MENTOR® MEMORYGEL® AND MENTOR® MEMORYGEL® XTRA SILICONE GEL-FILLED BREAST IMPLANTS

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INTRODUCTION - *DIRECTIONS TO THE PHYSICIAN*

The information supplied in this physician labeling document is intended to provide an overview of essential information about Mentor's MemoryGel® Silicone Gel-Filled Breast Implants and MemoryGel® Xtra Silicone Gel-Filled Breast Implants, including a device description, the indications for use, contraindications, warnings, precautions, important factors to discuss with a patient, adverse events, other reported conditions, a summary of clinical study results, returned devices, product evaluation, medical device reporting, and returned goods authorization.

Patient Counseling Information

You should review this document and patient labeling prior to counseling the patient about Mentor's MemoryGel Silicone Gel-Filled Breast Implants or and MemoryGel Xtra Silicone Gel-Filled Breast Implants and breast implant surgery. Please familiarize yourself with the content of this document and resolve any questions or concerns prior to proceeding with use of the device. As with any surgical procedure, breast implantation is NOT without risks. Breast implantation is an elective procedure, and the patient must be well counselled and understand the risk/benefit relationship.

Before making the decision to proceed with surgery, the surgeon or a designated patient counsellor should instruct the patient to read ***Important Information for Augmentation/Reconstruction Patients About Mentor® MemoryGel® Silicone Gel-Filled Breast Implants and Mentor® MemoryGel® Xtra Silicone Gel-Filled Breast Implants*** (patient labeling) and discuss with the patient the warnings, contraindications, precautions, important factors to consider, complications, Round Gel Core Study results, and all other aspects of the patient labeling. The physician should advise the patient of the potential complications and that medical management of serious complications may include additional surgery and explantation.

Informed Decision

Each patient should receive Mentor's ***Important Information for Augmentation/Reconstruction Patients About Mentor® MemoryGel® Silicone Gel-Filled Breast Implants and Mentor® MemoryGel® Xtra Silicone Gel-Filled Breast Implants*** during her initial visit/consultation, to allow her sufficient time to read and adequately understand the important information on the risks, follow-up recommendations, and benefits associated with silicone gel-filled breast implant surgery.

Allow the patient an adequate amount of time (generally between 1-2 weeks) before deciding whether to have primary breast augmentation surgery. In the case of a revision-augmentation and revision-reconstruction, it may be medically necessary to perform surgery sooner.

In order to document a successful informed decision process, the patient labeling includes an **Acknowledgment of Informed Decision** form at the end of the document, which is to be signed by both the patient and the surgeon and then retained in the patient's file.

DEVICE DESCRIPTION

Mentor MemoryGel Silicone Gel-Filled Breast Implants and Mentor MemoryGel Xtra Silicone Gel-Filled Breast Implants are devices with shells constructed from silicone elastomer. The shell is filled with MemoryGel Mentor's proprietary formulation of silicone gel. The shell is constructed of successive cross-linked layers of silicone elastomer, which give the prosthesis its elasticity and integrity.

There are two styles of shell: smooth and textured. MENTOR MemoryGel Breast Implants are available with a smooth or Siltex textured shell. MENTOR MemoryGel Xtra Breast Implants are available in a smooth shell only. In general, MENTOR MemoryGel Xtra Breast Implants have a higher fill than MENTOR MemoryGel Breast Implants. All implants, MemoryGel and MemoryGel Xtra are provided sterile.

The devices are round shaped.

INDICATIONS

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.
- **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

Patient Groups in which the product is contraindicated:

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

WARNINGS

1. Avoiding Implant Damage During Surgery and Medical Treatment or Procedures

Iatrogenic events inadvertently induced by a physician or surgeon, or by medical treatment or procedures, may contribute to premature implant failure.

- Do not allow sharp instruments, such as scalpels or needles, to contact the device during the implantation or other surgical procedures. Patients should be instructed to inform other treating physicians to observe this warning.
- The technique for inserting a gel device is significantly different than for a saline implant. Ensure that excessive force is not applied to a very small area of the shell during insertion of the device through the incision. Instead, apply force over as large an area of the implant as possible when inserting it. Avoid pushing the device into place with one or two fingers in a localized area, as this may create an area of weakness on the shell.

- An incision should be of appropriate length to accommodate the style, size, and profile of the implant. The incision will be longer than the one typically made for a saline breast augmentation. This will reduce the potential for creating excessive stress to the implant during insertion.

The range, mean, and mode of incision sizes used in Mentor's Round Gel Core Study were as follows:

Cohort	Surgical Approach	Incision Size (cm)		
		Mean	Mode	Maximum
Augmentation	Periareolar	2.7	3.0	3.0
	Inframammary	3.2	3.0	5.0
	Axillary	3.4	3.0	5.0
	Mastectomy Scar	4.0	4.0	4.0
Revision-Augmentation	Periareolar	4.1	3.0	14.0
	Inframammary	3.4	3.0	6.0
	Axillary	4.3	4.0	0
	Mastectomy Scar	7.0	6.0	8.0
Reconstruction	Periareolar	4.0	3.0	6.0
	Inframammary	5.4	3.0	10.0
	Mastectomy Scar	4.7	40	8.0
Revision-Reconstruction	Periareolar	4.0	3.0	6.0
	Inframammary	4.4	4.0	6.0
	Mastectomy Scar	6.3	7.0	9.0

- The anatomical limitations of periareolar and axillary incision sites may make insertion of the implant more difficult, increasing the risk of damage to the implant.
- Avoid creating wrinkles or folds in the device during the implantation or other procedures (e.g., revision surgery). A typical practice is to run your finger around the implant before closing to ensure the implant is lying flat and has no folds or wrinkles. Submuscular placement of the device makes the inspection for wrinkles or folds more difficult.
- Do not treat capsular contracture by closed capsulotomy or forceful external compression, which will likely result in implant damage, rupture, folds, and/or hematoma.
- Use care in subsequent procedures such as open capsulotomy, breast pocket revision, hematoma/seroma aspiration, biopsy, and lumpectomy to avoid damage to the implant shell. Re-positioning of the implant during subsequent procedures should be carefully evaluated by the medical team and care taken to avoid contamination of the implant. Use of excessive force during any subsequent procedure can contribute to localized weakening of the breast implant shell potentially leading to decreased device performance.
- Do not contact the implant with cautery devices.
- Do not immerse the implant in Betadine® solution. If Betadine® is used in the pocket, ensure that it is rinsed thoroughly so no residual solution remains in the pocket.
- Do not alter the implants or attempt to repair or insert a damaged implant.
- Do not re-use or resterilize any product that has been previously implanted. Breast implants are intended for single use only.
- Do not place more than one implant per breast pocket.
- Do not use the periumbilical approach to place the implant.

2. Microwave Diathermy

Do not use microwave diathermy in patients with breast implants, as it has been reported to cause tissue necrosis, skin erosion, and implant extrusion.

