Patient Educational Brochure

RECONSTRUCTION

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

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

WARNING:

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

MENTOR®

PATIENT EDUCATIONAL BROCHURE

RECONSTRUCTION

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

MENTOR®

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GLOSSARY

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

Breast Reconstruction	A surgical procedure to replace breast tissue or reconstruct a breast after tissue was taken out because of cancer or injury. Breast reconstruction also includes the surgical correction of a breast that has failed to develop properly due to a severe abnormality or congenital defect. The first time a breast implant is placed to replace breast tissue is referred to as "primary reconstruction." Any time there is another surgery to replace the implant, it is referred to as "revision-reconstruction."
Calcification/Calcium Deposits	The process of soft tissue hardening when the mineral calcium builds up in a certain place.
Capsular Contracture	Tightening of the scar tissue (also called a capsule) that normally forms around the breast implant during the healing process after surgery. In some women, the scar tissue (capsule) squeezes the implant. When this occurs, it is called capsular contracture. This results in firmness or hardening of the breast. Capsular contracture is classified by the Baker Grade Scale.
Capsule	Scar tissue that forms around the breast implant.
Capsulotomy (Closed)	An attempt to break the scar tissue capsule around the implant by pressing or pushing on the outside of the breast. This method does not require surgery but may rupture the implant and is contraindicated (meaning that the procedure is improper and should not be performed).
Capsulotomy (Open)	A surgery to create an incision or opening in the capsule (scar tissue).
Chest Wall	The system of structures outside the lungs that move as a part of breathing, including bones (the rib cage) and muscles (diaphragm and abdomen).
Congenital Anomaly	An abnormal body part that existed at birth. Also called a congenital malformation or congenital deformity.
Connective Tissue Disease/Disorder (CTD)	A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc. and/or the immune system. Connective tissue diseases ("CTDs") that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma.
Contraindication	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.
Contralateral	The opposite side of the body.
DIEP Flap	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.
Delayed Reconstruction	Breast reconstruction that takes place weeks, months, or years after a mastectomy.

Delayed Wound Healing	Unusually slow progress in the healing of a wound; surgical incision site fails to heal normally or takes longer to heal.
Displacement	Movement (shifting) of the implant from the usual or proper place.
Extracapsular Rupture	A type of rupture in which the silicone gel is outside of the scar capsule surrounding the breast implant (see Rupture).
Extracapsular Silicone	Silicone material outside the breast implant capsule.
Extrusion	Skin breakdown with the implant pressing through the skin or surgical incision.
Fibrocystic Breast Disease	Common, benign (noncancerous) changes in the tissues of the breast. The term "disease" is misleading, and many doctors prefer the term "change." The condition is so commonly found in breasts; it is believed to be a variation of "normal." Other related terms include "mammary dysplasia," "benign breast disease," and "diffuse cystic mastopathy."
Fibromyalgia	A chronic condition characterized by widespread pain in muscles and joints. It may include fatigue, difficulty sleeping, and morning stiffness.
Fibrous Tissues	Connective tissue composed mostly of fibers (for example, tendons).
Flap	A portion of tissue (which may include muscle, fat, and skin), moved from one part of the body to another. The tissue flap may or may not have its blood supply attached.
Free TRAM Flap	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.
Functional Living Index–Cancer	The Functional Living Index–Cancer (FLIC) is a questionnaire used to evaluate day-to-day functioning in patients who have cancer.
Gel Bleed/Gel Diffusion	When silicone gel leaks, "bleeds" or "diffuses" through the implant shell.
Granuloma	Noncancerous lumps that can form around foreign material, such as silicone. Like any lump, it should be evaluated to distinguish it from a lump that might be cancerous.
Groin	The fold where the lower abdomen meets the inner part of the thigh.
Hematoma	A collection of blood inside the body, for example in skin tissue or other body space.
Hypertrophic Scarring	An enlarged scar that remains after a wound heals.
Infection	The growth in the human body of microorganisms such as bacteria, viruses or fungi. An infection can occur as a result of any surgery.
Inflammation/Irritation	The response of the body to infection or injury resulting in swelling, redness, warmth and/or pain.

Inframammary Fold	The crease under the breast where the breast and chest meet.
Inframammary Incision	An incision made in the fold below the breast.
Inpatient Surgery	A surgical procedure in which the patient is required to stay overnight in the hospital.
Intracapsular Rupture	A type of rupture in which the silicone gel remains inside the scar tissue capsule surrounding the breast implant (see Rupture).
Lactation	The production and secretion of milk by the breast glands.
Latissimus Dorsi	Two triangular muscles running from the spinal column (backbone) to the shoulder.
Latissimus Dorsi Flap	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.
Latissimus Dorsi Flap Reconstruction	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.
Local Complications	Complications that occur in the breast or chest area.
Lumpectomy	Removal of a small amount of breast tissue.
Lymph Nodes	Lymph nodes are glands that play an important part in the body's defense against infection. They produce lymph, which travels throughout the body in the lymph system, and filters impurities from the body. Common areas where the lymph nodes can be felt with the fingers include: groin, armpit, neck, under the jaw and chin, behind the ears, and on the back of the head.
Lymphadenopathy	Enlarged lymph node(s).
Lymphedema	Swelling of the lymph node(s).
Malposition	When the implant is placed incorrectly during the initial surgery or when the implant has moved/shifted from its original position. Shifting can be caused by many factors, such as gravity, trauma, poor initial placement, and capsular contracture.
Mammary	Pertaining to the breast.
Mammography	A type of x-ray examination of the breasts used for detection of cancer.
Mammoplasty	Plastic surgery of the breast.
Mastectomy	Removal of breast tissue.
Mastopexy	Surgical procedure to raise and reshape sagging breasts.
MemoryGel™ Core Study	A Core study is the clinical study that supports the approval of a medical product (such as breast implants). For Mentor's breast implants, the MemoryGel™ Core Study includes augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients. Information on the safety and effectiveness of the implants are collected every year for 10 years after study participants get their implants.

