MENTOR®

Saline-Filled Breast Implant Surgery:

Making an Informed Decision

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

WARNING:

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

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GLOSSARY

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

Breast reconstruction — A surgical procedure to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality.

Calcification — Process of hardening by calcium salts.

Capsule — Scar tissue that forms around the breast implant. Sometimes this capsule squeezes the implant, resulting in capsular contracture (below).

Capsular contracture — A tightening of the tissue capsule surrounding an implant, resulting in firmness or hardening of the breast and in squeezing of the implant if severe. Capsular contracture is classified by Baker Grades. Grades III or IV are the most severe. Grade III often results in the need for additional surgery (reoperation) because of pain and possibly abnormal appearance. Grade IV usually results in the need for additional surgery (reoperation) because of pain and unacceptable appearance. Capsular contracture II may also result in the need for additional surgery. Capsular contracture is a risk for implant rupture. Below is a description of each Baker Grade.

- Grade I – Normally soft and natural appearance
- Grade II – A little firm, but breast looks normal
- Grade III – More firm than normal, and looks abnormal (change in shape)
- Grade IV – Hard, obvious distortion, and tenderness with pain

Capsulectomy — Surgical removal of the scar tissue capsule around the implant.

Capsulorrhaphy — Surgical stitching of a tear in the scar tissue capsule around the implant.

Capsulotomy (closed) — An attempt to break the scar tissue capsule around the implant by pressing or pushing on the outside of the breast. This method does not require surgery but is a known risk for rupture of the implant and is contraindicated.

Capsulotomy (open) — Surgical incision into the scar tissue capsule around the implant.

Congenital anomaly — An abnormal development in part of the body.

Connective tissue disease/ disorder (CTD) — A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc. and/or the immune system. Connective tissue diseases ("CTDs") that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma.

Contraindication	A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm.
Contralateral	Opposite side.
Deflation	Leakage of saline solution from the implant, often due to a valve leak or a tear or cut in the implant shell, with partial or complete collapse of the implant.
Delayed wound healing	Delayed progress in the healing of an opened wound.
DIEP Flap	A DIEP (deep interior epigastric artery perforator) flap (section of skin, and other tissue from the abdomen) that is disconnected from (completely cut away from) the blood vessels in the rest of the body before being relocated to the breast area for reconstruction. The blood vessels must then be surgically reconnected when the flap is placed at the breast.
Displacement	Movement of the implant from the usual or proper place.
Epidemiological	Relating to the science of explaining the relationships of factors that determine disease frequency and distribution.
Extrusion	Skin breakdown with the pressing out of the implant through the surgical wound or skin.
Fibromyalgia	A disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue.
Fibrous tissues	Connective tissues composed mostly of fibers.
Hematoma	A collection of blood within a space.
Hypertrophic scarring	An enlarged scar remaining after the healing of a wound.
Immune response	A bodily response to the presence of a foreign substance.
Infection	Invasion with microorganisms (for example, bacteria, viruses). An infection usually results in fever, swelling, redness, and/or pain.
Inflammation	The response of the body to infection or injury that is characterized by redness, swelling, warmth, pain, and/or loss of function.
Inframammary	Below the breast.

Inframammary fold	The crease at the base of the breast and the chest wall.
Inframammary incision	An incision made in the fold below the breast.
Inpatient surgery	A surgical procedure in which the patient is required to stay overnight in the hospital.
Lactation	The production and secretion of milk by the breast glands.
Malposition	Implant malposition or displacement is when the implant is not in the correct spot in the breast. This could have been due to incorrect placement of the implant during the surgery or due to shifting of the implant position over time.
Mammary	Pertaining to the breast.
Mammography	A type of x-ray examination of the breasts used for detection of cancer. A *screening* mammogram is an x-ray of the breast used to detect breast changes in women who have no signs or symptoms of breast cancer and a *diagnostic* mammogram is an x-ray of the breast that is used to check for breast cancer after a lump or other sign or symptom of breast cancer has been found.
Mammoplasty	Plastic surgery of the breast.
Mastopexy	Plastic surgery to move sagging breasts into a more elevated position.
Necrosis	Death of cells or tissues.
Outpatient surgery	A surgical procedure in which the patient is not required to stay in the hospital overnight.
Palpate	To feel with the hand.
Palpability	The ability to feel the implant.
Pectoralis	Major muscle of the chest.
Periareolar	Around the darkened or pigmented area surrounding the nipple of the breast.
Plastic surgery	Surgery intended for the improvement of appearance of the body.
Postoperatively	After surgery.

Primary breast augmentation	The first time a breast implant is placed for the purpose of breast augmentation.
Ptosis	Breast sagging that is usually the result of normal aging, pregnancy, or weight loss.
Reoperation	An additional surgery after your first breast implantation.
Revision-Augmentation	Refers to the correction or improvement of a primary augmentation. In the context of this document, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast augmentation.
Rheumatological Disease/ Disorder	A variety of diseases involving connective tissue structures of the body, especially the joints and fibrous tissue. These diseases are often associated with pain, inflammation, stiffness, and/or limitation of motion of the affected parts. Can include autoimmune diseases. Fibromyalgia is a rheumatological disorder.
Saline	A solution that is made up of water and a small amount of salt.
Scar revision	A surgical procedure to improve the appearance of a scar.
Seroma	A build-up of the watery portion of the blood in a tissue location.
Silicone elastomer	A type of silicone that has elastic properties similar to rubber.
Subglandular placement	Placement of a breast implant underneath and within the breast glands but on top of the chest muscle.
Submuscular placement	Placement of a breast implant wholly or partially underneath the chest muscle.
Surgical incision	A cut made to body tissue during surgery.
Symptom	Any perceptible change in the body or its functions that indicates disease or a phase of a disease.
Symptomatic	Any evidence or sign of disease or disorder reported by the patient.
Systemic	Pertaining to or affecting the body as a whole.
Tennessee Self Concept Scale	A questionnaire that evaluates how the patient sees herself and what she does, likes, and feels. The scale is intended to summarize her feeling of self-worth and self-image by measuring how she feels about moral-ethical, social, personal, physical, and family, identity, behavior, and self-satisfaction.

