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.

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- 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.

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.

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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:

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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 Problems:
Wound disruption or delayed wound healing is possible. Some areas of the skin may not heal normally and may take a long time to heal. Areas of skin may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue.

Individuals who have decreased blood supply to tissue from past surgery or radiation therapy may be at increased risk for wound healing and poor surgical outcome. Certain medical conditions, dietary supplements, and medications may delay and interfere with healing, such as massive weight loss, diabetes, tobacco use, and the use of steroids on an extended basis. Patients may have a healing delay that could result in the incisions coming apart, tissue loss, infection, and tissue changes, requiring additional medical care, surgery, and prolonged hospitalizations.

There are general risks associated with healing such as swelling, bleeding, the possibility of additional surgery, prolonged recovery, color changes, shape changes, infection, unmet patient goals and expectations, and added expense to the patient. There may also be a longer recovery owing to the length of surgery and anesthesia.

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

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. 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 an increased chance of bleeding and additional surgery. It is important to follow postoperative instructions and to limit exercise and strenuous activity for the instructed time period. 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 operated area. You could require a blood transfusion. 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 result in bleeding and decreased blood platelets.

Infection:
Infection, although uncommon, can occur after surgery. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional 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. Postoperative infections often result in more extensive scarring and predispose to revision surgery.

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 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 sides of the body). There is the possibility of visible marks in the skin from sutures. In some cases, scars may require surgical revision or further treatment.

Firmness:
Excessive firmness can occur after surgery due to internal scarring. The occurrence of this is not predictable. Additional treatment including surgery may 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 in the postoperative period. Chronic pain may occur very infrequently due to nerves becoming trapped in scar tissue or tissue stretching.

There are nerve endings that may be affected by healing scars from 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 due to the small sensory nerves involved with scar tissue. Often, massage and early non-surgical interventions resolve this. It is important to discuss postsurgical pain with your surgeon.

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.

Asymmetry/Deformity:
Symmetrical body appearance may not result after surgery. Factors such as skin tone, fatty deposits, skeletal prominence, and muscle tone may contribute to the normal asymmetry of body features. Most patients have differences between the right and left sides of their bodies before any surgery is performed. Additional surgery may be necessary to attempt to diminish any asymmetry/deformity.

Damage to Deeper Structures:
There is the potential for injury to deeper structures including nerves, blood vessels, muscles (weakness), and organs like the lungs (pneumothorax) and intestines 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:
Fatty tissue found deep in the skin might die. This may produce areas of firmness under the skin. Additional surgery to remove areas of fat necrosis may be necessary. There is the possibility that contour irregularities in the skin may result from fat necrosis.

Persistent Swelling (Lymphedema):
Persistent swelling of soft tissue can occur following surgery and may become permanent.

Surgical Anesthesia:
Both local and general anesthesia involves risk. There is the possibility of complications, injury, and even heart attack, stroke, blindness, disability, and death from all forms of surgical anesthesia or sedation.

Shock:

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In rare circumstances, your surgical procedure may 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.

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

Venous Thrombosis (Clot) and Sequelae:
Thrombosed veins, which resemble cords, occasionally develop in the area of the breast or around IV sites or other surgical sites, and usually resolve without medical or surgical treatment. It is important to discuss any birth control pills you are taking with your surgeon. Certain high estrogen pills may increase your risk of thrombosed veins. A personal history of bleeding and clotting problems may also increase your risk. Clots that form in the deeper blood vessels (often in the legs) can cause extremity swelling or move to the chest and become dangerous (as described above).

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 medications. Allergic reactions may require additional treatment. 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 the prescribed drug are possibilities. It is important for you to inform your physician of any problems you have had with any medication or allergies to medication, prescribed or over-the-counter, as well as the medications you now regularly take. Provide your surgeon with a list of the medications and supplements you are currently taking.

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

Fat/Air Embolism:
In rare cases, fat particles or air can enter the vascular system and can travel to the heart, lungs, or brain. This can result in significant complications including death.