Metastatic Disease	A stage of cancer after it has spread from its original site to other parts of the body.
Migration/Gel Migration	Movement of silicone material outside the breast implant to other areas of the body.
MRI (Magnetic Resonance Imaging)	MRI uses a magnetic field to create a 3-dimensional picture of a body part or organ. MRI is the imaging method that currently has the best ability to detect rupture of silicone gel breast implants.
Necrosis	Death of cells or tissues.
Oncologist	A medical doctor who specializes in diagnosing and treating cancer.
Outpatient Surgery	A surgical procedure in which the patient is not required to stay in the hospital overnight.
Palpability/Visibility	Palpability is when the implant can be felt through the skin. Visibility is when the implant can be seen through the skin.
Pectoralis	Major muscle of the chest.
Pedicle TRAM Flap	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.
Periareolar	The areola is the pigmented or darker colored area of skin surrounding the nipple. Periareolar refers to the area just around the areola.
Periumbilical	Around the belly button.
Plastic Surgery	Surgery intended to enhance or improve the appearance of the body.
Platinum	A metallic element used to help make both silicone elastomer (the rubbery material of the breast implant shell) and silicone gel.
Post-Mastectomy	After a mastectomy.
Postoperative	After surgery.
Precautions	Information that warns the reader of a potentially hazardous situation that, if not avoided, may result in minor or moderate injury.
Prepectoral Placement	When, after a mastectomy, the implant is placed under the skin but on top of the chest muscles. Also known as subcutaneous.
Primary Breast Reconstruction	The first time a breast implant is placed for the purpose of breast reconstruction.
Prosthesis	Any artificial device used to replace or represent a body part.
Ptosis	Sagging or drooping of the breast.
Quality of Life (QoL) Measures	Assessments that may contribute to the evaluation of benefit (effectiveness), including the Rosenberg Self-Esteem Scale (measures self-worth or self-acceptance), the Body Esteem Scale (measures a person's body image), 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).

Rectus Abdominus	A long, flat muscle extending the whole length of the front of the abdomen (stomach).
Redness/Bruising	Bleeding at the surgical site that causes discoloration and varies in degree and length of time. This is expected following breast implant surgery or other breast procedures.
Removal	Removal of the implant, with or without replacement using another implant.
Reoperation	Any additional surgery performed to the breast or chest area after the first breast implantation.
Revision-Reconstruction	Refers to the correction or improvement of a primary reconstruction. In the context of this document, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast reconstruction.
Rheumatological Disease/ Disorder	A variety of diseases involving connective tissue structures of the body, especially the joints and fibrous tissue. These diseases are often associated with pain, inflammation, stiffness, and/or limitation of motion of the affected parts. Can include autoimmune diseases. Fibromyalgia is a rheumatological disorder.
Risks	The chance or likelihood that an undesirable effect will occur.
Rosenberg Self-Esteem Scale	A questionnaire that measures overall self-esteem.
Rupture	A hole or tear in the shell of the implant that allows silicone gel filler material to leak from the shell.
Saline	Saltwater (a solution made of water and a small amount of salt).
Scar Revision	A surgical procedure to improve the appearance of a scar.
Scarring	Formation of tissue at an incision site; all wounds heal by the formation of a scar.
Seroma	Similar to a bruise, a seroma occurs when the watery portion of the blood collects around a surgical incision or around a breast implant.
SF-36 Scale	The Short Form 36 Health Scale; a questionnaire intended to measure physical, mental, and social health.
Silent Rupture	A breast implant rupture without symptoms or a visible change. Silent rupture cannot be felt by the woman or detected by a doctor through physical examination. Silent rupture can only be discovered through appropriate imaging techniques such as MRI.
Silicone	Silicone is a man-made material that can be found in several forms such as oil, gel, or rubber (elastomer). The exact make-up of silicone will be different depending on its use.
Silicone Elastomer	A type of silicone that has elastic properties similar to rubber.
Silicones – Low Molecular Weight (LMW)	Small silicone molecules that may be present in gel bleed/gel diffusion.

Subcutaneous Placement	When, after a mastectomy, the implant is placed under the skin but on top of the chest muscles. Also known as prepectoral placement.
Subglandular Placement	When the implant is placed under and within the breast glands (breast tissue), but on top of the chest muscles.
Submuscular Placement	When the implant is placed underneath the chest muscles.
Surgical Incision	A cut made to body tissue during surgery.
Suspected or Confirmed Rupture	The sum of all ruptures that were either suspected due to MRI imaging or actually confirmed as ruptured after explantation.
Symmastia	When the breast implants touch each other over the midline of the chest (where the cleavage area would normally be seen).
Symptom	Any perceptible change in the body or its functions that indicates disease or a phase of a disease.
Symptomatic	Experiencing symptoms; any evidence or sign of disease or disorder.
Symptomatic Rupture	A breast implant rupture that is associated with symptoms (such as lumps, persistent pain, swelling, hardening, or change in implant shape).
Systemic	Pertaining to or affecting the body as a whole.
Tennessee Self-Concept Scale (TSCS)	A questionnaire that evaluates how the patient sees herself and what she does, likes, and feels. The scale is intended to summarize an individual's feeling of self-worth, the degree to which the self-image is realistic, and whether or not that self-image is normal. It also measures the following aspects of how the patient feels about herself: moral-ethical, social, personal, physical, and family, identity, behavior, and self-satisfaction.
Tissue Expander	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.
Tissue Flap Reconstruction	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.
Toxic Shock Syndrome (TSS)	A rare, but life-threatening bacterial infection that may occur after surgery. Symptoms of TSS occur suddenly: a high fever, vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches, and/or drops in blood pressure, which may cause fainting. A doctor should be seen immediately for diagnosis and treatment if TSS is suspected.
TRAM Flap	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.

TRAM Flap Reconstruction	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.
Unilateral	Affecting only one side of the body.
Vascular Tissue	Blood vessels (arteries and veins) that carry blood to the skin and tissues of the body and back to the heart.
Warnings	A statement that alerts the reader about a situation that, if not avoided, could result in serious injury or death.
Wound Dehiscence (Wound Opening)	Opening of a wound.
Wrinkling/Rippling	Wrinkling of the implant that can be felt or seen through the skin.

1. HOW TO USE THIS EDUCATIONAL BROCHURE

Mentor, the company that sells 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 9 of this brochure.

After you receive this information, give yourself time to read and think about the information. Because breast implants will require monitoring and care for the rest of your life, you should wait 1 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.

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

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

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

2. SAFETY INFORMATION AVAILABLE ON WEBSITE:

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

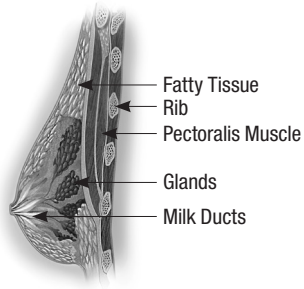
3. GENERAL INFORMATION ABOUT BREAST RECONSTRUCTION WITH BREAST IMPLANTS

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

3.1 What Gives the Breast Its Shape?

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

Figure 1
Anatomy 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.

