

Patient Educational Brochure

# RECONSTRUCTION

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

**PATIENT EDUCATIONAL BROCHURE**  
**RECONSTRUCTION**

**BREAST RECONSTRUCTION WITH  
MENTOR® MEMORYGEL™ AND MENTOR® MEMORYGEL™  
XTRA SILICONE GEL BREAST IMPLANTS**



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## GLOSSARY

<b>Abdomen</b>	The part of the body between the upper chest (breasts) and the pelvis (hips); often called the stomach.
<b>Anaplastic Large Cell Lymphoma (ALCL)</b>	ALCL is not breast cancer; it is a rare type of non-Hodgkin's lymphoma (cancer of the immune system).
<b>Areola</b>	The pigmented or darker colored area of skin surrounding the nipple.
<b>Asymmetry</b>	Uneven appearance between a woman's left and right breasts in terms of their size, shape or breast level.
<b>Atrophy</b>	Thinning or diminishing of tissue or muscle.
<b>Autoimmune Disease</b>	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, such as nerves, muscles, glands and the digestive system.
<b>Axillary</b>	Under the arm.
<b>Bilateral</b>	Relating to both the left and right side.
<b>Biocompatible</b>	The ability to exist along with living tissues or systems without causing harm.
<b>Biopsy</b>	The removal and examination of tissue, cells, or fluid from a living body.
<b>Body Dysmorphic Disorder (BDD)</b>	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.
<b>Body Esteem Scale</b>	A series of questions asking about a person's feelings about his or her body.
<b>Breast Augmentation</b>	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."
<b>Breast Implant</b>	Any surgically implanted artificial device intended to replace missing breast tissue or to enhance a breast.
<b>Breast Mass</b>	A lump in the breast.
<b>Breast Reconstruction</b>	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."
<b>Calcification/Calcium Deposits</b>	The process of soft tissue hardening when the mineral calcium builds up in a certain place.
<b>Capsular Contracture</b>	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.
<b>Capsule</b>	Scar tissue that forms around the breast implant.

<b>Capsulotomy (Closed)</b>	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).
<b>Capsulotomy (Open)</b>	A surgery to create an incision or opening in the capsule (scar tissue).
<b>Chest Wall</b>	The system of structures outside the lungs that move as a part of breathing, including bones (the rib cage) and muscles (diaphragm and abdomen).
<b>Congenital Anomaly</b>	An abnormal body part that existed at birth. Also called a congenital malformation or congenital deformity.
<b>Connective Tissue Disease/ Disorder (CTD)</b>	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.
<b>Contraindication</b>	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.
<b>Contralateral</b>	The opposite side of the body.
<b>DIEP Flap</b>	A DIEP (deep interior epigastric artery perforator) flap (section of skin, and other tissue from the abdomen) that is disconnected from (completely cut away from) the blood vessels in the rest of the body before being relocated to the breast area for reconstruction. The blood vessels must then be surgically reconnected when the flap is placed at the breast.
<b>Delayed Reconstruction</b>	Breast reconstruction that takes place weeks, months, or years after a mastectomy.
<b>Delayed Wound Healing</b>	Unusually slow progress in the healing of a wound; surgical incision site fails to heal normally or takes longer to heal.
<b>Displacement</b>	Movement (shifting) of the implant from the usual or proper place.
<b>Extracapsular Rupture</b>	A type of rupture in which the silicone gel is outside of the scar capsule surrounding the breast implant (see Rupture).
<b>Extracapsular Silicone</b>	Silicone material outside the breast implant capsule.
<b>Extrusion</b>	Skin breakdown with the implant pressing through the skin or surgical incision.
<b>Fibrocystic Breast Disease</b>	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.”
<b>Fibromyalgia</b>	A chronic condition characterized by widespread pain in muscles and joints. It may include fatigue, difficulty sleeping, and morning stiffness.
<b>Fibrous Tissues</b>	Connective tissue composed mostly of fibers (for example, tendons).
<b>Flap</b>	A portion of tissue (which may include muscle, fat, and skin), moved from one part of the body to another. The tissue flap may or may not have its blood supply attached.
<b>Free TRAM Flap</b>	A TRAM (transverse rectus abdominus musculocutaneous) flap (section of skin, muscle and other tissue from the abdomen) that is disconnected from (completely cut away from) the blood vessels in the rest of the body before being relocated to the breast area for reconstruction. The blood vessels must then be surgically reconnected when the flap is placed at the breast.
<b>Functional Living Index–Cancer</b>	The Functional Living Index–Cancer (FLIC) is a questionnaire used to evaluate day-to-day functioning in patients who have cancer.
<b>Gel Bleed/Gel Diffusion</b>	When silicone gel leaks, “bleeds” or “diffuses” through the implant shell.

<b>Granuloma</b>	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.
<b>Groin</b>	The fold where the lower abdomen meets the inner part of the thigh.
<b>Hematoma</b>	A collection of blood inside the body, for example in skin tissue or other body space.
<b>Hypertrophic Scarring</b>	An enlarged scar that remains after a wound heals.
<b>Infection</b>	The growth in the human body of microorganisms such as bacteria, viruses or fungi. An infection can occur as a result of any surgery.
<b>Inflammation/Irritation</b>	The response of the body to infection or injury resulting in swelling, redness, warmth and/or pain.
<b>Inframammary Fold</b>	The crease under the breast where the breast and chest meet.
<b>Inframammary Incision</b>	An incision made in the fold below the breast.
<b>Inpatient Surgery</b>	A surgical procedure in which the patient is required to stay overnight in the hospital.
<b>Intracapsular Rupture</b>	A type of rupture in which the silicone gel remains inside the scar tissue capsule surrounding the breast implant (see Rupture).
<b>Lactation</b>	The production and secretion of milk by the breast glands.
<b>Latissimus Dorsi</b>	Two triangular muscles running from the spinal column (backbone) to the shoulder.
<b>Latissimus Dorsi Flap</b>	A section of muscle and tissue on a person's back, consisting of the latissimus dorsi muscle, skin, fat, connective tissue, and vascular (blood vessels) tissue.
<b>Latissimus Dorsi Flap Reconstruction</b>	Breast reconstruction using a patient's own tissue (a latissimus dorsi flap) from the side of the back to create the new breast or provide enough skin and breast tissue to cover a breast implant.
<b>Local Complications</b>	Complications that occur in the breast or chest area.
<b>Lumpectomy</b>	Removal of a small amount of breast tissue.
<b>Lymph Nodes</b>	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.
<b>Lymphadenopathy</b>	Enlarged lymph node(s).
<b>Lymphedema</b>	Swelling of the lymph node(s).
<b>Malposition</b>	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.
<b>Mammary</b>	Pertaining to the breast.
<b>Mammography</b>	A type of x-ray examination of the breasts used for detection of cancer.
<b>Mammoplasty</b>	Plastic surgery of the breast.
<b>Mastectomy</b>	Removal of breast tissue.
<b>Mastopexy</b>	Surgical procedure to raise and reshape sagging breasts.

<b>MemoryGel™ Core Study</b>	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.
<b>Metastatic Disease</b>	A stage of cancer after it has spread from its original site to other parts of the body.
<b>Migration/Gel Migration</b>	Movement of silicone material outside the breast implant to other areas of the body.
<b>MRI (Magnetic Resonance Imaging)</b>	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.
<b>Necrosis</b>	Death of cells or tissues.
<b>Oncologist</b>	A medical doctor who specializes in diagnosing and treating cancer.
<b>Outpatient Surgery</b>	A surgical procedure in which the patient is not required to stay in the hospital overnight.
<b>Palpability/Visibility</b>	Palpability is when the implant can be felt through the skin. Visibility is when the implant can be seen through the skin.
<b>Pectoralis</b>	Major muscle of the chest.
<b>Pedicle TRAM Flap</b>	A TRAM flap (section of skin, muscle and other tissue from the abdomen) that stays connected to the blood vessels in the rest of the body while being relocated (through a tunnel under the skin) to the breast area for reconstruction.
<b>Periareolar</b>	The areola is the pigmented or darker colored area of skin surrounding the nipple. Periareolar refers to the area just around the areola.
<b>Periumbilical</b>	Around the belly button.
<b>Plastic Surgery</b>	Surgery intended to enhance or improve the appearance of the body.
<b>Platinum</b>	A metallic element used to help make both silicone elastomer (the rubbery material of the breast implant shell) and silicone gel.
<b>Post-Mastectomy</b>	After a mastectomy.
<b>Postoperative</b>	After surgery.
<b>Precautions</b>	Information that warns the reader of a potentially hazardous situation that, if not avoided, may result in minor or moderate injury.
<b>Prepectoral Placement</b>	When, after a mastectomy, the implant is placed under the skin but on top of the chest muscles. Also known as subcutaneous placement.
<b>Primary Breast Reconstruction</b>	The first time a breast implant is placed for the purpose of breast reconstruction.
<b>Prosthesis</b>	Any artificial device used to replace or represent a body part.
<b>Ptois</b>	Sagging or drooping of the breast.
<b>Quality of Life (QoL) Measures</b>	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), the Tennessee Self Concept Scale (TSCS), the SF-36 (measures physical, mental, and social health), and the Functional Living Index of Cancer (cancer patients only).
<b>Rectus Abdominus</b>	A long, flat muscle extending the whole length of the front of the abdomen (stomach).

<b>Redness/Bruising</b>	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.
<b>Removal</b>	Removal of the implant, with or without replacement using another implant.
<b>Reoperation</b>	Any additional surgery performed to the breast or chest area after the first breast implantation.
<b>Revision-Reconstruction</b>	Refers to the correction or improvement of a primary reconstruction. In the context of this document, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast reconstruction.
<b>Rheumatological Disease/ Disorder</b>	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.
<b>Risks</b>	The chance or likelihood that an undesirable effect will occur.
<b>Rosenberg Self-Esteem Scale</b>	A questionnaire that measures overall self-esteem.
<b>Rupture</b>	A hole or tear in the shell of the implant that allows silicone gel filler material to leak from the shell.
<b>Saline</b>	Saltwater (a solution made of water and a small amount of salt).
<b>Scar Revision</b>	A surgical procedure to improve the appearance of a scar.
<b>Scarring</b>	Formation of tissue at an incision site; all wounds heal by the formation of a scar.
<b>Seroma</b>	Similar to a bruise, a seroma occurs when the watery portion of the blood collects around a surgical incision or around a breast implant.
<b>SF-36 Scale</b>	The Short Form 36 Health Scale; a questionnaire intended to measure physical, mental, and social health.
<b>Silent Rupture</b>	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.
<b>Silicone</b>	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.
<b>Silicone Elastomer</b>	A type of silicone that has elastic properties similar to rubber.
<b>Silicones – Low Molecular Weight (LMW)</b>	Small silicone molecules that may be present in gel bleed/gel diffusion.
<b>Subcutaneous Placement</b>	When, after a mastectomy, the implant is placed under the skin but on top of the chest muscles. Also known as prepectoral placement.
<b>Subglandular Placement</b>	When the implant is placed under the breast glands (breast tissue), but on top of the chest muscles. This term is typically used in breast augmentation.
<b>Submuscular Placement</b>	When the implant is placed underneath the chest muscles.
<b>Surgical Incision</b>	A cut made to body tissue during surgery.
<b>Suspected or Confirmed Rupture</b>	The sum of all ruptures that were either suspected due to MRI imaging or actually confirmed as ruptured after explantation.
<b>Symmastia</b>	When the breast implants touch each other over the midline of the chest (where the cleavage area would normally be seen).
<b>Symptom</b>	Any perceptible change in the body or its functions that indicates disease or a phase of a disease.
<b>Symptomatic</b>	Experiencing symptoms; any evidence or sign of disease or disorder.

