FEEL BEAUTIFUL
STEVE LAVERSON, MD

BREAST AUGMENTATION CONSENT

INFORMED CONSENT for BREAST AUGMENTATION (saline implants)

INSTRUCTIONS

This document contains information about breast augmentation (augmentation mammaplasty). Please read each paragraph carefully and completely. If you have questions or there are words you don't know, ask Dr. Laverson. Your signature at the end confirms your understanding and your agreement to breast augmentation with implants.

GENERAL INFORMATION

Saline-filled breast implants have been approved by the United States Food and Drug Administration (USFDA) for use in breast augmentation and reconstruction. Breast implants that contain silicone gel are currently restricted to women who meet eligibility criteria to participate in approved study programs. Dr. Laverson is an investigator in the largest and most advanced of these studies. Let him know if you want more information about gel implants.

Augmentation mammaplasty is a surgical operation performed to enlarge the 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 replace 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. According to the USFDA, a woman must be at least 18 years of age for cosmetic breast augmentation.

Breast enlargement is accomplished by inserting a breast implant either behind the breast gland or under the chest muscles. Incisions are made to keep scars as inconspicuous as possible, usually under the breast, around the lower part of the areola, or in the armpit. Breast implants are 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 mammaplasty surgery must consider the following:

Breast augmentation or reconstruction with saline-filled implants may not be a one time surgery.

Breast implants of any type are <u>not</u> considered lifetime devices. They cannot be expected to last forever. You will likely (although not definitely) 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.

ALTERNATIVE TREATMENT

Augmentation mammaplasty is an elective surgical operation. Alternative treatment consists of not having the operation, and instead using padded bras, silicone spacers in the bra, and other external devices or hormone supplements to increase breast size. Each of these options is associated with advantages and disadvantages.

RISKS of AUGMENTATION MAMMAPLASTY SURGERY

Every surgical procedure involves risk. Because you are considering breast augmentation, you should understand risks associated with implants in general, and with this operation in particular. Your choice to have this surgical procedure is based on a comparison of risk to expected benefit. Although most women do not experience significant complications, they can be unpredictable. Please review the following possibilities and ask Dr. Laverson if any questions arise.

Depending on your anatomy, age, general health, and other factors, you have your own unique risk profile which may differ substantially from that of other women. Clinical data suggests that most women will be satisfied with the outcome of breast augmentation despite problems inherent with the procedure. Additional information about the implant devices may be obtained from the FDA, breast implant manufacturers, or the American Society of Plastic Surgeons.

Risks of Saline Breast Implants:

Device Failure– Breast implants, like other medical devices, can fail. Implants can break or leak. When a saline-filled implant deflates, its salt water filling will be absorbed by the body. Rupture can occur as a result of an injury, from no apparent cause, or during mammography. It is possible to damage an implant at the time of surgery. Damaged or broken implants cannot be repaired. Ruptured or deflated implants require replacement or removal. Breast implants can wear out, they cannot be expected to last forever.

<u>Capsular contracture</u>– 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 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.

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. An implant may become visible at the surface of the breast as a result of the device pushing though layers of skin. If tissue breakdown 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 can occur. Some wrinkling is normal and expected. This may be more pronounced in patients who have saline-filled implants with textured surfaces or thin breast tissue. It may be possible to feel the implant fill valve. Some patients may find palpable valve and wrinkles cosmetically undesirable. Palpable valve, wrinkling and/or folds may be confused with palpable tumors and questionable cases must be investigated. An implant may become visible at the surface of the breast as a result of the device pushing though layers of skin.

Change in nipple and skin sensation– Some change in nipple sensation is not unusual right after surgery. After several months, most patients have normal sensation. Partial or permanent loss of nipple and skin sensation may occur occasionally. Changes in sensation may affect sexual response or the ability to breast feed a baby.

Calcification– Calcium deposits can form in the scar tissue surrounding the implant and may cause pain, firmness, and be visible on mammography. These deposits must be identified as different from calcium deposits that are a sign of breast cancer. Should this occur, additional surgery may be necessary to remove and examine calcifications.

Chest wall deformity– Chest wall deformity has been reported secondary to the use of tissue expanders and breast implants. The consequences of chest wall deformity is of unknown significance.

Implant displacement– 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. Unusual techniques of implant placement may increase the risk of displacement or migration. Additional surgery may be necessary to correct this problem.

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 is unknown.

