KAT & CO
AESTHETICS

Informed Consent

Augmentation Mammaplasty with Silicone Gel-Filled Implants

Patient Name :
DOB :

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, as well as alternative treatment(s).

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

GENERAL INFORMATION

Augmentation 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 exists a significant difference between the size of the breasts.
- To restore breast shape after partial or total loss of the breasts for various conditions.
- To correct a failure for breast development due to a severe breast abnormality.
- To correct or improve results of existing breast implants for cosmetic or reconstructive reasons.

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

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

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. Breast implants may be manufactured in a variety of shapes, sizes, and with either smooth or textured surfaces. The method of implant selection and size, along with surgical approach for inserting and positioning breast implants will depend on your preferences, your anatomy and your surgeon's recommendation. The shape and size of the breasts prior to surgery will influence both the recommended treatment and the final results. If the breasts are not the same size or shape before surgery, it is unlikely that they will be completely symmetrical afterward.

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

Patients undergoing augmentation mammaplasty surgery must consider the following:

- Breast augmentation or reconstruction with silicone gel-filled implants may not be a onetime surgery.
- Breast implants of any type are not considered lifetime devices. They cannot be expected to last forever. You will likely require future surgery for implant replacement or removal.
- Changes that occur to the breasts following augmentation or reconstruction with implants are not reversible. There may be an unacceptable appearance to the breast if you later choose to have breast implants removed.
- Large volume primary augmentation or revision with larger sized implants 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 requiring surgical intervention to correct these complications.

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ALTERNATIVE TREATMENTS

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

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.

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

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

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 go into the breast tissue itself (extracapsular rupture and gel migration) or to more distant locations. Migrated silicone gel may be difficult or impossible to remove. Rupture of a breast implant may or may not produce local firmness in the breast.

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

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

A MRI (magnetic resonance imaging) study is advised to evaluate the possibility of implant rupture, yet it may not be 100% accurate in diagnosing implant integrity.

Capsular Contracture:

Scar tissue, which forms internally around the breast implant, can tighten and make the breast round, firm, and possibly painful. Excessive firmness of the breasts can occur soon after surgery or years later. The occurrence of symptomatic capsular contracture is not predictable. The incidence of symptomatic capsular contracture can be expected to increase over time. Capsular contracture may occur on one side, both sides or not at all. Treatment for capsular contracture may require surgery, implant replacement, or implant removal. Capsular contracture may reoccur after surgical procedures to treat this condition and it occurs more often in revision augmentation than primary augmentation. Some surgeons believe that preventative antibiotics during dental work and treatment for sinus infections and urinary tract infections may decrease this incidence. Discuss this with your surgeon. There may be an Off-Label FDA use for a drug called Singulair, which may have a softening effect on the capsule.

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

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

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

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

Implant Displacement and Tissue Stretching:
Displacement, rotation, or migration of a breast implant may occur from its initial placement and can be accompanied by discomfort and/or distortion in breast shape (visible rippling of the skin). Unusual techniques of implant placement may increase the risk of displacement or migration. Additional surgery may be necessary to attempt 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 which have the potential for trauma to the breast could potentially break or damage breast implants, or cause bleeding/seroma.

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

Change in Nipple and Skin Sensation:
You may experience a diminished (or loss of) sensitivity of the nipples and the skin of your breast. After several months, most patients have normal sensation. Partial or permanent loss of nipple and skin sensation may occur occasionally. Changes in sensation may affect sexual response or the ability to breast feed a baby.

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Anaplastic Large Cell Lymphoma (ALCL):

Women with saline and silicone gel breast implants may have a very small and possibly increased risk of developing anaplastic large cell lymphoma (ALCL) in the scar capsule adjacent to the implant. This is a very rare disease and is currently being investigated as to its relationship to breast implants, and whether this is even a cancer or a Lymphoproliferative Disorder. ALCL is an extremely rare cancer of the immune system which can occur anywhere in the body.

The British Association of Aesthetic Plastic Surgeons (BAAPS) have reassured women that worldwide there has only been about 150 cases reported out of 15 million patients who have had breast implants. The risk of death is only 1 in 2 million, and cure available for 94% of sufferers, so women should continue to feel that their implants are safe. ALCL is normally slow to progress and not aggressive, with a good likelihood of recovery. BAAPS members have been made aware of this extremely rare association for a while and are vigilant to make sure the right steps are taken if the condition is suspected in a patient with breast implants. Women can be reassured of the very nature of the rare association and there is no need for concern unless they develop sudden unexplained changes or swelling - although this could be for a number of reasons not related to ALCL.

