Product Insert Data Sheet

MENTOR® MEMORYSHAPE® BREAST IMPLANTS

112005-001 Rev C LAB100138639v7 Effective October 2018

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a licensed healthcare practitioner

MENTOR®

Make life more beautiful™

STERILE

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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 MemoryShape® 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 Mentor's MemoryShape® Breast Implant Core Study results, device retrieval efforts, product evaluation, how to report problems with an implant, and returned goods authorization.

Patient Counseling Information

You should review this document and patient labeling prior to counseling the patient about Mentor's MemoryShape® Breast Implants and breast implant surgery. MemoryShape® Breast Implant labeling materials are part of physician training, a requirement described below. 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 *Patient Educational Brochure: Breast Augmentation/Reconstruction with MENTOR® MemoryShape® Breast Implants* (patient brochures), and discuss with the patient the warnings, contraindications, precautions, important factors to consider, complications, and the MENTOR® MemoryShape® Breast Implant Post-Approval Cohort (Core) Study results presented in the patient brochure. You should advise the patient of the potential complications and that medical management of serious complications may include additional surgery and explantation.

Please refer to the INFORMATION TO BE DISCUSSED WITH THE PATIENT section of this document for additional patient counseling information.

Informed Decision

Each patient should receive Mentor's *Patient Educational Brochure: Breast Augmentation/Reconstruction with MENTOR® MemoryShape® 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 breast implant surgery.

Allow the patient at least 1 to 2 weeks to review and consider this information before deciding whether to have primary breast augmentation surgery. In the case of a revision-augmentation, primary reconstruction, and revision-reconstruction, it may be medically advisable to perform surgery sooner.

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

Device Tracking

Silicone gel breast implants are subject to device tracking per Food and Drug Administration (FDA) regulation. Tracking is intended to facilitate notifying patients in the event that important new information about a device becomes available. The laws that govern device tracking require physicians to report certain information relating to their practice, the breast implants used, and the patients who receive breast implants (21 CFR §821.30).[1] A physician prescribing MemoryShape® Breast Implants is required, by federal regulation, to comply with Device Tracking Regulations, and report to Mentor:

- The serial number of the implanted device(s),
- The date of the implant surgery,
- Patient's name,
- The patient's personal contact information (including address, telephone number and date of birth),
- Contact information for the prescribing physician's practice and the physician who regularly sees the patient for primary care, and
- (When applicable) the date the device was:
  - ➢ Explanted with the name, mailing address, and telephone number of the explanting physician;
  - ➢ Out of use due to patient death (date of death);
  - ➢ Returned to the manufacturer;
  - ➢ Permanently disposed of.

Tracking continues until the implant is returned, destroyed, explanted, or the patient becomes deceased. Tracking information will be recorded on the Device Tracking Form supplied by Mentor with each implant. The form should then be returned to Mentor by fax or submitted via www.MentorDirect.com

Mentor strongly recommends that all patients receiving MemoryShape® Breast Implants participate in Mentor's Device Tracking program.

Patients are not required by law to enroll themselves in any tracking program or device registry. However, if a patient declines to provide personal, identifying information, you must still provide all other non-patient specific information.

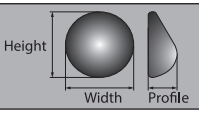
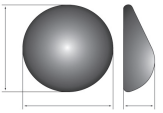
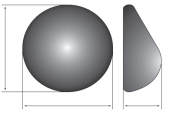
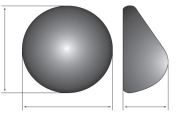
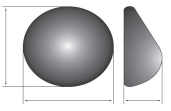
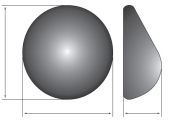
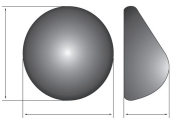
DEVICE DESCRIPTION

MENTOR® MemoryShape® Breast Implants are devices with shells constructed from medical grade silicone elastomer. The shell is filled with Mentor's proprietary formulation of medical grade silicone gel. The textured shell is constructed of successive cross-linked layers of silicone elastomer, and includes raised orientation marks on the anterior and posterior of the implant intended to help the physician orient the implant and ensure proper placement during implantation. Each MENTOR® MemoryShape® Breast Implant is provided sterile.

Physician Training

Completion of Mentor's MemoryShape® Device Training is required for all physicians in order to gain access to Mentor's MemoryShape® Breast Implants. Physician certification provides documentation of training in the use of these devices. Mentor has developed an online training and certification of participation process (The MemoryShape® Device Training) that may be accessed via www.MentorDirect.com

The following lists the catalog numbers and styles of MENTOR® MemoryShape® Breast Implants:

Breast Implant Description **Catalog Number (Style)**		**Height (H)** **Width (W)** **Profile Projections (P) Ranges**	**Size Range**
Medium Height, Moderate Profile 354-0908/1708 (Style MM)		H: 8.5 – 16.0 cm W: 9.0 – 17.0 cm P: 3.3 – 5.9 cm	120-775 cc
Medium Height, Moderate Plus Profile 334-0905/1505 (Style MM+)		H: 8.5 – 14.1 cm W: 9.0 – 15.0 cm P: 3.8 – 6.3 cm	140-650 cc
Medium Height, High Profile 334-0902/1452 (Style MH)		H: 8.5 – 13.6 cm W: 9.0 – 14.5 cm P: 4.6 – 7.1 cm	165-685 cc
Low Height, Moderate Plus Profile 334-0907/1607 (Style LM+)		H: 8.0 – 14.2 cm W: 9.0 – 16.0 cm P: 3.8 – 6.8 cm	125-690 cc
Tall Height, Moderate Plus Profile 334-0909/1509 (Style TM+)		H: 9.4 – 15.6 cm W: 9.0 – 15.0 cm P: 3.8 – 6.3 cm	145-680 cc
Tall Height, High Profile 334-0904/1454 (Style TH)		H: 9.4 – 15.1 cm W: 9.0 – 14.5 cm P: 4.6 – 7.1 cm	180-755 cc

INDICATIONS FOR USE

MENTOR® MemoryShape® 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 in women:

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

WARNINGS

Avoid Implant Damage During Surgery and Other Medical 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 cautery devices or sharp instruments, such as scalpels, suture needles, hypodermic needles, hemostats, Adson forceps or scissors 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 round silicone gel breast implant. This will reduce the potential for creating excessive stress to the implant during insertion. In the Mentor clinical trials, the mean incision size was 4.4 centimeters for the round MemoryGel® Breast Implants and 5.3 centimeters for the MemoryShape® Breast Implants.
- 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. Re-positioning of the implant during surgical 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 immerse the implant in any liquid such as Betadine® or other iodine 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.
- The use of surgical mesh together with the breast implant has not been studied in the Post-Approval Cohort (Core) Study.

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

Specific Populations

Safety and effectiveness has not been established in patients with:

- Autoimmune diseases (e.g., lupus and scleroderma),
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease),
- Planned chemotherapy following breast implant placement,
- Planned radiation therapy to the breast following breast implant placement,
- Conditions 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, or
- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders with your patient 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.

Surgical Precautions

Surgical precautions, such as those described below, should be undertaken to maximize a successful aesthetic result and the long-term performance of the device.

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 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.

Handle the implants with care during implantation as excessive force during implantation might cause gel fracture. (Gel fracture is a fissure or fault line in the gel within the implant as a result of excessive applied force.)

Implant Selection - In order to properly select the correct implant, the following considerations should be taken into account and, as appropriate, discussed with the patient:

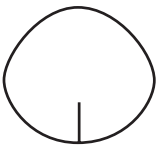
- The implant should be consistent in size with the patient's chest wall dimensions, including base width measurements, also considering the laxity of the tissue and the projection of the implant.
- A thorough discussion should be conducted with the patient, employing appropriate visual aids such as imaging, sizing implants, or other options to clarify her objectives and manage expectations, in order to 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.

Incision Site Selection

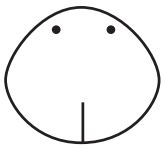
- The periareolar site is typically more concealed, but it may be associated with a higher likelihood of difficulties in successfully breast-feeding as compared to other incision sites.[2] A periareolar incision may result in changes in nipple sensation. As the incision for these implants will be longer than the one typically made for a saline or round silicone gel breast implant, the periareolar incision may not provide sufficient length in some patients.
- The inframammary incision is generally less concealed than the periareolar, but it may be associated with less breast-feeding difficulty than the periareolar incision site.[2]
- The axillary incision is less concealed than the periareolar site.
- The periumbilical approach has not been studied in Mentor's MemoryShape® Breast Implant Post-Approval Cohort (Core) Study and should not be used for a wide variety of reasons, including potential damage to the implant shell.

Implant Placement Selection

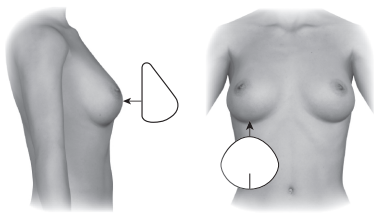
- A well-defined, dry pocket of adequate size and symmetry must be created for implant placement.
- Submuscular placement may make surgery last longer, may make recovery longer, may be more painful, and may make it more difficult to perform some reoperation procedures than subglandular placement. The possible benefits of this placement are that it may result in less palpable implants, less likelihood of capsular contracture,[3] 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,[4,5] and increased difficulty in imaging the breast with mammography.
- MENTOR® MemoryShape® Breast Implants contain raised orientation marks on the anterior and posterior of the implant. These marks help the physician orient the implant and ensure proper placement during implantation.



Anterior Orientation Marks



Posterior Orientation Marks



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. In order to avoid possible injury or damage to the incision site(s), you should advise your patients to avoid the following for the first month after the surgery:

- Sun exposure,
- Jerky movements or activities that stretch the skin at your incision site(s),
- Participating in sports or other activities that raise your pulse or blood pressure, and
- Unnecessary physical or emotional stress

She should be able to return to work within a few days.

Explantation - If it is necessary to perform explantation of the implant, care must be taken to minimize manipulation of the product. Evaluation of the condition of the device upon explantation should be performed by the explanting surgeon and Mentor (refer to DEVICE RETRIEVAL EFFORTS and PRODUCT EVALUATION).

INFORMATION TO BE DISCUSSED WITH THE PATIENT

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 1 to 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 breast implants. Section 4 of the patient brochures provides a more detailed listing of important factors for patients.

Rupture

Rupture of a silicone gel breast implant may be silent/asymptomatic (i.e., there are no symptoms experienced by the patient and no physical signs of changes with the implant), rather than symptomatic. You should advise your patient to undergo regular MRIs to screen for silent rupture even if she experiences 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 reading breast implant MRIs to diagnose a silent rupture. Diagnostic procedures will add to the cost of having implants, and patients should be aware or advised that these costs may exceed the cost of their initial surgery over their lifetime and that their insurance carrier may not cover these costs.

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 patient's breasts will likely be required, whether because of implant rupture, other complications, or unacceptable size/cosmetic outcomes. Patients should be advised that their risk of future complications increases with revision surgery as compared to primary augmentation or reconstruction surgery. Further, in a reoperation in which the implant is not removed (such as open capsulotomies or scar revision), there is a risk that the integrity of the implant's shell could be compromised inadvertently, 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, light-headedness, 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 might be symptoms of rupture of the implant. If the patient has any of these signs, the patient should be told to report them to her surgeon, 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 have 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 or 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. The Institute of Medicine (IOM), in its 1999 report on the safety of silicone breast implants, encourages mothers with silicone gel breast implants to breast-feed, stating that while breast implantation may increase the risk of lactation difficulties, there is no evidence of a hazard to the infant "beyond the loss of breast-feeding itself".[3] Other professional medical associations and independent scientific panels have echoed these conclusions and recommendations.[6,7]

Avoiding Damage During Other Treatment

Patients should inform other treating physicians of the presence of implants to minimize the risk of damage to the implants.

Smoking

As with any surgery, smoking may interfere with the healing process after breast implant surgery.

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,[8,9] necrosis, and implant extrusion.[10]

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 of breast implantation 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

Additional clinical safety and effectiveness data on MemoryShape® Breast Implants will be gathered through a 10-year post-approval study of newly enrolled US patients. It is important for you to relay any new safety information to your patients as soon as such information is provided to you.

GENERAL ADVERSE EVENTS ASSOCIATED WITH BREAST IMPLANT SURGERY

Potential adverse events that may occur with silicone gel breast implant surgery include: 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, lymphadenopathy, and additional complications.

Below is a description of these adverse events. For more specific adverse event rates/outcomes for MemoryShape® Breast Implants, refer to the MENTOR® MEMORYSHAPE® BREAST IMPLANT POST-APPROVAL COHORT (CORE) STUDY section.

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. 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.

Silicone gel 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 breast implant, pain, tingling, swelling, numbness, burning, or hardening of the breast.[11,12,13,14]

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 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.[3,15]

There may also be 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 been few health consequences associated with migrated gel reported in the literature.

Rupture rate information on Mentor's MemoryGel® Breast Implants is provided in a published European study known as the U.K. Sharpe and Collis Study.[16] Silent rupture was assessed by MRI on 149 patients implanted with textured MemoryGel® Breast Implants. The average age of the implants was approximately 10 years. The results suggest that by 13 years approximately 12% of implants will have ruptured. All ruptures were confirmed to be intracapsular. For information on MemoryShape® Breast Implants, refer to the MENTOR® MEMORYSHAPE® BREAST IMPLANT POST-APPROVAL COHORT (CORE) STUDY section of this brochure.

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 are extracapsular.[17] 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.[15] 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 gel 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.[15] 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.[18]
- 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.[12,14,19,20] 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,[14] these studies do not distinguish whether the women had ruptured or intact implants.

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,[3] 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).

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.

Reoperation

Patients should be advised that additional surgery to their breast and/or implant will likely be necessary over the course of their life. Reoperations can be required for many reasons including a patient's decision to change the size or type of her implants, or to otherwise improve her breast surgery outcome.

