causing these systemic symptoms. The data show no consistent trend of increased reports of newly developed fatigue, insomnia, or joint pain with longer exposure to the implant.

• Effects on Children Born to Mothers with Breast Implants

It is not known if a small amount of silicone may move through the breast implant shell and pass into breast milk. There is no test for detecting silicone in breast milk that is considered accurate. There has been a study published in 2000 that measured silicon levels (one component of silicone). It did not indicate higher levels of silicon in breast milk from women with silicone gel breast implants when compared to women without implants.[57]

In addition, questions have been raised about whether silicone gel breast implants could harm babies whose mothers had implants while pregnant. Two studies from the early 2000's in humans have found that the risk of birth defects overall is not increased in children born after breast implant surgery.[58,59] Although low birth weight was reported in a third study, from the same time period, other factors (for example, lower pre-pregnancy weight) may explain this finding.[60]

Overall, there is no evidence that shows that silicone gel breast implants have any harmful effects on the children of implanted women (based on literature published from 2000-2016).[9,10,58,59,60,79]

Suicide

Some studies have reported a higher incidence of suicide in women with breast implants, but it is not clear whether these suicides were associated with having silicone gel breast implants or some other underlying condition that can lead to suicide, depression and/or anxiety (based on literature published from 2003-2007).[29,61,62,63,64,65,66,67] One researcher[68] (published in 2003) believes that some women who want cosmetic surgery suffer from a disorder, called body dysmorphic disorder (BDD), which may cause them to think about suicide or attempt suicide.

The strongest predictor for suicide is having been hospitalized for any psychiatric condition. One study from 2004 found that women with breast implants were admitted to the hospital more often because of psychiatric problems before they even had their implant surgery, compared to women who had breast reduction or to the general population.[61] This may be a contributing factor to the reported higher incidence of suicide in women with breast implants.

- **Neurological Disease, Signs, and Symptoms**

Some women with breast implants have complained of neurological symptoms such as difficulties with vision, sensation, muscle strength, walking, balance, thinking, or remembering things. Some have been diagnosed with diseases such as multiple sclerosis (which is an autoimmune disease that affects the nerves). Some of these women believe their symptoms are related to their implants. A scientific expert panel from 2000 found that there is not enough reliable evidence that neurological problems may be caused by or associated with breast implants.[9] Other researchers from the same time period, have found more evidence that silicone gel breast implants do NOT cause neurological diseases or symptoms.[9,22,69] There is one published report from 2000 of an increased risk of multiple sclerosis among women with silicone gel breast implants[44]; these researchers did not find any increased risk of other neurological symptoms.

- **Potential Health Consequences of Gel Bleed**

Small quantities of low molecular weight (LMW) silicone compounds, as well as platinum (in zero oxidation state), have been found to diffuse (bleed) through an intact implant shell (based on literature published in 2000 and 2003).[9,70] The evidence is mixed as to whether there are any clinical consequences associated with gel bleed. For instance, studies on implants implanted for a long duration have suggested that such bleed may be a contributing factor in the development of capsular contracture[9] and lymphadenopathy (based on literature published in 2000 and 2005).[7] However, evidence against gel bleed being a significant contributing factor to capsular contracture and other local complications is provided by the fact that there are similar or lower complication rates for silicone gel-filled breast implants than for saline-filled breast implants. Saline-filled breast implants do not contain silicone gel and, therefore, gel bleed is not an issue for those products. Furthermore, toxicology testing has indicated that the silicone material used in Mentor's implants does not cause toxic reactions when large amounts are administered to test animals. It should also be noted that studies reported in the literature have demonstrated that the low concentration of platinum contained in breast implants is in the zero oxidation (most biocompatible) state (based on literature published from 1987-1999).[71,72,73,74]

Mentor performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may bleed out of intact implants into the body. Over 99% of the LMW silicones and platinum stayed in the implant.

Please see section 7.4 for additional information on the Materials present in MemoryGel Breast Implants

6. BENEFITS ASSOCIATED WITH BREAST IMPLANTS

Women choose primary breast augmentation surgery to increase the size and proportion of their breast(s). In addition, women choose revision-augmentation surgery (replacement of an existing breast implant) to correct or improve the result of a primary augmentation surgery.

According to literature reports, most women who have undergone breast implant surgery have reported high levels of satisfaction with their body image and the shape, feel, and size of their implants.[75]

In Mentor's MemoryGel™ Core Study, the MemoryGel™ Breast Implants were demonstrated to be effective in increasing the size of a woman's breast and most primary and revision-augmentation patients were pleased with the results of their implant surgery, with 297 (97%) of the 306 primary augmentation and 81 (99%) of the 82 revision-augmentation patients who answered the patient satisfaction question at the 10-year follow-up visit indicating they would have the breast implant surgery again. The results also showed that most women who underwent primary augmentation with MemoryGel™ Breast Implants had improved body-image and greater self-acceptance, while those who underwent revision-augmentation experienced improved chest body-image.

For more information on the benefits of breast augmentation with Mentor's MemoryGel™ Breast Implants based on the results of the MemoryGel™ Core Study, refer to Section 9.3 of this brochure.

7. PREPARING FOR BREAST AUGMENTATION WITH SILICONE GEL BREAST IMPLANTS

Deciding to have breast augmentation with implants is an important personal decision that has both benefits and risks. You should decide whether it is the right choice for you after discussing all the options with your plastic surgeon and any other doctors who are treating you. This section will give you the information you need to make an informed choice and help you make a number of decisions that have to be made before your surgery.

7.1 Should I Have Breast Augmentation?

Breast augmentation with MemoryGel™ Breast Implants or MemoryGel™ Xtra Breast Implants is one option that may be available to you if you wish to enhance the appearance of your breasts. A breast revision-augmentation surgery may be appropriate if you have had a breast augmentation with implants but need to complete, improve upon, or correct a part of that first surgery (called the primary augmentation).

Whether breast augmentation is right for you depends on many things, some of them personal. You should take into account your medical condition, general health, lifestyle, how you feel emotionally, and your breast size and shape before surgery, as well as your hopes for breast size and shape after surgery. All of these things will affect the outcome of your surgery. Discuss your goals for breast augmentation with your doctors. You may also wish to consult your family and friends and breast implant support groups, to help you learn about the options and decide.

Many women who choose implants as part of their augmentation say their augmented breast(s) help them feel more self-confident, feel better about their bodies, and/or give them a greater feeling of well-being. Other women are not satisfied with their implants because of complications, like capsular contracture, rupture, or pain.

7.2 Breast Augmentation with Implants – Understanding the Procedure

The surgical procedure for breast augmentation consists of choices you and your surgical team (surgeon(s), nurses, anesthetist, etc.) will make as you plan your surgery. These choices include:

- The surgical setting (where the surgery will be performed, for example, in a hospital, surgery center, or doctor's office),

- The type of anesthesia used,
- The location of the incisions made to insert the breast implants,
- How the implants will be placed in your breasts (subglandular or submuscular), and
- Whether your existing skin and/or breast tissue can cover implants.

Each of these is discussed in the sections that follow. The type of procedure that is available to you depends on your medical situation, breast shape and size, general health, lifestyle, and goals for the augmentation. Breast augmentation with silicone gel breast implants can usually be completed in a single surgery.

Surgical Setting

Breast augmentation surgery can be performed in a hospital, private surgery center, clinic, or in the surgeon's office. Be sure you are comfortable with the location of the surgery before it happens. If you are considering having surgery in a private surgery center or office, you may want to see the area where the surgery will be performed.

Anesthesia

Breast implant surgery may be performed under general or local anesthesia. All anesthetics carry some risk. Discuss the risks and benefits of the anesthetic your surgeon and anesthetist recommend for you before the surgery.

Incision Sites

Figure 2 shows the three incision sites (location of cut through which the breast implant is inserted in your body) usually used for breast augmentation surgery.

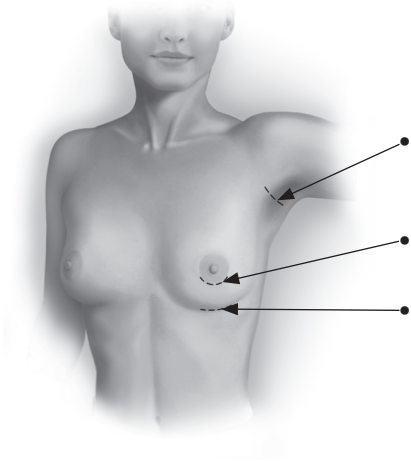


Figure 2
Incision sites for
Breast Augmentation Surgery

- Axillary – the incision is made in the armpit, which gives the surgeon easier access to the chest muscle,
- Periareolar – an incision is made around the nipple, and
- Inframammary – the most common incision, made under your breast at the crease where the breast meets the body.

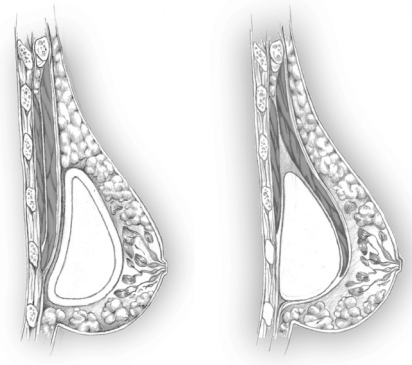
You may hear about a fourth incision site – the "periumbilical approach" (incision at your belly button). This way of placing breast implants has not been studied in Mentor's MemoryGel™ Core Study and should not be used. It may cause damage to the implant shell.

The incision will be longer than the one typically made for breast augmentation with a saline or round silicone gel breast implant. Your surgeon can explain which incision site he or she recommends for you and talk about the pros and cons of each with you.

Implant Placement

As shown in Figure 3, breast implants are placed beneath your breast tissue, either on top of the chest muscle (subglandular placement) or underneath part or all of the chest muscle (submuscular placement).

Figure 3
Breast Implant Placement



Subglandular Submuscular

Table 4 compares positive and negative aspects (pros and cons) of each method. The "best" placement depends on you and the characteristics of your body, the types of implants you choose, and your surgeon. Talk with your surgeon about his or her reasons for choosing one placement over the other and the advantages and disadvantages of each.

Table 4
Comparison of Submuscular and Subglandular Placement of Breast Implants

Submuscular Placement	Subglandular Placement
• Surgery time may be longer • Recovery may be longer • May be more painful • Future re-operation may be more difficult • Implants may feel more like a natural part of the breast (be less "palpable") • Capsular contracture may be less likely[7] • It may be easier to image breast with mammography • If you have thin or weakened breast tissue, submuscular positioning may work better	• Surgery time may be shorter • Recovery time may be shorter • May be less painful • Future reoperation may be easier • Implants may be more palpable (can feel the implant through breast tissue) • Capsular contracture may be more likely[76,77] • It may be harder to image breast with mammography

7.3 Choosing the Right Implant for You

MemoryGel™ Breast Implants and MemoryGel™ Xtra Breast Implants are available in several different shapes, profiles, and sizes to help each woman achieve the result that is best for her body. The MENTOR® MemoryGel™ Breast Implants and MENTOR® MemoryGel™ Xtra Breast Implants are filled with Mentor's cohesive gel. MENTOR® MemoryGel™ Xtra Breast Implants have a higher fill volume than MENTOR® MemoryGel™ Breast Implants of the corresponding styles. A summary of the distinguishing characteristics for the MemoryGel™ Breast Implants and MemoryGel™ Xtra Breast Implants is provided in Table 5 below.