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 costs and 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 and surgery to remove the scar capsule around the breast implant, implant removal or implant replacement.

Breast Implant Associated Squamous Cell Carcinoma (BIA-SCC):

There is a recent emerging evidence of a rare form of cancer related to breast implants called breast implant associated squamous cell carcinoma (BIA-SCC).
This is a very rare (16 cases so far world-wide) form of cancer, which has been reported on a background of a worldwide population of several tens of millions of women having breast implants. It should be noted that other cases of SCC have been reported in the breast unrelated to breast implants. Of the cases that have been documented, they presented between 11 and 40-years after the original breast implant surgery. They occurred with both smooth and textured surface implants, and with both silicone and saline filled implants. Patients reported delayed swelling of the breast (late seroma), pain, redness and often hardness (capsular contracture) of the breast. It should be stressed that with current data, this appears to be a very rare phenomenon.

Breast Disease:

Current medical information does not demonstrate an increased risk of breast cancer in women who have breast implant surgery for either cosmetic or reconstructive purposes. Individuals with a personal history or family history of breast cancer may be at a higher risk of developing breast cancer than a woman with no family history of this disease. It is recommended that all women perform periodic self -examination of their breasts, have mammography according to 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.

Mammography: It is important to continue to have regular mammography examinations and to perform periodic breast self-examination. Should a breast lump be detected with either mammography or self-examination, please contact your physician.

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

Immune System Diseases and Unknown Risks: A small number of women with breast implants have reported symptoms similar to those of known diseases of the immune system, such as systemic lupus erythematosus, rheumatoid arthritis, scleroderma, and other arthritis-like conditions. To date, after several large epidemiological studies of women with and without implants, there is no scientific evidence that women with either saline-filled or silicone gel-filled breast implants have an increased risk of these diseases. These diseases appear no more common in women with implants than those women without implants. The effect of breast implants in individuals with pre-existing immune system and connective-tissue disorders is unknown. There is the possibility of unknown risks associated with silicone breast implants and tissue expanders.

Patient Initials

Large Volume Breast Augmentation:

Patients who request an outcome of augmentation mammaplasty that produces disproportionately large breast size must consider that such a choice can place them at risk for a lethan optimal long-term outcome and the need for re-operation and additional expenses. The placement of excessively-sized breast implants exceeds the normal dimensions of the breast, produce irreversible tissue thinning, implant drop out, and visible/palpable rippling.

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

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 lymph node drainage of breast tissue to stage breastcancer.

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

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

Palpable Implant Edge:

This is more common in thin patients and in patients who chose excessively large implants.

Stretch Marks:
More common in younger patients with taut skin, tubular breasts and patients who chose to have excessively large implants.

Choice Of Implant Size And Shape: Bra cup size is variable and a cup size cannot be guaranteed. Choice of implant size and shape is the patient's responsibility. Change of implant size or shape will incur additional fees if the surgeon agrees to undertake the change.

Choice Of Implant Plane: The decision about placing the implant under or over the pectoralis muscle is a decision undertaken by the patient with the surgeon's guidance. This is sometimes not a clear decision as both have advantages and disadvantages. Change of implant plane will incur additional fees if the surgeon agrees to undertake the change.

Polyurethane Coated Silicone Gel Filled Implants: The potential benefits of PU coated silicone gel filled implants have been explained to you - possible reduction in capsular contracture rate and implant migration.

Leaflets from MHRA (Medicine and Healthcare products Regulatory Agency) and the implant Company have been provided to explain the risks and advantages.

The decision to choose the PU coated silicone gel filled implants rests solely with the patient.