Implant Removal

Patients should be advised that the implants are not considered lifetime devices and they will potentially undergo implant removal, with or without replacement, over the course of their life. Patients should also be advised that the changes to their breast following explantation might be irreversible.

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. Surgeons should instruct their patients to inform them if there is significant pain or if pain persists.

Changes in Nipple and Breast Sensation

Sensation in the nipple and breast can increase or decrease after implant surgery. Sensation is typically lost after complete mastectomy where the nipple itself is removed. This loss of feeling 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 breast-feed.

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, light-headedness, muscles aches, and/or 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

Patients should be informed that dissatisfaction with cosmetic results related to such things as incorrect size, scar deformity, hypertrophic scarring, capsular contracture, asymmetry, wrinkling, implant displacement/migration, and implant palpability/visibility might occur. Careful surgical planning or technique can minimize, but not preclude, the risk of such results. Pre-existing asymmetry may not be entirely correctable. Revision surgery may be indicated to maintain patient satisfaction but carries additional considerations and risks.

Breast-Feeding Complications

Breast-feeding difficulties have been reported following breast surgery, including breast reduction and breast augmentation. A periareolar surgical approach may further increase the chance of breast-feeding difficulties.

Additional Complications

After breast implant surgery, the following may occur and/or persist, with varying intensity and/or varying length of time: implant extrusion, necrosis, delayed wound healing, and breast tissue atrophy/chest wall deformity. Calcium deposits can form in the tissue capsule surrounding the implant with symptoms that may include pain and firmness. Lymphadenopathy has also been reported in some women with implants.

OTHER REPORTED CONDITIONS

There have been reports in the literature of other conditions in women with silicone gel breast implants. Many of these conditions have been studied to evaluate their potential association with breast implants. No cause and effect relationship has been established between breast implants and the conditions listed below. 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) Diagnoses or Syndromes

Connective tissue diseases include diseases such as lupus, scleroderma, rheumatoid arthritis, and fibromyalgia. There have been a number of published epidemiological studies, meta-analyses, and "weight-of-the-evidence" or critical reviews 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 breast implants would need to be very large.[3,12,14,20,21,22,23,24,25,26] 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.[3,22,23,24] 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.[14] Another study in a small group of women concluded that significantly more women with ruptured implants than intact implants reported debilitating chronic fatigue;[27] the women reported their symptoms after learning whether or not they had a ruptured implant.

Independent scientific panels and review groups have also concluded that there is no evidence to support an association between breast implants and connective tissue disease, or at least, if a risk cannot be absolutely excluded it is too small to be quantified.[3,7,24] A recently published systematic review reported there is limited or suggestive evidence of an association between breast implants and rheumatoid arthritis.[62]

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. Having these rheumatological signs and symptoms does not necessarily mean that a patient has a connective tissue disease. Scientific expert panels and literature reports have found no evidence of a consistent pattern of signs and symptoms in women with silicone gel breast implants.[3,19,28,29,30] 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.[31,32,33,34,35] 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.[31,35,36,37,38,39,40]

Brain Cancer - One study has reported an increased incidence of brain cancer in women with breast implants as compared to the general population.[41] The incidence of brain cancer, however, was not significantly increased in women with breast implants when compared to women who had other plastic surgeries; the study relied on very few cases and the authors relied upon death certificates for brain cancer diagnoses, which may reflect other cancers that have metastasized. Other recent large studies and a 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.[33,35,42,43,44,45,46]

Respiratory/Lung Cancer - One study has reported an increased incidence of respiratory/lung cancer in women with breast implants.[41] 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.[47,48,49] Several large studies have found no association between breast implants and respiratory/lung cancer.[33,35,43,44,46] A recently published systematic review reported there is limited or suggestive evidence of an association between breast implants and lung cancer.[62]

Reproductive System Cancers - One study has reported an increased incidence of cervical/vulvar cancer in women with breast implants.[41] The cause of this increase is unknown. However, there was no increased risk when compared to women who had other types of plastic surgery. Another study reported an increased incidence of vulvar cancer that has not been explained.[33] Other recent large studies concluded that the evidence does not support an association between reproductive system cancers and breast implants.[35,42,43,44,45,46]

Lympho-Hematopoietic Cancers - One study has reported an increased risk of leukemia in women with breast implants as compared to the general population.[41] However, there was no increased risk when compared to women who had other types of plastic surgery. Other recent large studies concluded that the evidence does not support an association between lympho-hematopoietic cancers and breast implants.[33,35,42,43,44,45,46]

Anaplastic Large 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. Several journal articles explore the risk factors for BIA-ALCL, including the methods used to create surface texture of the implant and the role of biofilm in causing disease, among others.

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.

Report all confirmed cases of BIA-ALCL to the FDA (https://www.fda.gov/Safety/MedWatch). In some cases, the FDA may contact you for additional information. The FDA will keep the identities of the reporter and the patient confidential.

FDA also recommends reporting cases of BIA-ALCL to the PROFILE Registry (https://www.thepsf.org/research/clinical-impact/profile.htm) where you can submit more comprehensive case data. This will help provide a better understanding of the etiology of BIA-ALCL.

For additional information on FDA's analysis and review of BIA-ALCL, please visit: **https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/ImplantsandProsthetics/BreastImplants/ucm239995.htm**

Other Cancers **-** There have been several studies published that examined the risk of other types of cancers, e.g., thyroid cancers, urinary system cancers, sarcoma, endocrine cancer, connective tissue cancer, cancer of the eye, and unspecified cancers in women with breast implants. All of those studies found no increased risk in women with breast implants.[14,28,33,41,43,44,45,46]

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.[3]

Suicide

In several studies, a higher incidence of suicide was observed in women with breast implants.[51,52,53,54] 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.[52]

Effects on Children

At this time, it is not known if a small amount of silicone may pass through the breast implant silicone shell into breast milk during breast-feeding. 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 breast implants when compared to women without implants.[55]

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.[56,57] Although low birth weight was reported in a third study, other factors (for example, lower pre-pregnancy weight) may explain this finding.[58] 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.[3,59] 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[3] and lymphadenopathy.[18] 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 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.[60] 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 MemoryShape® Breast 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 among LMW silicones and platinum, only platinum bled into the serum in measurable quantities. Platinum levels measured at 2 micrograms by 40 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 available evidence supports that the extremely low level of gel and platinum bleed is of no clinical consequence.

MENTOR® MEMORYSHAPE® BREAST IMPLANT POST-APPROVAL COHORT (CORE) STUDY

The safety and effectiveness of Mentor's silicone gel implants were evaluated in an open-label multicenter clinical study, referred to as the MENTOR® MemoryShape® Breast Implant Post-Approval Cohort (Core) Study. The information below provides more details about Mentor's MemoryShape® Breast Implant Post-Approval Cohort (Core) Study and the complications and benefits your patients may experience.

Study Design

Mentor's MemoryShape™ Breast Implant Post-Approval Cohort (Core) Study was a 10-year study to assess safety and effectiveness in primary augmentation, primary reconstruction, and revision (augmentation and reconstruction) patients. The MemoryShape™ Post-Approval Cohort (Core) Study consisted of 955 patients, including 572 primary augmentation patients, 124 revision-augmentation patients, 190 primary reconstruction patients, and 69 revision-reconstruction patients. Patients' medical histories were collected at baseline. Patient follow-up was at 10 weeks and annually through 10 years. MRI scans to detect silent rupture of the implant for a subset of patients were scheduled at 1, 2, 4, 6, 8, and 10 years. Safety assessments included complication rates and rates of reoperation. Effectiveness assessments included bra cup size change (primary augmentation patients only), circumferential chest size change, patient satisfaction, and quality-of-life (QoL) measures.

Patient Accounting and Baseline Demographic Profile

Mentor's MemoryShape® Breast Implant Post-Approval Cohort (Core) Study consisted of 955 patients, including 572 primary augmentation patients, 124 revision-augmentation patients, 190 primary reconstruction patients, and 69 revision-reconstruction patients. This document presents data through 3, 6, and 10 years post-implantation. Data are available through 3 years post-implantation for 85% of the eligible primary augmentation patients, 87% of the eligible revision-augmentation patients, 92% of the eligible primary reconstruction patients, and 91% of the eligible revision-reconstruction patients. Data are available through 6 years post-implantation for 72% of the eligible primary augmentation patients, 72% of the eligible revision-augmentation patients, 77% of the eligible primary reconstruction patients, and 76% of the eligible revision-reconstruction patients. Data are available through 10 years post-implantation for 60% of the eligible primary augmentation patients, 63% of the eligible revision-augmentation patients, 67% of the eligible primary reconstruction patients, and 74% of the eligible revision-reconstruction patients.

Table 1 provides demographic information for the MENTOR® MemoryShape® Breast Implant Post-Approval Cohort (Core) Study.

Table 1. MemoryShape® Breast Implant Post-Approval Cohort (Core) Study Patient Demographics by Cohort

Characteristic	Primary Augmentation N=572	Revision-Augmentation N=124	Primary Reconstruction N=190	Revision-Reconstruction N=69
Age (years)				
<20	16 (2.8%)	0 (0%)	2 (1.1%)	0 (0%)
20 to <30	137 (24.0%)	5 (4.0%)	7 (3.7%)	1 (1.4%)
30 to <40	242 (42.3%)	30 (24.2%)	26 (13.7%)	4 (5.8%)
40 to <50	150 (26.2%)	45 (36.3%)	84 (44.2%)	22 (31.9%)
50 to <60	24 (4.2%)	36 (29.0%)	45 (23.7%)	27 (39.1%)
60 and older	3 (0.5%)	8 (6.5%)	26 (13.7%)	15 (21.7%)
Median age	36 years	46 years	47 years	53 years
Marital status				
Married	361 (63.1%)	88 (71.0%)	145 (76.3%)	48 (69.6%)
Single	129 (22.6%)	12 (9.7%)	22 (11.6%)	11 (15.9%)
Divorced	65 (11.4%)	21 (16.9%)	18 (9.5%)	5 (7.2%)
Separated	10 (1.7%)	3 (2.4%)	0 (0%)	1 (1.4%)
Widowed	5 (0.9%)	0 (0%)	5 (2.6%)	4 (5.8%)
Not provided	2 (0.3%)	0 (0%)	0 (0%)	0 (0%)
Race				
Caucasian	518 (90.6%)	119 (96.0%)	178 (93.7%)	66 (95.7%)
Asian	13 (2.3%)	2 (1.6%)	1 (0.5%)	0 (0%)
African American	6 (1.0%)	0 (0%)	9 (4.7%)	1 (1.4%)
Other	30 (5.2%)	3 (2.4%)	2 (1.1%)	1 (1.4%)
Not provided	5 (0.9%)	0 (0%)	0 (0%)	1 (1.4%)
Education				
Less than 12 years	4 (0.7%)	1 (0.8%)	3 (1.6%)	2 (2.9%)
High school graduate	48 (8.4%)	15 (12.1%)	25 (13.2%)	9 (13.0%)
Some college	199 (34.8%)	44 (35.5%)	48 (25.3%)	23 (33.3%)
College graduate	255 (44.6%)	44 (35.5%)	73 (38.4%)	18 (26.1%)
Post graduate	58 (10.1%)	18 (14.5%)	37 (19.5%)	15 (21.7%)
Not provided	8 (1.4%)	2 (1.6%)	4 (2.1%)	2 (2.9%)

In the MemoryShape™ Breast Implant Post-Approval Cohort (Core) Study, 1,831 devices (MemoryShape® textured, medium height, moderate profile breast implant, style MM) were implanted in the 955 study patients. Table 2 presents the surgical placement of these devices by study cohort.

Table 2. Breast Implant Placement by Cohort

Implant Placement	Primary Augmentation N=1143	Revision-Augmentation N=247	Primary Reconstruction N=326	Revision-Reconstruction N=115
Submuscular/ Subpectoral	985 (86.2%)	165 (66.8%)	304 (93.3%)	113 (98.3%)
Subglandular	154 (13.5%)	80 (32.4%)	22 (6.7%)	2 (1.7%)
Other	4 (0.3%)[a]	2 (0.8%)[b]	0 (0%)	0 (0%)

[a] Partial retropectoral
[b] Prepectoral

With respect to other surgical baseline factors in the MemoryShape® Breast Implant Post-Approval Cohort (Core) Study, for both primary augmentation and revision-augmentation patients, the most common incision site was inframammary; while for primary reconstruction and revision-reconstruction patients, the most common incision site was the mastectomy scar.

Rupture Information on MENTOR® MemoryShape® Breast Implants

In Mentor's MemoryShape® Breast Implant Post-Approval Cohort (Core) Study, rupture was assessed for patients who had scheduled MRIs to screen for silent rupture (i.e., part of the MRI cohort). This population of patients was used as the basis for estimating the overall rupture rate because it is only in this sample that, in general, both silent ruptures and overt ruptures would have been detected. Of the 955 patients in the study, 419 patients were enrolled in the MRI cohort, including 252 primary augmentation, 56 revision-augmentation, 73 primary reconstruction, and 38 revision-reconstruction patients.

MRI scans to detect silent rupture of the implant for the MRI cohort were scheduled at 1, 2, 4, 6, 8, and 10 years. At 1, 2, 4, 6, 8, and 10 years, the overall follow-up rates for the MRI cohort across all indications were 71% (291 of 412 expected due), 86% (347 of 405 expected due), 72% (281 of 388 expected due), 63% (241 of 419 expected due), 56% (210 of 373 expected due), and 45% (165 of 368 expected due), respectively. Table 3a presents the estimated rupture rates through 1, 2, 4, 6, 8, and 10 years.

