MENTOR

Product Insert
Data Sheet

MENTOR MEMORYGEL™ SILICONE GEL-FILLED BREAST IMPLANTS

102872-001 Rev. C Effective November 2006

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

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, 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 and breast implant surgery. MemoryGel implant labeling materials are part of physician training, a requirement described below in this Introduction. 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 counseled and understand the risk/benefit relationship.

Before making the decision to proceed with surgery, the surgeon or a designated patient counselor should instruct the patient to read ***Important Information for Augmentation/Reconstruction Patients About Mentor MemoryGel™ Silicone Gel-Filled Breast Implants*** (patient labeling) and discuss with the patient the warnings, contraindications, precautions, important factors to consider, complications, Mentor 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 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 at least 1-2 weeks after reviewing and considering this information before deciding whether to have primary breast augmentation surgery. In the case of a revision-augmentation 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.

PHYSICIAN TRAINING - Completion of Mentor's Device Access Education Course is required for all physicians in order to gain access to Mentor's MemoryGel Silicone Gel-Filled Breast Implants. The Food and Drug Administration (FDA) will allow a 90-day transition period for all current Mentor Core Study and Adjunct Study investigators, after which these physicians/surgeons must also have completed the training program in order to have access to the Mentor product. Physician certification provides documentation of training in the use of these devices. Mentor has developed an online training and certification of participation process (The Device Access Education Course) that may be accessed via MemoryGel.com, or you may obtain a DVD of the training and certification material by contacting your Mentor sales representative.

DEVICE TRACKING **-** Silicone gel-filled breast implants are subject to Device Tracking by Federal regulation. Your compliance with this requirement is mandatory. This means that you will be required to report to Mentor the serial number of the device(s) you implant in a patient, the date of her surgery, her social security number, her personal contact information, and information relating to your practice. This information will be recorded on a Device Tracking Form supplied by Mentor with each silicone gel-filled breast implant.

Mentor strongly recommends that all patients receiving silicone gel-filled breast implants participate in Mentor's device tracking program. This will help ensure that Mentor has a record of each patient's contact information so that patients can be contacted in the event of a recall or other problems with the implants that they should

be made aware of. If a patient declines to provide personal, identifying information, you must still provide all other non-patient specific information.

DEVICE DESCRIPTION

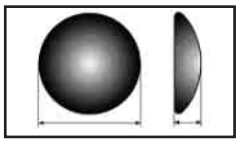
Mentor Silicone Gel-Filled Breast Implants are devices with shells constructed from silicone elastomer. The shell is filled with MemoryGel™, Mentor's proprietary formulation of silicone gel. The shell is constructed of successive cross-linked layers of silicone elastomer, which give the prosthesis its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

Prior to receiving Mentor's MemoryGel breast implants, a surgeon must complete a Device Access Education Course, which consists of 3 modules specific to these products and breast implant surgery.

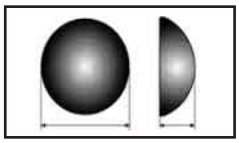
The following lists the catalog numbers and styles of Mentor MemoryGel round implants:

350-7100BC/7800BC: Moderate Profile, smooth shell surface
354-1007/8007: Moderate Profile, textured shell surface
350-1001BC/8001BC: Moderate Plus Profile, smooth shell surface
354-1001/8001: Moderate Plus Profile, textured surface
350-1254BC/8004BC: High Profile, smooth shell surface
354-4125/4800: High Profile, textured surface

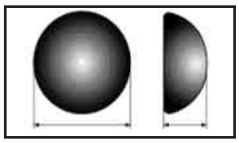
The following diagrams illustrate the Moderate, Moderate Plus, and High Profiles.



Moderate Profile



Moderate Plus Profile



High Profile

INDICATIONS

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

- **Breast augmentation for women at least 22 years old**. Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of a primary breast augmentation surgery.
- **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 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	8.0
Reconstruction	Periareolar	4.0	3.0	6.0
	Inframammary	5.4	3.0	10.0
	Mastectomy Scar	4.7	4.0	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:

- Autoimmune diseases (e.g., lupus and scleroderma).
- A compromised immune system (e.g., currently receiving immunosuppressive therapy).
- Patients with conditions or medications which 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.
- Patients 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 such that 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 their 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.
  - A recent report indicates that larger sized implants (>350cc) 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 breast feeding 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 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 counseled 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 at least 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 brochure. The form, once signed, acknowledges the patient's full understanding of the information provided in the 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 sensitivity of plastic surgeons familiar with implants to diagnose rupture is 30%[7] compared to 89% for MRI.[8] **Therefore, you**

should advise your patient that she will need to have regular MRIs over her lifetime to screen for silent rupture even if she is having no problems. The first MRI should be performed at 3 years postoperatively, then every 2 years, thereafter. The importance of these MRI evaluations should be emphasized. If rupture is noted on 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 breast implant MRI films for signs of rupture. Diagnostic procedures will add to the cost of having breast implants, and patients should be told that these costs may exceed the cost of their initial surgery over their lifetime and that these costs may not be covered by their insurance carrier.

