Mentor Worldwide LLC
P060028
MemoryShape™ Breast Implants
May 2013

PATIENT EDUCATIONAL BROCHURE

RECONSTRUCTION

BREAST RECONSTRUCTION WITH MENTOR® MEMORYSHAPE™ BREAST IMPLANTS

TABLE OF CONTENTS

GLOSSARY 4
1. HOW TO USE THIS EDUCATIONAL BROCHURE 17
2. GENERAL INFORMATION ABOUT BREAST 18
2.1 What Gives the Breast its Shape? 18
2.2 What is a Silicone Gel Breast Implant? 19
2.3 How Do Breast Implants Work in Breast Reconstruction? 19
3. DECIDING WHETHER TO HAVE BREAST RECONSTRUCTION SURGERY WITH IMPLANTS 19
3.1 Am I Eligible for Reconstruction with Silicone Gel Breast Implants? 20
3.2 Contraindications 21
3.3 Precautions 22
3.4 Warnings 23
3.5 What are the Alternatives to Implantation with Silicone Gel-Filled Breast Implants? 25
4. RISKS ASSOCIATED WITH BREAST IMPLANTS 25
4.1 What Are the Potential Complications? 34
4.2 What Are Other Reported Conditions? 44
5. BENEFITS ASSOCIATED WITH BREAST IMPLANTS 51
6. PREPARING FOR BREAST RECONSTRUCTION WITH 51
6.1 Should I have Breast Reconstruction? 52
6.2 Breast Reconstruction with Implants – Understanding the Procedure 52
6.3 Breast Reconstruction without Implants (Tissue Flap Reconstruction) 55
6.4 Choosing Breast Reconstruction with Breast Implants 59
6.5 Choosing the Right Implant for You 59
6.6 Surgical Setting and Anesthesia 61
6.7 Incision Sites 61
6.8 Implant Placement 62
6.9 Timing of Breast Reconstruction Surgery 63
6.10 Other Procedures at the Time of the Breast Reconstruction 64
6.11 Choosing a Surgeon 65
7. CARING FOR YOURSELF AFTER BREAST IMPLANT SURGERY 66
7.1 Postoperative Care in the Hours and Days after Surgery 66
7.2 Postoperative Care in the First Weeks after Surgery 67
7.3 Caring for Yourself in the Months and Years after Surgery 67
7.4 Monitoring Your Implants for Rupture 70
8. MENTOR'S CLINICAL STUDY RESULTS 71
8.1 Overview of the Study 71
8.2 What are the 3-Year and 6-Year Follow-up Rates? 72

8.3 What are the Benefits?....73
8.4 What were the 3-Year and 6-Year Complication Rates? 74
8.5 What are the Main Reasons for Reoperation?....77
8.6 What are the Main Reasons for Implant Removal? 80
8.7 What are Other Clinical Data Findings? 83
9. WHAT TO DO IF YOU HAVE A PROBLEM 86
10. WHERE TO FIND MORE INFORMATION 87
11. MENTOR'S IMPLANT TRACKING PROGRAM 88
11.1 Breast Implant Tracking 89
11.2 Device Identification Card 89
12. IMPORTANT CONTACT INFORMATION....90
13. WARRANTY INFORMATION....90
14. ACKNOWLEDGEMENT OF INFORMED DECISION 90
15. INDEX 93
16. REFERENCES....95

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.
Bilateral	Relating to both the left and right side.
Biocompatible	The ability to exist along with living tissues or systems without causing harm.
Biopsy	The removal and examination of tissue, cells, or fluid from a living body.
Body dysmorphic	A psychological condition characterized by excessive

disorder (BDD)	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 Questionnaire (BEQ)	A series of questions that ask 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	Any surgically implanted artificial device intended to replace missing breast tissue or to enhance a breast.
Breast mass	A lump in the breast.
Breast reconstruction	A surgical procedure to replace breast tissue or reconstruct a breast after tissue was taken out because of cancer or injury. Breast reconstruction also includes the surgical correction of a breast that has failed to develop properly due to a severe abnormality or congenital defect. The first time a breast implant is placed to replace breast tissue is referred to as "primary reconstruction." Any time there is another surgery to replace the implant, it is referred to as "revision-reconstruction."

Calcification/calcium deposits	The process of soft tissue hardening when the mineral calcium builds up in a certain place.
Capsular contracture	Tightening of the scar tissue (also called a capsule) that normally forms around the breast implant during the healing process after surgery. In some women, the scar tissue (capsule) squeezes the implant. When this occurs, it is called capsular contracture. This results in firmness or hardening of the breast. Capsular contracture is classified by the Baker Grade Scale.
Capsule	Scar tissue that forms around the breast implant.
Capsulotomy (closed)	An attempt to break the scar tissue capsule around the implant by pressing or pushing on the outside of the breast. This method does not require surgery but may rupture the implant and is contraindicated (meaning that the procedure is improper and should not be performed).
Capsulotomy (open)	A surgery to create an incision or opening in the capsule (scar tissue).
Chest wall	The system of structures outside the lungs that move as a part of breathing, including bones (the rib cage) and muscles (diaphragm and abdomen).
Congenital anomaly	An abnormal body part that existed at birth. Also called a congenital malformation or congenital deformity.
Connective tissue disease/disorder (CTD)	A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc. and/or the immune system. Connective tissue diseases (“CTDs”) that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma.

Contraindication	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.
Contralateral	The opposite side of the body.
Delayed reconstruction	Breast reconstruction that takes place weeks, months, or years after a mastectomy.
Delayed wound healing	Unusually slow progress in the healing of a wound; surgical incision site fails to heal normally or takes longer to heal.
Displacement	Movement (shifting) of the implant from the usual or proper place.
Extracapsular rupture	A type of rupture in which the silicone gel is outside of the scar capsule surrounding the breast implant (see Rupture).
Extrusion	Skin breakdown with the implant pressing through the skin or surgical incision.
Fibrocystic breast disease	Common, benign (noncancerous) changes in the tissues of the breast. The term "disease" is misleading, and many doctors prefer the term “change.” The condition is so commonly found in breasts, it is believed to be a variation of normal. Other related terms include “mammary dysplasia,” “benign breast disease,” and “diffuse cystic mastopathy.”
Fibromyalgia	A chronic condition characterized by widespread pain in muscles and joints. It may include fatigue, difficulty sleeping, and morning stiffness.
Fibrous tissues	Connective tissue composed mostly of fibers (for example, tendons).

Flap	A portion of tissue (which may include muscle, fat, and skin), moved from one part of the body to another. The tissue flap may or may not have its blood supply attached.
Free TRAM flap	A TRAM (transverse rectus abdominus musculocutaneous) flap (section of skin, muscle and other tissue from the abdomen) that is disconnected from (completely cut away from) the blood vessels in the rest of the body before being relocated to the breast area for reconstruction. The blood vessels must then be surgically reconnected when the flap is placed at the breast.
Gel bleed/gel diffusion	When silicone gel leaks or “bleeds” or “diffuses” through the implant shell.
Gel Fracture	The appearance of a fissure or fault line in the gel within the implant as a result of applied force.
Granuloma	Noncancerous lumps that can form around foreign material, such as silicone. Like any lump, it should be evaluated to distinguish it from a lump that might be cancerous.
Groin	The fold where the lower abdomen meets the inner part of the thigh.
Hematoma	A collection of blood inside the body, for example in skin tissue or other body space.
Hypertrophic scarring	An enlarged scar that remains after a wound heals.
Infection	The growth in the human body of microorganisms such as bacteria, viruses or fungi. An infection can occur as a result of any surgery.

Inflammation/irritation	The response of the body to infection or injury resulting in swelling, redness, warmth and/or pain.
Inframammary fold	The crease under the breast where the breast and chest meet.
Inframammary incision	An incision made in the fold below the breast.
Inpatient surgery	A surgical procedure in which the patient is required to stay overnight in the hospital.
Intracapsular rupture	A type of rupture in which the silicone gel remains inside the scar tissue capsule surrounding the breast implant (see Rupture).
Lactation	The production and secretion of milk by the breast glands.
Latissimus dorsi	Two triangular muscles running from the spinal column (backbone) to the shoulder.
Latissimus dorsi flap	A section of muscle and tissue on a person’s back, consisting of the latissimus dorsi muscle, skin, fat, connective tissue, and vascular [blood vessels] tissue.
Latissimus dorsi flap reconstruction	Breast reconstruction using a patient’s own tissue (a latissimus dorsi flap) from the side of the back to create the new breast or provide enough skin and breast tissue to cover a breast implant.
Local complications	Complications that occur in the breast or chest area.
Lumpectomy	Removal of a small amount of breast tissue.
Lymph nodes	Lymph nodes are glands that play an important part in the body's defense against infection. They produce lymph, which travels throughout the body in the lymph

	system, and filters impurities from the body. Common areas where the lymph nodes can be felt with the fingers include: groin, armpit, neck, under the jaw and chin, behind the ears, and on the back of the head.
Lymphadenopathy	Enlarged lymph node(s).
Lymphedema	Swelling of the lymph node(s).
Malposition	When the implant is placed incorrectly during the initial surgery or when the implant has moved/shifted from its original position. Shifting can be caused by many factors, such as gravity, trauma, poor initial placement, and capsular contracture.
Mammary	Pertaining to the breast.
Mammography	A type of x-ray examination of the breasts used for detection of cancer.
Mammoplasty	Plastic surgery of the breast.
Mastectomy	Partial or complete removal of the breast.
Mastopexy	Surgical procedure to raise and reshape sagging breasts.
MemoryShape™ 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 MemoryShape™ Core Study includes augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients. Information on the safety and effectiveness of the implants are collected every year for 10 years after study participants get their implants.
Metastatic disease	A stage of cancer after it has spread from its original site

	to other parts of the body.
Migration/gel migration	Movement of silicone material outside the breast implant to other areas of the body.
MRI (Magnetic Resonance Imaging)	MRI uses a magnetic field to create a 3-dimensional picture of a body part or organ. MRI is the imaging method that currently has the best ability to detect rupture of silicone gel breast implants.
Necrosis	Death of cells or tissues.
Oncologist	A medical doctor who specializes in diagnosing and treating cancer.
Outpatient surgery	A surgical procedure in which the patient is not required to stay in the hospital overnight.
Palpability/visibility	Palpability is when the implant can be felt through the skin. Visibility is when the implant can be seen through the skin.
Pectoralis	Major muscle of the chest.
Pedicle TRAM flap	A TRAM flap (section of skin, muscle and other tissue from the abdomen) that stays connected to the blood vessels in the rest of the body while being relocated (through a tunnel under the skin) to the breast area for reconstruction.
Periareolar	The areola is the pigmented or darker colored area of skin surrounding the nipple. Periareolar refers to the area just around the areola.
Periumbilical	Around the belly button.
Plastic surgery	Surgery intended to enhance or improve the appearance

	of the body.
Platinum	A metallic element used to help make both silicone elastomer (the rubbery material of the breast implant shell) and silicone gel.
Post-mastectomy	After a mastectomy.
Postoperative	After surgery.
Precautions	Information that warns the reader of a potentially hazardous situation that, if not avoided, may result in minor or moderate injury.
Primary breast reconstruction	The first time a breast implant is placed for the purpose of breast reconstruction
Prosthesis	Any artificial device used to replace or represent a body part.
Ptosis	Sagging or drooping of the breast.
Quality of Life (QoL) Measures	Assessments that may contribute to the evaluation of benefit (effectiveness), including the Rosenberg Self Esteem Scale (measures self-worth or self-acceptance), the Body Esteem Scale (measures a person's body image), the SF-36 (measures physical, mental, and social health), and the Breast Evaluation Questionnaire (measures breast satisfaction).
Rectus abdominus	A long flat muscle extending the whole length of the front of the abdomen (stomach).
Redness/bruising	Bleeding at the surgical site that causes discoloration and varies in degree and length of time. This is expected following breast implant surgery or other breast procedures.

Removal	Removal of the implant, with or without replacement using another implant.
Reoperation	Any additional surgery performed to the breast or chest area after the first breast implantation.
Revision-reconstruction	Refers to the correction or improvement of a primary reconstruction. In the context of this document, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast reconstruction.
Rheumatological disease/disorder	A variety of diseases involving connective tissue structures of the body, especially the joints and fibrous tissue. These diseases are often associated with pain, inflammation, stiffness, and/or limitation of motion of the affected parts. Can include autoimmune diseases. Fibromyalgia is a rheumatological disorder.
Risks	The chance or likelihood that an undesirable effect will occur
Rosenberg Self-Esteem Scale	A questionnaire that measures overall self-esteem.
Rupture	A hole or tear in the shell of the implant that allows silicone gel filler material to leak from the shell.
Saline	Saltwater (A solution made of water and a small amount of salt).
Scar revision	A surgical procedure to improve the appearance of a scar.
Scarring	Formation of tissue at an incision site; all wounds heal by the formation of a scar.

Seroma	Similar to a bruise, a seroma occurs when the watery portion of the blood collects around a surgical incision or around a breast implant.
SF-36 Scale	The Short Form 36 Health Scale; a questionnaire intended to measure physical, mental, and social health.
Silent rupture	A breast implant rupture without symptoms or a visible change. Silent rupture cannot be felt by the woman or detected by a doctor through physical examination. Silent rupture can only be discovered through appropriate imaging techniques such as MRI.
Silicone	Silicone is a man-made material that can be found in several forms such as oil, gel, or rubber (elastomer). The exact make-up of silicone will be different depending on its use.
Silicone elastomer	A type of silicone that has elastic properties similar to rubber.
Silicones - low molecular weight (LMW)	Small silicone molecules that may be present in gel bleed/gel diffusion.
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.
Tissue expander	An adjustable implant that can be inflated with salt water (saline) to stretch the tissue at the mastectomy site. This is used to create a new tissue flap that is large enough to cover the breast implant.
Tissue Flap Reconstruction	A surgical procedure used to reconstruct a breast using the patient's own tissue, taken from another part of the body. See also TRAM flap, TRAM flap reconstruction, Latissimus dorsi flap, and Latissimus dorsi flap reconstruction.
Toxic Shock Syndrome (TSS)	A rare, but life-threatening bacterial infection that may occur after surgery. Symptoms of TSS occur suddenly: a high fever, vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches, and/or drops in blood pressure, which may cause fainting. A doctor should be seen immediately for diagnosis and treatment if TSS is suspected.
TRAM flap	The transverse rectus abdominus musculocutaneous (TRAM) flap. This section of muscle and tissue consists of the transverse rectus abdominus muscle, skin, fat, connective tissue, and vascular (blood vessels) tissue. It is taken from the abdomen (stomach area) and can be used to create a new breast for reconstruction purposes. A TRAM flap is also sometimes used to add breast tissue and skin to cover a breast implant during reconstruction.

TRAM flap reconstruction	Breast reconstruction using a patient's own tissue (a TRAM flap) from the abdomen to create the new breast or provide enough skin and breast tissue to cover a breast implant.
Unilateral	Affecting only one side of the body.
Vascular tissue	Blood vessels (arteries and veins) that carry blood to the skin and tissues of the body and back to the heart.
Warnings	A statement that alerts the reader about a situation that, if not avoided, could result in serious injury or death.
Wound dehiscence (wound opening)	Opening of a wound.
Wrinkling/rippling	Wrinkling of the implant that can be felt or seen through the skin.

1. HOW TO USE THIS EDUCATIONAL BROCHURE

Mentor, the company that sells these MemoryShape™ Breast Implants, has designed this educational brochure to help you understand breast reconstruction with implants and to help you talk with your doctor(s) about breast reconstruction. Mentor sponsored a large clinical study of these breast implants (also referred to in this brochure as the "MemoryShape™ Core Study") that gathered data about these breast implants. There are 955 patients participating in the MemoryShape™ Core Study. A total of 572 patients had primary-augmentation, 124 patients had revision-augmentation, 191 patients had primary-reconstruction, and 68 patients had revision-reconstruction with Mentor MemoryShape™ 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, unless an earlier surgery is deemed necessary by your surgeon. If you are having a mastectomy, it may make sense to start or perform the complete reconstruction at the same time you have the mastectomy; in this case, there may be time considerations your doctor can discuss with you. If you are having revision-reconstruction surgery, your surgeon may advise you to have the surgery sooner.

If you decide to have the surgery, you will be asked to sign a statement before the surgery. The statement says you have read and understood the information in this brochure and that you have been informed of the benefits and risks of breast implants. This statement is called the "Acknowledgement 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 "Acknowledgement of Informed Decision".

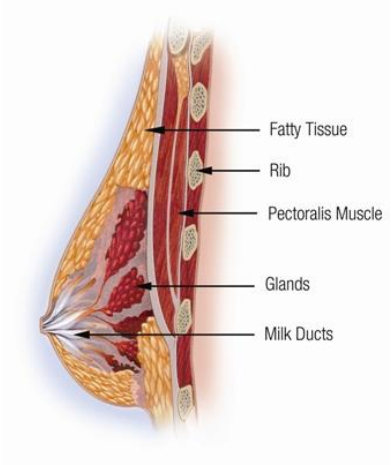
2. GENERAL INFORMATION ABOUT BREAST RECONSTRUCTION WITH BREAST IMPLANTS

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

2.1 What Gives the Breast its Shape?

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

Figure 1
Anatomy of the Breast



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

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.

The MENTOR® MemoryShape™ Breast Implants are shaped devices that are intended to provide more volume in the lower breast volume and less volume in the upper breast. The breast implants have a textured (Siltex®) shell constructed of silicone elastomer. The MemoryShape™ Breast Implants are filled with a more cohesive (firmer feeling) gel when compared to the round MENTOR® MemoryGel® Breast Implants. Raised orientation marks on the front and back of the MemoryShape™ Breast Implants are intended to help the surgeon ensure proper placement during surgery. More information on the types of MemoryShape™ Breast Implants can be found in Section 6.5 (*Choosing the Right Implant for You*).

2.3 How Do Breast Implants Work in Breast Reconstruction?

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

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

3. DECIDING WHETHER TO HAVE BREAST RECONSTRUCTION SURGERY WITH IMPLANTS

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

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

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

- **Primary reconstruction** to replace breast tissue that has been removed because of cancer or injury. Primary reconstruction is also used to replace breast tissue that has failed to develop properly because of a severe breast abnormality.

- **Revision-reconstruction** to correct or improve the result of primary reconstruction. Revision-reconstruction includes replacing an existing breast implant.

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

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

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

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

3.2 Contraindications

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

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

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

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

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

3.3 Precautions

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

- An autoimmune disease,
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease),
- Planned chemotherapy following breast implant placement,
- Planned radiation therapy to the breast following breast implant placement,
- Conditions that interfere with wound healing and/or blood clotting,
- Reduced blood supply to breast tissue, or
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder (BDD) 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 breast feeding. If you are planning to breast feed your infant, be prepared to use

formula and bottle-feed your baby in the event you have difficulty breast feeding.

- Mammograms of a reconstructed breast are not usually performed. The following may apply to the contralateral breast:
    - Mammography for detecting breast cancer (or cancer recurrence) may be more difficult with breast implants in place. You will need more views captured than during a routine mammogram. Therefore, the procedure will take more time and you will be exposed to more radiation than during a standard routine screening mammogram. However, the benefits of mammograms outweigh this risk. You must tell the technologist that you have silicone gel breast implants before the procedure. The technologist can then use special techniques to get the best possible views of your breast tissue.

- Your implants could rupture without you feeling the rupture or noticing any change in your breasts. In some of these instances even your doctor might not be able to tell that a rupture has occurred. A rupture that has no symptoms is called a “silent” rupture. The best way to diagnose a silent rupture is with 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.

- In general, private insurance that covers medically necessary mastectomies will also cover breast reconstructive surgery. Insurance coverage for reoperation procedures or additional surgeon’s visits following reconstruction may not be covered, depending on the policy. Because health insurance policies vary and

can change over time, no general guidance can be provided regarding coverage under any particular health insurance plan. Be sure to check with your insurance company to obtain specific information about the extent of your health coverage before having breast reconstruction with implants.

- Capsular contracture is not to be treated by closed capsulotomy or forceful external compression, which will likely result in implant damage, rupture, folds, and/or hematoma.

3.5 What are the Alternatives to Implantation with Silicone Gel-Filled Breast Implants?

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

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

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

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

4. RISKS ASSOCIATED WITH BREAST IMPLANTS

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

Tables 1 and 2 below present the potential risks associated with breast implant surgery, the likelihood of the risks based on the results from Mentor's MemoryShape™ Core Study through 3 and 6 years, as well as the possible effects of the events for primary and revision-reconstruction patients.

Table 1
Potential Risks Associated with Primary Breast Reconstruction

Event	Likelihood of the Event Occurring[1]		Possible Resulting Effects of the Event
	Year 3	Year 6	
Any Complication Excluding Rupture	54 out of 100 patients (54%)	65 out of 100 patients (65%)	• See specific complications below
Key Complications			
Any Reoperation	36 out of 100 patients (36%)	44 out of 100 patients (44%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Capsular Contracture Baker Grade III/IV	6 out of 100 patients (6%)	10 out of 100 patients (10%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Implant Removal with or without Replacement	14 out of 100 patients (14%)	22 out of 100 patients (22%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result

Event	Likelihood of the Event Occurring[1]		Possible Resulting Effects of the Event
	Year 3	Year 6	
Implant Removal with Replacement with Study Device	6 out of 100 patients (6%)	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 Rupture (Based on the MRI Cohort)[2]	-	2 out of 100 patients (2%)	• Implant removal
Infection	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Redness or rash • Pain or tenderness • Swelling • Fever • Reoperation • Implant removal
Other Complications Occurring in 1% or More of Patients[3]			
Asymmetry[4]	6 out of 100 patients (6%)	11 out of 100 patients (11%)	• Undesirable cosmetic result • Reoperation • Implant removal
Breast Sensation Changes[4]	1 out of 100 patients (1%)	1 out of 100 patients (1%)	• Increased or decreased breast sensitivity
Breast Pain[4]	3 out of 100 patients (3%)	3 out of 100 patients (3%)	• Resulting effects are contingent on underlying cause(s)
Capsular Contracture Baker Grade II with Surgical Intervention	2 out of 100 patients (2%)	4 out of 100 patients (4%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Capsular Contracture Baker Grade III	5 out of 100 patients (5%)	9 out of 100 patients (9%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Capsular Contracture Baker Grade IV	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Death[5]	1 out of 100 patients (1%)	4 out of 100 patients (4%)	-
Delayed Wound Healing[4]	1 out of 100 patients (1%)	1 out of 100 patients (1%)	• Pain or discomfort • Scarring • Implant extrusion • Necrosis • Reoperation • Implant removal

Event	Likelihood of the Event Occurring[1]		Possible Resulting Effects of the Event
	Year 3	Year 6	
Excess Skin/Tissue	4 out of 100 patients (4%)	4 out of 100 patients (4%)	• Reoperation •
Hypertrophic Scarring (irregular, raised scar)	1 out of 100 patients (1%)	2 out of 100 patients (2%)	• Scar revision procedure (reoperation) • Undesirable cosmetic result
Implant Immobility	2 out of 100 patients (2%)	4 out of 100 patients (4%)	• Undesirable cosmetic result • Reoperation • Implant removal
Implant Rotation	3 out of 100 patients (3%)	5 out of 100 patients (5%)	• Undesirable cosmetic result • Asymmetry • Visibility • Reoperation • Implant removal
Irritation/Inflammation	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Resulting effects are contingent on underlying cause(s)
Itching	Less than 1 out of 100 patients (1%)	1 out of 100 patients (1%)	• Pain and discomfort
Lack of Projection	5 out of 100 patients (5%)	9 out of 100 patients (9%)	• Undesirable cosmetic result • Reoperation • Implant removal
Loss of Definition of Inframammary Fold	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Reoperation • Implant removal
Mass/Cyst	3 out of 100 patients (3%)	5 out of 100 patients (5%)	• Pain or discomfort • Reoperation or other procedures
Metastatic Disease	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Pain or discomfort • Reoperation or other procedures
Miscarriage	1 out of 100 patients (1%)	2 out of 100 patients (2%)	• Pain and discomfort
New Diagnosis of Rheumatic Disease	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Pain and discomfort
Nipple Sensation Changes[4]	2 out of 100 patients (2%)	3 out of 100 patients (3%)	• Increased or decreased nipple sensitivity • Breastfeeding difficulties • May affect sexual response
Other: Missing	0 out of 100 patients (0%)	2 out of 100 patients (2%)	-
Patient Dissatisfied with Aesthetic Appearance of Breast	2 out of 100 patients (2%)	5 out of 100 patients (5%)	• Undesirable cosmetic result • Reoperation • Implant removal
Patient Dissatisfied with Feel of Implant	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Undesirable result • Reoperation • Implant removal

Event	Likelihood of the Event Occurring[1]		Possible Resulting Effects of the Event
	Year 3	Year 6	
Position Dissatisfaction[4]	Less than 1 out of 100 patients (1%)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Asymmetry • Reoperation • Implant removal
Ptosis (sagging)	3 out of 100 patients (3%)	6 out of 100 patients (6%)	• Undesirable cosmetic result • Wrinkling/Rippling • Reoperation • Implant removal
Recurrent Breast Cancer	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Reoperation or other procedures
Scarring	3 out of 100 patients (3%)	3 out of 100 patients (3%)	• Scar revision procedure (reoperation) • Undesirable cosmetic result
Seroma	3 out of 100 patients (3%)	3 out of 100 patients (3%)	• Swelling and bruising • Pain or discomfort • Infection • Incision and drainage (reoperation) • Implant removal
Shape Distortion	0 out of 100 patients (0%)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Asymmetry • Reoperation • Implant removal
Size Change – Patient Request	5 out of 100 patients (5%)	5 out of 100 patients (5%)	• Undesirable cosmetic result • Reoperation • Implant removal
Size Change – Physician Assessment Only	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Reoperation • Implant removal
Skin Lesion	1 out of 100 patients (1%)	2 out of 100 patients (2%)	• Pain or discomfort • Scarring • Implant extrusion • Necrosis • Reoperation • Implant removal
Suture Complication	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Pain and discomfort
Tenderness/ Soreness	Less than 1 out of 100 patients (1%)	1 out of 100 patients (1%)	• Pain and discomfort
Wrinkling[4]	3 out of 100 patients (3%)	4 out of 100 patients (4%)	• Discomfort • Undesirable cosmetic result • Reoperation • Implant removal

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

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

[3] The following complications occurred at a rate less than 1%: capsular contracture Baker grade unknown, external injury not related to breast implants, muscle atrophy, necrosis, new diagnosis of breast cancer, nipple complication, palpability-implant, swelling (excessive), symmastia, wound opening.
[4] Mild occurrences not included
[5] All causes of death were reported by the investigator to be unrelated to study procedure or device.

