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INFORMED CONSENT – BREAST IMPLANT REMOVAL

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you about the removal of breast implant(s), its risks, and 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, for example:

- Simple breast implant removal, without removal of capsule tissue around implant
- Removal of tissue surrounding the breast implant (capsulectomy)
- Removal of escaped silicone gel in breast tissue (extra capsular, outside of capsule layer) from silicone gel-filled implants (breast biopsy)
- Breast lift (mastopexy following breast implant and/or capsule removal)

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.

There are both risks and complications associated with this operation.

Individuals who choose to have revisions made in order to continue with breast implants must sign other consent documents for revision surgery. This document is intended for permanent removal of breast implants and/or capsule material that surrounds the implants or breast biopsy to remove silicone gel outside of the capsule layer.

Individuals who choose to undergo a breast lift (mastopexy) at the time of breast implant removal must sign an additional informed consent document for the breast lift (mastopexy).

ALTERNATIVE TREATMENTS

Alternative forms of non-surgical management consist of not undergoing breast-implant removal, or other procedures to replace, relocate, or revise existing situations where patients choose to continue with breast implants. Risks and potential complications are associated with alternative surgical forms of treatment.

RISKS OF SURGERY FOR BREAST IMPLANT REMOVAL

Every surgical procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications involved with surgery to remove breast implant(s). 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 women do not

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experience these complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks, potential complications, and consequences of breast implant removal.

Bleeding- It is possible to experience a bleeding episode during or after surgery. Individuals undergoing removal of capsule tissue or breast biopsy to remove escaped silicone gel (if applicable) are at a greater risk of bleeding than simple breast implant removal 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. Hematoma may contribute to scarring, infection or other problems. Do not take any aspirin or anti-inflammatory medications for ten days before or after 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. If blood transfusions are necessary to treat blood loss, there is the risk of blood-related infections such as hepatitis and HIV (AIDS). Heparin medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

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

Firmness- Excessive firmness of the breasts can occur after surgery due to internal scarring. The occurrence of this is not predictable. Additional treatment including surgery may be necessary.

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 the surrounding skin tone. Scar appearance may also vary within the same scar. Scars may be asymmetrical (appear different on the right and left side of the body). There is the possibility of visible marks in the skin from sutures. In some cases, scars may require surgical revision or treatment. Scars resulting from breast-implant removal may complicate future breast surgery.

Skin Wrinkling and Rippling- Visible and palpable wrinkling of breast skin can occur. This may require additional surgery to tighten loose skin following breast implant removal surgery.

Seroma- Tissue fluid may accumulate in the space where the breast implant was located. Additional treatment or surgery may be necessary to remove this fluid or remove the lining of the seroma pocket.

Ruptured Silicone Gel-Filled Breast Implants- As with any man-made object 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 implant rupture has occurred, it may not be possible to completely remove all of the silicone gel that has escaped. Implant shell material of textured breast implants may be impossible to completely remove. Calcification around implants can occur and may require removal of the scar tissue surrounding the implant (capsulectomy). It may not be possible to completely remove the scar tissue that has formed around a breast implant, implant parts, calcifications, or silicone gel. Additional surgery may be necessary in the future.

Delayed Healing and Tissue Necrosis- 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. Areas of skin or nipple tissue may die. Tissue death (necrosis) can potentially occur when surgery is performed to remove implants, capsule tissue, and procedures to tighten the skin and move the nipples upward (mastopexy). Necrosis has also been reported with the use of steroid drugs, after chemotherapy/radiation to breast tissue, due to smoking, microwave diathermy, and

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excessive heat or cold therapy. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Individuals who have decreased blood supply to breast tissue from past surgery or radiation therapy may be at increased risk for wound healing and poor surgical outcome. **Smokers have a greater risk of skin loss and wound healing complications.**

Damage to Deeper Structures- There is the potential for injury to deeper structures including nerves, blood vessels and muscles and lungs (pneumothorax) during this 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.

Change in Nipple and Skin Sensation-You may experience a diminished (or loss) in the sensitivity of the nipples and the skin of your breast that usually resolves in 3 to 4 weeks. Partial or permanent loss of the nipple and skin sensation is rare. However, decreased or permanent loss in nipple sensation is more likely to occur if extensive surgical dissection is needed to remove scar tissue or silicone gel from a broken implant. Changes in sensation may affect sexual response or the ability to breast-feed a baby.

Pain- You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist. Pain may be the result of surgical technique, capsular contracture, or sensory nerve entrapment or injury. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue.

Fat Necrosis- Fatty tissue found deep in 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.

Allergic Reactions- In rare cases, local allergies to tape, suture material and 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 medicines. 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.

