Informed Consent

Augmentation Mammaplasty with Silicone Gel-Filled Implants

INSTRUCTIONS

This is an informed consent document that has been prepared to help inform you about augmentation mammaplasty surgery with silicone gel-filled implants, its risks, and 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

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

Augmentation mammaplasty 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 is a significant difference between the sizes of the breasts.
- To restore breast shape after partial or total loss of the breasts in various conditions.
- To correct a failure of breast development due to a severe breast abnormality.
- To correct or improve the 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 reduced blood supply to the breast tissue from prior surgery or radiation therapy treatments may be at greater risk for complications and poor surgical outcomes.

Silicone breast implants are approved by the FDA for use in women who are at least 22 years of age. Women that meet this age criterion may utilize silicone implants for cosmetic breast augmentation or for revision surgery to correct or improve the results of a previous cosmetic breast augmentation. There is no age restriction on breast reconstruction procedures to restore breast shape after cancer, trauma, or for 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 periumbilical 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, as well as the surgical approach for inserting and positioning the breast implants will depend on your preferences, your anatomy, and your surgeon’s recommendations. 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 that 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 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 the breast implants removed.
- Large volume primary augmentation or revision with larger sized implants in excess of dimensional planning for your chest and breast size may increase the risk of complications such as implant extrusion, hematoma, infection, palpable implant folds, and visible skin wrinkling, which may require surgical intervention for correction.

ALTERNATIVE TREATMENTS

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

INHERENT 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 informational 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 not all patients experience these complications or adverse events, you should discuss each of them with your plastic surgeon to make sure you understand all of the 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 the surgical procedure. Additional advisory information on this subject should be reviewed by patients who are considering surgery that involves breast implants.

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

SPECIFIC 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 move 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 as reported during pre-market studies.

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, as 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 MRI examinations. Specifically, patients are advised to follow the recommendations for serial MRI examinations, starting at three years after surgery and then every two years thereafter. Patients may be responsible for the associated costs.

Capsular Contracture:

Scar tissue, which forms routinely around the breast implant internally, 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 occurs more commonly 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 in primary augmentation. Some surgeons believe that preventative antibiotics during dental work and in the treatment of sinus and urinary tract infections may decrease this incidence. Discuss this with your surgeon.

Calcification:

Calcium deposits can form in the scar tissue surrounding the implant and be visible on mammography, as well as causing pain and firmness. These deposits must be identified as distinct from the calcium deposits that signify breast cancer. Should this occur, additional surgery may be necessary to remove and examine the calcifications.

Implant Extrusion/Tissue Necrosis:

Lack of adequate tissue coverage, wound healing problems, 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, and due to smoking, microwave diathermy, and excessive heat or cold therapy. In some cases, incision sites fail to heal normally. Atrophy (weakening) 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 breakdown occurs and the implant becomes exposed, implant removal may be necessary. Permanent scar deformity may occur. It is impossible to predict the biologic response of a patient's tissues to the placement of breast implants or how they will heal following surgery.

Patient Name: **Patient Initials**: _____

Skin Wrinkling and Rippling:

Visible and palpable (discernible to the touch) 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.

Chest Wall Irregularities:

Chest wall irregularities have been reported secondary to the use of tissue expanders and breast implants, including rib deformity.

Implant Displacement and Tissue Stretching:

Displacement, rotation, or migration of a breast implant may occur from its initial placement, which can be accompanied by discomfort and/or distortion in the 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 to correct 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.

Unusual Activities and Occupations:

Activities and occupations that involve the potential for trauma to the breast could potentially break or damage breast implants, or cause bleeding/seroma.

Silicone Gel Bleed:

The evidence regarding the likelihood of clinical consequences associated with silicone gel bleed is mixed. 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 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. Overall, the body of available evidence supports that the extremely low levels of gel bleed are of no clinical consequence.

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 regain 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 breastfeed a baby.

Anaplastic Large Cell Lymphoma (ALCL):

Breast implant-associated anaplastic large cell lymphoma (BIA-ALCL) is a very rare type of lymphoma that can develop in the scar capsule near saline or silicone breast implants. This very rare disease is currently being investigated as to its relationship with breast implants. The family of ALCL is an extremely rare cancer of the immune system, which can occur anywhere in the body. Based on adverse event reports, the United States Food and Drug

Administration (FDA) estimates the total number of US cases of BIA-ALCL to be around 250. It has been noted that the majority of BIA-ALCL patients have a history of a textured-surface device. An exact single-number estimate of the risk for both textured and non-textured implants is not possible with the currently available data. Lifetime risk of BIA-ALCL has been estimated at 1:1,000 to 1: 30,000 for women with textured breast implants, and BIA-ALCL risk is currently under investigation. BIA-ALCL usually involves swelling of the breast at an average of 3 to 14 years after the initial breast implant operation. Most cases were cured by removal of the implant and the capsule surrounding the implant; however, rare cases have required chemotherapy and/or radiation therapy for treatment.