Unsatisfactory Results:
Although good results are expected, there is no guarantee or warranty, expressed or implied, as to the results that may be obtained. 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, while one side of the face may be droopier. The breast and trunk area exhibits the same possibilities. Many of these issues cannot be fully corrected with surgery. The more realistic your expectations are as to the results, the better your results will appear to you. Some patients never achieve their desired goals or results, 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,

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wound disruption, poor healing, contour irregularity, deformity, and loss of sensation may occur after surgery. Size may be incorrect. Unsatisfactory surgical scar location or appearance may occur. It may be necessary to perform additional surgery 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 the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with the formation of 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 medications to thin your blood and prevent clotting, such as Plavix®, Xarelto®, Coumadin®, Effient®, or Pradaxa®, discuss management of these medications around the time of surgery with your plastic surgeon. Your plastic surgeon may opt to 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 taking them without discussing it first with your plastic surgeon. Stopping these medications abruptly may result in a heart attack, stroke, or death. Be sure to check with your physician about any drug interactions that may exist with the 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, go immediately to the nearest emergency room.

When taking the prescribed pain medications after surgery, be aware that they can affect your thought processes and coordination. Do not drive, do not operate complex equipment, do not make any important decisions, and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

Sun Exposure – Direct or Tanning Salon:

The effects of the sun are damaging to the skin. Exposing the treated areas to sunlight 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 carries the risk of complications that may delay healing and your return to normal life. Please inform the surgeon of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of the surgery can occur. There are no guarantees that you will be able to resume all activities in the desired timeframe. Allow at least 10-14 days to travel via airplane. Medications may be required should you have a long flight/trip in order to prevent DVT/PE in the immediate postoperative 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 Procedures:

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.

Female Patient Information:

It is important to inform your plastic surgeon if you use birth control pills, 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.

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Intimate Relations after Surgery:
Since surgery involves the coagulation of blood vessels, increased activity of any kind may open these vessels leading to bleeding or hematoma. Activities that increase your pulse or heart rate may cause additional bruising, swelling, and the need for additional 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 improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery, and often are stressful. Prior to surgery, please openly discuss any history that you may have of significant emotional depression or mental health disorders with your surgeon. Although many individuals may benefit psychologically from the results of elective surgery, its effects on mental health cannot be accurately predicted.

ADDITIONAL NECESSARY SURGERY (Re-Operations)
Many variable conditions may influence the long-term results of surgery. It is unknown how your tissue may respond or how wound healing will occur after surgery. Secondary surgery 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 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, expressed or implied, as to the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. You and your surgeon will discuss the available options should additional surgery be advised. There may be additional costs and expenses for such additional procedures, including surgical fees, facility and anesthesia fees, pathology, and lab testing.

PATIENT COMPLIANCE
Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activities need to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon. Successful postoperative function depends on both the surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation, and the need for additional surgery. It is important that you participate in follow-up care, return for aftercare, and promote your recovery.

ATTESTATIONS

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Smoking, Second-hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray):
Patients who are currently smoking or using tobacco or nicotine products (patch, gum, or nasal spray) are at greater risk for significant surgical complications, such as skin loss, delayed healing, and additional scarring. Individuals exposed to secondhand 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, with coughing, breathing or airway problems, 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 secondhand 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 the use of nicotine products.

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

__ 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 four weeks before surgery and until your physician states it is safe to resume, if desired. I acknowledge that I will inform my physician if I continue to smoke within this timeframe, and I 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 to determine the presence of nicotine. If positive, your surgery may be cancelled and your surgery fee, scheduling fee, and other prepaid amounts may be forfeited. Be sure to honestly disclose your smoking status to your surgeon.

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

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

TO THE PATIENT CONSIDERING BREAST IMPLANTS FILLED WITH SALINE OR SILICONE GEL INTENDED FOR BREAST AUGMENTATION OR BREAST RECONSTRUCTION:

The review and understanding of this document is a critical step in making the decision whether you should choose breast implant surgery. You should learn about breast implants and then carefully consider the benefits and risks associated with breast implants and breast implant surgery before you make that decision. This form lists important risks, including those known or reported to be

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associated with the use of the device based on information from clinical trials, scientific literature, and reports from patients who have undergone device placement.

This Patient Decision Checklist is intended to supplement the additional patient information documents that should be provided to you by your physician. You should receive patient information documents that include important information about your specific breast implant, as well as a boxed warning and Patient Decision Checklist. After reviewing the information in the patient information documents for the specific implant that will be used, please read and discuss the items in this checklist carefully in consultation with your physician. You should place your initials in the location provided next to each item to indicate that you have read and understood the item. Your full signature at the end of this document confirms that you have read the materials and that your physician has answered all questions to your satisfaction.

