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Aesthetic, Breast and Reconstructive Surgery



INFORMED CONSENT – BREAST IMPLANT REMOVAL SURGERY

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you concerning breast implant removal surgery, its risks, as well as alternative treatment(s).

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 and agreed upon by you.

GENERAL INFORMATION

The removal of breast implants that have been placed either for cosmetic or reconstructive purposes is a surgical operation. Breast implant removal may be performed as a single surgical procedure or combined with additional procedures such as the following: removal of scar tissue surrounding the breast implant, breast biopsy, removal of escape silicone gel, secondary breast augmentation, breast lift (mastopexy). Implants that are found to be damaged or ruptured cannot be repaired; surgical removal or replacement is recommended. There are options concerning general versus local anesthesia for breast implant removal.

ALTERNATIVE TREATMENT

Breast implant removal is an elective surgical operation. Alternative treatment would consist of not undergoing the surgical procedure or additional procedures. Risks and potential complications are associated with alternative surgical forms of treatment.

RISKS OF BREAST IMPLANT REMOVAL 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. 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 implant removal.

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. Intra-operative blood transfusion may also be required. 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. If blood transfusions are needed to treat blood loss, there is a risk of blood related infections such as hepatitis and the Human Immunodeficiency Virus (the virus that causes AIDS).

Infection: Infection is unusual after surgery. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary.

Change in nipple and skin sensation: Your breasts will be sore after surgery, and you may experience a change in the sensitivity of the nipples. This usually resolves in 3 to 4 weeks. To have decreased sensation is rare. However, decreased or permanent loss in nipple sensation is more likely to occur if

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Patient Initials

01/07/08 version

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extensive surgical dissection is needed to remove scar tissue or silicone gel from a broken implant.

Skin contour irregularities: Contour irregularities and depressions may occur after breast implant removal surgery. Visible and palpable wrinkling of skin can occur. Residual skin irregularities at the ends of the incisions or “dog ears” are always a possibility as is skin pleating, when there is excessive redundant skin. This may improve with time, or it can be surgically corrected.

Skin discoloration/swelling: Bruising and swelling normally occurs following breast implant removal surgery. The skin in or near the surgical site can appear either lighter or darker than surrounding skin. Although uncommon, swelling and skin discoloration may persist for long periods of time and, in rare situations, may be permanent.

Skin Sensitivity: Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after surgery. Usually this resolve during healing, but in rare situations it may be chronic.

Scarring: All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of different color than surrounding skin. Scar appearance may also vary within the same scar, exhibit contour variations and “bunching” due to the amount of excess skin. Scars may be asymmetrical (appear different between right and left side of the body). Additional treatments including surgery may be necessary to treat abnormal scarring.

Sutures: Most surgical techniques use deep sutures. You may notice these sutures after your surgery. Sutures may spontaneously poke through the skin, become visible or produce irritation that requires removal.

Fat necrosis: Fatty tissue found deep to the skin might die. This may produce areas of firmness within the skin. Additional surgery to remove areas of fat necrosis may be necessary. There is the possibility of contour irregularities in the skin that may result from fat necrosis.

Damage to deeper structures: There is the potential for injury to deeper structures including, nerves, blood vessels, muscles, and lungs (pneumothorax) during any surgical procedure. The potential for this to occur varies according to the type of procedure being performed. Injury to deeper structures may be temporary or permanent.

Firmness- Excessive firmness of the breasts can occur after surgery due to internal scarring. The occurrence of this is not predictable.

Seroma- Fluid accumulations may accumulate in the space where the breast implant was located. Should this problem occur, it may require additional procedures for drainage of fluid.

Implant Removal- As with any prosthetic device implanted in the human body, device failure can occur. It is possible that an implant can rupture, causing silicone gel to be released from the implant. Implants also can rupture during the removal process. If the implant rupture has occurred, it may not be possible to completely remove all of the silicone gel that has escaped. Implant shell material of polyurethane shell breast implants may be impossible to completely remove. Calcification around implants can occur and may require removal of the scar tissue surrounding the implant. It may not be possible to completely remove the scar tissue or silicone gel that is found around a breast implant.

Delayed healing- Wound disruption or delayed wound healing is possible. Some areas of the breast skin or nipple region may not heal normally and may take a long time to heal. It is even possible to have loss of skin or nipple tissue. This may require frequent dressing changes or further surgery to remove the non-healed tissue. **Smokers have a greater risk of skin loss and wound healing complications.**

Asymmetry- Some asymmetry naturally occurs in humans. Factors such as skin tone, fatty deposits, skeletal prominence, and muscle tone may contribute to normal asymmetry in body features. Most patients have differences between the right and left side of their body before any surgery is performed. Breast asymmetry may occur after surgery. Additional surgery may be necessary to reshape breasts

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after implant removal.

Breast and Nipple Piercing Procedures- Individuals who currently wear body piercing jewelry in the breast region are advised that a breast infection could develop from this activity.

Shock: In rare circumstances, your surgical procedure can cause severe trauma, particularly when multiple or extensive procedures are performed. Although serious complications are infrequent, infections or excessive fluid loss can lead to severe illness and even death. If surgical shock occurs, hospitalization and additional treatment would be necessary.

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 per American Cancer Society guidelines, and to seek professional care should they notice a breast lump.

Health disorders- Currently, there is insufficient evidence to state that the removal of breast implants and capsules will alter the course or prevent autoimmune or other disorders. **The removal of breast implants may be of no health benefit to you.**

Allergic Reactions: In rare cases, local allergies to tape, suture material, glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur to drugs used during surgery and prescription medications. Allergic reactions may require additional treatment.