Table 5
Distinguishing Characteristics for the MemoryGel™ Breast Implants and MemoryGel™ Xtra Breast Implants

Device Description	Silicone Gel and Fill Type Description
MemoryGel™ Breast Implants	Cohesive Gel
MemoryGel™ Xtra Breast Implants	Cohesive Gel with a higher fill volume as compared to MemoryGel™ Breast Implants

MENTOR® MemoryGel™ Breast Implants and MENTOR® MemoryGel™ Xtra Breast Implants are available with smooth or textured shells. MemoryGel™ and MemoryGel™ Xtra Breast Implants are provided sterile.

Tables 6 and 7 list the styles for MENTOR® MemoryGel™ Breast Implants and MENTOR® MemoryGel™ Xtra Breast Implants.

MENTOR® MemoryGel™ Breast Implants are filled with cohesive gel and are available with smooth or textured shells. Table 6 provides an overview of the styles and sizes of the MemoryGel™ Breast Implants.

Table 6
MENTOR® MemoryGel™ Breast Implants

Implant Style	Shell Surface	Size Range (Volume)
Moderate Profile	Smooth	100 – 800 cc
	Textured	100 – 800 cc
Moderate Classic Profile	Smooth	130 – 800 cc
	Textured	130 – 800 cc
Moderate Plus Profile	Smooth	100 – 800 cc
	Textured	100 – 800 cc
High Profile	Smooth	125 – 800 cc
	Textured	125 – 800 cc
Ultra High Profile	Smooth	135 – 800 cc
	Textured	135 – 700 cc

MENTOR® MemoryGel™ Xtra Breast Implants are also filled with cohesive gel and generally have a higher fill volume than the MENTOR® MemoryGel™ Breast Implants. The MENTOR® MemoryGel™ Xtra Breast Implants are available with smooth or textured shells. Table 7 provides an overview of the styles and sizes of the MemoryGel™ Xtra Breast Implants.

Table 7
MENTOR® MemoryGel™ Xtra Breast Implants

Implant Style	Shell Surface	Size Range (Volume)
Moderate Plus Profile Xtra	Smooth	115 – 755 cc
	Textured	115 – 755 cc
Moderate High Profile Xtra	Smooth	130 – 775 cc
High Profile Xtra	Smooth	150 – 790 cc
	Textured	150 – 765 cc

When you and your doctor decide what you want your breasts to look like after augmentation, your doctor can help you choose the right implant to get the effect you want. Your body type, height, and weight will be factors your surgeon considers to help you achieve the best result.

Implant Size, Shape and Surface

Your surgeon will examine your breast tissue and skin to figure out if you will have enough to cover the implant. It is possible that you will not have enough skin and/or breast tissue to cover the implant you desire. In this case, you may be offered several choices.

Breast implants that are too big for the amount of breast tissue or skin can cause problems: They can speed up the effects of gravity; your breasts may droop or sag earlier with implants that are too large. Implants that are too large can also cause implant extrusion, skin wrinkling, infection, and hematoma. You may be able to feel folds on the implant created by it being squeezed too tightly by the surrounding tissue and skin. If you do not have enough skin, and it is stretched too thin over the implant, you may be able to feel or see the edges of the implant under your skin surface after surgery.

7.4 Materials Present in MemoryGel Breast Implants

Below is a summary of materials found in MemoryGel Breast Implants

The potential toxicity of the materials found in breast implants has been evaluated with both toxicity testing and risk assessments to assess the exposure levels and ensure that they are below the levels determined to likely be safe. However, individual responses to substances may vary, and all reactions cannot be predicted.

- **MemoryGel Breast Implants Breast Implant Device Materials**

Device Materials	Implant Component
Dimethyl Silicone Elastomer Dispersion	Shell, inner/outer layers
Diphenyl Silicone Elastomer Dispersion	Shell, barrier layer
MED 4750 Silicone Elastomer	Shell textured layer
MED 4750 Silicone Elastomer	Patch assembly
Silicone Gel: Base and Crosslinker; platinum cure	Gel

- **Laboratory Testing**
- **Diffusion Testing**

Most chemicals found in breast implants stay inside the shell of the implant but small quantities have been found to diffuse (gel bleed) through the implant shell of silicone gel-filled implants, even if the implant is intact and not ruptured or leaking.

Mentor conducted a laboratory study to assess what materials found in breast implants might diffuse out of the implant into surrounding fluid. In this study, new implants were immersed in a fluid that is similar to that fluid that naturally surrounds an implant placed in the breast. The fluid was heated to body temperature. This study, designed to mimic those conditions that a breast implant would be subject to in the human breast, showed that more than 99% of small silicone molecules and platinum remained within the breast implant. A risk assessment of the materials that diffuse from the implant was conducted to assess the exposure levels in comparison to the amount determined likely to be safe. The risk assessment documented these exposure levels would not be expected to result in a serious problem (known as an “adverse effect”). However, individual responses to chemicals may vary, and all reactions cannot be predicted.

Testing was also performed to identify the types and quantities of chemicals and heavy metals that are detected in breast implants. Details of the testing is provided below.

- **Chemicals That Might be Released from Breast Implants**

In addition to the diffusion study described above, Mentor conducted other laboratory tests in which breast implants were exposed to extraction liquids at high temperature (harsh conditions not present in the human body) to examine what substances might be released from the implant under such conditions. The materials found were grouped into two categories: *Volatiles* (chemicals that are released by breast implants as a gas) and *Extractables* (chemicals that are released by breast implants following soaking in water and/or organic solvent (liquid)).

Volatiles	Whole Device (ppm*)
D_3	0.18
D_4	0.46
D_5	1.47
Methoxytrimethylsilane	0.43
Dimethoxydimethylsilane	0.03
Methoxytriethoxysilane	ND
Tetramethyldiethyldisiloxane	0.04
Acetone	0.18
Isopropanol	0.26
2-Pentanone	ND
Methyl Butanoate	0.01
Ethylbenzene	ND
m- & p-xylene	0.08
4-Methyl-3-penten-2-one	0.01
o-xylene	ND
Alpha-Pinene	ND
Cyclohexanone	ND
1-Ethyl-2-methylbenzene	0.01
Decane	ND
Benzaldehyde	0.01
1,3,5-Trimethylbenzene	0.01
Limonene	0.01
Undecane	0.35
Acetophenone	0.01
Dodecane	0.07
Total Volatiles	**3.67**

*ppm = parts per million; parts per million (ppm) is a measure of concentration and refers to microgram per gram; 1 ppm is the same as 0.0001%.

Data preceded with a "<" symbol means that the level of the individual component, if present, was below the method of detection limit indicated.

ND = Not Detected

Breast implants are constructed from silicone polymers (including both the shell and gel of the implants). Silicone polymers have been used in medical applications for more than 50 years. Polymers are long chains of repeated linked materials, and low levels of shorter chains of these materials are often present in silicone and other medical polymers. These shorter chains represent most of the "*Extractables*" in the table below and most remain within the polymer material that makes up the breast implant when in the human body.

Extractables	Whole Device (ppm*)
D_4	0.5
D_5	<2.5
D_6	<4.8
D_7	<8.4
D_8	<8.4
D_9	<8.3
D_{10}	<10.92
D_{11}	<21.86
D_{12}	32.92
D_{13}	47.85
D_{14}	113.11
D_{15}	172.4
D_{16}	203.8
D_{17}	584.9
D_{18}	533.0
D_{19}	429.4
D_{20}	609.9
D_{21}	775.5
MD_7M	<1.3
MD_8M	1.5
MD_9M	2.8
$MD_{10}M$	6.2
$MD_{11}M$	<13.2
$MD_{12}M$	34.8
$MD_{13}M$	51.2
$MD_{14}M$	62.6
$MD_{15}M$	66.2
$MD_{16}M$	54.9
$MD_{17}M$	61.3
$D^{vi}D_{14}$	5.9
$D^{vi}D_{15}$	8.8
$D^{vi}D_{16}$	<14.4
$D^{vi}D_{17}$	22.6
$D^{vi}D_{18}$	35.1
$D^{vi}D_{19}$	<26.4
$D_{10}D^{Ph}$	ND
$D_{11}D^{Ph}$	ND
$D_{12}D^{Ph}$	ND
$D_2D^{Ph}{}_2$ (1)	2.0
$D_2D^{Ph}{}_2$ (2)	<1.3
$D_3D^{Ph}{}_2$ (1)	<20.2
$D_3D^{Ph}{}_2$ (2)	19.0
$D_4D^{Ph}{}_2$ (1)	<1.3
$D_4D^{Ph}{}_2$ (2)	<1.3

$D_5D^{Ph}_2$ (1)	ND
$D_5D^{Ph}_2$ (3)	ND
$D_5D^{Ph}_2$ (2)	ND
Siloxane	3.9
o-Xylene	<0.4
Di(Ethylhexyl) Phthalate	ND
Total (µg/g)	**<4086.7**

*ppm = parts per million; parts per million (ppm) is a measure of concentration and refers to microgram per gram; 1 ppm is the same as 0.0001%.

Data preceded with a "<" symbol means that the level of the individual component, if present, was below the method of detection limit indicated.

ND = Not Detected

Note: The substances listed as MD_xM, D_x, and VD_x such as MD9M, D12, and VD16, are the shorter chain straight or circular silicone materials that were described above and are comprised of dimethylsiloxane- (D), trimethylsiloxane, or methylvinyl siloxane subunits of the specified length. vi=vinyl; ph=phenyl

- **Heavy Metals Found in Breast Implants**

Both the shell and the gel components were extracted with aqueous (buffer) and organic solvents and analyzed by Inductively Coupled Plasma/Mass spectroscopy) (ICPM) for numerous metals. The metal concentrations obtained from the extracted residues are shown in the table below for the device, as a whole.

Heavy metals are present at trace levels in food, water and air, and some are essential nutrients. A risk assessment of the metals released was conducted to assess the exposure levels in comparison to the amount determined to likely be safe. The risk assessment documented that these exposure levels of the heavy metals would not be expected to result in a serious problem (known as an "adverse effect"). However, individual responses to heavy metals may vary, and all reactions cannot be predicted.

Metal	Concentration (*ppm)
Antimony	0.014
Arsenic	0.123
Barium	0.001
Beryllium	0.006
Cadmium	0.002
Chromium	0.028
Cobalt	0.052
Copper	0.025
Lead	0.011
Magnesium	0.391
Mercury	0.004
Molybdenum	0.001
Nickel	0.050
Platinum	0.299
Selenium	0.069
Silver	0.001
Tin	0.004
Titanium	0.033
Vanadium	0.310
Zinc	0.034

*ppm = parts per million; parts per million (ppm) is a measure of concentration and refers to microgram per gram; 1 ppm is the same as 0.0001%.

7.5 Other Procedures at the Time of the Breast Augmentation

Your surgeon may recommend having other cosmetic procedures during the same surgery to get the best results from your breast implants. In some cases, breast implants alone may not give you the results you want. If, in the past, you have lost a lot of weight, been pregnant, or breastfed, you may have sagging, stretched, or extra skin that is not completely filled out by breast tissue. In this case, your doctor may recommend doing a breast lift (mastopexy) to remove excess skin from the rest of the breast tissue in one or both breasts.

During mastopexy, your surgeon will remove a piece of skin from your breast (usually from under the breast or around the nipple). Then he or she will use stitches to close the incision where the skin was removed. This lifts the whole breast or nipple location and tightens the skin over the breast. This might cause more scarring than just having implants placed and may lengthen your recovery time. Mastopexy (to one or both breasts) may be done at the same time as the primary augmentation or may be done at a later, follow-up procedure. It is not always best to do multiple procedures during one surgery. Your doctors can discuss the risks and benefits of this procedure with you.

