

INFORMED CONSENT – REVISION OF BREAST RECONSTRUCTION

INSTRUCTIONS

This informed-consent document has been prepared to help inform you about revision of your breast reconstruction, 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

Breast reconstruction surgery is an operation frequently performed by plastic surgeons. Breast reconstruction is either “immediate” or “delayed.” Most breast reconstruction is immediate or started on the day of your breast cancer operation. Breast reconstruction may need to be delayed if the margins are not clear or if radiation treatment is planned. In some cases patients may elect to delay the reconstruction for personal reasons. Breast reconstruction is something you want not something you absolutely need. If the risk or potential complications are too much for you at this point, delaying the operation may be the right choice.

A reconstructed breast is never as good as the original breast. It is a process that requires a minimum of three stages to achieve an optimal result. The first stage always involves creating a breast mound and subsequent stages involve refinement of the mound, nipple creation, and symmetry procedures. Future stages may be delayed by adjuvant treatments such as chemotherapy or radiation. Wound problems related to breast reconstruction may delay these adjuvant treatments in some cases.

Typically, mastectomy or breast cancer operation involves removal of the breast tissue, node testing, and nipple removal. A mastectomy is similar to removing the orange from an orange peel. The peel or the skin of your breast is left behind but the tissue beneath is removed. The remaining skin is very thin and unhealthy in most cases. The first stage of breast reconstruction is limited by the quality of the overlying skin and the options available for reconstruction.

Reconstruction of one breast is far less complex and offers more options than the reconstruction of both breasts. The three main ways a plastic surgeon creates a breast is with an implant or tissue expander, an implant with back muscle (Lat. Flap with implant), or abdominal tissue (TRAM Flap). Each of these procedures has different indications and risks, and each approach can be modified in a number of ways. The patient’s age, weight, anatomy, previous surgeries, and health history often determine the procedure that is best for them.

ALTERNATIVE TREATMENTS

Placement of permanent breast implant following tissue expansion is an elective surgical operation.

Alternative treatment would consist of not undergoing the placement of a permanent implant, the use of external breast prostheses or padding, or the transfer of other body tissues to complete the breast reconstruction process. Risks and potential complications are also associated with alternative surgical forms of treatment.

RISKS OF REVISION OF BREAST RECONSTRUCTION SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand the risks involved with reconstructive breast surgery. 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 placement of permanent breast implant following tissue expansion breast reconstruction.

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

INFORMED CONSENT – REVISION OF BREAST RECONSTRUCTION

Inherent Surgical Risk of Breast Reconstruction

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. Hematoma may contribute to capsular contracture, 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.

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- Although 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. Individuals with an active infection in their body or weakened immune system should not undergo breast augmentation.

Scarring- All surgery leaves scars, some more visible than others. Excessive scarring is uncommon. 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.

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 and glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur in response to 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- You will experience pain after your surgery. 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. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue or due to tissue stretching.

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

INFORMED CONSENT – REVISION OF BREAST RECONSTRUCTION

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.

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 after a breast augmentation.

Change in Nipple and Skin Sensation- You may experience a diminished (or loss) of sensitivity of the nipples and the skin of your breast. 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.

Change in Nipple and Skin Sensation- Breast reconstruction cannot restore normal sensation to the breast or nipple.

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.

Fat Necrosis- Fatty tissue found in the flap or skin may die. This may produce areas of firmness within the skin. Additional surgery to remove areas of fat necrosis may be necessary (breast biopsy). There is the possibility of contour irregularities in the skin that may result from fat necrosis.

Skin Contour Irregularities- Contour and shape irregularities 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.

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. Areas of skin or nipple tissue may die. 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.**

Firmness- Excessive firmness of the breast can occur after surgery due to internal scarring or scarring around a breast implant, if one is used. The occurrence of this is not predictable and additional treatment including surgery may be necessary. Radiation therapy to the chest region after breast reconstruction with a TRAM flap may produce unacceptable firmness or other long-term complications.

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

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 additional treatment. If you experience shortness of breath, chest pain, or unusual heart beats, you should have this evaluated immediately.

INFORMED CONSENT – REVISION OF BREAST RECONSTRUCTION

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.

Additional Breast Implant Advisory Information

Breast Disease- Current medical information does not demonstrate an increased risk of breast cancer in women who have breast reconstruction for either cosmetic or reconstructive purposes. Individuals with a personal history or family history of breast cancer may be at a higher risk of developing breast cancer than a woman with no family history of this disease. It is recommended that all women perform periodic self-examination of their breasts, have mammography according to American Cancer Society guidelines, and to seek professional care should a breast lump be detected.

Breast Feeding- 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

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 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.

Radiation Therapy- Radiation therapy to the chest region before or after breast reconstruction can produce unacceptable firmness or other long-term complications.

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 surgery. Asymmetry in implant placement, displacement, nipple location, unanticipated breast shape and size, loss of function, wound disruption, poor healing, and loss of sensation 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, change implant size or remove and not replace implants.

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.

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.

INFORMED CONSENT – REVISION OF BREAST RECONSTRUCTION

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 bleeding. It is wise to refrain from sexual activity until your physician states it is safe.

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, 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.

ADDITIONAL SURGERY NECESSARY (Re-operations)

There are many variable conditions that may influence the long-term result after breast reconstruction. Secondary surgery may be necessary at some unknown time in the future to improve the appearance of the breasts or to improve the outcome of surgery. Should complications occur, additional surgery or other treatments may be necessary. 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 must 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 before surgery and afterwards.

HEALTH INSURANCE

Most insurance covers the first breast reconstruction operation. There may be additional requirements according to your insurance contract. Insurance coverage for future revision, new breast implants, or additional doctor's visits may not be covered, depending on the policy. Most health insurance companies exclude coverage for cosmetic surgical operations such as the augmentation mammoplasty and any complications that might occur from surgery. Please carefully review your health insurance subscriber information pamphlet. **Most insurance plans exclude coverage for secondary or revisionary surgery or due to complications of cosmetic surgery.**

INFORMED CONSENT – REVISION OF BREAST RECONSTRUCTION

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), 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 that is based on all the facts in your particular case and the current 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.

INFORMED CONSENT – REVISION OF BREAST RECONSTRUCTION

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

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

PLACEMENT OF PERMANENT BREAST IMPLANT FOLLOWING BREAST RECONSTRUCTION BY TISSUE EXPANSION SURGERY

I have received the following information sheet:

INFORMED CONSENT - PLACEMENT OF PERMANENT BREAST IMPLANT FOLLOWING BREAST RECONSTRUCTION BY TISSUE EXPANSION

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 and other personally identifying data 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. 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 _____