Patients with breast implants should be followed by a surgeon over time and seek professional care for implant-related symptoms such as pain, lumps, swelling, or asymmetry. Patients should monitor their breast implants with routine breast self-exams and follow standard medical recommendations for imaging (e.g., Mammography, Ultrasound, MRI). Abnormal screening results or implant-related symptoms may result in additional expenses for tests and/or procedures to properly diagnose and treat your condition. Tests and procedures could include but may not be limited to: obtaining breast fluid or tissue for pathology and laboratory evaluation, surgery to remove the scar capsule around the breast implant, implant removal, or implant replacement.

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, undergo routine mammography according to American Cancer Society guidelines, and seek professional care should a breast lump be detected. In the event that suspicious tissue is identified prior to or during breast surgery, additional tests and therapy with corresponding expenses may be warranted.

Interference with Sentinel Lymph Node Mapping Procedures:
Breast surgery procedures that involve cutting through breast tissue, similar to a breast biopsy, can potentially interfere with diagnostic procedures to determine the lymph node drainage of the breast tissue in the staging of breast cancer.

Future Pregnancy and Breast Feeding:
This surgery is not known to interfere with pregnancy. If you are planning a pregnancy, your breast skin may stretch and undermine the results of surgery. You may have more difficulty breastfeeding after this operation.

GENERAL RISKS OF SURGERY

Healing Issues:

Certain medical conditions, dietary supplements, and medication may delay and interfere with healing. Patients with massive weight loss may have a healing delay that could result in the incisions coming apart, infections, and tissue changes that would require additional medical care, surgeries, and prolonged hospitalizations. Patients with diabetes, or those taking medications (e.g., 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 surgeries. There are general risks associated with healing such as swelling, bleeding, possibility of additional surgeries, prolonged recovery, color and shape changes, infections, failure to meet the patient’s goals and expectations, and added expense to the patient. There may also be a longer recovery period due to the length of surgery and the anesthesia administered. Patients with significant skin laxity (like in a body lift procedure) will continue to have the same lax skin after surgery. The quality or elasticity of the skin will not change, and recurrence of skin looseness will occur at some time in the future, quicker for some than others. There are nerve endings that may become affected by healing scars from the surgery. While there may not be a major nerve injury, the small nerve endings may become too active during the healing

period, producing a painful or oversensitive area due to their associations with the scar tissue. Often, massage and early non-surgical interventions can resolve this. It is important to discuss post-surgical pain with your surgeon.

Bleeding:

It is possible, though unusual, to experience a bleeding episode during or after the surgery. Should post-operative bleeding occur, it may require emergency treatment to drain accumulated blood, or you may require a blood transfusion, though such occurrences are rare. The collection of blood that can occur under your skin following surgery is referred to as a hematoma. Increased activity too soon after surgery can lead to increased chance of bleeding and additional surgeries. It is important to follow postoperative instructions and limit exercise and strenuous activity for the instructed time. Non-prescription “herbs” and dietary supplements can increase the risk of surgical bleeding. Hematoma can occur at any time, usually in the first three weeks following injury to the operative area. If blood transfusions are necessary to treat blood loss, there is the risk of blood-related infections such as hepatitis and HIV (AIDS). Your surgeon may provide medications after your surgery to prevent blood clots. Medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

Infection:

Infection, although uncommon, can occur after surgery. Should an infection occur, additional treatment, including antibiotics, hospitalization, or even surgery, may be necessary. It is important to tell your surgeon of any other infections, such as a history of methicillin-resistant Staphylococcus aureus (MRSA) infections, an open wound, recent upper respiratory infection/pneumonia, ingrown toenail, insect bite, tooth abscess, or urinary tract infection. Infections in other parts of the body may lead to an infection in the operated area. Post-operative infections often result in more extensive scarring and predispose the patient to revision surgery.

Scarring:

All surgeries leave scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scarring may occur within the skin and deeper tissues. Scars may be unattractive, and of a 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 a possibility of visible marks in the skin from sutures. In some cases, scars may require surgical revision or treatment.

Firmness:

Excessive firmness can occur after surgery due to internal scarring. The occurrence of this is not predictable. Additional treatments including surgery may be necessary.

