



Informed Consent

Cutaneous (Skin) Flap Surgery

INSTRUCTIONS

This is an informed consent document that has been prepared to help inform you about cutaneous (skin) flap surgery, its risks, as well as alternative treatment(s).

It is important that you read this information carefully and completely. Please initial each page, indicating that you have read the page, and sign the consent form for surgery as proposed by your plastic surgeon and agreed upon by you.

GENERAL INFORMATION

The cutaneous (skin) flap is commonly used for repair or reconstruction of an open wound or a soft tissue deficit. It involves moving the skin (and potentially other soft tissues) from a donor site to the affected area. The skin flap maintains its own blood supply.

ALTERNATIVE TREATMENTS

Depending on your needs, alternative forms of non-surgical and surgical reconstruction may also be considered. You should discuss alternatives with your surgeon. Risks and potential complications are also associated with alternative surgical forms of treatment. Your surgeon will review which surgical procedures may be required to close your wound and provide you with a functional result that is the least disfiguring option. Sometimes more than one surgical procedure can be required to accomplish these goals.

INHERENT RISKS OF CUTANEOUS (SKIN) FLAP SURGERY

Every surgical procedure involves a certain amount of risk and it is important that you understand these risks and the possible complications associated with them. In addition, every procedure has limitations. An individual's choice to undergo a surgical procedure should be based on a comparison between the risks and the potential benefits. Although the majority of patients do not experience these complications, you should discuss each of them with your plastic surgeon to make sure you understand all of the possible consequences of cutaneous (skin) flap surgery.

SPECIFIC RISKS OF CUTANEOUS (SKIN) FLAP SURGERY

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. With cutaneous/local flaps and skin grafts diminished sensation can occur. Diminished (or loss of) skin sensation in the donor location for the cutaneous/local flaps as well as the location where the flap is placed may occur and this may not totally resolve after cutaneous/local flap surgery. Cutaneous/local flaps generally do not regain normal skin sensation. Injuries may occur secondary to this lack of sensation if the skin graft is subjected to excessive heat, cold, or physical force. Cutaneous/local flaps placed in areas of decreased sensation are prone to injury and loss. Care must be taken to avoid injury to these areas or complications may occur.

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. Contour irregularities and depressions may occur after cutaneous/local flap or skin graft surgery. Visible and palpable wrinkling or folds of skin can occur.

Inability to Restore Function:

In some situations, cutaneous/local flaps cannot restore normal function of intact skin or undamaged deeper structures. Although it may be possible to produce healing with a cutaneous/local flap, there can be a loss of function. Additional treatment and 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 a 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 a possibility of visible marks in the skin from sutures. In some cases, scars may require surgical revision or treatment.

Delayed Healing and Loss of Flap:

Wound disruption or delayed wound healing is possible. Some areas of skin may not heal normally and may take a long time to heal. Areas of skin may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue. Individuals who have decreased blood supply to tissue from past surgery or radiation therapy may be at increased risk of poor wound healing and poor surgical outcome. Smokers have a greater risk of skin loss and wound healing complications.

Fat Necrosis:

Fatty tissue in the flap or donor site may die. This may produce areas of firmness. Additional surgery to remove these areas of fat necrosis may be necessary. There is a possibility of contour irregularities from fat necrosis.

Seroma:

Pockets of fluid sometimes develop at either the donor or the recipient site. Additional procedures to drain this fluid accumulation may be necessary.

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 experience a delay in healing that could result in the incisions coming apart, infection, or tissue changes resulting in the need for additional medical care, surgery, or 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, possibility of additional surgery, prolonged recovery, color changes, shape changes, infection, not meeting patient goals and expectations, and added expense to the patient. There may also be a longer recovery period depending on the length of surgery and anesthesia. Should you experience healing issues your cutaneous/local flap or skin graft could fail. Wound separation may occur. Should this occur, additional treatment including surgery may be necessary. There are nerve endings that may be involved with healing scars from surgery. While there may not be a major nerve injury, the small nerve endings 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 the accumulated blood or you may require a blood transfusion, though such occurrences are rare. The collection of blood that can occur under your skin following surgery is referred to as a hematoma. Increased activity too soon after surgery can lead to an increased risk of bleeding and additional surgery. It is important to follow post-operative instructions and limit exercise and strenuous activity for the instructed time. Non-prescription “herbs” and dietary supplements can increase the risk of surgical bleeding. Hematomas 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 a risk of blood-related infections such as hepatitis and HIV (AIDS). Your surgeon may provide medications after your surgery to prevent blood clots. Medications that are used to prevent blood clots in veins can cause bleeding and decreased blood platelets.