Table 2

Potential Risks Associated with Revision-Reconstruction

Event	Likelihood of the Event Occurring[1]		Possible Resulting Effects of the Event
	Year 3	Year 6	
Any Complication Excluding Rupture	56 out of 100 patients (56%)	68 out of 100 patients (68%)	• See specific complications below
Key Complications			
Capsular Contracture Baker Grade III/IV	14 out of 100 patients (14%)	16 out of 100 patients (16%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Infection	3 out of 100 patients (3%)	3 out of 100 patients (3%)	• Redness or rash • Pain or tenderness • Swelling • Fever • Reoperation • Implant removal
Rupture (Based on the MRI Cohort)[2]	-	0 out of 100 patients (0%)	• Implant removal
Implant Removal with or without Replacement	21 out of 100 patients (21%)	34 out of 100 patients (34%)	• 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%)	11 out of 100 patients (11%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result

Event	Likelihood of the Event Occurring[1]		Possible Resulting Effects of the Event
	Year 3	Year 6	
Any Reoperation	28 out of 100 patients (28%)	45 out of 100 patients (45%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Other Complications Occurring in 1% or More of Patients[3]			
Asymmetry[4]	6 out of 100 patients (6%)	6 out of 100 patients (6%)	• Undesirable cosmetic result • Reoperation • Implant removal
Breast Pain[4]	3 out of 100 patients (3%)	3 out of 100 patients (3%)	• Resulting effects are contingent underlying cause(s)
Capsular Contracture Baker Grade II with Surgical Intervention	2 out of 100 patients (2%)	4 out of 100 patients (4%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Capsular Contracture Baker III	14 out of 100 patients (14%)	14 out of 100 patients (14%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Capsular Contracture Baker IV	0 out of 100 patients (0%)	3 out of 100 patients (3%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Death[5]	2 out of 100 patients (2%)	2 out of 100 patients (2%)	-
Excess Skin/Tissue	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Reoperation
Gel Fracture	0 out of 100 patients (0%)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Asymmetry • Reoperation • Implant removal
Hematoma	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Swelling and bruising • Pain or discomfort • Infection • Incision and drainage (reoperation) • Implant removal
Implant Immobility	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Reoperation • Implant removal

Event	Likelihood of the Event Occurring[1]		Possible Resulting Effects of the Event
	Year 3	Year 6	
Implant Rotation	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Asymmetry • Visibility • Reoperation • Implant removal
Irritation/Inflammation	3 out of 100 patients (3%)	3 out of 100 patients (3%)	• Resulting effects are contingent on underlying cause(s)
Lack of Projection	12 out of 100 patients (12%)	14 of 100 patients (14%)	• Undesirable cosmetic result • Reoperation • Implant removal
Loss of Definition of Inframammary Fold	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Reoperation • Implant removal
Metastatic Disease	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Pain or discomfort • Reoperation or other procedures
Muscle Atrophy (thinning)	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Palpability • Visibility • Reoperation • Implant removal
Numbness/Tingling (Paresthesia)	3 out of 100 patients (3%)	3 out of 100 patients (3%)	• Resulting effects are contingent underlying cause(s)
Palpability-Implant[4]	4 out of 100 patients (4%)	4 out of 100 patients (4%)	• Undesirable cosmetic result • Visibility • Reoperation • Implant removal
Patient Dissatisfied with Aesthetic Appearance of Breast	6 out of 100 patients (6%)	8 out of 100 patients (8%)	• Undesirable cosmetic result • Reoperation • Implant removal
Patient Dissatisfied with Feel of Implant	2 out of 100 patients (2%)	4 out of 100 patients (4%)	• Undesirable result • Reoperation • Implant removal
Position Dissatisfaction[4]	5 out of 100 patients (5%)	5 out of 100 patients (5%)	• Undesirable cosmetic result • Asymmetry • Reoperation • Implant removal
Ptosis (sagging)	5 out of 100 patients (5%)	12 out of 100 patients (12%)	• Undesirable cosmetic result • Wrinkling/Rippling • Reoperation • Implant removal
Recurrent Breast Cancer	2 out of 100 patients (2%)	4 out of 100 patients (4%)	• Reoperation or other procedures
Redness (Erythema)	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Resulting effects are contingent on underlying cause(s)

Event	Likelihood of the Event Occurring[1]		Possible Resulting Effects of the Event
	Year 3	Year 6	
Scarring	2 out of 100 patients (2%)	7 out of 100 patients (7%)	• Scar revision procedure (reoperation) • Undesirable cosmetic result
Seroma	5 out of 100 patients (5%)	5 out of 100 patients (5%)	• Swelling and bruising • Pain or discomfort • Infection • Incision and drainage (reoperation) • Implant removal
Silicone From Previous Rupture	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Reoperation •
Size Change – Patient Request	8 out of 100 patients (8%)	10 out of 100 patients (10%)	• Undesirable cosmetic result • Reoperation • Implant removal
Size Change – Physician Assessment Only	0 out of 100 patients (0%)	5 out of 100 patients (5%)	• Undesirable cosmetic result • Reoperation • Implant removal
Skin Lesion	2 out of 100 patients (2%)	4 out of 100 patients (4%)	• Pain or discomfort • Scarring • Implant extrusion • Necrosis • Reoperation • Implant removal
Swelling (Excessive)	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Pain or discomfort • Resulting effects are contingent on underlying cause(s)
Wrinkling[4]	10 out of 100 patients (10%)	12 out of 100 patients (12%)	• Discomfort • Undesirable cosmetic result • Reoperation • Implant removal

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

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

[3] No complications occurred at a rate less than 1%.

[4] Mild occurrences not included

[5] All causes of death were reported by the investigator to be unrelated to study procedure or device.

Using information from Mentor's MemoryShape™ Core Study, the risk of a patient experiencing any complication (excluding rupture) at some point through 3 and 6 years after implant surgery was calculated. This risk through 3 years was 54% for primary reconstruction patients and 56% for revision-reconstruction patients. This means that 54 out of 100 primary reconstruction patients and 56 out of 100 revision-reconstruction patients may experience a complication (of some kind) within 3 years after receiving implants. Through 6 years, this risk was 65% for primary reconstruction patients and 68% for revision-reconstruction patients. This means that 65 out of 100 primary reconstruction patients and 68 out of 100 revision-reconstruction patients may experience a complication (of some kind) within 6 years after receiving implants. For additional information on how often Mentor has reported these events in its studies of the implants, please read the section of this brochure on the MemoryShape™ Core Study (Section 8).

Mentor will continue its MemoryShape™ Core Study through the end of each patient's 10-year study term. In addition, Mentor has initiated additional post approval studies to address long-term outcomes in patients with MemoryShape™ 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 reconstruction or augmentation. However, whether or not a woman experiences capsular contracture at all and with what degree of severity varies from woman to woman.

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

The capsular contracture Baker Grade III/IV rates in Mentor's MemoryShape™ Core Study through 2, 3, 4, 5 and 6 years are presented in Table 3 (primary reconstruction: N=191; revision-reconstruction: N=68). The MemoryShape™ Core Study reported a 6% risk of experiencing Baker Grade III or IV capsular contracture for primary reconstruction patients through 3 years after receiving implants, and a 10% risk through 6 years. For revision-reconstruction patients, the risk was 14% through 3 years and 16% through 6 years. This means that 6 out of 100 primary reconstruction patients and 14 out of 100 revision-reconstruction patients may experience Baker Grade III or IV capsular contracture within 3 years after receiving implants, and 10 out of 100 primary reconstruction patients and 16 out of 100 revision-reconstruction 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	3 Year	4 Year	5 Year	6 Year
Primary Reconstruction, N=191	3.2%	5.6%	6.2%	7.6%	10.1%
Revision Reconstruction, N=68	6.1%	13.5%	13.5%	13.5%	16.4%

More details on capsular contracture results from the MemoryShape™ 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, you 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]

- **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 MemoryShape™ Core Study reported a 36% risk of experiencing reoperation for primary reconstruction patients through 3 years after receiving implants, and a 45% risk through 6 years. For revision-reconstruction patients, the risk was 28% through 3 years and 45% through 6 years. This means that 36 out of 100 primary reconstruction patients and 28 out of 100 revision-reconstruction patients may experience reoperation within 3 years after receiving implants, and 45 out of 100 primary or revision-reconstruction patients may experience reoperation within 6 years after receiving implants. For women receiving primary reconstruction implants, the most common

reasons for reoperation were asymmetry and breast mass/cyst. For women receiving revision-reconstruction implants, the most common reasons for additional surgery were severe capsular contracture and nipple complication. More details on reoperation from the MemoryShape™ 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 MemoryShape™ Core Study reported a 14% risk of implant removal (including removal with replacement for a size exchange) for primary reconstruction patients through 3 years after receiving implants, and a 22% risk through 6 years. For revision-reconstruction patients, the risk was 21% through 3 years and 34% through 6 years. This means that 14 out of 100 primary reconstruction patients and 21 out of 100 revision-reconstruction patients may experience implant removal within 3 years after receiving implants, and 22 out of 100 primary reconstruction patients and 34 out of 100 revision-reconstruction patients may experience implant removal within 6 years after receiving implants. More details on implant removal from the MemoryShape™ Core

Study are found in Section 8.6.

- **Pain**

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

- **Changes in Nipple and Breast Sensation**

After contralateral augmentation or if the nipple is not removed as part of a mastectomy in the reconstructed breast, feeling in the nipple and breast can change after implant surgery. Nipples may become more or less sensitive. They may be painfully sensitive or feel nothing at all. These changes are temporary for many women, but for some, sensation may never be what it was before implant surgery. They may affect a woman's sexual response or ability to breast feed. (See the paragraph on breast feeding below.)

- **Aesthetic Changes**

You may not be satisfied with the way your breasts look or feel after your surgery. Unsatisfactory results such as scarring or asymmetry, wrinkling of the skin, implant displacement/migration, incorrect size, unanticipated shape and/or implant palpability/visibility may occur.

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

- **Breast Feeding**

If you have a mastectomy and all your breast tissue is removed, you will not be

able to breast feed with that breast. If you have the opposite breast augmented as part of a reconstruction (contralateral augmentation), you should know that breast implant surgery might interfere with your ability to successfully breast feed. 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 breast feeding.[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 breast feeding difficulties.

The Institute of Medicine (IOM) and The American College of Obstetricians and Gynecologists (ACOG) encourage women with breast implants to try breast feeding. The IOM concluded, "Breast feeding should be encouraged in all mothers when possible, including those with silicone breast implants. There is evidence that breast implantation may increase the risk of insufficient lactation,[11] but no evidence that this poses a hazard to the infant beyond the loss of breast feeding itself. The evidence for the advantages of breast feeding to infant and mother is conclusive".[9,12] The MemoryShape™ Core Study collected information from patients who had babies after reconstruction with MemoryShape™ Breast Implants. None of the primary reconstruction or revision-reconstruction patients attempted to breastfeed through 6 years in Mentor's MemoryShape™ Core Study. Lactation experiences from the MemoryShape™ Core Study are also discussed in Section 8.7.

- **Implant Extrusion**

Extrusion is when the breast implant comes through the skin. This can happen if your surgical wound has not healed properly or if the skin over your breast weakens. Radiation therapy has been reported to increase the chances of implant extrusion.[13] Additional surgery is needed to fix implant extrusion. This can result in more scarring or loss of breast tissue. An extruding implant may have to be removed and not replaced.

- **Necrosis//Delayed Wound Healing**

Necrosis means that 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 time frame, talk to your surgeon immediately.

- **Breast Atrophy/Chest Wall Deformity**

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

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

- **Calcium Deposits**

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

Calcium deposits do not mean you are ill, but they can be mistaken for cancer. It may be difficult to tell if they are calcium deposits or cancer just by feeling them. They can show up on mammograms as possible cancer lumps. If you have hard lumps, your doctor may have to operate in order to perform a biopsy (remove a small piece of the lump for testing) or to remove the lump(s). Tell your doctor about any lumps your 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 MemoryShape™ 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] but, rates of brain cancer were not significantly higher in women with breast implants when compared to women who had other non-breast implant plastic surgeries.

- **Lympho-Hematopoietic Cancers**

Lympho-hematopoietic cancers are cancers that develop in the lymph nodes or certain blood cells. Lymph nodes and the affected cells are part of the body's immune system to fight infection. These kinds of cancers include non-Hodgkin's lymphoma, Hodgkin's disease, multiple myeloma, and leukemia. Although most studies have found no increased risk of these cancers for women with silicone gel breast implants.[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.[6,21,23,23,26,27,33,38]

- **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 reconstruction surgery to replace breast tissue that has been removed because of cancer or injury, or to replace breast tissue that has failed to develop properly because of a severe breast abnormality. In addition, women choose revision-reconstruction surgery (replacement of an existing implant) to correct or improve the result of primary reconstruction surgery.

In Mentor's MemoryShape™ Core Study, the results showed that most primary and revision-reconstruction patients were pleased with the results of their implant surgery, felt more comfortable afterwards, both when fully dressed and not fully dressed, and were more satisfied with their breast characteristics. In addition, 97 (98%) of the 99 primary reconstruction and 36 (97%) of the 37 of revision-reconstruction patients who answered the patient satisfaction question indicated they would make the same decision to have the breast implant surgery.

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

6. PREPARING FOR BREAST RECONSTRUCTION WITH SILICONE GEL BREAST IMPLANTS

Deciding to have breast reconstruction with implants is an important personal decision that has both benefits and risks. You should decide whether it is the right choice for you after discussing all the options with your plastic surgeon and any other doctors

who are treating you (for example, a general surgeon and/or oncologist). This section will give you the information you need to make an informed choice and help you make a number of decisions that have to be made before your surgery.

6.1 Should I have Breast Reconstruction?

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

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

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

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

6.2 Breast Reconstruction with Implants – Understanding the Procedure

The surgical procedure for breast reconstruction with implants consists of choices you and your surgical team (surgeon(s), nurses, anesthetist, etc.) will make as you plan

your surgery. If you are continuing treatment for cancer (like chemotherapy or radiation), your surgeon(s) should consult with your oncologist. For breast reconstruction, the type of procedure that is available to you depends on your medical situation, breast shape and size, general health, lifestyle, and goals for the reconstruction. The outcome of a mastectomy will affect the amount of breast tissue left to cover a breast implant.

Breast Reconstruction with Implants – Staging the Procedures

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

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

Use of Tissue Expander(s) in Breast Reconstruction Surgery

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

Placing an implant in a breast pocket that is too small can cause complications such as

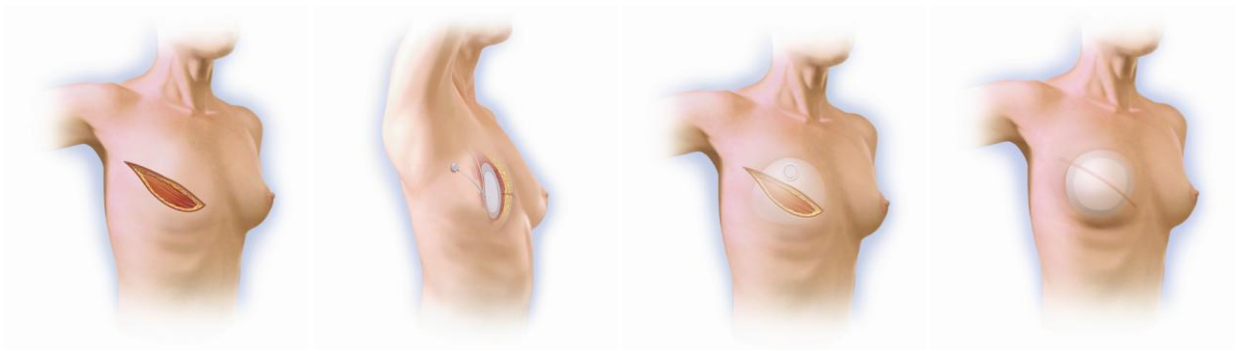
drooping or sagging at an earlier age, implant extrusion, skin wrinkling, infection, and hematoma. You may also be able to feel folds on the implant created by the implant being squeezed tightly by the surrounding skin and other breast-area tissue.

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

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

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

Figure 2
Breast Reconstruction Using a Tissue Expander and Breast Implant



* **

Post-Mastectomy | Tissue Expansion | Final Result

*tissue expander with remote injection dome

**tissue expander with integral injection dome

before nipple/areola reconstruction

6.3 Breast Reconstruction without Implants (Tissue Flap Reconstruction)

A tissue flap is skin, fat, and/or muscle taken from another part of your body, like your stomach, back, hip, or bottom. Two kinds of flaps are usually used for breast reconstruction surgeries: a flap from your stomach (called a “TRAM flap”) or a flap from your back (called a “latissimus dorsi flap”). In each case, the flap is moved to the chest where it is shaped into a new breast. In some cases, a tissue flap is used just to provide more skin or tissue, for example, to cover an implant.

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

An advantage of breast reconstruction using a tissue flap may be that usually no

other procedures are needed to make the opposite (unaffected) breast match the reconstructed breast.

TRAM Flap

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

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

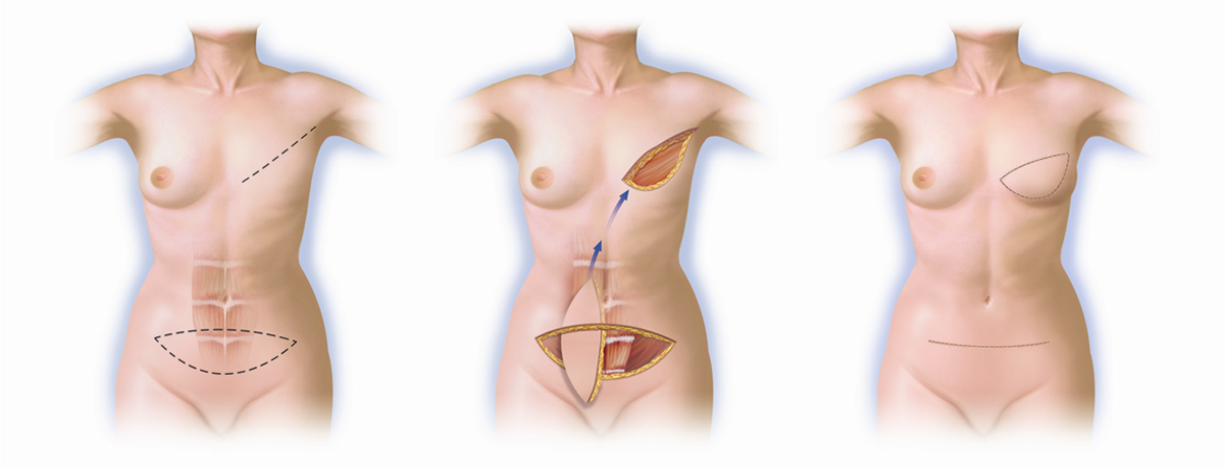
If you are considering becoming pregnant after your reconstruction, discuss this with your doctors before surgery. You will have a large scar on your abdomen and scarring on your reconstructed breast(s) that may be affected as your skin stretches to accommodate a growing baby.

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

The other possibility is a “free” TRAM flap. In this case, the tissue is taken from your abdomen and the blood supply is cut. The flap is taken off completely from your tummy and then relocated and sutured in place to create the new breast. The doctor must reconnect blood vessels at the breast site. This is a very involved procedure: your surgeon will need to use a microscope to do it and it usually takes longer than

a pedicle TRAM flap procedure. Your surgical team may ask a surgeon who specializes in surgery using a microscope to reconnect blood vessels to do that part of your procedure (a vascular surgeon). You may need to have a blood transfusion during or after a free TRAM flap procedure.

Figure 3
Breast Reconstruction Using a TRAM Flap

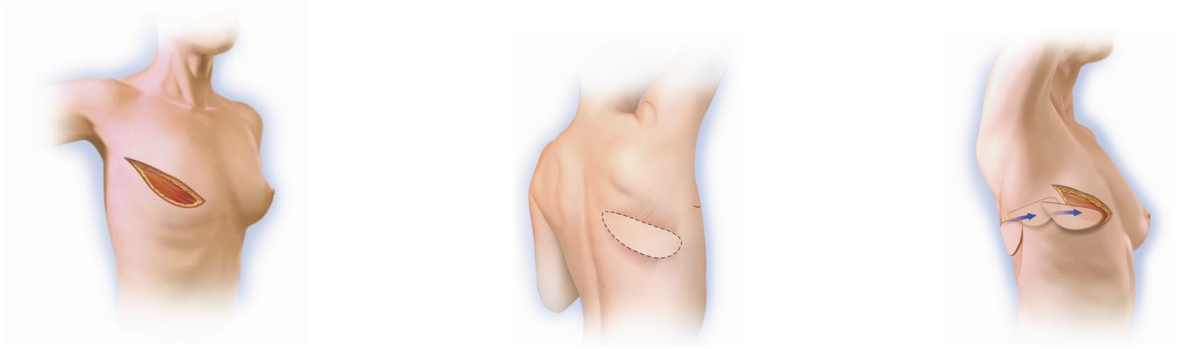


Post-Mastectomy | TRAM Flap | Final Result before nipple/areola reconstruction

Latissimus Dorsi Flap

Breast reconstruction using a latissimus dorsi flap is illustrated in Figure 4 below. During a latissimus dorsi flap reconstruction, a section of tissue [skin, fat, connective tissue, and vascular (blood vessels) tissue] is taken from your back. A latissimus dorsi flap is usually smaller than a TRAM flap, so this procedure may be better for a woman with smaller breasts. The latissimus dorsi flap procedure usually takes 2 to 4 hours of surgery. It is done in a hospital under general anesthesia. Most patients can resume their normal activities after 2 to 3 weeks.

Figure 4
Breast Reconstruction Using a Latissimus Dorsi Flap



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

Complications Associated with Flap Reconstruction

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

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

6.4 Choosing Breast Reconstruction with Breast Implants

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

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

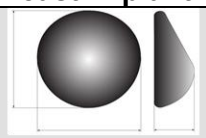
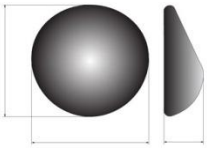
If you do not want to change your unaffected breast, discuss this with your surgeon well before the surgery so he or she can plan the procedure to give you the best result.

6.5 Choosing the Right Implant for You

MemoryShape™ Breast Implants are available in several different sizes to help each woman achieve the result that is best for her body. If you are having one breast reconstructed, but the other one is not affected, you and your doctor can choose the implant that will most closely match your unaffected breast.

Table 4 lists the MemoryShape™ Breast Implants that are available.

Table 4
MemoryShape™ Breast Implant Product Sizes

Breast Implant Description		**Size Range**
Medium Height, Moderate Profile		120-775 cc

.

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

Implant Size, Shape and Surface

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

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

6.6 Surgical Setting and Anesthesia

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

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

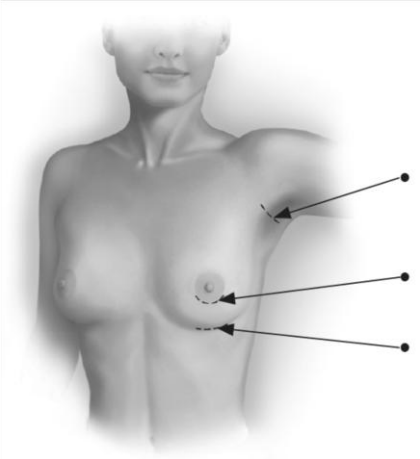
6.7 Incision Sites

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

Sometimes, a doctor will recommend placing an implant in the opposite breast after a unilateral (one breast only) mastectomy and reconstruction to create better symmetry. If you have an unaffected breast implanted to match a reconstructed breast, you may be able to choose the incision site. The three incision sites shown in Figure 5 below that are the incision sites usually used for breast contralateral augmentation surgery:

Figure 5

Incision Sites for Contralateral Augmentation Surgery



Axillary – the incision is made in the armpit, which gives the surgeon easier access to the chest muscle,

Periareolar – an incision is made around the nipple, and

Inframammary – the most common incision, made under your breast at the crease where the breast meets the body.