Skin Sensitivity:

Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after surgery. This usually resolves during healing, but in rare situations, it may be chronic.

Major Wound Separation:

Wounds may separate after surgery. Should this occur, additional treatment, including surgery, may be necessary.

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 suture removal.

Damage to Deeper Structures:

There is the potential for injury to deeper structures including nerves, blood vessels, muscles, and lungs (pneumothorax) during any 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.

Fat Necrosis:

Fat tissue found deep in the skin might die. This may produce areas of firmness within the skin. Additional surgery to remove areas of fat necrosis may be necessary. There is a possibility of contour irregularities in the skin that may result from fat necrosis.

Surgical Anesthesia:

Both local and general anesthesia involve risks. There is a possibility of complications, injuries, and even death 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 will be necessary.

Pain:

You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after surgery. If you are a chronic pain patient followed by a pain therapy practitioner, you may be asked to see this practitioner preoperatively to assist you in the management of your pain disorder during the post-operative period. Chronic pain may occur infrequently from nerves becoming trapped in scar tissues or due to tissue stretching.

There are nerve endings that may be affected by healing scars from the surgery. While there may not be a major nerve injury, small nerve endings may become too active during the healing period, producing a painful or oversensitive area when they are involved with scar tissues. Often, massages and early non-surgical interventions can resolve this issue. It is important to discuss post-surgical pain with your surgeon.

Cardiac and Pulmonary Complications:

Pulmonary complications may occur secondarily to blood clots (pulmonary emboli), fat deposits (fat emboli), pneumonia, 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 complication is a common risk with any surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heartbeats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatments.

Patient Name: **Patient Initials**: _____

Venous Thrombosis (Clot) 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 treatments. 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. Personal history of bleeding and clotting problems may also increase your risk of thrombosed veins.

Allergic Reactions:
In rare cases, local allergies to tape, suture material and glues, blood products, topical preparations, and 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 treatments. It is important to notify your physician of any previous allergic reactions.

Drug Reactions:
Unexpected drug allergies, lack of proper response to medication, or illness caused by prescribed drugs may occur. It is important for you to inform your physician of any problems and allergies you have had with any prescribed or over the counter medications, as well as medications you are currently taking on a regularly basis. Provide your surgeon with a list of medications and supplements you are currently taking.

Surgical Wetting Solutions:
There is a possibility that the large volumes of fluid containing dilute local anesthetic drugs and epinephrine injected into fat deposits during surgery may contribute to fluid overload or systemic reactions to these medications. Additional treatments including hospitalization may be necessary.

Persistent Swelling (Lymphedema):
Persistent swelling can occur following surgery.

Unsatisfactory Result:
Although good results are expected, there is no guarantee or warranty on the final results. The body is not symmetric, and almost everyone has some degree of unevenness, which may not be recognized in advance. One side of the face may be slightly larger, and one side of the face may be droopier. Similar possibilities exist for the breast and trunk areas. Many such issues cannot be fully corrected with surgery. The more realistic your expectations are, the better your results will appear to you. Some patients never achieve their desired goals or results, but at no fault of the surgeon or surgery. You may be disappointed with the results of surgery. Asymmetry, unanticipated shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. Size may be incorrect. The location or appearance of surgical scar may be unsatisfactory. It may be necessary to perform additional surgeries to improve your results. Unsatisfactory results may NOT improve with each additional treatment.

ADDITIONAL ADVISORIES

Medications and Herbal Dietary Supplements:
There are potential adverse reactions that occur as a result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with forming blood clots, and therefore may contribute to more bleeding issues. If you have a medical condition (such as heart arrhythmia, heart stent, blood vessels with blockages, or blood clots), and are taking anticoagulant medications such as Plavix®, Coumadin®, Xarelto®, Effient®, or Pradaxa® to thin your blood and prevent clotting, discuss management of these medications around the time of surgery with your plastic surgeon. Your plastic surgeon may sometimes coordinate a plan for these medications with the doctor that prescribed them for your medical condition. If you have been prescribed drugs for a

medical condition, do not stop them without discussing it first with your plastic surgeon. Abruptly stopping these medications may result in heart attacks, strokes, or death. Be sure to check with your physician about any drug interactions that may exist with medications that 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, immediately go 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, operate complex equipment, make any important decisions, or drink alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

Sun Exposure – Direct or Tanning Salon:
The effects of the sun are damaging to the skin. Sun exposure to the treated areas may result in increased scarring, color changes, and poor healing. Patients who tan, either outdoors or in a salon, should inform their surgeon and either delay treatment, or avoid tanning until the surgeon says it is safe to resume. The damaging effect of sun exposure occurs even with the use of sun block or clothing coverage.

