

MR. A. KARIDIS M.D. F.R.C.S.
Plastic Surgeon

INFORMED CONSENT FOR COSMETIC SURGERY
(Breast Augmentation)

TO THE PATIENT: You have the right, as a patient, to be informed about your condition and the recommended surgical, medical, or diagnostic procedure to be used so that you may make the decision whether or not to undergo the procedure after knowing the risks and hazards involved.

It is a legal requirement that before any surgical operation the patient reads and signs a consent form. It is important that you understand the risks and hazards involved with any surgery. Although the vast majority of patients do not experience the following complications you must be made aware of these. This disclosure is not meant to scare or alarm you; it is simply an effort to make you better informed so you may give or withhold your consent to the procedure.

I

voluntarily request Mr. A. Karidis as my surgeon, and such associates, technical assistants, and other health care providers as they deem necessary, to carry out the following surgery:

- I understand that no warranty or guarantee has been made to me as to result or cure. Although good results are expected it is possible that the result might not live up to expectations or the goals that have been established. In this connection I know that the practice of medicine and surgery is not an exact science and that therefore reputable physicians cannot guarantee results.**
- I realise that, as in all medical treatment, complications or delay in recovery may occur which could lead to the need for additional treatment or surgery, and could also result in economic loss to me because of my inability to return to normal activity as soon as anticipated. I understand that in the event of any revision surgery taking place for whatever reason then although the surgeons fee is waived in these circumstances, I will be responsible for any anaesthetists or theatre facility fee.
- I understand that Mr. Karidis may discover other or different conditions which may require additional or different procedures than those planned. I authorise him, and such associates, technical assistants, and other health care providers to perform such other procedures, which are advisable in their professional judgement.
- Although extremely rare in cosmetic surgery, I consent to the use of blood and blood products as deemed necessary.
- I understand that external incisions leave scars that are visible. The location of these incisions has been described to me. I also understand that it is impossible to predict the exact ultimate appearance of these scars despite meticulous technique. I have been advised that scars take upwards of eighteen months to mature and the changes that normally occur in their appearance during the healing period such as redness, lumpiness, and irregularities have been described to me. I also realise that although unsightly scars can be surgically revised, this does not provide any guarantee that the subsequent ensuing appearance of the scar will be invisible.

- ❑ I understand that there are risks and hazards related to the performance of the surgical procedures planned for me. I realise that common to surgical procedures is the potential for infection, swelling, bruising, bleeding, haematoma(local blood collection) seroma(accumulation of serum), blood clots in veins and lungs (extremely rare), and allergic reactions. Preventative measures to combat the possibility of blood clots in veins, such as preoperative TED(anti-embolic)stockings, intraoperative Flowtron Compression devices and early mobilisation are routinely deployed in Mr. Karidis's practice.
- ❑ I understand that complications outlined above also occur more frequently with patients who are obese, smoke, and have a history of lung or other chronic underlying medical conditions. High blood pressure that is not well controlled with medication may cause excess bleeding during or after surgery. Accumulations of excess blood under the skin may delay healing and cause scarring.
- ❑ I also realise that although unlikely, the following risks and hazards may also occur in connection with this procedure: unsatisfactory appearance, poor healing, skin loss(necrosis), nerve damage with associated sensory changes or prolonged pain and discomfort, or unattractive scarring.

I also realise that the following additional risks and hazards may occur in connection with **Breast Implants:**

❑ **General known risks:**

Infection, haematoma (blood collection), seroma(fluid collection) changes in sensation, postoperative pain, and delayed wound healing. Rarely, delayed wound healing may also result in implant extrusion.