Saline-Filled Breast Implant Surgery: Making an Informed Decision

SO YOU'RE CONSIDERING SALINE-FILLED BREAST IMPLANT SURGERY

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

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

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

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

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

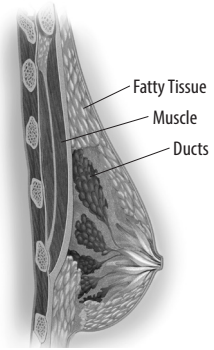
It is important to remember that the lifetime of breast implants varies by person and cannot be predicted. That means everyone with breast implants may need additional surgeries, but no one can predict when. The longer your implants are implanted, the greater the chances are that you will develop complications,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

SAFETY INFORMATION AVAILABLE ON WEBSITE

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

What Gives the Breast Its Shape?

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



What Is a Saline-Filled Breast Implant?

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

Are You Eligible for Saline-Filled Breast Implants?

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

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

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

- Whether you are undergoing augmentation or reconstruction, be aware that breast implantation may not be a one-time surgery. You are likely to need additional surgery and surgeon visits over the course of your life.
- Breast implants are not considered lifetime devices. You will likely undergo implant removal with or without replacement over the course of your life.
- Many of the changes to your breast following implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast.

- Breast implants may affect your ability to produce milk for breast feeding. Also, breast implants will not prevent your breasts from sagging after pregnancy.
- With breast implants, routine screening mammography will be more difficult, and you will need to have additional views, which means more time and radiation.
- For patients who have undergone breast implantation either as a cosmetic or a reconstructive procedure, health insurance premiums may increase, coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. You should check with your insurance company regarding these coverage issues.

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

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

Who Is Not Eligible for Breast Implants?

Implants are not to be used for:

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

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

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

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®* Antiseptic
- 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:

- An autoimmune disease,
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease),
- Planned chemotherapy following breast implant placement,
- Planned radiation therapy to the breast following breast implant placement,
- Conditions that interfere with wound healing and/or blood clotting,
- Reduced blood supply to breast tissue, and

- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. If you have been diagnosed with or treated for depression, an anxiety disorder, or another mental health condition, you should wait until your condition has resolved or stabilized before having breast implant surgery. Discuss any history of mental health disorders with your doctor(s) prior to surgery.

*Betadine is a registered trademark of Purdue Frederick Company.

Further considerations:

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

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

Breast implants come in a variety of shapes, surface textures, and sizes. There are 2 types/families of implants filled with saline—one referred to as Saline-Filled and the other referred to as Spectrum™ Implants. The Saline-Filled family of implants has a self-sealing valve located on the front (anterior) of the implant that is used for filling the device. The Spectrum™ family has a valve on the back (posterior) of the implant that allows saline to be added after surgery (postoperative adjustability). The implants are available with Siltex® Textured or smooth surface shells. Note: Siltex Textured Saline implants have been discontinued and are no longer manufactured.

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

Saline-Filled Breast Implant Family (fixed volume):

- Round Styles:

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

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

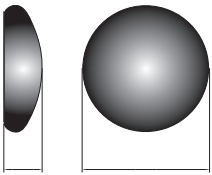
  Style 3000: Smooth shell surface, anterior diaphragm valve, high profile

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

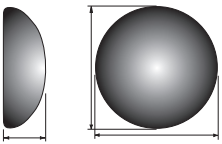
- Round Styles:

  Style 1400: Smooth shell surface, posterior filling valve

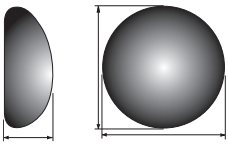
The following diagrams illustrate the round moderate profile, round moderate plus profile and the round high profile.



Round, moderate profile



Round, moderate plus profile



Round, high profile

WHAT ARE POTENTIAL BREAST IMPLANT COMPLICATIONS?

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

These complications include:

- **Deflation**

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

  Deflated implants require additional surgery to remove and to possibly replace the implant.

- **Capsular Contracture**

  The scar tissue or capsule that normally forms around the implant may tighten over time and squeeze/compress the implant, making it feel firm and leading to what is called capsular contracture. Capsular contracture may be more common following infection, hematoma (a collection of blood), and seroma (a build-up of the water portion of the blood). It is also more common with subglandular placement (behind the mammary gland and on top of the chest muscle). Symptoms range from mild firmness and mild discomfort to severe pain, distorted shape, palpability of the implant, and/or movement of the implant.

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

- **Pain**

  Pain of varying intensity and duration may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain associated with nerve entrapment or interference with muscle motion. You should tell your surgeon about severe pain.

- **Additional Surgeries**

  You should understand there is a high chance that you will need to have additional surgery at some point to replace or remove the implant. Also, problems such as deflation, capsular contracture, infection, shifting, and calcium deposits can require removal of the implants. Many women decide to have the implants replaced, but some women do not. If you choose not to, you may have cosmetically unacceptable dimpling and/or puckering of the breast following removal of the implant.

- **Dissatisfaction with Cosmetic Results**

  Dissatisfying results such as wrinkling, asymmetry, implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, hypertrophic (irregular, raised scar) scarring, and/or sloshing may occur. Careful surgical planning and technique can minimize but not always prevent such results.