PRECAUTIONS

1. Specific Populations

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

- Autoimmune diseases (e.g., lupus and scleroderma).
- Compromised immune system (e.g., currently receiving immunosuppressive therapy).
- Conditions or medications that interfere with wound healing ability (e.g., poorly controlled diabetes, or corticosteroid therapy) or blood clotting (such as concurrent coumadin therapy).
- Reduced blood supply to breast or overlying tissue.
- Radiation to the breast following implantation (undergoing radiation therapy).
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please advise the patient to discuss any history of mental health disorders with you 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.

There may be other patients with complicated medical histories who, in the surgeon's judgment, present risk factors for which breast implant safety and effectiveness have not been established. As with all surgery, you should review your patient's medical history to ensure that she is an appropriate candidate for breast implant surgery.

2. Surgical Precautions

- **Device Integrity** – The device should be tested for patency and shell integrity immediately prior to use. This can be accomplished by gently manipulating the prosthesis with hand and fingers, while carefully examining for rupture or leakage sites.
- **Surgical Technique** –The implantation of silicone gel-filled breast implants involves a variety of surgical techniques. Therefore, the surgeon is advised to use the method which her/his own practice and discretion dictate to be best for the patient, consistent with this product insert data sheet. It is advisable to have more than one size breast implant in the operating room at the time of surgery to allow for flexibility in determining the appropriate size implant to be used. A backup implant should also be available.
- **Implant Selection**
  Some of the important surgical and implant sizing variables that have been identified include the following:
  - ➢ The implant should be consistent in size with the patient's chest wall dimensions, including base width measurements, bearing in mind the laxity of the tissue and the projection of the implant.
  - ➢ A thorough discussion should be conducted with the patient, employing appropriate visual aids such as imaging, sizing implants, or other options to clarify her objectives and reduce the incidence of reoperation for size change.
  - ➢ The following may cause implants to be more palpable: textured implants, larger implants, subglandular placement, and an insufficient amount of skin/tissue available to cover the implant.
  - ➢ Available tissue must provide adequate coverage of the implant.

- One report indicates that larger sized implants (>350 cc) may increase 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.[1]

- **Incision Site Selection**
  - The periareolar site is typically more concealed, but it is associated with a higher likelihood of difficulties in successfully breastfeeding as compared to other incision sites.[2] A periareolar incision may result in changes in nipple sensation.
  - The inframammary incision is generally less concealed than the periareolar, but it is associated with less breast feeding difficulty than the periareolar incision site.[3]
  - The axillary incision is less concealed than the periareolar site.
  - The periumbilical approach has not been studied in Mentor's Round Gel Core Study and should not be used for a wide variety of reasons, including potential damage to the implant shell.

- **Implant Placement Selection**
  - A well-defined, dry pocket of adequate size and symmetry must be created to allow the implant to be placed flat on a smooth surface.
  - Submuscular placement may make surgery last longer, may make recovery longer, may be more painful, and may make it more difficult to perform some reoperation procedures than subglandular placement. The possible benefits of this placement are that it may result in less palpable implants, less likelihood of capsular contracture,[4] and easier imaging of the breast for mammography. Also, submuscular placement may be preferable if the patient has thin or weakened breast tissue.
  - Subglandular placement may make surgery and recovery shorter, may be less painful, and may be easier to access for reoperation than the submuscular placement. However, this placement may result in more palpable implants, greater likelihood of capsular contracture,[5,6] and increased difficulty in imaging the breast with mammography.

- **Maintaining Hemostasis/Avoiding Fluid Accumulation**
  - Careful hemostasis is important to prevent postoperative hematoma formation. Should excessive bleeding persist, implantation of the device should be delayed until bleeding is controlled. Postoperative evacuation of hematoma or seroma must be conducted with care to avoid breast implant contamination, or damage from sharp instruments, retraction, or needles.

- **Recording Procedure**
  - Each breast implant is supplied with two Patient Record Labels showing the catalog number and lot number for that device. Patient Record Labels are located on the internal product packaging attached to the label. To complete the Patient ID Card, adhere one Patient Record Label for each implant on the back of the Patient ID Card. The other label should be affixed to the patient's chart. The implanted position (left or right side) should be indicated on the label. If a Patient Record Label is unavailable, the lot number, catalog number, and description of the device may be copied by hand from the device label. The patient should be provided with the Patient ID Card for personal reference.

- **Postoperative Care**
  - You should advise your patient that she will likely feel tired and sore for several days following the operation, and that her breasts may remain swollen and sensitive to physical contact for a month or

longer. You should also advise her that she may experience a feeling of tightness in the breast area as her skin adjusts to her new breast size. For at least a couple of weeks, the patient should avoid any strenuous activities that could raise her pulse and blood pressure. She should be able to return to work within a few days. Breast massage exercises may also be recommended as appropriate.

INFORMATION FACTORS TO BE DISCUSSED WITH PATIENTS AS PART OF PHYSICIAN CONSULTATION

Breast implantation is an elective procedure and the patient must be thoroughly counselled on the risks, as well as the benefits, of these products and procedures. You should advise your patient that she must read the patient brochures for either augmentation or reconstruction, as applicable. You must read the patient brochures in their entirety. The brochures are intended as the primary means to relate uniform risk and benefit information to assist your patient in making an informed decision about primary breast augmentation and revision-augmentation, or primary reconstruction and revision-reconstruction surgery (as applicable), but are not intended to replace consultation with you. The patient should be advised to wait an adequate amount of time (generally between 1-2 weeks) after reviewing and considering this information, before deciding whether to have this surgery, unless an earlier surgery is deemed medically necessary.

Both you and your patient will be required to sign the "Acknowledgement of Informed Decision" form prior to surgery. The form can be found on the last page of each patient brochure. The form, once signed, acknowledges the patient's full understanding of the information provided in the patient brochure. The form should be retained in the patient's permanent clinical record.

Below are some of the important factors your patients need to be aware of when using silicone gel-filled breast implants. Section 1.4 of the patient brochures provides a more detailed listing of important factors for patients.

Rupture – Rupture of a silicone gel-filled breast implant is most often silent (i.e., there are no symptoms experienced by the patient and no physical sign of changes with the implant) rather than symptomatic.

The following six-step process is recommended for screening for silent 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 you should advise your patient to have her implant removed. You should provide her with a list of MRI facilities in her area that have at least a 1.5 Tesla magnet, a dedicated breast coil, and a radiologist experienced with looking for signs of rupture on breast implant MRI films.

- **Explantation** – Implants are not considered lifetime devices, and patients likely will undergo implant removal(s), with or without replacement, over the course of their life. When implants are explanted without replacement, changes to the patient's breasts may be irreversible. Complication rates are higher following revision surgery (removal with replacement).
- **Reoperation** – Additional surgeries to the patients' breasts and/or implants will likely be required, either because of rupture, other complications, or unacceptable cosmetic outcomes. Patients should be advised that their risk of future complications increases with revision surgery as compared to primary

augmentation or primary reconstruction surgery. There is a risk that implant shell integrity could be compromised inadvertently during reoperation surgery, potentially leading to product failure.