Table 3a. Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval) for Rupture by Patient (MRI Cohort)

	Primary Augmentation N=252	Revision-Augmentation N=56	Primary Reconstruction N=73	Revision-Reconstruction N=38
Year 1	0	0	0	0
Year 2	0	0	0	0
Year 4	1.0 (0.3, 4.1)	0	0	0
Year 6	2.2 (0.8, 5.8)	2.9 (0.4, 19.1)	0	0
Year 8	3.6 (1.6, 7.9)	9.6 (3.2, 27.1)	9.4 (3.1, 26.3)	0
Year 10	6.6 (3.4, 12.5)	9.6 (3.2, 27.1)	18.9 (8.1, 40.5)	0

In 2010, MRI screening was implemented for all study patients. Table 3b presents the estimated cumulative incidence rates for rupture through 10 years for the original non-MRI cohort.

Table 3b. Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval) for Rupture by Patient (Non-MRI Cohort)

At 8 and 10 years, the overall follow-up rates for the non-MRI cohort across all indications were 49% (232 of 472 expected due) and 45% (211 of 467 expected due), respectively.

	Primary Augmentation N=320	Revision-Augmentation N=68	Primary Reconstruction N=117	Revision-Reconstruction N=31
Year 8	4.1 (2.0, 8.4)	9.1 (3.0, 25.6)	5.1 (1.7, 14.9)	0
Year 10	6.4 (3.5, 11.6)	13.2 (5.1, 31.9)	7.2 (2.7, 18.2)	0

Overall, there were 17 suspected or confirmed reports of rupture for 17 patients in the MRI cohort and 20 suspected or confirmed reports of rupture for 18 patients in the original non-MRI cohort. Of the 37 suspected or confirmed ruptured implants in the overall study, including those found in the non-MRI cohort, 4 cases showed definite extracapsular silicone by MRI; 4 cases were indeterminate for extracapsular silicone. Table 4 summarizes the number and percentage of ruptures through 10 years at the patient and implant levels for the MRI cohort and original non-MRI cohort.

Table 4. Number and Percentage of Ruptures (Suspected or Confirmed) Through 10 Years

	MRI Cohort		Non-MRI Cohort	
	Patients	Implants	Patients	Implants
Primary Augmentation	9 (3.6%)	9 (1.8%)	10 (3.1%)	11 (1.7%)
Revision-Augmentation	3 (5.4%)	3 (2.7%)	4 (5.9%)	4 (3.0%)
Primary Reconstruction	5 (6.8%)	5 (4.1%)	4 (3.4%)	5 (2.5%)
Revision-Reconstruction	0	0	0	0
Overall	17 (4.1%)	17 (2.1%)	18 (3.4%)	20 (1.9%)

Table 5 presents the results for accuracy of MRI for evaluation of MemoryShape® Breast Implants. The MRI sensitivity for correctly identifying ruptured implants was 85%. The MRI specificity for correctly identifying non-ruptured implants was 100%.

Table 5. MRI Screening Conducted Prior to Explantation

Implants With History of MRI Screening, Explantation, and Product Evaluation	Rupture Confirmed on Explant	Non-Rupture Confirmed on Explant
MRI showed rupture	17*	0
MRI showed no rupture	3	48
MRI sensitivity	85%	
MRI specificity	100%	

* Of the suspected or confirmed ruptures in the study, 20 with prior MRI data have been explanted. In 17 of these 20 cases, rupture was confirmed by product evaluation after explant; for 2 devices, MRI performed prior to explantation and following physician suspicion of rupture did not detect rupture that was observed upon explantation; and for 1 device assessed as intact by MRI, but explanted due to a contralateral suspected rupture, the device was determined to be ruptured upon product evaluation.

Effectiveness Outcomes

The benefits of MemoryShape® Breast Implants were assessed by bra cup size change (primary augmentation patients only), circumferential chest size change, patient satisfaction, and quality-of-life (QoL) measures (self-worth, body image, physical, mental, and social health, and breast satisfaction). Patient satisfaction in Mentor's MemoryShape® Breast Implant Post-Approval Cohort (Core) Study was based on a single question of "Would the patient make the same decision to have this breast surgery?" The QoL measures were the Rosenberg Self Esteem Scale (measures self-worth or self-acceptance), the Body Esteem Scale (measures a person's body image), the SF-36 (measures physical, mental, and social health), and the Breast Evaluation Questionnaire (measures breast satisfaction). These outcomes were assessed before implantation and at 1, 2, 4, 6, 8, and 10 years after surgery.

Primary Augmentation Patients - For primary augmentation patients, 315 (55%) of the 572 patients enrolled were included in the analysis of cup size at 10 years. Of these 315 patients, 303 (96%) experienced at least one cup size increase. For circumferential chest size, 312 (54%) of the 572 patients enrolled were included in the analysis at 10 years. The overall average increase in circumferential chest size through 10 years was 2.1 inches.

At 10 years, 322 (56%) of the 572 patients enrolled answered the patient satisfaction question. Of these 322 patients, 311 (97%) stated to their surgeon that they would make the same decision to have breast surgery.

With regard to QoL measures at 10 years for primary augmentation patients, there was no significant change in the SF-36. There was a significant increase in the total score and the positive attitude score for the Rosenberg Self-Esteem Scale and the chest and sexual attractiveness subscales for the Body Esteem Scale. Of the 299 primary augmentation patients who answered the question "How satisfied with the general appearance of your breasts are you?", 211 (71%) were very satisfied; 70 (23%) were somewhat satisfied; 7 (2%) were neither satisfied nor dissatisfied; 10 (3%) were somewhat dissatisfied; and 1 (<1%) was very dissatisfied. Based on the Breast Evaluation Questionnaire, the average improvement from before getting implants was 73% for comfort when not fully dressed, 29% for comfort when fully dressed, and 106% for satisfaction with breast characteristics.

Revision-Augmentation Patients - For revision-augmentation patients, 62 (50%) of the 124 patients enrolled were included in the circumferential chest size analysis at 10 years. The overall average increase in circumferential chest size through 10 years was 0.6 inches.

At 10 years, 66 (53%) of the 124 revision-augmentation patients enrolled answered the patient satisfaction question. Of these 66 patients, 63 (95%) stated to their surgeon that they would make the same decision to have breast surgery.

With regard to QoL measures at 10 years for revision-augmentation patients, there was no significant change in the Rosenberg Self-Esteem Scale. There was a significant decrease in the mental component score of the SF-36 but no significant change in the physical component score. For the Body Esteem Scale, there was a significant decrease in the total score and an increase in the chest subscale. Of the 60 revision-augmentation patients who answered the question "How satisfied with the general appearance of your breasts are you?", 30 (50%) were very satisfied; 20 (33%) were somewhat satisfied; 1 (2%) was neither satisfied nor dissatisfied; and 9 (15%) were somewhat dissatisfied. Based on the Breast Evaluation Questionnaire, the average improvement from before getting implants was 24% for comfort when not fully dressed, 12% for comfort when fully dressed, and 43% for satisfaction with breast characteristics.

Primary Reconstruction Patients - For primary reconstruction patients, 79 (42%) of the 190 patients enrolled were included in the analysis of circumferential chest size at 10 years. The overall average increase in circumferential chest size through 10 years was 0.3 inches.

At 10 years, 87 (46%) of 190 primary reconstruction patients enrolled answered the patient satisfaction question. Of these 87 patients, 87 (100%) stated to their surgeon that they would make the same decision to have breast surgery.

With regard to QoL measures at 10 years for primary reconstruction patients, there was a significant increase in the physical component score of the SF-36 but no significant change in the mental component score. There was a significant decrease in the total score of the Rosenberg Self-Esteem Scale. For the Body Esteem Scale, there was a significant increase in the chest subscale. Of the 93 primary reconstruction patients who answered the question "How satisfied with the general appearance of your breasts are you?", 44 (47%) were very satisfied; 25 (27%) were somewhat satisfied; 8 (9%) were neither satisfied nor dissatisfied; 10 (11%) were somewhat dissatisfied; and 6 (6%) were very dissatisfied. Based on the Breast Evaluation Questionnaire, the average improvement from before getting implants was 24% for comfort when not fully dressed, 21% for comfort when fully dressed, and 43% for satisfaction with breast characteristics.

Revision-Reconstruction Patients - For revision-reconstruction patients, 33 (48%) of the 69 patients enrolled were included in the analysis of circumferential chest size at 10 years. The overall average increase in circumferential chest size through 10 years was 0.1 inches.

At 10 years, 34 (49%) of 69 revision-reconstruction patients enrolled answered the patient satisfaction question. Of these 34 patients, 32 (94%) stated to their surgeon that they would make the same decision to have breast surgery.

With regard to QoL measures at 10 years for revision-reconstruction patients, there was no significant change in the SF-36 or Rosenberg Self-Esteem Scale. For the Body Esteem Scale, there was a significant increase in the chest subscale. Of the 33 revision-reconstruction patients who answered the question "How satisfied with the general appearance of your breasts are you?", 9 (27%) were very satisfied; 9 (27%) were somewhat satisfied; 6 (18%) were neither satisfied nor dissatisfied; 6 (18%) were somewhat dissatisfied; and 3 (9%) were very dissatisfied. Based on the Breast Evaluation Questionnaire, the average improvement from before getting implants was 25% for comfort when not fully dressed, 20% for comfort when fully dressed, and 29% for satisfaction with breast characteristics.

Safety Outcomes

Tables 6a-6d provide the Kaplan-Meier estimated cumulative incidence rates for postoperative complications through 3, 6, and 10 years. The rates reflect the estimated percentage of patients who will experience the listed complication at least once within the first 3, 6, and 10 years after implantation. In Mentor's MemoryShape® Breast Implant Post-Approval Cohort (Core) Study, some complications occurred more than once for some patients. Refer to Tables 3a-3b for more detailed estimated rupture rates.

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 6a. Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), by Patient for Primary Augmentation Cohort, N=572

	Year 3 % (95% CI)	Year 6 % (95% CI)	Year 10 % (95% CI)
Any complication excluding rupture[a,b]	26.8 (23.4, 30.7)	33.9 (30.1, 38.0)	38.6 (34.7, 42.8)
Key Complications	**Year 3 % (95% CI)**	**Year 6 % (95% CI)**	**Year 10 % (95% CI)**
Any reoperation	13.8 (11.2, 16.9)	18.3 (15.3, 21.8)	22.3 (19.0, 26.0)
Capsular contracture Baker Grade III/IV	1.1 (0.5, 2.4)	2.5 (1.5, 4.2)	3.6 (2.3, 5.7)
Implant removal with or without replacement	5.0 (3.5, 7.1)	6.8 (5.0, 9.3)	9.2 (7.0, 12.0)
Implant removal with replacement with study device	1.8 (1.0, 3.3)	2.4 (1.4, 4.1)	4.0 (2.6, 6.2)
Implant rupture (based on the MRI cohort)[c]	–	2.2 (0.8, 5.8)	6.6 (3.4, 12.5)
Infection	0.7 (0.3, 1.9)	0.7 (0.3, 1.9)	0.7 (0.3, 1.9)
Other Complications ≥ 1%[b,d]	**Year 3 % (95% CI)**	**Year 6 % (95% CI)**	**Year 10 % (95% CI)**
Breast pain	2.1 (1.2, 3.8)	2.3 (1.4, 4.0)	2.8 (1.7, 4.6)
Breast sensation changes	2.5 (1.5, 4.2)	3.3 (2.1, 5.2)	3.9 (2.6, 5.9)
Capsular contracture Baker Grade III	1.1 (0.5, 2.4)	2.5 (1.5, 4.2)	3.6 (2.3, 5.7)
Implant rotation	<1	1.1 (0.5, 2.4)	1.1 (0.5, 2.4)
Mass/cyst	1.1 (0.5, 2.4)	2.1 (1.1, 3.7)	2.9 (1.8, 4.8)
Miscarriage	<1	1.9 (1.0, 3.5)	2.8 (1.7, 4.6)
New diagnosis of breast cancer	<1	<1	1.2 (0.5, 2.6)
Nipple sensation changes	4.1 (2.7, 6.1)	5.1 (3.5, 7.3)	5.5 (3.9, 7.8)
Palpability – implant	<1	<1	1.1 (0.5, 2.5)
Patient dissatisfied with aesthetic appearance of breast	1.1 (0.5, 2.4)	1.3 (0.6, 2.6)	1.3 (0.6, 2.6)
Position dissatisfaction	2.0 (1.1, 3.6)	2.2 (1.2, 3.8)	2.2 (1.2, 3.8)
Ptosis	2.4 (1.4, 4.0)	3.7 (2.4, 5.7)	5.0 (3.5, 7.3)
Size change – patient request	1.5 (0.7, 2.9)	1.7 (0.9, 3.1)	1.7 (0.9, 3.1)
Wrinkling	1.6 (0.8, 3.1)	2.4 (1.4, 4.1)	2.8 (1.7, 4.7)

[a] 213 primary augmentation patients experienced at least one complication or reoperation.

[b] Mild occurrences were excluded for all complications except reoperation, implant removal, implant rupture, capsular contracture, and infection.

[c] Implant rupture (based on the MRI cohort) was assessed by MRI at 1, 2, 4, 6, 8, and 10 years.

[d] The following complications occurred at a rate less than 1%: asymmetry, Baker II capsular contracture with surgical intervention, Baker IV capsular contracture, bruising, calcification, contour irregularities, death,[e] death – accident unrelated to study device,[e] death – metastatic disease,[e] delayed wound healing, double bubble, hematoma, hypertrophic scarring, implant movement upon muscle contraction, implant outline visible through skin, irritation/inflammation, lack of projection, lactation difficulties, loss of definition of inframammary fold, metastatic disease, new diagnosis of rheumatic disease, nipple complication, paresthesia, patient dissatisfied with feel of implant, patient would not have surgery again, pregnancy complication – ectopic, pregnancy complication – tubal, recurrent breast cancer, scarring, seroma, shape distortion, skin lesion, swelling (excessive), tenderness/soreness, and wound dehiscence.

[e] All causes of death were reported by the investigator to be unrelated to study procedure or device.

