MemoryGel PAS

(MemoryGel Postapproval Study)

Protocol: P030053 – Amendment 2

Original Protocol – dated 17Nov2006
Minor Revision – dated 12April2007
Amendment 1 – dated 25Sep2009
Amendment 2 – dated 14Nov2014
Administrative Change #1 – dated 06Feb2015

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PROTOCOL SIGNATURE PAGE

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Administrative Change #1 – 06 Feb 2014

Signature:

Jw Canady MD — 2/9/15

Sponsor's Medical Monitor: **Date**

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1.0 INTRODUCTION

On 17 Nov 2006, the U.S. Food and Drug Administration (FDA) approved Mentor's MemoryGel® silicone gel-filled breast implants for use in women who are undergoing primary or revisional breast augmentation and primary or revisional breast reconstruction surgery. The approval was conditional on Mentor conducting a 10-year study designed to collect long-term experience in U.S. women with MemoryGel implants. The MemoryGel Postapproval Study (MemoryGel PAS) is intended to satisfy one element of FDA's postapproval requirements.

As a condition to gaining access to MemoryGel products, physicians were required to sign up for the MemoryGel Gel-Filled Breast implants Post Approval study, and were asked to actively encourage 41,900 women to participate in the 10-year study. In addition, the study included 1,000 women who were undergoing breast implantation with saline breast implants to serve as concurrent controls for assessing rheumatologic and neurologic signs and symptoms.

Approximately 1,700 centers participated in the study and enrollment included 41,451 MemoryGel participants and 1039 saline participants. Study enrollment has been closed since 15 Oct 2008. As of the last annual study report (dated Nov 2013), the follow-up rates through six years were 21.8% for MemoryGel participants and 15.0% for saline participants.

Due in part to the low follow-up rate, which may limit interpretation of the data, FDA in collaboration with the American Society of Plastic Surgeons (ASPS), breast implant manufacturers, and patient representatives have been investigating innovative approaches to collect long-term data on silicone gel breast implants. As part of these efforts, recently, FDA has agreed to changes in the postapproval commitments for the MemoryGel silicone gel-filled breast implants that include changes to MemoryGel PAS. These changes are described in this amended protocol.

This amended protocol limits the scope of data collection under the original protocol to the collection of only secondary procedure/reoperation data. There are no longer requirements for scheduled office visits or annual participant questionnaires, which included the collection of data on conditions and diseases such as connective tissue disease, rheumatolgical signs and symptoms, and neurological disease. The limited data collected under this protocol amendment are similar in scope to the data collection planned for the National Breast Implant Registry, and therefore, this amended protocol will serve as a pilot for the future registry efforts.

2.0 OBJECTIVES

This amended protocol will collect data on secondary procedures/reoperations. The issues to be addressed include the following:

- What are the Kaplan-Meier (KM) implant removal and reoperation rates over time?
- What are the reasons for reoperation over time?

The postapproval study was originally designed to address the issues identified in Table 1, which includes reoperation data as described above.

Table 1. ***ORIGINAL POSTAPPROVAL STUDY OBJECTIVES***

Complication/ Condition/ Disease	***Issues to be Addressed***
Local Complications[1]	• *What are the Kaplan-Meier (KM) complication rates over time, including removal and reoperation rates?* • *What are the reasons for reoperation over time?*
Connective Tissue Disease (CTD)[2]	• *What are the types and rates of CTD diseases reported for women receiving Mentor MemoryGel implants and controls?*
Rheumatological Signs and Symptoms[3]	• *What are the types and rates of rheumatological signs and symptoms reported for women receiving Mentor MemoryGel implants and controls?*
Neurological Disease[4]	• *What are the types and rates of neurological diseases reported for women receiving Mentor MemoryGel implants and controls?*
Neurological Signs and Symptoms[5]	• *What are the types and rates of neurological signs and symptoms reported for women receiving Mentor MemoryGel implants and control group?*
Offspring	• *What are the rates of birth defects/congenital malformations (such as cleft lip, cleft palate, neural tube defect, esophageal deformity, and pyloric stenosis), premature birth, low birth weight, neonatal intensive care, and chronic illnesses (such as autoimmune disorders, cancer, and neurological disease) in children born to women receiving Mentor MemoryGel implants and controls?*
Reproductive	• *Of those women who attempted to have children, what are the rates of miscarriage and stillbirths for women receiving Mentor MemoryGel implants and controls?*
Lactation	• *Of those women who attempted to breast feed, how many were able in each of the groups (women receiving Mentor MemoryGel implants and controls)? What are the types and rates of lactation problems for women receiving Mentor MemoryGel implants and controls?*
Cancer[6]	• *What are the types and rates of cancer reported for women receiving Mentor MemoryGel implants and controls?*
Suicide[7]	• *What are the rates of suicide for women receiving Mentor MemoryGel implants and controls?*
Mammography	• *What is the rate of rupture with mammography in women receiving Mentor MemoryGel implants?* • *Are there interference issues (i.e., is there an effect with respect to the timing of breast cancer diagnosis?)*
MRI Compliance and Results	• *How many women receiving Mentor MemoryGel implants obtained MRIs as described in the patient brochure (i.e., at year 3 and every 2 years, thereafter)? If not this schedule, how often did they get one?* • *What are the rupture rates based on the MRI findings?*

[1] *To include (patient-reported key local complications): infection; breast pain; capsular contracture (Baker Grades I-IV); rupture; removal; and reoperation. Physicians will*

report all local complications, including reasons for reoperation, with or without removal, and reasons for removal, during scheduled and unscheduled/interim visits (see complications form in Section 15).

[2] *To include the following diseases diagnosed or reviewed and confirmed by a board-certified rheumatologist; scleroderma, lupus, rheumatoid arthritis, Sjögren's Disease, fibromyalgia, and other CTDs or autoimmune diseases [participant to specify in questionnaire]. Separately, a survey-based evaluation of fibromyalgia, determined through patient reports via a validated instrument that correlates to rheumatologist diagnosis, will be included (Katz, R.S., F. Wolfe and K. Michaud. 2006. Fibromyalgia diagnosis: a comparison of clinical, survey, and American College of Rheumatology criteria. Arthritis Rheum. 54(1):169-176).*

[3] *To include: persistent joint stiffness that lasts at least one hour, over a period of two weeks or longer; persistent non-traumatic joint pain (more than 3 months); persistent joint swelling (more than 1 week); persistent muscle pain (more than 3 months); pain in taking a deep breath for more than a few days (pleurisy); persistent sleep disorders at night; persistent fatigue; persistent cognitive problems; frequent muscle cramps; persistent skin redness on both cheeks; loss of weight without dieting; skin that persistently feels tight, stretched, or hidebound; skin that breaks out routinely after being in the sun, other than sunburn; fingers becoming unusually pale, numb, or uncomfortable in the cold; excessively dry eyes or mouth; persistent unexplained fevers; ulcers in mouth for more than 3 weeks; difficulty swallowing; and unusual hair loss.*

[4] *To include the following diseases diagnosed or reviewed and confirmed by a board-certified neurologist: multiple sclerosis (MS); myositis (polymyositis, dermatomyositis, inclusion body myositis); and other neurological diseases [participant to specify in questionnaire].*

[5] *To include: persistent or recurrent tingling or numbness with a duration of at least several weeks; episode of sudden visual loss or double vision; persistent or recurrent dizziness; persistent memory problems, difficulty concentrating on simple tasks, such as reading, television, etc., lasting at least 3 months; difficulty with balance; new difficulty walking that is not related to arthritis; persistent muscle weakness with a duration of at least several weeks; loss of control of bowel or bladder that happens suddenly or urine retention; jaw weakness leading to difficulty chewing; and seizure, convulsion, or fit.*

[6] *Cancers: breast, lung, brain, and other cancers [participant to specify in questionnaire].*

[7] *Suicide information will be obtained from relevant sources, including the Social Security Death Index and designated contacts.*

3.0 DESIGN

This protocol amendment includes participant follow-up only. Study enrollment has been closed since 15 Oct 2008 and no new study participants will be enrolled. Data collection will only take place if a participant requires a secondary procedure/reoperation. There are no longer requirements for scheduled office visits or annual participant questionnaires. The study is currently in year 7 and follow-up will continue through 10 years or until the National Breast Implant Registry opens for data collection, whichever occurs first.

