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**UNITED STATES DISTRICT COURT**

**CENTRAL DISTRICT OF CALIFORNIA**

**SARA EBRAHIMI, an individual,**

**Plaintiff,**

**v.**

**MENTOR WORLDWIDE LLC; JOHNSON & JOHNSON SERVICES, INC;**

**Defendants.**

Case No._____

**COMPLAINT FOR:**

**1) STRICT PRODUCT LIABILITY [FAILURE TO WARN]**

**2) STRICT PRODUCT LIABILITY [MANUFACTURING DEFECT]**

**3) NEGLIGENCE PER SE**

**DEMAND FOR JURY TRIAL**

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Plaintiff Sara Ebrahimi ("Sara Ebrahimi"), by and through her attorneys, based on information and belief, alleges against Defendants Mentor Worldwide LLC ("**Mentor**"), and Johnson & Johnson Services, Inc. ("**Johnson & Johnson**") (herein referred to collectively as "**Defendants**") as follows:

## I. NATURE OF THE ACTION

1. Sara Ebrahimi brings this action against Defendants, and each of them, based on their defective manufacturing of Mentor MemoryGel™ Silicone Gel Breast Implants, repeated failure to follow the requirements imposed by the Food and Drug Administration ("FDA") in connection with approval of Mentor's premarket approval application (PMA), and failure to warn the FDA and ultimate users of known dangerous propensities.

2. Founded in 1969, Mentor is a leading supplier of medical products for the global aesthetic market. The company develops, manufactures, and markets, science-based products for surgical and non-surgical medical procedures that allow patients to improve their quality of life. The company is focused on three strategic areas: breast, body and facial aesthetics and is the only manufacturer whose breast implants are made in the U.S.A. Mentor joined the Johnson & Johnson Family of Companies in 2009 and is part of its Global Surgery Group.

3. In 1976, Congress passed the Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic ("FD&C) Act. Breast implants were placed into Class II devices and reviewed through the premarket notification [510(k)] process. In 1988, in response to emerging safety concerns, the FDA re-classified breast implants to class III devices (requiring premarket approval), which was finalized in 1991 when the FDA published a final 515(b) regulation calling for new silicone gel-filled breast implant applications for premarket approval.

4. Premarket approval (PMA) is the FDA process of scientific and regulatory review to evaluate the safety and effectiveness of Class III medical devices. Class III devices are those that support or sustain human life, are of substantial importance in preventing impairment of human health, or which present a potential, unreasonable risk of illness or injury. Due to the level of risk associated with Class III devices, the FDA has determined that general and special controls alone are insufficient to assure the safety and effectiveness of class III devices.

Therefore, these devices require a PMA under section 515 of the FD&C Act in order to obtain marketing clearance.

5. In January 1992, the FDA announced a voluntary moratorium on silicone gel-filled breast implants, requesting that manufacturers stop supplying them and surgeons stop implanting them, while the FDA reviewed new safety and effectiveness information that had been submitted. In April 1992, the FDA determined that none of the PMAs submitted for Mentor's MemoryGel Silicone Gel Breast Implants contained sufficient data to support approval, and therefore, Mentor's MemoryGel Silicone Gel Breast Implants were no longer marketed in the U.S. However, the FDA also determined that access to silicone gel-filled breast implants for reconstruction and revision patients should continue, and implants used for these indications should be considered to be investigational devices, and women who received them should be followed through adjunct clinical studies.

6. In December 2003, Mentor Worldwide LLC ("Mentor") submitted a PMA for its MemoryGel Silicone Gel Breast Implants. In 2006, the FDA approved Mentor's PMA. Exhibit 1. This was the first time silicone gel-filled breast implants were available for augmentation, in addition to reconstruction and revision, since the moratorium was established in 1992. As conditions of approval, Mentor was required to conduct six post-approval studies to further characterize the safety and effectiveness of their MemoryGel Silicone Gel Breast Implants and to answer scientific questions that the premarket clinical trials were not designed to answer.

## II. PARTIES

### A. Plaintiff Sara Ebrahimi

7. Plaintiff, Sara Ebrahimi ("Plaintiff" or "Ms. Ebrahimi"), is a resident of Bellevue, Washington.

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**B. Defendant Mentor**


8. Defendant Mentor is a company incorporated under the laws of California with its principal place of business located at 201 Mentor Drive, Santa Barbara, CA. Defendant Mentor is a wholly-owned subsidiary of Defendant Johnson & Johnson.

**C. Defendant Johnson & Johnson**

Johnson & Johnson

9. Defendant Johnson & Johnson is a corporation organized and existing under the laws of the State of New Jersey, having its headquarters at One Johnson & Johnson Plaza, New Brunswick, New Jersey 08933.

10. The Johnson & Johnson corporate family includes a multitude of wholly-owned subsidiaries and affiliated companies all over the world, including Mentor Worldwide, LLC. The Johnson & Johnson entities are so interwoven that they act and operate as a single entity. Johnson & Johnson's 2016 10-K, filed with the Securities and Exchange Commission on February 24, 2016 explains, "…The Surgery franchise sales amounted to $9.2 billion in 2015, which included

operational growth of 2.7% over 2014. Operational growth in Specialty Surgery was primarily driven by Mentor products."

**D. Agents and Co-Conspirators**

11. At all times herein mentioned, each of the Defendants hereinabove was the agent, servant, employee, partner, alter ego, aider and abettor, co-conspirator and/or joint venturer of each of the remaining Defendants named herein and were at all times operating and acting within the purpose and scope of said agency, service, employment, partnership, conspiracy and/or joint venture, and each Defendant has ratified and approved the acts of each of the remaining Defendants.

## III. JURISDICTION AND VENUE

12. This court has subject matter jurisdiction based on diversity of the parties and the amount in controversy exceeds $75,000.00 as required under 28 U.S.C. § 1331.

13. Venue is appropriately in the Central District of California pursuant to 28 U.S.C. § 1391(a), in that: (a) Defendant Mentor has its principle place of business in California; and (b) a substantial part of the events giving rise to this action occurred in this District.

## IV. FACTUAL ALLEGATIONS

**A. Silicone Implants—Background**

14. At all relevant times, Mentor designed, manufactured, and distributed Mentor breast implants, including the Mentor MemoryGel Silicone Gel Breast Implants.

15. The FDA, after the enactment of the MDA, allowed the use of silicone-filled breast implants as long as manufacturers later provided "reasonable assurance" of the products' safety and effectiveness. 21 U.S.C. §360e(d)(2). In 1988, in response to emerging safety concerns, the FDA re-classified breast implants to class III devices (requiring premarket approval), which was finalized in 1991 when the FDA published a final 515(b) regulation allowing for PMAs for silicone gel-filled breast implants.

16. In 1992, the FDA determined that there were insufficient data for approval, and Mentor's MemoryGel Silicone Gel Breast Implants were no longer marketed in the U.S., with

the exception of use in reconstruction and revision patients. In 2006, the FDA approved Mentor's PMA. Exhibit 1. As conditions of approval, Mentor was required to conduct six post-approval studies to further characterize the safety and effectiveness of their MemoryGel Silicone Gel Breast Implants and to answer long term questions that the premarket clinical trials were not designed to answer.

**B. Sara Ebrahimi Background**

17. In 2013, Sara Ebrahimi consulted with a board-certified plastic surgeon in Encino, California to discuss breast augmentation. She reviewed the Mentor brochure (Exhibit 2) before consenting to the surgery.

18. In fact, the information related to her and the brochure confirmed for her that problems previously associated with silicone implants had been remedied before they were brought back on the market in 2006.

19. On June 5, 2013, Ms. Ebrahimi underwent Bilateral Silicone Breast Augmentation in Encino, California and was implanted with Mentor MemoryGel Silicone Gel Breast Implants. Prior to the surgery, Ms. Ebrahimi was a healthy and driven individual and lived a healthy lifestyle.

20. On June 12, 2013, Ms. Ebrahimi developed pain in both breasts along with mild hardening that persisted. Several days later, on July 2, 2013, Ms. Ebrahimi developed an enlarged lymph node. By August 2013, Ms. Ebrahimi had developed progressive severe pain in her left breast accompanied by lateral malposition. She also experienced chest pain, pressure in her ribs, fatigue, increased pain in her lymph nodes, and weakness.

21. On October 2, 2013, Ms. Ebrahimi underwent revision surgery on her left breast due to lateral malposition. She was still experiencing pain in her ribs, swollen lymph nodes, and suffering from general fatigue and weakness.

22. In February 2014, bloodwork done on Ms. Ebrahimi showed high homocysteine (an amino acid linked to the development of stroke and heart disease) and a moderate level of CRP (C-reactive protein, which is a substance produced by the liver in response to inflammation.). By November 2014, she had developed photosensitivity with hives and itching

after sun exposure, brittleness and cracking of her nails, easy bruising, shortness of breath, poor wound healing, and some lateral malposition of right breast. Soon thereafter she developed cognitive difficulties and immune dysfunction. Her fatigue and weakness had progressed to the point where she was often bedridden throughout the day.

23. By June 2015, Ms. Ebrahimi began experiencing slow shrinkage of both breasts. She had a metallic taste in her mouth, suffered from night sweats, headaches, foul body odor, cognitive dysfunction, nausea, and dizziness. In July 2015, she was diagnosed with Lymphadenopathy, which is a swelling of the lymph nodes, indicative of infection. An ultrasound procedure on the left side revealed extremely dense breast tissue.

24. Ms. Ebrahimi's symptoms continued to worsen, so she had more bloodwork done in January 2016. The results revealed low white blood cells, increasing thyroid antibodies/autoimmune antibodies, EBV (Epstein—Barr virus), CMV (Cytomegalovirus,), and varicella zoster (a virus). These results are indicative of a generalized weakened condition. By February 7, 2016, Ms. Ebrahimi's chronic, incapacitating fatigue and illness forced her to move from Los Angeles to Bellevue to live with her parents so that they could care for her.

25. Throughout the first half of 2016, Ms. Ebrahimi's symptoms continued to worsen. She also developed Hashimotos disease (an autoimmune disorder in which the immune system attacks the body's own tissues), skin rashes, and digestive and gastrointestinal issues. New bloodwork in May 2016 showed high levels of homocysteine (increasing the risk of stroke and heart disease) and other abnormalities, all of which indicated a systemic toxicity due to her body's reaction to the toxic elements contained within the gel of the implants. As a result, her physician recommended removal of her implants.

26. In July 2016, Ms. Ebrahimi underwent heavy metal testing and was found to have high or excessive levels of 10 different metals listed in Mentor's PMA Summary of Effectiveness, including: antimony, barium, chromium, copper, mercury, molybdenum, nickel, titanium, vanadium and zinc. The test revealed the presence of 5 of the other metals listed Mentor's application. She has been diagnosed with silicone toxicity, and strongly advised that it

was medically necessary to have the implants removed immediately. Ms. Ebrahimi is scheduled to have her implants removed in October 2016.

### C. Mentor PMA Approval

27. On November 17, 2006, the FDA approved Mentor's PMA, which allowed Mentor to market its MemoryGel Silicone Gel Breast Implants, conditioned upon six requirements. The FDA required Mentor to (1) Continue and complete their **core post-approval study**, (2) Conduct a **large post-approval study** to assess long-term outcomes and identify rare adverse events by enrolling 41,900 silicone gel-filled breast implant patients and 1,000 saline-filled breast implant patients and follow them for 10 years, (3) Conduct a **device-failure study** in concert with their large post-approval study to further identify the modes and causes of failure of explanted devices over the 10-year period, (4) Complete a **focus-group study** to evaluate how easily patients understand the information in the informed decision brochure about the risks associated with the use of silicone breast implants, (5) Complete an **informed decision study** to monitor the process of how patient labeling is distributed to women considering silicone gel-filled breast implants, and (6) Complete the Mentor **adjunct study**, which was in place after 1992, when the FDA allowed Mentor to market silicone gel-filled breast implants for reconstruction after mastectomy, correction of congenital deformities, or replacement of existing implants. Women who received silicone gel-filled breast implants for these purposes were enrolled in Adjunct Studies so that data about device performance and safety could be collected. Participant enrollment began in 1992 for Mentor. As a condition of approval of silicone gel-filled breast implants in 2006, Mentor was required to close enrollment of new patients into the Adjunct Studies but continue to follow existing participants through their 5-year post-implant evaluations

#### i. Core Post-Approval Study

28. As one of the conditions of approval, the FDA specifically required Mentor to continue their Core Study, which had been underway and published in Mentor's PMA. Exhibit 3. There were 1008 patients enrolled in that study. Mentor was to continue the study until all patients had completed their 10-year evaluation in order to assess the long-term clinical performance of their product. Mentor was required to collect data via annual physician follow-

up evaluations. The primary changes to the protocol from premarket to post approval were that all non-MRI patients should have an MRI at years 6, 8, and 10 and that all patients who were explanted without replacement were to be evaluated through 10 years. Mentor was also required to update their patient and physician labeling to reflect the results of the 5 and 10-year Core Study findings and to report to the FDA significant new information regardless of when the information became available.

29. According to the FDA website, the core post-approval study follow-up rates at nine years post-implant were only 59 percent. The lack of a sufficient statistical sample, due to the low follow-up rate, hampered Mentor's ability to alter the labeling and defeated the purpose of the study in assessing the long-term clinical performance of the product. Furthermore, the FDA requirements specifically mandated evaluation through 10 years, but the report schedule illustrates that reporting was only done for six years. The reported findings of this study lack statistical reliability in the sub-groups (cohorts): primary augmentation, revision augmentation, primary construction, and revision reconstruction.

30. In the primary augmentation cohort, Mentor only reported the reasons for reoperation in 36% of the sample. Mentor failed to disclose to the FDA the reasons why only about one-third of the sample were included in this aspect of the study.

31. In the revision augmentation cohort, reoperation rate was 43%. Mentor reported the most common reason for reoperation, which was capsular contraction, at 30.4%. Mentor failed to disclose other significant reasons why women in this category needed reoperation.

32. In the primary construction cohort, Mentor reported reoperation rates at 49%. Mentor reported that of that group, 53% needed reoperation because of asymmetry, capsular contraction, rupture, and breast mass. Fully 47% of women in this category needed reoperation for which Mentor failed to document or explain the reasons.

33. In the revision reconstruction cohort, reoperation was performed on 50.7% of the women surveyed. The most frequently reported reasons were capsular contraction and breast mass totaling 36% of reoperations. Other reported reasons, including connective tissue and

neurologic disorders and gel bleed were downplayed even though they were significant given the small sample studied.

ii. **Large Post-Approval Study**

34. The FDA's approval also required Mentor to conduct a 10-year large post approval study, consistent with a protocol submitted to the FDA by Mentor on September 26, 2006. Exhibit 4.

35. That protocol required patient enrollment within 90 days of issuance of the PMA. The Large Post-Approval Study was to be a separate study from the Core Study and was to include 41,900 Mentor silicone gel patients and 1,000 saline-filled breast implant patients as the control group. The purpose of this study was to address specific issues for which the Core Study was not designed to fully answer, including a real-world assessment of long-term local complications, such as connective tissue disease (CTD), CTD signs and symptoms, neurological disease, neurological signs and symptoms; offspring, reproductive, and lactation issues; cancer rates, suicide, mammography issues, rupture results, and MRI compliance. The data was to be collected through annual patient questionnaires, either completed via the internet, mail, or telephone. The study also required physician evaluations at years 1, 4-6, 9 and 10 to collect data on complications. Mentor was required to update their patient and physician labeling to reflect the 5 and 10-year study findings, as well as at any other time if necessary to report significantly new information from the study.

36. At the outset, the actual number of enrolled patients was 41, 451, over 500 patients fewer than the PMA requirements. Of those patients, 113 did not provide important information. At year 7, the overall follow-up rate was 20.1% (8,331 participants out of 41,452), leaving 79.9% of the desired statistics unavailable for evaluation.

37. This was a study of significant importance required by the FDA for post market approval. The study was designed to address a critical spectrum of health issues for women with breast implants. Mentor did not comply with the required data collection. With a 79% dropout rate, the study failed to demonstrate that use of the Mentor silicone gel implants was safe. The

inadequate results are even more disconcerting because the data collection was designed to examine reasons for reoperation—previously unevaluated—including MRI results, and rheumatologic or neurological symptoms. The lack of participation and reliable results from this study show that Mentor has failed to comply with FDA requirements. Mentor did not follow through with data collection, only 21% were followed up on after three years, leaving 79% not followed up on for the 3-year data collection. 79.9% were not followed up on for the 7-year data collection, and no follow-up rate was provided for the 10-year data collection.

iii. **Device Failure Study**

38. In order to ascertain the reasons for and frequency of device failure, the FDA specifically required that "Mentor must continue preclinical studies to characterize the long-term modes and causes of failure of explanted retrieved devices for the 10-year duration of the large postapproval study." Exhibit 5. This study was to address the following specific issues: "(1) further evaluation of iatrogenic failures to address issues raised by the April 2005 Panel, (2) the characterization of when surgical instrument damage occurs, (3) further evaluation and characterization of failures due to localized shell stress, and (4) any correlation between surgical factors (e.g., incision size) and device rupture." Mentor was also required to update their patient and physician labeling to reflect any relevant findings from this study.

39. Mentor's Device Failure Study report of summary findings to the FDA did not list sample size, did not list results of the data findings (no clinical data and no visual inspection data), did not list safety findings, did not list any recommendations or summary of safety and data or follow-up on the data, and did not list any changes to labeling, all in violation of this condition established in the approval of Mentor's PMA.