3.2 What Is a Silicone Gel Breast Implant?

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

MENTOR® MemoryGel™ Breast Implants and 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 7.5 *(Choosing the Right Implant for You)*.

3.3 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 7.2.

4. 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.

4.1 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.

4.2 Contraindications

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

MemoryGel™ Breast Implants and MemoryGel™ Xtra Breast Implants are contraindicated in the following circumstances because the risk of undergoing breast 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.

4.3 Precautions

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

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

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

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

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

4.4 Warnings

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

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

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

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

- Breast implants are not expected to last for the rest of your life, and breast implantation may not be a one-time surgery. It is likely that you will need other surgery related to your breast implants over the course of your life. These additional surgeries can include implant removal with or without replacement, or they can include other surgical procedures.
- Many of the changes to your breast that may occur as a result of breast implant surgery will be permanent and cannot be undone. If you have your implants removed, your skin may be permanently dimpled, puckered, or wrinkled.

- Breast implants may interfere with your ability to produce milk (lactate) for breastfeeding. If you are planning to breastfeed your infant, be prepared to use formula and bottle-feed your baby in the event you have difficulty breastfeeding.
- 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. It is recommended that you have periodic imaging (e.g., MRI, ultrasound) of your silicone gel-filled implants to screen for implant rupture regardless of whether your implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on your medical history or circumstances (i.e., screening mammography for breast cancer). Even if you have no symptoms, you should have your first ultrasound or MRI at 5-6 years after your initial implant surgery and then every 2-3 years thereafter. If you have symptoms at any time or uncertain ultrasound results for breast implant rupture, an MRI is recommended.
- Routine self-examination of your breasts may be more difficult with implants. However, you should still perform an examination of your breasts every month for cancer screening. Ask your surgeon to help you distinguish the implant from your breast tissue. You should perform an examination of your breasts for the presence of lumps, swelling, hardening, or change in implant shape, which may be signs of rupture of the implant. Report any of these symptoms or persistent pain to your doctor. Your surgeon may recommend an evaluation via MRI to check for rupture.
- 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.

4.5 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).

5. RISKS ASSOCIATED WITH BREAST IMPLANTS

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

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

Table 1
Potential Risks Associated with Breast Reconstruction[1]

	Likelihood of the Event Occurring Through 10 Years		
Event	**Primary Reconstruction Patients N=251**	**Revision-Reconstruction Patients N=60**	**Possible Resulting Effects of the Event**
Key Complications			
Any Reoperation	49 out of 100 patients (49%)	51 out of 100 patients (51%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result

Table 1 *Continued on next page*

Table 1 *(Continued)*

Event		Likelihood of the Event Occurring Through 10 Years: Primary Reconstruction Patients N=251	Likelihood of the Event Occurring Through 10 Years: Revision-Reconstruction Patients N=60	Possible Resulting Effects of the Event
Key Complications				
Implant Removal with or without Replacement		33 out of 100 patients (33%)	38 out of 100 patients (38%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Capsular Contracture Baker Grade III/IV		20 out of 100 patients (20%)	37 out of 100 patients (37%)	• Pain or discomfort • Breast hardness/ firmness • Reoperation • Implant removal
Rupture[2]	Initial MRI Cohort[3]	33 out of 100 patients (33%)	39 out of 100 patients (39%)	• Implant removal • Silicone migration • Pain • Discomfort • Change in breast shape and size
	Supplemental MRI Cohort[3]	36 out of 100 patients (36%)	44 out of 100 patients (44%)	
Other Risks Occurring in 1% or More of Patients				
Capsular Contracture Baker Grade III		18 out of 100 patients (18%)	33 out of 100 patients (33%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant Removal
Nipple Sensation Changes		1 out of 100 patients (1%)	0 out of 100 patients (0%)	• Increased or decreased nipple sensitivity • Breast-feeding difficulties • May affect sexual response
Capsular Contracture Baker Grade IV		6 out of 100 patients (6%)	11 out of 100 patients (11%)	• Pain or discomfort • Breast hardness/ firmness • Reoperation • Implant removal
Ptosis (sagging)		5 out of 100 patients (5%)	5 out of 100 patients (5%)	• Undesirable cosmetic result • Wrinkling/Rippling • Reoperation • Implant removal

Table 1 *Continued on next page*

Table 1 *(Continued)*

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	
Other Risks Occurring in 1% or More of Patients			
Breast Pain	5 out of 100 patients (5%)	5 out of 100 patients (5%)	• Resulting effects are contingent on underlying cause(s)
Hypertrophic Scarring (irregular, raised scar)	3 out of 100 patients (3%)	0 out of 100 patients (0%)	• Scar revision procedure (reoperation) • Undesirable cosmetic result
Capsular Contracture Baker Grade II with Surgical Intervention	4 out of 100 patients (4%)	2 out of 100 patients (2%)	• Pain or discomfort • Breast hardness/ firmness • Reoperation • Implant removal
New Diagnosis of Rheumatic Disease	3 out of 100 patients (3%)	3 out of 100 patients (3%)	• Pain or discomfort
Asymmetry	9 out of 100 patients (9%)	13 out of 100 patients (13%)	• Undesirable cosmetic result • Reoperation • Implant removal
Hematoma	1 out of 100 patients (1%)	2 out of 100 patients (2%)	• Swelling and bruising • Pain or discomfort • Infection • Incision and drainage (reoperation) • Implant removal
Implant Malposition/ Displacement	2 out of 100 patients (2%)	7 out of 100 patients (7%)	• Undesirable cosmetic result • Asymmetry • Visibility • Reoperation • Implant removal
Infection	6 out of 100 patients (6%)	0 out of 100 patients (0%)	• Redness or rash • Pain or tenderness • Swelling • Fever • Reoperation • Implant removal
New Diagnosis of Breast Cancer	<1 out of 100 patients (<1%)	4 out of 100 patients (4%)	• Reoperation or other procedures
Wrinkling	3 out of 100 patients (3%)	7 out of 100 patients (7%)	• Discomfort • Undesirable cosmetic result • Reoperation • Implant removal

Table 1 *Continued on next page*

Table 1 *(Continued)*

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	
Other Risks Occurring in 1% or More of Patients			
Delayed Wound Healing	<1 out of 100 patients (<1%)	2 out of 100 patients (2%)	• Pain or discomfort • Scarring • Implant extrusion • Necrosis • Reoperation • Implant removal
Granuloma	0 out of 100 patients (0%)	2 out of 100 patients (2%)	• Pain or discomfort • Reoperation or other procedures
Extrusion	1 out of 100 patients (1%)	2 out of 100 patients (2%)	• Pain or discomfort • Scarring • Reoperation • Implant removal
Lymphadenopathy	1 out of 100 patients (1%)	0 out of 100 patients (0%)	• Pain or discomfort • Reoperation or other procedures
Necrosis	1 out of 100 patients (1%)	0 out of 100 patients (0%)	• Reoperation or other procedures • Implant removal
Other complications[4]	29 out of 100 patients (29%)	28 out of 100 patients (28%)	• Resulting effects are contingent on underlying cause(s)

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

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

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

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

Using information from Mentor's MemoryGel™ Core Study, the risk of a patient experiencing any complication (excluding rupture) at some point through 10 years after implant surgery was calculated. 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 9).

