

Informed Consent

Participation as a Research Subject in the “Study of the Safety and Effectiveness of the Mentor Round Low-Bleed Silicone Gel-filled Mammary Prosthesis in Women Undergoing Primary Breast Augmentation, Reconstruction or Revision (Core Gel Study)”

Sponsor: Mentor, 201 Mentor Drive, Santa Barbara, CA 93111 USA

Patient: _____ Study ID: _____

Principal Investigator: _____

1. PURPOSE AND BACKGROUND OF THIS STUDY

You are being asked to take part in a research study of breast implants. This study is sponsored by Mentor, a manufacturer of plastic surgery products. The purpose of this study is to determine the safety and effectiveness of the smooth and textured surface Mentor Round Low-Bleed Silicone Gel-filled Mammary Prosthesis in women who are undergoing primary breast augmentation, primary breast reconstruction or revision. For example, safety information on the rate of capsular contracture, rupture, and infection will be collected, and used to help determine device safety. These implants are investigational devices. This Consent form gives you information about your breast implant procedure and your participation in this study. Your signature verifies that you have read this document and received a copy.

Approximately 1000 patients at centers across the United States will be enrolled in this research study. These patients will be implanted with silicone breast prostheses and monitored for 10 years to collect information on risks associated with the implant surgery as well as changes in the way these patients feel about themselves.

Breast implants have been used in nearly two million women since the early 1960s. There are known risks and potential complications from having breast implants. Since 1992 the Food and Drug Administration (FDA) has allowed limited silicone gel implants to clinical studies of breast reconstruction after mastectomy for cancer, correction of deformities, or replacement of damaged implants. The FDA has not formally approved these gel-filled breast implants as safe and effective because additional scientific evidence needs to be collected. Your participation will help answer the remaining questions.

Your participation is voluntary.

2. ELIGIBILITY REQUIREMENTS

INCLUSION CRITERIA

You will be allowed to enter the study if the following criteria are met:

- You were born female and 18 years of age or older.

- Are a candidate for one of the following:
 - Primary breast augmentation (general breast enlargement or sagging after breast feeding)
 - Primary breast reconstruction (for cancer, trauma, surgical loss of breast or congenital deformity)
 - Revision surgery (if you currently have a silicone filled implant or a saline filled implant).
- Sign the Informed Consent
- Agree to follow the procedures for explant analysis.
- Agree to comply with the follow-up procedures, including returning for all follow-up visits.

EXCLUSION CRITERIA

You will *not* be allowed to enter the study if you meet any of the following criteria:

- You are pregnant.
- Have nursed a child within three months of this study enrollment.
- Have been implanted with any silicone implant other than breast implants (e.g. silicone artificial joints or facial implants).
- Have a confirmed diagnosis of the following rheumatic diseases or syndromes: SLE, Sjogren's syndrome, scleroderma, polymyositis, or any connective tissue disorder, rheumatoid arthritis, crystalline arthritis, infectious arthritis, spondyarthropathies, any other inflammatory arthritis, osteoarthritis, fibromyalgia, or chronic fatigue syndrome.
- Currently have a condition that could increase risk or complicate wound healing (except reconstruction patients).
- Are an Augmentation patient and have a diagnosis of active cancer of any type.
- Have an infection or an accumulation of pus in a body tissue (abscess), anywhere in the body.
- Have a tissue condition that is clinically incompatible with the implant (e.g. tissue damage resulting from radiation, inadequate tissue, or compromised vascularity).
- Have any condition, or are under treatment for any condition, that your doctor determines to be an unwarranted surgical risk.
- Have a physical abnormality that could lead to significant postoperative complications.
- Have characteristics that are unrealistic/unreasonable with the risks involved with the surgical procedure.
- Have a premalignant breast disease without a subcutaneous mastectomy.
- Have untreated or inappropriately treated breast cancer, without mastectomy.
- Have an implanted metal or metal devices, history of claustrophobia, or other condition that would make a MRI scan prohibitive.

