Patient Educational Brochure

AUGMENTATION

Breast Augmentation with

MENTOR® MemoryGel™ Silicone Gel Breast Implants

MENTOR®

Make life more beautiful™

PATIENT EDUCATIONAL BROCHURE

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BREAST AUGMENTATION WITH MENTOR® MEMORYGEL™ SILICONE GEL BREAST IMPLANTS

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TABLE OF CONTENTS

GLOSSARY

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

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

Contraindication	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.
Delayed Wound Healing	Unusually slow progress in the healing of a wound; surgical incision site fails to heal normally or takes longer to heal.
Displacement	Movement (shifting) of the implant from the usual or proper place.
Extracapsular Rupture	A type of rupture in which the silicone gel is outside of the scar capsule surrounding the breast implant (see Rupture).
Extrusion	Skin breakdown with the implant pressing through the skin or surgical incision.
Fibrocystic Breast Disease	Common, benign (noncancerous) changes in the tissues of the breast. The term "disease" is misleading, and many doctors prefer the term "change." The condition is so commonly found in breasts, it is believed to be a variation of normal. Other related terms include "mammary dysplasia," "benign breast disease," and "diffuse cystic mastopathy."
Fibromyalgia	A chronic condition characterized by widespread pain in muscles and joints. It may include fatigue, difficulty sleeping, and morning stiffness.
Fibrous Tissues	Connective tissue composed mostly of fibers (for example, tendons).
Gel Bleed/Gel Diffusion	When silicone gel leaks or "bleeds" or "diffuses" through the implant shell.
Granuloma	Noncancerous lumps that can form around foreign material, such as silicone. Like any lump, it should be evaluated to distinguish it from a lump that might be cancerous.
Groin	The fold where the lower abdomen meets the inner part of the thigh.
Hematoma	A collection of blood inside the body, for example in skin tissue or other body space.
Hypertrophic Scarring	An enlarged scar that remains after a wound heals.
Infection	The growth in the human body of microorganisms such as bacteria, viruses or fungi. An infection can occur as a result of any surgery.

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

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

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

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

1. HOW TO USE THIS EDUCATIONAL BROCHURE

Mentor, the company that sells MemoryGel™ Breast Implants, has designed this educational brochure to help you understand breast augmentation and to help you talk with your doctor(s) about breast augmentation. Mentor sponsored a large clinical study of these breast implants (also referred to in this brochure as the "MemoryGel™ Breast Implant Core Study") that gathered data about these breast implants. There are 1,008 patients participating in the MemoryGel™ Breast Implant Core Study. A total of 552 patients had primary-augmentation, 145 patients had revision-augmentation, 251 patients had primary-reconstruction, and 60 patients had revision-reconstruction with MENTOR® MemoryGel™ Breast Implants. Results from this study are presented in Section 8 of this brochure.

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

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

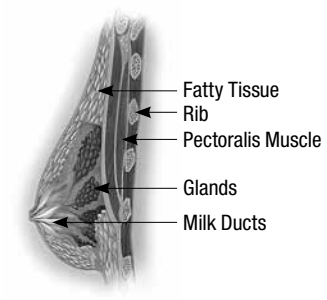
2. GENERAL INFORMATION ABOUT BREAST AUGMENTATION WITH BREAST IMPLANTS

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

2.1 What Gives the Breast Its Shape?

As shown in Figure 1, your breast consists of milk ducts, glands, blood vessels, and nerves that are surrounded by fatty tissue. Glandular tissue is firm and gives the breast its shape. The fatty tissue gives the breast its soft feel. The chest muscle (the pectoralis major muscle) is located underneath all this breast tissue but does not have much effect on the shape or feel of the breast.

Figure 1.
Anatomy of the Breast



2.2 What Is a Silicone Gel Breast Implant?

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

MENTOR® MemoryGel™ Breast Implants 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. More information on the types of MemoryGel™ Breast Implants can be found in Section 6.3 (*Choosing the Right Implant for You*).

2.3 How Do Breast Implants Work in Breast Augmentation?

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

3. DECIDING WHETHER TO HAVE BREAST AUGMENTATION SURGERY WITH IMPLANTS

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

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

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

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

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

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

3.2 Contraindications

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

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

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

Surgery in general is not recommended in patients with an active infection, existing cancer or pre-cancer and existing pregnancy (unless the surgery is to treat the infection, cancer or pregnancy as recommended by your doctor), as it may interfere with the treatment of the infection or the cancer and safety of the pregnancy/nursing. In addition, these conditions may interfere with the healing after surgery.

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

3.3 Precautions

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

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

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

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

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

3.4 Warnings

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

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

WARNING – The following is a list of possible complications associated with breast implant surgery. Make sure you read and understand these before deciding whether to have breast implant surgery. Please refer to the following sections in this brochure for more detail on these factors: Section 4 - *RISKS ASSOCIATED WITH BREAST IMPLANTS*, Section 7 - *CARING FOR YOURSELF AFTER BREAST IMPLANT SURGERY* and Section 8 - *MENTOR'S CLINICAL STUDY RESULTS*.

- Breast implants are not expected to last for the rest of your life, and breast implantation may not be a one-time surgery. It is likely that you will need other surgery related to your breast implants over the course of your life. These additional surgeries can include implant removal with or without replacement, or they can include other surgical procedures.
- Many of the changes to your breast that may occur as a result of breast implant surgery will be permanent and cannot be undone. If you have your implants removed, your skin may be permanently dimpled, puckered, or wrinkled.
- Breast implants may interfere with your ability to produce milk (lactate) for breastfeeding. If you are planning to breastfeed your infant, be prepared to use formula and bottle-feed your baby in the event you have difficulty breastfeeding.
- 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 an MRI examination. An MRI is similar to using x-ray imaging but an MRI machine uses magnetism and not x-ray radiation. Because silent ruptures can occur and because they are difficult to detect, you should have an MRI 3 years after your breast implant surgery and then every 2 years after that for as long as you have your breast implants.

- Routine self-examination of your breasts may be more difficult with implants. However, you should still perform an examination of your breasts every month for cancer screening. Ask your surgeon to help you distinguish the implant from your breast tissue. You should perform an examination of your breasts for the presence of lumps, swelling, hardening, or change in implant shape, which may be signs of rupture of the implant. Report any of these symptoms or persistent pain to your doctor. Your surgeon may recommend an evaluation via MRI to check for rupture.
- After undergoing breast augmentation surgery, you may experience changes in your healthcare insurance. Your health insurance premiums may increase; your coverage may be dropped or discontinued; you may not be able to get health insurance coverage in the future; and/or insurance may not cover treatment of complications associated with your breast implants. Be sure to check with your insurance company about these potential issues and understand the complete extent of your health coverage before having breast augmentation with implants.
- Capsular contracture is not to be treated by closed capsulotomy or forceful external compression, which will likely result in implant damage, rupture, folds, and/or hematoma.

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

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

- Electing to have no surgery,
- Wearing a padded bra or external prosthesis,
- Having a breast lift surgery (mastopexy) without implant(s),
- Having breast augmentation with saline-filled implants, or
- Having fat injection(s).

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

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

4. RISKS ASSOCIATED WITH BREAST IMPLANTS

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

Tables 1 and 2 below present the potential risks associated with breast implant surgery, the likelihood of the risks based on the results from Mentor's MemoryGel™ Breast Implant Core Study through 6 years, as well as the possible effects of the events for primary and revision-augmentation patients.

Table 1.
Potential Risks Associated with Primary Breast Augmentation

Event	Likelihood of the Event Occurring[1] Through 6 Years	Possible Resulting Effects of the Event
Key Complications		
Capsular Contracture Baker Grade III/IV	10 out of 100 patients (10%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Infection	2 out of 100 patients (2%)	• Redness or rash • Pain or tenderness • Swelling • Fever • Reoperation • Implant removal
Implant Removal with or without Replacement	7 out of 100 patients (7%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Implant Removal with Replacement with Study Device	4 out of 100 patients (4%)	
Any Reoperation	19 out of 100 patients (19%)	
Implant Rupture[2]	3 out of 100 patients (3%)	• Implant removal
Other Complications ≥ 1%		
Nipple Sensation Changes[3]	12 out of 100 patients (12%)	• Increased or decreased nipple sensitivity • Breastfeeding difficulties • May affect sexual response
Hypertrophic Scarring (irregular, raised scar)	7 out of 100 patients (7%)	• Scar revision procedure (reoperation) • Undesirable cosmetic result
Ptosis (sagging)	6 out of 100 patients (6%)	• Undesirable cosmetic result • Wrinkling/Rippling • Reoperation • Implant removal
Breast Mass	5 out of 100 patients (5%)	• Pain or discomfort • Reoperation or other procedures
Miscarriage	3 out of 100 patients (3%)	• Pain or discomfort

Table 1. *Continued on next page*

Table 1. *(Continued)*

Event	Likelihood of the Event Occurring[1] Through 6 Years	Possible Resulting Effects of the Event
Other Complications ≥ 1%		
Hematoma	3 out of 100 patients (3%)	• Swelling and bruising • Pain or discomfort • Infection • Incision and drainage (reoperation) • Implant removal
Breast Sensation Changes[3]	3 out of 100 patients (3%)	• Increased or decreased breast sensitivity
Breast Pain[3]	2 out of 100 patients (2%)	• Resulting effects are contingent on underlying cause(s)
Lactation Difficulties	2 out of 100 patients (2%)	• Painful breastfeeding • Inability to successfully breastfeed
Capsular Contracture Baker Grade II with Surgical Intervention	2 out of 100 patients (2%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
New Diagnosis of Rheumatic Disease	1 out of 100 patients (1%)	• Pain or discomfort
Seroma	1 out of 100 patients (1%)	• Swelling and bruising • Pain or discomfort • Infection • Incision and drainage (reoperation) • Implant removal
Wrinkling[3]	1 out of 100 patients (1%)	• Discomfort • Undesirable cosmetic result • Reoperation • Implant removal

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

[2] MRI cohort; MRI screening for silent rupture is scheduled at 1, 2, 4, and 6 years (results provided in Table 10).

[3] Mild occurrences not included.

Table 2.
Potential Risks Associated with Revision-Augmentation

Event	Likelihood of the Event Occurring[1] Through 6 Years	Possible Resulting Effects of the Event
Key Complications		
Capsular Contracture Baker Grade III/IV	22 out of 100 patients (22%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Infection	1 out of 100 patients (1%)	• Redness or rash • Pain or tenderness • Swelling • Fever • Reoperation • Implant removal
Implant Removal with or without Replacement	18 out of 100 patients (18%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Implant Removal with Replacement with Study Device	9 out of 100 patients (9%)	
Any Reoperation	33 out of 100 patients (33%)	
Implant Rupture[2]	7 out of 100 patients (7%)	• Implant removal
Other Complications ≥1%		
Nipple Sensation Changes[3]	13 out of 100 patients (13%)	• Increased or decreased nipple sensitivity • Breastfeeding difficulties • May affect sexual response
Hypertrophic Scarring (irregular raised scar)	8 out of 100 patients (8%)	• Scar revision procedure (reoperation) • Undesirable cosmetic result
Breast Mass	6 out of 100 patients (6%)	• Pain or discomfort • Reoperation or other procedures
Capsular Contracture Baker Grade II with Surgical Intervention	5 out of 100 patients (5%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Hematoma	3 out of 100 patients (3%)	• Swelling and bruising • Pain or discomfort • Infection • Incision and drainage (reoperation) • Implant removal
Miscarriage	2 out of 100 patients (2%)	• Pain or discomfort

Table 2. *Continued on next page*

Table 2. *(Continued)*

Event	Likelihood of the Event Occurring[1] Through 6 Years	Possible Resulting Effects of the Event
Other Complications ≥1%		
Granuloma	2 out of 100 patients (2%)	• Pain or discomfort • Reoperation or other procedures
Delayed Wound Healing[3]	2 out of 100 patients (2%)	• Pain or discomfort • Scarring • Implant extrusion • Necrosis • Reoperation • Implant removal
Seroma	2 out of 100 patients (2%)	• Swelling and bruising • Pain or discomfort • Infection • Incision and drainage (reoperation) • Implant removal
New Diagnosis of Breast Cancer	2 out of 100 patients (2%)	• Reoperation or other procedures
New Diagnosis of Rheumatic Disease	2 out of 100 patients (2%)	• Pain or discomfort
Lactation Difficulties	2 out of 100 patients (2%)	• Painful breastfeeding • Inability to successfully breastfeed
Ptosis (sagging)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Wrinkling/Rippling • Reoperation • Implant removal
Wrinkling[3]	2 out of 100 patients (2%)	• Discomfort • Undesirable cosmetic result • Reoperation • Implant removal
Breast Pain[3]	1 out of 100 patients (1%)	• Resulting effects are contingent on underlying cause(s)
Extrusion	1 out of 100 patients (1%)	• Pain or discomfort • Scarring • Reoperation • Implant removal
Inflammation of Breast	1 out of 100 patients (1%)	• Resulting effects are contingent on underlying cause(s)

Table 2. *Continued on next page*

Table 2. *(Continued)*

Event	Likelihood of the Event Occurring[1] Through 6 Years	Possible Resulting Effects of the Event
Other Complications ≥1%		
Implant Malposition/ Displacement	1 out of 100 patients (1%)	• Undesirable cosmetic result • Asymmetry • Visibility • Reoperation • Implant removal
Breast Sensation Changes[3]	1 out of 100 patients (1%)	• Increased or decreased breast sensitivity

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

[2] MRI cohort; MRI screening for silent rupture is scheduled at 1, 2, 4, and 6 year (results provided in Table 10).