As in the original protocol, there will be no concurrent controls needed as a source of comparison for secondary procedures/reoperations (see local complications category in original study design Tables 1 and 2). Thus, saline implant participants will not have data collected under this amended protocol.

Mentor will employ third party study entities that will be responsible for the following: (1) collecting data from surgeons; (2) entering data into and administering the study database; (3) generating follow-up reports as well as datasets; (4) meeting with Mentor on a regular basis; and (5) analyzing the study data. Mentor will be responsible for: (1) IRB approval; (2) monitoring third party entities; (3) analyzing the study data; and (4) periodic reporting to FDA.

The postapproval study was originally designed as follows:

> *MemoryGel™ PAS uses a current cohort design of the first 41,900 women receiving Mentor's MemoryGel implants, with 10 years of follow-up. It will include augmentation, reconstruction, and revision patients, each in their naturally occurring proportions at participating study sites.*
>
> *For the purpose of assessing rheumatological and neurological signs and symptoms, there also will be 1,000 saline breast implant patients from the participating surgeons' practices who will serve as concurrent controls. Concurrent control participants will be enrolled by approximately 30 physicians who routinely use saline implants. These investigative sites will be selected with the objective of obtaining the desired number of controls in an appropriate time frame, e.g. roughly the same time frame as the recruitment of MemoryGel subjects. These sites are to enroll all saline subjects meeting the specified eligibility criteria until 1,000 controls are recruited into this study.*
>
> *Women will be enrolled into the postapproval study consistent with the flow chart in Figure 1. Baseline data will be collected from the participant using survey methodology. Limited data on operative characteristics will be collected from the surgeon. Follow-up data will be collected from the participant by a combination of mail, Internet, and telephone survey methodologies annually from 1–10 years, and on an interim/unscheduled basis, as needed, for key local complications and results of MRI evaluations (MemoryGel patients only), and results from rheumatological or neurological referral evaluations (MemoryGel and saline patients). Additionally, the surgeon will see the MemoryGel participants at year 1, a second time during years 4–6, a third time during years 9–10, and at unscheduled/interim visits. All local complications, including reasons for reoperation, with or without removal, and reasons for removal, reported by the participant or diagnosed by the surgeon will be recorded during these visits.*
>
> *Controls for the postapproval study, including the concurrent controls, are indicated in Table 2.*
>
> *Mentor will employ third party study entities that will be responsible for: (1) tracking participants throughout the 10-year study period; (2) collecting the baseline and follow-up questionnaire data and interim local complication forms from participants; (3) collecting data from surgeons; (4) entering data into and administering the study database; (4) generating enrollment and follow-up reports as well as datasets; (5) meeting with Mentor on a regular basis; and (6) analyzing the study data. Mentor will be responsible for: (1) physician enrollment; (2) IRB approval; (3) monitoring the third party entities; (4) study initiation; and (5) periodic reporting to FDA.*

Table 2. CONTROLS

Complication/ Condition/ Disease	***Control***
Local Complications	*None needed*
CTD	*National norms*[1]
Rheumatological Signs and Symptoms	*Concurrent control group (saline breast implant patients)*
Neurological Disease	*National norms*[2]
Neurological Signs and Symptoms	*Concurrent control group (saline breast implant patients)*
Offspring	*National norms*[3]
Reproductive	*National norms*[4]
Lactation	*National norms*[5]
Cancer	*National norms*[6]
Suicide	*National norms*[7]
Mammography	*None needed*
MRI Compliance and Results	*None needed*

[1] *The sources for the comparison data will include Mayes et al. (2003) (Mayes, M., et al. 2003. Prevalence, incidence, survival, and disease characteristics of systemic sclerosis in a large US population. Arthritis & Rheumatism 48(8):2246-55), and may also include, as appropriate, relevant historical controls such as Brinton et al. (2004) (Brinton, L.A., et al. 2004. Risk of connective tissue disorders among breast implant patients. Am. J. Epidemiol. 160(7):619-27) and/or other reliable and relevant sources, including new sources that may become available during the course of this postapproval study. The sources for comparison data for fibromyalgia may include: Brinton et al. (2004), the saline implant concurrent controls, and/or other reliable and relevant sources, including new sources that may become available during the course of this postapproval study.*

[2] *The sources for the comparison data may include, as appropriate, relevant historical controls for each disease, such as Brinton et al. (2004) and Hennekens et al. (1996) (Hennekens, C.H., et al. 1996. Self-reported breast implants and connective-tissue diseases in female health professionals. A retrospective cohort study. JAMA. 275(8):616-21), and/or other reliable and relevant sources, including new sources that may become available during the course of this postapproval study.*

[3] *The sources for the comparison data may include, as appropriate, relevant historical controls such as the Centers for Disease Control's Pregnancy Risk Assessment Monitoring System (PRAMS), Center for Disease Control's Vital and Health Statistics, National Birth Defects Prevention Network, the California Birth Defects Monitoring Registry, the National Institutes of Health's (NIH's) First and Second Trimester Evaluation of Risk for Aneuploidy (FASTER) Trial, National Health and Nutrition Examination Survey (NHANES), and /or other reliable and relevant sources, including new sources that may become available during the course of this postapproval study, such as the National Children's Study.*

[4] *The sources for the comparison data may include, as appropriate, relevant historical controls such as Centers for Disease Control, National Survey of Family Growth, Centers for Disease Control Vital and Health Statistics, National Birth Defects Prevention Network, NIH's FASTER Trial, and/or other reliable and relevant sources, including new sources that may become available during the course of this postapproval study.*

[5] *The sources for the comparison data may include, as appropriate, relevant historical controls such as the CDC's Pregnancy Risk Assessment Monitoring System (PRAMS) and /or other reliable and relevant sources, including new sources that may become available during the course of this postapproval study.*

[6] *The sources for the comparison data may include, as appropriate, relevant historical controls such as Surveillance Epidemiology and End Results (SEER), Brinton et al. (2000, 2001) (Brinton, L.A., et al. 2000. Breast cancer following augmentation mammoplasty (United States). Cancer Causes Control. 11(9):819-27. J. Long Term Eff. Med. Implants. 12(4):271-9; Brinton, LA., et al. 2001. Cancer risk at sites other than the breast following augmentation mammoplasty. Ann. Epidemiol. 11:248-56), Deapen et al. 1997 (Deapen, D.M., et al. 1997. Are breast implants anticarcinogenic? A 14-year follow-up of the Los Angeles study. Plast. Reconstr. Surg. 99:1346-1353), and /or other reliable and relevant sources, including new sources that may become available during the course of this postapproval study.*

[7] *The sources for the comparison data may include, as appropriate, relevant historical controls such as National Violent Death Reporting System, U.S. Census data (2002), Brinton et al. (2001, 2006) (Brinton,*

L.A., et al. 2001. Mortality among augmentation mammoplasty patients. Epidemiol. 12(3):321-6; Brinton, L.A., et al. 2006. Mortality rates among augmentation mammoplasty patients: an update. Epidemiol. 17(2):162-9) and/or other reliable and relevant sources, including new sources that may become available during the course of this postapproval study.

4.0 PARTICIPANT POPULATION

Study enrollment has been closed since 15 Oct 2008 and no new study participants will be enrolled. Approximately 1,700 centers participated in the study and enrollment included 41,451 MemoryGel participants and 1,039 saline participants. As of the last annual study report (dated Nov 2013), the follow-up rates through six years were 21.8% for MemoryGel participants and 15.0% for saline participants.