You should ask your doctor to clarify any terms you do not understand. Also, your doctor must provide a copy of this document to you.

3. DEVICE DESCRIPTION

Two types of Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses will be used in the study: the Siltex textured surface device and the smooth surface device. Each implant is a silicone elastomer (rubber) mammary device that is supplied individually packaged in a doubled wrapped packaging system, sterile, and non-pyrogenic (does not cause fever). Each device consists of a silicone shell encasing a silicone gel filler material with a patch on the posterior side of the device. The basic smooth device shell consists of a silicone layer sandwiched in between two other silicone layers. This construction acts as a barrier to slow the diffusion of (spread) any gel filler materials through the shell. The Siltex textured shell consists of a smooth shell to which is bonded an additional layer of silicone with a textured pattern imprinted into its surface. The Siltex shell is intended to prevent tissue ingrowth. The implants will be available in sizes 100cc through 800ccs.

Your plastic surgeon will discuss these implants with you and explain why a particular implant may be best suited for you.

4. SECOND OPINIONS

If any problems or complications occur during the study, you may be asked or wish to obtain second opinions. You have the right to consult a physician of your choice.

5. STUDY PROCEDURES

You will talk about your procedure and participation in this Study with your doctor, in advance, and you should take sufficient time to think about your participation. You should check with your insurance company prior to the operation, as the surgery may affect your coverage.

Your participation in this study will be for a period of ten years. You will be seen at 6 months, 1, 2, 3, 4, 5, 6, 7, 8, 9, 10 years. It is very important that you come back for **all** postoperative visits, as the information obtained from those exams is extremely important in the study of these devices.

For patients who have undergone breast implantation either as a cosmetic or a reconstructive procedure, health insurance premiums may increase, coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. Check with your insurance company regarding these coverage issues.

Baseline

If you agree to be in this research study, you will first have to be examined by your doctor to determine if you are a good candidate and if you are eligible. This screening may involve referral to other specialists. Follow-up visits to other specialists may also be required. During this visit, a medical history and physical examination will be completed.

Your doctor will ask you questions about any rheumatology diseases and symptoms you might have and you will be asked to fill out quality of life questionnaires.

Rheumatology Assessment

Your doctor will administer a rheumatic disease diagnosis questionnaire prior to your surgery. This is required to provide information about the possible relationship breast implants may have with connective tissue disorders, arthritis and rheumatic conditions. This questionnaire will be administered again at the 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 year visits after your surgery.

Quality of Life Questionnaires

You will be asked to complete Quality of Life questionnaires prior to your surgery. These are “paper and pencil” questionnaires, which will take approximately 30 minutes to complete. These are required to measure how you feel about your body before and after your breast implant procedure and are a very important part of the research. You will be asked to complete these questionnaires again at the 1, 2, 4, 6, 8, and 10 year visits after your surgery.

Description of the Operation

A surgeon using accepted standards of practice will perform your operation. The operation may be performed in a physician’s office, a hospital operating room or in an outpatient surgical center. Hospitalization may or may not be required. Your doctor will explain the particular type of implant that will be used, how and where it will be placed and the type of anesthesia to be used. He/she will also give you an overall description of the operation.

You may require surgery to correct any complications that may arise or revisions such as change in implant size that you may request.

Follow-up Visits

After your surgery, you will be asked to make visits at the following time periods after the surgery: 6 months, 1, 2, 3, 4, 5, 6, 7, 8, 9, and 10 years. Each visit will take about 60 minutes. Your doctor will perform an evaluation of the status of the implant and you will be examined for the presence of any post –surgical complications.

You are making a commitment to continue in the study for the duration and to complete all of these follow-up visits. The information obtained from these visits is important in the study of these breast implants. If you move, arrangements will be made with your doctor for follow-up with another doctor in your area.