Travel Plans:
Any surgery holds the risk of complications that may delay healing and your return to normal life. Please let the surgeon know of any travel plans, important commitments that were already scheduled or planned, or time demands that are important to you, so that surgery can occur at appropriate times. There are no guarantees that you will be able to resume all activities in the desired timeframe. Allow at least 10-14 days prior to travel via airplane. Medications may be required should you have a long flight/trip to prevent DVT/PE in the immediate post-operative period.

Long-term Results:
Subsequent alterations in the appearance of your body may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause or other circumstances not related to your surgery.

Body Piercing:
Individuals who currently wear body-piercing jewelry in the surgical region are advised that an infection could develop from this activity. Body-piercing jewelry should be removed prior to your surgical procedure.

Nails:
To determine your vitals status during surgery, your anesthesia provider may require access to your fingernails for monitoring. Make sure to have at least two fingernails free of nail polish or acrylic nails on the date of your surgery.

Jewelry:
Jewelry should not be brought with you at the time of your surgical procedure. Items, such as earrings, wedding rings, and necklaces should be removed and placed in a safe place.

Future Pregnancy and Breastfeeding:
This surgery is not known to interfere with pregnancy. If you are planning a pregnancy, your breast skin may stretch and offset the results of surgery. You may have more difficulty breast-feeding after this operation.

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

Patient Name: **Patient Initials**: _____

Intimate Relations After Surgery:
Recovery from surgery involves coagulation of blood vessels, and increased activity of any kind may open these vessels, leading to bleeding, or hematoma. Activity that increases your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery to control bleeding. It is wise to refrain from intimate physical activities until your physician states it is safe.

Mental Health Disorders and Elective Surgery:
It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvements rather than perfection. Complications or less-than-satisfactory results are sometimes unavoidable, may require additional surgeries, and are often stressful. Please openly discuss with your surgeon, prior to surgery, any past history of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

ADDITIONAL SURGERY NECESSARY (Re-Operations)
There are many variable conditions that may influence the long-term result of the surgery. It is unknown how your tissue may respond or how wound healing will occur after surgery. Secondary surgeries may be necessary to perform additional tightening or repositioning of body structures. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited above are associated with this surgery. Other complications and risks can occur but are less common. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty on the expected results. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. You and your surgeon will discuss the options available should additional surgeries be advised. There may be additional costs and expenses for such additional procedures, including surgical fees, facility and anesthesia fees, and pathology and lab testing.

PATIENT COMPLIANCE
Follow all physician's instructions carefully; this is essential for the success of your surgical 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 activities need 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 activities that increase your pulse or heart rate may cause bruising, swelling, fluid accumulation, and the need for return to surgery. It is important that you participate in follow-up care and return for aftercare to promote your recovery after surgery.

ATTESTATIONS

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray):
Patients who are currently smoking or use tobacco or nicotine products (patch, gum, or nasal spray) are at greater risk for significant surgical complications of skin loss, delayed healing, and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smoking may have a significant negative effect on anesthesia and recovery from anesthesia, and can lead to coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of these types of complications. Please indicate your current status regarding these items below**:**

___ I am a non-smoker and do not use nicotine products. I understand the potential 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.

___ I have smoked and stopped approximately _____ ago. I understand I may still have the effects and therefore risks from smoking in my system, if not enough time has lapsed.

___ I have been advised to stop smoking immediately and have been informed of the risks, benefits, expectations, and alternatives to my surgery if I continue smoking.

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. I acknowledge that I will inform my physician if I continue to smoke within this timeframe, and understand that for my safety, the surgery, if possible, may be delayed.

Smoking may have such a negative effect on your surgery that a urine or blood test just before surgery may be done just before surgery to determine the presence of nicotine. If positive, your surgery may be cancelled. Your surgery, the scheduling fee, and other prepaid amounts may be forfeited. Honestly disclose smoking status to your surgeon.

Sleep Apnea/CPAP:
Individuals who have breathing disorders such as “obstructive sleep apnea,” and who may rely upon CPAP devices (continuous positive airway pressure) or utilize nighttime oxygen are advised that they are at a substantive risk for respiratory arrest and death when they take narcotic pain medications following surgery. This is an important consideration when evaluating the safety of surgical procedures in terms of very serious complications, including death, that relate to pre-existing medical conditions. Surgery may be considered only with post-surgery monitoring is conducted in a hospital setting in order to reduce the risk of potential respiratory complications, and to safely manage pain following surgery.

