

“MEDICAL INTERVENTION (SURGERY) RISKS” Annex #2 INFORMED CONSENT –BREAST RECONSTRUCTION WITH LATISSIMUS MUSCLE FLAP

INSTRUCTIONS

This informed-consent document has been prepared to help inform you of breast reconstruction with latissimus muscle flap surgery, 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 and agreed upon by you.

GENERAL INFORMATION

There are a variety of surgical techniques for breast reconstruction. Most mastectomy patients are medically appropriate for breast reconstruction, either immediately following breast removal or at a later time. The best candidates, however, are women whose cancer, as far as can be determined, seems to be eliminated by mastectomy. There are legitimate reasons to delay breast reconstruction. Some women may be advised by their surgeon or oncologist to wait until other forms of necessary cancer treatment are completed. Other patients may require more complex breast reconstruction procedures. Women who smoke, or who have other health conditions, such as obesity or high blood pressure, may be advised to postpone surgery. In any case, being informed of your options concerning breast reconstruction can help you prepare for a mastectomy with a more positive outlook on the future.

Breast reconstruction has no known effect on altering the natural history of breast cancer or interfering with other forms of breast cancer treatment such as chemotherapy or radiation.

In breast reconstruction with the latissimus dorsi, a muscle located on the back along with its attached skin is transferred to the chest region for the breast reconstruction procedure. The muscle flap maintains its own blood supply, and helps nourish the tissue that is transferred to the chest wall region. There are several variations on the surgical technique of latissimus muscle flap breast reconstruction, including microvascular surgery to attach the flap to the chest region. In some cases, your plastic surgeon may recommend that a breast implant or expander be inserted underneath the muscle flap to give the breast mound additional projection.

Muscle flap techniques of breast reconstruction are useful in the following situations:

- Inadequate chest wall tissue for breast reconstruction with implants or expanders
- Past history of radiation to chest wall after mastectomy
- Patients with concerns about silicone breast implant/expander
- Failure of earlier breast reconstruction

Contraindications to latissimus muscle flap breast reconstruction procedure exist:

- A patient who is medically or psychologically unsuitable for breast reconstruction
- Previous injury to the latissimus dorsi muscle from surgery or other treatments

A separate consent form for the use of breast implants in conjunction with breast reconstruction with latissimus muscle flap may be necessary.

ALTERNATIVE TREATMENTS

Latissimus muscle flap breast reconstruction is an elective surgical operation. Alternative treatment would consist of the use of external breast prostheses or padding, tissue expansion technique of breast reconstruction, breast implants, or the transfer of other body tissues for breast reconstruction. Risks and potential complications are associated with alternative surgical forms of treatment.

RISKS OF BREAST RECONSTRUCTION WITH LATISSIMUS MUSCLE FLAP

Every surgical procedure involves a certain amount of risk, and it is important that you understand the risks involved with breast reconstruction with latissimus muscle flap and the possible use of a breast implant in addition to

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the muscle flap. In the event that a latissimus muscle flap is used without a breast implant, risks associated with breast implants would not be applicable. An individual's choice to undergo a surgical procedure is based on the comparison of the risk to potential benefit. Although the majority of women do not experience the following complications, you should discuss each of them with your plastic surgeon to make sure you understand the risks, potential complications, and consequences of breast reconstruction with latissimus muscle flap.

Specific Risks of Breast Reconstruction with Latissimus Muscle Flap

Delayed Healing and Loss of Flap: Wound disruption or delayed wound healing is possible. It is possible to have areas of the chest wall or latissimus dorsi muscle flap die. This may require frequent dressing changes or further surgery to remove the non-living tissue. Individuals who have decreased blood supply to breast tissue from past surgery or radiation therapy may be at increased risk for delayed wound healing and poor surgical outcome. **Smokers have a greater risk of skin loss and wound healing complications. Second-hand smoke can also have similar negative effects on wound healing.**

Implant Extrusion: Lack of adequate tissue coverage may result in exposure and extrusion of a breast implant, if used, in addition to the latissimus muscle flap. If tissue breakdown occurs and the breast implant becomes exposed, removal is necessary. It may not be possible to place a new implant at the same time. You may have to allow for complete wound healing without an implant before your breast reconstruction can be completed.

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 or surgery may be necessary. Radiation therapy to the chest region after breast reconstruction with a latissimus muscle flap may produce unacceptable firmness or other long-term complications.

Loss of Latissimus Muscle Function: There is anticipated loss of normal function in the latissimus dorsi muscle after it is transferred to the chest wall. Weakness in movements of the shoulder and upper arm can occur.

Change in Nipple and Skin Sensation: Breast reconstruction cannot restore normal sensation to your breast or nipple. Skin that is transferred as part of the muscle flap will lack sensation. Numbness may occur in the skin on the back where the latissimus muscle was located. Changes in sensation may affect sexual response or the ability to breast-feed a baby.

Asymmetry: Some breast asymmetry naturally occurs in most women. Differences in breast and nipple shape, size, or symmetry may also occur after surgery. Additional surgery may be necessary to correct asymmetry after a breast reconstruction with latissimus muscle flap.

Breast Implants: Risks associated with the potential use of breast implants are covered in a separate informed-consent form.