- **Infection**

  Infection can occur with any surgery. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. Infections with an implant present are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved.

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

- **Hematoma/Seroma**

  Hematoma is a collection of blood inside a body cavity, and a seroma is a collection of the watery portion of the blood (in this case, around the implant or around the incision). Postoperative hematoma and seroma may contribute to infection and/or capsular contracture. Swelling, pain, and bruising may result. If a hematoma occurs, it will usually be soon after surgery. However, this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, large ones will require the placement of surgical drains for proper healing. A small scar can result from surgical draining. Implant deflation/rupture can occur from surgical draining if damage to the implant occurs during the draining procedure.

- **Changes in Nipple and Breast Sensation**

  Feeling in the nipple and breast can increase or decrease after implant surgery. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. Changes in feeling can be temporary or permanent and may affect your sexual response or your ability to nurse a baby. (See the paragraph on breast feeding below.)

- **Breast Feeding**

  At this time, it is not known if a small amount of silicone may diffuse (pass through) from the saline-filled breast implant silicone shell and may find its way into breast milk. If this occurs, it is not known what effect it may have on the nursing infant. Although there are no current methods for detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone-filled gel implants when compared to women without implants. With respect to the ability to successfully breast feed after breast implantation, one study reported up to 64% of women with implants who were unable to breast feed compared to 7% without implants. The periareolar incision site may significantly reduce the ability to successfully breast feed.

- **Calcium Deposits in the Tissue Around the Implant**

  Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish calcium deposits from cancer.

- **Delayed Wound Healing**

  In some instances, the incision site takes longer to heal than normally.

- **Extrusion**

  Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion, which is when the breast implant comes through the skin.

- **Necrosis**

  Necrosis is the formation of dead tissue around the implant. This may prevent wound healing and require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis. Factors associated with increased necrosis include infection, use of steroids in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

- **Breast Tissue Atrophy/Chest Wall Deformity**

  The pressure of the breast implant may cause the breast tissue to thin and shrink. This can occur while implants are still in place or following implant removal without replacement.

What Are Other Reported Conditions?

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

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

The information discussed in this section is based on studies published in the medical literature reviews through 2016[62] that include women with many different types, brands, and models of breast implants for augmentation and/or reconstruction.

Cancer

- **Breast Cancer**

Patients with breast implants do not seem to have greater risk of developing breast cancer (based on literature published from 2000-2016). [10,11,12,13,14,15,16,17,18,19,20,57,62]

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

Some studies have suggested that breast implants may interfere with or delay breast cancer detection by mammography and/or biopsy. However, other studies reported that breast implants neither delayed breast cancer detection nor affected cancer survival (based on literature published from 2000-2006).[12, 20, 21, 22, 23]

- **Brain Cancer**

Most studies of brain cancer in women with silicone gel breast implants have found no increased risk (based on literature published from 2000-2007). [11, 13, 15, 18, 19, 20, 24] One study from the same time period reported a higher rate of brain cancer in women with breast implants, compared to the general population, [21, 25] but, rates of brain cancer were not significantly higher in women with breast implants when compared to women who had other non-breast implant plastic surgeries.

- **Lympho-Hematopoietic Cancers**

Lympho-hematopoietic cancers are cancers that develop in the lymph nodes or certain blood cells. Lymph nodes and the affected cells are part of the body's immune system to fight infection. These kinds of cancers include non-Hodgkin's lymphoma, Hodgkin's disease, multiple myeloma, and leukemia. Most studies (based on literature published from 1999-2007) have found no increased risk of these cancers for women with silicone gel breast implants. [6, 7, 8, 9, 11, 13, 15, 18, 19, 20] Breast implants have been associated with the development of a cancer of the immune system called breast implant-associated anaplastic large cell lymphoma (BIA-ALCL). This cancer occurs more commonly in patients with textured breast implants than smooth implants, although rates are not well defined. Some patients have died from BIA-ALCL. Please review additional information on BIA-ALCL below

- **Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)[26]**

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

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

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

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

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

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

In addition, if you are diagnosed with BIA-ALCL, talk to your doctor about reporting it to the PROFILE Registry (https://www.thepsf.org/research/clinical-impact/profile.htm). Every case of BIA-ALCL should be reported to the PROFILE Registry because this helps provide a better understanding of the disease.

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

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

- **Respiratory/Lung Cancer**

Several studies have found that women with silicone gel breast implants are not at greater risk for lung cancer (based on literature published from 2000-2007).[11,13,15,18,19,20] One study from the same time period found an increased risk of respiratory/lung cancer in women with breast implants [21, 25] compared to women who had other kinds of plastic surgery (non-breast implant). However, the risk of lung cancer was not higher than national lung cancer rates for the general population. Other studies of women in Sweden and Denmark have found that women who get breast implants are more likely to be current smokers than women who get breast reduction surgery or other types of cosmetic surgery [27, 28, 29]; this may increase their risk for lung cancer (based on literature published from 1997-2003). A published systematic review from 2016 reported there is limited or suggestive evidence of an association between breast implants and lung cancer.[57]

- **Reproductive System Cancer**

Reproductive system cancers in women are cancers of the cervix, ovaries, uterus, vulva, vagina, and other female genital organs. Most studies [11, 13, 15, 18, 19, 20] found that women with silicone gel breast implants have no greater risk of these cancers than women without implants (based on literature published from 2000-2007). One study from the same time period reported an increased incidence of cervical/vulvar cancer in women with breast implants.[21, 25]