<b>Symptomatic Rupture</b>	A breast implant rupture that is associated with symptoms (such as lumps, persistent pain, swelling, hardening, or change in implant shape).
<b>Systemic</b>	Pertaining to or affecting the body as a whole.
<b>Tennessee Self-Concept Scale (TSCS)</b>	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.
<b>Tissue Expander</b>	An adjustable implant that can be inflated with salt water (saline) to stretch the tissue at the mastectomy site. This is used to create a new tissue flap that is large enough to cover the breast implant.
<b>Tissue Flap Reconstruction</b>	A surgical procedure used to reconstruct a breast using the patient's own tissue, taken from another part of the body. See also TRAM flap, TRAM flap reconstruction, Latissimus dorsi flap, and Latissimus dorsi flap reconstruction.
<b>Toxic Shock Syndrome (TSS)</b>	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.
<b>TRAM Flap</b>	The transverse rectus abdominus musculocutaneous (TRAM) flap. This section of muscle and tissue consists of the transverse rectus abdominus muscle, skin, fat, connective tissue, and vascular (blood vessels) tissue. It is taken from the abdomen (stomach area) and can be used to create a new breast for reconstruction purposes. A TRAM flap is also sometimes used to add breast tissue and skin to cover a breast implant during reconstruction.
<b>TRAM Flap Reconstruction</b>	Breast reconstruction using a patient's own tissue (a TRAM flap) from the abdomen to create the new breast or provide enough skin and breast tissue to cover a breast implant.
<b>Unilateral</b>	Affecting only one side of the body.
<b>Vascular Tissue</b>	Blood vessels (arteries and veins) that carry blood to the skin and tissues of the body and back to the heart.
<b>Warnings</b>	A statement that alerts the reader about a situation that, if not avoided, could result in serious injury or death.
<b>Wound Dehiscence (Wound Opening)</b>	Opening of a wound.
<b>Wrinkling/Rippling</b>	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 these MemoryGel™ Breast Implants and MemoryGel™ Xtra Breast Implants, has designed this educational brochure to help you understand breast reconstruction with implants and to help you talk with your doctor(s) about breast reconstruction. Mentor sponsored a large clinical study (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 8 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 to 2 weeks after reviewing and considering this information before deciding whether to have the surgery, unless an earlier surgery is deemed necessary by your surgeon. If you are having a mastectomy, it may make sense to start or perform the complete reconstruction at the same time you have the mastectomy; in this case, there may be time considerations your doctor can discuss with you. If you are having revision-reconstruction surgery, your surgeon may advise you to have the surgery sooner.

If you decide to have the surgery, you will be asked to sign a statement before the surgery. The statement says you have read and understood the information in this brochure and that you have been informed of the benefits and risks of breast implants. This statement is called the “Acknowledgment of Informed Decision,” and there is a copy of it at the end of this brochure. Make sure all of your questions have been answered and you understand the information in this brochure, before you sign the “Acknowledgment of Informed Decision.”

## **2. GENERAL INFORMATION ABOUT BREAST RECONSTRUCTION WITH BREAST IMPLANTS**

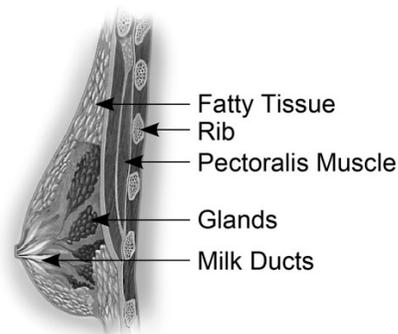
The information in this section provides some general information about breast reconstruction with breast implants.

### **2.1 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. 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.

Breast cancer surgery (full or partial mastectomy or lumpectomy) can greatly change the shape and appearance of your breast. When a woman has a mastectomy, some, much, or all of the breast tissue may be removed, and some skin may be removed as well. There will be scarring and the tissue (skin and breast tissue) may be more sensitive because of the surgery, or chemotherapy, and/or radiation treatments. All of these can affect the size, shape, and overall outcome of reconstruction with breast implants.

**Figure 1.**  
**Anatomy of the Breast**



## 2.2 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 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™ Breast Implants and MemoryGel™ Xtra Breast Implants can be found in Section 6.5 (*Choosing the Right Implant for You*).

## 2.3 How Do Breast Implants Work in Breast Reconstruction?

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 (sometimes called subcutaneous or prepectoral implant placement) or underneath part or all of the chest muscle (submuscular implant placement). Breast implants are also used in cosmetic augmentation to increase breast size, improve shape, and to restore symmetry. In this circumstance, the implants are placed either superficial to your pectoralis chest muscle (sometimes called subcutaneous or subglandular implant placement) or underneath part or all of the chest muscle (submuscular implant placement).

When breast implants are used to reconstruct a breast, the reconstruction may be done in several ways. Any reconstruction will likely take more than one surgery to complete and may be done in stages. These are discussed in Section 6.2.

## 3. DECIDING WHETHER TO HAVE BREAST RECONSTRUCTION SURGERY WITH IMPLANTS

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

### 3.1 Am I Eligible for Reconstruction with Silicone Gel Breast Implants?

Breast implants have been approved for use in reconstruction in these cases:

- **Primary reconstruction** to replace breast tissue that has been removed because of cancer or injury. Primary reconstruction is also used to replace breast tissue that has failed to develop properly because of a severe breast abnormality.
- **Revision-reconstruction** to correct or improve the result of primary reconstruction. Revision-reconstruction includes replacing an existing breast implant.

Women who do not fall into the above categories, but who desire cosmetic breast augmentation, may also use MENTOR® MemoryGel™ Breast Implants or MemoryGel™ Xtra Breast Implants. If you do not qualify for breast reconstruction and are interested in cosmetic breast augmentation, a different educational brochure that describes breast augmentation is available for you to read.

If you have lost or will lose breast tissue due to treatment for cancer or injury, other factors will affect whether or not breast implants are appropriate for you. These factors include your body type, the size and shape of your breast(s) before mastectomy, the amount of skin and breast tissue left after the mastectomy, the stage of your cancer, and follow-up treatments like chemotherapy or radiation that may affect the implant(s).

If you are considering reconstruction to correct a congenital anomaly or severe breast abnormality, the following factors may determine whether breast implants are appropriate for you: body type, size and shape of your breasts, whether your left and right breasts are sized, shaped, or located differently from each other, the amount of skin and breast tissue you have, and the size and placement of your chest muscles.

Your doctor can discuss whether or not you are a good candidate for reconstruction with implants given your medical situation.

### 3.2 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 reconstruction 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
- 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 reconstruction 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.

### 3.3 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.

### 3.4 Warnings

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 4 - *RISKS ASSOCIATED WITH BREAST IMPLANTS*, Section 7 - *CARING FOR YOURSELF AFTER BREAST IMPLANT SURGERY* and Section 8 - *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.
- Mammograms of a reconstructed breast are not usually performed. The following may apply to the contralateral breast:
  - 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. Because silent ruptures can occur and because they are difficult to detect, you should have an MRI 3 years after your breast implant surgery and then every 2 years after that for as long as you have your breast implants.
- 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.
- In general, private insurance that covers medically necessary mastectomies will also cover breast reconstructive surgery. Insurance coverage for reoperation procedures or additional surgeon’s visits following reconstruction may not be covered, depending on the policy. Because health insurance policies vary and can change over time, no general guidance can be provided regarding coverage under any particular health insurance plan. Be sure to check with your insurance company to obtain specific information about the extent of your health coverage before having breast reconstruction 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.

### **3.5 What Are the Alternatives to Implantation with Silicone Gel-Filled Breast Implants?**

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

- Deciding not to reconstruct your breast(s) with implants,
- Wearing a padded bra or external prosthesis,
- Having a breast reconstruction surgery using your own tissue (a “flap procedure”), or
- Having breast reconstruction with saline-filled implants,
- 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, or
- Having revision breast reconstruction with saline-filled implants,
- Having fat injection(s).

## **4. 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.

Tables 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-reconstruction patients.

**Table 1.  
Potential Risks Associated with Breast Reconstruction<sup>1</sup>**

Event		Likelihood of the Event Occurring Through 10 Years		Possible Resulting Effects of the Event
		Primary Reconstruction Patients N=251	Revision-Reconstruction Patients N=60	
<b>Key Complications</b>				
Any Reoperation		49 out of 100 patients (49%)	51 out of 100 patients (51%)	<ul style="list-style-type: none"> <li>• Infection</li> <li>• Scarring</li> <li>• Hematoma or Seroma</li> <li>• Delayed wound healing</li> <li>• Necrosis</li> <li>• Pain or Discomfort</li> <li>• Anesthesia-related complications</li> <li>• Loss of breast tissue</li> <li>• Undesirable cosmetic result</li> </ul>
Implant Removal with or without Replacement		33 out of 100 patients (33%)	38 out of 100 patients (38%)	<ul style="list-style-type: none"> <li>• Infection</li> <li>• Scarring</li> <li>• Hematoma or Seroma</li> <li>• Delayed wound healing</li> <li>• Necrosis</li> <li>• Pain or Discomfort</li> <li>• Anesthesia-related complications</li> <li>• Loss of breast tissue</li> <li>• Undesirable cosmetic result</li> </ul>
Capsular Contracture Baker Grade III/IV		20 out of 100 patients (20%)	37 out of 100 patients (37%)	<ul style="list-style-type: none"> <li>• Pain or discomfort</li> <li>• Breast hardness/firmness</li> <li>• Reoperation</li> <li>• Implant removal</li> </ul>
Rupture <sup>2</sup>	Initial MRI Cohort <sup>3</sup>	33 out of 100 patients (33%)	39 out of 100 patients (39%)	<ul style="list-style-type: none"> <li>• Implant removal</li> <li>• Silicone migration</li> <li>• Pain</li> <li>• Discomfort</li> <li>• Change in breast shape and size</li> </ul>
	Supplemental MRI Cohort <sup>3</sup>	36 out of 100 patients (36%)	44 out of 100 patients (44%)	
<b>Other Risks Occurring in 1% or more of Patients</b>				
Capsular Contracture Baker Grade III		18 out of 100 patients (18%)	33 out of 100 patients (33%)	<ul style="list-style-type: none"> <li>• Pain or discomfort</li> <li>• Breast hardness/firmness</li> <li>• Reoperation</li> <li>• Implant Removal</li> </ul>
Nipple Sensation Changes		1 out of 100 patients (1%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Increased or decreased nipple sensitivity</li> <li>• Breast-feeding difficulties</li> <li>• May affect sexual response</li> </ul>
Capsular Contracture Baker Grade IV		6 out of 100 patients (6%)	11 out of 100 patients (11%)	<ul style="list-style-type: none"> <li>• Pain or discomfort</li> <li>• Breast hardness/firmness</li> <li>• Reoperation</li> <li>• Implant removal</li> </ul>
Ptosis (sagging)		5 out of 100 patients (5%)	5 out of 100 patients (5%)	<ul style="list-style-type: none"> <li>• Undesirable cosmetic result</li> <li>• Wrinkling/Rippling</li> <li>• Reoperation</li> <li>• Implant removal</li> </ul>
Breast Pain		5 out of 100 patients (5%)	5 out of 100 patients (5%)	<ul style="list-style-type: none"> <li>• Resulting effects are contingent on underlying cause(s)</li> </ul>
Hypertrophic Scarring (irregular, raised scar)		3 out of 100 patients (3%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Scar revision procedure (reoperation)</li> <li>• Undesirable cosmetic result</li> </ul>
Capsular Contracture Baker Grade II with Surgical Intervention		4 out of 100 patients (4%)	2 out of 100 patients (2%)	<ul style="list-style-type: none"> <li>• Pain or discomfort</li> <li>• Breast hardness/firmness</li> <li>• Reoperation</li> <li>• Implant removal</li> </ul>