- **Infection** – Signs of acute infection reported in association with breast implants include erythema, tenderness, fluid accumulation, pain, and fever. In rare instances, as with other invasive surgeries, Toxic Shock Syndrome (TSS) has been noted in women after breast implant surgery. It is a life-threatening condition. Symptoms of TSS occur suddenly and include a high fever (102°F, 38.8°C or higher), vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches and drops in blood pressure which may cause fainting. Patients should be instructed to contact a doctor immediately for diagnosis and treatment if they have these symptoms.
- **Breast Examination Techniques** – Patients should perform breast self-examinations monthly and be shown how to distinguish the implant from their breast tissue. The patient should not manipulate or squeeze the implant excessively. The patient should be told that the presence of lumps, persistent pain, swelling, hardening, or change in the implant shape may be signs of symptomatic rupture of the implant. If the patient has any of these signs, they should be told to report them, and possibly have an MRI evaluation to screen for rupture.
- **Mammography** – Patients should be instructed to undergo routine mammography exams as per their primary care physician's recommendations. The importance of having these exams should be emphasized. Patients should be instructed to inform their mammographers about the presence, type, and placement of their implants. Patients should request a diagnostic mammography, rather than a screening mammography, because more pictures are taken with diagnostic mammography. Breast implants may complicate the interpretation of mammographic images by obscuring underlying breast tissue and/or by compressing overlying tissue. Accredited mammography centers, technicians with experience in imaging patients with breast implants, and use of displacement techniques are needed to adequately visualize breast tissue in the implanted breast. The current recommendations for preoperative/screening mammograms are no different for women with breast implants than for those women without implants. Presurgical mammography with a mammogram following the procedure may be performed to establish a baseline for routine future mammography in augmentation patients.
- **Lactation** – Breast implant surgery may interfere with the ability to successfully breastfeed, either by reducing or eliminating milk production.
- **Avoiding Damage During Treatment** – Patients should inform other treating physicians of the presence of implants to minimize the risk of damage to the implants.
- **Smoking** – Smoking may interfere with the healing process.
- **Radiation to the Breast** – Mentor has not tested the in vivo effects of radiation therapy in patients who have breast implants. The literature suggests that radiation therapy may increase the likelihood of capsular contracture, necrosis, and implant extrusion.
- **Mental Health and Elective Surgery** – It is important that all patients seeking to undergo elective, surgery have realistic expectations that focus on improvement rather than perfection. Request that your patient openly discuss with you, prior to surgery, any history that she may have of depression or other mental health disorders.
- **Long-Term Effects** – Mentor will continue its Round Gel Core Study through 10 years. In addition, Mentor has undertaken 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 its Round Gel Core Study and separate Round Gel post-approval study. It is also important for you to relay any new safety information to your patients as it becomes available.

ADVERSE EVENTS

Potential adverse events that may occur with silicone gel-filled breast implant surgery include the following: implant rupture, capsular contracture, reoperation, implant removal, pain, changes in nipple and breast sensation, infection, scarring, asymmetry, wrinkling, implant displacement/migration, implant palpability/visibility, breastfeeding complications, hematoma/seroma, implant extrusion, necrosis, delayed wound healing, breast tissue atrophy/chest wall deformity, calcium deposits, and lymphadenopathy.

Below is a description of these adverse events. For specific adverse event rates/outcomes for Mentor implants, refer to the Mentor Round Gel Core Study sections below.

- **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 patient 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 implants 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 (e.g., during closed capsulotomy; refer to WARNINGS); 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 conclusively known whether these tests have identified all causes of rupture. These laboratory studies are continuing post-approval.

Rupture – Round Gel Core Study

Mentor's Round Gel Core Study enrolled 552 women undergoing breast augmentation for the primary augmentation. Of these women, 202 were enrolled in the MRI sub-study, of which, 115 underwent MRI screening for silent rupture at 4 years following breast implantation. The rupture rate (suspected and confirmed) was 1.8% in primary augmentation patients through 4 years. There were 2 primary augmentation patients in the Round Gel Core Study with suspected implant ruptures detected via MRI that were later determined not to be ruptured, and 1 patient who had suffered a hard fall who was found to have a confirmed rupture when the implant was removed. Of the 145 women enrolled in the revision-augmentation cohort, 56 women were enrolled in the MRI sub-study. Thirty-eight revision-augmentation women underwent MRI screening at 4 years and the rupture rate was 7.3%. Three patients had a suspected ruptured implant that was determined not to be ruptured. One woman had removal of her breast implants after MRI, and both implants were ruptured. The other implant ruptures have not yet been confirmed with removal and examination of the implant.

Mentor's Round Gel Core Study also enrolled 251 women undergoing breast reconstruction for primary reconstruction. Of these women, 134 were enrolled in the MRI sub-study, of which, 97 underwent MRI screening for silent rupture at 4 years breast implantation. The rupture rate was 0.8% in primary reconstruction patients through 4 years. 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. Of the 60 women enrolled in the revision-reconstruction cohort, 28 were enrolled in the revision-reconstruction MRI sub-study. Eighteen revision-reconstruction patients underwent MRI screening at 4 years and the rupture rate was 0%. There were no ruptures in the non-MRI cohorts. The Round Gel Core Study is currently ongoing, with a total of 10 years of follow-up planned to help determine the long-term rupture rate for Mentor implants.

Further information on the estimated incidence rate of rupture for 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 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.[7]

Health Consequences of Rupture

If rupture occurs, silicone gel may either remain within the scar tissue capsule surrounding the implant (intracapsular rupture), move outside the capsule (extracapsular rupture), or gel may move beyond the breast (migrated gel). No confirmed cases of extracapsular rupture of Mentor's Round MemoryGel breast implants were observed in Mentor's Round Gel Core Study, or in a limited, long-term follow-up study from the U.K. (Sharpe & Collis) of Mentor's 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 were extracapsular.[8] Extracapsular ruptures appear largely to be the result of closed capsulotomy (refer to WARNINGS) 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.[9] 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.[10]

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.[11] 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 these women. This type of information pertains to a variety of silicone implants from a variety of manufacturers and implant models, and 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 and/or breakdown

of tissues in direct contact with the gel in a few cases. There have been reports of silicone presence in the liver of patients with silicone breast implants. Movement of silicone gel material to lymph nodes in the axilla also has been reported, even in women without evidence of rupture, leading to lymphadenopathy, as discussed below.[12] 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.[13] 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.[14,15,16,17] A number of epidemiology studies have evaluated large populations of women with breast implants from a variety of manufacturers and implant models. These studies do not, taken together, support an association of breast implants and a diagnosed rheumatic disease. Other than one small study,[18] these studies do not distinguish whether the women had ruptured or intact implants.

The autoantibody status of 64 Danish women who had at least 1 ruptured implant according to MRI evaluation was compared to 98 Danish women who had intact implants.[19] 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 2 years prior to this evaluation no longer had measurable levels at the subsequent examination.