CONSIDERATIONS FOR A CANDIDATE FOR SUCCESSFUL BREAST IMPLANTATION

I understand that I am not a candidate for breast implants if any of the following situations applies to me:

- I have an active infection anywhere in my body;
- I have an existing cancer or pre-cancer of my breast tissue that has not been adequately treated; or
- I am pregnant or nursing.

I understand that if I have any of the following conditions, I may be at a higher risk for a poor surgical outcome:

- Medical condition that affects my body's ability to heal (e.g.,diabetes, connective tissue disorder);
- Active smoker or a former smoker;
- Currently taking drugs that weaken the body's natural resistance to disease, such as steroids and chemotherapy drugs (e.g., prednisone, tacrolimus, sirolimus, mycophenolate, azathioprine, cyclosporine, methotrexate, chlorambucil, leflunomide, or cyclophosphamide);
- History of chemotherapy or planned chemotherapy following breast implant placement;
- History of radiation therapy or planned radiation following breast implant placement;
- Conditions that interfere with wound healing or blood clotting(e.g., hemophilia, von Willebrand disease, factor V Leiden, hyperhomocysteinemia, protein C deficiency, antithrombin III deficiency, or systemic lupus erythematosus); or
- Reduced blood supply to the breast tissue.

I understand the following conditions have not been adequately studied to determine whether the conditions put me at higher risk:

- Autoimmune disease (e.g., Hashimoto's, Lupus, Rheumatoid Arthritis) or family history of autoimmune disease (breast implant premarket clinical studies have not evaluated the safety of breast implants in patients with autoimmune disease);
- Clinical diagnosis of depression or other mental health disorder(including body dysmorphic disorder or eating disorder); or
- Have other products permanently implanted in the breast.

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RISKS OF BREAST IMPLANT SURGERY

I understand that there are risks of undergoing breast implant surgery. I understand that risks of undergoing breast implant surgery may include:

- breast pain (reported in up to 11.7% of patients[1]),
- skin or nipple areola sensitivity changes or loss (nipple complications reported in up to 6.3% of patients[1] and breast/skin sensation changes reported in up to 2.2% of patients[1]),
- asymmetry (reported in up to 23.2% of patients[1]),
- impact of aging or weight change on size and shape of breast(ptosis reported in up to 4.9% of patients[1]),
- infection requiring possible removal of implant (reported in up to3.2% of patients[1]),
- swelling (reported in up to 9.2% of patients[1]),
- scarring (hypertrophic scarring reported in up to 6.6%of patients[1]),
- fluid collections (seroma) (reported in up to 6.7% of patients[1]),
- hematoma (reported in up to 2.1% of patients[1]),
- tissue death of breast skin or nipple (tissue/skin necrosis reported in up to 2.3% of patients[1]),
- inability to breast feed (lactation complications reported in up to 30% of patients[1]),
- complications of anesthesia (may occur but specific rates are not publicly available in the Allergan Core Study),
- bleeding (may occur but specific rates are not publicly available in the Allergan Core Study),
- chronic pain (may occur but specific rates are not publicly available in the Allergan Core Study),
- damage to surrounding tissue, such as muscle, nerves, and blood vessels (may occur but specific rates are not publicly available in the Allergan Core Study), and
- impact on imaging of breast tissue (may occur but specific rates are not publicly available in the Allergan Core Study).

My physician has discussed these risks and has provided me with the patient information documents (including the boxed warning) with information on the types of risks that are possible and expected rates of occurrence.

My physician has discussed the potential use of other implanted products during my breast implant surgery. My physician has also discussed the risks and benefits of using these implanted products and their planned surgical approach.

Patient Initials: _____

RISK OF CANCER- Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL)

I understand that breast implants are associated with the development of a type of cancer of the immune system called Breast Implant-Associated Anaplastic Large Cell Lymphoma (BIA-ALCL). Information regarding the number of medical device reports of BIA-ALCL can be found on FDA's website.[2]

As of July 2019, literature reports various estimates for the incidence of BIA-ALCL. These estimated incidence rates range from a high of 1 per 3, 817 patients to 1 in 30,000. (Clemens et al, 2017, Loch-Wilkinson et al, 2017, De Boer et al, 2018).

_____ **Patient Initials**

I have received information regarding the overall incidence rates of BIA-ALCL and the rates as they pertain to my specific breast implant.