5.1 What Are the Potential Complications?

• Infection

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

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

• Hematoma or Seroma

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

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

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

• Capsular Contracture

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

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

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

Capsular contracture may be more common if you have had a breast infection or hematoma/seroma. The chances of having contracture typically increase the longer you have your implants. Capsular contracture is a risk factor for implant rupture,[9] and it is one of the most common reasons for reoperation. It also seems that women who have additional surgery to replace their implants (revision surgery) are more likely to have capsular contracture than women having their first 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

Cohort	2 Year	4 Year	6 Year	8 Year	10 Year
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 9.4.

• Rupture

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

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

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

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

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

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

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

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

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

methodology attempts to take in to account the loss of patients in the study over time by calculating a rate based on the available patient data for any given timepoint.

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

Initial MRI Cohort		
	Primary Reconstruction	**Revision-Reconstruction**
Suspected or Confirmed		
By Patient:	32.7%	38.8%
By Implant:	24.3%	25.8%
Confirmed		
By Patient:	23.0%	17.7%
By Implant:	19.0%	12.3%
Supplemental MRI Cohort		
	Primary Reconstruction	**Revision-Reconstruction**
Suspected or Confirmed		
By Patient:	36.1%	43.9%
By Implant:	28.1%	44.4%
Confirmed		
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.[1,77] Silent rupture was assessed by MRI on 101 patients implanted with textured MemoryGel™ Breast Implants. The average age of the implants was approximately 10 years. The results suggest that by 12 years approximately 15% (95% CI, 5.6-24.5%) of implants will have ruptured. All ruptures were confirmed to be intracapsular. For more information on MemoryGel™ Breast Implants, refer to the MENTOR'S CLINICAL STUDY RESULTS, section 9 of this brochure.

- **Reoperation**

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

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 9.5.

- **Implant Removal**

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

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

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

The MemoryGel™ Core Study reported a 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 9.6.

- **Pain**

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

- **Changes in Nipple and Breast Sensation**

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.[9,10] If your surgeon uses an incision around the colored portion surrounding the nipple (periareolar surgical approach), it may further increase the chance of breastfeeding difficulties.

The Institute of Medicine (IOM) and The American College of Obstetricians and Gynecologists (ACOG) encourage women with breast implants to try breastfeeding. The IOM concluded, "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,[11] 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."[9,12] 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 9.7.

- **Implant Extrusion**

Extrusion is when the breast implant comes through the skin. This can happen if your surgical wound has not healed properly or if the skin over your breast weakens. Radiation therapy has been reported to increase the chances of implant extrusion.[13] 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.[7] These reports were in women who had implants from a variety of manufacturers and implant models.

5.2 What Are Other Reported Conditions?

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

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

The information discussed in this section is based on studies published in the medical literature reviews through 2016[76] that include women with many different types, brands, and models of breast implants for augmentation and/or reconstruction.

Cancer

- **Breast Cancer**

Patients with breast implants do not seem to have greater risk of developing breast cancer. (based on literature published from 2000-2016).[18,19,20,21,22,23,24,25,26,27,28,76]

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

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

- **Brain Cancer**

Most studies of brain cancer in women with silicone gel breast implants have found no increased risk. (based on literature published from 2000-2007). [19,21,23,26,27,28,32] One study from the same time period reported a higher rate of brain cancer in women with breast implants, compared to the general population,[29,33] 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. Most studies (based on literature published from 1999-2007) have found no increased risk of these cancers for women with silicone gel breast implants, [14, 15, 16, 17, 19,21,23,26,27,28] Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL)[34]

This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL. Please review additional information on BIA-ALCL below.

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

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

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

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

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

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

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

In addition, if you are diagnosed with BIA-ALCL, talk to your doctor about reporting it to the PROFILE Registry (https://www.thepsf.org/research/clinical-impact/profile.htm). Every case

of BIA-ALCL should be reported to the PROFILE Registry because this helps provide a better understanding of the disease.

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

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

• Respiratory/Lung Cancer

Several studies have found that women with silicone gel breast implants are not at greater risk for lung cancer (based on literature published from 2000-2007).[19,21,23,26,27,28] One study from the same time period found an increased risk of respiratory/lung cancer in women with breast implants[29,33] compared to women who had other kinds of plastic surgery (non-breast implant). However, the risk of lung cancer was not higher than national lung cancer rates for the general population. Other studies of women in Sweden and Denmark have found that women who get breast implants are more likely to be current smokers than women who get breast reduction surgery or other types of cosmetic surgery[35,36,37]; this may increase their risk for lung cancer (based on literature recently published from 1997-2003). A published systematic review from 2016 reported there is limited or suggestive evidence of an association between breast implants and lung cancer.[76]

• Reproductive System Cancer

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

• Other Cancers

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

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

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

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

Other CTDs include:

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

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

Some scientific evidence supports the conclusion that there is no increased risk of CTDs or autoimmune disorders for women with silicone gel breast implants (based on literature published from 1996-2011). [4,5,9,38,41,42,43,44,45,46,47,48,49,50,51,52,53,54] Some independent scientific panels and review groups have also concluded that the weight of the evidence shows no relationship between breast implants and CTDs, or at least if a risk cannot be absolutely excluded, it is too small to be measured (based on literature published from 1998-2001). [9,55,56] A published systematic review from 2016 reported there is limited or suggestive evidence of an association between breast implants and rheumatoid arthritis.[76]

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 published in 2000 that measured silicon levels (one component of silicone). It did not indicate higher levels of silicon in breast milk from women with silicone gel breast implants when compared to women without implants.[57]

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

Overall, there is no evidence that shows that silicone gel breast implants have any harmful effects on the children of implanted women (based on literature published from 2000-2016). [9,10,58,59,60,76]

• Suicide

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

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

• Neurological Disease, Signs, and Symptoms

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

• Potential Health Consequences of Gel Bleed

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

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

Please see section 7.6 for additional information on the Materials present in MemoryGel Breast Implants.