New Diagnosis of Rheumatic Disease	3 out of 100 patients (3%)	3 out of 100 patients (3%)	<ul style="list-style-type: none"> <li>• Pain or discomfort</li> </ul>
Asymmetry	9 out of 100 patients (9%)	13 out of 100 patients (13%)	<ul style="list-style-type: none"> <li>• Undesirable cosmetic result</li> <li>• Reoperation</li> <li>• Implant removal</li> </ul>
Hematoma	1 out of 100 patients (1%)	2 out of 100 patients (2%)	<ul style="list-style-type: none"> <li>• Swelling and bruising</li> <li>• Pain or discomfort</li> <li>• Infection</li> <li>• Incision and drainage (reoperation)</li> <li>• Implant removal</li> </ul>
Implant Malposition/ Displacement	2 out of 100 patients (2%)	7 out of 100 patients (7%)	<ul style="list-style-type: none"> <li>• Undesirable cosmetic result</li> <li>• Asymmetry</li> <li>• Visibility</li> <li>• Reoperation</li> <li>• Implant removal</li> </ul>
Infection	6 out of 100 patients (6%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Redness or rash</li> <li>• Pain or tenderness</li> <li>• Swelling</li> <li>• Fever</li> <li>• Reoperation</li> <li>• Implant removal</li> </ul>
New Diagnosis of Breast Cancer	<1 out of 100 patients (<1%)	4 out of 100 patients (4%)	<ul style="list-style-type: none"> <li>• Reoperation or other procedures</li> </ul>
Wrinkling	3 out of 100 patients (3%)	7 out of 100 patients (7%)	<ul style="list-style-type: none"> <li>• Discomfort</li> <li>• Undesirable cosmetic result</li> <li>• Reoperation</li> <li>• Implant removal</li> </ul>
Delayed Wound Healing	<1 out of 100 patients (<1%)	2 out of 100 patients (2%)	<ul style="list-style-type: none"> <li>• Pain or discomfort</li> <li>• Scarring</li> <li>• Implant extrusion</li> <li>• Necrosis</li> <li>• Reoperation</li> <li>• Implant removal</li> </ul>
Granuloma	0 out of 100 patients (0%)	2 out of 100 patients (2%)	<ul style="list-style-type: none"> <li>• Pain or discomfort</li> <li>• Reoperation or other procedures</li> </ul>
Extrusion	1 out of 100 patients (1%)	2 out of 100 patients (2%)	<ul style="list-style-type: none"> <li>• Pain or discomfort</li> <li>• Scarring</li> <li>• Reoperation</li> <li>• Implant removal</li> </ul>
Lymphadenopathy	1 out of 100 patients (1%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Pain or discomfort</li> <li>• Reoperation or other procedures</li> </ul>
Necrosis	1 out of 100 patients (1%)	0 out of 100 patients (0%)	<ul style="list-style-type: none"> <li>• Reoperation or other procedures</li> <li>• Implant removal</li> </ul>
Other complications <sup>4</sup>	29 out of 100 patients (29%)	28 out of 100 patients (28%)	<ul style="list-style-type: none"> <li>• Resulting effects are contingent on underlying cause(s)</li> </ul>

<sup>1</sup> Based on the results of the MENTOR® MemoryGel™ Core Study.

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

<sup>3</sup> 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.

<sup>4</sup> 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. This risk through 10 years was 67% for primary reconstruction patients and 74% for revision-reconstruction patients. This means that 67 out of 100 primary reconstruction patients and 74 out of 100 revision-reconstruction patients may experience a complication (of some kind) within 10 years after receiving implants. For additional information on how often Mentor has reported these events in its studies of the implants, please read the section of this brochure on the MemoryGel™ Core Study (Section 8).

#### **4.1 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,<sup>9</sup> 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 reconstruction or augmentation. 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 21% risk of experiencing Baker Grade III or IV capsular contracture for primary reconstruction patients through 10 years after receiving implants. For revision-reconstruction patients, the risk was 37% through 10 years. This means that 21 out of 100 primary reconstruction patients and 37 out of 100 revision-reconstruction 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**

<b>Cohort</b>	<b>2 Year</b>	<b>4 Year</b>	<b>6 Year</b>	<b>8 Year</b>	<b>10 Year</b>
Primary Reconstruction, N=251	7.0%	9.4%	13.7%	16.4%	20.5%
Revision-Reconstruction, N=60	11.9%	17.2%	20.9%	29.2%	36.9%

More details on capsular contracture results from the MemoryGel™ Core Study are found in Section 8.4.

**• 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.<sup>1,2</sup> 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.

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 workup 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) (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.<sup>3,4,5,6,7</sup> 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.<sup>3,6,8</sup> 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.<sup>7</sup>

Most doctors and researchers agree that there is NO evidence that ruptured implants or migrated gel causes any disease that affects the whole body (systemic disease) like Connective Tissue Disease (CTD) or cancer. However, one group of researchers<sup>4,5</sup> reported that women who had migrated silicone gel had a higher risk of getting a CTD. This is discussed more fully in Section 4.2.

Studies on breast implants that women have had for a long time suggest that gel bleed may play a role in capsular contracture.<sup>9</sup> 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**

<b>Initial MRI Cohort</b>		
	<b>Primary Reconstruction</b>	<b>Revision-Reconstruction</b>
<i>Suspected or Confirmed</i>		
By Patient:	32.7%	38.8%
By Implant:	24.3%	25.8%
<i>Confirmed</i>		
By Patient:	23.0%	17.7%
By Implant:	19.0%	12.3%
<b>Supplemental MRI Cohort</b>		
	<b>Primary Reconstruction</b>	<b>Revision-Reconstruction</b>
<i>Suspected or Confirmed</i>		
By Patient:	36.1%	43.9%
By Implant:	28.1%	44.4%
<i>Confirmed</i>		
By Patient:	27.7%	23.6%
By Implant:	21.3%	25.6%

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.<sup>1,77</sup> 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 MENTOR’S CLINICAL STUDY RESULTS, section 8 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.

MemoryGel™ Core Study reported a 49% risk of experiencing reoperation for primary reconstruction and 51% risk for revision-reconstruction patients through 10 years after receiving implants. This means that 49 out of 100 primary reconstruction patients and 51 out of 100 revision-reconstruction patients may experience reoperation within 10 years after receiving implants. For women receiving primary reconstruction implants, the most common reason for reoperation was asymmetry. For women receiving revision-reconstruction implants, the most common reason for additional surgery was capsular contracture Baker Grade III/IV. More details on reoperation from the MemoryGel™ Core Study are found in Section 8.5.

• **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 33% risk of implant removal (including removal with replacement for a size exchange) for primary reconstruction patients through 10 years after receiving implants. For revision-reconstruction patients, the risk was 38% through 10 years. This means that 33 out of 100 primary reconstruction patients and 38 out of 100 revision-reconstruction 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 8.6.

#### • 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

After contralateral augmentation or if the nipple is not removed as part of a mastectomy in the reconstructed breast, 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.)

#### • Aesthetic Changes

You may not be satisfied with the way your breasts look or feel after your surgery. Unsatisfactory results such as scarring or asymmetry, 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

If you have a mastectomy and all of your breast tissue is removed, you will not be able to breastfeed with that breast. If you have the opposite breast augmented as part of a reconstruction (contralateral augmentation), you should know that 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.<sup>9,10</sup> 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, "Breast feeding 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,<sup>11</sup> but no evidence that this poses a hazard to the infant beyond the loss of breast feeding itself. The evidence for the advantages of breast feeding to infant and mother is conclusive."<sup>9,12</sup> The MemoryGel™ Core Study collected information from patients who had babies after reconstruction with MemoryGel™ Breast Implants. Through 10 years, 8 primary reconstruction (non-mastectomy) patients attempted to breastfeed and 1 experienced difficulty. None of the revision-reconstruction patients attempted to breastfeed. Lactation experiences from the MemoryGel™ Core Study are also discussed in Section 8.7.

- **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.<sup>13</sup> 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 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 time frame, 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.

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 arm pit. 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.<sup>7</sup> These reports were in women who had implants from a variety of manufacturers and implant models.

## **4.2 What Are Other Reported Conditions?**

Some women with breast implants have reported health problems that they believe are related to their implants, although the connection between their implants and their health problems has not been proven. Examples of such health problems include autoimmune diseases or connective tissue disease, cancer, or neurological problems (problems with the brain or nerves).

Studies have not shown that breast implants can cause these conditions. Most studies suggest that there is no connection between breast implants and these medical conditions. However, you should be aware of them. 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 that include women with many different types, brands, and models of breast implants for augmentation and/or reconstruction.

The following potential long-term health effects of breast implants have been studied in relation to breast implants in general:

- **Cancer**

At this time, there is no scientific evidence that silicone gel breast implants increase the risk of any kind of cancer in women, but this possibility cannot be completely ruled out. Major research groups agree that silicone gel breast implants do not cause cancer.<sup>14,15,16,17</sup>

- **Breast Cancer**

Patients with breast implants do not seem to have greater risk of developing breast cancer.<sup>18,19,20,21,22,23,24,25,26,27,28</sup>

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.<sup>20,28,29,30,31</sup>

- **Brain Cancer**

Most studies of brain cancer in women with silicone gel breast implants have found no increased risk.<sup>19,21,23,26,27,28,32</sup>

One study reported a higher rate of brain cancer in women with breast implants, compared to the general population,<sup>29,33</sup> but, 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. Although most studies have found no increased risk of these cancers for women with silicone gel breast implants,<sup>19,21,23,26,27,28</sup> some reports have suggested a possible association between a type of anaplastic large cell lymphoma (ALCL) and breast implants.<sup>34</sup>

#### Anaplastic Large Cell Lymphoma

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, BIA-ALCL was diagnosed years after the breast implant was placed. The earliest report was 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.theptf.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/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm064106.htm>.

For additional information on FDA's analysis and review of BIA-ALCL, please visit:

<https://www.fda.gov/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl>.

#### • **Respiratory/Lung Cancer**

Several studies have found that women with silicone gel breast implants are not at greater risk for lung cancer.<sup>19,21,23,26,27,28</sup> One study found an increased risk of respiratory/lung cancer in women with breast implants<sup>29,33</sup> 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<sup>35,36,37</sup>; this may increase their risk for lung cancer. A recently published systematic review reported there is limited or suggestive evidence of an association between breast implants and lung cancer.<sup>76</sup>

#### • **Reproductive System Cancer**

Reproductive system cancers in women are cancers of the cervix, ovaries, uterus, vulva, vagina, and other female genital organs. Most studies<sup>19,21,23,26,27,28</sup> found that women with silicone gel breast implants have no greater risk of these cancers than women without implants. One study reported an increased incidence of cervical/vulvar cancer in women with breast implants.<sup>29,33</sup>

#### • **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.<sup>6,21,23,26,27,33,38</sup>

#### • **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. 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.<sup>4,5,9,38,39,40</sup>

Some scientific evidence supports the conclusion that there is no increased risk of CTDs or autoimmune disorders for women with silicone gel breast implants.<sup>4,5,9,38,41,42,43,44,45,46,47,48,49,50,51,52,53,54</sup> 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.<sup>9,55,56</sup> A published systematic review reported there is limited or suggestive evidence of an association between breast implants and rheumatoid arthritis.<sup>76</sup>

Some patients have reported resolution of symptoms when the implants are removed without replacement. Patients in the 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 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.<sup>57</sup>

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

Overall, there is no evidence that shows that silicone gel breast implants have any harmful effects on the children of implanted women.<sup>9,10,58,59,60</sup>

#### • 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.<sup>29,61,62,63,64,65,66,67</sup> One researcher<sup>68</sup> 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 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.<sup>61</sup> 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 found that there is not enough reliable evidence that neurological problems may be caused by or associated with breast implants.<sup>9</sup> Other researchers have found more evidence that silicone gel breast implants do NOT cause neurological diseases or symptoms.<sup>9,22,69</sup> There is one published report of an increased risk of multiple sclerosis among women with silicone gel breast implants<sup>44</sup>; 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.<sup>9,70</sup> 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<sup>9</sup>

and lymphadenopathy.<sup>7</sup> 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.<sup>71,72,73,74</sup>

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. The overall body of available evidence supports that the extremely low level of gel bleed is of no clinical consequence.