- **Other Cancers**

Studies have examined other types of cancer including eye, urinary tract (related to the bladder and urethra), connective tissue (fibrous tissues like tendons, cartilage, and bone that provide structure and support throughout the body), and endocrine system (the parts of the body that make hormones). Studies show that women with silicone gel breast implants have no greater risk of these types of cancers compared to the general population (based on literature published from 2000-2007) [3, 13, 15, 18, 19, 25, 30]

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

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

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

Other CTDs include:

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

Some women with breast implants have experienced signs and symptoms that could be related to the immune system but that do not fit into a definable disease, like those listed above. These signs and symptoms include: painful or swollen joints, tightness, tingling, numbness, reddened swollen skin, swollen glands or lymph nodes, unusual or unexplained fatigue, swollen hands and feet, excessive hair loss, memory problems, headaches, and muscle weakness, pain, cramping and/or burning. Individual patient risk for developing these symptoms has not been well established. Some scientific expert panels and literature reports have found no evidence of a consistent pattern of signs and symptoms in women with silicone gel-filled breast implants (based on literature published from 2000-2004). [1,2,4, 30, 31, 32]

Some scientific evidence supports the conclusion that there is no increased risk of CTDs or autoimmune disorders for women with silicone gel breast implants (based on literature published from 1996-2011). [1, 2, 4, 30, 33-46] Some independent scientific panels and review groups have also concluded that the weight of the evidence shows no relationship between breast implants and CTDs, or at least if a risk cannot be absolutely excluded, it is too small to be measured (based on literature published from 1998-2001). [4, 47,48] A published systematic review from 2016 reported there is limited or suggestive evidence of an association between breast implants and rheumatoid arthritis.[57]

Effects on Children Born to Mothers with Breast Implants

It is not known if a small amount of silicone may move through the breast implant shell and pass into breast milk. There is no test for detecting silicone in breast milk that is considered accurate. There has been a study published in 2000 that measured silicon levels (one component of silicone). It did not indicate higher levels of silicon in breast milk from women with silicone gel breast implants when compared to women without implants.[49]

In addition, questions have been raised about whether silicone gel breast implants could harm babies whose mothers had implants while pregnant. Two studies from the early 2000's in humans have found that the risk of birth defects overall is not increased in children born after breast implant surgery. [50, 51] Although low birth weight was reported in a third study from the same time period, other factors (for example, lower pre-pregnancy weight) may explain this finding [52].

Overall, there is no evidence that shows that silicone gel breast implants have any harmful effects on the children of implanted women (based on literature published from 2000-2016). [4,5,50, 51, 52, 57]

Suicide

Some studies have reported a higher incidence of suicide in women with breast implants, but it is not clear whether these suicides were associated with having silicone gel breast implants or some other underlying condition that can lead to suicide, depression and/or anxiety (based on literature published from 2003-2007). [21, 53-59] One researcher[60] (published in 2003) believes that some women who want cosmetic surgery suffer from a disorder, called body dysmorphic disorder (BDD), which may cause them to think about suicide or attempt suicide.

The strongest predictor for suicide is having been hospitalized for any psychiatric condition. One study from 2004 found that women with breast implants were admitted to the hospital more often because of psychiatric problems before they even had their implant surgery, compared to women who had breast reduction or to the general population.[53] This may be a contributing factor to the reported higher incidence of suicide in women with breast implants.

Neurological Disease, Signs, and Symptoms

Some women with breast implants have complained of neurological symptoms such as difficulties with vision, sensation, muscle strength, walking, balance, thinking, or remembering things. Some have been diagnosed with diseases such as multiple sclerosis (which is an autoimmune disease that affects the nerves). Some of these women believe their symptoms are related to their implants. A scientific expert panel from 2000 found that there is not enough reliable evidence that neurological problems may be caused by or associated with breast implants.[4] Other researchers from the same time period, have found more evidence that silicone gel breast implants do NOT cause neurological diseases or symptoms. [4,14,61] There is one published report from 2000 of an increased risk of multiple sclerosis among women with silicone gel breast implants[36]; these researchers did not find any increased risk of other neurological symptoms.

MENTOR'S CLINICAL STUDIES

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

surgery) and 1 in 2.5 for reconstruction patients (with the most common type of additional surgery being capsule-related). The information below provides more details about the complications and benefits you may experience.

Please note that textured saline-filled breast implants have been discontinued however the results of the Clinical Studies and Post Approval Studies provided below include results from both the smooth and textured implants.

Description of Studies

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

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

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

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

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

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

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

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

NA: Not Available or insufficient data to perform an analysis of risk of the complication.

* Data on 47% of the 2385 patients enrolled in the study.

AUGMENTATION RESULTS FROM SPS

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

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

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

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

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

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

What Were the Reasons for Implant Removal for Augmentation Patients?

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

Main Reason for Augmentation Implant Removal through 3 Years[1]	N=137 Implants Removed
	%
Patient Request for Size/Shape Change	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%

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

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

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

Complication Following Replacement of Augmentation Implant	3-Year Complication Rate N=120 Implants
Additional Operations (Reoperation)	16%
Wrinkling	15%
Implant Removal	12%
Capsular Contracture III/IV or grade unknown	9%
Leakage/Deflation	4%
Asymmetry	4%
Breast Pain	3%
Hematoma	2%
Scarring	2%

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

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

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

[a]2 aug pts had 2 unconfirmed CTDs

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

What Were the Benefits from the SPS for Augmentation Patients?