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

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

6.8 Implant Placement

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

6.9 Timing of Breast Reconstruction Surgery

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

Breast reconstruction with or without implants can be done at the time of a mastectomy surgery (immediate reconstruction) or months to years after (delayed reconstruction). There are medical, financial, and emotional factors to consider when choosing when to have breast reconstruction. There may be reasons your doctor would advise you to begin breast reconstruction at the time of your mastectomy, but these reasons may not always outweigh your need to carefully consider your options and think about whether reconstruction with breast implants is right for you. Give yourself enough time to consider your decision and gather information to help you decide.

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

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

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

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

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

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

6.10 Other Procedures at the Time of the Breast Reconstruction

Your surgeon may recommend having other aesthetic procedures during the same surgery to get the best results from your breast implants. In some cases, breast implants alone may not give you the results you want. If, in the past, you have lost a lot of weight, been pregnant, or breast fed, you may have sagging, stretched, or extra skin that is not completely filled out by breast tissue. Or, after mastectomy, your reconstructed breast may be firmer and higher than your opposite breast. In these cases, your surgeon may recommend doing a breast lift (mastopexy) to remove excess skin from the rest of the breast tissue in one or both breasts. Sometimes mastopexy is recommended in the unaffected breast to create better symmetry after reconstruction.

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

6.11 Choosing a Surgeon

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

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

7. CARING FOR YOURSELF AFTER BREAST IMPLANT SURGERY

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

7.1 Postoperative Care in the Hours and Days after Surgery

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

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

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

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

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

7.2 Postoperative Care in the First Weeks after Surgery

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

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

7.3 Caring for Yourself in the Months and Years after Surgery

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

Mammograms

Mammograms of a reconstructed breast are not usually performed. The following may apply to the contralateral breast, if an implant is present, or to the reconstructed breast if it is being imaged:

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

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

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

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

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

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

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

Other Breast Exams

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

You can find brochures about how to perform breast self-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.[75]

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

If your implant ruptures, it is more likely that you will not experience any symptoms and you will not 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, but utilizing magnets instead of ionizing radiation) 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 MemoryShape™ Breast Implant, Mentor conducted the MemoryShape™ 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 MemoryShape™ Breast Implants. The results of the MemoryShape™ Core Study should not be used to predict your own experience with the MemoryShape™ Breast Implant, but the information can be used as a general guide about what you may expect. Your own benefits and complications depend on many individual factors.

8.1 Overview of the Study

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

There are 955 patients participating in the MemoryShape™ Core Study. A total of 572 patients had primary augmentation, 124 patients had revision-augmentation, 191 patients had primary reconstruction, and 68 patients had revision-reconstruction. Of these patients, 252 primary augmentation patients, 56 revision-augmentation patients, 74 primary reconstruction patients and 37 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 MemoryShape™ 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 Short Form Health Survey (SF-36), and the Breast Evaluation Questionnaire.

The 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 reconstruction with MENTOR® MemoryShape™ Breast Implants, based on the experiences of the reconstruction patients in the MemoryShape™ Core Study.

8.2 What are the 3-Year and 6-Year Follow-up Rates?

The study enrolled 191 primary reconstruction patients and 124 revision-reconstruction patients. At the 3-year follow-up visit, data are reported for 93% of the eligible primary reconstruction patients and 91% of the eligible revision-reconstruction patients. At the 6-year follow-up visit, data are reported for 73% of the eligible primary reconstruction

patients and 76% of the eligible revision-reconstruction patients.

8.3 What are the Benefits?

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

Primary Reconstruction Patients

Most primary reconstruction patients were pleased with the results of their implant surgery though 6 years. Eighty-five of the 191 patients enrolled were included in the circumferential chest size analysis. The average increase in circumferential chest size was 0.3 inches (0.8 centimeters). In regards to overall satisfaction, 97 (98%) of the 99 primary reconstruction patients who answered the patient satisfaction question indicated they would make the same decision to have breast surgery. From before breast surgery to 6 years, there was a significant decrease observed in the Self Esteem Scale total score, and a significant increase in the Body Esteem Scale chest score. According to their scores on a questionnaire about a variety of general QoL concepts (health, mental, and social well being), there was a significant improvement in the physical component score, but no significant change in the mental component score compared to their QoL before getting implants. Other findings of the MemoryShape™ Core Study showed that in regards to satisfaction, of the 106 primary reconstruction patients that answered the question “How satisfied with the general appearance of your breasts are you?”; 39 (37%) were very satisfied, 30 (28%) were somewhat satisfied, 7 (7%) were neither satisfied nor dissatisfied, 24 (23%) were somewhat dissatisfied and 6 (6%) were very dissatisfied. Based on the Breast Evaluation Questionnaire, the average improvement from before getting implants was 10% for comfort when not fully dressed, 8% for comfort when fully dressed, and 26% for satisfaction with breast characteristics.

Revision-Reconstruction Patients

Most revision-reconstruction patients were pleased with the results of their

additional implant surgery through 6 years. Thirty-six of the 68 patients enrolled were included in the circumferential chest size analysis. The average increase in circumferential chest size was 0.2 inches (0.5 centimeters). In regards to overall satisfaction, 36 (97%) of the 37 revision-reconstruction patients who answered the patient satisfaction question indicated they would make the same decision to have breast surgery. From before breast surgery to 6 years, there was a significant increase observed in the Body Esteem Scale chest score. According to their scores on a questionnaire about a variety of general QoL concepts (health, mental, and social well being), there was no significant change compared to their QoL before getting implants. Other findings of the MemoryShape™ Core Study showed that in regards to satisfaction, of the 38 revision-reconstruction patients that answered the question "How satisfied with the general appearance of your breasts are you?"; 10 (26%) were very satisfied, 13 (34%) were somewhat satisfied, 2 (5%) were neither satisfied nor dissatisfied, 8 (21%) were somewhat dissatisfied and 5 (13%) were very dissatisfied. Based on the Breast Evaluation Questionnaire, the average improvement from before getting implants was 29% for comfort when not fully dressed, 12% for comfort when fully dressed, and 32% for satisfaction with breast characteristics.

8.4 What were the 3-Year and 6-Year Complication Rates?

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

Primary Reconstruction

The complications observed in women who had primary reconstruction through 3 and 6 years are presented in Table 6. The most common reported complication within the first 3 and 6 years after primary reconstruction surgery was reoperation (36% or approximately 36 out of 100 through 3 years; and 44% or approximately 44 out of 100 through 6 years).

Table 6
3-Year and 6-Year Complication Rates for Primary Reconstruction Patients, N=191 Patients

	Year 3 %	Year 6 %
Any Complication Excluding Rupture[1]	54.4	64.9
Key Complications		
Any Reoperation	36.1	44.5
Capsular Contracture Baker Grade III/IV	5.6	10.1
Implant Removal with or without Replacement	13.8	21.8
Implant Removal with Replacement with Study Device	6.0	7.4
Implant Rupture (Based on the MRI Cohort)[2]	-	1.6
Infection	1.6	1.6
Other Complications Occurring in 1% or More of Patients[3]		
Asymmetry[4]	6.0	10.6
Breast Sensation Changes[4]	1.1	1.1
Breast pain[4]	2.8	2.8
Capsular Contracture Baker II w/ Surgical Intervention	1.7	4.2
Capsular Contracture Baker III	4.6	9.1
Capsular Contracture Baker IV	1.6	1.6
Death[5]	1.1	4.5
Delayed Wound Healing[4]	1.0	1.0
Excess Skin/tissue	4.3	4.3
Hypertrophic Scarring	1.1	2.4
Implant Immobility	2.4	3.8
Implant Rotation	3.4	5.1
Irritation/Inflammation	2.1	2.1
Itching	0.5	1.3
Lack Of Projection	5.0	8.5
Loss Of Definition Of Inframammary Fold	1.7	2.3
Mass/cyst	2.8	4.6
Metastatic Disease	2.3	2.3
Miscarriage	0.6	2.1
New Diagnosis of Rheumatic Disease[6]	1.7	1.7
Nipple Sensation Changes[4]	2.3	2.9
Other: Missing	0	1.6
Patient Dissatisfied With Aesthetic Appearance Of Breast	2.2	5.1
Patient Dissatisfied With Feel Of Implant	1.7	1.7
Position Dissatisfaction[4]	0.5	2.1
Ptosis (sagging)	2.9	5.8
Recurrent Breast Cancer	1.7	2.5
Scarring	2.9	2.9
Seroma	2.7	3.4

Shape Distortion	0	1.6
Size Change-Patient Request	5.0	5.0
Size Change-Physician Assessment only	2.1	2.1
Skin Lesion	1.1	1.8
Suture Complication	1.7	1.7
Tenderness/ Soreness	0.5	1.4
Wrinkling[4]	3.3	4.0

[1] 129 primary reconstruction patients experienced at least one or more complication or reoperation
[2]Implant Rupture (based on the MRI cohort) was assessed by MRI at 1, 2, 4, and 6 years (results provided in Table 10); there were no cases of rupture reported through 6 years in the non-MRI cohort of primary reconstruction patients (N=117).
[3]The following complications occurred at a rate less than 1%: capsular contracture Baker unknown, external injury not related to breast implants, muscle atrophy, necrosis, new diagnosis of breast cancer, nipple complication, palpability-implant, swelling (excessive), symmastia, wound opening.
[4]Mild occurrences were not included
[5]All causes of death were reported by the investigator to be unrelated to study procedure or device.
[6]There were 3 diagnoses in 3 primary reconstruction patients: rheumatoid arthritis (10 months post implantation), other inflammatory arthritis (11 months post implantation), and other mechanical/degenerative condition (16 months post implantation).

Revision-Reconstruction

The complications observed in women who had revision-reconstruction through 3 and 6 years are presented in Table 7. The most common reported complication within the first 3 and 6 years after revision-reconstruction surgery was reoperation (28% or approximately 28 out of 100 through 3 years; and 45% or approximately 45 out of 100 through 6 years).

Table 7
3-Year and 6-Year Complication Rates for Revision-Reconstruction Patients, N=68 Patients

	Year 3 %	Year 6 %
Any Complication Excluding Rupture[1]	55.5	67.7
Key Complications		
Any Reoperation	28.4	45.4
Capsular Contracture Baker Grade III/IV	13.5	16.4
Implant Removal with or without Replacement	21.0	34.2
Implant Removal with Replacement with Study Device	4.4	10.8
Implant Rupture (Based on the MRI Cohort)[2]	-	0
Infection	3.0	3.0
Other Complications Occurring in 1% or More of Patients[3]		
Asymmetry[4]	6.1	6.1
Breast pain[4]	3.3	3.3

Capsular Contracture Baker II w/ Surgical Intervention	1.5	3.7
Capsular Contracture Baker III	13.5	13.5
Capsular Contracture Baker IV	0	3.0
Death[5]	1.7	1.7
Excess Skin/tissue	1.6	1.6
Gel Fracture[6]	0	2.0
Hematoma	1.5	1.5
Implant Immobility	1.9	1.9
Implant Rotation	1.5	1.5
Irritation/Inflammation	3.0	3.0
Lack Of Projection	11.8	13.7
Loss Of Definition Of Inframammary Fold	1.5	1.5
Metastatic Disease	1.6	1.6
Muscle Atrophy	1.5	1.5
Numbness/Tingling (Paresthesia)	3.4	3.4
Palpability-Implant[4]	3.5	3.5
Patient Dissatisfied With Aesthetic Appearance Of Breast	6.3	8.4
Patient Dissatisfied With Feel Of Implant	1.5	3.8
Position Dissatisfaction[4]	4.9	4.9
Ptosis (sagging)	5.0	12.2
Recurrent Breast Cancer	1.5	3.6
Redness (Erythema)	1.5	1.5
Scarring	1.5	6.5
Seroma	4.6	4.6
Silicone From Previous Rupture	1.5	1.5
Size Change-Patient Request	7.8	9.9
Size Change-Physician Assessment only	0	4.8
Skin Lesion	1.8	4.3
Swelling (Excessive)	1.5	1.5
Wrinkling[4]	9.5	12.2

[1] 46 revision-reconstruction patients experienced at least one complication or reoperation
[2] Rupture was assessed by MRI at 1, 2, 4, and 6 years (results provided in Table 10); there were no cases of rupture reported through 6 years in the non-MRI cohort of revision reconstruction patients (N=31).
[3]No complications occurred at a rate less than 1%.
[4]Mild occurrences not included
[5]All causes of death were reported by the investigator to be unrelated to study procedure or device.
[6]Gel fracture occurred in 1 revision-reconstruction patient.

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

Primary Reconstruction

In Mentor's MemoryShape™ Core Study, 36% of the primary reconstruction patients had at least one reoperation through 3 years (a total of 80 reoperations performed in 68 patients). Through 6 years, 42% of the patients had at least one reoperation (a total of 108 reoperations performed in 81 patients). Table 8 provides the main reasons for reoperation. The most common reason for reoperation through both 3 and 6 years in these patients was asymmetry.

Table 8
Main Reasons for Reoperation in Primary Reconstruction Patients

Primary Reason for Reoperation	Year 3 n (%) of 80 Reoperations[1]	Year 6 n (%) of 108 Reoperations[2]
Asymmetry	12 (15.0)	13 (12.0)
Capsular Contracture Baker Grade II with Surgical Intervention	1 (1.3)	2 (1.9)
Capsular Contracture Baker Grade III/IV	4 (5.0)	6 (5.6)
Breast Mass/Cyst	5 (6.3)	8 (7.4)
Calcification	0	1 (0.9)
Delayed Wound Healing	1 (1.3)	1 (0.9)
Excess Skin/tissue	6 (7.5)	6 (5.6)
Extrusion	1 (1.3)	1 (0.9)
Implant Rotation	4 (5.0)	4 (3.7)
Infection	1 (1.3)	1 (0.9)
Lack of Projection	3 (3.8)	5 (4.6)
New Diagnosis of Breast Cancer	0	1 (0.9)
Nipple-Unacceptably Low Sensitivity	0	1 (0.9)
Position Dissatisfaction	5 (6.3)	7 (6.5)
Ptosis (sagging)	0	1 (0.9)
Scarring	5 (6.3)	5 (4.6)
Seroma	2 (2.5)	7 (6.5)
Size Change-Patient Request	4 (5.0)	4 (3.7)
Size Change-Physician Assessment only	4 (5.0)	4 (3.7)

Primary Reason for Reoperation	Year 3 n (%) of 80 Reoperations[1]	Year 6 n (%) of 108 Reoperations[2]
Wrinkling	4 (5.0)	5 (4.6)
Other	10 (12.5)	12 (11.1)
Excessive Skin Along Incision	1 (1.3)	1 (0.9)
Implant Immobility	0	2 (1.9)
Lack of Nipple Projection	1 (1.3)	1 (0.9)
Patient Dissatisfied with Aesthetic Appearance of Breast	2 (2.5)	2 (1.9)
Recurrent Breast Cancer	2 (2.5)	2 (1.9)
Skin Lesion	1 (1.3)	1 (0.9)
Suspected Rupture	1 (1.3)	1 (0.9)
Suture Complications	1 (1.3)	1 (0.9)
Missing	9 (11.3)	14 (13.0)

[1] 80 reoperations in 68 patients
[2] 108 reoperations in 81 patients

Revision-Reconstruction

In the Mentor's MemoryShape™ Core Study, 28% of the revision reconstruction patients had at least one reoperation through 3 years (a total of 23 reoperations performed in 19 revision-reconstruction patients). Through 6 years, 43% of the patients had at least one reoperation (a total of 36 reoperations in 29 patients). Table 9 provides the main reasons for reoperation. The two most common reasons for reoperation through 3 years were nipple complication and wrinkling, and through 6 years the most common reasons were capsular contracture III/IV and nipple complication.

Table 9
Main Reasons for Reoperation in Revision-Reconstruction Patients

Primary Reason for Reoperation	Year 3 n (%) of 23 Reoperations[1]	Year 6 n (%) of 36 Reoperations[2]
Asymmetry	2 (8.7)	3 (8.3)
Capsular Contracture I with Surgical Intervention	1 (4.3)	2 (5.6)
Capsular Contracture Baker Grade III/IV	2 (8.7)	4 (11.1)
Breast pain	1 (4.3)	1 (2.8)
Infection	1 (4.3)	1 (2.8)
Lack of Projection	1 (4.3)	3 (8.3)
Nipple Complication	3 (13.0)	4 (11.1)
Position Dissatisfaction	2 (8.7)	2 (5.6)

Primary Reason for Reoperation	Year 3 n (%) of 23 Reoperations[1]	Year 6 n (%) of 36 Reoperations[2]
Seroma	1 (4.3)	1 (2.8)
Size Change-Patient Request	2 (8.7)	3 (8.3)
Wrinkling	3 (13.0)	3 (8.3)
Other	4 (17.4)	8 (22.2)
Breast Mass/cyst	0	1 (2.8)
Excess Skin/tissue	0	1 (2.8)
Implant Immobility	0	1 (2.8)
Patient Dissatisfied with Aesthetic Appearance of Breast	1 (4.3)	2 (5.6)
Recurrent Breast Cancer	1 (4.3)	1 (2.8)
Scarring	1 (4.3)	1 (2.8)
Skin Lesion	1 (4.3)	1 (2.8)
Missing	0	1 (2.8)

[1] 23 reoperations in 19 patients
[2] 36 reoperations in 29 patients

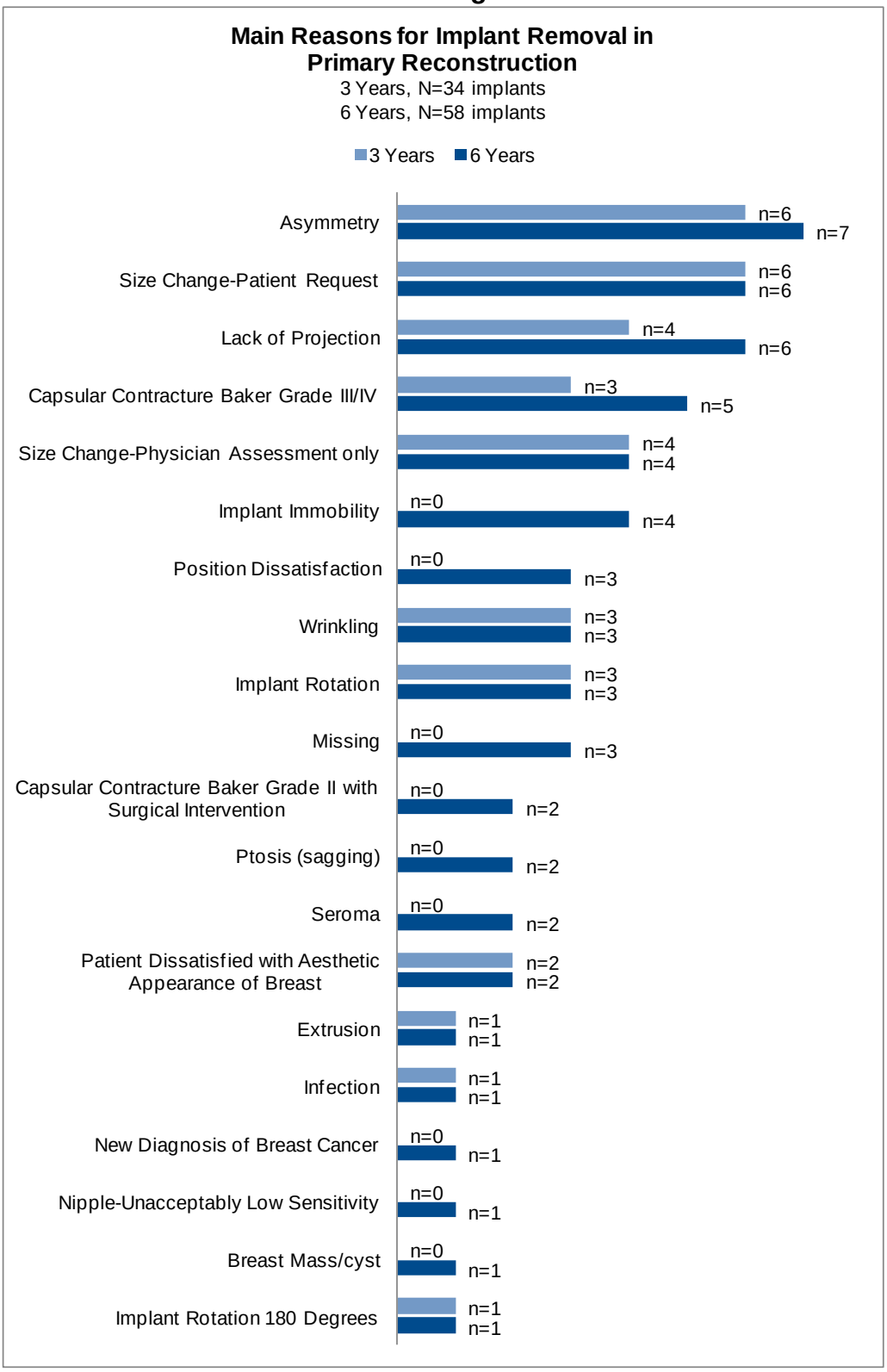
8.6 What are the Main Reasons for Implant Removal?

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

Primary Reconstruction

The main reasons for implant removal among primary reconstruction patients in the MemoryShape™ Core Study through 3 and 6 years are shown in Figure 6 below. There were a total of 34 implants removed in 26 patients through 3 years, and a total of 58 implants removed in 39 patients through 6 years. Of the 34 implants removed through 3 years, 11 (32%) were replaced with a study device; of the 58 implants removed through 6 years, 13 (22%) were replaced with a study device. The most common reasons for implant removal through 3 years (6 each of the 34 implants removed) were asymmetry and patient requested size change. Through 6 years, the most common reason for implant removal (7 of the 58 implants removed) was asymmetry. Note that the 6-year results also include any events that occurred by 3 years.

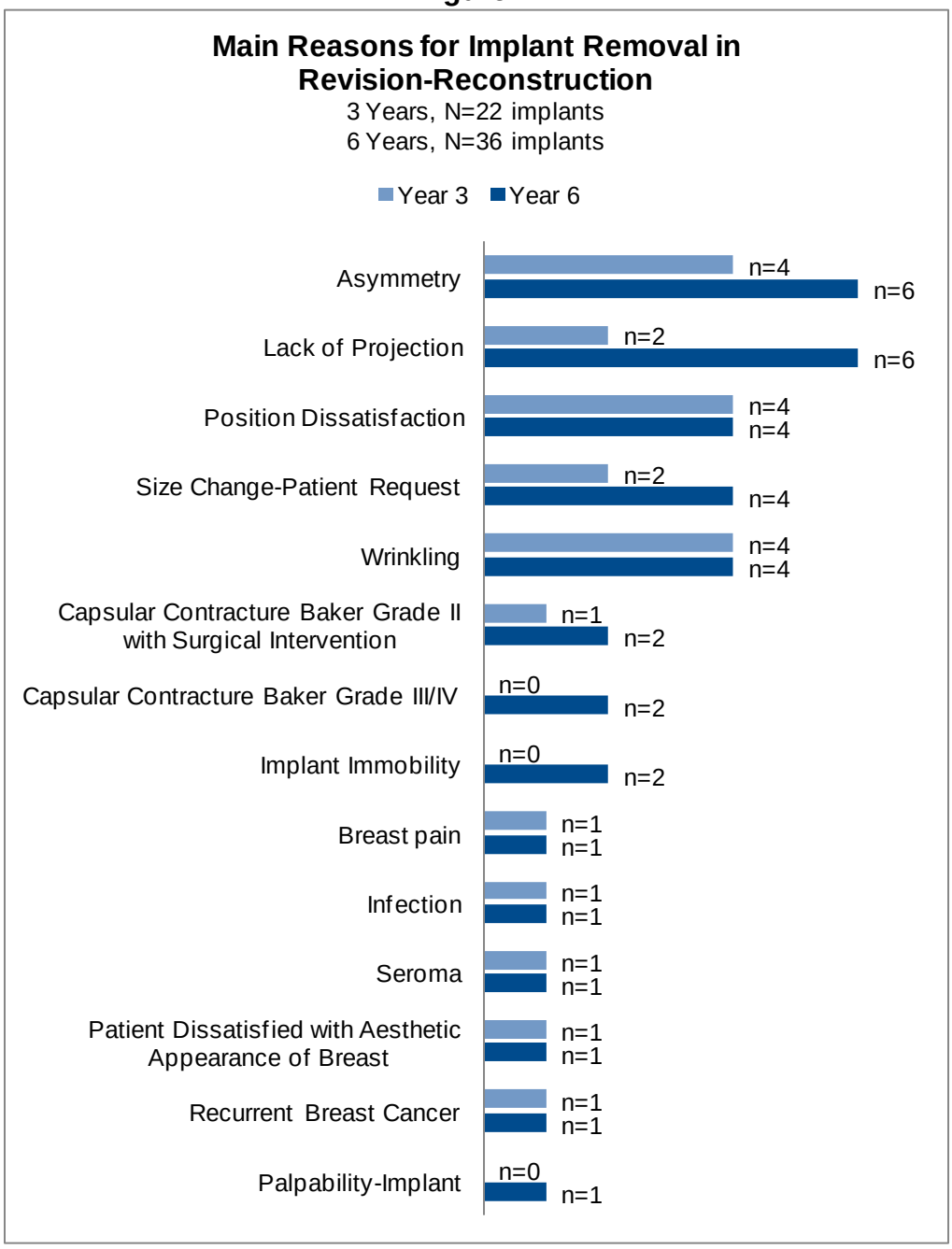
Figure 6


Main Reasons for Implant Removal in Primary Reconstruction
3 Years, N=34 implants
6 Years, N=58 implants
3 Years
6 Years
Asymmetry
n=6
n=7
Size Change-Patient Request
n=6
n=6
Lack of Projection
n=4
n=6
Capsular Contracture Baker Grade III/IV
n=3
n=5
Size Change-Physician Assessment only
n=4
n=4
Implant Immobility
n=0
n=4
Position Dissatisfaction
n=0
n=3
Wrinkling
n=3
n=3
Implant Rotation
n=3
n=3
Missing
n=0
n=3
Capsular Contracture Baker Grade II with Surgical Intervention
n=0
n=2
Ptosis (sagging)
n=0
n=2
Seroma
n=0
n=2
Patient Dissatisfied with Aesthetic Appearance of Breast
n=2
n=2
Extrusion
n=1
n=1
Infection
n=1
n=1
New Diagnosis of Breast Cancer
n=0
n=1
Nipple-Unacceptably Low Sensitivity
n=0
n=1
Breast Mass/cyst
n=0
n=1
Implant Rotation 180 Degrees
n=1
n=1

Revision-Reconstruction

The main reasons for implant removal among revision reconstruction patients in the MemoryShape™ Core Study through 3 and 6 years are shown in Figure 7 below. There were a total of 22 implants removed in 14 patients through 3 years, and a total of 36 implants removed in 22 patients through 6 years. Of the 22 implants removed through 3 years, 4 (18%) were replaced with a study device; of the 36 implants removed through 6 years, 8 (22%) were replaced with a study device. The most common reasons for implant removal through 3 years (4 each of the 22 implants removed) were asymmetry, position dissatisfaction, and wrinkling. Through 6 years, the most common reason for removal (6 each of the 36 implants removed) were asymmetry and lack of projection. Note that the 6-year results also include any events that occurred by 3 years.