6. 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.[78]

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 9.3 of this brochure.

7. 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.

7.1 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 4.5.

7.2 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.

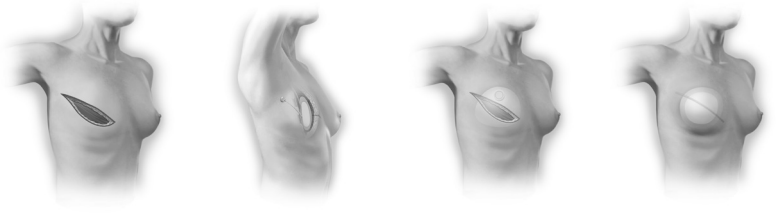
Placing an implant in a breast pocket that is too small can cause complications such as drooping or sagging at an earlier age, implant extrusion, skin wrinkling, infection, and hematoma. You may also be able to feel folds on the implant created by the implant being squeezed tightly by the surrounding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



* **

Post-Mastectomy | Tissue Expansion | Final Result

*tissue expander with remote injection dome
**tissue expander with integral injection dome

before nipple/areola reconstruction

7.3 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.

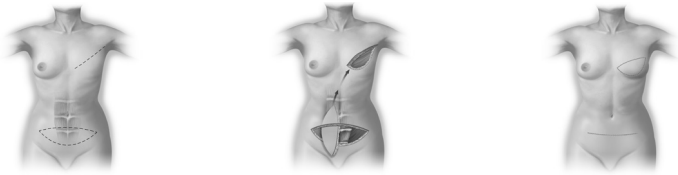
The TRAM flap procedure is done in the hospital under general anesthesia. Your hospital stay may range from 2 to 5 days. The recovery time may be 6 to 8 weeks. You will have two incision sites (on your abdomen and on your breast) resulting in two wounds to heal after surgery and, therefore, two scars. 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



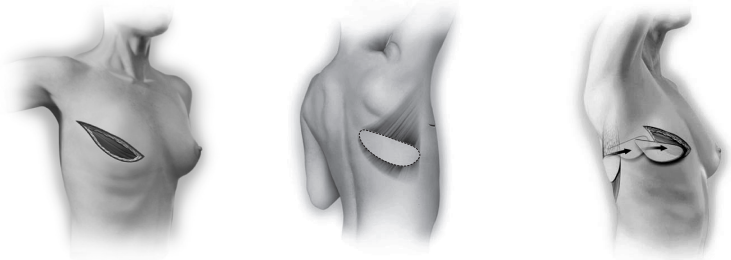
Post-Mastectomy | TRAM Flap | Final Result

before nipple/areola reconstruction

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

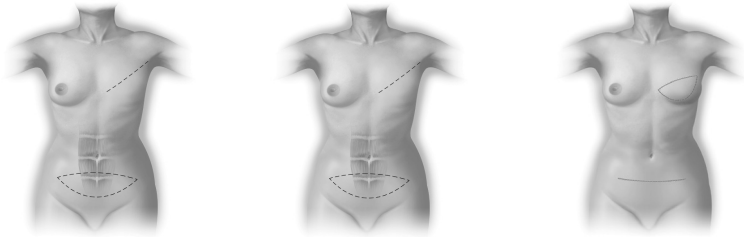


Post-Mastectomy | View Showing Section of Tissue to Be Removed | Latissimus Dorsi Flap Procedure

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



Post Mastectomy

The flap of fat and skin is transferred to the breast and the blood vessels are reattached

Final result

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.

7.4 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.

7.5 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.

The MENTOR® MemoryGel™ Breast Implants and MENTOR® MemoryGel™ Xtra Breast Implants are filled with Mentor's cohesive gel. MENTOR® MemoryGel™ Xtra Breast Implants have a higher fill volume than MENTOR® MemoryGel™ Breast Implants of the corresponding styles. A summary of the distinguishing characteristics for the MemoryGel™ Breast Implants and MemoryGel™ Xtra Breast Implants is provided in Table 4 below.

Table 4
Distinguishing Characteristics for the MemoryGel™ Breast Implants and MemoryGel™ Xtra Breast Implants

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

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

Tables 5 and 6 list the styles for MENTOR® MemoryGel™ Breast Implants and MENTOR® MemoryGel™ Xtra Breast Implants.

MENTOR® MemoryGel™ Breast Implants are filled with cohesive gel and are available with smooth or textured shells. Table 5 provides an overview of the styles and sizes of the MemoryGel™ Breast Implants.

Table 5
MENTOR® MemoryGel™ Breast Implants

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

MENTOR® MemoryGel™ Xtra Breast Implants are also filled with cohesive gel and generally have a higher fill volume than the MENTOR® MemoryGel™ Breast Implants. The MENTOR® MemoryGel™ Xtra Breast Implants are available with smooth or textured shells. Table 6 provides an overview of the styles and sizes of the MemoryGel™ Xtra Breast Implants.

Table 6
MENTOR® MemoryGel™ Xtra Breast Implants

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

When you and your doctor decide what you want your breasts to look like after 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.

7.6 Materials Present in MemoryGel Breast Implants

Below is a summary of materials found in MemoryGel Breast Implants

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

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

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

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

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

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

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

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

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

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

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

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

ND = Not Detected

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

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

Table *Continued on next page*

Table *(Continued)*

Extractables	Whole Device (ppm*)
$D_2D^{Ph}{}_2$ (1)	2.0
$D_2D^{Ph}{}_2$ (2)	<1.3
$D_3D^{Ph}{}_2$ (1)	<20.2
$D_3D^{Ph}{}_2$ (2)	19.0
$D_4D^{Ph}{}_2$ (1)	<1.3
$D_4D^{Ph}{}_2$ (2)	<1.3
$D_5D^{Ph}{}_2$ (1)	ND
$D_5D^{Ph}{}_2$ (3)	ND
$D_5D^{Ph}{}_2$ (2)	ND
Siloxane	3.9
o-Xylene	<0.4
Di(Ethylhexyl) Phthalate	ND
Total Extractables	**<4086.7**

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

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

ND = Not Detected

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

- **Heavy Metals Found in Breast Implants**

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

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

Metal	Concentration (ppm*)
Antimony	0.014
Arsenic	0.123
Barium	0.001
Beryllium	0.006
Cadmium	0.002
Chromium	0.028
Cobalt	0.052
Copper	0.025

Table *Continued on next page*

Table *(Continued)*

Metal	Concentration (ppm*)
Lead	0.011
Magnesium	0.391
Mercury	0.004
Molybdenum	0.001
Nickel	0.050
Platinum	0.299
Selenium	0.069
Silver	0.001
Tin	0.004
Titanium	0.033
Vanadium	0.310
Zinc	0.034

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

7.7 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 anesthetist recommend for you before the surgery.