General Risks of Surgery

Healing Issues: Certain medical conditions, dietary supplements and medications may delay and interfere with healing. Patients with massive weight loss may have a healing delay that could result in the incisions coming apart, infection, and tissue changes resulting in the need for additional medical care, surgery, and prolonged hospitalizations. Patients with diabetes or those taking medications such as steroids on an extended basis may have prolonged healing issues. Smoking will cause a delay in the healing process, often resulting in the need for additional surgery. There are general risks associated with healing such as swelling, bleeding, and the length of surgery and anesthesia that include a longer recovery and the possibility of additional surgery, prolonged recovery, color changes, shape changes, infection, not meeting goals and expectations, and added expense to the patient. Patients with significant skin laxity (patients seeking facelifts, breast lifts, abdominoplasty, and body lifts) will continue to have the same lax skin after surgery. The quality or elasticity of skin will not change and recurrence of skin looseness will occur at some time in the future, quicker for some than others. There are nerve endings that may become involved with healing scars during surgery such as suction-assisted lipectomy, abdominoplasty, facelifts, body lifts, and extremity surgery. While there may not be a major nerve injury, the small nerve endings

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during the healing period may become too active producing a painful or oversensitive area due to the small sensory nerve involved with scar tissue. Often massage and early non-surgical intervention resolves this. It is important to discuss post-surgical pain with your surgeon.

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 you may require a blood transfusion, though such occurrences are rare. Increased activity too soon after surgery can lead to increased chance of bleeding and additional surgery. It is important to follow postoperative instructions and limit exercise and strenuous activity for the instructed time. Do not take any aspirin or anti-inflammatory medications for at least 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, usually in the first three weeks following injury to the operative area. 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, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary. It is important to tell your surgeon of any other infections, such as ingrown toenail, insect bite, or urinary tract infection. Remote infections, infections in other parts of the body, may lead to an infection in the operated area.

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.

Skin Contour Irregularities: Contour and shape irregularities may occur. Visible and palpable wrinkling of skin may occur. 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.

Skin Discoloration / Swelling: Some bruising and swelling normally occur. 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 resolves during healing, but in rare situations it may be chronic.

Major Wound Separation: Wounds may separate after surgery. Should this occur, additional treatment including surgery may be necessary.

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.

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.

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.

Seroma: Infrequently, fluid may accumulate between the skin and the underlying tissues following surgery, trauma or vigorous exercise. Should this problem occur, it may require additional procedures for drainage of fluid.

Surgical Anesthesia: Both local and general anesthesia involve risk. There is the possibility of complications, in-

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jury, and even death from all forms of surgical anesthesia or sedation.

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.

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

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. If you experience shortness of breath, chest pain, or unusual heart beats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

Venous Thrombosis and Sequelae: Thrombosed veins, which resemble cords, occasionally develop in the area of the breast or around IV sites, and usually resolve without medical or surgical treatment. It is important to discuss with your surgeon any birth control pills you are taking. Certain high estrogen pills may increase your risk of thrombosed veins.

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.

Persistent Swelling (Lymphedema): Persistent swelling in the legs can occur following surgery.

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, unanticipated shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. Size may be incorrect. Unsatisfactory surgical scar location or appearance may occur. It may be necessary to perform additional surgery to improve your results.

ADDITIONAL ADVISORIES

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

Patients who are currently smoking or use tobacco 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, 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.

Medications and Herbal Dietary Supplements: There are potential adverse reactions that occur as the result of taking over-the-counter, herbal, and/or prescription medications. Aspirin and medications that contain aspirin interfere with clotting and can cause more bleeding. These include non-steroidal anti-inflammatories such as Motrin, Advil, and Alleve. It is very important not to stop drugs that interfere with platelets, such as Plavix, which is used after a stent. It is important if you have had a stent and are taking Plavix that you inform the plastic surgeon. Stopping Plavix may result in a heart attack, stroke and even death. 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,

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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.

Sun Exposure – Direct or Tanning Salon: The effects of the sun are damaging to the skin. Exposing the treated areas to sun may result in increased scarring, color changes, and poor healing. Patients who tan, either outdoors or in a salon, should inform their surgeon and either delay treatment, or avoid tanning until the surgeon says it is safe to resume. The damaging effect of sun exposure occurs even with the use sun block or clothing coverage.

Travel Plans: Any surgery holds the risk of complications that may delay healing and delay your return to normal life. Please let the surgeon know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of surgery can occur. There are no guarantees that you will be able to resume all activities in the desired time frame.

Breast disease: Current medical information does not demonstrate an increased risk of breast disease, breast cancer, or recurrence of breast cancer in women who have reconstructive breast surgery. Breast disease and breast cancer can occur independently of breast surgery. It is recommended that all women perform regular self-examination of their breasts, have mammograms according to American Cancer Society guidelines, and seek professional care should a breast lump be detected. All patients should continue their breast cancer surveillance program as instructed by their oncologist and cancer surgeon.

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

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 region are advised that an infection could develop from this activity.

Pregnancy and Breast Feeding: There is no evidence that muscle flap surgery has any effect on fertility or pregnancy. If a woman has undergone a mastectomy, it is unlikely that she would be able to breast feed a baby on the affected side.

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

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 bleeding. It is wise to refrain from intimate physical activities 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.

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ADDITIONAL SURGERY NECESSARY (Re-Operations)

Many variable conditions may influence the long-term result of breast reconstruction with latissimus muscle flap surgery. Secondary surgery may be necessary to perform additional tightening or repositioning of the breasts. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly associated with breast reconstruction with latissimus muscle flap 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 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.

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 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.