[3] Mild occurrences not included.

Using information from Mentor's MemoryGel™ Breast Implant Core Study, the risk of a patient experiencing any complication (excluding rupture) at some point through 6 years after implant surgery was calculated. Through 6 years, this risk was 44% for primary augmentation patients and 54% for revision-augmentation patients. This means that 44 out of 100 primary augmentation patients and 54 out of 100 revision-augmentation patients may experience a complication (of some kind) within 6 years after receiving implants. For additional information on events reported in the MemoryGel™ Breast Implant Core Study, please read the section of this brochure on the MemoryGel™ Breast Implant Core Study (Section 8).

Mentor will continue its MemoryGel™ Breast Implant Core Study through the end of each patient's 10-year study term. In addition, Mentor has a post approval study to address long-term outcomes in patients with MemoryGel™ Breast Implants. Mentor will update its product labeling on a regular basis with the results of these studies.

4.1 What Are the Potential Complications?

• Infection

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

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

• Hematoma or Seroma

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

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

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

• Capsular Contracture

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

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

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

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

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

The capsular contracture Baker Grade III/IV rates in Mentor's MemoryGel™ Breast Implant Core Study through 2, 4, and 6 years are presented in Table 3. The MemoryGel™ Breast Implant Core Study reported a 10% risk of experiencing Baker Grade III or IV capsular contracture for primary augmentation patients through 6 years after receiving implants. For revision-augmentation patients, the risk was 22% through 6 years. This means that 10 out of 100 primary augmentation patients and 22 out of 100 revision-augmentation patients may experience Baker Grade III or IV capsular contracture within 6 years after receiving implants.

Table 3.
Capsular Contracture Baker Grade III/IV Rates by Patient

Cohort	2 Year	4 Year	6 Year
Primary Augmentation, N=552	8.0%	9.0%	9.8%
Revision-Augmentation, N=145	18.2%	19.7%	22.1%

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

• Rupture

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

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

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

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

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

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

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

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

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

Studies on breast implants that women have had for a long time suggest that gel bleed may play a role in capsular contracture.[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).

Rupture rate information on Mentor's MemoryGel™ Breast Implants is provided in a published European study known as the U.K. Sharpe and Collis Study.[2] Silent rupture was assessed by MRI on 149 patients implanted with textured MemoryGel™ Breast Implants. The average age of the implants was approximately 10 years. The results suggest that by 13 years approximately 12% of implants will have ruptured. All ruptures were confirmed to be intracapsular. For more information on MemoryGel™ Breast Implants, refer to the MENTOR® MEMORYGEL™ BREAST IMPLANT CORE STUDY section of this brochure.

- **Reoperation**

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

The MemoryGel™ Breast Implant Core Study reported a 19% risk of experiencing reoperation for primary augmentation patients through 6 years after receiving implants. This means that 19 out of 100 primary augmentation patients may experience reoperation within 6 years after receiving implants. The most common reasons for reoperation were capsular contracture Baker Grade III/IV and patient request for size/style change. For revision-augmentation patients, the risk was 33% through 6 years. This means that 33 out of 100 revision-augmentation patients may experience reoperation within 6 years after receiving implants. The most common reasons for reoperation were capsular contracture Baker Grade III/IV and breast mass. More details on reoperation from the MemoryGel™ Breast Implant Core Study are found in Section 8.5.

- **Implant Removal**

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

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

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

The MemoryGel™ Breast Implant Core Study reported a 7% risk of implant removal (including removal with replacement for a size exchange) for primary augmentation patients through 6 years. For revision-augmentation patients, the risk was 18% through 6 years. This means that 7 out of 100 primary augmentation patients may experience implant removal within 6 years after receiving implants, and 18 out of 100 revision-augmentation patients may experience implant removal within 6 years after receiving implants. More details on implant removal from the MemoryGel™ Breast Implant Core Study are found in Section 8.6.

- **Pain**

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

- **Changes in Nipple and Breast Sensation**

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

- **Cosmetic Changes**

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

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

- **Breastfeeding**

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

The Institute of Medicine (IOM) and The American College of Obstetricians and Gynecologists (ACOG) encourage women with breast implants to try breastfeeding. The IOM concluded, "Breastfeeding should be encouraged in all mothers when possible, including those with silicone breast implants. There is evidence that breast implantation may increase the risk of insufficient lactation,[11] but no evidence that this poses a hazard to the infant beyond the loss of breastfeeding itself. The evidence for the advantages of breastfeeding to infant and mother is conclusive".[9,12] The MemoryGel™ Breast Implant Core Study collected information from patients who had babies after augmentation with MemoryGel™ Breast Implants. Ten of the 61 primary augmentation patients who attempted to breastfeed following breast implant surgery experienced difficulty with breastfeeding through 6 years in Mentor's MemoryGel™ Breast Implant Core Study. Two of the 10 the revision-augmentation patients who attempted to breastfeed after receiving breast implants had difficulty. Lactation experiences from the MemoryGel™ Breast Implant Core Study are also discussed more in Section 8.7.

• Implant Extrusion

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

• Necrosis/Delayed Wound Healing

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

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

• Breast Atrophy/Chest Wall Deformity

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

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

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

• Calcium Deposits

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

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

• Enlarged Lymph Nodes

There are a large number of lymph glands in the body, but it is the lymph nodes in the armpit that drain the breast area of fluid. Some patients with breast implants have been found to have enlarged lymph nodes in the 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.

4.2 What Are Other Reported Conditions?

Mentor will continue its MemoryGel™ Breast Implant Core Study through 10 years. Mentor will update the information it publishes about its implants (including this patient brochure) with the results of this study. Contact your surgeon or Mentor (See Section 10 on Important Contact information) for updates. Some women with breast implants have reported health problems that they believe are related to their implants, although the connection between their implants and their health problems has not been proven. Examples of such health problems include autoimmune diseases or connective tissue disease, cancer, or neurological problems (problems with the brain or nerves).

Studies have not shown that breast implants can cause these conditions. Most studies suggest that there is no connection between breast implants and these medical conditions. However, you should be aware of them. It is possible that there are risks that are not known and could be associated with breast implants in the future.

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

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

- **Cancer**

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

- **Breast Cancer**

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

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.[20,28,29,30,31]

- **Brain Cancer**

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

- **Lympho-Hematopoietic Cancers**

Lympho-hematopoietic cancers are cancers that develop in the lymph nodes or certain blood cells. Lymph nodes and the affected cells are part of the body's immune system to fight infection. These kinds of cancers include non-Hodgkin's lymphoma, Hodgkin's disease, multiple myeloma, and leukemia. Although most studies have found no increased risk of these cancers for women with silicone gel breast implants,[19,21,23,26,27,28] some reports have suggested a possible association between a type of anaplastic large cell lymphoma (ALCL) and breast implants.[34]

Anaplastic Large Cell Lymphoma

Women with breast implants may have a very small, but increased risk of developing anaplastic large cell lymphoma, or ALCL, in the scar tissue and fluid adjacent to the implant. ALCL is not breast cancer—it is a rare type of non-Hodgkin's lymphoma (cancer of the immune system).

ALCL has been reported globally in patients with an implant history that includes Mentor's and other manufacturers' breast implants.

Most patients were diagnosed when they sought medical treatment for implant-related symptoms such as pain, lumps, swelling, or asymmetry that developed after their initial surgical sites were fully healed. In the cases reported, ALCL was typically diagnosed years after the implant surgery.

Your physician should consider the possibility of ALCL if, after your surgical site is fully healed, you see changes in the way the area around the implant looks or feels—including swelling or pain around the implant. If ALCL is suspected, your physician will refer you to an appropriate specialist for evaluation which may involve obtaining fluid and tissue samples from around your breast implant. If ALCL is confirmed, your physician will develop an individualized treatment plan for you. Because of the small number of cases worldwide and variety of available treatment options, there is no single defined treatment.

If you have breast implants and have no symptoms, you do not need to do anything additional, but you should continue to routinely monitor your breast implants and follow your routine medical care. Removing the implants is not recommended in women with no symptoms without a diagnosis of ALCL.

If you do not currently have breast implants but 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.

For additional and the most up-to-date information please visit: **www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm**

- **Respiratory/Lung Cancer**

Several studies have found that women with silicone gel breast implants are not at greater risk for lung cancer.[19,21,23,26,27,28] One study 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.

- **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. One study 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.[6,19,21,23,26,27,33,38]

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

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

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

Other CTDs include:

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

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

The scientific evidence strongly supports the conclusion that there is no increased risk of CTDs or autoimmune disorders for women with silicone gel breast implants.[4,5,9,38,41,42,43,44,45,46,47,48,49,50,51,52,53,54] 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.[9,55,56]

• Effects on Children Born to Mothers with Breast Implants

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

In addition, questions have been raised about whether silicone gel breast implants could harm babies whose mothers had implants while pregnant. Two studies in humans have found that the risk of birth defects overall is not increased in children born after breast implant surgery.[58,59] Although low birth weight was reported in a third study, 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.[9,10,58,59,60]

• 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.[29,61,62,63,64,65,66,67] One researcher[68] believes that some women who want cosmetic

surgery suffer from a disorder, called body dysmorphic disorder (BDD), which may cause them to think about suicide or attempt suicide.

The strongest predictor for suicide is having been hospitalized for any psychiatric condition. One study found that women with breast implants were admitted to the hospital more often because of psychiatric problems before they even had their implant surgery, compared to women who had breast reduction or to the general population.[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 found that there is not enough reliable evidence that neurological problems may be caused by or associated with breast implants.[9] Other researchers have found more evidence that silicone gel breast implants do NOT cause neurological diseases or symptoms.[9,22,69] There is one published report 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.[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.[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.[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. The overall body of available evidence supports that the extremely low level of gel bleed is of no clinical consequence.

5. BENEFITS ASSOCIATED WITH BREAST IMPLANTS

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

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

In Mentor's MemoryGel™ Breast Implant Core Study, the MemoryGel™ Breast Implants were demonstrated to be effective in increasing the size of a women's breast and most primary and revision-augmentation patients were pleased with the results of their implant surgery, with 336 (98%) of the 342 primary augmentation and 89 (99%) of the 90 revision-augmentation patients who answered the patient satisfaction question indicating they would have the breast implant surgery again. The results also showed that most women

who underwent primary augmentation with MemoryGel™ Breast Implants had improved body-image and greater self-acceptance, while those who underwent revision-augmentation experienced improved chest body-image.

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

6. PREPARING FOR BREAST AUGMENTATION WITH SILICONE GEL BREAST IMPLANTS

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

6.1 Should I Have Breast Augmentation?

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

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

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

6.2 Breast Augmentation with Implants – Understanding the Procedure

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

- The surgical setting (where the surgery will be performed, for example, in a hospital, surgery center, or doctor's office),
- The type of anesthesia used,
- The location of the incisions made to insert the breast implants,
- How the implants will be placed in your breasts (subglandular or submuscular), and
- Whether your existing skin and/or breast tissue can cover implants.

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

Surgical Setting

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

Anesthesia

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

Incision Sites

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

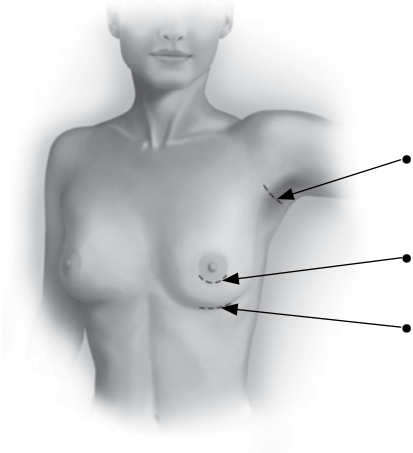


Figure 2.
Incision sites for
Breast Augmentation Surgery

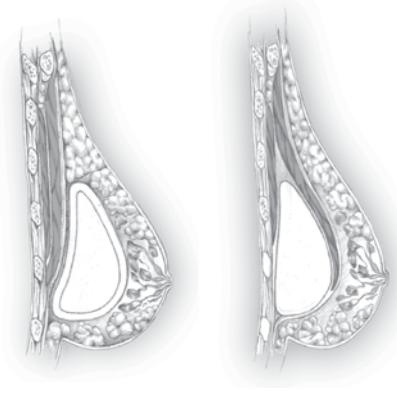
- Axillary – the incision is made in the armpit, which gives the surgeon easier access to the chest muscle,
- Periareolar – an incision is made around the nipple, and
- Inframammary – the most common incision, made under your breast at the crease where the breast meets the body.

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

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

Implant Placement

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



Subglandular Submuscular

Figure 3.
Breast Implant Placement

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

Table 4.
Comparison of Submuscular and Subglandular Placement of Breast Implants

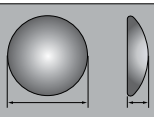
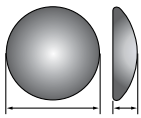
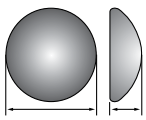
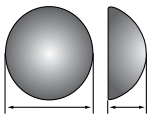
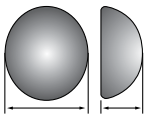
Submuscular Placement	Subglandular Placement
• Surgery time may be longer • Recovery may be longer • May be more painful • Future re-operation may be more difficult • Implants may feel more like a natural part of the breast (be less "palpable") • Capsular contracture may be less likely[7] • It may be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

6.3 Choosing the Right Implant for You

MemoryGel™ Breast Implants are available in several different shapes, profiles, and sizes to help each woman achieve the result that is best for her body.

Table 5 lists the styles of MemoryGel™ Breast Implants that are available.