Patient Initials _____

GENERAL RISKS OF SURGERY

Healing Issues:

Certain medical conditions, dietary supplements and medications may delay and interfere with healing. Patients with massive weight loss may have a healing delay that could result in the incisions coming apart, infection, and tissue changes resulting in the need for additional medical care, surgery, and prolonged hospitalizations. Patients with diabetes or those taking medications such as steroids on an extended basis may have prolonged healing issues. Smoking will cause a delay in the healing process, often resulting in the need for additional surgery. There are general risks associated with healing such as swelling, bleeding, possibility of additional surgery, prolonged recovery, color changes, shape changes, infection, not meeting patient goals and expectations, and added expense to the patient. There may also be a longer recovery due to the length of surgery and anesthesia. Patients with significant skin laxity (patients seeking facelifts, breast lifts, abdominoplasty, and body lifts) will continue to have the same lax skin after surgery. The quality or elasticity of skin will not change and recurrence of skin looseness will occur at some time in the future, quicker for some than others. There are nerve endings that may become involved with healing scars from surgery such as suction-assisted lipectomy, abdominoplasty, facelifts, body lifts, and extremity surgery. While there may not be a major nerve injury, the small nerve endings during the healing period may become too active producing a painful or oversensitive area due to the small sensory nerve involved with scar tissue. Often, massage and early non-surgical intervention resolves 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 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. Increased activity too soon after surgery can lead to increased chance of bleeding and additional surgery. It is important to follow postoperative instructions and limit exercise and strenuous activity for the instructed time. Do not take any aspirin or anti-inflammatory medications for at least ten days before or after surgery, as this may increase the risk of bleeding. Non-prescription “herbs” and dietary supplements can increase the risk of surgical bleeding. Hematoma can occur at any time, 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). Heparin medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

In breast implant surgery, hematoma may contribute to capsular contracture, infection or other problems.

Infection:

Infection is unusual 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 ingrown toenail, insect bite, or urinary tract infection. Remote infections, infection in other part of the body, may lead to an infection in the operated area.

Infection in Breast Implant Patients:

Subacute or chronic infections may be difficult to diagnose. Should an infection occur, treatment including antibiotics, possible removal of the implant, or additional surgery may be necessary. Infections with the presence of a breast implant are harder to treat than infections in normal body tissues. If an infection does not respond to antibiotics, the breast implant may have to be removed. After the infection is treated, a new breast implant can usually be reinserted. It is rare that an infection would occur around an implant from a bacterial infection elsewhere in the body, however, prophylactic antibiotics may be considered for subsequent dental or other surgical procedures. In extremely rare instances, life - threatening infections, including toxic shock syndrome have been noted after breast implant surgery. Individuals with an active infection in their body should not undergo surgery, including breast augmentation. Although infection is unusual after this type of surgery, it may appear in the immediate post-operative period or at any time following the insertion of a breast implant. It is important to tell your surgeon of any other infections, such as ingrown toenail, insect bite, or urinary tract infection. Remote infections, infection in other part of the body, may lead to an infection in the operated area.

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

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.

Change in Skin Sensation:
It is common to experience diminished (or loss of) skin sensation in areas that have had surgery. Diminished (or complete loss of) skin sensation may not totally resolve.

Skin Contour Irregularities:
Contour and shape irregularities may occur. Visible and palpable wrinkling of skin may occur. Residual skin irregularities at the ends of the incisions or “dog ears” are always a possibility when there is excessive redundant skin. This may improve with time, or it can be surgically corrected.

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

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

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.

Delayed Healing:
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. Smokers have a greater risk of skin loss and wound healing complications.

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:
Fatty 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 the possibility of contour irregularities in the skin that may result from fat necrosis.

_____Patient Initials

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

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

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

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

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

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

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

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 medications you now regularly take.

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

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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 systemic reaction to these medications. Additional treatment 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 expressed or implied, on 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, one side of the face droopier. The breast and trunk area exhibits the same possibilities. Many of such issues cannot be fully corrected with surgery. The more realistic your expectations as to results, the better your results will be in your eye. 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, wound disruption, poor healing, 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.

ADDITIONAL ADVISORIES

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray):
Patients who are currently smoking or use tobacco or nicotine products (Electonic cigarettes, patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying and delayed healing and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. There is evidence to suggest that smoking may increase the risk of capsular contracture around an implant. Additionally, smoking may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication.

I am a non-smoker and do not use nicotine products. I understand the potential risk of second-hand smoke exposure causing surgical complications. If I am a smoker, I will stop smoking at least 4 weeks before and after surgery (8 weeks total). I understand if I do not stop smoking (this included electronic cigarettes that contain nicotine) there are increased risks of wound breakdown and skin necrosis which will affect the aesthetic result.