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

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

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

AUGMENTATION RESULTS FROM POST-APPROVAL STUDY

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

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

Augmentation Complications	5-Year Complication Rate By Patient 5 Years	7-Year Complication Rate By Patient 7 Years	10-Year Complication Rate By Patient 10 Years
	N=1264	N=1264	N=1264
Reoperation	20%	25%	36%
Implant Removal	14%	19%	29%
Capsular Contracture III/IV or unknown	10%	11%	18%
Implant Deflation	10%	17%	25%
Breast Pain	7%	12%	25%

The reasons for reoperation through 3, 5, 7 and 10 years are shown below. The reasons for reoperation at 3 years are included below because the original labeling only reported the types of surgical procedures. While there may be some overlap of these two, they are different sets of data. An example of a type of additional surgical procedure is saline adjustment; an example of a reason for reoperation is infection. There were 255 reoperations performed in 146 patients through 3 years. There were 343 reoperations performed in 198 patients through 5 years. There were 464 reoperations in 259 patients at 7 years. There were 646 reoperations in 347 patients at 10 years. There may have been multiple reasons for one reoperation; therefore, the 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). The most common reason for reoperation through 10 years was leakage/

deflation (30% of the 646 reoperations). Note that the percentages are smaller for some of the reasons for reoperation because the number of reoperations has increased.

Augmentation Reason for Reoperation[1]	3-Years N=255 Reoperations	5-Years N=343 Reoperations	7-Years N=464 Reoperations	10-Years N=646 Reoperations
Patient Request for Size/Shape Change	33%	29%	24%	21%
Capsular Contracture	19%	17%	15%	13%
Leakage/Deflation[2]	14%	19%	28%	30%
Wrinkling	12%	11%	10%	9%
Asymmetry	10%	8%	6%	6%
Sagging	9%	9%	8%	6%
Hypertrophic Scarring	9%	6%	5%	3%
Hematoma/Seroma	6%	4%	3%	2%
Infection	5%	4%	3%	2%
Cosmetic Revision	5%	4%	3%	3%
Breast Mass/Tumor/Cyst Excision or Biopsy	3%	4%	5%	5%
Breast Pain	1%	1%	1%	<1%
Delayed Wound Healing	1%	1%	<1%	<1%
Irritation/Inflammation	1%	1%	<1%	<1%
Extrusion	1%	1%	<1%	<1%
Lymphadenopathy	<1%	<1%	<1%	<1%
Contralateral Replacement	0%	3%	8%	10%
Other[3]	0%	0%	0%	1%

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

[2] Includes reoperations where the reason for reoperation was not reported so deflation was assigned as worst case.

[3] Includes prophylactic implant removal, allergic reaction, atypical ductal hyperplasia, sclerosing adenosis, and prophylactic mastectomy.

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

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

[1] Includes removals where the reason for the removal was not reported so deflation was assigned as worst case.

[2] Includes prophylactic implant removal, fibroid tumors and allergic reaction.

RECONSTRUCTION RESULTS FROM SPS

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

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

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

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

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

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

What Were the Reasons for Implant Removal for Reconstruction Patients?

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

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

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

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

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

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

Complication Following Replacement of Reconstruction Implant	3-Year Complication Rate N=76 Implants
Additional Operation (Reoperation)	31%
Leakage/Deflation	23%
Implant Removal	21%
Capsular Contracture III/IV or grade unknown	19%
Asymmetry	17%
Wrinkling	16%
Breast Pain	13%
Infection	5%
Irritation/Inflammation	3%
Seroma	3%
Extrusion	2%
Hematoma	2%
Scarring	2%
Necrosis	1%

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

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

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

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

[a] 7 recon pts had 2 unconfirmed CTDs

What Were the Benefits of the SPS for Reconstruction Patients?

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

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

RECONSTRUCTION RESULTS FROM POST-APPROVAL STUDY

In terms of patient accountability, of the 335 reconstruction patients expected for follow-up at 5 years, data were collected for 52%. Of the 309 reconstruction patients expected for follow-up at 7 years, data were collected for 71%. Of the 280 reconstruction patients expected for follow-up at 10 years, data were collected for 66%. Please note that the follow-up rate at 3-years was 78% which makes the 3-year data more reliable than the 5-year, 7-year or 10-year data. There was some 5-year data reported for 73% of the reconstruction patients at some time from 3 to 10 years postoperatively. There was some 7-year data reported for 79% of the reconstruction patients at some time from 3 to 10 years postoperatively. There was some 10-year

data reported for 66% of the reconstruction patients at some time from 9 to 10 years postoperatively. It is assumed that information obtained at a later time (for example, at 7 years) applies to an earlier time (for example, at 5 years), which relies on patient memory over time. This is not as reliable as information obtained at an earlier time.

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

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

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

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

[1] If there was more than one reason reported per patient, all reasons are included in this table. This table excludes patients in which staged reconstruction was the only reason for reoperation.

[2] Includes prophylactic implant removal and prophylactic mastectomy.

[3] Includes 1 removal of axillary lymph nodes.

The main reasons for implant removal through 5 years, 7 years and 10 years are shown below. There were 135 implants removed in 112 patients at 5 years, 180 implants removed in 142 patients at 7 years and 206 implants removed in 158 patients at 10 years. The most common reason for removal though 5 years and 7 years was capsular contracture (29% of the 135 implants removed at 5 years, and 29% of the 180 implants removed at 7 years). The most common reason for removal through 10 years was leakage/deflation (28% of the 206 implants removed at 10 years). Note that the percentages are smaller for some of the reasons for removal because the number of removals has increased.