Table 6b. Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), by Patient for Revision-Augmentation Cohort, N=124

	Year 3 % (95% CI)	Year 6 % (95% CI)	Year 10 % (95% CI)
Any complication excluding rupture[a,b]	36.6 (28.8, 45.8)	45.4 (37.0, 54.7)	52.9 (44.2, 62.2)
Key Complications	**Year 3 % (95% CI)**	**Year 6 % (95% CI)**	**Year 10 % (95% CI)**
Any reoperation	17.2 (11.5, 25.1)	25.0 (18.2, 33.9)	35.0 (27.0, 44.7)
Capsular contracture Baker Grade III/IV	5.1 (2.3, 11.0)	9.1 (5.0, 16.3)	15.5 (9.8, 24.1)
Implant removal with or without replacement	10.6 (6.3, 17.6)	14.1 (9.0, 21.7)	25.9 (18.7, 35.2)
Implant removal with replacement with study device	4.2 (1.8, 9.8)	5.1 (2.3, 11.1)	10.8 (6.1, 18.9)
Implant rupture (based on the MRI cohort)[c]	—	2.9 (0.4, 19.1)	9.6 (3.2, 27.1)
Infection	0.8 (0.1, 5.6)	1.9 (0.5, 7.4)	1.9 (0.5, 7.4)
Other Complications ≥ 1%[b,d]	**Year 3 % (95% CI)**	**Year 6 % (95% CI)**	**Year 10 % (95% CI)**
Asymmetry	1.7 (0.4, 6.6)	1.7 (0.4, 6.6)	2.8 (0.9, 8.4)
Breast sensation changes	2.6 (0.9, 8.0)	2.6 (0.9, 8.0)	3.7 (1.4, 9.7)
Capsular contracture Baker Grade II with surgical intervention	<1	1.8 (0.5, 7.1)	1.8 (0.5, 7.1)
Capsular contracture Baker Grade III	3.4 (1.3, 8.8)	5.3 (2.4, 11.5)	10.6 (6.0, 18.4)
Capsular contracture Baker Grade IV	1.7 (0.4, 6.8)	3.8 (1.4, 9.8)	4.9 (2.1, 11.5)
Death – metastatic disease[e]	0	0	1.1 (0.2, 7.4)
Death – suicide[e]	0	0	1.1 (0.2, 7.5)
Delayed wound healing	0	1.1 (0.2, 7.2)	1.1 (0.2, 7.2)
Implant rotation	1.7 (0.4, 6.6)	2.7 (0.9, 8.2)	2.7 (0.9, 8.2)
Mass/cyst	<1	2.8 (0.9, 8.5)	2.8 (0.9, 8.5)
New diagnosis of rheumatic disease	0	1.0 (0.1, 7.0)	2.1 (0.5, 8.1)
Nipple complication	0	2.0 (0.5, 7.9)	2.0 (0.5, 7.9)
Nipple sensation changes	5.2 (2.4, 11.2)	5.2 (2.4, 11.2)	5.2 (2.4, 11.2)
Palpability – implant	2.5 (0.8, 7.7)	3.5 (1.3, 9.1)	4.5 (1.9, 10.6)
Patient dissatisfied with aesthetic appearance of breast	2.6 (0.8, 7.7)	3.6 (1.4, 9.4)	4.7 (2.0, 10.9)
Patient dissatisfied with feel of implant	<1	1.8 (0.5, 7.3)	3.1 (1.0, 9.4)
Position dissatisfaction	3.5 (1.3, 9.1)	4.5 (1.9, 10.4)	4.5 (1.9, 10.4)
Ptosis	1.8 (0.5, 7.0)	5.8 (2.6, 12.4)	10.0 (5.5, 17.9)
Shape distortion	0	0	1.1 (0.2, 7.3)
Size change – patient request	1.7 (0.4, 6.5)	1.7 (0.4, 6.5)	2.8 (0.9, 8.5)
Wound dehiscence	1.6 (0.4, 6.4)	1.6 (0.4, 6.4)	1.6 (0.4, 6.4)
Wrinkling	4.9 (2.2, 10.6)	5.9 (2.8, 11.9)	7.0 (3.5, 13.6)

[a] 63 revision-augmentation patients experienced at least one complication or reoperation.

[b] Mild occurrences were excluded for all complications except reoperation, implant removal, implant rupture, capsular contracture, and infection.

[c] Implant rupture (based on the MRI cohort) was assessed by MRI at 1, 2, 4, 6, 8, and 10 years.

[d] The following complications occurred at a rate less than 1%: breast pain, calcification, double bubble, hypertrophic scarring, implant movement upon muscle contraction, lack of projection, miscarriage, new diagnosis of breast cancer, size change – physician assessment only, and skin lesion.

[e] All causes of death were reported by the investigator to be unrelated to study procedure or device.

Table 6c. Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), by Patient for Primary Reconstruction Cohort, N=190

	Year 3 % (95% CI)	Year 6 % (95% CI)	Year 10 % (95% CI)
Any complication excluding rupture[a,b]	48.1 (41.2, 55.4)	58.6 (51.6, 65.7)	68.9 (62.1, 75.5)
Key Complications	**Year 3 % (95% CI)**	**Year 6 % (95% CI)**	**Year 10 % (95% CI)**
Any reoperation	34.4 (28.1, 41.7)	42.0 (35.2, 49.5)	52.7 (45.5, 60.2)
Capsular contracture Baker Grade III/IV	5.0 (2.6, 9.4)	10.3 (6.5, 16.1)	14.3 (9.6, 21.1)
Implant removal with or without replacement	13.8 (9.6, 19.6)	21.2 (15.9, 27.8)	34.1 (27.6, 41.7)
Implant removal with replacement with study device	5.4 (3.0, 9.8)	6.7 (3.9, 11.5)	16.7 (11.5, 23.9)
Implant rupture (based on the MRI cohort)[c]	—	0	18.9 (8.1, 40.5)
Infection	1.6 (0.5, 5.0)	1.6 (0.5, 5.0)	1.6 (0.5, 5.0)
Other Complications ≥ 1%[b,d]	**Year 3 % (95% CI)**	**Year 6 % (95% CI)**	**Year 10 % (95% CI)**
Asymmetry	5.9 (3.3, 10.5)	10.0 (6.3, 15.7)	11.5 (7.5, 17.6)
Breast sensation changes	1.1 (0.3, 4.5)	1.1 (0.3, 4.5)	1.1 (0.3, 4.5)
Breast pain	2.8 (1.2, 6.6)	2.8 (1.2, 6.6)	3.7 (1.6, 8.2)
Capsular contracture Baker Grade II with surgical intervention	<1	3.1 (1.3, 7.4)	3.1 (1.3, 7.4)
Capsular contracture Baker Grade III	4.0 (1.9, 8.2)	9.3 (5.7, 15.0)	12.5 (8.1, 19.1)
Capsular contracture Baker Grade IV	1.6 (0.5, 4.9)	1.6 (0.5, 4.9)	2.5 (0.9, 6.6)
Death – metastatic disease[e]	1.1 (0.3, 4.4)	4.3 (2.1, 8.8)	5.7 (3.0, 10.8)
Delayed wound healing	1.1 (0.3, 4.1)	1.1 (0.3, 4.1)	1.1 (0.3, 4.1)
Excess skin/tissue	2.2 (0.8, 5.8)	2.2 (0.8, 5.8)	2.2 (0.8, 5.8)
Implant immobility	0	1.3 (0.3, 5.1)	2.0 (0.7, 6.1)
Implant rotation	2.3 (0.9, 5.9)	3.6 (1.6, 7.9)	3.6 (1.6, 7.9)
Lack of projection	2.8 (1.2, 6.6)	4.7 (2.4, 9.3)	4.7 (2.4, 9.3)
Metastatic disease	2.2 (0.9, 5.9)	2.9 (1.2, 6.7)	4.5 (2.1, 9.3)
Miscarriage	1.2 (0.3, 4.6)	3.1 (1.3, 7.4)	3.1 (1.3, 7.4)

Table 6c. *Continued to next page*

Table 6c. *(Continued)*

Other Complications ≥ 1%[b,d]	Year 3 % (95% CI)	Year 6 % (95% CI)	Year 10 % (95% CI)
New diagnosis of rheumatic disease	<1	<1	1.6 (0.4, 6.5)
Nipple sensation changes	2.3 (0.9, 6.0)	2.9 (1.2, 6.8)	2.9 (1.2, 6.8)
Palpability – implant	0	<1	1.4 (0.4, 5.6)
Position dissatisfaction	<1	1.9 (0.6, 5.9)	2.7 (1.0, 7.3)
Ptosis	1.1 (0.3, 4.5)	2.4 (0.9, 6.3)	2.4 (0.9, 6.3)
Recurrent breast cancer	2.2 (0.8, 5.8)	4.2 (2.0, 8.7)	6.5 (3.5, 11.8)
Scarring	1.7 (0.6, 5.2)	1.7 (0.6, 5.2)	1.7 (0.6, 5.2)
Seroma	1.1 (0.3, 4.4)	1.8 (0.6, 5.4)	2.6 (1.0, 6.9)
Shape distortion	0	1.4 (0.4, 5.5)	1.4 (0.4, 5.5)
Size change – patient request	2.8 (1.2, 6.6)	2.8 (1.2, 6.6)	3.5 (1.6, 7.6)
Skin lesion	<1	1.2 (0.3, 4.7)	1.2 (0.3, 4.7)
Wrinkling	2.7 (1.2, 6.5)	3.4 (1.5, 7.4)	5.5 (2.9, 10.5)

[a] 128 primary reconstruction patients experienced at least one complication or reoperation.

[b] Mild occurrences were excluded for all complications except reoperation, implant removal, implant rupture, capsular contracture, and infection.

[c] Implant rupture (based on the MRI cohort) was assessed by MRI at 1, 2, 4, 6, 8, and 10 years.

[d] The following complications occurred at a rate less than 1%: autoimmune hepatitis, capsular contracture, contour irregularities, erythema, extrusion, irritation/inflammation, itching, leukemia, loss of definition of inframammary fold, lymphadenopathy, mass/cyst, muscle atrophy, nipple complication, patient dissatisfied with aesthetic appearance of breast, pregnancy complication – ectopic, size change – physician assessment only, suture complication, and wound dehiscence.

[e] All causes of death were reported by the investigator to be unrelated to study procedure or device.

Table 6d. Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), by Patient for Revision-Reconstruction Cohort, N=69

	Year 3 % (95% CI)	Year 6 % (95% CI)	Year 10 % (95% CI)
Any complication excluding rupture[a,b]	46.8 (35.8, 59.3)	58.6 (47.3, 70.4)	73.9 (63.0, 83.8)
Key Complications	**Year 3 % (95% CI)**	**Year 6 % (95% CI)**	**Year 10 % (95% CI)**
Any reoperation	29.5 (20.1, 41.9)	44.9 (33.9, 57.6)	59.7 (48.0, 71.8)
Capsular Contracture Baker Grade III/IV	16.4 (9.1, 28.5)	16.4 (9.1, 28.5)	16.4 (9.1, 28.5)
Implant Removal with or without replacement	22.1 (14.0, 34.0)	34.4 (24.4, 47.2)	49.0 (37.6, 61.8)
Implant Removal with replacement with study device	5.9 (2.3, 15.1)	11.8 (5.8, 23.5)	27.9 (17.4, 43.0)
Implant Rupture (Based on the MRI Cohort)[c]	—	0	0
Infection	2.9 (0.7, 11.3)	2.9 (0.7, 11.3)	2.9 (0.7, 11.3)

Table 6d. *Continued to next page*

Table 6d. *(Continued)*

Other Complications ≥ 1%[b,d]	Year 3 % (95% CI)	Year 6 % (95% CI)	Year 10 % (95% CI)
Asymmetry	4.6 (1.5, 13.6)	4.6 (1.5, 13.6)	7.3 (2.7, 19.1)
Breast pain	1.8 (0.3, 12.2)	1.8 (0.3, 12.2)	1.8 (0.3, 12.2)
Capsular contracture Baker Grade II with surgical intervention	0	2.0 (0.3, 13.6)	2.0 (0.3, 13.6)
Capsular contracture Baker Grade III	16.4 (9.1, 28.5)	16.4 (9.1, 28.5)	16.4 (9.1, 28.5)
Capsular contracture Baker Grade IV	0	2.3 (0.3, 15.1)	2.3 (0.3, 15.1)
Death – metastatic disease[e]	1.7 (0.2, 11.4)	1.7 (0.2, 11.4)	7.3 (2.3, 21.8)
Erythema (redness)	1.4 (0.2, 9.8)	1.4 (0.2, 9.8)	1.4 (0.2, 9.8)
Implant rotation	3.3 (0.8, 12.7)	3.3 (0.8, 12.7)	3.3 (0.8, 12.7)
Lack of projection	6.7 (2.6, 17.0)	8.6 (3.7, 19.5)	8.6 (3.7, 19.5)
Mass/cyst	0	2.1 (0.3, 13.9)	2.1 (0.3, 13.9)
Metastatic disease	3.0 (0.8, 11.5)	3.0 (0.8, 11.5)	5.5 (1.7, 16.7)
New diagnosis of rheumatic disease	1.4 (0.2, 9.8)	1.4 (0.2, 9.8)	1.4 (0.2, 9.8)
Palpability – implant	1.6 (0.2, 10.9)	1.6 (0.2, 10.9)	4.0 (1.0, 15.5)
Paresthesia (numbness/tingling)	1.8 (0.3, 12.0)	1.8 (0.3, 12.0)	1.8 (0.3, 12.0)
Patient dissatisfied with aesthetic appearance of breast	3.1 (0.8, 11.7)	5.1 (1.6, 15.1)	7.5 (2.8, 19.2)
Patient dissatisfied with feel of implant	0	2.0 (0.3, 13.6)	2.0 (0.3, 13.6)
Position dissatisfaction	6.2 (2.4, 15.7)	6.2 (2.4, 15.7)	9.0 (3.7, 20.9)
Ptosis	1.9 (0.3, 12.7)	4.1 (1.0, 15.6)	4.1 (1.0, 15.6)
Recurrent breast cancer	1.5 (0.2, 10.0)	3.4 (0.9, 13.3)	3.4 (0.9, 13.3)
Scarring	0	2.0 (0.3, 13.1)	2.0 (0.3, 13.1)
Seroma	1.6 (0.2, 10.7)	1.6 (0.2, 10.7)	1.6 (0.2, 10.7)
Size change – patient request	2.9 (0.7, 11.3)	5.0 (1.6, 14.8)	5.0 (1.6, 14.8)
Swelling (excessive)	1.4 (0.2, 9.8)	1.4 (0.2, 9.8)	1.4 (0.2, 9.8)
Wrinkling	9.2 (4.2, 19.5)	11.4 (5.5, 22.7)	14.0 (7.1, 26.6)

[a] 50 revision-reconstruction patients experienced at least one complication or reoperation.