7.8 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.

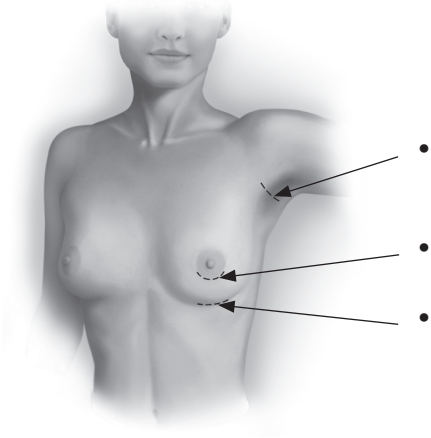


Figure 6
Incision sites for
Breast Augmentation Surgery

- 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.

7.9 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.

7.10 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 7 compares the pros and cons of immediate and delayed breast reconstruction.

Table 7
Comparison of Immediate and Delayed Breast Reconstruction with Implants – Pros and Cons of Each

Timing	Pros	Cons
Immediate	• Mastectomy and first stage of reconstruction accomplished with one surgery • Uses one incision • Typically fewer hospital days overall • Costs may be lower	• If follow-up chemotherapy or radiation is needed, may increase risk of complications (capsular contracture, implant extrusion, necrosis) • Initial operative time may be longer • Initial recovery time may be longer
Delayed	• Gives you plenty of time to decide if reconstruction with implants is right for you • 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)	• Adds at least one additional surgery • May mean an additional scar • Costs may be higher

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

7.11 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.

7.12 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.)

8. CARING FOR YOURSELF AFTER BREAST IMPLANT SURGERY

How you feel after your surgery and the level of care you need in the first few days vary from patient to patient and depend on the extent of your surgery (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.

8.1 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.

8.2 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.

8.3 Caring for Yourself in the Months and Years After Surgery

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

Mammograms

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

Other Breast Exams

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

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

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

Protecting Your Implants

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

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

Things to Call Your Doctor About Right Away

Call your doctor immediately if you have:

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

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

Physical Limitations

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

8.4 Monitoring Your Implants for Rupture

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

Detecting Rupture

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

If your implant(s) ruptures, you may experience certain symptoms. Any of the following may indicate that your implant has ruptured: hard knots or lumps surrounding the implant or in the armpit, changes in breast size or shape, pain, tingling, swelling, numbness, burning, and/or hardening of the breast.[75]

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.

Recommended Imaging Schedule for Implant RUPTURE Surveillance

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

It is recommended that you have periodic imaging (ultrasound or magnetic resonance imaging (MRI)) of your silicone gel-filled breast implants to screen for implant rupture regardless of whether your implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on your medical history or circumstances (i.e., screening mammography for breast cancer, please refer to the Mammograms section above for additional information). Even if you have no symptoms, you should have your first ultrasound or MRI at 5-6 years after your initial implant surgery and then every 2-3 years thereafter. If you have symptoms at any time or uncertain ultrasound results for breast implant rupture, an MRI is recommended.

What to Do if You Suspect an Implant Rupture

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

What to Do if the Implant Rupture Is Confirmed

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

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

9. MENTOR'S CLINICAL STUDY RESULTS

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

9.1 Overview of the Study

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

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

Assessment of the safety of the MemoryGel™ Breast Implants was based on the incidence of complications, including device failures. Effectiveness was assessed based on changes in bra size, chest circumference, patient satisfaction, and measures of quality of life. Several

scales and questionnaires about these topics were used to collect information for analysis, including a global satisfaction question, the Rosenberg Self-Esteem Scale, the Body Esteem Scale, the 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**.

9.2 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.

9.3 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, 6, 8 and 10 years after their surgery).

Primary Reconstruction Patients

Most primary reconstruction patients were pleased with the results of their implant surgery through 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 revision-reconstruction.

9.4 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 6 years are presented in Table 8. The most common reported complication within the first 10 years after primary reconstruction surgery was reoperation (49% or approximately 49 out of 100).

Table 8
Complication Rates for Primary Reconstruction Patients, N=251 Patients

Key Complications[1]		%		
		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[2]	Initial MRI Cohort[3]	0.8	6.9	32.7
	Supplemental MRI Cohort[3]	N/A	16.1	36.1
Capsular Contracture Baker Grade III, IV		8.4	13.7	20.5
Infection		5.3	5.8	5.8
Other Complications ≥ 1% at 10 years				
Other Complications[4]		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

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

[2] These estimated rates were determined through use of Kaplan-Meier methodology, which attempts to take loss of patients to follow-up 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.

[3] Two groups of patients underwent MRI screening for rupture. One group of patients, identified as the Initial MRI Cohort, was scheduled to receive MRI exams at 1, 2, 4, 6, 8 and 10 years post implantation. As there was no MRI

exam scheduled at 3 years, 2 year rupture data is provided in this table. The second group of patients, identified as the Supplemental MRI Cohort, was scheduled to receive MRI exams at 8 and 10 years post implantation. A small portion of the patients in the Supplemental MRI Cohort who had not yet reached their 6-year follow up visit also had an MRI at the 6-year post implantation timepoint. As the 6-year MRI data is the first available for the Supplemental MRI Cohort, rupture data is not available (N/A) at 3 years for this cohort.

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

Revision-Reconstruction

The complications observed in women who had revision-reconstruction through 10 years are presented in Table 9. The most common reported complication within the first 10 years after revision-reconstruction surgery was reoperation (51% or approximately 51 out of 100).

Table 9
Complication Rates for Revision-Reconstruction Patients, N=60 Patients

Key Complications[1]		% through 3 years	% through 6 years	% through 10 years
Any Reoperation		28.3	35	50.7
Rupture[2]	Initial MRI Cohort[3]	0	4.6	38.7
	Supplemental MRI Cohort[3]	N/A	5.6	43.9
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
Other Complications ≥ 1% at 10 years				
Capsular Contracture Baker Grade III		15.4	19	32.8
Other Complications[4]		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	7
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

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

severe allergic reaction, silicone in lymph node, stillborn delivery, suicide, suspected new cancer.

