

## **INFORMED CONSENT - AUGMENTATION MAMMAPLASTY WITH SILICONE GEL-FILLED IMPLANTS**

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## **INFORMED CONSENT - AUGMENTATION MAMMAPLASTY WITH SILICONE GEL-FILLED IMPLANTS**

### **INSTRUCTIONS**

This is an informed-consent document that has been prepared to help inform you concerning augmentation mammoplasty surgery with silicone gel-filled implants, its risks, as well as alternative treatment(s).

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page and sign the consent for surgery as proposed by your plastic surgeon and agreed upon by you.

### **GENERAL INFORMATION**

**As of November, 2006, silicone gel-filled breast implant devices have been approved by the United States Food and Drug Administration (FDA) for use in breast augmentation and reconstruction.**

Augmentation mammoplasty is a surgical operation performed to enlarge the female breasts for a number of reasons:

- To enhance the body contour of a woman, who for personal reasons feels that her breast size is too small.
- To correct a loss in breast volume after pregnancy.
- To balance breast size, when there exists a significant difference between the size of the breasts.
- To restore breast shape after partial or total loss of the breasts for various conditions.
- To correct a failure for breast development due to a severe breast abnormality.
- To correct or improve results of existing breast implants for cosmetic or reconstructive reasons.

Breast implant surgery is contraindicated in women with untreated breast cancer or pre-malignant breast disorders, active infection anywhere in the body, or individuals who are currently pregnant or nursing.

Individuals with a weakened immune system (currently receiving chemotherapy or drugs to suppress the immune system), conditions that interfere with blood clotting or wound healing, or have reduced blood supply to the breast tissue from prior surgery or radiation therapy treatments may be at greater risk for complications and poor surgical outcome.

Silicone breast implants are approved by the FDA for use in women that are at least 22 years of age. Women that meet this age criteria may utilize the silicone implants for cosmetic breast augmentation or for revision surgery to correct or improve results of earlier cosmetic breast augmentation. There is no age restriction on breast reconstruction procedures to restore breast shape after cancer, trauma, or severe breast abnormalities.

Breast enlargement is accomplished by inserting a breast implant either behind the breast tissue, or partially or completely under the chest muscles. Incisions are made to keep scars as inconspicuous as possible, usually under the breast, around a portion of areola, or in the armpit. According to the FDA it is not recommended to use the peri-umbilical approach to insert gel-filled implants. Breast implants may be manufactured in a variety of shapes, sizes, and with either smooth or textured surfaces. The method of implant selection and size, along with surgical approach for inserting and positioning breast implants will depend on your preferences, your anatomy and your surgeon's recommendation. The shape and size of the breasts prior to surgery will influence both the recommended treatment and the final results. If the breasts are not the same size or shape before surgery, it is unlikely that they will be completely symmetrical afterward.

Conditions which involve sagging of the breast or diminished skin tone (stretch marks) may require additional surgical procedures (breast lift) to reposition the nipple and areola upward and to remove loose skin.

Patients undergoing augmentation mammoplasty surgery must consider the following:

- Breast augmentation or reconstruction with silicone gel-filled implants may not be a one time surgery.
- Breast implants of any type are not considered lifetime devices. They cannot be expected to last forever. You will likely require future surgery for implant replacement or removal.
- Changes that occur to the breasts following augmentation or reconstruction with implants are not reversible. There may be an unacceptable appearance to the breast if you later choose to have breast implants removed.

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- Large volume primary augmentation or revision with larger sized implants (>350cc) may increase the risk of complications such as implant extrusion, hematoma, infection, palpable implant folds, and visible skin wrinkling requiring surgical intervention to correct these complications.

### **ALTERNATIVE TREATMENT**

Augmentation mammoplasty with silicone gel-filled implants is an elective surgical operation. Alternative treatment would consist of not undergoing the surgical procedure or use of external breast prostheses or padding, saline-filled implants, or the transfer of other body tissues to enlarge/rebuild breast size. Risks and potential complications are associated with alternative surgical forms of treatment.

### **RISKS OF AUGMENTATION MAMMAPLASTY SURGERY**

Every surgical procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications or adverse events associated with them. In addition, every procedure has limitations in terms of the outcome that patients will achieve afterwards. Additional information concerning breast implants may be obtained from the FDA, package-insert sheets supplied by the implant manufacturer, or other information pamphlets required by individual state laws.