40. Overall, Mentor blatantly failed to meet the FDA's requirements. Mentor merely filed a report with minimal information just to show that they were following reporting protocol.

iv. **Focus Group Study**

41. This condition required Mentor to complete a focus group study of the augmentation and reconstruction patient groups. Exhibit 6. An independent group was to obtain responses from patients on the adequacy of the format and content of the approved labeling.

Upon completion of the focus group study, Mentor was to provide a report of the findings and a revised patient and physician labeling based on those findings.

42. Mentor used only 35 women to evaluate how patients understood the safety and labeling brochures. Some respondents concluded that the true purpose of the brochure was to protect Mentor, rather than inform patients about the risks of breast implant surgery. Respondents reported that the information on the labeling did not help them understand the risks and complications associated with breast implants. Respondents also felt the brochure fell short of providing information on the benefits of breast implants and did not acknowledge the deeply personal benefits of body image and self-esteem, especially for women who lose their breast to cancer.

43. The recommendations for labeling changes included adding information clearly describing differences between restoration, replacement, reconstruction, and revision early in the main body of the brochure; adding information on potential complications based on the likelihood of occurrence; providing more information about benefits; and providing more qualitative information to help women make more informed decisions.

44. Despite the long list of recommendations for labeling changes, no further tests were done. Moreover, the small number of women studied and the blatant disregard for the recommendations for labeling exemplifies that the PMA requirements were not met by Mentor.

v. **Informed Decision Study**

45. The Informed Decision Study required Mentor to distribute their approved patient labeling to all physicians intending to use the silicone gel products. Exhibit 7. Both the physician and the patient were intended to sign designated sections in order to best assure that the patient had obtained the labeling in sufficient time prior to surgery to read it and understand the risks and other information associated with the Mentor device. Mentor was to conduct the survey randomly, selecting 50 physicians on an annual basis, collect the results and provide a summary of the findings to the FDA under the condition the FDA was to evaluate the findings and advise Mentor if and when the annual survey was no longer necessary. In addition, Mentor was to provide training on this process as part of their physician training program.

46. The summary of findings filed by mentor did not list the sample size of patients enrolled. It only provided insight for one year (2011) and reported that 54 surveys were returned by 50 physicians and did not list what went into the survey or which points were assessed.

vi. **Mentor Adjunct Study**

47. The final condition imposed by the FDA required Mentor to continue the adjunct study. Exhibit 8. This study was originally designed to serve a public health need for reconstruction and revision patients, but because that need was no longer an issue (because of the PMA), Mentor was required to: (1) cease new patient enrollment into the study, and (2) continue to follow-up on all currently-enrolled Mentor Adjunct Study patients through 5 years. The data from the follow-up study was to be reported as part of the annual reports required by the PMA.

48. In addition to addressing the health needs of reconstruction and revision patients, the study was to gather data regarding short-term implant complications.

49. After completion of the study, Mentor reported on only 36.8% of the patients in the reconstruction cohort; 49.7% revision-reconstruction cohort; and approximately 33% of the revision-augmentation cohort. Mentor reported to the FDA that "poor patient compliance significantly limited interpretation of the available safety results."

**D. Mentor Violated the PMA Conditions**

50. Mentor's duty to the scientific community and women who have undergone augmentation for any reason—at the insistence of the FDA—was to design an effective study. It was Mentor's obligation to design and execute a study where women were able to access internet forms that are easily understood and provide a working forum to report their experience with implants. Mentor intentionally and systematically failed to make this happen which is a violation of the FDA's conditions for approval. Data collection was sparse and potential serious side effects and harmful complications were downplayed and under-reported due to inadequate sample size.

51. All six of these studies were supposed to support long-term safety. The poor follow-up rates and inadequate data confirm Mentor's intentional and systematic failure to follow

FDA requirements. Halfway through the ten-year prospective post-marketing studies mandated by the FDA, well over 50% of the 80,000 women in the study groups were dropped or otherwise eliminated from the studies. Of the patients who were accounted for, significant numbers reported systemic ailments which can only be attributed to gel bleed introducing known toxins including silicone, heavy metals and chemicals into their bodies. Mentor was aware, or should have been aware that the gel contained chemicals and metals toxic to the human body but failed to adequately report that to the FDA and warn their patients of their dangerous consequences.

52. Upon information and belief, a Mentor chemist of 15 years reported to the FDA that the implants are more likely to break than the company reported. Exhibit 9. It has also been reported that the silicone is more likely to leak, even when the implants are intact, and that platinum used in the implants is more dangerous than reported. Mentor knew of these risks associated with implants, but covered them up by terminating studies, sponsoring only self-serving research they could control, and by misrepresenting the risks to the users, physicians, and regulatory agencies.

**E. Mentor Intentionally Failed to Warn Patients and Doctors**

53. Arsenic, antimony, barium, cobalt, mercury, nickel, copper, zinc, chromium, titanium, vanadium, selenium, tin, and molybdenum are chemical constituents of Mentor's silicone-gel implants and/or are present in the implants as a relic of the manufacturing process. Absent silicone gel bleed beyond that which Mentor disclosed to the FDA, heavy metals at the levels present in Ms. Ebrahimi's body would not be found.

54. Mentor's Product Insert Data Sheet (Exhibit 10) regarding the implants state that "[s]mall 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.....Mentor performed a laboratory test to analyze the silicones and platinum (used in the manufacturing process), which may bleed out of intact MemoryGel Breast Implants into the body....Over 99% of the LMW silicones and platinum stayed in the implant. The overall body of available evidence supports that the extremely low level of gel bleed is of no clinical consequence."

55. The nature and extent of Ms. Ebrahimi's injuries and test results evidence a significant gel bleed, as opposed a bleed of "small quantities" of gel, or an "extremely low level of gel bleed."

56. Mentor failed to warn consumers, healthcare providers, and the FDA that a significant gel bleed was a potential risk of a properly manufactured MemoryGel Silicone Gel Breast Implant.

57. The risk of a significant gel bleed was not disclosed or discussed in what Mentor calls its "Directions for Use" or in its consumer labeling, despite the availability of substantial evidence that such was a significant potential risk of use, even in a properly manufactured product, was present.

58. The occurrence of a significant gel bleed, and the presence of neurotoxic levels of arsenic, antimony, barium, cobalt, mercury, nickel, copper, zinc, chromium, titanium, vanadium, selenium, tin, and molybdenum in Ms. Ebrahimi's body shows the following:

a. The implants placed into Ms. Ebrahimi were different from those approved by the FDA;

b. The manufacturing of the implants Ms. Ebrahimi received deviated from federal requirements; and

c. The implants Ms. Ebrahimi received were inconsistent with, and deviated from, the product specifications submitted to the FDA.

59. In a FDA report on Mentor's breast implants entitled *FDA Update on the Safety of Silicone Gel-Filled Breast Implants* (Exhibit 11), the FDA advised that, since Mentor began post-approval studies on 2007, Mentor found 43.5% of implants retrieved from patients participating in the large post-approval study had ruptures, and 25% of 97 implants that were explanted and returned to Mentor for evaluation from August 2000 to August 2009 in the Core Study had ruptured.

60. Based upon Mentor's reports, the FDA separately stated that "The most common cause of rupture reported in the device retrieval studies is damage to the implant during the implantation surgery. However, only a small proportion of breast implants are returned to the

manufacturers for evaluation. This limits the ability to identify trends in failure modes." It is unclear what "damage to the implant during surgery" means, whether due to the foreseeable handling of the devices, weakness in the shell due to manufacturing defects, or other foreseeable factors.

61. Mentor knew of multiple risks associated with implants, and responded by terminating studies, sponsoring only self-serving research they could control, and by misrepresenting the risks to the users, physicians, and regulatory agencies.

62. Mentor's duty to the scientific community and women who have undergone augmentation for any reason—at the insistence of the FDA—was to design an effective study. Mentor intentionally and systematically failed to make this happen which is a violation of the FDA's directives for compliance with the conditions of approval of the PMA.

## V. VIOLATIONS ALLEGED

### FIRST CAUSE OF ACTION

**Strict Product Liability—Failure To Warn**

(Against All Defendants)

63. Plaintiff incorporates and re-alleges every allegation set forth in Paragraphs 1-62.

64. At all times relevant herein, Defendants were engaged in the business of designing, developing, manufacturing, testing, packaging, promoting, marketing, distributing, labeling, and/or selling the Mentor MemoryGel Silicone Gel Breast Implants.

65. At all times relevant herein, Defendants intended for the MemoryGel Silicone Gel Breast Implants to be surgically implanted into the bodies of members of the general public, including Plaintiff, and knew or should have known that the product would be surgically implanted into members of the general public, including Plaintiff.

66. Plaintiff used the MemoryGel Breast Implant in the manner intended by Defendants and/or in a manner reasonably foreseeable by Defendants.

67. Plaintiff could not, in the exercise of reasonable care, have discovered the defects herein mentioned and perceived their danger.

68. Plaintiff reasonably relied upon the skill, superior knowledge and judgment of Defendants when she consented to the implantations of the MemoryGel Breast Implants into her body.

69. Defendants had a duty to warn Plaintiff of the dangers associated with the MemoryGel Silicone Gel Breast Implants.

70. The MemoryGel Silicone Gel Breast Implants were defective and unreasonably dangerous when it left the possession of Defendants in that they contained warnings insufficient to alert consumers, including Plaintiff, of the dangerous risks and complications associated with the MemoryGel Silicone Gel Breast Implants, including but not limited to, their propensity to cause injury, through leakage of the silicone gel into the tissues of the user's body, thereby introducing toxic metals and chemicals into those tissues, resulting in serious, dangerous and harmful side effects and complications all to the detriment of the health and well-being of the users of their product, including Plaintiff.

71. Defendants knew or should have known the gel contained in the implants contained metals and toxic chemicals in such quantities that would be extremely harmful to users of their product if the gel were allowed to escape its shell and "bleed" into the user's body. Defendants also knew or should have known that there was a significant risk of rupture or seepage of the gel through the shell and into the tissues of the user's body. Defendants failed to adequately warn users, including Plaintiff, of Defendants' products and of these potential serious and harmful risks.

72. Defendants, in failing to provide follow-through studies required by the granting of the PMA to market and sell their product, failed to warn the FDA of the risks described above.

73. Had Plaintiff received adequate warnings regarding the risks of the MemoryGel Silicone Gel Breast Implants, she would not have used them.

74. As a direct and proximate result of the foregoing acts and omissions, Plaintiff suffered severe and permanent physical injuries. Plaintiff has endured, and will continue to endure, substantial pain and suffering. Plaintiff has incurred significant expenses for medical care and treatment, and will continue to incur such expenses in the future. Plaintiff has suffered

and will continue to suffer economic loss, and have otherwise been physically, emotionally and economically injured.

75. The wrongful acts, representations and/or omissions of Defendants, hereinabove set forth, were made, adopted, approved, authorized, endorsed and/or ratified by Defendants' officers, directors, or managing agents, and were done maliciously, oppressively, fraudulently and/or with a willful and knowing disregard of the probably dangerous consequences for the health and safety of its products users, including Plaintiff. In making, adopting, approving, authorizing, endorsing and/or ratifying such conduct hereinabove set forth, the officers, directors and/or managing agents of Defendants acted with a willful and/or knowing disregard of the probably dangerous consequences, and/or acted with an awareness of the probably dangerous consequences of their conduct and deliberately dialed to avoid those consequences, thereby creating a substantial risk of injury to Plaintiff and other users of their products. Plaintiffs are entitled to punitive and exemplary damages in an amount to be ascertained, which is appropriate to punish to set an example of Defendants and deter such behavior by them in the future.

WHEREFORE, Plaintiff prays as hereinafter set forth.

## SECOND CAUSE OF ACTION

**Strict Product Liability—Manufacturing Defect**

(Against All Defendants)

76. Plaintiff incorporates and re-alleges every allegation set forth in Paragraphs 1-75.

77. Defendants manufactured, distributed and/or sold the MemoryGel Silicone Gel Breast Implants that were implanted into Plaintiff's body.

78. At the time Defendants placed MemoryGel Silicone Gel Breast Implants into the stream of commerce, the implants were defective in their manufacture in that they did not meet the current good manufacturing practices required by the FDA, standards under which the PMA was submitted and which was accepted by the FDA.

79. The MemoryGel Silicone Gel Breast Implant used in Plaintiff's surgery contained a manufacturing defect which Defendants did not intend and the FDA did not allow.

80. Specifically, the bleeding of silicone that occurred in the MemoryGel Silicone Gel Breast Implants used in Plaintiff's surgery, due to porous or weak containment in the Implant shell, is inconsistent with specifications of the product as submitted to the FDA for approval, and constituted a manufacturing defect.

81. Defendants' actions, hereinafter described, violate the FDA's Quality System Regulations and Current Good Manufacturing Practices, 21 C.F.R. § 820.1, *et seq.*, which, among other things, require that each manufacturer put procedures in place to test products for compliance with product specifications, document and check compliance with product specifications before products are accepted for sale and use, and identify and control all products that fail to conform with product specifications.

82. Defendants knew that the defect was such that it would not be discovered through reasonable inspection by the users of the product, including Plaintiff.

83. Plaintiff, a foreseeable user of the Defendants' product, was unaware of these defects when she consented to have them implanted in her body.

84. As a direct and legal result of the manufacturing defects contained in their MemoryGel Silicone Gel Breast Implants, Plaintiff was injured in her health and well-being as described hereinabove when the toxins contained in the gel began to seep into the tissues of her body within a short time after the implants were placed in her body.

85. As a direct and legal result of the introduction of toxic chemicals and heavy metals into her body that resulted from aforementioned manufacturing defects, Plaintiff suffered the injuries and damages as herein alleged.

WHEREFORE, Plaintiff prays for relief as hereinafter set forth.

## THIRD CAUSE OF ACTION

**Negligence Per Se**

(Against All Defendants)

86. Plaintiff incorporates and re-alleges every allegation set forth in Paragraphs 1- 85.

87. At all relevant times, Defendants had a duty to plaintiff to use reasonable care in manufacturing and selling Mentor MemoryGel Silicone Gel Breast Implants.

88. At all relevant times, Defendants were required to comply with the FDA's Quality System Regulations and Current Good Manufacturing Practices, 21 C.F.R. § 820.1, *et seq.*, which, among other things, require that each manufacturer put procedures in place to test products for compliance with product specifications, document and check compliance with product specifications before products are accepted for sale and use, and identify and control all products that fail to conform with product specifications.

89. At all relevant times, Defendants were required to comply with the regulations and testing requirements imposed by the granting of the PMA by the FDA for the MemoryGel Silicone Gel Breast Implants, including the requirement that follow-through studies be conducted.

90. The aforementioned statutes and/or regulations were intended to protect against the type of harm suffered by Plaintiff, and Plaintiff is within the class or persons for whose protection the aforementioned statutes and/or regulations were adopted.

91. Defendants breached the aforementioned statutes and/or regulations when they manufactured and sold the defective MemoryGel Silicone Gel Breast Implants to Plaintiff, as set forth in detail above.

92. As a direct and legal result of Defendants' wrongful acts and/or omissions, Plaintiff has experienced significant mental and physical pain and suffering, has sustained permanent injury, has undergone medical treatment and will likely undergo further medical treatment and procedures, has suffered financial or economic loss, including, but not limited to obligations for medical services and expenses, lost income and other damages

WHEREFORE, Plaintiff prays for relief as hereinafter set forth.

## PRAYER FOR RELIEF

WHEREFORE, Plaintiff prays for relief as set forth below:

A. Actual damages, statutory damages, punitive or treble damages, and such other

relief as provided by the statutes cited herein;

B. Pre-judgment and post-judgment interest on such monetary relief;

C. Equitable relief in the form of an injunction prohibiting the illicit conduct described herein;

D. The costs of bringing this suit, including reasonable attorneys' fees; and

E. All other relief to which Plaintiff may be entitled at law or equity.

DATED: September 28, 2016

**COTCHETT, PITRE & McCARTHY, LLP**

By: _____
Robert B. Hutchinson

*Counsel for Plaintiff Sara Ebrahimi,*

**DEMAND FOR JURY TRIAL**

Plaintiff hereby requests a jury trial on any and all claims so triable.

DATED: September 28, 2016

**COTCHETT, PITRE & McCARTHY, LLP**

By: _____
Robert B. Hutchinson

*Counsel for Plaintiff Sara Ebrahimi, Inc.*

# EXHIBIT 1

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Kristine Foss
Vice President, Clinical and Regulatory Affairs
Mentor Corporation
201 Mentor Drive
Santa Barbara, California 93111

NOV 17 2006

Re: P030053
Mentor MemoryGel™ Silicone Gel-Filled Breast Implants (Moderate Profile Style 7000, High Profile Style 4000, and Moderate Plus Profile Style 8000)
Filed: December 12, 2003
Amended: January 16, 20, and 26, February 24, August 31, 2004; January 4 and 18, March 3, April 1, July 13, August 16 and 22, 2005; June 30 and October 3, 2006
Procode: FTR

Dear Ms. Foss:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Mentor MemoryGel™ Silicone Gel-Filled Breast Implants. This device is indicated for breast augmentation for women at least 22 years old and for breast reconstruction for women of any age. 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 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 result of a primary breast reconstruction surgery.

We are pleased to inform you that the PMA is approved. You may begin commercial distribution of the device in accordance with the conditions described below and in the "Conditions of Approval" (enclosed).