Figure 7



8.7 What are Other Clinical Data Findings?

The 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 additional post approval studies.

Rupture

In the MemoryShape™ Core Study, there are 74 primary reconstruction patients and 37 revision-reconstruction 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 71% (291 of 411 expected due), 83% (334 of 403 expected due), 72% (279 of 387 expected due), and 56% (212 of 380 expected due), respectively.

For primary reconstruction patients in the MRI cohort (N=74), the estimated rate of suspected or confirmed rupture was approximately 1.5% through 6 years. This means that through 6 years, an estimated 1 to 2 of every 100 primary reconstruction patients will have a ruptured breast implant. For revision-reconstruction patients (N=37), there have been no reports of rupture through 6 years. The specific estimated rates of suspected or confirmed rupture through 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 Reconstruction[1], N=74	1.6% (n=1)	1.6% (n=1)	1.6% (n=1)	1.6% (n=1)
Revision-Reconstruction, N=37	0% (n=0)	0% (n=0)	0% (n=0)	0% (n=0)

[1] One report of a ruptured replacement study implant (primary reconstruction) from the MRI cohort was not included in the rupture analyses because the patient no longer had the original study implant; only original study implants were included in the analyses.

Overall, there were 9 suspected or confirmed reports of rupture for 9 of the patients participating in the study, 7 reports among patients in the MRI cohort (4 primary augmentation, 1 revision-augmentation, and 2 primary reconstruction patients) and 2 reports among patients not in the MRI cohort (1 primary augmentation and 1 revision-augmentation patient). One report of a ruptured replacement study implant (primary reconstruction) from the MRI cohort was not included in the rupture analyses because the patient no longer had the original study implant; only original

study implants were included in the analyses. Of the 9 suspected or confirmed ruptured implants in the overall study, including the 2 that were found in the non-MRI cohort, 1 case was indeterminate for extracapsular silicone by MRI. There were no cases of migrated gel. The rupture rate beyond 6 years in Mentor's MemoryShape™ Core Study continues to be investigated.

Cancer

There was one primary reconstruction patient and no revision-reconstruction patients with new diagnoses of breast cancer through 6 years in Mentor's MemoryShape™ Core Study. Four primary reconstruction patients and two revision-reconstruction patients had a diagnosis of recurrent breast cancer through 6 years. 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 MemoryShape™ Core Study.

Connective Tissue Disease (CTD)

In the MemoryShape™ Core Study, there were 3 primary reconstruction patients and no revision-reconstruction patients with a new diagnosis of a CTD by a rheumatologist. There were 3 diagnoses for the 3 primary reconstruction patients: rheumatoid arthritis (10 months post implantation), other inflammatory arthritis (11 months post implantation), and other mechanical/degenerative condition (16 months post implantation). It cannot be concluded that these CTD diagnoses were caused by the breast implants because there was no comparison group of similar women without implants.

CTD Signs and Symptoms

The MemoryShape™ Core Study collected information on CTD signs and symptoms (that did not result in a diagnosis of a CTD). For all four cohorts combined (primary and revision–augmentation, primary reconstruction, and revision-reconstruction), a significant increase in combined pain was found after adjusting for the effect of age. At 6 years, compared to before having implants, a significant decrease in night sweats was found for primary reconstruction patients, while no significant changes were found for revision-reconstruction.

The MENTOR® MemoryShape™ 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

None of the primary reconstruction or revision-reconstruction patients attempted to breastfeed through 6 years in Mentor's MemoryShape™ Core Study.

Reproduction Complications

Reproduction complications that were examined in the MemoryShape™ Core Study include miscarriage and having a stillborn baby. Three primary reconstruction patients and no revision-reconstruction patients reported a miscarriage in Mentor's MemoryShape™ Core Study through 6 years.

Suicide

There were no reports of suicide in primary reconstruction or revision-reconstruction patients in the MemoryShape™ 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 MemoryShape™ 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 MemoryShape™ Breast Implant. It also discusses safety information and research performed on implants in general and on MENTOR® MemoryShape™ 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 MemoryShape™ 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 at (866) 250-5115.

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

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

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

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

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

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

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

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 MemoryShape™ 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 MemoryShape™ Breast Implants are manufactured for 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. These programs apply to all recipients of Mentor breast implant products. For more information, please contact Mentor's Consumer Affairs Department at (866) 250-5115 or visit www.mentorwwllc.com.

14. ACKNOWLEDGEMENT OF INFORMED DECISION

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

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

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

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

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

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

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

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

Patient or Guardian Name (Printed)

Patient or Guardian Signature

Date

By my signature below, I acknowledge that:

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

Implanting Surgeon Name (Printed)

Implanting Surgeon Signature

Date

15. INDEX

Alternatives to Breast Implantation.....25
Anaplastic Large Cell Lymphoma (ALCL)46, 85
Anesthesia..... 54, 56, 57, 61, 66
Asymmetry..... 41, 78, 80, 82
Autoimmune Disease..... 22, 48, 50
Axillary Incision 62
Benefits.....51, 73
Biopsy.....38, 45
Body Dysmorphic Disorder (BDD)..... 22, 49
Breast Augmentation.....20
Breast Feeding/Lactation 23, 41, 86
Breast Implant.....19
Breast Implant Product Sizes 60
Breast Mass.....78, 80
Breast Reconstruction..... 20, 51
Breast Self-Exams 68
Breast Tissue Atrophy.....43
Breast Tissue Expander.....53
Calcium Deposits/Calcification 43, 78
Cancer 20, 24, 39, 45, 47, 78, 79, 80, 85
Capsular Contracture 35, 50, 69, 75, 76, 78, 79
Capsule.....35, 71
Capsulotomy.....37
Chest Wall Deformity 43
Complications 23, 26, 34, 50, 58, 75, 76
Congenital Anomaly..... 20, 63
Connective Tissue Disease (CTD)39, 48, 85
Contraindications 21
CTD Signs and Symptoms.....85
Delayed Reconstruction..... 63, 64
Delayed Wound Healing 42, 78
Device Identification Card 69, 89
Device Tracking 89
Effects on Children.....49
Fibromyalgia 48
Fibrous Tissue 47, 48
Food and Drug Administration (FDA) 47, 87, 88
Gel Bleed/Gel Diffusion..... 37, 50, 68
Gel Migration 38
Granuloma.....39
Hematoma 35, 60
Immediate Reconstruction 63, 64
Implant Displacement.....41
Implant Extrusion 42, 43, 60
Implant Palpability 41
Implant Removal 23, 40, 75, 76
Implant Rupture.... 37, 68, 70, 71, 79, 84, 90
Infection 34, 60, 66, 75, 76, 78, 79
Inframammary Incision 62
Latissimus Dorsi Flap 57
Low Molecular Weight (LMW) Silicone 50
Lumpectomy 18
Lymphadenopathy.....44, 50
Magnetic Resonance Imaging (MRI) .24, 69, 70, 71
Mammography 24, 45, 67
Mastectomy.....52, 53
Mastopexy.....59, 64
MedWatch.....87
MemoryShape™ Core Study.....85
MENTOR® MemoryShape™ Core Study26, 71
Necrosis.....42
Neurological Disease 50
Pain.....41, 79
Periareolar Incision 62
Periumbilical Approach.....62
Plastic Surgery.....65, 88
Platinum.....50
Postoperative Care 66, 67
Precautions.....22
Ptosis (sagging) 78
Reoperation 39, 75, 76
Reproduction Complications.....86
Revision-Reconstruction 20
Risks.....26, 44
rupture.....85
Saline..... 25, 50, 54
Scar Revision.....78
Scarring..... 41, 42, 78, 80
Seroma 35, 78, 80
Silent Rupture 24, 70
Silicone 19, 49, 50
Subglandular Placement 19
Submuscular Placement 19
Suicide 49, 86
Summary of Safety and Effectiveness Document (SSED) 88
Surgical Incision.....26
Symptomatic Rupture.....70
Systemic Disease.....39

Tissue Flap Procedure 52, 55
Tissue Flap Reconstruction 25
Toxic Shock Syndrome (TSS) 34
TRAM Flap 56
Warnings 23
Wrinkling 41, 60, 79, 80, 82

16. REFERENCES

1 Collis, N., et al. Magnetic Resonance Imaging and Explantation Investigation of Long-Term Silicone Gel Implant Integrity. Plast. Reconstr. Surg. 120(5): 1401-1406 (2007).

2 Hölmich, L.R., et al. Prevalence of silicone breast implant rupture among Danish women. Plast. Reconstr. Surg. 108(4):848-858 (2001).

3 Gaubitz, M., Jackisch, C., Domschke, W., Heindel, W. & Pfleiderer, B. Silicone breast implants: correlation between implant ruptures, magnetic resonance spectroscopically estimated silicone presence in the liver, antibody status and clinical symptoms. Rheumatology (Oxford) 41, 129-135; discussion 123-124 (2002).

4 Brown, S. L., Duggirala, H. J. & Pennello, G. An association of silicone-gel breast implant rupture and fibromyalgia. Curr Rheumatol Rep 4, 293-298 (2002).

5 Brown, S. L., Pennello, G., Berg, W. A., Soo, M. S. & Middleton, M. S. Silicone gel breast implant rupture, extracapsular silicone, and health status in a population of women. J Rheumatol 28, 996-1003 (2001).

6 Hölmich, L. R. et al. Self-reported diseases and symptoms by rupture status among unselected Danish women with cosmetic silicone breast implants. Plast Reconstr Surg 111, 723-732; discussion 733-724 (2003).

7 Katzin, W. E., Centeno, J. A., Feng, L. J., Kiley, M. & Mullick, F. G. Pathology of lymph nodes from patients with breast implants: a histologic and spectroscopic evaluation. Am J Surg Pathol 29, 506-511 (2005).

8 Berner, I., Gaubitz, M., Jackisch, C. & Pfleiderer, B. Comparative examination of complaints of patients with breast-cancer with and without silicone implants. Eur J Obstet Gynecol Reprod Biol 102, 61-66 (2002).

9 Bondurant, S., Ernster, V. L. & Herdman, R. Safety of Silicone Breast Implants. Committee on the Safety of Silicone Breast Implants, Division of Health Promotion and Disease Prevention, Institute of Medicine. (National Academy Press., 2000).

10 Brown, S. L., Todd, J. F., Cope, J. U. & Sachs, H. C. Breast implant surveillance reports to the U.S. Food and Drug Administration: maternal child health problems. J Long Term Eff Med Implants 16, 281-290 (2006).

11 Hurst, N.M. Lactation after augmentation mammoplasty. Obstet. Gynecol. 87(1):30-4 (1996).

12 American College of Obstetrics and Gynecology (ACOG). Breastfeeding: Maternal and Infant Aspects. Educational Bulletin Number 258 (July 2000).

13 Kronowitz, S. J. & Robb, G. L. Radiation therapy and breast reconstruction: a critical review of the literature. Plast Reconstr Surg 124, 395-408 (2009).

14 International Agency for Research on Cancer (IARC). Vol. 74 (IARC Press 1999).

15 European Committee on Quality Assurance (EQUAM) and Medical Devices in Plastic Surgery. Consensus declaration on breast implants 23-6-2000. Israel, European Committee

16 National Institutes of Health (NIH). Breast implants: Status of research at the National Institutes of Health (2005).

17 Herdman, R.C., et al. Silicone breast implants and cancer. Cancer Invest. 2001;19(8):821-32 (2001).

18 Brisson, J. et al. Cancer incidence in a cohort of Ontario and Quebec women having bilateral breast augmentation. Int J Cancer 118, 2854-2862 (2006).

19 Brinton, L. A. et al. Breast cancer following augmentation mammoplasty (United States). Cancer Causes Control 11, 819-827 (2000).

20 Deapen, D., Hamilton, A., Bernstein, L. & Brody, G. S. Breast cancer stage at diagnosis and survival among patients with prior breast implants. Plast Reconstr Surg 105, 535-540 (2000).

21 Deapen, D. M., Hirsch, E. M. & Brody, G. S. Cancer risk among Los Angeles women with cosmetic breast implants. Plast Reconstr Surg 119, 1987-1992 (2007).

22 Englert, H. et al. Women's health after plastic surgery. Intern Med J 31, 77-89 (2001).

23 Friis, S. et al. Cancer risk among Danish women with cosmetic breast implants. Int J Cancer 118, 998-1003 (2006).

24 Hölmich, L. R. et al. Stage of breast cancer at diagnosis among women with cosmetic breast implants. Br J Cancer 88, 832-838 (2003).

25 Jakub, J. W. et al. Breast cancer in patients with prior augmentation: presentation, stage, and lymphatic mapping. Plast Reconstr Surg 114, 1737-1742 (2004).

26 McLaughlin, J. K. et al. Long-term cancer risk among Swedish women with cosmetic breast implants: an update of a nationwide study. J Natl Cancer Inst 98, 557-560 (2006).

27 Mellemkjaer, L. et al. Cancer occurrence after cosmetic breast implantation in Denmark. Int J Cancer 88, 301-306 (2000).

28 Pukkala, E. et al. Incidence of breast and other cancers among Finnish women with cosmetic breast implants, 1970-1999. J Long Term Eff Med Implants 12, 271-279 (2002).

29 Brinton LA, et al. Mortality rates among augmentation mammoplasty patients: An update. Epidemiology. Mar;17(2):162-9 (2006).

30 Jakubietz, M. G., Jeffrey, J., Jakubietz, R. & Rohrich, R.J. Breast augmentation: Cancer concerns and mammography - A literature review. Plast. Reconstr. Surg. 113, 117e-122e (2004).

31 Miglioretti, D. L. et al. Effect of breast augmentation on the accuracy of mammography and cancer characteristics. Jama 291, 442-450 (2004).

32 McLaughlin, J.K. and L. Lipworth. 2004. Brain cancer and cosmetic breast implants: A review of the epidemiological evidence. Ann. Plast. Surg. 52(2):15-17.

33 Brinton, L. A. et al. Cancer risk at sites other than the breast following augmentation mammoplasty. Ann Epidemiol 11, 248-256 (2001).

34 de Jong, D. et al. Anaplastic large-cell lymphoma in women with breast implants. Jama 300, 2030-2035 (2008).

35 Cook, L. S. et al. Characteristics of women with and without breast augmentation. Jama 277, 1612-1617 (1997).

36 Fryzek, J. P. et al. Characteristics of women with cosmetic breast augmentation surgery compared with breast reduction surgery patients and women in the general population of Sweden. Ann Plast Surg 45, 349-356 (2000).

37 Kjøller, K. et al. Characteristics of women with cosmetic breast implants compared with women with other types of cosmetic surgery and population-based controls in Denmark. Ann Plast Surg 50, 6-12 (2003).

38 Breiting, V. B. et al. Long-term health status of Danish women with silicone breast implants. Plast Reconstr Surg 114, 217-226; discussion 227-218 (2004).

39 Fryzek, J.P., et al. Self-reported symptoms among women after cosmetic breast implant and breast reduction surgery. Plast. Reconstr. Surg. 107:206-13 (2001).

40 Kjøller, K., et al. Self-reported musculoskeletal symptoms among Danish women with cosmetic breast implants. Ann Plast Surg. 52(1):1-7 (2004).

41 Blackburn, W. D., Jr. & Everson, M. P. Silicone-associated rheumatic disease: an unsupported myth. Plast Reconstr Surg 99, 1362-1367 (1997).

42 Brinton, L. A. et al. Risk of connective tissue disorders among breast implant patients. Am J Epidemiol 160, 619-627 (2004).

43 Fryzek, J. P. et al. A nationwide study of connective tissue disease and other rheumatic conditions among Danish women with long-term cosmetic breast implantation. Ann Epidemiol 17, 374-379 (2007).

44 Greenland, S. & Finkle, W. D. A retrospective cohort study of implanted medical devices and selected chronic diseases in Medicare claims data. Ann Epidemiol 10, 205-213 (2000).

45 Hochberg, M. C. & Perlmutter, D. L. The association of augmentation mammoplasty with connective tissue disease, including systematic sclerosis (scleroderma): a meta-analysis. Curr Top Microbiol Immunol 210, 411-417 (1996).

46 Janowsky, E. C., Kupper, L. L. & Hulka, B. S. Meta-analyses of the relation between silicone breast implants and the risk of connective-tissue diseases. N Engl J Med 342, 781-790 (2000).

47 Kjøller, K. et al. Connective tissue disease and other rheumatic conditions following cosmetic breast implantation in Denmark. Arch Intern Med 161, 973-979 (2001).

48 Lamm, S. H. Silicone breast implants, breast cancer and specific connective tissue diseases: A systematic review of the data in the epidemiological literature Int. J. Toxicol. 17, 497-457 (1998).

49 Lewin, S. L. & Miller, T. A. A review of epidemiologic studies analyzing the relationship between breast implants and connective tissue diseases. Plast Reconstr Surg 100, 1309-1313 (1997).

50 Silverman, B. G. et al. Reported complications of silicone gel breast implants: an epidemiologic review. Ann Intern Med 124, 744-756 (1996).

51 Vermeulen, R. C. & Scholte, H. R. Rupture of silicone gel breast implants and symptoms of pain and fatigue. J Rheumatol 30, 2263-2267 (2003).

52 Wolfe, F. & Anderson, J. Silicone filled breast implants and the risk of fibromyalgia and rheumatoid arthritis. J Rheumatol 26, 2025-2028 (1999).

53 Wong, O. A critical assessment of the relationship between silicone breast implants and connective tissue diseases. Regul Toxicol Pharmacol 23, 74-85 (1996).

54 Lipworth et al. Silicone breast implants and connective tissue disease: no association. Semin. Immunopathol. 33(3):287-294 (2011).

55 Independent Review Group (IRG). Silicone Gel Breast Implants: Report of the IRG (United Kingdom) (1998).

56 Tugwell, P. et al. Do silicone breast implants cause rheumatologic disorders? A systematic review for a court-appointed national science panel. Arthritis Rheum 44, 2477-2484 (2001).

57 Lugowski, S. J. et al. Analysis of silicon in human tissues with special reference to silicone breast implants. J Trace Elem Med Biol 14, 31-42 (2000).

58 Kjøller, K. et al. Health outcomes in offspring of Danish mothers with cosmetic breast implants. Ann Plast Surg 48, 238-245 (2002).

59 Signorello, L. B., Fryzek, J. P., Blot, W. J., McLaughlin, J. K. & Nyren, O. Offspring health risk after cosmetic breast implantation in Sweden. Ann Plast Surg 46, 279-286 (2001).

60 Hemminki, E., Hovi, S. L., Sevon, T. & Asko-Seljavaara, S. Births and perinatal health of infants among women who have had silicone breast implantation in Finland, 1967-2000. Acta Obstet Gynecol Scand 83, 1135-1140 (2004).

61 Jacobsen, P. H. et al. Mortality and suicide among Danish women with cosmetic breast implants. Arch Intern Med 164, 2450-2455 (2004).

62 Koot, V. C., Peeters, P. H., Granath, F., Grobbee, D. E. & Nyren, O. Total and cause specific mortality among Swedish women with cosmetic breast implants: prospective study. BMJ 326, 527-528 (2003).

63 Le, G. M. et al. Breast implants following mastectomy in women with early stagebreast cancer: prevalence and impact on survival. Breast Cancer Res 7, R184-193 (2005).

64 Lipworth, L. et al. Excess mortality from suicide and other external causes of death among women with cosmetic breast implants. Ann Plast Surg 59, 119-123; discussion 124-115 (2007).

65 McLaughlin, J. K., Lipworth, L. & Tarone, R. E. Suicide among women with cosmetic breast implants: a review of the epidemiologic evidence. J Long Term Eff Med Implants 13, 445-450 (2003).

66 Pukkala, E. et al. Causes of death among Finnish women with cosmetic breast implants, 1971-2001. Ann Plast Surg 51, 339-342; discussion 343-334 (2003).

67 Villeneuve, P. J. et al. Mortality among Canadian women with cosmetic breast implants. Am J Epidemiol 164, 334-341 (2006).

68 Klesmer, J. Mortality in Swedish women with cosmetic breast implants: body dysmorphic disorder should be considered. British Medical Journal; 326, 1266-1267 (2003).

69 Winther, J. F. et al. Neurological disease among women with silicone breast implants in Denmark. Acta Neurol Scand 103, 93-96 (2001).

70 Flassbeck, D. et al. Determination of siloxanes, silicon, and platinum in tissues of women with silicone gel-filled implants. Anal Bioanal Chem 375, 356-362 (2003).

71 Chandra, G., Lo, P. Y., Hitchcock, P. & Lappert, M. F. A convenient and novel route to bis(alkyne)platinum(0) and other platinum(0) complexes from Speier's hydrosilylation catalyst. Organometallics, 191-192 (1987).

72 Lappert, M. F. & Scott, F. P. A. The reaction pathway from Speier's to Karstedt's hydrosilylation catalyst. J. Organomet. Chem. 492, C11-C13 (1995).

73 Lewis, L. N. et al. Mechanism of Formation of Platinum(0) Complexes Containing Silicon-Vinyl Ligands. Organometallics 14, 2202-2213 (1995).

74 Stein, J. In situ determination of the active catalyst in hydrosilylation reactions using highly reactive Pt(0) catalyst precursors. J. Am. Chem. Soc. 121, 3693-3703 (1999).

