

Breast Augmentation OPTIONS



the power to transform[®]



MENTOR



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INTRODUCTION

For many women, feeling confident, alive and vibrant goes hand in hand with looking their best. For thousands of women, achieving such confidence and personal satisfaction has come from choosing breast augmentation. Following their procedure, many women have gone on to experience a transformation in how they feel about themselves and their bodies.

There are many reasons women choose breast augmentation, some of them include:

- Enlarging their breasts to make their bodies more proportional
- Reshaping and enlarging breasts that have lost their shape due to breast feeding
- Balancing breasts that differ in size or shape

Your reasons are unique and very personal, and your decisions about breast augmentation should be made by you and your physician based on your personal needs, desires and expectations.

Today there are many options available for women that decide breast augmentation is right for them. These options include saline-filled breast implants and Mentor MemoryGel™ breast implants.

This brochure is designed to help you understand these options so that, together with your physician, you can make the choices that are right for you.



Patient and Medical Professional Services

As you learn about breast augmentation and face important decisions, it's normal to have questions. To help answer those questions and provide you with objective and straightforward information, Mentor offers a free, person-to-person service called *Patient and Medical Professional Services*.

Patient and Medical Professional Services is led by an experienced team of nursing professionals who are available to answer your questions through a toll-free number. The service is intended to provide you with balanced, honest information and to encourage you to be fully informed so you can discuss your options with your physician before making a decision. Contacting *Patient and Medical Professional Services* is easy. Just call **(800) MENTOR – 8**.



SELECTING A PHYSICIAN

As with any surgery, the single most important factor in achieving the results you desire is selecting the best physician for your breast augmentation procedure. Choosing the right surgeon is a responsibility that you shouldn't take lightly. Never let yourself be pressured into making fast decisions. Instead, take as much time as you need to do your own research and check a surgeon's training and experience.

In addition to medical experience, you should consider the physician's personal communication skills as well. Make sure they take the time to answer your questions and that they speak to you in a patient, respectful manner that makes you feel comfortable. You'll also be spending a lot of time interacting with your physician's staff, so you'll also want to make sure you feel comfortable with them.

There are many ways to find a qualified physician. Referrals from friends or family members who've had breast augmentation is always a great way to start. Through our web site, www.mentor4me.com, Mentor provides a list of qualified physicians that can help you with your search. In addition, you may also contact a number of respected professional organizations, such as:

- The American Society of Plastic Surgeons (ASPS)
- The American Society for Aesthetic Plastic Surgery (ASAPS)
- The American Academy of Cosmetic Surgeons (AACCS)
- Your local medical society

Questions to ask about a physician's experience

When choosing a surgeon who is experienced in breast augmentation procedures, you should know the answers to the following types of questions:

- How many breast augmentation implantation procedures does he/she perform per year?
- How many years has he/she performed breast augmentation procedures?
- Has he/she obtained training certification from Mentor to use its MemoryGel™ breast implants?
- Is he/she board certified, and if so, with which board?
- In which state(s) is he/she licensed to practice surgery? (Note that some states provide information on disciplinary action and malpractice claims/settlements to prospective patients, either by request or on the Internet.)
- What is the most common complication he/she encounters with breast augmentation?

- What is his/her reoperation rate with breast augmentation, and what is the most common type of reoperation he/she performs?
- Can he/she perform this surgery in a hospital, as well as in the surgeon's independent surgery center? (Note that hospitals require the demonstration of evidence of appropriate training in specific procedures before allowing surgeons to operate in their facilities.)

Questions to ask about the breast augmentation procedure

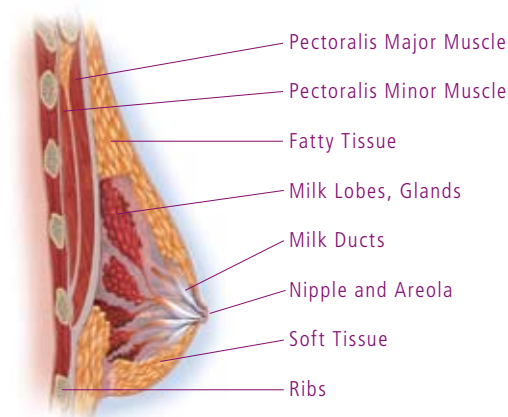
In addition to learning about a physician's training and experience, you'll also want to gain a better understanding of breast augmentation. The following are questions you should have physicians answer during your initial consultation.

- What are the risks and complications associated with having breast implants? (See *Complications, Precautions and Warnings for Breast Implants*, pg. 18)
- How many operations on my implanted breast(s) can I expect over my lifetime?
- How will my breasts look if I choose to have the implants removed without replacement?
- What shape, size, surface texturing, incision site and placement site are recommended for me?
- How will my ability to breast-feed be affected?
- How can I expect my implanted breasts to look over time?
- How can I expect my implanted breasts to look after pregnancy or after breast-feeding?
- What are my options if I'm dissatisfied with the cosmetic outcome of my implanted breasts?
- What alternate procedures or products are available if I choose not to have breast implants?
- Do you have before and after photos I can look at for each procedure, and what results are reasonable for me?

After you've had initial consultations with all the physicians on

your list and had your questions answered, take your time and choose the surgeon you feel most comfortable with and believe is the best match for you.

BREAST ANATOMY



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

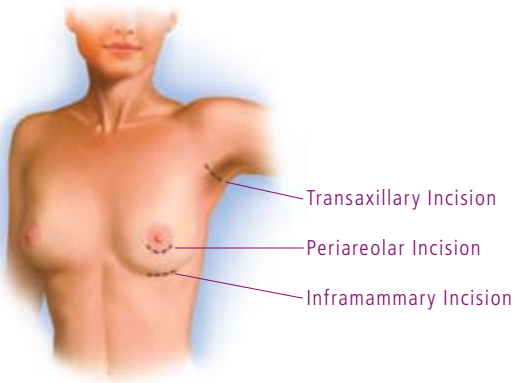
It is important to realize that implants are used to make the breast larger. Implants alone may not adequately lift the breast, or correct the effects of pregnancy, weight loss or skin stretching. Your surgeon may suggest additional procedures at the time of your breast augmentation, such as a mastopexy, to help achieve improved breast lift.

INCISION AND PLACEMENT CHOICES

Incisions

You should discuss with your surgeon the pros and cons for the incision site specifically recommended for you.

The incision size for a gel breast augmentation will be larger than for a saline breast augmentation. There are three common incision sites: under the arm (axillary), around the nipple (periareolar), or within the breast fold (inframammary).



- **Periareolar** – This incision is typically more concealed, but since it also involves cutting through the breast tissue it is associated with a higher likelihood of breast feeding difficulties, as compared to the other incision sites.¹ Cutting through the tissue may increase the chance that there will be a change in breast or nipple sensation.
- **Inframammary** – This incision is generally less concealed than the periareolar and it's associated with less breast feeding difficulties than the periareolar incision site. It is also the most commonly used incision site at the present time, and is felt to give the best access to, and control of, the breast implant pocket.
- **Axillary** – This incision is less concealed than the periareolar and is associated with less breast feeding difficulties than the periareolar incision site. If the incision is made under the arm, the surgeon may use a probe fitted with a miniature camera, along with minimally invasive (very small) instruments, to create a "pocket" for the breast implant. This approach is more difficult, and may increase the risk of damage to, and unexpected location of, the implant.
- **Umbilical (belly button)** – This incision site has not been studied in Mentor's Core Study and should not be used for a wide variety of reasons, including potential damage to the implant shell.

Your doctor will explain each incision choice to you in greater detail and help you make a decision that is right for you.

Implant placement

The breast implant can be placed either partially under the pectoralis major muscle (submuscular) or on top of the muscle and under the breast glands (subglandular). You should discuss with your surgeon the advantages and disadvantages of the implant placement selected for you. Each implant location has benefits and negative features of which you need to be aware, as described in the table below.

Comparison between submuscular versus subglandular placement

SUBMUSCULAR PLACEMENT	SUBGLANDULAR PLACEMENT
Surgery may be longer	Surgery may be shorter
Recovery may be longer	Recovery may be shorter
May be more painful	May be less painful
Reoperation may be more difficult	May provide easier access for reoperation
Less visible and palpable implants	More visible and palpable implants
Less likelihood of capsular contracture ²	Greater likelihood of capsular contracture ^{3,4}
Easier imaging during mammography exam	More difficult imaging during mammography exam
May be preferable if you have thin or weakened breast tissue	May not be recommended if you have thin or weakened breast tissue



Submuscular Placement



Subglandular Placement

TYPES OF BREAST IMPLANTS

A breast implant is a sac (implant shell) of silicone elastomer filled with silicone gel or saline, which is surgically implanted under your breast tissue or under your chest muscle. Mentor makes two basic types: saline and MemoryGel™ breast implants.

For over 20 years, Mentor has been recognized world wide as a leading manufacturer of the highest quality breast implants. Our rich history is filled with industry firsts, innovative product designs and groundbreaking research. While other manufacturers have come and gone, Mentor has a record of continually producing leading-edge breast augmentation products.