7.6 Choosing a Surgeon

The following are types of questions you should consider when choosing a surgeon:

- In which states is he or she licensed to practice surgery?
- Has he or she completed residency requirements in plastic surgery from a recognized and accredited academic program?
- Is he or she board certified in the United States? If so, which board?
- How many breast augmentation surgeries does he or she perform each year?
- How many years has he or she been doing breast augmentation surgeries?
- What is the most common complication he or she encounters with breast augmentation patients?
- What is his or her reoperation rate for augmentation patients? And what is the most common type of reoperation that he or she performs in his or her practice?
- Will he or she perform all of my surgery in a hospital? (Many surgeons perform breast implant surgery or components of breast augmentation in their own outpatient surgery centers. Hospitals require surgeons to prove that they are properly trained before they can operate in the hospital.)

8. CARING FOR YOURSELF AFTER BREAST IMPLANT SURGERY

How you feel after your surgery and the level of care you need in the first few days vary from patient to patient and depend on the extent of your surgery. Your wounds will take several weeks or more to heal completely. Talk with your surgeon after your surgery about how to care for yourself and how long your recovery should take.

8.1 Postoperative Care in the Hours and Days After Surgery

The first few hours after your initial augmentation surgery will be spent recovering in the hospital. You may be there for several days or you may be able to go home sooner. During these first days after your surgery, you will need to follow some simple directions to take care of yourself. Your surgeon will give you specific directions about what to do. Follow your surgeon's directions.

If you have had general anesthesia, you will remain in the hospital or surgery center until the anesthesia wears off. You may have drains in your breasts so that fluid or blood will drain out of the wound at the incision site.

You will probably leave your surgery wearing a bandage to protect the wounds and support your breasts. Your surgeon will tell you how long to keep your breasts bandaged. Eventually, you will be able to wear a bra for support instead of the bandages. Your doctor will give you instructions about bathing or washing the area during the first few days. He or she may tell you not to take baths for a certain period of time.

Call your doctor immediately if you think you may have an infection. If your incision sites or breasts are red, swollen, hot, painful, or are weeping (draining white or yellow fluid) or if you have a fever, chills, aches, nausea, or vomiting, you may have an infection.

If you do not have any complications, you will probably be able to go back to most of your usual daily activities in 1 to 2 weeks after surgery.

8.2 Postoperative Care in the First Weeks After Surgery

In the weeks after your augmentation, the skin over your breasts may feel tight as it adjusts to your new breast size. After your stitches are removed, your doctor may tell you to massage your incision site(s) with a cream or lotion to keep the skin from drying out; this may make you more comfortable as well. Use the product(s) he or she recommends.

Your doctor may have special directions about avoiding exercise or activities that compress or put pressure on your breasts during the first weeks after surgery. Follow your doctor's directions.

8.3 Caring for Yourself in the Months and Years After Surgery

There are some things you should do to make sure your breasts stay healthy and to take care of your implants: mammograms, breast exams, and protecting your implants from certain types of damage. It will be important to monitor your breasts for breast cancer. Also monitor regularly for breast implant rupture.

Mammograms

A mammogram is a special way of x-raying the breast. Whether or not you have breast implants, having a mammogram is considered the best way to detect breast cancer. However, there are some special considerations for women with breast implants:

- Breast implants can make it harder to see breast cancer on a mammogram.
- Breast implants can make it harder for the technologist to perform the mammogram.

The machine that does a mammogram squeezes the breast to make it as flat as possible while taking a picture. The pressure from this squeezing could make your implant rupture or cause gel bleed. You must tell the technologist that you have silicone gel breast implants before the procedure. The technologist can then use special techniques to get the best possible views of your breast tissue. He or she can also take steps to reduce the likelihood that your implants will rupture due to the mammogram.

It is a good idea to have a mammogram before your breast implant surgery. This establishes a baseline to which future mammograms can be compared. You are also encouraged to have another mammogram 6 months to 1 year after your implant surgery to establish a baseline with the implant present.

After that, the recommendations for mammograms are the same as for women without implants; have a mammogram every 1 to 2 years, starting at age 40, or as advised by your doctor. When you go for a mammogram, do the following things to get the most reliable pictures of your breast(s):

When you schedule a mammogram, tell the office that you have breast implants. Find a mammographer who is experienced with imaging implanted breasts. (Your doctor should be able to help you find a qualified mammographer.) Your physician may request a "diagnostic" mammogram instead of a "screening" mammogram because more pictures are taken for a diagnostic mammogram. Make sure your mammographer knows what type of implants you have and how they are placed (for example, on top of the chest muscle or underneath).

Carry your Implant ID Card (that you will receive after surgery) with you and show it to the mammographer.

Other Breast Exams

Perform self-breast exams regularly. Once a month, after your period ends, is a good time to examine your breasts.

You can find brochures about how to perform self-breast exams through your doctor, a women's health clinic, or online. Your doctor can show you how to do a self-breast exam. Ask your doctor to help you learn to tell the difference between your breast implant and breast tissue. This will help you do your self-breast exams without squeezing your implant too much. If you see or feel that something has changed, talk to your doctor promptly.

It is important to have regular exams by a doctor as well. It may be hard for you to feel changes in your breast because the implant is there, especially if you have capsular contracture. The doctor will look at your breasts and palpate your breasts like in a self-exam to feel for any changes. If your doctor finds anything, he or she may refer you for a mammogram to help diagnose the change. Your doctor may also ask for an MRI if he/she suspects rupture.

Protecting Your Implants

To protect your implants, you should make sure that any healthcare practitioners (doctors, emergency medical technologists, nurses, massage therapists, acupuncturists, chiropractors, physical therapists, etc.) treating you know that you have silicone gel breast implants. If they do not know about your implants, they may damage them by accident and your implants could rupture. Carry your Implant ID Card with you and show it to healthcare practitioners before receiving treatment.

You should also protect your implants by guarding against any strong or repeated pressure on your breasts.

Things to Call Your Doctor About Right Away

Call your doctor immediately if you have:

- Signs of an infection (including, but not limited to: redness, swelling, tenderness of the skin, or pain),
- Signs of capsular contracture (including, but not limited to: loss of symmetry, increased firmness or feeling of tightness within the breast),
- A lump,
- Skin around the nipple that has become dimpled or indented,
- Unexplained discharge from the nipple,
- Unilateral or bilateral swelling or enlargement of the breast(s),
- Change in the position, visibility, or shape of your implant, or
- An injury to your breast(s).

If your implant becomes damaged, it may have to be removed.

Physical Limitations

After you have healed from surgery, you should be able to carry on normal activities including sports. Avoid situations that put a lot of pressure on your breasts or may cause trauma to your breast. Ask your doctor if there are any activities he or she does not recommend.

8.4 Monitoring Your Implants for Rupture

Rupture is a rare occurrence with silicone gel breast implants. However, the following information will help you to monitor your implants for evidence of rupture.

Detecting Rupture

A variety of factors can cause your breast implants to develop a tear or hole in the shell. These tears or holes are usually called ruptures because they can allow silicone gel from inside the implant to exit your implant.

If your implant(s) ruptures, you may experience certain symptoms. Any of the following may indicate that your implant has ruptured: hard knots or lumps surrounding the implant or in the armpit, changes in breast size or shape, pain, tingling, swelling, numbness, burning, and/or hardening of the breast.[78]

If you feel any of these symptoms, contact your doctor for an exam.

If your implant ruptures, it is more likely that you will not experience any symptoms and you will not even know your implant has ruptured. In these situations, even your doctor may not be able to determine that a rupture has occurred. This is referred to as a "silent" rupture.

Recommended Imaging Schedule for Implant RUPTURE Surveillance

The guidelines for surveillance of breast implant rupture are as follows:

It is recommended that you have periodic imaging (ultrasound or magnetic resonance imaging (MRI)) of your silicone gel-filled breast implants to screen for implant rupture regardless of whether your implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on your medical history or circumstances (i.e., screening mammography for breast cancer, please refer to the Mammograms section above for additional information).

Even if you have no symptoms, you should have your first ultrasound or MRI at 5-6 years after your initial implant surgery and then every 2-3 years thereafter. If you have symptoms at any time or uncertain ultrasound results for breast implant rupture, an MRI is recommended.

What to Do if You Suspect an Implant Rupture

If you suspect that an implant has ruptured or if you suspect that silicone gel has moved out of your implants, call your doctor right away and schedule an exam. Your doctor may recommend an MRI or other kinds of tests to help diagnose possible rupture. MRI is currently considered the best way to diagnose rupture.

What to Do if the Implant Rupture Is Confirmed

If your doctor confirms that you have a ruptured implant or that silicone gel has bled (moved) out of your implant shell, he or she will talk with you about your options. As a precaution, Mentor recommends that ruptured implants be taken out permanently and either replaced with a new implant or not replaced, depending on your preference or medical need.

If your implant is taken out, your surgeon may also have to remove some of your breast tissue (the tissue capsule that forms around the breast implant), which will involve additional surgery, with associated risks and costs. In some cases, it may not be possible to replace your implants.

9. MENTOR'S CLINICAL STUDY RESULTS

As part of the marketing approval requirements for the MemoryGel™ Breast Implants, Mentor conducted the MemoryGel™ Core Study with patients who received the implants for augmentation (primary and revision) and reconstruction (primary and revision). The results of the study will provide you with useful information on the experience of other women who have received MemoryGel™ Breast Implants. The results of the MemoryGel™ Core Study should not be used to predict your own experience with the MemoryGel™ Breast Implants, but the information can be used as a general guide about what you may expect. Your own benefits and complications depend on many individual factors.

9.1 Overview of the Study

The MemoryGel™ Core Study was a prospective, 10-year, multicenter clinical study conducted to examine the safety and effectiveness of the MENTOR® MemoryGel™ Breast Implants in patients undergoing primary augmentation, primary reconstruction, revision-augmentation, and revision-reconstruction of the breast.

A total of 1,008 patients participated in the MemoryGel™ Core Study. A total of 552 patients had primary augmentation, 145 patients had revision-augmentation, 251 patients had primary reconstruction, and 60 patients had revision-reconstruction. Of these patients, 202 primary augmentation patients, 56 revision-augmentation patients, 134 primary reconstruction patients, and 28 revision-reconstruction patients were assessed for implant rupture for MRI at years 1, 2, 4, 6, 8, and 10 after receiving implants.

Assessment of the safety of the MemoryGel™ Breast Implants was based on the incidence of complications, including device failures. Effectiveness was assessed based on changes in bra size, chest circumference, patient satisfaction, and measures of quality of life. Several scales and questionnaires about these topics were used to collect information for analysis, including a global satisfaction question, the Rosenberg Self-Esteem Scale, the Body Esteem Scale, the Tennessee Self-Concept Scale (TSCS), and the Short Form Health Survey (SF-36).

The MemoryGel™ Core Study followed patients through 10 years after their breast implant surgery. Results provided here represent these 10 years of data. This brochure may be updated should new information become available. You should also ask your surgeon if he or she has received any updated clinical information. Updated breast implant safety information is also available on Mentor's patient website https://www.breastimplantsbymentor.com/MENTOR-implant-safety-information. Additionally, the status of Mentor's ongoing post approval studies can be viewed on FDA's website https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm.

The following sections provide more information about the complications and benefits you may experience following augmentation with MENTOR® MemoryGel™ Breast Implants, based on the experiences of the augmentation patients in the MemoryGel™ Core Study.

9.2 What Were the 10-Year Follow-up Rates?

The study enrolled 552 primary augmentation patients and 145 revision-augmentation patients. At the 10-year follow-up visit, data are reported for 57% of the eligible primary augmentation patients and 64% of the eligible revision-augmentation patients.

9.3 What Were the Benefits?

The benefits of MemoryGel™ Breast Implants were examined by measuring the change in bra size (in terms of cup size and chest circumference) and assessing patient satisfaction and quality-of-life (QoL). Patient satisfaction and QoL were determined using several scales and questionnaires before implantation and at scheduled follow-up visits (1, 2, 4, 6, 8 and 10 years after their surgery).