When MRI findings of rupture are found (such as subcapsular lines, characteristic folded wavy lines, teardrop sign, keyhole sign, noose sign), or if there are signs or symptoms of rupture, you should remove the implant and any gel you determine your patient has, 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 your patient has symptoms, such as breast hardness, a change in breast shape or size, and/or breast pain, you should recommend that she has an MRI to determine whether rupture is present.[20,21]

- **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 patients undergoing revision surgery than in patients undergoing primary implantation surgery. Capsular contracture is a risk factor for implant rupture, and it is one of the most common reasons for reoperation in augmentation and 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 four 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, the risk of capsular contracture Baker Grades III/IV through 4 years was 9% for primary augmentation, 20% for revision-augmentation, 10% for primary reconstruction, and 20% for revision-reconstruction.

Patients should also be advised that 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 breast tissue. Capsular contracture may happen again after these additional surgeries. Capsular contracture may increase the risk of rupture.[3]

- **Reoperation**

The patient should assume that she will need to have additional surgeries (reoperations). Patients may decide to change the size or type of their implants, requiring a reoperation, or they may have a reoperation to improve or correct their outcome.

Reoperation – Round Gel Core Study

The risk rate of reoperation at least 1 time through 4 years was 16% for primary augmentation, 28% for revision-augmentation, 31% for primary reconstruction, and 33% for revision-reconstruction. Problems, such as, but not limited to, rupture, capsular contracture, hypertrophic scarring (irregular, raised scar), asymmetry, infection, and shifting can require additional surgery. Summary tables are provided in the Mentor Round Gel Core Study section that describes the reasons for reoperation during the first 4 years after receiving the implants.

- **Implant Removal**

Implant Removal – Round Gel Core Study

For women receiving primary augmentation implants in Mentor's Round Gel Core Study, 5% had their implants removed at least once through 4 years. For women receiving revision-augmentation implants in Mentor's Round Gel Core Study, 13% had their implants removed at least once through 4 years. The most common reasons for implant removal were patient request for style/size change and severe capsular contracture.

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 for implant removal was severe capsular contracture.

Most women who have their implants removed, have them replaced with new implants, but some women do not. If patients choose not to replace their implants, they should be advised that they may have cosmetically unacceptable dimpling, puckering, wrinkling, and/or other potentially permanent cosmetic changes of the breast following removal of the implant. Even if a patient has her implants replaced, implant removal may result in loss of breast tissue. Also, implant replacement increases a patient's risk of future complications. For example, the risks of severe capsular contracture double for both augmentation and reconstruction patients with implant replacement compared to first time placement. Patients should consider the possibility of having her implants replaced and its consequences when making their decision to have implants.

- **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. The surgeon should instruct his or her patients to inform them if there is significant pain or if pain persists.

- **Changes in Nipple and Breast Sensation**

Feeling in the nipple and breast can increase or decrease after implant surgery and 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. The range of changes varies from intense sensitivity to no feeling in the nipple or breast following surgery. While some of these changes can be temporary, they can also be permanent, and may affect the patient's sexual response or ability to nurse.

- **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. As with many other surgical procedures, in rare instances, Toxic Shock Syndrome (TSS) has been noted in women after breast implant surgery. It is a life-threatening condition. Symptoms of TSS occur suddenly and include a high fever (102°F, 38.8°C or higher), vomiting, diarrhea, a sunburn-like rash, red eyes, dizziness, lightheadedness, muscle aches and drops in blood pressure which may cause fainting. Patients should be instructed to contact a doctor immediately for diagnosis and treatment if they have these symptoms.

- **Hematoma/Seroma**

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

- **Unsatisfactory Results**

Unsatisfactory results such as wrinkling, asymmetry, implant displacement/migration, incorrect size, implant palpability/visibility, 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. Careful preoperative planning and surgical technique can minimize, but not always prevent, unsatisfactory results.

- **Breastfeeding Complications**

Breastfeeding difficulties have been reported following breast surgery, including breast reduction and breast augmentation. If you use a periareolar surgical approach, it may further increase the chance of breastfeeding difficulties.

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

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

- **Extrusion**

Extrusion may occur when the wound has not closed or when breast tissue covering the 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 breast tissue.

- **Necrosis**

Necrosis may prevent or delay wound healing and require surgical correction, which may result in additional scarring and/or loss of 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. Smoking may interfere with the healing process. 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.

- **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**

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-filled implants had abnormal tissue reactions, granulomas, and the presence of silicone.[22] 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. 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.

- **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.[23,24,25,26,27,28,29,30,31,32] 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.[33,34,35,36] 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.[37]

- **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 gel-filled breast implants.[38,39,40,41,42] Having these rheumatological signs and symptoms does not necessarily mean that a patient has a connective tissue disease; however, you should advise your patient that she may experience these signs and symptoms after undergoing breast implantation. If a patient has an increase in these signs or symptoms, you should refer your patient to 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.[43,44,45,46,47] 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.[48,49,50,51,52]

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 four 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.

Lymphomas, including anaplastic large T-cell lymphoma (ALCL) – Based on information reported to global regulatory agencies and found in medical literature, an association has been identified between breast implants and the development of anaplastic large cell lymphoma (ALCL), a type of non-Hodgkin's lymphoma. Women with breast implants have a very small but increased risk of developing Breast Implant Associated ALCL (BIA-ALCL) in the fluid or scar capsule adjacent to the implant, with documented potential for local, regional, and distant spread of the cancer with mortality reported in rare cases.

BIA-ALCL has been reported globally in patients with an implant history that includes Mentor's and other manufacturers' breast implants with various surface properties, styles, and shapes. Most of the cases in the literature reports describe a history of the use of textured implants. 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.[61,62,63]

You should consider the possibility of BIA-ALCL when a patient presents with late onset, persistent peri-implant seroma. In some cases, patients presented with capsular contracture or masses adjacent to the breast implant. When testing for BIA-ALCL, collect fresh seroma fluid and representative portions of the capsule, and send to a laboratory with appropriate expertise for pathology tests to rule out ALCL, including immunohistochemistry testing for CD30 and ALK (anaplastic lymphoma kinase). If your patient is diagnosed with peri-implant BIA-ALCL, develop an individualized treatment plan in coordination with a multidisciplinary care team. Because of the small number of cases worldwide, there is no worldwide consensus on the treatment regimen for peri-implant BIA-ALCL. However, the National Comprehensive Cancer Network (NCCN) recommends surgical treatment that includes implant removal and complete capsulectomy ipsilaterally as well as contralaterally, where applicable.

Other cancers – One study has reported an increased incidence of stomach cancer and leukemia in women with breast implants compared to the general population.[64] 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.[65]

- **Suicide**

In several studies, a higher incidence of suicide was observed in women with breast implants.[66,67,68,69] The reason for the observed increase is unknown, but it was found that women with breast implants had higher rates of hospital admission due to psychiatric causes prior to surgery, as compared with women who had breast reduction or in the general population of Danish women.[70]

- **Effects on Children**

At this time, it is not known if a small amount of silicone may pass through from the breast implant silicone shell into breast milk during breastfeeding. Although there are no current established methods for accurately detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone gel-filled breast implants when compared to women without implants.[71]

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.[72,73] Although low birth weight was reported in a third study, other factors (for example, lower pre-pregnancy weight) may explain this finding.[74] This author recommended further research on infant health.

