



Informed Consent-Augmentation Mammoplasty

INSTRUCTIONS

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

Please read and sign the consent for surgery as proposed by Dr. Thompson.

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 and regain proportionality.
- As a reconstructive technique for various conditions
- Replacement of breast implants for medical or cosmetic reasons

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.

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

Patients undergoing augmentation mammoplasty surgery must consider the possibility of future revisionary surgery. Breast implants cannot be expected to last forever.

Healing takes time so do not expect the final results immediately after surgery. Also, one side will heal slightly differently than the other since one arm is used more for daily activities.

ALTERNATIVE TREATMENTS

Augmentation mammoplasty is an elective surgical operation and therefore an alternative treatment would be not to have surgery. Another option is fat grafting where fat is removed via liposuction and placed to increase breast volume.

RISKS OF AUGMENTATION MAMMOPLASTY 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 concerning breast implants may be obtained from the FDA or package-insert sheets supplied by the implant manufacturer.

Although the majority of women do not experience complications, make sure you understand the risks, potential complications, and consequences of breast augmentation. **Good results are expected, but are not guaranteed.**

Specific Risks of Augmentation Mammoplasty Surgery

Bleeding: It is possible, though unusual, to experience a bleeding episode during or after surgery. The overall risk is about 1 percent. The most common time for a bleeding problem to occur is the second or third week and is usually due to excessive use of arms and lifting. Should post-operative bleeding occur, it may require urgent treatment to drain accumulated blood (hematoma). Do not take any aspirin or anti-inflammatory medications for 14 days before surgery, as this may increase the risk of bleeding, and follow all post-operative instruction. Inform the office of any herbs you may take.

Infection: Infection is unusual after this type of surgery, and in my experience the risk is 0.1% or less. Should an infection occur, treatment including antibiotics, possible removal of the implant, or additional surgery may be necessary. 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 extremely rare that a late 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 contaminated surgical procedures to reduce the risks of capsular contraction.

Capsular contracture: Scar tissue, which forms internally around the breast implant, can tighten and make the breast round and firm. This firmness of the breasts can occur soon after surgery or years later. Although the occurrence of symptomatic capsular contracture is not entirely predictable, 2% of the patients who have had breast augmentation will have surgical revisions for capsular contracture over the years following their initial surgery. Capsular contracture may occur on one side or both sides, and most occur years after surgery. We recommend massage of the breast following the surgery to prevent capsular contraction and use of antibiotics for certain procedures.

Change in nipple and skin sensation: Some change in nipple sensation is not unusual right after surgery. After several months, most patients have normal sensation. There have been isolated instances of increased sensation of the areola area. In general the larger the implants, the more it will stretch nerves and therefore sensory change is more likely.

Skin scarring: The scarring that occurs is permanent and the quality of the scar is not totally predictable.

Implants: Breast implants, similar to other medical devices, can fail. Implants can break or leak. When a saline-filled implant deflates, the fluid inside (salt water) will be harmlessly absorbed by the body. Rupture can occur as a result of an injury or from no apparent cause by simple wear and tear. Ruptured or deflated saline implants require replacement or removal. The implant manufacturers estimated a 5% deflation rate for over a 10 year period per implant or 10% for two implants. Silicone implants do not leak but can develop defects in 0.5% of patients over 10 years.

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

Mammography: Breast implants have a hazy appearance on mammograms and can obscure details of the breast tissue adjacent to the implant and extra views may be needed.

Skin wrinkling and rippling: Wrinkling and rippling can occur around the margin of implants and when there is little overlying tissue, this may be felt, or when the overlying tissue is extremely thin, it may be seen. The pressure of huge implants may thin the breast tissue allowing ripples to be felt or seen.

Pregnancy and breast feeding: Although 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.

Implant displacement: Displacement or migration of a breast implant may occur from its initial placement and can be accompanied by discomfort and/or distortion in breast shape. The implants are affected by gravity and the tissues of the inferior aspect of the breasts may stretch out allowing the implants to drop. This occurs most often when a thin person with large implants takes up a sport, like running, without using a proper support garment. **A special support garment is recommended for athletic women who have large breast implants.**

Surgical anesthesia: Both local and general anesthesia involves risk. Although anesthesia complications are very infrequent, there is the possibility of injury, and even death from all forms of surgical anesthesia or sedation. It is important to inform your doctor of any medication you take, including herbs and over the counter products.

Breast disease: Current medical information does not demonstrate an increased risk of breast disease or breast cancer in women who have breast implant surgery. 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 seek professional care should they notice a breast lump.

Seroma: Fluid may accumulate around the implant following surgery, trauma or vigorous exercise.

Smoking: Smoking is known to increase the risks of anesthesia and can slow healing. It is advised that smoking be discontinued prior to and following the surgery, until recovery is complete.

Shape Change: When implants are placed under the pectoralis muscle, the initial pressure of the stretched muscle will flatten the implant making a superior bulge. Over the course of 8-12 weeks the muscle will normally relax allowing the implant to “drop” or change to a more natural shape. This may occur on one side before the other. However, even after years have passed a forceful contraction of a strong pectoralis muscle may momentarily cause a flattening of the implant and a slight superior bulge.

Long term results: Subsequent alterations in breast shape, such as sagginess, may occur as the result of aging, weight loss or gain, pregnancy, or other circumstances not related to augmentation mammoplasty. Patients may develop asymmetry as the natural breast tissue enlarges or shrinks on one side more than the other. This surgery will not stop the aging process and the native breast tissue may change with pregnancy and aging. If you place a very large implants then years later remove them, there may be loose skin.

Immune system diseases and unknown risks: To date, there is no scientific evidence that women with either silicone gel-filled or saline-filled breast implants have an increased risk of developing immune system diseases. The effects of breast implants in individuals with pre-existing connective-tissue disorders are 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.

Asymmetry: If there is a difference between breast size, shape or position prior to surgery (asymmetry), there will be asymmetry after the surgery, Breast augmentation by itself will not correct many forms of asymmetry.

Size: Although every attempt is made to place an implant, which will give the desired size, this is not always possible and therefore, there is no guarantee of breast size.

Unsatisfactory result: You may be disappointed with the results of surgery and it may be necessary to perform additional surgery at additional expenses to improve your results. 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. Complications may necessitate further surgery with additional cost.**

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.

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.

Consent for Surgery

1. I hereby authorize Dr. Thompson and such assistants as may be selected to perform the following procedure or treatment: **bilateral augmentation mammoplasty**
2. I have received the Informed Consent for Augmentation Mammoplasty
3. 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.
4. 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.
5. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained.
6. I consent to the photographing 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 by the pictures.
7. I authorize disclosure of complete information concerning medical finding and treatment from the initial office visit until the date of the conclusion of such treatment, to those individuals who are required to receive such information for the purpose of medical quality assurance and peer review.
8. **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.
I AM SATISFIED WITH THE EXPLANATION.**

Patient Signature

Date

Witness

**I CONSENT TO THE USE OF MY BEFORE AND AFTER PHOTOGRAPHS FOR THE PURPOSES OF
EDUCATING FUTURE PERSPECTIVE PATIENTS, PROVIDED MY IDENTITY IS NOT DISCLOSED.**

Patient Signature

Date