Table 5.
MemoryGel™ Breast Implant Styles

 Width Profile	Breast Implant Description Size Range
	**Moderate Profile** smooth and textured shell surface 100-800 cc **Moderate Classic Profile** smooth and textured shell surface 130–800 cc
	**Moderate Plus Profile** smooth and textured shell surface 100-800 cc
	**High Profile** smooth and textured shell surface 125-800 cc
	**Ultra High Profile** smooth shell surface 135-800 cc textured shell surface 135-700 cc

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

Implant Size, Shape and Surface

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

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

6.4 Other Procedures at the Time of the Breast Augmentation

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

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

6.5 Choosing a Surgeon

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

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

7. CARING FOR YOURSELF AFTER BREAST IMPLANT SURGERY

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

7.1 Postoperative Care in the Hours and Days After Surgery

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

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

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

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

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

7.2 Postoperative Care in the First Weeks After Surgery

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

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

7.3 Caring for Yourself in the Months and Years After Surgery

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

Mammograms

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

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

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

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

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

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

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

Other Breast Exams

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

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

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

Protecting Your Implants

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

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

Things to Call Your Doctor About Right Away

Call your doctor immediately if you have:

- Signs of an infection,
- A lump,
- Skin around the nipple that has become dimpled or drawn in,
- Discharge from the nipple,
- Change in the position or shape of your implant, or
- Injury to your breast(s).

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

Physical Limitations

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

7.4 Monitoring Your Implants for Rupture

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

Detecting Rupture

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

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

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

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

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

What to Do if You Suspect an Implant Rupture

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

What to Do if the Implant Rupture Is Confirmed

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

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

8. MENTOR'S CLINICAL STUDY RESULTS

As part of the marketing approval requirements for the MemoryGel™ Breast Implants, Mentor conducted the MemoryGel™ Breast Implant 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™ Breast Implant Core Study should not be used to predict your own experience with the MemoryGel™ Breast Implants, but the information can be used as a general guide about what you may expect. Your own benefits and complications depend on many individual factors.

8.1 Overview of the Study

The MemoryGel™ Breast Implant Core Study is 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.

There are 1,008 patients participating in the MemoryGel™ Breast Implant 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 are 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 is based on the incidence of complications, including device failures. Effectiveness was assessed based on changes in bra size, chest circumference, patient satisfaction, and measures of quality of life. Several scales and questionnaires about these topics were used to collect information for analysis, including a global satisfaction question, the Rosenberg Self-Esteem Scale, the Body Esteem Scale, the Tennessee Self Concept Scale (TSCS), and the Short Form Health Survey (SF-36).

The MemoryGel™ Breast Implant Core Study will continue to follow patients through 10 years after their breast implant surgery. Results provided here represent the first 6 years of data. This brochure will be updated as more information becomes available. You should also ask your surgeon if he or she has received any updated clinical information.

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

8.2 What Are the 6-Year Follow-up Rates?

The study enrolled 552 primary augmentation patients and 145 revision augmentation patients. At the 6-year follow-up visit, data are reported for 64% of the eligible primary augmentation patients and 70% of the eligible revision-augmentation patients.

8.3 What Are the Benefits?

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

Primary Augmentation Patients

Most primary augmentation patients were pleased with the results of their implant surgery though 6 years. Three hundred and eleven out of the 552 patients enrolled were included in the analysis of cup size. Almost all (98%) had increased their bra size by at least one cup size. Three hundred and thirty-two of the 552 patients enrolled were included in the circumferential chest size analysis. The average increase in circumferential chest size was 2.9 inches (7.4 centimeters). In regards to overall satisfaction, 336 (98%) of the 342 primary augmentation patients who answered the patient satisfaction question indicated they would make the same decision to have breast surgery.

With regard to QoL measures at 6 years for primary augmentation patients, there was no significant change in the SF-36 or the total score of the TSCS. There was a significant increase in the total score and the positive attitude score for the Rosenberg Self Esteem Scale and the total score and chest and sexual attractiveness subscales for the Body Esteem Scale.

Revision-Augmentation Patients

Most revision-augmentation patients were pleased with the results of their additional implant surgery through 6 years. Bra size changes were not analyzed for revision-augmentation patients. Eighty-seven of the 145 patients enrolled were included in the circumferential chest size analysis. The average increase in circumferential chest size was 1.3 inches (3.2 centimeters). In regards to overall satisfaction, 89 (99%) of the 90 primary augmentation patients who answered the patient satisfaction question indicated they would make the same decision to have breast surgery.

With regard to QoL measures at 6 years for revision-augmentation patients, there was a significant decrease in the Mental Component Score of the SF-36, indicating a negative effect of treatment. There was a significant increase in the chest score of the Body Esteem Scale and no significant changes in the Rosenberg Self Esteem scale. For the TSCS, there was a significant decrease, suggesting a lessening in self-concept as measured by this assessment.

8.4 What Were the 6-Year Complication Rates?

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

Primary Augmentation

The complications observed in women who had primary augmentation through 6 years are presented in Table 6. The most common reported complication within the 6 years after primary augmentation surgery was reoperation (19% or approximately 19 out of 100).

Table 6.
6-Year Complication Rates for Primary Augmentation Patients, N=552 Patients

Key Complications	**%**
Capsular Contracture Baker Grade III, IV	9.8
Infection	1.6
Implant Removal with or without Replacement	6.7
Implant Removal with Replacement with Study Device	3.7
Any Reoperation	19.1
Rupture (MRI Cohort)[1]	3.4
Other Complications ≥ 1%	**%**
Nipple Sensation Changes[2]	11.8
Hypertrophic Scarring (irregular, raised scar)	6.8
Ptosis (sagging)	5.7
Breast Mass	4.7
Miscarriage	3.1
Hematoma	2.9
Breast Sensation Changes[2]	2.8
Breast Pain[2]	2.0
Lactation Difficulties	2.0
Capsular Contracture Baker Grade II with Surgical Intervention	1.5
New Diagnosis of Rheumatic Disease[3]	1.3
Seroma	1.1
Wrinkling[2]	1.1

[1] Rupture was assessed by MRI at 1, 2, 4 and 6 years (results provided in Table 10).

[2] Mild occurrences were excluded.

[3] There were 9 diagnoses for the 7 primary augmentation patients: carpal tunnel syndrome, chronic fatigue, fibromyalgia (2 cases), Hashimoto's thyroiditis, hypothyroidism, other inflammatory arthritis, systemic lupus erythematosus, and thyroiditis.

Revision-Augmentation

The complications observed in women who had revision-augmentation through 6 years are presented in Table 7. The most common reported complication within the first 6 years after revision-augmentation surgery was reoperation (33% or approximately 33 out of 100).

Table 7.
6-Year Complication Rates for Revision-Augmentation Patients, N=145 Patients

Key Complications	**%**
Capsular Contracture Baker Grade III, IV	22.1
Infection	1.4
Implant Removal with or without Replacement	17.8
Implant Removal with Replacement with Study Device	8.9
Any Reoperation	33.1
Rupture (MRI Cohort)[1]	7.2
Other Complications ≥ 1%	**%**
Nipple Sensation Changes[2]	12.9
Hypertrophic Scarring (irregular, raised scar)	7.7
Breast Mass	6.4
Capsular Contracture Baker Grade II with Surgical Intervention	5.0
Hematoma	2.8
Miscarriage	2.4
Granuloma	2.4
Wrinkling[2]	2.2
Ptosis (sagging)	2.2
Delayed Wound Healing[2]	2.1
Seroma	2.1
New Diagnosis of Breast Cancer	1.8
New Diagnosis of Rheumatic Disease[3]	1.6
Lactation Difficulties	1.5
Breast Pain[2]	1.4
Extrusion	1.4
Inflammation of Breast	1.4
Implant Malposition/Displacement	1.4
Breast Sensation Changes[2]	1.4

[1] Rupture was assessed by MRI at 1, 2, 4 and 6 years (results provided in Table 10).

[2] Mild occurrences were excluded.

[3] There were 3 diagnoses for the 3 revision-augmentation patients: celiac disease, fibromyalgia, and rheumatoid arthritis.

8.5 What Are the Main Reasons for Reoperation?

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

Primary Augmentation

In Mentor's MemoryGel™ Breast Implant Core Study, there were 141 reoperations performed in 104 patients. The risk of experiencing at least one reoperation for primary augmentation patients was 19% (approximately 19 out of 100 patients) through 6 years. Table 8 provides

the main reasons for reoperation. The two most common reasons for reoperation through 6 years in these patients were capsular contracture Baker Grade III/IV and patient requested size change.

Table 8.
Main Reasons for Reoperation in Primary Augmentation Patients

Primary Reason for Reoperation	Year 6 N=141 Reoperations[1] n (%)
Capsular Contracture Baker Grade III/IV	38 (27.0)
Size Change	17 (12.1)
Hypertrophic Scarring (irregular, raised scar)	16 (11.3)
Breast Mass	13 (9.2)
Hematoma/Seroma	12 (8.5)
Asymmetry	6 (4.3)
Capsular Contracture Baker Grade II	6 (4.3)
Implant Malposition	4 (2.8)
Ptosis (sagging)	4 (2.8)
Breast/Skin Lesions	4 (2.8)
Implant removal – patient request	3 (2.1)
Infection	3 (2.1)
Breast Pain	2 (1.4)
Calcification	2 (1.4)
Extrusion/Necrosis	2 (1.4)
Capsular Tear	1 (0.7)
Delayed Wound Healing	1 (0.7)
Drainage from Incision After Cat Scratched	1 (0.7)
Palpability	1 (0.7)
Previous Surgical Complication	1 (0.7)
Rupture	1 (0.7)
Suspected Rupture	1 (0.7)
Suture Complication	1 (0.7)
Wrinkling	1 (0.7)

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

Revision-Augmentation

In Mentor's MemoryGel™ Breast Implant Core Study, there were 72 reoperations performed in 47 revision-augmentation patients. The risk of experiencing at least one reoperation for revision-augmentation patients was 33% (approximately 33 of 100 patients) through 6 years. Table 9 provides the main reasons for reoperation. The two most common reasons for reoperation through 6 years were capsular contracture Baker Grade III/IV and breast mass.

Table 9.
Main Reasons for Reoperation in Revision-Augmentation Patients

Primary Reason for Reoperation	Year 6 N=72 Reoperations[1] n (%)
Capsular Contracture Baker Grade III/IV	20 (27.8)
Breast Mass	9 (12.5)
Size Change	7 (9.7)
Capsular Contracture Baker Grade II	5 (6.9)
Delayed Wound Healing	5 (6.9)
Hematoma/Seroma	5 (6.9)
Hypertrophic Scarring (irregular, raised scar)	3 (4.2)
Asymmetry	2 (2.8)
Breast Cancer	2 (2.8)
Extrusion	2 (2.8)
Implant Malposition/Displacement	2 (2.8)
Ptosis (sagging)	2 (2.8)
Infection	1 (1.4)
Patient Dissatisfied with Appearance	1 (1.4)
Rupture	1 (1.4)
Shape Change	1 (1.4)
Skin Lesions	1 (1.4)
Suspected Rupture	1 (1.4)
Unknown	1 (1.4)
Wrinkling	1 (1.4)

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

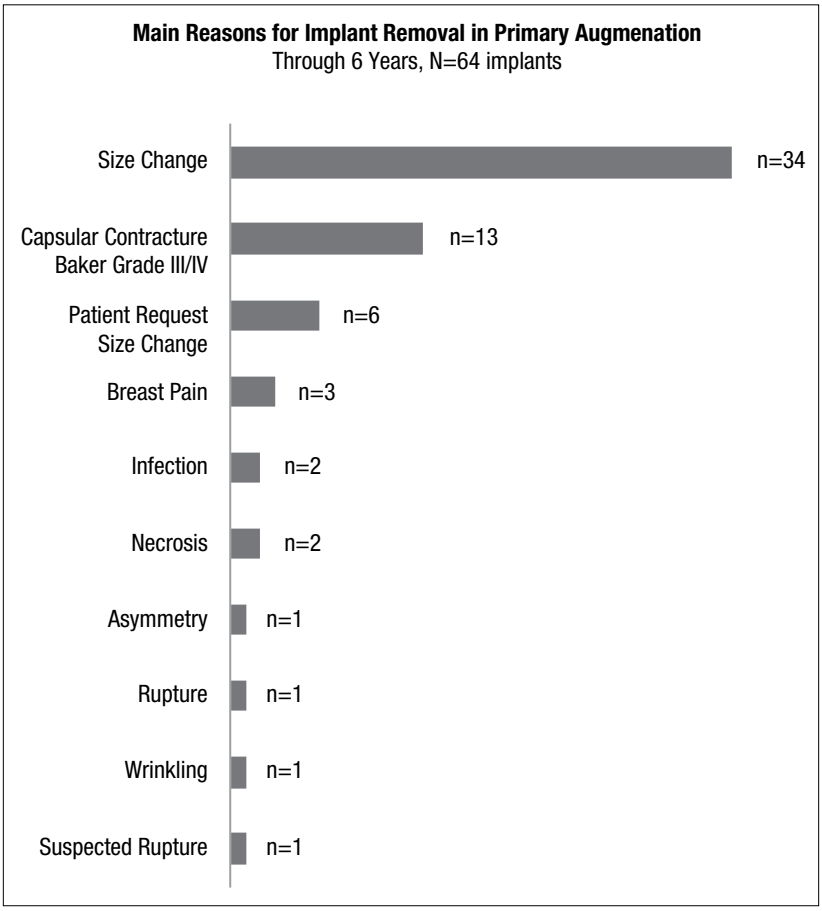
8.6 What Are the Main Reasons for Implant Removal?