Please consider the following symptoms of sleep apnea:

___ I am frequently tired upon waking, and throughout the day

___ I have trouble staying asleep at night

___ I have been told that I snore or stop breathing during sleep

___ I wake up throughout the night or constantly turn from side to side

___ I have been told that my legs or arms jerk while I’m sleeping

___ I make abrupt snorting noises during sleep

___ I feel tired or fall asleep during the day

It is important for you to inform and discuss any of the above symptoms that you have experienced with your surgeon.

DVT/PE Risks and Advisory:
There is a risk of blood clots, DVT, and PE with every surgical procedure. It varies with the risk factors below. The higher the risk factors, the greater the risk, and the more involved you must be in both understanding these risks and, when permitted by your physician, walking and moving your legs. There may also be leg stockings, squeezing active leg devices, and possibly medicines to help lower your risk.

There are many conditions that may increase or affect risks of clotting. Inform your doctor about any past or present history of any of the following:

_____Past History of Blood Clots
_____Family History of Blood Clots
_____Birth Control Pills
_____Hormone Stimulating Drugs
_____Swollen Legs
_____History of Cancer
_____Large Dose of Vitamins
_____Varicose Veins
_____Past Illnesses of the Heart, Liver, Lung, or Gastrointestinal Tract.
_____History of Multiple Spontaneous Abortions or Miscarriages

_____I understand the risks relating to DVT/PE, and how important it is to comply with therapy as discussed with my surgeon. The methods of preventative therapy include:

_____Early ambulation when allowes
_____Compression devices (SCD/ICD)
_____Anticoagulation protocols when Allowed

For high risk patients, the risks of VTE are still high even with appropriate chemoprophylaxis. If your surgery is elective and you are a high risk patient, it is best to consider with not proceeding with such elective surgery.

COMMUNICATION ACKNOWLEDGEMENT – CONSENT

There are many ways to communicate with you. It is important to keep appointments and let us know if problems or issues arise. Methods of communication are by telephone, text, pager, answering service if available, email, and regular mail. If an emergency arises, keep us alerted to your progress so we may aid in any necessary treatments. Please do not leave a message after hours or on weekends on the office answering machine if any urgent or emergent situation exists, as there is a delay in retrieving such messages. All attempts will be made to preserve your privacy in accordance with HIPAA rules.

Please confirm below all acceptable ways of communicating with you:

____ Telephone
____ Home (- -)
____ Work (- -)
____ Cell (- -)
____ Text
____ Pager – Answering service if available
____ Email – with up-to-date email address (@)
____ Regular mail and delivery

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 under 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 current 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.

STATEMENT
This facility is a office based surgery doctor's office regulated pursuant to the rules of the Board of Medicine as set forth in Rule Chapter 64B8, F.A.C.

STATEMENT
Dr. Salzhauer, elects not to carry medical malpractice insurance as permitted by Florida law.

STATEMENT
The records shall contain written anesthesia informed consent from the patient reflecting the patient's knowledge of identified risks, consent to the procedure, type of anesthesia and anesthesia provider, and that a choice of anesthesia provider exists, i.e., anesthesiologist, another appropriately trained physician as provided in this rule, certified registered nurse anesthetist, or physician assistant qualified as set forth in subparagraph 64B8-30.012(2)(b)6., F.A.C.

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.

Patient Name: **Patient Initials**: _____

CONSENT for SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr. Michael Salzhauer and assistants who may be selected to perform **Augmentation Mammaplasty with Silicone Gel-Filled Implants.** I have received the following information sheet: **Augmentation Mammaplasty with Silicone Gel-Filled Implants.**

2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those outlined above. I therefore authorize the above physician and assistants or designees to perform such other procedures, which are deemed necessary and desirable, based on his or her professional judgment. The authority granted under this paragraph shall include all conditions that require treatments and those not known to my physician at the time the procedure has begun.

3. I consent to the administration of such anesthetics as considered necessary or advisable. I understand that all forms of anesthesia involve risks and the possibility of complications, injury, and sometimes death.

4. I understand what my surgeon can and cannot do, and understand that 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 to 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 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 that may be removed.

8. I am aware that there are potential significant risks to my health with the utilization of blood products, and I consent to their utilization should they be deemed necessary by my surgeon and/or his/her appointees.

9. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.

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. I opt out of having this procedure _____.

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 Signature: _____ Date:

Physician Signature: _____ Date: