



Informed Consent – Augmentation Mammoplasty Saline

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about augmentation mammoplasty surgery with saline implants, its risks, as well as alternative treatment(s).

It is important that you read this information carefully and completely and sign the consent for surgery as proposed by your plastic surgeon and agreed upon by you.

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 is a significant difference between the sizes of the breasts.
- To restore breast shape after partial or total loss of the breasts in various conditions.
- To correct or improve the results of existing breast implants for cosmetic or reconstructive reasons.

Breast implant surgery is contraindicated in women with untreated breast cancer or pre-malignant breast disorders, active infection anywhere in the body, or individuals who are currently pregnant or nursing. Individuals with a weakened immune system (currently receiving chemotherapy or drugs to suppress the immune system), conditions that interfere with blood clotting or wound healing, or reduced blood supply to the breast tissue from prior surgery or radiation therapy treatments may be at greater risk for complications and poor surgical outcomes.

According to the United States Food and Drug Administration (FDA), a woman must be at least 18 years of age in order to undergo cosmetic breast augmentation with saline-filled breast implants. There is no age restriction on breast reconstruction procedures to restore breast shape after cancer, trauma, or for severe breast abnormalities.

Breast enlargement is accomplished by inserting a breast implant either behind the breast tissue or partially or completely under the chest muscles. Incisions are made to keep scars as inconspicuous as possible, usually under the breast, around the lower part of the areola, or in the armpit. When breast implants are inserted during the breast reconstruction process, tissue expanders are used to stretch healthy skin in order to provide coverage for a breast implant. Breast implants are manufactured in a variety of shapes, sizes, and with either smooth or textured surfaces. The method of implant selection and size, as well as the surgical approach for inserting and positioning the breast implants will depend on your preferences, your anatomy, and your surgeon's recommendations. The shape and size of the breasts prior to surgery will influence both the recommended treatment and the final results. If the breasts are not the same size or shape before surgery, it is unlikely that they will be completely symmetrical afterward.

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

Patients undergoing augmentation mammoplasty surgery must consider the following:

- Breast augmentation or reconstruction with saline-filled implants may not be a one-time surgery.
- Breast implants of any type are **not** considered lifetime devices. They cannot be expected to last forever. You will likely require future surgery for implant replacement or removal.
- Changes that occur to the breasts following augmentation or reconstruction with implants are not reversible. There may be an unacceptable appearance to the breast if you later choose to have the breast implants removed.
- Large volume primary augmentation or revision with larger sized implants in excess of dimensional planning for your chest and breast size may increase the risk of complications such



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as implant extrusion, hematoma, infection, palpable implant folds, and visible skin wrinkling, which may require surgical intervention for correction.

ALTERNATIVE TREATMENTS

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

INHERENT RISKS OF AUGMENTATION MAMMAPLASTY SURGERY

Every surgical procedure involves a certain amount of risk, and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. Additional information concerning breast implants may be obtained from the FDA, package-insert sheets supplied by the implant manufacturer, or other informational pamphlets required by individual state laws.

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

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

SPECIFIC RISKS OF SALINE-FILLED BREAST IMPLANTS

Implants:

Breast implants, similar to other medical devices, can fail. When a saline-filled implant ruptures, the saline material is absorbed by the body, but the shell material remains. Rupture can occur as a result of an injury, from no apparent cause (silent rupture), or during mammography. It is 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, as they are not guaranteed to last a lifetime, and future surgery may be required to replace one or both implants. An ultrasound or other radiological study may be necessary to evaluate the possibility of implant rupture or deflation yet may not be 100% accurate in diagnosing implant integrity. Patients may be responsible for the costs associated with this. Saline-filled breast implants may not have the same contour or feel as do silicone-filled breast implants. The shape of your breasts after surgery depends on many factors such as your skin thickness, position, placement of the implants, and technique. You should discuss with your surgeon the possibility of a different and less than desirable contour or shape, as well as feel of your result.

Capsular Contracture:

Scar tissue, which forms routinely around the breast implant internally, can tighten and make the breast round, firm, and possibly painful. Excessive firmness of the breasts can occur soon after surgery or years later. The occurrence of symptomatic capsular contracture is not predictable, and its incidence can be expected to increase over time. Capsular contracture may occur on one side, both sides, or not at all. It occurs more commonly with implant placement in front of the chest muscle layer. Treatment for capsular contracture may require surgery, implant replacement, or implant removal. Capsular contracture may reoccur after surgical procedures to treat this condition and it occurs more often in revision augmentation than in primary augmentation. Some surgeons believe that taking preventative antibiotics during dental work and in the treatment of sinus and urinary tract infections may decrease this incidence. Discuss this with your surgeon.

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Calcification:

Calcium deposits can form in the scar tissue surrounding the implant and be visible on mammography, as well as causing pain and firmness. These deposits must be identified as distinct from the calcium deposits that signify breast cancer. Should this occur, additional surgery may be necessary to remove and examine the calcifications.

Implant Extrusion/Tissue Necrosis:

Lack of adequate tissue coverage, wound healing problems, or infection may result in exposure and extrusion of the implant through the skin. Tissue breakdown (necrosis) has been reported with the use of steroid drugs, after chemotherapy/radiation to breast tissue, and due to smoking, microwave diathermy, and excessive heat or cold therapy. In some cases, incision sites fail to heal normally. Atrophy (weakening or tissue loss) of breast tissue may occur. An implant may become visible at the surface of the breast as a result of the device pushing through layers of skin. If tissue breakdown occurs and the implant becomes exposed, implant removal may be necessary. Permanent scar deformity may occur. It is impossible to predict the biologic response of a patient's tissues to the placement of breast implants or how they will heal following surgery.