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

Primary Augmentation

The main reasons for implant removal among primary augmentation patients in the MemoryGel™ Breast Implant Core Study through 6 years are shown in Figure 4. There were a total of 64 implants removed in 36 patients through 6 years. Of the 64 implants removed, 33 (52%) were replaced with a study device. The most common reason for implant removal through 6 years was patient requested size change (34 of the 64 implants removed).

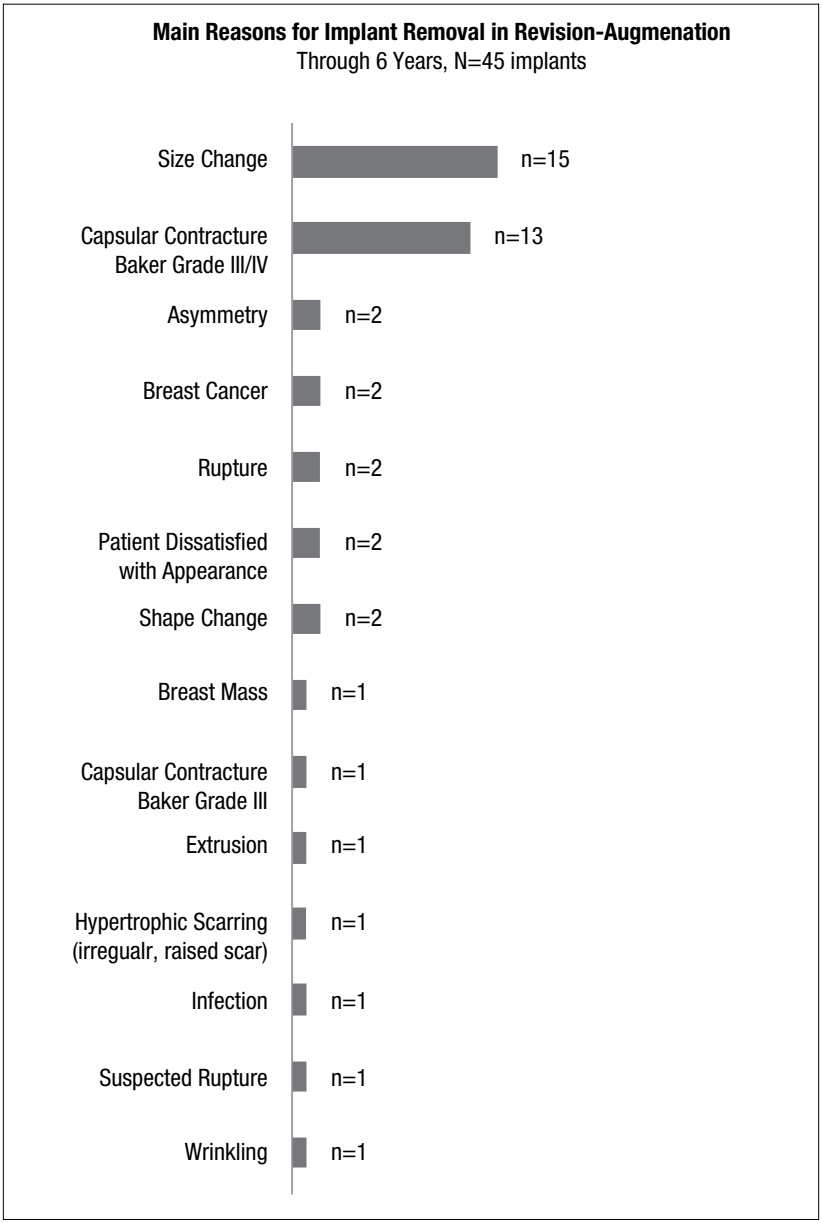
Figure 4.


Main Reasons for Implant Removal in Primary Augmenation
Through 6 Years, N=64 implants
Size Change
n=34
Capsular Contracture Baker Grade III/IV
n=13
Patient Request Size Change
n=6
Breast Pain
n=3
Infection
n=2
Necrosis
n=2
Asymmetry
n=1
Rupture
n=1
Wrinkling
n=1
Suspected Rupture
n=1

Revision-Augmentation

The main reasons for implant removal among revision augmentation patients in the MemoryGel™ Breast Implant Core Study through 6 years are shown in Figure 5. There were a total of 45 implants removed in 25 patients through 6 years. Of the 45 implants removed, 21 (47%) were replaced with a study device. The most common reason for implant removal through 6 years was patient requested size change (15 of the 45 implants removed).

Figure 5.



8.7 What Are Other Clinical Data Findings?

The MemoryGel™ Breast Implant 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. These study endpoints, along with others, are being further evaluated as part of a post approval study.

Rupture

In the MemoryGel™ Breast Implant Core Study, there are 202 primary augmentation patients and 56 revision-augmentation patients enrolled in an MRI cohort study who have routine MRI screening of their implants to track rupture (scheduled at 1, 2, 4, 6, 8, and 10 years). At 1, 2, 4, and 6 years, the overall follow-up rates for the MRI cohort across all indications were 38% (161 of 420 expected due), 78% (327 of 418 expected due), 67% (273 of 408 expected due), and 53% (217 of 406 expected due), respectively.

For primary augmentation patients in the MRI cohort, the estimated rate of suspected or confirmed rupture was approximately 3% through 6 years. This means that through 6 years, an estimated 3 of every 100 primary augmentation patients will have a ruptured breast implant. For revision-augmentation patients, the estimated rate of suspected or confirmed rupture was approximately 7% through 6 years. This means that through 6 years, an estimated 7 of every 100 revision-augmentation patients will have a ruptured breast implant. The specific estimated rates of suspected or confirmed rupture through 1, 2, 4, and 6 years are presented in Table 10.

Table 10.
Complication Rates for Rupture by Patient in MRI Cohort

Cohort	1 Year %	2 Year %	4 Year %	6 Year %
Primary Augmentation, N=202	0	0	0.7	3.4
Revision-Augmentation, N=56	0	2.0	4.3	7.2

Overall, there have been 19 suspected or confirmed ruptured implants among 16 of the patients (4 primary augmentation, 3 revision-augmentation, 8 primary reconstruction, and 1 revision-reconstruction) participating in the MRI cohort and 16 suspected or confirmed ruptured implants among 14 of the patients (2 primary augmentation, 1 revision-augmentation, 10 primary reconstruction, and 1 revision-reconstruction) participating in the non-MRI cohort. Of the 35 suspected or confirmed ruptured implants in the overall study, 4 cases were indeterminate for extracapsular silicone by MRI. There were no cases of migrated gel. The rupture rate beyond 6 years in Mentor's MemoryGel™ Breast Implant Core Study continues to be investigated.

Rupture rate information on Mentor's MemoryGel™ Breast Implants is also provided in a published European study known as the U.K. Sharpe and Collis Study.[2] Silent rupture was assessed by MRI on 149 patients implanted with textured MemoryGel™ Breast Implants. The average age of the implants was approximately 10 years. The results suggest that by 13 years approximately 12% of implants will have ruptured. All ruptures were confirmed to be intracapsular.

Cancer

There were no primary augmentation patients and 2 revision-augmentation patients with new diagnoses of breast cancer through 6 years in Mentor's MemoryGel™ Breast Implant Core Study. There were no reports of other new cancers, such as brain, respiratory, or cervical/vulvar in any cohort.

Through 6 years, there were no reports of ALCL in any patient cohort in the MemoryGel™ Breast Implant Core Study.

Connective Tissue Disease (CTD)

In the MemoryGel™ Breast Implant Core Study through 6 years, there were 7 primary augmentation patients and 3 revision-augmentation patients reported to have a new diagnosis of CTD by a rheumatologist. There were 9 diagnoses for the 7 primary augmentation patients: carpal tunnel syndrome (within 5 years), chronic fatigue (within 1 year), fibromyalgia (2 cases – within 3 and 4 years), Hashimoto's thyroiditis (within 2 years), hypothyroidism (within 2 years), other inflammatory arthritis (within 5 years), systemic lupus erythematosus (within 4 years), and thyroiditis (within 2 years). There were 3 diagnoses for the 3 revision-augmentation patients: celiac disease (within 6 years), fibromyalgia (within 3 years), and rheumatoid arthritis (within 3 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: an increase for combined pain among primary augmentation patients and an increase for joint pain and fatigue among overall patients (augmentation and reconstruction). No statistically significant differences for individual signs and symptoms were found for the revision-augmentation patients.

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

Lactation Complications

Lactation complications, including difficulties with breastfeeding, were examined in the MemoryGel™ Breast Implant Core Study. Ten of the 61 primary augmentation patients who attempted to breastfeed following breast implant surgery experienced difficulty with breastfeeding through 6 years in Mentor's MemoryGel™ Breast Implant Core Study. Two of the 10 revision-augmentation patients who attempted to breastfeed after receiving breast implants had difficulty.

Reproduction Complications

Reproduction complications that were examined in the MemoryGel™ Breast Implant Core Study include miscarriage and having a stillborn baby. Sixteen primary augmentation patients and 3 revision-augmentation patient reported a miscarriage in Mentor's MemoryGel™ Breast Implant Core Study through 6 years.

Suicide

There were no reports of suicide in primary augmentation or revision-augmentation patients in the MemoryGel™ Breast Implant Core Study through 6 years.

9. WHAT TO DO IF YOU HAVE A PROBLEM

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

_____

_____

_____

_____

_____

(Write your doctor's contact information here)

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

You can report any serious problem directly to the FDA through its voluntary reporting program called MedWatch. (See **http://www.fda.gov/medwatch**). There is a special form you must use for voluntary reporting (FDA Form 3500). You can obtain it several ways:

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

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

10. WHERE TO FIND MORE INFORMATION

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

You can find more detailed information on the studies (in animals and humans or other laboratory testing) done on MemoryGel™ Breast Implants in Mentor's Summary of Safety and Effectiveness Document (SSED) on FDA's website at: **http://www.fda.gov/breastimplants**

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

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

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

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

The American Society for Aesthetic Plastic Surgery - **http://www.surgery.org**

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

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

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

11. MENTOR'S IMPLANT TRACKING PROGRAM

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

11.1 Breast Implant Tracking

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

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

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

11.2 Device Identification Card

After your surgery, your surgeon will provide you a card that contains important information about your breast implants. This card will have the catalog and serial number of your implants, along with other information. Carry the card with you and show it to doctors or other healthcare providers when you visit them. It will help them treat you appropriately and protect your breast implants during any medical treatment you need in the future.

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

Your doctor should keep a copy of the Device Identification Card with your medical records.

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

12. IMPORTANT CONTACT INFORMATION

Your MemoryGel™ Breast Implants are manufactured and sold by:

Mentor Worldwide LLC
201 Mentor Drive
Santa Barbara, CA 93111 USA

(800) MENTOR8
www.mentorwwllc.com

Your surgeon's name and contact information:

_____

_____

_____

_____

_____

13. WARRANTY INFORMATION

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

14. ACKNOWLEDGMENT OF INFORMED DECISION

ACKNOWLEDGMENT OF INFORMED DECISION (Copy for Patient File)

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

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

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

Y/N I have had adequate time to read and fully understand the information in this brochure,

Y/N I have had an opportunity to discuss this information with my surgeon and to ask any questions I may have,

Y/N I have carefully considered options other than augmentation surgery with breast implants and have decided to proceed with silicone gel breast implant surgery,

Y/N I have been advised to wait an adequate amount of time after reviewing and considering this information before scheduling my silicone gel breast implant surgery,

Y/N I will retain this brochure, and I am aware that I may also ask my surgeon for a copy of this signed acknowledgment.

_____

Patient Name (Printed)

_____ _____

Patient Signature* Date

*A patient must be at least 22 years old for primary and revision breast augmentation with silicone gel breast implants.

By my signature below, I acknowledge that:

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

_____

Implanting Surgeon Name (Printed)

_____ _____

Implanting Surgeon Signature Date

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ACKNOWLEDGMENT OF INFORMED DECISION (Copy for Patient)

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Y/N I have been advised to wait an adequate amount of time after reviewing and considering this information before scheduling my silicone gel breast implant surgery,

Y/N I will retain this brochure, and I am aware that I may also ask my surgeon for a copy of this signed acknowledgment.

_____

Patient Name (Printed)

_____ _____

Patient Signature* Date

*A patient must be at least 22 years old for primary and revision breast augmentation with silicone gel breast implants.

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- My patient has been given an opportunity to ask any and all questions related to this brochure, or any other issues of concern;
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- This *Acknowledgment of Informed Decision* will be retained in my patient's permanent record.

_____

Implanting Surgeon Name (Printed)

_____ _____

Implanting Surgeon Signature Date

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15. INDEX

16. REFERENCES

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Saline-Filled Breast Implant Surgery:

Making an Informed Decision

Saline-Filled Breast Implant Surgery: Making an Informed Decision

Updated May 2009

Table of Contents

Page No.

GLOSSARY

Areola	The pigmented or darker colored area of skin surrounding the nipple of the breast.
Asymmetry	Lack of proportion of shape, size, and/or position between the two breasts.
Autoimmune disease	A disease in which the body mounts an "attack" response to its own tissues or cell types. Normally, the body's immune mechanism is able to distinguish clearly between what is a normal substance and what is foreign. In autoimmune diseases, this system becomes defective and mounts an attack against normal parts of the body, causing tissue injury. Certain diseases such as rheumatoid arthritis, lupus, and scleroderma are considered to be autoimmune diseases.
Axillary	Pertaining to the armpit area.
Biocompatible	The condition of being compatible with living tissues or systems without being toxic.
Biopsy	The removal and examination of tissues, cells, or fluid from the body.
Body Esteem Scale (BES)[i]	A questionnaire that which asks about a person's body image. For females, the questionnaire asks about sexual attractiveness, weight concern, and physical condition.
Breast augmentation	A surgical procedure to increase breast size. For this document, it refers to placement of a breast implant. The first time a breast implant is placed to increase breast size, it is called primary augmentation. All subsequent times the implant is replaced, it is called revision-augmentation.
Breast Evaluation Questionnaire (BEQ)[ii]	A questionnaire that asks about a person's breast satisfaction and quality of life after breast surgery. Subscales of the Breast Evaluation Questionnaire include comfort not fully dressed, comfort fully dressed, and satisfaction with breast characteristics.