- **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 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, and it is a life-threatening condition. Symptoms of TSS occur suddenly: 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 contact a physician immediately for diagnosis and treatment for any of 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, she 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 breast feed, 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.
- **Insurance coverage** – Patients should be advised that health insurance premiums may increase, insurance coverage may be dropped, and/or future coverage may be denied based on the presence of breast implants. Treatment of complications may not be covered as well. Patients should check with their insurance company regarding coverage issues before undergoing surgery.
- **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 Core Study through 10 years. In addition, Mentor has undertaken a separate 10-year postapproval study to address specific issues for which the Mentor Core Study was not designed to fully answer, as well as to

provide a real-world assessment of some endpoints. The endpoints in the large postapproval 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 Mentor Core Study and separate postapproval 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: implant rupture, capsular contracture, reoperation, implant removal, pain, changes in nipple and breast sensation, infection, scarring, asymmetry, wrinkling, implant displacement/migration, implant palpability/visibility, breast feeding 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 Core Study section 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 they are more likely to occur the longer the implant is implanted. 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, which is contraindicated); trauma; compression during mammographic imaging; and severe capsular contracture. Breast implants may also simply wear out over time. Laboratory studies have identified some of the types of rupture for Mentor's product; however, it is not conclusively known whether these tests have identified all causes of rupture. These laboratory studies will continue postapproval.

Silicone gel-filled implant ruptures are most often silent. (MRI examination is currently the best method to screen for silent rupture.) This means that most of the time neither you nor your patient will know if the implant has a tear or hole in the shell. This is why MRI is recommended at 3 years and then every 2 years, thereafter, to screen for rupture. Sometimes there are symptoms associated with gel implant rupture. These symptoms

include hard knots or lumps surrounding the implant or in the armpit, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast.

When MRI findings of rupture are found (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.[9,10]

There are also consequences of rupture. If rupture occurs, silicone gel may either remain within the scar tissue capsule surrounding the implant (intracapsular rupture), move outside the capsule (extracapsular rupture), or gel may move beyond the breast (migrated gel). There is also a possibility that rupture may progress from intracapsular to extracapsular and beyond. There have also been health consequences reported in the literature. See below for details.

Rupture Information on Mentor Implants

In Mentor's Core Study, rupture was assessed for patients who had scheduled MRIs to screen for silent rupture (i.e., part of the MRI cohort) and those who were not assessed for rupture by MRI (i.e., part of the non-MRI cohort). Mentor's Core Study included rupture rate data from the non-MRI cohort at years 1, 2, and 3 and from the MRI cohort at years 1 and 2. All reported ruptures were from patients in the MRI cohort. The rupture rates were 0.5% for primary augmentation, 7.7% for revision-augmentation, 0.9% for primary reconstruction, and 0% for revision-reconstruction. There were 8 ruptured/suspected ruptured implants in 6 patients through 3 years. Only 2 of the implants were explanted and confirmed to be ruptured; the other implants remain as suspected rupture based on MRI evaluation. Of these 8 implants, 4 showed intracapsular gel and 4 showed extracapsular gel on MRI (3 implants with extracapsular gel were in 2 revision-augmentation patients and 1 was in a primary reconstruction patients). For one of these implants with extracapsular gel, this was a confirmed case in which the device was explanted and the intracapsular gel rupture progressed into an extracapsular gel rupture as shown by MRIs at approximately 10 months and approximately 2 years. There were no cases of migrated gel.

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

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

Additional Information on Consequences of Rupture from Literature

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

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

- Local breast complications reported in the published literature that were associated with rupture include breast hardness, a change in breast shape or size, and breast pain.[13] These symptoms are not specific to rupture, as they also are experienced by women who have capsular contracture.
- There have been rare reports of gel movement to nearby tissues such as the chest wall, armpit, or upper abdominal wall, and to more distant locations down the arm or into the groin. This has led to nerve damage, granuloma formation 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.[14]

- 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 fibromylagia.[15,16,17,18] 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[19], these studies do not distinguish whether the women had ruptured or intact implants.

- **Capsular Contracture**

The scar tissue (capsule) that normally forms around the implant may tighten over time and compress the implant, making it feel firm and leading to what is called capsular contracture. Capsular contracture may be more common following infection, hematoma, and seroma, and the chance of it happening may increase over time. Capsular contracture occurs more commonly in patients undergoing revision surgery than in patients undergoing primary implantation surgery. Capsular contracture is a risk factor for implant rupture, and it is the most common reason 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 4 levels depending on its severity. Baker Grades III or IV are considered severe and often additional surgery is needed to correct these grades:

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

In Mentor's Core Study, the risk of capsular contracture Baker Grade III/IV through 3 years was 8.1% for primary augmentation, 18.9% for revision-augmentation, 8.3% for primary reconstruction, and 16.3% 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.[20]

- **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. In Mentor's Core Study, the risk rate of reoperation at least one time through 3 years was 15.4% for primary augmentation, 28.0% for revision-augmentation, 27.0% for primary reconstruction, and 29.1% 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 Core Study section that describes the reasons for reoperation during the first 3 years after receiving the implants.

- **Implant Removal**

For women receiving primary augmentation implants in Mentor's Core Study, 4.7% had their implants removed at least once through 3 years. Patient choice and severe capsular contracture were the most common reasons for implant removal. For women receiving revision-augmentation implants in Mentor's Core Study, 12.3% had their implants removed at least once through 3 years. The most common reasons were patient choice and severe capsular contracture.