An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. While all patients do not experience these complications or adverse events, you should discuss each of them with your plastic surgeon to make sure you understand all possible consequences of breast augmentation. Adverse events associated with breast implants can be inherent to this type of implanted medical device or relate to complications of a surgical procedure. Additional advisory information regarding this subject should be reviewed by patients considering surgery that involves breast implants.

While every patient experiences her own individual risks and benefits following breast implant surgery, clinical data suggests that most women will be satisfied with the outcome of breast implant surgery despite the occurrence of problems inherent with the surgery.

### **Inherent Risks Of Silicone Gel-filled Breast Implants:**

**Implants-** Breast implants, similar to other medical devices, can fail. When a silicone gel-filled implant ruptures, the gel material is usually contained within the scar tissue surrounding the implant (intracapsular rupture). In some cases, the gel may escape beyond the capsule layer and go into the breast tissue itself (extracapsular rupture and gel migration) or to more distant locations. Migrated silicone gel may be difficult or impossible to remove. Rupture of a breast implant may or may not produce local firmness in the breast. Patients are advised to refer to individual manufacturer's informational materials regarding the incidence of device rupture reported during pre-market studies.

It is impossible to predict the biologic response that a patient's tissues will exhibit to the placement of breast implants or how you will heal following surgery.

Rupture can occur as a result of an injury, from no apparent cause or during mammography. Rupture of a silicone breast implant is most often undetected (silent rupture). It is possible to damage an implant at the time of surgery. Damaged or broken implants cannot be repaired. According to the FDA, ruptured or damaged implants require replacement or removal. Breast implants can wear out, they are not guaranteed to last a lifetime and future surgery may be required to replace one or both implants.

A MRI (magnetic resonance imaging) study is advised to evaluate the possibility of implant rupture, yet it may not be 100% accurate in diagnosing implant integrity. It should be noted that the FDA recommends regular screening MRI examinations. Specifically patients are advised to follow recommendations for serial MRI examinations, starting at 3 years after surgery and then every 2 years thereafter.

**Capsular Contracture-** Scar tissue, which forms internally around the breast implant, can tighten and make the breast round, firm, and possibly painful. Excessive firmness of the breasts can occur soon after surgery or years later. The occurrence of symptomatic capsular contracture is not predictable. The incidence of symptomatic

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capsular contracture can be expected to increase over time. Capsular contracture may occur on one side, both sides or not at all. It is more common with implant placement in front of the chest muscle layer. Treatment for capsular contracture may require surgery, implant replacement, or implant removal. **Capsular contracture may reoccur after surgical procedures to treat this condition** and it occurs more often in revision augmentation than primary augmentation.

**Implant Extrusion / Tissue Necrosis**- Lack of adequate tissue coverage or infection may result in exposure and extrusion of the implant through the skin. Tissue breakdown (necrosis) has been reported with the use of steroid drugs, after chemotherapy/radiation to breast tissue, due to smoking, microwave diathermy, and excessive heat or cold therapy. In some cases, incision sites fail to heal normally. Atrophy of breast tissue may occur. An implant may become visible at the surface of the breast as a result of the device pushing through layers of skin. If tissue break down occurs and the implant becomes exposed, implant removal may be necessary. Permanent scar deformity may occur.

**Skin Wrinkling and Rippling**- Visible and palpable wrinkling of implants and breast skin can occur. Some wrinkling is normal and expected with silicone gel-filled breast implants. This may be more pronounced in patients who have silicone gel-filled implants with textured surfaces or thin breast tissue. Palpable wrinkling and/or folds may be confused with palpable tumors and questionable cases must be investigated.

**Calcification**- Calcium deposits can form in the scar tissue surrounding the implant and may cause pain, firmness, and be visible on mammography. Deposits of calcium can be seen on mammograms and can be mistaken as cancer, resulting in additional surgery for biopsy and/or removal of the implant.

**Chest Wall Irregularities**- Chest wall irregularities have been reported secondary to the use of tissue expanders and breast implants. Residual skin irregularities at the ends of the incisions or "dog ears" are always a possibility when there is excessive redundant skin. This may improve with time, or it can be surgically corrected.