75 Hölmich, L.R., et al. Untreated silicone breast implant rupture. Plast. Reconstr. Surg. 114:204-214 (2004).

PATIENT EDUCATIONAL BROCHURE

AUGMENTATION

BREAST AUGMENTATION WITH MENTOR® MEMORYSHAPE™ BREAST IMPLANTS

TABLE OF CONTENTS

GLOSSARY **4**
1. HOW TO USE THIS EDUCATIONAL BROCHURE **15**
2. GENERAL INFORMATION ABOUT BREAST AUGMENTATION WITH BREAST IMPLANTS **16**
2.1 What Gives the Breast its Shape? 16
2.2 What is a Silicone Gel Breast Implant? 16
2.3 How Do Breast Implants Work in Breast Augmentation? 17
3. DECIDING WHETHER TO HAVE BREAST AUGMENTATION SURGERY WITH IMPLANTS **17**
3.1 Am I Eligible for Augmentation with Silicone Gel Breast Implants? 17
3.2 Contraindications 18
3.3 Precautions 19
3.4 Warnings 20
3.5 What are the Alternatives to Implantation with Silicone Gel Breast Implants? 22
4. RISKS ASSOCIATED WITH BREAST IMPLANTS **22**
4.1 What Are the Potential Complications? 31
4.2 What Are Other Reported Conditions? 41
5. BENEFITS ASSOCIATED WITH BREAST IMPLANTS **47**
6. PREPARING FOR BREAST AUGMENTATION WITH SILICONE GEL BREAST IMPLANTS **48**
6.1 Should I have Breast Augmentation? 48
6.2 Breast Augmentation with Implants – Understanding the Procedure 49
6.3 Choosing the Right Implant for You 52
6.4 Other Procedures at the Time of the Breast Augmentation 53
6.5 Choosing a Surgeon 54
7. CARING FOR YOURSELF AFTER BREAST IMPLANT SURGERY **55**
7.1 Postoperative Care in the Hours and Days after Surgery 55
7.2 Postoperative Care in the First Weeks after Surgery 56
7.3 Caring for Yourself in the Months and Years after Surgery 56
7.4 Monitoring Your Implants for Rupture 59
8. MENTOR'S CLINICAL STUDY RESULTS **60**
8.1 Overview of the Study 61
8.2 What are the 3-Year and 6-Year Follow-up Rates? 62
8.3 What are the Benefits? 62
8.4 What were the 3-Year and 6-Year Complication Rates? 63
8.5 What are the Main Reasons for Reoperation? 67
8.6 What are the Main Reasons for Implant Removal? 70
8.7 What are Other Clinical Data Findings? 74
9. WHAT TO DO IF YOU HAVE A PROBLEM **77**
10. WHERE TO FIND MORE INFORMATION **78**

11. MENTOR'S IMPLANT TRACKING PROGRAM 79
11.1 Breast Implant Tracking 79
11.2 Device Identification Card 79
12. IMPORTANT CONTACT INFORMATION 80
13. WARRANTY INFORMATION 81
14. ACKNOWLEDGEMENT OF INFORMED DECISION 81
15. INDEX 84
16. REFERENCES 85

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 Questionnaire (BEQ)	A series of questions that ask 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	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.
Gel fracture	The appearance of a fissure or fault line in the gel within the implant as a result of applied force.

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.
MemoryShape™ 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 MemoryShape™ 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), the SF-36 (measures physical, mental, and social health), and the Breast Evaluation Questionnaire (measures breast satisfaction).
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.
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 MemoryShape™ 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 "MemoryShape™ Core Study") that gathered data about these breast implants. There are 955 patients participating in the MemoryShape™ Core Study. A total of 572 patients had primary-augmentation, 124 patients had revision-augmentation, 191 patients had primary-reconstruction, and 68 patients had revision-reconstruction with MENTOR® MemoryShape™ 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 "Acknowledgement 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 "Acknowledgement of Informed Decision".

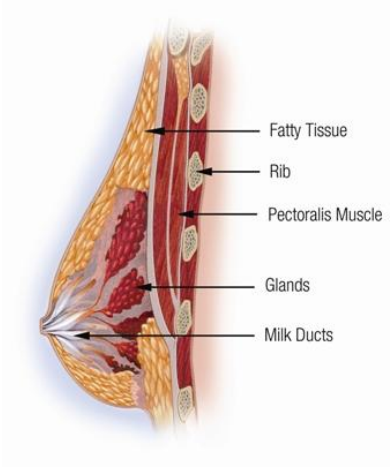
2. GENERAL INFORMATION ABOUT BREAST AUGMENTATION WITH BREAST IMPLANTS

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.

The MENTOR® MemoryShape™ Breast Implants are shaped devices that are intended to provide more volume in the lower breast and less volume in the upper breast. The breast implants have a textured (Siltex®) shell constructed of silicone elastomer. The MemoryShape™ Breast Implants are filled with a more cohesive (firmer feeling) gel when compared to the round MENTOR® MemoryGel® Breast Implants. Raised orientation marks on the front and back of the MemoryShape™ Breast Implants are intended to help the surgeon ensure proper placement during surgery. More information on the types of MemoryShape™ 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 MemoryShape™ Breast Implants. This is considered breast reconstruction with implants.

A different educational brochure that describes breast reconstruction with MemoryShape™ 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.

MemoryShape™ 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,
- 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, or
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder (BDD) 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 breast feeding. If you are planning to breast feed your infant, be prepared to use

formula and bottle-feed your baby in the event you have difficulty breast feeding.

- 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), or
- Having breast augmentation with saline-filled implants.
- Having fat injection(s)

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

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

4. RISKS ASSOCIATED WITH BREAST IMPLANTS

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

general, surgery-related complications and implant-related complications.

Tables 1 and 2 below present the potential risks associated with breast implant surgery, the likelihood of the risks based on the results from Mentor's MemoryShape™ Core Study through 3 and 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]		Possible Resulting Effects of the Event
	Year 3	Year 6	
Any Complication Excluding Rupture	35 out of 100 patients (35%)	45 out of 100 patients (45%)	• See specific complication below
Key Complications			
Any Reoperation	14 out of 100 patients (14%)	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
Capsular Contracture Baker Grade III/IV	1 out of 100 patients (1%)	2 out of 100 patients (2%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Implant Removal with or without Replacement	5 out of 100 patients (5%)	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	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Implant Rupture[2] (Based on the MRI Cohort)	-	3 out of 100 patients (3%)	• Implant removal
Infection	1 out of 100 patients (1%)	1 out of 100 patients (1%)	• Redness or rash • Pain or tenderness • Swelling • Fever • Reoperation • Implant removal
Other Complications Occurring in 1% or More of Patients[3]			
Breast Sensation Changes[4]	3 out of 100 patients (3%)	4 out of 100 patients (4%)	• Increased or decreased breast sensitivity
Breast Pain[4]	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Resulting effects are contingent on underlying cause(s)
Capsular Contracture Baker III	1 out of 100 patients (1%)	2 out of 100 patients (2%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Hematoma	1 out of 100 patients (1%)	1 out of 100 patients (1%)	• Swelling and bruising • Pain or discomfort • Infection • Incision and drainage (reoperation) • Implant removal

Hypertrophic Scarring (irregular, raised scar)	3 out of 100 patients (3%)	3 out of 100 patients (3%)	• Scar revision procedure (reoperation) • Undesirable cosmetic result
Implant Rotation	1 out of 100 patients (1%)	1 out of 100 patients (1%)	• Undesirable cosmetic result • Asymmetry • Visibility • Reoperation • Implant removal
Mass/Cyst	4 out of 100 patients (4%)	6 out of 100 patients (6%)	• Pain or discomfort • Reoperation or other procedures
Miscarriage	1 out of 100 patients (1%)	2 out of 100 patients (2%)	• Pain or discomfort
New Diagnosis of Rheumatic Disease	Fewer than 1 out of 100 patients (<1%)	1 of 100 patients (1%)	• Pain or discomfort
Nipple Sensation Changes[4]	4 out of 100 patients (4%)	4 out of 100 patients (4%)	• Increased or decreased nipple sensitivity • Breastfeeding difficulties • May affect sexual response
Patient Dissatisfied with Aesthetic Appearance of Breast	2 out of 100 patients (2%)	3 out of 100 patients (3%)	• Undesirable cosmetic result • Reoperation • Implant removal
Patient Dissatisfied with Feel of Implant	Fewer than 1 out of 100 patients (<1%)	1 out of 100 patients (1%)	• Undesirable result • Reoperation • Implant removal
Position Dissatisfaction[4]	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Reoperation • Implant removal
Ptosis (sagging)	8 out of 100 patients (8%)	15 out of 100 patients (15%)	• Undesirable cosmetic result • Wrinkling/Rippling • Reoperation • Implant removal
Scarring	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Scar revision procedure (reoperation) • Undesirable cosmetic result
Size Change – Patient Request	3 out of 100 patients (3%)	4 out of 100 patients (4%)	• Undesirable cosmetic result • Reoperation • Implant removal
Wrinkling[4]	2 out of 100 patients (2%)	3 out of 100 patients (3%)	• Discomfort • Undesirable cosmetic result • Reoperation • Implant removal

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

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

[3] The following complications occurred at a rate less than 1%: asymmetry, bruising, calcification, capsular contracture Baker II w/ surgical intervention, capsular contracture Baker IV, death, delayed wound healing, fibrocystic disease, granuloma, implant movement upon muscle contraction, implant outline visible through skin, intermittent pop while wearing a certain type of bra, irritation/inflammation, lactation difficulties, loss of definition of inframammary fold, metastatic disease, new diagnosis of breast cancer, nipple complication, other: missing, palpability-implant, numbness/tingling (paresthesia), patient would not have surgery again, rash, seroma, shape distortion, size change-physician assessment only, skin lesion, suture complication, swelling (excessive), tenderness/ soreness, thickened capsule, wound dehiscence.

[4] Mild occurrences not included

Table 2

Potential Risks Associated with Revision-Augmentation

Event	Likelihood of the Event Occurring[1]		Possible Resulting Effects of the Event
	Year 3	Year 6	
Any Complication Excluding Rupture	41 out of 100 patients (41%)	53 out of 100 patients (53%)	• See specific complications below
Key Complications			
Any Reoperation	18 out of 100 patients (18%)	24 out of 100 patients (24%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Capsular Contracture Baker Grade III/IV	5 out of 100 patients (5%)	10 out of 100 patients (10%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Implant Removal with or without Replacement	11 out of 100 patients (11%)	14 out of 100 patients (14%)	• 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%)	5 out of 100 patients (5%)	• Infection • Scarring • Hematoma or Seroma • Delayed wound healing • Necrosis • Pain or Discomfort • Anesthesia-related complications • Loss of breast tissue • Undesirable cosmetic result
Implant Rupture[2] (Based on the MRI Cohort)	-	4 out of 100 patients (4%)	• Implant removal
Infection	1 out of 100 patients (1%)	2 out of 100 patients (2%)	• Redness or rash • Pain or tenderness • Swelling • Fever • Reoperation • Implant removal

Other Complications Occurring in 1% or More of Patients[3]			
Asymmetry[4]	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Reoperation • Implant removal
Breast Sensation Changes[4]	3 out of 100 patients (3%)	3 out of 100 patients (3%)	• Increased or decreased breast sensitivity
Calcification[4]	0 out of 100 patients (0%)	1 out of 100 patients (1%)	• Pain or discomfort • Firmness • Reoperation • Implant removal
Capsular Contracture Baker II with Surgical Intervention	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Capsular Contracture Baker III	3 out of 100 patients (3%)	6 out of 100 patients (6%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Capsular Contracture Baker IV	2 out of 100 patients (2%)	4 out of 100 patients (4%)	• Pain or discomfort • Breast hardness/firmness • Reoperation • Implant removal
Delayed Wound Healing[4]	0 out of 100 patients (0%)	1 out of 100 patients (1%)	• Pain or discomfort • Scarring • Implant extrusion • Necrosis • Reoperation • Implant removal
Fibrocystic Disease	0 out of 100 patients (0%)	1 out of 100 patients (1%)	• Pain or discomfort
Hypertrophic Scarring (irregular, raised scar)	3 out of 100 patients (3%)	3 out of 100 patients (3%)	• Scar revision procedure (reoperation) • Undesirable cosmetic result
Implant Rotation	3 out of 100 patients (3%)	3 out of 100 patients (3%)	• Undesirable cosmetic result • Asymmetry • Visibility • Reoperation • Implant removal
Mass/Cyst	5 out of 100 patients (5%)	7 out of 100 patients (7%)	• Pain or discomfort • Reoperation or other procedures
Miscarriage	0 out of 100 patients (0%)	1 out of 100 patients (1%)	• Pain or discomfort
Nipple Complication	0 out of 100 patients (0%)	1 out of 100 patients (1%)	• Pain or discomfort • Reoperation • Implant removal

Nipple Sensation Changes[4]	5 out of 100 patients (5%)	5 out of 100 patients (5%)	• Increased or decreased nipple sensitivity • Breastfeeding difficulties • May affect sexual response
Palpability-Implant[4]	3 out of 100 patients (3%)	4 out of 100 patients (4%)	• Undesirable cosmetic result • Visibility • Reoperation • Implant removal
Patient Dissatisfied with Aesthetic Appearance of Breast	3 out of 100 patients (3%)	8 out of 100 patients (8%)	• Undesirable cosmetic result • Reoperation • Implant removal
Patient Dissatisfied with Feel of Implant	3 out of 100 patients (3%)	5 out of 100 patients (5%)	• Undesirable result • Reoperation • Implant removal
Patient Would Not Make Decision to Have Breast Surgery Again	0 out of 100 patients (0%)	1 out of 100 patients (1%)	• Undesirable cosmetic result • Reoperation • Implant removal
Position Dissatisfaction[4]	3 out of 100 patients (3%)	4 out of 100 patients (4%)	• Undesirable cosmetic result • Reoperation • Implant removal
Ptosis (sagging)	5 out of 100 patients (5%)	14 out of 100 patients (14%)	• Undesirable cosmetic result • Wrinkling/Rippling • Reoperation • Implant removal
Scarring	0 out of 100 patients (0%)	2 out of 100 patients (2%)	• Scar revision procedure (reoperation) • Undesirable cosmetic result
Size Change – Patient Request	7 out of 100 patients (7%)	7 out of 100 patients (7%)	• Undesirable cosmetic result • Reoperation • Implant removal
Size Change – Physician Assessment Only	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Undesirable cosmetic result • Reoperation • Implant removal
Skin Lesion	0 out of 100 patients (0%)	1 out of 100 patients (1%)	• Pain or discomfort • Scarring • Implant extrusion • Necrosis • Reoperation • Implant removal
Tenderness/ Soreness	0 out of 100 patients (0%)	1 out of 100 patients (1%)	• Pain or discomfort • Reoperation • Implant removal

Wound Opening	2 out of 100 patients (2%)	2 out of 100 patients (2%)	• Pain or discomfort • Scarring • Implant extrusion • Necrosis • Reoperation • Implant removal
Wrinkling[4]	5 out of 100 patients (5%)	6 out of 100 patients (6%)	• Discomfort • Undesirable cosmetic result • Reoperation • Implant removal

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

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

[3] The following complications occurred at a rate less than 1%: breast pain, death, implant movement upon muscle contraction, implant outline visible through skin, irritation/inflammation, lack of projection, new diagnosis of breast cancer, new diagnosis of rheumatic disease, seroma, suture complication, thickened capsule.

[4] Mild occurrences not included

Using information from Mentor's MemoryShape™ Core Study, the risk of a patient experiencing any complication (excluding rupture) at some point through 3 and 6 years after implant surgery was calculated. This risk through 3 years was 35% for primary augmentation patients and 41% for revision-augmentation patients. This means that 35 out of 100 primary augmentation patients and 41 out of 100 revision-augmentation patients may experience a complication (of some kind) within 3 years after receiving implants. Through 6 years, this risk was 45% for primary augmentation patients and 53% for revision-augmentation patients. This means that 45 out of 100 primary augmentation patients and 53 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 MemoryShape™ Core Study, please read the section of this brochure on the MemoryShape™ Core Study (Section 8).

Mentor will continue its MemoryShape™ Core Study through the end of each patient's 10-year study term. In addition, Mentor has initiated additional post approval studies to address long-term outcomes in patients with MemoryShape™ 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 MemoryShape™ Core Study through 2, 3, 4, 5 and 6 years are presented in Table 3 (primary augmentation

cohort: N=572; revision-augmentation cohort: N=124). The MemoryShape™ Core Study reported a 1% risk of experiencing Baker Grade III or IV capsular contracture for primary augmentation patients through 3 years after receiving implants, and a 2% risk through 6 years. For revision-augmentation patients, the risk was 5% through 3 years and 10% through 6 years. This means that 1 out of 100 primary augmentation patients and 5 out of 100 revision-augmentation patients may experience Baker Grade III or IV capsular contracture within 3 years after receiving implants, and 2 out of 100 primary augmentation patients and 10 out of 100 revision-augmentation patients may experience Baker Grade III or IV capsular contracture within 6 years after receiving implants.

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

Cohort	2 Year	3 Year	4 Year	5 Year	6 Year
Primary Augmentation, N=572	0.7%	1.1%	1.5%	2.4%	2.4%
Revision-Augmentation, N=124	5.2%	5.2%	8.3%	8.3%	9.7%

More details on capsular contracture results from the MemoryShape™ 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, you 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] .

- **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 MemoryShape™ Core Study reported a 14% risk of experiencing reoperation for primary augmentation patients through 3 years after receiving implants, and an 18% risk through 6 years. For revision-augmentation patients, the risk was 18% through 3 years and 24% through 6 years. This means that 14 out of 100 primary augmentation patients and 18 out of 100 revision-augmentation patients may experience reoperation within 3 years after receiving implants, and 18 out of 100 primary augmentation patients and 24 out of 100 revision-augmentation patients may experience reoperation within 6 years after receiving implants. For women receiving primary augmentation implants, the most common reasons for reoperation were breast mass/cyst and patient request for size/style change, and ptosis (sagging). For women receiving revision-augmentation implants, the most common reasons for reoperation were breast mass/cyst, position dissatisfaction, wound dehiscence (wound opening), and wrinkling. More details on reoperation from the MemoryShape™ 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 MemoryShape™ Core Study reported a 5% risk of implant removal (including removal with replacement for a size exchange) for primary augmentation patients through 3 years after receiving implants, and a 7% risk through 6 years. For revision-augmentation patients, the risk was 11% through 3 years and 14% through 6 years. This means that 5 out of 100 primary augmentation patients and 11 out of 100 revision-augmentation patients may experience implant removal within 3 years after receiving implants, and 7 out of 100 primary augmentation patients and 14 out of 100 revision-augmentation patients may experience implant removal within 6 years after receiving implants. More details on implant removal from the MemoryShape™ 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 breast feed. (See the paragraph on breast feeding 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.

- **Breast Feeding**

Breast implant surgery might interfere with your ability to successfully breast feed. 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 breast feeding.[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 breast feeding difficulties.

The Institute of Medicine (IOM) and The American College of Obstetricians and Gynecologists (ACOG) encourage women with breast implants to try breast feeding. The IOM concluded, "Breast feeding should be encouraged in all mothers when possible, including those with silicone breast implants. There is evidence that breast implantation may increase the risk of insufficient lactation,[11] but no evidence that this poses a hazard to the infant beyond the loss of breast feeding itself. The evidence for the advantages of breast feeding to infant and mother is conclusive".[9,12] The MemoryShape™ Core Study collected information from patients who had babies after augmentation with MemoryShape™ Breast Implants. Four of the 44 primary augmentation patients who attempted to breastfeed following breast implant surgery experienced difficulty with breastfeeding through 6 years, while all 4 of the revision-augmentation patients who attempted to breastfeed after receiving breast implants had no difficulty. Lactation experiences from the MemoryShape™ 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.[13] Additional surgery is needed to fix implant extrusion. This can result in more scarring

or loss of breast tissue. An extruding implant may have to be removed and not replaced.

- **Necrosis/Delayed Wound Healing**

Necrosis means that 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 time frame, talk to your surgeon immediately.

- **Breast Atrophy/Chest Wall Deformity**

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

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 your 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 MemoryShape™ 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 MemoryShape™ Core Study, the MemoryShape™ 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. The results also showed that most women who underwent primary or revision augmentation with MemoryShape™ Breast Implants felt more comfortable afterwards, both when fully dressed and not fully dressed, and were more satisfied with their breast characteristics. In addition, 360 (97%) of the 373 primary augmentation and 69 (95%) of the 73 revision-augmentation patients who answered the patient satisfaction question indicated they would make the same decision to have the breast implant surgery.

For more information on the benefits of breast augmentation with Mentor's MemoryShape™ Breast Implants based on the results of the MemoryShape™ 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 MemoryShape™ 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

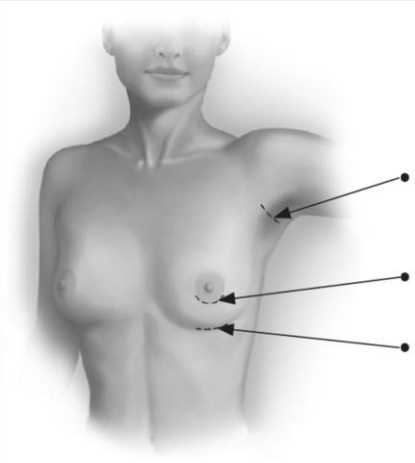
Breast implant surgery may be performed under general or local anesthesia. All anesthetics carry some risk. Discuss the risks and benefits of the anesthetic your surgeon and anesthetist recommend for you before the surgery.

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 MemoryShape™ Core Study and should not be used. It may cause damage to the implant shell.

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

Implant Placement

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

Figure 3
Breast Implant Placement

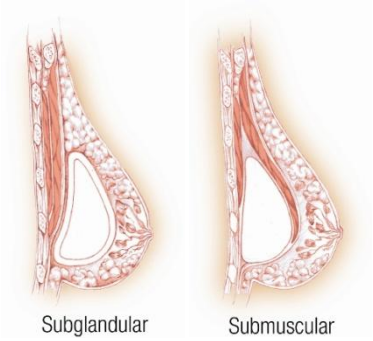


Table 4 compares positive and negative aspects (pros and cons) of each method. The "best" placement depends on you and the characteristics of your body, the types of implants you choose, and your surgeon. Talk with your surgeon about his or her reasons for choosing one placement over the other and the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

Table 4
Comparison of Submuscular and Subglandular Placement of Breast Implants

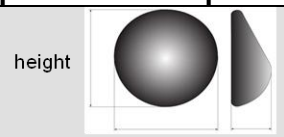
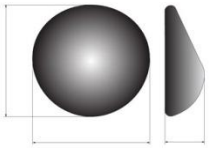
Submuscular Placement	Subglandular Placement
• Surgery time may be longer • Recovery may be longer • May be more painful • Future re-operation may be more difficult • Implants may feel more like a natural part of the breast (be less "palpable") • Capsular contracture may be less likely [7] • It may be 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

MemoryShape™ Breast Implants are available in several different sizes to help each woman achieve the result that is best for her body.

Table 5 lists the MemoryShape™ Breast Implants that are available.

Table 5
MemoryShape™ Breast Implant Product Sizes

Breast Implant Description		Size Range
Medium Height, Moderate Profile		120-775 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 breast fed, 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 breast self-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, but utilizing magnets instead of ionizing radiation) 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 MemoryShape™ Breast Implant, Mentor conducted the MemoryShape™ 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 MemoryShape™ Breast Implants. The

results of the MemoryShape™ Core Study should not be used to predict your own experience with the MemoryShape™ Breast Implant, but the information can be used as a general guide about what you may expect. Your own benefits and complications depend on many individual factors.

8.1 Overview of the Study

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

There are 955 patients participating in the MemoryShape™ Core Study. A total of 572 patients had primary augmentation, 124 patients had revision-augmentation, 191 patients had primary reconstruction, and 68 patients had revision-reconstruction. Of these patients, 252 primary augmentation patients, 56 revision-augmentation patients, 74 primary reconstruction patients and 37 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 MemoryShape™ 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 Short Form Health Survey (SF-36), and the Breast Evaluation Questionnaire.

The 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® MemoryShape™ Breast Implants, based on the experiences of the augmentation patients in the MemoryShape™ Core Study.

8.2 What are the 3-Year and 6-Year Follow-up Rates?

The study enrolled 572 primary augmentation patients and 124 revision augmentation patients. At the 3-year follow-up visit, data are reported for 85% of the eligible primary augmentation patients and 86% of the eligible revision-augmentation patients. At the 6-year follow-up visit, data are reported for 69% of the eligible primary augmentation patients and 66% of the eligible revision-augmentation patients.

8.3 What are the Benefits?

The benefits of MemoryShape™ 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 sixty-four out of the 572 patients enrolled were included in the analysis of cup size. Almost all (97%) had increased their bra size by at least one cup size, and most (72%) increased their bra size more than two cup sizes. Some increased their bra size less than 1 cup size (3%). Three hundred sixty-six of the 572 patients enrolled were included in the circumferential chest size analysis. The average increase in circumferential chest size was 2.1 inches (5.3 centimeters). In regards to overall satisfaction, 360 (97%) of the 373 primary augmentation patients who answered the patient satisfaction question indicated they would make the same decision to have breast surgery. From before breast surgery to 6 years, there were significant increases observed in the Self Esteem Scale (total and positive attitude scores) and the Body Esteem Scale (total and chest scores and sexual attractiveness). According to their scores on a questionnaire about a variety of general QoL concepts (health, mental, and social well being), there was no significant change compared to their QoL before getting implants. Other findings of the MemoryShape™ Core Study showed that of the 356 primary augmentation patients that answered the question "How satisfied with the general appearance of your breasts are you?"; 254 (71%) were

very satisfied, 71 (20%) were somewhat satisfied, 8 (2%) were neither satisfied nor dissatisfied, 19 (5%) were somewhat dissatisfied and 4 (1%) were very dissatisfied. Based on the Breast Evaluation Questionnaire, the average improvement from before getting implants was 62% for comfort when not fully dressed, 25% for comfort when fully dressed, and 86% for satisfaction with breast characteristics.

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. Seventy out of the 124 patients enrolled were included in the circumferential chest size analysis. The average increase in circumferential chest size was 0.7 inches (1.8 centimeters). In regards to overall satisfaction, 69 (95%) of the 73 primary augmentation patients who answered the patient satisfaction question indicated they would make the same decision to have breast surgery. From before breast surgery to 6 years, there was a significant increase observed in the Body Esteem Scale chest score and significant decrease in the total score. According to their scores on a questionnaire about a variety of general QoL concepts (health, mental and social well-being), there was no significant change compared to their QoL before getting implants. Other findings of the MemoryShape™ Core Study showed of the 68 revision-augmentation patients that answered the question “How satisfied with the general appearance of your breasts are you?”; 29 (43%) were very satisfied, 27 (40%) were somewhat satisfied, 8 (12%) were somewhat dissatisfied and 4 (6%) were very dissatisfied. Based on the Breast Evaluation Questionnaire, the average improvement from before getting implants was 11% for comfort when not fully dressed, 5% for comfort when fully dressed, and 28% for satisfaction with breast characteristics.