[b] Mild occurrences were excluded for all complications except reoperation, implant removal, implant rupture, capsular contracture, and infection.

[c] Implant rupture (based on the MRI cohort) was assessed by MRI at 1, 2, 4, 6, 8, and 10 years.

[d] No complications occurred at a rate less than 1%.

[e] All causes of death were reported by the investigator to be unrelated to study procedure or device.

Main Reasons for Reoperation

This section includes the main reasons for reoperation. The rates exclude planned secondary surgeries and reoperations for which the only reason for reoperation was staged reconstruction. Percentages are based upon the number of reoperations. If multiple procedures were performed on a patient on the same date, they are considered to constitute a single reoperation, regardless of whether one or both breasts were involved.

If a bilateral reoperation had different primary reasons for reoperation for the left and right breast implants, a hierarchy of reasons for reoperation was used in order to establish a primary reason for reoperation. In these cases, the following hierarchy was used: Baker Grade III capsular contracture, Baker Grade II capsular contracture with surgical intervention, breast pain, wrinkling, palpability-implant, asymmetry, ptosis, nipple complication, new diagnosis of breast cancer, breast mass/cyst, position dissatisfaction, patient dissatisfied with feel of implant, size change-patient request, size change- physician assessment only, and prophylactic mastectomy. These reasons are a complete list for all the cases of bilateral reoperation where a different primary reason for reoperation was given for the left and right breast implants.

Through 10 years, there were 285 additional surgical procedures performed in 150 reoperations involving 121 primary augmentation patients. The most common reasons for reoperation through 10 years were breast mass/cyst, patient requested size change, and calcification. Table 7a provides the main reason for reoperation following initial implantation through 3, 6, and 10 years for primary augmentation patients.

Table 7a. Main Reasons for Reoperation for Primary Augmentation Cohort

Primary Reason for Reoperation	Year 3 N=94 Reoperations[a] n (%)	Year 6 N=128 Reoperations[b] n (%)	Year 10 N=150 Reoperations[c] n (%)
Asymmetry	4 (4.3)	5 (3.9)	5 (3.3)
Baker Grade II capsular contracture with surgical intervention	2 (2.1)	2 (1.6)	2 (1.7)
Baker Grade III capsular contracture	3 (3.2)	3 (2.3)	4 (2.7)
Breast mass/cyst	9 (9.6)	22 (17.2)	30 (20.0)
Breast pain	2 (2.1)	2 (1.6)	3 (2.0)
Breast – unacceptably low sensitivity	0	1 (0.8)	1 (0.7)
Calcification	9 (9.6)	12 (9.4)	13 (8.7)
Delayed wound healing	1 (1.1)	1 (0.8)	1 (0.7)
Granuloma	1 (1.1)	1 (0.8)	1 (0.7)
Hematoma	5 (5.3)	5 (3.9)	5 (3.3)
Hypertrophic scarring	6 (6.4)	6 (4.7)	6 (4.0)
Infection	3 (3.2)	3 (2.3)	3 (2.0)
Irritation/inflammation	1 (1.1)	1 (0.8)	1 (0.7)
New diagnosis of breast cancer	2 (2.1)	6 (4.7)	8 (5.3)

Table 7a. *Continued to next page*

Table 7a. *(Continued)*

Primary Reason for Reoperation	Year 3 N=94 Reoperations[a] n (%)	Year 6 N=128 Reoperations[b] n (%)	Year 10 N=150 Reoperations[c] n (%)
New diagnosis of rheumatic disease	0	0	1 (0.7)
Nipple – unacceptably low sensitivity	1 (1.1)	1 (0.8)	1 (0.7)
Patient dissatisfied with aesthetic appearance of breast	2 (2.1)	3 (2.3)	3 (2.0)
Position dissatisfaction	4 (4.3)	7 (5.5)	7 (4.7)
Ptosis	5 (5.3)	8 (6.3)	8 (5.3)
Rupture	0	2 (1.6)	7 (4.7)
Scarring	3 (3.2)	3 (2.3)	3 (2.0)
Seroma	2 (2.1)	2 (1.6)	2 (1.3)
Size change – patient request	13 (13.8)	15 (11.7)	16 (10.7)
Skin lesion	2 (2.1)	3 (2.3)	3 (2.0)
Wound dehiscence	2 (2.1)	2 (1.6)	2 (1.3)
Wrinkling	2 (2.1)	2 (1.6)	2 (1.3)
Other	10 (10.6)	10 (7.8)	11 (7.3)
Contour irregularities	1 (1.1)	1 (0.8)	1 (0.7)
Double bubble	1 (1.1)	1 (0.8)	1 (0.7)
Excess skin/tissue	2 (2.1)	2 (1.6)	2 (1.3)
Implant movement upon muscle contraction	1 (1.1)	1 (0.8)	1 (0.7)
Implant rotation	2 (2.1)	2 (1.6)	2 (1.3)
Loss of definition of inframammary fold	1 (1.1)	1 (0.8)	1 (0.7)
Nipple complication	2 (2.1)	2 (1.6)	3 (2.0)
Missing	3 (3.2)	0	1 (0.7)

[a] 78 patients
[b] 102 patients
[c] 121 patients

Through 10 years, there were 137 additional surgical procedures performed in 51 reoperations involving 40 revision-augmentation patients. The most common reasons for reoperation in revision-augmentation patients through 10 years were patient requested size change, breast mass/cyst, wound dehiscence, position dissatisfaction, and wrinkling. Table 7b provides the main reason for reoperation following initial implantation through 3, 6, and 10 years for revision-augmentation patients.

Table 7b. Main Reasons for Reoperation for Revision-Augmentation Cohort

Primary Reason for Reoperation	Year 3 N=26 Reoperations[a] n (%)	Year 6 N=38 Reoperations[b] n (%)	Year 10 N=51 Reoperations[c] n (%)
Asymmetry	1 (3.8)	2 (5.3)	2 (3.9)
Baker Grade II capsular contracture with surgical intervention	0	1 (2.6)	2 (3.9)
Baker Grade III capsular contracture	0	1 (2.6)	2 (3.9)
Baker Grade IV capsular contracture	0	0	1 (2.0)
Breast mass/cyst	1 (3.8)	5 (13.2)	6 (11.8)
Breast pain	1 (3.8)	1 (2.6)	1 (2.0)
Calcification	0	1 (2.6)	1 (2.0)
Delayed wound healing	1 (3.8)	1 (2.6)	1 (2.0)
Hypertrophic scarring	1 (3.8)	1 (2.6)	1 (2.0)
New diagnosis of breast cancer	1 (3.8)	1 (2.6)	1 (2.0)
New diagnosis of rheumatic disease	0	0	1 (2.0)
Position dissatisfaction	4 (15.4)	4 (10.5)	4 (7.8)
Ptosis	1 (3.8)	1 (2.6)	2 (3.9)
Rupture	1 (3.8)	1 (2.6)	1 (2.0)
Size change – patient request	3 (11.5)	3 (7.9)	6 (11.8)
Wound dehiscence	5 (19.2)	5 (13.2)	5 (9.8)
Wrinkling	3 (11.5)	4 (10.5)	4 (7.8)
Other	3 (11.5)	6 (15.8)	9 (17.6)
Contour irregularities*	1 (3.8)	2 (5.3)	2 (3.9)
Ductal ectasia	0	1 (2.6)	1 (2.0)
Explant due to contralateral rupture	0	0	1 (2.0)
Implant movement upon muscle contraction	1 (3.8)	1 (2.6)	1 (2.0)
Patient dissatisfied with aesthetic appearance of breast	1 (3.8)	1 (2.6)	2 (3.9)
Patient dissatisfied with feel of implant	0	0	1 (2.0)
Skin lesion	0	1 (2.6)	1 (2.0)
Missing	1 (3.8)	0	1 (2.0)

[a] 21 patients
[b] 30 patients
[c] 40 patients
* The Contour Irregularities category includes reported terms of "Upper pole fullness" and " Ridging".

Through 10 years, there were 278 additional surgical procedures performed in 142 reoperations involving 95 primary reconstruction patients. The most common reasons for reoperation through 10 years were asymmetry, seroma, breast mass/cyst, position dissatisfaction, and wrinkling. Table 7c provides the main reasons for reoperations following initial implantation through 3, 6, and 10 years for primary reconstruction patients.

Table 7c. Main Reasons for Reoperation for Primary Reconstruction Cohort

Primary Reason for Reoperation	Year 3 N=80 Reoperations[a] n (%)	Year 6 N=113 Reoperations[b] n (%)	Year 10 N=142 Reoperations[c] n (%)
Asymmetry	14 (17.5)	15 (13.3)	19 (13.4)
Baker Grade II capsular contracture with surgical intervention	1 (1.3)	3 (2.7)	5 (3.5)
Baker Grade III capsular contracture	2 (2.5)	4 (3.5)	6 (4.2)
Baker Grade IV capsular contracture	2 (2.5)	2 (1.8)	2 (1.4)
Breast mass/cyst	6 (7.5)	8 (7.1)	10 (7.0)
Calcification	0	1 (0.9)	1 (0.7)
Delayed wound healing	1 (1.3)	1 (0.9)	1 (0.7)
Excess skin/tissue	8 (10.0)	8 (7.1)	8 (5.6)
Extrusion	1 (1.3)	1 (0.9)	1 (0.7)
Implant immobility	0	2 (1.8)	3 (2.1)
Implant rotation	4 (5.0)	4 (3.5)	4 (2.8)
Infection	1 (1.3)	1 (0.9)	1 (0.7)
Lack of projection	3 (3.8)	6 (5.3)	6 (4.2)
Lymphadenopathy	0	0	1 (0.7)
Nipple – unacceptably low sensitivity	0	1 (0.9)	1 (0.7)
Position dissatisfaction	5 (6.3)	7 (6.2)	9 (6.3)
Ptosis	0	1 (0.9)	1 (0.7)
Recurrent breast cancer	2 (2.5)	2 (1.8)	6 (4.2)
Rupture	0	0	6 (4.2)
Scarring	5 (6.3)	5 (4.4)	5 (3.5)
Seroma	3 (3.8)	14 (12.4)	14 (9.9)
Size change – patient request	4 (5.0)	4 (3.5)	5 (3.5)
Size change – physician assessment only	4 (5.0)	4 (3.5)	4 (2.8)
Wrinkling	4 (5.0)	5 (4.4)	9 (6.3)
Other	6 (7.5)	8 (7.1)	8 (5.6)
Chest mass/cyst	0	1 (0.9)	1 (0.7)
Fluid drainage	1 (1.3)	1 (0.9)	1 (0.7)
Nipple complications	1 (1.3)	1 (0.9)	1 (0.7)
Patient dissatisfied with aesthetic appearance of breast	1 (1.3)	1 (0.9)	1 (0.7)
Skin lesion	1 (1.3)	2 (1.8)	2 (1.4)
Suspected rupture	1 (1.3)	1 (0.9)	1 (0.7)
Suture complications	1 (1.3)	1 (0.9)	1 (0.7)
Missing	4 (5.0)	6 (5.3)	6 (4.2)

[a] 65 patients
[b] 78 patients
[c] 95 patients

Through 10 years, there were 136 additional surgical procedures performed in 49 reoperations involving 39 revision-reconstruction patients. The most common reasons for reoperation through 10 years were lack of projection, Baker Grade III capsular contracture, patient requested size change, and wrinkling. Table 7d provides the main reasons for reoperation following initial implantation through 3, 6, and 10 years for revision-reconstruction patients.

Table 7d. Main Reasons for Reoperation for Revision-Reconstruction Cohort

Primary Reason for Reoperation	Year 3 N=25 Reoperations[a] n (%)	Year 6 N=38 Reoperations[b] n (%)	Year 10 N=49 Reoperations[c] n (%)
Asymmetry	2 (8.0)	3 (7.9)	4 (8.2)
Baker Grade II capsular contracture with surgical intervention	1 (4.0)	2 (5.3)	2 (4.1)
Baker Grade III capsular contracture	2 (8.0)	4 (10.5)	5 (10.2)
Breast pain	1 (4.0)	1 (2.6)	1 (2.0)
Infection	1 (4.0)	1 (2.6)	1 (2.0)
Lack of projection	1 (4.0)	3 (7.9)	6 (12.2)
Nipple complication	3 (12.0)	3 (7.9)	3 (6.1)
Position dissatisfaction	2 (8.0)	2 (5.3)	3 (6.1)
Ptosis	0	0	1 (2.0)
Seroma	2 (8.0)	2 (5.3)	2 (4.1)
Size change – patient request	2 (8.0)	3 (7.9)	5 (10.2)
Wrinkling	4 (16.0)	4 (10.5)	5 (10.2)
Other	4 (16.0)	10 (26.3)	11 (22.4)
Breast mass/cyst	0	2 (5.3)	2 (4.1)
Excess skin/tissue	0	1 (2.6)	1 (2.0)
Implant immobility	0	1 (2.6)	1 (2.0)
Patient dissatisfied with aesthetic appearance of breast	1 (4.0)	2 (5.3)	2 (4.1)
Recurrent breast cancer	1 (4.0)	1 (2.6)	1 (2.0)
Scarring	1 (4.0)	1 (2.6)	1 (2.0)
Shape distortion	0	0	1 (2.0)
Skin lesion	1 (4.0)	2 (5.3)	2 (4.1)

[a] 20 patients
[b] 30 patients
[c] 39 patients

Main Reasons for Breast Implant Removal

Through 10 years, 92 implants were removed in 49 primary augmentation patients. Of these 92 implants, 36 (39%) were replaced with a study device. The most common reason for implant removal was patient requested size change. Table 8a provides the main reasons for implant removal among primary augmentation patients through 3, 6, and 10 years.