## **5. BENEFITS ASSOCIATED WITH BREAST IMPLANTS**

Women choose primary breast reconstruction surgery to replace breast tissue that has been removed because of cancer or injury, or to replace breast tissue that has failed to develop properly because of a severe breast abnormality. In addition, women choose revision-reconstruction surgery (replacement of an existing implant) to correct or improve the result of primary reconstruction 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.<sup>78</sup> In Mentor's MemoryGel™ Core Study, the results showed that most primary and revision- reconstruction patients experienced improved chest body image and were pleased with the results of their implant surgery, with 111 (99%) of the 112 primary reconstruction and 34 (94%) of the 36 revision-reconstruction patients who answered the patient satisfaction question at the 10-year follow-up visit indicating they would have the breast implant surgery again.

For more information on the benefits of breast reconstruction with Mentor's MemoryGel™ Breast Implants based on the results of the MemoryGel™ Core Study, refer to Section 8.3 of this brochure.

## **6. PREPARING FOR BREAST RECONSTRUCTION WITH SILICONE GEL BREAST IMPLANTS**

Deciding to have breast reconstruction 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 (for example, a general surgeon and/or oncologist). 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.

### **6.1 Should I Have Breast Reconstruction?**

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

Whether breast reconstruction is right for you depends on many things, some of them are 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 reconstruction surgery with your doctors. You may also wish to consult your family and friends, breast implant support groups and breast cancer support groups to help you learn about the options and decide.

Many women who choose implants as part of their reconstruction say their reconstructed 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.

You should know that there are alternatives to primary breast reconstruction with silicone gel implants. For example, a breast can also be reconstructed using your own tissue and skin taken from another part of your body (a "tissue flap") or a combination of tissue and implant(s) can be used. Other alternatives are discussed in Section 3.5.

### **6.2 Breast Reconstruction with Implants – Understanding the Procedure**

The surgical procedure for breast reconstruction with implants consists of choices you and your surgical team (surgeon(s), nurses, anesthetist, etc.) will make as you plan your surgery. If you are continuing treatment for cancer (like chemotherapy or radiation), your surgeon(s) should consult with your oncologist. For breast reconstruction, 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 reconstruction. The outcome of a mastectomy will affect the amount of breast tissue left to cover a breast implant.

## Breast Reconstruction with Implants – Staging the Procedures

Breast reconstruction is usually done in stages. It often takes more than one surgery. A primary (first) reconstruction after mastectomy is often started during the same surgery as your mastectomy, but you may need follow-up surgeries to finish and make the reconstructed breast match the other breast. The stages may include:

- Putting in a soft tissue expander, an implanted silicone shell that can be filled with more and more saline solution to slowly stretch your skin enough to allow it to cover an implant (more information is provided below),
- Taking out the tissue expander and putting in a breast implant (silicone gel or saline-filled),
- Surgery to adjust the shape and/or size of the opposite breast so it matches the reconstructed breast, and
- Nipple reconstruction (if you have a mastectomy, the nipple is usually removed; usually a new nipple is created later, as an outpatient procedure after the initial reconstruction surgery is finished; a nipple may be created using skin taken from the opposite breast or another part of your body).

### Use of Tissue Expander(s) in Breast Reconstruction Surgery

Placing a tissue expander may be one step in your breast reconstruction. If you are having a mastectomy, the surgeon will remove breast tissue and also some skin. Afterwards, your chest will be flatter and tighter. For many women (especially if you had small-to-medium-sized breasts before your mastectomy), there will not be enough skin and tissue to cover a breast implant comfortably; the breast “pocket” (space for an implant) will be too small.

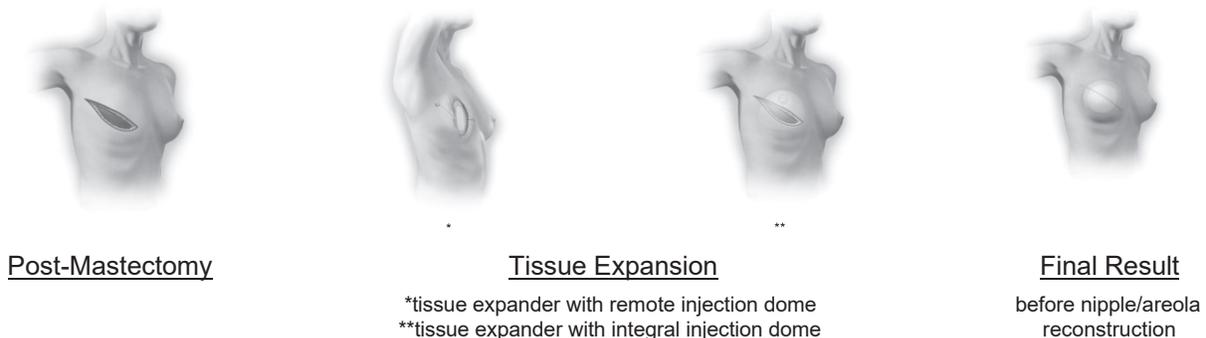
Placing an implant in a breast pocket that is too small can cause complications such as drooping or sagging at an earlier age, implant extrusion, skin wrinkling, infection, and hematoma. You may also be able to feel folds on the implant created by the implant being squeezed tightly by the surrounding skin and other breast-area tissue.

Tissue expanders (also called soft-tissue expanders) are devices that are used when there is not enough skin or breast tissue to cover an implant. They are made of a silicone elastomer (stretchy, rubbery silicone) shell like a breast implant but are empty of filler when they are put in your breast. The tissue expander has a port (valve) that will lie under your skin after it is placed. Your surgeon can then gradually fill the tissue expander with sterile saline solution (saltwater) over several weeks or months by injecting the saline into the device through the port under your skin. As the device expands, it will cause your breast skin and tissues to stretch like a woman’s abdomen stretches during pregnancy. Eventually, the skin and breast tissue are stretched enough to create a space for your breast implant, as shown in Figure 2 below.

A tissue expander can be placed at the time of your mastectomy or months or years later. Your reconstruction surgeon can tell you whether tissue expansion may be necessary in your case.

The tissue expander is placed surgically, usually in an operating room under general anesthesia. You may be able to go home the same day or may stay overnight at the hospital. Most women can go back to their usual activities within 2 to 3 weeks after the expander is placed. If you have a tissue expander placed during the same surgery as your mastectomy, the breast tissues are usually numb from the mastectomy; you may not feel pain after the tissue expander surgery. You will probably feel tightness, pressure, or discomfort each time the tissue expander is filled with saline. This can last a week or more, but goes away as the skin and tissues stretch. Tissue expansion may take up to 4 to 6 months.

**Figure 2.**  
**Breast Reconstruction Using a Tissue Expander and Breast Implant**



### 6.3 Breast Reconstruction without Implants (Tissue Flap Reconstruction)

A tissue flap is skin, fat, and/or muscle taken from another part of your body, like your stomach, back, hip, or bottom. Three kinds of flaps are usually used for breast reconstruction surgeries: a flap that includes muscles from your stomach (called a “TRAM flap”), a flap that does not include muscle from your stomach (called a “DIEP flap”), or a flap from your back (called a “latissimus dorsi flap”). In each case, the flap is moved to the chest where it is shaped into a new breast. In some cases, a tissue flap is used just to provide more skin or tissue, for example, to cover an implant.

Breast reconstruction using only your own tissue flap is major surgery and you will likely have a longer recovery time than for breast reconstruction using just a breast implant. Some women who have a tissue flap reconstruction return to their normal activities after a few weeks. Others may take up to a full year to get back to their normal lifestyle.

An advantage of breast reconstruction using a tissue flap may be that usually no other procedures are needed to make the opposite (unaffected) breast match the reconstructed breast.

#### TRAM Flap

The TRAM flap (the transverse rectus abdominus musculocutaneous flap) is named for the section of the abdomen from which the tissue flap is taken – that consists of the transverse rectus abdominus muscle and some tissue (skin, fat, connective tissue, and vascular [blood vessels] tissue) surrounding it. As shown in Figure 3 below, during a TRAM flap procedure your doctor will take the TRAM flap from your abdomen and move it to your breast to replace the breast tissue that was lost during your cancer surgery.

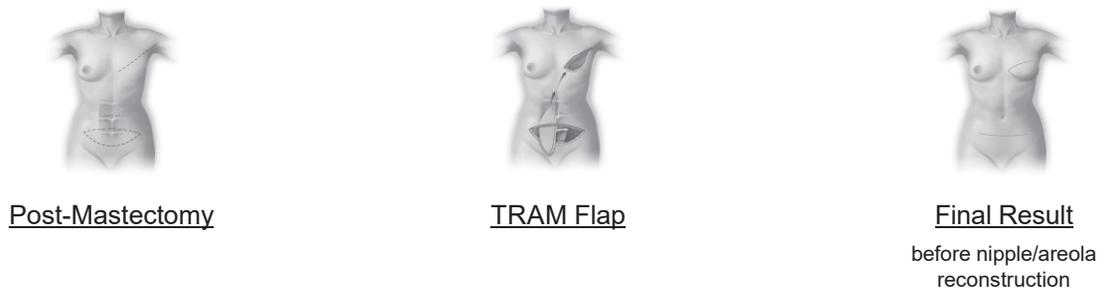
The TRAM flap procedure is done in the hospital under general anesthesia. Your hospital stay may range from 2 to 5 days. The recovery time may be 6 to 8 weeks. You will have two incision sites (on your abdomen and on your breast) resulting in two wounds to heal after surgery and, therefore, two scars. Both TRAM flap methods can cause temporary or permanent muscle weakness in your tummy (because the muscles there have been cut).

If you are considering becoming pregnant after your reconstruction, discuss this with your doctors before surgery. You will have a large scar on your abdomen and scarring on your reconstructed breast(s) that may be affected as your skin stretches to accommodate a growing baby.

The TRAM flap procedure can be done two ways. In one method, the tissue flap is removed from your abdomen but the blood vessels are not cut. The TRAM flap is then moved through a tunnel made under your skin up to the breast area where it is sutured into place to create the new breast. This is called a “pedicle” TRAM flap procedure. It usually takes 3 to 6 hours in surgery to complete.

The other possibility is a “free” TRAM flap. In this case, the tissue is taken from your abdomen and the blood supply is cut. The flap is taken off completely from your tummy and then relocated and sutured in place to create the new breast. The doctor must reconnect blood vessels at the breast site. This is a very involved procedure: Your surgeon will need to use a microscope to do it and it usually takes longer than a pedicle TRAM flap procedure. Your surgical team may ask a surgeon who specializes in surgery using a microscope to reconnect blood vessels to do that part of your procedure (a vascular surgeon). You may need to have a blood transfusion during or after a free TRAM flap procedure.

**Figure 3.**  
**Breast Reconstruction Using a TRAM Flap**

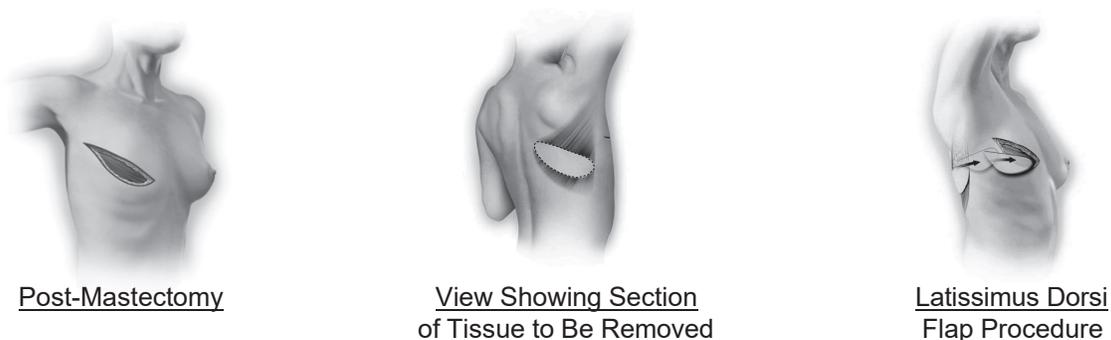


#### Latissimus Dorsi Flap

Breast reconstruction using a latissimus dorsi flap is illustrated in Figure 4 below. During a latissimus dorsi flap reconstruction, a section of tissue (skin, fat, connective tissue, and vascular [blood vessels] tissue) is taken from

your back. A latissimus dorsi flap is usually smaller than a TRAM flap, so this procedure may be better for a woman with smaller breasts. The latissimus dorsi flap procedure usually takes 2 to 4 hours of surgery. It is done in a hospital under general anesthesia. Most patients can resume their normal activities after 2 to 3 weeks.