Breast implant	An internal artificial device or implant intended to replace the breast.
Breast mass	A lump or body in the breast.
Breast reconstruction	A surgical procedure to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality.
Calcification	Process of hardening by calcium salts.
Capsule	Scar tissue that forms around the breast implant. Sometimes this capsule squeezes the implant, resulting in capsular contracture (below).
Capsular contracture	A tightening of the tissue capsule surrounding an implant, resulting in firmness or hardening of the breast and in squeezing of the implant if severe. Capsular contracture is classified by Baker Grades. Grades III or IV are the most severe. Grade III often results in the need for additional surgery (reoperation) because of pain and possibly abnormal appearance. Grade IV usually results in the need for additional surgery (reoperation) because of pain and unacceptable appearance. Capsular contracture II may also result in the need for additional surgery. Capsular contracture is a risk for implant rupture. Below is a description of each Baker Grade. • Grade I – Normally soft and natural appearance • Grade II – A little firm, but breast looks normal • Grade III – More firm than normal, and looks abnormal (change in shape) • Grade IV – Hard, obvious distortion, and tenderness with pain
Capsulectomy	Surgical removal of the scar tissue capsule around the implant.
Capsulorrhaphy	Surgical stitching of a tear in the scar tissue capsule around the implant.

Capsulotomy (closed)	An attempt to break the scar tissue capsule around the implant by pressing or pushing on the outside of the breast. This method does not require surgery but is a known risk for rupture of the implant and is contraindicated.
Capsulotomy (open)	Surgical incision into the scar tissue capsule around the implant.
Congenital anomaly	An abnormal development in part of the body.
Connective tissue disease/disorder (CTD)	A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc. and/or the immune system. Connective tissue diseases ("CTDs") that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma.
Contraindication	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.
Contralateral	Opposite side.
Deflation	Leakage of saline solution from the implant, often due to a valve leak or a tear or cut in the implant shell, with partial or complete collapse of the implant.
Delayed wound healing	Delayed progress in the healing of an opened wound.
Displacement	Movement of the implant from the usual or proper place.
Epidemiological	Relating to the science of explaining the relationships of factors that determine disease frequency and distribution.
Extrusion	Skin breakdown with the pressing out of the implant through the surgical wound or skin.
Fibromyalgia	A disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue.
Fibrous tissues	Connective tissues composed mostly of fibers.

Hematoma	A collection of blood within a space.
Hypertrophic scarring	An enlarged scar remaining after the healing of a wound.
Immune response	A bodily response to the presence of a foreign substance.
Infection	Invasion with microorganisms (for example, bacteria, viruses). An infection usually results in fever, swelling, redness, and/or pain.
Inflammation	The response of the body to infection or injury that is characterized by redness, swelling, warmth, pain, and/or loss of function.
Inframammary	Below the breast.
Inframammary fold	The crease at the base of the breast and the chest wall.
Inframammary incision	An incision made in the fold below the breast.
Inpatient surgery	A surgical procedure in which the patient is required to stay overnight in the hospital.
Lactation	The production and secretion of milk by the breast glands.
Malposition	Implant malposition or displacement is when the implant is not in the correct spot in the breast. This could have been due to incorrect placement of the implant during the surgery or due to shifting of the implant position over time.
Mammary	Pertaining to the breast.
Mammography	A type of X-ray examination of the breasts used for detection of cancer. A *screening* mammogram is an X-ray of the breast used to detect breast changes in women who have no signs or symptoms of breast cancer and a *diagnostic* mammogram is an X-ray of the breast that is used to check for breast cancer after a lump or other sign or symptom of breast cancer has been found.

Mammoplasty	Plastic surgery of the breast.
Mastopexy	Plastic surgery to move sagging breasts into a more elevated position.
Necrosis	Death of cells or tissues.
Outpatient surgery	A surgical procedure in which the patient is not required to stay in the hospital overnight.
Palpate	To feel with the hand.
Palpability	The ability to feel the implant.
Pectoralis	Major muscle of the chest.
Periareolar	Around the darkened or pigmented area surrounding the nipple of the breast.
Plastic surgery	Surgery intended for the improvement of appearance of the body.
Postoperatively	After surgery.
Primary breast augmentation	The first time a breast implant is placed for the purpose of breast augmentation.
Ptosis	Breast sagging that is usually the result of normal aging, pregnancy, or weight loss.
Reoperation	An additional surgery after your first breast implantation.
Revision-Augmentation	Refers to the correction or improvement of a primary augmentation. In the context of this document, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast augmentation.
Rheumatological Disease/Disorder	A variety of diseases involving connective tissue structures of he 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.

Saline	A solution that is made up of water and a small amount of salt.
Scar revision	A surgical procedure to improve the appearance of a scar.
Seroma	A build-up of the watery portion of the blood in a tissue location.
Silicone elastomer	A type of silicone that has elastic properties similar to rubber.
Subglandular placement	Placement of a breast implant underneath and within the breast glands but on top of the chest muscle.
Submuscular placement	Placement of a breast implant wholly or partially underneath the chest muscle.
Surgical incision	A cut made to body tissue during surgery.
Symptom	Any perceptible change in the body or its functions that indicates disease or a phase of a disease.
Symptomatic	Any evidence or sign of disease or disorder reported by the patient.
Systemic	Pertaining to or affecting the body as a whole.
Tennessee Self Concept Scale[iii]	A questionnaire that evaluates how the patient sees herself and what she does, likes, and feels. The scale is intended to summarize her feeling of self-worth and self-image by measuring how she feels about moral-ethical, social, personal, physical, and family, identity, behavior, and self-satisfaction.

Saline-Filled Breast Implant Surgery: Making an Informed Decision

So You're Considering Saline-Filled Breast Implant Surgery

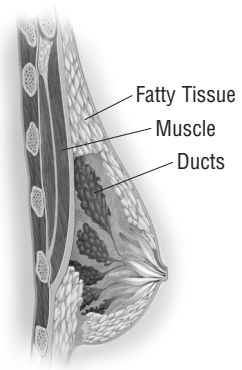
The purpose of this brochure is to help you in making an informed decision about having breast implants for augmentation (breast enlargement), reconstruction (restoration) or breast revision (replacement) surgery. This brochure is not intended to replace consultation with your surgeon. This educational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

Please read this entire brochure carefully, and if you have any questions or there are things you do not understand, please discuss them with your surgeon before making any decisions.

You should wait at least 1-2 weeks after reviewing and considering this information before deciding whether to have primary breast augmentation surgery. In the case of a revision-augmentation; however, your surgeon may find it medically necessary to perform surgery sooner.

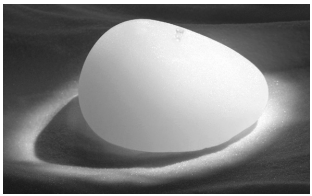
What Gives the Breast Its Shape?

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



What Is a Saline-Filled Breast Implant?

A breast implant is a sac (implant shell) of silicone elastomer (rubber), which is surgically implanted under your chest tissues, and then filled with saline, a saltwater solution, through a valve.



Are You Eligible for Saline-Filled Breast Implants?

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

- **Breast Augmentation** — This procedure is done to increase the size and proportions of a woman's breasts. **A woman must be at least 18 years old for breast augmentation.**
- **Breast Reconstruction** — This procedure is done to restore a woman's breast shape after a mastectomy or injury that resulted in either partial or total loss of the breast(s), or to correct a birth defect.

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

- Whether you are undergoing augmentation or reconstruction, be aware that breast implantation may not be a one-time surgery. You are likely to need additional surgery and surgeon visits over the course of your life.
- Breast implants are not considered lifetime devices. You will likely undergo implant removal with or without replacement over the course of your life.
- Many of the changes to your breast following implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast.
- Breast implants may affect your ability to produce milk for breast feeding. Also, breast implants will not prevent your breasts from sagging after pregnancy.
- With breast implants, routine screening mammography will be more difficult, and you will need to have additional views, which means more time and radiation.
- For patients who have undergone breast implantation either as a cosmetic or a reconstructive procedure, health insurance premiums may increase, coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. You should check with your insurance company regarding these coverage issues.

  Augmentation — Insurance does not cover breast augmentation and may not cover reoperation (additional surgery) and additional surgeon's visits following augmentation.

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

Who Is Not Eligible for Breast Implants?

Implants are not to be used for:

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

What are Contraindications, Warnings, and Precautions for You to Consider?

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

- Placement of drugs/substances inside the implant other than sterile saline
- Any contact of the implant with Betadine®*
- Injection through implant shell
- Alteration of the implant
- Stacking of implants: more than one implant per breast per breast pocket

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

- Autoimmune diseases such as lupus and scleroderma
- Conditions that interfere with wound healing and blood clotting
- A weakened immune system (for example, currently receiving immunosuppressive therapy)
- Reduced blood supply to breast tissue

*Betadine is a registered trademark of Purdue Frederick Company.

Further considerations:

- **Pre-implantation Mammography** — You may wish to undergo a preoperative mammogram and another one at 6 months to 1 year after implantation to establish a baseline.

- **Interference with Mammography** — The implant may interfere with finding breast cancer during mammography and also may make it difficult to perform mammography. Therefore, it is essential that you tell your mammography technologist that you have an implant before the procedure. The technologist can use special techniques to minimize the possibility of rupture and to get the best possible views of the breast tissue. Because the breast is squeezed during mammography, it is possible for an implant to rupture during the procedure. More x-ray views are necessary with these special techniques; therefore, women with breast implants will receive more radiation. However, the benefit of the mammogram in finding cancer outweighs the risk of the additional x-rays.
- **Distinguishing the implant from breast tissue during breast self-examination** — You should perform a breast self-examination monthly on your implanted breast. In order to do this effectively, you should ask your surgeon to help you distinguish the implant from your breast tissue. Any new lumps should be evaluated with a biopsy. If a biopsy is performed, care must be taken to avoid puncturing the implant.
- **Long-Term Effects** — Mentor studied the long-term safety and effectiveness of saline-filled breast implants for 10 years. Mentor monitored the chance of implant rupture, reoperation, implant removal, and capsular contracture (hardening of the tissues around the implant) and also conducted mechanical testing to assess the long-term likelihood of implant rupture.
- **Capsule Procedures** — You should be aware that closed capsulotomy, the practice of forcible squeezing or pressing on the fibrous capsule around the implant to break the scar capsule, is not recommended, as this may result in breakage of the implant.

What Types of Saline-Filled Breast Implants Are Available from Mentor?

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

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

Saline-Filled Breast Implant Family (fixed volume):

- Round Styles:

  Style 1600: Smooth shell surface, anterior filling valve, moderate profile

  Style 2000: Smooth shell surface, anterior filling valve, moderate plus profile

  Style 2600: Siltex®- textured shell surface, anterior filling valve, moderate profile

  Style 3000: Smooth shell surface, anterior diaphragm valve, high profile

- Contour Styles:

  Style 2700: Siltex®- textured shell surface, anterior filling valve, high profile

  Style 2900: Siltex®- textured shell surface, anterior filling valve, moderate profile

Spectrum™ Breast Implant Family (postoperative adjustment of volume):

- Round Styles:

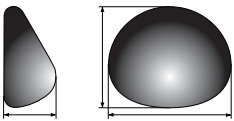
  Style 1400: Smooth shell surface, posterior filling valve

  Style 2400: Siltex® textured shell surface, posterior filling valve

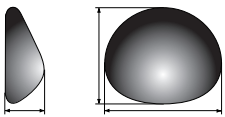
- Contour Styles:

  Style 2500: Siltex® textured shell surface, posterior filling valve, high profile

The following diagrams illustrate the high and moderate contour profiles.

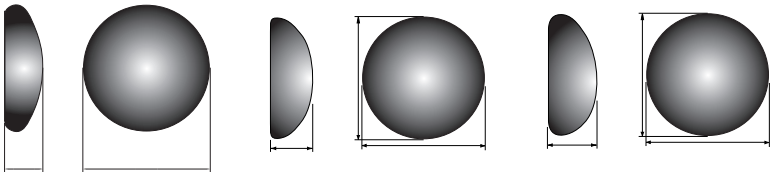


Contour, high profile



Contour, moderate profile

The following diagrams illustrate the round moderate profile, round moderate plus profile and the round high profile.



Round, moderate profile Round, moderate plus profile Round, high profile

What Are Potential Breast Implant Complications?

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

These complications include:

- **Deflation**
  Saline-filled breast implants deflate when the saline solution leaks either through an unsealed or damaged valve or through a break in the implant shell. Implant deflation can occur immediately or slowly over a period of days and is noticed by loss of size or shape of your breast. Some implants can deflate in the first few months, after several years, or at any time in between. Causes of deflation include damage by surgical instruments during surgery, overfilling or underfilling of the implant with saline solution, capsular contracture, closed capsulotomy, stresses such as trauma or intense physical manipulation, excessive compression during mammographic imaging, umbilical incision placement, and unknown/unexplained reasons. You should also be aware that the breast implant may wear out over time and deflate.