Table 8a. Main Reasons for Breast Implant Removal for Primary Augmentation Cohort

Primary Reason for Implant Removal	Year 3 N=55 Implants Removed[a] n (%)	Year 6 N=72 Implants Removed[b] n (%)	Year 10 N=92 Implants Removed[c] n (%)
Asymmetry	5 (9.1)	6 (8.3)	6 (6.5)
Baker Grade II capsular contracture with surgical intervention	3 (5.5)	3 (4.2)	3 (3.3)
Baker Grade III/IV capsular contracture	3 (5.5)	3 (4.2)	5 (5.4)
Breast pain	0	0	2 (2.2)
Breast – unacceptably low sensitivity	0	1 (1.4)	1 (1.1)
New diagnosis of breast cancer	0	2 (2.8)	5 (5.4)
New diagnosis of rheumatic disease	0	0	2 (2.2)
Position dissatisfaction	4 (7.3)	6 (8.3)	6 (6.5)
Ptosis	2 (3.6)	4 (5.6)	4 (4.3)
Rupture	0	2 (2.8)	8 (8.7)
Size change – patient request	26 (47.3)	30 (41.7)	32 (34.8)
Wrinkling	4 (7.3)	4 (5.6)	4 (4.3)
Other	8 (14.5)	10 (13.9)	13 (14.1)
Contour irregularities	2 (3.6)	2 (2.8)	2 (2.2)
Explant due to contralateral rupture	0	0	1 (1.1)
Implant replacement due to contralateral rupture	0	0	2 (2.2)
Implant rotation	2 (3.6)	2 (2.8)	2 (2.2)
Patient dissatisfied with aesthetic appearance of breast	4 (7.3)	6 (8.3)	6 (6.5)
Missing	0	1 (1.4)	1 (1.1)

[a] 28 patients
[b] 38 patients
[c] 49 patients

Through 10 years, 55 implants were removed in 29 revision-augmentation patients. Of these 55 implants, 20 (36%) were replaced with a study device. The most common reason for implant removal was patient requested size change. Table 8b provides the main reasons for implant removal among revision-augmentation patients through 3, 6, and 10 years.

Table 8b. Main Reasons for Breast Implant Removal for Revision-Augmentation Cohort

Primary Reason for Implant Removal	Year 3 N=24 Implants Removed[a] n (%)	Year 6 N=31 Implants Removed[b] n (%)	Year 10 N=55 Implants Removed[c] n (%)
Asymmetry	2 (8.3)	3 (9.7)	3 (5.5)
Baker Grade II capsular contracture with surgical intervention	0	2 (6.5)	4 (7.3)
Baker Grade III/IV capsular contracture	0	0	5 (9.1)
Breast pain	1 (4.2)	1 (3.2)	1 (1.8)
New diagnosis of breast cancer	2 (8.3)	2 (6.5)	2 (3.6)
New diagnosis of rheumatic disease	0	0	2 (3.6)
Position dissatisfaction	1 (4.2)	2 (6.5)	2 (3.6)
Ptosis	0	0	2 (3.6)
Rupture	1 (4.2)	1 (3.2)	1 (1.8)
Size change – patient request	7 (29.2)	7 (22.6)	13 (23.6)
Size change – physician assessment only	1 (4.2)	1 (3.2)	1 (1.8)
Wrinkling	4 (16.7)	5 (16.1)	5 (9.1)
Wound dehiscence	1 (4.2)	1 (3.2)	1 (1.8)
Other	4 (16.7)	6 (19.4)	11 (20.0)
Contour irregularities*	2 (8.3)	4 (12.9)	4 (7.3)
Explant due to contralateral rupture	0	0	1 (1.8)
Patient dissatisfied with feel of implant	0	0	2 (3.6)
Patient dissatisfied with aesthetic appearance of breast	2 (8.3)	2 (6.5)	4 (7.3)
Missing	0	0	2 (3.6)

[a] 17 patients
[b] 16 patients
[c] 29 patients
* The Contour Irregularities category includes reported terms of "Upper pole fullness" and " Ridging".

Through 10 years, 92 implants were removed in 60 primary reconstruction patients. Of these 92 implants, 35 (38%) were replaced with a study device. The most common reason for implant removal was asymmetry. Table 8c provides the main reasons for implant removal among primary reconstruction patients through 3, 6, and 10 years.

Table 8c. Main Reasons for Breast Implant Removal for Primary Reconstruction Cohort

Primary Reason for Implant Removal	Year 3 N=35 Implants Removed[a] n (%)	Year 6 N=56 Implants Removed[b] n (%)	Year 10 N=92 Implants Removed[c] n (%)
Asymmetry	6 (17.1)	7 (12.5)	13 (14.1)
Baker Grade II capsular contracture with surgical intervention	0	2 (3.6)	7 (7.6)
Baker Grade III/IV capsular contracture	3 (8.6)	5 (8.9)	7 (7.6)
Extrusion	1 (2.9)	1 (1.8)	1 (1.1)
Infection	1 (2.9)	1 (1.8)	1 (1.1)
Nipple – unacceptably low sensitivity	0	1 (1.8)	1 (1.1)
Position dissatisfaction	0	3 (5.4)	7 (7.6)
Ptosis	0	2 (3.6)	2 (2.2)
Rupture	0	0	6 (6.5)
Seroma	0	2 (3.6)	2 (2.2)
Size change – patient request	6 (17.1)	6 (10.7)	9 (9.8)
Size change – physician assessment only	4 (11.4)	4 (7.1)	4 (4.3)
Wrinkling	2 (5.7)	2 (3.6)	8 (8.7)
Other	10 (28.6)	18 (32.1)	21 (22.8)
Explant due to contralateral rupture	0	0	1 (1.1)
Implant immobility	0	4 (7.1)	6 (6.5)
Implant rotation	4 (11.4)	4 (7.1)	4 (4.3)
Lack of projection	4 (11.4)	7 (12.5)	7 (7.6)
Patient dissatisfied with aesthetic appearance of breast	2 (5.7)	2 (3.6)	2 (2.2)
Recurrent breast cancer	0	0	1 (1.1)
Missing	2 (5.7)	2 (3.6)	3 (3.3)

[a] 26 patients
[b] 39 patients
[c] 60 patients

Through 10 years, 53 implants were removed in 32 revision-reconstruction patients. Of these 53 implants, 22 (42%) were replaced with a study device. The most common reason for implant removal was lack of projection. Table 8d provides the main reasons for implant removal among revision-reconstruction patients through 3, 6, and 10 years.

Table 8d. Main Reasons for Breast Implant Removal for Revision-Reconstruction Cohort

Primary Reason for Implant Removal	Year 3 N=23 Implants Removed[a] n (%)	Year 6 N=38 Implants Removed[b] n (%)	Year 10 N=53 Implants Removed[c] n (%)
Asymmetry	4 (17.4)	6 (15.8)	7 (13.2)
Baker Grade II capsular contracture with surgical intervention	1 (4.3)	2 (5.3)	2 (3.8)
Baker Grade III/IV capsular contracture	0	2 (5.3)	3 (5.7)
Breast pain	1 (4.3)	1 (2.6)	1 (1.9)
Infection	1 (4.3)	1 (2.6)	1 (1.9)
Palpability – implant	0	1 (2.6)	1 (1.9)
Position dissatisfaction	4 (17.4)	4 (10.5)	6 (11.3)
Seroma	1 (4.3)	1 (2.6)	1 (1.9)
Size change – patient request	2 (8.7)	4 (10.5)	8 (15.1)
Wrinkling	5 (21.7)	5 (13.2)	7 (13.2)
Other	4 (17.4)	11 (28.9)	16 (30.2)
Breast mass/cyst	0	1 (2.6)	1 (1.9)
Implant immobility	0	2 (5.3)	2 (3.8)
Lack of projection	2 (8.7)	6 (15.8)	11 (20.8)
Patient dissatisfied with aesthetic appearance of breast	1 (4.3)	1 (2.6)	1 (1.9)
Recurrent breast cancer	1 (4.3)	1 (2.6)	1 (1.9)

[a] 15 patients
[b] 23 patients
[c] 32 patients

Other Clinical Data Findings

Below is a summary of clinical findings from Mentor's MemoryShape® Breast Implant Post Approval Cohort (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 the MENTOR® MemoryShape® Breast Implant Post-Approval New Enrollment Study.

CTD Diagnoses

In the MemoryShape™ Breast Implant Post-Approval Cohort (Core) Study, there were 9 primary augmentation patients, 4 revision-augmentation patients, 4 primary reconstruction patients, and 1 revision-reconstruction patient reported to have a new diagnosis of a CTD by a rheumatologist. There were 10 diagnoses for the 9 primary augmentation patients: spondyloarthropathies (25 months post implantation), fibromyalgia (34, 37, and 98 months post implantation), undifferentiated connective tissue disease (41 months post implantation), Sjögren's syndrome (42 months post implantation), systemic lupus

erythematosus (42 and 48 months post implantation), and rheumatoid arthritis (50 and 79 months post implantation). There were 7 diagnoses for 4 revision-augmentation patients: rheumatoid arthritis (11 months post implantation), fibromyalgia (55 and 76 months post implantation), Sjögren's syndrome (55 months post implantation), Raynaud's syndrome (55 months post implantation), undifferentiated connective tissue disorder (55 months post implantation), and systemic lupus erythematosus (121 months post implantation). There were 4 diagnoses for 4 primary reconstruction patients: rheumatoid arthritis (10 months post implantation), other inflammatory arthritis (11 months post implantation), hallux rigidus (49 months post implantation), and Raynaud's syndrome (118 months post implantation). There were 2 diagnoses for 1 revision-reconstruction patient: rheumatoid arthritis and systemic lupus erythematosus (both 97 months post implantation). It cannot be concluded that these CTD diagnoses were caused by the implants because there was no comparison group of similar women without implants.

CTD Signs and Symptoms

Compared to before having implants, the following significant change was found in the rheumatologic symptoms and physical examination findings after adjusting for the age effect: decreased night sweats in the primary reconstruction cohort. No significant changes were found in the primary augmentation, revision-augmentation, or revision-reconstruction cohorts. The MemoryShape® Breast Implant Post-Approval Cohort (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 changes were due to the implants or not, based on the MemoryShape® Breast Implant Post-Approval Cohort (Core) Study. However, your patient should be aware that she may experience an increase in these types of symptoms after receiving breast implants.

Cancer

Six primary augmentation patients and 1 revision-augmentation patient had new diagnoses of breast cancer through 10 years in Mentor's MemoryShape® Breast Implant Post-Approval Cohort (Core) Study. There were no new cases of breast cancer in the primary reconstruction and revision-reconstruction cohorts. One primary augmentation patient, 11 primary reconstruction patients, and 2 revision-reconstruction patients had a diagnosis of recurrent breast cancer. There were no cases of recurrent breast cancer in the revision-augmentation cohort.

Through 10 years, there were no reports of other new cancers, such as brain, respiratory, or cervical/vulvar in any cohort. Through 10 years, there were no cases of ALCL in any cohort.

Lactation Complications

Nine of the 74 primary augmentation patients and 1 of the 2 primary reconstruction patients who attempted to breastfeed following breast implantation experienced difficulty with breastfeeding through 10 years in Mentor's MemoryShape® Breast Implant Post-Approval Cohort (Core) Study. All 6 of the revision-augmentation patients who attempted to breastfeed after receiving breast implants had no difficulty. None of the revision-reconstruction patients attempted to breastfeed.

Reproduction Complications

Sixteen primary augmentation patients, 1 revision-augmentation patient, and 5 primary reconstruction patients reported a miscarriage in Mentor's MemoryShape® Breast Implant Post-Approval Cohort (Core) Study through 10 years. There were no reports of miscarriage in the revision-reconstruction cohort.

Suicide

There was 1 report of suicide in the revision-augmentation cohort in Mentor's MemoryShape® Breast Implant Post-Approval Cohort (Core) Study through 10 years. There were no reports of suicide in the primary augmentation, primary reconstruction, and revision-reconstruction cohorts.

Study Strengths and Weaknesses

Mentor's MemoryShape® Breast Implant Post-Approval Cohort (Core) Study has a number of strengths. The study was prospective and multi-centered, with a large number of sites (43), a large number of patients (955) and long follow-up period (10 years). The study included all four categories of patients for which use of the implant is approved: primary augmentation, revision augmentation, primary reconstruction, and revision reconstruction. Furthermore, a sub-study of 419 enrolled subjects underwent MRI assessments throughout the study period to identify "silent" ruptures that otherwise would likely go undetected.

The study extensively investigated both the safety and effectiveness of the implant, based on both investigator and patient assessments. Investigator assessments included evaluation of postoperative complications at 10 weeks post-implantation and annually from years 1 through 10; types of reoperations and reasons for explantation; signs and symptoms of connective tissue, autoimmune, and rheumatological disease; physical examinations; mammogram results, and MRI evaluation for rupture. Investigator satisfaction was also studied. Patient assessments included reporting of postoperative complications at scheduled or unscheduled visits as necessary, changes in 4 different quality-of-life questionnaires at years 1, 2, 4, 6, 8 and 10, and a global subject satisfaction questionnaire regarding the decision to undergo breast implant surgery again through the 10-year visit.

