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**Important Information for Reconstruction Patients
About Mentor® MemoryGel® and Mentor® MemoryGel® Xtra
Silicone Gel-Filled Breast Implants**

June 2019

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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 which asks about a person’s body image.
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 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.
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. Baker Grades III and IV are the most severe. Baker Grade III often results in the need for additional surgery (reoperation) because of pain and possibly abnormal appearance. Baker 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 known risk for implant rupture. Below is a description of each Baker Grade. <ul style="list-style-type: none"> • Baker Grade I – Normally soft and natural appearance • Baker Grade II – A little firm, but breast looks normal • Baker Grade III – More firm than normal, and looks abnormal (change in shape) • Baker Grade IV – Hard, obvious distortion, and tenderness with pain
Capsule	Scar tissue that forms around the breast implant. Sometimes this capsule squeezes the implant, resulting in capsular contracture (below).
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 (see Section 1.4).
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.
Contour Profile Gel (CPG)	Mentor’s shaped implant. This is a tear-drop shaped implant, manufactured with Mentor’s more cohesive (firmer feeling) gel.
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.
Core Study (Round Gel)	The primary clinical study of augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients that supported the approval of the premarket approval (PMA) application. Safety and effectiveness data are collected yearly through 10 years, with the follow-up from years 4 through 10 being performed as part of a post-approval Round Gel Core Study.
CPG Core Study	The primary clinical study of augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients that supported the approval of the premarket approval (PMA) application. Safety and effectiveness data are collected yearly through 10 years, with the follow-up from years 3 through 10 being performed as part of a post-approval CPG Core Study.
Delayed reconstruction	Breast reconstruction that takes place weeks, months, or years after a mastectomy.
Delayed wound healing	Delayed progress in the healing of an opened wound.
Displacement	Movement of the implant from the usual or proper place.
Epidemiological	Relating to the science of explaining the relationships of factors that determine disease frequency and distribution.
Extracapsular rupture	A type of rupture in which the silicone gel is outside of the scar tissue capsule surrounding the implant.
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.
Flap	A portion of tissue (which may include muscle, fat, and skin) moved from one part of the body to another. The tissue flap may or may not have its blood supply attached.
Follicular cyst	Any closed sac, usually containing liquid, resulting from the blocking of a duct or small gland.
Functional Living Index-Cancer (FLIC)	The Functional Living Index-Cancer (FLIC) is a questionnaire used to evaluate day-to-day functioning in patients who have cancer.
Granuloma	A lump or mass made of inflammatory cells surrounding a foreign substance due to longstanding inflammation.
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.
Intracapsular rupture	A type of rupture in which the silicone gel remains inside the scar tissue capsule surrounding the implant.
Lactation	The production and secretion of milk by the breast glands.
Latissimus dorsi	Two triangular muscles running from the spinal column to the shoulder.
Low molecular weight (LMW) silicones	Components of silicone of smaller molecular weight that may bleed out of silicone gel.
Lumpectomy	Removal of a small amount of breast tissue.
Lymphadenopathy	Enlargement of the lymph node(s).
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.
MRI	Magnetic resonance imaging. A radiographic examination that has the ability to detect rupture of silicone gel-filled breast implants.
Mammary	Pertaining to the breast.
Mammography	A type of X-ray examination of the breasts used for detection of cancer.
Mammoplasty	Plastic surgery of the breast.
Mastectomy	The removal of breast tissue due to the presence of a cancerous or precancerous growth. <u>Subcutaneous mastectomy</u> : surgical removal of the breast tissues, but sparing the skin, nipple, and areola. <u>Total mastectomy</u> : surgical removal of the breast including the nipple, areola, and most of the overlying skin. <u>Modified radical mastectomy</u> : surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the lymphatic-bearing tissue in the axilla. <u>Radical mastectomy</u> : surgical removal of the entire breast including the nipple, areola, and overlying skin, as well as the pectoral muscles, lymphatic bearing tissue in the axilla, and various other neighboring tissue.
Mastopexy	Plastic surgery to move sagging breasts into a more elevated position.
Metastatic Disease	Spreading of cancer cells from the original site to other parts of the body.
Migration	Movement of silicone materials outside the breast implant.
Necrosis	Death of cells or tissues.
Oncologist	A doctor who studies, identifies, and treats cancer.
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 reconstruction	The first time a breast implant is placed for the purpose of breast reconstruction.
Ptoisis	Breast sagging that is usually the result of normal aging, pregnancy, or weight loss.
Rectus abdominus	A long flat muscle extending the whole length of the front of the abdomen (stomach).
Reoperation	An additional surgery after your first breast implantation.
Revision-Reconstruction	Refers to the correction or improvement of a primary reconstruction. In the context of this document, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast reconstruction.
Rheumatological Disease/ Disorder	A variety of diseases involving connective tissue structures of the body, especially the joints and fibrous tissue. These diseases are often associated with pain, inflammation, stiffness, and/or limitation of motion of the affected parts. Can include autoimmune diseases. Fibromyalgia is a rheumatological disorder.
Rosenberg Self-Esteem Scale	A questionnaire that measures self-esteem.
Rupture	A tear or hole in the implant shell. Silicone implant ruptures may be silent or symptomatic. Ruptures can be intracapsular or extracapsular.
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.
SF-36 Scale	A questionnaire intended to measure health-related quality of life. It includes questions that measure physical, mental, and social health.
Silicone elastomer	A type of silicone that has elastic properties similar to rubber.
Silent rupture	A breast implant rupture without symptoms and which is not apparent except through appropriate imaging techniques such as MRI. Most silicone breast implant ruptures are silent. (see symptomatic rupture below)
Subglandular placement	Placement of a breast implant underneath and within the breast glands but on top of the chest muscle.
Surgical incision	A cut made to body tissue during surgery.
Symmastia	Joining together of implants in the middle of the chest resulting in loss of cleavage.
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.
Symptomatic rupture	A breast implant rupture that is associated with symptoms (such as lumps, persistent pain, swelling, hardening, or change in implant shape). Some silicone breast implant ruptures are symptomatic, but most are silent.
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.
Tissue expander	An adjustable implant that can be inflated with saline to stretch the tissue at the mastectomy site to create a new tissue flap for implantation of the breast implant.

IMPORTANT INFORMATION FOR RECONSTRUCTION PATIENTS ABOUT MENTOR® MEMORYGEL® AND MENTOR® MEMORYGEL® XTRA SILICONE GEL-FILLED IMPLANTS

1. Considerations for Silicone Gel-Filled Breast Implant Reconstruction

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

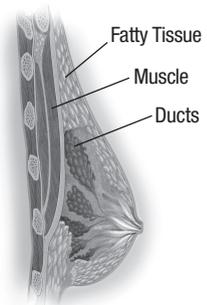
Please read this entire brochure carefully, and if you have any questions or there are things you do not understand, please discuss them with your surgeon before making any decisions. As part of your decision, both you and your surgeon will be required to sign the last page of this brochure to confirm your understanding of what you have read.

You should wait at least 1-2 weeks after reviewing and considering this information before deciding whether to have primary breast reconstruction or replacement (revision-reconstruction) surgery, unless an earlier surgery is deemed medically necessary by your surgeon.

1.1. What Gives the Breast Its Shape?

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

Breast cancer surgery can significantly change the shape of the breast, to a greater or lesser degree, depending on how much breast tissue is removed in a partial or complete mastectomy; how much skin is removed at the time of surgery; and how much tissue reaction or scarring there is in the remaining breast and skin in response to chemotherapy or radiation therapy.



1.2. What Is a Silicone Gel-Filled Breast Implant?

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



1.3. Are You Eligible for Silicone Gel-Filled Breast Implants?

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

- **Breast augmentation for women at least 22 years old.** Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery. (A separate patient brochure is available and should be read for breast augmentation.)
- **Breast reconstruction.** Breast reconstruction includes primary reconstruction to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. Breast reconstruction also includes revision surgery to correct or improve the results of a primary breast reconstruction surgery.

Contraindications

Breast implant surgery should not be performed in:

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

Precautions

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

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

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

- You should be aware that there are many factors that will affect the outcome and timing of your reconstruction with breast implants, such as the stage of your disease, the type and extent of cancer removal surgery you have had, the amount of skin and soft tissue available for the reconstruction, and additional treatments such as chemotherapy and radiation, which you may require.
- Breast implants are not lifetime devices, and breast implantation is likely not a one-time surgery. You will likely need additional unplanned surgeries on your reconstructed and/or contralateral augmented breasts

because of complications or unacceptable cosmetic outcomes. These additional surgeries can include implant removal with or without replacement, or they can include other surgical procedures. When you have your implants replaced (revision-reconstruction), your risk of future complications increases compared to first time (primary) reconstruction surgery, so you should review the complication rates for revision-reconstruction patients to see what future risks you may experience.

- Many of the changes to your breast and chest wall following preparation and implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed and not replaced, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast.
- If you undergo a mastectomy, removal of the breast tissue eliminates the ability to breastfeed with the removed breast. In addition, contralateral breast augmentation may affect your ability to breastfeed, either by reducing or eliminating milk production.
- Rupture of a silicone gel-filled breast implant is most often silent. This means that neither you nor your surgeon will know that your implants have a rupture most of the time.
- The health consequences of ruptured silicone gel-filled breast implants have not been fully established. Refer to Section 2 (Rupture) below for a review of the literature information regarding this issue.
- If implant rupture is noted by MRI, you should speak to your surgeon about whether you should have the implant removed, with or without replacement.
- With breast implants, routine screening mammography for breast cancer will be more difficult. You should continue to undergo routine mammography screening as recommended by your primary care physician. The implant may interfere with finding breast cancer during mammography. Because the breast and implant are squeezed during mammography, an implant could potentially rupture during the procedure, although this occurrence is rare. More x-ray views are necessary for women with breast implants; therefore, you will receive more exposure to radiation. However, the benefit of having the mammogram to find cancer outweighs the risk of the additional x-rays. Be sure to inform the mammography technologist that you have implants.
- You should perform an examination of your breasts every month for cancer screening; however, this may be more difficult with implants. You should ask your surgeon to help you distinguish the implant from your breast tissue.
- You should perform an examination of your breasts for the presence of lumps, persistent pain, swelling, hardening, or change in implant shape, which may be signs of symptomatic rupture of the implant. These should be reported to your surgeon and possibly evaluated with an ultrasound, mammogram, or MRI to screen for rupture.
- The timing for any revision following reconstruction surgery should be discussed with your surgeon so that all issues such as the potential effects of radiation, chemotherapy, and additional cancer surgery or treatments can be fully discussed.
- You should inform any other doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.
- Capsular contracture is not to be treated by closed capsulotomy or forceful external compression, which will likely result in implant damage, rupture, folds, and/or hematoma.

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

2. Breast Implant Complications

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

• Rupture

Breast implants are not lifetime devices. Breast implants rupture when the shell develops a tear or hole. Rupture can occur at any time after implantation, but it is more likely to occur the longer the implant is implanted. Silicone gel-filled implant ruptures are most often silent. This means that most of the time neither you nor your plastic surgeon will know if the implant has a tear or hole in the shell. However, sometimes there are symptoms associated with gel implant rupture. These symptoms include hard knots or lumps surrounding the implant or in the armpit, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast. If you are experiencing these symptoms, you should discuss them with your physician.