Asymmetry- Some breast asymmetry naturally occurs in most women. Differences in terms of breast and nipple shape, size, or symmetry may also occur after surgery. Additional surgery may be necessary to attempt improvement of asymmetry.

Skin Discoloration / Swelling- Some bruising and swelling normally occurs after breast implant removal. 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.

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 suture removal.

Cardiac and Pulmonary Complications- 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 emboli can be life threatening or fatal in some circumstances. 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 swelling in your legs or blood clots that may contribute to this condition. Cardiac complications are a risk with any surgery and anesthesia, even in patients without symptoms. Should any of these complications occur, you may require hospitalization and

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additional treatment. If you experience shortness of breath, chest pain, or unusual heartbeats after surgery, you should seek medical attention immediately.

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.

Skin Contour Irregularities- Contour and shape irregularities may occur. Visible and palpable wrinkling may occur. One breast may be smaller than the other. Nipple position and shape will not be identical one side to the next. Residual skin irregularities at the ends of the incisions or "dog ears" are always a possibility when there is excessive redundant skin. This may improve with time, or it can be surgically corrected.

Additional Advisories Regarding Breast Implant Removal Surgery:

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 and delayed healing. Individuals exposed to second-hand smoke are also at potential risk for similar complications attributable to nicotine exposure. Additionally, smoking 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.

_____ 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.

Mammography- It is important 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.

Psychological / Appearance Changes- It is possible that after breast implant removal you may experience a strong negative effect on your physical appearance, including significant loss of breast volume, distortion, and wrinkling of the skin. Your appearance may be worse than prior to your surgery for the placement of the breast implants. There is the possibility of severe psychological disturbances including depression. It is possible that you or your partner will lose interest in sexual relations.

Health Disorders Alleged To Be Caused By Breast Implants- Currently there is insufficient evidence to state that the removal of breast implant(s) and capsule(s) will alter the course or prevent autoimmune or other disorders alleged to be caused by breast implants. **The removal of breast implants may be of no health benefit to you.**

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 and surgical procedures to remove them. Individuals with a personal history or family history of breast cancer may be at higher risk of developing breast cancer than a woman with no family history of this

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disease. It is recommended that all women perform periodic self-examination of their breasts, have mammography per American Cancer Society guidelines, and seek professional care should they notice a breast lump.

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 lymph node drainage of breast tissue to stage breast cancer.

Breast Feeding Following Implant Removal- It is not known if there are increased risks in nursing for a woman who has undergone breast implant removal. 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.

Long-Term Results- Subsequent alterations in breast shape may occur as the result of aging, sun exposure, weight loss, weight gain, pregnancy, menopause, or other circumstances not related to your breast implant removal surgery. Breast sagginess may normally occur.

Unsatisfactory Result- Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. You may be disappointed with the results of breast implant removal surgery. Asymmetry in nipple location, unanticipated breast shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. Breast asymmetry may occur after surgery. Breast size may be incorrect. Unsatisfactory surgical scar location may occur. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. It may be necessary to perform additional surgery to improve your results.

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.

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

Medications- There are potential 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 and coordination. 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.

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. Activity that increases 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 intimate physical activities until your physician states it is safe.

ADDITIONAL SURGERY NECESSARY (Re-operations)

There are many variable conditions that may influence the long-term result of breast implant removal surgery. It is unknown how your breast tissue may respond to implant removal or how wound healing will occur after surgery. Secondary surgery may be necessary at some unknown time in the future to improve the outcome of breast implant removal surgery. Should complications occur, additional surgery or other treatments may be necessary. Even though risks

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and complications occur infrequently, the risks cited are particularly associated with breast implant removal surgery. 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. In some situations, it may not be possible to achieve optimal results with a single surgical procedure.

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.

REGULATORY MATTERS

According to USFDA regulations, you must comply with the submission of personal information to a device registry if required to do so regarding implant removal surgery.

HEALTH INSURANCE-

Most health insurance companies exclude coverage for the removal of breast implants or any complications that might occur from breast implants. Some carriers have excluded breast diseases in patients who have breast implants. Please carefully review your health insurance subscriber-information pamphlet. Most insurance plans exclude coverage for secondary or revisionary surgery due to complications of cosmetic 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. You may be advised some time in the future to have a MRI (magnetic resonance imaging) scan to determine the condition of your breast implants. You would be responsible for future costs of such imaging studies.

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). 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 current state

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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

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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 that 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.

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. 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
- d. THAT I ACCEPT RESPONSIBILITY FOR THE CLINICAL DECISIONS MADE ALONG WITH THE FINANCIAL COSTS OF ALL FUTURE TREATMENTS TO REVISE, OPTIMIZE OR IMPROVE OUTCOMES.

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-11). I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date _____ Witness _____

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