The strength of these assessments is that they represent a comprehensive and consistent evaluation of the known or suspected safety risks that women undergoing breast implantation surgery may encounter from both a physician and patient perspective.

Limitations of these assessments are inherent due to the nature of changing practice over the past 10 years since the study was initiated. Most notably, quality of life assessments have changed since study initiation, and were thus not implemented in the study. Although informative, the quality of life metrics employed in the study were not breast specific as is the case with more modern assessments.

Weaknesses of the study included the open-label nature and lack of a control group. The overall follow-up rate of 63% at 10 years, while consistent with FDA guidance at the time of the study design and with the study protocol, is lower than desired to optimally minimize potential bias.

This study was not designed to detect rare events that may occur in women undergoing breast implantation surgery, rather the sample size was determined to provide acceptable precision in the estimation of commonly occurring complications following implantation.

Due to the open-label nature and lack of a control group in this study, the results presented are descriptive in nature and may not be able to be generalized to a larger population.

MENTOR® MEMORYSHAPE® BREAST IMPLANT CONTINUED ACCESS STUDY

The safety and effectiveness of Mentor's silicone gel implants were evaluated in an open-label multicenter clinical study, referred to as the MENTOR® MemoryShape® Breast Implant Continued Access (CA) Study. The information below provides more details about Mentor's MemoryShape® Breast Implant CA Study and the complications your patients may experience.

CA Study Design

After enrollment into Mentor's MemoryShape® Core Study was completed, additional patients were enrolled under a CA Study to allow for continued physician experience with the five styles (MM, MM+, MH, TM+, and LM+) of the MemoryShape® Breast Implants. Like the Core Study, the CA Study collected safety information on patients who received implants for either augmentation (primary and revision) or reconstruction (primary and revision).

The US CA Study involved the same investigators that enrolled patients into the US Core Study. Style MM was available to enrolled patients at the start of the study in 2004; the four additional styles became available to enrolled patients in 2007.

Patients' medical histories were collected at baseline. Patient follow-up was at 10 weeks and annually through 5 years or longer. The design of the US CA Study was essentially the same as that of the US Core Study in terms of the study population and safety data collection. There were a few differences: Scheduled MRIs, rheumatic examinations, and effectiveness data (change in chest circumference and bra cup size) were not collected.

The CA Study results through 5 years are reported in this document.

CA Study: Patient Accounting and Baseline Demographic Profile

Mentor's MemoryShape® Breast Implant CA Study consisted of 3637 patients, including 2379 primary augmentation patients, 555 revision-augmentation patients, 444 primary reconstruction patients, and 259 revision-reconstruction patients. This document presents data through 5 years post-implantation. Data are available through 5 years post- implantation for 57% of the eligible primary augmentation patients, 65% of the eligible revision-augmentation patients, 61% of the eligible primary reconstruction patients, and 67% of the eligible revision-reconstruction patients. Demographic and baseline characteristics were generally similar across the MemoryShape® styles. Table 9 provides demographic information for each cohort in the MENTOR® MemoryShape® Breast Implant CA Study.

Table 9. MemoryShape® Breast Implant CA Study Patient Demographics by Cohort

Characteristic	Primary Augmentation N=2379	Revision-Augmentation N=555	Primary Reconstruction N=444	Revision-Reconstruction N=259
Age (years)				
<20	78 (3.3%)	0 (0.0%)	7 (1.6%)	0 (0.0%)
20 to <30	633 (26.6%)	27 (4.9%)	19 (4.3%)	0 (0.0%)

Table 9. *Continued to next page*

Table 9. *(Continued)*

Characteristic	Primary Augmentation N=2379	Revision-Augmentation N=555	Primary Reconstruction N=444	Revision-Reconstruction N=259
30 to <40	948 (39.8%)	102 (18.4%)	56 (12.6%)	10 (3.9%)
40 to <50	553 (23.2%)	189 (34.1%)	141 (31.8%)	59 (22.8%)
50 to <60	149 (6.3%)	178 (32.1%)	143 (32.2%)	105 (40.5%)
60 and older	11 (0.5%)	57 (10.3%)	76 (17.1%)	83 (32.0%)
Not provided	7 (0.3%)	2 (0.4%)	2 (0.5%)	2 (0.8%)
Median Age	35.6 years	46.2 years	48.8 years	54.9 years
Marital Status				
Single	684 (28.8%)	74 (13.3%)	62 (14.0%)	12 (4.6%)
Married	1413 (59.4%)	358 (64.5%)	304 (68.5%)	184 (71.0%)
Separated	35 (1.5%)	10 (1.8%)	4 (0.9%)	5 (1.9%)
Divorced	177 (7.4%)	90 (16.2%)	46 (10.4%)	34 (13.1%)
Widowed	18 (0.8%)	15 (2.7%)	15 (3.4%)	10 (3.9%)
Not provided	52 (2.2%)	8 (1.4%)	13 (2.9%)	14 (5.4%)
Race				
Caucasian	2076 (87.3%)	523 (94.2%)	389 (87.6%)	235 (90.7%)
African American	24 (1.0%)	2 (0.4%)	26 (5.9%)	7 (2.7%)
Asian	127 (5.3%)	6 (1.1%)	6 (1.4%)	4 (1.5%)
Not provided	152 (6.4%)	24 (4.3%)	23 (5.2%)	13 (5.0%)
Education				
Less than 12 years	10 (0.4%)	1 (0.2%)	5 (1.1%)	1 (0.4%)
High school graduate	200 (8.4%)	55 (9.9%)	46 (10.4%)	26 (10.0%)
Some college	524 (22.0%)	127 (22.9%)	80 (18.0%)	37 (14.3%)
College graduate	660 (27.7%)	198 (35.8%)	126 (28.4%)	73 (28.2%)
Post graduate	227 (9.5%)	79 (14.2%)	65 (14.6%)	23 (8.9%)
Not provided	758 (31.9%)	95 (17.1%)	122 (27.5%)	99 (38.2%)

As shown in Table 10, Style MM was used most commonly across all cohorts. This is consistent with the availability of this style for patients approximately 3 years longer than any other style within the CA Study.

Table 10. Percentage of Implant Styles per Cohort for the CA Study

Style	All Cohorts (N=3637) n (%)	Primary Augmentation (N=2379) n (%)	Revision-Augmentation (N=555) n (%)	Primary Reconstruction (N=444) n (%)	Revision-Reconstruction (N=259) n (%)
MM	2015 (55.4%)	1369 (57.5%)	383 (69.0%)	164 (36.9%)	99 (38.2%)
MM+	800 (22.0%)	633 (26.6%)	94 (16.9%)	48 (10.8%)	25 (9.7%)
MH	434 (11.9%)	124 (5.2%)	39 (7.0%)	172 (38.7%)	99 (38.2%)
TM+	259 (7.1%)	190 (8.0%)	26 (4.7%)	22 (5.0%)	21 (8.1%)
LM+	77 (2.1%)	38 (1.6%)	9 (1.6%)	23 (5.2%)	7 (2.7%)
Mixed*	52 (1.4%)	25 (1.1%)	4 (0.7%)	15 (3.4%)	8 (3.1%)

* A patient with different style breast implants on each body side.

CA Study: Safety Outcomes

Tables 11a-11d provide the Kaplan-Meier estimated cumulative incidence rates for postoperative complications through 5 years. The rates reflect the estimated percentage of patients who will experience the listed complication at least once within the first 5 years after implantation. In Mentor's MemoryShape® Breast Implant CA Study, some complications occurred more than once for some patients.

In general, complication rates for the CA study were similar to or lower than those associated with the MENTOR® MemoryShape® Post-Approval Cohort (Core) Study.

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 11a. Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), by Patient for Primary Augmentation Cohort, N=2379

	Year 5 % (95% CI)
Any complication or reoperation[a]	17.5 (15.7, 19.5)
Key Complications	**Year 5 % (95% CI)**
Any reoperation	9.5 (8.1, 11.1)
Capsular contracture Baker Grade III/IV	0.8 (0.5, 1.6)
Implant removal with or without replacement	4.5 (3.5, 5.7)
Implant removal with replacement with study device	1.6 (1.0, 2.4)
Infection	0.7 (0.4, 1.2)
Other Complications ≥ 1%[b]	**Year 5 % (95% CI)**
Hypertrophic scarring	1.2 (0.8, 1.8)
Mass/cyst	1.8 (1.2, 2.6)
Ptosis	3.1 (2.3, 4.2)
Size change – patient request	1.3 (0.8, 2.0)

[a] 299 primary augmentation patients experienced at least one complication or reoperation.

[b] The following complications were reported and occurred at a rate less than 1%: asymmetry,[c] breast pain,[c] breast sensation changes,[c] bruising, calcification,[c] capsular contracture Baker II with surgical intervention, capsular contracture Baker III, capsular contracture Baker IV, contact dermatitis, contour irregularities, death,[d] delayed wound healing,[c] double bubble, drainage, erythema, excess skin/tissue, external injury to breast, extrusion, hematoma, immobile implant, implant rotation, irritation/inflammation, lactation difficulties, loss of definition of inframammary fold, Lyme disease, lymphadenopathy, miscarriage, Mondor's disease, multiple sclerosis, necrosis, nerve pain, neuropathic pain, new diagnosis of breast cancer, new diagnosis of rheumatic disease, nipple complication,[c] nipple sensation changes,[c] other: missing, palpability-implant,[c] patient dissatisfied with aesthetic appearance of breast, patient dissatisfaction, patient dissatisfied with breast size, patient requested removal, position dissatisfaction,[c] scarring, sensation changes, seroma, size change – physician assessment only, skin complication, skin lesion, small cell lung cancer, sternal pain, suture complication, swelling (excessive), symmastia, wound dehiscence, and wrinkling.

[c] Mild occurrences were excluded.

[d] All causes of death were reported by the investigator to be unrelated to study procedure or device.

Table 11b. Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), by Patient for Revision-Augmentation Cohort, N=555

	Year 5 % (95% CI)
Any complication or reoperation[a]	22.0 (18.3, 26.3)
Key Complications	**Year 5 % (95% CI)**
Any reoperation	16.6 (13.3, 20.5)
Capsular contracture Baker Grade III/IV	0.5 (0.1, 2.0)
Implant removal with or without replacement	8.6 (6.3, 11.6)
Implant removal with replacement with study device	2.8 (1.6, 4.9)
Infection	1.2 (0.5, 2.6)
Other Complications ≥ 1%[b]	**Year 5 % (95% CI)**
Hematoma	1.7 (0.8, 3.4)
Hypertrophic scarring	1.6 (0.8, 3.3)
Implant rotation	1.5 (0.7, 3.3)
Mass/cyst	2.8 (1.4, 5.3)
Ptosis	1.1 (0.4, 2.9)
Seroma	2.0 (1.1, 3.6)
Size change – patient request	1.9 (1.0, 3.8)
Wrinkling[c]	2.0 (1.1, 3.9)

[a] 98 revision-augmentation patients experienced at least one complication or reoperation.

[b] The following complications were reported and occurred at a rate less than 1%: asymmetry,[c] breast pain,[c] breast sensation changes,[c] capsular contracture Baker II with surgical intervention, capsular contracture Baker III, capsular contracture Baker IV, death,[d] delayed wound healing,[c] drainage, erythema, extrusion, lack of projection, low breast volume, lymphoma, new diagnosis of breast cancer, new diagnosis of rheumatic disease, nipple complication,[c] patient dissatisfied with aesthetic appearance of breast, position dissatisfaction, rib pain, scarring, size change – physician assessment only, swelling (excessive), and wound dehiscence.

[c] Mild occurrences were excluded.

[d] All causes of death were reported by the investigator to be unrelated to study procedure or device.

Table 11c. Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), by Patient for Primary Reconstruction Cohort, N=444

	Year 5 % (95% CI)
Any complication or reoperation[a]	34.8 (29.0, 41.5)
Key Complications	**Year 5 % (95% CI)**
Any reoperation	28.3 (23.0, 34.6)
Capsular contracture Baker Grade III/IV	3.1 (1.6, 6.1)
Implant removal with or without replacement	17.7 (13.3, 23.4)
Implant removal with replacement with study device	9.2 (6.2, 13.3)
Infection	1.8 (0.9, 3.7)
Other Complications ≥ 1%[b]	**Year 5 % (95% CI)**
Asymmetry[c]	2.6 (1.3, 5.0)
Capsular contracture Baker II with surgical intervention	1.5 (0.6, 3.5)
Capsular contracture Baker III	2.5 (1.2, 5.5)
Contour irregularities	1.7 (0.5, 5.8)
Death[d]	2.3 (0.8, 6.3)
Implant rotation	1.8 (0.8, 3.9)
Mass/cyst	1.7 (0.6, 5.1)
New diagnosis of breast cancer	1.3 (0.3, 5.8)
Ptosis	1.1 (0.4, 3.5)
Seroma	1.3 (0.5, 3.1)
Size change – patient request	1.3 (0.5, 3.1)
Wound dehiscence	1.2 (0.5, 3.0)
Wrinkling[c]	1.3 (0.5, 3.5)

[a] 108 primary reconstruction patients experienced at least one complication or reoperation.

[b] The following complications were reported and occurred at a rate less than 1%: atrophy, breast pain,[c] capsular contracture Baker IV, contralateral explant due to wound dehiscence, delayed wound healing,[c] erythema, excess skin/tissue, extrusion, hematoma, hypertrophic scarring, implant removal due to contralateral breast cancer, irritation/inflammation, metastatic cancer, necrosis, nipple complication,[c] other: missing, palpability – implant,[c] patient dissatisfied with aesthetic appearance of breast, patient requested removal, position dissatisfaction,[c] pregnancy complication – ectopic, recurrent breast cancer, rupture, scarring, size change – physician assessment only, skin complication, small 2 mm opening down to the implant right breast, and swelling (excessive).