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) of the act. FDA has also determined that, to ensure the safe and effective use of the device, the device is further restricted within the meaning of section 520(e) under the authority of section 515(d)(1)(B)(ii), (1) insofar as the labeling specify the requirements that apply to the training of practitioners who may use the device as approved in this order and (2) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act. More specifically, completion of your physician training program is required as a condition of access to your product. FDA will, however, allow a 90-day

transition period for all current Core Study and Adjunct Study investigators, after which these physicians must also have completed the training program in order to have access to the Mentor product.

In addition to the postapproval requirements outlined in the enclosure, you have agreed to the conditions of approval described in items 1 through 6 below.

1. Core Postapproval Study

   You must continue your Core Study until all patients have completed their 10-year evaluation in order to assess the long-term clinical performance of your product. Data are to be collected via annual physician follow-up evaluations. The primary changes to the protocol from premarket to postapproval are that all non-MRI patients will have a MRI at years 6, 8, and 10 and that all patients who were explanted without replacement will be evaluated through 10 years, as per the protocol. You must also update your patient and physician labeling to reflect 5 and 10-year Core Study findings, as soon as these data are available, as well as any other timepoint deemed necessary by FDA if significantly new information from this study becomes available.

2. Large Postapproval Study

   You must conduct the 10-year large postapproval study, as per the protocol that was submitted to FDA on September 26, 2006. This study, which will begin patient enrollment within 90 days of PMA approval, will be a separate study from the Core Study and will include 41,900 Mentor silicone gel patients and 1,000 saline-filled breast implant patients as the control group. The purpose of this study is to address specific issues for which the Core Study was not designed to fully answer, as well as to provide a real-world assessment of some endpoints. The endpoints include long-term local complications, connective tissue disease (CTD), CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI compliance and rupture results. Data are to be collected via annual patient questionnaires, either completed via the web, mail, or telephone. There will also be physician evaluations at years 1, 4-6, and 9-10 to collect local complication data. You must update your patient and physician labeling to reflect 5 and 10-year large postapproval study findings, as soon as these data are available, as well as any other timepoint deemed necessary by FDA if significantly new information from this study becomes available.

   On a quarterly basis, you must submit a report to FDA that includes: (1) the number enrolled by implant group (silicone versus saline); (2) the number enrolled by indication (primary augmentation, revision-augmentation, primary reconstruction, revision-reconstruction) and implant group; (3) the number enrolled by race/ethnicity and implant group; (4) the enrollment rate versus the stated goals; and (5) the follow-up rates versus the stated goals. FDA will inform you when quarterly reports are no longer necessary.

Every 6 months for the first 2 years and then annually, thereafter, you are to submit a progress report that includes: (1) the status of patient enrollment as it compares to the stated goals; (2) the status of the race/ethnicity distribution as it compares to the stated goals; (3) detailed patient and device accounting; (4) a summary of findings for all study endpoints; and (5) the reasons why eligible patients were not enrolled into the study.

3. Device Failure Studies

You must continue preclinical studies to further characterize the long-term modes and causes of failure of explanted retrieved devices for the 10-year duration of the large postapproval study. In addition, you must perform additional studies to address the following specific issues:

- further evaluation of iatrogenic failures to address issues raised by the April 2005 Panel
- the characterization of when surgical instrument damage occurs
- further evaluation and characterization of failures due to localized shell stress
- any correlation between surgical factors (e.g., incision size) and device rupture.

You must also update your patient and physician labeling to reflect any relevant findings.

4. Focus Group Study

You must complete a focus group study of the augmentation and reconstruction patient labeling. This will involve an independent group obtaining responses from patients on the format and content of the approved labeling. Upon completion of the focus group study, you must provide a supplement with a report of the focus group study findings and revised patient and physician labeling based on those findings.

5. Informed Decision Process

As part of your formal informed decision process, you must distribute your approved patient labeling. Both the physician and the patient are intended to sign designated sections in order to best assure that a patient has obtained the labeling in an adequate enough time prior to surgery to read it and has understood the risks and other information associated with the Mentor device. You must administer your approved survey to a random selection of 50 physicians on an annual basis to determine the success of this process and provide a summary of the survey findings to FDA. FDA will inform you when a survey summary is no longer necessary. In addition, you are to provide training on this process as part of your physician training program.

6. Mentor Adjunct Study

You must cease new enrollment into the Mentor Adjunct Study (P910037 and P910038) and continue follow-up of all currently-enrolled Mentor Adjunct Study patients through their 5-year evaluations. You are to report these data as part of annual reports for P030053.

Expiration dating for this device has been established and approved at 5 years.

CDRH does not evaluate information related to contract liability warranties, however you should be aware that any such warranty statements must be truthful, accurate, and not misleading, and must be consistent with applicable Federal and State laws.

CDRH will notify the public of its decision to approve your PMA by making available a summary of the safety and effectiveness data upon which the approval is based. The information can be found on the FDA CDRH Internet HomePage located at http://www.fda.gov/cdrh/pmapage.html. Written requests for this information can also be made to the Dockets Management Branch, (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. The written request should include the PMA number or docket number. Within 30 days from the date that this information is placed on the Internet, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act (the act).

Failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

You are reminded that, as soon as possible and before commercial distribution of your device, you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form. The labeling will not routinely be reviewed by FDA staff when PMA applicants include with their submission of the final printed labeling a cover letter stating that the final printed labeling is identical to the labeling approved in draft form. If the final printed labeling is not identical, any changes from the final draft labeling should be highlighted and explained in the amendment.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and should reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have any questions concerning this approval order, please contact Mr. Stephen Rhodes at (240) 276-3638.

Sincerely yours,

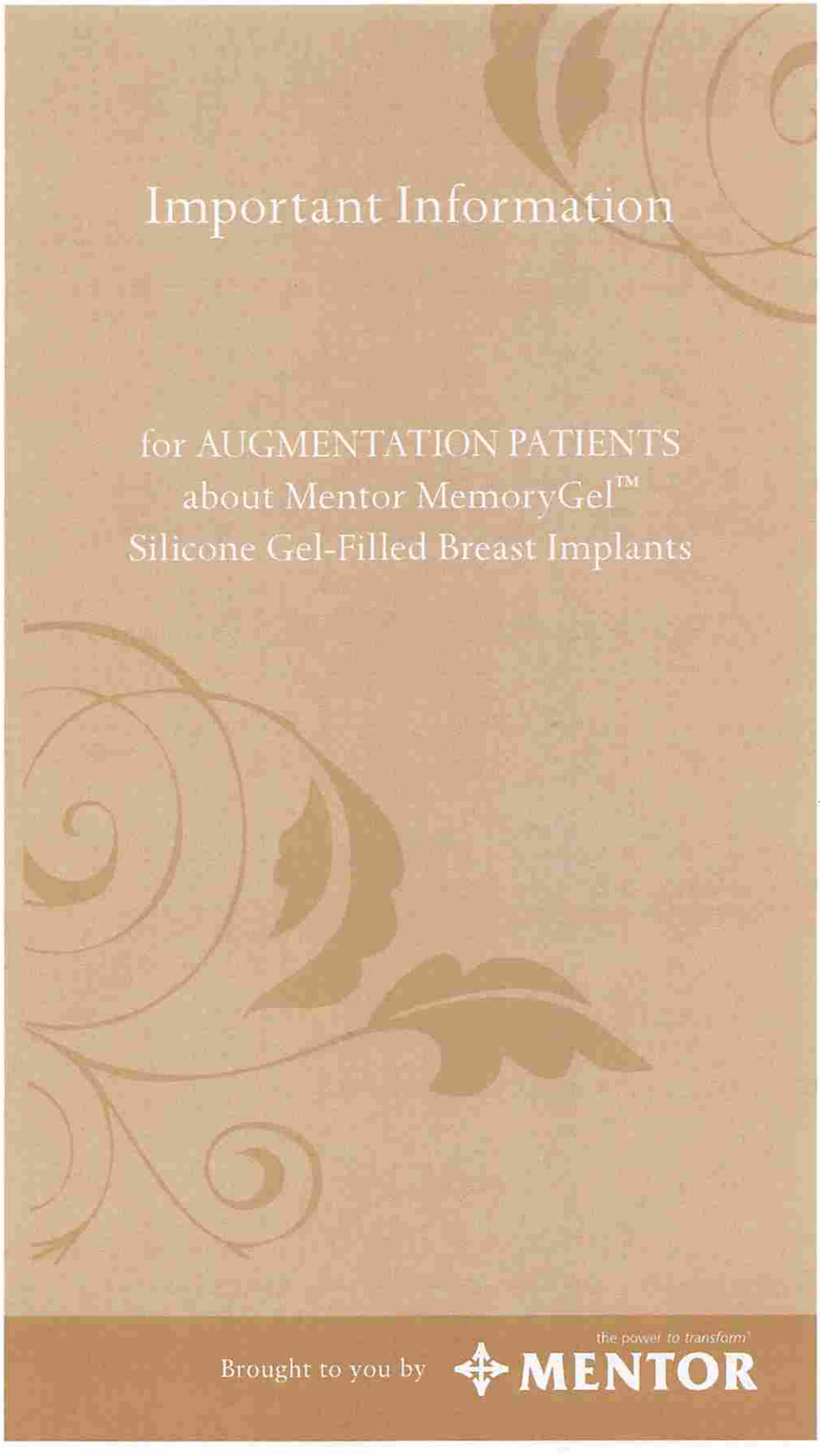
Donna-Bea Tillman, Ph.D., M.P.A.
Director
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# EXHIBIT 2

# Important Information

for AUGMENTATION PATIENTS
about Mentor MemoryGel™
Silicone Gel-Filled Breast Implants



# Important Information for Augmentation Patients about Mentor MemoryGel™ Silicone gel-Filled Breast Implants January 2008

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## GLOSSARY

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|---|---|
| **Areola** | The pigmented or darker colored area of skin surrounding the nipple of the breast. |
| **Asymmetry** | Lack of proportion of shape, size, and/or position between the two breasts. |
| **Autoimmune disease** | A disease in which the body mounts an "attack" response to its own tissues or cell types. Normally, the body's immune mechanism is able to distinguish clearly between what is a normal substance and what is foreign. In autoimmune diseases, this system becomes defective and mounts an attack against normal parts of the body, causing tissue injury. Certain diseases such as rheumatoid arthritis, lupus, and scleroderma are considered to be autoimmune diseases. |
| **Axillary** | Pertaining to the armpit area. |
| **Biocompatible** | The condition of being compatible with living tissues or systems without being toxic. |
| **Biopsy** | The removal and examination of tissues, cells, or fluid from the body. |
| **Body Esteem Scale (BES)** | A questionnaire which asks about a person's body image. |
| **Breast augmentation** | A surgical procedure to increase breast size. For this document, it refers to placement of a breast implant. The first time a breast implant is placed to increase breast size, it is called primary augmentation. All subsequent times the implant is replaced, it is called revision-augmentation. |
| **Breast implant** | An internal artificial device or implant intended to replace the breast. |
| **Breast mass** | A lump or body in the breast. |
| **Breast reconstruction** | A surgical procedure to replace breast tissue that has been removed due to cancer or trauma or that has failed to develop properly due to a severe breast abnormality. |

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| **Calcification** | Process of hardening by calcium salts. |
| **Capsule** | Scar tissue that forms around the breast implant. Sometimes this capsule squeezes the implant, resulting in capsular contracture (below). |
| **Capsular contracture** | A tightening of the tissue capsule surrounding an implant, resulting in firmness or hardening of the breast and in squeezing of the implant if severe. Capsular contracture is classified by Baker Grades. Baker Grades III or IV are the most severe. Baker Grade III often results in the need for additional surgery (reoperation) because of pain and possibly abnormal appearance. Baker Grade IV usually results in the need for additional surgery (reoperation) because of pain and unacceptable appearance. Capsular contracture Baker Grade II may also result in the need for additional surgery. Capsular contracture is a risk for implant rupture. Below is a description of each Baker Grade.<br>• Baker Grade I – Normally soft and natural appearance<br>• Baker Grade II – A little firm, but breast looks normal<br>• Baker Grade III – More firm than normal, and looks abnormal (change in shape)<br>• Baker Grade IV – Hard, obvious distortion, and tenderness with pain |
| **Capsulectomy** | Surgical removal of the scar tissue capsule around the implant. |
| **Capsulorrhaphy** | Surgical stitching of a tear in the scar tissue capsule around the implant. |
| **Capsulotomy (closed)** | An attempt to break the scar tissue capsule around the implant by pressing or pushing on the outside of the breast. This method does not require surgery but is a known risk for rupture of the implant and is contraindicated. |

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| **Capsulotomy (open)** | Surgical incision into the scar tissue capsule around the implant. |
| **Congenital anomaly** | An abnormal development in part of the body. |
| **Connective tissue disease/disorder (CTD)** | A disease, group of diseases, or conditions affecting connective tissue, such as muscles, ligaments, skin, etc. and/or the immune system. Connective tissue diseases ("CTDs") that involve the immune system include autoimmune diseases such as rheumatoid arthritis, lupus, and scleroderma. |
| **Contraindication** | A use that is improper and should not be followed. Failure to follow contraindications identified in the labeling could cause serious harm. |
| **Contralateral** | Opposite side. |
| **Core Study** | The primary clinical study of augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients that supported the approval of the premarket approval (PMA) application. Safety and effectiveness data are collected yearly through 10 years, with the follow-up from years 4 through 10 being performed as part of a postapproval Core Study. |
| **Delayed wound healing** | Delayed progress in the healing of an opened wound. |
| **Displacement** | Movement of the implant from the usual or proper place. |
| **Epidemiological** | Relating to the science of explaining the relationships of factors that determine disease frequency and distribution. |
| **Extracapsular rupture** | A type of rupture in which the silicone gel is outside of the scar tissue capsule surrounding the implant. |
| **Extrusion** | Skin breakdown with the pressing out of the implant through the surgical wound or skin. |

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| **Fibromyalgia** | A disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue. |
| **Fibrous tissues** | Connective tissues composed mostly of fibers. |
| **Granuloma** | A lump or mass made of inflammatory cells surrounding a foreign substance due to longstanding inflammation. |
| **Hematoma** | A collection of blood within a space. |
| **Hypertrophic scarring** | An enlarged scar remaining after the healing of a wound. |
| **Immune response** | A bodily response to the presence of a foreign substance. |
| **Infection** | Invasion with microorganisms (for example, bacteria, viruses). An infection usually results in fever, swelling, redness, and/or pain. |
| **Inflammation** | The response of the body to infection or injury that is characterized by redness, swelling, warmth, pain, and/or loss of function. |
| **Inframammary** | Below the breast. |
| **Inframammary fold** | The crease at the base of the breast and the chest wall. |
| **Inframammary incision** | An incision made in the fold below the breast. |
| **Inpatient surgery** | A surgical procedure in which the patient is required to stay overnight in the hospital. |
| **Intracapsular rupture** | A type of rupture in which the silicone gel remains inside the scar tissue capsule surrounding the implant. |
| **Lactation** | The production and secretion of milk by the breast glands. |
| **Low molecular weight silicones** | Components of silicone of smaller molecular weight that may bleed (leak) out of silicone gel. |

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| **Lymphadenopathy** | Enlargement of the lymph node(s). |
| **Malposition** | Implant malposition or displacement is when the implant is not in the correct spot in the breast. This could have been due to incorrect placement of the implant during the surgery or due to shifting of the implant position over time. |
| **MRI** | Magnetic resonance imaging. A radiographic examination that currently has the best ability to detect rupture of silicone gel-filled breast implants. |
| **Mammary** | Pertaining to the breast. |
| **Mammography** | A type of X-ray examination of the breasts used for detection of cancer. |
| **Mammoplasty** | Plastic surgery of the breast. |
| **Mastopexy** | Plastic surgery to move sagging breasts into a more elevated position. |
| **Metastatic Disease** | Spreading of cancer cells from the original site to other parts of the body. |
| **Migration** | Movement of silicone materials outside the breast implant. |
| **Necrosis** | Death of cells or tissues. |
| **Outpatient surgery** | A surgical procedure in which the patient is not required to stay in the hospital overnight. |
| **Palpate** | To feel with the hand. |
| **Palpability** | The ability to feel the implant. |
| **Pectoralis** | Major muscle of the chest. |
| **Periareolar** | Around the darkened or pigmented area surrounding the nipple of the breast. |
| **Plastic surgery** | Surgery intended for the improvement of appearance of the body. |
| **Postoperatively** | After surgery. |
| **Primary breast augmentation** | The first time a breast implant is placed for the purpose of breast augmentation. |
| **Ptosis** | Breast sagging that is usually the result of normal aging, pregnancy, or weight loss. |

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| **Reoperation** | An additional surgery after your first breast implantation. |
| **Revision-Augmentation** | Refers to the correction or improvement of a primary augmentation. In the context of this document, it refers to surgical removal and replacement of breast implants that were placed originally for primary breast augmentation. |
| **Rheumatological Disease/Disorder** | A variety of diseases involving connective tissue structures of the body, especially the joints and fibrous tissue. These diseases are often associated with pain, inflammation, stiffness, and/or limitation of motion of the affected parts. Can include autoimmune diseases. Fibromyalgia is a rheumatological disorder. |
| **Rosenberg Self Esteem Scale** | A questionnaire that measures self esteem. |
| **Rupture** | A tear or hole in the implant shell. Silicone implant ruptures may be silent or symptomatic. Ruptures can be intracapsular or extracapsular. |
| **Saline** | A solution that is made up of water and a small amount of salt. |
| **Scar revision** | A surgical procedure to improve the appearance of a scar. |
| **Seroma** | A build-up of the watery portion of the blood in a tissue location. |
| **SF-36 Scale** | A questionnaire intended to measure health-related quality of life. It includes questions that measure physical, mental, and social health. |
| **Silicone elastomer** | A type of silicone that has elastic properties similar to rubber. |
| **Silent rupture** | A breast implant rupture without symptoms and which is not apparent except through appropriate imaging techniques such as MRI. Most silicone breast implant ruptures are silent. (see symptomatic rupture below) |

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| **Subglandular placement** | Placement of a breast implant underneath and within the breast glands but on top of the chest muscle. |
| **Submuscular placement** | Placement of a breast implant wholly or partially underneath the chest muscle. |
| **Surgical incision** | A cut made to body tissue during surgery. |
| **Symptom** | Any perceptible change in the body or its functions that indicates disease or a phase of a disease. |
| **Symptomatic** | Any evidence or sign of disease or disorder reported by the patient. |
| **Symptomatic rupture** | A breast implant rupture that is associated with symptoms (such as lumps, persistent pain, swelling, hardening, or change in implant shape). Some silicone breast implant ruptures are symptomatic, but most are silent. |
| **Systemic** | Pertaining to or affecting the body as a whole. |
| **Tennessee Self Concept Scale** | A questionnaire that evaluates how the patient sees herself and what she does, likes, and feels. |

# Important Information for Augmentation Patients about Mentor MemoryGel™ Silicone Gel-Filled Implants

## 1. Considerations for Silicone Gel-Filled Breast Implant Augmentation

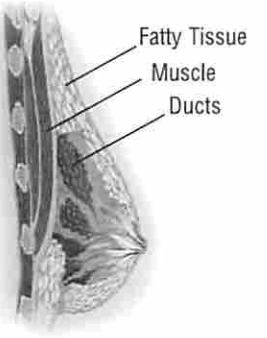
The purpose of this brochure is to help you in making an informed decision about having breast implants for augmentation (breast enlargement) or breast revision-augmentation (replacement) surgery. This brochure is not intended to replace consultation with your surgeon. This educational brochure is set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

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

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

### 1.1. What Gives the Breast Its Shape?

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




It is important to realize that implants are used to make the breast larger. The implants alone may not adequately lift the breast, or correct the effects of pregnancy, weight loss, or skin stretching. Your surgeon may suggest additional procedures at the time of the breast augmentation, such as mastopexy, to help achieve improved breast lift.