[2] These estimated rates were determined through use of Kaplan-Meier methodology, which attempts to take loss of patients to follow-up 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.

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

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

9.5 What Were the Main Reasons for Reoperation?

Patients may require a reoperation for a number of reasons, including size and/or style change, implant removal (with or without replacement), capsular contracture procedures, incision and drainage, implant repositioning, scar revision, etc. In addition, patients 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™ 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 10 provides the main reasons for reoperation. The most common reason for reoperation in these patients was asymmetry.

Table 10
Main Reasons for Reoperation in Primary Reconstruction Patients

Primary Reason for Reoperation	N=157 Reoperations[1] 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)

Table 10 *Continued on next page*

Table 10 *Continued*

Primary Reason for Reoperation	N=157 Reoperations[1] n (%)		
	through 3 years	through 6 years	through 10 years
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)

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

Revision-Reconstruction

In Mentor's MemoryGel™ 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 11 provides the main reasons for reoperation. The most common reason for reoperation was capsular contracture Baker Grade III/IV.

Table 11
Main Reasons for Reoperation in Revision-Reconstruction Patients

Primary Reason for Reoperation	N=47 Reoperations[1] 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)

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

9.6 What Were the Main Reasons for Implant Removal?

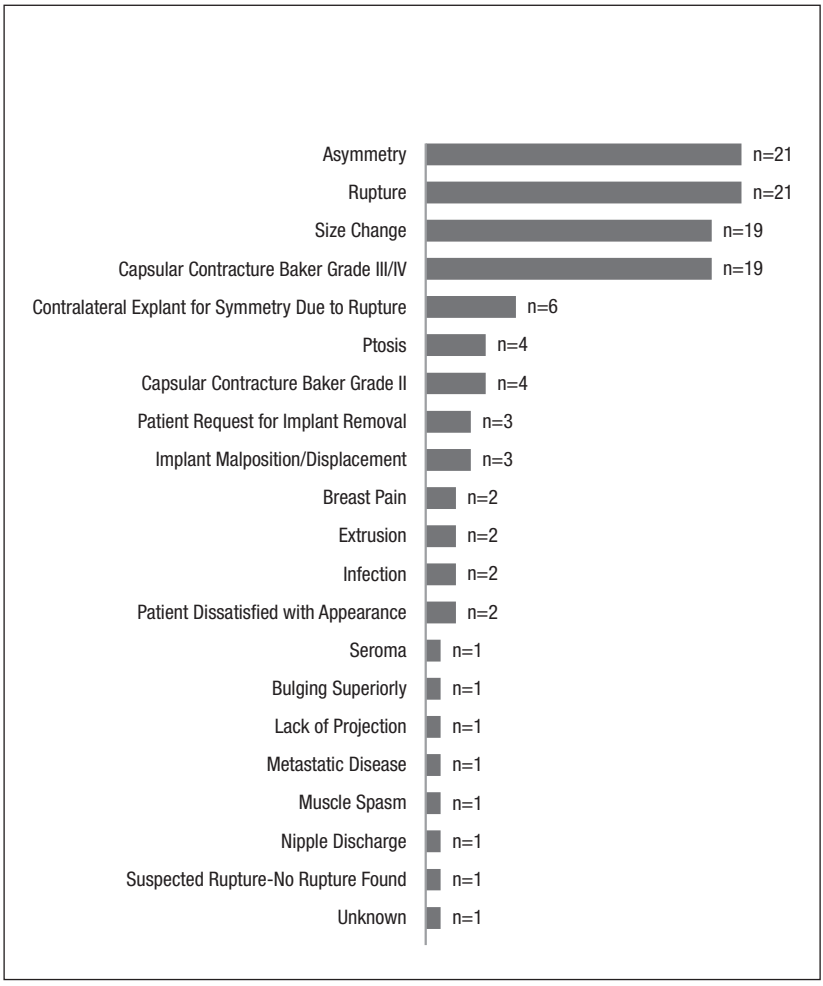
Breast implants may be removed (with or without replacement) in response to a complication or to improve the cosmetic result.

Primary Reconstruction

The main reasons for implant removal among primary reconstruction patients in the MemoryGel™ 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 reasons for implant removal were asymmetry and rupture (each accounting for 21 of the 116 implants removed).

Figure 7

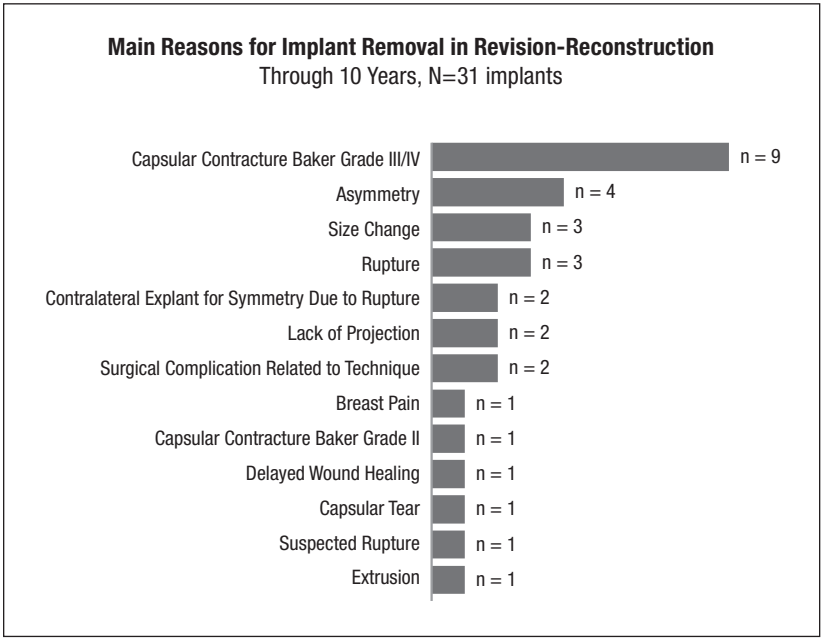
Main Reasons for Implant Removal in Primary Reconstruction
Through 10 Years, N=116 implants



Revision-Reconstruction

The main reasons for implant removal among revision-reconstruction patients in the MemoryGel™ Core Study through 10 years are shown in Figure 8 below. There were a total of 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