It is important to refrain from smoking at least 4 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 with in this time frame, 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 test just before surgery may be done which will prove the presence of Nicotine. If positive, your surgery may be cancelled and your surgery, scheduling fee, and other prepaid amounts may be forfeited. Honestly disclose smoking to your surgeon.

Sleep Apnea / CPAP:
Individuals who have breathing disorders such as “Obstructive Sleep Apnea” and who may rely upon CPAP devices (constant 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 monitoring afterwards in a hospital setting in order to reduce risk of potential respiratory complications and to safely manage pain following surgery.

 _____Patient Initials

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.

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 bleeding. These include non-steroidal anti-inflammatories such as Ibuprofen and Neurofen. It is very important not to stop drugs that interfere with platelets, such as Clopidogrel, which is used after a stent. It is important if you have had a stent and are taking Clopidogrel that you inform the plastic surgeon. Stopping Clopidogrel may result in a heart attack, stroke and even death. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process and coordination. Do not drive, do not operate complex equipment, do not make any important decisions and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

Obesity:

There is clinical evidence to suggest that risk of complications associated with anaesthesia and surgery is increased with obesity (BMI of more than 30). This may result in poor wound healing, infection, wound breakdown, poor scarring and suboptimal aesthetic result.

Sun Exposure – Direct or Tanning Salon:

The effects of the sun are damaging to the skin. Exposing the treated areas to sun 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 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 already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame.

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. Weight changes can affect the result of surgery; it is essential when assessing results of surgery that your weight is similar to that at the time of surgery.

_____Patient Initials

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 lymph node drainage of breast tissue to stage breast cancer.

Body-Piercing Procedures:
Individuals who currently wear body-piercing jewelry in the surgical region are advised that an infection could develop from this activity.

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 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, 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. It is the responsibility of patients to ensure that they are not pregnant at the time of surgery. Anaesthetic and medication used may affect the foetus and/or jeopardize the pregnancy.

Intimate Relations After Surgery:
Surgery involves coagulating of blood vessels and increased activity of any kind may open these vessels leading to a bleed, 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 improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery and often are stressful. Please openly discuss with your surgeon, prior to surgery, any history that you may have 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.

DVT/PE Risks and Advisory:
There is a risk of blood clots, Deep Vein Thrombosis (DVT) and Pulmonary Embolus (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
Swollen Legs
History of Cancer
Large Dose Vitamins
Varicose Veins
Past Illnesses of the Heart, Liver, Lung, or Gastrointestinal Tract.

_____Patient Initials

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 allowed

Compression devices (SCD/ICD)

ASA protocol when allowed (Aspirin)

Heparin protocol when allowed

Enoxaparin protocol when allowed

The risks of DVT/PE may be almost as great as the prophylactic therapy when involving Aspirin, Heparin, and Exoxaparin. Be aware that if your surgery is elective, those patients with very high risks should consider not proceeding with such elective surgery.

ADDITIONAL SURGERY NECESSARY

There are many variable conditions that may influence the long-term result 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 particularly associated with this surgery. Other complications and risks can occur but are even more uncommon. The practice of medicine and surgery is not an exact science. Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. You and your surgeon will discuss the options available 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 activity needs to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon. Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

REVISION POLICY

Surgical revision is a common part of elective surgery. Your procedure will not stop you from aging, sagging, scarring or experiencing skin changes that are noted genetically controlled. If the cosmetic result of your surgery does not match the surgeon's expectations, revision surgery will be carried out without the surgeon's fee, provided that this is identified by the consultant within 6 months of the surgery. There will be a fee chargeable to cover facility and staffing costs.

Revision surgery is usually carried out at least after 3 to 12 months after the initial surgery to allow inflammation too to settle. If the cosmetic result of your surgery meets the consultant's expectations, further surgery will be chargeable at the prevailing rates. This revision policy applies only to patients who have complied with post-operative instructions, orders and visits. If you decide to seek a second opinion from another doctor or surgeon, you will be personally responsible for any cost incurred.