❑ **Specific known risks:**

- **Rupture.** The implant can break as a result of damage from trauma, defect or normal wear over time. Rupture releases the gel filling. As modern silicone cohesive gels nowadays act as a solid unit and do not leak as in the older liquid form gels, ruptures may go unnoticed. This may however sometimes result in breast flattening, softening, tenderness, and a palpable mass. As a result of the thicker gel consistency, the contents usually remain confined and contained by the tissue capsule around the implant but may in certain situations also migrate into the breast, arm pit lymph nodes, and other places in the body. Rupture when detected, requires surgical removal of the implant and gel mass and replacement as necessary.
- **Capsular contracture(Hardening).** The scar tissue that normally forms around the implant may tighten and squeeze the implant(1% incidence). This can cause firmness, pain, and in severe case, a misshapen appearance. This could also require further surgery or removal of the implants.
- **Interference with standard mammography.** The implant can interfere with the early detection of breast cancer by hiding some breast tissue from standard mammographic views. Standard mammographic screening should not be used on breasts with implants. The radiologist performing the mammography should always be told about the presence of the breast implants. The radiologist should then be experienced with special techniques for imaging and diagnosing breasts with implants.
- **Calcification.** Calcium deposits may form in the capsule tissue around the implant in rare cases. This may cause hardening and pain. This type of calcium deposit sometimes may also resemble the type of calcium deposits associated with early breast cancer. In these situations special imaging and radiological experience is required to differentiate the two entities.
- **Wrinkling and folds.** Any implant surface may form wrinkles or creases. These may be noticeable on the surface of the skin, depending on how much tissue covers the implant. This is much more commonly associated with the less viscous fillers such as saline, and significantly less with the newer cohesive silicone gel implants, but can theoretically happen with any implant. It constitutes mainly a cosmetic problem rather than a medical one.
- **Changes in sensation.** The surgery may affect sensation or feeling in the nipples and surrounding skin area. Sensation may increase or decrease and although usually temporary, may be permanent. Nerve regeneration may take up to 2 years to complete.

- **Extrusion.** In very rare cases, the implant may push through the tissue covering and become exposed. This is most likely to occur if the overlying tissue is already damaged or becomes damaged from lack of blood circulation (ischaemia) associated with an excessively large or displaced implant.
 - **Dissatisfaction with cosmetic result.** Although every attempt will be made to make both breasts exactly the same following surgery, their appearance may not be identical in size or shape. This most likely reflects any pre-existing differences in size or shape. In fact it is highly unusual for any one individual to have two identical breasts. Dissatisfying results may also include unsightly scar or scar deformities, firmness, displacement, migration, unanticipated contour, and palpability of implant.
 - **Gel diffusion.** Minute quantities of silicone may diffuse, or "bleed" through the envelope of the implant. The detection of minute quantities of silicone in women with and without implant (because silicones are used in many consumer and medical products) remains an incidental finding of no proven significance.
 - **Autoimmune disease and Cancer.** Individual patient case reports have suggested a potential association between silicone breast implants and connective tissue disorders. The Ministry of Health, leading physicians, including plastic surgeons, rheumatological specialists, and the American Medical Association emphasise that there is no scientific evidence linking silicone breast implants to connective tissue disorders or cancer. Additionally there is currently no evidence to suggest that children of mothers with breast implants can develop immunological problems.
 - **Self-examination.** Certain studies have suggested that women with breast implants may not recognise breast cancer until it has progressed to a more advanced stage. In this regard it is important that women undergoing this operation carry out diligent self-examination post operatively with appropriate attention paid to any abnormalities that develop.
 - **Breast Feeding and Pregnancy.** Due to the normal hormonal influences of pregnancy your own breast tissue will enlarge accordingly and your skin overlying this will also stretch and subsequently the breasts may droop. It is impossible to predict to what degree this will occur. Although many times this resolves with the involution of pregnancy, a breast uplift to restore this breast drop may sometimes be required. Breast implantation usually does not interfere with breast feeding since the implant is inserted under-not in- the breast tissue and therefore the milk glands and ducts to the nipples are unaffected. Most women report no difficulties in nursing after implantation, though some individuals experience difficulty with breast feeding regardless of whether or not they have breast implants.
 - **Explantation.** You should not consider your implants lifetime devices; Revision surgery, including explantation (removal of implants) and replacement, may be indicated at any time although rough guidelines indicate a lifespan of between 15-20 years. Medical management of any of the above complications may also include explantation.
- I understand that there are many variable conditions in addition to risk and potential surgical complications that may influence the long term results of any surgery (i.e. smoking, genetics). I also understand that even though risks and complications occur infrequently, the risks cited above are the ones that are particularly associated with my surgery. Other complications and risks can occur but are even more uncommon (less than 0.1%)
- THIS PARAGRAPH PERTAINS TO SMOKERS:** Smokers are recognised to have a significantly higher risk of post operative wound healing problems with a subsequently higher potential of infection as well as operative and post operative bleeding. Patients should discontinue smoking for two weeks before and two weeks after surgery. Although it helps to stop smoking before and after surgery, this does not completely eliminate the increased risks resulting from long-term smoking. Smoking also has a long term adverse effect on the skin and ageing process.
- ANAESTHESIA:** I acknowledge that the anaesthetist has reviewed the proposed anaesthetic with me and answered my questions in this regard. I understand that anaesthesia involves additional risks and hazards but I request the use of anaesthetics for the relief and protection from pain during the planned and additional procedures. I realise the anaesthesia may have to be changed possibly without explanation to me. Although modern anaesthesia is considered safe I understand that certain complications may very occasionally result from the use of any anaesthetic, such as drug reactions (usually minor), respiratory, recovery problems and although extremely