Reconstruction Main Reason for Removal	5-Years N=135 Implants Removed	7-Years N=180 Implants Removed	10-Years N=206 Implants Removed
Capsular Contracture	29%	29%	27%
Leakage/Deflation	25%	28%	28%
Infection	22%	16%	15%
Patient Request for Size/Shape/Change	8%	9%	8%
Necrosis Extrusion	5%	4%	3%
Asymmetry	4%	4%	5%
Breast Pain	3%	2%	2%
Breast Mass or Cancer	2%	2%	2%
Delayed Wound Healing	2%	1%	1%
Wrinkling	1%	1%	1%
Cosmetic Revision	1%	1%	1%
Contralateral Replacement	0%	2%	2%
Position Change	0%	1%	2%
Sagging	0%	0%	1%
Hypertrophic Scarring	0%	1%	1%
Irritation/Inflammation	0%	1%	1%
Other	0%	0%	2%

BREAST AUGMENTATION CONSIDERATIONS

Special Considerations for Breast Augmentation

What Are the Alternatives to Breast Augmentation?

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

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

What Questions Do You Ask Your Surgeon about Breast Augmentation?

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

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

Other Factors to Consider in Breast Augmentation

- **Choosing a Surgeon**

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

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

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

- **Implant Shape and Size**

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

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

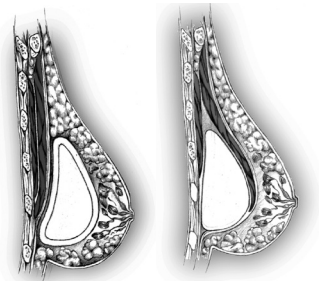
- **Palpability**

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

- **Implant Placement**

  The breast implant can be placed either partially under the pectoralis major muscle (submuscular) or on top of the muscle and under the breast glands (subglandular). You should discuss with your surgeon the advantages and disadvantages of implant placement selected for you.

  The submuscular placement may make surgery last longer, may make recovery longer, may be more painful, and may make it more difficult to have some reoperation procedures than the subglandular placement. The possible benefits of this placement



Subglandular Submuscular

are that it may result in less palpable implants, less capsular contracture, and easier imaging of the breast with mammography.

The subglandular placement may make surgery and recovery shorter, may be less painful, and may be easier to access for reoperation than the submuscular placement. However, this placement may result in more palpable implants, more capsular contracture, and more difficult imaging of the breast with mammography.

- **Incision Sites**

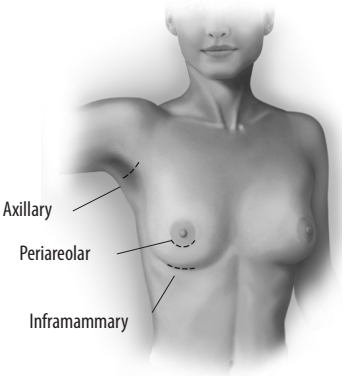
  To permit the smallest possible incision, the implant is typically inserted empty, and then filled with saline. You should discuss with your surgeon the pros and cons for the incision site specifically recommended for you, depending on whether you will be having augmentation or reconstruction.

  There are 3 common incision sites: under the arm (axillary), around the nipple (periareolar), or within the breast fold (inframammary). If the incision is made under the arm, the surgeon may use a probe fitted with a miniature camera, along with minimally invasive (very small) instruments, to create a "pocket" for the breast implant.

  - Periareolar — This incision is the most concealed, but is associated with a higher likelihood of inability to successfully breast feed, as compared to the other incision sites.
  - Inframammary — This incision is less concealed than periareolar and associated with less difficulty than the periareolar incision site when breast feeding.
  - Axillary — This incision is less concealed than periareolar and associated with less difficulty than the periareolar incision site when breast feeding.
  - Umbilical/endoscopic — This incision site has not been studied and is not recommended.

- **Surgical Setting and Anesthesia**

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



Additional Procedures at the Time of Breast Augmentation

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

In these situations, your surgeon may recommend a breast lift (mastopexy) to remove some of the extra skin, or to lift the breasts, at the time of implant placement. Mastopexy involves removing a strip of skin from under the breast or around the

nipple to lift the nipple and breast location, and tighten the skin over the breast. Your surgeon will discuss the potential risks, and the location of the additional scars which might be required to lift your breasts or to remove the extra skin.

- **Postoperative Care**

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

  Postoperative care may involve the use of a postoperative bra, compression bandage, or jog bra for extra support and positioning while you heal. At your surgeon's recommendation, you will most likely be able to return to work within a few days, although for at least a couple of weeks you should avoid any strenuous activities that could raise your pulse and blood pressure. Your surgeon may also recommend breast massage exercises.

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

BREAST RECONSTRUCTION CONSIDERATIONS

Special Considerations for Breast Reconstruction

Should You Have Breast Reconstruction?

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

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

What Are the Alternatives to Breast Reconstruction?

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

What Are the Choices in Reconstructive Procedures?

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

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

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

Reconstruction Incision Sites

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

Surgical Settings and Anesthesia

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

Breast Reconstruction with Breast Implants

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

The Timing of Your Breast Implant Reconstruction

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

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

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

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

Surgical Considerations to Discuss with Your Surgeon

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

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

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

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

What Is the Breast Implant Reconstruction Procedure?