For women receiving primary reconstruction implants in Mentor's Core Study, 12.4% had their implants removed at least once through 3 years. Patient choice and asymmetry were the most common reasons for implant removal. For women receiving revision-reconstruction implants in Mentor's Core Study, 13.6% had their implants removed at least once through 3 years. The most common reason was asymmetry.

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 their 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 patient 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 has been noted in women after breast implant surgery, and it is a life-threatening condition. Symptoms include sudden fever, vomiting, diarrhea, fainting, dizziness, and/or sunburn-like rash. 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.

- **Breast Feeding Complications**

Breast feeding 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 breast feeding difficulties.

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

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

- **Extrusion**

Extrusion 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 implants had abnormal tissue reactions, granulomas, and the presence of silicone.[21] 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 is a disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue. There have been a number of published epidemiological studies which have looked at whether having a breast implant is associated with having a typical or defined connective tissue disease. The study size needed to conclusively rule out a smaller risk of connective tissue disease ($\leq$2) among women with silicone gel-filled breast implants would need to be very large.[22,23,24,25,26,27,28,29,30,31] 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.[32,33,34,35] 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.[36]

- **CTD Signs and Symptoms**

Literature reports have also been made associating silicone breast implants with various rheumatological signs and symptoms such as fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes. Scientific expert panels and literature reports have found no evidence of a consistent pattern of signs and symptoms in women with silicone breast implants.[37,37,39,40,41] 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.

- **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.[42,43,44,45,46] 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.[47,48,49,50,51]

Brain cancer – One recent study has reported an increased incidence of brain cancer in women with breast implants as compared to the general population.[52] The incidence of brain cancer, however, was not significantly increased in women with breast implants when compared to women who had other plastic surgeries. Another recently published review of four large studies in women with cosmetic implants concluded that the evidence does not support an association between brain cancer and breast implants.[53]

Respiratory/lung cancer – One study has reported an increased incidence of respiratory/lung cancer in women with breast implants.[54] 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.[55,56,57]

Cervical/vulvar cancer – One study has reported an increased incidence of cervical/vulvar cancer in women with breast implants.[58] The cause of this increase is unknown.

Other cancers – One study has reported an increased incidence of stomach cancer and leukemia in women with breast implants compared to the general population.[59] 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.[60]

- **Suicide**

In several studies, a higher incidence of suicide was observed in women with breast implants.[61,62,63,64] 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.[65]

- **Effects on Children**

At this time, it is not known if a small amount of silicone may pass through from the breast implant silicone shell into breast milk during breastfeeding. Although there are no current established methods for accurately detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone gel-filled implants when compared to women without implants.[66]

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.[67,68] Although low birth weight was reported in a third study, other factors (for example, lower pre-

pregnancy weight) may explain this finding.[69] 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. [70,71] The evidence is mixed as to whether there are any clinical consequences associated with gel bleed. For instance, studies on implants implanted for a long duration have suggested that such bleed may be a contributing factor in the development of capsular contracture[72] and lymphadenopathy.[73] However, evidence against gel bleed being a significant contributing factor to capsular contracture and other local complications, is provided by the fact that there are similar or lower complication rates for silicone gel-filled breast implants than for saline-filled breast implants. Saline-filled breast implants do not contain silicone gel and, therefore, gel bleed is not an issue for those products. Furthermore, toxicology testing has indicated that the silicone material used in the Mentor implants does not cause toxic reactions when large amounts are administered to test animals. It 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.[74] 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 were 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 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 Mentor 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 Core Study results indicate that the risk of any complication (including reoperation) at some point through 3 years after implant surgery is 36.6% for primary augmentation patients, 50.1% for revision-augmentation patients, 49.4% for primary reconstruction patients, and 47.5% for revision-reconstruction patients. The information below provides more details about the complications and benefits your patients may experience.

The results of the Mentor Core Study are discussed below.

Study Design:
The Mentor Core Study is a 10-year study to assess safety and effectiveness in augmentation, reconstruction, and revision (augmentation and reconstruction) patients. The Mentor Core Study consisted of 1,007 patients, including 551 primary augmentation patients, 146 revision-augmentation patients, 251 primary reconstruction patients, and 59 revision-reconstruction patients. Patients' medical histories were collected at baseline. Patient follow-up is at 6 months, 12 months, 24 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 circumferential chest size change and bra cup size change (augmentation patients only), and measures of patients' satisfaction and assessments of quality of life (QoL). The results through 3 years are currently being reported, and the study is currently ongoing. Mentor will periodically update this labeling as more information becomes available.

Patient Accounting and Baseline Demographic Profile:
The Mentor Core Study consisted of 1,007 patients, including 551 primary augmentation patients, 146 revision-augmentation patients, 251 primary reconstruction patients, and 59 revision-reconstruction patients. Of these, 202 primary augmentation patients, 57 revision-augmentation patients, 134 primary reconstruction patients, and 27 revision-reconstruction patients are in the MRI cohort, which means that they are assessed for silent rupture by MRI at years 1, 2, 4, 6, 8, and 10. At this time, MRIs have been

performed at years 1 and 2, and the follow-up rates for the MRI cohort ranged from 84% to 93% at the 2-year timepoint across indications. However, as a whole, data are available through 3 years post-implantation for 88% of the eligible augmentation patients, 87% of the eligible revision-augmentation patients, 82% of the eligible reconstruction patients, and 86% of the revision-reconstruction patients.