MemoryGel™ Breast Implants

MemoryGel™ implants feature a unique cohesive gel, which is not a liquid or semi-liquid. It holds together uniformly while retaining the natural give that resembles breast tissue. Mentor's MemoryGel™ breast implants have either a textured or smooth surface shell, and are available in a wide range of sizes and profiles to fit different body types.



Saline Breast Implants

Mentor's saline-filled breast implants come in a variety of shapes, sizes, profiles and surface textures. They are all filled with a saltwater solution that is similar to the fluid that makes up most of the human body. Saline implants are inserted into the body without fluid, and then filled during surgery through a fill-tube. When the fill-tube is removed, the implant automatically seals itself.



Implant shapes and sizes

Depending on the desired shape you wish to achieve, you and your surgeon have implants with three different round profiles, or styles, from which to choose. Generally, the larger you want your cup size, the larger the breast implant your surgeon will consider. Breast implants are measured in cubic centimeters, or cc's, not in

cup sizes. This is because the size of the implant used depends on the size and shape of the individual woman's chest.

Your surgeon will also evaluate your existing breast and skin tissue to determine if you have enough to cover the breast implant you are considering, or, in some cases such as after pregnancy, too much extra skin. If you desire a breast implant size that is too large for your tissue, your surgeon may warn you that the breast implant edges may be visible or palpable following your surgery. Also, excessively large breast implants may speed up the effects of gravity on the breast, and can result in droop or sag at an earlier age.

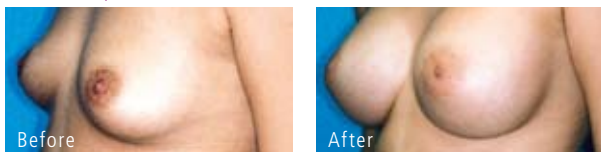
A recent report indicates that larger sized implants (greater than 350 cc) may be too large for many women, increasing the risk of developing complications such as extrusion, hematoma, infection, palpable implant folds and visible skin wrinkling. Surgical intervention could be required to correct these complications.³

Implant profiles

In addition to size and shape, breast implants are available in different profiles (which refers to the amount of forward projection off the chest wall). With respect to the profile you'd like to achieve, you and your physician may choose a round or contoured implant.

Round implants are the most popular choice, and are available as saline-filled or MemoryGel™ breast implants. Both types come in a variety of profiles: Moderate, Moderate Plus and High. High profile implants provide the greatest forward projection for a more prominent silhouette, and are designed for a narrower chest area.

Product Implanted: Moderate Profile Saline



Photos courtesy of Dr. Jon Paul Trevisani (Maitland, Florida)

Product Implanted: High Profile Saline



Photos courtesy of Dr. Louis L. Strock (Fort Worth, Texas)

Contoured implants are only available with a saline fill. They provide a more mature, sloped breast shape, and they come in Moderate and High Profile styles. However, it's important to know that when contoured implants are placed beneath the chest muscle, they may assume a round shape.

Together with your physician, you can decide which implant shape, size and profile is right for you.

Implant surfaces

Breast implants are available with either a smooth or textured surface. Currently, smooth-surfaced breast implants are the most popular choice among women and physicians. Smooth implants are less likely than textured implants to be felt, or palpable, through the skin.

Additional factors, such as implant placement, size and the amount of skin and tissue coverage over an implant could influence how palpable it is. For example, implants placed subglandularly (above the chest muscle) tend to be more palpable than implants placed submuscularly (below the chest muscle).

Some studies suggest that surface texturing reduces the chance of severe capsular contracture,⁵ while other studies do not.^{3,5} Mentor's Core Study did not show a difference in the likelihood of developing capsular contracture with textured implants compared to smooth-surfaced implants.

A textured implant may require a larger incision because the rougher textured surface makes it harder to place into the pocket without undue stress, which might damage the implant or decrease its durability.

Your physician can help you decide which implant surface is most appropriate for you.



Options for every body

Mentor offers a number of specialized saline-filled and MemoryGel™ breast implant products that are designed to meet your unique, personal needs. Mentor implants are available in a wide variety of sizes, profiles and surface texture choices, which provides surgeons with more options to help you achieve the best match for your body type.

Below is a closer look at some of the features of our saline-filled and MemoryGel™ breast implants. Your physician can further explain their different benefits, and discuss which type of implant is the right choice for you.

MemoryGel® Breast Implants



Smooth Round
Moderate Profile



Siltex® Round
Moderate Profile



Smooth Round
Moderate Plus Profile



Siltex® Round
Moderate Plus Profile



Smooth Round
High Profile



Siltex® Round
High Profile

- FDA approved
- Filled with Mentor's proprietary cohesive gel
- Gel filler uniformly holds together and retains a natural give that resembles breast tissue
- Set fill volume
- Three projection options: Moderate, Moderate Plus and High Profile
- Two shell surface options: smooth and textured
- Covered by Mentor's Standard or Enhanced limited warranty and lifetime replacement policy

Saline Breast Implants



Smooth Round
Moderate Profile



Siltex® Round
Moderate Profile



Smooth Round
Moderate Plus Profile



Smooth Round
High Profile



Siltex® Contour
Profile® Moderate



Siltex® Contour
Profile® High

- FDA approved
- Filled with a saltwater solution similar to the fluid that makes up most of the human body
- Slightly firmer feel than gel
- Flexible fill volume that can be adjusted by surgeon during procedure
- Three projection options: Moderate, Moderate Plus and High Profile
- Two shell surface options: smooth and textured
- Covered by Mentor's Standard or Enhanced limited warranty and lifetime replacement policy

Mentor Spectrum® Adjustable Saline Implants



Smooth Round
Spectrum®



Siltex® Round
Spectrum®



Siltex® Contour
Profile® Spectrum®

For many women, selecting the breast size they want is understandably the most difficult part of choosing implants. To help make this process easier, Mentor offers its innovative line of Spectrum® breast implants.

Spectrum® implants are the only postoperatively adjustable saline-filled breast implants that enable your physician to adjust the size of your implant for up to six months after your procedure.

SURGICAL SETTING AND ANESTHESIA

Augmentation surgery is usually performed on an outpatient basis in a specialized operating room that may be located in a hospital, a surgery center or a surgical suite in the surgeon's office. General anesthesia is commonly used, and local anesthesia with sedation is also an option. You should be sure to check with your surgeon and with the facility where the surgery will take place to become aware of the tests, presurgical examinations, and length of time you need to be without food or your routine medications prior to your surgical procedure.

POSTOPERATIVE CARE

You will probably feel somewhat tired and sore for several days following your operation, and your breasts may remain swollen and sensitive to physical contact for a month or longer. You may also experience a feeling of tightness in the breast area as your skin adjusts to your new breast size. The feeling in the breasts and nipple area also may be diminished during this time of swelling and immediate post surgery recovery. Other possible complications are described throughout this patient guide.

Postoperative care depends on each patient's situation and may involve the use of a specific postoperative bra, compression bandage, or jog bra for extra support and positioning while you heal. Some surgeons may not want you to wear a bra at all for a period of time following your surgery. At your surgeon's recommendation, you will most likely be able to return to work within a few days, although for at least a couple of weeks you should avoid any strenuous activities that could raise your pulse and blood pressure, or require strenuous use of your arms and chest. Your surgeon may also recommend breast massage exercises.

Note: *If you experience fever, do not feel well, or see noticeable swelling and/or redness or drainage in your implanted breast(s), you should contact your surgeon immediately.*

MENTOR PRODUCT REPLACEMENT POLICY AND LIMITED WARRANTIES

Your choice to have breast reconstruction is a personal, long-term decision. Because breast implants should not be considered lifetime devices*, we offer a product replacement policy and two limited warranty programs.

- **Mentor's Lifetime Product Replacement Policy** provides for the free lifetime product replacement of its saline-filled and MemoryGel™ breast implants, worldwide. When implant replacement is required, and the Mentor Product Replacement Policy applies, Mentor will provide, throughout the patient's lifetime, the same or similar Mentor breast implant at no cost. If a more expensive product is requested, Mentor will invoice your surgeon for the price difference.
- **The Mentor Standard Advantage Limited Warranty** is free of charge to all patients who are implanted with Mentor saline-filled or MemoryGel™ breast implants in the United States and Puerto Rico.
- **The Mentor Enhanced Advantage Limited Warranty** is available for women who are implanted with Mentor saline-filled or MemoryGel™ breast implants in the United States and Puerto Rico. You must pay a \$100.00 enrollment fee within 45 days of your breast implantation.

Your surgeon will provide you with a copy of Mentor's Product Replacement and Limited Warranty program for breast implants. However, it is not intended to replace any discussion between you and your physician. Prior to your surgery, your physician should advise you about possible risks and complications associated with breast implant surgery, including deflation or rupture.

With both the Mentor Standard Advantage and Mentor Enhanced Advantage Limited Warranties, it's important for you to also maintain your own records to ensure validation of your enrollment. This is necessary because it's possible your doctor may only be required to retain your records for a limited period of time depending upon the laws of your state.

* When undergoing breast augmentation, be aware that breast implantation may not be a one-time surgery. You should read and fully understand "Important Information for Augmentation Patients about Mentor MemoryGel™ Silicone Gel-Filled Breast Implants."