Primary Augmentation Patients

Most primary augmentation patients were pleased with the results of their implant surgery through 10 years. Two hundred and fifty-two out of the 552 patients enrolled were included in the analysis of cup size. Almost all (98%) had increased their bra size by at least one cup size. Two hundred and ninety-five of the 552 patients enrolled were included in the circumferential chest size analysis. The average increase in circumferential chest size was 2.9 inches (7.5 centimeters). In regards to overall satisfaction, 297 (97%) of the 306 primary augmentation patients who answered the patient satisfaction question indicated they would make the same decision to have breast surgery.

According to their scores on a questionnaire about a variety of general QoL concepts (health, mental, and social well-being), at 10 years, primary augmentation patients showed a statistically significant, negative treatment effect in the Mental Component Score of the SF-36 and no significant change in the total score of the TSCS. There were statistically significant, positive treatment effects in the total score and the positive attitude score for the Rosenberg Self Esteem Scale and in the total score and the chest and sexual attractiveness subscales for the Body Esteem Scale.

Revision-Augmentation Patients

Most revision-augmentation patients were pleased with the results of their additional implant surgery through 10 years. Bra size changes were not analyzed for revision-augmentation patients. Seventy-seven of the 145 patients enrolled were included in the circumferential chest size analysis. The average increase in circumferential chest size was 1.1 inches (2.9 centimeters). In regards to overall satisfaction, 81 (99%) of the 82 primary augmentation patients who answered the patient satisfaction question indicated they would make the same decision to have breast surgery.

According to their scores on a questionnaire about a variety of general QoL concepts (health, mental, and social well-being), at 10 years, revision-augmentation patients showed a statistically significant, negative treatment effect in the Mental Component Score of the SF-36. There was a statistically significant, positive treatment effect in the chest score of the Body Esteem Scale. There was no statistically significant treatment effect in the total score or positive attitude score for the Rosenberg Self-Esteem Scale. However, there was a statistically significant treatment effect in the total score of the TSCS.

9.4 What Were the 10-Year Complication Rates?

The safety of MENTOR® MemoryGel™ Breast Implants was determined by assessing the incidence of complications, including device failures.

Primary Augmentation

The complications observed in women who had primary augmentation through 10 years are presented in Table 8. The most common reported complication within the 10 years after primary augmentation surgery was reoperation (25% or approximately 25 out of 100).

Table 8
Complication Rates for Primary Augmentation Patients, N=552 Patients

Key Complications[1]		% through 3 years	% through 6 years	% through 10 years
Any Reoperation		16.5	20.1	25.5
Rupture[2]	Initial MRI Cohort[3]	0.0	3.7	24.2
	Supplemental MRI Cohort[3]	N/A	1.2	21.4
Capsular Contracture Baker Grade III, IV		8.2	9.6	12.1
Implant Removal with or without Replacement		4.4	6.6	11.6
Infection		0.7	0.7	0.7
Other Complications ≥ 1% at 10 years				
Other Complications[4]		7.4	12.4	15.2
Capsular Contracture Baker Grade III		7.7	8.6	10.9
Nipple Sensation Changes		6.8	6.9	7.5
Ptosis (sagging)		1.1	2.3	4.1
Capsular Contracture Baker Grade IV		1.7	2.6	3.7
Hypertrophic Scarring (irregular, raised scar)		2.6	2.8	3.0
Breast Sensation Changes		2.4	2.8	3.0
Breast Pain		1.6	2.0	2.9
Capsular Contracture Baker Grade II with Surgical Intervention		1.1	1.5	2.4
New Diagnosis of Rheumatic Disease		0.9	1.5	2.4
Lactation Difficulties		0.4	1.4	1.6
Wrinkling		0.7	1.1	1.3
Hematoma		1.1	1.1	1.1
Implant Malposition/Displacement		0.4	0.8	1.0

[1] Mild occurrences were not included except for the following complications: abnormal mammogram, Baker II capsular contracture with surgical intervention, Baker III capsular contracture, Baker IV capsular contracture, breast mass, contralateral explant, deep vein thrombosis, ectopic pregnancy, extrusion, implant removal-patient request, lymphoma, mammogram evidence of free silicone outside capsule, metastatic disease, milky appearance of implant, miscarriage, necrosis, new diagnosis of breast cancer, new diagnosis of rheumatic disease, patient desired to switch to saline, patient request for new implants, pre-eclampsia, premature delivery, recurrent breast cancer, recurrent breast cancer metastasis, rupture per physical examination contrary to medical opinion of principal investigator, severe allergic reaction, silicone in lymph node, stillborn delivery, suicide, suspected new cancer.

[2] These estimated rates were determined through use of Kaplan-Meier methodology, which attempts to take loss of patients to follow-up over time into account by calculating a rate based on the available patient data for any given timepoint. Overall rupture occurrence is the number of suspected or confirmed ruptures in a patient group divided by the number of patients enrolled in that group. Overall rupture occurrence for both the Initial and Supplemental MRI cohorts was 54/552 (9.8%) for the primary augmentation cohort.

[3] Two groups of patients underwent MRI screening for rupture. One group of patients, identified as the Initial MRI Cohort, was scheduled to receive MRI exams at 1, 2, 4, 6, 8 and 10 years post implantation. As there was no MRI exam scheduled at 3 years, 2 year rupture data is provided in this table. The second group of patients, identified as the Supplemental MRI Cohort, was scheduled to receive MRI exams at 8 and 10 years post implantation. A small portion of the patients in the Supplemental MRI Cohort who had not yet reached their 6-year follow up visit also had an MRI at the 6-year post implantation timepoint. As the 6-year MRI data is the first available for the Supplemental MRI Cohort, rupture data is not available (N/A) at 3 years for this cohort.

[4] Other complications include abnormal mammogram, acute swelling, breast mass, breast trauma external cause, bruise on breast, contracted scar on breast, contralateral explant, deep vein thrombosis, ectopic pregnancy, Epstein-Barr virus infection, erythema of breast, excessive bruising, superior pole fullness, excessive implant movements, fibroadenoma, fibrocystic breast changes, fluid accumulation, granuloma, implant removal-patient request, inflammation of breast, inframammary fold dissatisfaction, irritation on breast, lack of projection, low projection, lymphoma, mammogram evidence of free silicone outside capsule, metastatic disease, milky appearance of implant, miscarriage, muscle spasm, nipple complications, nipple discharge, occasional burning discomfort of skin, palpability--implant, patient desired to switch to saline, patient dissatisfaction, patient request for new implants, patient would not have surgery again, pre-eclampsia, premature delivery, rash, recurrent breast cancer, recurrent breast cancer metastasis, red drainage from incision, rupture per physical examination contrary to medical opinion of principal investigator, scar dissatisfaction, scarring, severe allergic reaction, silicone bleed, silicone in lymph node, skin lesion, stillborn delivery, suicide, suspected new cancer, suspected rupture- not ruptured, symmastia.

Revision-Augmentation

The complications observed in women who had revision-augmentation through 10 years are presented in Table 9. The most common reported complication within the first 10 years after revision-augmentation surgery was reoperation (44% or approximately 44 out of 100).

Table 9
Complication Rates for Revision-Augmentation Patients, N=145 Patients

Key Complications[1]		% through 3 years	% through 6 years	% through 10 years
Any Reoperation		29.0	36.3	43.7
Capsular Contracture Baker Grade III, IV		18.9	21.9	24.4
Implant Removal with or without Replacement		11.8	17.5	24.1
Rupture[2]	Initial MRI Cohort[3]	2.0	9.4	23.7
	Supplemental MRI Cohort[3]	N/A	2.4	7.5
Infection		0.7	0.7	0.7
Other Complications ≥ 1% at 10 years				
Capsular Contracture Baker Grade III		18.2	21.3	24.0
Other Complications[4]		10.0	12.4	19.0
Capsular Contracture Baker Grade IV		6.3	7.1	7.9
Nipple Sensation Changes		7.0	7.9	7.9
Capsular Contracture Baker Grade II with Surgical Intervention		4.2	5.0	5.0
New Diagnosis of Rheumatic Disease		1.5	2.3	4.4
Hypertrophic Scarring (irregular, raised scar)		4.2	4.2	4.2
Breast Pain		1.4	1.4	3.2
Wrinkling		2.1	2.9	2.9
Hematoma		2.8	2.8	2.8

Table 9 *Continued on next page*

Implant Malposition/Displacement	1.4	1.4	2.3
Breast Sensation Changes	2.1	2.1	2.1
Seroma	2.1	2.1	2.1
Delayed Wound Healing	2.1	2.1	2.1
New Diagnosis of Breast Cancer	0.0	1.7	1.7
Ptosis (sagging)	0.7	1.6	1.6
Calcification	0.7	1.5	1.5
Extrusion	1.4	1.4	1.4

[1] Mild occurrences were not included except for the following complications: abnormal mammogram, Baker II capsular contracture with surgical intervention, Baker III capsular contracture, Baker IV capsular contracture, breast mass, contralateral explant, deep vein thrombosis, ectopic pregnancy, extrusion, implant removal-patient request, lymphoma, mammogram evidence of free silicone outside capsule, metastatic disease, milky appearance of implant, miscarriage, necrosis, new diagnosis of breast cancer, new diagnosis of rheumatic disease, patient desired to switch to saline, patient request for new implants, pre-eclampsia, premature delivery, recurrent breast cancer, recurrent breast cancer metastasis, rupture per physical examination contrary to medical opinion of principal investigator, severe allergic reaction, silicone in lymph node, stillborn delivery, suicide, suspected new cancer.

[2] These estimated rates were determined through use of Kaplan-Meier methodology, which attempts to take loss of patients to follow-up over time into account by calculating a rate based on the available patient data for any given timepoint. Overall rupture occurrence is the number of suspected or confirmed ruptures in a patient group divided by the number of patients enrolled in that group. Overall rupture occurrence for both the Initial and Supplemental MRI cohorts was 11/145 (7.6%) for the revision-augmentation cohort.

[3] Two groups of patients underwent MRI screening for rupture. One group of patients, identified as the Initial MRI Cohort, was scheduled to receive MRI exams at 1, 2, 4, 6, 8 and 10 years post implantation. As there was no MRI exam scheduled at 3 years, 2 year rupture data is provided in this table. The second group of patients, identified as the Supplemental MRI Cohort, was scheduled to receive MRI exams at 8 and 10 years post implantation. A small portion of the patients in the Supplemental MRI Cohort who had not yet reached their 6-year follow up visit also had an MRI exam at the 6-year post implantation timepoint. As the 6-year MRI data is the first available for the Supplemental MRI Cohort, rupture data is not available (N/A) at 3 years for this cohort.

[4] Other complications include abnormal mammogram, acute swelling, breast mass, breast trauma external cause, bruise on breast, contracted scar on breast, contralateral explant, deep vein thrombosis, ectopic pregnancy, Epstein-Barr virus infection, erythema of breast, excessive bruising, superior pole fullness, excessive implant movements, fibroadenoma, fibrocystic breast changes, fluid accumulation, granuloma, implant removal-patient request, inflammation of breast, inframammary fold dissatisfaction, irritation on breast, lack of projection, low projection, lymphoma, mammogram evidence of free silicone outside capsule, metastatic disease, milky appearance of implant, miscarriage, muscle spasm, nipple complications, nipple discharge, occasional burning discomfort of skin, palpability--implant, patient desired to switch to saline, patient dissatisfaction, patient request for new implants, patient would not have surgery again, pre-eclampsia, premature delivery, rash, recurrent breast cancer, recurrent breast cancer metastasis, red drainage from incision, rupture per physical examination contrary to medical opinion of principal investigator, scar dissatisfaction, scarring, severe allergic reaction, silicone bleed, silicone in lymph node, skin lesion, stillborn delivery, suicide, suspected new cancer, suspected rupture- not ruptured, symmastia.