The postapproval study was originally designed with the following eligibility criteria:

Eligibility Criteria: MemoryGel Breast Implant Participants

Inclusion Criteria

To be included in the study, each MemoryGel participant must be a woman who:

1. *Is a candidate for breast augmentation with Mentor MemoryGel breast implants and is at least 22 years old (primary or revision)[1]* ***OR*** *is a candidate for breast reconstruction (primary or revision)[2] with Mentor MemoryGel breast implants*
2. *Signs an Acknowledgement of Informed Decision from the patient brochure*
3. *Signs an Informed Consent Form and an Authorization to Disclose Health Information and Release Medical Records*
4. *Completes the baseline questionnaire (as evidenced by the participant's signature on the last page of the questionnaire).*
5. *Agrees to authorize return of the device(s) to Mentor if the device is explanted*
6. *Agrees via Informed Consent to comply with study follow-up, including full participation in all follow-up questionnaires and responding to questionnaires in their entirety*
7. *Is a U.S. resident*

Exclusion Criteria

Consistent with the labeling, a woman is not eligible to receive Mentor MemoryGel implants and enroll in the postapproval study if she meets any of the following exclusion criteria:

1. *Has active infection anywhere in her body.*
2. *Has existing breast cancer or pre-cancer of the breast without adequate treatment for those conditions.*
3. *Is currently pregnant or nursing.*

Eligibility Criteria: Saline Breast Implant Control Participants

Inclusion Criteria

To be included in the study, each saline control participant must be a woman who:

1. *Is a candidate for breast augmentation and is at least 18 years old (primary or revision)* ***OR*** *is a candidate for breast reconstruction (primary or revision) with saline breast implants.*
2. *Signs an Informed Consent Form and an Authorization to Disclose Health Information and Release Medical Records*
3. *Completes the baseline questionnaire (as evidenced by the participant's signature on the last page of the questionnaire).*
4. *Agrees to authorize return of the device(s) to Mentor if they are Mentor devices.*
5. *Agrees via Informed Consent to comply with study follow-up, including full participation in all follow-up questionnaires and responding to questionnaires in their entirety*
6. *Is a U.S. resident*

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[1] Breast augmentation includes primary breast augmentation to increase the breast size, as well as revision surgery to correct or improve the result of an original primary breast augmentation surgery.

[2] 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 includes revision surgery to correct or improve the result of an original primary breast reconstruction surgery.

Exclusion Criteria

A woman is not eligible to enroll in the postapproval study as a saline control participant if she meets any of the following exclusion criteria:

1. *Has current or past, unilateral or bilateral, silicone breast implants*
2. *Has active infection anywhere in her body*
3. *Has existing breast cancer or pre-cancer of the breast without adequate treatment for those conditions*
4. *Is currently pregnant or nursing*

Documentation of Non-Enrollment

There may be circumstances where a participant meets all of the eligibility criteria, but ends up not enrolling in the MemoryGel™ PAS. To understand why this may occur there are two forms to document these reasons:

1. *Non-Enrollment Form*
2. *Non-Participation Form*

Non-Enrollment Form

*The Non-Enrollment Form is used when a patient has **begun the enrollment process** and decides not to enroll (due to diagnosis of excluded condition, personal reasons, etc.); or the physician believes that the patient should not be enrolled (e.g., due to an ongoing clinical diagnosis of depression or other mental health disorder).*

Non-Participation Form

The Non-Participation Form should be used after a patient has been counseled and educated about their choices in seeking MemoryGel™ implants, has not begun the MGPAS enrollment process, and declines to participate in MemoryGel™ PAS.

5.0 POSTAPPROVAL STUDY EVALUATIONS

PHYSICIAN AGREEMENT

As a condition to receiving Mentor's MemoryGel Silicone Gel-filled Breast Implants, surgeons were required to participate as a site in the postapproval study. Participating physicians were required to sign a Physician Agreement indicating that they would adhere to the MemoryGel™ PAS study protocol. As part of the Agreement, which will continue to apply under this protocol amendment, the physician committed to:

- confirm that any necessary IRB approval (national or local) has been obtained;
- review and become thoroughly familiar with the study protocol;
- answer all the participant's questions about her role in MemoryGel™ PAS;
- adhere to the study protocol;
- ensure that the surgeon's staff understands and will adhere to the study protocol;
- assist MemoryGel™ PAS participants in identifying an MRI facility with a dedicated breast coil and sufficiently strong magnets (at least 1.5 Tesla); and
- comply with Mentor's procedures regarding return of explanted MemoryGel devices.

The postapproval study Agreement originally included the following additional physician commitments that were specific to enrollment, office visits, and annual questionnaires:

- *counsel and educate women seeking MemoryGel™ implants about their choices, and encourage them to enroll in the MemoryGel™ PAS to assist Mentor Corporation to comply with post-approval conditions, and explain how their participation will contribute to furthering the scientific data collected on silicone breast implants, and counsel them about their voluntary participation in MemoryGel™ PAS;*
- *identify saline implant control implant participants according to the study protocol and randomization schedule and counsel them about their voluntary participation in MemoryGel™ PAS;*
- *ensure Informed Consent and Authorization to Disclose Health Information and Release Medical Records are completed prior to implantation of MemoryGel or saline implants;*

- *ensure that all enrollment documents as required by the protocol, are sent promptly to the third party study entity identified on the Business Return Envelopes provided to the surgeon;*
- *complete an Operative form for each study participant and return the form promptly to the third party study entity on the Business Return Envelopes provided to the surgeon (control participants will receive standard of care, not recorded as part of this protocol.);*
- *see each MemoryGel participant at Year 1, a second time during Years 4-6, a third time during Years 9-10, and also for unscheduled/interim visits to record all local complications and reasons for reoperation, with or without removal, and reasons for removal (control participants will receive standard of care, not recorded as part of the study.);*
- *assist MemoryGel™ PAS participants in identifying a board-certified rheumatologist and/or neurologist as appropriate;*
- *provide ongoing encouragement and communication to participants regarding completion of annual questionnaires through 10 years*

STUDY EVALUATIONS

This protocol amendment includes the following evaluations:

Evaluation	**Evaluator**
Unscheduled/interim reporting of secondary procedures/reoperations*	Surgeon

*MemoryGel participants only

Surgeon evaluations are being done to record reoperation procedure information and reasons for reoperation, with or without removal, for the MemoryGel participants only. These data were also recorded under the original protocol. A flow chart of the postapproval study process is depicted in Figures 1 and 2 (gray highlights show completed actions). All data will be forwarded to a third party study entity that will be responsible for administering the study database and analyzing the study data.

