

Consent for Breast Augmentation Procedure using Cohesive Silicone Gel Implants

N.B. Please read this consent form for surgery carefully. It covers common issues with the breast reduction procedure.

Patient's name: _____

1. I authorise Dr Sanjay Azad to perform on me the operation known as a breast augmentation (breast enlargement).
2. The nature and effects of the operation, the risks and complications involved, as well as alternative methods of treatment have been fully explained to me by Dr Sanjay Azad and I understand them. I authorise Dr Sanjay Azad to perform any other procedure that she may deem desirable in attempting to improve the condition stated in Paragraph 1 or any unhealthy or unforeseen condition that may be encountered during the operation.
3. Complications after a breast augmentation can be those after any surgical procedure. The following points, among others, have been specifically made clear:

- a) The appearance of my breasts will change over time due to ageing of my soft tissues, hormonal influences, alterations in weight, sun exposure and ageing of the device (breast implant). I take responsibility for my long term follow up.

I understand that cohesive silicone gel implants will be used. These are "form stable" and have no risk of leakage. They have been manufactured to the highest standard and are FDA approved. I understand that breast implants are a man-made device and deteriorate over time. I understand that they will need to be changed during a surgical operation. No guarantee can be given about how long they last for nor how my body will tolerate them.

- b) The need to change the implants may be very soon after inserting them (e.g. months), or much longer (e.g. more than a decade). Changing the implants is not included in the cost of the procedure I am about to have.
- c) I have been shown a presentation about breast augmentation and also received a Breast Augmentation brochure. I fully appreciate that each result is individual with no overall guarantee of a defined outcome.
- d) The procedure has been performed for several decades and is safe. Research indicates that the material implanted in the body does not cause malignancy, nor connective tissue disease in human subjects. A rare form of Lymphoma has recently been noted in a very tiny number of women with breast implants, worldwide. It is not clear whether there is a cause and effect relationship or whether it is just coincidental.
- e) Inserting a foreign body into the human body increases the risk of infection of the implants. I understand I need to be vigilant **whenever** I have an infection anywhere else in my body (teeth/gum, urine, skin, throat/chest) and understand that I need to see my Family Doctor and to obtain antibiotics.
- f) I understand that if I develop an infection in one or both implants, that the implants need to be removed and I will be without implants for a period before they can be put back in. Removal of the implants will incur additional costs. Replacements of the implants will incur additional costs.
- g) I understand the body covers foreign material with an internal scar. This scar may become thickened and shortened like "shrink-wrap". As a result, the breasts may become firm (capsular contracture). This condition may be permanent and may cause pain and discomfort.

- h) The true cause of Capsular Contracture is not known. It is thought that it may be related to a subclinical infection (bio-film) / blood in the cavity / smooth walled implants / tiny amounts of free silicone in the pocket. The only way to prevent Capsular Contracture is to avoid having breast implants. Capsular contracture is best treated by removing the capsule surgically, and creating new pocket for new implants. **Removal of the capsule and removal and replacement of the implants will incur additional costs.** If the capsular contracture is thought to be caused by an infection, the implants may not be replaced at the same operation.
- i) There is a possibility that my body may not tolerate implants, thereby necessitating their removal. This event occurs in a small percentage of cases. **Removal of the implants will entail cost extra.**
- j) In some patients the margin of the implants will be felt, even if the implants are put under the pectoralis major muscle. This is more likely in thin patients.
- k) The incision will heal with a scar that will be permanent. Individuals scar differently and the result therefore will differ for each individual. Scars can become thickened, raised and/or red and can develop into hypertrophic (raised) scars or even keloids (itchy). The scar will be in the infra-mammary fold.
- l) Postoperative bleeding may rarely occur around the implant, thus requiring an emergency operation. This may occur during my initial admission. Drains are typically not used except if there was postoperative bleeding.
- m) After being exposed to cold temperatures (e.g. swimming in cold water), the breasts may feel cooler than surrounding body tissues.
- n) Pregnancy is not recommended for at least six (6) months after operation. Breast feeding is not guaranteed. Although the implant is placed under the breast and does not interfere with any of the breast gland or ducts, successful breast feeding depends on many factors.
- o) Numbness or hypersensitivity of the nipple, areola or breasts may occur following operation. Loss of sensation may be PERMANENT.
- p) There is a risk of wound break down, chest infections, heart and lung complications and deep vein thrombosis. This risk is increased in **obese people and smokers/nicotine substitutes.**
- q) Imaging of the breast by mammography, ultrasound and MRI is still possible with breast implants. My implants may need to be removed if a malignant lump is discovered. I must continue with monthly self-examination of my breasts. My implants may need to be removed if a malignant lump is discovered.
- r) I understand my operation may be cancelled on the day if I am still **smoking/using nicotine.** I confirm that Dr Sanjay Azad has advised me on the risks and possible complication associated with **smoking smoking/nicotine use** and its effects on surgery and the postoperative recovery period. I also confirm that Dr Sanjay Azad has strongly advised me to stop smoking/using nicotine and I accept all responsibility for the outcome of my surgery related to smoking if I had not done so 8 weeks prior and 8 weeks after surgery.
- s) No guarantee has been given concerning size and shape of the breasts. Good results are expected but not guaranteed.
- t) Implants are subject to displacement such as rotation, flipping over, bottoming out and symmastia (breast meeting in the middle).
- u) If I am unhappy with the size or shape or position of my implants, I understand that repeat surgery cannot take place before one year has passed. **The cost of this surgery is not included in the original cost.**
- v) I understand that I may look worse after the operation if I have complications. I understand that the practice of medicine and surgery is not an exact science and that reputable practitioners cannot guarantee results. No guarantee or assurance had been given by Dr Sanjay Azad or anyone else as to the results that may be obtained.

4. No surgeries are a guaranteed success and therefore a second procedure or a touch-up may be required to achieve the desired appearance. **These costs are not included in the original cost.**
5. I understand that I may look worse after the operation if I have complications.
6. I understand that the two sides of the human body (left and right) are not the same and can never be made the same or identical.
7. I was given the opportunity to ask questions and to raise concerns regarding my condition, the procedure and the risks and my treatment options with Dr Sanjay Azad during my consultations. My questions and concerns have been discussed and answered to my satisfaction.
8. I consent to the administration of anaesthetics by the expert anaesthetist responsible.
9. I consent to the admittance of authorised observers (student nurses/doctors) to the operating room, for the purpose of advancing medical education.
10. I give permission for Dr Sanjay Azad to take still or motion clinical photographs with the understanding that such photographs form part of my clinical records and remain the property of Dr Sanjay Azad.
11. I certify that I have read the above authorisation, that the explanations referred to therein were made to my satisfaction and that I fully understand such explanations and the above authorisation.

CONSENT FOR PROCEDURE

(1) I, _____, hereby consent to undergo the investigation, treatment or operative procedure, _____, ordered by or to be performed by Dr. Sanjay Azad, Consultant Plastic Surgeon.

(2) The nature and anticipated effect of what is proposed including the significant risks and alternatives available have been explained to me. I am satisfied with these explanations and I have understood them.

(3) I also consent to such additional or alternative investigations, treatments or operative procedures as in the opinion of Dr. Sanjay Azad, Consultant Plastic Surgeon are immediately necessary.

(4) I further agree that in his discretion, Dr. Sanjay Azad may make use of the assistance of other surgeons, physicians, and hospital medical staff (including trainees) and may permit them to order or perform all or part of the investigation, treatment, or operative procedure, and I agree that they shall have the same discretion in my investigation and treatment as Dr. Sanjay Azad.

Dated _____
day / month / year

Witness _____

Patient _____