Magnetic Resonance Imaging (MRI)

Breast implants may not last a lifetime. The shell may rupture due to wear and tear, or direct injury. Rupture should be suspected if there is a change in character of the implant such as a new, persistent burning sensation on one side or a change in softness, texture or shape of the implant and may be difficult to diagnose without surgical exploration or a magnetic resonance imaging (MRI) scan. This type of examination produces a picture of your breasts without using x-rays and is commonly used in the x-ray departments of most hospitals to detect problems in bones, lungs and all other areas of the body.

The MRI scan has been determined to be the best way to find out if your implant has ruptured without performing surgery. In order to detect a "silent rupture" (a rupture without any symptoms or visible changes), you may be in a subset of patients who will undergo an MRI scan at 1, 2, 4, 6, 8, and 10 years after your surgery. If you do, you will have to lay on your stomach with your breast in a special holder. You will then be placed in the machine, which may be open or may be like going into a tunnel. Some patients experience an uneasiness at being in a closed space. While the machine is taking images of your breast, it will make a noise. In order to have an MRI scan, you must not have any implanted metal or metal devices in your body, or a history of claustrophobia. The procedure should take about an hour. Mentor will pay for the MRI scans.

Any patient who is suspected of having a ruptured implant while in the study will be examined by her doctor and undergo an MRI scan to see if her implants are ruptured. Mentor will pay for these MRI scans.

6. IMPLANT REGISTRY

As a participant in this study you will be asked to participate in the breast implant patient registry. This will allow Mentor to notify you, if necessary, of any new information about the safety of your silicone-filled breast implant(s). Every effort will be made to keep the information in the registry confidential and that information will only be provided to the FDA upon their request. However, under certain circumstances, Congress has the right to get clinical data from the FDA or a court could order disclosure of certain information that could include your clinical study records.

Your doctor will provide you with identification information, which pertains to your implant(s) after your surgery. This will let you know what type of implant you have. This should be kept with your important papers for future reference. You should also remain in contact with your doctor to get current important information or, if you leave your doctor, you should leave a forwarding address.

7. BENEFITS OF BREAST IMPLANTS

Breast augmentation surgery is elective surgery designed to improve your appearance. Women with breast cancer have reported that breast reconstruction with mammary implants has aided in their recovery from breast cancer and has reduced emotional stress by helping to return their body to a more natural appearance.

You may benefit other women by providing information about possible health problems associated with breast implants and to help demonstrate the safety and effectiveness of the device. There are no direct additional benefits to you beyond receiving this implant.

8. RISKS AND DISCOMFORTS OF THE OPERATION

Breast surgery requires an incision. As with any surgical procedure, there are risks such as:

Infection: (severe infection on rare occasions results in Toxic Shock Syndrome or TSS). An infection can result from any surgery and produce swelling, tenderness, pain and fever. Almost all infections appear within a few days of the operation but may appear at any time after your surgery. If you get a serious infection, which doesn't go away with antibiotics, your implant may have to be removed.

Hematoma Formation: a collection of blood in the surgical area.

Seroma: (fluid accumulation around the implant which may or may not require removal). Your body will absorb both areas of fluid accumulation (seromas) and small hematomas, but large ones may have to be drained surgically to permit proper healing. Surgical techniques, under most circumstances, can minimize though not eliminate them.

Scarring: Any incision in the skin will leave a scar that is permanent. While your surgeon will use plastic surgical techniques to make this as inconspicuous as possible, some patients have a skin quality that results in more conspicuous scars no matter how the incision is repaired.

There are risks from anesthetics as well.

9. RISKS AND DISCOMFORTS OF BREAST IMPLANTS

Breast implants have certain specific risks and complications, which may include:

Capsular Contracture: The normal healing scar membrane that forms around the implant can, in some women, tighten and squeeze the implant. This can cause the implant to feel firm. This firmness can range from slight to quite hard and the firmest ones can cause varying degrees of discomfort or pain. In addition to the firmness capsular contracture can result in a misshapen breast, visible surface wrinkling and/or displacement of the implant. Detection of breast cancer by mammography may also be more difficult.