Infection:

Infection, although uncommon, can occur after surgery. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary. It is important to make your surgeon aware of any other infections, such as a history of MRSA infections, open wounds, recent upper respiratory infections/pneumonia, ingrown toenails, insect bites, tooth abscesses, or urinary tract infections. Infections in other parts of the body, may lead to an infection in the operated area. Post-operative infections often result in more extensive scarring and can predispose to revision surgery.

Ileus:

The return of bowel function following surgery is important. An ileus is a disruption in bowel function caused by the failure of peristalsis or hypomobility of your bowels/gut resulting in a lack of defecation and possibly repeated vomiting. Anesthetics and medications like pain medications given to you at the time of surgery can contribute to the development of an ileus in the post-operative period. An ileus can result in abdominal distention, vomiting, inability to absorb oral medications and possibly hospitalization. Repeated vomiting could result in aspiration pneumonia and respiratory failure. It is essential to have regular bowel function after your surgery.

Scarring:

All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, this surgery will result in long, prominent scars that are permanent. Abnormal scarring 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 also a possibility of visible marks in the skin from sutures. These scars may become raised, red, or discolored in the first few weeks/months, but usually settle down over time. However, some patients are prone to “hypertrophic” or “keloid” scars i.e. prominent, raised, red scars that do not settle. Further treatment with medication and/or surgery may be required.

Staged Reconstruction:

Some reconstructive procedures require more than one surgery to restore your surgical defect or open wound. Your surgeon may advise you that in the long term it may be in your best interest to have staged reconstruction to obtain the best possible functional or aesthetic result.

Alternative Graft Materials:

Alternative grafting materials such as Integra[®] or Biobrane[®] may be utilized during the procedure. These materials can be synthetic (man-made) or derived from animals (porcine or bovine), or another part of your body may be required as a graft (auricular or ear cartilage/fat grafting). Your surgeon will advise you when such materials are going to be considered or utilized to assist in your reconstruction.

Firmness:

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

Skin Discoloration/Swelling:

Some bruising and swelling will 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. These sutures may be noticeable after your surgery. Sutures may spontaneously poke through the skin, become visible, or cause irritation that requires suture removal.

Damage to Deeper Structures:

In the process of skin cancer removal, deeper structures, such as nerves and muscles may have to be sacrificed. Reconstruction of your surgical defect could include nerve repair or grafting. Your surgeon will advise you if such a procedure may be required. Further, there is a potential for injury to deeper structures including nerves, blood vessels and muscles 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.

Surgical Anesthesia:

Both local and general anesthesia involves risk. There is a possibility of complications, injury, 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, infection 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 surgery. If you are a chronic pain patient in regular contact with a Pain Therapy Practitioner, you may be asked to see this practitioner preoperatively to assist you in the management of your pain disorder in the post-operative period. On rare occasions, chronic pain may occur if nerves become trapped in scar tissue or due to tissue stretching.

Certain nerve endings may become involved in healing scars from surgery. While there may not be a major nerve injury, the small nerve endings during the healing period may become too active producing a painful or oversensitive area due to the small sensory nerve involved in scar tissue. Often, massage therapy and early non-surgical intervention resolves this. It is important to discuss post-surgical pain with your surgeon.

Cardiac and Pulmonary Complications:

Pulmonary complications may occur secondary to blood clots (pulmonary emboli), fat deposits (fat emboli), pneumonia, 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 migrating to the lungs causing a major blood clot that may result in death. It is important to discuss with your physician any 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 pains, or unusual heartbeats, seek medical attention immediately. Should any of these complications occur, you may require hospitalization and additional treatment.

Venous Thrombosis (Clot) and Sequelae:

Thrombosed veins, which resemble cords, occasionally develop in the breast area 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, as well as a personal history of bleeding or clotting problems.

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. It is important to notify your physician of any previous allergic reactions.

Drug Reactions:

Unexpected drug allergies, lack of proper response to medication, or illness caused by the prescribed drug are possibilities. It is important for you to inform your physician of any problems you have had with any medication or allergies to medication, prescribed or over the counter, as well as medications you currently take regularly. Provide your surgeon with a list of medications and supplements you are currently taking.

Persistent Swelling (Lymphedema):

Persistent swelling 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. The body is not symmetrical and almost everyone has some degree of unevenness, which may not be recognized in advance. One side of the face may be slightly larger, one side of the face droopier. The same applies to the breast and trunk area. Many of such issues cannot be fully corrected with surgery. The more realistic your expectations are, the better your results will appear to you. Some patients never achieve their desired goals or results, at no fault of the surgeon or surgery. You may be disappointed with the results of the 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. Unsatisfactory results may NOT improve with each additional treatment.