9.5 What Were the Main Reasons for Reoperation?

Patients may require a reoperation for a number of reasons, including size and/or style change, implant removal (with or without replacement), capsular contracture procedures, incision and drainage, implant repositioning, scar revision, etc. In addition, patients may require more than one surgical procedure during a given reoperation.

Primary Augmentation

In Mentor's MemoryGel™ Core Study, there were 189 reoperations performed in 133 patients. The risk of experiencing at least one reoperation for primary augmentation patients was 25% (approximately 25 out of 100 patients) through 10 years. Table 10 provides the main reasons for reoperation. The two most common reasons for reoperation were capsular contracture Baker Grade III/IV and breast mass.

Table 10
Main Reasons for Reoperation in Primary Augmentation Patients

Primary Reason for Reoperation	N=189 Reoperations[1] n (%)		
	through 3 years	through 6 years	through 10 years
Capsular Contracture Baker Grade III/IV	33 (26.2)	37 (24.8)	40 (21.2)
Breast Mass	10 (7.9)	14 (9.4)	20 (10.6)
Size Change	13 (10.3)	14 (9.4)	18 (9.5)
Hypertrophic Scarring (irregular, raised scar)	12 (9.5)	14 (9.4)	14 (7.4)
Hematoma	13 (10.3)	13 (8.7)	13 (6.9)
Rupture	0 (0.0)	1 (0.7)	11 (5.8)
Asymmetry	5 (4.0)	6 (4.0)	9 (4.8)
Capsular Contracture Baker Grade II	7 (5.6)	7 (4.7)	8 (4.2)
Ptosis (sagging)	4 (3.2)	4 (2.7)	7 (3.7)
Calcification	1 (0.8)	2 (1.3)	5 (2.6)
Infection	4 (3.2)	4 (2.7)	4 (2.1)
Implant Malposition/Displacement	2 (1.6)	4 (2.7)	4 (2.1)
Seroma	4 (3.2)	4 (2.7)	4 (2.1)
Implant Removal – Patient Request	0 (0.0)	4 (2.7)	4 (2.1)
New Diagnosis of Breast Cancer	0 (0.0)	0 (0.0)	4 (2.1)
Wrinkling	3 (2.4)	3 (2.0)	3 (1.6)
Skin Lesion	2 (1.6)	3 (2.0)	3 (1.6)
Delayed Wound Healing	2 (1.6)	2 (1.3)	2 (1.1)
Breast Pain	1 (0.8)	2 (1.3)	2 (1.1)
Fluid Accumulation	2 (1.6)	2 (1.3)	2 (1.1)
Suspected Rupture	1 (0.8)	1 (0.7)	2 (1.1)
Necrosis	1 (0.8)	1 (0.7)	1 (0.5)
Cosmetic	1 (0.8)	1 (0.7)	1 (0.5)
Drainage from Incision after Cat Scratched	1 (0.8)	1 (0.7)	1 (0.5)
Lymphadenopathy	0 (0.0)	1 (0.7)	1 (0.5)
Mole on Breast	0 (0.0)	0 (0.0)	1 (0.5)
Nipple Retraction	1 (0.8)	1 (0.7)	1 (0.5)
Patient Dissatisfied with Appearance	1 (0.8)	1 (0.7)	1 (0.5)
Previous Surgical Complication	1 (0.8)	1 (0.7)	1 (0.5)
Silicone Bleed	0 (0.0)	0 (0.0)	1 (0.5)
Suture Complication	1 (0.8)	1 (0.7)	1 (0.5)

[1] All reoperations were counted, with the primary reason for each reoperation presented.

Revision-Augmentation

In Mentor's MemoryGel™ Core Study, there were 92 reoperations performed in 61 revision-augmentation patients. The risk of experiencing at least one reoperation for revision-augmentation patients was 44% (approximately 44 of 100 patients) through 10 years. Table 11 provides the main reasons for reoperation. The two most common reasons for reoperation through 10 years were capsular contracture Baker Grade III/IV and size change.

Table 11.
Main Reasons for Reoperation in Revision-Augmentation Patients

Primary Reason for Reoperation	N=92 Reoperations[1] n (%)		
	through 3 years	through 6 years	through 10 years
Capsular Contracture Baker Grade III/IV	18 (28.6)	23 (29.1)	23 (25.0)
Size Change	5 (7.9)	7 (8.9)	9 (9.8)
Breast Mass	5 (7.9)	8 (10.1)	8 (8.7)
Rupture	0 (0.0)	1 (1.3)	6 (6.5)
Capsular Contracture Baker Grade II	5 (7.9)	5 (6.3)	5 (5.4)
Delayed Wound Healing	5 (7.9)	5 (6.3)	5 (5.4)
Hematoma	4 (6.3)	4 (5.1)	4 (4.3)
Hypertrophic Scarring (irregular, raised scar)	4 (6.3)	4 (5.1)	4 (4.3)
Asymmetry	2 (3.2)	3 (3.8)	3 (3.3)
Ptosis (sagging)	1 (1.6)	2 (2.5)	3 (3.3)
Extrusion	2 (3.2)	2 (2.5)	2 (2.2)
Skin Lesion	1 (1.6)	1 (1.3)	2 (2.2)
Implant Malposition/Displacement	2 (3.2)	2 (2.5)	2 (2.2)
Seroma	2 (3.2)	2 (2.5)	2 (2.2)
Calcification	2 (3.2)	2 (2.5)	2 (2.2)
Fibroadenoma	0 (0.0)	1 (1.3)	2 (2.2)
Implant Removal-Patient Request	0 (0.0)	0 (0.0)	2 (2.2)
Wrinkling	1 (1.6)	1 (1.3)	1 (1.1)
Breast Cancer	0 (0.0)	1 (1.3)	1 (1.1)
Infection	1 (1.6)	1 (1.3)	1 (1.1)
New Diagnosis of Breast Cancer	0 (0.0)	1 (1.3)	1 (1.1)
Patient Dissatisfied with Appearance	1 (1.6)	1 (1.3)	1 (1.1)
Shape Change	1 (1.6)	1 (1.3)	1 (1.1)
Suspected Rupture	0 (0.0)	0 (0.0)	1 (1.1)
Suspected Rupture-No Rupture Found	1 (1.6)	1 (1.3)	1 (1.1)

[1] All reoperations were counted, with the primary reason for each reoperation presented.

9.6 What Were the Main Reasons for Implant Removal?

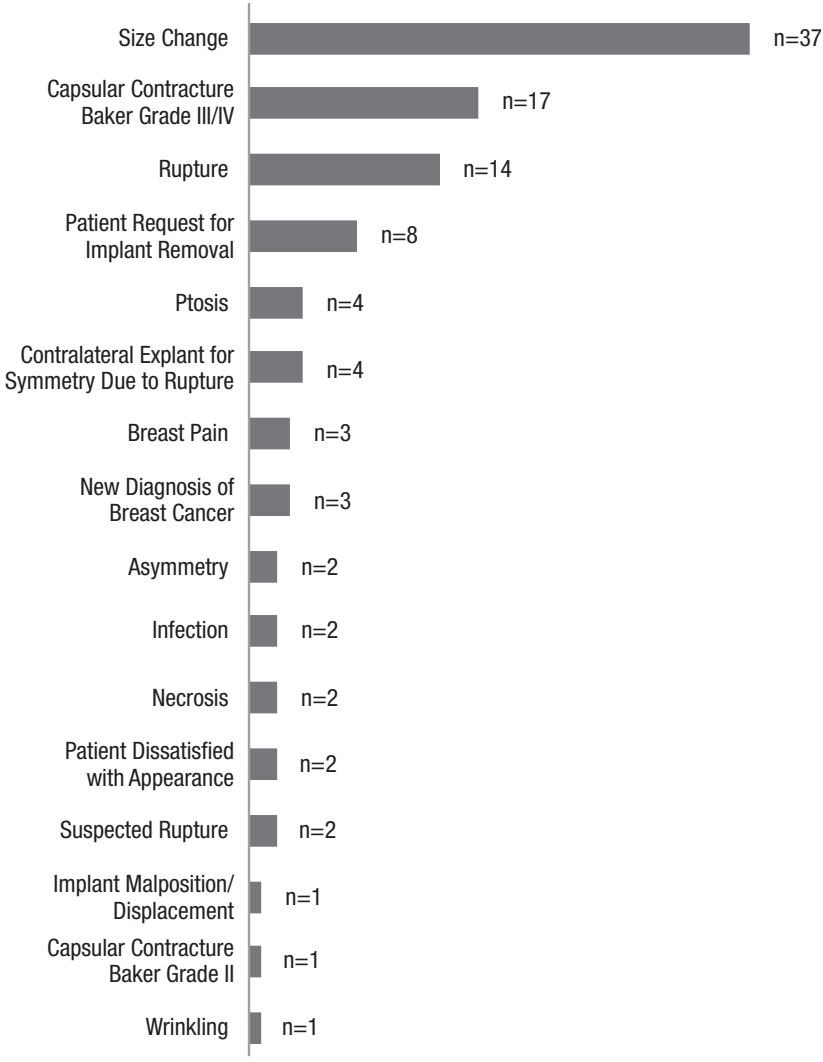
Breast implants may be removed (with or without replacement) in response to a complication or to improve the cosmetic result.

Primary Augmentation

The main reasons for implant removal among primary augmentation patients in the MemoryGel™ Core Study through 10 years are shown in Figure 4. There were a total of 103 implants removed in 58 patients through 10 years. Of the 103 implants removed, 61 (59%) were replaced with a study device. The most common reason for implant removal through 10 years was patient requested size change (37 of the 103 implants removed).

Figure 4

Main Reasons for Implant Removal in Primary Augmentation
Through 10 Years, N=103 implants

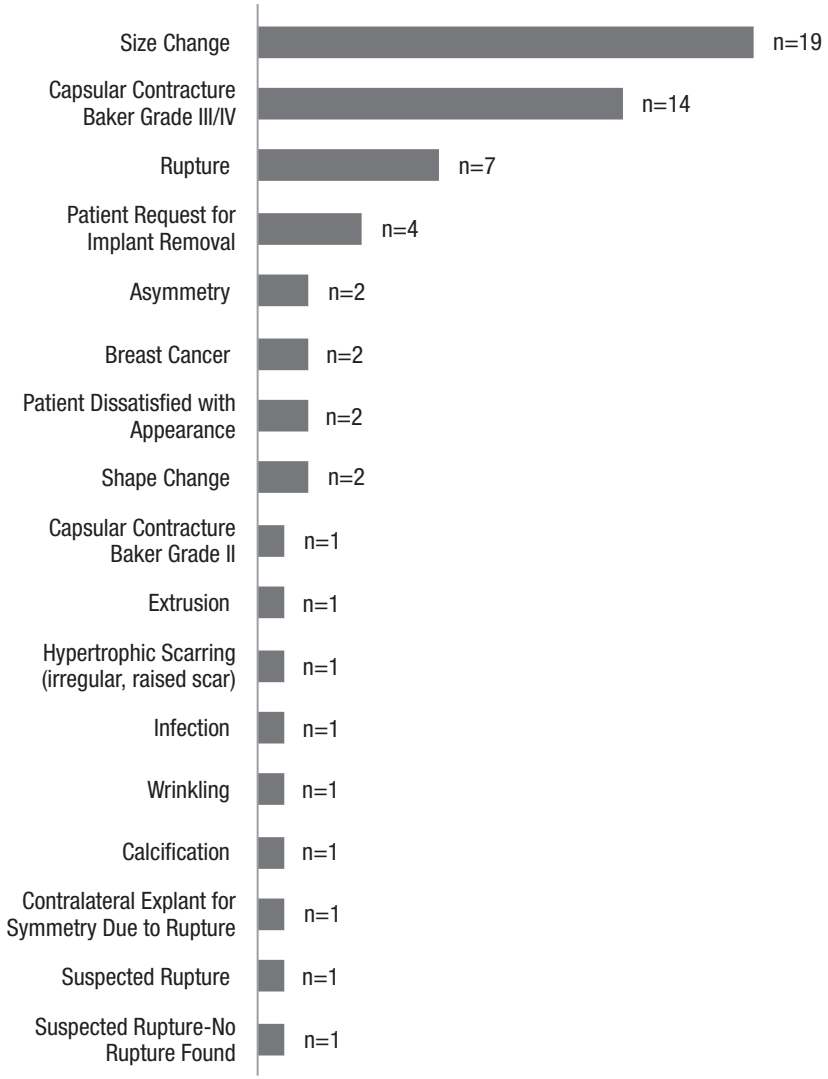


Revision-Augmentation

The main reasons for implant removal among revision-augmentation patients in the MemoryGel™ Core Study through 10 years are shown in Figure 5. There were a total of 61 implants removed in 33 patients through 10 years. Of the 61 implants removed, 31 (51%) were replaced with a study device. The most common reason for implant removal through 10 years was patient-requested size change (19 of the 61 implants removed).