Demographic information for the Mentor Core Study with regard to race is as follows: 90% of the Mentor 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 Mentor 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 Mentor Core Study, for primary 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. For revision-augmentation patients, the most frequently used devices were smooth 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 implants, the most common incision site was mastectomy scar, and the most frequent site of placement was submuscular.

Core Effectiveness Outcomes:
Effectiveness was assessed by cup/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, 370 (67%) out of the original 551 patients were included in the analysis of cup size at 3 years. Of these 370 patients, 359 (97%) experienced at least one cup size increase; the average increase in circumferential chest size was 2.8 inches.

At 3 years, 456 (83%) of the 551 patients enrolled completed the patient satisfaction question. Of these 456 patients, 445 (98%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 3 years, an increase in self esteem was noted for 45% of patients after primary breast augmentation on the Rosenberg Self Esteem Scale. There was no change on the overall score of the Body Esteem Scale, but the Sexual Attractiveness Subscale and the Chest Score of the Body Esteem Scale increased. There was no change in the SF-36 after primary augmentation. There was no change in the overall score for the TSCS.

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

At 3 years, 118 (81%) of the 146 patients enrolled answered the patient satisfaction question. Of these 118 patients, 111 (94%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 3 years, no change in self esteem was noted following revision-augmentation surgery on the Rosenberg Self Esteem Scale. No changes were noted in the Body Esteem scale. There were no changes in SF-36. There was no change in the overall TSCS score.

Primary Reconstruction Patients: For primary reconstruction patients, 183 (72.9%) out of the original 251 patients were included in the analysis of circumferential chest size at 3 years. Of these 183 patients, the average increase in circumferential chest size was 1.3 inches.

At 3 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 3 years for primary reconstruction patients, a significant improvement in functioning was observed as measured by the Functional Living Index of Cancer. No change was observed on Rosenberg Self Esteem Scale. 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 Sexual Attractiveness Subscale of the Body Esteem Scale significantly improved. There was no change in any of the ten SF-36 scales.

Revision-Reconstruction Patients: For revision-reconstruction patients, 45 (76%) out of the original 59 patients were included in the analysis of circumferential chest size at 3 years. Of these patients, the average increase in circumferential chest size was 0.9 inches.

At 3 years, 48 (81%) of the 59 patients enrolled answered the patient satisfaction question. Of these 48 patients, 47 (98%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 3 years for revision-reconstruction patients, no change was observed on the Rosenberg Self Esteem Scale or in the Tennessee Self Concept Scale. For the Body Esteem Scale, two of six scales worsened over time, but, after adjusting for the aging effect, none of the changes were significant. The Sexual Attractiveness Subscale of the Body Esteem Scale significantly improved over time. Although some of the SF-36 scales showed decreases over time, after adjusting for the aging effect, changes in seven of ten SF-36 scales were not statistically significant.

Safety Outcomes – Complications:
Mentor's 10-year Core Study of 1,007 patients is continuing. All patients available for follow-up have been evaluated at the 3-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. Mentor Core Study: 3-Year Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Primary Augmentation Cohort
N=551

Key Complications	%	CI
Reoperation	15.4	12.3, 18.4
Capsular Contracture Baker Grade III / IV	8.1	5.8, 10.4
Implant Removal with Replacement with Study Device	2.8	1.4, 4.2
Implant Removal without Replacement	2.3	1.0, 3.6
Infection	1.5	0.5, 2.5
Rupture (MRI Cohort)[1]	0.5	0, 1.6
Other Complications ≥ 1%[2]	**%**	**CI**
Nipple Complications[3]	10.4	7.8,12.9
Scarring/Hypertrophic Scarring[3]	6.7	4.6, 8.8
Breast Mass[3]	3.1	1.6, 4.6
Hematoma[3]	2.6	1.2, 3.9
Ptosis[3]	2.3	1.0, 3.6
Breast Sensation Changes[3]	2.2	1.0, 3.4
Breast Pain[3]	1.7	0.6, 2.8
Miscarriage[4]	1.5	0.5, 2.6
Trauma[5]	1.3	0.2,2.3

1 - There was 1 patient with signs of rupture by MRI of one of her implants through the 3-year point. This has not yet been confirmed with removal and visual inspection of the implant.
2 - The following complications were reported at a rate less than 1%: anaphylaxis, asymmetry, biopsy pending, bruising, deep vein thrombosis, granuloma, implant malposition/displacement, inflammation, lactation difficulties, new diagnosis of rheumatic disease (1 patient with Hashimoto's Thyroiditis, 1 patient with rheumatoid arthritis, and 1 patient with hypothyroidism), necrosis, placement damage (damage to breast implants during insertion, which were then removed while the patient was still on the operating table), position dissatisfaction, positive antinuclear antibodies negative for lupus, suture reaction, rash, seroma, and wrinkling.
3 - Mild occurrences were excluded.
4 - Preoperative miscarriage data were not collected.
5 - Lifted child and stroller; trauma sustained from motor vehicle accident; trauma to breast from fall; and first and second degree frostbite from ice bags placed on breasts the day after surgery to relieve operative pain.

