

Laurence Kirwan M.D., F.R.C.S  
Plastic Surgeon  
**INFORMED CONSENT FOR AUGMENTATION MAMMAPLASTY**

**INSTRUCTIONS**

This is an informed-consent document that has been prepared to help your plastic surgeon inform you about augmentation mammoplasty, its risks, and alternative treatments.

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.

**GENERAL INFORMATION**

Augmentation mammoplasty is a surgical operation performed to enlarge the 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.
- As a reconstructive technique for various conditions

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.

Silicone gel-filled implants are no longer widely available for purely cosmetic breast augmentation. Silicone gel-filled implants are available for some conditions within a study protocol supervised by the United States Food and Drug Administration (FDA). Saline-filled breast implants are still widely available for cosmetic breast augmentation. All breast implants are subject to device tracking according to federal law.

Breast enlargement is accomplished by inserting a breast implant either behind the breast tissue or under the chest muscles. Incisions are made to keep scars as inconspicuous as possible, usually under the breast, around the lower part of the areola, or in the armpit. The method of inserting and positioning breast implants will depend on your preferences, your anatomy and your surgeon's recommendation.

**ALTERNATIVE TREATMENT**

Augmentation mammoplasty is an elective surgical operation. Alternative treatment would consist of not undergoing the surgical procedure, the use of external breast prostheses or padding, or the transfer of other body tissues to enlarge breast size.

**RISKS of AUGMENTATION MAMMAPLASTY SURGERY**

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with augmentation mammoplasty. Additional information may be obtained from the FDA, package-insert sheets supplied by the implant manufacturer, or other information 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. Although the majority of women do not experience the following complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks, potential complications, and consequences of breast augmentation.

**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 blood transfusion. Do not take any aspirin or anti-inflammatory medications for **three weeks** before surgery, as this may increase the risk of bleeding.

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**Infection**- Infection is unusual after this type of surgery. Should an infection occur, treatment including possible removal of the implant, antibiotics or additional surgery may be necessary. It is extremely rare that an infection would occur around an implant from a bacterial infection elsewhere in the body.

**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. Although the occurrence of symptomatic capsular contracture is not predictable, it generally occurs in less than 20 percent of patients. 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. External pressure (closed capsulotomy) may break up scarring, but can potentially rupture the implant.

**Change in nipple and skin sensation**- Breasts are usually sore after surgery. Some change in nipple sensation is not unusual right after surgery. After several months, most patients have normal sensation. Partial or permanent loss of nipple and skin sensation may occur occasionally.

**Skin scarring**- Excessive scarring is uncommon. In rare cases, abnormal scars may result. Scars may be unattractive and of different color than surrounding skin. Additional surgery may be needed to treat abnormal scarring after surgery.

**Implants**- Breast implants, similar to other medical devices, can fail. Implants can break or leak. When a saline-filled implant deflates, its salt water filling will be absorbed by the body. Rupture can occur as a result of an injury, from no apparent cause, or during mammography. It is possible to damage an implant at the time of surgery. Damaged or broken implants cannot be repaired. Ruptured or deflated implants require replacement or removal. Breast implants do not have an indefinite lifespan and will eventually require replacement surgery.

**Degradation of breast implants**- It is possible that small pieces of the implant material may separate from the outer surface of breast implants. This is of unknown significance.

**Implant extrusion**- Lack of adequate tissue coverage or infection may result in exposure and extrusion of the implant. Skin breakdown has been reported with the use of steroid drugs or after radiation therapy to breast tissue. If tissue breakdown occurs and the implant becomes exposed, implant removal may be necessary.

**Mammography**- If you are over 35 years of age, pre-operative mammography is recommended prior to surgery. Post-operative mammography is performed according to American Cancer Society guidelines. Breast implants may make mammography more difficult and may obscure the detection of breast cancer. Implant rupture can occur from breast compression during mammography. Inform your radiologist of the presence of breast implants so that appropriate mammogram studies may be obtained. Ultrasound, specialized mammography and MRI studies may be of benefit to evaluate breast lumps and the condition of the implant(s).

**Skin wrinkling and rippling**- Visible and palpable wrinkling of implants can occur. Some wrinkling is normal and expected. This may be more pronounced in patients who have saline-filled implants or thin breast tissue.

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**Pregnancy and breast feeding**- There is insufficient evidence regarding the absolute safety of breast implants in relation of fertility, pregnancy or breast feeding. While there is no convincing evidence of any special danger of breast implants for pregnant women or their children, studies are continuing to look for possible problems.

**Calcification**- Calcium deposits can form in the tissue surrounding the implant and may cause pain, firmness, and be visible on mammography. Should this occur, additional surgery may be necessary to correct his problem.

**Immune system diseases and unknown disorders**- Some 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. These symptoms include joint pain or swelling, fever, fatigue, thyroid problems, breast pain and musculoskeletal pain. A connection between implanted silicone and connective-tissue disorders has been reported in the medical literature. To date, there is no scientific evidence that women with either silicone gel-filled or saline-filled breast implants have an increased risk of these diseases, but the possibility cannot be excluded. If a causal relationship is established, the theoretical risk of immune and unknown disorders may be low. The effects of breast implants in individuals with pre-existing connective-tissue disorders is unknown.