Figure 5

Main Reasons for Implant Removal in Revision-Augmentation
Through 10 Years, N=61 implants



9.7 What Were Other Clinical Data Findings?

The MemoryGel™ Core Study evaluated several possible long-term health effects that have been reported in breast implant patients. These include rupture, cancer, CTD, CTD signs and symptoms, complications with lactation, reproductive complications, and suicide.

Rupture

The rupture rate calculations were based on MRI data. There are two groups of patients that underwent screening for rupture with MRI. One group of patients was scheduled from the beginning of the study to receive MRI exams at 1, 2, 4, 6, 8, and 10 years (Initial MRI cohort). The second group of patients was later scheduled to receive MRI exams at 8 and 10 years, and at 6 years for those patients who had not reached their 6-year post implantation follow up visit (Supplemental MRI cohort). Suspected or confirmed rupture is a number that is the sum of all ruptures that were either suspected due to MRI imaging or actually confirmed as ruptured after explantation. The estimated rate of suspected or confirmed rupture was calculated using the Kaplan-Meier estimated cumulative incidence, which is specifically designed to take into account patients who were lost to follow-up (for example, if a patient did not return for a follow-up visit or withdrew from the study). The results after 10 years of follow up are provided in this brochure in the following ways:

- Patient level (rupture per patient)
- Implant level (rupture per implant)
- Using data through the patient's last MRI exam

Primary Augmentation

For Primary Augmentation patients in the Initial MRI cohort, the estimated rupture rate based on confirmed and suspected ruptures was 24.2% at the patient level and 14.9% at the implant level based on follow-up through the patient's last MRI exam at 10 years after implantation. This means that through 10 years, based only on MRI exam, an estimated 24 of every 100 Primary Augmentation patients may have a suspected or actual ruptured breast implant and 15 of every 100 Primary Augmentation implants may be a suspected or actual rupture.

Table 12 below summarizes the Kaplan-Meier estimated cumulative incidence rates through 10-years for suspected or confirmed (combined) versus confirmed ruptures at the patient and the implant level for the Initial MRI Cohort Primary Augmentation patients and the Supplemental MRI Cohort Primary Augmentation patients. It should be noted that the relatively lower sample size (lower follow up rates) at 10 years reduces the accuracy of these estimated rupture rates.

Table 12
Suspected or Confirmed Versus Confirmed Kaplan-Meier Estimated Cumulative Incidence of Rupture Based on Last MRI Exam Through 10 Years

Primary Augmentation			
Initial MRI Cohort		**Supplemental MRI Cohort**	
Enrolled: 202 patients with 417 implants Follow-up at 10 years: 89/195 patients (46%), 173/402 implants (43%)*		Enrolled: 350 patients with 713 implants Follow-up at 10 years: 124/335 patients (37%), 234/681 implants (34%)*	
Suspected or Confirmed	Kaplan-Meier estimated rate, % (95% Confidence Interval)	*Suspected or Confirmed*	Kaplan-Meier estimated rate, % (95% Confidence Interval)
25 patients 31 implants	24.2% 14.9%	29 patients 34 implants	21.4% 12.5%
Confirmed 11 patients 15 implants	 9.8% 7.4%	*Confirmed* 10 patients 12 implants	 7.6% 4.6%

*Excluding those patients or implants that were discontinued due to death or explantation

Overall, of the 65 out of 1130 Primary Augmentation implants that were suspected of rupture, 1 implant showed evidence of extracapsular silicone (silicone gel outside of the scar capsule surrounding the breast implant), but the evidence for this extracapsular silicone was considered indeterminate (not certain). None of the ruptures in the Initial MRI cohort and 3 of the ruptures in the Supplemental MRI cohort were symptomatic, meaning the patient had physical symptoms related to the rupture. The rest of the ruptures were "silent" meaning there were no physical symptoms before the rupture (or suspected rupture) was identified by the MRI. Four Primary Augmentation patients experienced a local complication (calcification, capsular contracture grade III, hypertrophic scarring, and ptosis) that first occurred after suspected or confirmed rupture. At 10-years post-implant, 92% (or 92 of 100 patients) of the Primary Augmentation patients with suspected or confirmed rupture indicated that they would make the same decision to have breast implant surgery.

Revision-Augmentation

For Revision-Augmentation patients in the Initial MRI cohort, the estimated rate based on confirmed and suspected ruptures was 23.7% at the patient level and 16.5% at the implant level based on follow-up through the patients' last MRI exam at 10 years after implant. This means that through 10 years, based only on MRI exam, an estimated 24 of every 100 Revision-Augmentation patients may have a suspected or confirmed ruptured breast implant and 17 of every 100 Revision-Augmentation implants may be a suspected or actual rupture.

Table 13 below summarizes the Kaplan-Meier estimated cumulative incidence rates through 10-years for suspected or confirmed (combined) versus confirmed ruptures at the patient and the implant level for the Initial MRI Cohort Revision-Augmentation patients and for the Supplemental MRI Cohort Revision-Augmentation patients. It should be noted that the relatively lower sample size (lower follow up rates) at 10 years reduces the accuracy of these estimated rupture rates.

Table 13
Suspected or Confirmed Versus Confirmed Kaplan-Meier Estimated Cumulative Incidence of Rupture Based on Last MRI Exam Through 10 Years

Revision-Augmentation			
Initial MRI Cohort		**Supplemental MRI Cohort**	
Enrolled: 56 patients with 110 implants Follow-up at 10 years: 25/52 patients (48%), 44/102 implants (43%)*		Enrolled: 89 patients with 182 implants Follow-up at 10 years: 33/74 patients (45%), 62/152 implants (41%)*	
Suspected or Confirmed	Kaplan-Meier estimated rate	*Suspected or Confirmed*	Kaplan-Meier estimated rate
8 patients	23.7%	3 patients	7.5%
11 implants	16.5%	5 implants	6.3%
Confirmed		*Confirmed*	
5 patients	13.9%	2 patients	2.6%
7 implants	9.9%	2 implants	7.9%

*Excluding those patients or implants that were discontinued due to death or explantation

Overall, 16 out of 292 Revision-Augmentation implants were suspected of rupture. None of the ruptures in either the Initial MRI cohort or the Supplemental MRI cohort were symptomatic, meaning the patient had physical symptoms related to the rupture. The rest of the ruptures were "silent" meaning there were no physical symptoms before the rupture (or suspected rupture) was identified by the MRI. One Revision-Augmentation patient experienced a local complication (capsular contracture grade III) that first occurred after suspected or confirmed rupture. At 10-years post-implant, 100% (or 100 of 100 patients) of the Revision-Augmentation patients with suspected or confirmed rupture indicated that they would make the same decision to have breast implant surgery.

Of the 16 suspected or confirmed ruptured implants, 4 showed evidence of extracapsular silicone (silicone gel outside of the scar capsule surrounding the breast implant). For 3 of these 4 implants, the evidence for extracapsular silicone was considered indeterminate (not certain).

The overall occurrence of (suspected or confirmed) rupture provided in Table 14 reflect the number of suspected or confirmed ruptures in a patient group divided by the number of patients enrolled in that group. The overall occurrence is likely underestimated due to some patients not returning for follow-up and therefore possibly not reporting a rupture. The estimated Kaplan-Meier rates of suspected or confirmed rupture through 1, 2, 4, 6, 8 and 10 years are also presented in Table 14 for the Primary Augmentation and Revision-Augmentation patients in the Initial and Supplemental MRI cohorts. The estimated Kaplan-Meier complication rates attempt to account for patients not returning for follow-up and adjusts the estimated rupture rate accordingly. Note that all ruptures presented in Table 14 include those caused by iatrogenic damage (damage caused by a surgical instrument upon implantation or removal of the device) and non-iatrogenic damage (ruptures resultant from device failure).

Table 14
Adverse Event Risk Rates for Suspected or Confirmed Rupture by Patient

Indication (N Enrolled Initial + Supplemental MRI Cohort)	Overall Occurrence of Rupture 10 Years n (%)[a]	Estimated (Kaplan-Meier) Complication Rates for Suspected or Confirmed Rupture						
		Cohort (N Enrolled)	1 Year	2 Years	4 Years	6 Years	8 Years	10 Years
Primary Augmentation (N=552)	**54 (9.8%)[b]**	**Initial MRI** (N=202)	**0%**	**0%**	**1.3%**	**3.7%**	**10.3%**	**24.2%**
		Supplemental MRI (N=350)	**-**	**-**	**-**	**1.2%**	**8.9%**	**21.4%**
Revision-Augmentation (N=145)	**11 (7.6%)[c]**	**Initial MRI** (N=56)	**0%**	**2.0%**	**4.2%**	**9.4%**	**12.3%**	**23.7%**
		Supplemental MRI (N=89)	**-**	**-**	**-**	**2.4%**	**7.5%**	**7.5%**

[a] Overall occurrence of rupture is the number of suspected or confirmed ruptures in a patient group divided by the number of patients enrolled in that group.

[b] 33 patients with suspected but not confirmed ruptures. 2 patients symptomatic

[c] 7 patients with suspected but not confirmed ruptures. 0 patients symptomatic

Overall, there have been 42 suspected or confirmed ruptured implants among 33 of the patients (25 primary augmentation and 8 revision-augmentation, participating in the augmentation segments of the Initial MRI cohort and 39 suspected or confirmed ruptured implants among 32 of the patients (29 primary augmentation, and 3 revision-augmentation) participating in the augmentation segments of the Supplemental MRI cohort. Of the 81 suspected or confirmed ruptured implants in the augmentation segments of the overall study, 4 cases were indeterminate for extracapsular silicone by MRI. There was 1 case of migrated gel.

Rupture rate information on Mentor's MemoryGel™ Breast Implants was also provided during the FDA's 2005 Panel Meeting regarding MRI and Explantation Investigation of silicone gel implants from the European study known as the U.K. Sharpe and Collis Study.[2,80] Silent rupture was assessed by MRI on 101 augmentation patients implanted with textured MemoryGel™ Breast Implants. The average age of the implants was approximately 10 years. The results suggest that by 12 years approximately 15% of implants will have ruptured. All ruptures were confirmed to be intracapsular.

Cancer

For primary augmentation patients, there were 3 (0.7%) patients with 4 new diagnoses of breast cancer in Mentor's MemoryGel™ Core Study. As previous breast cancer was an exclusion criterion for primary augmentation patients, there were no reports of breast cancer reoccurrence in this cohort. For revision-augmentation patients, 2 (1.7%) patients had a new diagnosis of breast cancer.