  Deflated implants require additional surgery to remove and to possibly replace the implant.
- **Capsular Contracture**
  The scar tissue or capsule that normally forms around the implant may tighten over time and squeeze/compress the implant, making it feel firm and leading to what is called capsular contracture. Capsular contracture may be more common following infection hematoma (a collection of blood), and seroma (a build-up of the water portion of the blood). It is also more common with subglandular placement (behind

the mammary gland and on top of the chest muscle). Symptoms range from mild firmness and mild discomfort to severe pain, distorted shape, palpability of the implant, and/or movement of the implant.

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

- **Pain**
  Pain of varying intensity and duration may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain associated with nerve entrapment or interference with muscle motion. You should tell your surgeon about severe pain.
- **Additional Surgeries**
  You should understand there is a high chance that you will need to have additional surgery at some point to replace or remove the implant. Also, problems such as deflation, capsular contracture, infection, shifting, and calcium deposits can require removal of the implants. Many women decide to have the implants replaced, but some women do not. If you choose not to, you may have cosmetically unacceptable dimpling and/or puckering of the breast following removal of the implant.
- **Dissatisfaction with Cosmetic Results**
  Dissatisfying results such as wrinkling, asymmetry, implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, hypertrophic (irregular, raised scar) scarring, and/or sloshing may occur. Careful surgical planning and technique can minimize but not always prevent such results.
- **Infection**
  Infection can occur with any surgery. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. Infections with an implant present are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved.

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

- **Hematoma/Seroma**
  Hematoma is a collection of blood inside a body cavity, and a seroma is a collection of the watery portion of the blood (in this case, around the implant or around the incision). Postoperative hematoma and seroma may contribute to infection and/or capsular contracture. Swelling, pain, and bruising may result. If a hematoma occurs, it will usually be soon after surgery. However, this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, large ones will require the placement of surgical drains for proper healing. A small scar can result from surgical draining. Implant deflation/rupture can occur from surgical draining if damage to the implant occurs during the draining procedure.
- **Changes in Nipple and Breast Sensation**
  Feeling in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. Changes in feeling can be temporary or permanent and may affect your sexual response or your ability to nurse a baby. (See the paragraph on breast feeding below.)
- **Breast Feeding**
  At this time it is not known if a small amount of silicone may diffuse (pass through) from the saline-filled breast implant silicone shell and may find its way into breast milk. If this occurs, it is not known what effect it may have on the nursing infant. Although there are no current methods for detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone-filled gel implants when compared to women without implants. With respect to the ability to successfully breast feed after breast implantation, one study reported up to 64% of women with implants who were unable to breast feed compared to 7% without implants. The periareolar incision site may significantly reduce the ability to successfully breast feed.
- **Calcium Deposits in the Tissue Around the Implant**
  Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish calcium deposits from cancer.
- **Delayed Wound Healing**
  In some instances, the incision site takes longer to heal than normally.
- **Extrusion**
  Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion, which is when the breast implant comes through the skin.

- **Necrosis**
  Necrosis is the formation of dead tissue around the implant. This may prevent wound healing and require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis. Factors associated with increased necrosis include infection, use of steroids in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.
- **Breast Tissue Atrophy/Chest Wall Deformity**
  The pressure of the breast implant may cause the breast tissue to thin and shrink. This can occur while implants are still in place or following implant removal without replacement.

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

- **Connective Tissue Disease (CTD)**
  Concern over the association of breast implants to the development of autoimmune or connective tissue diseases, such as lupus, scleroderma, or rheumatoid arthritis, was raised because of cases reported in the literature of small numbers of women with implants. A review of several large epidemiological studies of women with and without implants indicates that these diseases are no more common in women with implants than those in women without implants. However, a lot of women with breast implants believe that their implants caused a connective tissue disease.
- **Cancer**
  Published studies indicate that breast cancer is no more common in women with implants than those without implants.
- **Second Generation Effects**
  There have been concerns raised regarding potential damaging effects on children born of mothers with saline-filled breast implants. A review of the published literature on this issue suggests that the information is insufficient to draw definitive conclusions.

Mentor's Clinical Studies

Although you will experience your own risks (complications) and benefits following breast implant surgery, this section describes the specific complications and benefits of Mentor's saline-filled breast implants. Mentor's clinical studies indicate, for example, that while most women can expect to experience at least one complication at some point through 3 years after implant surgery, most women were satisfied with their

implants. The studies also indicate that the chance of additional surgery is 1 in 8 for augmentation patients (with implant removal and replacement as the most common type of additional surgery) and 1 in 2.5 for reconstruction patients (with the most common type of additional surgery being capsule-related). The information below provides more details about the complications and benefits you may experience.

Description of Studies

Mentor conducted clinical testing of its saline-filled breast implants to determine the short-term and most common complications, as well as benefits, of their implants. These were assessed in the following studies:

- The Large Simple Trial (LST)
- Saline Prospective Study (SPS)

The LST was designed to determine the 1-year rates of capsular contracture, infection, deflation, and implant removal. There were 2,066 augmentation patients, 104 reconstruction patients, and 215 revision patients enrolled. Of these enrolled patients, 47% returned for their 1-year visit.

The SPS was designed as a 3-year study to assess all complications with breast implants as well as patient satisfaction, body image, and self-concept. Patients were followed annually and data through 3 years are available. The SPS enrolled 1,264 augmentation patients and 428 reconstruction patients. Seventy-six (76%) percent of augmentation patients and (78%) of reconstruction patients returned for their 3-year visit. The outcomes of the patients lost to follow-up are not known. The SPS results in this brochure represent data through 3 years.

After product approval, Mentor switched data collection to a post-approval study. The post-approval study involved the collection of some safety data from SPS patients through their 10-year post-implantation timepoint. The data were collected from questionnaires that were mailed out to the patients each year. The post-approval data presented includes earlier data shown in the SPS tables with new information added to it. The post-approval data are shown in the "Augmentation Results from Post-Approval Study" and "Reconstruction Results from Post-Approval Study" sections which follow:

What Were the 1-Year Complication Rates from the LST?

The table below shows the complication rates for augmentation, reconstruction and revision patients through 1 year. The rates reflect the number of patients out of 100 who experienced the listed complication. For example, 5% or 5 out of 100 augmentation patients experienced capsular contracture at some time within 1 year after implantation. However, this does not mean that 5% of the patients still have capsular contracture at 1 year.

Complications	1-Year Complication Rate*		
	Augmentation	Reconstruction	Revision
Capsular Contracture	5%	29%	15%
Implant Removal	4%	10%	6%
Implant	1%	NA	2%
Infection	1%	NA	NA

NA: Not Available or insufficient data to perform an analysis of risk of the complication.
* Data on 47% of the 2385 patients enrolled in the study.

AUGMENTATION RESULTS FROM SPS

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

The 3-year complication rates (including all levels of severity, from mild to severe) are shown from the most common to the least common in the table below. The rates reflect the number of augmentation patients out of 100 who experienced the listed complication at least once within the first 3 years after implantation. Some complications occurred more than once for some patients. The most common complication experienced within the first 3 years of implantation was wrinkling (21% or 21 patients out of 100).

Augmentation Complications	3-Year Complication Rate N=1264 Patients
Wrinkling	21%
Additional Operation (Reoperation)	13%
Loss of Nipple Sensation	10%
Capsular Contracture III/IV or grade unknown	9%
Implant Removal	8%
Asymmetry	7%
Intense Nipple Sensation	5%
Breast Pain	5%
Leakage/Deflation	3%
Implant Palpability	2%
Infection	2%
Sagging	2%
Hypertrophic Scarring	2%
Hematoma	2%

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

The following table provides a breakdown of the types of surgical procedures that were performed through the 3 years after the initial implantation. There were a total of 358 additional surgical procedures performed in 147 augmentation patients. Of these 147 patients, most reported multiple additional surgical procedures during a single reoperation. The most common type of additional surgical procedure was implant removal with replacement (32% of the 358 procedures).

Type of Additional Surgical Treatment	N=358 procedures
	%
Implant Removal with Replacement	32%
Capsule Related	22%
Scar or Wound Revision	19%
Reposition Implant	8%
Saline Adjustment	8%
Mastopexy	6%
Implant Removal without Replacement	3%
Biopsy/Cyst Removal	2%
Breast Reduction or Mastectomy	<1%%
Nipple Related	<1%%
Total	**100%**

What Were the Reasons for Implant Removal for Augmentation Patients?

The main reasons for implant removal among augmentation patients in the SPS over the 3 years are shown in the table below. There were 137 implants removed in 87 patients. Of these 137 implants, 82% were replaced. The most common reason for implant removal was patient request for a size or shape change (37% of the 137 implants removed).

Main Reason for Augmentation Implant Removal through 3 Years[1]	N=137 implants removed %
Patient Request for Size/Shape Change	5%
Leakage/Deflation	5%
Capsular Contracture	5%
Wrinkling	5%
Infection	5%
Asymmetry	4%
Hematoma/Seroma	2%
Sagging	2%
Scarring	2%
Cosmetic Revision	2%
Breast Cancer	<1%

[1]Correction to some rates reported at 3 years. Total number of implants increased by 1.

What Were the Complication Rates After Implant Replacement for Augmentation Patients?

There were 74 augmentation patients who had 120 implants removed and replaced with Mentor implants. The table below reflects the number of replaced implants (not patients) out of 100 implants associated with the listed complications within 3 years following replacement. For example, there was a reoperation in 16% or 16 out of 100 implants at some time within 3 years after replacement.

Complication Following Replacement of Augmentation Implant	3-Year Complication Rate N=120 implants
Additional Operations (Reoperation)	16%
Wrinkling	15%
Implant Removal	12%
Capsular Contracture III/IV or grade unknown	8%
Leakage/Deflation	4%
Asymmetry	4%
Breast Pain	3%
Hematoma	2%
Scarring	2%

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

Breast disease and connective tissue disease (CTD) were reported in some patients through 3 years after implantation in the SPS. Although there were 1,264 augmentation patients enrolled in the SPS, not every patient returned for each follow-up visit. Therefore, the percentage of patients with these events cannot be determined. Only the number of events can be provided. New cases of breast cancer were reported in 2 augmentation patients. The table below shows the number of reports of CTD through 3 years after implantation. Some patients may have reported more than one CTD. Confirmed reports were based on a diagnosis by a doctor. Unconfirmed reports were based on self-reports by the patients.

Number of Reports of CTD in AUGMENTATION Patients in the SPS Study		
Connective Tissue Disease	No. of Confirmed Reports	No. of Unconfirmed Reports
Osteoarthritis		1
Rheumatoid Arthritis	1	3
Arthritis (type unknown)		15
Lupus Erythematosus	1	
Total	**2**	**19[a]**
[a]2 aug pts had 2 unconfirmed CTDs		

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

What Were the Benefits from the SPS for Augmentation Patients?

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

For augmentation patients, 955 out of the original 1,264 patients (76%) still had implants and were in the study after 3 years. Of these 955 patients, 917 (96%) experienced an increase of at least one cup size at 3 years; the average increase in chest circumference was 2.8 inches. Of the 955 patients still in the study, 860 (90%) indicated being satisfied with the general appearance of their breasts, as measured by the Breast Evaluation Questionnaire (BEQ).

Most augmentation patients who still had their original implants and were still in the study at 3 years exhibited an improvement in the 2 measured subscales of the Multidimensional Body-Self Relation Questionnaire (MBSRQ) (which measures comfort with your general appearance). The Tennessee Self-Concept Scale (which measures self-concept) showed a slight increase at 3 years compared to before implantation.

AUGMENTATION RESULTS FROM POST-APPROVAL STUDY

In terms of patient accountability, of the 1,221 augmentation patients expected for follow-up at 5 years, data were collected for 5%. Of the 1,191 augmentation patients expected for follow-up at 7 years, data were collected for 50%. Of the 1,097 augmentation patients expected for follow-up at 10 years, data were collected for 60%. Please note that follow-up rate at 3 years was 76%, which makes the 3-year data more reliable than the 5-year, 7-year or 10-year data. There was some data reported for 54% of the 1,221 augmentation patients at some time from 3 to 10 years postoperatively. There was some 7-year data reported for 71% of the augmentation patients at some time from 3 to 10 years postoperatively. There was some 10-year data reported for 60% of the augmentation patients at some time from 9 to 10 years postoperatively. It is assumed that information obtained at a later time (for example, at 7 years) applies to an earlier time (for example, at 5 years), which relies on patient memory over time. This is not as reliable as information obtained at an earlier time.

The 5-year, 7-year and 10-year complication rates are shown in the table below. The rates reflect the number of augmentation patients out of 100 who experienced the listed complication at least once within the first 5 years, 7 years and 10 years after implantation. The most common complication experienced through 5 years, 7 years and 10 years of implantation was reoperation. (20% or 20 patients out of 100 at 5 years, 25% or 25 patients out of 100 at 7 years, and 36% or 36 patients out of 100 at 10 years).