8.4 What were the 3-Year and 6-Year Complication Rates?

The safety of MENTOR® MemoryShape™ 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 3 and

6 years are presented in Table 6. The most common reported complication within the first 3 and 6 years after primary augmentation surgery was reoperation (14% or approximately 14 out of 100 through 3 years; and 18% or approximately 18 out of 100 through 6 years).

Table 6
3-Year and 6-Year Complication Rates for Primary Augmentation Patients, N=572 Patients

	Year 3 %	Year 6 %
Any Complication Excluding Rupture[1]	35.0	44.8
Key Complications		
Any Reoperation	13.6	18.1
Capsular Contracture Baker Grade III/IV	1.1	2.4
Implant Removal with or without Replacement	5.0	7.0
Implant Removal with Replacement with Study Device	1.8	2.5
Implant Rupture (Based on the MRI Cohort)[2]	-	2.6
Infection	0.9	0.9
Other Complications Occurring at a Rate of 1% or Greater[3]		
Breast Sensation Changes[4]	2.7	3.6
Breast Pain[4]	2.2	2.4
Capsular Contracture Baker III	1.1	2.4
Hematoma	1.2	1.2
Hypertrophic Scarring	2.5	2.5
Implant Rotation	1.1	1.1
Mass/cyst	3.7	5.9
Miscarriage	0.8	1.6
New Diagnosis of Rheumatic Disease[5]	0.4	1.4
Nipple Sensation Changes[4]	3.7	4.4
Patient Dissatisfied With Aesthetic Appearance Of Breast	2.2	2.8
Patient Dissatisfied With Feel Of Implant	0.9	1.1
Position Dissatisfaction[4]	1.8	2.0
Ptosis (sagging)	7.9	14.6
Scarring	2.2	2.4
Size Change-Patient Request	3.3	3.7
Wrinkling[4]	1.8	2.7

[1] 247 primary augmentation patients experienced at least one complication or reoperation
[2]Implant Rupture (based on the MRI cohort) was assessed by MRI at 1, 2, 4, and 6 years (results provided in Table 10); there was also one case of rupture reported through 6 years in a primary augmentation patient in the non-MRI cohort (N=320).
[3]Mild occurrences not included
[4]The following complications occurred at a rate less than 1%: asymmetry, bruising, calcification, capsular contracture Baker II w/ surgical intervention, capsular contracture Baker IV, death[6], delayed wound healing, fibrocystic disease, granuloma, implant movement upon muscle contraction, implant outline visible through skin, intermittent pop while wearing a certain type of bra, irritation/inflammation, lactation difficulties, loss of definition of inframammary fold, metastatic disease, new diagnosis of breast cancer, nipple complication, other: missing, palpability-implant, numbness/tingling (paresthesia), patient would not have surgery again, rash, seroma, shape distortion, size change-physician assessment only, skin lesion, suture complication, swelling (excessive), tenderness/ soreness, thickened capsule, wound opening.
[5]There were 10 diagnoses in 7 primary augmentation patients: Spondyarthropathies (25 months post implantation), other connective tissue disease (35 months post implantation), Sjögren's syndrome (35 and 42 months post implantation), systemic lupus erythematosus (35, 42, and 44 months post implantation), fibromyalgia (36 and 37 months post implantation), and undifferentiated connective tissue disease (41 months post implantation).
[6]All causes of death were reported by the investigator to be unrelated to study procedure or device.

Revision-Augmentation

The complications observed in women who had revision-augmentation through 3 and 6 years are presented in Table 7. The most common reported complication within the first 3 and 6 years after revision-augmentation surgery was reoperation (18% or approximately 18 out of 100 through 3 years; and 24% or approximately 24 out of 100 through 6 years).

Table 7
3-Year and 6-Year Complication Rates for Revision-Augmentation Patients, N=124 Patients

	Year 3 %	Year 6 %
Any Complication Excluding Rupture[1]	41.0	53.3
Key Complications		
Any Reoperation	18.2	24.1
Capsular Contracture Baker Grade III/IV	5.2	9.7
Implant Removal with or without Replacement	10.8	13.6
Implant Removal with Replacement with Study Device	4.2	5.3
Implant Rupture (Based on the MRI Cohort)[2]	-	3.6
Infection	0.8	2.1
Occurring at a Rate of≥ 1% or Greater[3]		
Asymmetry[4]	1.7	1.7
Breast Sensation Changes[4]	2.7	2.7
Calcification[4]	0	1.1

Capsular Contracture Baker II w/ Surgical Intervention	1.7	1.7
Capsular Contracture Baker III	3.4	5.5
Capsular Contracture Baker IV	1.7	4.2
Delayed Wound Healing[4]	0	1.2
Fibrocystic Disease	0	1.2
Hypertrophic Scarring	3.4	3.4
Implant Rotation	2.6	2.6
Mass/cyst	5.4	6.6
Miscarriage	0	1.1
Nipple Complication	0	1.1
Nipple Sensation Changes[4]	5.3	5.3
Palpability-Implant[4]	2.6	3.5
Patient Dissatisfied With Aesthetic Appearance Of Breast	2.6	8.1
Patient Dissatisfied With Feel Of Implant	3.4	4.6
Patient Would Not Make Decision to Have Breast Surgery Again	0	1.2
Position Dissatisfaction[4]	2.7	3.7
Ptosis (sagging)	5.3	14.4
Scarring	0	2.2
Size Change-Patient Request	6.6	6.6
Size Change-Physician Assessment only	1.7	1.7
Skin Lesion	0	1.1
Tenderness/ Soreness	0	1.3
Wound Opening	2.4	2.4
Wrinkling[4]	4.9	5.9

[1] 65 revision –augmentation patients experienced at least one complication or reoperation
[2]Rupture was assessed by MRI at 1, 2, 4, and 6 years (results provided in Table 10); there was also one case of rupture reported through 6 years in a revision augmentation patient in the non-MRI cohort (N=68).
3The following complications occurred at a rate less than 1%: breast pain, death[5], implant movement upon muscle contraction, implant outline visible through skin, irritation/inflammation, lack of projection, new diagnosis of breast cancer, new diagnosis of rheumatic disease[6], seroma, suture complication, thickened capsule.
[4]Mild occurrences not included
[5]All causes of death were reported by the investigator to be unrelated to study procedure or device.
[6]There was 1 diagnosis for the revision-augmentation patient: rheumatoid arthritis (11 months post implantation).

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 MemoryShape™ Core Study, 13% of the primary augmentation patients had at least one reoperation through 3 years (a total of 94 reoperations performed in 76 patients). Through 6 years, 17% of the patients had at least one reoperation (a total of 122 reoperations performed in 98 patients). Table 8 provides the main reasons for reoperation. The two most common reasons for reoperation through both 3 and 6 years in these patients were patient requested size change and breast mass/cyst.

Table 8
Main Reasons for Reoperation in Primary Augmentation Patients

Primary Reason for Reoperation	Year 3 n (%) of 94 Reoperations[1]	Year 6 n (%) of 122 Reoperations[2]
Asymmetry	4 (4.3)	5 (4.1)
Capsular Contracture Baker Grade II with Surgical Intervention	2 (2.1)	2 (1.6)
Capsular Contracture Baker Grade III/IV	3 (3.2)	3 (2.5)
Breast Mass/Cyst	9 (9.6)	18 (14.8)
Breast pain	2 (2.1)	2 (1.6)
Calcification	7 (7.4)	8 (6.6)
Delayed Wound Healing	1 (1.1)	1 (0.8)
Granuloma	1 (1.1)	1 (0.8)
Hematoma	5 (5.3)	5 (4.1)
Hypertrophic Scarring (irregular, raised scar)	7 (7.4)	8 (6.6)
Infection	3 (3.2)	3 (2.5)
Irritation/Inflammation	1 (1.1)	1 (0.8)
New Diagnosis of Breast Cancer	2 (2.1)	7 (5.7)
Nipple-Unacceptably Low Sensitivity	1 (1.1)	1 (0.8)
Position Dissatisfaction	4 (4.3)	7 (5.7)
Ptosis (sagging)	7 (7.4)	10 (8.2)
Rupture	0	2 (1.6)
Seroma	2 (2.1)	2 (1.6)
Size Change-Patient Request	14 (14.9)	15 (12.3)
Wound Opening	2 (2.1)	2 (1.6)
Wrinkling	2 (2.1)	2 (1.6)
Other	12 (12.8)	13 (10.7)
Excess Skin/Tissue	1 (1.1)	1 (0.8)
Implant Movement Upon Muscle Contraction	1 (1.1)	1 (0.8)
Implant Rotation	2 (2.1)	2 (1.6)
Loss of Definition of Inframammary Fold	1 (1.1)	1 (0.8)
Nipple Complication	2 (2.1)	2 (1.6)
Patient Dissatisfied with Aesthetic Appearance of Breast	2 (2.1)	2 (1.6)
Scarring	2 (2.1)	2 (1.6)
Skin Lesion	1 (1.1)	2 (1.6)
Missing	3 (3.2)	4 (3.3)

[1] 94 reoperations in 76 patients
[2] 122 reoperations in 98 patients

Revision-Augmentation

In the Mentor's MemoryShape™ Core Study, 18% of the revision-augmentation patients had at least one reoperation through 3 years (a total of 26 reoperations performed in 22 revision-augmentation patients). Through 6 years, 23% of the patients had at least one reoperation (a total of 36 reoperations in 28 patients). Table 9 provides the main reasons for reoperation. The two most common reasons for reoperation through 3 years were position dissatisfaction and wound opening, and through 6 years the most common reasons were breast mass/cyst, position dissatisfaction, wound opening and wrinkling.

Table 9
Main Reasons for Reoperation in Revision-Augmentation Patients

Primary Reason for Reoperation	Year 3 n (%) of 26 Reoperations[1]	Year 6 n (%) of 36 Reoperations[2]
Asymmetry	1 (3.8)	2 (5.6)
Capsular Contracture Baker Grade III/IV	0	1 (2.8)
Breast Mass/Cyst	1 (3.8)	4 (11.1)
Breast pain	1 (3.8)	1 (2.8)
Calcification	0	1 (2.8)
Delayed Wound Healing	1 (3.8)	1 (2.8)
Hypertrophic Scarring (irregular, raised scar)	1 (3.8)	1 (2.8)
New Diagnosis of Breast Cancer	1 (3.8)	1 (2.8)
Position Dissatisfaction	4 (15.4)	4 (11.1)
Ptosis (sagging)	2 (7.7)	2 (5.6)
Rupture	1 (3.8)	1 (2.8)
Size Change-Patient Request	3 (11.5)	3 (8.3)
Wound Opening	4 (15.4)	4 (11.1)
Wrinkling	3 (11.5)	4 (11.1)
Other	2 (7.7)	5 (13.9)
Implant Movement Upon Muscle Contraction	1 (3.8)	1 (2.8)
Patient Dissatisfied with Aesthetic Appearance of Breast	1 (3.8)	1 (2.8)
Skin Lesion	0	2 (5.6)
Upper Pole Fullness	0	1 (2.8)
Missing	1 (3.8)	1 (2.8)

[1] 26 reoperations in 22 patients
[2] 36 reoperations in 28 patients

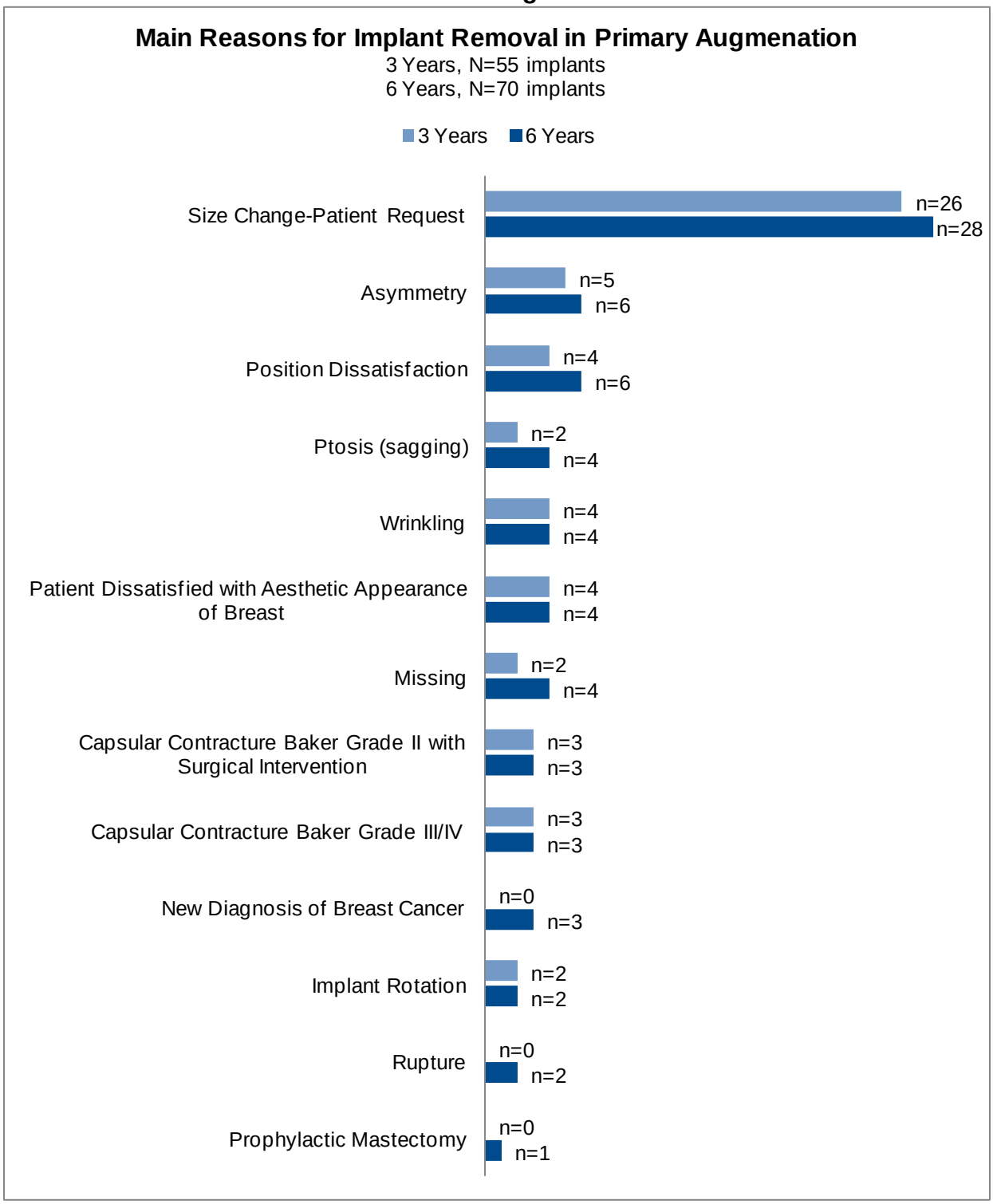
8.6 What are the Main Reasons for Implant Removal?

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 MemoryShape™ Core Study through 3 and 6 years are shown in Figure 4 below. There were a total of 55 implants removed in 28 patients through 3 years, and a total of 70 implants removed in 37 patients through 6 years. Of the 55 implants removed through 3 years, 19 (35%) were replaced with a study device; of the 70 implants removed through 6 years, 22 (31%) were replaced with a study device. The most common reason for implant removal through both 3 years (26 of the 55 implants removed) and 6 years (28 of the 70 implants removed) was patient requested size change. Note that the 6-year results also include any events that occurred by 3 years.

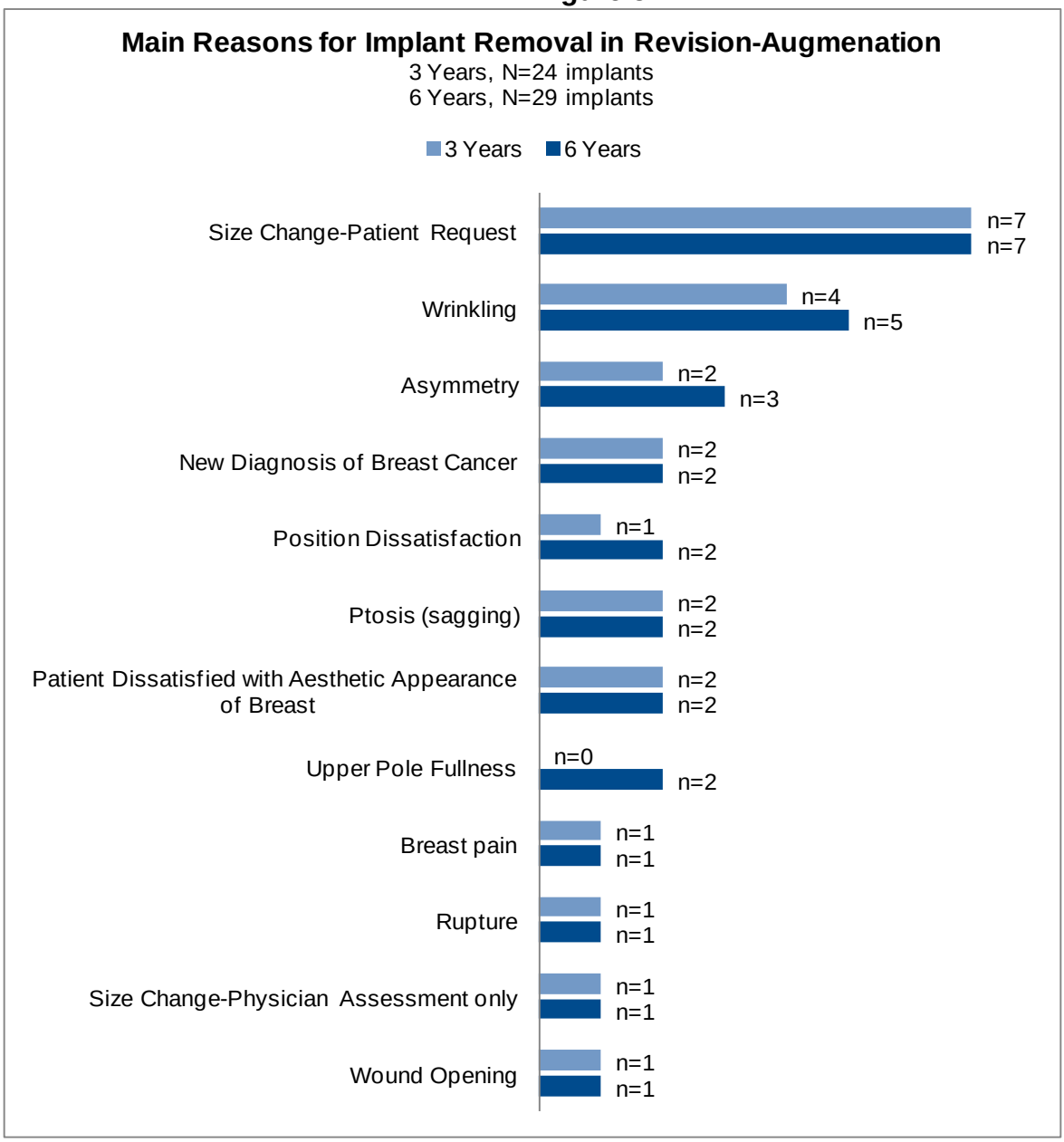
Figure 4


Main Reasons for Implant Removal in Primary Augmenation
3 Years, N=55 implants
6 Years, N=70 implants
3 Years
6 Years
Size Change-Patient Request
n=26
n=28
Asymmetry
n=5
n=6
Position Dissatisfaction
n=4
n=6
Ptosis (sagging)
n=2
n=4
Wrinkling
n=4
n=4
Patient Dissatisfied with Aesthetic Appearance of Breast
n=4
n=4
Missing
n=2
n=4
Capsular Contracture Baker Grade II with Surgical Intervention
n=3
n=3
Capsular Contracture Baker Grade III/IV
n=3
n=3
New Diagnosis of Breast Cancer
n=0
n=3
Implant Rotation
n=2
n=2
Rupture
n=0
n=2
Prophylactic Mastectomy
n=0
n=1

Revision-Augmentation

The main reasons for implant removal among revision augmentation patients in the MemoryShape™ Core Study through 3 and 6 years are shown in Figure 5 below. There were a total of 24 implants removed in 13 patients through 3 years, and a total of 29 implants removed in 16 patients through 6 years. Of the 24 implants removed through 3 years, 9 (38%) were replaced with a study device; of the 29 implants removed through 6 years, 10 (35%) were replaced with a study device. The most common reason for implant removal through both 3 years (7 of the 24 implants removed) and 6 years (7 of the 29 implants removed) was patient requested size change. Note that the 6-year results also include any events that occurred by 3 years.

Figure 5


Main Reasons for Implant Removal in Revision-Augmenation
3 Years, N=24 implants
6 Years, N=29 implants
3 Years
6 Years
Size Change-Patient Request
n=7
n=7
Wrinkling
n=4
n=5
Asymmetry
n=2
n=3
New Diagnosis of Breast Cancer
n=2
n=2
Position Dissatisfaction
n=1
n=2
Ptosis (sagging)
n=2
n=2
Patient Dissatisfied with Aesthetic Appearance of Breast
n=2
n=2
Upper Pole Fullness
n=0
n=2
Breast pain
n=1
n=1
Rupture
n=1
n=1
Size Change-Physician Assessment only
n=1
n=1
Wound Opening
n=1
n=1

8.7 What are Other Clinical Data Findings?

The 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 additional post approval studies.

Rupture

In the MemoryShape™ Core Study, there are 252 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 71% (291 of 411 expected due), 83% (334 of 403 expected due), 72% (279 of 387 expected due), and 56% (212 of 380 expected due), respectively.

For primary augmentation patients in the MRI cohort (N=252), 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 in the MRI cohort (N=56), the estimated rate of suspected or confirmed rupture was approximately 4% through 6 years. This means that through 6 years, an estimated 4 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=252	0% (n=0)	0% (n=0)	1.1% (n=2)	2.6% (n=4)
Revision-Augmentation, N=56	0% (n=0)	0% (n=0)	0% (n=0)	3.6% (n=1)

Overall, there were 9 suspected or confirmed reports of rupture for 9 of the patients participating in the study, 7 reports among patients in the MRI cohort (4 primary augmentation, 1 revision-augmentation, and 2 primary reconstruction patients) and 2 reports among patients not in the MRI cohort (1 primary augmentation and 1 revision-augmentation patient). One report of a ruptured replacement study implant (primary reconstruction) from the MRI cohort was not included in the rupture analyses because the patient no longer had the original study implant; only original study implants were included in the analyses. Of the 9 suspected or confirmed ruptured implants in the overall study, including the 2 that were found in the non-MRI cohort, 1 case was indeterminate for extracapsular silicone by MRI. There were no cases of migrated gel. The rupture rate beyond 6 years in Mentor's MemoryShape™ Core Study continues to be investigated.

Cancer

There were four primary augmentation patients and one revision-augmentation patient with new diagnoses of breast cancer through 6 years in Mentor's MemoryShape™ 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 MemoryShape™ Core Study.

Connective Tissue Disease (CTD)

In the MemoryShape™ Core Study, there were 7 primary augmentation patients and 1 revision-augmentation patient with a new diagnosis of a CTD by a rheumatologist. There were 10 diagnoses for the 7 primary augmentation patients: spondyarthropathy (25 months post implantation), other CTD (35 months post implantation), Sjögren's syndrome (2 cases – 35 and 42 months post implantation), systemic lupus erythematosus (3 cases – 35, 42, and 44 months post implantation), fibromyalgia (2 cases – 36 and 37 months post implantation), and undifferentiated connective tissue disease (41 months post implantation). There was 1 diagnosis for the revision-augmentation patient: rheumatoid arthritis (11 months post implantation). It cannot be concluded that these CTD diagnoses were caused by the breast implants because there was no comparison group of similar women without implants.

CTD Signs and Symptoms

The MemoryShape™ Core Study collected information on CTD signs and symptoms (that did not result in a diagnosis of a CTD). For all four cohorts combined (primary, revision-augmentation, primary reconstruction, and revision-reconstruction), a significant increase in combined pain was found after adjusting for the effect of age. No significant changes were found, however, for either primary augmentation or revision-augmentation patients at 6 years compared to before having implants.

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

Lactation Complications

Lactation complications, including difficulties with breast feeding, were examined in the MemoryShape™ Core Study. Four of the 44 primary augmentation patients who attempted to breastfeed following breast implant surgery experienced difficulty with breastfeeding through 6 years in Mentor's MemoryShape™ Core Study. All 4 of the revision-augmentation patients who attempted to breastfeed after receiving breast implants had no difficulty.

Reproduction Complications

Reproduction complications that were examined in the MemoryShape™ Core Study include miscarriage and having a stillborn baby. Eight primary augmentation patients and one revision-augmentation patient reported a miscarriage in Mentor's MemoryShape™ Core Study through 6 years.