The postapproval study originally included the following evaluations:

Evaluation	***Evaluator***
Baseline questionnaire (preoperative)	*Participant*
Operative procedure	*Surgeon*
Follow-up questionnaire annually, 1-10 years	*Participant*
Unscheduled/interim reporting of key local complications and results of MRI evaluations	*Participant**
Unscheduled/interim reporting of results from rheumatological or neurological referral evaluations	*Participant*
1 visit in Year 1	*Surgeon**
1 visit in Years 4-6	*Surgeon**
1 visit in Years 9-10	*Surgeon**
Unscheduled/Interim visits	*Surgeon**
Questionnaire at time of any participant discontinuation (when possible)	*Participant***

**MemoryGel participants only*
***In addition, the third party study entity will complete a Discontinuation Form documenting the date and reasons for discontinuation*

Surgeon evaluations are being done to record all local complications (including reasons for reoperation, with or without removal, and reasons for removal) for the MemoryGel participants only.
Because of the mobility and general good health of participants who will be receiving MemoryGel implants, Mentor will encourage the appropriate medical societies to host Internet-available listings of surgeons who are available to perform follow-up evaluations of any MemoryGel participant in the postapproval study.
A flow chart of the postapproval study process is depicted in Figures 1 and 2. All participant and surgeon data will be forwarded to a third party study entity that will be responsible for administering the study database and analyzing the study data

Figure 1
PROTOCOL AMENDMENT 2 POST APPROVAL STUDY PROCESS FLOW CHART: MEMORYGEL PARTICIPANTS

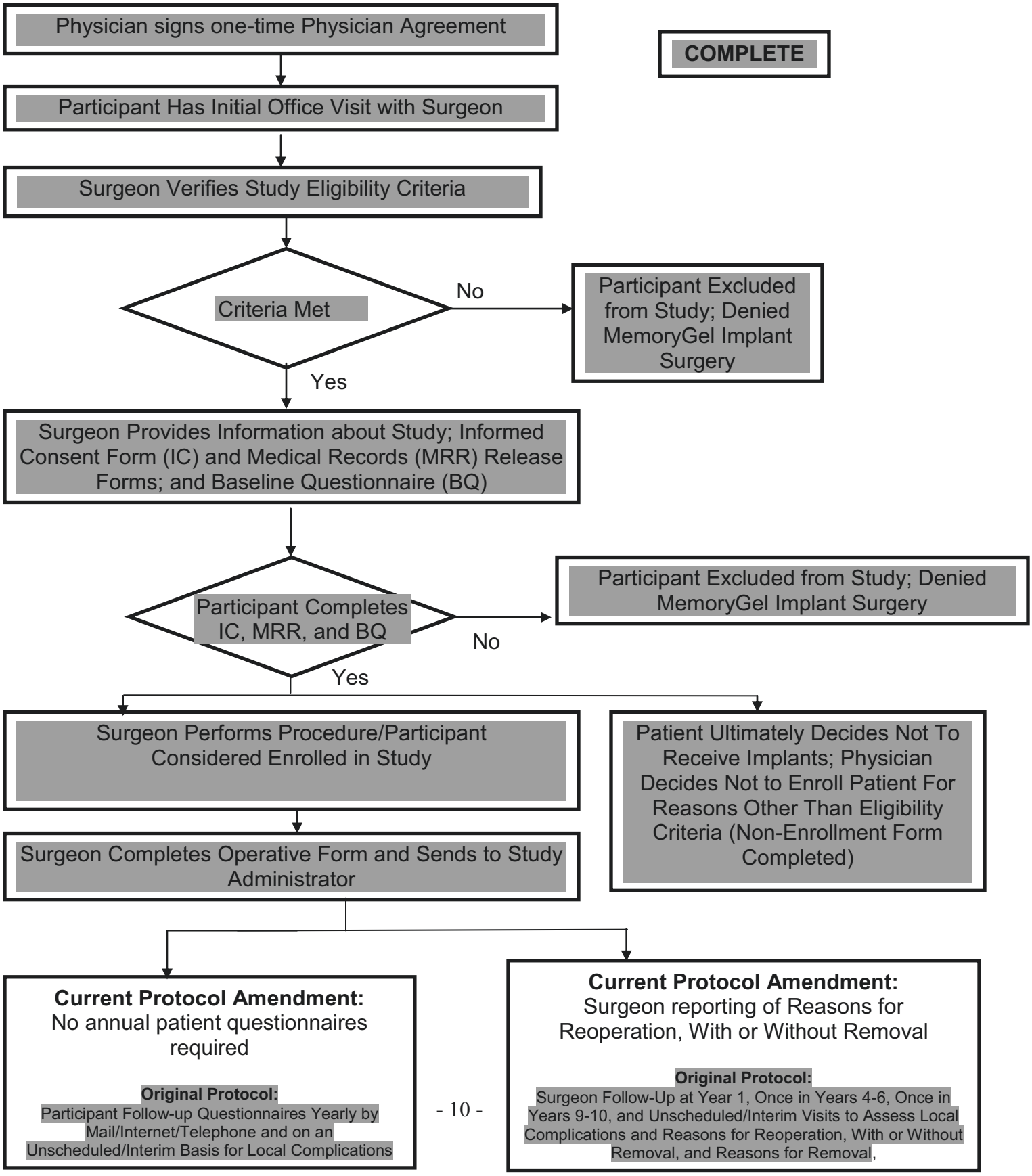
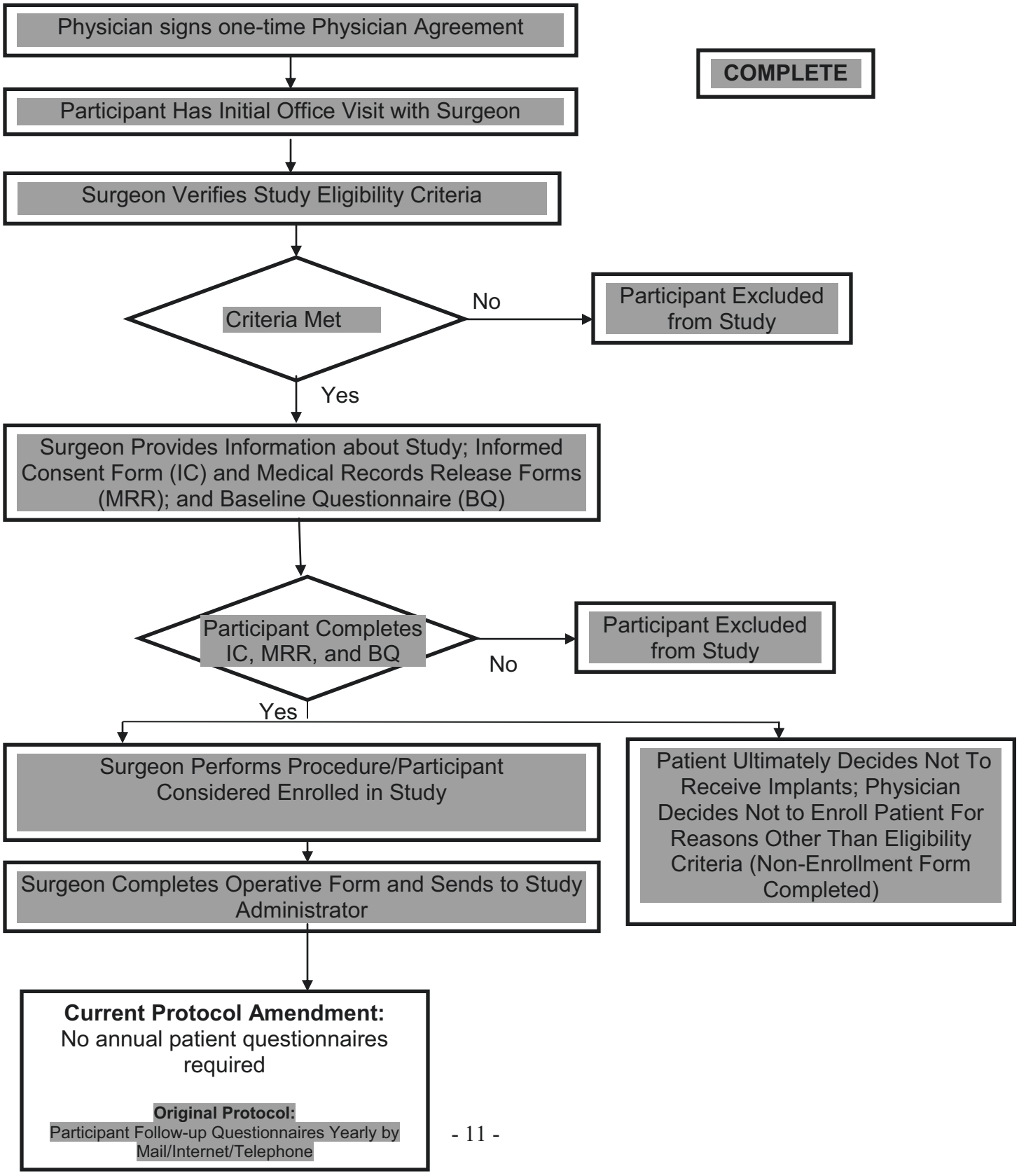


Figure 2
PROTOCOL AMENDMENT 2 POST APPROVAL STUDY PROCESS FLOW CHART: SALINE CONTROL PARTICIPANTS



5.1 Participant Follow-up

The study is currently in year 7 and follow-up will continue through 10 years or until the National Breast Implant Registry opens for data collection, whichever occurs first. At each follow-up contact, the following data will be collected:

- Updated participant and physician contact information
- Updated patient medical history
- Explantation and reoperation information
- Reasons for reoperation, with or without removal.

