

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

Name:

Date of birth: Tel./email.....

Address:

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

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 from various conditions.
- To correct a failure of 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.

Breast enlargement is accomplished by inserting a breast implant either behind the breast tissue or partially under the chest muscles. Incisions are made to keep scars as inconspicuous as possible, usually under the breast (or around a portion of areola). 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.
- 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 the transfer of other body tissues to enlarge/rebuild breast size.

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. 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. Rupture of a breast implant may or may not produce local firmness in the breast. 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). Damaged or broken implants cannot be repaired. 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.

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 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.

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 thin breast tissue.

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.

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). Additional surgery may be necessary to attempt to correct this problem. It may not be possible to resolve this problem once it has occurred.

General Risks of Surgery:

Healing Issues: Certain medical conditions, dietary supplements and medications may delay and interfere with healing. Patients with massive weight loss may have a healing delay that could result in the incisions coming apart, infection, and tissue changes resulting in the need for additional medical care, surgery, and prolonged hospitalizations. Patients with diabetes or those taking medications such as steroids on an extended basis may have prolonged healing issues. Smoking will cause a delay in the healing process, often resulting in the need for additional surgery. There are general risks associated with healing such as swelling, bleeding, and the length of surgery and anesthesia that include a longer recovery and the possibility of additional surgery, prolonged recovery, color changes, shape changes, infection, not meeting expectations, and added expense to the patient. Patients with significant skin laxity (patients seeking breast lift) will continue to have the same lax skin after surgery. The quality or elasticity of skin will not change and recurrence of skin looseness will occur at some time in the future, quicker for some than others.

Bleeding: It is possible, though unusual, to experience a bleeding episode during or after surgery. Should postoperative bleeding occur, it may require emergency treatment to drain accumulated blood or you may require a blood transfusion, though such occurrences are rare. Increased activity too soon after surgery can lead to increased chance of bleeding and additional surgery. It is important to follow postoperative instructions and limit exercise and strenuous activity for the instructed time.

Infection in Breast Implant Patients: 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 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 should not undergo surgery, including breast augmentation. Although 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. It is important to tell your surgeon of any other infections, such as ingrown toenail, insect bite, Or urinary tract infection. Remote infections, infection in other part of the body, may lead to an infection in the operated area.

Pain: You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after the mammoplasty. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.

Scarring: All surgery leaves scars, some more visible than others. 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. Scars may be asymmetrical. In some cases scars may require surgical revision or 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. 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.

Skin Discoloration / Swelling: Some bruising and swelling normally occur. 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.

Skin Sensitivity: Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after surgery. Usually this resolves during healing, but in rare situations it may be chronic.

Seroma: Infrequently, fluid may accumulate around the implant following surgery, trauma or vigorous exercise. Should this problem occur, it may require additional procedures for drainage of fluid. Excess fluid accumulation around an implant secondary to too much activity, too early, may increase capsular contracture occurrence.

Risk of Surgical Anesthesia: Both local and general anesthesia involve risk. There is the possibility of complications from all forms of surgical anesthesia or sedation.

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.

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. If you experience shortness of breath, chest pain, or unusual heart beats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

Venous Thrombosis and Sequelae: Thrombosed veins, which resemble cords, occasionally develop in the area of the breast or around IV sites, and usually resolve without medical or surgical treatment. It is important to discuss with your surgeon any birth control pills you are taking. Certain high estrogen pills may increase your risk of thrombosed veins.

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 in response to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

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.

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 subjectively 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.

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 a 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 local Oncological Society guidelines, and seek professional care should a breast lump be detected. 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. You may be advised to undergo a MRI study in the future to verify the condition of your 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.

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 erythematosus, rheumatoid arthritis, scleroderma, and other arthritis-like conditions. To date, after several large epidemiological studies of women with and without implants, there is no scientific evidence that women with either saline-filled or silicone gel-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 effect 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 and tissue expanders.

Large Volume Breast Augmentation: Patients who request an outcome of augmentation mammoplasty that produces a 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, and visible/palpable rippling.

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

CONSENT FOR SURGERY

1. I hereby authorize DrJacek Jarlinski to perform AUGMENTATION MAMMAPLASTY

I have received the following information sheet:

INFORMED CONSENT – AUGMENTATION MAMMAPLASTY WITH SILICONE GEL-FILLED BREAST IMPLANTS

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 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 understand what my surgeon can and cannot do, and I understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.

5. I realize that not having the operation is an option.

6. I consent to be photographed before and after the operation to be performed, including appropriate portions of my body, for medical purposes, provided my identity is not revealed by the pictures.

Date:.....

Patient Signature.....