**Implant Displacement and Tissue Stretching**- Displacement, rotation, or migration of a breast implant may occur from its initial placement and can be accompanied by discomfort and/or distortion in breast shape (visible rippling of the skin). Unusual techniques of implant placement may increase the risk of displacement or migration. Additional surgery may be necessary to attempt correct of this problem. It may not be possible to resolve this problem once it has occurred.

**Surface Contamination of Implants**- Skin oil, lint from surgical drapes, or talc may become deposited on the surface of the implant at the time of insertion. The consequences of this are unknown.

**Asymmetry**- Some breast asymmetry naturally occurs in most women. Differences in terms of breast and nipple shape, size, or symmetry may also occur after surgery. Additional surgery may be necessary to attempt improvement of asymmetry after a breast augmentation.

**Unusual Activities and Occupations**- Activities and occupations which have the potential for trauma to the breast could potentially break or damage breast implants, or cause bleeding/seroma.

**Silicone Gel Bleed**- The evidence is mixed regarding whether there are any clinical consequences associated with silicone gel bleed. Over time, extremely small amounts of silicone gel material and platinum can pass through the shell layer of the implant and coat the outside of the implant. Studies indicate that a small amounts of platinum in its most biologically compatible (zero oxidation) state are contained within silicone gel. Microgram amounts of platinum in this state have been found to diffuse outside of breast implants. This may contribute to capsular contracture and lymph node swelling. The overall body of available evidence supports that the extremely low levels of gel bleed is of no clinical consequence.

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### **Inherent Surgical Risk of Breast Implant Surgery:**

**Bleeding-** It is possible, though unusual, to experience a bleeding episode during or after surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood or blood transfusion. Intra-operative blood transfusion may also be required. Hematoma may contribute to capsular contracture, infection or other problems. Some hematomas may require drainage or additional surgical treatment. Do not take any aspirin or anti-inflammatory medications for ten days before or after surgery, as this may increase the risk of bleeding. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding. Hematoma can occur at any time following injury to the breast. If blood transfusions are necessary to treat blood loss, there is the risk of blood-related infections such as hepatitis and HIV (AIDS). Heparin medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

**Seroma-** Fluid may accumulate around the implant following surgery, trauma or vigorous exercise. Additional treatment may be necessary to drain fluid accumulation around breast implants. This may contribute to infection, capsular contracture, or need for implant removal.

**Infection-** Infection can occur with any surgery or implant procedure. It may appear in the immediate post-operative period or at any time following the insertion of a breast implant. Sub acute or chronic infections may be difficult to diagnose. Should an infection occur, treatment including antibiotics, possible removal of the implant, or additional surgery may be necessary. Infections with the presence of a breast implant are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the breast implant may have to be removed. After the infection is treated, a new breast implant can usually be reinserted. It is extremely rare that an infection would occur around an implant from a bacterial infection elsewhere in the body, however, prophylactic antibiotics may be considered for subsequent dental or other surgical procedures. In extremely rare instances, life-threatening infections, including toxic shock syndrome have been noted after breast implant surgery. Individuals with an active infection in their body or weakened immune system should not undergo breast augmentation.

**Scarring-** All surgery leaves scars, some more visible than others. Excessive scarring is uncommon. Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of different color than the surrounding skin tone. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). There is the possibility of visible marks in the skin from sutures. In some cases scars may require surgical revision or treatment.

**Surgical Anesthesia-** Both local and general anesthesia involves risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia or sedation.

**Allergic Reactions-** In rare cases, local allergies to tape, suture material and glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

**Change in Nipple and Skin Sensation-** You may experience a diminished (or loss) of sensitivity of the nipples and the skin of your breast. Partial or permanent loss of nipple and skin sensation may occur. Changes in nipple sensation may affect sexual response or the ability to breast feed a baby.

**Thrombosed Veins-** Thrombosed veins, which resemble cords, occasionally develop in the area of the breast and usually resolve without medical or surgical treatment.

**Pain-** You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after breast implant surgery. Pain may be the result of improper implant size, placement, surgical technique, capsular contracture, or sensory nerve entrapment or injury. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching. If you experience significant pain or your pain persists, tell your surgeon.

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**Skin Discoloration / Swelling**- Some bruising and swelling normally occurs after breast augmentation. The skin in or near the surgical site can appear either lighter or darker than surrounding skin. Although uncommon, swelling and skin discoloration may persist for long periods of time and, in rare situations, may be permanent.