The following things may cause your implant to rupture: damage by surgical instruments; stressing the implant during implantation and weakening it; folding or wrinkling of the implant shell; excessive force to the chest (for example, during closed capsulotomy; see Section 1.4); trauma; compression during mammographic imaging; and severe capsular contracture. Breast implants may also simply wear out over time. Laboratory studies have identified some of the types of rupture for Mentor's product; however, it is not known whether these tests have identified all causes of rupture. These laboratory studies are ongoing.

Rupture – Round Gel Core Study

In Mentor's Round Gel Core Study, rupture was assessed for patients who had scheduled MRIs to screen for rupture (i.e., part of the MRI cohort) and those who were not assessed for rupture by MRI (i.e., part of the non-MRI cohort). For primary reconstruction patients in the MRI cohort, the rupture rate was approximately 0.8% through 4 years. This means that through 4 years, 1 of every 100 primary reconstruction women had at least

one ruptured breast implant. There was one primary reconstruction patient in the Round Gel Core Study with a suspected rupture by MRI who died. There were two primary reconstruction patients with suspected implant ruptures detected by MRI. The implants were confirmed to be intact when they were removed. For revision-reconstruction patients in the MRI cohort, the rupture rate was 0% through 4 years. There were no ruptures in the non-MRI cohorts for either the primary reconstruction or revision-reconstruction patients through 4 years. The rupture rate beyond 4 years in Mentor's Round Gel Core Study is currently unknown. The Round Gel Core Study will continue to monitor patients for rupture.

Further information on the estimated incidence rate of rupture for round MemoryGel implants is provided by a limited set of long-term follow-up data from an MRI study in the U.K. (Sharpe and Collis). In this study, textured round MemoryGel implants placed subglandularly in 101 patients by a single physician, with follow-up of 4-12 years, were evaluated for rupture status by MRI with confirmation by explantation. Based on their results, at 12 years, the estimated cumulative rate of silent ruptures is 15% for the patients and 9% for implants. By implant, at 12 years, the cumulative rate of 9% is the best statistical estimate, and 19% is a worst-case statistical estimate. By patient, at 12 years, the cumulative rate of 15.1% is the best statistical estimate, and 24.5% is the worst-case statistical estimate. These data are consistent with a published MRI-based rupture study of current silicone gel-filled breast implants from a variety of manufacturers.¹

Rupture – CPG Core Study

In Mentor's CPG Core Study, rupture was assessed for patients who had scheduled MRIs to screen for rupture (i.e., part of the MRI cohort) and those who were not assessed for rupture by MRI (i.e., part of the non-MRI cohort). For primary reconstruction patients in the MRI cohort, the rupture rate was 0% through 3 years. This means that through 3 years, 0 of every 100 primary reconstruction women had at least one ruptured breast implant. For revision-reconstruction patients in the MRI cohort, the rupture rate was 0% through 3 years. There were no ruptures reported in the non-MRI cohorts for either the primary reconstruction or revision-reconstruction patients through 3 years. The rupture rate beyond 3 years in Mentor's CPG Core Study continues to be investigated. The Mentor CPG Core Study will continue to monitor patients for rupture.

With respect to the literature, there was a study published that examined 186 Danish women with MRI found a rupture rate of 2% for implants that were implanted after 1988. Of the ruptures reported in this study, most (86%) were silent and some were found at surgery (14%).² The authors reported that the rupture rate increased significantly with increasing implant age. This type of information pertains to a variety of silicone implants from a variety of manufacturers and implant models, and it is not specific to Mentor's implants.

Consequences of Rupture Reported in Literature

If rupture occurs, silicone gel may either remain within the scar tissue capsule surrounding the implant (intracapsular rupture), move outside the capsule (extracapsular rupture), or gel may move beyond the breast (migrated gel). No confirmed cases of extracapsular rupture of Mentor's MemoryGel breast implants were observed in Mentor's Round Gel or CPG Core Studies, or in a limited, long-term follow-up MRI clinical study from the U.K. (Sharpe & Collis) of Mentor's Round MemoryGel devices. Studies of Danish women evaluated with MRI involving a variety of manufacturers and implant models showed that about three-fourths of implant

ruptures are intracapsular and the remaining one-fourth are extracapsular.³ Extracapsular ruptures appear largely to be the result of closed capsulotomy (see Section 1.4) and/or trauma to the chest area. For example, there was a significantly higher prevalence of extracapsular ruptures (14.7%) in these Danish women who had undergone closed capsulotomy as compared to those who had not.⁴ In a study of British women, one patient observed to have severe bilateral silicone granulomas and bilateral extracapsular ruptures suffered a fractured sternum in a traffic accident.⁵

There is a possibility that rupture may progress from intracapsular to extracapsular and beyond. Studies of Danish women indicate that over a 2-year period, about 10% of the implants with intracapsular rupture progressed to extracapsular rupture as detected by MRI.⁶ This means that for women with silicone gel rupture within the scar tissue capsule detected via MRI after 2 years, 1 in 10 of these women will have progression of the gel outside the scar tissue capsule. Approximately half of the women whose ruptures had progressed from intra- to extracapsular reported that they experienced trauma to the affected breast during this time period or had undergone mammography. In the other half, no cause was given. In the women with extracapsular rupture, after 2 years, the amount of silicone seepage outside the scar tissue capsule increased for about 14% of the women. This means that for 100 women with silicone gel rupture outside the scar tissue capsule, the amount of gel outside the scar tissue capsule increased for 14 women 2 years later. This type of information pertains to a variety of silicone implants from a variety of manufacturers and implant models, and it is not specific to Mentor's implants.

The health consequences of implant rupture have not been fully established. There have been rare reports of gel movement to nearby tissues such as the chest wall, armpit, or upper abdominal wall, and to more distant locations down the arm or into the groin. This has led to nerve damage, granuloma formation (see glossary), and/or breakdown of tissues in direct contact with the gel in a few cases. There have been reports of silicone presence in the liver of patients with silicone breast implants. Movement of silicone gel materials to lymph nodes in the axilla also has been reported, even in women without evidence of rupture, leading to lymphadenopathy.⁷ These reports were in women who had implants from a variety of manufacturers and implant models.

Local breast complications reported in the published literature that were associated with rupture include breast hardness, a change in breast shape or size, and breast pain.⁸ These symptoms are not specific to rupture, as they also are experienced by women who have capsular contracture. Most of the Danish women evaluated in these studies, whose ruptured implants were left in place for two years, reported no symptoms.

Concerns have been raised over whether ruptured implants are associated with the development of connective tissue or rheumatic diseases and/or symptoms such as fatigue and fibromyalgia.^{9,10,11,12} A number of epidemiology studies have evaluated large populations of women with breast implants from a variety of manufacturers and implant models. These studies do not, taken together, support an association of breast implants with a typical, diagnosed rheumatic disease.¹³ Other than one small study,¹⁴ few studies distinguish whether the women had ruptured or intact implants.

The autoantibody status of 64 Danish women who had at least one ruptured implant according to MRI evaluation was compared to 98 Danish women who had intact implants.¹⁵ Blood samples were obtained

to measure antinuclear antibodies, rheumatoid factor, and cardiolipin immunoglobulin G and M antibodies, which are all used to assess the presence of autoimmune disease. There was no increase in any of these autoantibodies in the women with ruptured implants as compared to those with intact implants, and women whose ruptures progressed from intracapsular to extracapsular over a period of 2 years did not have progression of autoantibody production. In fact, a number of women who had measurable levels of one or more antibodies two years prior to this evaluation no longer had measurable levels at the subsequent examination.

When ultrasound, mammogram or MRI findings of rupture are found, or if your surgeon determines you have signs or symptoms of rupture, your surgeon may recommend that you have the implant and any gel removed, with or without replacement of the implant. It also may be necessary to remove the tissue capsule as well as the implant, which will involve additional surgery, with associated costs. If you have symptoms such as breast hardness, a change in breast shape or size, and/or breast pain, you should have an ultrasound, mammogram or MRI to determine whether rupture is present.^{16,17}

• **Capsular Contracture**

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

Symptoms of capsular contracture range from mild firmness and mild discomfort to severe pain, distorted shape of the implant, and palpability (ability to feel the implant). Capsular contracture is graded into 4 levels depending on its severity:

Baker Grade I:	the breast is normally soft and looks natural
Baker Grade II:	the breast is a little firm but looks normal
Baker Grade III:	the breast is firm and looks abnormal
Baker Grade IV:	the breast is hard, painful, and looks abnormal

Baker Grades III and IV are considered severe and often additional surgery is needed to correct these grades.

Capsular Contracture – Round Gel Core Study

In Mentor's Round Gel Core Study, for women receiving reconstruction implants for the first time, the risk of severe capsular contracture was 10% through 4 years. This means 10 out of every 100 women who received Mentor implants for primary breast reconstruction had severe capsular contracture at least once during the first 4 years after receiving the implants.

For women receiving revision-reconstruction implants, the risk of severe capsular contracture was 20% through 4 years. This means 20 out of every 100 women who received Mentor implants for breast revision-reconstruction had severe capsular contracture at least once during the first 4 years after receiving the implants.

Additional surgery may be needed in cases where pain and/or firmness are severe. This surgery ranges from removal of the implant capsule tissue, to removal and possible replacement of the implant itself. This surgery may result in loss of your breast tissue. Capsular contracture may happen again after these additional surgeries. Capsular contracture may increase the risk of rupture.¹⁸

Capsular Contracture – CPG Core Study

In Mentor's CPG Core Study, for women receiving reconstruction implants for the first time, the risk of severe capsular contracture was 6% through 3 years. This means that 6 out of every 100 women who received Mentor CPG implants for primary breast reconstruction had severe capsular contracture at least once during the first 3 years after receiving the implants.

For women receiving revision-reconstruction implants, the risk of severe capsular contracture was 16% through 3 years. This means that 16 out of every 100 women who received Mentor CPG implants for breast revision-reconstruction had severe capsular contracture at least once during the first 3 years after receiving the implants.

Additional surgery may be needed in cases where pain and/or firmness are severe. This surgery ranges from removal of the implant capsule tissue, to removal and possible replacement of the implant itself. This surgery may result in loss of your breast tissue. Capsular contracture may happen again after these additional surgeries. Capsular contracture may increase the risk of rupture.¹⁹

• **Additional Surgeries (Reoperations) – Round Gel Core Study**

You should assume that you will need to have additional surgeries (reoperations). In the Mentor Round Gel Core Study, the reoperation rate was 31% for primary reconstruction patients, which means that 31 out of every 100 women who received Mentor implants for primary reconstruction had a reoperation during the first 4 years after receiving the implants. The reoperation rate was 33% for revision-reconstruction patients, which means that 33 out of every 100 women who received Mentor implants for revision-reconstruction had a reoperation during the first 4 years after receiving the implants.

Patients may decide to change the size or type of their implants, requiring additional surgery. Problems such as rupture, capsular contracture, hypertrophic scarring (irregular, raised scar), asymmetry, infection, and shifting can require additional surgery. Summary tables are provided in Section 3.5 that describe the reasons for performing additional surgeries experienced in the Round Gel Core Study. For women receiving primary reconstruction implants, the three most common reasons for reoperation were asymmetry followed by biopsy followed by patient requested style/size exchange and severe capsular contracture. For women receiving revision-reconstruction implants, the most common reasons for additional surgery were biopsy, followed by severe capsular contracture.