If you wish to have this contracture softened, the scar tissue can be released or removed by making an incision into the breast during an operation called an Open Capsulotomy.

Your surgeon may recommend a technique called a closed capsulotomy in which he/she will apply forceful external pressure to the breasts to "break up" the scar tissue. Mentor does not recommend this technique because it could result in several complications such as breakage of the implant, bleeding, displacement of the implant resulting in asymmetry or distortion.

Your surgeon will explain the possible complications, as well as help you determine the best method for correcting capsular contracture.

Calcification of the capsule surrounding the implant can also occur. This can contribute to the hardening of the tissue and may be painful. Sometimes it may be necessary to remove the implant and/or the calcified capsule.

Deflation/Rupture/Leakage

Breast implants **are not lifetime devices** and cannot be expected to last forever. Some implants deflate or rupture in the first few months after being implanted and some deflate after several years; others are intact 10 or more years after the surgery.

a. Silicone Gel-Filled Breast Implants – When silicone gel-filled implants rupture, some women may notice decreased breast size, nodules (hard knots), uneven appearance of the breasts, pain or tenderness, tingling, swelling, numbness, burning, or changes in sensation.

Other women may unknowingly experience a rupture without any symptoms (i.e., “silent rupture”). Magnetic resonance imaging (MRI) with equipment specifically designed for imaging the breast may be used for evaluating patients with suspected rupture or leakage of their silicone gel-filled implant.

Silicone gel which escapes the fibrotic capsule surrounding the implant may migrate away from the breast. The free silicone may cause lumps called granulomas to form in the breast or other tissues where the silicone has migrated, such as the chest wall, armpit, arm, or abdomen.

Plastic surgeons usually recommend removal of the implant if it has ruptured, even if the silicone is still enclosed within the scar tissue capsule, because the silicone gel may eventually leak into surrounding tissues. If you are considering the removal of an implant and the implantation of another one, be sure to discuss the benefits and risks with your doctor.

FDA completed a retrospective study on rupture of silicone gel-filled breast implants.¹ This study was performed in Birmingham, Alabama and included women who had their first breast implant before 1988. Women with silicone gel-filled breast implants had a MRI examination of their breasts to determine the status of their current breast implants.

The 344 women who received a MRI examination had a total of 687 implants. Of the 687 implants in the study, at least two of the three study radiologists agreed that 378 implants were ruptured (55%). This means that 69% of the 344 women had at least one ruptured breast implant. Of the 344 women, 73 (21%) had extracapsular silicone gel in one or both breasts. Factors that were associated with rupture included increasing age of the implant, the implant manufacturer, and submuscular rather than subglandular location of the implant. A summary of the findings of this study is also available on FDA’s website at <http://www.fda.gov/cdrh/breastimplants/studies/biinterview.pdf> and

¹ Brown SL, Middleton MS, Berg WA, Soo MS, Pennello G. Prevalence of rupture of silicone gel breast implants in a population of women in Birmingham, Alabama. American Journal of Roentgenology 2000; 175:1-8

<http://www.fda.gov/cdrh/breastimplants/studies/birupture.pdf>

Robinson et al. studied 300 women who had their implants for 1 to 25 years and had them removed for a variety of reasons.² Visible signs of rupture in 51% of the women studied were found. Severe silicone leakage (silicone outside the implant without visible tears or holes) was seen in another 20%. Robinson et al. also noted that the chance of rupture increases as the implant ages.

Other studies indicate that silicone may escape the capsule in 11-23% of rupture cases.^{3,4,5,6}

For the Core Gel Study, a randomly selected subset of 405 patients will undergo MRI scans at 1, 2, 4, 6, 8, and 10 years. The purpose of this substudy is to determine the rate of silent rupture. Scans will be sent to a central reading center to be read by an independent breast MRI radiologist. This radiologist will be blinded to the patient name and site. The results will be entered into the study database. All patients, whether or not they are randomized to undergo MRI scans, will be directed to see their physician whenever the patient believes a rupture has occurred.