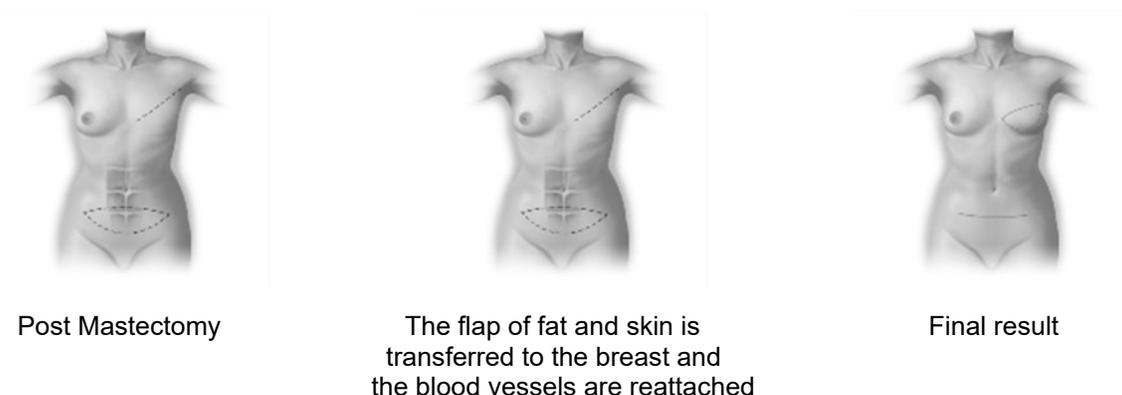
**Figure 4.**  
**Breast Reconstruction Using a Latissimus Dorsi Flap**



### DIEP Flap

The DIEP flap (the deep interior epigastric artery perforator flap) is named for the blood vessels in the abdomen that are harvested with the tissue that is being transferred. As shown in Figure 5 below, during a DIEP flap procedure, the surgeon removes a section of fat, skin and blood vessels (without muscle) from the abdomen and moves it to the chest and reattaches the blood vessels to reconstruct the breast. A DIEP flap procedure typically takes six to eight hours of surgery under general anesthesia. The DIEP procedure may require a blood transfusion. You should obtain details, such as procedure details, expectations, risks and benefits, length of hospital stay and recovery time from your surgeon about the DIEP procedure you are considering. The DIEP flap procedure results in a large scar on the abdomen as well as additional scars on the reconstructed breast. As compared with the TRAM flap, the DIEP flap minimizes the risk of hernia, as muscle is not removed in the DIEP flap procedure.

**Figure 5.**  
**Breast Reconstruction Using a DIEP Flap**



### Complications Associated with Flap Reconstruction

Flap reconstruction is major surgery, especially TRAM flap reconstruction. It is more involved than a mastectomy and more involved than reconstruction with implants. Patients who choose this method of reconstruction should be in good general health and have strong emotional motivation. If you are very overweight, smoke cigarettes, have had other surgeries at the flap site, or have circulatory problems (problems with your heart or blood vessels), you may not be a good candidate for tissue flap reconstruction. If you are very thin, you may not be able to have tissue flap reconstruction because there may not be enough extra tissue on your abdomen or back to form a new breast. Complications of flap reconstruction procedures may include:

- Temporary or permanent muscle weakness in your abdominal muscles for TRAM flap and in your back or side for latissimus dorsi flap
- Distorted navel (belly button) and/or the need for the doctor to build a new belly button after the TRAM procedure
- Loss of feeling in the abdomen and/or reconstructed breast. You will probably not have normal sensation in that breast because nerves are cut during the surgery.
- A blood transfusion is sometimes necessary after a free TRAM flap procedure.

#### **6.4 Choosing Breast Reconstruction with Breast Implants**

Your doctor(s) can tell you whether you are a good candidate for breast reconstruction with implants, given your health and medical condition. Your surgeon may recommend some other procedures for the opposite (nonimplanted) breast to make your breasts look more symmetrical after reconstruction. The other procedures may include:

- Having an implant in the other breast (contralateral augmentation mammoplasty),
- Having the other breast made smaller (contralateral reduction mammoplasty) by surgically removing breast tissue and skin, or
- Having a surgery to lift one or both breasts (mastopexy) so they are at the same level on your chest. This is done by surgically removing a strip of skin from under your breast or around your nipple to lift and tighten the skin.

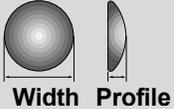
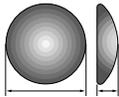
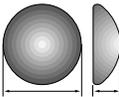
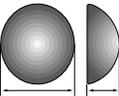
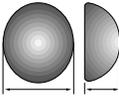
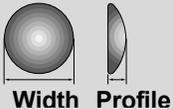
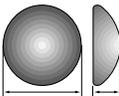
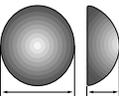
If you do not want to change your unaffected breast, discuss this with your surgeon well before the surgery so he or she can plan the procedure to give you the best result.

#### **6.5 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. If you are having one breast reconstructed, but the other one is not affected, you and your doctor can choose the implant that will most closely match your unaffected breast.

Table 4 lists the styles of MemoryGel™ Breast Implants and MemoryGel™ Xtra Breast Implants that are available.

**Table 4.  
MemoryGel™ and MemoryGel™ Xtra Breast Implant Styles**

 Width Profile	<b>MemoryGel™ Breast Implant Description Size Range</b>
	<b>Moderate Profile</b> smooth and textured shell surface 100-800 cc  <b>Moderate Classic Profile</b> smooth and textured shell surface 130–800 cc
	<b>Moderate Plus Profile</b> smooth and textured shell surface 100-800 cc
	<b>High Profile</b> smooth and textured shell surface 125-800 cc
	<b>Ultra High Profile</b> smooth shell surface 135-800 cc textured shell surface 135-700 cc
 Width Profile	<b>MemoryGel™ Xtra Breast Implant Description Size Range</b>
	<b>Moderate Plus Profile Xtra</b> smooth shell surface 115-755 cc textured shell surface 115-755 cc
	<b>High Profile Xtra</b> smooth shell surface 150-790 cc textured shell surface 150-765 cc

When you and your doctor decide what you want your breasts to look like after reconstruction, 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. This is especially important after mastectomy. 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. For example, 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.

## 6.6 Surgical Setting and Anesthesia

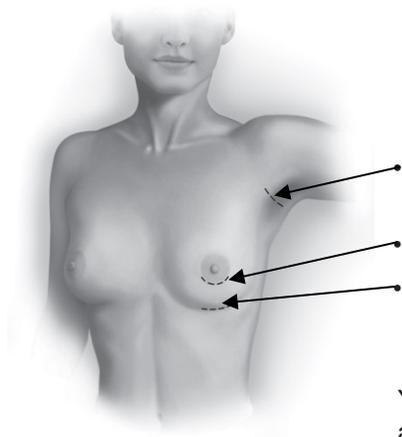
Primary reconstruction surgery is usually performed in a hospital under general anesthesia. If you are having a mastectomy, the reconstruction will often be started at the same time. You will probably stay in the hospital for one or more nights after your surgery (inpatient surgery).

Some stages of the reconstruction may be performed later in a different setting. For example, you may be able to have nipple reconstruction or placement of an implant (after having had a soft-tissue expander) as an outpatient. All anesthetics carry some risk. Discuss the risks and benefits of the anesthetic your surgeon and anesthesiologist recommend for you before the surgery.

## 6.7 Incision Sites

If you decide to have breast reconstruction with implants after a mastectomy, your doctor will choose the incision sites based on the type of mastectomy surgery that is planned for you. The extent of the mastectomy you need will determine the length and location of the incisions. In most cases, the breast reconstruction will start at the time of the mastectomy procedure, so the surgeon will use the same incision. Even if you have a breast reconstruction that starts after you have had a mastectomy, the incision can usually be made at the mastectomy scar so you won't have another scar.

Sometimes, a doctor will recommend placing an implant in the opposite breast after a unilateral (one breast only) mastectomy and reconstruction to create better symmetry. If you have an unaffected breast implanted to match a reconstructed breast, you may be able to choose the incision site. The three incision sites shown in Figure 6 are the incision sites usually used for breast contralateral augmentation surgery.



**Figure 6.**  
**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 the MemoryGel™ Core Study and should not be used. It may cause damage to the implant shell.

Your surgeon can explain which incision site he or she recommends for you and talk about the pros and cons of each with you.

## 6.8 Implant Placement

Breast implants are placed beneath your breast tissue, either on top of the chest muscle (sometimes called subcutaneous, prepectoral, or subglandular placement) or underneath part or all of the chest muscle (submuscular placement). If you are having reconstruction after breast cancer surgery, your doctor will tell you which placement is likely to work best given the amount of skin and tissue left after the mastectomy. For breast reconstruction after a mastectomy, the implant is usually placed submuscularly.

## 6.9 Timing of Breast Reconstruction Surgery

This discussion applies to reconstruction following breast cancer surgery such as mastectomy. Similar considerations apply to reconstruction surgery following trauma or to correct a congenital anomaly.

Breast reconstruction with or without implants can be done at the time of a mastectomy surgery (immediate reconstruction) or months to years after (delayed reconstruction). There are medical, financial, and emotional factors to consider when choosing when to have breast reconstruction. There may be reasons your doctor would advise you to begin breast reconstruction at the time of your mastectomy, but these reasons may not always

outweigh your need to carefully consider your options and think about whether reconstruction with breast implants is right for you. Give yourself enough time to consider your decision and gather information to help you decide.

Immediate reconstruction starts during the same surgery as your mastectomy. After the cancerous tissues and some skin are removed, a breast implant may be inserted. More often, a soft tissue expander (a silicone shell that can be inflated with saline solution over time) is placed and your incision closed with stitches. The tissue expander is inflated with sterile saline solution over a period of weeks or months. This allows your skin to grow and stretch so there will be enough skin to cover the breast implant, which is placed during a later surgery. Most breast reconstructions take several steps to finish.

Immediate reconstruction may allow you to spend fewer days in the hospital overall and save money by combining your mastectomy and the first stage of reconstruction. However, if you need to have chemotherapy or radiation after your mastectomy, these may damage the implant or increase your risk of capsular contracture, implant extrusion (the implant comes through the skin), and/or necrosis.

Table 5 compares the pros and cons of immediate and delayed breast reconstruction.

**Table 5.**  
**Comparison of Immediate and Delayed Breast Reconstruction with Implants – Pros and Cons of Each**

Timing	Pros	Cons
Immediate	<ul style="list-style-type: none"> <li>• Mastectomy and first stage of reconstruction accomplished with one surgery</li> <li>• Uses one incision</li> <li>• Typically fewer hospital days overall</li> <li>• Costs may be lower</li> </ul>	<ul style="list-style-type: none"> <li>• If follow-up chemotherapy or radiation is needed, may increase risk of complications (capsular contracture, implant extrusion, necrosis)</li> <li>• Initial operative time may be longer</li> <li>• Initial recovery time may be longer</li> </ul>
Delayed	<ul style="list-style-type: none"> <li>• Gives you plenty of time to decide if reconstruction with implants is right for you</li> <li>• Allows chemotherapy/radiation to be completed before implants are present (less of an increased risk of capsular contracture, implant extrusion, or necrosis due to chemotherapy or radiation)</li> </ul>	<ul style="list-style-type: none"> <li>• Adds at least one additional surgery</li> <li>• May mean an additional scar</li> <li>• Costs may be higher</li> </ul>

Discuss these factors with your surgeon(s) and your oncologist so they may help you understand the “pros” and “cons” in your specific case.