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

Breast Reconstruction with Implants – Staging the Procedures

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

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

Use of Tissue Expander(s) in Breast Reconstruction Surgery

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

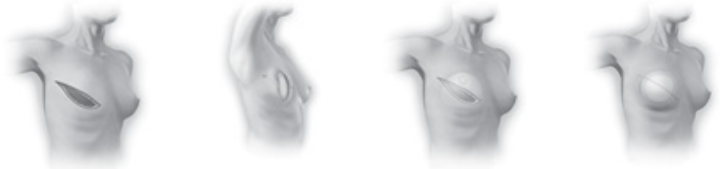
Placing an implant in a breast pocket that is too small can cause complications such as drooping or sagging at an earlier age, implant extrusion, skin wrinkling, infection, and hematoma. You may also be able to feel folds on the implant created by the implant being squeezed tightly by the surrounding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

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

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

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

Figure 2
Breast Reconstruction Using a Tissue Expander and Breast Implant



Post-Mastectomy

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

Final Result
before nipple/areola reconstruction

Breast Reconstruction without Implants (Tissue Flap Reconstruction)

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

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

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

TRAM Flap

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

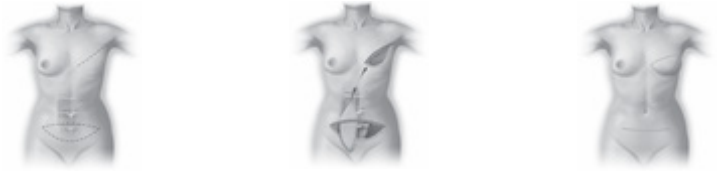
The TRAM flap procedure is done in the hospital under general anesthesia. Your hospital stay may range from 2 to 5 days. The recovery time may be 6 to 8 weeks. You will have two incision sites (on your abdomen and on your breast) resulting in two wounds to heal after surgery and, therefore, two scars.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

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

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

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

Figure 3
Breast Reconstruction Using a TRAM Flap



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

Latissimus Dorsi Flap

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

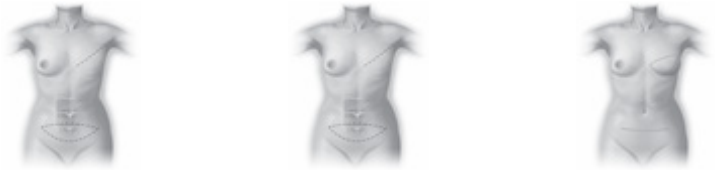
Figure 4
Breast Reconstruction Using a Latissimus Dorsi Flap

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

DIEP Flap

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

Figure 5
Breast Reconstruction Using a DIEP Flap



Post-Mastectomy

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

Final Result

Complications Associated with Flap Reconstruction

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

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

Choosing Breast Reconstruction with Breast Implants

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

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

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

POSTOPERATIVE CARE

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

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

What Questions Do You Ask Your Surgeon about Breast Reconstruction?

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

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

16. How much pain or discomfort will I feel, and for how long?
17. How long will I be in the hospital?
18. Will I need blood transfusions, and can I donate my own blood?
19. When will I be able to resume my normal activity (sexual activity or athletic activity)?

Other Factors to Consider in Breast Reconstruction

- **Choosing a Surgeon**

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

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

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

- **Implant Shape and Size**

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

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

- **Palpability**

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

MATERIALS PRESENT IN SALINE FILLED BREAST IMPLANTS

Below is a summary of materials found in Mentor's Saline Breast Implants.

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

Saline Implants Breast Implant Device Materials:

Device Materials	Implant Component
Dimethyl Silicone Elastomer Dispersion	Shell
Silicone Elastomers	Shell
Dibutyltin dilaurate (crosslinking catalyst)	Shell

Laboratory Testing:

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

Chemicals That Might be Released from Breast Implants

Mentor conducted laboratory tests in which breast implants were exposed to extraction liquids at high temperature (harsh conditions not present in the human body) to examine what substances might be released from the implant under such conditions. The materials found were grouped into two categories: Volatiles (chemical that are released by breast implants as a gas) and Extractables (chemicals that are released by breast implants following soaking in water and/or organic solvent (liquid)).

Volatile	Whole Device (Smooth,Saline-filled) (ppm*)
D_3	0.97
D_4	6.36
D_5	12.35
Isopropanol	1.88
Toluene	0.03
Xylenes	3.89

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

Note: The substances listed as Dx are circular silicone molecules comprised of dimethylsiloxane- (D) subunits of the specified length

Extractables:

Breast implant are constructed from silicone polymers Silicone polymers have been used in medical applications for more than 50 years. Polymers are long chains of repeated linked materials, and low levels of shorter chains of these materials are often present in silicone and other medical polymers. These shorter chains represent most of the "Extractables" in the table below.

Extractable	Whole Device (Smooth,Saline-filled) (ppm*)
D_6	<6.3
D_{10}	90.4
D_{15}	347.3
D_{20}	62.3

* ppm = parts per million; parts per million (ppm) is a measure of concentration and refers to microgram per gram; 1 ppm is the same as 0.0001%.Data preceded with a "<" symbol means that the level of the individual component, if present, was below the method of detection limit indicated.

Note: The substances listed as Dx are circular silicone molecules comprised of dimethylsiloxane- (D) subunits of the specified length.

Heavy Metals Found in Breast Implants

Implants were extracted with aqueous (buffer) and organic solvents and analyzed by Inductively Coupled Plasma/Mass spectroscopy) (ICPMS) and cold vapor atomic absorption (CVAA) for numerous metals. The metal concentrations obtained from the extracted residues are shown in the table below for the device.

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

Metal	Whole Device (Smooth, Saline-filled)(ppm*)
Tin	0.5
Platinum	0.78
Arsenic	ND
Lead	ND
Zinc	0.26

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

ND= Not Detected

IF YOU EXPERIENCE A PROBLEM, SHOULD YOU REPORT IT?

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

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(Write your doctor's contact information here)

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

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

a. Complete Form 3500 and submit it online at https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm

b. Download Form 3500 from the website https://www.accessdata.fda.gov/scripts/medwatch/medwatch-online.htm and print it out, fill it in, and send it to the FDA, or

c. Call the FDA to get a reporting package at 1-800-FDA-1088 (1-800-332-1088).