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

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

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

Mentor MemoryGel Silicone Gel-Filled Breast Implants 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 result of a primary breast reconstruction surgery. (A separate patient brochure is available for and should be read for breast reconstruction.)

**Contraindications**

Breast implant surgery should not be performed in:

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

**Precautions**

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

- Autoimmune diseases (for example, lupus and scleroderma).
- A weakened immune system (for example, currently taking drugs that weaken the body's natural resistance to disease).
- Conditions that interfere with wound healing and blood clotting.
- Reduced blood supply to breast tissue.
- Radiation to the breast following implantation.

- Clinical diagnosis of depression or other mental health disorders, including body dysmorphic disorder and eating disorders. Please discuss any history of mental health disorders with your surgeon prior to surgery. Patients with a diagnosis of depression, or other mental health disorders, should wait until resolution or stabilization of these conditions prior to undergoing breast implantation surgery.

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

- Breast implants are not lifetime devices, and breast implantation is likely not a one-time surgery. You will likely need additional unplanned surgeries on your breasts because of complications or unacceptable cosmetic outcomes. These additional surgeries can include implant removal with or without replacement, or they can include other surgical procedures. When you have your implants replaced (revision-augmentation), your risk of future complications increases compared to first time (primary) augmentation surgery, so you should also review the complication rates for revision-augmentation patients to see what future risk rates you may experience.
- Many of the changes to your breast following implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed and not replaced, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast, which can be permanent.
- Breast implants may affect your ability to breast feed, either by reducing or eliminating milk production.
- Rupture of a silicone gel-filled breast implant is most often silent. This means that neither you nor your surgeon will know that your implants have a rupture most of the time. In fact, the ability of a physical examination by a plastic surgeon who is familiar with breast implants to detect silicone breast implant rupture is 30%[1] compared to 89% for MRI.[2] You will need regular screening MRI examinations over your lifetime in order to determine if silent rupture is present. You should have your first MRI at 3 years after your initial implant surgery and then every 2 years, thereafter. The cost of MRI screening may exceed the cost of your initial surgery over your lifetime. This cost, which may not be covered by your insurance, should be considered in making your decision.
- If implant rupture is noted on MRI, you should have the implant removed, with or without replacement.

- With breast implants, routine screening mammography for breast cancer will be more difficult. If you are of the proper age for mammography screening, you should continue to undergo routine mammography screening as recommended by your primary care physician. The implant may interfere with finding breast cancer during mammography. Because the breast and implant are squeezed during mammography, an implant may rupture during the procedure. More x-ray views are necessary for women with breast implants; therefore, you will receive more exposure to radiation. However, the benefit of having the mammogram to find cancer outweighs the risk of the additional x-rays. Be sure to inform the mammography technologist that you have implants.
- You should perform an examination of your breasts every month for cancer screening; however, this may be more difficult with implants. You should ask your surgeon to help you distinguish the implant from your breast tissue.
- You should perform an examination of your breasts for the presence of lumps, persistent pain, swelling, hardening, or change in implant shape, which may be signs of symptomatic rupture of the implant. These should be reported to your surgeon and possibly evaluated with an MRI to screen for rupture.
- After undergoing breast augmentation surgery (either primary or revision), your health insurance premiums may increase, your insurance coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. You should discuss the complete extent of your insurance coverage with your insurance company before undergoing surgery.
- You should inform any other doctor who treats you of the presence of your implants to minimize the risk of damage to the implants.
- Mentor will continue its ongoing Core Study through 10 years to further evaluate the long-term safety and effectiveness of these products. In addition, Mentor has initiated a separate, 10-year postapproval study to address specific issues for which the Mentor Core Study was not designed to fully answer, as well as to provide a real-world assessment of some endpoints. The endpoints in the large postapproval study include long-term local complications, connective tissue disease (CTD), CTD signs and symptoms, neurological disease, neurological signs and symptoms, offspring issues, reproductive issues, lactation issues, cancer, suicide, mammography issues, and MRI

compliance and results. Mentor will update its labeling as appropriate with the results of these two studies. You should also ask your surgeon if he/she has any available updated clinical information.

- It is important that you read this entire brochure because you need to understand the risks and benefits and to have realistic expectations of the outcome of your surgery.

## 2. Potential Breast Implant Complications

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

**• Rupture**

Breast implants are not lifetime devices. Breast implants rupture when the shell develops a tear or hole. Rupture can occur at any time after implantation, but they are more likely to occur the longer the implant is implanted. The following things may cause your implant to rupture: damage by surgical instruments; stressing the implant during implantation and weakening it; folding or wrinkling of the implant shell; excessive force to the chest (for example, during closed capsulotomy, which is contraindicated); trauma; compression during mammographic imaging; and severe capsular contracture. Breast implants may also simply wear out over time. Laboratory studies have identified some of the types of rupture for Mentor's product; however, it is not known whether these tests have identified all causes of rupture. These laboratory studies will continue postapproval.

Silicone gel-filled implant ruptures are most often silent. (MRI examination is currently the best method to screen for silent rupture.) This means that most of the time neither you nor your plastic surgeon 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. However, sometimes there are symptoms associated with gel implant rupture. These symptoms include hard knots or lumps surrounding the implant or in the armpit, change or loss of size or shape of the breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast.

When MRI findings of rupture are found, or if your surgeon determines you have signs or symptoms of rupture, you should have the implant and any gel removed, with or without replacement of the implant. It also may be necessary to remove the tissue capsule as well as the implant, which will involve additional surgery, with associated costs. If you have symptoms such as breast hardness, a change in breast shape or size, and/or breast pain, you should have an MRI to determine whether rupture is present.[3,4]

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

Rupture Information on Mentor Implants

In Mentor's Core Study, rupture was assessed for patients who had scheduled MRIs to screen for silent rupture (i.e., part of the MRI cohort) and those who were not assessed for rupture by MRI (i.e., part of the non-MRI cohort). For primary augmentation patients in the MRI cohort, the rupture rate was 0.5% through 3 years. This means that through 3 years, 1 of every 200 primary augmentation women had at least one ruptured breast implant. There was one primary augmentation patient in the Mentor Core Study with a suspected implant rupture detected via MRI, which has not been confirmed with examination of the implant following removal.

For revision-augmentation patients in the MRI cohort of the Mentor Core Study, the rupture rate was 7.7% through 3 years. This means that about 8 of 100 women had at least one ruptured breast implant through 3 years. All of these implant ruptures were silent and were only detected by MRI. One woman had removal of her breast implants after MRI, and both implants were ruptured. The other implant ruptures have not yet been confirmed with removal and examination of the implant.

There were no ruptures reported in the non-MRI cohorts for either the primary augmentation or revision-augmentation patients of the Mentor Core Study through 3 years. Across all patients in the Mentor Core Study, of the 8 implants reported as ruptured, 4 showed intracapsular gel and 4 showed extracapsular gel on MRI (3 implants with extracapsular gel were in 2 revision-augmentation patients and 1 was in a primary reconstruction patients). For one of these implants with extracapsular gel, this was a confirmed case

in which the device was explanted and the intracapsular gel rupture progressed into an extracapsular gel rupture as shown by MRIs at approximately 10 months and approximately 2 years. There were no cases of migrated gel.

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

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

Additional Information on Consequences of Rupture from Literature

Studies of Danish women evaluated with MRI involving a variety of manufacturers and implant models showed that about three-fourths of implant ruptures are intracapsular and the remaining one-fourth is extracapsular.[5] 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.[6] This means that for women with silicone gel rupture within the scar tissue capsule detected via MRI after 2 years, 1 in 10 of these women had progression of the gel outside the scar tissue capsule. 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 means that for 100 women with silicone gel rupture outside the scar tissue capsule, the amount of gel outside the scar tissue capsule increased for 14 women 2 years later. This type of information pertains to a variety of silicone implants from a variety of manufacturers and implant models, and it is not specific to Mentor 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.[7] 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 (see glossary) and/or breakdown of tissues in direct contact with the gel in a few cases. There have been reports of silicone presence in the liver of patients with silicone breast implants. Movement of silicone gel material to lymph nodes in the axilla also has been reported, even in women without evidence of rupture, leading to lymphadenopathy.[8]

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

**• Capsular Contracture**

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

Symptoms of capsular contracture range from mild firmness and mild discomfort to severe pain, distorted shape of the implant, and palpability (ability to feel the implant). Capsular contracture is graded into 4 levels depending on its severity. Baker Grades III or IV are considered severe and often additional surgery is needed to correct these grades:

| | |
|---|---|
| Baker Grade I: | the breast is normally soft and looks natural |
| Baker Grade II: | the breast is a little firm but looks normal |

| | |
|---|---|
| Baker Grade III: | the breast is firm and looks abnormal |
| Baker Grade IV: | the breast is hard, painful, and looks abnormal |

In Mentor's Core Study, for women receiving augmentation implants for the first time, the risk of severe capsular contracture was 8% through 3 years. This means that 8 out of every 100 women who received Mentor implants for primary breast augmentation had severe capsular contracture at least once during the first 3 years after receiving the implants.

For women receiving revision-augmentation implants, the risk of severe capsular contracture was 19% through 3 years. This means that 19 out of every 100 women who received Mentor implants for breast revision-augmentation had severe capsular contracture at least once during the first 3 years after receiving the implants.

Additional surgery may be needed in cases where pain and/or firmness are severe. This surgery ranges from removal of the implant capsule tissue, to removal and possible replacement of the implant itself. This surgery may result in loss of your breast tissue. Capsular contracture may happen again after these additional surgeries. Capsular contracture may increase the risk of rupture.[14]

- **Additional Surgeries (Reoperations)**

You should assume that you will need to have additional surgeries (reoperations). In the Mentor Core Study, the reoperation rate was 15% for primary augmentation patients, which means that 15 out of every 100 women who received Mentor implants for primary augmentation had a reoperation during the first 3 years after receiving the implants. The reoperation rate was 28% for revision-augmentation patients, which means that 28 out of every 100 women who received Mentor implants for revision-augmentation had a reoperation during the first 3 years after receiving the implants.

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

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

For women receiving primary augmentation implants in Mentor's Core Study, 5% had their implants removed at least once through 3 years. Patient choice and severe capsular contracture were the most common reasons for implant removal. For women receiving revision-augmentation implants in Mentor's Core Study, 12% had their implants removed at least once through 3 years. The most common reasons were patient choice and severe capsular contracture.

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

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

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

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

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

**• Hematoma/Seroma**
Hematoma is a collection of blood within the space around the implant, and 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.

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

**• Calcium Deposits in the Tissue Around the Implant**
Calcium deposits can form in the tissue capsule surrounding the

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

- **Extrusion**

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

- **Necrosis**

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

- **Delayed Wound Healing**

Some patients may experience a prolonged wound healing time. Delayed wound healing may increase the risk of infection, extrusion, and necrosis. Depending on the type of surgery or the incision, wound healing times may vary. Smoking may interfere with the healing process. You should contact your surgeon immediately if your wound does not heal within the period of time he/she has discussed with you.

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

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

- **Lymphadenopathy**

Lymphadenopathy is a chronic enlargement of the lymph nodes. A lymph node is a round mass of tissue which makes cells as part of

your immune system. The lymph nodes in the armpit (axilla) drain the breast area of fluid. Sometimes the enlarged lymph nodes are painful. If they become too large or painful, the lymph node(s) may need to be surgically removed. Painful and/or enlarged lymph nodes should be reported to your doctor.

Literature reports associate lymphadenopathy with both intact and ruptured silicone breast implants. One study reported that armpit lymph nodes from women with both intact and ruptured silicone gel implants had abnormal tissue reactions, granulomas, and the presence of silicone.[15] These reports were in women who had implants from a variety of manufacturers and implant models.

**Other Reported Conditions**

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

- **Connective Tissue Disease (CTD)**

Connective tissue diseases include diseases such as lupus, scleroderma, and rheumatoid arthritis. Fibromyalgia is a disorder characterized by chronic pain in the muscles and soft tissues surrounding joints, with tenderness at specific sites in the body. It is often accompanied by fatigue. There have been a number of published epidemiological studies which have looked at whether having a breast implant is associated with having a typical or defined connective tissue disease. The study size needed to conclusively rule out a smaller risk of connective tissue disease among women with silicone gel-filled breast implants would need to be very large.[16,17,18,19,20,21,22,23,24,25] 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.[26,27,28,29] 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.[30]

- **CTD Signs and Symptoms**

Literature reports have also been made associating silicone breast implants with various rheumatological signs and symptoms such as fatigue, exhaustion, joint pain and swelling, muscle pain and cramping, tingling, numbness, weakness, and skin rashes.

Scientific expert panels and literature reports have found no evidence of a consistent pattern of signs and symptoms in women with silicone breast implants.[31,32,33,34,35] Having these rheumatological signs and symptoms does not necessarily mean you have a connective tissue disease; however, you should be aware that you may experience these signs and symptoms after undergoing breast implantation. If you notice an increase in these signs or symptoms, you should consider seeing a rheumatologist to determine whether these signs or symptoms are due to a connective tissue disorder or autoimmune disease.

- **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.[36,37,38,39,40] 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.[41,42,43,44,45]

Brain cancer – One recent study has reported an increased incidence of brain cancer in women with breast implants as compared to the general population.[46] The incidence of brain cancer, however, was not significantly increased in women with breast implants when compared to women who had other plastic surgeries. Another recently published review of four large studies in women with cosmetic implants concluded that the evidence does not support an association between brain cancer and breast implants.[47]

Respiratory/lung cancer – One study has reported an increased incidence of respiratory/lung cancer in women with breast implants.[48] 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.[49,50,51]

Cervical/vulvar cancer – One study has reported an increased incidence of cervical/vulvar cancer in women with breast implants.[52] The cause of this increase is unknown.

Other cancers – One study has reported an increased incidence of stomach cancer and leukemia in women with breast implants compared to the general population.[53] This increase was not significant when compared to women who had other types of plastic surgeries.

**• Neurological Disease, Signs, and Symptoms**
Some women with breast implants have complained of neurological symptoms (such as difficulties with vision, sensation, muscle strength, walking, balance, thinking or remembering things) or diseases (such as multiple sclerosis), which they believe are related to their implants. A scientific expert panel report found that the evidence for a neurological disease or syndrome caused by or associated with breast implants is insufficient or flawed.[54]

**• Suicide**
In several studies, a higher incidence of suicide was observed in women with breast implants.[55,56,57,58] 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.[59]

**• Effects on Children**
At this time, it is not known if a small amount of silicone may pass through from the breast implant silicone shell into breast milk during breastfeeding. Although there are no current established methods for accurately detecting silicone levels in breast milk, a study measuring silicon (one component in silicone) levels did not indicate higher levels in breast milk from women with silicone gel-filled implants when compared to women without implants.[60]

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.[61,62] Although low birth weight was reported in a third study, other factors (for example, lower pre-pregnancy weight) may explain this finding.[63] 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.[64,65] 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[66] and lymphadenopathy.[57] However, evidence against gel bleed being a significant contributing factor to capsular contracture and other local complications, is provided by the fact that there are similar or lower complication rates for silicone gel-filled breast implants than for saline-filled breast implants. Saline-filled breast implants do not contain silicone gel and, therefore, gel

bleed is not an issue for those products. Furthermore, toxicology testing has indicated that the silicone material used in the Mentor implants does not cause toxic reactions when large amounts are administered to test animals. It also should 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.[68] In addition, two separate studies sponsored by Mentor have demonstrated that the low concentration of platinum contained in its breast implants is in the zero oxidation (most biocompatible) state.

