

INFORMED-CONSENT-OPEN CAPSULECTOMY AND BREAST IMPLANT EXCHANGE

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about open capsulectomy and breast implant exchange, 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

The open capsulectomy is a surgical operation performed to treat scarring which occurs around breast implants or to revise the shape of the pocket where the implant is placed. This usually involves surgical removal or cutting of scar tissue that forms around a breast implant and the placement of a new breast implant. In some situations, it may be possible to put the existing breast implant back, once the shape of the pocket has been changed.

Scar tissue, which forms internally around a breast implant, can tighten and make the breast round, firm, and possibly painful. Excessive firmness of the breasts can occur soon after the original surgery or years later. 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. Calcification can occur within the scar tissue that surrounds breast implants. Treatment for capsular contracture may require surgery, implant replacement, or implant removal.

Individuals with old, damaged or broken implants may consider open capsulectomy surgery and breast implant exchange as a way to maintain the long-term results from their original surgery, whether for cosmetic or reconstructive purposes. You may be advised by your surgeon to consider replacing of your breast implants with new ones, irrespective of how long you have had them. In some situations, you may be advised to consider new breast implants with a textured outer surface or to consider silicone gel-filled implants through an approved study program. A separate consent form for the use of silicone gel implants according to the approved study program is required. Patients undergoing open capsulectomy surgery and breast implant exchange must consider the possibility of future revisionary surgery. Breast implants do not have an indefinite lifespan and will eventually require replacement surgery.

Depending on the extent of the scarring problem, it may be necessary to place the implant in a deeper location, underneath the pectoralis muscle on the chest. Incisions for the open capsulectomy procedure may be placed in different locations than those used for the original surgery. If the breasts are not the same size or shape before surgery, it is unlikely that they will be completely symmetrical afterward. Conditions which 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.

As of May, 2000, saline-filled breast implant devices have been approved by the United States Food and Drug Administration (USFDA) for use in breast augmentation and reconstruction. Breast implants that contain silicone gel are currently restricted to women who meet eligibility criteria to participate in approved study programs.

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 have reduced blood supply to the breast tissue from prior surgery or radiation therapy treatments may be at greater risk for complications and poor surgical outcome.

ALTERNATIVE TREATMENT

Open capsulectomy and breast implant exchange is an elective surgical operation. Alternative treatment would consist of not undergoing surgery or removal of your breast implants (explantation). Risks and potential complications are associated with alternative treatments that involve surgery.

RISKS of OPEN CAPSULECTOMY AND BREAST IMPLANT EXCHANGE SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with open capsulectomy with breast implant exchange. 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.

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 open capsulectomy with breast implant exchange.

Problems associated with breast implants can be inherent to this type of implanted medical device or relate to complications of a surgical procedure. Additional advisory information regarding this subject should be reviewed by patients considering surgery that involves breast implants.

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

Inherent Risks of Saline Breast Implants:

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 .

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. The occurrence of symptomatic capsular contracture is not predictable. 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. It is more common 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.

Implant extrusion / Tissue necrosis- Lack of adequate tissue coverage 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, due to smoking, microwave diathermy, and excessive heat or cold therapy. In some cases, incision sites fail to heal normally. 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.

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 with textured surfaces or thin breast tissue. It may be possible to feel the implant fill 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.

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. Changes in sensation may affect sexual response or the ability to breast feed a baby.

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.

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.

Implant displacement- Displacement, rotation, 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.

Breast feeding- Breast milk is the best food for babies. 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. A study measuring elemental silicon (a component of silicone) in human breast milk did not indicate higher levels from women with silicone-filled gel implants when compared to women without implants.. Cow's milk contains higher levels of elemental silicon as compared to human milk. Implant placement techniques that involve incisions through the nipple and areolar locations may reduce the ability to successfully breast feed. If a woman has undergone a mastectomy, it is unlikely that she would be able to breast feed a baby on the side where the breast was removed.

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/seroma.