Gel Bleed: Silicone gel is made up of a sponge like mesh filled with silicone in oil form. This oil is used in many medical products such as syringes, pills and anti-gas medications such as Mylanta. It is known that some very small amounts of the oil part of the gel “bleeds” through the implant’s covering or envelope. Although most of this stays in the implant pocket or is trapped in the surrounding scar, minute amounts of this silicone could possibly travel (migrate) to different parts of the body.

Silicone oil has not been demonstrated to cause cancer or other illnesses.

Changes in Nipple and Breast Sensation/Breast Pain: Any surgery on the breast, including a biopsy or breast implant surgery, can result in the breast and/or nipple being oversensitive or undersensitive on one or both sides. This change can vary in degree and may be temporary or permanent. It may affect comfort while nursing or sexual response.

Most women undergoing augmentation or reconstruction with a mammary prosthesis will experience some breast and/or chest pain postoperatively. While this pain normally subsides in most women as they heal after surgery, it can become a chronic problem in other women.

¹ Robinson OG, Bradley EL, Wilson DS. Analysis of explanted silicone implants: a report of 300 patients. *Ann Plast Surg* 1995; 34:1-7.

³ Vinnik CA. Migratory silicone – clinical aspects. *Silicone in Medical Devices – Conference Proceedings* 1991 February 1-2, Baltimore, MD. U.S. Department of Health and Human Services, FDA Publication No. 92-4249 (p 59-67)

⁴ Duffy MJ, Woods JE. Health risks of failed silicone gel breast implants: a 30-year clinical experience. *Plast Reconstr Surg* 1994;94:295-299

⁵ Berg WA, Caskey CI, Hamper UM, Kuhlman JE, Anderson ND, Chang BW, Sheth S, Zerhouni EA. Single- and double-lumen silicone breast implant integrity: Prospective evaluation of MR and US criteria. *Radiology* 1995;197:45-52

⁶ Gorczyca DP, Schneider E, DeBruhl ND, Foo TKF, Ahn CY, Sayre JW, Shaw WW, Bassett LW. Silicone breast implant rupture. Comparison between three-point Dixon and fast spin-echo MR imaging. *AJR* 1994;162:305-310

Chronic pain can be associated with hematoma, migration, infection, and implants that are too large or capsular contracture. Sudden severe pain may be associated with implant rupture.

Interference with Mammography in Detection of Cancer: An implant may interfere with the detection of early breast cancer because it may “hide” suspicious lesions in the breast during an x-ray examination. It is especially important for women who are at high risk of developing breast cancer to consider this before having implants. The earlier cancer is detected, the better a chance for a cure.

Regular self-examination is very important for all women but especially if you have implants. You are urged to contact the American Cancer Society for literature and instructions on the early detection of cancer.

Since the breast is compressed during mammography, it is possible, but rare, for an implant to rupture. These problems can be reduced, but not eliminated, by asking if the personnel at the facility are experienced in performing mammography on women with implants. Before the mammography exam, you should tell the technologist that you have implants. The technologist should take special care when compressing the breast to avoid rupture. Also, an experienced technologist should know how to push the implant away from the breast tissue to get the best possible views of the tissue. Even when this special technique is used, some breast tissue may be missed in the x-ray. More x-ray views are necessary with these special techniques; therefore, women with breast implants will receive more radiation. However, the benefit of the mammogram in finding cancer outweighs the risk of the additional x-rays.

Calcium Deposits: Small spots of calcium in the breast are often found in any breast and can be seen on x-rays (mammography). These deposits may not occur in breasts with implants and may not appear for years after the implant surgery. They are benign (noncancerous) and cause no problems but must be differentiated from the calcium that is often seen in breast cancers. An expert radiologist can usually tell a benign (non-cancerous) calcium spot from a malignant one but occasionally a biopsy may be necessary to make this distinction. Some patients may develop a thin layer of calcium in the scar capsule that surrounds the implant. This is almost always associated with capsular contracture but otherwise causes no known problem.