9.7 What Were Other Clinical Data Findings?

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

Rupture

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

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

Primary 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 12 below summarizes the Kaplan-Meier estimated cumulative incidence rates through 10-years for suspected or confirmed (combined) versus confirmed ruptures at the patient and the implant level for the Initial MRI Cohort Primary 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 12
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%)*	
Suspected or Confirmed	Kaplan-Meier estimated rate	*Suspected or Confirmed*	Kaplan-Meier estimated rate
25 patients	32.7%	18 patients	36.1%
29 implants	24.3%	21 implants	28.1%
Confirmed		*Confirmed*	
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 13 below summarizes the Kaplan-Meier estimated cumulative incidence rates through 10-years for suspected or confirmed (combined) versus confirmed ruptures at the patient and the implant level for the Initial MRI Cohort Revision-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 13
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%)*	
Suspected or Confirmed 6 patients 6 implants	Kaplan-Meier estimated rate 38.8% 25.8%	*Suspected or Confirmed* 6 patients 8 implants	Kaplan-Meier estimated rate 43.9% 44.4%
Confirmed 3 patients 3 implants	 17.7% 12.3%	*Confirmed* 3 patients 4 implants	 23.6% 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 14 reflect the number of suspected or confirmed ruptures in a patient group divided by the number of patients enrolled in that group. The overall occurrence is likely underestimated due to some patients not returning for follow-up and therefore possibly not reporting a rupture. The estimated Kaplan-Meier rates of suspected or confirmed rupture through 1, 2, 4, 6, 8, and 10 years are also presented in Table 14 for the Primary Reconstruction and Revision-Reconstruction patients in the Initial and Supplemental MRI cohorts. The estimated Kaplan-Meier complication rates attempt to account for patients not returning for follow-up and adjust the estimated rupture rates accordingly. Note that all ruptures presented in Table 14 include those caused by iatrogenic damage (damage caused by a surgical instrument upon implantation or removal of the device) and non-iatrogenic damage (ruptures resultant from device failure).

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

Indication (N Enrolled Initial + Supplemental MRI Cohort)	Overall Occurrence of Rupture 10 Years n (%)[a]	Estimated (Kaplan-Meier) Complication Rates for Suspected or Confirmed Rupture						
		Cohort (N Enrolled)	1 Year	2 Years	4 Years	6 Years	8 Years	10 Years
Primary Reconstruction (N=251)	**43 (17.1%)[b]**	**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%)[c]**	**Initial MRI** (N=28)	0%	0%	0%	4.6%	15.8%	38.8%
		Supplemental MRI (N=32)	-	-	-	5.6%	11.9%	43.9%

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

[b] 11 patients with suspected but not confirmed ruptures. 1 patient symptomatic.

[c] 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.[1,77] 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%) patients 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.

10. WHAT TO DO IF YOU HAVE A PROBLEM

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

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(Write your doctor's contact information here)

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

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

a) Complete Form 3500 and submit it online at **https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm**
b) 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
c) Call the FDA to get a reporting package at 1-800-FDA-1088 (1-800-332-1088).

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

11. WHERE TO FIND MORE INFORMATION

Safety information available on website:

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

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

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

Mentor has more information about its MemoryGel™ Breast Implants and MemoryGel™ Xtra Breast Implants that are available to you. You may request a copy of the package insert given to surgeons that describes how to use the MemoryGel™ Breast 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 about breast implants on FDA's website, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P030053. This site includes links to Mentor's studies (in animals and humans or other laboratory testing) done on MemoryGel™® Breast Implants in Mentor's Summary of Safety and Effectiveness Document (SSED)

There are several other sources of information about breast implants and breast implant surgery. Professional organizations for surgeons offer helpful information on their websites about making decisions about plastic/cosmetic surgery and about choosing a surgeon. You can find this information at the following websites:

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

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

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

12. MENTOR'S IMPLANT TRACKING PROGRAM

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

12.1 Breast Implant Tracking

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

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

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

12.2 Implant ID Card

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

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

If you have your breast implants replaced, you will get a new Implant ID Card for those implants. Your doctor should keep a copy of the Implant ID Card with your medical records.

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

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

13. IMPORTANT CONTACT INFORMATION

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

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

www.mentorwwllc.com

Your surgeon's name and contact information:

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14. WARRANTY INFORMATION

Mentor's Lifetime Product Replacement Policy and Advantage Limited Warranties provide limited replacement and limited financial reimbursement in the event of shell leakage or breakage resulting in breast implant rupture. 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.mentorwwllc.com**

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

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

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

16. PATIENT DECISION CHECKLIST:

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

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

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

Considerations for a Candidate for Successful Breast Implantation

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

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

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

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

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

- Autoimmune disease (e.g.,Hashimoto's, Lupus, Rheumatoid Arthritis) or family history of autoimmune disease (breast implant premarket clinical studies have not evaluated the safety of breast implants in patients with autoimmune disease);

- linical diagnosis of depression or other mental health disorder (including body dysmorphic disorder or eating disorder); or
- Have other products permanently implanted in the breast.

Patient Initials: _____

Risks of Breast Implant Surgery

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

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

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

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

Patient Initials: _____

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

I understand that breast implants are associated with the development of a type of cancer of the immune system called Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA- ALCL). Information regarding the number of medical device reports of BIA-ALCL can be found on FDA's website (See "Medical Device Reports of Breast Implant-Associated Anaplastic Large Cell Lymphoma," available at https://www.fda.gov/medical-devices/breast-implants/medical-device-reports-breast-implant-associated-anaplastic-large-cell-lymphoma).

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

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

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

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

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

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

Patient Initials: _____

Systemic Symptoms

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

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

Patient Initials: _____

Breast-Implant Specific Risks

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

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

I understand that my breast implant may rupture or leak at any time, and that the longer I have my implants, the more likely I am to experience a complication such as rupture. I understand that gel bleed (small quantities of chemicals diffusing from the implant shell) of silicone gel-filled implants may occur. I understand that if I have a saline-filled implant, my breast may deflate in appearance if there is a rupture or leakage of the saline.

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

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

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

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

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

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

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

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

Patient Initials: _____

Recommended Follow-up

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

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

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

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

Patient Initials: _____

Questions for My Physician

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

Patient Initials: _____

Options Following Mastectomy

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

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

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

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

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

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

Patient Initials: _____

Breast Augmentation Options

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

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

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

Patient Initials: _____

CONFIRMATION OF DISCUSSION OF RISKS

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

_____

Printed Name

_____

Patient Signature and Date

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

_____

Printed Name

_____

Physician Signature and Date

17. INDEX

18. REFERENCES

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