- **Potential Health Consequences of Gel Bleed**

Small quantities of low molecular weight (LMW) silicone compounds, as well as platinum (in zero oxidation state), have been found to diffuse ("bleed") through an intact implant shell.[75,76] Studies on implants implanted for a long duration have suggested that such bleed may be a contributing factor in the development of capsular contracture[77] and lymphadenopathy.[78] 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.[79] 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. The test method was developed to represent, as closely as possible, conditions in the body surrounding an intact implant. The results indicate that only the LMW silicones D4, D5, and D6, and platinum, bled into the serum in measurable quantities. In total, 4.7 micrograms of these three LMW silicones was detected: Platinum levels measured at 4.1 micrograms by 60 days, by which time an equilibrium level was reached and no more platinum was extracted from the device. Over 99% of the LMW silicones and platinum stayed in the implant. The overall body of available evidence supports that the extremely low level of gel bleed is of no clinical consequence.

MENTOR ROUND GEL CORE STUDY

The safety and effectiveness of Mentor's silicone gel-filled implants were evaluated in an open-label multicenter clinical study, referred to as the Round Gel Core Study.

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 in this document.

Mentor's Round Gel Core Study results indicate that the risk of any complication (including reoperation) at some point through 4 years after implant surgery is 39% for primary augmentation patients, 50% for revision-augmentation patients, 52% for primary reconstruction patients, and 55% for revision-reconstruction patients.

The information below provides more details about the complications and benefits your patients may experience. The results of the Mentor Round Gel Core Study are discussed below.

Study Design:

The Round Gel Core Study is a 10-year study to assess safety and effectiveness in augmentation, reconstruction, and revision (augmentation and reconstruction) patients. The Round Gel Core Study consisted of 1,008 patients, including 552 primary augmentation patients, 145 revision-augmentation patients, 251 primary reconstruction patients, and 60 revision-reconstruction patients. Patients' medical histories were collected at baseline. Patient follow-up is at 6 months and annually through 10 years. MRI scans to detect silent rupture of the implant for a subset of patients are scheduled at 1, 2, 4, 6, 8, and 10 years. Safety assessments include complication rates and rates of reoperation. Effectiveness assessments include bra cup size change (primary augmentation patients only), circumferential chest size change, patient satisfaction, and assessments of quality of life (QoL). The results through 4 years are currently being reported, and the study is currently ongoing. Mentor will periodically update this labelling as more information becomes available.

Patient Accounting and Baseline Demographic Profile:

The Round Gel Core Study consisted of 1,008 patients, including 552 primary augmentation patients, 145 revision-augmentation patients, 251 primary reconstruction patients, and 60 revision-reconstruction patients. Of these, 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. At this time, MRIs have been performed at years 1, 2 and 4, and the follow-up rates for the MRI cohort ranged from 58% to 76% at the 4-year time point across indications. However, as a whole, data are available through 4 years post implantation for 80% of the eligible augmentation patients, 79% of the eligible revision-augmentation patients, 87% of the eligible reconstruction patients, and 77% of the revision-reconstruction patients.

Demographic information for the Round Gel Core Study with regard to race is as follows: 90% of the Round Gel Core Study patients were Caucasian, 2% were Asian, 2% were African American, and 6% were other. The mean age at surgery was 35 years for primary augmentation patients, 42 for revision-augmentation patients, 45 years for primary reconstruction patients, and 51 years for revision-reconstruction patients. Most of the Round Gel Core Study patients were married (56% of the primary augmentation patients, 60% for revision-augmentation, 69% of the primary reconstruction patients, and 66% of the revision-reconstruction patients). Approximately 82% had some college education.

With respect to surgical baseline factors in the Round Gel Core Study, for primary augmentation and revision-augmentation patients, the most frequently used devices were smooth surface implants, the most common incision site was inframammary, and the most frequent site of placement was submuscular. With regard to primary reconstruction patients, the most frequently used devices were textured surface implants, the most common incision site was the mastectomy scar, and submuscular placement was the site of placement. For revision-reconstruction patients, the most frequently used devices were smooth surface implants, the most common incision site was mastectomy scar, and the most frequent site of placement was submuscular.

Round Gel Core Effectiveness Outcomes:

Effectiveness was assessed by bra cup (primary augmentation patients only), circumferential chest size measurements, patient satisfaction, and quality of life (QoL). Mentor's patient satisfaction was based on a single question of "Would the patient have this breast surgery again?" The QoL measures were the Rosenberg Self-Esteem Scale, the Body Esteem Scale, the Tennessee Self-Concept Scale (TSCS), the SF-36, and the Functional Living Index of Cancer.

Primary Augmentation Patients: For primary augmentation patients, 368 (67%) out of the original 552 patients were included in the analysis of cup size at 4 years. Of these 368 patients, 363 (99%) experienced at least 1 cup size increase. The average increase in circumferential chest size was 7.1 centimeters.

At 4 years, 394 (71%) of the 552 primary augmentation patients enrolled answered that question. Of these 394 patients, 385 (98%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 4 years, an increase in self-esteem was noted for patients after primary breast augmentation on the Rosenberg Self-Esteem Scale. There was an improvement in the overall score of the Body Esteem Scale and the Sexual Attractiveness Subscale, and the Chest Score of the Body Esteem Scale also increased. The SF-36 is a collection of scales assessing mental and physical health, and there was no improvement in the SF-36 after primary augmentation. The Tennessee Self Concept Scale (TSCS) is a survey completed by the patient that evaluates how the patient sees herself and what she does, likes, and feels. There was no change in the overall score for the TSCS.

Revision-Augmentation Patients: For revision-augmentation patients, 97 (67%) out of the original 145 patients were included in the analysis of circumferential chest size at 4 years. For these 97 patients, the average increase in circumferential chest size was 2.6 centimeters.

At 4 years, 97 (67%) of the 145 revision-augmentation patients enrolled answered that question. Of these 97 patients, 93 (96%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 4 years, no change in self-esteem was noted following revision augmentation surgery on the Rosenberg Self-Esteem Scale or the Body Esteem Scale, but the Chest Score of the Body Esteem Scale was significantly improved. The SF-36 is a collection of scales assessing mental and physical health, and there was no improvement in SF-36. The Tennessee Self Concept Scale (TSCS) is a survey completed by the patient that evaluate show the patient sees herself and what she does, likes, and feels. There was no change in the overall TSCS score.

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.

At 4 years, 189 (75%) of the 251 patients enrolled answered the patient satisfaction 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.

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 on the 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.

Safety Outcomes – Complications:

Mentor's 10-year Round Gel Core Study of 1,008 patients is continuing. All patients available for follow-up have been evaluated at the 4-year timepoint. Complications from this study are provided in Tables 1a-1d below. Note: Complications are defined as adverse events occurring in connection with the breast implant surgery, breast implants and/or the breast mound, and systemic diseases.