**Sutures**- Most surgical techniques use deep sutures. You may notice these sutures after your surgery. Sutures may spontaneously poke through the skin, become visible or produce irritation that requires removal.

**Damage to Deeper Structures**- There is the potential for injury to deeper structures including nerves, blood vessels and muscles and lungs (pneumothorax) during this surgical procedure. The potential for this to occur varies according to the type of procedure being performed. Injury to deeper structures may be temporary or permanent.

**Delayed Healing**- Wound disruption or delayed wound healing is possible. Some areas of the breast skin or nipple region may not heal normally and may take a long time to heal. Areas of skin or nipple tissue may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Individuals who have decreased blood supply to breast tissue from past surgery or radiation therapy may be at increased risk for wound healing and poor surgical outcome. **Smokers have a greater risk of skin loss and wound healing complications.**

**Cardiac and Pulmonary Complications**- Pulmonary complications may occur secondarily to both blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anesthesia. Pulmonary emboli can be life-threatening or fatal in some circumstances. Inactivity and other conditions may increase the incidence of blood clots traveling to the lungs causing a major blood clot that may result in death. It is important to discuss with your physician any past history of swelling in your legs or blood clots that may contribute to this condition. Cardiac complications are a risk with any surgery and anesthesia, even in patients without symptoms. Should any of these complications occur, you may require hospitalization and additional treatment. If you experience shortness of breath, chest pain, or unusual heart beats after surgery, seek medical attention immediately.

**Shock**- In rare circumstances, your surgical procedure can cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

### **Additional Breast Implant Advisory Information:**

**Breast Disease**- Current medical information does not demonstrate an increased risk of breast cancer in women who have breast implant surgery for either cosmetic or reconstructive purposes. Individuals with a personal history or family history of breast cancer may be at higher risk of developing breast cancer than a woman with no family history of this disease. It is recommended that all women perform periodic self-examination of their breasts, have mammography according to American Cancer Society guidelines, and to seek professional care should a breast lump be detected. Care must be exercised during all breast biopsy procedures to avoid damaging the breast implant.

**Mammography**- Breast implants may make mammography more difficult and may obscure the detection of breast cancer. Any breast implant can impair the detection of breast cancer, regardless of the type of implant or where it is placed in relation to the breast. Implant rupture can occur from breast compression during mammography. Inform your mammography technologist of the presence of breast implants so that appropriate mammogram studies may be obtained. Patients with capsular contracture may find mammogram techniques painful and the difficulty of breast imaging will increase with the extent of contracture. Ultrasound, specialized mammography and MRI studies may be of benefit to evaluate breast lumps and the condition of the implant(s). Because more x-ray views are necessary with specialized mammography techniques, women with breast implants will receive more radiation than women without implants who receive a normal exam. However, the benefit of the mammogram in finding cancer outweighs the risk of additional x-rays. Patients may wish to undergo a preoperative mammogram and another one after implantation to

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establish a baseline view of their breast tissue. For information regarding MRI screening to verify the condition of your breast implants in side your body, see the implant information in the section on Inherent Risks of Silicone Gel-filled Breast Implants.

**Other Cancer Incidence-** Some reports in the medical literature indicate that patients may be at increased risk for cancer of the brain, respiratory/lung, cervical/vulva, stomach, and leukemia. Other studies have not found evidence to support an association between silicone breast implants and cancer.

**Damage During Other Treatments-** Patients are advised to inform treating physicians and caregivers that they have breast implants to minimize risk of damage to the implants.

**Second-Generation Effects-** A review of the published medical literature regarding potential damaging effect on children born of mothers with breast implants is insufficient to draw definitive conclusions that this represents a problem.

**Breast Feeding-** Breast milk is the best food for babies. Women with breast implants have successfully breast fed their babies however, some women experience difficulties. It is not known if there are increased risks in nursing for a woman with breast implants. A study measuring elemental silicon (a component of silicone) in human breast milk did not indicate higher levels from women with silicone-filled gel implants when compared to women without implants. Cow's milk contains higher levels of elemental silicon as compared to human milk. Implant placement techniques that involve incisions through the nipple and areola locations may reduce the ability to successfully breast feed. If a woman has undergone a mastectomy, it is unlikely that she would be able to breast feed a baby on the side where the breast was removed.