Table 1b. Mentor Core Study: 3-Year Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Revision-Augmentation Cohort
N=146 Patients

Key Complications	%	CI
Reoperation	28.0	20.4, 35.6
Capsular Contracture Baker Grade III / IV	18.9	12.5, 25.4
Rupture (MRI Cohort)[1]	7.7	0.4, 15.0
Implant Removal with Replacement with Study Device	6.5	2.4, 10.6
Implant Removal without Replacement	5.9	1.9, 9.8
Infection	1.4	0, 3.4
Other Complications ≥ 1%[2]	**%**	**CI**
Nipple Complications[3]	10.5	5.5, 15.5
Scarring/Hypertrophic Scarring[3]	8.4	3.9, 13.0
Breast Mass[3]	6.6	2.4, 10.7
Hematoma[3]	2.8	0.09, 5.4
Breast Sensation Changes[3]	2.1	0, 4.5
Seroma	2.1	0, 4.4
Delayed Wound Healing[3]	2.1	0, 4.4
Wrinkling[3]	2.1	0, 4.5
Ptosis[3]	1.5	0, 3.6
Breast Pain[3]	1.5	0, 3.4
Inflammation[3]	1.4	0, 3.3
Implant Malposition[3]	1.4	0, 3.3
Implant Extrusion	1.4	0, 3.3

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

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

3 - Mild occurrences were excluded.

Table 1c. Mentor Core Study: 3-Year Cumulative First Occurrence Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Primary Reconstruction Cohort
N=251 Patients

Key Complications	%	CI
Reoperation	27.0	21.4, 32.6
Capsular contracture Baker Grade III/IV	8.3	4.7, 11.9
Implant Removal with Replacement with Study Device	7.4	4.1, 10.7
Implant Removal without Replacement	5.7	3.3, 9.6
Infection	5.7	2.8, 8.6
Rupture (MRI Cohort)[1]	0.9	0, 2.5
Other Complications ≥ 1%[2]	**%**	**CI**
Ptosis[3]	6.9	2.7, 11.2
Scarring/Hypertrophic Scarring[3]	6.8	3.6, 10.0
Asymmetry[3]	6.7	3.4, 10.0
Seroma	4.9	2.2, 7.5
Breast Mass[3]	3.6	1.1, 6.0
Nipple Complications[3]	3.3	0.8, 5.7
Wrinkling[3]	2.6	0.5, 4.6
Breast Pain[3]	2.2	0.3, 4.2
Metastatic Disease	1.8	0.05, 3.6
Implant Malposition[3]	1.7	0.05, 3.3
Recurrent Breast Cancer[4]	1.7	0.05, 3.4
Hematoma[4]	1.3	0, 2.8
Implant Extrusion	1.2	0, 2.6
Breast Sensation Changes[3]	1.0	0, 2.5
Rash[3]	1.0	0, 2.3

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

2 - The following complications occurred at a rate less than 1%: deep vein thrombosis, delayed wound healing, lymphadenopathy, miscarriage, muscle spasm, necrosis, new diagnosis of breast cancer, new diagnosis of rheumatic disease (1 patient with fibromyalgia), redness, stitch abscess, tight benilli suture, trauma to breast due to car accident.

3 - Mild occurrences were excluded.

4 - The general recurrence rate for breast cancer reported in the medical literature ranges from 5 to 25%.[75,76,777]

Table 1d. Mentor Core Study: 3-Year Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), By Patient for Revision-Reconstruction Cohort
N=59 Patients

Key Complications	%	CI
Reoperation	29.1	17.4, 40.7
Capsular Contracture Baker Grade III/IV	16.3	5.0, 27.6
Implant Removal with Replacement with Study Device	8.8	3.8, 19.9
Implant Removal without Replacement	5.2	1.7, 15.2
Infection	0	-
Rupture (MRI Cohort)	0	-
Other Complications ≥ 1%[1]	**%**	**CI**
Asymmetry[2]	8.9	1.4, 16.3
Implant Malposition[2]	8.5	1.4, 15.7
Wrinkling[2]	7.0	0.4, 13.6
Breast Mass[2]	7.0	0.4, 13.7
Granuloma	5.1	0, 10.7
Scarring/Hypertrophic Scarring[2]	3.6	0, 8.4
Breast Pain[2]	3.5	0, 8.2
Hematoma[2]	3.5	0, 8.2
New Diagnosis of Rheumatic Disease[3]	3.5	0, 8.1
Ptosis[2]	3.4	0, 8.0
Breast Sensation Changes[2]	1.9	0, 5.7
Numbness in Both Hands at Night	1.8	0, 5.3
Seroma	1.7	0, 5.0
Nipple Complications[2]	1.7	0, 5.0
Inflammation	1.7	0, 5.1
Recurrent Breast Cancer[4]	1.7	0, 5.0
New Diagnosis of Breast Cancer	1.7	0, 5.1
Delayed Wound Healing	1.7	0, 5.0
Trauma[5]	1.7	0, 5.0
Capsule Tear	1.7	0, 5.0
Implant Extrusion	1.7	0, 5.0

1 - No complications occurred at a rate of <1%.
2 - Mild occurrences were excluded.
3 - These rheumatic diagnoses were fibromyalgia (1 patient) and pyoderma gangrenosum (1 patient).
4 - The general recurrence rate for breast cancer reported in the medical literature ranges from 5 to 25%.[78,79,80]
5 - Trauma to breast from fall.