Augmentation Complications	5-Year Complication Rate By Patient 5 Years	7-Year Complication Rate By Patient 7 Years	10-Year Complication Rate By Patient 10 Years
	N=1264	N=1191	N=1097
Reoperation	20%	25%	36%
Implant Removal	14%	19%	29%
Capsular Contracture III/IV or unknown	10%	11%	18%
Implant Deflation	10%	16%	25%
Breast Pain	7%	12%	25%

The reasons for reoperation through 3, 5, 7 and 10 years are shown below. The reasons for reoperation at 3 years are included below because the original labeling only reported the types of surgical procedures. While there may be some overlap of these two, they are different sets of data. An example of a type of additional surgical procedure is saline adjustment; an example of a reason for reoperation is infection. There were 255 reoperations performed in 146 patients through 3 years. There were 343 reoperations performed in 198 patients through 5 years. There were 464 reoperations in 259 patients at 7 years. There were 646 reoperations in 347 patients at 10 years. There may have been multiple reasons for one reoperation; therefore, the per-centages in the table below do not add up to 100%. The most common reason for reoperation through 5 years was patient request for size/shape change. (29% of the 343 reoperations). The most common reason for reoperation through 7 years was leakage/deflation. (28% of the 464 reoperations). The most common reason for reoperation through 10 years was leakage/deflation. (30% of the 646 reoperations). Note that the percentages are smaller for some of the reasons for reoperation because the number of reoperations has gotten bigger.

Augmentation Reason for Reoperation[1]	3-Years N=255 Reoperations	5-Years N=343 Reoperations	7-Years N=464 Reoperations	10-Years N=646 Reoperations
Patient Request for Size/Shape Change	33%	29%	24%	21%
Capsular Contracture	19%	17%	15%	13%
Leakage/Deflation[2]	14%	19%	27%	30%
Wrinkling	12%	11%	10%	9%
Asymmetry	10%	8%	6%	6%
Sagging	9%	9%	8%	6%
Hypertrophic Scarring	9%	6%	5%	3%
Hematoma/Seroma	6%	4%	3%	2%
Infection	5%	4%	3%	2%
Cosmetic Revision	5%	4%	3%	3%
Breast Mass/Tumor/Cyst Excision or Biopsy	3%	4%	5%	5%
Breast Pain	1%	1%	1%	<1%
Delayed Wound Healing	1%	1%	<1%	<1%
Irritation/Inflammation	1%	1%	<1%	<1%
Extrusion	1%	1%	<1%	<1%
Lymphadenopathy	<1%	<1%	<1%	<1%
Contralateral Replacement	0%	3%	8%	10%
Other[3]	0%	0%	0%	<1%

[1]If there was more than one reason reported per patient, all reasons are included in this table.
[2]Includes reoperations where the reason for reoperation was not reported so deflation was assigned as worst case.
[3]Includes prophylactic implant removal, allergic reaction, atypical ductal hyperplasia, sclerosing adenosis, and prophylactic mastectomy.

The primary reasons for implant removal through 5 years, 7 years and 10 years are shown below. There were 211 implants removed in 132 patients at 5 years. There were 324 implants removed in 191 patients at 7 years. There were 487 implants removed in 272 patients at 10 years. The most common reason for removal through 5 years was patient request for size/shape change (30% of the 211 implants removed). The most common reason for removal through 7 years was leakage/deflation (38% of the 324 implants removed). The most common reason for removal through 10 years was leakage/deflation (39% of the 487 implants removed). Note that the percentages are smaller for some of the reasons for removal because the number of removals has gotten bigger.

Augmentation Main Reason for Removal	5-Years N=211 Implants Removed	7-Years N=324 Implants Removed	10-Years N=487 Implants Removed
Patient Request for Size/Style Change	30%	24%	21%
Leakage/Deflation[1]	30%	38%	39%
Capsular Contracture	15%	12%	11%
Wrinkling	6%	6%	6%
Contralateral Replacement	5%	10%	13%
Infection	4%	2%	2%
Asymmetry	3%	2%	3%
Breast Mass or Cancer	2%	1%	1%
Cosmetic Revision	2%	1%	1%
Sagging	1%	1%	1%
Hematoma/Seroma	1%	1%	1%
Hypertrophic Scarring	1%	1%	<1%
Other[2]	0%	0%	<1%

[1]Includes removals where the reason for the removal was not reported so deflation was assigned as worst case.
[2]Includes prophylactic implant removal, fibroid tumors and allergic reaction.

RECONSTRUCTION RESULTS FROM SPS

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

The 3-year complication rates (including all levels of severity, from mild to severe) are shown from the most common to the least common in the table below. The rates reflect the number of reconstruction patients out of 100 who experienced the listed complication at least once within the first 3 years after implantation. Some complications occurred more than once for some patients. The most common complication experienced within the first 3 years of implantation was reoperation (40% or 40 patients out of 100).

Reconstruction Complications	3-Year Complication Rate N=416 patients
Additional Operation (Reoperation)	40%
Loss of Nipple Sensation	35%
Capsular Contracture III/IV or grade unknown	30%
Asymmetry	28%
Implant Removal	27%
Wrinkling	20%
Breast Pain	17%
Infection	9%
Leakage/Deflation	9%
Irritation/Inflammation	8%
Delayed Wound Healing	6%
Seroma	6%
Hypertrophic Scarring	5%
Extrusion	2%
Tissue/Skin Necrosis	2%
Hematoma	1%
Position Change	1%

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

The following table provides a breakdown of the types of surgical procedures that were performed through the 3 years after the initial implantation. There were a total of 353 additional surgical procedures in 149 reconstruction patients (excluding those that were planned reconstruction such as nipple reconstruction). Of these 149 patients, most reported multiple surgical procedures during a single reoperation. The most common type of additional surgical procedure was capsule related. (28% of the 353 procedures).

Type of Additional Surgical Treatment	N=353 procedures
	%
Capsule Related	28%
Implant Removal with Replacement	19%
Scar or Wound Revision	13%
Implant Removal without Replacement	11%
Nipple Related (unplanned)	8%
Saline Adjustment	7%
Reposition Implant	6%
Biopsy/Cyst Removal	<1%
Breast Reduction or Mastectomy	<1%
Mastopexy	<1%
Total	**100%**

What Were the Reasons for Implant Removal for Reconstruction Patients?

The main reasons for implant removal among reconstruction patients in the SPS over the 3 years are shown in the table below. There were 116 implants removed in 97 patients.

Of the 116 implants removed among reconstruction patients, 60% were replaced. The most common reasons for implant removal were correction of capsular contracture (30% of the 116 implants removed), and infection (24% of 116 implants removed).

Main Reason for Reconstruction Implant Removal through 3 Years[1]	N=116 implants removed
	%
Capsular Contracture	30%
Infection	24%
Leakage/Deflation	22%
Patient Request for Size/Style Change	6%
Necrosis/Extrusion	5%
Asymmetry	4%
Breast Pain	3%
Delayed Wound Healing	2%
Cosmetic Revision	1%
Wrinkling	1%
Breast Cancer	<1%

[1]Corrections to some rates reported at 3 years. Total number of implants removed did not change.

What Were the Complication Rates After Implant Replacement for Reconstruction Patients?

There were 66 reconstruction patients who had 76 implants removed and replaced with Mentor implants. The table below reflects the number of replaced implants (not patients) out of 100 implants associated with the listed complications within 3 years following replacement. For example, there was a reoperation in 31% or 31 out of 100 implants at some time within the 3 years after replacement.

Complication Following Replacement of Reconstruction Implant	3-Year Complication Rate N=76 implants
Additional Operation (Reoperation)	40%
Leakage/Deflation	35%
Implant Removal	30%
Capsular Contracture III/IV or grade unknown	28%
Asymmetry	27%
Wrinkling	20%
Breast Pain	17%
Infection	9%
Irritation/Inflammation	9%
Seroma	8%
Extrusion	6%
Hematoma	6%
Scarring	5%
Necrosis	2%

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

Breast disease and connective tissue disease (CTD) were reported in some patients through 3 years after implantation in the SPS. Although there were 416 reconstruction patients enrolled in the SPS, not every patient returned for each follow-up visit. Therefore, the percentage of patients with these events cannot be determined. Only the number of events can be provided. There were no new cases of breast disease. The table below shows the number of reports of CTD through 3 years after implantation. Some patients may have reported more than one CTD. Confirmed reports were based on a diagnosis by a doctor. Unconfirmed reports were based on self-reports by the patients.

Number of Reports of CTD in RECONSTRUCTION Patients in the SPS Study		
Connective Tissue Disease	No. of Confirmed Reports	No. of Unconfirmed Reports
Osteoarthritis	2	8
Rheumatoid Arthritis		2
Arthritis (type unknown)	1	18
Ankylosing Spondylitis	1	
Total	**4**	**28**[a]
[a]7 recon pts had 2 unconfirmed CTDs		

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

What Were the Benefits of the SPS for Reconstruction Patients?

The SPS measured a variety of outcomes that assessed the benefits of the implants. For reconstruction, these outcomes included breast size change. These outcomes were assessed before implantation and at 3 years after surgery for those patients who still had their original implants.

For reconstruction patients, 283 out of the original 416 patients (68%) still had implants and were in the study after 3 years. Of these 283 patients, the average increase in chest circumference was 1.5 inches.

RECONSTRUCTION RESULTS FROM POST-APPROVAL STUDY

In terms of patient accountability, of the 335 reconstruction patients expected for follow-up at 5 years, data were collected for 52%. Of the 309 reconstruction patients expected for follow-up at 7 years, data were collected for 71%. Of the 279 reconstruction patients expected for follow-up at 10 years, data were collected for 66%. Please note that the follow-up rate at 3-years was 78% which makes the 3-year data more reliable than the 5-year, 7-year or 10-year data. There was some 5-year data reported for 73% of the reconstruction patients at some time from 3 to 10 years postoperatively. There was some 7-year data reported for 79% of the reconstruction patients at some time from 3 to 10 years postoperatively. There was some 10-year data reported for 66% of the reconstruc-

tion patients at some time from 9 to 10 years postoperatively. It is assumed that information obtained at a later time (for example, at 7 years) applies to an earlier time (for example, at 5 years), which relies on patient memory over time. This is not as reliable as information obtained at an earlier time.

The 5-year, 7-year and 10-year complication rates are shown in the table below. The rates reflect the number of reconstruction patients out of 100 who experienced the listed complication at least once within the first 5 years, 7 years and 10 years after implantation. The most common complication experienced through 5 years was reoperation (43% or 43 patients out of 100). The most common complication experienced through 7 years was reoperation or capsular contracture (50% or 50 patients out of 100). The most common complication experienced through 10 years was capsular contracture (59% or 59 patients out of 100).

Reconstruction Complications	5-Year Complication Rate By Patient	7-Year Complication Rate By Patient	10-Year Complication Rate By Patient
	N=416	N=295	N=280
Reoperation	43%	50%	56%
Implant Removal	30%	39%	45%
Capsular Contracture III/IV or unknown	29%	49%	59%
Implant Deflation	18%	27%	33%
Breast Pain	16%	29%	37%

The reasons for reoperation through 3, 5, 7 and 10 years are shown below. The reasons for reoperation at 3 years are included below because the original labeling only reported the types of surgical procedures. While there may be some overlap of these two, they are different sets of data. An example of a type of additional surgical procedure is saline adjustment; an example of a reason for reoperation is infection. There were 209 reoperations performed in 149 patients through 3 years. There were 232 reoperations performed in 162 patients through 5 years. There were 279 reoperations performed in 185 patients through 7 years. There were 313 reoperations in 203 patients through 10 years. There may have been multiple reasons for one reoperation; therefore, the percentages in the table below do not add up to 100%. The most common reason for reoperation through 5 years was capsular contracture (29% of the 232 reoperations). The most common reason for reoperation through 7 years was capsular contracture (31% of the 279 reoperations). The most common reason

for reoperation through 10 years was capsular contracture (29% of the 313 reoperations). Note that the percentages are smaller for some of the reasons for reoperation because the number of reoperations has gotten bigger.

Reconstruction Reason for Reoperation[1]	3-Years N=209 Reoperations	5-Years N=232 Reoperations	7-Years N=279 Reoperations	10-Years N=313 Reoperations
Capsular Contracture	30%	29%	31%	29%
Asymmetry	22%	20%	17%	17%
Patient Request for Size/ Shape Change	16%	16%	15%	14%
Staged Reconstruction	16%	15%	12%	11%
Infection	16%	15%	12%	12%
Leakage/Deflation	13%	15%	19%	19%
Delayed Wound Healing	9%	8%	7%	6%
Breast Pain	8%	7%	7%	6%
Hematoma/Seroma	8%	7%	6%	5%
Hypertrophic Scarring	6%	6%	5%	5%
Wrinkling	6%	5%	5%	4%
Extrusion	4%	4%	4%	3%
Necrosis	4%	4%	3%	3%
Cosmetic Revision	4%	4%	3%	3%
Irritation/Inflammation	4%	3%	3%	3%
Breast Mass or Cancer[3]	2%	2%	2%	4%
Valve Malposition	1%	<1%	<1%	<1%
Lymphadenopathy	1%	<1%	<1%	<1%
Contralateral Replacement	0%	<1%	1%	2%
Position Change	0%	0%	<1%	1%
Other[2]	0%	0%	0%	<1%

[1]If there was more than one reason reported per patient, all reasons are included in this table. This table excludes patients in which staged reconstruction was the only reason for reoperation.
[2]Includes prophylactic implant removal and prophylactic mastectomy.
[3]Includes 1 removal of axillary lymph nodes.

The main reasons for implant removal through 5 years, 7 years and 10 years are shown below. There were 135 implants removed in 112 patients at 5 years, 180 implants removed in 142 patients at 7 years and 206 implants removed in 158 patients at 10 years. The most common reason for removal though 5 years and 7 years was capsular contracture (29% of the 135 implants removed at 5 years, and 29% of the 180 implants removed at 7 years). The most common reason for removal through 10 years was leakage/deflation. (27% of the 206 implants removed at 10 years). Note that the percentages are smaller for some of the reasons for removal because the number of removals has gotten bigger.