Skin Wrinkling and Rippling:

Visible and palpable (discernible to the touch) wrinkling of implants and breast skin can occur. Some wrinkling is normal and expected with saline-filled breast implants. This may be more pronounced in patients who have saline-filled implants with textured surfaces or thin breast tissue. It may be possible to feel the implant fill valve. Some patients may consider the palpable valve and wrinkles cosmetically undesirable. A palpable valve, wrinkling, and/or folds may be confused with palpable tumors, and questionable cases must be investigated.

Chest Wall Irregularities:

Chest wall irregularities have been reported secondary to the use of tissue expanders and breast implants, including rib deformity.

Implant Displacement and Tissue Stretching:

Displacement, rotation, or migration of a breast implant may occur from its initial placement, which can be accompanied by discomfort and/or distortion in the breast shape (visible rippling of the skin). Unusual techniques of implant placement may increase the risk of displacement or migration. Additional surgery may be necessary to attempt to correct this problem. It may not be possible to resolve this problem once it has occurred.

Surface Contamination of Implants:

Skin oil, lint from surgical drapes, or talc may become deposited on the surface of the implant at the time of insertion. The consequences of this are unknown.

Unusual Activities and Occupations:

Activities and occupations that involve the potential for trauma to the breast could potentially break or damage breast implants, or cause bleeding/seroma.

Change in Nipple and Skin Sensation:

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



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Anaplastic Large Cell Lymphoma (ALCL):

Breast implant associated anaplastic large cell lymphoma (BIA-ALCL) is an uncommon type of lymphoma that can develop in the scar capsule near saline or silicone breast implants. This disease is currently being investigated as to its relationship with breast implants. The family of ALCL is a rare cancer of the immune system, which can occur anywhere in the body. Based on adverse event reports, the United States Food and Drug Administration (FDA) estimates the total number of cases of BIA-ALCL to be over 573 cases. It has been noted that most BIA-ALCL has been estimated at 1:2,207 – 1:86,029 for women with textured implants, and BIA-ALCL risk is currently under investigation. BIA-ALCL usually involves swelling of the breast at an average of 8-10 years after the initial breast implant operation. Most cases were cured by removal of the implant; however, rare cases have required chemotherapy and/or radiation therapy for treatment.

Patients with breast implants should be followed by a surgeon over time and seek professional care for implant related symptoms such as pain, lumps, swelling, or with routine breast self-exams and follow standard medical recommendations for imaging (e.g. Mammography, Ultrasound, MRI). Abnormal screening results or implant-related symptoms may result in additional expenses for tests and/or procedures to properly diagnose and treat your condition. Tests and procedures could include but may not be limited to: obtaining breast fluid or tissue for pathology and laboratory evaluation, surgery to remove the scar capsule around the breast implant, implant removal, or implant replacement.

For the most current information on BIA-ALCL please visit the FDA website at:

<https://www.fda.gov/medical-devices/breast-implants/questions-and-answers-about-breast-implant-associated-anaplastic-large-cell-lymphoma-bia-alcl>

Breast Disease:

Current medical information does not demonstrate an increased risk of breast cancer in women who have breast implant surgery for either cosmetic or reconstructive purposes. Individuals with a personal history or family history of breast cancer may be at a higher risk of developing breast cancer than a woman with no family history of this disease. It is recommended that all women perform periodic self-examination of their breasts, undergo routine mammography according to American Cancer Society guidelines, and seek professional care should a breast lump be detected. In the event that suspicious tissue is identified prior to or during breast surgery, additional tests and therapy with corresponding expenses may be warranted.

Interference with Sentinel Lymph Node Mapping Procedures:

Breast surgery procedures that involve cutting through breast tissue, similar to a breast biopsy, can potentially interfere with diagnostic procedures to determine the lymph node drainage of the breast tissue in the staging of breast cancer.

Future Pregnancy and Breast Feeding:

This surgery is not known to interfere with pregnancy. If you are planning a pregnancy, your breast skin may stretch and undermine the results of surgery. You may have more difficulty breastfeeding after this operation.



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1. I, _____, hereby authorize Dr. _____ and assistants who may be selected to perform **augmentation mammoplasty surgery with saline implants**.

I have received the following information sheet: **Augmentation Mammoplasty Saline**

Additions to surgical plan: _____

2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those outlined above. I therefore authorize the above physician and assistants or designees to perform such other procedures, which are deemed necessary and desirable, based on his or her professional judgment. The authority granted under this paragraph shall include all conditions that require treatments and those not known to my physician at the time the procedure has begun.
3. I consent to the administration of such anesthetics as considered necessary or advisable. I understand that all forms of anesthesia involve risks and the possibility of complications, injury, and sometimes death.
4. I understand what my surgeon can and cannot do, and understand that 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 televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific, or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the disposal of any tissue, medical devices, or body parts that may be removed.
8. I am aware that there are potential significant risks to my health with the utilization of blood products, and I consent to their utilization should they be deemed necessary by my surgeon and/or his/her appointees.
9. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
10. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
11. I realize that not having the operation is an option. I opt out of having this procedure _____.
12. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
 - a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
 - b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
 - c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-12). I AM SATISFIED WITH THE EXPLANATION.

Patient Signature

Surgeon Signature

Date/Time

Witness