Unlike silicone gel-filled implants, the saline-filled implants contain salt water. Any risk related to silicone gel would not be associated with saline-filled implants. However, gel-filled and saline-filled devices have a silicone rubber envelope. An increased risk of autoimmune disease is possible even from saline implants. Reliable medical laboratory tests to determine antibodies to silicone do not exist. It has not been proved that there is a relationship between silicone antibodies and disease in women with breast implants. Currently, there is insufficient evidence to state that there is a health benefit from removing breast implant(s) and scar-tissue capsule(s) will alter autoimmune disease or prevent its potential occurrence.

In very few women who have breast implants, a variety of other symptoms and conditions have been reported, suggestive of an auto-immune multiple-sclerosis-like syndrome. Additional complaints involve the musculoskeletal, skin, nervous, and immune systems. The relationship of breast implants to these conditions has been hypothesized, although not scientifically proven. Because such disease states are rare, they are difficult to research. There is the possibility of unknown risks associated with silicone breast implants and tissue expanders.

**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 is unknown.

**Chest wall deformity**- Chest wall deformity has been reported secondary to the use of tissue expanders and breast implants. The consequences of chest wall deformity is of unknown significance.

**Unusual activities and occupations**- Activities and occupations which have the potential for trauma to the breast could potentially break or damage breast implants.

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**Allergic reactions**- In rare cases, local allergies to tape, suture material, or topical preparations have been reported. Systemic reactions which are more serious may occur to drugs used during surgery and prescription medicines. Allergic reactions may require additional treatment.

**Breast disease**- Current medical information does not demonstrate an increased risk of breast disease or breast cancer in women who have breast implant surgery for either cosmetic or reconstructive purposes. Breast disease can occur independently of breast implants. It is recommended that all women perform periodic self examination of their breasts, have mammography according to American Cancer Society guidelines, and to seek professional care should they notice a breast lump.

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

**Other**- You may be disappointed with the results of surgery. Asymmetry in implant placement, breast shape and size may occur after surgery. Unsatisfactory placement or poor surgical scar location may occur. It may be necessary to perform additional surgery to improve your results.

**Removal/replacement of breast implants**-Future removal or replacement of breast implants and the surrounding scar tissue envelope involves a surgical procedure with risks and potential complications.

### **HEALTH INSURANCE**

Most health insurance companies exclude coverage for cosmetic surgical operations such as the augmentation mammoplasty or any complications that might occur from surgery. Some insurance carriers may exclude breast diseases in patients who have breast implants. Please carefully review your health insurance subscriber information pamphlet.

### **ADDITIONAL SURGERY NECESSARY**

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 augmentation mammoplasty; 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 any guarantee or warranty expressed or implied, on the results that may be obtained.

### **FINANCIAL RESPONSIBILITIES**

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of implants and surgical supplies, anesthesia, laboratory tests, and possible outpatient hospital charges, depending on where the surgery is performed. Depending on whether the cost of surgery is covered by an insurance plan, you will be responsible for necessary co-payments, deductibles, and charges not covered. Additional costs may occur should complications develop from the surgery. Secondary surgery or surgical center day-surgery charges involved with revisionary surgery would also be your responsibility.

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**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). 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 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.**

1. I hereby authorize Laurence Kirwan, MD, FRCS, FACS and such assistants as may be selected to perform the following procedure or treatment:

**I have received the following information sheet: INFORMED CONSENT SURGERY (specific procedure)**

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 acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
5. I consent to the photographing or televising of 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.
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 authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
9. 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 PROPOSEDSIGN AND CIRCLE A OR B

6.

Patient's Signature \_\_\_\_\_

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revised 23,2000

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**A. I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-9). I HAVE BEEN ASKED IF I WANT A MORE DETAILED EXPLANATION, BUT I AM SATISFIED WITH THE EXPLANATION AND DO NOT WANT MORE INFORMATION.**

**I understand and agree that any dispute or litigation with respect to the treatment or procedure of the above listed items (1-9) will be heard and settled in the city in which the procedure occurred in the United Kingdom, and the law of the United Kingdom shall govern all aspects of such dispute or litigation.**

**B. I CONSENT TO THE TREATMENT OR PROCEDURE AND ABOVE LISTED ITEMS (1-9). I REQUESTED AND RECEIVED, IN SUBSTANTIAL DETAIL, FURTHER EXPLANATION OF THE PROCEDURE OR TREATMENT, OTHER ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT AND INFORMATION ABOUT THE MATERIAL RISKS OF THE PROCEDURE OR TREATMENT**

**I understand and agree that any dispute or litigation with respect to the treatment or procedure of the above listed items (1-9) 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.**

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Patient or Person Authorized to Sign for Patient

Date \_\_\_\_\_ Witness \_\_\_\_\_

NOTHING BY MOUTH AFTER MIDNIGHT / RELEASE FROM RESPONSIBILITY / PEER REVIEW

Date: \_\_\_\_\_ Time: \_\_\_\_\_

\_\_\_\_\_ (Name of patient or myself) has not had anything to eat or drink, including water, since midnight, in preparation for surgery scheduled today. (Pre-operative medications can be taken with a sip of water). I authorize Mr. Kirwan to disclose complete information concerning his medical findings and treatment of the undersigned, from the initial office visit until date of conclusion of such treatment, to those individuals who in Mr. Kirwan's sole determination, are required to receive such information for the purposes of *medical treatment, medical quality assurance and peer review.*

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Patient

Parent Or Guardian If Applicable

Witness: \_\_\_\_\_

Signature: \_\_\_\_\_