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

## 3. Mentor Core Study Results for Augmentation and Revision-Augmentation

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

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

### 3.1. Overview of Mentor Core Study

The Mentor Core Study is a 10-year study to assess safety and effectiveness in augmentation, reconstruction, and revision (revision-augmentation and revision-reconstruction) patients. Patient follow-up is at 6 months, 12 months, 24 months, and annually through 10 years. Safety is assessed by complications, such as implant rupture, capsular contracture, and reoperation.

Benefit (effectiveness) is assessed by patient satisfaction and measures of quality of life (QoL).

The Mentor Core Study consists of 1,007 patients, including 551 primary augmentation patients, 146 revision-augmentation patients, 251 primary reconstruction patients, and 59 revision-reconstruction patients. Of these patients, 202 primary augmentation patients, 57 revision-augmentation patients, 134 primary reconstruction patients, and 27 revision-reconstruction patients are in the MRI cohort, which means that they are assessed for silent rupture by MRI at years 1, 2, 4, 6, 8, and 10. The study is currently ongoing, with the results through 3 years reported in this brochure. Mentor will periodically update this brochure as more information becomes available. You should also ask your surgeon if he/she has any available updated clinical information.

Mentor's Core Study results indicate that the risk of at least one occurrence of any complication (including reoperation) at some point through 3 years after implant surgery is 37% for primary augmentation patients and 50% for revision-augmentation patients. The information below provides more details about the complications and benefits you may experience.

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

### 3.2. What were the 3-Year Follow-up Rates in Augmentation Patients?

At the 3-year follow-up visit, data are reported for 88% of the eligible primary augmentation patients and 87% of the eligible revision-augmentation patients.

### 3.3. What were the Benefits for Augmentation Patients?

The Mentor Core Study measured a variety of outcomes that assessed the benefits of the implants. For augmentation, these outcomes included breast size change, satisfaction, and QoL measures. These outcomes were assessed before implantation and at 1, 2, and 3 years after surgery for those patients who still had their original implants and came back for follow-up visits.

**Primary Augmentation Patients:** For primary augmentation patients, 370 (67%) out of the original 551 patients were included in the analysis of cup size at 3 years. Of these 370 patients, 359 (97%) experienced at least one cup size increase. The average increase in circumferential chest size was 2.8 inches.

Mentor's satisfaction assessment was based on a single question of "Would the patient have this breast surgery again?" At 3 years, 456 (83%) of the 551 primary augmentation patients enrolled answered that question. Of these 456 patients, 445 (98%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 3 years, an increase in self esteem was noted for 45% of patients after primary breast augmentation on the Rosenberg Self Esteem Scale. There was no change on the overall score of the Body Esteem Scale, but the Sexual Attractiveness Subscale and the Chest Score of the Body Esteem Scale increased. The SF-36 is a collection of scales assessing mental and physical health, and there was no change in the SF-36 after primary augmentation. The Tennessee Self Concept Scale (TSCS) is a survey completed by the patient that evaluates how the patient sees herself and what she does, likes, and feels. There was no change in the overall score for the TSCS.

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

Mentor's patient satisfaction was based on a single question of "Would the patient have this breast surgery again?" At 3 years, 118 (81%) of the 146 revision-augmentation patients enrolled answered that question. Of these 118 patients, 111 (94%) stated to their surgeon that they would have the breast implant surgery again.

With regard to QoL measures at 3 years, no change in self esteem was noted following revision-augmentation surgery on the Rosenberg Self Esteem Scale or the Body Esteem Scale. The SF-36 is a collection of scales assessing mental and physical health, and there were no changes in SF-36. The Tennessee Self Concept Scale (TSCS) is a survey completed by the patient that evaluates how the patient sees herself and what she does, likes, and feels. There was no change in the overall TSCS score.

### 3.4. What Were the 3-Year Complication Rates in Augmentation Patients?

The 3-year complication rates are shown from the most common to the least common in Table 1 (primary augmentation) and Table 2 (revision-augmentation) below. The rates reflect the percentage of augmentation patients who experienced the listed complication at least once within the first 3 years after implantation. Some

complications occurred more than once for some patients. The two most common complications experienced by primary augmentation patients within the first 3 years of implantation were reoperation (15.4%) and nipple sensation changes (10.4%).

**Table 1 — 3-Year Complication Rates for Primary Augmentation Patients**
**N=551 Patients**

| Key Complications | % |
|---|---|
| Reoperation | 15.4 |
| Capsular Contracture Baker Grade III/IV | 8.1 |
| Implant Removal with Replacement with Study Device | 2.8 |
| Implant Removal without Replacement | 2.3 |
| Infection | 1.5 |
| Rupture (MRI Cohort)[1] | 0.5 |
| **Other Complications occurring in ≥ 1% of patients[2]** | **%** |
| Nipple Complications[3] | 10.4 |
| Scarring/Hypertrophic Scarring[3] | 6.7 |
| Breast Mass[3] | 3.1 |
| Hematoma[3] | 2.6 |
| Ptosis (sagging)[3] | 2.3 |
| Breast Sensation Changes[3] | 2.2 |
| Breast Pain[3] | 1.7 |
| Miscarriage[4] | 1.5 |
| Trauma[5] | 1.3 |

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

The two most common complications experienced by patients within the first 3 years of revision-augmentation surgery were reoperation (28.0%) and capsular contracture Baker Grades III/IV (18.9%). Notice that the rates for these two complications are higher than for primary augmentation. (For primary augmentation, reoperation was 15.4% and capsular contracture was 8.1%.)

**Table 2 — 3-Year Complication Rates for Revision-Augmentation Patients**
**N=146 Patients**

| **Key Complications** | **%** |
|---|---|
| Reoperation | 28.0 |
| Capsular Contracture Baker Grade III/IV | 18.9 |
| Rupture (MRI Cohort)[1] | 7.7 |
| Implant Removal with Replacement with Study Device | 6.5 |
| Implant Removal without Replacement | 5.9 |
| Infection | 1.4 |
| **Other Complications occurring in ≥ 1% of patients[2]** | **%** |
| Nipple Complications[3] | 10.5 |
| Scarring/Hypertrophic Scarring[3] | 8.4 |
| Breast Mass[3] | 6.6 |
| Hematoma[3] | 2.8 |
| Breast Sensation Changes[3] | 2.1 |
| Seroma | 2.1 |
| Delayed Wound Healing[3] | 2.1 |
| Wrinkling[3] | 2.1 |
| Ptosis (sagging)[3] | 1.5 |
| Breast Pain[3] | 1.5 |
| Inflammation[3] | 1.4 |
| Implant Malposition[3] | 1.4 |
| Extrusion of Intact Implant | 1.4 |

1 - Of the 4 patients who had signs of rupture on MRI, 1 patient had removal of her implants, which showed rupture of both of her implants. This occurred 2 years after she entered the Mentor Core Study as a revision-augmentation patient.
2 - The following complications were reported at a rate less than 1%: back and neck pain related to large implants, ectopic pregnancy, false positive for rupture on mammogram, granuloma, lactation difficulties, miscarriage, muscle spasm, new diagnosis of rheumatic disease (1 patient with rheumatoid arthritis), implant palpability/visibility, and trauma (blunt injury to left breast from being hit by fireworks).
3 - Mild occurrences were excluded.

### 3.5. What Were the Main Reasons for Reoperation in Augmentation Patients?

There may be one or more reasons identified for having a reoperation (additional surgery after the primary or revision breast augmentation). Furthermore, there may be multiple surgical procedures (for example, implant removal with or without replacement, capsule procedures, incision and drainage, implant reposition, scar revision, etc.) performed during a reoperation. In Mentor's Core Study, there were 176 additional surgical procedures performed in 109 reoperations involving 83 primary augmentation patients.

Table 3 below provides the main reason for each reoperation in primary augmentation patients following initial implantation that were performed through 3 years. The most common reason for reoperation through 3 years in primary augmentation patients was because of capsular contracture (40 of 109 reoperations).

**Table 3 — Main Reasons for Reoperation in Primary Augmentation Patients through 3 Years**

| Reason for Reoperation | n |
|---|---|
| Capsular Contracture Baker Grade II, III, IV | 40 |
| Patient Request for Style/Size Change | 16 |
| Hematoma/Seroma | 12 |
| Scarring/Hypertrophic Scarring | 12 |
| Biopsy | 6 |
| Asymmetry | 5 |
| Ptosis (sagging) | 4 |
| Infection | 3 |
| Delayed Wound Healing | 2 |
| Implant Malposition | 2 |
| Wrinkling | 2 |
| Breast Pain | 1 |
| Extrusion of Intact Implant | 1 |
| Necrosis | 1 |
| Suspected Rupture[1] | 1 |
| Tear in Capsule | 1 |
| Total | 109 |

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

In Mentor's Core Study, there were 105 additional surgical procedures performed in 58 reoperations involving 39 revision-augmentation patients. Table 4 below provides the main reason for each reoperation in revision-augmentation patients following initial implantation that were performed through 3 years. The most common reason for reoperation in revision-augmentation patients through 3 years was capsular contracture (23 of 58 reoperations).

**Table 4 — Main Reasons for Reoperation in Revision-Augmentation Patients through 3 Years**

| Reason for Reoperation | n |
|---|---|
| Capsular Contracture Baker Grade II, III, IV | 23 |
| Patient Request for Style/Size Change | 7 |
| Biopsy | 6 |
| Hematoma/Seroma | 5 |
| Delayed Wound Healing | 5 |
| Scarring/Hypertrophic Scarring | 3 |
| Extrusion of Intact Implant | 2 |
| Implant Malposition | 2 |
| Asymmetry | 1 |
| Ptosis (sagging) | 1 |
| Infection | 1 |
| Wrinkling | 1 |
| Suspected Rupture[1] | 1 |
| Total | 58 |

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

### 3.6. What Were the Main Reasons for Implant Removal in Augmentation Patients?

The main reasons for implant removal among primary augmentation patients in the Mentor Core Study over the 3 years are shown in Table 5 below. There were 45 implants removed in 26 patients. Of these 45 implants, 24 were replaced. The most common reason for implant removal was patient request for style/size change (31 of the 45 implants removed).

**Table 5 – Main Reasons for Implant Removal in Primary Augmentation Patients through 3 Years**

| Reason for Removal | n |
|---|---|
| Patient Request for Style/Size Change | 31 |
| Capsular Contracture Baker Grade III/IV | 5 |
| Breast Pain | 2 |
| Infection | 2 |
| Necrosis | 2 |
| Suspected Rupture[1] | 1 |
| Contralateral Explantation | 1 |
| Wrinkling | 1 |
| Total | 45 |

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

The main reasons for implant removal among revision-augmentation patients in the Mentor Core Study over the 3 years are shown in Table 6 below. There were 30 implants removed in 18 patients. Of these 30 implants, 14 were replaced. The most common reason for implant removal was patient request (12 of the 30 implants removed).

**Table 6 – Main Reasons for Implant Removal in Revision-Augmentation Patients through 3 Years**

| Reason for Removal | n |
|---|---|
| Patient Request for Style/Size Change | 12 |
| Capsular Contracture Baker Grade III/IV | 10 |
| Patient Dissatisfied with Appearance | 2 |
| Asymmetry | 1 |
| Extrusion of Intact Implant | 1 |
| Scarring/Hypertrophic Scarring | 1 |
| Infection | 1 |
| Suspected Rupture[1] | 1 |
| Abnormal Mammogram | 1 |
| Total | 30 |

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

### 3.7. What Were Other Clinical Data Findings in Augmentation Patients?

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

CTD Diagnoses

Three primary augmentation patients and one revision-augmentation patient in the Mentor Core Study were reported to have a new diagnosis of CTD according to a rheumatologist. These diagnoses were Hashimoto's Thyroiditis at 2 years, two cases of rheumatoid arthritis at 2 and 3 years, and hypothyroidism at 2 years. 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

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

Cancer

There were no primary augmentation patients with new diagnoses of breast cancer through 3 years in Mentor's Core Study. As previous breast cancer was an exclusion criteria for primary augmentation patients, there were no reports of breast cancer reoccurrence in this indication. There were no reports of new diagnoses or reoccurrence of breast cancer in revision-

augmentation patients. There were no reports of other cancers, such as brain, respiratory, or cervical/vulvar.

Lactation Complications

Two (8%) of the 25 primary augmentation patients who attempted to breast feed following breast implantation in Mentor's Core Study through 3 years experienced difficulty with breast feeding. Of the 7 revision-augmentation patients who attempted to breast feed after receiving breast implants, 1 (14%) had difficulty breast feeding.

Reproduction Complications

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

Suicide

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

## 4. Surgery Considerations for Receiving Breast Implants

This section provides a discussion of surgical considerations for breast augmentation.

### 4.1. Surgical Considerations for Breast Augmentation

#### 4.1.1. What Are the Alternatives to Breast Augmentation with Silicone Breast Implants?

For primary augmentation patients, alternatives may include:

- Accept your breasts as they are and have no surgery.
- Wear a padded bra or external prostheses.
- Have mastopexy surgery (breast lift) without an implant.
- Have surgery with saline implants.

For revision-augmentation patients, alternatives may include:

- No revision
- Removal with or without replacement.

#### 4.1.2. Choosing a Surgeon

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

- How many breast augmentation implantation procedures does he/she perform per year?

- How many years has he/she performed breast augmentation procedures?
- Has he/she obtained training certification from Mentor to use its silicone gel-filled breast implants?
- Is he/she board certified, and if so, with which board?
- In which state(s) is he/she licensed to practice surgery? (Note that some states provide information on disciplinary action and malpractice claims/settlements to prospective patients, either by request or on the Internet.)
- What is the most common complication he/she encounters with breast augmentation?
- What is his/her reoperation rate with breast augmentation, and what is the most common type of reoperation he/she performs?
- Can he/she perform this surgery in a hospital, as well as in the surgeon's independent surgery center? (Note that hospitals require the demonstration of evidence of appropriate training in specific procedures before allowing surgeons to operate in their facilities.)

### 4.1.3. Implant Shape and Size

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

Your surgeon will also evaluate your existing breast and skin tissue to determine if you have enough to cover the breast implant you are considering, or, in some cases such as after pregnancy, too much extra skin. If you desire a breast implant size that is too large for your tissue, the surgeon may warn you that breast implant edges may be visible or palpable postoperatively. Also, excessively large breast implants may speed up the effects of gravity on the breast, and can result in droop or sag at an earlier age. A recent report indicates that larger sized implants (greater than 350cc) may be too large for many women, increasing the risk of developing complications such as implant extrusion, hematoma, infection, palpable implant folds, and visible skin wrinkling requiring surgical intervention to correct these complications.[69]

### 4.1.4. Surface Texturing

Some studies suggest that surface texturing reduces the chance of severe capsular contracture,[70] while other studies do not.[71,72] Mentor's Core Study did not show a difference in the likelihood of

developing capsular contracture with textured implants compared to smooth-surfaced implants.

A textured implant may require a larger incision because the rougher textured surface makes it harder to place into the pocket without undue stress, which might damage the implant or decrease its durability.

### 4.1.5. Implant Placement

The breast implant can be placed either partially under the pectoralis major muscle (submuscular) or on top of the muscle and under the breast glands (subglandular). You should discuss with your surgeon the advantages and disadvantages of the implant placement selected for you, as described in Table 7 below.

Subglandular Submuscular

**Table 7 – Comparison between Submuscular versus Subglandular Placement**

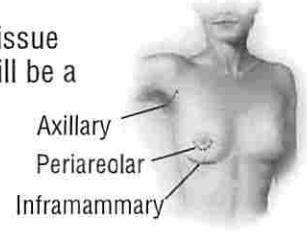
| Submuscular Placement | Subglandular Placement |
|---|---|
| Surgery may be longer | Surgery may be shorter |
| Recovery may be longer | Recovery may be shorter |
| May be more painful | May be less painful |
| Reoperation may be more difficult | May provide easier access for reoperation |
| Less visible and palpable implants | More visible and palpable implants |
| Less likelihood of capsular contracture[73] | Greater likelihood of capsular contracture[74,75] |
| Easier imaging during mammography exam | More difficult imaging during mammography exam |
| May be preferable if you have thin or weakened breast tissue | May not be recommended if you have thin or weakened breast tissue. |

### 4.1.6. Incision Sites

You should discuss with your surgeon the pros and cons for the incision site specifically recommended for you.

The incision size will be larger than for a saline breast augmentation. There are 3 common incision sites: under the arm (axillary), around the nipple (periareolar), or within the breast fold (inframammary).

- **Periareolar** - This incision is typically more concealed, but since it also involves cutting through the breast tissue, it is associated with a higher likelihood of breast feeding difficulties, as compared to the other incision sites.[76] Cutting through the tissue may increase the chance that there will be a change in breast and/or nipple sensation.




- **Inframammary** - This incision is generally less concealed than periareolar and associated with less breast feeding difficulties than the periareolar incision site. It is also the most commonly used incision site at the present time, and is felt to give the best access to and control of the breast implant pocket.
- **Axillary** - This incision is less concealed than periareolar and associated with less breast feeding difficulties than the periareolar incision site. If the incision is made under the arm, the surgeon may use a probe fitted with a miniature camera, along with minimally invasive (very small) instruments, to create a "pocket" for the breast implant. This approach is more difficult, and may increase the risk of damage to, and unexpected location of, the implant.
- **Umbilical** (belly button) - This incision site has not been studied in Mentor's Core Study and should not be used for a wide variety of reasons, including potential damage to the implant shell.