Suicide

There were no reports of suicide in primary augmentation or revision-augmentation patients in the MemoryShape™ 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 MemoryShape™ 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 MemoryShape™ Breast Implant. It also discusses safety information and research performed on implants in general and on MENTOR® MemoryShape™ 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 MemoryShape™ 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 MemoryShape™ 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 MemoryShape™ 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. ACKNOWLEDGEMENT OF INFORMED DECISION

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 acknowledgement.

_____

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

15. INDEX

Alternatives to Breast Implantation, 22
Anaplastic Large Cell Lymphoma (ALCL), 42, 43, 75
Anesthesia, 50, 55
Asymmetry, 38, 68, 69
Autoimmune Disease, 19, 45, 47
Axillary Incision, 51
Benefits, 48, 62
Biopsy, 35, 42
Body Dysmorphic Disorder (BDD), 19, 46
Breast Augmentation, 15, 17, 48
Breast Feeding/Lactation, 21, 38, 76
Breast Implant, 16
Breast Implant Product Sizes, 53
Breast Mass, 67, 68, 69
Breast Reconstruction, 18
Breast Self-Exams, 58
Breast Tissue Atrophy, 39
Calcium Deposits/Calcification, 40
Cancer, 18, 21, 35, 41, 42, 44, 68, 69, 75
Capsular Contracture, 32, 47, 58, 64, 65, 68, 69
Capsule, 32, 60
Capsulotomy, 34
Chest Wall Deformity, 39
Complications, 20, 23, 31, 47, 64, 65
Congenital Anomaly, 18
Connective Tissue Disease (CTD), 35, 44, 75
Contraindications, 18
CTD Signs and Symptoms, 76
Delayed Wound Healing, 39, 68, 69
Device Identification Card, 58, 80
Device Tracking, 79
Effects on Children, 46
Fibromyalgia, 45, 65, 75
Fibrous Tissue, 44, 45
Food and Drug Administration (FDA), 43, 77, 78
Gel Bleed/Gel Diffusion, 33, 47, 57
Gel Migration, 34
Granuloma, 35, 68
Hematoma, 31, 53, 68
Implant Displacement, 38
Implant Extrusion, 39, 53
Implant Palpability, 38
Implant Removal, 20, 36, 64, 65, 70
Implant Rupture, 33, 57, 59, 60, 74, 81
Infection, 31, 53, 56, 64, 65, 68
Inflammation, 68
Inframammary Incision, 51
Intracapsular Rupture, 35
Low Molecular Weight (LMW) Silicone, 47
Lymphadenopathy, 40, 47
Magnetic Resonance Imaging (MRI), 21, 58, 60, 74
Mammography, 21, 42, 56
Mastopexy, 22, 54
MedWatch, 77
MemoryShape™ Core Study, 75
MENTOR® MemoryShape™ Core Study, 23, 61
Necrosis, 39
Neurological Disease, 47
Pain, 37, 68, 69
Periareolar Incision, 51
Periumbilical Approach, 51
Plastic Surgery, 54, 79
Platinum, 47
Postoperative Care, 55, 56
Precautions, 19
Ptosis (sagging), 68, 69
Reoperation, 35, 64, 65, 67
Reproduction Complications, 76
Revision-Augmentation, 15, 17
Risks, 23, 41, 78
rupture, 35, 75
Saline, 22, 47
Scar Revision, 67
Scarring, 38, 39, 68, 69
Seroma, 31, 68
Silent Rupture, 21, 60
Silicone, 16, 46, 47
Subglandular Placement, 17, 51, 52
Submuscular Placement, 17, 51, 52
Suicide, 46, 76
Summary of Safety and Effectiveness Document (SSED), 78
Surgical Incision, 23
Symptomatic Rupture, 59
Systemic Disease, 35
Toxic Shock Syndrome (TSS), 31
Warnings, 20
Wrinkling, 38, 53, 68, 69

16. REFERENCES

1 Holmich, L.R., et al. 2001. Prevalence of silicone breast implant rupture among Danish women. Plast. Reconstr. Surg. 108(4):848-858.

2 Collis, N., et al. Magnetic Resonance Imaging and Explantation Investigation of Long-Term Silicone Gel Implant Integrity. Plast. Reconstr. Surg. 120(5): 1401-1406 (2007).

3 Gaubitz, M., Jackisch, C., Domschke, W., Heindel, W. & Pfleiderer, B. Silicone breast implants: correlation between implant ruptures, magnetic resonance spectroscopically estimated silicone presence in the liver, antibody status and clinical symptoms. Rheumatology (Oxford) 41, 129-135; discussion 123-124 (2002).

4 Brown, S. L., Duggirala, H. J. & Pennello, G. An association of silicone-gel breast implant rupture and fibromyalgia. Curr Rheumatol Rep 4, 293-298 (2002).

5 Brown, S. L., Pennello, G., Berg, W. A., Soo, M. S. & Middleton, M. S. Silicone gel breast implant rupture, extracapsular silicone, and health status in a population of women. J Rheumatol 28, 996-1003 (2001).

6 Hölmich, L. R. et al. Self-reported diseases and symptoms by rupture status among unselected Danish women with cosmetic silicone breast implants. Plast Reconstr Surg 111, 723-732; discussion 733-724 (2003).

7 Katzin, W. E., Centeno, J. A., Feng, L. J., Kiley, M. & Mullick, F. G. Pathology of lymph nodes from patients with breast implants: a histologic and spectroscopic evaluation. Am J Surg Pathol 29, 506-511 (2005).

8 Berner, I., Gaubitz, M., Jackisch, C. & Pfleiderer, B. Comparative examination of complaints of patients with breast-cancer with and without silicone implants. Eur J Obstet Gynecol Reprod Biol 102, 61-66 (2002).

9 Bondurant, S., Ernster, V. L. & Herdman, R. Safety of Silicone Breast Implants. Committee on the Safety of Silicone Breast Implants, Division of Health Promotion and Disease Prevention, Institute of Medicine. (National Academy Press., 2000).

10 Brown, S. L., Todd, J. F., Cope, J. U. & Sachs, H. C. Breast implant surveillance reports to the U.S. Food and Drug Administration: maternal-child health problems. J Long Term Eff Med Implants 16, 281-290 (2006).

11 Hurst, N.M. Lactation after augmentation mammoplasty. Obstet. Gynecol. 87(1):30-4 (1996).

12 American College of Obstetrics and Gynecology (ACOG). Breastfeeding: Maternal and Infant Aspects. Educational Bulletin Number 258 (July 2000).

13 Kronowitz, S. J. & Robb, G. L. Radiation therapy and breast reconstruction: a critical review of the literature. Plast Reconstr Surg 124, 395-408 (2009).

14 International Agency for Research on Cancer (IARC). Vol. 74 (IARC Press 1999).

15 European Committee on Quality Assurance (EQUAM) and Medical Devices in Plastic Surgery. Consensus declaration on breast implants 23- 6- 2000. Israel, European Committee on Quality Assurance (EQUAM). 4th Consensus Declaration (2000).

16 National Institutes of Health (NIH). Breast implants: Status of research at the National Institutes of Health (2005).

17 Herdman, R.C., et al. Silicone breast implants and cancer. Cancer Invest. 2001;19(8):821-32 (2001).

18 Brinton, L. A. et al. Breast cancer following augmentation mammoplasty (United States). Cancer Causes Control 11, 819-827 (2000).

19 Brisson, J. et al. Cancer incidence in a cohort of Ontario and Quebec women having bilateral breast augmentation. Int J Cancer 118, 2854-2862 (2006).

20 Deapen, D., Hamilton, A., Bernstein, L. & Brody, G. S. Breast cancer stage at diagnosis and survival among patients with prior breast implants. Plast Reconstr Surg 105, 535-540 (2000).

21 Deapen, D. M., Hirsch, E. M. & Brody, G. S. Cancer risk among Los Angeles women with cosmetic breast implants. Plast Reconstr Surg 119, 1987-1992 (2007).

22 Englert, H. et al. Women's health after plastic surgery. Intern Med J 31, 77-89 (2001).

23 Friis, S. et al. Cancer risk among Danish women with cosmetic breast implants. Int J Cancer 118, 998-1003 (2006).

24 Hölmich, L. R. et al. Stage of breast cancer at diagnosis among women with cosmetic breast implants. Br J Cancer 88, 832-838 (2003).

25 Jakub, J. W. et al. Breast cancer in patients with prior augmentation: presentation, stage, and lymphatic mapping. Plast Reconstr Surg 114, 1737-1742 (2004).

26 McLaughlin, J. K. et al. Long-term cancer risk among Swedish women with cosmetic breast implants: an update of a nationwide study. J Natl Cancer Inst 98, 557-560 (2006).

27 Mellemkjaer, L. et al. Cancer occurrence after cosmetic breast implantation in Denmark. Int J Cancer 88, 301-306 (2000).

28 Pukkala, E. et al. Incidence of breast and other cancers among Finnish women with cosmetic breast implants, 1970-1999. J Long Term Eff Med Implants 12, 271-279 (2002).

29 Brinton, L. A., Lubin, J. H., Murray, M. C., Colton, T. & Hoover, R. N. Mortality rates among augmentation mammoplasty patients: an update. Epidemiology 17, 162-169 (2006).

30 Jakubietz, M. G., Jeffrey, J., Jakubietz, R. & Rohrich, R.J. Breast augmentation: Cancer concerns and mammography - A literature review. Plast. Reconstr. Surg. 113, 117e-122e (2004).

31 Miglioretti, D. L. et al. Effect of breast augmentation on the accuracy of mammography and cancer characteristics. Jama 291, 442-450 (2004).

32 McLaughlin, J.K. and L. Lipworth. Brain cancer and cosmetic breast implants: A review of the epidemiological evidence. Ann. Plast. Surg. 52(2):15-17 (2004).

33 Brinton, L. A. et al. Cancer risk at sites other than the breast following augmentation mammoplasty. Ann Epidemiol 11, 248-256 (2001).

34 de Jong, D. et al. Anaplastic large-cell lymphoma in women with breast implants. Jama 300, 2030-2035 (2008).

35 Cook, L. S. et al. Characteristics of women with and without breast augmentation. Jama 277, 1612-1617 (1997).

36 Fryzek, J. P. et al. Characteristics of women with cosmetic breast augmentation surgery compared with breast reduction surgery patients and women in the general population of Sweden. Ann Plast Surg 45, 349-356 (2000).

37 Kjoller, K. et al. Characteristics of women with cosmetic breast implants compared with women with other types of cosmetic surgery and population-based controls in Denmark. Ann Plast Surg 50, 6-12, (2003).

38 Breiting, V. B. et al. Long-term health status of Danish women with silicone breast implants. Plast Reconstr Surg 114, 217-226; discussion 227-218 (2004).

39 Fryzek, J.P., et al. Self-reported symptoms among women after cosmetic breast implant and breast reduction surgery. Plast. Reconstr. Surg. 107:206-13 (2001).

40 Kjøller, K., et al. Self-reported musculoskeletal symptoms among Danish women with cosmetic breast implants. Ann Plast Surg. 52(1):1-7 (2004).

41 Blackburn, W. D., Jr. & Everson, M. P. Silicone-associated rheumatic disease: an unsupported myth. Plast Reconstr Surg 99, 1362-1367 (1997).

42 Brinton, L. A. et al. Risk of connective tissue disorders among breast implant patients. Am J Epidemiol 160, 619-627 (2004).

43 Fryzek, J. P. et al. A nationwide study of connective tissue disease and other rheumatic conditions among Danish women with long-term cosmetic breast implantation. Ann Epidemiol 17, 374-379 (2007).

44 Greenland, S. & Finkle, W. D. A retrospective cohort study of implanted medical devices and selected chronic diseases in Medicare claims data. Ann Epidemiol 10, 205-213 (2000).

45 Hochberg, M. C. & Perlmutter, D. L. The association of augmentation mammoplasty with connective tissue disease, including systematic sclerosis (scleroderma): a meta-analysis. Curr Top Microbiol Immunol 210, 411-417 (1996).

46 Janowsky, E. C., Kupper, L. L. & Hulka, B. S. Meta-analyses of the relation between silicone breast implants and the risk of connective-tissue diseases. N Engl J Med 342, 781-790 (2000).

47 Kjoller, K. et al. Connective tissue disease and other rheumatic conditions following cosmetic breast implantation in Denmark. Arch Intern Med 161, 973-979 (2001).

48 Lamm, S. H. Silicone breast implants, breast cancer and specific connective tissue diseases: A systematic review of the data in the epidemiological literature Int. J. Toxicol. 17, 497-457 (1998).

49 Lewin, S. L. & Miller, T. A. A review of epidemiologic studies analyzing the relationship between breast implants and connective tissue diseases. Plast Reconstr Surg 100, 1309-1313 (1997).

50 Silverman, B. G. et al. Reported complications of silicone gel breast implants: an epidemiologic review. Ann Intern Med 124, 744-756 (1996).

51 Vermeulen, R. C. & Scholte, H. R. Rupture of silicone gel breast implants and symptoms of pain and fatigue. J Rheumatol 30, 2263-2267 (2003).

52 Wolfe, F. & Anderson, J. Silicone filled breast implants and the risk of fibromyalgia and rheumatoid arthritis. J Rheumatol 26, 2025-2028 (1999).

53 Wong, O. A critical assessment of the relationship between silicone breast implants and connective tissue diseases. Regul Toxicol Pharmacol 23, 74-85 (1996).

54 Lipworth et al. Silicone breast implants and connective tissue disease: no association. Semin. Immunopathol. 33(3):287-294 (2011).

55 Independent Review Group (IRG). Silicone Gel Breast Implants: Report of the IRG (United Kingdom) (1998).

56 Tugwell, P. et al. Do silicone breast implants cause rheumatologic disorders? A systematic review for a court-appointed national science panel. Arthritis Rheum 44, 2477-2484 (2001).

57 Lugowski, S. J. et al. Analysis of silicon in human tissues with special reference to silicone breast implants. J Trace Elem Med Biol 14, 31-42 (2000).

58 Kjoller, K. et al. Health outcomes in offspring of Danish mothers with cosmetic breast implants. Ann Plast Surg 48, 238-245 (2002).

59 Signorello, L. B., Fryzek, J. P., Blot, W. J., McLaughlin, J. K. & Nyren, O. Offspring health risk after cosmetic breast implantation in Sweden. Ann Plast Surg 46, 279-286 (2001).

60 Hemminki, E., Hovi, S. L., Sevon, T. & Asko-Seljavaara, S. Births and perinatal health of infants among women who have had silicone breast implantation in Finland, 1967-2000. Acta Obstet Gynecol Scand 83, 1135-1140 (2004).

61 Jacobsen, P. H. et al. Mortality and suicide among Danish women with cosmetic breast implants. Arch Intern Med 164, 2450-2455 (2004).

62 Koot, V. C., Peeters, P. H., Granath, F., Grobbee, D. E. & Nyren, O. Total and cause specific mortality among Swedish women with cosmetic breast implants: prospective study. BMJ 326, 527-528 (2003).

63 Le, G. M. et al. Breast implants following mastectomy in women with early-stage breast cancer: prevalence and impact on survival. Breast Cancer Res 7, R184-193 (2005).

64 Lipworth, L. et al. Excess mortality from suicide and other external causes of death among women with cosmetic breast implants. Ann Plast Surg 59, 119-123; discussion 124-115 (2007).

65 McLaughlin, J. K., Lipworth, L. & Tarone, R. E. Suicide among women with cosmetic breast implants: a review of the epidemiologic evidence. J Long Term Eff Med Implants 13, 445-450 (2003).

66 Pukkala, E. et al. Causes of death among Finnish women with cosmetic breast implants, 1971-2001. Ann Plast Surg 51, 339-342; discussion 343-334 (2003).

67 Villeneuve, P. J. et al. Mortality among Canadian women with cosmetic breast implants. Am J Epidemiol 164, 334-341 (2006).

68 Klesmer, J. Mortality in Swedish women with cosmetic breast implants: body dysmorphic disorder should be considered. BMJ 326, 1266-1267 (2003).

69 Winther, J. F. et al. Neurological disease among women with silicone breast implants in Denmark. Acta Neurol Scand 103, 93-96 (2001).

70 Flassbeck, D. et al. Determination of siloxanes, silicon, and platinum in tissues of women with silicone gel-filled implants. Anal Bioanal Chem 375, 356-362 (2003).

71 Chandra, G., Lo, P. Y., Hitchcock, P. & Lappert, M. F. A convenient and novel route to bis(alkyne)platinum (0) and other platinum(0) complexes from Speier's hydrosilylation catalyst. Organometallics, 191-192 (1987).

72 Lappert, M. F. & Scott, F. P. A. The reaction pathway from Speier's to Karstedt's hydrosilylation catalyst. J. Organomet. Chem. 492, C11-C13 (1995).

73 Lewis, L. N. et al. Mechanism of Formation of Platinum (0) Complexes Containing Silicon-Vinyl Ligands. Organometallics 14, 2202-2213 (1995).

74 Stein, J. In situ determination of the active catalyst in hydrosilylation reactions using highly reactive Pt(0) catalyst precursors. J. Am. Chem. Soc. 121, 3693-3703 (1999).

75 FDA. FDA Update on the Safety of Silicone Gel-Filled Breast Implants. (June 2011).

76 Henriksen, T. F. et al. Surgical intervention and capsular contracture after breast augmentation: a prospective study of risk factors. Ann Plast Surg 54, 343-351 (2005).

77 Kulmala, I. et al. Local complications after cosmetic breast implant surgery in Finland. Ann Plast Surg 53, 413-419 (2004).

78 Hölmich, L.R., et al. Untreated silicone breast implant rupture. Plast. Reconstr. Surg. 114:204-214 (2004).

Mentor Worldwide LLC
P060028
MemoryShape™ Breast Implants
May 2013

Quick Facts about Breast Augmentation and Reconstruction

with MENTOR® MemoryShape™ Breast Implants

QUICK FACTS ABOUT BREAST AUGMENTATION AND RECONSTRUCTION WITH MENTOR® MEMORYSHAPE™ BREAST IMPLANTS

ABOUT THIS BROCHURE

This brochure is intended to provide you with a high level overview of the facts about breast implant surgery with Mentor's FDA-Approved MemoryShape™ Breast Implants. This brochure is not intended to replace consultation with your surgeon. For a complete review of the benefits and risks of breast implant surgery, please read the appropriate patient educational brochure, Breast Augmentation with MENTOR® MemoryShape™ Breast Implants or Breast Reconstruction with MENTOR® MemoryShape™ Breast Implants, available from your surgeon and posted on www.mentorwwllc.com. You may also contact Mentor directly at 1-800-MENTOR-8 for a copy of the brochure.

INDICATIONS

Mentor's MemoryShape™ Breast Implants are indicated for:

- Breast augmentation for women at least 22 years old. Breast augmentation includes primary breast augmentation as well as revision surgery to correct or improve the result of primary breast augmentation surgery.

- Breast reconstruction. Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the results of a primary breast reconstruction surgery.

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 your breast implant surgery.

COMPLICATIONS

Complications are defined as adverse events occurring in connection with the breast implant surgery, breast implants and/or the breast mound, and systemic diseases. The definition of a few key terms may assist the reader in understanding the complications presented below.

- MRI Cohort: A randomized subset of subjects who were to undergo MRI scans at 1, 2, 4, 6, 8, and 10 years after implant surgery.

- Non-MRI Cohort: Subjects who were not a part of the original MRI cohort but who were later asked to undergo MRI scans at 6, 8, and 10 years after implant surgery.
- Capsular Contracture Baker Grade: Normally, a healing scar forms an envelope around the implant, which, on occasion, will shrink sufficiently to squeeze the implant, producing varying degrees of firmness. The implant can feel hard, be painful and/or distorted. Capsular contracture is graded in severity on a scale of I to IV by Baker classification, with Grade I being the mildest and Grade IV being the most severe.

The tables below present the complication rates reported in Mentor's MemoryShape™ Core Study through 3-years and 6-years for primary augmentation and revision augmentation patients (Table 1) and for primary reconstruction and revision-reconstruction patients (Table 2).

Table 1
Complication Rates Reported through 3-Years and 6-Years for
Primary Augmentation (N=572) and Revision-Augmentation (N=124) Patients

	Primary Augmentation		Revision Augmentation	
	Year 3 %	Year 6 %	Year 3 %	Year 6 %
Any Complication Excluding Rupture	35.0	44.8	41.0	53.3
Key Complications				
Any Reoperation	13.6	18.1	18.2	24.1
Capsular Contracture Baker III, IV	1.1	2.4	5.2	9.7
Implant Removal with or without Replacement	5.0	7.0	10.8	13.6
Implant Removal with Replacement with Study Device	1.8	2.5	4.2	5.3
Implant Rupture (Based on the MRI Cohort)[1]	-	2.6	-	3.6
Infection	0.9	0.9	0.8	2.1
Other Complications Occurring at a Rate of 1% or Greater[2]				
Asymmetry[3]	0.7	0.7	1.7	1.7
Breast Pain[3]	2.2	2.4	0.9	0.9
Breast Sensation Changes[3]	2.7	3.6	2.7	2.7
Calcification[3]	0.2	0.4	0	1.1
Capsular Contracture Baker II W/ Surgical Intervention	0.6	0.6	1.7	1.7
Capsular Contracture Baker III	1.1	2.4	3.4	5.5
Capsular Contracture Baker IV	0.2	0.2	1.7	4.2
Delayed Wound Healing[3]	0.2	0.2	0	1.2
Fibrocystic Disease	0.2	0.7	0	1.2

	Primary Augmentation		Revision Augmentation	
	Year 3 %	Year 6 %	Year 3 %	Year 6 %
Hematoma	1.2	1.2	0	0
Hypertrophic Scarring	2.5	2.5	3.4	3.4
Implant Rotation	1.1	1.1	2.6	2.6
Mass/Cyst	3.7	5.9	5.4	6.6
Miscarriage	0.8	1.6	0	1.1
New Diagnosis of Rheumatic Disease[4]	0.4	1.4	0.9	0.9
Nipple Complication	0.3	0.3	0	1.1
Nipple Sensation Changes[3]	3.7	4.4	5.3	5.3
Palpability-Implant[3]	0.7	0.9	2.6	3.5
Patient Dissatisfied with Aesthetic Appearance of Breast	2.2	2.8	2.6	8.1
Patient Dissatisfied with Feel of Implant	0.9	1.1	3.4	4.6
Patient Would Not Make Decision to Have Breast Surgery Again	0.4	0.6	0	1.2
Position Dissatisfaction[3]	1.8	2.0	2.7	3.7
Ptosis (sagging)	7.9	14.6	5.3	14.4
Scarring	2.2	2.4	0	2.2
Size Change-Patient Request	3.3	3.7	6.6	6.6
Size Change-Physician Assessment Only	0.2	0.2	1.7	1.7
Skin Lesion	0.5	0.8	0	1.1
Tenderness/ Soreness	0.4	0.8	0	1.3
Wound Opening (Dehiscence)	0.7	0.7	2.4	2.4
Wrinkling[3]	1.8	2.7	4.9	5.9

[1] Rupture was assessed by MRI at 1, 2, 4, and 6 years (results are provided in Table 10 of the appropriate Patient Educational Brochure); there were also 2 cases of rupture reported through 6 years in the non-MRI cohort (1 primary augmentation and 1 revision-augmentation)

[2] The following complications occurred at a rate less than 1%: bruising, death[5], granuloma, implant movement upon muscle contraction, implant outline visible through skin, intermittent pop while wearing a certain type of bra, irritation/inflammation, lack of projection, lactation difficulties, loss of definition of inframammary fold, metastatic disease, new diagnosis of breast cancer, other: missing, numbness/tingling (paresthesia), rash, seroma, shape distortion, suture complication, swelling (excessive), thickened capsule.

[3] Mild occurrences not included

[4] There were 10 diagnoses in 7 primary augmentation patients: spondyarthropathies (25 months post implantation), other connective tissue disease (35 months post implantation), Sjögren's syndrome (35 and 42 months post implantation), systemic lupus erythematosus (35, 42, and 44 months post implantation), fibromyalgia (36 and 37 months post implantation), and undifferentiated connective tissue disease (41 months post implantation). There was 1 diagnosis for the revision-augmentation patient: rheumatoid arthritis (11 months post implantation).

[5] All causes of death were reported by the Investigator to be unrelated to study procedure or device.