### 6.10 Other Procedures at the Time of the Breast Reconstruction

Your surgeon may recommend having other aesthetic 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 breast fed, you may have sagging, stretched, or extra skin that is not completely filled out by breast tissue. Or, after mastectomy, your reconstructed breast may be firmer and higher than your opposite breast. In these cases, your surgeon may recommend doing a breast lift (mastopexy) to remove excess skin from the rest of the breast tissue in one or both breasts. Sometimes mastopexy is recommended in the unaffected breast to create better symmetry after reconstruction.

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 reconstruction 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 with you.

### 6.11 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 reconstruction surgeries does he or she perform each year?
- How many years has he or she been doing breast reconstruction surgeries?
- What is the most common complication he or she encounters with breast reconstruction patients?
- What is his or her reoperation rate for reconstruction patients? And what is the most common type of reoperation that he or she performs (after completing the initial reconstruction with implants) 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 reconstruction in their own surgery centers. Hospitals require surgeons to prove that they are properly trained before they can operate in the hospital.)

## **7. 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 (especially if you are having surgery for cancer). 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.

### **7.1 Postoperative Care in the Hours and Days After Surgery**

The first few hours after your initial reconstruction 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 wound(s) and support your breasts. Your surgeon will tell you how long to keep your breast(s) 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.

### **7.2 Postoperative Care in the First Weeks After Surgery**

In the weeks after your reconstruction, the skin over your breasts may feel tight as it adjusts to your new breast size. This may be true even if you had tissue expansion first, with a soft tissue expander. 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.

### **7.3 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**

Mammograms of a reconstructed breast are not usually performed. The following may apply to the contralateral breast:

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 want to 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 Device Identification 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 Device Identification 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.

### **7.4 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.<sup>75</sup>

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 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.

MRI examination (taking pictures of your implants with a device similar to an x-ray machine) is the best way to tell if a silent rupture has happened. For this reason, it is strongly recommended that you have an MRI the third year after your surgery and then every 2 years after that for as long as you have your breast implants.

#### **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.

## **8. MENTOR'S CLINICAL STUDY RESULTS**

As part of the marketing approval requirements for the MemoryGel™ Breast Implant, 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 Implant, 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.

### **8.1 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 Short Form Health Survey (SF-36), the Tennessee Self-Concept Scale (TSCS), and the Functional Living Index of Cancer (cancer patients only).

The MemoryGel™ Core Study followed patients through 10 years after their breast implant surgery.

The following sections provide more information about the complications and benefits you may experience following reconstruction with MENTOR® MemoryGel™ Breast Implants, based on the experiences of the reconstruction patients in the MemoryGel™ Core Study. 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](https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm).

## **8.2 What Were the 10-Year Follow-Up Rates?**

The study enrolled 251 primary reconstruction patients and 60 revision-reconstruction patients. At the 10-year follow-up visit, data are reported for 73% of the eligible primary reconstruction patients and 67% of the eligible revision-reconstruction patients.

## **8.3 What Were the Benefits?**

The benefits of MemoryGel™ Breast Implants were examined by measuring the change in 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, and 6 years after their surgery).

### **Primary Reconstruction Patients**

Most primary reconstruction patients were pleased with the results of their implant surgery though 10 years. Eighty-six of the 251 patients enrolled were included in the circumferential chest size analysis. The average increase in circumferential chest size was 1.9 inches (4.9 centimeters). In regards to overall satisfaction, 111 (99%) of the 112 primary reconstruction 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 reconstruction patients showed no significant treatment effects in the Mental and Physical Component Scores of the SF-36, the total score and positive attitude score of the Rosenberg Self Esteem Scale, or in the total score of the TSCS. For the Body Esteem Scale, there was no significant treatment effect in the total score or sexual attractiveness score, but there was a significant, positive treatment effect in the chest scale score.

### **Revision-Reconstruction Patients**

Most revision-reconstruction patients were pleased with the results of their additional implant surgery through 10 years. Twenty-nine of the 60 patients enrolled were included in the circumferential chest size analysis. The average increase in circumferential chest size was 1.6 inches (4.2 centimeters). In regards to overall satisfaction, 34 (94%) of the 36 revision-reconstruction 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-reconstruction patients showed significant, negative treatment effects in the Mental and Physical Component Scores of the SF-36. There was no significant treatment effect observed in the total score or positive attitude score of the Rosenberg Self-Esteem Scale. For the Body Esteem Scale, there was a significant, negative treatment effect in the total score and a significant, positive treatment effect for the chest scale score. There was a significant, negative treatment effect in the total score of the TSCS, suggesting a lessening in self-concept as measured by this assessment. For the Functional Living Index of Cancer, there were significant, positive treatment effects for delayed post-mastectomy patients and revision patients with a history of cancer and having at least one reconstruction-revision.

## 8.4 What Were the 10-Year Complication Rates?

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

### Primary Reconstruction

The complications observed in women who had primary reconstruction through 10 years are presented in Table 6. The most common reported complication within the first 10 years after primary reconstruction surgery was reoperation (49% or approximately 49 out of 100).

**Table 6.**  
**Complication Rates for Primary Reconstruction Patients, N=251 Patients**

Key Complications <sup>1</sup>	%		
	through 3 years	through 6 years	through 10 years
Any Reoperation	28.7	35.5	49.0
Implant Removal with or without Replacement	13.0	18.6	33.4
Rupture <sup>2</sup>	Initial MRI Cohort <sup>3</sup>	0.8	6.9
	Supplemental MRI Cohort <sup>3</sup>	N/A	16.1
Capsular Contracture Baker Grade III, IV	8.4	13.7	20.5
Infection	5.3	5.8	5.8
<b>Other Complications ≥ 1% at 10 years</b>			
Other Complications <sup>4</sup>	14.9	22.6	29.3
Capsular Contracture Baker Grade III	7.1	12.0	17.7
Asymmetry	6.2	7.2	9.5
Capsular Contracture Baker Grade IV	1.3	2.3	6.1
Breast Pain	3.4	3.4	5.2
Ptosis (sagging)	1.8	2.3	4.8
Capsular Contracture Baker Grade II with Surgical Intervention	3.0	3.0	4.2
Wrinkling	2.5	3.5	3.5
Hypertrophic Scarring (irregular, raised scar)	2.9	2.9	2.9
New Diagnosis of Rheumatic Disease	0.4	0.9	2.7
Implant Malposition/Displacement	1.7	1.7	2.3
Extrusion	1.2	1.2	1.2
Lymphadenopathy	0.0	0.5	1.1

<sup>1</sup> 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.

<sup>2</sup> These estimated rates were determined through use of Kaplan-Meier methodology, which attempts to take loss of patients to follow-up 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 43/251 (17.1%) for the primary reconstruction cohort.

<sup>3</sup> 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.

<sup>4</sup> 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-Reconstruction

The complications observed in women who had revision-reconstruction through 10 years are presented in Table 7. The most common reported complication within the first 10 years after revision-reconstruction surgery was reoperation (51% or approximately 51 out of 100).

**Table 7.**  
**Complication Rates for Revision-Reconstruction Patients, N=60 Patients**

Key Complications <sup>1</sup>	%		
	through 3 years	through 6 years	through 10 years
Any Reoperation	28.3	35.0	50.7
Rupture <sup>2</sup>	Initial MRI Cohort <sup>3</sup>	0.0	4.6
	Supplemental MRI Cohort <sup>3</sup>	N/A	5.6
Implant Removal with or without Replacement	13.3	23.4	37.8
Capsular Contracture Baker Grade III, IV	15.4	20.9	36.9
Infection	0.0	0.0	0.0
<b>Other Complications ≥ 1% at 10 years</b>			
Capsular Contracture Baker Grade III	15.4	19.0	32.8
Other Complications <sup>4</sup>	16.8	20.7	27.8
Asymmetry	6.9	12.7	12.7
Capsular Contracture Baker Grade IV	1.8	3.8	10.7
Wrinkling	5.1	7.0	7.0
Implant Malposition/Displacement	6.7	6.7	6.7
Ptosis (sagging)	3.3	3.3	5.5
Breast Pain	5.2	5.2	5.2
New Diagnosis of Breast Cancer	1.7	1.7	3.9
New Diagnosis of Rheumatic Disease	3.4	3.4	3.4
Capsular Contracture Baker Grade II with Surgical Intervention	1.8	1.8	1.8
Delayed Wound Healing	1.7	1.7	1.7
Granuloma	1.7	1.7	1.7
Extrusion	1.7	1.7	1.7
Hematoma	1.7	1.7	1.7

<sup>1</sup> 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.

<sup>2</sup> These estimated rates were determined through use of Kaplan-Meier methodology, which attempts to take loss of patients to follow-up 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 12/60 (20%) for the revision-reconstruction cohort.

<sup>3</sup> 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.

<sup>4</sup> 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 physician 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.

### **8.5 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 often require more than one surgical procedure to complete their reconstruction. This is called “staged” reconstruction and procedures that represent a particular stage in the reconstruction, such as skin or nipple-related procedures, may also be considered reoperations.

## Primary Reconstruction

In Mentor's MemoryGel™ Breast Implant Core Study, there were 157 reoperations performed in 115 patients. The risk of experiencing at least one reoperation for primary reconstruction patients was 49% (approximately 49 out of 100 patients) through 10 years. Table 8 provides the main reasons for reoperation. The most common reason for reoperation in these patients was asymmetry.

**Table 8.**  
**Main Reasons for Reoperation in Primary Reconstruction Patients**

Primary Reason for Reoperation	N=157 Reoperations <sup>1</sup> n (%)		
	through 3 years	through 6 years	through 10 years
Asymmetry	20 (23.0)	23 (19.5)	26 (16.6)
Rupture	0 (0.0)	3 (2.5)	20 (12.7)
Capsular Contracture Baker Grade III/IV	7 (8.0)	13 (11.0)	18 (11.5)
Breast Mass	10 (11.5)	16 (13.6)	17 (10.8)
Size Change	8 (9.2)	9 (7.6)	11 (7.0)
Implant Malposition/Displacement	9 (10.3)	9 (7.6)	9 (5.7)
Ptosis (sagging)	2 (2.3)	3 (2.5)	6 (3.8)
Capsular Contracture Baker Grade II	2 (2.3)	3 (2.5)	4 (2.5)
Infection	4 (4.6)	4 (3.4)	4 (2.5)
Extrusion	3 (3.4)	3 (2.5)	3 (1.9)
Lymphadenopathy	0 (0.0)	2 (1.7)	3 (1.9)
Metastatic Disease	3 (3.4)	3 (2.5)	3 (1.9)
Seroma	1 (1.1)	1 (0.8)	2 (1.3)
Breast Pain	1 (1.1)	2 (1.7)	2 (1.3)
Delayed Wound Healing	2 (2.3)	2 (1.7)	2 (1.3)
Hypertrophic Scarring (irregular, raised scar)	1 (1.1)	2 (1.7)	2 (1.3)
Wrinkling	1 (1.1)	2 (1.7)	2 (1.3)
Lack of Projection	1 (1.1)	2 (1.7)	2 (1.3)
Skin Lesion	1 (1.1)	1 (0.8)	2 (1.3)
Suspected Rupture, No Rupture Found	0 (0.0)	2 (1.7)	2 (1.3)
Suture Complication	2 (2.3)	2 (1.7)	2 (1.3)
Wide Scar	2 (2.3)	2 (1.7)	2 (1.3)
Hematoma	1 (1.1)	1 (0.8)	1 (0.6)
Necrosis	1 (1.1)	1 (0.8)	1 (0.6)
Bulging Superiorly	0 (0.0)	1 (0.8)	1 (0.6)
Dysplastic Nevus on Areolar Complex	0 (0.0)	0 (0.0)	1 (0.6)
Extra skin	1 (1.1)	1 (0.8)	1 (0.6)
Implant Removal – Patient Request	0 (0.0)	0 (0.0)	1 (0.6)
Breast Cancer	0 (0.0)	1 (0.8)	1 (0.6)
Mass/Cyst	0 (0.0)	0 (0.0)	1 (0.6)
Muscle Spasm	1 (1.1)	1 (0.8)	1 (0.6)
Patient Dissatisfied with Appearance	1 (1.1)	1 (0.8)	1 (0.6)
Recurrent Breast Cancer	1 (1.1)	1 (0.8)	1 (0.6)
Shape Change	0 (0.0)	0 (0.0)	1 (0.6)
Suspected New Cancer	1 (1.1)	1 (0.8)	1 (0.6)

<sup>1</sup> All reoperations were counted, with the primary reason for each reoperation presented.