### 4.1.7. Additional Procedures at the Time of Breast Augmentation

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

In these situations, your surgeon may recommend a breast lift (mastopexy) to remove some of the extra skin, or to lift the breasts, at the time of implant placement. Mastopexy involves removing a strip of skin from under the breast or around the nipple to lift the nipple and breast location, and tighten the skin over the breast. Your surgeon will discuss the potential risks, and the location of the additional scars which might be required to lift your breasts or to remove the extra skin.

### 4.1.8. Palpability

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

### 4.1.9. Surgical Setting and Anesthesia

Augmentation surgery is usually performed on an outpatient basis, in a specialized operating room which may be located in a hospital, a surgery center, or surgical suite in the surgeon's office. General anesthesia is commonly used, and local anesthesia with sedation is also an option. You should be sure to check with your surgeon and with the facility where the surgery will take place, to become aware of the tests, presurgical examinations, and length of time you need to be without food or your routine medications prior to the surgical procedure.

### 4.1.10. Postoperative Care

You will probably feel somewhat tired and sore for several days following the operation, and your breasts may remain swollen and sensitive to physical contact for a month or longer. You may also experience a feeling of tightness in the breast area as your skin adjusts to your new breast size. The feeling in the breasts and nipple area also may be diminished during this time of swelling and immediate post surgery recovery. Other possible complications have been described above.

Postoperative care depends on each patient's situation, may involve the use of a special postoperative bra, compression bandage, or jog bra for extra support and positioning while you heal. Some surgeons may not want you to wear a bra at all for a period of time following the surgery. At your surgeon's recommendation, you will most likely be able to return to work within a few days, although for at least a couple of weeks you should avoid any strenuous activities that could raise your pulse and blood pressure, or require strenuous use of your arms and chest. Your surgeon may also recommend breast massage exercises.

Note: If you experience fever, do not feel well, or see noticeable swelling and/or redness or drainage in your implanted breast(s), you should contact your surgeon immediately.

### 4.2. Other Factors to Consider In Revision-Augmentation Surgery

Some revision surgeries require removal of an intact implant (for example, capsulotomy and pocket adjustments), while others do not require removal of the implant. Any device that has been removed during revision surgery should not be reimplanted. Mentor breast implants are "for single use only."

## 5. Follow-Up Examinations

### 5.1. Breast Self-Examinations

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

### 5.2. Screening for Silent Rupture

**Because most ruptures of silicone breast implants are silent, in most cases, neither you nor your surgeon will be able to find evidence of rupture. Therefore, evaluation of your implants is needed to screen for implant rupture. The best method of screening is currently MRI at a center with a breast coil, with a magnet of at least 1.5 Tesla. The MRI should be read by a radiologist who is familiar with looking for implant rupture.**

**It is recommended that your first MRI evaluation take place starting at 3 years after implant surgery and then every 2 years, thereafter, even if you are experiencing no problems with your implant. If signs of rupture are seen on MRI, then you should have your implant removed, with or without replacement. More information on rupture is provided in Section 2 of this brochure. Your doctor should assist you in locating a radiology/screening center, as well as a radiologist who is familiar with the technique and equipment for proper MRI screening for silent rupture of your breast implant.**

### 5.3. Symptomatic Rupture

Symptoms associated with rupture may include hard knots or lumps surrounding the implant or in the armpit, loss of size of the

breast or implant, pain, tingling, swelling, numbness, burning, or hardening of the breast. If you notice any of these changes, see your plastic surgeon so that he or she can examine the implants for rupture and determine whether you need to have an MRI examination to find out if your symptoms are due to rupture of the implant. If rupture has occurred, you should have your implant removed. More information on rupture is provided in Section 2 of this brochure.

You should monitor your breast implants for signs of symptomatic rupture when you check your breasts for lumps monthly. Examine your breast tissue by feeling for lumps. Then feel the breast implants. Move the implants around while looking in the mirror. Look for changes in shape, size, and feel of the implants. Know, and pay attention to, how the breast implants feel.

### 5.4. Mammography

The current recommendations for getting screening/preoperative mammograms are no different for women with breast implants than for those without implants. Mammography exams should be interpreted by radiologists experienced in the evaluation of women with breast implants. It is essential that you tell your mammography technologist that you have an implant before the procedure. You should request a diagnostic mammogram, rather than a screening mammogram, because more pictures are taken with diagnostic mammography. The technologist can use special techniques to reduce the possibility of rupture and to get the best possible views of the breast tissue. More information on mammography is provided in Section 1.4.

## 6. The Types of Silicone Gel-Filled Breast Implants Available from Mentor

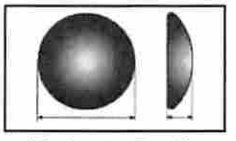
Mentor's silicone gel-filled breast implants, referred to as MemoryGel products, come in a variety of profiles and sizes. All currently available MemoryGel breast implants have either a textured shell or smooth surface shell.

Table 8 below shows the MemoryGel implant styles that were approved. Be sure to familiarize yourself with the different features of breast implants and to discuss the best type(s) of implants for you with your surgeon.

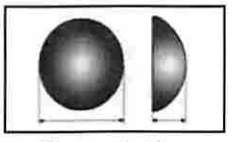
**Table 8 — Approved MemoryGel Implant Styles**

| Catalog Number | Breast Implant Description | Size Range |
|---|---|---|
| 350-7100BC/7800BC | Smooth, Round, Moderate Profile | 100-800 cc |
| 354-1007/8007 | Textured Round, Moderate Profile | 100-800 cc |
| 350-1001BC/8001BC | Smooth, Round, Moderate Plus Profile | 100-800 cc |
| 354-1001/8001 | Textured, Round, Moderate Plus Profile | 100-800 cc |
| 350-1254BC/8004BC | Smooth, Round, High Profile | 125-800 cc |
| 354-4125/4800 | Textured, Round, High Profile | 125-800 cc |

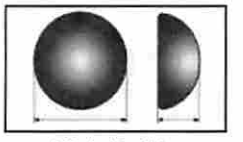
The following diagrams illustrate the high, moderate plus, and moderate profiles.



**Moderate Profile**



**Moderate Plus Profile**



**High Profile**

## 7. How to Report Problems with Your Implant

The Food and Drug Administration (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. If you believe that you have experienced one or more serious problems related to your breast implants, you are encouraged to report the serious problem(s) through your health professional to the FDA. Although reporting by doctors or other health professionals is preferred, women may also report any serious problem directly through FDA's MedWatch voluntary reporting system. 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 MedWatch form completed by your doctor for your records.** The

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.

## 8. Device Tracking

Silicone gel-filled breast implants are subject to Device Tracking by Federal regulation. This means that your physician will be required to report to Mentor the serial number of the device(s) you receive, the date of surgery, and information relating to the physician's practice. This information will be recorded on the Device Tracking Form supplied by Mentor with each silicone gel-filled breast implant.

Mentor strongly recommends that all patients receiving silicone gel-filled breast implants participate in Mentor's device tracking program. This will help ensure that Mentor has a record of each patient's contact information so that all patients, including you, can be contacted in the case of a recall or other problems with your implants that you should be made aware of. Please inform Mentor whenever your contact information changes.

## 9. Product Replacement Policy and Limited Warranties

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

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

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

- Financial assistance: For the first ten years following a breast implant procedure, Mentor will provide financial assistance up to $1200 to help cover operating room, anesthesia, and

surgical charges not covered by insurance. Financial assistance applies to covered events only (see below). Operating room and anesthesia charges will be given payment priority. In order to qualify for financial assistance, you will need to sign a Release Form.

- Free contralateral (opposite side) implant replacement upon surgeon request.
- Non-cancelable terms.

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

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

With both the Mentor Standard Advantage and Mentor Enhanced Advantage Limited Warranties, it is important for you to also maintain your own records to ensure validation of your enrollment, as it is possible your surgeon may not retain your records for the entire duration of the limited warranty.

**Products Covered**

The Mentor Standard Advantage Limited Warranty coverage applies to all Mentor gel-filled and saline-filled breast implants that are implanted in the United States and Puerto Rico, provided they have been:

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

**Events Covered**
The Mentor Lifetime Product Replacement Policy, and the Standard Mentor Advantage and Enhanced Advantage Limited Warranties coverages apply to the following:

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

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

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

**Filing for Financial Assistance**

- To file a Mentor Advantage claim for product replacement and/or financial assistance, the surgeon must contact the Mentor Product Evaluation Department at 1-866-250-5115 prompt #1 prior to replacement surgery.
- For financial assistance claims, a patient-specific Release form will be generated that you must sign and return.
- For either replacement or financial assistance claims, the surgeon must send the explanted, decontaminated Mentor breast implant(s) within six months of the date of explantation (implant removal) to:

  Mentor Product Evaluation
  3041 Skyway Circle North
  Irving, Texas 75038-3540

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

This is a summary of the coverage of the Mentor Advantage and Enhanced Advantage Limited Warranties. It is an overview only and

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

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

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

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

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

## 10. Other Sources of Additional Information

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

For more detailed information on the preclinical and clinical studies conducted by Mentor, you are referred to the Summary of Safety and Effectiveness Data (SSED) for this product at http://www.fda.gov/cdrh/breastimplants/.

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

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

**Mentor Corporation**
1-800-MENTOR8
www.mentorcorp.com

**Institute of Medicine Report on the Safety of Silicone Implants**
www.nap.edu/catalog/9618.html

**Food and Drug Administration**
1-888-INFO-FDA or 240-276-3101
**http://www.fda.gov/cdrh/breastimplants/**

You can find important information in the FDA breast implant consumer handbook, which is available through the phone number or website provided above.

**American Society of Plastic Surgeons**
http://www.plasticsurgery.org/public_education/Silicone-Breast-Implant-Surgery.cfm

## ACKNOWLEDGMENT OF INFORMED DECISION

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

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

**Y/N** I have had adequate time to read and fully understand this brochure;

**Y/N** I have had an opportunity to ask my surgeon any questions I may have about this brochure or any other issues related to breast implants or breast implant surgery;

**Y/N** I have considered the alternatives to silicone breast implants and have decided to proceed with silicone breast implant surgery;

**Y/N** I have been advised to wait an adequate amount of time after reviewing and considering this information, before scheduling my silicone breast implant surgery; and

**Y/N** I will retain this brochure, and I am aware that I may also ask my surgeon for a copy of this signed acknowledgment.

_____
PATIENT (PRINT NAME)

_____ _____
SIGNATURE OF PATIENT* DATED

* A patient must be at least 22 years old for primary and revision breast augmentation with silicone breast implants.

By my signature below, I acknowledge that:

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

_____ _____
SIGNATURE OF SURGEON DATED

## ACKNOWLEDGMENT OF INFORMED DECISION

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

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

**Y/N** I have had adequate time to read and fully understand this brochure;

**Y/N** I have had an opportunity to ask my surgeon any questions I may have about this brochure or any other issues related to breast implants or breast implant surgery;

**Y/N** I have considered the alternatives to silicone breast implants and have decided to proceed with silicone breast implant surgery;

**Y/N** I have been advised to wait an adequate amount of time after reviewing and considering this information, before scheduling my silicone breast implant surgery; and

**Y/N** I will retain this brochure, and I am aware that I may also ask my surgeon for a copy of this signed acknowledgment.

_____
PATIENT (PRINT NAME)

_____ _____
SIGNATURE OF PATIENT* DATED

* A patient must be at least 22 years old for primary and revision breast augmentation with silicone breast implants.

By my signature below, I acknowledge that:

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

_____ _____
SIGNATURE OF SURGEON DATED

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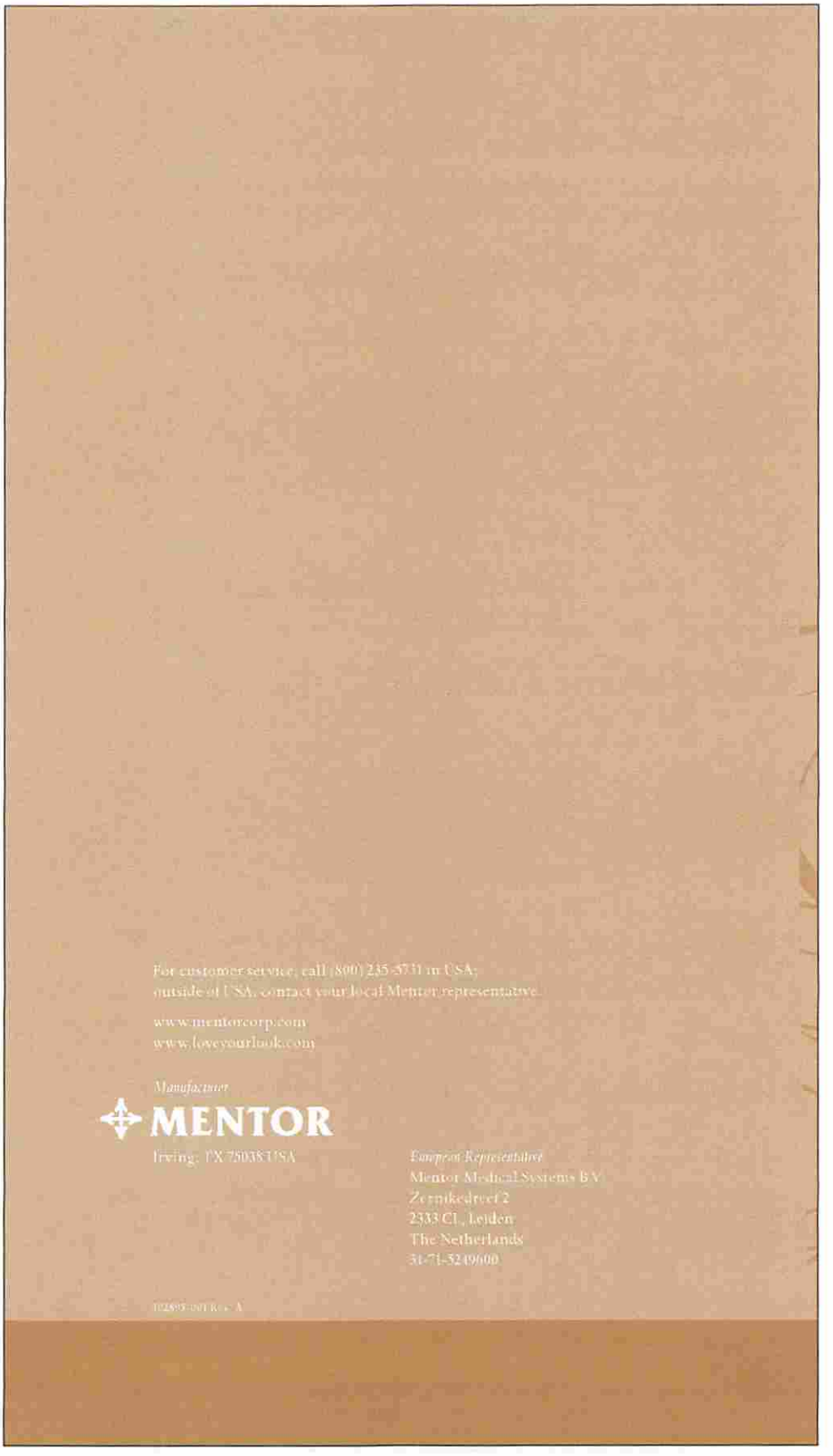
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# EXHIBIT 3

# Post-Approval Studies

## Post-Approval Studies

- In January 2005, the oversight responsibility of the Post-Approval Studies Program was transferred to the Division of Epidemiology (DEPI) of the Office of Surveillance and Biometrics (OSB)/Center for Devices and Radiological Health (CDRH).
- The CDRH Post-Approval Studies Program encompasses design, tracking, oversight, and review responsibilities for studies mandated as a condition of approval of a premarket approval (PMA) application, protocol development product (PDP) application, or humanitarian device exemption (HDE) application. The program helps ensure that well-designed post-approval studies (PAS) are conducted effectively and efficiently and in the least burdensome manner.
- CDRH has established an automated, internal tracking system that efficiently identifies the reporting status of active PAS studies ordered since January 1, 2005 based on study timelines incorporated in study protocols and agreed upon by the CDRH and applicants. This system represents CDRH's effort to ensure that all PAS commitments are fulfilled in a timely manner.
- In addition, CDRH launched this publicly available webpage to keep all stakeholders informed of the progress of each PAS. The webpage displays general information regarding each PAS, as well as the overall study status (based on protocol-driven timelines and the adequacy of the data) and the applicant's reporting status for each submission due.