There was one reported case of brain carcinoma (Revision-Augmentation) and one case of skin cancer (Revision-Augmentation). In addition, there were no cases of breast implant-associated anaplastic large-cell lymphoma (BIA-ALCL) reported in any cohort.

Connective Tissue Disease (CTD)

In the MemoryGel™ Core Study, there were 10 primary augmentation patients and 4 revision-augmentation patients reported to have a new diagnosis of CTD by a rheumatologist. There were 11 diagnoses for the 10 primary augmentation patients: carpal tunnel syndrome (within 5 years), fibromyalgia (3 cases – 2 within 4 years and 1 within 7 years), Hashimoto's thyroiditis (within 2 years), other inflammatory arthritis (within 5 years), rheumatoid arthritis (2 cases – within 2 and 8 years), sarcoidosis (within 9 years), spondyarthropathies (within 7 years), and systemic lupus erythematosus (within 4 years). There were 4 diagnoses for the 4 revision-augmentation patients: fibromyalgia (within 3 years), rheumatoid arthritis (within 3 years), scleroderma (within 9 years), and unknown type of arthritis (within 5 years). It cannot be concluded that these CTD diagnoses were caused by the implants because there was no comparison group of similar women without implants.

CTD Signs and Symptoms

Compared to before having implants, the following significant changes in individual signs and symptoms were found in the rheumatologic symptoms and physical examination findings after adjusting for the age effect: a decrease for heart murmurs among primary augmentation patients and a decrease for neck pain/stiffness among revision-augmentation patients. For individual signs and symptoms, a statistically significant decrease was found in the cardiovascular category for primary augmentation patients.

The MemoryGel™ Core Study was not designed to evaluate the cause and effect associations because there is no comparison group of women without implants, and because other contributing factors, such as medications and lifestyle/exercise, were not studied. Therefore, it cannot be determined whether any differences are due to the implants. However, you should be aware that you may experience an increase in symptoms after receiving breast implants.

Lactation Complications

Lactation complications, including difficulties with breastfeeding, were examined in the MemoryGel™ Core Study. Fifteen of the 83 primary augmentation patients who attempted to breastfeed following implantation experienced lactation difficulties in Mentor's MemoryGel™ Core Study. Two of the 11 revision-augmentation patients who attempted to breastfeed after receiving breast implants experienced lactation difficulties.

Reproduction Complications

Reproduction complications that were examined in the MemoryGel™ Core Study include miscarriage and having a stillborn baby. Eighteen primary augmentation patients and 3 revision-augmentation patients reported a miscarriage.

Suicide

There was one report of suicide in the revision-augmentation cohort in Mentor's MemoryGel™ Core Study.

Other Deaths

There was one instance of death by other causes in the primary augmentation cohort, due to acute alcohol intoxication.

Study Strengths and Weaknesses

Mentor's MemoryGel™ Core Study has a number of strengths. The study was prospective and multi-centered, with a large number of sites (48), a large number of patients (1,008) and long follow-up period (10 years). The study also included all four categories of patients for which use of the implant is approved: primary augmentation, revision-augmentation, primary reconstruction, and revision-reconstruction. Finally, a substudy of 420 enrolled patients underwent MRI assessments throughout the study period to identify "silent" ruptures that otherwise would likely go undetected. Adding to the strengths of this study were the extensive, long term, investigations of both the safety and effectiveness of the implant, based on assessments made by both the surgeon and by enrolled patients. These assessments, which are shared throughout this brochure, represent a comprehensive and consistent evaluation of the known or suspected safety risks that women undergoing breast implantation surgery may encounter from both a physician and patient perspective. Weaknesses of the study included the study's open-label nature, lack of a control group, and a follow-up rate of 62% at 10 years which is lower than desired to optimally minimize potential bias. Furthermore, it should be noted that this study was not designed to detect rare events that may occur in women undergoing breast implantation surgery. Important to note is that the results of the study are descriptive in nature and may not be able to be generalized to a larger population, nor do they necessarily represent all possible postoperative complications that a woman undergoing breast implantation surgery can expect.

10. WHAT TO DO IF YOU HAVE A PROBLEM

If you have a problem with your breast implant(s), tell your doctor about it immediately. Your doctor may need to examine you.

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(Write your doctor's contact information here)

In addition to informing your doctor, you can report a problem to Mentor and/or to the U.S. Food and Drug Administration (FDA). Your doctor or other healthcare provider may do this or you may report it yourself.

You can report any serious problem (sometimes referred to as an "adverse event") directly to the FDA through its voluntary reporting program called MedWatch (See **http://www.fda.gov/medwatch**). An adverse event is considered serious and should be reported when it results in a hospitalization, disability, congenital problem with your child, or other medical or surgical intervention. There is a special form you must use for voluntary reporting (FDA Form 3500). You can obtain it several ways:

- Complete Form 3500 and submit it online at **https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm**

- Download Form 3500 from the website **https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm** and print it out, fill it in, and send it to the FDA, or
- Call the FDA to get a reporting package at 1-800-FDA-1088 (1-800-332-1088).

If you need to complete a Form 3500, the FDA recommends that you take Form 3500 to your doctor, who can help you to complete it.

11. WHERE TO FIND MORE INFORMATION

SAFETY INFORMATION AVAILABLE ON WEBSITE:

If you are considering breast implant surgery, you should discuss the risks and benefits with your health care provider.

Mentor's website, **breastimplantsbymentor.com**, includes important safety information as well as links to the latest version of Mentor's Patient Educational Brochures. You should check this website periodically to view Mentor safety updates.

You may also visit the FDA's Breast Implants website for additional information https://www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants .

Mentor has more information about its MemoryGel™ Breast Implants and MemoryGel™ Xtra Breast Implants that are available to you. You may request a copy of the package insert given to surgeons that describes how to use the MemoryGel™ Breast Implants and MemoryGel™ Xtra Breast Implants. It also discusses safety information and research performed on implants in general and on MENTOR® MemoryGel™ Breast Implants and MENTOR® MemoryGel™ Xtra Breast Implants in particular. Note that this document is intended only for surgeons, so it has a large amount of undefined medical and technical language.

You can find more detailed information about MemoryGel breast implants on FDA's website, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030053. This site includes links to Mentor's studies (in animals and humans or other laboratory testing) done on MemoryGels® Breast Implants in Mentor's Summary of Safety and Effectiveness Document (SSED).

There are several other sources of information about breast implants and breast implant surgery.

Professional organizations for surgeons offer helpful information on their websites about making decisions about plastic/cosmetic surgery and about choosing a surgeon. You can find this information at the following websites:

The Aesthetic Society - **http://www.surgery.org**

American Society of Plastic Surgeons - **http://www.plasticsurgery.org**

In collaboration with the U.S. Food and Drug Administration (FDA) and breast implant device manufacturers, The Plastic Surgery Foundation (PSF) has developed the **National Breast Implant Registry (NBIR)** for the purpose of strengthening national surveillance for breast implant devices in the United States. The NBIR is a database that collects information on breast implant procedures and devices. Collecting this information will allow the NBIR, plastic surgeons, and breast implant manufacturers to identify trends and other helpful safety information that can be used to improve the safety of breast implants for you and future patients. You are encouraged to ensure that your surgeon is participating in this registry.

12. MENTOR'S IMPLANT TRACKING PROGRAM

Each breast implant is assigned a unique serial number that allows Mentor to identify the implant(s) and locate important information about how and when they were manufactured. Mentor has developed a breast implant tracking program to help facilitate contacting you with updated information if needed.

12.1 Breast Implant Tracking

At the time of your breast implant surgery, you will be asked to participate in Mentor's breast implant tracking program. This will help to ensure that Mentor has a record of your contact information and can contact you in the event there is updated information on your breast implant(s) that you need to know about.

Federal regulations require Mentor to track its MemoryGel™ Breast Implants and MemoryGel™ Xtra Breast Implants. Your surgeon will report the serial number(s) of your breast implants to Mentor, along with the date of your surgery, your personal contact information, and contact information about his or her practice. Mentor maintains this information in a confidential manner.

Your doctor or his or her staff will fill out the Device Tracking Form and return it to Mentor.

12.2 Implant ID Card

After your surgery, your surgeon will provide you a card that contains important information about your breast implants. This card will have the catalog and serial number of your implants, along with other information.

Carry the card with you and show it to doctors or other healthcare providers when you visit them. It will help them treat you appropriately and protect your breast implants during any medical treatment you need in the future.

If you have your breast implants replaced, you will get a new Implant ID Card for those implants.

Your doctor should keep a copy of the Implant ID Card with your medical records.

Please inform Mentor whenever your contact information, e.g., mailing address, email, etc., changes so that we may keep you up to date with important information about your breast implant(s).

You can contact Mentor's Customer Service Department at (800) 235-5731.

13. IMPORTANT CONTACT INFORMATION

Your MemoryGel™ Breast Implants and MemoryGel™ Xtra Breast Implants are manufactured for and sold by:

MENTOR
3041 Skyway Circle North
Irving, TX 75038-3540 USA
1 (800) MENTOR8

www.mentorwwllc.com

Your surgeon's name and contact information:

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14. WARRANTY INFORMATION

Mentor's Lifetime Product Replacement Policy and Advantage Limited Warranties provide limited replacement and limited financial reimbursement in the event of shell leakage or breakage resulting in breast implant rupture. For more information, please contact Mentor's Consumer Affairs Department at (866) 250-5115 or visit www.mentorwwllc.com.

15. PATIENT DECISION CHECKLIST – TO BE COMPLETED PRIOR TO SURGERY

Please review each section of the Patient Decision Checklist provided in the section below. Please place your initials at the end of each section if you understand the information presented or, if there are sections that you are unsure about, write down your questions and discuss them with your surgeon before deciding to have breast implant surgery.

The risks associated with breast surgery and breast implant-specific risks reflect the highest estimated cumulative occurrence of each risk across all groups of patient (augmentation and reconstruction, both primary and revision) in the 10 year core study.

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16. PATIENT DECISION CHECKLIST

To the patient considering breast implants filled with saline or silicone gel intended for breast augmentation or breast reconstruction:

The review and understanding of this document is a critical step in making the decision whether you should choose breast implant surgery. You should learn about breast implants and then carefully consider the benefits and risks associated with breast implants and breast implant surgery before you make that decision. This form lists important risks, including those known or reported to be associated with the use of the device based on information from clinical trials, scientific literature, and reports from patients who have undergone device placement.

This patient decision checklist is intended to supplement the additional patient labeling that should be provided to you by your physician. You should receive a patient booklet/brochure that includes important information about your specific breast implant, as well as a boxed warning and patient decision checklist. After reviewing the information in the patient information booklet/brochure for the specific implant that will be used, please read and discuss the items in this checklist carefully in consultation with your physician. You should place your initials in the location provided next to each item to indicate that you have read and understood the item. Your full signature at the end of this document means that you have read the materials and that your physician has answered all questions to your satisfaction.

Considerations for a Candidate for Successful Breast Implantation

I understand that I am not a candidate for breast implants if any of the following situations applies to me:

- I have an active infection anywhere in my body;
- I have an existing cancer or pre-cancer of my breast tissue that has not been adequately treated; or
- I am pregnant or nursing

I understand that if I have any of the following conditions, I may be at a higher risk for a poor surgical outcome:

- Medical condition that affects my body's ability to heal (e.g., diabetes, connective tissue disorder);
- Active smoker or a former smoker;
- Currently taking drugs that weaken the body's natural resistance to disease, such as steroids and chemotherapy drugs (e.g., prednisone, tacrolimus, sirolimus, mycophenolate, azathioprine, cyclosporine, methotrexate, chlorambucil, leflunomide, or cyclophosphamide);
- History of chemotherapy or planned chemotherapy following breast implant placement;
- History of radiation therapy or planned radiation following breast implant placement;
- Conditions that interfere with wound healing or blood clotting (e.g., hemophilia, von Willebrand disease, factor V Leiden, hyperhomocysteinemia, protein C deficiency, anti- thrombin III deficiency, or systemic lupus erythematosus); or
- Reduced blood supply to the breast tissue.