Reconstruction Main Reason for Removal	5-Years N=135 Implants Removed	7-Years N=180 Implants Removed	10-Years N=206 Implants Removed
Capsular Contracture	29%	29%	27%
Leakage/Deflation	25%	28%	28%
Infection	21%	16%	15%
Patient Request for Size/Shape/ Change	8%	9%	8%
Necrosis Extrusion	5%	4%	3%
Asymmetry	4%	4%	5%
Breast Pain	3%	2%	2%
Breast Mass or Cancer	1%	2%	2%
Delayed Wound Healing	1%	1%	1%
Wrinkling	1%	1%	1%
Cosmetic Revision	1%	1%	1%
Contralateral Replacement	0%	2%	2%
Position Change	0%	1%	2%
Sagging	0%	0%	1%
Hypertrophic Scarring	0%	1%	1%
Irritation/Inflammation	0%	1%	1%
Prophylactic Implant Removal	0%	0%	1%
Prophylactic Mastectomy	0%	0%	1%

Breast Augmentation Considerations
Special Considerations for Breast Augmentation

What Are the Alternatives to Breast Augmentation?

- Accept your breasts as they are
- Wear a padded bra or external prostheses
- Have mastopexy surgery (breast lift) without an implant
- Have surgery with gel-filled implants
- For revision-augmentation, alternatives may include:
  - No revision
  - Removal with or without replacement

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

What Questions Do You Ask Your Surgeon about Breast Augmentation?

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

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

Other Factors to Consider In Breast Augmentation

• ***Choosing a Surgeon***

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

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

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

- ***Implant Shape and Size***

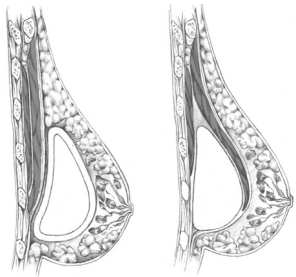
  Depending on the desired shape you wish to achieve, you and your surgeon may choose a round or contoured implant shape. Generally, the larger you want your cup size, the larger the breast implant the surgeon will consider (measured in cubic centimeters, or cc's). You should be aware that contoured implants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

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

- ***Surface Texturing***

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

- ***Palpability***
  The following may cause implants to be more palpable (more easily felt): textured implants, larger implants, subglandular placement, and the amount of skin/tissue available to cover the implant.
- ***Implant Placement***
  The breast implant can be placed either partially under the pectoralis major muscle (submuscular) or on top of the muscle and under the breast glands (subglandular). You should discuss with your surgeon the advantages and disadvantages of implant placement selected for you.

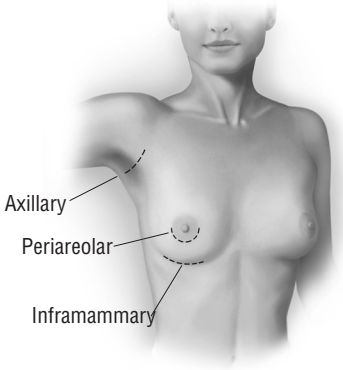
  Subglandular Submuscular

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

  The subglandular placement may make surgery and recovery shorter, may be less painful, and may be easier to access for reoperation than the submuscular placement. However, this placement may result in more palpable implants, more capsular contracture, and more difficult imaging of the breast with mammography.
- ***Incision Sites***
  To permit the smallest possible incision, the implant is typically inserted empty, and then filled with saline. You should discuss with your surgeon the pros and cons for the incision site specifically recommended for you, depending on whether you will be having augmentation or reconstruction.

  There are 3 common incision sites: under the arm (axillary), around the nipple (periareolar), or within the breast fold (inframammary). If the incision is made under the arm, the surgeon may use a probe fitted with a miniature camera, along with minimally invasive (very small) instruments, to create a “pocket” for the breast implant.
  - Periareolar - This incision is the most concealed, but is associated with a higher likelihood of inability to successfully breast feed, as compared to the other incision sites.
  - Inframammary - This incision is less concealed than periareolar and associated with less difficulty than the periareolar incision site when breast feeding.

- Axillary - This incision is less concealed than periareolar and associated with less difficulty than the periareolar incision site when breast feeding.
- Umbilical/endoscopic - This incision site has not been studied and is not recommended.



- ***Surgical Setting and Anesthesia***
  Augmentation surgery is usually performed on an outpatient basis, either in a hospital operating room, surgery center, or surgical suite in the surgeon's office. General anesthesia is commonly used, and local anesthesia is also an option. The surgery usually lasts 1 to 2 hours. Your surgeon will make an incision and create a pocket for the breast implant. Then the breast implant will be placed in the pocket, filled, and positioned. Finally, the incision will be closed, usually with stitches, and possibly taped.

Additional Procedures at the Time of Breast Augmentation

Your surgeon will examine your breasts and help you make decisions to obtain the best result in your individual situation. In some cases, particularly after pregnancy or significant weight loss, implants alone may not address all of the issues, such as sagging or extra skin, affecting your breasts. This is particularly true when there is extra skin remaining from when the breasts were engorged with milk, or when you might have been carrying more weight.

In these situations, your surgeon may recommend a breast lift (mastopexy) to remove some of the extra skin, or to lift the breasts, at the time of implant placement. Mastopexy involves removing a strip of skin from under the breast or around the nipple to lift the nipple and breast location, and tighten the skin over the breast. Your surgeon will discuss the potential risks, and the location of the additional scars which might be required to lift your breasts or to remove the extra skin.

- ***Postoperative Care***

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

Postoperative care may involve the use of a postoperative bra, compression bandage, or jog bra for extra support and positioning while you heal. At your surgeon's

recommendation, you will most likely be able to return to work within a few days, although for at least a couple of weeks you should avoid any strenuous activities that could raise your pulse and blood pressure. Your surgeon may also recommend breast massage exercises.

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

Breast Reconstruction Considerations

Special Considerations for Breast Reconstruction

Should You Have Breast Reconstruction?

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

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

What Are the Alternatives to Breast Reconstruction?

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

What Are the Choices in Reconstructive Procedures?

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

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

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

Reconstruction Incision Sites

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

Surgical Settings and Anesthesia

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

Breast Reconstruction with Breast Implants

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

The Timing of Your Breast Implant Reconstruction

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

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

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

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

Surgical Considerations to Discuss with Your Surgeon

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

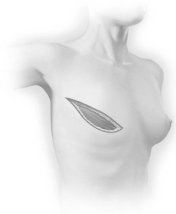
- Immediate Reconstruction: One-stage immediate reconstruction with a breast implant (implant only).

  Two-stage immediate reconstruction with a tissue expander, followed by delayed reconstruction several months later with a breast implant.
- Delayed Reconstruction: Two-stage delayed reconstruction with a tissue expander, followed several months later by replacement with a breast implant.

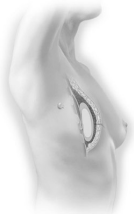
What Is the Breast Implant Reconstruction Procedure?

- One-Stage Immediate Breast Implant Reconstruction
  Immediate one-stage breast reconstruction may be done at the time of your mastectomy. After the general surgeon removes your breast tissue, the plastic surgeon will then implant a breast implant that completes the one-stage reconstruction. In reconstruction following mastectomy, a breast implant is most often placed submuscularly.
- Two-Stage (Immediate or Delayed) Breast Implant Reconstruction Breast reconstruction usually occurs as a two-stage procedure, starting with the placement of a breast tissue expander, which is replaced several months later with a breast implant. The tissue expander placement may be done immediately, at the time of your mastectomy, or be delayed until months or years later.

Stage 1: Tissue Expansion



Mastectomy Scar

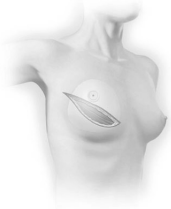


Expander/Implant with remote injection dome

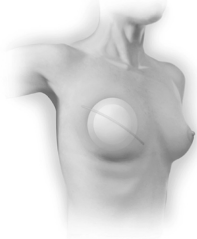
During a mastectomy, the general surgeon removes skin as well as breast tissue, leaving the chest tissues flat and tight. To create a breast-shaped space for the breast implant, a tissue expander is placed under the remaining chest tissues.

The tissue expander is a balloon-like device made from elastic silicone rubber.

It is inserted unfilled, and over time, sterile saline fluid is added by inserting a small needle through the skin to the filling port of the device. As the tissue expander fills, the tissues over the expander begin to stretch, similar to the gradual expansion of a woman's abdomen during pregnancy. The tissue expander creates a new breast-shaped pocket for a breast implant.



Tissue expander with integral injection dome



Final result with implant

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

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

Stage 2: Placing the Breast Implant

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

Breast Reconstruction Without Implants: Tissue Flap Procedures

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

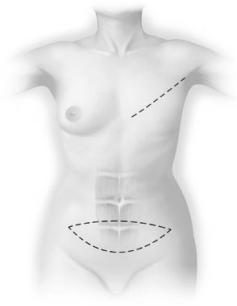
The tissue flap may be left attached to the blood supply and moved to the breast area through a tunnel under the skin (a pedicled flap), or it may be removed completely and reattached to the breast area by microsurgical techniques (a free flap). Operating time is generally longer with free flaps because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

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

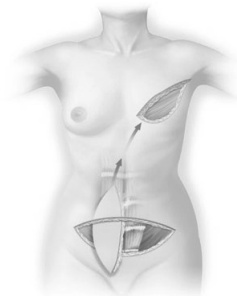
The most common types of tissue flaps are the TRAM (transverse rectus abdominus musculocutaneous flap) (which uses tissue from the abdomen) and the Latissimus Dorsi flap (which uses tissue from the upper back).

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

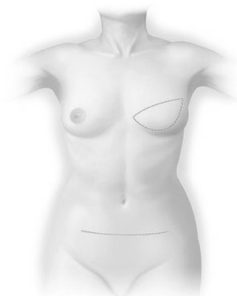
The TRAM Flap (Pedicle or Free)



Step 1: Mastectomy is performed and the donor site is marked



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

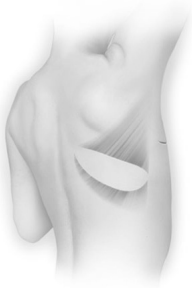


Step 3: Final Result

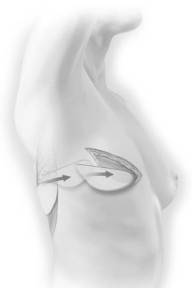
During a TRAM flap procedure, the surgeon removes a section of tissue from your abdomen and moves it to your chest to reconstruct the breast. The TRAM flap is sometimes referred to as a "tummy tuck" reconstruction, because it may leave the stomach area flatter.

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

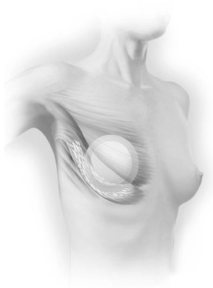
The Latissimus Dorsi Flap With or Without Breast Implants



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



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



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

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

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

• ***Postoperative Care***

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

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

What Questions Do You Ask Your Surgeon about Breast Reconstruction?

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

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

Other Factors to Consider In Breast Reconstruction

• Choosing a Surgeon

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

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

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

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

  Your surgeon will also evaluate your existing tissue to determine if you have enough to cover the breast implant. If you desire a breast implant size too large for your tissue, the surgeon may warn you that breast implant edges may be apparent or visible postoperatively. You may even risk surgical complications. Also, excessively large breast implants may speed up the effects of gravity and result in earlier droop or sag.
- ***Surface Texturing***
  Textured-surface implants were designed to reduce the chance of capsular contracture. Some information in the literature on small numbers of patients suggests that surface texturing reduces the chance of severe capsular contracture, but clinical information from studies of a large number of women with Mentor implants show no difference in the likelihood of developing capsular contracture with textured implants compared to smooth-surfaced implants (see "What Are the Risks Based on Mentor's Clinical Studies?" above).

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

If You Experience a Problem, Should You Report It?

The Food and Drug Administration (FDA) requires that serious injuries (defined as those that need medical or surgical intervention to prevent permanent damage) be reported by hospitals if they are aware of the serious injuries. If you believe that you have experienced one or more serious problems related to your breast implants, you are encouraged to report the serious problem(s) through your health professional to the FDA. Although reporting by doctors or other health professionals is preferred, women may also report any serious problem directly through FDA's MedWatch voluntary reporting system. You can report by telephone to 1-800-FDA-1088; by FAX, use Form 3500 to 1-800-FDA-0178; electronically at http://www.fda.gov/medwatch/index.html; or by mail to MedWatch Food and Drug Administration, HF-2, 5600 Fishers Lane Rockville, MD 20857-9787. **Keep a copy of the MedWatch form completed by your doctor for your records.** The information reported to MedWatch is entered into databases to be used to follow safety trends (patterns) of a device and to determine whether further follow-up of any potential safety issues related to the device is needed.

What Are Other Sources of Additional Information?

General Resources about Implants:

Upon request, you will be provided with a copy of the Directions for Use (package insert). You can request a copy from your surgeon or from Mentor. For more detailed information on the preclinical and clinical studies conducted by Mentor, you are referred to the Summary of Safety and Effectiveness Data for this product at http://www.fda.gov/cdrh/pdf/p990075b.pdf.

You will be given a device identification card with the style and serial number of your breast implant(s).

Mentor Corporation 1-800-MENTOR8 www.mentorcorp.com

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

Food and Drug Administration 1-888-INFO-FDA or 301-827-3990
http://www.fda.gov/cdrh/breastimplants/

Breast Reconstruction Resources

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

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

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

Breast Cancer Network of Strength (formally Y-ME National Organization for Breast Cancer) Information and Support 1-800-221-2141
www.networkofstrength.org

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

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