Table 1a. Round Gel Core Study: 4-Year Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Primary Augmentation Cohort
N=552

Key Complications	%	CI
Reoperation	16.0	13.2, 19.4
Capsular Contracture Baker Grade III/IV	8.8	6.7, 11.6
Implant Removal with Replacement with Study Device	2.8	1.7, 4.6
Implant Removal with Replacement with Unknown Device	0	–
Implant Removal without Replacement	2.4	1.3, 4.1
Infection	1.5	0.7, 2.9
Rupture[1]	1.8	0.6, 5.5
Complications > 1%[2]	**%**	**CI**
Nipple Complications[3]	12.0	9.5, 15.1
Hypertrophic Scarring	6.8	5.0, 9.3

Table 1a. *Continued on next page*

Table 1a. *(Continued)*

Other (Non-cosmetic)[4]	5.8	4.0, 8.3
Breast Mass	4.0	2.6, 6.1
Ptosis	3.0	1.8, 4.9
Breast Sensation Changes[3]	2.6	1.6, 4.4
Hematoma	2.5	1.5, 4.3
Breast Pain[3]	1.9	1.0, 3.5
Miscarriage	1.7	0.9, 3.3
Capsular Contracture Baker Grade II with Surgical Intervention	1.1	0.5, 2.4
External Injury Not Related to Breast Implants	1.0	0.4, 2.3

[1] There were 2 patients with suspected ruptures by MRI that were later determined to be no ruptures, and 1 patient who had suffered a hard fall with a confirmed rupture at explant in the augmentation group at 4 years.

[2] The following complications occurred at a rate less than 1%: asymmetry, breast lesion, car accident with seat belts tender and burning, creasing of implants with palpable fold points, deep vein thrombosis, distortion of breast not related to capsular contraction, ecchymosis, excessive implant movements, excessive implant movement with muscle flexion, explanted due to right side being removed, fibrocystic changes, granuloma, implant malposition/displacement, implant palpability, implant riding high, inadequate milk supply, inflammation, inframammary fold too high, lactation difficulties, Mondor's disease, necrosis, new diagnosis of rheumatic disease, placement damage, positive nuclear antibodies negative for lupus, rash, right Montgomery gland infection, rippling, seroma, stillborn birth, suture reaction, thin spot in muscle wall, and wrinkling.

[3] Mild occurrences were excluded.

[4] Any complication other than ptosis, hypertrophic scarring, asymmetry, or wrinkling.

Table 1b. Round Gel Core Study: 4-Year Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Revision-Augmentation Cohort

N=145 Patients

Key Complications	%	CI
Reoperation	28.4	21.7, 36.7
Capsular Contracture Baker Grade III/IV	19.9	14.2, 27.6
Rupture[1]	7.3	2.8, 18.3
Implant Removal with Replacement with Study Device	8.2	4.6, 14.4
Implant Removal with Replacement with Unknown Device	0.9	0.1, 6.2
Implant Removal without Replacement	5.0	2.4, 10.3
Infection	1.4	0.4, 5.6
Complications > 1%[2]	**%**	**CI**
Nipple Complications[3]	12.3	7.8, 19.1
Hypertrophic Scarring	8.6	5.0, 14.7
Breast Mass	7.2	3.9, 13.0
Other (Non-cosmetic)[4]	6.9	3.0, 11.5

Table 1b. *Continued on next page*

Table 1b. *(Continued)*

Capsular Contracture Baker Grade II with Surgical Intervention	5.1	2.5, 10.5
Miscarriage	2.9	0.9, 8.9
Hematoma	2.8	1.1, 7.2
Ptosis	2.3	0.7, 6.9
Breast Sensation Changes[3]	2.1	0.7, 6.4
Seroma	2.1	0.7, 6.3
Delayed Wound Healing	2.1	0.7, 6.3
Breast Pain[3]	2.1	0.7, 6.5
Wrinkling	1.4	0.4, 5.5
Inflammation	1.4	0.4, 5.5
Implant Malposition	1.4	0.4, 5.4
Extrusion (intact)	1.4	0.4, 5.5

[1] Three patients had a suspected rupture determined to be no rupture and 1 patient had a bilateral rupture confirmed at explant.

[2] The following complications occurred at a rate less than 1%: back and neck pain related to large implants, external injury not related to breast implant, lactation difficulties, muscle spasm, new diagnosis of rheumatic disease, palpability, shape change, siliconoma, skin lesion, surgical removal of ectopic pregnancy.

[3] Mild occurrences were excluded.

[4] Any complication other than ptosis, hypertrophic scarring, asymmetry, or wrinkling.

Table 1c. Round Gel Core Study: 4-Year Cumulative First Occurrence Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Primary Reconstruction Cohort

N=251 Patients

Key Complications	%	95% CI
Reoperation	31.2	25.7, 37.6
Capsular Contracture Baker Grade 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

Table 1c. *Continued on next page*

Table 1c. *(Continued)*

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 from 5 to 25%.[80,81,82]

Table 1d. Round Gel Core Study: 4-Year Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Revision-Reconstruction Cohort

N=60 Patients

Key Complications	%	95% CI
Reoperation	32.8	22.2, 46.7
Capsular Contracture III/IV	19.7	11.4, 32.9
Implant Removal with Replacement with Study Device	8.6	3.7, 19.4
Implant Removal with Replacement with Unknown Device	2.3	0.3, 15.4
Implant Removal without Replacement	7.9	2.9, 20.2
Infection	0	–
Rupture	0	–

Table 1d. *Continued on next page*

Table 1d. *(Continued)*

Complications > 1%[1]	%	95% CI
Asymmetry[2]	13.2	6.4, 26.1
Ptosis	7.3	2.8, 18.5
Wrinkling[2]	6.9	2.6, 17.3
Breast Mass	5.2	1.7, 15.3
Implant Malposition/Displacement	5.1	1.7, 15.0
Granuloma	5.0	1.6, 14.7
Surgical Complications Related to Technique	5.1	1.7, 15.1
Nipple Sensation Changes[2]	3.9	1.0, 14.9
Breast Pain[2]	3.4	0.9, 12.9
Hematoma	3.4	0.9, 13.0
New Diagnosis of Rheumatic Disease	3.4	0.9, 12.9
Symmastia	3.4	0.9, 12.8
Indented Scar	2.4	0.4, 16.1
Pain	2.0	0.3, 13.6
Secondary Injury While Moving	1.9	0.3, 12.7
Breast Sensation Changes	1.9	0.3, 12.4
Lack of Definition of Fold	1.9	0.3, 12.4
Nipple Related Unplanned	1.8	0.3, 11.8
Hypertrophic Scarring	1.8	0.3, 11.8
Numbness in Both Hands at Night	1.8	0.3, 11.8
Capsular Contracture II with Surgical Intervention	1.8	0.3, 11.8
Irritated Breast Scars	1.7	0.2, 11.3
Seroma	1.7	0.2, 11.3
Inflammation	1.7	0.2, 11.4
Recurrent Breast Cancer	1.7	0.2, 11.4
New Diagnosis of Breast Cancer	1.7	0.2, 11.4
Delayed Wound Healing	1.7	0.2, 11.3
External Injury Not Related to Breast Implant	1.7	0.2, 11.3
Capsule Tear	1.7	0.2, 11.3
Extrusion (intact)	1.7	0.2, 11.3
Follicular Cyst	1.7	0.2, 11.4

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

[2] Mild occurrences were excluded.