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

WHAT ARE OTHER SOURCES OF ADDITIONAL INFORMATION?

General Resources about Implants:

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

In the US, Mentor's website, **breastimplantsbymentor.com**, includes important safety information as well as links to the latest version of Mentor's Patient Educational Brochures. You should check this website periodically to stay up to date on any new safety information posted. You may also visit the FDA's Breast Implants website for additional information https://www.fda.gov/medical-devices/implants-and-prosthetics/breast-implants.

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

You can find more detailed information about Saline-Filled and Spectrum Breast Implants breast implants on FDA's website, https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpma/pma.cfm?id=P990075. This site includes links to Mentor's studies (in animals and humans or other laboratory testing) in Mentor's Summary of Safety and Effectiveness Document (SSED)

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

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

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

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

IMPORTANT CONTACT INFORMATION

Your Saline and Spectrum Breast Implants are manufactured and sold by:

MENTOR

3041 Skyway Circle North

Irving, TX 75038-3540 USA

1 (800) MENTOR8

www.mentorwwllc.com

Your surgeon's name and contact information:

_____

_____

_____

_____

_____

MENTOR'S US IMPLANT TRACKING PROGRAM

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

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

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

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

Implant ID Card

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

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

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

Your doctor should keep a copy of the Implant ID Card with your medical records.

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

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

PATIENT DECISION CHECKLIST – TO BE COMPLETED PRIOR TO SURGERY

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

The risks associated with breast surgery and breast implant-specific risks reflect the highest estimated cumulative occurrence of each risk across all groups of patients (augmentation and reconstruction, both primary and revision) in the Saline Prospective Study (SPS) from the 3-year or 10-year cumulative rate.

PATIENT DECISION CHECKLIST

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

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

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

Considerations for a Candidate for Successful Breast Implantation

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

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

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

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

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

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

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

Patient Initials: _____

Risks of Breast Implant Surgery

I understand that there are risks of undergoing breast implant surgery. The percentages displayed below are the highest rate from either the 3-year or 10-year cumulative risk rate reported in the Mentor Saline Prospective Study (SPS) (3-Year (labeled with (a) and 10-Year (labeled with (b)). I understand that risks of undergoing breast implant surgery may include:

- breast pain (reported in up to 37.2%[b] of patients),
- skin or nipple areola sensitivity changes or loss (loss of nipple sensation reported in up to 34.5%[a] of patients, and intense nipple sensitivity reported in up to 4.8%[a] of patients)
- asymmetry (reported in up to 27.9%[a] of patients),
- impact of aging or weight change on size and shape of breast (ptosis reported in up to 1.5%[a] of patients),
- infection requiring possible removal of implant (reported in up to 9%[a] of patients),
- swelling (may occur but specific rates are not publicly available in the Mentor Saline Prospective study analysis),
- scarring (hypertrophic scarring reported in up to 4.9%[a] of patients),
- fluid collections (seroma) (reported in up to 5.9%[a] of patients),
- hematoma (reported in up to 1.5%[a] of patients),
- tissue death of breast skin or nipple (tissue/skin necrosis reported in up to 2%[a] of patients),
- inability to breast feed (may occur but specific rates are not publicly available in the Mentor Saline Prospective study analysis),
- complications of anesthesia (may occur but specific rates are not publicly available in the Mentor Saline Prospective study analysis),
- bleeding (may occur but specific rates are not publicly available in the Mentor Saline Prospective study analysis),
- chronic pain (may occur but specific rates are not publicly available in the Mentor Saline Prospective study analysis),
- damage to surrounding tissue, such as muscle, nerves, and blood vessels (may occur but specific rates are not publicly available in the Mentor Saline Prospective study analysis), and
- impact on imaging of breast tissue (may occur but specific rates are not publicly available in the Mentor Saline Prospective study analysis).

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

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

Patient Initials: _____

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

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

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

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

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

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

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

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

Patient Initials: _____

Systemic Symptoms

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

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

I understand that breast implants and breast surgery may interfere with my ability to successfully breastfeed.

Patient Initials: _____

Breast-Implant Specific Risks

I understand that a breast implant is NOT a lifetime device and the longer I have my implants, the more likely I am to experience a complication and the more likely I am to require a reoperation requiring the replacement or removal of my breast implant. As many as 20 percent of women who receive breast implants for augmentation have to have their implants removed within 8 to 10 years, but my implants may last for a shorter or longer time.

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

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

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

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

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

The percentages displayed below are the highest rate from either the 3-year or 10-year cumulative risk rate reported in the Mentor Saline Prospective Study (SPS) (3-Year (labeled with (a) and 10-Year (labeled with (b)). I understand that the long-term risks of breast implants may include:

- painful or tightening of scar tissue (capsule) around my implant (capsular contracture) (capsular contracture III/IV reported in up to 59.4%[b] of patients),
- rupture or leaking of the implant (reported in up to 33.2%[b] of patients),
- wrinkling of the implant (reported in up to 20.8%[a] of patients),
- visibility of the implant edges (palpability of implants reported in up to 1.6%[a] of patients),
- shifting of the implant (implant malposition reported in up to 1.1%[a] of patients), or
- reoperation (reported in up to 56.0%[b] of patients).

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

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

Patient Initials: _____

Recommended Follow-up

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

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

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

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

Patient Initials: _____

Questions for My Physician

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

Patient Initials: _____

Options Following Mastectomy

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

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

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

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

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

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

Patient Initials: _____

Breast Augmentation Options

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

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

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

Patient Initials: _____

CONFIRMATION OF DISCUSSION OF RISKS

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

_____

Printed Name

_____

Patient Signature and Date

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

_____

Printed Name

_____

Physician Signature and Date

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