Additional Surgeries (Reoperations) – CPG Core Study

You should assume that you will need to have additional surgeries (reoperations). In the Mentor CPG Core Study, the reoperation rate was 35% for primary reconstruction patients, which means that 35 out of every 100 women who received Mentor CPG implants for primary reconstruction had a reoperation during the first 3 years after receiving the implants. The reoperation rate was 24% for revision-reconstruction patients, which means that 24 out of every 100 women who received Mentor CPG implants for revision-reconstruction had a reoperation during the first 3 years after receiving the implants.

Patients may decide to change the size or type of their implants, requiring additional surgery. Problems such as rupture, capsular contracture, hypertrophic scarring (irregular, raised scar), asymmetry, infection, and shifting can require additional surgery. Summary tables are provided in Section 4.5 that describe the reasons for performing additional surgeries in the CPG Core Study.

For women receiving primary reconstruction implants, the most common reasons for reoperation were asymmetry, excess tissue, and position dissatisfaction. For women receiving revision-reconstruction implants, the most common reasons for additional surgery were asymmetry, severe capsular contracture, patient dissatisfaction, patient requested size change, and wrinkling.

• Implant Removal

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

Implant Removal – Round Gel Core Study

For women receiving primary reconstruction implants in Mentor's Round Gel Core Study, 15% had their implants removed at least once through 4 years. Patient request for style/size change and asymmetry were the most common reasons for implant removal.

For women receiving revision-reconstruction implants in Mentor's Round Gel Core Study, 17% had their implants removed at least once through 4 years. The most common reason was severe capsular contracture.

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

Implant Removal – CPG Core Study

For women receiving primary reconstruction implants in Mentor's CPG Core Study, 14% had their implants removed at least once through 3 years. Asymmetry and patient requested size change were the most common reasons for implant removal.

For women receiving revision-reconstruction implants in Mentor's CPG Core Study, 21% had their implants removed at least once through 3 years. The most common reasons for implant removal were asymmetry, position dissatisfaction, and wrinkling.

• **Unsatisfactory Results**

Unsatisfactory results such as wrinkling, asymmetry, implant displacement (shifting), incorrect size, unanticipated shape, implant palpability, scar deformity, and/or hypertrophic scarring, may occur. Some of these results may cause discomfort. Pre-existing asymmetry may not be entirely correctable by implant surgery. Revision surgery may be recommended to maintain patient satisfaction, but carries additional considerations and risks. Selecting an experienced plastic surgeon may minimize, but not necessarily prevent, unsatisfactory results.

• **Pain**

Pain of varying intensity and length of time may occur and persist following breast implant surgery. In addition, improper size, placement, surgical technique, or capsular contracture may result in pain. You should tell your surgeon about significant pain or if your pain persists.

• **Changes in Nipple and Breast Sensation**

Feeling in the nipple and breast are typically lost after complete mastectomy where the nipple itself is removed and can be severely lessened by partial mastectomy. Radiation therapy also can significantly reduce sensation in the remaining portions of the breast or chest wall. The placement of breast implants for reconstruction may further lessen the sensation in the remaining skin or breast tissue. While some of these changes can be temporary, they can also be permanent, and may affect your sexual response or your ability to nurse a baby with the remaining breast.

• **Infection**

Infection can occur with any surgery or implant. Most infections resulting from surgery appear within a few days to weeks after the operation. However, infection is possible at any time after surgery. In addition, breast and nipple piercing procedures may increase the possibility of infection. Infections in tissue with an implant present are harder to treat than infections in tissue without an implant. If an infection does not respond to antibiotics, the implant may have to be removed, and another implant may be placed after the infection is resolved (cleared up). As with many other surgical procedures, in rare instances, toxic shock syndrome has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscles aches, and/or drops in blood pressure, which may cause fainting. You should contact your doctor immediately for diagnosis and treatment if you have these symptoms.

- **Hematoma/Seroma**

Hematoma is a collection of blood within the space around the implant, and seroma is a build-up of fluid around the implant. Having a hematoma and/or seroma following surgery may result in infection and/or capsular contracture later on. Symptoms from a hematoma or seroma may include swelling, pain, and bruising. If a hematoma or seroma occurs, it will usually be soon after surgery. However, this can also occur at any time after injury to the breast. While the body absorbs small hematomas and seromas, some will require surgery, typically involving draining and potentially placing a surgical drain in the wound temporarily for proper healing. A small scar can result from surgical draining. Implant rupture also can occur from surgical draining if there is damage to the implant during the draining procedure.

- **Breastfeeding**

Breastfeeding difficulties have been reported following breast surgery, including breast reduction and breast augmentation. If your surgeon uses a periareolar surgical approach (an incision around the colored portion surrounding the nipple), it may further increase the chance of breastfeeding difficulties in the remaining breast.

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

Calcium deposits can form in the tissue capsule surrounding the implant. Symptoms may include pain and firmness. Deposits of calcium can be seen on mammograms and can be mistaken for possible cancer, resulting in additional surgery for biopsy and/or removal of the implant to distinguish calcium deposits from cancer. If additional surgery is necessary to examine and/or remove calcifications, this may cause damage to the implants. Calcium deposits also occur in women who undergo breast reduction procedures, in patients who have had hematoma formation, and even in the breasts of women who have not undergone any breast surgery. The occurrence of calcium deposits increases significantly with age.

- **Extrusion**

Extrusion is when the breast implant comes through your skin. This may occur, for example, when your wound has not closed or when breast tissue covering your implants weakens. Radiation therapy has been reported to increase the likelihood of extrusion. Extrusion requires additional surgery and possible removal of the implant, which may result in additional scarring and/or loss of your breast tissue.

- **Necrosis**

Necrosis is the death of cells or tissues. This may prevent or delay wound healing and require surgical correction, which may result in additional scarring and/or loss of your breast tissue. Implant removal may also be necessary. Factors associated with increased necrosis include infection, use of steroids, smoking, chemotherapy, radiation, and excessive heat or cold therapy.

- **Delayed Wound Healing**

Some patients may experience a prolonged wound healing time. Delayed wound healing may increase the risk of infection, extrusion, and necrosis. Depending on the type of surgery or the incision, wound

healing times may vary. Smoking may interfere with the healing process. You should contact your surgeon immediately if your wound does not heal within the period of time he/she has discussed with you.

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

The pressure of the breast implant may cause breast tissue thinning (with increased implant visibility and palpability) and chest wall deformity. This can occur while implants are still in place or following implant removal without replacement. Either of these conditions may result in additional surgeries and/or unacceptable dimpling/puckering of the breast.

- **Lymphadenopathy**

Lymphadenopathy is a chronic enlargement of the lymph nodes. A lymph node is a round mass of tissue which makes cells as part of your immune system. The lymph nodes in the armpit (axilla) drain the breast area of fluid. Sometimes the enlarged lymph nodes are painful. If they become too large or painful, the lymph node(s) may need to be surgically removed. Painful and/or enlarged lymph nodes should be reported to your doctor.

Literature reports associate lymphadenopathy with both intact and ruptured silicone breast implants. One study reported that armpit lymph nodes from women with both intact and ruptured silicone gel implants had abnormal tissue reactions, granulomas, and the presence of silicone.²⁰ These reports were in women who had implants from a variety of manufacturers and implant models.

Other Reported Conditions

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

- **Connective Tissue Disease (CTD)**

Connective tissue diseases include diseases such as lupus, scleroderma, and rheumatoid arthritis. Fibromyalgia, another CTD, is a disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue. There have been a number of published epidemiological studies that have looked at whether having a breast implant is associated with having a typical or defined connective tissue disease. The study size needed to conclusively rule out a smaller risk of connective tissue disease among women with silicone gel-filled breast implants would need to be very large.^{21,22,23,24,25,26,27,28,29,30} The published studies taken together show that breast implants are not significantly associated with a risk of developing a typical or defined connective tissue disease.^{31,32,33,34} These studies do not distinguish between women with intact and ruptured implants. Only one study evaluated specific connective tissue disease diagnoses and symptoms in women with silent ruptured versus intact implants, but it was too small to rule out a small risk.³⁵

- **CTD Signs and Symptoms**

Literature reports have also been made associating silicone breast implants with various rheumatological signs and symptoms such as fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes. Scientific expert panels and literature reports have found no evidence of a consistent pattern of signs and symptoms in women with silicone breast implants.^{36,37,38,39,40}

Having these rheumatological signs and symptoms does not necessarily mean you have a connective tissue disease; however, you should be aware that you may experience these signs and symptoms after undergoing breast implantation. If you notice an increase in these signs or symptoms, you should consider seeing a rheumatologist to determine whether these signs or symptoms are due to a connective tissue disorder or autoimmune disease.

- **Immunotoxicity**

While there is no scientific evidence that silicone can cause hypersensitivity reactions in humans, some animal testing reports in the literature suggest that silicone gel may cause an adjuvant effect. The biological mechanism and clinical significance for these findings in animal models remain unknown.

- **Cancer**

Breast Cancer – Reports in the medical literature indicate that patients with breast implants are not at a greater risk than those without breast implants for developing breast cancer.^{41,42,43,44,45} Some reports have suggested that breast implants may interfere with or delay breast cancer detection by mammography and/or biopsy; however, other reports in the published medical literature indicate that breast implants neither significantly delay breast cancer detection nor adversely affect cancer survival of women with breast implants.^{46,47,48,49,50,51} A review of the available published medical literature concludes that women with breast implants do not have an increased risk of breast cancer or death associated with breast cancer, and that, if they do have breast cancer, the detection of their cancer and their survival are not affected by their implants.⁵² You should discuss this with your surgeon if you are thinking about placing a breast implant in the remaining breast to balance it with the reconstructed breast.

Brain cancer – One study has reported an increased incidence of brain cancer in women with breast implants as compared to the general population.⁵³ The incidence of brain cancer, however, was not significantly increased in women with breast implants when compared to women who had other plastic surgeries. Other published reviews of large studies in women with cosmetic implants concluded that the evidence does not support an association between brain cancer and breast implants.^{54,55}

Respiratory/lung cancer – One study has reported an increased incidence of respiratory/lung cancer in women with breast implants.⁵⁶ 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.^{57,58,59}

Cervical/vulvar cancer – One study has reported an increased incidence of cervical/vulvar cancer in women with breast implants.⁶⁰ The cause of this increase is unknown, but it has been suggested that the increased

risk observed is more likely to reflect other factors in these patients that put them at higher risk of getting this kind of cancer (such as multiple sexual partners).⁶¹

Lymphomas, including anaplastic large T-cell lymphoma (ALCL)

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, BIA-ALCL was diagnosed years after the breast implant was placed. The earliest report was one year after implant placement and the latest was 23 years after the implant surgery. About half the cases occurred within the first 7 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. Reports in the medical literature show that high-surface-area textured breast implants are associated with an increased risk of developing BIA-ALCL as compared to low surface-area textured implants.^{62,63,64}

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.

Other cancers – One study has reported an increased incidence of stomach cancer and leukemia in women with breast implants compared to the general population.⁶⁵ This increase was not significant when compared to women who had other types of plastic surgeries.