## Links

- Guidance Document: "Procedures for Handling Post-Approval Studies Imposed by PMA Order"[6]
- PAS Webpage FAQs[7]
- Tools for Conducting PAS
  - Letter to PAS Participants[8]
  - Letter to PAS Investigators[9]
- Post-Approval Studies Workshops
  - Report on Implementation of Post-Approval Studies for Medical Devices Workshop (June 2009)[10]

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| **General** | |
| Application Number | P030053 |
| Current Protocol Accepted | 11/17/2006 |
| Study Name | OSB Lead-Core |
| Study Status | Completed |
| **General Study Protocol Parameters** | |
| Study Design | Prospective Cohort Study |
| Study involve follow-up of premarket cohort (Y/N) | Yes |
| Data Source | New Data Collection |
| Comparison Group | No Control |
| Analysis Type | Analytical |
| Study Population | Adolescent: 13-18 yrs, Transit. Adolescent B (as adults) : 18-21 yrs, Adult: >21 |
| **Detailed Study Protocol Parameters** | |
| Study Design Description | The Core study is a 10-year prospective, open-label, multi-center cohort study to evaluate the safety and effectiveness of MemoryGel breast implants ⊟ |
| Study Population Description | The study populaiton is as per device indication. This device is indicated for breast augmentation for women at least 22 years old and for breast reconstruction for women of any age. Breast Augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the results of a primary breast augmentation surgery. 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. ⊟ |
| Sample Size | 1000 patients at up to 40 sites |
| Data Collection | Safety endpoints include point prevalence on a per patient and per device basis of rates of occurrence of all adverse events and time to occurrence of the complication; Effectiveness endpoints include patient satisfaction measured by validated quality of life questionnaires and change in breast size measured by both bra and cup size and the chest/bust circumference. ⊟ |
| Followup Visits and Length of Followup | 11 follow-up visits (6 months and annually 1-10 years after surgery) during 10 years of study |
| **Final Study Results** | |
| Actual Number of Patients Enrolled | 1,008 |
| Actual Number of Sites Enrolled | 48 |
| Patient Followup Rate | 62% at 10 years |
| Final Safety Findings | For the Primary Augmentation cohort, the 10-year Kaplan-Meier estimated cumulative incidence rates for the key complications at the patient level were: capsular contracture III/IV, 12.1%; infection, 1.6%; explantation with or without replacement, 11.6%; explantation with replacement with study device, 7.4%; |

and any reoperation, 25.5%. The most frequently reported primary reasons for reoperation were capsular contracture II/III/IV (25.4% of reoperations) and breast mass (10.6% of reoperations).

For the Revision-Augmentation cohort, the rates were: capsular contracture III/IV, 24.4%; infection,

1.4%; explantation with or without replacement, 24.1%; explantation with replacement with study device,

13.6%; and any reoperation, 43.6%. The most frequently reported primary reason for reoperation was capsular contracture II/III/IV (30.4% of reoperations).

For the Primary Reconstruction cohort, the rates were: capsular contracture III/IV, 20.5%; infection,

6.2%; explantation with or without replacement, 33.4%; explantation with replacement with study device,

19.8%; and any reoperation, 49.0%. The most frequently reported primary reasons for reoperation were asymmetry (16.6% of reoperations), capsular contracture II/III/IV (14.0% of reoperations), rupture (12.7% of reoperations), and breast mass (10.8% of reoperations).

For the Revision-Reconstruction cohort, the rates were: capsular contracture III/IV, 36.9%; infection, 0%;

explantation with or without replacement, 37.8%; explantation with replacement with study device,

24.8%; and any reoperation, 50.7%. The most frequently reported primary reasons for reoperation were capsular contracture II/III/IV (23.4% of reoperations) and breast mass (12.8% of reoperations).

Overall, the most frequently reported reasons for explantation through 10 years were size change, capsular contracture II/III/IV, and rupture. Based on the MRI cohort, the overall Kaplan-Meier estimated cumulative rupture rates at 10 years were 27.9% and 18.5% for patients and implants, respectively

Final Effectiveness Findings

The overall mean changes in circumferential chest size were positive and statistically significant. The overall mean bra cup size increase from baseline across all follow-up visits was 1.8 cup sizes and was statistically significant. At the 10-year follow-up visit, overall 97.6% of patients indicated they would make the same decision to have breast implant surgery.

Study Strengths and Weaknesses

One of the study strengths is that the study is a prospective, multicenter study that provides long term data up to 10 years on the safety and effectiveness of the device. The weaknesses of the study were the lack of

a comparison group and lack of statistical power to detect rare events due to the small sample size.

Recommendations for Labeling Changes

The labeling will be updated based on the 10-year safety and effectiveness results reported in the Core

PAS final report.

**OSB Lead-Core Schedule**

| Report Schedule | Report Date Due | FDA Receipt Date | Reporting Status |
|---|---|---|---|
| CORE 1 year Study Report | 11/17/2007 | 11/16/2007 | On Time |
| CORE 2 Year Study Report | 11/16/2008 | 11/17/2008 | Overdue/Received |
| CORE 3 Year Study Report | 12/11/2009 | 12/14/2009 | Overdue/Received |
| CORE 4 Year Study Report | 11/16/2010 | 11/16/2010 | On Time |
| CORE 5 Year Study Report | 11/16/2011 | 11/17/2011 | On Time |
| CORE 6 Year Study Report - FINAL | 11/13/2012 | 11/13/2012 | On Time |

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10. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/PostApprovaStudies/UCM208562.pdf

Page Last Updated: 08/29/2016

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# EXHIBIT 4

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- In addition, CDRH launched this publicly available webpage to keep all stakeholders informed of the progress of each PAS. The webpage displays general information regarding each PAS, as well as the overall study status (based on protocol-driven timelines and the adequacy of the data) and the applicant's reporting status for each submission due.

## Links

- Guidance Document: "Procedures for Handling Post-Approval Studies Imposed by PMA Order"[6]
- PAS Webpage FAQs[7]
- Tools for Conducting PAS
  - Letter to PAS Participants[8]
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- Post-Approval Studies Workshops
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## Contact Information

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| **General** | |
| Application Number | P030053 |
| Current Protocol Accepted | 10/01/2014 |
| Study Name | OSB Lead-Large PAS |
| Study Status | Revised/Replaced Study |
| **General Study Protocol Parameters** | |
| Study Design | Prospective Cohort Study |
| Study involve follow-up of premarket cohort (Y/N) | No |
| Data Source | New Data Collection |
| Comparison Group | Concurrent & Historical Control |
| Analysis Type | Analytical |
| Study Population | Adolescent: 13-18 yrs, Transit. Adolescent B (as adults) : 18-21 yrs, Adult: >21 |
| **Detailed Study Protocol Parameters** | |
| Study Design Description | The Large post-approval study is a 10-year cohort study to address specific issues for which the Core Study was not designed to fully answer, as well as to provide a long-term real-world assessment of study endpoints |
| Study Population Description | Study Population consists of women who receive MemoryGel and saline breast implants for augmentation, revision-augmentation, reconstruction and revision-reconstruction . This device is indicated for breast augmentation for women at least 22 years old and for breast reconstruction for women of any age. Breast Augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the results of a primary breast augmentation surgery. 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. |
| Sample Size | 41,900 MemoryGel and 1,000 saline patients |
| Data Collection | Baseline data will be collected from the study subjects using patient self-administered questionnaire during the visit for preoperative evaluation. For MemoryGel patients, information on local complications including reasons for re-operation with or without removal of breast implants and reasons for removal, results of MRI evaluations, and results of rheumatologic or neurological evaluations will be collected during scheduled follow-up and on an interim/unscheduled basis, as needed. |
| Followup Visits and Length of Followup | 3 surgeon visits (1, 4-6 and 9-10 years post-implantation) and 10 annual follow-up questionnaire completed by participants during 10 years of study |
| **Final Study Results** | |
| Actual Number of Patients Enrolled | A total of 41,452 MemoryGel participants were enrolled in the study. |

Enrollment by indication was:
26,173 primary augmentation participants, 8382 revision-augmentation participants, 5023 primary reconstruction participants, 1761 revision-reconstruction participants, and 113 participants with missing indication information.

⊟

**Actual Number of Sites Enrolled**
2,342

**Patient Followup Rate**
At year 7, the overall follow-up rate was 20.1%.

Follow-up rate by indication was: 19.2% primary
augmentation group, 17.6% revision-augmentation group, 27.9% primary reconstruction group, 22.7% revision-reconstruction group, and 22% missing indication group.

⊟

**Final Safety Findings**

Participant Reported Complications and Reoperations

For MemoryGel participants in the primary augmentation cohort, the cumulative incidence
rate at 7 years of participant reported key local complications/reoperations was estimated to be 35.9% for any complication or reoperation, 3.3% for breast infection, 19.6% for breast pain related to implants, 8.7% for capsular contracture Baker Grade II, 7.2% for capsular contracture Baker Grades III/IV, 0.7% for MRI confirmed rupture, 8.2% for suspected rupture, 6.2% for implant removal, and 11.7% for reoperation.

For MemoryGel participants in the revision-augmentation cohort, the cumulative incidence rate at 7 years of participant reported key local complications/reoperations was estimated to be 50.8% for any complication or reoperation, 4.0% for breast infection, 25.0% for breast pain related to implants, 20.2% for capsular contracture Baker Grade II, 18.0% for capsular contracture Baker Grades III/IV, 2.8% for MRI confirmed rupture, 14.2% for suspected rupture, 12.5% for implant removal, and 18.9% for reoperation.

For MemoryGel participants in the primary reconstruction cohort, the cumulative incidence rate at 7 years of participant reported key local complications/reoperations was estimated to be 53.4% for any complication or reoperation, 6.3% for breast infection, 29.6% for breast pain related to implants, 12.3% for capsular contracture Baker Grade II, 12.7% for capsular contracture Baker Grades III/IV, 2.2% for MRI confirmed rupture, 12.5% for suspected rupture, 15.9% for implant removal, and 24.7% for reoperation.

For MemoryGel participants in the revision-reconstruction cohort, the cumulative incidence rate at 7 years of participant reported key local complications/reoperations was estimated to be 58.5% for any complication or reoperation, 5.9% for breast infection, 27.8% for breast pain related to implants, 16.1% for capsular contracture Baker Grade II, 18.3% for capsular contracture Baker Grades III/IV, 2.6% for MRI confirmed rupture, 15.6% for suspected rupture, 17.4% for implant removal, and 26.6% for reoperation.

Reasons for Reoperation

Among MemoryGel participants the Kaplan-Meier estimated cumulative incidences through seven years following implantation of participant reported reoperation are 11.7% for primary augmentation participants, 18.9% for revision-augmentation participants, 24.7% for primary reconstruction participants, and 26.6% for revision-reconstruction participants.

Among primary augmentation participants, the two most frequent reasons for reoperation (at the procedure level) were capsular contracture Baker Grade: II/III/IV (26.8% of procedures) and patient requested size change (21.0%).

Among revision-augmentation participants, the two most frequent reasons for reoperation were capsular contracture Baker Grades II/III/IV and patient requested size change (31.1% and 19.9% of procedures, respectively).

Among primary reconstruction participants, the two most frequent reasons for reoperation were asymmetry (22.1%) and capsular contracture Baker Grades II/III/IV (20.0%).

Among revision-reconstruction participants, the two most frequent reasons for reoperation were asymmetry and capsular contracture Baker Grades II/III/I\ (24.4% and 21.4%, respectively).

Reasons for Explantation

In the two augmentation cohorts, the most frequent reason for explantation during the seven years after implantation was patient requested size change (58.9% and 44.8% of procedures among participants in the primary augmentation and revision-augmentation cohorts, respectively). In the two reconstruction cohorts, the most frequent reason for explantation was asymmetry (26.4% and 31.2% of procedures among participants in the primary reconstruction and revision-reconstruction cohorts, respectively).

Due to word limits, the safety results are continued in the effectiveness section below.

⊟

**Final Effectiveness Findings**

There were no study objectives related to effectiveness. The information that follows is a continuation
of safety findings.

Types of Additional Procedures

Among MemoryGel participants having reoperations during the seven years after implantaton, the most frequent type of procedure in each cohort and overall was implant removal with or without replacement with any device (48.9% of procedures overall). Also frequent in each of the cohorts were capsulectomy (12.3% of procedures overall), pocket adjustment (8.2% of procedures overall), and open capsulotomy (7.5% of procedures overall).

Connective Tissue Disease and Fibromyalgia

Among all MemoryGel participants, there were a total of 349 new cases of rheumatoid arthritis (incidence rate per 10,000 person-years of 32.2), 46 new cases of scleroderma (incidence rate = 4.2), 66 new cases of SLE (incidence rate = 6.0), 62 new cases of Sjögren?s disease (incidence rate = 5.7), 204 new cases of other CTDs (incidence rate = 18.8), and 307 new cases of fibromyalgia (incidence rate = 28.4).

Cancer

Overall, 532 MemoryGel participants without a history of cancer at baseline experienced newly diagnosed cases of cancer. There were 116 participants wit

newly diagnosed cases of breast cancer, 5 with lung cancer, 3 with brain cancer, and 408 with other types of cancer, including 65 with melanoma. The incidence rates (per 10,000 person-years) were 63.8, 13.9, 0.6, 0.4, and 48.9 for all types of cancer, breast cancer, lung cancer, brain cancer, and other cancers, respectively. The incidence rate (per 10,000 person-years) was 7.8 for melanoma.

Neurological Disease

There were a total of 394 new cases of neurological disease among MemoryGel participants. There were 47 new cases of multiple sclerosis, 17 of myositis and 332 of other types of neurological diseases. The incidence rates (per 10,000 person-years) were 35.8, 4.3, 1.5, and 30.7 for all types of neurological diseases, multiple sclerosis, myositis, and other neurological diseases, respectively. The most

common ?other neurological diseases? included epilepsy, headache, peripheral neuropathy, stroke, trigeminal neuralgia, and tumor.

Rheumatological and Neurological Signs and Symptoms

Overall, the estimates of mean post-baseline prevalence for MemoryGel participants were highest for persistent non-traumatic joint pain (estimate = 12.9% and persistent sleep disorders at night (estimate = 25.8%).

Reproduction and Offspring

Overall, a total of 3133 post-operative pregnancies have been reported among MemoryGel participants. Among them, there were a total of 501 miscarriages or stillbirths (16.0%), with 416 miscarriages (13.3%) and 85 stillbirths (2.7%). Overall, a total of 1710 offspring have been reported among MemoryGel participants. Among these, there were 234 premature births (13.7%), 155 low birth weight babies (9.1%), and 194 babies that required neonatal intensive care (11.3%). There were no reported births of children with cleft lip, neural tube defect, or pyloric stenosis. There was one reported birth of cleft palate and one of esophageal deformity. There were 25 reported births (1.5% of births) with other birth defects or congenital malformations.

Suicide

There have been a total of 173 known deaths among the MemoryGel participants. There have been 5 known suicides among these 173 deaths.

Anaplastic Large Cell Lymphoma

There has been one confirmed case of Anaplastic Large Cell Lymphoma (ALCL) in a Large PAS participant.

MRI Compliance and Rupture

At years 1, 2, 3, 4, 5, 6, and 7, only 3.4%, 4.7%, 5.2%, 5.5%, 4.9%, 4.5%, and 4.4%, respectively, of MemoryGel participants reported having had an MRI since completing their last questionnaire. Overall, of the 2051 MemoryGel participants with an MRI, there were 132 participants (6.4%) with rupture.

⊟

Study Strengths and Weaknesses

Overall, there are a total of 255,541 person-years of follow-up among MemoryGel participants. However, results
are difficult to interpret due to the very low follow-up rate. Loss to follow-up can introduce study bias and limits the interpretation of the study results, as those that remain in the study may not be comparable to those that were lost. FDA and the sponsor have agreed to replace the original LARGE study requirement with a new study design to fulfill the condition of approval.

It should also be noted that not all reported cases of CTD or neurological diseases were confirmed as board-certified diagnosed cases. Therefore, the current cases reported in this study (self-reported by participants as diagnosed by a board-certified specialist, rheumatologist or neurologist) may not represent the actual rate.

⊟

Recommendations for Labeling Changes

Due to very low follow-up rate, labeling changes are not recommended.