Delayed Wound Healing: In some cases, the incision site fails to heal normally.

Extrusion: Unstable or compromised tissue covering and/or interruption of wound healing may result in extrusion, which is when the breast implant comes through the skin.

Necrosis: Necrosis is the formation of dead tissue around the implant. This may prevent wound healing and require surgical correction and/or implant removal. Permanent scar deformity may occur following necrosis. Factors associated with increased necrosis include infection, use of steroids in the surgical pocket, smoking, chemotherapy/radiation, and excessive heat or cold therapy.

Breast Tissue Atrophy/Chest Wall Deformity: The pressure of the breast implant may cause the breast tissue to thin and shrink. This can occur while implants are still in place or following implant removal without replacement.

Dissatisfaction with Cosmetic Results: You may not be satisfied with the appearance of your breasts after implants. The surgeon has only limited control over the final shape which is finally determined by how your chest, your breast and the implant all fit together. Incorrect implant size, excessive scarring and misplacement of implants may interfere with satisfactory appearance. Asymmetry (unequal breast size or shape) may not be totally corrected even by different sized implants. The implanted breast may sag or droop (ptosis) over time, much like a natural breast.

In addition, breast implants will not prevent your breast(s) from sagging after pregnancy. Very rarely the implant may change position or break through the skin, particularly if you have very thin breast tissue covering it. You may be able to feel or see wrinkles in the implant through your skin.

Granulomas: These are non-cancerous lumps that can form when certain body cells surround foreign material, such as silicone. Like any lump, it should be further evaluated to distinguish it from a lump that might be cancerous and require biopsy.

Resurgery: Whether you are undergoing augmentation or reconstruction, you should understand that there is a high chance that you will need to have additional surgery at some point to replace or remove the implant. Also, problems such as rupture, capsular contracture, infection, shifting, and calcium deposits can require removal of the implants. Many women decide to have the implants replaced, but some women do not. Those who do may have cosmetically unacceptable dimpling and/or puckering of the breast following removal of the implant.

10. UNKNOWN RISKS

The long-term biological effects of silicone compounds in women have received a great deal of attention over the last 25 years. Both rupture and gel bleed may result in silicone going to other parts of the body. Concerns have included connective tissue disease, immunological and neurological disorders, and the risk of cancer.

Connective Tissue Disorders: There have been reports describing an association between certain silicone-based products and certain connective tissue disorders. These are a group of disorders in which the body reacts to its own tissue as though it was foreign material. These disorders can cause long-term, serious, disabling health problems. Symptoms may include pain and swelling of joints, tightness, redness or swelling of the skin, swollen glands or lymph nodes, unusual and unexplained fatigue, swelling of the hands and feet, and unusual hair loss. Generally, people who have these relatively rare connective tissue disorders experience a combination of these and other symptoms.

Some cases of these disorders have been reported in women with breast implants. Some of these women have reported a reduction in symptoms after their implants were removed.

Neurological Symptoms: There have been some reports of patients experiencing neurological symptoms at variable times after breast implant surgery. Some of the complaints have involved difficulties with vision, sensation, muscle strength, walking, and balance.

Cancer: There is presently no established scientific evidence that links either silicone gel-filled or saline-filled breast implants with cancer. However, the possibility cannot be ruled out.

Birth Defects: Preliminary animal studies and a study in humans show no evidence that birth defects are caused by silicone implants. However, to rule out that possibility for humans, further scientific studies are necessary to show whether or not breast implants are associated with birth defects.

Breast feeding: Many women with breast implants have nursed their babies successfully. Any breast surgery, such as breast biopsy or partial mastectomy, that removes a great deal of breast tissue, or even breast implant surgery, could theoretically interfere with your ability to nurse your baby or the amount of milk available.