**Neurological Disease, Signs and Symptoms-** Some women with breast implants have complained of neurologic symptoms, which they believe are related to their implants. A scientific expert panel found that the evidence for a neurological disease of symptom caused by or associated with breast implants is insufficient or flawed.

**Long Term Results-** Subsequent alterations in breast shape may occur as the result of aging, weight loss, weight gain, pregnancy, menopause, or other circumstances not related to your augmentation mammoplasty. Breast sagging may normally occur.

**Unsatisfactory Result-** Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. You may be disappointed with the results of surgery. Asymmetry in implant placement, displacement, nipple location, unanticipated breast shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. Breast size may be incorrect. Unsatisfactory surgical scar location may occur. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. It may be necessary to perform additional surgery to improve your results, change implant size or remove and not replace implants.

**Removal / Replacement of Breast Implants-** Future revision, removal, or replacement of breast implants and the surrounding scar tissue envelope involves surgical procedures with risks and potential complications. Implant replacement increases the risk of future complications. There may be an unacceptable appearance of the breasts following removal of the implant.

**Capsule Squeeze Procedures-** Closed capsulotomy, the process of forcefully squeezing the fibrous capsule around a breast implant to break up scarring is should not be performed. Closed capsulotomy may result in implant damage, rupture, folds, and or hematoma.

**Immune System Diseases-** A small number of women with breast implants have reported symptoms similar to those of known diseases of the immune system, such as systemic lupus erythematosus, rheumatoid arthritis, scleroderma, and other arthritis-like conditions. To date, after several large epidemiological studies of women with and without implants, breast implants are not significantly associated with a risk of developing connective tissue disease, nor has the scientific evidence demonstrated a consistent pattern of its signs and symptoms. The FDA

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determined that the safety and effectiveness of silicone breast implants have not been established in patients with pre-existing autoimmune diseases.

**Unknown Risks-** There is the possibility of unknown risks associated with silicone breast implants and tissue expanders.

**Breast and Nipple Piercing Procedures-** Individuals with breast implants seeking to undergo body piercing procedures to the breast region must consider the possibility that an infection could develop anytime following this procedure. Should an infection occur, it is possible that it could spread to the breast implant space. Treatment including antibiotics, possible removal of the implant, or additional surgery may be necessary. Infections with the presence of a breast implant are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the breast implant may have to be removed. Individuals who currently wear body piercing jewelry in the breast region are advised that a breast infection could develop.

**Interference with Sentinel Lymph Node Mapping Procedures-** Breast augmentation procedures (periareolar or transmammary) that involve cutting through breast tissue, similar to a breast biopsy in order to place breast implants, can potentially interfere with diagnostic procedures to determine lymph node drainage of breast tissue to stage breast cancer. If this is a concern, individuals considering breast augmentation by these approaches may elect to consider another surgical approach (inframammary or standard periareolar).

**Large Volume Breast Augmentation-** Patients who request an outcome of augmentation mammoplasty that produces disproportionately large breast size must consider that such a choice can place them at risk for a less than optimal long term outcome and the need for re-operation and additional expenses. The placement of excessively-sized breast implants exceeds the normal dimensions of the breast, produce irreversible tissue thinning, implant drop out, visible/palpable rippling and synmastia, a condition where breast mounds are abnormally located in the center of the chest. Large volume primary augmentation or revision with larger sized implants (>350cc) may increase the risk of complications such as implant extrusion, hematoma, infection, palpable implant folds, and visible skin wrinkling requiring surgical intervention to correct these complications.

**Mental Health Disorders and Elective Surgery-** It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery and often are emotionally stressful. Please openly discuss with your surgeon, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. The FDA determined that the safety and effectiveness of silicone breast implants has not been established in patients with a diagnosis of depression or other mental health conditions. The FDA recommends that patients with such diagnosis's wait until resolution or stabilization of these conditions prior to undergoing breast implant surgery. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

**Female Patient Information-** It is important to inform your plastic surgeon if you use of birth control pills, estrogen replacement, or if you suspect that you are pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

**Medications-** There are potential adverse reactions that occur as the result of taking over the counter, herbal, and/or prescription medications. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

**Breast Implant Technology / Technologic Improvements in Breast Implants-** The technology of breast implant design, development and manufacture will continue to progress and improve. Newer or future generations of implants may be better in some way from currently available ones.