_____Patient Initials

FINANCIAL RESPONSIBILITIES

Self Funding:
The total fees quoted for surgery at the Clinic include:

- Pre-operative assessment before admission if necessary.
- Nursing care and facilities.
- Theatre fees, drugs and dressings.
- 1 set of compression garment
- Surgeon and Anaesthestist's fees (excluding consultation fees).
- Prosthesis.
- Histology.
- Removal of stitches, dressings if required.
- Post-operative consultation by the surgeon, usually at 3 months and as required up to 1 year
- The treatment of any related physical conditions or complications that become apparent within 30 days of discharge provided a) such conditions or complications are treated at the Clinic b) that you have followed the post-operative advice given.

The clinic fees do not include preoperative tests (these are very rarely required) or take home drugs.

Booking of surgery is provisional on payment of a deposit and confirmed only on payment of the full fees. There is a non-refundable £500 administration charge within this fee (which will be retained in all cancellations/ rescheduling).

Cancellation of the booking within 30 days to 14 days of the surgery date will incur a charge equivalent to 50% of the full fees .
Cancellation of the booking within 14 days of the surgery date will incur a loss of the full fees.
Cancellation must be done through speaking with a member of the Kat & Co Clinic (Tel: 0121 456 7930) either in person or over the telephone. Emails, written cancellation or voice messages are not accepted as they may not be received.

If the surgery is carried out at the Hospital, the total fees include the hospital accommodation and meals as well as take home drugs for up to 5 days.

I understand and unconditionally and irrevocably accept my financial responsibilities ___

Private Medical Insurance
You have been given the CSSD code/codes and fees for your surgery. Insurance companies and individual policies do vary considerably with respect to the renumeration. You are therefore advised to clarify your level of coverage with your insurance company. Shortfalls and payments are your responsibility.

I understand and unconditionally and irrevocably accept my financial responsibilities ___

SECOND CONSULTATION AND WAIVER

It is good medical practice for patients to attend a second consultation (free of charge) pre surgery. This is to allow patients to ask further questions and to prepare fully for the surgery and recovery.

I have attended the second consultation and if I have not I waive my right to this consultation and its potential benefit

_____**Patient Initials**

TWO WEEKS COOLING OFF PERIOD AND WAIVER

The GMC Good Practice Guidelines suggest a minimum of 2 weeks between consultation and surgery. This is to ensure that patients have a reasonable period of time to reflect on the implication of the proposed surgery, to make a fully informed decision without any pressure to proceed and to ask any further questions.

I have waited longer than two weeks between consultation and surgery and if not I am freely electing to waive my right to this cooling off period and confirm that I wish to proceed with the proposed treatment

TRAVELLING TO THE CLINIC FOR DAY CASE SURGERY (NOT APPLICABLE TO HOSPITAL SURGERY)

With the exception of minor surgery like mole removal, you should avoid driving yourself home after your treatment.
We strongly advise patients who live more than an hour from the clinic to arrange to stay locally for at least 24 hours for safety and comfort. Remaining local will facilitate any return to the clinic should you need to do so. You should also have an escort to watch over you for the first 24 hours after surgery.

BODY MASS INDEX (BMI) CRITERIA FOR DAY CASE SURGERY AT THE CLINIC (NOT APPLICABLE TO HOSPITAL SURGERY)

For patients undergoing Twilight Anaesthesia or TIVA (Total Intravenous Anaesthesia), the maximum BMI for safety is 30 or under. For abdominoplasty (tummy tuck), the BMI cutoff is 27 and below.

For patients undergoing Local Anaesthesia, Local Anaesthesia with oral sedation or intravenous sedation (midazolam), the maximum BMI for safety is 40 or under.

Please talk to us if you need advice or support with weight management. Exceeding the recommended BMI may mean cancellation of your surgery and the cancellation policy will apply.

DISCLAIMER

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

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

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 Initials

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1. I hereby authorize Dr _____ and such assistants as may be selected to perform the following procedure or treatment: 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 above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.

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

4. I understand what my surgeon can and cannot do, and understand there are no warranties or guarantees, implied or specific about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks 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 videoed before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for documentation and use of the photos/videos for medical, scientific, educational or commercial purposes, provided my identity is not revealed by the photos/ videos. Separate consent will be sought if your identity cannot be concealed.

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 consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
9. I 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.
10. I realize that not having the operation is an option.

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 (1-11). I AM SATISFIED WITH THE EXPLANATION.

_____

Patient or Person Authorized to Sign for Patient

Date _____ Physician_ KimKat _____

 _____**Patient Initials**