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 551 augmentation patients, there were 83 (15%) who underwent 176 surgical procedures in 109 reoperations over the 3 years of follow-up in the Mentor Core Study. The most common reason for reoperation through 3 years was because of capsular contracture Baker Grade II, III, or IV (36.7% of 109 reoperations). Table 2a below provides the main reason for each reoperation following initial implantation that was performed through 3 years for primary augmentation patients.

Table 2a: Main Reasons for Reoperation through 3-Years for Primary Augmentation Cohort

Reason for Reoperation	n	% (of 109 Reoperations)
Capsular Contracture Baker Grade II/III/IV	40	36.7
Patient Request For Style/Size Change	16	14.7
Hematoma/Seroma	12	11.0
Scarring/Hypertrophic Scarring	12	11.0
Biopsy	6	5.5
Asymmetry	5	4.6
Ptosis	4	3.7
Infection	3	2.8
Delayed Wound Healing	2	1.8
Implant Malposition	2	1.8
Wrinkling	2	1.8
Breast Pain	1	0.9
Implant Extrusion	1	0.9
Necrosis	1	0.9
Suspected Rupture[1]	1	0.9
Tear in Capsule	1	0.9
Total	109	100

1 - The device was removed and found to be intact.

There were 105 additional surgical procedures performed in 58 reoperations involving 39 revision-augmentation patients. The most common reason for reoperation through 3 years was capsular contracture Baker Grade II, III, or IV (39.6% of the 58 reoperations). Table 2b below provides the main reason for each reoperation following initial implantation that was performed through 3 years for revision-augmentation patients.

Table 2b: Main Reasons for Reoperation through 3 Years for Revision-Augmentation Cohort

Reason for Reoperation	n	% (of 58 Reoperations)
Capsular Contracture Baker Grade II/III/IV	23	39.7
Patient Request For Style/Size Change	7	12.1
Biopsy	6	10.3
Hematoma/Seroma	5	8.6
Delayed Wound Healing	5	8.6
Scarring/Hypertrophic Scarring	3	5.2
Implant Extrusion	2	3.4
Implant Malposition	2	3.4
Asymmetry	1	1.7
Ptosis	1	1.7
Infection	1	1.7
Wrinkling	1	1.7
Suspected Rupture[1]	1	1.7
Total	58	100

1 - The device was removed and found to be intact.

There were 143 additional surgical procedures performed in 79 reoperations involving 66 primary reconstruction patients. The most common reason for reoperation through 3 years was because of asymmetry (20.3% of 79 reoperations). Table 2c below provides the main reasons for the reoperations following initial implantation that were performed through 3 years for primary reconstruction patients.

Table 2c: Main Reasons for Reoperation through 3 Years for Primary Reconstruction Cohort

Reason for Reoperation	n	% (of 79 Reoperations)
Asymmetry	16	20.3
Biopsy	11	13.9
Capsular Contracture Baker Grade II/III/IV	10	12.7
Implant Malposition	9	11.4
Patient Request for Style/Size Change	9	11.4
Infection	4	5.1
Scarring/Hypertrophic Scarring	3	3.8
Ptosis	3	3.8
Hematoma/Seroma	3	3.8
Breast Cancer	3	3.8
Implant Extrusion	2	2.5
Nipple Complications (unplanned)	2	2.5
Delayed Wound Healing	1	1.3
Breast Pain	1	1.3
Implant Palpability/Visibility	1	1.3
Muscle Spasm	1	1.3
Total	79	100

There were 54 additional surgical procedures performed in 24 reoperations involving 17 revision-reconstruction patients. The most common reason for reoperation through 3 years was because of biopsy (29.2% of 24 reoperations). Table 2d below provides the main reason for each reoperation following initial implantation that was performed through 3 years for revision-reconstruction patients.

Table 2d: Main Reasons for Reoperation through 3 Years for Revision-Reconstruction Cohort

Reason for Reoperation	n	% (of 24 Reoperations)
Biopsy	7	29.2
Other[1]	3	12.5
Capsular Contracture Baker Grade III/IV	3	12.5
Implant Malposition	2	8.3
Suspected Rupture[2]	1	4.2
Asymmetry	1	4.2
Breast Cancer	1	4.2
Implant Extrusion	1	4.2
Hematoma/Seroma	1	4.2
Nipple Complications (unplanned)	1	4.2
Patient Request For Style/Size Change	1	4.2
Ptosis	1	4.2
Wrinkling	1	4.2
Total	24	100

1 - Includes 1 follicular cyst palpable nodule, 1 palpable nodule, and 1 pocket tear
2 - The device was removed and found to be intact.

Safety Outcomes - Reasons for Implant Removal:
The main reasons for implant removal among primary augmentation patients in the Mentor Core Study over the 3 years are shown in Table 3a below. Of the 551 primary augmentation patients, there were 26 patients (5%) who had 45 implants removed over the 3 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 (68.9% of the 45 implants removed) for primary augmentation patients.

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

Reason for Removal	n	% (of 45 Explants)
Patient Request for Style/Size Change	31	68.9
Capsular Contracture Baker Grade III/IV	5	11.1
Breast Pain	2	4.4
Infection	2	4.4
Necrosis	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.

The main reasons for implant removal among revision-augmentation patients in the Mentor Core Study over the 3 years are shown in Table 3b below. Of the 146 revision-augmentation patients, there were 18 patients (12.3%) who had 30 implants removed over the 3 years of follow-up in the Mentor Core Study. Of the 30 implants removed, 14 (47%) were replaced. The most common reason for implant removal was patient request (40.0% of the 30 implants removed) for revision-augmentation patients.

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

Reason for Removal	n	% (of 30 Explants)
Patient Request for Style/Size Change	12	40.0
Capsular Contracture Baker Grade III/IV	10	33.3
Patient Dissatisfied with Appearance	2	6.7
Asymmetry	1	3.3
Implant Extrusion	1	3.3
Scarring/Hypertrophic Scarring	1	3.3
Infection	1	3.3
Suspected Rupture[1]	1	3.3
Abnormal Mammogram	1	3.3
Total	30	100

1 - The device was removed and found to be intact.

The main reasons for implant removal among primary reconstruction patients in the Mentor Core Study over the 3 years are shown in Table 3c below. Of the 251 primary reconstruction patients, there were 31 patients (12%) who had 41 implants removed over the 3 years of follow-up in the Mentor Core Study. Of the 41 primary reconstruction implants removed, 23 (56.1%) were replaced. The most common reason for implant removal was patient request (36.6% of the 41 implants removed) for primary reconstruction patients.

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

Reason for Removal	n	% (of 41 Explants)
Patient Request for Style/Size Change	15	36.6
Asymmetry	10	24.4
Capsular Contracture Baker Grade II/III/IV	5	12.2
Implant Malposition	3	7.3
Implant Extrusion	2	4.9
Infection	2	4.9
Hematoma	1	2.4
Lack of Projection	1	2.4
Muscle Spasm	1	2.4
Recurrent Breast Cancer	1	2.4
Total	41	100

The main reasons for implant removal among revision-reconstruction patients in the Mentor Core Study over the 3 years are shown in Table 3d below. Of the 59 revision-reconstruction patients, there were 8 patients (13.6%) who had 11 implants removed over the 3 years of follow-up in the Mentor Core Study. Of the 11 implants removed, 7 (63.6%) were replaced. The most common reason for implant removal was capsular contracture III/IV (27.3% of the 11 implants removed) for revision-reconstruction patients.

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

Reason for Removal	n	% (of 11 Explants)
Capsular Contracture Baker Grade III/IV	3	27.3
Asymmetry	2	18.2
Patient Request for Style/Size Change	2	18.2
Symmastia	2	18.2
Implant Extrusion	1	9.1
Pocket Tear	1	9.1
Total	1	100

Other Clinical Data Findings

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

CTD Diagnoses

Three primary augmentation patients and one revision-augmentation patient in the Mentor Core Study were reported to have a new diagnosis of CTD according to a rheumatologist. These diagnoses were Hashimoto's Thyroiditis at 2 years, two cases of rheumatoid arthritis at 2 and 3 years, and hypothyroidism at 2 years. One primary reconstruction patient and two revision-reconstruction patients in the Mentor Core Study were reported to have a new diagnosis of CTD according to a rheumatologist. These diagnoses were two cases of fibromyalgia, both at 1 year, and pyoderma gangrenosum at 1 year. 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 fatigue, exhaustion, joint swelling, joint pain, numbness of hands, frequent muscle cramps, and the combined categories of fatigue, pain, and fibromyalgia-like symptoms in primary augmentation patients and for joint pain in revision-augmentation and primary 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-reconstruction patients. The Mentor Core Study was not designed to evaluate cause and effect associations because there is no comparison group of women without implants, and because other contributing factors, such as medications and lifestyle/exercise, were not studied. Therefore, it cannot be determined whether these increases were due to the implants or not. 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 3 years in Mentor's Core Study. As previous breast cancer was an exclusion criteria for primary augmentation patients, there were no reports of breast cancer reoccurrence in this cohort. There were no reports of new diagnoses or reoccurrence in revision-augmentation patients. For primary reconstruction patients, 1 (0.5%) patient had a new diagnosis of breast cancer and 4 (1.7%) 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 (8%) of the 25 primary augmentation patients who attempted to breast feed following breast implantation in Mentor's Core Study through 3 years experienced difficulty with breast feeding. Of the 7 revision-augmentation patients who attempted to breast feed after

receiving breast implants, 1 (14%) had difficulty breast feeding. For primary reconstruction patients, of the 3 women who attempted to breastfeed, none experienced lactation difficulties. None of the revision-reconstruction patients attempted to breast feed.

Reproduction Complications

Eight (1.5%) of the primary augmentation patients in Mentor's Core Study reported a miscarriage through 3 years. For primary reconstruction patients, 2 (0.9%) patients reported a miscarriage. There were no reports of miscarriage in revision-augmentation or revision-reconstruction patients.

Suicide

There were no reports of suicide in any of the four cohorts in Mentor's Core Study through 3 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.

DEVICE RETRIEVAL EFFORTS

Mentor requests that any explanted devices be sent to Mentor Corporation, Product Evaluation Department, 3041 Skyway Circle North, Irving, TX 75038 USA for examination and analysis. Please call 1-800-258-3487 for instructions and shipping information for return of explanted devices.