Safety Outcomes – Main Reasons for Reoperation:

This section includes the main reasons for reoperation. The rates exclude planned secondary surgeries and reoperations. If more than one reason for the reoperation was reported, the hierarchy used was: rupture/deflation; infection; capsular contracture; necrosis/extrusion; hematoma/seroma; delayed wound healing; breast pain; implant malposition; wrinkling; palpability/visibility; asymmetry; ptosis; scarring; nipple complications; device injury/iatrogenic; breast cancer mass; biopsy; and patient request for style/size change.

Of the 552 primary augmentation patients, there were 86 (16%) who underwent 181 surgical procedures in 113 reoperations over the 4 years of follow-up in the Round Gel Core Study. The most common reason for reoperation through 4 years was because of capsular contracture Baker Grade II/III/IV (36% of 113 reoperations). Table 2a below provides the main reason for each reoperation following initial implantation that was performed through 4 years for primary augmentation patients.

Table 2a. Main Reasons for Reoperation through 4-Years for Primary Augmentation Cohort

Reason for Reoperation	n	% (of 113 Reoperations)
Capsular Contracture Baker Grade II/III/IV	41	36.3
Patient Request for Style/Size Change	15	13.3
Hematoma/Seroma	12	10.6
Scarring/Hypertrophic Scarring	12	10.6
Biopsy	9	8.0
Asymmetry	6	5.3
Ptosis (sagging)	4	3.5
Infection	3	2.7
Wrinkling	3	2.7
Delayed Wound Healing	2	1.8
Implant Malposition	2	1.8
Breast Pain	1	0.9
Extrusion of Intact Implant	1	0.9
Necrosis	1	0.9
Suspected Rupture[1]	1	0.9
Total	113	100

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

There were 110 additional surgical procedures performed in 60 reoperations involving 40 revision-augmentation patients. The most common reason for reoperation through 4 years was capsular contracture Baker Grade II/III/IV (40% of the 60 reoperations). Table 2b below provides the main reason for each reoperation following initial implantation that was performed through 4 years for revision-augmentation patients.

Table 2b. Main Reasons for Reoperation through 4 Years for Revision-Augmentation Cohort

Reason for Reoperation	n	% (of 60 Reoperations)
Capsular Contracture Baker Grade II/III/IV	24	40.0
Patient Request for Style/Size Change	6	10.0
Biopsy	6	10.0
Hematoma/Seroma	5	8.4
Delayed Wound Healing	4	6.7
Scarring/Hypertrophic Scarring	3	5.0
Extrusion of Intact Implant	2	3.3
Implant Malposition	2	3.3
Asymmetry	2	3.3
Ptosis (sagging)	1	1.7
Infection	1	1.7
Wrinkling	1	1.7
Irritation/Inflammation	1	1.7
Rupture	1	1.7
Suspected Rupture[1]	1	1.7
Total	60	100

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

There were 166 additional surgical procedures performed in 92 reoperations involving 75 primary reconstruction patients. The most common reason for reoperation through 4 years was because of asymmetry (20% of 92 reoperations). Table 2c below provides the main reasons for the reoperations following initial implantation that were performed through 4 years for primary reconstruction patients.

Table 2c. Main Reasons for Reoperation through 4 Years for Primary Reconstruction Cohort

Reason for Reoperation	n	% (of 92 Reoperations)
Asymmetry	18	19.6
Biopsy	13	14.1
Capsular Contracture Baker Grade 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

Table 2c. *Continued on next page*

Table 2c. *(Continued)*

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

There were 59 additional surgical procedures performed in 28 reoperations involving 19 revision-reconstruction patients. The most common reason for reoperation through 4 years was because of biopsy (29% of 28 reoperations). Table 2d below provides the main reason for each reoperation following initial implantation that was performed through 4 years for revision-reconstruction patients.

Table 2d. Main Reasons for Reoperation through 4 Years for Revision-Reconstruction Cohort

Reason for Reoperation	n	% (of 28 Reoperations)
Biopsy	8	28.6
Capsular Contracture Baker Grade 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).

Safety Outcomes – Reasons for Implant Removal:

The main reasons for implant removal among primary augmentation patients in the Round Gel Core Study over the 4 years are shown in Table 3a below. Of the 552 primary augmentation patients, there were 26 patients (5%) who had 45 implants removed over the 4 years of follow-up. Of the 45 primary augmentation implants removed, 24 implants (53%) were replaced. The most common reason for implant removal was patient request (60% of the 45 implants removed) for primary augmentation patients.

Table 3a. Main Reasons for Implant Removal through 4 Years for Primary Augmentation Cohort

Reason for Removal	n	% (of 45 Reoperations)
Patient Request for Style/Size Change	27	60.0
Capsular Contracture Baker Grade III/IV	7	15.6
Breast Pain	2	4.4
Infection	2	4.4
Necrosis	2	4.4
Patient Request for Size Change	2	4.4
Suspected Rupture[1]	1	2.2
Contralateral Explantation	1	2.2
Wrinkling	1	2.2
Total	45	100

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

The main reasons for implant removal among revision-augmentation patients in the Round Gel Core Study over the 4 years are shown in Table 3b below. Of the 145 revision-augmentation patients, there were 19 patients (13%) who had 33 implants removed over the 4 years of follow-up in the Round Gel Core Study. Of the 33 implants removed, 18 (55%) were replaced. The most common reason for implant removal was patient request (36% of the 33 implants removed) for revision-augmentation patients.

Table 3b. Main Reasons for Implant Removal through 4 Years for Revision-Augmentation Cohort

Reason for Removal	n	% (of 28 Reoperations)
Patient Request for Style/Size Change	12	36.4
Capsular Contracture Baker Grade III/IV	11	33.3
Rupture	2	6.1
Breast Mass	1	3.0
Explant to Match Other Side	1	3.0
Asymmetry	1	3.0
Capsular Contracture Baker Grade II	1	3.0
Extrusion of Intact Implant	1	3.0
Scarring/Hypertrophic Scarring	1	3.0
Infection	1	3.0
Suspected Rupture[1]	1	3.0
Total	33	100

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

The main reasons for implant removal among primary reconstruction patients in the Round Gel Core Study over the 4 years are shown in Table 3c below. Of the 251 primary reconstruction patients, there were 37 patients (15%) who had 50 implants removed over the 4 years of follow-up in the Round Gel Core Study. Of the 50 primary reconstruction implants removed, 25 (50%) were replaced. The most common reason for implant removal was patient request for style/size change (36% of the 50 implants removed) for primary reconstruction patients.