• **Neurological Disease, Signs, and Symptoms**

Some women with breast implants have complained of neurological symptoms (such as difficulties with vision, sensation, muscle strength, walking, balance, thinking or remembering things) or diseases (such as multiple sclerosis), which they believe are related to their implants. A scientific expert panel report found

that the evidence for a neurological disease or syndrome caused by or associated with breast implants is insufficient or flawed.⁶⁶

- **Suicide**

In several studies, a higher incidence of suicide was observed in women with breast implants.^{67, 68, 69, 70} The reason for this increase is unknown, but it was found that women with breast implants had higher rates of hospital admission due to psychiatric causes prior to surgery, as compared with women who had breast reduction or in the general population of Danish women.⁷¹

- **Effects on Children**

At this time, it is not known if a small amount of silicone may pass through from the breast implant silicone shell into breast milk. Although there are no current established methods for accurately detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone gel-filled implants when compared to women without implants.⁷²

In addition, concerns have been raised regarding potential damaging effects on children born to mothers with implants. Two studies in humans have found that the risk of birth defects overall is not increased in children born after breast implant surgery.^{73, 74} Although low birth weight was reported in a third study, other factors (for example, lower pre-pregnancy weight) may explain this finding.⁷⁵ This author recommended further research on infant health. A review of the available literature on the potential effects on children born to mothers with breast implants concludes that the evidence does not support an association between breast implants and health problems in children.⁷⁶

- **Potential Health Consequences of Gel Bleed**

Small quantities of low molecular weight (LMW) silicone compounds, as well as platinum (in zero oxidation state), have been found to diffuse ("bleed") through an intact implant shell.^{77, 78} Studies on implants implanted for a long duration have suggested that such bleed may be a contributing factor in the development of capsular contracture⁷⁹ and lymphadenopathy.⁸⁰ Evidence against gel bleed being a significant contributing factor to capsular contracture and other local complications is provided by the fact that there are similar or lower complication rates for silicone gel-filled breast implants than for saline-filled breast implants. Saline-filled breast implants do not contain silicone gel and, therefore, gel bleed is not an issue for those products. Furthermore, toxicology testing has indicated that the silicone material used in the Mentor implants does not cause toxic reactions when large amounts are administered to test animals. It should also be noted that studies reported in the literature have demonstrated that the low concentration of platinum contained in breast implants is in the zero oxidation (most biocompatible) state.⁸¹ In addition, two separate studies sponsored by Mentor have demonstrated that the low concentration of platinum contained in its breast implants is in the zero oxidation (most biocompatible) state.

Mentor performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may bleed out of intact implants into the body. Over 99% of the LMW silicones and platinum stayed in the implant. The overall body of available evidence supports that the extremely low level of gel bleed is of no clinical consequence.

3. Mentor Round Gel Core Study Results for Reconstruction and Revision-Reconstruction

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

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

3.1. Overview of Mentor Round Gel Core Study

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

The Mentor Round Gel Core Study consists of 1,008 patients, including 552 primary augmentation patients, 145 revision-augmentation patients, 251 primary reconstruction patients, and 60 revision-reconstruction patients. Of these patients, 202 primary augmentation patients, 56 revision-augmentation patients, 134 primary reconstruction patients, and 28 revision-reconstruction patients are in the MRI cohort, which means that they are assessed for silent rupture by MRI at years 1, 2, 4, 6, 8, and 10. The study is currently ongoing, with the results through 4 years reported in this brochure. Mentor will periodically update this brochure as more information becomes available. You should also ask your surgeon if he/she has any available updated clinical information.

Mentor's Round Gel Core Study results indicate that the risk of at least one occurrence of any complication (including reoperation) at some point through 4 years after implant surgery is 52% for primary reconstruction patients and 55% for revision-reconstruction patients. The information below provides more details about the complications and benefits you may experience.

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

3.2. What Was the 4-Year Follow-Up Rate in the Mentor Round Gel Core Study Reconstruction Patients?

At the 4-year follow-up visit, data are reported for 87% of the eligible primary reconstruction patients, and 77% of the eligible revision-reconstruction patients.

3.3. What Were the Benefits for the Mentor Round Gel Core Study Reconstruction Patients?

The Round Gel Core Study measured a variety of outcomes that assessed the benefits of the implants. For reconstruction, these outcomes included circumferential chest size, satisfaction, and quality of life (QoL) measures. These outcomes were assessed before implantation and at 1, 2, and 3 years after surgery for those patients who still had their original implants and came back for follow-up visits.

Primary Reconstruction Patients: For primary reconstruction patients, 179 (71%) out of the original 251 patients were included in the analysis of circumferential chest size at 4 years. For these 179 patients, the average increase in circumferential chest size was 3.6 centimeters.

Mentor's satisfaction assessment was based on a single question of "Would the patient have this breast surgery again?" At 4 years, 189 (75%) out of 251 primary reconstruction patients enrolled answered that question. Of these 189 patients, 185 (98%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 4 years for primary reconstruction patients, no change was observed in the Functional Living Index of Cancer or the Rosenberg Self-Esteem Scale. The Tennessee Self-Concept Scale (TSCS) is a survey completed by the patient that evaluates how the patient sees herself and what she does, likes, and feels. There was no change in the overall score for the TSCS. There was no change on the overall score of the Body Esteem Scale. The Chest Score of the Body Esteem Scale significantly improved. The SF-36 is a collection of scales assessing mental and physical health. Seven of the 10 scores were similar postoperatively as compared to preoperatively. After adjusting for the aging effect, none of the 10 scores showed a statistically significant overall mean change from baseline.

Revision-Reconstruction Patients: For revision-reconstruction patients, 38 (63%) out of the original 60 patients were included in the analysis of circumferential chest size at 4 years. For these patients, the average increase in circumferential chest size was 3.8 centimeters.

Mentor's patient satisfaction was based on a single question of "Would the patient have this breast surgery again?" At 4 years, 40 (67%) out of 60 revision-reconstruction patients enrolled answered that question. Of these 40 patients, 37 (93%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 4 years for revision-reconstruction patients, no change was observed on the Rosenberg Self-Esteem Scale or Tennessee Self-Concept Scale. For the Body Esteem Scale, after adjusting for the aging effect, no significant changes were observed. The Sexual Attractiveness Subscale of the Body Esteem Scale significantly improved over time. The SF-36 is a collection of scales assessing mental

and physical health. Although most of the 10 scales showed decreases over time, only 2 scores showed statistically significant overall mean change from baseline after adjusting for the aging effect.

3.4. What Were the 4-Year Complication Rates in the Mentor Round Gel Core Study Reconstruction Patients?

The 4-year complication rates are shown from the most common to the least common in Table 1 (reconstruction) and Table 2 (revision-reconstruction) below. The rates reflect the percentage of reconstruction patients who experienced the listed complication at least once within the first 4 years after implantation. Some complications occurred more than once for some patients. The two most common complications experienced by primary reconstruction patients within the first 4 years of implantation were reoperation (31%) and capsular contracture III/IV (10%).

**Table 1. 4-Year Complication Rates for the Mentor Round Gel Core Study Primary Reconstruction Patients
N=251 Patients**

Key Complications	%	95% CI
Reoperation	31.2	25.7, 37.6
Capsular Contracture III/IV	10.1	6.8, 14.9
Implant Removal with Replacement with Study Device	7.9	5.1, 12.1
Implant Removal with Replacement with Unknown Device	1.1	0.3, 4.2
Implant Removal without Replacement	7.8	4.9, 12.4
Infection	6.2	3.8, 10.0
Rupture ¹	0.8	0.1, 5.7
Complications >1%²	%	95% CI
Other (Non-cosmetic) ³	8.3	5.3, 13.0
Asymmetry ⁴	7.6	4.8, 12.0
Ptosis	6.3	3.7, 10.7
Hypertrophic Scarring	6.3	3.9, 10.3
Seroma	4.8	2.8, 8.4
Breast mass	4.1	2.2, 7.9
Wrinkling ⁴	3.1	1.5, 6.6
Breast Pain ⁴	2.2	0.9, 5.1
Recurrent Breast Cancer ⁵	2.2	0.9, 5.3
Nipple Sensation Changes ⁴	2.1	0.9, 5.1
Implant Malposition/Displacement	2.1	0.9, 5.0
Miscarriage	1.9	0.7, 5.1
Metastatic disease	1.8	0.7, 4.7
Capsular Contracture II with Surgical Intervention	1.8	0.7, 4.7
Extrusion (intact)	1.6	0.6, 4.3
New Diagnosis of Breast Cancer	1.4	0.5, 4.4
Hematoma	1.3	0.4, 3.9
New Diagnosis of Rheumatic Disease	1.1	0.3, 4.6

¹ There was 1 patient with a suspected rupture by MRI who died, there were 2 patients with suspected ruptures by MRI that were confirmed to be intact on explant in the reconstruction group at 4 years.

² The following complications occurred at a rate less than 1%: breast sensation changes, burning sensation in nipple, capsular contracture secondary to radiation therapy, deep vein thrombosis, delayed wound healing, distant metastasis (sternum, back, and liver), distortion of breast shape not related to capsular contracture, dog ear scars from mastectomy, external injury not related to breast implant, loss of fullness, loss of inframammary fold, lymphadenopathy, muscle spasms, necrosis, nipple complications, occasional

burning discomfort of skin, rash, redness, skin lesion, stitch abscess, surgical complications related to technique, tight benelli suture, and wide scars.

³ Any complication other than ptosis, hypertrophic scarring, asymmetry, or wrinkling.

⁴ Mild occurrences were excluded.

⁵ The general recurrence rate for breast cancer reported in the medical literature ranges 5 to 25%.^{82, 83, 84}

The two most common complications experienced by patients within the first 3 years of revision-reconstruction surgery were reoperation (33%) and capsular contracture III/IV (20%). Notice that the rates for capsular contracture are higher than for primary reconstruction. (For primary reconstruction, reoperation was 31% and capsular contracture III/IV was 10%.)

Table 2. 4-Year Complication Rates for the Mentor Round Gel Core Study Revision- Reconstruction Patients N=60 Patients

Key Complications	%
Reoperation	32.8
Capsular Contracture III/IV	19.7
Implant Removal with Replacement with Study Device	8.6
Implant Removal with Replacement with Unknown Device	2.3
Implant Removal without Replacement	7.9
Infection	0
Rupture	0
Complications >1% ¹	%
Asymmetry ²	13.2
Ptosis	7.3
Wrinkling ²	6.9
Breast mass	5.2
Implant Malposition/Displacement	5.1
Granuloma	5.0
Surgical Complications Related to Technique	5.1
Nipple Sensation Changes ²	3.9
Breast Pain ²	3.4
Hematoma	3.4
New Diagnosis of Rheumatic Disease	3.4
Symmastia	3.4
Indented Scar	2.4
Pain	2.0

Table 2. Continued on next page

Table 2. (Continued)

Secondary Injury While Moving	1.9
Breast Sensation Changes	1.9
Lack of Definition of Fold	1.9
Nipple Related Unplanned	1.8
Hypertrophic Scarring	1.8
Numbness in Both Hands at Night	1.8
Capsular Contracture II with Surgical Intervention	1.8
Irritated Breast Scars	1.7
Seroma	1.7
Inflammation	1.7
Recurrent Breast Cancer	1.7
New Diagnosis of Breast Cancer	1.7
Delayed Wound Healing	1.7
External Injury Not Related to Breast Implant	1.7
Capsule Tear	1.7
Extrusion (intact)	1.7
Follicular Cyst	1.7

¹ No complications occurred at a rate of <1%.

² Mild occurrences were excluded.

3.5. What Were the Main Reasons for Reoperation in the Mentor Round Gel Core Study Reconstruction Patients?

There may be one or more reasons identified for having a reoperation (additional surgery after the primary or revision breast reconstruction). Furthermore, there may be multiple surgical procedures (for example, implant removal with or without replacement, capsule procedures, incision and drainage, implant reposition, scar revision, etc.) performed during a reoperation. In Mentor's Round Gel Core Study, there were 166 additional surgical procedures performed in 92 reoperations involving 75 primary reconstruction patients.