In recent years there has been some question as to whether small amounts of silicone that “bleeds” from gel-filled breast implants can find its way into breast milk, and, if this were to occur, could that affect the child. If you are considering breast-feeding, you are urged to check with your doctor or the FDA’s Breast Implant Information line at (800-532-4440) for the most current information. The American Academy of Pediatrics has stated that “there is no reason why a woman with implants should refrain from nursing.”

11. ALTERNATIVE PROCEDURES TO PARTICIPATION IN THIS STUDY

You may choose not to participate in this study. There are several alternative procedures to breast augmentation with silicone gel-filled breast implants. These include having nothing done or wearing an external prosthesis inside your bra. Breasts can be made by transferring fatty tissues from other parts of the body such as the stomach, buttock or back (flap procedure). For many women, saline-filled breast implants are also an alternative.

Your doctor will discuss these and other procedures and their relative risks and benefits.

12. IMPORTANT FACTORS TO CONSIDER WHEN DECIDING TO HAVE GEL-FILLED IMPLANTS

- Whether you are undergoing augmentation or reconstruction, be aware that breast implantation may not be a one time surgery. You are likely to need additional surgery and doctor visits over the course of your life.
- Breast implants are not considered lifetime devices. You will likely undergo implant removal with or without replacement over the course of your life.

- Many of the changes to your breast following implantation are irreversible (cannot be undone). If you later choose to have your implant(s) removed, you may experience unacceptable dimpling, puckering, wrinkling, or other cosmetic changes of the breast.
- Breast implants may affect your ability to produce milk for breast feeding. Also, breast implants will not prevent your breast from sagging after pregnancy.
- With breast implants, routine screening mammography will be more difficult, and you will need to have additional views, which means more time and radiation.
- For patients who have undergone breast implantation either as a cosmetic or a reconstructive procedure, health insurance premiums may increase, coverage may be dropped, and/or future coverage may be denied. Treatment of complications may not be covered as well. You should check with your insurance company regarding these coverage issues.

Augmentation - Insurance does not cover breast augmentation and may not cover reoperation (additional surgery) and additional doctor's visits following augmentation.

Reconstruction - Most insurance covers the first breast reconstruction operation. Insurance coverage for reoperation procedures or additional doctor's visits following reconstruction may not be covered, depending on the policy.

13. COSTS/FINANCIAL INCENTIVES

All costs incurred for this surgical procedure are between you and your doctor(s), including the cost of standard visits and any additional procedures or visits to another specialist that may be required for the operation. If, during the course of the study, you exhibit signs of a rheumatological condition, you will be referred to a rheumatologist for an evaluation at Mentor's expense. Mentor will also pay for the MRI examinations if you are in the group required to undergo MRI procedures, or if you are suspected of having a ruptured implant.

Mentor will provide to you installment payments that may assist with costs incurred as a result of your participation in this Study. Incentive checks will be made out in your name and mailed directly to your home. You will be paid after the completion of the following post-operative visits:

Payment	Visit	Payment	Visit
	Implantation		5 year visit
	6 month visit		6 year visit
	12 month visit		7 year visit
	24 month visit		8 year visit
	Bonus if no visits are missed through 24 months		9 year visit
	3 year visit		10 year visit
	4 year visit		Bonus if no visits are missed through 10 years (all 11 postoperative visits)
Total incentives for all visits			
Total incentive with no missed postoperative visits			

14. COMPENSATION FOR INJURY

Compensation for physical injuries, complications or medical treatment from your participation in this study is not available from Mentor other than outlined in the attached Mentor Warranty. If your complication is related to rupture, you will be reimbursed under the warranty policy. If a problem occurs, medical treatment will continue to be available. Your doctor will let you know what to do if you experience any complications while you are in this Study.