Inherent Surgical Risk of Breast Implant Surgery:

Bleeding (Hematoma)- 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). Hematoma may contribute to capsular contracture, infection or other problems. Do not take any aspirin or anti-inflammatory medications for ten days before surgery, as this may increase the risk of bleeding. Non-prescription "herbs" and dietary supplements can increase the risk of surgical bleeding. Hematoma can occur at any time following injury to the breast.

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. This may contribute to infection, capsular contracture, or other problems.

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. In extremely rare instances, life-threatening infections, including toxic shock syndrome have been noted after breast implant surgery.

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.

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.

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.

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

Pain- Pain of varying intensity and duration may occur and persist after breast implant surgery. Pain may be the result of improper implant size, placement, surgical technique, capsular contracture, or sensory nerve entrapment or injury.

Inability to remove capsular scar tissue- It may not be possible to completely remove all scar tissue that has formed around the breast implant(s). It may not be possible to completely remove textured implant shell material that has become adherent to the scar layer.

Damage to adjacent structures- Scar tissue may be adherent to breast tissue, muscle or the chest wall. These structures may be damaged during capsulectomy surgery to remove the scar capsule.

Escaped silicone gel material- In situations that involve damaged, leaking, or ruptured silicone gel breast implants, gel material can escape into the space inside the scar capsule layer around the breast implant. In other situations, gel material may have escaped outside of the scar capsule layer into the breast and other tissue. Additional surgical procedures may be needed to remove escaped gel material. It may not be possible to completely remove escaped gel material discovered during surgery.

Additional Breast Implant Advisory Information:

Breast cancer- 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. 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. Care must be exercised during breast biopsy procedures to avoid damaging the breast implant.

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

Risks of open capsulectomy and breast implant exchange, continued

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. Patients may wish to undergo a preoperative mammogram and another one after implantation to establish a baseline view of their breast tissue.

Second generation effects- A review of the published medical literature regarding potential damaging effect on children born of mothers with breast implants is insufficient to draw definitive conclusions that this represents a problem.

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 the original breast implant surgery. Breast sagging may normally occur.

Unsatisfactory result- You may be disappointed with the results of surgery. Asymmetry in implant placement, displacement, nipple location, unanticipated breast shape and size may occur after surgery. Breast size may be incorrect. Unsatisfactory surgical scar location may occur. It may be necessary to perform additional surgery to improve your results or remove implants. 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 breast implants removed.

Removal / replacement of breast implants- Future revision, removal, or replacement of breast implants and the surrounding scar tissue envelope involves surgical procedures with risks and potential

complications. There may be an unacceptable appearance of the breasts following removal of the implant.

Capsule procedures- Closed capsulotomy, the process of forcefully squeezing the fibrous capsule around a breast implant to break up scarring is not recommended. This may result in rupture of the breast implant or other complications.

Immune system diseases and unknown risks- A small number of 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. To date, after several large epidemiological studies of women with and without implants, there is no scientific evidence that women with either silicone gel-filled or saline-filled breast implants have an increased risk of these diseases. These diseases appear no more common in women with implants than those women without implants. The effects of breast implants in individuals with pre-existing immune system and connective-tissue disorders is unknown. There is the possibility of unknown risks associated with silicone breast implants and tissue expanders.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical operations such as the augmentation mammoplasty and any complications that might occur from surgery. Some insurance carriers may possibly exclude breast diseases in patients who have breast implants. However, in some situations involving breast implants placed for the purpose of breast reconstruction, your insurance plan may consider open capsulectomy with implant exchange a covered benefit. Please carefully review your health insurance subscriber information pamphlet and call your insurance company.

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 open capsulectomy with breast implant exchange; 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 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.

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 / PROCEDURE or TREATMENT

1. I hereby authorize Dr. John P. Stratis and such assistants as may be selected to perform the following procedure or treatment:

I have received the following information sheet:

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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 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.
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 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 which 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. THE FOLLOWING 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 PROPOSE

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.

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.