Table 3 below provides the main reason for each reoperation in primary reconstruction patients following initial implantation that were performed through 4 years. The most common reason for reoperation through 4 years was because of asymmetry (20% of 92 reoperations).

Table 3. Main Reasons for Reoperation in the Mentor Round Gel Core Study Primary Reconstruction Patients through 4 Years

Reason for Reoperation	n	% (of 92 Reoperations)
Asymmetry	18	19.6
Biopsy	13	14.1
Capsular Contracture II, III, IV	14	15.2
Implant Malposition	8	8.7
Patient Request for Style/Size Change	11	12.0
Infection	4	4.3
Scarring/Hypertrophic Scarring	5	5.4
Ptosis (sagging)	3	3.3
Hematoma/Seroma	3	3.3
Breast Cancer	4	4.3
Extrusion of Intact Implant	2	2.2
Delayed Wound Healing	1	1.1
Breast Pain	3	3.3
Implant Palpability/Visibility	1	1.1
Muscle Spasm	1	1.1
Loss of Fullness	1	1.1
Total	92	100

In Mentor's Round Gel Core Study, there were 59 additional surgical procedures performed in 28 reoperations involving 19 revision-reconstruction patients. Table 4 below provides the main reason for each reoperation in revision-reconstruction patients following initial implantation that were performed through 4 years. The most common reason for reoperation through 4 years was because of biopsy (29% of 28 reoperations).

Table 4. Main Reasons for Reoperation in the Mentor Round Gel Core Study Revision – Reconstruction Patients through 4 Years

Reason for Reoperation	n	% (of 28 Reoperations)
Biopsy	8	28.6
Capsular Contracture III/IV	4	14.3
Implant Malposition	2	7.1
Ptosis (sagging)	2	7.1
Hypertrophic Scarring	2	7.1
Suspected Rupture ¹	1	3.6
Asymmetry	1	3.6
Breast Cancer	1	3.6
Extrusion of Intact Implant	1	3.6
Hematoma/Seroma	1	3.6
Patient Request for Style/Size Change	1	3.6
Breast Pain	1	3.6
Wrinkling	1	3.6
Capsular Tear	1	3.6
Palpable Nodule	1	3.6
Total	28	100

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

3.6. What Were the Reasons for Implant Removal in the Mentor Round Gel Core Study Reconstruction Patients?

The main reasons for implant removal among primary reconstruction patients in the Round Gel Core Study over the 4 years are shown in Table 5 below. There were 50 implants removed in 37 patients. Of these 50 implants, 25 (50%) were replaced. The most common reason for implant removal was patient request for style/size change (36% of the 50 implants removed).

Table 5. Main Reasons for Implant Removal in the Mentor Round Gel Core Study Primary Reconstruction Patients through 4 Years

Reasons for Removal	n	% (of 50 Explants)
Patient Request for Style/Size Change	18	36.0
Asymmetry	11	22.0
Capsular Contracture II, III, IV	7	14.0
Implant Malposition	3	6.0
Breast Pain	2	4.0
Extrusion of Intact Implant	2	4.0
Infection	2	4.0
Hematoma	1	2.0
Lack of Projection	1	2.0
Muscle Spasm	1	2.0
Recurrent Breast Cancer	1	2.0
Ptosis	1	2.0
Total	50	100

The main reasons for implant removal among revision-reconstruction patients in the Round Gel Core Study over the 4 years are shown in Table 6 below. There were 13 implants removed in 10 patients. Of these 13 implants, 7 (54%) were replaced. The most common reason for implant removal was capsular contracture III/IV (31% of the 13 implants removed).

Table 6. Main Reasons for Implant Removal for the Mentor Round Gel Core Study Revision-Reconstruction Patients through 4 Years

Reasons for Removal	n	% (of 13 of Explants)
Capsular Contracture III/IV	4	30.8
Asymmetry	2	15.4
Patient Request for Style/Size Change	2	15.4
Symmastia	2	15.4
Breast Pain	1	7.7
Extrusion of Intact Implants	1	7.7
Pocket Tear	1	7.7
Total	13	100

3.7. What Were Other Clinical Data Findings in the Mentor Round Gel Core Study Reconstruction Patients?

Below is a summary of clinical findings from Mentor's Round Gel Core Study with regard to connective tissue disease (CTD), CTD signs and symptoms, cancer, lactation complications, reproduction complications, and

suicide. These issues, along with others, are being further evaluated as part of a Mentor post-approval study involving patients followed through 10 years.

CTD Diagnoses

Two primary reconstruction patients and two revision-reconstruction patients in the Mentor Round Gel Core Study were reported to have a new diagnosis of CTD according to a rheumatologist. These diagnoses were two cases of fibromyalgia, both at 1 year, pyoderma gangrenosum at 1 year, and Morton's Neuroma at 3 years. It cannot be concluded that these CTD diagnoses were caused by the implants because there was no comparison group of similar women without implants.

CTD Signs and Symptoms

In Mentor's Round Gel Core Study, data on over 100 self-reported signs and symptoms, including 50 self-reported rheumatological symptoms, were collected. Compared to before having the implants, a significant increase was found for joint pain and frequent muscle cramps in the primary reconstruction patients, and an increase in combined pain was found in the revision-reconstruction patients. These increases were not found to be related to simply getting older. The Mentor Round Gel Core Study was not designed to evaluate cause and effect associations because there is no comparison group of women without implants, and because other contributing factors, such as medications and lifestyle/exercise, were not studied. Therefore, it cannot be determined whether this increase was due to the implants or not, based on the Round Gel Core Study. However, you should be aware that you may experience an increase in these symptoms after receiving breast implants.

Cancer

For primary reconstruction patients, 3 (1.2%) patients had a new diagnosis of breast cancer and 5 (2.2%) patients had a reoccurrence of breast cancer. For revision-reconstruction, 1 (1.7%) patient had a new diagnosis of breast cancer and 1 (1.7%) patient had a recurrence of breast cancer. There were no reports of other cancers, such as brain, respiratory, or cervical/vulvar.

Lactation Complications

The one (0.4%) primary reconstruction patient who attempted to breastfeed experienced no lactation difficulties. None of the revision-reconstruction patients attempted to breastfeed post-surgery.

Reproduction Complications

For primary reconstruction patients, 4 (1.6%) patients reported a miscarriage. None of the revision-reconstruction patients suffered a miscarriage.

Suicide

There were no reports of suicide in either the primary reconstruction or revision-reconstruction indications in Mentor's Round Gel Core Study through 3 years.

4. Mentor CPG Core Study Results for Reconstruction and Revision-Reconstruction

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

As a note, supplemental safety information was also obtained from the literature to help assess long-term rupture rate and the consequences of rupture for this product. The literature, which had the most available information on the consequences of rupture, was also used to assess other potential complications associated with round silicone gel-filled and CPG implants. The key literature is referenced in this document.

4.1. Overview of the Mentor CPG Core Study

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

The CPG Core Study consists of 955 patients, including 572 primary augmentation patients, 124 revision-augmentation patients, 191 primary reconstruction patients, and 68 revision-reconstruction patients. Of these, 252 primary augmentation patients, 56 revision-augmentation patients, 74 primary reconstruction patients, and 37 revision-reconstruction patients are in the MRI cohort, which means that they are assessed for silent rupture by MRI at years 1, 2, 4, 6, 8, and 10.

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

Mentor's CPG Core Study results indicate that the risk of any complication or reoperation at some point through 3 years after implant surgery is 48% for primary reconstruction patients and 51% for revision-reconstruction patients. The information below provides more details about the complications and benefits you may experience.

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

4.2. What Was the 3-Year Follow-Up Rate in the Mentor CPG Core Study Reconstruction Patients?

At the 3-year follow-up visit, data are reported for 90% of the eligible primary reconstruction patients, and 89% of the eligible revision-reconstruction patients.

4.3. What Were the Benefits for the Mentor CPG Core Study Reconstruction Patients?

The CPG Core Study measured a variety of outcomes that assessed the benefits of the implants. For reconstruction, these outcomes included circumferential chest size, satisfaction, and quality of life (QoL) measures. These outcomes were assessed before implantation and at 1 and 2 years after surgery for those patients who still had their original implants and came back for follow-up visits.

Primary Reconstruction Patients: For primary reconstruction patients, 150 (79%) out of the original 191 patients were included in the analysis of circumferential chest size at 3 years. Of these 150 patients, the average increase in circumferential chest size was 0.3 centimeters, indicating that the chest mound has been restored.

Mentor's satisfaction assessment was based on a single question of "Would the subject make the same decision to have this breast surgery?" At 3 years, 158 (83%) out of 191 primary reconstruction patients enrolled answered that question. For these 158 patients, 148 (94%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 2 years for primary reconstruction patients, no change was observed on Rosenberg Self-Esteem Scale or the overall score of the Body Esteem Scale. The Chest Subscale of the Body Esteem Scale significantly improved. The SF-36 is a collection of scales assessing mental and physical health, and there was significant improvement in the Physical Functioning, Vitality, and Mental Health Scales. The Breast Evaluation Questionnaire (BEQ) is a questionnaire developed to assess breast satisfaction and quality of life outcomes among breast surgery patients. When asked how satisfied she was with the general appearance of her breasts, the large majority of primary reconstruction patients (74.4%) said they "very satisfied or somewhat satisfied." For the three factors of 1) Comfort when not fully dressed, 2) Comfort when fully dressed, and 3) Satisfaction with breast attributes, there was a significant improvement in the primary reconstruction cohort for all three factors from preoperative to 2 years postoperative.

Revision-Reconstruction Patients: For revision-reconstruction patients, 51 (75%) out of the original 68 patients were included in the analysis of circumferential chest size at 3 years. For these patients, the average increase in circumferential chest size was 0.3 centimeters.

Mentor's patient satisfaction was based on a single question of "Would the subject make the same decision to have this breast surgery?" At 3 years, 51 (75%) out of 68 revision-reconstruction patients enrolled answered that question. Of these 51 patients, 48 (94%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 2 years for revision-reconstruction patients, no change was observed on the Rosenberg Self-Esteem Scale, the SF-36, or the overall Body Esteem Scale. However, the Chest Subscale of the Body Esteem Scale significantly improved over time. When asked how satisfied she was with the general appearance of her breasts, the majority of revision-reconstruction patients (60.3%) said they "very satisfied or somewhat satisfied." For the three factors of 1) Comfort when not fully dressed, 2) Comfort when

fully dressed, and 3) Satisfaction with breast attributes, there was a significant improvement in the revision-reconstruction cohort for all three factors from preoperative to 2 years postoperative.

4.4. What Were the 3-year Complication Rates in the Mentor CPG Core Study Reconstruction Patients?

The 3-year complication rates are shown in Table 7 (primary reconstruction) and Table 8 (revision-reconstruction). The rates reflect the percentage of reconstruction patients who experienced the listed complication at least once within the first 3 years after implantation. Some complications occurred more than once for some patients. The two most common complications experienced by primary reconstruction patients within the first 3 years of implantation were reoperation (35%) and implant removal without replacement (8%).

**Table 7. 3-Year Complication Rates for the Mentor CPG Core Study Primary Reconstruction Patients
N=191 Patients**

Key Complications	%
Reoperation	34.6
Capsular Contracture III/IV	6.0
Implant Removal with Replacement with Study Device	6.6
Implant Removal without Replacement	7.9
Infection	2.2
Implant Rotation	3.5
Rupture (MRI Cohort) ¹	0
Other Complications occurring in $\geq 1\%$ of the patients ¹	%
Capsular Contracture III	5.0
Lack of Projection	4.6
Asymmetry ²	4.4
Patient Requested Size Change	3.9
Excess Tissue	3.3
Wrinkling ²	3.3
Ptosis	2.9
Irritation/Inflammation	2.7
Seroma	2.7
Nipple Sensation Changes ²	2.3
Scarring	2.3
Patient Dissatisfied with Aesthetic Appearance of Breast	2.2
Recurrent Breast Cancer	1.7
Breast Pain ²	1.7

Table 7. Continued on next page

Table 7. (Continued)

Mass/Cyst	1.5
New Diagnosis of Rheumatic Disease	1.1
Loss of Definition of Inframammary Fold	1.1
Capsular Contracture II with Surgical Intervention	1.7
Capsular Contracture IV	1.6
Hypertrophic Scarring	1.7
Size Change (Physician Assessment Only)	1.7
Delayed Wound Healing ²	1.0

¹ The following complications occurred at a rate less than 1%: breast mass/cyst not associated with breast implant, breast sensation changes, external injury not related to breast implants, metastatic disease, necrosis, nipple complication, position dissatisfaction, skin blistering, skin lesion, suture complication, swelling (excessive), tightness of skin over implant, wound dehiscence, and wound itching.

² Mild occurrences were excluded.

The two most common complications experienced by patients within the first 3 years of revision-reconstruction surgery were reoperation (24%) and explant without replacement (18%). Notice that the rate for explant without replacement is higher than for primary reconstruction. (For primary reconstruction, the rate for implant removal without replacement was 8%.)

**Table 8. 3-Year Complication Rates for the Mentor CPG Core Study Revision-Reconstruction Patients
N=68 Patients**

Key Complications	%
Reoperation	24.3
Capsular Contracture III/IV	15.9
Implant Removal with Replacement with Study Device	4.4
Implant Removal without Replacement	17.6
Infection	3.0
Implant Rotation	1.5
Rupture (MRI Cohort)	0
Other Complications occurring in $\geq 1\%$ of the patients¹	%
Capsular Contracture III	15.9
Lack of Projection	12.7
Wrinkling ²	9.5
Patient Dissatisfied with Aesthetic Appearance of Breast	6.3
Position Dissatisfaction ²	5.0
Patient Requested Size Change	4.7

Table 8. Continued on next page

Table 8. (Continued)

Seroma	4.6
Asymmetry ²	4.5
Implant Palpability ²	4.2
Ptosis	3.1
Irritation/Inflammation	3.0
Breast Pain	1.9
Metastatic Disease	1.6
Excess Tissue	1.6
Tightness of Skin Over Implant	1.5
Atrophy of Pectoralis Muscle	1.5
Capsular Contracture II with Surgical Intervention	1.5
Hematoma	1.5
Erythema	1.5
Excessive Swelling	1.5
Loss of Definition of Inframammary Fold	1.5
Recurrent Breast Cancer	1.5
Scarring	1.5
Skin Paraesthesia	1.5

¹ No complications occurred at a rate of <1%.

² Mild occurrences were excluded.

4.5. What Were the Main Reasons for Reoperation in the Mentor CPG Core Study Reconstruction Patients?

There may be one or more reasons identified for having a reoperation (additional surgery after the primary or revision breast reconstruction). Furthermore, there may be multiple surgical procedures (for example, implant removal with or without replacement, capsule procedures, incision and drainage, implant reposition, scar revision, etc.) performed during a reoperation. In Mentor's CPG Core Study, there were 126 additional surgical procedures performed in 73 reoperations involving 64 primary reconstruction patients.

Table 9 below provides the main reason for each reoperation in primary reconstruction patients following initial implantation that were performed through 3 years. The most common reason for reoperation through 3 years in primary reconstruction patients was asymmetry (12% of 73 reoperations).

Table 9. Main Reasons for Reoperation in the Mentor CPG Core Study Primary Reconstruction Patients through 3 Years

Reason for Reoperation	n	% (of 73 Reoperations)
Asymmetry	9	12.3
Excess Tissue	7	9.6
Position Dissatisfaction	6	8.2
Scarring	4	5.5
Patient Requested Size Change	4	5.5
Size Change (Physician Assessment Only)	4	5.5
Wrinkling	4	5.5
Lack of Projection	3	4.1
Implant Rotation	3	4.1
Breast Mass/Cyst Not Associated with Breast Implant	2	2.7
Capsular Contracture III	2	2.7
Capsular Contracture IV	2	2.7
Implant Extrusion	2	2.7
Mass/Cyst	2	2.7
Patient Dissatisfied with Aesthetic Appearance of Breast	2	2.7
Recurrent Breast Cancer	2	2.7
Seroma	2	2.7
Capsular Contracture II with Surgical Intervention	1	1.4
Delayed Wound Healing	1	1.4
Infection	1	1.4
Nipple Complication	1	1.4
Skin Lesion	1	1.4
Reason Unknown	8	11.0
Total	73	100

In Mentor's CPG Core Study, there were 48 additional surgical procedures performed in 18 reoperations involving 16 revision-reconstruction patients. Table 10 below provides the main reason for each reoperation in revision-reconstruction patients following initial implantation that were performed through 3 years. The most common reason for reoperation through 3 years was wrinkling (17% each of 18 reoperations).

Table 10. Main Reasons for Reoperation in the Mentor CPG Core Study Revision-Reconstruction Patients through 3 Years

Reason for Reoperation	n	% (of 18 Reoperations)
Wrinkling	3	16.7
Asymmetry	2	11.1
Capsular Contracture III	2	11.1
Patient Requested Size Change	2	11.1
Position Dissatisfaction	2	11.1
Capsular Contracture II with Surgical Intervention	1	5.6
Breast Pain	1	5.6
Lack of Projection	1	5.6
Infection	1	5.6
New Diagnosis of Breast Cancer	1	5.6
Patient Dissatisfied with Aesthetic Appearance of Breast	1	5.6
Seroma	1	5.6
Total	18	100

4.6. What Were the Reasons for Implant Removal in the Mentor CPG Core Study Reconstruction Patients?

The main reasons for implant removal among primary reconstruction patients in the CPG Core Study over the 3 years are shown in Table 11 below. There were 34 implants removed in 26 patients. Of these 34 implants, 12 (35%) were replaced. The most common reasons for implant removal were asymmetry and patient requested size change (18% each of the 34 implants removed).

Table 11. Main Reasons for Implant Removal in the Mentor CPG Core Study Primary Reconstruction Patients through 3 Years

Reason for Removal	n	% (of 34 Explants)
Asymmetry	6	17.6
Patient Dissatisfied with Aesthetic Appearance of Breast	4	11.8
Patient Requested Size Change	6	17.6
Capsular Contracture III/IV	3	8.8
Size Change (Physician Assessment Only)	4	11.8
Lack of Projection	4	11.8
Wrinkling	3	8.8
Implant Extrusion	1	2.9
Infection	1	2.9
Implant Rotation	1	2.9
Reason Unknown	1	2.9
Total	34	100

The main reasons for implant removal among revision-reconstruction patients in the CPG Core Study over the 3 years are shown in Table 12 below. There were 22 implants removed in 14 patients. Of these 22 implants, 4 (18%) were replaced. The most common reasons for implant removal were asymmetry, position dissatisfaction, and wrinkling (18% each of 22 implants removed).

Table 12. Main Reasons for Implant Removal in the Mentor CPG Core Study Revision-Reconstruction Patients through 3 Years

Reason for Removal	n	% (of 34 Explants)
Asymmetry	4	18.2
Wrinkling	4	18.2
Position Dissatisfaction	4	18.2
Patient Request for Size Change	2	9.1
Lack of Projection	2	9.1
Infection	1	4.5
New Diagnosis of Breast Cancer	1	4.5
Seroma	1	4.5
Capsular Contracture II with Surgical Intervention	1	4.5
Breast Pain	1	4.5
Patient Dissatisfied with Aesthetic Appearance of Breast	1	4.5
Total	22	100

4.7. What Were Other Clinical Data Findings in the Mentor CPG Core Study Reconstruction Patients?

Below is a summary of clinical findings from Mentor's CPG Core Study with regard to connective tissue disease (CTD), CTD signs and symptoms, cancer, lactation complications, neurological disease, neurological signs and symptoms, reproduction complications, and suicide. These issues, along with other endpoints, are being further evaluated as part of a Mentor U.S. (Round Gel) post-approval study of patients followed through 10 years.

CTD

Three primary reconstruction patients in the Mentor CPG Core Study were reported to have a new diagnosis of CTD according to a rheumatologist. These diagnoses were 1 case of rheumatoid arthritis at 10 months, 1 case of reactive arthritis at 11 months, and 1 case of other mechanical or degenerative, non-inflammatory rheumatic conditions at 16 months. It cannot be concluded that these CTD diagnoses were caused by the implants because there was no comparison group of similar women without implants.

CTD Signs and Symptoms

In Mentor's CPG Core Study, data on over 100 self-reported signs and symptoms, including 50 self-reported rheumatological symptoms, were collected. Compared to before having the implants, no significant increases were found for any individual signs and symptoms in the primary reconstruction or revision-reconstruction

patients. The Mentor CPG Core Study was not designed to evaluate cause and effect associations because there is no comparison group of women without implants, and because other contributing factors, such as medications and lifestyle/exercise, were not studied. However, you should be aware that you may experience an increase in these symptoms after receiving breast implants.

Cancer

There were no new cases of breast cancer reported in either the primary reconstruction or revision-reconstruction patients. For primary reconstruction patients, 3 (1.6%) patients had a diagnosis recurrent breast cancer and for revision-reconstruction, 1 (1.5%) patient had a diagnosis of recurrent breast cancer. There were no reports of other new cancers, such as brain, respiratory, or cervical/vulvar in either cohort.

Neurological Disease, Signs, and Symptoms

In the Mentor CPG Core Study, data on patient-reported neurological disease and signs and symptoms were collected at each postoperative visit. Examples of neurological symptoms included weakness, numbness of feet, ringing in ears, and fatigue. Investigators also performed a physical exam at each postoperative visit.

Through 3 years, there were no reports of patients with neurological diseases in either indication. Compared to before implantation, no significant increases for neurological signs and symptoms were found in primary reconstruction or revision-reconstruction patients.

Lactation Complications

None of the primary reconstruction patients or revision-reconstruction patients attempted to breastfeed.

Reproduction Complications

There were no reports of miscarriage in either the primary reconstruction or the revision-reconstruction cohorts in Mentor's CPG Core Study through 3 years.

Suicide

There were no reports of suicide in either the primary reconstruction or the revision-reconstruction cohorts in Mentor's CPG Core Study through 3 years.

5. Surgery Considerations for Receiving Breast Implants

This section provides a discussion of surgical considerations for primary breast reconstruction, followed by a discussion of general surgical considerations, and surgical considerations for revision-reconstruction.