unlikely, death(1:250,000). Other risks and hazards include minor throat discomfort post operatively (temporary only), as well as injury to vocal cords, or teeth (very rare). Please inform the anaesthetist regarding any previous dental work.

- THIS PARAGRAPH PERTAINS TO FEMALE PATIENTS ONLY:**
Anaesthetic agents can be harmful to the foetus of a pregnant woman. General anaesthesia should be avoided during pregnancy whenever possible. I hereby state that I am not pregnant and accept the responsibility of making this determination.
- I hereby give permission to Mr. Karidis or any assistant he may designate to take photographs for diagnostic purposes and to enhance the medical record. I agree that these photographs will remain his property and that he may use these discreetly for medical, scientific or other publications and presentations provided my identity is not revealed. No photographs which can identify me facially will ever be used in any popular press or media without my expressed consent.
- I have been told that a medical grade synthetic implant may be used (where applicable) in the above mentioned operation and have been advised of the risks as well as alternative methods of treatment. I also understand that occasionally the body can reject implants.
- I certify that I fully informed Mr. Karidis correctly and to the best of my knowledge of my full medical history and status. I understand that withholding medical information could lead to complications or problems that may have been prevented if that information were known prior to my surgery.
- I agree to follow the instructions given to be by Mr. Karidis to the best of my ability before, during and after the above mentioned surgical procedure, and will notify Mr. Karidis of any problems following my surgery.
- I understand and agree that any dispute or litigation with respect to the treatment or procedure of the above will be heard and settled in the city in which the procedure occurred in the United Kingdom, and the laws of England and Wales shall govern all aspects of such dispute or litigation.
- I certify that Mr. Karidis has discussed the operation with me to my satisfaction; this form fully explained to me, that I have read it or have had it read to me, that the blank spaces have been filled in, and that I understand its contents. I have been given an opportunity to ask questions about my condition, alternative forms of anaesthesia and treatment, risks of non treatment, the procedures to be used, and the risks and hazards involved, and I believe that I have sufficient information to give this informed consent.

DO NOT SIGN THIS FORM UNLESS YOU HAVE READ IT AND FEEL THAT YOU UNDERSTAND IT. PLEASE ASK ANY QUESTIONS YOU MIGHT HAVE BEFORE SIGNING.

I hereby accept that the essential information necessary to make an informed decision has been given to me. All questions have been implicitly answered to my satisfaction.

Patients Name

Date

Address

City

Patients Signature

I hereby certify that I have discussed all the above with the patient. I have offered to answer any questions regarding the procedure and believe the patient fully understands what I have explained and answered.

Mr. A. Karidis
Consultant Plastic Surgeon

Date