I understand that this cancer has been reported more frequently for textured breast implants, but patients with smooth surfaced implants have also been diagnosed.

I understand that patients with breast implants have a risk of developing BIA-ALCL within the scar tissue and fluid surrounding the breast implant.

I understand that BIA-ALCL typically takes several years to develop after implantation, but cases have been reported as early as within one year. Typical symptoms to be aware of may include: breast tightness, pain, lumps, or swelling of the breast months or years after I receive my implants.

I understand that treatment for BIA-ALCL involves an operation to remove the implants and the surrounding scar tissue capsule.

Based on the stage of the cancer at diagnosis, some patients have required chemotherapy or radiation. While BIA-ALCL typically responds well to therapy, some patients have died from BIA-ALCL. Diagnosis and treatment may be at my own expense and is not always covered by insurance.

SYSTEMIC SYMPTOMS

I understand that some patients who have received breast implants have reported a variety of systemic symptoms including joint pain, fatigue, rash, memory loss, and "brain fog" that some patients have called breast implant illness. While the causes of these symptoms are unclear, some patients have reported relief of these symptoms with removal of their implants and surrounding scar capsule; however, not all patients may experience improvement in their symptoms. Researchers are working to better understand the possible link between breast implants and these symptoms.

I also understand that some patients with breast implants have reported health problems in their children after birth or breastfeeding. A causal link has not been established between breast implants and these reported health problems in children and more research is needed. I understand that breast implants and breast surgery may interfere with my ability to successfully breastfeed.

Patient Initials: _____

BREAST-IMPLANT SPECIFIC RISKS

I understand that a breast implant is NOT a lifetime device and the longer I have my implants, the more likely I am to experience a complication and the more likely I am to need a reoperation requiring the replacement or removal of my breast implant. As many as 32.4% of women who received breast implants for augmentation had their implants removed within 10 years, but my implants may last for a shorter or longer period of time. (The percentage reported is from the 10-year Core Clinical Study for Natrelle Silicone gel-filled breast implants. The rate specified represents the largest reported cumulative 10-year rate across all groups of augmentation patients in the study (both primary and revision)).

I understand that my breast implant may rupture or leak at any time, and that the longer I have my implants, the more likely I am to experience a complication such as rupture. I understand that gel bleed (small quantities of gel diffusing from the implant shell) of silicone gel-filled implants may occur. I understand that if I have a saline-filled implant, my breast may deflate in appearance if there is a rupture or leakage of the saline.

_____ **Patient Initials**

I understand that if I have a silicone gel-filled breast implant, I or the physician may not be able to tell on physical exam whether my implant has ruptured or is leaking silicone gel. Because rupture or leakage of silicone gel-filled breast implants is difficult to detect,

I understand that periodic imaging evaluation is recommended for screening of silicone gel-filled breast implant rupture. It is recommended that I have periodic imaging of my silicone gel-filled breast implants to screen for implant rupture regardless of whether my implants are for cosmetic augmentation or reconstruction. These recommendations do not replace other additional imaging that may be required depending on my medical history or circumstances (i.e.,screening mammography for breast cancer).

Even if I have no symptoms, I should have regular imaging evaluations as described in the "Recommended Follow-Up" section below. These imaging evaluations may not detect all ruptures or leaks, and the expense may not be covered by my medical insurance.

I understand that there are rare case reports of silicone migrating from breast implants into tissues (e.g., chest wall, lymph nodes under the arm) and organs (e.g., liver, lungs). It may not be possible to remove migrated silicone.

I understand that all breast implants can affect mammography and breast exams, which could potentially delay the diagnosis of breast cancer. Mammography can also cause the breast implant to rupture or leak. I should tell the mammography technician if I have breast implants.

I understand that the long-term risks of breast implants may include:

- painful or tightening of scar tissue (capsule) around my implant (capsular contracture III/IV) (reported in up to 28.7%of patients[1]),
- rupture or leaking of the implant (reported in up to 35.4%of patients[1]),
- wrinkling of the implant (wrinkling/rippling reported in up to10.2% of patients[1]),
- visibility of the implant edges (implant palpability/visibilityreported in up to 6.7% of patients[1]),
- shifting of the implant (implant malposition reported in up to13.3% of patients[1]), or
- reoperation (reported in up to 71.5% of patients[1]).