15. CONFIDENTIALITY

Your confidentiality will be protected as much as possible throughout this study. Records generated during this study which identify you by name will be maintained as confidential, with the exception that those records, as well as your medical records, may be reviewed by authorized representatives from your doctor's office and from Mentor. In addition, authorized representatives from the U.S. Food and Drug Administration may inspect the records. Results of data collected will be reported as numbers only, no names. Under certain circumstances, your clinical records could be obtained by Congress or a court order. While every effort will be taken to keep this information confidential, under these special circumstances, this could mean public disclosure of your surgery and loss of your privacy.

16. LEGAL RISK AND ANALYSIS OF REMOVED IMPLANT

If your implant needs to be removed, Mentor requests the implant be returned to Product Evaluation to be analyzed. This could have implications in any legal action involving your implant. Mentor will ask your permission to analyze it, a process that may alter or destroy it. You will be contacted first through your doctor and asked whether you wish to give permission for such an evaluation. Results of the analysis will be made available to you, your doctor and/or the FDA upon request. Mentor and the FDA believe there is scientific benefit to testing an explanted implant

17. QUESTIONS

During the course of the study, you will be informed by your doctor regarding any new information about Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses, which may become known during the study. You also have the right to ask questions and have them answered.

For questions about your procedure and any research related injury, you should contact your doctor, Dr. _____ at () _____.

For questions regarding your participation in the Study and your rights as a research patient, please contact the local, national, or non-local independent reviewer of the research listed below:

Western Institutional Review Board (WIRB)
3535 7th Ave., NW
Olympia, Washington 98502
206-943-1410 FAX 206-943-4522

18. VOLUNTARY PARTICIPATION AND WITHDRAWAL FROM STUDY

Your participation in this Study is voluntary and your decision not to participate will not result in loss of benefits to which you are otherwise entitled; however, you will not receive Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses without being in this Study. You may drop out at any time and you will still receive all necessary medical care.

19. ACKNOWLEDGEMENT

I was provided this Informed Consent in advance and met with my doctor, to discuss the information. All my questions have been answered to my satisfaction and I have been provided a copy of this Informed Consent and the Experimental Patient's Bill of Rights (in California only).

Patient/Patient's Signature

Date

Patient/Patient's Printed Name

Signature of Person Obtaining Consent

Date

Warranty Summary for Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses

A. What Does the Warranty Cover?

The warranty covers patients' uninsured, out-of-pocket costs that are directly related to breast implant revision surgery. When the warranty applies, Mentor provides the following:

- **Free Lifetime Replacement:** Throughout a patient's lifetime Mentor will replace, at no cost, the same or a similar type of Mentor breast implant when implant replacement is required. If a more expensive product is requested, Mentor will invoice the surgeon for the price difference.
- **Financial Assistance:** For the first five years following a breast implant procedure, Mentor will provide financial assistance up to \$████, per revision surgery to help cover operating room expenses and anesthesia expenses not covered by insurance.

B. What Products are covered?

The Mentor breast implant warranty automatically applies to Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses that are implanted as part of the this Study, provided these implants have been:

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

C. What Events are Covered?

This Mentor breast implant warranty applies to rupture of any all Mentor Round Low-Bleed Silicone Gel-filled Mammary Prostheses.

Other loss-of-shell integrity events also may be covered by this warranty. A physician retained by Mentor will determine if specific, additional events should be covered. However, events listed in section D of this brochure will not be covered.

D. What Events are Not Covered?

The Mentor breast implant warranty does not cover the following:

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

E. How are Claims Filed?

To file a warranty claim for covered events, the surgeon must contact Mentor's Consumer Affairs Department.

Warranty Summary for Mentor Round Low-Bleed Silicone Gel-filled Mammary Protheses

- When necessary materials from the surgeon are received and confirmed by Mentor, replacement product(s) and/or a check will be issued to the appropriate party in accordance with Mentor's warranty.
- Prior to reimbursement for revision surgery, the surgeon must complete all forms and requested documentation about medical treatments and expenses