5.1. Surgical Considerations for Primary Breast Reconstruction

Your decision to have breast reconstruction is an important personal choice involving both risks and benefits. There are other options for breast reconstruction that do not involve breast implants. Be sure to ask your surgeon for a detailed explanation of each alternative to help you decide which reconstruction option is most suitable for you and your lifestyle. This brochure is intended to provide general information about silicone breast implants and surgery but is not a substitute for a thorough consultation with your surgeon. You are

advised to carefully review and consider all the information you have received before deciding whether to have reconstruction surgery. Prepare a list of questions after reading this brochure and discuss them with your surgeon.

5.1.1. Should You Have Primary 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 should consult your surgeon to discuss your personal goals for breast reconstruction, and you may also 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 reconstructive surgeon, ask your general surgeon for a referral for the names of experienced, board-certified surgeons in your area. Your general surgeon, breast reconstruction surgeon, and oncologist should work together to plan your mastectomy and reconstruction procedure and to advise you based on your specific clinical needs and desired outcome.

5.1.2. What Are the Options in Primary 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.

5.1.3. What Are the Choices in Primary 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.

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 combination of skin, fat, and/or muscle that is moved from your stomach, back, or other area of your body to the chest area, and shaped into a new breast. A tissue flap also may be used to provide skin or other tissue needed to make up for what was removed at the time of surgery or changed following radiation therapy. Your surgeon can help you decide what method of breast reconstruction is most suitable for your particular situation.

Whether or not you have reconstruction with or without breast implants, you will probably undergo additional surgeries to improve symmetry and appearance. These additional surgeries may be part of a several stage reconstruction of the removed breast, or to shape the remaining breast to bring it into better balance with the reconstructed one. Most commonly, breast implants are placed after a space has been created for them using a temporary soft tissue expander that can be placed at the time of mastectomy or at a later time.

Portions of the reconstruction may be done in stages. 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 to obtain a better colour

match. Nipple reconstruction is usually done as a separate outpatient procedure after the initial reconstruction surgery is complete.

5.1.3.1. Breast Reconstruction with Breast Implants

Your surgeon will decide whether your health and medical condition make you an appropriate candidate for breast implant reconstruction. Your surgeon may recommend breast implantation of the opposite, uninvolved breast in order to make them more alike, 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 to lift the nipple and breast location, 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.

5.1.3.2. Reconstruction Incision Sites

In reconstructive surgery, the incision placement and length are decided by your surgeon, and largely influenced by the type of cancer surgery that is planned for you.

5.1.3.3. Surgical Settings and Anesthesia

Reconstruction surgery is usually performed on an inpatient basis in an operating room when it begins at the same time as the mastectomy. Some of the stages, such as nipple reconstruction, or placement of the implant after soft tissue expansion, can be done as an outpatient. General anesthesia is most often used.

5.1.4. The Timing of Your Primary Breast Implant Reconstruction

The following description applies to reconstruction following mastectomy, but similar considerations apply to reconstruction following breast trauma or reconstruction for congenital anomalies. The breast reconstruction process may begin at the time of your mastectomy (immediate reconstruction) or months to years afterwards (delayed reconstruction). This decision is made after consultation with the cancer treatment team based on your individual situation. Immediate reconstruction may involve placement of a breast implant, but typically involves placement of a tissue expander, which is used to recreate skin that was removed during the cancer surgery. The tissue expander 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.

A potential advantage to immediate reconstruction is that your breast reconstruction starts at the time of your mastectomy and that there may be cost savings and potentially fewer days in the hospital for you in combining the mastectomy procedure with the first stage of the reconstruction. However, there may be a higher risk of capsular contracture, implant extrusion, and other complications associated with immediate reconstruction as a result of postoperative radiation and chemotherapy treatments. Your initial operative time and recovery time may also 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 general surgeon, reconstructive surgeon, and oncologist, the pros and cons of the options available in your individual case.

5.1.5. What Is the Primary Breast Implant Reconstruction Procedure?

- One-Stage Immediate Breast Implant Reconstruction

Immediate one-stage breast reconstruction may be done at the time of your mastectomy. After the general surgeon removes your breast tissue, the reconstructive surgeon will then place a breast implant that completes the one-stage reconstruction. In reconstruction following mastectomy, a breast implant is most often placed submuscularly, underneath the muscle of the chest wall.

- Two-Stage (Immediate or Delayed) Breast Implant Reconstruction

Breast reconstruction usually occurs as a two-stage procedure, starting with the placement of a breast tissue expander, which is replaced several months later with a breast implant after enough new skin has been created to obtain the best result. The tissue expander placement may be done immediately, at the time of your mastectomy, or be delayed until months or years later.

Stage 1: Tissue Expansion



Mastectomy Scar



Expander/Implant with remote injection dome

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

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



Tissue expander with integral injection dome



Final result with implant

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

Because the chest skin is usually numb from the mastectomy surgery, it is possible that you may not experience much pain from the placement of the tissue expander or the needle sticks that follow to fill it with saline solution. However, you may experience feelings of pressure, tightness, and discomfort after each filling of the expander. These feelings stop after several days, once the tissue expands, but they may last for a week or more. The tissue expansion process typically lasts 4 to 6 months.

Stage 2: Placing the Breast Implant

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

5.1.6. Primary Breast Reconstruction Without Implants: Tissue Flap Procedures

In some patients, the breast may be reconstructed by surgically moving an area of skin, fat, and muscle from one area of your body to another. The section of tissue may be taken from such areas as your abdomen, upper back, upper hip, or buttocks in order to provide enough tissue to match a large remaining breast, to replace tissue removed or damaged at the time of mastectomy or following radiation therapy.

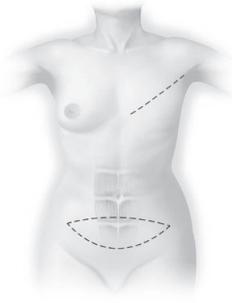
The tissue flap may be left attached to the blood supply and moved to the breast area through a tunnel under the skin (a pedicle flap), or it may be removed completely and reattached to the breast area by microsurgical techniques to reconnect the tiny blood vessels from the flap to vessels on the chest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

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

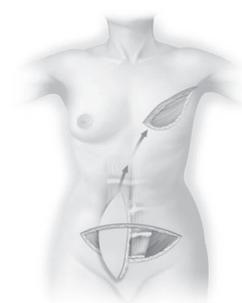
advantage of flap procedures over implantation is that alteration of the unaffected breast is generally not needed to improve symmetry.

The most common types of tissue flaps are the TRAM (transverse rectus abdominus musculocutaneous flap) (which uses tissue from the abdomen) and the latissimus dorsi flap (which uses tissue from the upper back). In most patients the TRAM flap can provide enough tissue to completely rebuild the breast mound, but breast implants are frequently needed to complete the reconstruction for patients having latissimus flaps because there is rarely enough fatty tissue in the flap to completely rebuild the breast mound.

It is important for you to be aware that flap surgery, particularly the TRAM flap, is a major operation, and more extensive than your mastectomy operation. It requires good general health and strong emotional motivation. If you are very overweight, smoke cigarettes, have had previous surgery at the flap site, or have any circulatory problems, you may not be a good candidate for a tissue flap procedure. In addition, if you are very thin, you may not have enough tissue in your abdomen or back to create a breast mound with this method. You should discuss with your surgeon whether you would be a candidate for either of these procedures. There potentially are complications associated with flap procedures that you also should discuss with your surgeon.



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



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



Step 3: Final Result

5.1.6.1. The TRAM Flap (Pedicle or Free)

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

A pedicle TRAM flap procedure typically takes 3 to 6 hours of surgery under general anesthesia; a free TRAM flap procedure generally takes longer. The TRAM procedure may require a blood transfusion. Typically, the hospital stay is 2 to 5 days. You can resume normal daily activity after 6 to 8 weeks. Some women, however, report that it takes up to 1 year to resume a normal lifestyle.

You may have temporary or permanent muscle weakness in the abdominal area. If you are considering pregnancy after your reconstruction, you should discuss this with your surgeon. You will have a large scar on your abdomen and may also have additional scars on your reconstructed breast.

5.1.6.2. The Latissimus Dorsi Flap With or Without Breast Implants

During a latissimus dorsi flap procedure, the surgeon moves a section of tissue from your back to your chest to reconstruct the breast. Because the latissimus dorsi flap is usually thinner and smaller than the TRAM flap, this procedure may be more appropriate for reconstructing a smaller breast. This flap is frequently used when there is not enough skin available to use a soft tissue expander alone, or when there is too much tightness after mastectomy, or when radiation therapy has been used. Latissimus flaps may be combined with soft tissue expanders in a variation of the two-stage breast reconstruction technique.

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

5.2 General Surgical Considerations

5.2.1 Choosing a Surgeon

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

- Has he/she received professional training, including techniques specific to plastic surgery and breast implantation?
- How many breast reconstruction implantation procedures does he/she perform per year?
- How many years has he/she performed breast reconstruction procedures?
- Is he/she board certified, and if so, with which board?
- What is the most common complication he/she encounters with breast reconstruction?
- What is his/her reoperation rate with breast reconstruction, and what is the most common type of reoperation he/she performs?

5.2.2 Implant Shape and Size

Depending on the desired shape you wish to achieve, you and your surgeon have implants with three different round profiles, or styles, from which to choose. Generally, the larger you want your cup size, the larger the breast implant the surgeon will consider (measured in cubic centimeters, or cc's), not in cup sizes, because this depends on the size and shape of the individual woman's chest.

Your surgeon will also evaluate your existing breast and skin tissue to determine if you have enough to cover the breast implant you are considering, or, in some cases such as after pregnancy, too much extra skin. If you desire a breast implant size that is too large for your tissue, the surgeon may warn you that breast

implant edges may be visible or palpable postoperatively. Also, excessively large breast implants may speed up the effects of gravity on the breast and can result in droop or sag at an earlier age. One report indicates that larger sized implants (greater than 350 cc) may be too large for many women, increasing the risk of developing complications such as implant extrusion, hematoma, infection, palpable implant folds, and visible skin wrinkling requiring surgical intervention to correct these complications.⁸⁵

5.2.3 Surface Texturing

Some studies suggest that surface texturing reduces the chance of severe capsular contracture,⁸⁶ while other studies do not.^{87,88} Mentor's Round Gel Core Study did not show a difference in the likelihood of developing capsular contracture with textured implants compared to smooth-surfaced implants. Mentor's CPG implants are only available with a textured surface.

5.2.4 Palpability

Implants may be more palpable or noticeable if there is an insufficient amount of skin/tissue available to cover the implant and/or when the implant is placed subglandularly.

5.2.5 Postoperative Care

Depending on the type of surgery you have (i.e., immediate or delayed), the postoperative recovery period will vary. Possible complications that may occur have been described above. Ask your surgeon to advise you on specific postoperative care instructions.

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

5.2.6 Surgical Considerations for Breast Revision-Reconstruction

You should re-read the section above titled "Surgical Considerations for Primary Breast Reconstruction," as they are applicable to you.

Additional surgery may be considered at any time following original breast reconstruction for correction of complications, such as capsular contracture, infection, hematoma (bleeding), or seroma, or to improve the aesthetic outcome such as implant size/style change or pocket modification. Any device that has been removed during revision surgery should not be reimplanted. Mentor breast implants are "for single use only."

Occasionally, for breast reconstruction patients, temporary removal of the implant may be suggested by the oncologist to facilitate ongoing surveillance for breast cancer recurrence or additional chemotherapeutic or radiation treatment regimens. Effective and sometimes aggressive disease treatment modalities always are a first priority for the patient and their healthcare team. Once the suggested treatment regimen is completed, surgical revision-reconstruction, including implant replacement, can be considered.