I understand the following conditions have not been adequately studied to determine whether the conditions put me at higher risk:

- Autoimmune disease (e.g.,Hashimoto's, Lupus, Rheumatoid Arthritis) or family history of autoimmune disease (breast implant premarket clinical studies have not evaluated the safety of breast implants in patients with autoimmune disease);
- Clinical diagnosis of depression or other mental health disorder (including body dysmorphic disorder or eating disorder); or
- Have other products permanently implanted in the breast.

Patient Initials:_____

_____

Patient's Name

Risks of Breast Implant Surgery

I understand that there are risks of undergoing breast implant surgery. The percentages displayed below were reported in the 10-year core study for MemoryGel breast implants. Each rate specified below represents the largest reported cumulative 10-year rate across all groups of patients in the study (augmentation and reconstruction, both primary and revision). I understand that risks of undergoing breast implant surgery may include:

- breast pain (reported in up to 5.2% of patients),
- skin or nipple areola sensitivity changes or loss(nipple sensation changes reported in up to 7.9% of patients, breast sensation changes reported in up to 3% of patients),
- asymmetry (reported in up to 12.7% of patients),
- impact of aging or weight change on size and shape of breast (ptosis reported in up to 5.5% of patients),
- infection requiring possible removal of implant (reported in up to 5.8% of patients),
- swelling (may occur but specific rates are not publicly available in the MemoryGel Core study analysis),
- scarring (hypertrophic scarring reported in up to 4.2% of patients),
- fluid collections (seroma) (reported in up to 2.1% of patients),
- hematoma (reported in up to 2.8% of patients),
- tissue death of breast skin or nipple (necrosis reported in up to 0.9% of patients),
- inability to breast feed (lactation difficulties reported in up to 1.6% of patients),
- complications of anesthesia (may occur but specific rates are not publicly available in the MemoryGel Core study analysis),
- bleeding (may occur but specific rates are not publicly available in the MemoryGel Core study analysis),
- chronic pain (may occur but specific rates are not publicly available in the MemoryGel Core study analysis),
- damage to surrounding tissue, such as muscle, nerves, and blood vessels (may occur but specific rates are not publicly available in the MemoryGel Core study analysis), and
- impact on imaging of breast tissue (may occur but specific rates are not publicly available in the MemoryGel Core study analysis).

My physician has discussed these risks and has provided me with the patient information booklet/brochure (including the boxed warning) with information on the types of risks that are possible and expected rates of occurrence.

My physician has discussed the potential use of other implanted products during my breast implant surgery. My physician has also discussed the risks and benefits of using these implanted products and their planned surgical approach.

Patient Initials:_____

Risks of Cancer-Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

I understand that breast implants are associated with the development of a type of cancer of the immune system called Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA- ALCL). Information regarding the number of medical device reports

of BIA-ALCL can be found on FDA's website (See "Medical Device Reports of Breast Implant-Associated Anaplastic Large Cell Lymphoma," available at https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma.).

As of July 2019, literature reports various estimates for the incidence of BIA-ALCL. These estimated incidence rates have ranged from a high of 1 per 3,817 patients to a low estimate of 1 in 30,000 (Clemens et al, 2017; Loch-Wilkinson et al, 2017; De Boer et al, 2018).

I have received information regarding the overall incidence rates of BIA- ALCL and the rates as they pertain to my specific breast implant.

I understand that this cancer has been reported more frequently for textured breast implants, but that patients with smooth surfaced implants have also been diagnosed.

I understand that patients with breast implants have a risk of developing BIA-ALCL within the scar tissue and fluid surrounding the breast implant.

I understand that BIA-ALCL typically takes several years to develop after implantation, but cases have been reported as early as within one year. Typical symptoms to be aware of include: swelling, breast tightness, pain, lumps, or swelling of the breast months or years after I receive my implants.

I understand that treatment for BIA-ALCL involves an operation to remove the implants and the surrounding scar tissue capsule. Based on the stage of the cancer at diagnosis, some patients have required chemotherapy or radiation. While BIA-ALCL typically responds well to therapy, some patients have died from BIA-ALCL. Diagnosis and treatment may be at my own expense and is not always covered by insurance.

Patient Initials:_____

Systemic Symptoms

I understand that some patients who have received breast implants have reported a variety of systemic symptoms including joint pain, fatigue, rash, memory loss, and "brain fog" that some patients have called breast implant illness. While the causes of these symptoms are unclear, some patients have reported relief of these symptoms with removal of their implants and surrounding scar tissue capsule, however not all patients may experience

improvement in their symptoms. Researchers are working to better understand the possible link between breast implants and these symptoms.

I also understand that some patients with breast implants have reported health problems in their children after birth or breastfeeding. While a causal link between breast implants and these reported health problems in children has not been demonstrated, more research is needed. I understand that breast implants and breast surgery may interfere with my ability to successfully breastfeed.

Patient Initials:_____

Breast-Implant Specific Risks

I understand that a breast implant is NOT a lifetime device and the longer I have my implants, the more likely I am to experience a complication and the more likely I am to require a reoperation requiring the replacement or removal of my breast implant. As many as 24.1 percent of women who received breast implants for augmentation had

their implants removed within 10 years, but my implants may last for a shorter or longer time
(the percentage reported is from the 10-year core study for MemoryGel breast implants. This rate specified represents the largest reported cumulative 10-year rate across all groups of augmentation patients in the study (both primary and revision)).

I understand that my breast implant may rupture or leak at any time, and that the longer I have my implants, the more likely I am to experience a complication such as rupture.

I understand that gel bleed (small quantities of chemicals diffusing from the implant shell) of silicone gel-filled implants may occur. I understand that if I have a saline-filled implant, my breast may deflate in appearance if there is a rupture or leakage of the saline.

I understand that if I have a silicone gel-filled breast implant, I or the physician may not be able to tell on physical exam whether my implant has ruptured or is leaking silicone gel. Because rupture or leakage of silicone gel-filled breast implants is difficult to detect, I understand that periodic imaging evaluation is recommended for screening of silicone gel-filled breast implant rupture. It is recommended that I have periodic imaging of my silicone gel-filled breast implants to screen for implant rupture regardless of whether my implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on my medical history or circumstances (i.e., screening mammography for breast cancer).

Even if I have no symptoms, I should have regular imaging evaluations as described in the “Recommended Follow-Up” section below. These imaging evaluations may not detect all ruptures or leaks, be costly, and the expense may not be covered by my medical insurance.

I understand that silicone can migrate from my implant into nearby tissues (e.g., chest wall, lymph nodes under the arm) and organs (e.g., liver, lungs) where it may not be possible to remove.

I understand that all breast implants can interfere with mammography and breast exams, which could delay the diagnosis of breast cancer. Mammography can also cause the breast implant to rupture or leak. I should tell the mammography technician if I have breast implants.

The percentages displayed below were reported in the 10-year core study for MemoryGel breast implants. Each rate specified below represents the largest reported cumulative 10-year rate across all groups of patients in the study (augmentation and reconstruction, both primary and revision). I understand that the long-term risks of breast implants may

include:

- painful or tightening of scar tissue (capsule) around my implant (capsular contracture III/IV reported in up to 36.9% of patients),
- rupture or leaking of the implant (rupture reported in up to 43.9% of patients),
- wrinkling of the implant (reported in up to 7.0% of patients),
- visibility of the implant edges (may occur but specific rates are not publicly available in the MemoryGel Core Study analysis)
- shifting of the implant (implant malposition/displacement reported in up to 6.7% of patients), or
- reoperation (reported in up to 50.7% of patients).

_____

Patient’s Name

I understand that I will receive a patient device card (i.e. Implant ID Card) after my surgery that has information on each of my specific implants. I understand that it is important for me to keep each card in case I or my physician need to know what kind of implant I have many years later.

I understand that all breast implants contain chemicals and heavy metals. I understand that most of these chemicals stay inside the shell of the implant, but small quantities have been found to diffuse (gel bleed) through the implant shell of silicone gel-filled implants, even if the implant is intact and not ruptured or leaking. A list of the components, chemicals, and heavy metals is available in the patient information booklet/brochure.

Patient Initials:_____

Recommended Follow-up

Even if I have no symptoms, I should have my first ultrasound or MRI at 5-6 years after my initial implant surgery and then every 2-3 years thereafter. If I have symptoms or uncertain ultrasound results for breast implant rupture at any time, an MRI is recommended.

I understand that I will need routine and regular follow-up with my physician as long as I have a breast implant for examination of my breast implant as well as to discuss any updates regarding breast implant issues.

National Breast Implant Registry (NBIR): I understand and have discussed with my physician that there is a National Breast Implant Registry where information regarding my health and breast implant information can be entered. The NBIR may help understand the long-term safety and performance of breast implants.

Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma (ALCL) etiology and Epidemiology (PROFILE): I understand and have discussed with my physician that there is a registry (PROFILE) where information is collected to better understand BIA-ALCL in patients with breast implants.

Patient Initials:_____

Questions for My Physician

I have had the opportunity to ask my physician questions about his or her experience, medical degree, specialty of training, and credentials. I understand that breast implants have associated procedural risks and should only be used by physicians who are appropriately trained.

Patient Initials:_____

Options Following Mastectomy

I understand that breast reconstruction is an elective procedure which I can choose to do or not.

I understand that I may choose not to have breast reconstruction (“going flat”) and may choose to use an external prosthesis in my bra to look like I have a breast when wearing clothes.

I understand the surgical options for breast reconstruction, including the use of a breast implant and the use of my own tissue (“autologous reconstruction”).

I understand that if my breast implants are ever removed, I may be left with dimpling, chest wall concavity, puckering, or sagging of my breasts or skin.

_____

Patient’s Name

I understand that more surgeries may be necessary in the future due to complications or to remove or replace the breast implants.

I have discussed all of the options for breast reconstruction with my provider, including whether I am a candidate and the benefits and risks of each, and I believe that breast reconstruction with a breast implant is the best option for me.

Patient Initials:_____

BREAST AUGMENTATION OPTIONS

I understand that breast augmentation is an elective procedure to increase the size of my breasts.

I understand that breast augmentation may result in permanent changes to my breast tissue and if my implants are ever removed, I may be left with unsatisfactory appearance, changes to the size and shape of my breasts, including but not limited to dimpling, chest-wall concavity, puckering, sagging, or different incision size or location.

If I am an augmentation patient, any additional surgeries or medical procedures will likely be at my own expense.

Patient Initials:_____

CONFIRMATION OF DISCUSSION OF RISKS

Patient: I acknowledge that I have received and read the patient information booklet/brochure for the specific implant that will be used during my surgery and that I have had time to discuss the information in it and on this document with my physician. I have had the opportunity to ask questions and understand the benefits and risks of breast implants for me, given my specific health conditions. I have considered alternatives to breast implants, including reconstruction without breast implants, no reconstruction/augmentation, and their benefits and risks.

_____

Printed Name

_____

Patient Signature and Date

Physician: I acknowledge that I have discussed the benefits and risks of breast implants as described elsewhere in the patient information booklet/brochure and in this checklist. I have also explained the benefits and risks of the alternatives. I have encouraged the patient to ask questions, and I have addressed all questions.

_____

Printed Name

_____

Physician Signature and Date

17. INDEX

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