Table 3c. Main Reasons for Implant Removal through 4 Years for Primary Reconstruction Cohort

Reason for Removal	n	% (of 50 Reoperations)
Patient Request for Style/Size Change	18	36.0
Asymmetry	11	22.0
Capsular Contracture Baker Grade 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 3d below. Of the 60 revision-reconstruction patients, there were 10 patients (17%) who had 13 implants removed over the 4 years of follow-up in the Round Gel Core Study. Of the 13 implants removed, 7 (54%) were replaced. The most common reason for implant removal was capsular contracture Baker Grade III/IV (31% of the 13 implants removed) for revision-reconstruction patients.

Table 3d. Main Reasons for Implant Removal through 4 Years for Revision-Reconstruction Cohort

Reason for Removal	n	% (of 50 Reoperations)
Capsular Contracture Baker Grade 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

Other Clinical Data Findings

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 other endpoints, are being further evaluated as part of a Mentor post-approval study of patients followed through 10 years.

CTD Diagnoses

Three primary augmentation patients and 1 revision-augmentation patient in the Mentor Round Gel Core Study were reported to have a new diagnosis of CTD according to a rheumatologist. These diagnoses were Hashimoto's Thyroiditis at 2 years, rheumatoid arthritis at 3 years, and hypothyroidism at 2 years, and a combined case of fibromyalgia and chronic fatigue syndrome at 3.5 years. Two primary reconstruction patient and 2 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 2 cases of fibromyalgia, both at 1 year, pyoderma gangrenosum at 1 year and Morton's Neuroma at 3 years. These data should be interpreted with caution because there was no comparison group of similar women without implants.

CTD Signs and Symptoms

Data on over 100 self-reported signs and symptoms, including about 50 self-reported rheumatological symptoms, were collected. Compared to before having the implants, significant increases were found for weakness, neck pain/stiffness, generalized aching, joint pain, frequent muscle pain, numbness of hands, combined fatigue, and combined pain in primary augmentation patients. Significant increases were found for frequent muscle cramps and joint pain in primary reconstruction patients, and combined pain for revision-reconstruction patients. These increases were not found to be related to simply getting older over time. No significant increases were found for any individual signs and symptoms in the revision-augmentation patients. 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 these increases were due to the implants or not. However, your patient should be aware that she may experience an increase in these symptoms after receiving breast implants.

Cancer

There were no primary augmentation patients with new diagnoses of breast cancer through 4 years in Mentor's Round Gel Core Study. As previous breast cancer was an exclusion criterion for primary augmentation patients, there were no reports of breast cancer reoccurrence in this cohort. There were no reports of new diagnoses or reoccurrence in revision-augmentation patients. 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 in any indication.

Lactation Complications

Two (13%) of the 15 primary augmentation patients who attempted to breast feed following breast implantation in Mentor's Round Gel Core Study through 4 years experienced difficulty with breast feeding, and 1 (7%) reported inadequate milk. Of the 3 revision-augmentation patients who attempted to breast feed after receiving breast implants, 1 (33%) had difficulty breastfeeding. For primary reconstruction patients, the 1 (0.4%) woman who attempted to breastfeed experienced no lactation difficulties. None of the revision-reconstruction patients attempted to breastfeed.

Reproduction Complications

Nine (1.6%) of the primary augmentation patients and 3 (2.1%) of the revision-augmentation patients in Mentor's Round Gel Core Study reported a miscarriage through 4 years. For primary reconstruction patients, 4 (1.6%) patients reported a miscarriage. There were no reports of miscarriage in revision-reconstruction patients.

Suicide

There were no reports of suicide in any of the 4 cohorts in Mentor's Round Gel Core Study through 4 years.

DEVICE IDENTIFICATION CARD

Enclosed with each silicone gel-filled breast implant is a Patient ID Card. To complete the Patient ID Card, place one device identification sticker for each implant on the back of the card. Stickers are located on the internal product packaging attached to the label. If a sticker is unavailable, the lot number, catalog number and description of the device may be copied by hand from the device label. Patients should be provided with these cards for personal reference.

PRODUCT EVALUATION

Mentor requires that any complications and/or explantation resulting from the use of this device be brought to the immediate attention of your local Mentor representative, who will be responsible for informing the Mentor Complaint Department. If explantation is necessary, analysis will be performed on the explanted device and the patient and the physician must be asked for permission to allow tests to be performed which might alter the condition of the device.

RETURNED GOODS AUTHORIZATION

Authorization for return of merchandise should be obtained from your local Mentor representative prior to the return of merchandise. Merchandise must have all manufacturer's seals intact to be eligible for credit or replacement. Returned products may be subject to a restocking charge.

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 Limited Warranty, it is important for the patient to also maintain her own records to ensure validation of her enrollment.

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 coverage 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.

* 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 may be selected (subject to a charge of the difference between product list prices). Refer to 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.

Filing for Financial Assistance

- To file a Mentor Advantage claim for product replacement and/or financial assistance, the surgeon must contact Mentor, a unit of Johnson & Johnson Medical Products, a division of Johnson & Johnson Inc. prior to replacement surgery.
- For financial assistance claims, a patient-specific Release form will be generated that the patient 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 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 the patient's completion of a full general release, financial assistance will be issued.

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 the surgeon or by going to www.mentorwwllc.com.

THESE ARE LIMITED WARRANTIES ONLY AND ARE 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.

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SYMBOLS GLOSSARY

ISO 15223-1 Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied

Title 21 Code of Federal Regulations Parts 801.109

Serial number
ISO 15223-1 Reference 5.1.7
Indicates the manufacturer's serial number so that a specific medical device can be identified.

Catalogue number
ISO 15223-1 Reference 5.1.6
Indicates the manufacturer's catalogue number so that the medical device can be identified

Batch code
ISO 15223-1 Reference 5.1.5
Indicates the manufacturer's batch code so that the batch or lot can be identified.

Use-by date
ISO 15223-1 Reference 5.1.4
Indicates the date after which the medical device is not to be used.

Diameter, Projection

Not returnable if opened

Do not re-use
ISO 15223-1 Reference 5.4.2
Indicates a medical device that is intended for one use, or for use on a single patient during a single procedure.

Do not resterilize
ISO 15223-1 Reference 5.2.6
Indicates a medical device that is not to be resterilized.

Caution
ISO 15223-1 Reference 5.4.4
Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself.

Consult instructions for use
ISO 15223-1 Reference 5.4.3
Indicates the need for the user to consult the instructions for use.

Sterilized using steam or dry heat
ISO 15223-1 Reference 5.2.5
Indicates a medical device that has been sterilized using steam or dry heat.

Non-pyrogenic
ISO 15223-1 Reference 5.6.3
Indicates a medical device that is non-pyrogenic.

Not made with natural rubber latex

Date of manufacture
ISO 15223-1 Reference 5.1.3
Indicates the date when the medical device was manufactured.

Manufacturer
ISO 15223-1 Reference 5.1.1
Indicates the medical device manufacturer, as defined in EU Directives 90/385/EEC, 93/42/EEC and 98/79/EC.

CAUTION: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner.
Title 21 Code of Federal Regulations Parts 801.109

MENTOR

For customer service call Mentor, a unit of Johnson & Johnson Medical Products, a division of Johnson & Johnson Inc., **at** 1-800-668-6069 **or contact your local Mentor representative.**
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