Table 2
Complication Rates Reported through 3-Years and 6-Years for
Primary Reconstruction (N=191) and Revision-Reconstruction (N=68) Patients

	Primary Reconstruction		Revision Reconstruction	
	Year 3 %	Year 6 %	Year 3 %	Year 6 %
Any Complication Excluding Rupture	54.4	64.9	55.5	67.6
Key Complications				
Any Reoperation	36.1	44.5	28.4	45.4
Capsular Contracture Baker III, IV	5.6	10.1	13.5	16.4
Implant Removal with or without Replacement	13.8	21.8	21.0	34.2
Implant Removal with Replacement with Study Device	6.0	7.4	4.4	10.8
Implant Rupture (Based on the MRI Cohort)[1]	-	1.6	-	0
Infection	1.6	1.6	3.0	3.0
Other Complications Occurring at a Rate of 1% or Greater[2]				
Asymmetry[3]	6.0	10.6	6.1	6.1
Breast Pain[3]	2.8	2.8	3.3	3.3
Breast Sensation Changes[3]	1.1	1.1	0	0
Capsular Contracture Baker II W/ Surgical Intervention	1.7	4.2	1.5	3.7
Capsular Contracture Baker III	4.6	9.1	13.5	13.5
Capsular Contracture Baker IV	1.6	1.6	0	3.0
Death[4]	1.1	4.5	1.7	1.7
Delayed Wound Healing[3]	1.0	1.0	0	0
Excess Skin/Tissue	4.3	4.3	1.6	1.6
Gel Fracture[5]	0	0	0	2.0
Hematoma	0	0	1.5	1.5
Hypertrophic Scarring	1.1	2.4	0	0
Implant Immobility	2.4	3.8	1.9	1.9
Implant Rotation	3.4	5.1	1.5	1.5
Irritation/Inflammation	2.1	2.1	3.0	3.0
Itching	0.5	1.3	0	0
Lack of Projection	5.0	8.5	11.8	13.7
Loss of Definition Of Inframammary Fold	1.7	2.3	1.5	1.5
Mass/Cyst	2.8	4.6	0	0
Metastatic Disease	2.3	2.3	1.6	1.6
Miscarriage	0.6	2.1	0	0
Muscle Atrophy	0	0.6	1.5	1.5
New Diagnosis Of Rheumatic Disease[6]	1.7	1.7	0	0

	Primary Reconstruction		Revision Reconstruction	
	Year 3 %	Year 6 %	Year 3 %	Year 6 %
Nipple Sensation Changes[3]	2.3	2.9	0	0
Numbness/Tingling (Paresthesia)	0	0	3.4	3.4
Other: Missing	0	1.6	0	0
Palpability-Implant[3]	0	0.7	3.5	3.5
Patient Dissatisfied with Aesthetic Appearance of Breast	2.2	5.1	6.3	8.4
Patient Dissatisfied with Feel of Implant	1.7	1.7	1.5	3.8
Position Dissatisfaction[3]	0.5	2.1	4.9	4.9
Ptosis (sagging)	2.9	5.8	5.0	12.2
Recurrent Breast Cancer	1.7	2.5	1.5	3.6
Redness (Erythema)	0	0	1.5	1.5
Scarring	2.9	2.9	1.5	6.5
Seroma	2.7	3.4	4.6	4.6
Shape Distortion	0	1.6	0	0
Silicone From Previous Rupture	0	0	1.5	1.5
Size Change-Patient Request	5.0	5.0	7.8	9.9
Size Change-Physician Assessment Only	2.1	2.1	0	4.8
Skin Lesion	1.1	1.8	1.8	4.3
Suture Complication	1.7	1.7	0	0
Swelling (Excessive)	0.5	0.5	1.5	1.5
Tenderness/ Soreness	0.5	1.4	0	0
Wrinkling[3]	3.3	4.0	9.5	12.2

[1] Rupture was assessed by MRI at 1, 2, 4, and 6 years (results are provided in Table 10 of the appropriate Patient Educational Brochure); there were no cases of rupture reported through 6 years in the non-MRI cohort of primary reconstruction and revision-reconstruction patients

[2] The following complications occurred at a rate less than 1%: capsular contracture Baker Grade unknown, external injury not related to breast implants, necrosis, new diagnosis of breast cancer, nipple complication, symmastia, wound opening (dehiscence).

[3] Mild occurrences not included

[4] All causes of death were reported by the Investigator to be unrelated to study procedure or device.

[5] Gel fracture occurred in 1 revision-reconstruction patient.

[6] There were 3 diagnoses in 3 primary reconstruction patients: rheumatoid arthritis (10 months post implantation), other inflammatory arthritis (11 months post implantation), and other mechanical/degenerative condition (16 months post implantation).

OTHER REPORTED CONDITIONS

There have been reports in the literature of other conditions in women with silicone gel breast implants. Many of these conditions have been studied to evaluate their potential association with breast implants. No cause and effect relationship has been established between breast implants and the conditions listed below. Furthermore, there is the possibility of risks, yet unknown, which in the future could be determined to be associated with breast implants. It should also be noted that the conditions listed below were reported by both augmentation and/or reconstruction patients, as well as from a variety of manufacturers and implant models.

- Connective tissue diseases such as: lupus, scleroderma, rheumatoid arthritis, and fibromyalgia.
- Rheumatological signs and symptoms such as: fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes.
- Cancer, such as: breast cancer, brain cancer, respiratory/lung cancer, reproductive system cancers (cervical/vulvar cancer), lympho-hematopoietic cancers including anaplastic large cell lymphoma (ALCL), and other cancers.
- Neurological symptoms (such as difficulties with vision, sensation, muscle strength, walking, balance, thinking or remembering things) or diseases (such as multiple sclerosis).
- Suicide
- Effects on children born to mothers with breast implants, or effects on children from breastfeeding.
- Potential health consequences of gel bleed.

IMPLANT REMOVAL

Breast implants may be removed (with or without replacement) in response to a complication or to improve the cosmetic result. In Mentor's MemoryShape™ Core Study, through 6 years, the most common reason for implant removal in all four study cohorts was patient request for an implant size change.

Figures 1 through 4 below present the reasons for implant removal in Mentor's MemoryShape™ Core Study through 3-years and 6-years. Note that the 6-year results also include any events that occurred by 3 years.

Figure 1. Reasons for Implant Removal through 3-Years and 6-Years
Primary Augmentation Cohort
3 Years, N=55 implants 6 Years, N=70 implants

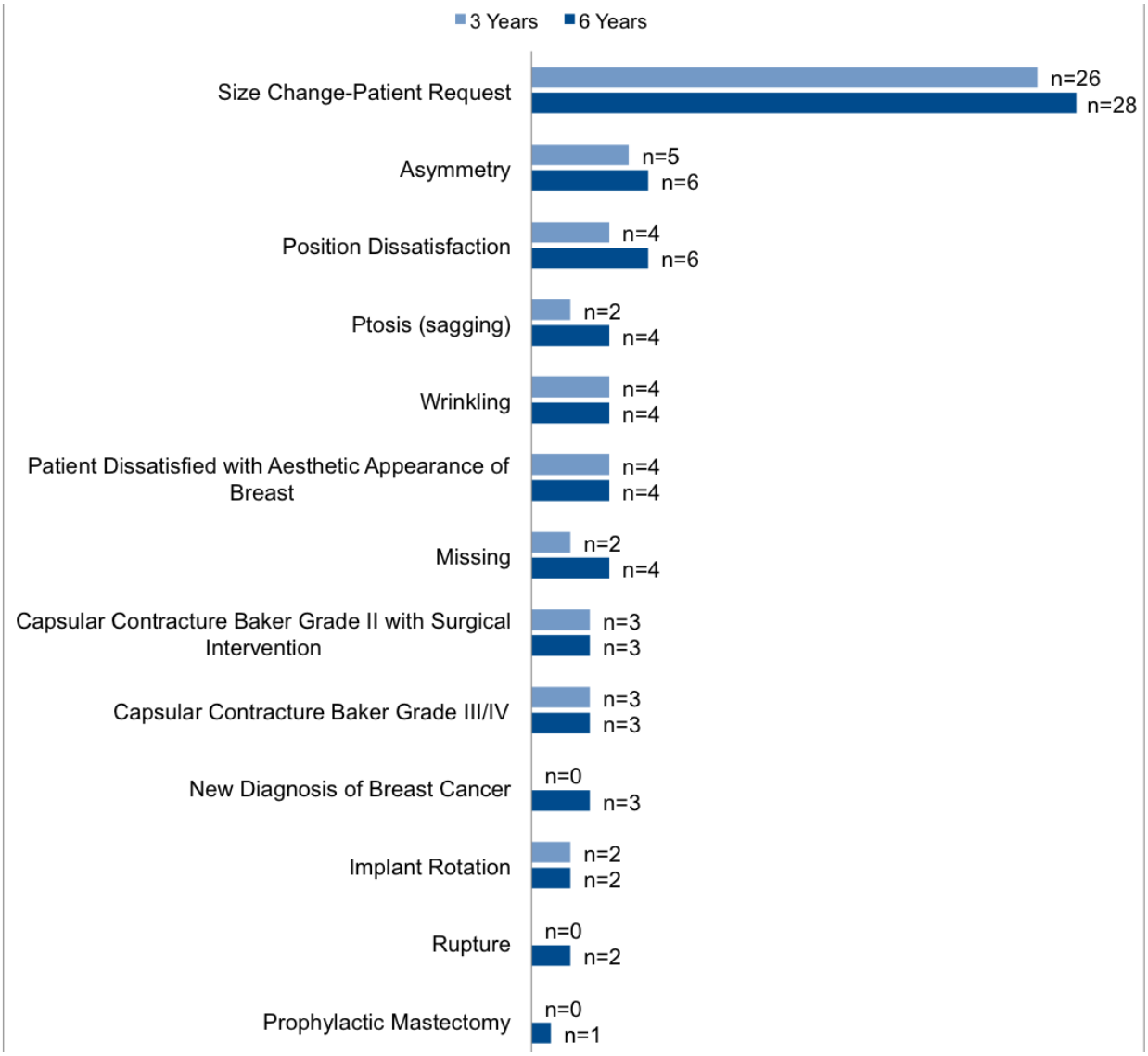


Figure 2. Reasons for Implant Removal through 3-Years and 6-Years
Revision-Augmentation Cohort
3 Years, N=24 implants 6 Years, N=29 implants

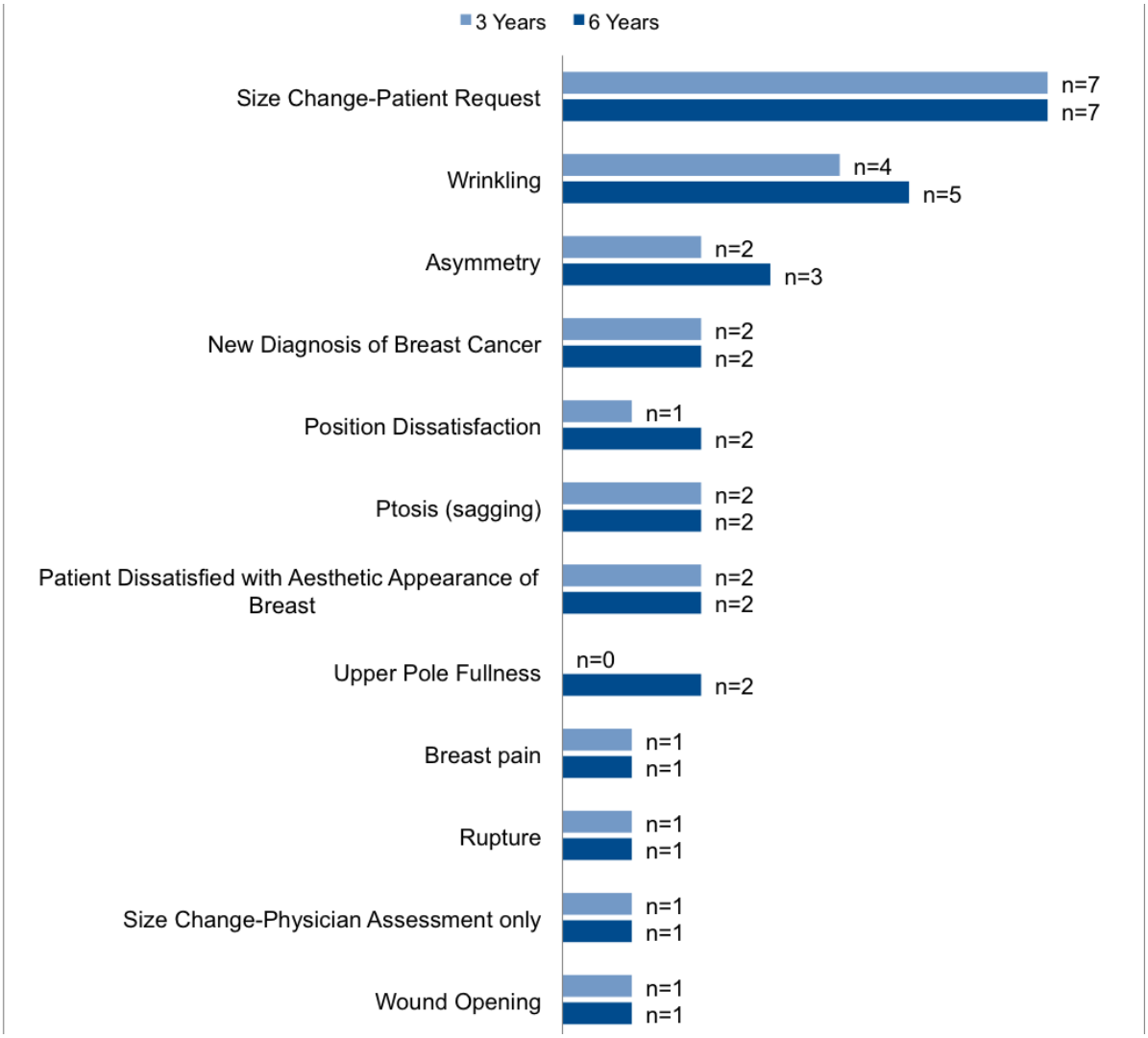


Figure 3. Reasons for Implant Removal through 3-Years and 6-Years
Primary Reconstruction Cohort
3 Years, N=34 implants 6 Years, N=58 implants

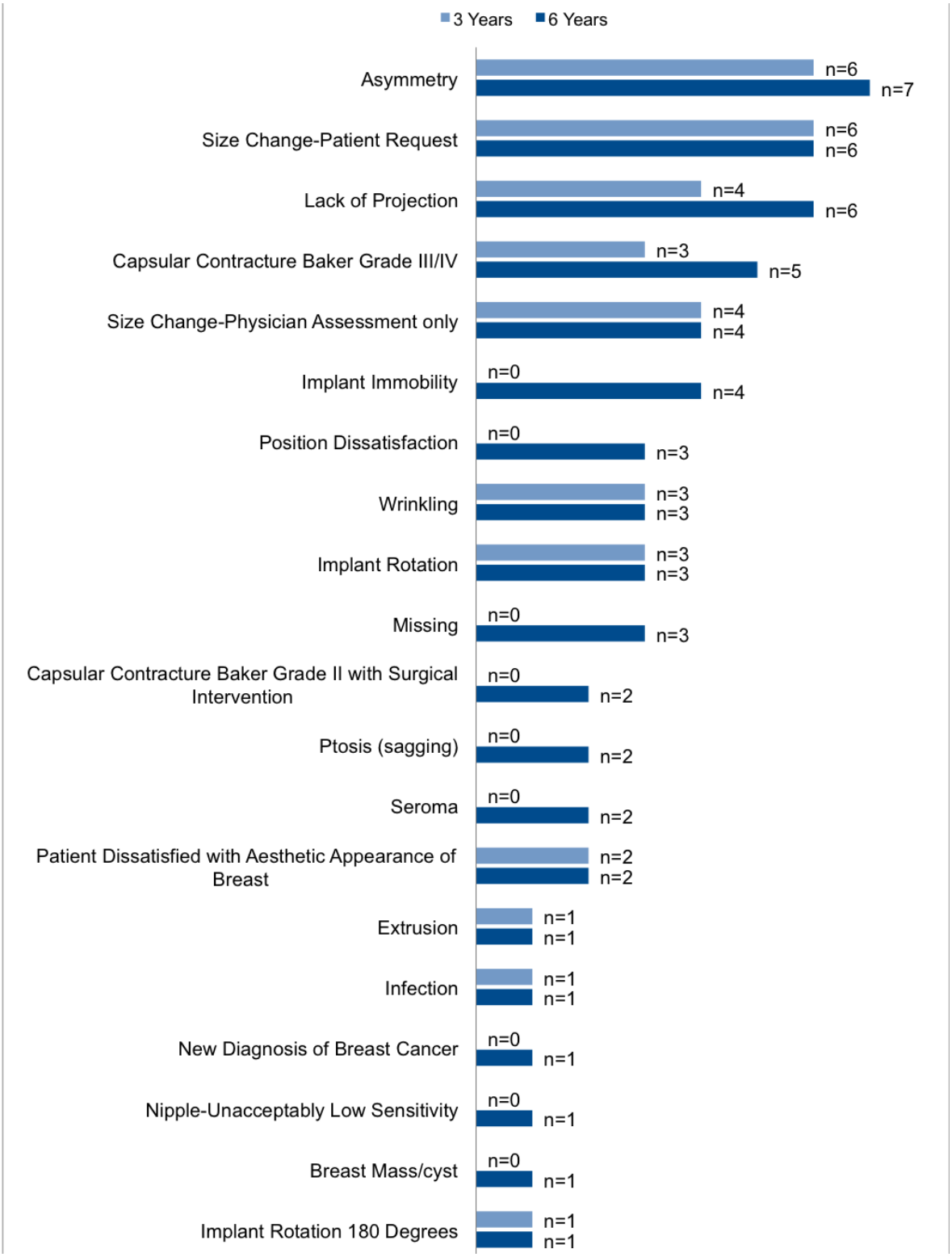
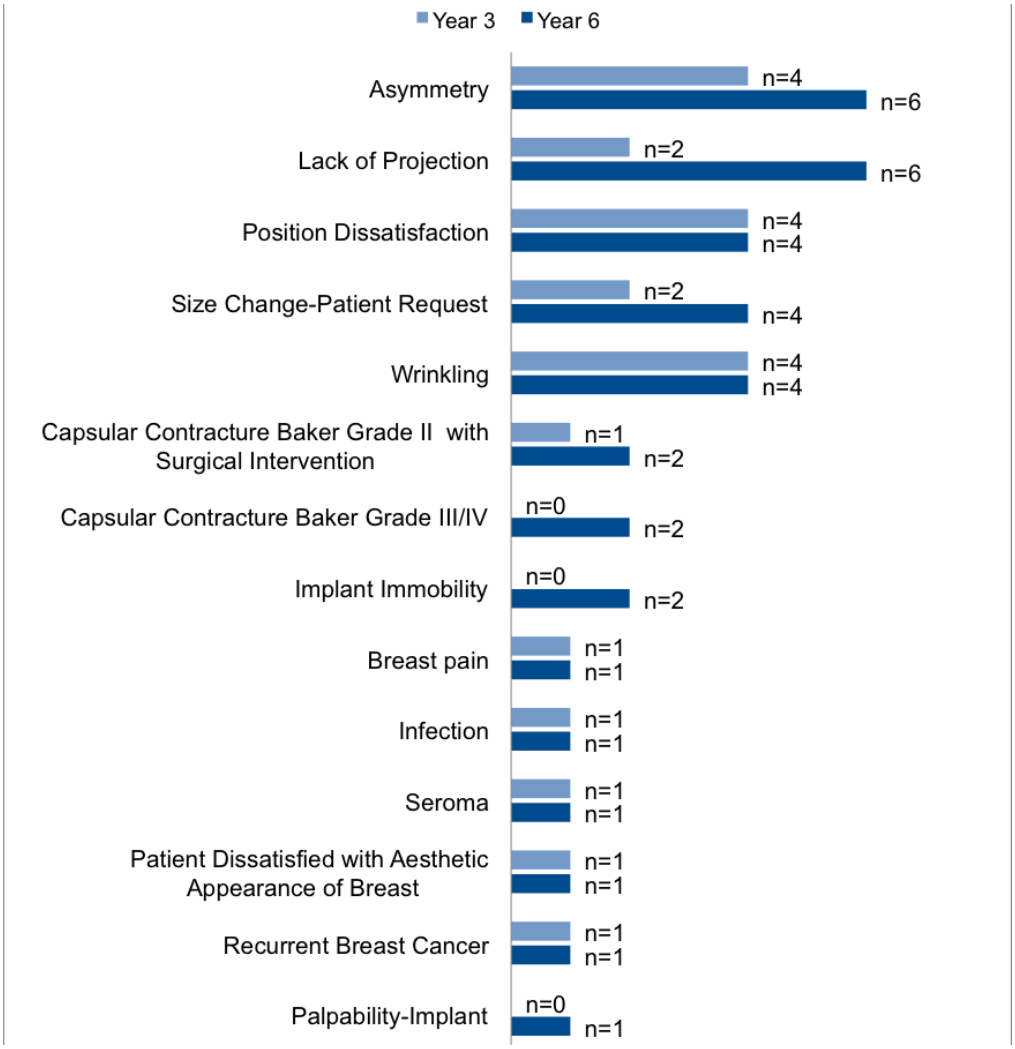


Figure 4. Reasons for Implant Removal through 3-Years and 6-Years Revision-Reconstruction Cohort
3 Years, N=22 implants 6 Years, N=36 implants



For a more detailed review of potential complications, please refer to Section 4, Risks Associated with Breast Implants, of the appropriate Patient Educational Brochure for breast augmentation or reconstruction with MENTOR® MemoryShape™ Breast Implants.

IMPORTANT FACTORS TO CONSIDER

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.

CONTRAINDICATIONS

Breast implant surgery should NOT be performed in:

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

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, or
- 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.

WARNINGS

WARNING – Below is a list of warnings associated with breast implant surgery. For a more detailed review of warnings, please refer to Section 3.4, *Warnings*, of the appropriate *Patient Educational Brochure*.

- Smoking can make it harder for your body to heal. Do not smoke before your breast implant surgery or while you are recovering.
- Breast implants are not expected to last for the rest of your life, and breast implantation may not be a one-time surgery.

- Many of the changes to your breast that may occur as a result of breast implant surgery will be permanent and cannot be undone.
- Breast implants may interfere with your ability to produce milk (lactate) for breast-feeding.
- Mammography for detecting breast cancer (or cancer recurrence) may be more difficult with breast implants in place. Be sure to notify the technologist that you have breast implants prior to the procedure.
- Your implants could rupture without you noticing any change in your breasts (called a "silent" rupture). 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.
- 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.
- After undergoing breast implant surgery, you may experience changes in your healthcare insurance. Be sure to check with your insurance company about potential issues and understand the complete extent of your health coverage before having breast implant surgery.

For a complete review of the risks and benefits please read the appropriate Mentor patient educational brochure for breast augmentation or reconstruction, ***Breast Augmentation with MENTOR® MemoryShape™ Breast Implants*** or ***Breast Reconstruction with MENTOR® MemoryShape™ Breast Implants***.

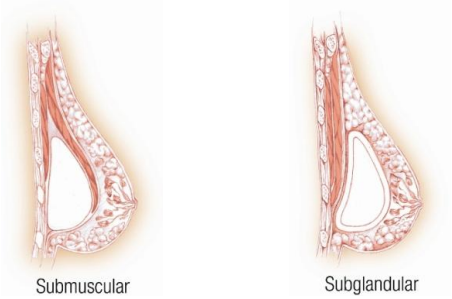
BREAST IMPLANT SURGERY – UNDERSTANDING THE PROCEDURE

Before your breast implant surgery, you and your plastic surgeon will discuss the implant placement and surgical incision options, as well as your expected postoperative care.

IMPLANT PLACEMENT

Your surgeon will consult with you and suggest where the breast implant is to be placed. Implants are placed beneath your breast tissue, either on top of the chest muscle (subglandular placement) or underneath part or all of the chest muscle (submuscular placement).

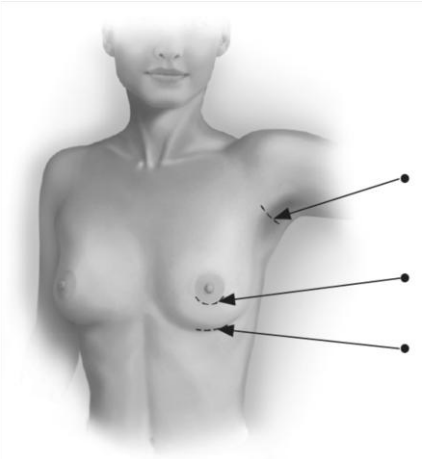
Figure 5. Implant Placement



INCISION SITES

Your surgeon will suggest the best incision site option for your particular surgery. There are three common incision sites to consider:

Figure 6. Incision Sites



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.

The incision with the MemoryShape™ Breast Implant will be longer than the one typically made for breast augmentation with a saline or round silicone gel breast implant.

For breast reconstruction after a mastectomy, your doctor will choose the incision sites based on the type of mastectomy surgery that is planned for you. Sometimes, a doctor will recommend placing an implant in the opposite breast after a unilateral (one breast only) mastectomy and reconstruction to create better symmetry. If you have an unaffected breast implanted to match a reconstructed breast, you may be able to choose the incision site (refer to Figure 6).

POSTOPERATIVE CARE

In the weeks after your breast implant surgery, 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.

BREAST IMPLANTS ARE NOT LIFETIME DEVICES

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. 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, or to address some of the complications mentioned in Table 1 and Table 2 above.

ADDITIONAL INFORMATION

For additional information or if you have questions regarding the Mentor MemoryShape™ Breast Implants, please visit Mentor's website at http://www.mentorwwllc.com or call
Mentor at 1 (800) MENTOR8.

Additional information about silicone gel breast implants can be obtained from the United States Food and Drug Administration (FDA) at http://www.fda.gov/breastimplants.