5.2.7 What Are the Alternatives to Surgical Revision-Reconstruction?

- Conservative treatment may be tried to improve implant-related concerns such as implant massage to slow progressive capsular contracture or the use of special garments (bras, bandeaus etc.) to improve implant placement.

- Aesthetic outcomes can be accepted as is or improved with undergarment choices, including the use of supplementary padding to correct volume asymmetries.
- In some cases, there is no recommended alternative to surgical revision. For example, complications may require timely surgical revision to prevent a localized complication such as infection from progressing to a systemic health concern. Similarly, an implant that is clinically suspected to be ruptured and is confirmed by MRI, should be removed.

6. Follow-up Examinations

6.1. Breast Self-Examinations

You should perform a breast self-examination monthly. This may be more difficult with an implant in place. In order to do this effectively, you should ask your surgeon to help you tell the difference between the implant and your breast tissue. Care should be taken not to squeeze the implant excessively. Any new lumps may be evaluated with a biopsy, as appropriate. If a biopsy is performed, care must be taken to avoid injuring the implant.

6.2. Screening for Rupture

In consideration of all the available scientific information, it has been suggested that the process for determining implant integrity (e.g. rupture) should be related to clinical signs and symptoms. Thus, the following six-step process is recommended for screening for silicone gel-filled implant rupture:

1. Patient self-examination;
2. New symptom or sign suspected;
3. Physician physical examination, related to a periodic review or new symptoms and signs, suggests findings that warrant further investigation;
4. Ultrasound, mammogram or both of the implant and the breast involved should be acquired;
5. MRI if ultrasound is inconclusive. The MRI should be performed at a center with a breast coil, with a magnet of at least 1.5 Tesla. The MRI should be read by a radiologist who is familiar with looking for implant rupture; and
6. If signs of rupture are seen on ultrasound, mammogram and/or MRI, then in consultation with your plastic surgeon, you may decide to have your implant removed, with or without replacement.

6.3. Mammography

After a complete mastectomy, mammography generally is not required. In patients who have had partial mastectomies, the current recommendations for getting screening/preoperative mammograms are no different for women with breast implants than for those without implants. Mammography exams should be interpreted by radiologists experienced in the evaluation of women with breast implants. It is essential that you tell your mammography technologist that you have an implant before the procedure. You should request a diagnostic mammogram, rather than a screening mammogram, because more pictures are taken with diagnostic mammography. The technologist can use special techniques to reduce the possibility of rupture and to get the best possible views of the breast tissue. More information on mammography is provided in Section 1.4.

7. The Types of Silicone Gel Breast Implants Available from Mentor

Mentor's silicone gel-filled breast implants, referred to as Round MemoryGel and CPG products, come in a variety of profiles and sizes. All currently available Round MemoryGel breast implants have either a textured shell or smooth surface shell. MemoryGel Xtra Breast Implants are available in a smooth shell only.

Mentor's CPG breast implants also come in a variety of profiles and sizes. All currently available CPG breast implants have a textured shell surface shell. Be sure to familiarize yourself with the different features of breast implants and to discuss the best type(s) of implants for you with your surgeon.

8. Product Replacement Policy and Limited Warranties

The following is a description of the assistance available from the Mentor Lifetime Product Replacement Policy and the Mentor Advantage Limited Warranty.

Mentor's Free Lifetime Product Replacement Policy

- Automatically applies to all recipients of Mentor breast implant products.
- Provides that regardless of the age of the implant, when confirmed deflation or rupture occurs, you are eligible for 1 to 2 no charge replacement breast implant products of any size in a similar style.

The **Mentor Advantage** is free of charge to all patients who are implanted with Mentor saline-filled breast or silicone gel-filled implant products. When the limited warranty applies, Mentor provides the following:

- Lifetime product replacement policy*
- 10 years and up to \$1200(CAD) financial assistance for operating room, anesthesia, and surgical charges not covered by insurance**
- Free contralateral (opposite side) implant replacement upon surgeon request
- Non-cancellable terms.

With the Mentor Advantage Warranty, it is important for you to also maintain your own records to ensure validation of your enrolment, as it is possible your surgeon may not retain your records for the entire duration of the limited warranty.

Products Covered

The Mentor Advantage coverage applies to all Mentor breast implants that are implanted in Canada after May 1, 2005[†], provided implants have been:

- Implanted in accordance with the Mentor package insert, current to the date of implantation, and other notifications or instructions published by Mentor; and
- Used by appropriately qualified, licensed surgeons, in accordance with accepted surgical procedures.

Events Covered

The Mentor Advantage coverage applies to the following:

- Deflation due to crease fold failure, patient trauma, or unknown cause
- Loss of valve integrity

- Other loss-of-shell-integrity events also may be covered by this program. Mentor reserves the right to determine if specific, additional, events should be covered.

Events Not Covered

The Mentor Advantage does not apply to the following:

- Removal of intact implants due to capsular contracture, wrinkling, or rippling.
- Loss of implant shell integrity resulting from reoperative procedures, open capsulotomy, or closed compression capsulotomy procedures.
- Removal of intact implants for size alteration.

Filing for Financial Assistance

- To file a Mentor Advantage claim for product replacement and/or financial assistance, the surgeon must contact Mentor Medical Systems Canada prior to replacement surgery.
- For financial assistance claims, a patient-specific Release form will be generated that you must sign and return.
- For either replacement or financial assistance claims, the surgeon must send the explanted, decontaminated Mentor breast implant(s) within six months of the date of explantation (implant removal) to:

Mentor, a unit of Johnson & Johnson Medical Products, a division of Johnson & Johnson Inc.
200 Whitehall Drive
Markham, ON Canada
L3R 0T5

- Upon receipt, review and approval of the completed claim, including receipt of the explanted product and your completion of a full general release, financial assistance will be issued.

* Lifetime Product Replacement Policy: Mentor will provide replacement Mentor product of any size in the same or similar style as the originally implanted product free of charge for the lifetime of the patient. Upon surgeon's request, a different implant style maybe selected (subject to a charge of the difference between product list prices). See the Mentor Advantage Limited Warranty for eligibility and program details

** Operating room and anesthesia charges to be given payment priority. In order to qualify for financial assistance, you will need to sign a Release form.

† For breast implants implanted prior to this date, contact Mentor Worldwide for information regarding any applicable warranty terms.

This is a summary of the coverage of the Mentor Advantage Limited Warranty. It is an overview only and not a complete statement of the program. A copy of the complete Mentor Advantage Limited Warranty for saline-filled and silicone gel-filled breast implants may be obtained by writing or calling:

Mentor, a unit of Johnson & Johnson Medical Products, a division of Johnson & Johnson Inc.
200 Whitehall Drive
Markham, ON
Canada L3R 0T5
1-800-668-6069

A copy of the complete programs may also be obtained from your surgeon or by going to www.mentorwllc.com.

THIS IS A LIMITED WARRANTY ONLY AND IS SUBJECT TO THE TERMS AND CONDITIONS SET FORTH AND EXPLAINED IN THE APPLICABLE MENTOR LIMITED WARRANTIES. ALL OTHER WARRANTIES, WHETHER EXPRESS OR IMPLIED, BY OPERATION OF LAW OR OTHERWISE, INCLUDING BUT NOT LIMITED TO, IMPLIED WARRANTIES OF MERCHANTABILITY AND FITNESS ARE EXCLUDED.

Mentor reserves the right to cancel, change, or modify the terms of the Mentor Advantage coverage. Any such cancellation, change, or modification will not affect the currently stated terms of the Mentor Advantage coverage for those already enrolled.

9. Other Sources of Additional Information

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

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

For additional information or questions about Mentor breast implants, please call 1-800-MENTOR8.

Mentor Worldwide LLC

1-800-525-0245

www.mentorwllc.com

Institute of Medicine Report on the Safety of Silicone Implants

www.nap.edu/catalog/9618.html

Health Canada

http://www.hc-sc.gc.ca/iyh-vsv/med/implants_e.html

You can find important information in the Health Canada “It’s Your Health - Breast Implants” handbook, which is available through the website provided above.

Canadian Society of Plastic Surgeons

<http://www.plasticsurgery.ca>

Breast Reconstruction Resources

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

Canadian Cancer Society

1-416-961-7223

www.cancer.ca

National Cancer Institute of Canada

1-416-961-4223

www.ncic.cancer.ca

Canadian Breast Cancer Network

1-800-685-8820

www.cbcn.ca

ACKNOWLEDGMENT OF INFORMED DECISION

I understand that this patient brochure, "Important Information for Reconstruction Patients About Mentor® MemoryGel® Silicone Gel-Filled Breast Implants and Mentor® MemoryGel® Xtra Silicone Gel-Filled Breast Implants," is intended to provide the information regarding the risks and benefits of silicone gel-filled breast implants, both general and specific to Mentor's MemoryGel products. I understand that silicone breast implant surgery involves risks and benefits, as described in this brochure. I also understand that the long-term (i.e., 10-year) safety and effectiveness of silicone gel-filled breast implants continue to be studied. I understand that reading and fully understanding this brochure is required, but that there also must be consultation with my surgeon.

By circling the correct response and signing below, I acknowledge:

- Y/N** I have had adequate time to read and fully understand the Informed Decision brochure;
- Y/N** I have had an opportunity to ask my surgeon any questions I may have about this brochure or any other issues related to breast implants or breast implant surgery;
- Y/N** I have considered the alternatives to silicone breast implants and have decided to proceed with silicone breast implant surgery;
- Y/N** I have been advised to wait an adequate amount of time after reviewing and considering this information, before scheduling my silicone breast implant surgery, unless an earlier surgery was deemed medically necessary by my surgeon; and
- Y/N** I will retain this brochure, and I am aware that I may also ask my surgeon for a copy of this signed acknowledgment.

PATIENT (PRINT NAME)

SIGNATURE OF PATIENT

DATED: _____

IF PATIENT IS A MINOR:

SIGNATURE OF GUARDIAN

DATED: _____

By my signature below, I acknowledge that:

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

SIGNATURE OF SURGEON

DATED: _____

ACKNOWLEDGMENT OF INFORMED DECISION

I understand that this patient brochure, "Important Information for Reconstruction Patients About Mentor® MemoryGel® Silicone Gel-Filled Breast Implants and Mentor® MemoryGel® Xtra Silicone Gel-Filled Breast Implants," is intended to provide the information regarding the risks and benefits of silicone gel-filled breast implants, both general and specific to Mentor's MemoryGel products. I understand that silicone breast implant surgery involves risks and benefits, as described in this brochure. I also understand that the long-term (i.e., 10-year) safety and effectiveness of silicone gel-filled breast implants continue to be studied. I understand that reading and fully understanding this brochure is required, but that there also must be consultation with my surgeon.

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- Y/N** I have considered the alternatives to silicone breast implants and have decided to proceed with silicone breast implant surgery;
- Y/N** I have been advised to wait an adequate amount of time after reviewing and considering this information, before scheduling my silicone breast implant surgery, unless an earlier surgery was deemed medically necessary by my surgeon; and
- Y/N** I will retain this brochure, and I am aware that I may also ask my surgeon for a copy of this signed acknowledgment.

PATIENT (PRINT NAME)

SIGNATURE OF PATIENT

DATED: _____

IF PATIENT IS A MINOR:

SIGNATURE OF GUARDIAN

DATED: _____

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

SIGNATURE OF SURGEON

DATED: _____

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