**OSB Lead-Large PAS Schedule**

| Report Schedule | Report Date Due | FDA Receipt Date | Reporting Status |
|---|---|---|---|
| Large PAS 3 month report | 02/16/2007 | 02/16/2007 | On Time |
| Large PAS 6 month report | 05/18/2007 | 05/18/2007 | On Time |
| Large PAS Semi-annual Report | 05/18/2007 | 05/18/2007 | On Time |
| Large PAS 9 month report | 08/17/2007 | 08/17/2007 | On Time |
| Large PAS 1 year report | 11/17/2007 | 11/16/2007 | On Time |
| Large PAS 15 month report | 02/16/2008 | 02/15/2008 | On Time |
| Large PAS 18 month report | 05/17/2008 | 05/16/2008 | On Time |
| Large PAS 21 month report | 08/16/2008 | 08/18/2008 | Overdue/Received |
| Large PAS 2 year report | 11/16/2008 | 11/10/2008 | On Time |
| Large PAS 27 month report | 02/15/2009 | 02/17/2009 | Overdue/Received |
| Large PAS 30 month report | 05/17/2009 | 05/18/2009 | Overdue/Received |
| Large PAS 33 month report | 08/16/2009 | 08/14/2009 | On Time |
| Large PAS 3 year report | 11/16/2009 | 11/16/2009 | On Time |
| Large PAS 39 month report | 02/15/2010 | 02/12/2010 | On Time |
| Large PAS 42 month report | 05/17/2010 | 05/17/2010 | On Time |
| Large PAS 45 month report | 08/16/2010 | 08/16/2010 | On Time |
| Large PAS 4 year report | 11/16/2010 | 11/16/2010 | On Time |
| Large PAS 51 month report | 02/15/2011 | 02/15/2011 | On Time |
| Large PAS 54 month report | 05/18/2011 | 05/18/2011 | On Time |
| Large PAS 57 month report | 08/16/2011 | 08/16/2011 | On Time |
| Large PAS 5 year report | 11/16/2011 | 11/17/2011 | On Time |
| Large PAS 63 month report | 02/15/2012 | 02/15/2012 | On Time |
| Large PAS 66 month report | 05/16/2012 | 05/15/2012 | On Time |
| Large PAS 6 year report | 11/15/2012 | 11/07/2012 | On Time |
| Large PAS 7 year report | 11/15/2013 | 11/12/2013 | On Time |
| Large PAS 8 year report | 11/15/2014 | 11/13/2014 | On Time |
| final report | 05/31/2015 | 05/28/2015 | On Time |

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10. http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/PostmarketRequirements/PostApprovaStudies/UCM208562.pdf

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# EXHIBIT 5

# Post-Approval Studies

## Post-Approval Studies

- In January 2005, the oversight responsibility of the Post-Approval Studies Program was transferred to the Division of Epidemiology (DEPI) of the Office of Surveillance and Biometrics (OSB)/Center for Devices and Radiological Health (CDRH).
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| **General** | |
| Application Number | P030053 |
| Current Protocol Accepted | 11/17/2006 |
| Study Name | OSB Lead-Device Failure Study |
| Study Status | Other |
| Study Progress Reason | Other reason |
| **General Study Protocol Parameters** | |
| Study Design | Bench/Lab Study |
| Study involve follow-up of premarket cohort (Y/N) | No |
| Data Source | New Data Collection |
| Comparison Group | No Control |
| Analysis Type | Descriptive |
| Study Population | Adolescent: 13-18 yrs, Transit. Adolescent B (as adults) : 18-21 yrs, Adult: >21 |
| **Detailed Study Protocol Parameters** | |
| Study Design Description | The device failure study involves two components. The first component involves the collection of implant/surgery information and clinical data at the time of explantation. The second component involves visual inspection and physical testing of the explanted devices. ⊟ |
| Study Population Description | All explanted devices are to be returned to Mentor and analyzed and tested |
| Sample Size | All returned devices are analyzed. |
| Data Collection | An analysis was performed on the following categories to identify specific trends correlating to device failures: device type, size, clinical variables, visual observations, in-vivo time, surgical approach, device placement, incision size, pocket irrigation usage. Explanted devices underwent the following physical testing to assess the physical characteristics of the explanted devices: tension set, joint strength, ultimat elongation, gel cohesion. ⊟ |
| Followup Visits and Length of Followup | There is no patient follow-up in this study |

## OSB Lead-Device Failure Study Schedule

| Report Schedule | Report Date Due | FDA Receipt Date | Reporting Status |
|---|---|---|---|
| 2 year report | 11/16/2008 | 11/14/2008 | On Time |
| 3 year report | 11/16/2009 | 11/16/2009 | On Time |
| 4 year report | 11/16/2010 | 11/09/2010 | On Time |
| 5 year report | 11/16/2011 | 11/09/2011 | On Time |
| 6 year report | 11/15/2012 | 11/15/2012 | On Time |

| | | | |
|---|---|---|---|
| 7 year report | 11/15/2013 | 11/12/2013 | On Time |
| Change in Report Requirements/Study Status | 09/10/2014 | | On Time |

*** Sponsor is reporting failure study data in the regular PMA Annual Report.**

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# EXHIBIT 6

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| **General** | |
| Application Number | P030053 |
| Current Protocol Accepted | 11/17/2006 |
| Study Name | OSB Lead-Focus Group |
| Study Status | Completed |
| **General Study Protocol Parameters** | |
| Study Design | Prospective Cohort Study |
| Study involve follow-up of premarket cohort (Y/N) | No |
| Data Source | New Data Collection |
| Comparison Group | No Control |
| Analysis Type | Descriptive |
| Study Population | Adolescent: 13-18 yrs, Transit. Adolescent B (as adults) : 18-21 yrs, Adult: >21 |
| **Detailed Study Protocol Parameters** | |
| Study Design Description | The Focus Group study is a one time study designed to evaluate how easily patients understand the information in the informed decision brochure about the risks associated with the use of silcone breast implants. A total of 35 women participated in one of four group interviewers for the study. Two discussion groups were conducted for women considering breast implants for augmentation and two group interviews were conducted with women considering breast implantssfor reconstruction. Each group was composed of eight tc ten women. A trained female moderator led the discussion groups, which were each abouat 2 hours long. Respondents received a $150 honorarium in return for their time. Group interviewrs were conducted in a professional resaraevh facilities that alloesd for observation and audio recording. |
| Study Population Description | The study population is as per device indication. This device is indicated for breast augmentation for women at least 22 years old and for breast reconstruction for women of any age. Breast Augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the results of a primary breast augmentation surgery. 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. |
| Sample Size | 35 women in one of each of 4 groups. Two were held in Dallas, Texas and two in San Francisco, California. These sites were selected based on the volume of breast implant surgeries condcuted in these areas. |
| Data Collection | The study used two methods of data collection: discussion groups and a self-administered survey-- to capture both group level and individual level data. A female moderator led each discussion group using a discussion guide prepared in advance by the contracted research firm with the assitance of Mentor Corporation. Two versions of the brochure were tested, one designed for augmentation patients and one designe for reconstruction patients. Endpoints included respondents' reactions to the overall layout oand format of the brochures, content ordering, an iollustrations and tables.. Data were collected on respondents' comprehesnion and perceived relevance of the content. Throughout the discussion, data were gathered on respondents' suggestions for improvements. |

| | |
|---|---|
| Followup Visits and Length of Followup | No Follow-up required |
| **Final Study Results** | |
| Actual Number of Patients Enrolled | 35 women distributed over 4 groups. |
| Actual Number of Sites Enrolled | 2 (San Francisco and Dallas) |
| Patient Followup Rate | not applicable |
| Final Safety Findings | No safety findings. Key findings reported by sponsor are summarized here. Overall reaction to both versions of brochures tested was positive. Group discusions and self-administered survey indicate that solid understanding of the information in brochures. Respondents all agreed that brochure was more comprehensive than anything else they had seen. Respondents had difficulty understanding particular points in the brochure. Misost respondents interpreted the informtion on MRIs for the detection of silent ruptures to mean that MRIs were recommended a replacements for mammography. Many respondents perceived that silicone breast implnats are fragile and prone to rupture. Many were alarmed by this and teh combination of the fact that most ruptures are silent. A few respondents concluded that the true purpose of the brochure was to protect Mentor, rather than inform patietns about breast implant surgery. Respondents reported taht most of the information did not help them weigh the relative importance of risks and complications associated with breast implants. Brochure fell short of provideing infiormation on the benefits of breast implants and did not acknowledge the deeply personal benefits of body image and self-esteem, especially for women who lose their breast to cancer. ⊟ |
| Study Strengths and Weaknesses | Discussion groups are useful for exploring attitudes, knowledge and beliefs. Readers should be cautious in intrepreting the data and in making generalizations about the target population as a whole. Given the qualitative nature of the data, they suggest general tendencies but can not be considered definitive. The study is limited by its small sample size and the selection of a non-probablistic sample. ⊟ |
| Recommendations for Labeling Changes | Add information clearly describing differences between restoration, replacement, reconstruction, and revision early in the main body of the brochure. add informtion on Organize information on potential complications based onteh likelihood of occurrence and calling attention to the relative importance of each possible outcome. Provide more information about benefits. provie more qualitative information (personal testimony, caes histories) to help women make more informed decisions. Include more illustrations, visual white space, color and bolding. mke illustrations, larger, darker, ,orerealistinc and more clearly labelled. ⊟ |

**OSB Lead-Focus Group Schedule**

| Report Schedule | Report Date Due | FDA Receipt Date | Reporting Status |
|---|---|---|---|
| Focus Group Study Final Report | 11/17/2007 | 11/16/2007 | On Time |

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# EXHIBIT 7

# Post-Approval Studies

## Post-Approval Studies

- In January 2005, the oversight responsibility of the Post-Approval Studies Program was transferred to the Division of Epidemiology (DEPI) of the Office of Surveillance and Biometrics (OSB)/Center for Devices and Radiological Health (CDRH).
- The CDRH Post-Approval Studies Program encompasses design, tracking, oversight, and review responsibilities for studies mandated as a condition of approval of a premarket approval (PMA) application, protocol development product (PDP) application, or humanitarian device exemption (HDE) application. The program helps ensure that well-designed post-approval studies (PAS) are conducted effectively and efficiently and in the least burdensome manner.
- CDRH has established an automated, internal tracking system that efficiently identifies the reporting status of active PAS studies ordered since January 1, 2005 based on study timelines incorporated in study protocols and agreed upon by the CDRH and applicants. This system represents CDRH's effort to ensure that all PAS commitments are fulfilled in a timely manner.
- In addition, CDRH launched this publicly available webpage to keep all stakeholders informed of the progress of each PAS. The webpage displays general information regarding each PAS, as well as the overall study status (based on protocol-driven timelines and the adequacy of the data) and the applicant's reporting status for each submission due.

## Links

- Guidance Document: "Procedures for Handling Post-Approval Studies Imposed by PMA Order"[6]
- PAS Webpage FAQs[7]
- Tools for Conducting PAS
  - Letter to PAS Participants[8]
  - Letter to PAS Investigators[9]
- Post-Approval Studies Workshops
  - Report on Implementation of Post-Approval Studies for Medical Devices Workshop (June 2009)[10]

## Contact Information

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| | |
|---|---|
| **General** | |
| Application Number | P030053 |
| Current Protocol Accepted | 11/17/2006 |
| Study Name | OSB Lead-Informed Decision Process |
| Study Status | Completed |
| **General Study Protocol Parameters** | |
| Study Design | Other Study Design |
| Study involve follow-up of premarket cohort (Y/N) | No |
| Data Source | New Data Collection |
| Comparison Group | No Control |
| Analysis Type | Descriptive |
| Study Population | Adolescent: 13-18 yrs, Transit. Adolescent B (as adults) : 18-21 yrs, Adult: >21 |
| **Detailed Study Protocol Parameters** | |
| Study Design Description | The Informed Decision Process study is a random survey of physicians on an annual basis to determine the success of the informed decision process provided to woman who is seeking breast implants surgery |
| Study Population Description | Each year, a random selection of 50 physicians are targeted for a survey to determine the success of the patient informed consent process. |
| Sample Size | A total of 50 physicians surveyed each year |
| Data Collection | Survey is administered to 50 physicians and asks questions on the level of understanding a patient has after consulting the Allergan patient planner. |
| Followup Visits and Length of Followup | There are no follow up visits in this study |
| **Final Study Results** | |
| Actual Number of Patients Enrolled | The Informed Decision Process consisted of yearly surveys. Each year a different sample was selected for the survey. These are the results for 2011 annual report.<br><br>54 surveys were returned. Per the condition of approval, the sponsor did administer the survey to a random selection of 50 physicians. |
| Actual Number of Sites Enrolled | N/A |
| Patient Followup Rate | N/A |
| Final Safety Findings | N/A |

| | |
|---|---|
| Final Effectiveness Findings | The majority of respondents (94.2%) said the Informed Decision Brochure was of value in helping patients to understand the risks and benefits of implant surgery. |
| Study Strengths and Weaknesses | The sample of physicians was chosen randomly, which is a strength of the study. However, the observational, cross-sectional design of the study does not allow for any hypothesis testing. The results are descriptional only. |
| Recommendations for Labeling Changes | Mentor has no current plans to change the Informed Decision Process based on the survey results. |

**OSB Lead-Informed Decision Process Schedule**

| Report Schedule | Report Date Due | FDA Receipt Date | Reporting Status |
|---|---|---|---|
| 2 year report | 11/16/2008 | 11/12/2008 | On Time |
| 3 year report | 11/16/2009 | 11/16/2009 | On Time |
| 4 year report | 11/16/2010 | 11/05/2010 | On Time |
| 5 year report | 11/16/2011 | 11/07/2011 | On Time |

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# EXHIBIT 8

# Post-Approval Studies

## Post-Approval Studies

- In January 2005, the oversight responsibility of the Post-Approval Studies Program was transferred to the Division of Epidemiology (DEPI) of the Office of Surveillance and Biometrics (OSB)/Center for Devices and Radiological Health (CDRH).
- The CDRH Post-Approval Studies Program encompasses design, tracking, oversight, and review responsibilities for studies mandated as a condition of approval of a premarket approval (PMA) application, protocol development product (PDP) application, or humanitarian device exemption (HDE) application. The program helps ensure that well-designed post-approval studies (PAS) are conducted effectively and efficiently and in the least burdensome manner.
- CDRH has established an automated, internal tracking system that efficiently identifies the reporting status of active PAS studies ordered since January 1, 2005 based on study timelines incorporated in study protocols and agreed upon by the CDRH and applicants. This system represents CDRH's effort to ensure that all PAS commitments are fulfilled in a timely manner.
- In addition, CDRH launched this publicly available webpage to keep all stakeholders informed of the progress of each PAS. The webpage displays general information regarding each PAS, as well as the overall study status (based on protocol-driven timelines and the adequacy of the data) and the applicant's reporting status for each submission due.

## Links

- Guidance Document: "Procedures for Handling Post-Approval Studies Imposed by PMA Order"[6]
- PAS Webpage FAQs[7]
- Tools for Conducting PAS
  - Letter to PAS Participants[8]
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## Contact Information

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| | |
|---|---|
| **General** | |
| Application Number | P030053 |
| Current Protocol Accepted | 11/17/2006 |
| Study Name | OSB Lead-Adjunct Study |
| Study Status | Completed |
| **General Study Protocol Parameters** | |
| Study Design | Prospective Cohort Study |
| Study involve follow-up of premarket cohort (Y/N) | Yes |
| Data Source | New Data Collection |
| Comparison Group | No Control |
| Analysis Type | Analytical |
| Study Population | Adolescent: 13-18 yrs, Transit. Adolescent B (as adults) : 18-21 yrs, Adult: >21 |
| **Detailed Study Protocol Parameters** | |
| Study Design Description | The Adjunct study is a 5-year study, in which patients will be followed at 1, 3, and 5 years postoperatively to assess satisfaction and occurrence of local complications. ⊟ |
| Study Population Description | The study population is as per device indication. This device is indicated for breast augmentation for women at least 22 years old and for breast reconstruction for women of any age. Breast Augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the results of a primary breast augmentation surgery. 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. ⊟ |
| Sample Size | number of study sites: 2,958; 12,811 reconstruction patients were implanted with 23,090 implants |
| Data Collection | Safety endpoints include clinical complications such as infection, seroma, implant rupture and capsular contracture at 1 ,3, 5 years of follow-up and rheumatologic/immunologic symptoms and connective tissue disorders at 3, 5 years of follow-up ⊟ |
| Followup Visits and Length of Followup | 3 follow-up visits during 5 years of study (1, 3, 5 years post-implantation) |
| **Final Study Results** | |
| Actual Number of Patients Enrolled | 147,585 |
| Actual Number of Sites Enrolled | 4,684 |
| Patient Followup Rate | 44.0% at 1 year, 24.7% at 3 years, 13.8% at 5 years |
| Final Safety Findings | The 3 most commonly reported complications using the Kaplan-Meier cumulative incidence estimates at 5 years were: asymmetry (18.6%), wrinkling (9.9%), and Capsular Contracture, Baker III/IV (8.3%) in the Reconstruction Cohort; asymmetry (23.7%), wrinkling (14.3%), and Capsular Contracture, Baker III/IV (11.7%) in the Revision-Reconstruction Cohort; wrinkling (12.3%), asymmetry (11.4%), and Capsular Contracture, |

Baker III/IV (9.2%) in the Revision- Augmentation Cohort.

The most common reasons by cohort for removal were: capsular contracture (36.4%), infection

(13.2%), and patient request for size and implant change (10.5%) in the Reconstruction Cohort;

capsular contracture (37.4%), leakage/rupture/ deflation (12.2%), and infection (11.5%) in the Revision-Reconstruction Cohort; capsular contracture (36.1%), leakage/rupture/ deflation (16.1%), and patient request for size and implant change (10.3%) in the Revision-Augmentation Cohort.

The Kaplan-Meier cumulative rupture rates at 5 years were: 1.8% in the Reconstruction Cohort; 3.6%

in the Revision-Reconstruction Cohort; 3.5% in the Revision-Augmentation Cohort.

Bilateral implantation, white, infra-mammary surgical approach and sub-glandular surgical approach showed a higher risk of rupture, and reconstruction, smooth surface implant, high profile implant, high education and sub-muscular surgical placement showed a lower risk of rupture.

Rheumatoid arthritis was the most common patient-reported rheumatic disease at 0.6%. Fibromyalgia and Raynaud's phenomenon were the most commonly reported rheumatic syndromes at 0.8% and 0.5% respectively.

⊟

Final Effectiveness Findings: N/A

Study Strengths and Weaknesses: A large number of patients were enrolled in the adjunct study. However, the study was originally

designed to address the public health needs of reconstruction and revision patients before device approval and to gather safety data regarding short-term post-implant complications under a limited clinical protocol without follow-up goals. The overall patient follow-up rates at 1, 3 and 5 years in this final report were only 44.0%, 24.7% and 13.8% respectively. The poor patient compliance significantly limited meaningful interpretation of the available safety results.

⊟

Recommendations for Labeling Changes: No

**OSB Lead-Adjunct Study Schedule**

| Report Schedule | Report Date Due | FDA Receipt Date | Reporting Status |
|---|---|---|---|
| 2 year report | 11/16/2008 | 11/12/2008 | On Time |
| 3 year report | 11/16/2009 | 11/12/2009 | On Time |
| 4 year report | 11/16/2010 | 11/04/2010 | On Time |
| 5 year report | 11/16/2011 | 11/04/2011 | On Time |
| final report | 11/02/2012 | 11/02/2012 | On Time |

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