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### **Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray)-**

Patients, who are currently smoking, use tobacco products, or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying and delayed healing. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smokers may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication. Please indicate your current status regarding these items below:

\_\_\_\_\_ I am a non-smoker and do not use nicotine products. I understand the risk of second-hand smoke exposure causing surgical complications.

\_\_\_\_\_ I am a smoker or use tobacco / nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired.

### **ADDITIONAL SURGERY NECESSARY (Re-operations)-**

There are many variable conditions that may influence the long term result of breast augmentation surgery. It is unknown how your breast tissue may respond to implants or how wound healing will occur after surgery. Secondary surgery may be necessary at some unknown time in the future to replace your breast implants or to improve the outcome of breast augmentation surgery. You may elect to or be advised to have your breast implants removed and not replaced in the future. Should complications occur, additional surgery or other treatments may be necessary. The rate of reoperation after breast augmentation is variable according to individual manufacturers studies. Patients are advised to discuss with their surgeon his or her personal reoperation rate after reading the information books on breast implants supplied by the manufacturers. A significant number of patients seek reoperation for desired size changes. Discuss with your surgeon what size and shape you are seeking and if that is possible. Understand the policy for reoperation, should you desire a change.

Even though risks and complications occur infrequently, the risks cited are particularly associated with breast augmentation surgery. Other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. Additional surgery to improve your outcome or correct a complication of breast augmentation may not be successful.

**Patient Compliance-** Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon. Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation around implants and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

**Regulatory Matters-** Silicone gel implants are subject to device tracking by FDA regulations. Patients are advised to follow recommendations regarding periodic aftercare and guidelines for MRI imaging studies to rule out device rupture. Patients enrolled in post-market studies are advised to comply with the requirements of the studies.

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### **HEALTH INSURANCE**

Please carefully review your health insurance subscriber-information pamphlet. Although silicone gel breast implants are FDA approved medical devices, most group and private health insurance plans exclude coverage for cosmetic surgical operations, including breast augmentation. Most health insurance plans do not cover the costs of treating complications associated with cosmetic breast augmentation procedures such as secondary or revisionary surgery. MRI screening examination costs may not be covered by medical insurance. In addition, some women with breast implants have been unable to obtain medical insurance coverage in the individual insurance market. Private/group insurance plans that cover medically necessary mastectomies generally cover breast reconstructive surgery.

### **FINANCIAL RESPONSIBILITIES**

The cost of surgery involves several charges for the services provided. The total includes fees charged by your surgeon, the cost of surgical supplies, anesthesia, laboratory tests, and possible outpatient hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revision surgery will also be your responsibility. You have been advised to have MRI (magnetic resonance imaging) scans to determine the condition of your breast implants. You would be responsible for the future costs of such imaging studies that may not be covered by your medical insurance.

**In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.**

### **DISCLAIMER**

Informed-consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s), including no surgery. The informed-consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances.

However, informed-consent documents should not be considered all inclusive in defining other methods of care and risks encountered. Your plastic surgeon may provide you with additional or different information which is based on all the facts in your particular case and the state of medical knowledge.

Informed-consent documents are not intended to define or serve as the standard of medical care. Standards of medical care are determined on the basis of all of the facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

**It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.**

# CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1. I hereby authorize Dr. Edward J. Love and such assistants as may be selected to perform the following procedure or treatment: **AUGMENTATION MAMMAPLASTY**

I have received the following information sheet:

**INFORMED-CONSENT FOR SILICONE GEL-FILLED BREAST AUGMENTATION  
(AUGMENTATION MAMMAPLASTY) SURGERY**

2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. I acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained.
5. I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the disposal of any tissue, medical devices or body parts which may be removed.
8. I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
9. I authorize the release of my Social Security number and other personally identifying data to appropriate agencies for legal reporting and medical-device registration.
10. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
11. I realize that not having the operation is an option.
12. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
  - a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
  - b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
  - c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-12). I AM SATISFIED WITH THE EXPLANATION.

\_\_\_\_\_  
Patient or Person Authorized to Sign for Patient

Date \_\_\_\_\_ Witness \_\_\_\_\_