## Revision-Reconstruction

In Mentor's MemoryGel™ Breast Implant Core Study, there were 47 reoperations performed in 30 revision-reconstruction patients. The risk of experiencing at least one reoperation for revision-reconstruction patients was 74% (approximately 74 out of 100 patients) through 10 years. Table 9 provides the main reasons for reoperation. The most common reason for reoperation was capsular contracture Baker Grade III/IV..

**Table 9.**  
**Main Reasons for Reoperation in Revision-Reconstruction Patients**

Primary Reason for Reoperation	N=47 Reoperations <sup>1</sup> n (%)		
	through 3 years	through 6 years	through 10 years
Capsular Contracture Baker Grade III/IV	3 (12.0)	5 (14.3)	10 (21.3)
Breast Mass	3 (12.0)	6 (17.1)	6 (12.8)
Rupture	0 (0.0)	0 (0.0)	3 ( 6.4)
Skin Lesion	3 (12.0)	3 (8.6)	3 ( 6.4)
Asymmetry	1 (4.0)	2 (5.7)	2 ( 4.3)
Ptosis (sagging)	1 (4.0)	2 (5.7)	2 ( 4.3)
Breast Cancer	2 (8.0)	2 (5.7)	2 ( 4.3)
Size Change	0 (0.0)	1 (2.9)	2 ( 4.3)
Breast Pain	0 (0.0)	1 (2.9)	1 ( 2.1)
Capsular Contracture Baker Grade II	1 (4.0)	1 (2.9)	1 ( 2.1)
Delayed Wound Healing	0 (0.0)	0 (0.0)	1 ( 2.1)
Extrusion	1 (4.0)	1 (2.9)	1 ( 2.1)
Hematoma	1 (4.0)	1 (2.9)	1 ( 2.1)
Wrinkling	1 (4.0)	1 (2.9)	1 ( 2.1)
Calcification	1 (4.0)	1 (2.9)	1 ( 2.1)
Capsular Tear	1 (4.0)	1 (2.9)	1 ( 2.1)
Lack of Projection	1 (4.0)	1 (2.9)	1 ( 2.1)
Mass/Cyst	1 (4.0)	1 (2.9)	1 ( 2.1)
Mastectomy Scars	0 (0.0)	0 (0.0)	1 ( 2.1)
Metastatic Disease	1 (4.0)	1 (2.9)	1 ( 2.1)
New Diagnosis of Breast Cancer	0 (0.0)	0 (0.0)	1 ( 2.1)
Surgical Complication Related to Technique	1 (4.0)	1 (2.9)	1 ( 2.1)
Suspected Rupture	0 (0.0)	1 (2.9)	1 ( 2.1)
Suspected Rupture-No Rupture Found	1 (4.0)	1 (2.9)	1 ( 2.1)
Symmastia	1 (4.0)	1 (2.9)	1 ( 2.1)

<sup>1</sup> All reoperations were counted, with the primary reason for each reoperation presented.

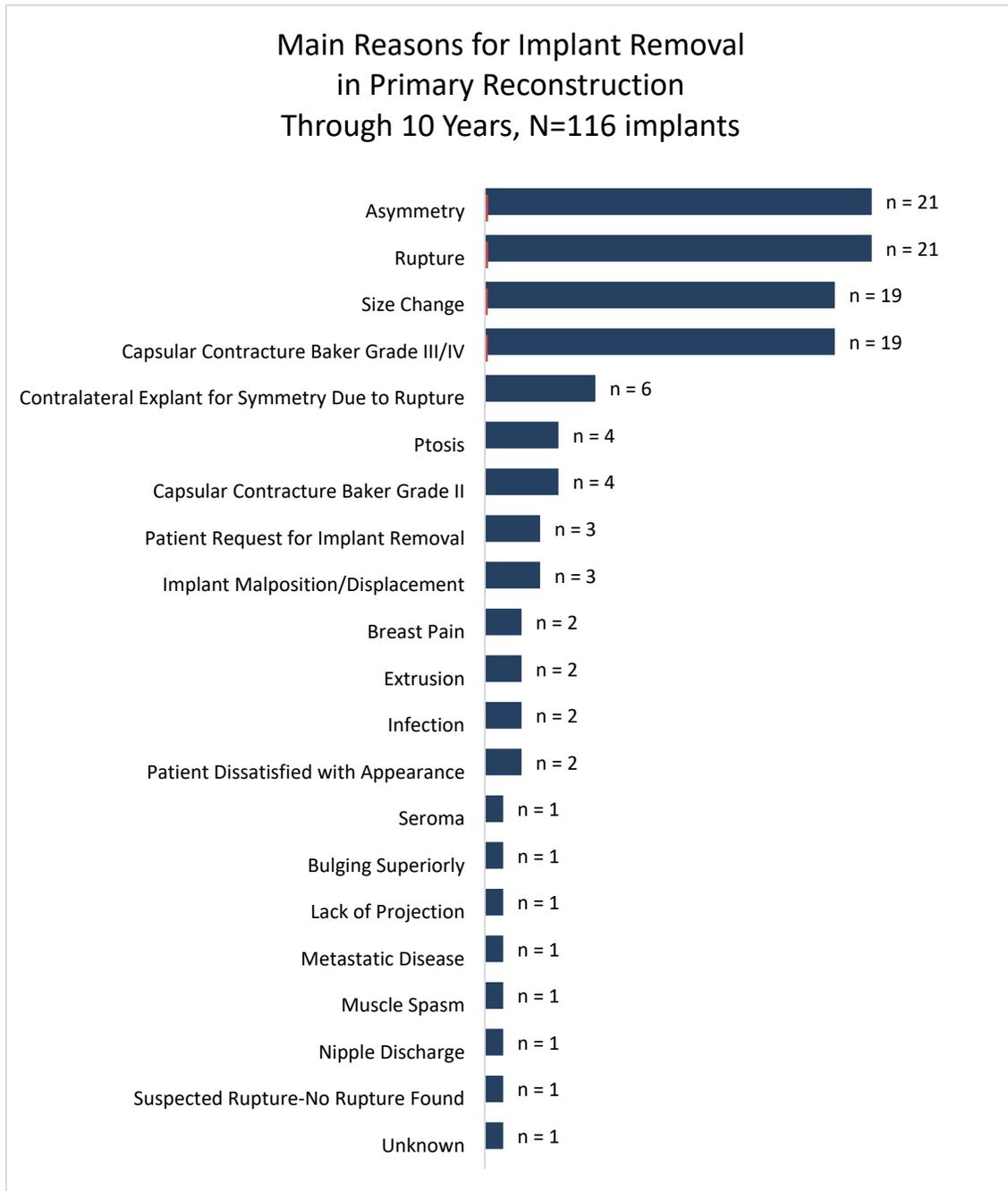
### 8.6 What Were the Main Reasons for Implant Removal?

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

### Primary Reconstruction

The main reasons for implant removal among primary reconstruction patients in the MemoryGel™ Breast Implant Core Study through 10 years are shown in Figure 7 below. There were a total of 116 implants removed in 76 patients through 10 years. Of the 116 implants removed, 62 (53%) were replaced with a study device. The most common reason for implant removal were asymmetry and rupture (each accounting for 21 of the 116 implants removed).

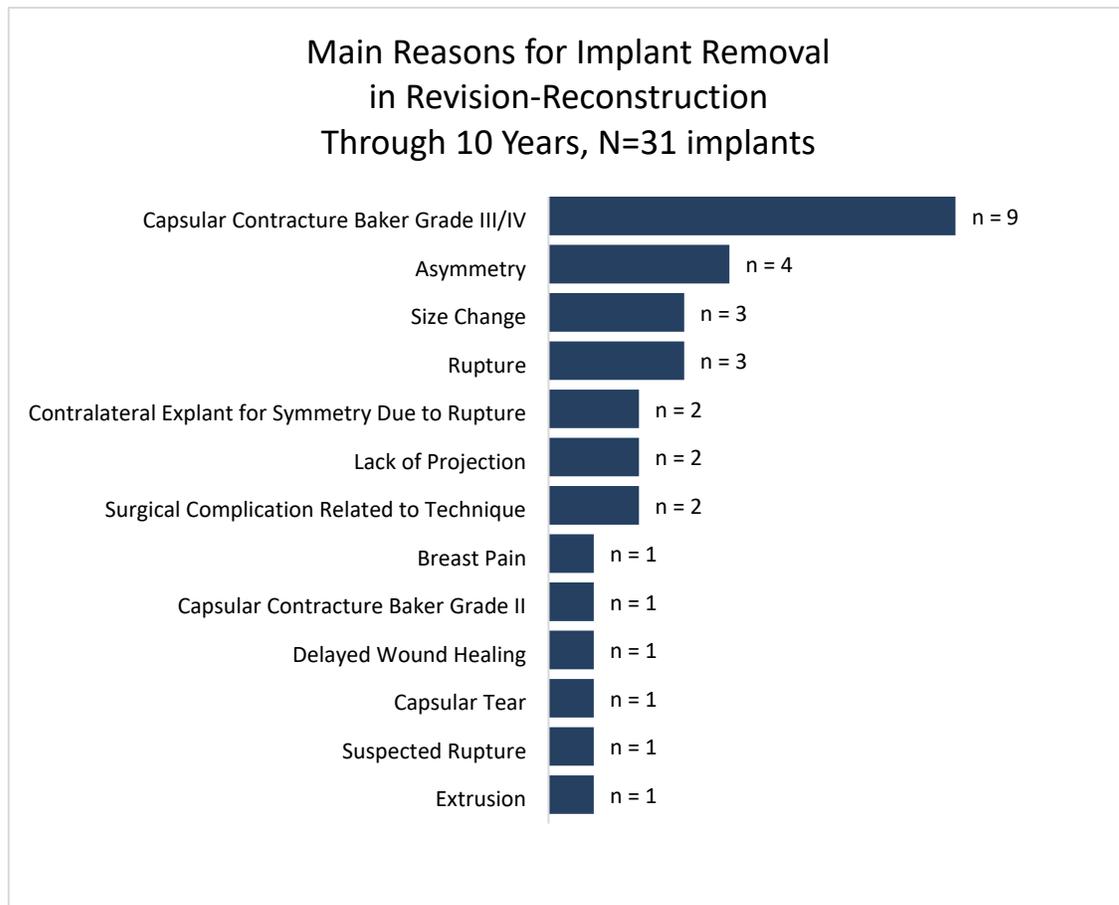
Figure 7



## Revision-Reconstruction

The main reasons for implant removal among revision-reconstruction patients in the MemoryGel™ Breast Implant Core Study through 10 years are shown in Figure 8 below. There were 31 implants removed in 22 patients through 10 years. Of the 31 implants removed, 19 (61%) were replaced with a study device. The most common reason for implant removal was capsular contracture Baker Grade III/IV (9 of the 31 implants removed).

Figure 8.



### 8.7 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 Reconstruction

For Primary Reconstruction patients in the Initial MRI cohort, the estimated rupture rate based on confirmed and suspected ruptures was 32.7% at the patient level and 24.3% at the implant level based on follow-up through the patient's last MRI exam at 10 years after implant. This means that through 10 years, based only on MRI exam, an estimated 33 of every 100 Primary Reconstruction patients may have a suspected or actual ruptured breast implant and 24 out of every 100 Primary Reconstruction implants may be a suspected or actual rupture. Table 10 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 Reconstruction patients and the Supplemental MRI Cohort Primary Reconstruction patients. It should be noted that the relatively lower sample size (lower follow-up rate) by year 10 of follow-up reduces the accuracy of these estimated rupture rates.