[c] Mild occurrences were excluded.

[d] All causes of death were reported by the investigator to be unrelated to study procedure or device.

Table 11d. Cumulative Kaplan-Meier Adverse Event Risk Rates (95% Confidence Interval), by Patient for Revision-Reconstruction Cohort, N=259

	Year 5 % (95% CI)
Any complication or reoperation[a]	31.2 (24.2, 39.6)
Key Complications	**Year 5 % (95% CI)**
Any reoperation	23.7 (17.3, 31.9)
Capsular contracture Baker Grade III/IV	6.1 (3.1, 11.8)
Implant removal with or without replacement	15.8 (10.4, 23.6)
Implant removal with replacement with study device	5.5 (2.6, 11.4)
Infection	0.8 (0.2, 3.3)
Other Complications ≥ 1%[b]	**Year 5 % (95% CI)**
Capsular contracture Baker II with surgical intervention	2.1 (0.8, 5.8)
Capsular contracture Baker III	5.1 (2.3, 10.8)
Capsular contracture Baker IV	1.0 (0.3, 4.0)
Contralateral explant due to Baker III capsular contracture	1.3 (0.2, 8.7)
Contour irregularities	4.3 (1.6, 11.0)
Death[d]	1.1 (0.3, 4.4)
Lack of projection	2.2 (0.5, 10.0)
Implant rotation	1.6 (0.4, 6.7)
Position dissatisfaction[c]	2.5 (1.0, 6.0)
Recurrent breast cancer	1.9 (0.6, 6.2)
Size change – patient request	1.8 (0.7, 4.6)

[a] 55 revision-reconstruction patients experienced at least one complication or reoperation.

[b] The following complications occurred at a rate less than 1%: asymmetry,[c] breast pain,[c] calcification,[c] delayed wound healing,[c] external injury not related to breast implants, hypertrophic scarring, irritation/inflammation, mass/cyst, metastatic cancer, new diagnosis of rheumatic disease, other: missing, scarring, seroma, and tightness of skin over implant.

[c] Mild occurrences were excluded.

[d] All causes of death were reported by the investigator to be unrelated to study procedure or device.

CA Study: Main Reasons for Reoperation

Patients may require a reoperation for a number of reasons such as size and/or style change, implant removal (with or without replacement), capsular contracture procedures, incision and drainage, implant repositioning, scar revision, etc. In addition, patients often require more than one surgical procedure to complete their reconstruction such as skin or nipple-related procedures.

This section includes a summary of the types of additional surgical procedures performed in the CA study. Percentages are based upon the number of patients with any additional procedure, not the total number of patients in a cohort. If multiple procedures were performed on a patient on the same date, they are considered to constitute a single reoperation, regardless of whether one or both breasts were involved.

Of the 2379 primary augmentation patients, 160 (6.7%) patients had a total of 398 additional surgical procedures in 190 reoperations through 5 years. The most frequently reported additional surgical procedures were implant removal, incision and drainage, scar revision, and mastopexy.

Of the 555 revision-augmentation patients, 73 (13.2%) patients had a total of 168 additional surgical procedures in 85 reoperations through 5 years. The most frequently reported additional surgical procedures were implant removal, incision and drainage, and capsulectomy.

Of the 444 primary reconstruction patients, 87 (19.6%) patients had a total of 245 additional surgical procedures in 120 reoperations through 5 years. The most frequently reported additional surgical procedures were implant removal, capsulotomy, capsulectomy, and fat grafting.

Of the 259 revision-reconstruction patients, 39 (15.1%) patients had a total of 105 additional surgical procedures in 46 reoperations through 5 years. The most frequently reported additional surgical procedures were implant removal, capsulectomy, and capsulotomy.

Table 12 provides the types of additional surgical procedures through 5 years in the CA Study occurring at ≥1%, where the percentage is calculated as the number of patients with a given procedure divided by the total number of patients with additional procedures for that cohort.

Table 12. Types of Additional Surgical Procedures Through 5 Years by Cohort

Type of Additional Surgical Procedures ≥1%	Primary Augmentation (N=160*) n (%)	Revision-Augmentation (N=73*) n (%)	Primary Reconstruction (N=87*) n (%)	Revision-Reconstruction (N=39*) n (%)
Additional procedures for breast reconstruction	1 (0.6)	0 (0.0)	8 (9.2)	2 (5.1)
Biopsy	12 (7.5)	8 (11.0)	5 (5.7)	1 (2.6)
Biopsy and tissue adjustment	0 (0.0)	1 (1.4)	0 (0.0)	0 (0.0)
Capsulectomy	16 (10.0)	9 (12.3)	14 (16.1)	13 (33.3)
Capsulorrhaphy	5 (3.1)	1 (1.4)	0 (0.0)	1 (2.6)
Capsulotomy	14 (8.8)	8 (11.0)	16 (18.4)	10 (25.6)
Cyst aspiration	3 (1.9)	1 (1.4)	0 (0.0)	0 (0.0)
Dermis placed	1 (0.6)	0 (0.0)	4 (4.6)	2 (5.1)
Excision of mass/cyst	1 (0.6)	0 (0.0)	1 (1.1)	0 (0.0)
Explant with replacement with study device	24 (15.0)	12 (16.4)	27 (31.0)	8 (20.5)
Explant without replacement with study device	46 (28.8)	26 (35.6)	23 (26.4)	16 (41.0)
Exploration	0 (0.0)	2 (2.7)	0 (0.0)	0 (0.0)
Fat grafting	1 (0.6)	2 (2.7)	14 (16.1)	7 (17.9)
Fat grafting and dermis placed	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)
Implant removed, pocket irrigated, implant placed back in pocket	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)
Implant reposition	20 (12.5)	7 (9.6)	8 (9.2)	3 (7.7)
Incision and drainage	25 (15.6)	21 (28.8)	11 (12.6)	2 (5.1)
Incision revision	0 (0.0)	1 (1.4)	3 (3.4)	0 (0.0)
Inframammary fold revision	2 (1.3)	1 (1.4)	2 (2.3)	1 (2.6)
Laser hair removal	0 (0.0)	0 (0.0)	1 (1.1)	0 (0.0)
Liposuction	0 (0.0)	0 (0.0)	3 (3.4)	0 (0.0)
Liquid nitrogen treatment to keratotic lesion	2 (1.3)	0 (0.0)	0 (0.0)	0 (0.0)
Mastectomy	2 (1.3)	1 (1.4)	1 (1.1)	1 (2.6)

Table 12. *Continued to next page*

Table 12. *(Continued)*

Type of Additional Surgical Procedures ≥1%	Primary Augmentation (N=160*) n (%)	Revision-Augmentation (N=73*) n (%)	Primary Reconstruction (N=87*) n (%)	Revision-Reconstruction (N=39*) n (%)
Mastectomy and dermis placed	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)
Mastopexy	22 (13.8)	5 (6.8)	6 (6.9)	2 (5.1)
Nipple procedure	4 (2.5)	2 (2.7)	4 (4.6)	0 (0.0)
Pocket revision	8 (5.0)	0 (0.0)	2 (2.3)	1 (2.6)
Port removal	0 (0.0)	0 (0.0)	1 (1.1)	0 (0.0)
Removal of implant, washout, debridement, and replacement	0 (0.0)	0 (0.0)	1 (1.1)	0 (0.0)
Scar revision	22 (13.8)	4 (5.5)	8 (9.2)	3 (7.7)
Skin adjustment	4 (2.5)	1 (1.4)	10 (11.5)	0 (0.0)
Skin biopsy	1 (0.6)	1 (1.4)	0 (0.0)	1 (2.6)
Tissue expander placement, wound debridement, and collagen grafting	0 (0.0)	0 (0.0)	0 (0.0)	1 (2.6)
Wound debridement	1 (0.6)	0 (0.0)	2 (2.3)	0 (0.0)

* The number of patients with additional procedures is given in the column header and is used as the denominator in the calculation of percentages.

DEVICE IDENTIFICATION CARD

Enclosed with each silicone gel breast implant is a Patient ID Card. To complete the Patient ID Card, place one device identification sticker (Patient Record Label) 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 the Mentor Complaint Department for examination and analysis. For instructions on the return of the explanted devices, please call 1-866-250-5115 or send an email to RA-MNTUS-Intake@its.jnj.com prior to sending any devices back to Mentor.

PRODUCT EVALUATION

Mentor requires that any complication 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.

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

US 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 the 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 local Mentor representative prior to the return of the 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 ADVANTAGE LIMITED WARRANTIES

Mentor's Lifetime Product Replacement Policy and Advantage Limited Warranties provide limited replacement and limited financial reimbursement in the event of shell leakage or breakage resulting in breast implant rupture.

For more information, please contact Mentor's Customer Quality Department at (866) 250-5115 or visit www.mentorwwllc.com.

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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


Width, height, projection

Not made with natural rubber latex

Low Height, Moderate Plus Profile

Medium Height, Moderate Plus Profile

Medium Height, Moderate Profile

Medium Height, High Profile

Tall Height, Moderate Plus Profile

Tall Height, High Profile


Not returnable if opened

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

Do not reuse
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.


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.

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.


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

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.


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.


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

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


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

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

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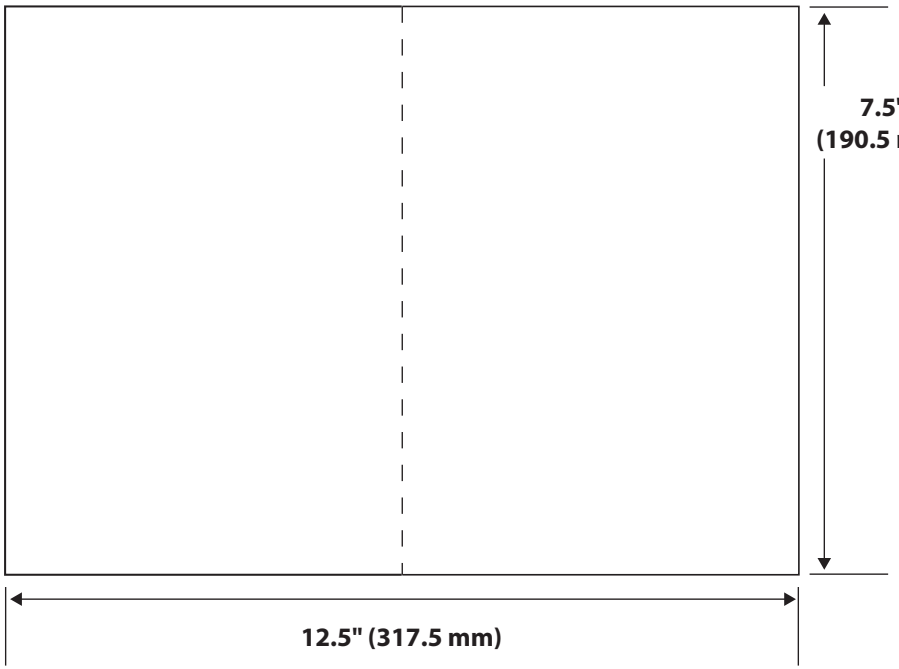

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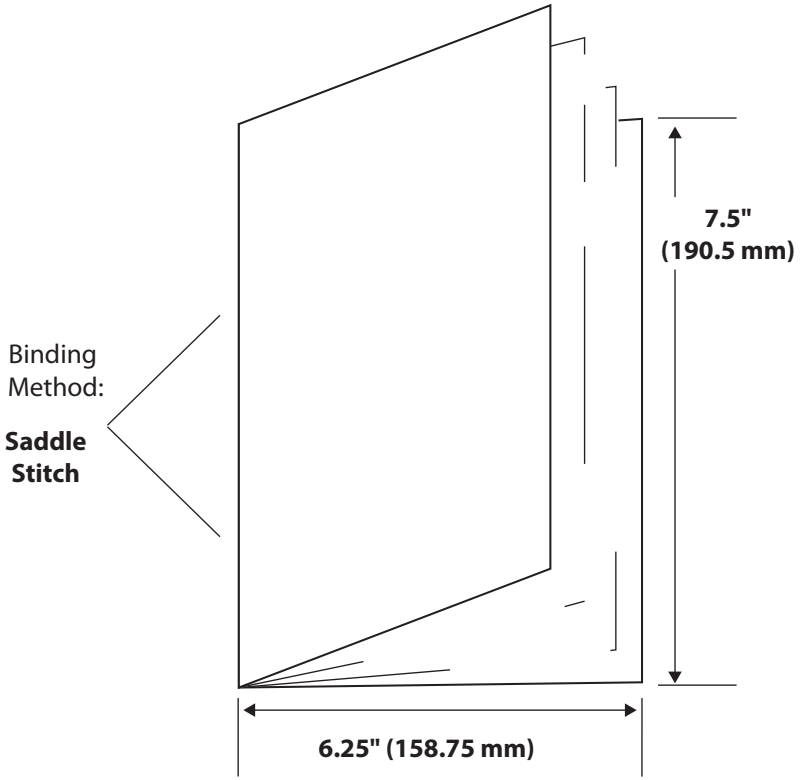

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MENTOR® MemoryShape® Breast Implants	**PIDS**	**LAB100138639v7**	**n/a**	**Saddle Stitch**	**Black**

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12.5" x 7.5" **317.5 mm x 190.5 mm**	**6.25" x 7.5"** **158.75 mm x 190.5 mm**	**112005-001 Rev C**	**60**	**en**	[X]	☐	**n/a**	☐

BLEED SIZE		NONE	BLEED ALL SIDES	BLEED TOP	BLEED RIGHT	BLEED LEFT	BLEED BOTTOM
.5" (12.7 mm) ☐	.125" (3.175 mm) ☐	[X]	☐	☐	☐	☐	☐

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