The surgeon/investigative site will submit the completed data collection forms via Internet or mail to a third party entity for entry into the study database

5.2 Explantation and Discontinuation

In the event a participant indicates her intention to withdraw from the study, the reason for withdrawal will be recorded. The surgeon or a third party entity will complete the Discontinuation Form provided in Section 15.

For details on the postapproval study evaluations under the original study design, including baseline, operative procedure, participant follow-up (annually, 1 to 10 years), physician follow-up, and explantations and discontinuation, see the previous protocol version (Amendment 1).

6.0 RETURNED DEVICES

Pursuant to Mentor's policies and procedures, explanted MemoryGel and Mentor saline breast implants should be returned to Mentor Product Evaluation regardless of the reason for explant. Consistent with the patient's return authorization granted at the outset of her study participation, surgeons should return the explant to Mentor, using a product return kit.

Please call 1-866-250-5115 for instructions and shipping information for return of explanted devices.

Mentor will use a good faith effort to obtain MemoryGel explanted devices if it becomes aware that explantation has occurred and the surgeon has not returned the devices. Mentor's saline breast implants, if explanted, will be handled in accordance with current standard operating procedures.

Upon receipt of the returned explant, Mentor Product Evaluation will examine the device by conducting a comprehensive investigation including visual and physical testing of the explanted device to try to determine the cause of a complaint, if any, or the condition of the device in accordance with established procedures and protocols. These analyses will be part of separate postapproval retrieval stud(ies) and/or product evaluation activities, and will not be considered part of this study.

Mentor requests that any explanted devices be sent to Mentor Worldwide, Product Evaluation Department, 3041 Skyway Circle North, Irving, TX 75038 USA for examination and analysis.

7.0 MEDICAL DEVICE REPORTING

On a routine basis, the third party entity will report to Mentor pre-specified events (e.g., death of a participant) involving MemoryGel and Mentor saline breast implants consistent with Medical Device Reporting (MDR) standards. All data, including MDR-reported data, will be part of the annual reports for the MemoryGel™ PAS.

8.0 SURVEY METHODOLOGY

There are no longer requirements for annual participant questionnaires. See the previous protocol amendment (Amendment 1) for the methodology for collecting questionnaire data for MemoryGel™ PAS.

9.0 DATA COLLECTION

This section describes the proposed data collection strategy and management plan for MemoryGel™ PAS.

Physician Evaluation Data (MemoryGel Participants Only)
MemoryGel participants will be evaluated for reasons for reoperation, with or without removal, and reasons for removal by their surgeons at unscheduled/interim visits. The physician will submit the completed complications form via Internet or mail to the third party study entity for entry into the study database.

Because of the mobility and general good health of participants who will be receiving MemoryGel implants, at the participant's request, Mentor or third party delegate will provide patients with listings of regional surgeons who may be available to perform reoperation evaluations on any MemoryGel participant in the study.

There are no longer requirements for annual participant questionnaires. See the previous protocol amendment (Amendment 1) for the survey data collection details for MemoryGel™ PAS.

9.1 Quality Assurance

The proposed MemoryGel™ PAS modes of data collection will be subject to strict quality assurance procedures.

9.2 Management

Mentor will employ a third party study entity that will develop systems and structures to effectively and efficiently manage the data collection for MemoryGel™ PAS. The third party study entity will have experience in creating, maintaining, and management of systems that ensure timely production of study data. Quality Assurance must be built into the management structure and into methods for collecting data and delivering data files with their documentation.

10.0 MEDICAL RECORDS

The postapproval study was originally designed to address the issues identified in Table 1 and, in certain circumstances (see protocol Amendment 1), medical records of MemoryGel participants were to be obtained to confirm information provided by the participant. Medical records will be not obtained under this amended protocol.

11.0 STATISTICAL CONSIDERATIONS

11.1 Statistical Analyses

This section describes the analyses to be conducted under this protocol amendment. It is important to recognize that this study is observational. As a result, data from this study can be used only to establish association, not causality, and data should be evaluated within the context of the broader composite of literature relating to the study endpoints. All of the analyses under this protocol amendment will be based on the MemoryGel participants only.

Complications/Reoperations

The cumulative incidence of key local complications (explantation, and reoperation) for women with MemoryGel implants will be estimated based on physician evaluations for the MemoryGel participants using Kaplan-Meier methodology to estimate the time to the first occurrence of the complication or reoperation. Ninety-five percent confidence intervals will be computed. In addition, the relative frequency of reasons for reoperation will be computed.

Under the original protocol, the purpose of the inclusion of the saline participants was to serve as concurrent controls for assessing rheumatologic and neurologic signs. Rheumatological and neurological data will not be collected under this protocol amendment.

Mentor will generate the following final clinical study reports for submission to FDA:

- One final report at the end of the study phase conducted under Amendment 1, including data from beginning of the study through the end of the study phase under Amendment 1. The statistical analysis will be conducted as described in the original protocol (see below).
- One final report at the end of the study phase conducted under Amendment 2, including data from the execution of Amendment 2 to the end of the study. The statistical analysis will be conducted as described above.

The original analyses conducted to address each of the postapproval study's original objectives are identified below and correspond to issues outlined in Table 1:

> *It is important to recognize that this study is observational. As a result, data from this study can be used only to establish association, not causality, and data should be evaluated within the context of the broader composite of literature relating to these issues. All of the analyses, except for the analyses of rheumatological and neurological signs and symptoms, will be based on the MemoryGel participants only.*
>
> ***CTDs, Fibromyalgia, Cancer, Neurological Diseases and Suicide***
>
> *The incidence of CTDs (by type), fibromyalgia, cancer (by type), neurological disease (by type), and suicide will each be estimated as the ratio of the number of new cases to the number of person-years of exposure (i.e., observed person-years with silicone breast implants) for MemoryGel participants only. Ninety-five percent confidence intervals will be computed. For CTDs, the incidences of scleroderma, lupus, rheumatoid arthritis, Sjögren's Disease, fibromyalgia, and other CTDs will each be estimated. For cancer, the incidences of breast, brain, lung, and other cancers will each be estimated. For neurological diseases, the incidences of MS, myositis, and other neurological diseases will each be*

estimated. In addition, Mentor will examine the prevalence of depression and anxiety. Ninety-five percent confidence intervals will be computed.

The relative risk for women with MemoryGel implants as compared to national norms will be estimated, standardizing for age, race, and other relevant characteristics, when appropriate. The relative risk will be tested for significance based on a one-sided test conducted at the 0.05 level of significance. Ninety-five percent confidence intervals will also be computed. The sources for the comparison data will include Mayes et al. (2003), and may also include, as appropriate, relevant historical controls such as Brinton et al. (2000, 2001a and b, 2004, and 2006), Hennekens et al. (1996), Deapen et al. 1997, Surveillance Epidemiology and End Results (SEER), National Violent Death Reporting System, U.S. Census data (2002), and/or other reliable and relevant sources, including new sources that may become available during the course of this study. The sources for the comparison data for fibromyalgia will include Brinton et al. 2004, the saline control participants, and/or other reliable and relevant sources, including new sources that may become available during the course of this study.

The baseline questionnaire, as well as the follow-up questionnaire, includes recommendations to all participants to see a rheumatologist or neurologist when the participant indicates she is experiencing certain combinations of signs and symptoms. At baseline, a participant will be advised to see a rheumatologist or neurologist if she identifies certain trigger signs and symptoms as specified in the questionnaire. If a participant does not choose to wait until her specialist evaluation before receiving implants, like all participants, she will be followed for the duration of the study, regardless of what the finding is.

Offspring

Through the course of the 10-year study, the incidence of birth defects/congenital malformations (total, and individual defects where appropriate national norms are, or will become, available), premature birth, low birth weight, and neonatal intensive care among women with MemoryGel implants will be estimated simply as the ratio of the number of offspring with these conditions to the total number of offspring of MemoryGel study participants. Ninety-five percent confidence intervals will be computed. The incidence of chronic illnesses (such as autoimmune disorders, cancer, and neurological disease), among children born to study participants after implantation of MemoryGel implants will be estimated as the ratio of number of new cases to the number of person-years. Ninety-five percent confidence intervals will be computed.

The relative risk for women with MemoryGel implants as compared to national norms will be estimated, standardizing for age, race, and other relevant characteristics of the mother, when appropriate. The relative risks will be tested for significance using one-sided tests conducted at the 0.05 level of significance. Ninety-five percent confidence intervals will be computed. The sources for the comparison data may include, as appropriate, relevant historical controls such as National Birth Defects Prevention Network, PRAMS, FASTER trial, the California Birth Defects Monitoring Registry, National Health and Nutrition Examination Survey (NHANES), and/or other reliable and relevant sources, including new sources that may become available during the course of this postapproval study, such as the National Children's Study.

Complications/Reoperations

The cumulative incidence of key local complications (breast pain, infection, rupture, capsular contracture (Baker grades I-IV), explantation, and reoperation) for women with MemoryGel implants will be estimated based on the annual questionnaires as well as the three physician evaluations for the MemoryGel participants using Kaplan-Meier methodology to estimate the time to the first occurrence of the complication or reoperation. Ninety-five percent confidence intervals will be computed. In addition, the relative frequency of reasons for reoperation will be computed.

Reproductive

Incidence of reproductive outcomes (miscarriage and stillbirth) will be estimated as the ratio of the number of women with these outcomes to the total number of pregnancies among MemoryGel participants. The relative risks will be tested for significance using one-sided tests conducted at the 0.05 level of significance. Ninety-five percent confidence intervals will be computed.

The relative risk of reproductive difficulties for women with MemoryGel implants compared to national norms will be estimated, standardizing for age, race, and other relevant characteristics of the mother, when appropriate. The sources for the comparison data may include, as appropriate, relevant historical controls as Burkman et al. (2003), Centers for Disease Control National Survey of Family Growth, Centers for Disease Control Vital and Health Statistics, National Birth Defects Prevention Network, FASTER trial, and/or other reliable and relevant sources, including new sources that may become available during the course of this study.

Lactation

The rate at which women with MemoryGel breast implants are able to breast feed will be examined. For each MemoryGel participant who gives birth during the 10-year study period, the proportion of births for which she is able to breast feed successfully among all births for which she desires to breast feed will be calculated. This proportion will be averaged across MemoryGel participants.

The relative risk of lactation difficulties for women with MemoryGel implants as compared to national norms or other similar women without these implants (e.g., other plastic surgery controls, if available) will be estimated, standardizing for age, race, and other relevant characteristics of the mother, when appropriate. The sources for the comparison data may include, as appropriate, relevant historical controls such as PRAMS, and/or other reliable and relevant sources, including new sources that may become available during the course of this postapproval study.

In addition, the relative frequencies of various types of lactation difficulties will be calculated.

Mammography

The issue of mammography as a potential cause of ruptures will be analyzed using a Cox proportional hazards model of time to rupture with number of mammograms as a time varying covariate. In this model, all ruptures, both symptomatic and silent (identified by MRI), will be included. The number of mammograms will include mammography where a patient has been recalled for re-imaging. The coefficient of the time varying covariate will provide an estimate of the effect, if any, on risk of rupture of each mammogram. By collecting information on the timing of mammography and information concerning the stage of breast cancer upon first diagnosis, an analysis of any potential interference issues also will be performed.

MRIs

The frequency with which women with MemoryGel implants undergo MRI screening will be examined in three ways. First, the time to first MRI will be examined using the method of Kaplan-Meier. Similarly, the time to second MRI following the first MRI will be examined using the Kaplan-Meier method. Finally, the overall frequency of MRIs will be examined by computation of the ratio of the number of MRIs to the total number of person-years with MemoryGel implants.

MRI findings will be utilized in the analysis of overall rupture rates (including both symptomatic ruptures and "silent ruptures" detected by MRI) over time). These data will be analyzed using the method of Kaplan-Meier. In this analysis, both symptomatic ruptures and silent ruptures detected by MRI will be considered ruptures, except that implants with symptomatic and silent ruptures which are explanted and determined on physical examination by Mentor not to have been ruptured will be considered to be intact.

Rheumatological and Neurological Signs and Symptoms

In contrast to all of the above analyses, this analysis will be based on both the MemoryGel participants and the concurrent saline controls. The study will collect information on rheumatological and neurological signs and symptoms.

For each individual rheumatological and neurological sign and symptom, the rheumatological categories for persistent fatigue, combined pain, and fibromyalgia-like symptoms, and the combined neurological categories for central nervous system-related, peripheral nervous system-related, and muscle-related signs and symptoms, the post-baseline prevalence will be estimated for each participant as the proportion of post-baseline contacts in which the participant reports the sign or symptom to be present at the time of the contact. These proportions will be averaged across MemoryGel participants and averaged across the controls. For all of the above, except the individual signs and symptoms, the proportions for the control participants will be compared to the corresponding proportions for the approximately 10,000 MemoryGel participants with whom they are concurrent. Regression analyses will be used to adjust for differences in age, race, and other relevant patient characteristics. The significance of the difference between the two will be tested for significance using a one-sided test conducted at the 0.05 level of significance. These means will be compared using a test based on the normal approximation. In addition, 95% confidence intervals for the estimated prevalences will be computed.

These analyses will be performed for the following rheumatological signs and symptoms categories:

- *Persistent fatigue*
- *Combined pain*
  - *persistent non-traumatic joint pain (more than 3 months),* ***OR***
  - *persistent muscle pain (more than 3 months),* ***OR***
  - *pain in taking a deep breath for more than a few days (pleurisy)*
- *Fibromyalgia-like symptoms*[3]
  - *VAS fatigue scale ≥6* ***AND***
  - *Regional pain scale (RPS)-derived body pain questionnaire ≥8*

Additionally, these analyses will be performed for the following combined neurological categories:

- *Central nervous system (CNS)-related*
  - *persistent memory problems and difficulty concentrating on simple tasks, such as reading or television lasting at least 3 months,* ***OR***
  - *seizure, convulsion, or fit* ***OR***
  - *episode of sudden visual loss or double vision,* ***OR***
  - *persistent or recurrent dizziness,* ***OR***
  - *sudden onset loss of bowel or bladder or urine retention),* ***OR***
  - *difficulty with balance* ***OR***
  - *new difficulty walking not associated with arthritis,* ***OR***
  - *persistent or recurrent tingling or numbness lasting at least several weeks,* ***OR***
  - *persistent weakness in muscles lasting at least several weeks*
- *Peripheral nervous-system-related*
  - *difficulty with balance* ***OR***
  - *new difficulty walking not associated with arthritis,* ***OR***
  - *persistent or recurrent tingling or numbness,* ***OR***
  - *persistent weakness in muscles lasting at least several weeks*
- *Muscle-related*
  - *difficulty with balance* ***OR***
  - *new difficulty walking not associated with arthritis,* ***OR***
  - *persistent weakness in muscles lasting at least several weeks,* ***OR***
  - *jaw weakness leading to difficulty chewing,* ***OR***
  - *difficulty swallowing; frequent muscle cramps*

[3] Fibromyalgia-type symptoms will be assessed using a validated survey instrument employing a combination of a VAS fatigue scale and a regional pain scale (RPS)-derived body pain questionnaire. Details of the methodology are provided in Katz, Wolfe, and Michaud (2006) (Katz, R.S., F. Wolfe, and K. Michaud. 2006. Fibromyalgia diagnosis: a comparison of clinical, survey, and American College of Rheumatology criteria. *Arthritis Rheum.* 54(1):169-176), Wolfe (2003) (Wolfe, F. 1003. Pain extent and diagnosis: development and validation of the regional pain scale in 12,779 patients with rheumatic disease. *j. Rheumatol*. 30(2):369-378), and Wolfe (2003) (Wolfe, F. 2003. Fatigue assessments in rheumatoid arthirits: Comparative performance of Visual Analog Scales and longer fatigue questionnaires in 7760 patients. *J. Rheumatol.*31:1896-902). This protocol relies on the VAS fatigue scale and RPS-derived body pain questionnaire items that are used by Dr. Wolfe.

11.2 Sample Size Determination

Study enrollment has been closed since 15 Oct 2008 and no new study participants will be enrolled.

The sample size for the postapproval study originally was determined in the following manner:

It is assumed that it is required to have 80% power to be able to detect as statistically significant a relative risk of 2.0 for adverse events that occur, without implants, with a frequency of 2.85 per 100,000. This figure is based on the incidence of scleroderma as reported by Mayes et al. (2003). It is assumed this would be based on a one-sided test conducted at the $\alpha = 0.05$ level of significance. Based on these specifications, it was determined that approximately 338,000 person-years would be required.

Patients are to be followed for 10 years. For purposes of sample size calculation, assuming a follow-up rate of 65% at 10 years and a linear loss to follow-up, there would be an average of 8.075 person-years per participant. Thus, in order to obtain the 338,000 person-years, a total of 41,900 MemoryGel participants would be required.

The concurrent control sample size was selected in order to be able to detect a relative risk of 2.0 for MemoryGel participants as compared to control participants, for rheumatologic and neurologic signs and symptoms with a prevalence of approximately 2% among MemoryGel participants. It is assumed this would be based on a one-sided test conducted at the 0.05 level of significance with a power of 80%. Similar combined rheumatologic categories of signs and symptoms from Mentor's existing Core Study of these silicone gel implants all have estimated prevalence of at least 2% after year 2. These data will be analyzed by first computing, for each participant, the proportion of time points in which the participant reports the sign or symptom as being prevalent and then calculating the mean of these participant-level proportions across participants within each group. For purposes of sample size calculation, it is assumed that these means will be compared using a simple test based on the normal approximation.

Given an expected 65% follow-up rate at 10 years, it is assumed participants will have reports, on average, at 8 time points. The correlation between different reporting time points for an individual participant is taken into account. From Mentor's existing Core Study of silicone gel-filled breast implants, for the three combined categories of signs and symptoms correlations between time points that are 1 year apart range from 0.47 to 0.59, and correlations between time points that are 2 years apart range from 0.35 to 0.41. As expected, the correlations decrease with distance between time points. On average, considering all pairs of time points and ignoring loss to follow-up, time points will be 3.7 years apart. (For example, years 1 and 3 are 2 years apart and years 1 and 10 are 9 years apart.) Thus, it is assumed that the correlation, on average, would not be higher than 0.30. Based on the above, it was determined that a sample size of 1,000 concurrent controls would be more than sufficient.

12.0 INSTITUTIONAL REVIEW BOARD APPROVAL

National or local IRB approval will be required for each site. If local IRB approval is needed then a copy of that approval should be forwarded to Mentor.

13.0 INFORMED CONSENT AND AUTHORIZATION OF MEDICAL RECORDS RELEASE

Active study participants will not require re-consent as the currently approved informed consent will continue to be applicable for this protocol amendment. Less data collection is required under this protocol amendment as data collection is limited to secondary procedure/reoperation time points; however, the patient data to be collected were part of the original protocol. Therefore, this amendment does not require an informed consent addendum as there are no new risks or benefits to the patients for participating.

Refer to Section 14.0 for information on re-consenting of participants discontinued due to patient non-compliance.

A listing of participants and their status - active or discontinued (with reason for discontinuation) - will be provided to the investigative site when protocol amendment 2 is initiated.

The postapproval study was originally designed with the following informed consent requirements:

> *Written informed consent must be obtained from each participant prior to the participant being enrolled into this postapproval study. The Informed Consent Form (see Section 15.0) will detail the participant's obligations and rights under the study protocol. Attached to this form will be an Authorization to Disclose Health Information and Release Medical Records form, also to be signed by the participant (see Section 15.0). Both the Informed Consent Form and the Disclosure and Release Authorization address applicable privacy requirements.*
>
> *The Informed Consent and Release Authorization Forms must be signed and presented to the surgeon before the participant can be enrolled into the postapproval study. The forms will be in triplicate. The surgeon will mail the original signed forms in a Business Reply Envelope (BRE), along with the sealed envelope containing the first (baseline) questionnaire, to the third party study entity. The surgeon will keep the second copy of the informed consent and medical records release authorization for retention in the participant's records. The third copy will be kept by the participant.*
>
> *Consents and releases will be broad enough to secure permission to: access medical records required to be collected by this protocol; contact individuals that the participant has designated as a means to locate the participant; use Social Security Numbers to search proprietary databases (e.g., the National Change of Address (NCOA) database, the Social Security Death Index database, and other proprietary databases) as needed. Consents and releases will also permit participant data and information to be provided to the Food and Drug Administration (FDA), Institutional Review Boards (IRBs), and/or courts as needed. Additionally, informed consents and releases will make reference to the agreement of the participant to cooperate in allowing the third party study entity to obtain medical records required by this protocol.*

14.0 RE-CONSENTING OF PARTICIPANTS DISCONTINUED DUE TO PATIENT NON-COMPLIANCE

To maximize the collection of re-operation data, participants discontinued due to patient non-compliance prior to this protocol amendment will be offered the opportunity to re-consent and re-establish participation.

Prior to this protocol amendment, a participant was considered discontinued due to patient non-compliance when the following criteria were met:

- If, within the past three (3) years, the patient has not completed an annual follow-up questionnaire per the study protocol either on-line, by mail, or by telephone; and

- If, within the past three (3) years, a Surgeons Local Complication Form pertaining to an in-person office visit by the patient per the study protocol has not been filed by the investigating physician.

If a participant discontinued due to patient non-compliance presents for re-operation or secondary procedure they should be informed by the investigator that the protocol has been amended and there is an option to re-consent.

Participants discontinued due to patient non-compliance who wish to voluntarily reinstate participation will be provided with the IRB approved Addendum to Informed Consent for review. The investigating physician or designee will conduct the informed consent discussion. If the patient agrees to reinstate participation the Addendum to Informed Consent form will be signed and dated by both the participant and person obtaining consent.

15.0 CONFIDENTIALITY

The identity of participants enrolled in the postapproval study and the information contained in their study records will be kept confidential in accordance with this protocol and the Informed Consent and Medical Release Authorization forms.

To ensure confidentiality, each participant will be tracked via a unique participant identifier. Participant names and contact information will be stored separately from participant data. Confidentiality will be protected throughout the study period.

Although a third party study entity will have complete access to all study data, the participant's name and data will not be disclosed, except to the FDA, IRBs, or courts of law as needed. In those events, Mentor will also receive access. Also, pursuant to consents and medical records release authorizations, the participant's name (but not data) will be disclosed to the participant's physicians, as part of medical record collection required by this protocol. Additionally, the participant's Social Security number may be used to search proprietary databases (e.g., the National Change of Address (NCOA) database, the Social Security Death Index database, and other proprietary databases) as needed.

Data analyses and reports made available for review as required by the FDA and IRBs, will be reported as confidential statistical information.

Any research, presentations, and/or publications of study findings by Mentor, medical societies, or other third parties will not disclose participant names or other participant identifying information.

16.0 FORMS

Secondary Procedures/Reoperations
Discontinuation Form

MENTOR **MGPAS Amendment 2**

MGPAS Amendment 2 #085 Patient / Physician Information #001

Participant No: ☐☐☐☐☐☐☐ Site No: ☐☐☐☐ Participant Initials: ☐☐☐

REOPERATION

DataFax Code: 0 1

DATE OF CONTACT

Date of Contact: ☐☐ ☐☐☐ ☐☐☐☐
DD MMM YYYY

PATIENT INFORMATION

Name (First, MI, Last): _____

Date of Birth: ☐☐ ☐☐☐ ☐☐☐☐ *DD MMM YYYY*

Weight: ☐☐☐.☐ lb

SSN: ☐☐☐ ☐☐ ☐☐☐☐

Address: _____

City, State, Zip Code: _____

Country: ☐ US ☐ Canada

Phone Number: _____

Cell Phone Number: _____

Fax Number: _____

Email Address: _____

PHYSICIAN INFORMATION

Reporting Physician Name (First, MI, Last): _____
(Principal Investigator)

Surgical Facility Address: _____

City, State, Zip Code: _____

Phone Number: _____

Fax Number: _____

Email Address: _____

Primary Care Physician Name (First, MI, Last): _____

Address: _____

City, State, Zip Code: _____

Phone Number: _____

Fax Number: _____

Email Address: _____

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MENTOR **MGPAS Amendment 2**

MGPAS Amendment 2 #085 Reoperation (Page 1 of 3) #002

Participant No: Site No: Participant Initials:

REOPERATION

DataFax Code: 0 1

REOPERATION (Page 1 of 3)

PATIENT MEDICAL HISTORY

Breast Cancer Since Last Study Visit:

Right Breast: ☐ Yes ☐ No

Left Breast: ☐ Yes ☐ No

Breast or Chest Wall Radiotherapy Since Last Study Visit:

Right Breast: ☐ Yes ☐ No

Left Breast: ☐ Yes ☐ No

Medical Problems Since Last Study Visit: ☐ Yes ☐ No

If YES, mark all that apply:

- ☐ Diabetes
- ☐ Thyroid Disease
- ☐ Liver Disease
- ☐ Renal Disease
- ☐ Cardiac Disease
- ☐ Hypertension
- ☐ Other, specify: _____

REOPERATION

Date of Reoperation: DD MMM YYYY

Operation:

Right:	Left:
☐	☐ None
☐	☐ Replacement
☐	☐ Explant Only
☐	☐ Capsulectomy Only
☐	☐ Other, specify: _____

Capsulectomy:

Right:	Left:
☐	☐ None
☐	☐ Full Capsulectomy
☐	☐ Partial Capsulectomy

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MENTOR MGPAS Amendment 2

MGPAS Amendment 2 #085 Reoperation (Page 2 of 3) #003

Participant No: Site No: Participant Initials:

REOPERATION

DataFax Code: 01

REOPERATION (Page 2 of 3)

ADDITIONAL PROCEDURE INFORMATION - RIGHT

Drains used? ☐ Yes ☐ No ☐ Unknown

If YES, was closed suction used? ☐ Yes ☐ No

Acellular Dermal Matrix (ADM) used (ex. Collagen-mesh, etc.)? ☐ Yes ☐ No ☐ Unknown

Type, if known (human, porcine, bovine, synthetic, etc.): _____

Brand Name: _____

Were any other implantable devices or products implanted at this surgery? ☐ Yes ☐ No ☐ Unknown

Type, if known: _____

Was fat grafting performed during this procedure? ☐ Yes ☐ No ☐ Unknown

ADDITIONAL PROCEDURE INFORMATION - LEFT

Drains used? ☐ Yes ☐ No ☐ Unknown

If YES, was closed suction used? ☐ Yes ☐ No

Acellular Dermal Matrix (ADM) used (ex. Collagen-mesh, etc.)? ☐ Yes ☐ No ☐ Unknown

Type, if known (human, porcine, bovine, synthetic, etc.): _____

Brand Name: _____

Were any other implantable devices or products implanted at this surgery? ☐ Yes ☐ No ☐ Unknown

Type, if known: _____

Was fat grafting performed during this procedure? ☐ Yes ☐ No ☐ Unknown

REPLACEMENT DEVICE INFORMATION

Right:	Left:		
☐	☐	None	
☐	☐	Mentor MemoryGel	
☐	☐	Mentor MemoryShape	
☐	☐	Mentor Saline, cc: _____	Manufacturer:
☐	☐	Other silicone gel breast implant	_____
☐	☐	Other saline breast implant, cc: _____	_____

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MENTOR **MGPAS Amendment 2**

MGPAS Amendment 2 #085 Reoperation (Page 3 of 3) #004

Participant No: ☐☐☐☐☐☐☐ Site No: ☐☐☐☐ Participant Initials: ☐☐☐

REOPERATION

DataFax Code: 01

REOPERATION (Page 3 of 3)

RIGHT		LEFT		
Mark ALL that apply	Mark ONE primary	Mark ALL that apply	Mark ONE primary	
☐		☐		Not Done/Not Applicable

REASON FOR REOPERATION (Complication):

☐	☐	☐	☐	Capsular Contracture, mark one Baker Grade: ☐ Grade II ☐ Grade III ☐ Grade IV
☐	☐	☐	☐	Extracapsular Extravasation
☐	☐	☐	☐	Hematoma
☐	☐	☐	☐	Infection
☐	☐	☐	☐	Ptosis
☐	☐	☐	☐	Seroma
☐	☐	☐	☐	Skin Necrosis
☐	☐	☐	☐	Wound Problems
☐	☐	☐	☐	Wrinkling/Rippling

REASON FOR REOPERATION (Device Maintenance):

☐	☐	☐	☐ Correction of Asymmetry
☐	☐	☐	☐ Device Migration
☐	☐	☐	☐ Implant Malposition
☐	☐	☐	☐ Suspected Rupture/Deflation

REASON FOR REOPERATION (Patient Request/Other):

☐	☐	☐	☐ Patient wishes change in shape/size/style
☐	☐	☐	☐ Need for Biopsy
☐	☐	☐	☐ Staged Reconstruction
☐	☐	☐	☐ Tumor
☐	☐	☐	☐ Other, specify: _____

_____ Date: ☐☐ ☐☐☐ ☐☐☐☐

Reporting Physician (Principal Investigator) Signature DD MMM YYYY

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MENTOR **MGPAS Amendment 2**

MGPAS Amendment 2 #085 Discontinuation #099

Participant No: ☐☐☐☐☐☐☐ Site No: ☐☐☐☐ Participant Initials: ☐☐☐

DISCONTINUATION

Date of Discontinuation:

☐☐ ☐☐☐ ☐☐☐☐
DD *MMM* *YYYY*

Reason for Discontinuation: *(Mark one only)*

- ☐ Completed 10-year study
- ☐ Consent withdrawn
- ☐ Lost to follow-up
- ☐ Death, cause of Death: _____
- ☐ Other, specify: _____

_____ Date: ☐☐ ☐☐☐ ☐☐☐☐
Principal Investigator's Signature *DD* *MMM* *YYYY*

_____
Principal Investigator's Printed Name