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INFORMED CONSENT AUGMENTATION MAMMAPLASTY

INSTRUCTIONS

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

It is important that you read this information carefully and completely. Please sign the bottom of each page, indicating that you have read the page and sign the consent for surgery as proposed by your plastic surgeon.

GENERAL INFORMATION

Indications

Augmentation mammaplasty 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
- 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. 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.

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

ALTERNATIVE TREATMENT

Augmentation mammaplasty is an elective surgical operation. Alternative treatment would consist of 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 mammaplasty. Additional information concerning breast implants may be obtained from the FDA, package-insert sheets supplied by the implant manufacturer, or other information pamphlets required by individual state laws and the Health Protection Branch in Canada.

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.

 Patient initials: _____

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 (hematoma). Do not take any aspirin or anti-inflammatory medications for ten days before surgery, as this may increase the risk of bleeding.

Infection- Infection is unusual after this type of surgery. It may appear in the immediate post operative period or at any time following the insertion of a breast implant. Subacute or chronic infections may be difficult to diagnose. Should an infection occur, treatment including antibiotics, possible removal of the implant, or additional surgery may be necessary. Infections with the presence of a breast implant are harder to treat than infections in normal body tissues. 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 an 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 surgical procedures.

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.

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. 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 cannot be expected to last forever .

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. Smoking may interfere with the healing process.

Mammography- 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 mammography technologist of the presence of breast implants so that appropriate mammogram studies may be obtained. Patients with capsular contracture may find mammogram techniques painful and the difficulty of breast imaging will increase with the extent of contracture. Ultrasound, specialized mammography and MRI studies may be of benefit to evaluate breast lumps and the condition of the implant(s). Because more x-ray views are necessary with specialized mammography techniques, women with breast implants will receive more radiation than women without implants who receive a normal exam. However, the benefit of the mammogram in finding cancer outweighs the risk of additional x-rays.

 Patient initials: _____

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. It may be possible to feel the implant valve. Some patients may find palpable valve and wrinkles cosmetically undesirable. Palpable valve, wrinkling and/or folds may be confused with palpable tumors and questionable cases must be investigated. An implant may become visible at the surface of the breast as a result of the device pushing though layers of skin.

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 or if the children of women with breast implants are more likely to have health problems. There is insufficient evidence regarding the absolute safety of breast implants in relation of fertility, pregnancy or breast feeding. Some women with breast implants have reported health problems in their breast fed children. Only very limited research has been conducted in this area and at this time there is no scientific evidence that this is a problem.

Calcification- Calcium deposits can form in the scar tissue surrounding the implant and may cause pain, firmness, and be visible on mammography. These deposits must be identified as different from calcium deposits that are a sign of breast cancer. Should this occur, additional surgery may be necessary to remove and examine calcifications.

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. Difficult techniques of implant placement may increase the risk of displacement or migration. Additional surgery may be necessary to correct this problem.

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.

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.

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, or cause bleeding.

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

Breast disease/ Anaplastic Large Cell Lymphoma (ALCL)- This is a rare form of lymphoma, and has been associated with breast implants. It is rare, occurring in 98 distinct cases (estimated 10 million women worldwide have breast implants). Its incidence is estimated to be 1:300,000. It occurs on average 8 years after implant surgery. Despite this rare event, breast implants are still approved for use by the FDA and Health Canada. Treatment of this disease involves removal of breast implants and capsules. It is recommended that all women perform periodic self examination of their breasts, have mammography according to Cancer Society guidelines, and seek professional care should they notice a breast lump or develop a late seroma.

Seroma- Fluid may accumulate around the implant following surgery, trauma or vigorous exercise. Additional treatment may be necessary to drain fluid accumulation around breast implants.

Long term results- Subsequent alterations in breast shape may occur as the result of aging, weight loss or gain, pregnancy, or other circumstances not related to augmentation mammaplasty. Breast sagginess may normally occur.

Thrombosed veins- Thrombosed veins, which resemble cords, occasionally develop in the area of the breast and resolve without medical or surgical treatment.

Immune system diseases and unknown risks- Some women with breast implants have reported symptoms similar to those of known diseases of the immune system, such as systemic lupus erythematosis, rheumatoid arthritis, scleroderma, and other arthritis-like conditions. 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 either breast implant(s) and scar-tissue capsule(s) or that removal 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.

Current studies have only looked for the symptoms of known autoimmune diseases, rather than the variety of symptoms that women report experiencing. Some of the reported symptoms include:

- rash
- general aching
- unusual hair loss
- unexplained or unusual loss of energy
- swollen glands or lymph nodes
- fever
- swelling and/or joint pain or arthritis-like pain
- memory problems, headaches
- muscle weakness or burning
- nausea, vomiting
- irritable bowel syndrome
- greater chance of getting colds, viruses, flu

Questions have been raised about the potential for the saline solution used to fill breast implants to become contaminated with bacteria or fungus. These organisms may present a risk to the patient in the event of implant leakage or deflation.

There is the possibility of unknown risks associated with silicone breast implants and tissue expanders.

Toxic shock syndrome- This is an extremely rare complication following breast augmentation, reconstruction, or tissue expansion with silicone implants.

Patient initials: _____

Unsatisfactory result- You may be disappointed with the results of surgery. Asymmetry in implant placement, breast shape and size may occur after surgery. Unsatisfactory surgical scar location or displacement may occur. Pain may occur following surgery. 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 mammaplasty and any complications that might occur from surgery**. Some insurance carriers may possibly 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 mammaplasty; 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 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 hospital day-surgery charges involved with revisionary surgery would also be your responsibility.

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.

Patient initials: _____

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INFORMED-CONSENT FOR AUGMENTATION MAMMAPLASTY

1. 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.

2. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involves 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.

4. 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 by the pictures.

5. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.

6. I consent to the disposal of any tissue, medical devices or body parts which may be removed.

7. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration if applicable.

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 (1-8).
I AM SATISFIED WITH THE EXPLANATION.

Name: _____ X_____
Patient or Person Authorized to Sign for Patient

Date_____ _____Witness

By signing I acknowledge that I have read and understand this information

Patient initials: _____