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

Long Term Results: Subsequent alterations in breast appearance may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause or other circumstances not related to your surgery.

Pain- You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after breast implant removal surgery. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.

Unsatisfactory result- Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. There is the possibility of a poor result from the breast implant removal surgery. You may be disappointed with the size and shape of your breasts. Asymmetry in nipple location, unanticipated breast shape and size may occur after surgery. Breast size may be incorrect. Unsatisfactory surgical scar location visible deformities, loss of function, wound disruption, poor healing, and loss of sensation may occur. It may be necessary to perform additional surgery to improve your results.

ADDITIONAL ADVISORIES:

Surgical wetting solutions-There is the possibility that large volumes of fluid containing dilute local anesthetic drugs and epinephrine that is injected into fatty deposits during surgery may contribute to fluid overload or systemic reaction to these medications

Deep Venous Thrombosis, Cardiac and Pulmonary Complications: Surgery, especially longer procedures, may be associated with the formation of, or increase in, blood clots in the venous system. Pulmonary complications may occur secondarily to both blood clots (pulmonary emboli), fat deposits (fat emboli) or partial collapse of the lungs after general anesthesia. Pulmonary and fat emboli can be life-threatening or fatal in some circumstances. Air travel, inactivity and other conditions may increase the incidence of blood clots traveling to the lungs causing a major blood clot that may result in death. It is important to discuss with your physician any past history of blood clots, swollen legs or the use of high estrogen birth control pills that may contribute to this condition. Cardiac complications are a risk with any

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surgery and anesthesia, even in patients without symptoms. If you experience shortness of breath, chest pains, or unusual heart beats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

Smoking, Second-Hand Smoke Exposure, Nicotine Products (Patch, Gum, Nasal Spray):

Patients who are currently smoking, use tobacco products, or nicotine products (patch, gum, or nasal spray) are at a greater risk for significant surgical complications of skin dying, delayed healing, and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smokers may have a significant negative effect on anesthesia and recovery from anesthesia, with coughing and possibly increased bleeding. Individuals who are not exposed to tobacco smoke or nicotine-containing products have a significantly lower risk of this type of complication. Please indicate your current status regarding these items below:

_____ I am a non-smoker and do not use nicotine products. I understand the risk of second-hand smoke exposure causing surgical complications.

_____ I am a smoker or use tobacco / nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

It is important to refrain from smoking at least 6 weeks before surgery and until your physician states it is safe to return, if desired.

Female Patient Information: It is important to inform your plastic surgeon if you use birth control pills, estrogen replacement, or if you believe you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, allowing for conception and pregnancy.

It is also essential to continue to have regular mammography examinations and to perform periodic breast self-examination. Should a breast lump be detected with either mammography or self-examination, please contact your physician.

Intimate Relations After Surgery- Surgery involves coagulating of blood vessels and increased activity of any kind may open these vessels leading to a bleed, or hematoma. Increased activity that increased your pulse or heart rate may cause additional bruising, swelling, and the need for return to surgery and control of bleeding. It is wise to refrain from sexual activity until your physician states it is safe.

Mental Health Disorders and Elective Surgery- It is important that all patients seeking to undergo elective surgery have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional surgery and often are stressful. Please openly discuss with your surgeon, prior to surgery, any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective surgery, effects on mental health cannot be accurately predicted.

Medications: There are many adverse reactions that occur as the result of taking over the counter, herbal, and/or prescription medications. Be sure to check with your physician about any drug interactions that may exist with medications which you are already taking. If you have an adverse reaction, stop the drugs immediately and call your plastic surgeon for further instructions. If the reaction is severe, go immediately to the nearest emergency room. When taking the prescribed pain medications after surgery, realize that they can affect your thought process. Do not drive, do not operate complex equipment, do not make any important decisions and do not drink any alcohol while taking these medications. Be sure to take your prescribed medication only as directed.

ADDITIONAL SURGERY NECESSARY

Should complications occur additional surgery or other treatments may be necessary. Secondary surgery may be necessary to obtain optimal results. Even though risks and complications occur infrequently, the risks cited are particularly associated with breast implant removal. 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

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results that may be obtained. With breast implant removal surgery, it may not be possible to achieve optimal results with a single surgical procedure. This may require multiple surgical sessions to produce a final outcome.

PATIENT COMPLIANCE

Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are not subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and drains should not be removed unless instructed by your plastic surgeon. Successful post-operative function depends on both surgery and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation around implants and the need for return to surgery. It is wise to refrain from intimate physical activities after surgery until your physician states it is safe. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic surgical operations or any complications that might occur from surgery. Please carefully review your health insurance subscriber-information or contact your insurance company for a detailed explanation of their policies. **Most insurance plans exclude coverage for secondary or revisionary surgery.**

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your surgeon, the cost of 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. The fees charged for this procedure do not include any potential future costs for additional procedures that you elect to have or require in order to revise, optimize, or complete your outcome. Additional costs may occur should complications develop from the surgery. Secondary surgery or hospital day-surgery charges involved with revision surgery will also be your responsibility. **In signing the consent for this surgery/procedure, you acknowledge that you have been informed about its risk and consequences and accept responsibility for the clinical decisions that were made along with the financial costs of all future treatments.**

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), including no surgery. 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.

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CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1. I hereby authorize Dr. _____ 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 involve risk and the possibility of complications, injury, and sometimes death.
4. I acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained.
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 which may be removed.
8. I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
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.
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 or Person Authorized to Sign for Patient

Date _____ Witness _____