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

Primary Reconstruction			
Initial MRI Cohort		Supplemental MRI Cohort	
Enrolled: 134 patients with 211 implants Follow-up at 10 years: 76/112 patients (68%), 99/173 implants (57%)*		Enrolled: 117 patients with 174 implants Follow-up at 10 years: 47/85 patients (55%), 60/129 implants (47%)*	
<i>Suspected or Confirmed</i>	Kaplan-Meier estimated rate	<i>Suspected or Confirmed</i>	Kaplan-Meier estimated rate
25 patients	32.7%	18 patients	36.1%
29 implants	24.3%	21 implants	28.1%
<i>Confirmed</i>		<i>Confirmed</i>	
18 patients	23.0%	14 patients	27.7%
24 implants	19.0%	16 implants	21.3%

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

Overall, of the 50 out of 385 Primary Reconstruction implants suspected of rupture, 7 showed evidence of extracapsular silicone (silicone gel outside of the scar capsule surrounding the breast implant). For 4 of these 7 implants, the evidence for extracapsular silicone was considered indeterminate (not certain). One rupture in the Initial MRI cohort and no 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. Seven Primary Reconstruction patients experienced a local complication (3 patients with capsular contracture Baker grade III, and 1 patient each with capsular contracture Baker grade IV, lymphadenopathy, ptosis, and seroma) that first occurred after suspected or confirmed rupture. At 10 years post-implant, 97.6% (or 98 of 100 patients) of the Primary Reconstruction patients with suspected or confirmed rupture indicated that they would make the same decision to have breast implant surgery.

### Revision-Reconstruction

For revision-reconstruction patients in the Initial MRI cohort, the estimated rate based on suspected or confirmed ruptures was 38.8% at the patient level and 25.8% at the implant level through 10 years. This means that through 10 years based only on MRI exam, an estimated 39 of every 100 Revision-Reconstruction patients may have a suspected or actual ruptured breast implant and 26 of every 100 Revision-Reconstruction implants may be a suspected or actual rupture.

Table 11 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-Reconstruction patients and for the Supplemental MRI Cohort Revision-Reconstruction 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 11. Suspected or Confirmed Versus Confirmed Kaplan-Meier Estimated Cumulative Incidence of Rupture Based on Last MRI Exam Through 10 Years**

Revision-Reconstruction			
Initial MRI Cohort		Supplemental MRI Cohort	
Enrolled: 28 patients with 47 implants Follow-up at 10 years: 15/26 patients (58%), 18/45 implants (40%)*		Enrolled: 32 patients with 44 implants Follow-up at 10 years: 11/25 patients (44%), 12/34 implants (35%)*	
<i>Suspected or Confirmed</i>	Kaplan-Meier estimated rate	<i>Suspected or Confirmed</i>	Kaplan-Meier estimated rate
6 patients	38.8%	6 patients	43.9%
6 implants	25.8%	8 implants	44.4%
<i>Confirmed</i>		<i>Confirmed</i>	
3 patients	17.7%	3 patients	23.6%
3 implants	12.3%	4 implants	25.6%

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

Overall, of the 14 out of 91 implants suspected of rupture, none showed evidence of extracapsular silicone (silicone gel outside of the scar capsule surrounding the breast implant). One rupture in the Initial MRI cohort and no 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. Two Revision- Reconstruction patients experienced a local complication (1 patient with rash and 1 patient with capsular contracture grade IV and death due to metastatic breast cancer) that first occurred after suspected or confirmed rupture. At 10-years post-implant, 87.5% (or 88 of 100) of the patients with suspected or confirmed rupture indicated that they would make the same decision to have breast implant surgery.

The *overall* occurrence of (suspected or confirmed) rupture provided in Table 12 reflect the number of suspected or confirmed ruptures in a patient group divided by the number of patients enrolled in that group. The estimated (Kaplan-Meier) complication rates for rupture by patient presented in Table 12 attempt to account for patients not returning for follow-up and adjust the estimated rupture rates accordingly. Note that all ruptures presented in Table 12 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 12. 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 (%) <sup>a</sup>	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 Reconstruction (N=251)	43 (17.1%) <sup>b</sup>	Initial MRI (N=134)	0.8%	0.8%	4.7%	6.9%	14.8%	32.7%
		Supplemental MRI (N=117)	-	-	-	16.1%	20.2%	36.1%
Revision-Reconstruction (N=60)	12 (20.0%) <sup>c</sup>	Initial MRI (N=28)	0%	0%	0%	4.6%	15.8%	38.8%
		Supplemental MRI (N=32)	-	-	-	5.6%	11.9%	43.9%

<sup>a</sup> 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.

<sup>b</sup> 11 patients with suspected but not confirmed ruptures. 1 patient symptomatic.

<sup>c</sup> 6 patients with suspected but not confirmed ruptures. 1 patient symptomatic.

Overall, there have been 35 suspected or confirmed ruptured implants among 31 of the patients (25 primary reconstruction and 6 revision-reconstruction) participating in the reconstruction segments of the Initial MRI cohort and 29 suspected or confirmed ruptured implants among 24 of the patients (18 primary reconstruction, and 6 revision-reconstruction) participating in the reconstruction segments of the Supplemental MRI cohort. Of the 64 suspected or confirmed ruptured implants in the reconstruction segments of the overall study, 4 cases were indeterminate for extracapsular silicone by MRI. There were 3 cases 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.<sup>1,77</sup> 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 reconstruction patients, 1 (0.5%) patient had a new diagnosis of breast cancer and 4 (2.0%) patients had a recurrence of breast cancer in Mentor's MemoryGel™ Core Study. For revision- reconstruction, 2 (3.9%) patient had a new diagnosis of breast cancer and there were no reports of a recurrence of breast cancer.

There was one reported case of lung and bone cancer (revision-reconstruction), and one case each of lung cancer, lymphoma, and liver cancer all in primary reconstruction patients. 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 5 primary reconstruction patients, and 5 revision-reconstruction patients reported to have a new diagnosis of CTD by a rheumatologist. There were 8 diagnoses for the 5 primary reconstruction patients: fibromyalgia (within 1 year), Raynaud's syndrome (2 cases – within 5 and 9 years), rheumatoid arthritis (within 7 years), Sjogren's syndrome (3 cases – 2 within 7 years and 1 within 10 years), and systemic lupus erythematosus (within 10 years) . There were 6 diagnoses for the 5 revision-reconstruction patients: chronic fatigue (within 9 years), fibromyalgia (within 1 year), other connective tissue disorder (within 3 years), other inflammatory arthritis (within 4 years), pyoderma gangrenosum (within 1 year), and systemic lupus erythematosus (within 9 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: decreases for insomnia, joint swelling and night sweats among primary reconstruction patients. No statistically significant results were found for the revision- reconstruction patients. For individual signs and symptoms, significant decreases for the joint and CNS categories were found for primary reconstruction patients.

The Mentor 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 breast-feeding, were examined in the MemoryGel™ Core Study. Eight primary reconstruction (non-mastectomy) patients attempted to breastfeed and 1 experienced lactation difficulties. None of the revision-reconstruction patients attempted to breastfeed.

### **Reproduction Complications**

Reproduction complications that were examined in the MemoryGel™ Core Study include miscarriage and having a stillborn baby. Six primary reconstruction patients reported a miscarriage and there were no reports of miscarriage in the revision-reconstruction cohort.

### **Suicide**

There were no reports of suicide in primary reconstruction or revision-reconstruction patients in the MemoryGel™ Core Study.

### **Other Deaths**

There was one instance of death by other causes in the primary reconstruction cohort, due to hypertrophic cardiomyopathy.

### **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.

## **9. 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 directly to the FDA through its voluntary reporting program called MedWatch. (See <http://www.fda.gov/medwatch>). 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.

## **10. WHERE TO FIND MORE INFORMATION**

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 Implant 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 on the studies (in animals and humans or other laboratory testing) done on MemoryGel™ Breast Implants in Mentor's Summary of Safety and Effectiveness Document (SSED) on the FDA's website at: <http://www.fda.gov/breastimplants>.

You can find these resources on Mentor's website at <http://www.mentorwwllc.com> or through Mentor's Consumer Affairs Department at (866) 250-5115.

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

The U.S. Food and Drug Administration (FDA) has published a breast implant complications booklet titled "Breast Implants: Local Complications and Adverse Outcomes." It contains descriptions of the risks of having breast implants (similar to this brochure) and links to more information. The booklet is available through the FDA website at: <http://www.fda.gov/breastimplants>

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 American Society for Aesthetic Plastic Surgery - <http://www.surgery.org>

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

In 2000, the Institute of Medicine (IOM) published a comprehensive review of studies that have looked at the safety of silicone gel breast implants. The report is available on the website <http://www.iom.edu/Reports/1999/Safety-of-Silicone-Breast-Implants.aspx>

Patient groups offer support and information to women who have had problems with their breast implants. Several such websites are listed at: <http://www.fda.gov/breastimplants>

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

## **11. 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.

### **11.1 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.

### **11.2 Device Identification Card**

After your surgery, your surgeon will provide you with 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 Device Identification Card for those implants.

Your doctor should keep a copy of the Device Identification 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).***

## **12. 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  
972-252-6060  
[www.mentorwillc.com](http://www.mentorwillc.com)

Your surgeon's name and contact information:

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### **13. 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. These programs apply to all recipients of Mentor breast implant products. For more information, please contact Mentor's Consumer Affairs Department at (866) 250-5115 or visit [www.mentorwllc.com](http://www.mentorwllc.com)

### **14. ACKNOWLEDGMENT OF INFORMED DECISION**

#### **ACKNOWLEDGMENT OF INFORMED DECISION (Copy for Patient File)**

I understand that this patient brochure provided by Mentor is intended to provide information regarding the benefits and risks of silicone gel breast implants. I understand that some of this information is about breast implants in general and some is specific to Mentor's breast implants. I understand that choosing to have reconstruction breast surgery with implants involves both benefits and risks. I also understand that scientists and doctors have not been able to identify or quantify all of the risks of breast reconstruction with implants and that, over time, additional information may become available.

I have had adequate time to review and understand the information in this brochure and my questions and concerns have been addressed by my doctor. I have considered alternatives to reconstruction surgery, including the use of external prostheses, flap procedures or surgery with saline-filled breast implants, and I am choosing to proceed with silicone gel breast implant surgery.

By circling my response for each statement below and signing below, I acknowledge that:

- Y/N** I have had adequate time to read and fully understand the information in this brochure,
- Y/N** I have had an opportunity to discuss this information with my surgeon and to ask any questions I may have,
- Y/N** I have carefully considered options other than reconstruction surgery with breast implants and have decided to proceed with silicone gel breast implant surgery,
- Y/N** I have been advised to wait an adequate amount of time after reviewing and considering this information before scheduling my silicone gel breast implant surgery,
- Y/N** I will retain this brochure, and I am aware that I may also ask my surgeon for a copy of this signed acknowledgment.

\_\_\_\_\_  
Patient or Guardian Name (Printed)

\_\_\_\_\_  
Patient or Guardian Signature

\_\_\_\_\_  
Date

By my signature below, I acknowledge that:

- My patient has been given an opportunity to ask any and all questions related to this brochure, or any other issues of concern;
- All questions outlined above have been answered "Yes" by my patient;
- My patient has had an adequate amount of time before making her final decision, unless an earlier surgery was deemed medically necessary, and
- This *Acknowledgment of Informed Decision* will be retained in my patient's permanent record.

\_\_\_\_\_  
Implanting Surgeon Name (Printed)

\_\_\_\_\_  
Implanting Surgeon Signature

\_\_\_\_\_  
Date



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