Breast feeding– Breast milk is excellent food for babies. Many women with breast implants have successfully breast fed their babies. 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 areolar 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.

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.

Risks of Breast Implant Surgical Procedure:

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 (hematoma). Do not take any aspirin or anti-inflammatory medications for ten days before 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.

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 other problems.

Infection– Infection is unusual after this type of surgery. It may appear in the immediate post operative period or at any time following the insertion of a breast implant. Subacute 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.

Skin scarring– Excessive scarring is uncommon. In rare cases, abnormal scars may result. Scars may be unattractive and of different color than surrounding skin. Additional surgery may be needed to treat abnormal scarring after surgery.

Damage to Deeper Structures –There is potential for injury to deeper structures including nerves, blood vessels, muscles, and lungs (pneumothorax) during this surgical procedure. The potential for this to occur varies according to the type of procedure. Injury to deeper structures may need additional procedures for repair, and may result in temporary or permanent effects.

Delayed Healing – Wound disruption or delayed 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 (lung) complications may occur from blood clots (pulmonary emboli), fat (fat emboli), or partial collapse of the lungs after anesthesia. Emboli can be life-threatening or fatal. Hospitalization would be required. Inactivity and other conditions may increase the risk of blood clots traveling to the lungs, a serious and possibly fatal condition. Discuss with Dr. Laverson any past history of swelling in your legs or blood clots. Cardiac (heart) complications are a risk with any surgery, even if you have no prior symptoms. If you experience chest pain, shortness of breath, lightheadedness, dizziness, or unusual heart beats, call Dr. Laverson or seek emergency medical attention right away!

Surgical anesthesia– Both local and general anesthesia involve 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, or topical preparations have been reported. Systemic reactions which are more serious may result from drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

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

Pain– 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.

Additional Breast Implant Advisory Information:

Breast cancer– 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. It is recommended that all women perform periodic self examination of their breasts, have mammography according to American Cancer Society guidelines, and seek professional care should they notice a breast lump. Care must be exercised during 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 establish a baseline view of their breast tissue.

Breast Feeding – Breast milk is the best food for babies. Many women with breast implants have successfully breast fed their babies. It is ***not known*** if there are increased risks of 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 compared to women without implants. Cow's milk contains higher levels of elemental silicon than 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.

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.

Long term results– Subsequent alterations in breast shape may occur as the result of aging, weight loss or gain, pregnancy, or other circumstances not related to augmentation mammaplasty. Breasts may sag downward normally with the passage of time.

Unsatisfactory result– Although good results are expected and usually achieved, there is no guarantee or warranty of a satisfactory final result. You may be disappointed with the outcome of surgery. Asymmetry between right and left sides, displacement of the implants, unnatural or unattractive nipple location, unanticipated breast shape and/or size may be the result of surgery. Breast size may be too large or too small. The scar may be poorly located. It may be necessary to perform additional surgery to improve your results by removing, replacing, or repositioning breast 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. There may be an unacceptable appearance of the breasts following removal of the implant.

Capsule procedures– Closed capsulotomy, the process of forcefully squeezing the fibrous capsule around a breast implant to break up scarring is not recommended. This may result in rupture of the breast implant or other complications.

Immune system diseases and unknown risks– 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 erythematosis, rheumatoid arthritis, scleroderma, and other arthritis-like conditions. To date, after several large studies of women with and without implants, there is **no scientific evidence that women with either silicone gel-filled or saline-filled breast implants have an increased risk of these diseases**. These diseases appear no more common in women with implants than those women without implants. The effects of breast implants in individuals with pre-existing immune system and connective-tissue disorders is unknown. There is the possibility of unknown risks associated with silicone breast implants.

Breast and Nipple Piercing Procedures – Women with breast implants considering nipple piercing should consider the possibility that an infection could develop at the site of piercing. Should an infection occur, it is possible that this could spread to the breast implant space. Treatment including antibiotics, removal of the implant, and/or other surgery may be necessary. Infections of a breast implant are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the implant will have to be removed.

Interference with Sentinel Lymph Node Mapping Procedures – Breast augmentation approaches that involve cutting through the breast gland can interfere with diagnostic procedures to determine lymph node drainage of the breast for cancer staging. If this is a concern, breast augmentation should be performed by the inframammary approach.

Large Volume Breast Augmentation – Those who request an outcome of augmentation mammaplasty that produces disproportionately large breast size must realize this choice results in increased risk of poor long term outcome and the need for re-operation with attendant expense and possible complications. Placement of excessively sized implants exceeds the normal dimensions of the breast and causes irreversible thinning of surrounding tissue, implant drop out / bottoming out, and rippling of the implant edges that can be seen and/or felt.

Mental Health Disorders and Cosmetic Surgery – All patients choosing cosmetic surgery should have realistic expectations that focus on improvement rather than perfection. Complications or unsatisfactory results are sometimes unpredictable, unavoidable, may require additional surgery, and are often stressful. Please openly discuss with Dr. Laverson before your surgery any history of significant depression or other mental or emotional disorders. Although many people benefit psychologically from the results of cosmetic surgery, effects on mental health cannot be accurately predicted.

Breast Implant Technology – The technology of breast implant design and manufacture will continue to progress and improve. Newer or future generations of implants may be better than those currently available.

HEALTH INSURANCE

Health insurance companies exclude coverage for cosmetic surgical operations such as augmentation mammaplasty and complications of surgery. Please carefully review your health insurance subscriber information pamphlet and underwriting policies. Dr. Laverson provides a CosmetAssure® policy that covers some potential medical complications which occur rarely after breast augmentation.

ADDITIONAL SURGERY NECESSARY (Re-operations)

Should complications occur, additional surgery or other treatments may be necessary. Even though complications occur infrequently, the risks cited above are particularly associated with augmentation mammaplasty; 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 regarding the final result of breast augmentation surgery.

PATIENT COMPLIANCE

Follow Dr. Laverson's instructions for a successful outcome. Surgical wound closures should not be subjected to excessive force, motion, or trauma during healing. Protective dressings should not be removed unless instructed to do so. Your activity must be restricted. A good result depends on the surgical procedure and your care after the procedure. Physical activity that increases pulse or blood pressure may cause bruising, bleeding, swelling, fluid accumulation around implants, and the need for return to surgery. Refrain from sex after breast augmentation for four weeks or longer. Please return to Dr. Laverson for follow up appointments after surgery to detect and correct problems.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for services provided. The total includes fees charged by Dr. Laverson, the cost of implants and surgical supplies, anesthesia, outpatient surgery center charges, the post-surgical bra, and the CosmetAssure® insurance policy. Additional costs may occur should complications develop from the surgery, or if you are dissatisfied with the result and want an additional procedure to revise or improve the appearance or size of the breasts. When you sign the consent for surgery, you are accepting responsibility for the implant size selected and other decisions made in planning your procedure. You are also accepting responsibility for the financial cost of future treatments.

DISCLAIMER

Informed consent documents are used to communicate information about the proposed treatment along with disclosure of risks and alternative forms of treatment(s). The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most patients in most circumstances. This document, however, should not be considered all inclusive in defining other methods of care and risks encountered. Dr. Laverson 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.

CONSENT FOR BREAST AUGMENTATION WITH SALINE IMPLANTS

1. Dr. Steve Laverson and assistant(s) is requested and authorized to perform BILATERAL BREAST AUGMENTATION WITH SALINE IMPLANTS upon me. I have read and understand the above information, including risks, short and long term complications and changes to my body, and including alternative treatments.

2. Rarely, during the course of plastic surgery, unforeseen conditions mandate procedures different than or additional to those above. Dr. Laverson is authorized to perform such other procedures that are in the exercise of his best professional judgment necessary, desirable, and in my own best interest. The authority granted under this paragraph shall include all conditions that require treatment and are not known at the time the procedure commences.

3. I consent to the administration of anesthetics considered necessary or advisable. All forms of anesthesia involve some risk and the possibility of complications, injury, and rarely death.

4. No guarantee has been given by anyone regarding the final result of these surgical procedures.

5. Preoperative photographs are authorized for my medical record and documentation of my condition. These photographs may be used to demonstrate results of the procedure to other prospective patients provided my identity is not revealed by the pictures.

6. Dr. Laverson is authorized to report my social security number to implant manufacturer and or United States Government if requested.

7. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:

a. THE ABOVE TREATMENT OR PROCEDURE (breast augmentation)

b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT

c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

MY SIGNATURE BELOW INDICATES MY REQUEST FOR AND CONSENT TO BILATERAL BREAST AUGMENTATION SURGERY WITH SALINE IMPLANTS, INCLUDING ITEMS 1-7 ABOVE.

_____ _____

signature date

_____ _____

witness date