

INFORMED CONSENT - RECONSTRUCTION WITH MUSCLE FLAP

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INSTRUCTIONS

This informed-consent document has been prepared to help inform you of reconstruction with muscle flap surgery, 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.

There is a variety of surgical techniques for reconstruction. Most patients are medically appropriate for reconstruction, either immediately following injury or at a later time. There are legitimate reasons to delay reconstruction. Some patients may be advised by their surgeon to wait until other forms of necessary treatment are completed. Other patients may require more complex reconstruction procedures. Patients 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 reconstruction can help you

Muscle flap reconstruction has no known effect on altering the natural history or interfering with other

Muscle flap techniques of reconstruction involve the use of a variety of different regional or distant muscle(s) suitable for the reconstruction of a particular defect. The muscle flap maintains its own blood supply, and helps nourish the tissue that is transferred to the defect. Following the reconstruction of the defect, the donor site is closed primarily, with a skin graft, or other technique particular to your situation. There are several variations on the surgical technique of muscle flap reconstruction, including microvascular surgery, to attach the muscle flap to local blood vessels around the defect.

ALTERNATIVE TREATMENTS

Muscle flap reconstruction is an elective surgical operation. Alternative treatment would consist of the use of conservative wound treatment until the wound is healed or amputation of an affected limb if determined nonviable. Potential risks and complications are associated with alternative surgical forms of treatment.

RISKS OF MUSCLE FLAP RECONSTRUCTION

Every surgical procedure involves a certain amount of risk, and it is important that you understand the risks involved with muscle flap reconstruction. 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 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 muscle flap

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 (hematoma) or blood transfusion. Intra-operative blood transfusion may also be required. 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- An infection is unusual after this type of surgery. If an infection occurs, treatment including antibiotics, hospitalization, or additional surgery may be necessary.

Skin Contour Irregularities- Contour and shape irregularities may occur. Residual skin irregularities at

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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.

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

Skin Discoloration / Swelling- Some bruising and swelling normally occurs following muscle flap reconstruction. 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. Additionally, these areas may have exaggerated responses to hot or cold

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

Delayed Healing and Loss of Flap- Wound disruption or delayed wound healing is possible. It is possible to have areas of the surrounding skin or 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 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.

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

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. There is the possibility of contour irregularities in the skin that may result from fat necrosis.

Seroma- Pockets of tissue fluid sometime develop either in the donor or recipient site after muscle flap reconstruction. Additional procedures to drain this fluid accumulation may be necessary.

Firmness- Excessive firmness of the wound can occur after surgery due to internal scarring. The occurrence of this is not predictable and additional treatment including surgery may be necessary. Radiation therapy to the wound region after muscle flap reconstruction may produce unacceptable

Microvascular Surgery- Flap loss may result if a blockage occurs at the point of arterial or venous attachment to the muscle flap.

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.

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.

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Patient's Initials _____

Weakness of Muscle Function- Following transfer of muscle and tissue there is anticipated loss of normal function. Patients may notice a feeling of weakness while doing exercises or similar movements.

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Abdominal Wall Hernia- On rare occasions, the area of the abdominal wall where the muscle has been taken will become weak and produce a hernia. Very rarely, re-operation for repair of this hernia may be necessary. In some cases, mesh will be inserted at the time of the reconstructive procedure to help

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 muscle flap reconstruction surgery. Asymmetry in muscle flap placement, unanticipated shape and size, loss of function, wound disruption, poor healing, and loss of sensation may occur after surgery. Unsatisfactory surgical scar location or visible deformities at the ends of the incisions (dog ears) may occur. Muscle flap reconstruction by any technique may fail due to complications attributable to previous surgery or from chemotherapy/radiation therapy treatments that are independent of the muscle flap procedure. It may be necessary to perform additional surgery to improve your results.

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

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

Thrombosed Veins- Thrombosed veins, which resemble cords, occasionally develop in the area of the

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 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 blood clots or swollen legs 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 pains, or unusual heart beats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

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

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. 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, delayed healing, and additional scarring. Individuals exposed to second-hand smoke are also at potential risk for similar

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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

_____ ^^ I am a smoker or use tobacco / nicotine products. I understand the risk of surgical

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

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

ADDITIONAL SURGERY NECESSARY

Many variable conditions may influence the long-term result of muscle flap reconstructive surgery. Secondary surgery may be necessary to perform additional tightening or debulking of the muscle flaps. 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 reconstruction using muscle flaps. 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.

HEALTH INSURANCE

Most insurance carriers consider muscle flap reconstruction surgery a covered benefit. However, there may be additional requirements. Please review your health insurance subscriber-information pamphlet, call your insurance company, and discuss this further with your plastic surgeon. **Many insurance plans exclude coverage for secondary or revisionary surgery.**

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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.**

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

It is important that you read the above information carefully and have all of your questions answered before signing the consent on the next page.

CONSENT FOR SURGERY / PROCEDURE or TREATMENT

1. I hereby authorize Dr. Thomas J. Meeks D.O. and such assistants as may be selected to perform the following procedure or treatment:

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2.1 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

3.1 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.

4.1 acknowledge that no guarantee or representation has been given by anyone as to the results that

5.1 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,

6. For purposes of advancing medical education, I consent to the admittance of observers to the

7.1 consent to the disposal of any tissue, medical devices or body parts which may be removed.

8.1 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

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9.1 authorize the release of my Social Security number to appropriate agencies for legal reporting and

10.1 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.

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-

Patient or Person Authorized to Sign for Patient

Date _____ Witness