PRODUCT EVALUATION

Mentor requires that any complications or explantation resulting from the use of this device be brought to the immediate attention of the Product Evaluation Department at Mentor, 3041 Skyway Circle North, Irving, TX 75038 USA.

HOW TO REPORT PROBLEMS WITH AN IMPLANT

FDA requires that serious injuries (defined as those that need medical or surgical intervention to prevent permanent damage) be reported by hospitals if they are aware of the serious injuries. In addition, injuries or complications can be voluntarily reported directly by the patient to FDA's MedWatch.

If you have a patient who has experienced one or more serious problems related to her breast implants, you are encouraged to report the serious problem(s) to the FDA through the MedWatch voluntary reporting system. Examples of serious problems include disability, hospitalization, harm to offspring, and medical or surgical intervention to prevent lasting damage.

You are also required to report any product problem or serious adverse event to Mentor. Deaths must be reported to Mentor and FDA. You can report by telephone to 1-800-FDA-1088; by FAX, use Form 3500 to 1-800-FDA-0178; electronically at http://www.fda.gov/medwatch/index.html; or by mail to MedWatch Food and Drug Administration, HF-2, 5600 Fishers Lane Rockville, MD 20857-9787**. Keep a copy of the completed MedWatch form for your records.**

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

RETURNED GOODS AUTHORIZATION

- **U.S. Customers**

Merchandise returned must have all manufacturers' seals intact and must be returned within 60 days from date of invoice to be eligible for credit or replacement. Please contact Mentor Customer Service Department for details. Returned products may be subject to restocking charges.

- **International Customers**

Authorization for return of merchandise should be obtained from your respective dealer. Other conditions noted above also apply.

- **Product Replacement Policy and Limited Warranties**

The following is a description of the assistance available from Mentor Lifetime Product

Replacement Policy, and the Mentor Advantage and Enhanced Advantage Limited Warranties.

Mentor's free Lifetime Product Replacement Policy involves the free lifetime product replacement for its gel-filled and saline-filled breast implants, worldwide. When implant replacement is required and the Mentor Product Replacement Policy applies (see below), Mentor will provide, throughout a patient's lifetime, the same or similar Mentor breast implant at no cost. If a more expensive product is requested, Mentor will invoice the surgeon for the price difference.

The **Mentor Standard Advantage Limited Warranty** is free of charge to all patients who are implanted with Mentor gel-filled or saline-filled breast implants in the United States and Puerto Rico. When the limited warranty applies, Mentor provides the following:

- Financial assistance: For the first ten years following a breast implant procedure, Mentor will provide financial assistance up to $1200 to help cover operating room, anesthesia, and surgical charges not covered by insurance. Financial assistance applies to covered events only (see below). Operating room and anesthesia charges will be given payment priority. In order to qualify for financial assistance, the patient will need to sign a Release Form.
- Free contralateral (opposite side) implant replacement upon surgeon request.
- Non-cancelable terms.

The **Mentor Enhanced Advantage Limited Warranty** is an optional limited warranty available for women who are implanted with Mentor gel-filled or saline-filled breast implants in the United States and Puerto Rico. To be eligible, the Mentor Enhanced Advantage Limited Warranty must be purchased for an enrollment fee of $100 within 45 days from implantation. When the warranty applies, Mentor provides the following:

- Financial assistance: For the first ten years following a breast implant procedure, Mentor will provide financial assistance up to $2400 to help cover operating room, anesthesia, and surgical charges not covered by insurance. Financial assistance applies to covered events only (see below). Operating room and anesthesia charges will be given payment priority. In order to qualify for financial assistance, the patient will need to sign a Release Form.
- Free contralateral implant replacement upon surgeon request.
- Non-cancelable terms.

With both the Mentor Standard Advantage and Mentor Enhanced Advantage Limited Warranties, it is important for the patient to also maintain her own records to ensure validation of her enrollment.

Products Covered

The Mentor Standard Advantage Limited Warranty coverage applies to all Mentor gel-filled and saline-filled breast implants that are implanted in the United States and Puerto Rico, provided they 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 Lifetime Product Replacement Policy, and the Standard Mentor Advantage and Enhanced Advantage Limited Warranties coverages apply to the following:

- Rupture due to localized stress, folding, manufacturing defect, patient trauma, or unknown cause
- Other loss-of-shell integrity events, such as surgical damage may also be covered by these programs. Mentor reserves the right to determine if specific, additional events should be covered.

Events Not Covered

The Mentor Lifetime Product Replacement Policy and the Mentor Standard Advantage and Enhanced Advantage Limited Warranties coverages do not apply to the following:

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

Filing for Financial Assistance

- To file a Mentor Advantage claim for product replacement and/or financial assistance, the surgeon must contact the Mentor Product Evaluation Department at 1-866-250-5115 prompt #1 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 Product Evaluation
  3041 Skyway Circle North
  Irving, Texas 75038-3540

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

Consumer Affairs Department
Mentor Corporation
201 Mentor Drive
Santa Barbara, CA 93111
1-800-525-0245

A copy of the complete programs may also be obtained from the surgeon or by going to www.mentorcorp.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 and Enhanced Advantage coverages. Any such cancellation, change, or modification will not affect the currently stated terms of the Mentor Advantage and Enhanced Advantage coverages for those already enrolled.

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