I understand that I will receive a Device Identification Card after my surgery that has information on each of my specific implants. I understand that it is important for me to keep each card in case, at some time in the future, I or my physician need to know what kind of implant I received many years later.

I understand that breast implant manufacturing requires the use of chemicals and heavy metals. I understand that most of these chemicals stay inside the shell of the implant. Small quantities may diffuse (gel bleed) through the implant shell of silicone gel-filled implants, even if the implant is intact and not ruptured or leaking.

A list of the components, chemicals, and heavy metals is available in the section entitled, **"*NATRELLE*® Silicone-Filled/Saline-Filled Breast Implant Device Materials"** of the patient information document.

Patient Initials: _____

_____ **Patient Initials**

RECOMMENDED FOLLOW-UP

Even if I have no symptoms, I should have my first ultrasound or MRI at 5-6 years after my initial implant surgery and then every 2-3years thereafter. If I have symptoms or uncertain ultrasound results for breast implant rupture, an MRI is recommended.

I understand that for as long as I have my breast implant(s), I will need routine and regular follow-up with my physician, for examination of my breast implant(s) as well as to discuss any updates regarding breast implant issues.

National Breast Implant Registry (NBIR): I understand and have discussed with my physician that there is a National Breast Implant Registry where information regarding my health and breast implant information can be entered. The NBIR may help understand the long-term safety and performance of breast implants.

Patient Registry and Outcomes For breast Implants and anaplastic large cell Lymphoma (ALCL) etiology and Epidemiology (PROFILE):

I understand and have discussed with my physician that there is a registry (PROFILE) where information is collected to better understand BIA-ALCL in patients with breast implants.

Patient Initials:_____

QUESTIONS FOR MY PHYSICIAN

I have had the opportunity to ask my physician questions about his or her experience, medical degree, specialty of training, and credentials. I understand that breast implants have associated procedural risks and should only be used by physicians who are appropriately trained.

Patient Initials: _____

OPTIONS FOR MASTECTOMY

I understand that breast reconstruction is an elective procedure, which I can choose to do or not.

I understand that I may choose not to have breast reconstruction (“going flat”) and may choose to use an external prosthesis in my bra to look like I have a breast when wearing clothes.

I understand the surgical options for breast reconstruction, including the use of a breast implant and the use of my own tissue(“autologous reconstruction”).

I understand that if my breast implants are ever removed, I may be left with dimpling, chest wall concavity, puckering, or sagging of my breasts or skin.

I understand that more surgeries may be necessary in the future due to complications or to remove or replace the breast implants.

I have discussed all of the options for breast reconstruction with my surgeon, including whether I am a candidate and the benefits and risks of each, and I believe that breast reconstruction with a breast implant is the best option for me.

Patient Initials: _____

_____ **Patient Initials**

BREAST AUGMENTATION OPTIONS

I understand that breast augmentation is an elective procedure to increase the size of my breasts.

I understand that breast augmentation may result in permanent changes to my breast tissue and if my implants are ever removed,

I may be left with an unsatisfactory appearance, changes to the size and shape of my breasts, including but not limited to dimpling,chest-wall concavity, puckering, sagging, or different incision size or location.

If I am an augmentation patient, any additional surgeries or medical procedures will likely be at my own expense.

Patient Initials: _____

It is important that you read the above information carefully and have all of your questions answered before signing the consents below.

CONFIRMATION OF DISCUSSION OF RISKS

Patient: I acknowledge that I have received and read the patient information documents for the specific implant that will be used during my surgery and that I have had time to discuss the information in it and on this document with my physician. I have had the opportunity to ask questions and understand the benefits and risks of breast implants for me, given my specific health conditions. I have considered alternatives to breast implants, including reconstruction without breast implants, no reconstruction/augmentation, and their respective benefits and risks.

_____

Patient Signature and Date

Physician: I acknowledge that I have discussed the benefits and risks of breast implants as described elsewhere in the patient information documents and in this checklist. I have also explained the benefits and risks of the alternatives. I have encouraged the patient to ask questions, and I have addressed all questions.

_____

Physician Signature and Date

_____ **Patient Initials**

CONSENT for SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr. David Deisher / Dr. Stewart Humphrey and such assistants as 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 described above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are necessary and desirable in the exercise of his or her professional judgment. 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 that there are no warranties or guarantees, implied or specific, as to 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 the 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. 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/Time _____ Witness _____

_____ **Patient Initials**