CONSIDERATIONS

Mentor's saline-filled breast implants for breast augmentation surgery are intended for females who are at least 18 years old. Women having breast augmentation surgery with MemoryGel™ breast implants must be at least 22 years old. If you are considering augmentation surgery with saline implants, please read Mentor's brochure titled, *Saline-Filled Implant Surgery: Making An Informed Decision*.

If you are considering MemoryGel™ implants, please read: *Important Information for Augmentation Patients about Mentor MemoryGel™ Silicone Gel-Filled Breast Implants*. Both brochures contain current information about breast implants. After reading and signing the Acknowledgment of Informed Decision page in each brochure, your doctor will help you decide which implant type is the right choice for you.

Breast implants are not lifetime devices, and breast implantation is likely not a one-time surgery. You will likely need additional unplanned surgeries on your breasts because of complications or unacceptable cosmetic outcomes. These additional surgeries can include implant removal with or without replacement, or they can include other surgical procedures. When you have your implants replaced (revision-augmentation), your risk of future complications increases compared to first-



time (primary) augmentation surgery; so you should also review the complication rates for revision-augmentation patients to see what future risk rates you may experience.

Many of the changes to your breasts following implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed and not replaced, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast, which can be permanent.

Breast implants may affect your ability to breast feed, either by reducing or eliminating milk production.

Should you decide against having breast augmentation surgery, you have the option of accepting the look of your breasts as they are, or wearing a padded bra or external prosthesis.

BREAST AUGMENTATION RESOURCES

Upon request, you'll be provided with a copy of the package insert (*Directions For Use*). You can request a copy from your surgeon or from Mentor. The package insert has many undefined medical and technical terms because it contains information directed only to the surgeon.

For more detailed information on the preclinical and clinical studies conducted by Mentor, please refer to the Summary of Safety and Effectiveness Data (SSED) for this product at www.fda.gov/cdrh/breastimplants/.

If you should decide to have breast augmentation, you will be given a device identification card with the style and serial number of your breast implant(s). This will be given to you right after your surgery. It is important that you keep a copy of this card because you may need to refer to the information at a later date.

For additional information or questions about Mentor breast implants, please call **1-800-MENTOR-8**. The following list of resources may help you obtain additional information so you can make an informed decision about breast augmentation.

Mentor Corporation

1-800-MENTOR-8

www.mentorcorp.com

www.mentor4me.com

Institute of Medicine Report on the Safety of Silicone Implants

www.nap.edu/catalog/9618.html

Food and Drug Administration

1-888-INFO-FDA or 301-827-3990

www.fda.gov/cdrh/breastimplants/

You can find important information in the FDA breast implant consumer handbook, which is available through the phone number or web site provided above.

American Society of Plastic Surgeons

[www.plasticsurgery.org/publiceducation/](http://www.plasticsurgery.org/publiceducation/silicone-breast-implant-surgery.cfm)

[silicone-breast-implant-surgery.cfm](http://www.plasticsurgery.org/publiceducation/silicone-breast-implant-surgery.cfm)

Mentor's saline-filled breast implants have been demonstrated to be effective for augmentation patients in a prospective 36-month study of 1,264 patients. In addition to an increase in bra cup size reported by 96% of patients, other statistically significant implant surgery benefits were demonstrated, as described below.

- Increased satisfaction with breast size, shape and firmness (following augmentation, 80% - 90% of patients reported satisfaction).⁶
- Increased comfort with appearance (following augmentation, 90% of patients were somewhat or very comfortable with the appearance of their breasts while alone or with their partner, as compared to 10% prior to augmentation).⁶
- Increased satisfaction with physical appearance.⁷
- Improved self-esteem.⁸

COMPLICATIONS, PRECAUTIONS AND WARNINGS FOR SALINE-FILLED BREAST IMPLANTS

SALINE-FILLED & SPECTRUM® MAMMARY PROSTHESES

Caution: Federal (USA) law restricts this device to sale by or on the order of a physician.

Device Description

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

Are You Eligible for Saline-Filled Breast Implants?

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

- **Breast Augmentation** – This procedure is done to increase the size and proportions of a woman’s breasts. A woman must be at least 18 years old for breast augmentation.

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

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

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

Who Is Not Eligible for Breast Implants?

Implants are not to be used for

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

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

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

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

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

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

Further considerations:

- **Preimplantation Mammography** – You may wish to undergo a preoperative mammogram and another one 6 months to 1 year after implantation to establish a baseline.
- **Interference with Mammography** – The implant may interfere with finding breast cancer during mammography and also may make it difficult to perform mammography. Therefore, it is essential that you tell your mammography technologist that you have an implant before the procedure. The technologist can use special techniques to minimize the possibility of rupture and to get the best possible views of the breast tissue. Because the breast is squeezed during mammography, it is possible for an implant to rupture during the procedure. More x-ray views are necessary with these special techniques; therefore, women with breast implants will receive more radiation. However, the benefit of the mammogram in finding cancer outweighs the risk of the additional x-rays.
- **Distinguishing the Implant From Breast Tissue During Breast Self-Examination** – You should perform a breast self-examination monthly on your implanted breast. In order to do this effectively, you should ask your surgeon to help you distinguish the implant from your breast tissue. Any new lumps should be evaluated with a biopsy. If a biopsy is performed, care must be taken to avoid puncturing the implant.
- **Long-Term Effects** – The long-term safety and effectiveness of breast implants have not been studied; however, Mentor is monitoring the long-term (i.e., 10-year) chance of implant rupture, reoperation, implant removal and capsular contracture (hardening of the tissues around the implant). Mentor is also conducting mechanical testing to assess the long-term likelihood of implant rupture. Mentor will update this brochure with this information and time frames later.
- **Capsule Procedures** – You should be aware that closed capsulotomy, the practice of forcible squeezing or pressing on the fibrous capsule around the implant to break the scar capsule, is not recommended, as this may result in breakage of the implant.

What Are Potential Breast Implant Complications?

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

- **Deflation/Rupture** – Breast implants deflate when the saline solution

*Betadine is a registered trademark of Purdue Frederick Company.

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

- **Capsular Contracture** – The scar tissue or capsule that normally forms around the implant may tighten and squeeze the implant and is called capsular contracture. Capsular contracture is more common following infection, hematoma and seroma. It is also more common with subglandular placement (behind the mammary gland and on top of the chest muscle). Symptoms range from mild firmness and mild discomfort to severe pain, distorted shape, palpability of the implant and/or movement of the implant.

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

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

In rare instances, toxic shock syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness and/or sunburn-like rash. A doctor should be seen immediately for diagnosis and treatment for this condition.
- **Hematoma/Seroma** – Hematoma is a collection of blood inside a body cavity, and a seroma is a collection of the watery portion of the blood (in this case, around the implant or around the incision). Postoperative hematoma and seroma may contribute to infection and/or capsular contracture. Swelling, pain and bruising may result. If a hematoma occurs, it will usually be soon after surgery. However, this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, large ones will

require the placement of surgical drains for proper healing. A small scar can result from surgical draining. Implant deflation/rupture can occur from surgical draining if damage to the implant occurs during the draining procedure.

- **Changes in Nipple and Breast Sensation** – Feeling in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. Changes in feeling can be temporary or permanent and may affect your sexual response or your ability to nurse a baby. (See the paragraph on breast-feeding below.)
- **Breast-Feeding** – At this time it is not known if a small amount of silicone may diffuse (pass through) from the saline-filled breast implant silicone shell and may find its way into breast milk. If this occurs, it is not known what effect it may have on the nursing infant. Although there are no current methods for detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone-filled gel implants when compared to women without implants.

With respect to the ability to successfully breast-feed after breast implantation, one study reported up to 64% of women with implants who were unable to breast-feed compared to 7% without implants. The periareolar incision site may significantly reduce the ability to successfully breast-feed.

- **Calcium Deposits in the Tissue Around the Implant** – Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish calcium deposits from cancer.
- **Delayed Wound Healing** – In some instances, the incision site takes longer to heal than normal.
- **Extrusion** – Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion, which is when the breast implant comes through the skin.
- **Necrosis** – Necrosis is the formation of dead tissue around the implant. This may prevent wound healing and require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis. Factors associated with increased necrosis include infection, use of steroids in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.
- **Breast Tissue Atrophy/Chest Wall Deformity** – The pressure of the breast implant may cause the breast tissue to thin out and shrink. This can occur while implants are still in place or following implant removal without replacement.

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

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

MENTOR'S CLINICAL STUDIES

Although you will experience your own risks (complications) and benefits following breast implant surgery, this section describes the specific complications and benefits of Mentor's saline-filled breast implants. Mentor's clinical studies indicate, for example, that while most women can expect to experience at least one complication at some point through 3 years after implant surgery, most women were satisfied with their implants. The studies also indicate that the chance of additional surgery is 1 in 8 for augmentation patients (with implant removal and replacement as the most common type of additional surgery). The information below provides more details about the complications and benefits you may experience.

Description of Studies

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

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

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

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

After product approval, Mentor switched data collection to a post-approval study. The post-approval study involves the collection of some safety data from SPS patients through their 10-year postimplantation timepoint. The data are collected from questionnaires that are mailed out to the patients each year. The post-approval data presented includes earlier data shown in the SPS tables with new information added to it. **The 5-year post-approval data are shown in the "Augmentation Results from Post-approval Study" section below.**

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

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

COMPLICATIONS	1-YEAR COMPLICATION RATE	
	Augmentation	Revision
Capsular Contracture	5%	15%
Implant Removal	4%	6%
Implant Leakage/Deflation	1%	2%
Infection	1%	NA

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

AUGMENTATION RESULTS FROM SPS

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

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

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

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

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

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

What Were the Reasons for Implant Removal for Augmentation Patients?

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

Main Reason for Augmentation Implant Removal through 3 Years ¹	N=137 Implants Removed
Patient Request for Size/Shape Change	37%
Leakage/Deflation	24%
Capsular Contracture	18%
Wrinkling	5%
Infection	5%
Asymmetry	4%
Hematoma/Seroma	2%
Sagging	2%
Scarring	2%
Cosmetic Revision	2%
Breast Cancer	1%
Total	100%

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

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

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

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

Breast disease and connective tissue disease (CTD) were reported in some patients through 3 years after implantation in the SPS. Although there were 1,264 augmentation patients enrolled in the SPS, not every patient returned for each follow-up visit. Therefore, the percentage of patients with these events cannot be determined. Only the number of events can be provided. New cases of breast cancer were reported in 2 augmentation patients.

The table below shows the number of reports of CTD through 3 years after implantation. Some patients may have reported more than one CTD. Confirmed reports were based on a diagnosis by a doctor. Unconfirmed reports were based on self-reports by the patients.

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

Number of Reports of CTD in AUGMENTATION Patients in the SPS Study		
Connective Tissue Disease	No. of Confirmed Reports	No. of Unconfirmed Reports
Osteoarthritis		1
Rheumatoid Arthritis	1	3
Arthritis (type unknown)		15
Lupus Erythematosus	1	
Total	2	19¹

What Were the Benefits from the SPS for Augmentation Patients?

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

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

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

AUGMENTATION RESULTS FROM POST-APPROVAL STUDY

In terms of patient accountability, of the 1,221 augmentation patients expected for follow-up at 5 years, data were collected for 5%. Of the 1,191 augmentation patients expected for follow-up at 7 years, data were collected for 50%. Please note that follow-up rate at 3 years was 76%, which makes the 3-year data more reliable than the 5-year or 7-year data. There was some data reported for 54% of the 1,221 augmentation patients at some time from 3 to 10 years postoperatively.

There was some 7-year data reported for 71% of the augmentation patients at some time from 3 to 10 years postoperatively. It is assumed that information obtained at a later time (for example, at 7 years) applies to an earlier time (for example, at 5 years), which counts on patient memory over time. This is not as reliable as information obtained at an earlier time.

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

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

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

Reason for Reoperation ¹	3-Years N=255 Reoperations	5-Years N=343 Reoperations	7-Years N=464 Reoperations
Patient Request for Size/Shape Change	33%	29%	24%
Capsular Contracture	19%	17%	15%
Leakage/Deflation ²	14%	19%	28%
Wrinkling	12%	11%	10%
Asymmetry	10%	8%	6%
Sagging	9%	9%	8%
Hypertrophic Scarring	9%	6%	5%
Hematoma/Seroma	6%	4%	3%
Infection	5%	4%	3%
Cosmetic Revision	5%	4%	3%
Breast Mass/Tumor/Cyst Excision or Biopsy	3%	4%	5%
Breast Pain	1%	1%	1%
Delayed Wound Healing	1%	1%	<1%
Irritation/Inflammation	1%	1%	<1%
Extrusion	1%	1%	<1%
Lymphadenopathy	<1%	<1%	<1%
Contralateral Replacement	0	3%	8%

¹If there was more than one reason reported per patient, all reasons are included in this table.

²Includes reoperations where the reason for reoperation was not reported.

The main reasons for implant removal through 5 years and 7 years are shown below. There were 324 implants removed in 191 patients at 7 years. The most common reason for removal through 7 years was leakage/deflation (38% of the 324 implants removed). Note that the percentages are smaller for some of the reasons for removal because the number of removals has gotten bigger.

Main Reason for Removal	5-Years N=135 Implants Removed	7-Years N=324 Implants Removed
Patient Request for Size/Style Change	30%	24%
Leakage/Deflation ¹	30%	39%
Capsular Contracture	15%	12%
Wrinkling	6%	6%
Contralateral Replacement	5%	10%
Infection	4%	2%
Asymmetry	3%	2%
Breast Mass or Cancer	2%	1%
Cosmetic Revision	2%	1%
Sagging	1%	1%
Hematoma/Seroma	1%	1%
Hypertrophic Scarring	1%	1%

¹Includes aesthetic removals where the reason for the removal was not reported.

If You Experience a Problem, Should You Report It?

If you believe that you have experienced a serious problem(s) related to your breast implants, you should have your health professional report the problem(s) to the FDA. You are encouraged to report any adverse events through their health professionals. Although reporting by physicians or other health professionals is preferred, women may also report any serious problem directly through the MedWatch voluntary reporting system. An adverse event is serious and should be reported when it results in an initial or prolonged hospitalization, disability, congenital anomaly or medical or surgical intervention.

This information reported to MedWatch is entered into databases to be used to follow safety trends (patterns) of a device and to determine whether further follow-up of any potential safety issues related to the device is needed.

To report, use MedWatch form 3500, which may be obtained through the FDA's website at <http://www.fda.gov/medwatch/index.html>. You may also call 1-888-463-INFOFDA (1-888-463-6332) from 10:00 a.m.-4:00 p.m. Eastern Time, Monday through Friday, to receive an additional FDA MedWatch package. Keep a copy of the MedWatch form completed by your doctor for your records.

COMPLICATIONS, PRECAUTIONS AND WARNINGS FOR MEMORYGEL™ SILICONE GEL-FILLED IMPLANTS

What Is a Silicone Gel-Filled Breast Implant?

A breast implant is a sac (implant shell) of silicone elastomer (rubber) filled with silicone gel, which is surgically implanted either under your breast tissue or under your chest muscle.

Are You Eligible for Silicone Gel-Filled Breast Implants?

Mentor MemoryGel Silicone Gel-Filled Breast Implants are indicated for females for the following uses (procedures):

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

Contraindications

Breast implant surgery should not be performed in:

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

Precautions

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

- Autoimmune diseases (for example, lupus and scleroderma).
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease).
- Conditions that interfere with wound healing and blood clotting.
- Reduced blood supply to breast tissue.
- Radiation to the breast following implantation.
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders with your surgeon prior to surgery. Patients with a

diagnosis of depression, or other mental health disorders, should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery.

Important Factors You Should Consider When Choosing Silicone Gel-Filled Implants.

- Breast implants are not lifetime devices, and breast implantation is likely not a one-time surgery. You will likely need additional unplanned surgeries on your breasts because of complications or unacceptable cosmetic outcomes. These additional surgeries can include implant removal with or without replacement, or they can include other surgical procedures. When you have your implants replaced (revision-augmentation), your risk of future complications increases compared to first time (primary) augmentation surgery, so you should also review the complication rates for revision-augmentation patients to see what future risk rates you may experience.
- Many of the changes to your breast following implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed and not replaced, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast, which can be permanent.
- Breast implants may affect your ability to breast feed, either by reducing or eliminating milk production.
- Rupture of a silicone gel-filled breast implant is most often silent. This means that neither you nor your surgeon will know that your implants have a rupture most of the time. In fact, the ability of a physical examination by a plastic surgeon who is familiar with breast implants to detect silicone breast implant rupture is 30%⁹ compared to 89% for MRI.¹⁰ You will need regular screening MRI examinations over your lifetime in order to determine if silent rupture is present. You should have your first MRI at 3 years after your initial implant surgery and then every 2 years, thereafter. The cost of MRI screening may exceed the cost of your initial surgery over your lifetime. This cost, which may not be covered by your insurance, should be considered in making your decision.
- If implant rupture is noted on MRI, you should have the implant removed, with or without replacement.
- With breast implants, routine screening mammography for breast cancer will be more difficult. If you are of the proper age for mammography screening, you should continue to undergo routine mammography screening as recommended by your primary care physician. The implant may interfere with finding breast cancer during mammography. Because the breast and implant are squeezed during mammography, an implant may rupture during the procedure. More x-ray views are necessary for women with breast implants; therefore, you will receive more exposure to radiation. However, the benefit of having the mammogram to find cancer outweighs the risk of the additional x-rays. Be sure to inform the mammography technologist that you have implants.
- You should perform an examination of your breasts every month for cancer screening; however, this may be more difficult with implants. You should 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, persistent pain, swelling, hardening, or change in implant shape, which may be signs of symptomatic rupture of the implant. These should be reported to your surgeon and possibly evaluated with an MRI to screen for rupture.
- After undergoing breast augmentation surgery (either primary or revision), your health insurance premiums may increase, your insurance coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. You should discuss the complete extent of your insurance coverage with your insurance company before undergoing surgery.

- You should inform any other doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.
- Mentor will continue its ongoing Core Study through 10 years to further evaluate the long-term safety and effectiveness of these products. In addition, Mentor has initiated a separate, 10-year post-approval study to address specific issues for which the Mentor Core Study was not designed to fully answer, as well as to provide a real-world assessment of some endpoints. The endpoints in the large post-approval study include long-term local complications, connective tissue disease (CTD), CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI compliance and results. Mentor will update its labeling as appropriate with the results of these two studies. You should also ask your surgeon if he/she has any available updated clinical information.
- It is important that you read this entire brochure because you need to understand the risks and benefits and to have realistic expectations of the outcome of your surgery.

POTENTIAL BREAST IMPLANT COMPLICATIONS

Undergoing any type of surgical procedure involves risks (some serious) such as the effects of anesthesia, infection, swelling, redness, bleeding, pain, and even death, which need to be balanced against the benefits of the breast augmentation surgery. There are potential complications specific to breast implant surgery and breast implants, as described below. It should also be noted that the cited references include data from augmentation and/or reconstruction patients, as well as from a variety of manufacturers and implant models.

- **Rupture** – Breast implants are not lifetime devices. Breast implants rupture when the shell develops a tear or hole. Rupture can occur at any time after implantation, but they are more likely to occur the longer the implant is implanted. The following things may cause your implant to rupture: damage by surgical instruments; stressing the implant during implantation and weakening it; folding or wrinkling of the implant shell; excessive force to the chest (for example, during closed capsulotomy, which is contraindicated); trauma; compression during mammographic imaging; and severe capsular contracture. Breast implants may also simply wear out over time. Laboratory studies have identified some of the types of rupture for Mentor's product; however, it is not known whether these tests have identified all causes of rupture. These laboratory studies will continue post-approval.

Silicone gel-filled implant ruptures are most often silent. (MRI examination is currently the best method to screen for silent rupture.) This means that most of the time neither you nor your plastic surgeon will know if the implant has a tear or hole in the shell. This is why MRI is recommended at 3 years and then every 2 years, thereafter, to screen for rupture. However, sometimes there are symptoms associated with gel implant rupture. These symptoms include hard knots or lumps surrounding the implant or in the armpit, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast.

When MRI findings of rupture are found, or if your surgeon determines you have signs or symptoms of rupture, you should have the implant and any gel removed, with or without replacement of the implant. It also may be necessary to remove the tissue capsule as well as the implant, which will involve additional surgery, with associated costs. If you have symptoms such as breast hardness, a change in breast shape or size, and/or breast pain, you should have an MRI to determine whether rupture is present.^{2,11}

There are also consequences of rupture. If rupture occurs, silicone gel may either remain within the scar tissue capsule surrounding the implant (intracapsular rupture), move outside the capsule (extracapsular rupture), or

gel may move beyond the breast (migrated gel). There is also a possibility that rupture may progress from intracapsular to extracapsular and beyond. There have also been health consequences reported in the literature. See below for details.

Rupture Information on Mentor Implants

In Mentor's Core Study, rupture was assessed for patients who had scheduled MRIs to screen for silent rupture (i.e., part of the MRI cohort) and those who were not assessed for rupture by MRI (i.e., part of the non-MRI cohort). For primary augmentation patients in the MRI cohort, the rupture rate was 0.5% through 3 years. This means that through 3 years, 1 of every 200 primary augmentation women had at least one ruptured breast implant. There was one primary augmentation patient in the Mentor Core Study with a suspected implant rupture detected via MRI, which has not been confirmed with examination of the implant following removal.

For revision-augmentation patients in the MRI cohort of the Mentor Core Study, the rupture rate was 7.7% through 3 years. This means that about 8 of 100 women had at least one ruptured breast implant through 3 years. All of these implant ruptures were silent and were only detected by MRI. One woman had removal of her breast implants after MRI, and both implants were ruptured. The other implant ruptures have not yet been confirmed with removal and examination of the implant.

There were no ruptures reported in the non-MRI cohorts for either the primary augmentation or revision-augmentation patients of the Mentor Core Study through 3 years. Across all patients in the Mentor Core Study, of the 8 implants reported as ruptured, 4 showed intracapsular gel and 4 showed extracapsular gel on MRI (3 implants with extracapsular gel were in 2 revision-augmentation patients and 1 was in a primary reconstruction patients). For one of these implants with extracapsular gel, this was a confirmed case in which the device was explanted and the intracapsular gel rupture progressed into an extracapsular gel rupture as shown by MRIs at approximately 10 months and approximately 2 years. There were no cases of migrated gel.

Further rupture rate information on Mentor implants is provided from an unpublished European study known as the U.K. Sharpe and Collis Study. Silent rupture was assessed by a single MRI on 101 augmentation patients implanted with textured Mentor implants by one surgeon. The average age of the implants was approximately 9 years. Silent rupture was found in approximately 10% of these augmentation patients, which includes one patient for which the device was not explanted to confirm rupture. There were no cases of extracapsular rupture or migrated gel.

Additional information on rupture will be collected through Mentor's post-approval Core Study and large post-approval study.

Additional Information on Consequences of Rupture from Literature

Studies of Danish women evaluated with MRI involving a variety of manufacturers and implant models showed that about three-fourths of implant ruptures are intracapsular and the remaining one-fourth is extracapsular.¹² Additional studies of Danish women indicate that over a 2-year period, about 10% of the implants with intracapsular rupture progressed to extracapsular rupture as detected by MRI.¹¹ This means that for women with silicone gel rupture within the scar tissue capsule detected via MRI after 2 years, 1 in 10 of these women had progression of the gel outside the scar tissue capsule. Approximately half of the women whose ruptures had progressed from intracapsular to extracapsular reported that they experienced trauma to the affected breast during this time period or had undergone mammography. In the other half, no cause was given. In the women with extracapsular rupture, after 2 years, the amount of silicone seepage outside the scar tissue capsule increased for about 14% of these women. This means that for 100 women with silicone gel rupture outside the scar tissue capsule, the amount of gel

outside the scar tissue capsule increased for 14 women 2 years later. This type of information pertains to a variety of silicone implants from a variety of manufacturers and implant models, and it is not specific to Mentor implants.

Below is a summary of information related to the health consequences of implant rupture, which have not been fully established. These reports were in women who had implants from a variety of manufacturers and implant models.

- Local breast complications reported in the published literature that were associated with rupture include breast hardness, a change in breast shape or size, and breast pain.¹¹ These symptoms experienced by women who have capsular contracture.

There have been rare reports of gel movement 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. This has led to nerve damage, granuloma formation (see glossary) and/or breakdown of tissues in direct contact with the gel in a few cases. There have been reports of silicone presence in the liver of patients with silicone breast implants. Movement of silicone gel material to lymph nodes in the axilla also has been reported, even in women without evidence of rupture, leading to lymphadenopathy.¹³

- Concerns have been raised over whether ruptured implants are associated with the development of connective tissue or rheumatic diseases and/or symptoms such as fatigue and fibromyalgia.^{14,15,16,17} A number of epidemiology studies have evaluated large populations of women with breast implants from a variety of manufacturers and implant models. These studies do not, taken together, support a significant association of breast implants with a typical, diagnosed rheumatic disease. Other than one small study,¹⁶ these studies do not distinguish whether the women had ruptured or intact implants.

- **Capsular Contracture** – The scar tissue (capsule) that normally forms around the implant may tighten over time and compress the implant, making it feel firm and leading to what is called capsular contracture. Capsular contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time. Capsular contracture occurs more commonly in revision-augmentation than in primary augmentation. Because you may have your initial implants replaced, you should be aware that your risk of capsular contracture increases with revision-augmentation. Capsular contracture is a risk factor for implant rupture, and it is the most common reason for reoperation.

Symptoms of capsular contracture range from mild firmness and mild discomfort to severe pain, distorted shape of the implant, and palpability (ability to feel the implant). Capsular contracture is graded into 4 levels depending on its severity. Baker Grades III or IV are considered severe and often additional surgery is needed to correct these grades:

Baker Grade I: the breast is normally soft and looks natural

Baker Grade II: the breast is a little firm but looks normal

Baker Grade III: the breast is firm and looks abnormal

Baker Grade IV: the breast is hard, painful, and looks abnormal

In Mentor's Core Study, for women receiving augmentation implants for the first time, the risk of severe capsular contracture was 8% through 3 years. This means that 8 out of every 100 women who received Mentor implants for primary breast augmentation had severe capsular contracture at least once during the first 3 years after receiving the implants.

For women receiving revision-augmentation implants, the risk of severe capsular contracture was 19% through 3 years. This means that 19 out of every 100 women who received Mentor implants for breast revision-augmentation had severe capsular contracture at least once during the first 3 years after receiving the implants.

Additional surgery may be needed in cases where pain and/or firmness are severe. This surgery ranges from removal of the implant capsule tissue, to removal and possible replacement of the implant itself. This surgery may

result in loss of your breast tissue. Capsular contracture may happen again after these additional surgeries. Capsular contracture may increase the risk of rupture.²

- **Additional Surgeries (Reoperations)** – You should assume that you will need to have additional surgeries (reoperations). In the Mentor Core Study, the reoperation rate was 15% for primary augmentation patients, which means that 15 out of every 100 women who received Mentor implants for primary augmentation had a reoperation during the first 3 years after receiving the implants. The reoperation rate was 28% for revision-augmentation patients, which means that 28 out of every 100 women who received Mentor implants for revision-augmentation had a reoperation during the first 3 years after receiving the implants.

Patients may decide to change the size or type of their implants, requiring additional surgery. Problems such as rupture, capsular contracture, hypertrophic scarring (irregular, raised scar), asymmetry, infection, and shifting can require additional surgery. Summary tables are provided on pages 39-43 that describe the reasons for performing additional surgeries in the Mentor Core Study. For women receiving primary augmentation implants, the three most common reasons for reoperation were severe capsular contracture, patient request for size/style change, and hematoma/seroma. For women receiving revision-augmentation implants, the three most common reasons for additional surgery were severe capsular contracture, patient request for style/size change, and biopsy.

- **Implant Removal** – Because these are not lifetime devices, the longer you have your 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. Having your implants removed and replaced increases your chances of getting future complications. For women receiving primary augmentation implants in Mentor's Core Study, 5% had their implants removed at least once through 3 years. Patient choice and severe capsular contracture were the most common reasons for implant removal. For women receiving revision-augmentation implants in Mentor's Core Study, 12% had their implants removed at least once through 3 years. The most common reasons were patient choice and severe capsular contracture.

Most women who have their implants removed, 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 your 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.

- **Unsatisfactory Results** – Unsatisfactory results such as wrinkling, asymmetry, implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, and/or hypertrophic scarring, may occur. Some of these results may cause discomfort. Pre-existing asymmetry may not be entirely correctable by implant surgery. Revision surgery may be recommended to maintain patient satisfaction, but carries additional considerations and risks. Selecting an experienced plastic surgeon may minimize, but not necessarily prevent, unsatisfactory results.
- **Pain** – Pain of varying intensity and length of time may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain. You should tell your surgeon about significant pain or if your pain persists.

- **Changes in Nipple and Breast Sensation** – Feeling in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. While some of these changes can be temporary, they can also be permanent, and may affect your sexual response or your ability to nurse a baby. (See the paragraph on breast feeding below.)
- **Infection** – Infection can occur with any surgery or implant. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. In addition, breast and nipple piercing procedures may increase the possibility of infection. Infections in tissue with an implant present are harder to treat than infections in tissue without an implant. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved (cleared up). As with many other surgical procedures, in rare instances, toxic shock syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. You should contact your doctor immediately for diagnosis and treatment if you have these symptoms.
- **Hematoma/Seroma** – Hematoma is a collection of blood within the space around the implant, and a seroma is a build-up of fluid around the implant. Having a hematoma and/or seroma following surgery may result in infection and/or capsular contracture later on. Symptoms from a hematoma or seroma may include swelling, pain, and bruising. If a hematoma or seroma occurs, it will usually be soon after surgery. However, this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, some will require surgery, typically involving draining and potentially placing a surgical drain in the wound temporarily for proper healing. A small scar can result from surgical draining. Implant rupture also can occur from surgical draining if there is damage to the implant during the draining procedure.
- **Breast Feeding** – Breast feeding difficulties have been reported following breast surgery, including breast reduction and breast augmentation. If your surgeon uses a periareolar surgical approach (an incision around the colored portion surrounding the nipple), it may further increase the chance of breast feeding difficulties.
- **Calcium Deposits in the Tissue Around the Implant** – Calcium deposits can form in the tissue capsule surrounding the implant. Symptoms may include pain and firmness. Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish calcium deposits from cancer. If additional surgery is necessary to examine and/or remove calcifications, this may cause damage to the implants. Calcium deposits also occur in women who undergo breast reduction procedures, in patients who have had hematoma formation, and even in the breasts of women who have not undergone any breast surgery. The occurrence of calcium deposits increases significantly with age.
- **Extrusion** – Extrusion is when the breast implant comes through your skin. This may occur, for example, when your wound has not closed or when breast tissue covering your implants weakens. Radiation therapy has been reported to increase the likelihood of extrusion. Extrusion requires additional surgery and possible removal of the implant, which may result in additional scarring and/or loss of your breast tissue.
- **Necrosis** – Necrosis is the death of cells or tissues. This may prevent or delay wound healing and require surgical correction, which may result in additional scarring and/or loss of your breast tissue. Implant removal may also be necessary. Factors associated with increased necrosis include infection, use of steroids, smoking, chemotherapy, radiation, and excessive heat or cold therapy.

- **Delayed Wound Healing** – Some patients may experience a prolonged wound healing time. Delayed wound healing may increase the risk of infection, extrusion, and necrosis. Depending on the type of surgery or the incision, wound healing times may vary. Smoking may interfere with the healing process. You should contact your surgeon immediately if your wound does not heal within the period of time he/she has discussed with you.
- **Breast Tissue Atrophy/Chest Wall Deformity** – The pressure of the breast implant may cause breast tissue thinning (with increased implant visibility and palpability) and chest wall deformity. This can occur while implants are still in place or following implant removal without replacement. Either of these conditions may result in additional surgeries and/or unacceptable dimpling/puckering of the breast.
- **Lymphadenopathy** – Lymphadenopathy is a chronic enlargement of the lymph nodes. A lymph node is a round mass of tissue which makes cells as part of your immune system. The lymph nodes in the armpit (axilla) drain the breast area of fluid. Sometimes the enlarged lymph nodes are painful. If they become too large or painful, the lymph node(s) may need to be surgically removed. Painful and/or enlarged lymph nodes should be reported to your doctor.

Literature reports associate lymphadenopathy with both intact and ruptured silicone breast implants. One study reported that armpit lymph nodes from women with both intact and ruptured silicone gel implants had abnormal tissue reactions, granulomas, and the presence of silicone.¹³ These reports were in women who had implants from a variety of manufacturers and implant models.

Other Reported Conditions

There have been reports in the literature of other conditions in women with silicone gel-filled breast implants. Many of these conditions have been studied to evaluate their potential association with breast implants. Although no cause and effect relationship has been established between breast implants and the conditions listed below, you should be aware of these reports. Furthermore, there is the possibility of risks, yet unknown, which in the future could be determined to be associated with breast implants.

- **Connective Tissue Disease (CTD)** – Connective tissue diseases include diseases such as lupus, scleroderma, and rheumatoid arthritis. Fibromyalgia is a disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue. There have been a number of published epidemiological studies which have looked at whether having a breast implant is associated with having a typical or defined connective tissue disease. The study size needed to conclusively rule out a smaller risk of connective tissue disease among women with silicone gel-filled breast implants would need to be very large.^{2,15,16,17,18,19,20,21,22,23} The published studies taken together show that breast implants are not significantly associated with a risk of developing a typical or defined connective tissue disease.^{2,19,20,21} These studies do not distinguish between women with intact and ruptured implants. Only one study evaluated specific connective tissue disease diagnoses and symptoms in women with silent ruptured versus intact implants, but it was too small to rule out a small risk.¹⁶
- **CTD Signs and Symptoms** – Literature reports have also been made associating silicone breast implants with various rheumatological signs and symptoms such as fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes.

Scientific expert panels and literature reports have found no evidence of a consistent pattern of signs and symptoms in women with silicone breast implants.^{2,14,24,25,26} Having these rheumatological signs and symptoms does not necessarily mean you have a connective tissue disease; however, you should

be aware that you may experience these signs and symptoms after undergoing breast implantation. If you notice an increase in these signs or symptoms, you should consider seeing a rheumatologist to determine whether these signs or symptoms are due to a connective tissue disorder or autoimmune disease.

- **Cancer**

Breast Cancer – Reports in the medical literature indicate that patients with breast implants are not at a greater risk than those without breast implants for developing breast cancer.^{27,28,29,30,31} Some reports have suggested that breast implants may interfere with or delay breast cancer detection by mammography and/or biopsy; however, other reports in the published medical literature indicate that breast implants neither significantly delay breast cancer detection nor adversely affect cancer survival of women with breast implants.^{27,31,32,33,34}

Brain cancer – One recent study has reported an increased incidence of brain cancer in women with breast implants as compared to the general population.³⁵ The incidence of brain cancer, however, was not significantly increased in women with breast implants when compared to women who had other plastic surgeries. Another recently published review of four large studies in women with cosmetic implants concluded that the evidence does not support an association between brain cancer and breast implants.³⁶

Respiratory/lung cancer – One study has reported an increased incidence of respiratory/lung cancer in women with breast implants.³⁵ 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.^{37,38,39}

Cervical/vulvar cancer – One study has reported an increased incidence of cervical/vulvar cancer in women with breast implants.³⁵ The cause of this increase is unknown.

Other cancers – One study has reported an increased incidence of stomach cancer and leukemia in women with breast implants compared to the general population.³⁵ This increase was not significant when compared to women who had other types of plastic surgeries.

- **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) or diseases (such as multiple sclerosis), which they believe are related to their implants. A scientific expert panel report found that the evidence for a neurological disease or syndrome caused by or associated with breast implants is insufficient or flawed.²

- **Suicide** – In several studies, a higher incidence of suicide was observed in women with breast implants.^{40,41,42,43} The reason for the observed increase is unknown, but it was found that women with breast implants had higher rates of hospital admission due to psychiatric causes prior to surgery, as compared with women who had breast reduction or in the general population of Danish women.⁴¹

- **Effects on Children** – At this time, it is not known if a small amount of silicone may pass through from the breast implant silicone shell into breast milk during breastfeeding. Although there are no current established methods for accurately detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone gel-filled implants when compared to women without implants.⁴⁴

In addition, concerns have been raised regarding potential damaging effects on children born to mothers with implants. Two studies in humans have found that the risk of birth defects overall is not increased in children born after breast implant surgery.^{45,46} Although low birth weight was reported in a third study, other factors (for example, lower pre-pregnancy weight) may explain this finding.⁴⁷ This author recommended further research on infant health.

- **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.^{2,48} 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 contracture² and lymphadenopathy.¹³ 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 the Mentor implants does not cause toxic reactions when large amounts are administered to test animals. It also should 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.⁴⁹ In addition, two separate studies sponsored by Mentor have demonstrated that the low concentration of platinum contained in its breast implants is in the zero oxidation (most biocompatible) state.

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.

MENTOR CORE STUDY RESULTS FOR AUGMENTATION AND REVISION-AUGMENTATION

This section of this brochure summarizes the results of the Mentor Core Study conducted on Mentor’s silicone gel-filled breast implants for primary augmentation and revision-augmentation. The Mentor Core Study is the primary clinical study for this product. The results of the Mentor Core Study give you useful information on the experience of other women with Mentor silicone gel-filled implants. While the results cannot be used to predict your individual outcome, they can be used as a rough guide of what you may expect. Your own complications and benefits depend on many individual factors.

As a note, supplemental safety information was also obtained from the Mentor Adjunct Study, the U.K. Sharpe/Collis Study, and the literature to help assess long-term rupture rate and the consequences of rupture for this product. The literature, which had the most available information on the consequences of rupture, was also used to assess other potential complications associated with silicone gel-filled breast implants. The key literature information is referenced throughout the Breast Implant Complications section above.

Overview of Mentor Core Study

The Mentor Core Study is a 10-year study to assess safety and effectiveness in augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients. Patient follow-up is at 6 months, 12 months, 24 months, and annually through 10 years. Safety is assessed by complications, such as implant rupture, capsular contracture, and reoperation. Benefit (effectiveness) is assessed by patient satisfaction and measures of quality of life (QoL).

The Mentor Core Study consists of 1,007 patients, including 551 primary augmentation patients, 146 revision-augmentation patients, 251 primary reconstruction patients, and 59 revision-reconstruction patients. Of these patients, 202 primary augmentation patients, 57 revision-augmentation patients, 134 primary reconstruction patients, and 27 revision-reconstruction patients are in the MRI cohort, which means that they are assessed for silent rupture by MRI at years 1,

2, 4, 6, 8, and 10. The study is currently ongoing, with the results through 3 years reported in this brochure. Mentor will periodically update this brochure as more information becomes available. You should also ask your surgeon if he/she has any available updated clinical information.

Mentor's Core Study results indicate that the risk of at least one occurrence of any complication (including reoperation) at some point through 3 years after implant surgery is 37% for primary augmentation patients and 50% for revision-augmentation patients. The information below provides more details about the complications and benefits you may experience.

Described below are the benefits and complications reported in the Mentor Core Study for augmentation patients. The findings are described separately for primary augmentation and revision-augmentation patients.

What were the 3-Year Follow-up Rates in Augmentation Patients?

At the 3-year follow-up visit, data are reported for 88% of the eligible primary augmentation patients and 87% of the eligible revision-augmentation patients.

What were the Benefits for Augmentation Patients?

The Mentor Core Study measured a variety of outcomes that assessed the benefits of the implants. For augmentation, these outcomes included breast size change, satisfaction, and QoL measures. These outcomes were assessed before implantation and at 1, 2, and 3 years after surgery for those patients who still had their original implants and came back for follow-up visits.

Primary Augmentation Patients

For primary augmentation patients, 370 (67%) out of the original 551 patients were included in the analysis of cup size at 3 years. Of these 370 patients, 359 (97%) experienced at least one cup size increase. The average increase in circumferential chest size was 2.8 inches.

Mentor's satisfaction assessment was based on a single question of "Would the patient have this breast surgery again?" At 3 years, 456 (83%) of the 551 primary augmentation patients enrolled answered that question. Of these 456 patients, 445 (98%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 3 years, an increase in self esteem was noted for 45% of patients after primary breast augmentation on the Rosenberg Self Esteem Scale. There was no change on the overall score of the Body Esteem Scale, but the Sexual Attractiveness Subscale and the Chest Score of the Body Esteem Scale increased. The SF-36 is a collection of scales assessing mental and physical health, and there was no change in the SF-36 after primary augmentation. The Tennessee Self Concept Scale (TSCS) is a survey completed by the patient that evaluates how the patient sees herself and what she does, likes, and feels. There was no change in the overall score for the TSCS.

Revision-Augmentation Patients

For revision-augmentation patients, 116 (79%) out of the original 146 patients were included in the analysis of circumferential chest size at 3 years. For these 116 patients, the average increase in circumferential chest size was 2.4 inches.

Mentor's patient satisfaction was based on a single question of "Would the patient have this breast surgery again?" At 3 years, 118 (81%) of the 146 revision-augmentation patients enrolled answered that question. Of these 118 patients, 111 (94%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 3 years, no change in self esteem was noted following revision-augmentation surgery on the Rosenberg Self Esteem Scale or the Body Esteem Scale. The SF-36 is a collection of scales assessing mental and physical health, and there were no changes in SF-36. The Tennessee Self Concept Scale (TSCS) is a survey completed by the patient that evaluates how the patient sees

herself and what she does, likes, and feels. There was no change in the overall TSCS score.

What Were the 3-Year Complication Rates in Augmentation Patients?

The 3-year complication rates are shown from the most common to the least common in Table 1 (primary augmentation) and Table 2 (revision-augmentation) below. The rates reflect the percentage of augmentation patients who experienced the listed complication at least once within the first 3 years after implantation. Some complications occurred more than once for some patients. The two most common complications experienced by primary augmentation patients within the first 3 years of implantation were reoperation (15.4%) and nipple sensation changes (10.4%).

Table 1 – 3-Year Complication Rates for Primary Augmentation Patients (N=551 Patients)

Key Complications	%
Reoperation	15.4
Capsular Contracture Baker Grade III/IV	8.1
Implant Removal with Replacement with Study Device	2.8
Implant Removal without Replacement	2.3
Infection	1.5
Rupture (MRI Cohort) ¹	0.5
Other Complications occurring in $\geq 1\%$ of patients ²	%
Nipple Complications ³	10.4
Scarring/Hypertrophic Scarring ³	6.7
Breast Mass ³	3.1
Hematoma ³	2.6
Ptosis (sagging) ³	2.3
Breast Sensation Changes ³	2.2
Breast Pain ³	1.7
Miscarriage ⁴	1.5
Trauma ⁵	1.3

¹ There was 1 patient with signs of rupture by MRI of one of her implants through the 3-year timepoint. This has not yet been confirmed with removal and visual inspection of the implant.

² The following complications were reported at a rate less than 1%: anaphylaxis, asymmetry, biopsy pending, bruising, deep vein thrombosis, granuloma, implant malposition/displacement, inflammation, lactation difficulties, new diagnosis of rheumatic disease (1 patient with Hashimoto's Thyroiditis, 1 patient with rheumatoid arthritis, and 1 patient with hypothyroidism), necrosis, placement damage (damage to breast implants during insertion, which were then removed while the patient was still on the operating table), position dissatisfaction, positive antinuclear antibodies negative for lupus, rash, suture reaction, seroma, and wrinkling.

³ Mild occurrences were excluded.

⁴ Preoperative miscarriage data were not collected.

⁵ Lifted child and stroller; trauma sustained from motor vehicle accident; trauma to breast from fall; and first and second degree frostbite from ice bags placed on breasts the day after surgery to relieve operative pain.

The two most common complications experienced by patients within the first 3 years of revision-augmentation surgery were reoperation (28.0%) and capsular contracture Baker Grades III/IV (18.9%). Notice that the rates for these two complications are higher than for primary augmentation. (For primary augmentation, reoperation was 15.4% and capsular contracture was 8.1%.)

Table 2 – 3-Year Complication Rates for Revision-Augmentation Patients (N=146 Patients)

Key Complications	%
Reoperation	28.0
Capsular Contracture Baker Grade III/IV	18.9
Rupture (MRI Cohort) ¹	7.7
Implant Removal with Replacement with Study Device	6.5
Implant Removal without Replacement	5.9
Infection	1.4
Other Complications occurring in $\geq 1\%$ of patients ²	%
Nipple Complications ³	10.5
Scarring/Hypertrophic Scarring ³	8.4
Breast Mass ³	6.6
Hematoma ³	2.8
Breast Sensation Changes ³	2.1
Seroma	2.1
Delayed Wound Healing ³	2.1
Wrinkling ³	2.1
Ptosis (sagging) ³	1.5
Breast Pain ³	1.5
Inflammation ³	1.4
Implant Malposition ³	1.4
Extrusion of Intact Implant	1.4

¹ Of the 4 patients who had signs of rupture on MRI, 1 patient had removal of her implants, which showed rupture of both of her implants. This occurred 2 years after she entered the Mentor Core Study as a revision-augmentation patient.

² The following complications were reported at a rate less than 1%: back and neck pain related to large implants, ectopic pregnancy, false positive for rupture on mammogram, granuloma, lactation difficulties, miscarriage, muscle spasm, new diagnosis of rheumatic disease (1 patient with rheumatoid arthritis), implant palpability/visibility, and trauma (blunt injury to left breast from being hit by fireworks).

³ Mild occurrences were excluded.

What Were the Main Reasons for Reoperation in Augmentation Patients?

There may be one or more reasons identified for having a reoperation (additional surgery after the primary or revision breast augmentation). Furthermore, there may be multiple surgical procedures (for example, implant removal with or without replacement, capsule procedures, incision and drainage, implant reposition, scar revision, etc.) performed during a reoperation. In Mentor's Core Study, there were 176 additional surgical procedures performed in 109 reoperations involving 83 primary augmentation patients.

Table 3 below provides the main reason for each reoperation in primary augmentation patients following initial implantation that were performed through 3 years. The most common reason for reoperation through 3 years in primary augmentation patients was because of capsular contracture (40 of 109 reoperations).

TABLE 3 – MAIN REASONS FOR REOPERATION IN PRIMARY AUGMENTATION PATIENTS THROUGH 3 YEARS

Reason for Reoperation	n
Capsular Contracture Baker Grade II, III, IV	40
Patient Request for Style/Size Change	16
Hematoma/Seroma	12
Scarring/Hypertrophic Scarring	12
Biopsy	6
Asymmetry	5
Ptosis (sagging)	4
Infection	3
Delayed Wound Healing	2
Implant Malposition	2
Wrinkling	2
Breast Pain	1
Extrusion of Intact Implant	1
Necrosis	1
Suspected Rupture ¹	1
Tear in Capsule	1
TOTAL	109

¹ The device was removed and found to be intact (not ruptured).

In Mentor’s Core Study, there were 105 additional surgical procedures performed in 58 reoperations involving 39 revision-augmentation patients. Table 4 below provides the main reason for each reoperation in revision-augmentation patients following initial implantation that were performed through 3 years. The most common reason for reoperation in revision-augmentation patients through 3 years was capsular contracture (23 of 58 reoperations).

TABLE 4 – MAIN REASONS FOR REOPERATION IN REVISION-AUGMENTATION PATIENTS THROUGH 3 YEARS

REASON FOR REOPERATION	n
Capsular Contracture Baker Grade II, III, IV	23
Patient Request for Style/Size Change	7
Biopsy	6
Hematoma/Seroma	5
Delayed Wound Healing	5
Scarring/Hypertrophic Scarring	3
Extrusion of Intact Implant	2
Implant Malposition	2
Asymmetry	1
Ptosis (sagging)	1
Infection	1
Wrinkling	1
Suspected Rupture ¹	1
TOTAL	58

¹The device was removed and found to be intact (not ruptured).

What Were the Main Reasons for Implant Removal in Augmentation Patients?

The main reasons for implant removal among primary augmentation patients in the Mentor Core Study over the 3 years are shown in Table 5 below. There were 45 implants removed in 26 patients. Of these 45 implants, 24 were replaced. The most common reason for implant removal was patient request for style/size change (31 of the 45 implants removed).

TABLE 5 – MAIN REASONS FOR IMPLANT REMOVAL IN PRIMARY AUGMENTATION PATIENTS THROUGH 3 YEARS

REASON FOR REMOVAL	n
Patient Request for Style/Size Change	31
Capsular Contracture Baker Grade III, IV	5
Breast Pain	2
Infection	2
Necrosis	2
Suspected Rupture ¹	1
Contralateral Explantation	1
Wrinkling	1
TOTAL	45

¹The device was removed and found to be intact (not ruptured).

The main reasons for implant removal among revision-augmentation patients in the Mentor Core Study over the 3 years are shown in Table 6 below. There were 30 implants removed in 18 patients. Of these 30 implants, 14 were replaced. The most common reason for implant removal was patient request (12 of the 30 implants removed).

TABLE 6 – MAIN REASONS FOR IMPLANT REMOVAL IN REVISION-AUGMENTATION PATIENTS THROUGH 3 YEARS

REASON FOR REMOVAL	n
Patient Request for Style/Size Change	12
Capsular Contracture Baker Grade III/IV	10
Patient Dissatisfied with Appearance	2
Asymmetry	1
Extrusion of Intact Implant	1
Scarring/Hypertrophic Scarring	1
Infection	1
Suspected Rupture ¹	1
Abnormal Mammogram	1
TOTAL	30

¹The device was removed and found to be intact (not ruptured).

What Were Other Clinical Data Findings in Augmentation Patients?

Below is a summary of clinical findings from Mentor’s Core Study with regard to connective tissue disease (CTD), CTD signs and symptoms, cancer, lactation complications, reproduction complications, and suicide. These issues, along with others, are being further evaluated as part of a Mentor large post-approval study involving patients followed through 10 years.

- CTD Diagnoses** – Three primary augmentation patients and one revision-augmentation patient in the Mentor Core Study were reported to have a new diagnosis of CTD according to a rheumatologist. These diagnoses were Hashimoto’s Thyroiditis at 2 years, two cases of rheumatoid arthritis at 2 and 3 years, and hypothyroidism at 2 years. It cannot be concluded that these CTD diagnoses were caused by the implants because there was no comparison group of similar women without implants.
- CTD Signs and Symptoms** – Data on over 100 self-reported signs and symptoms, including about 50 self-reported rheumatological symptoms, were collected. Compared to before having the implants, significant increases were found for fatigue, exhaustion, joint swelling, joint pain, numbness of hands, frequent muscle cramps, and the combined categories of fatigue, pain, and fibromyalgia-like symptoms in primary augmentation patients, and for joint pain in revision-augmentation patients. These increases were not found to be related to simply getting older over time. The Mentor Core Study was not designed to evaluate 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 these increases were due to the implants or not, based on the Mentor Core Study. However, you should be aware that you may experience an increase in these symptoms after receiving breast implants.
- Cancer** – There were no primary augmentation patients with new diagnoses of breast cancer through 3 years in Mentor’s Core Study. As previous breast cancer was an exclusion criteria for primary augmentation patients, there were no reports of breast cancer reoccurrence in this indication. There were no reports of new diagnoses or reoccurrence of breast cancer in revision augmentation patients. There were no reports of other cancers, such as brain, respiratory, or cervical/vulvar.
- Lactation Complications** – Two (8%) of the 25 primary augmentation patients who attempted to breast feed following breast implantation in

Mentor's Core Study through 3 years experienced difficulty with breast feeding. Of the 7 revision-augmentation patients who attempted to breast feed after receiving breast implants, 1 (14%) had difficulty breast feeding.

- **Reproduction Complications** – Eight (1.5%) of the primary augmentation patients in Mentor's Core Study reported a miscarriage through 3 years. There were no reports of miscarriage in revision-augmentation patients.
- **Suicide** – There were no reports of suicide in either the primary augmentation or revision-augmentation indications in Mentor's Core Study through 3 years.

HOW TO REPORT PROBLEMS WITH YOUR IMPLANT

The Food and Drug Administration (FDA) requires that serious injuries (defined as those that need medical or surgical intervention to prevent permanent damage) be reported by hospitals if they are aware of the serious injuries. If you believe that you have experienced one or more serious problems related to your breast implants, you are encouraged to report the serious problem(s) through your health professional to the FDA. Although reporting by doctors or other health professionals is preferred, women may also report any serious problem directly through FDA's MedWatch voluntary reporting system. You can report by telephone to **1-800-FDA-1088**; by FAX, use Form 3500 to **1-800-FDA-0178**; electronically at <http://www.fda.gov/medwatch/index.html>; or by mail to:

MedWatch Food and Drug Administration

HF-2, 5600 Fishers Lane
Rockville, MD 20857-9787.

Keep a copy of the MedWatch form completed by your doctor for your records. The information reported to MedWatch is entered into databases to be used to follow safety trends (patterns) of a device and to determine whether further follow-up of any potential safety issues related to the device is needed.

MENTOR – A COMPANY THAT CARES

Founded in 1969, Mentor is a leading supplier of medical products in over 60 countries throughout the world. With over 20 years of experience making breast implants, our exceptional record of quality and longevity has gained us a tremendous level of respect in the medical community.

Mentor breast implants are made at our U.S. based state-of-the-art manufacturing plant in Dallas. This advanced manufacturing facility features many groundbreaking engineering advances that are new to the breast implant industry.

Mentor conducts research, development and manufacturing at several facilities throughout Europe and the United States. The company also has sales and distribution outlets around the world.

Mentor is proud of the quality built into each of our breast implants, and you can be assured that behind your decision to use our products is a company that understands your hopes and desires, and a company that truly cares.



FOOTNOTES:

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

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