ADDITIONAL ADVISORIES

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 blood clot formation, and therefore, may contribute to more bleeding issues. If you have a medical condition (such as heart arrhythmia, heart stent, blood vessels with blockages, or blood clots) and are taking medications to thin your blood and prevent clotting, such as Plavix[®], Coumadin[®], Xarelto[®], Effient[®], or Pradaxa[®], discuss the management of these medications around the time of surgery with your plastic surgeon. Your plastic surgeon may sometimes coordinate a plan for these medications with the doctor that prescribed them for your medical condition. If you have been prescribed drugs for a medical condition, do not stop them without discussing it first with your plastic surgeon. Stopping these medications abruptly may result in a heart attack, stroke, or death. Be sure to check with your physician about any drug interactions that may exist with any medications 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.

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 of sun block or clothing coverage.

Travel Plans:

Any surgery holds the risk of complications that may delay healing and 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 timeframe. Allow at least 10-14 days to travel via airplane. Medications may be required should you have a long flight/trip to prevent DVT/PE in the immediate post-operative period.

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.

Body Piercing:

Individuals who currently wear body jewelry in the surgical region are advised that an infection could develop from this activity. Body jewelry should be removed prior to your surgical procedure.

Nails:

To determine your vitals status during surgery your anesthesia provider may require access to your fingernails for monitoring. Make sure to have at least two fingernails free of nail polish or acrylic nails on the date of your surgery.

Jewelry:

Jewelry should not be brought with you at the time of your surgical procedure. Items, such as earrings, wedding rings, and necklaces should be removed and placed in a safe place.

Future Pregnancy and Breastfeeding:

This surgery is not known to interfere with pregnancy. If you are planning a pregnancy, your breast skin may stretch and offset the results of surgery. You may have more difficulty breast-feeding after this operation.

Female Patient Information:

It is important to inform your plastic surgeon if you use birth control pills or estrogen replacement, or if you suspect you may be pregnant. Many medications including antibiotics may neutralize the preventive effect of birth control pills, meaning there may be a risk of unplanned conception and pregnancy.

Intimate Relations After Surgery:

Surgery involves the coagulation 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 to 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 are often stressful. Please openly discuss with your surgeon, prior to surgery, any history that you may have of significant 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.

ADDITIONAL SURGERY NECESSARY (Re-Operations):

There are many variable conditions that may influence the long-term result of surgery. It is unknown how your tissue may respond or how wounds will heal after surgery. Secondary surgery may be necessary to perform additional tightening or repositioning of body structures. Should complications occur, additional surgery or other treatments may be necessary. Even though risks and complications occur infrequently, the risks cited are associated with this surgery. Other complications and risks can occur but are less common. 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, regarding the results that may be obtained. In some situations, it may not be possible to achieve optimal results with a single surgical procedure. You and your surgeon will discuss the options available should additional surgery be advised. There may be additional costs and expenses for such additional procedures, including surgical fees, facility and anesthesia fees, pathology, and lab testing.

PATIENT COMPLIANCE:

Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that 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 to return to surgery. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after surgery.

ATTESTATIONS

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 loss and 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 these types of complications. Please indicate your current status regarding the items below:

I am a non-smoker and do not use nicotine products. I understand the potential 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.

I have smoked and stopped approximately _____ ago. I understand I may still have the effects and therefore risks from smoking in my system, if not enough time has lapsed.

I have been advised to stop smoking immediately and have been informed of the risks, benefits, expectations, and alternatives to my surgery if I continue smoking.

It is important to refrain from smoking for at least 6 weeks before surgery and until your physician states it is safe to return, if desired. I acknowledge that I will inform my physician if I continue to smoke within this timeframe, and I understand that for my safety, the surgery, if possible, may be delayed.

Smoking may have such a negative effect on your surgery that a urine or blood test just before surgery may be done which will prove the presence of nicotine. If positive, your surgery may be cancelled and your surgery, scheduling fee, and other prepaid amounts may be forfeited. Honestly disclose your smoking habits with your surgeon.

Sleep Apnea/CPAP:

Individuals who have breathing disorders such as “Obstructive Sleep Apnea” and who may rely upon CPAP devices (continuous positive airway pressure) or utilize nighttime oxygen are advised that they are at substantive risk of respiratory arrest and death when they take narcotic pain medications following surgery. This is an important consideration when evaluating the safety of surgical procedures in terms of potentially serious complications, including death, that relate to pre-existing medical conditions. Surgery may be considered only with monitoring afterwards in a hospital setting in order to reduce the risk of potential respiratory complications and to safely manage pain following surgery.

Please consider the following symptoms of sleep apnea:

- I am frequently tired upon waking and throughout the day
- I have trouble staying asleep at night
- I have been told that I snore or stop breathing during sleep
- I wake up throughout the night or constantly turn from side to side
- I have been told that my legs or arms jerk while I’m sleeping
- I make abrupt snorting noises during sleep
- I feel tired or fall asleep during the day

It is important for you to inform and discuss any of the above symptoms that you have experienced with your surgeon.

DVT/PE Risks and Advisory:

There is a risk of blood clots, Deep Vein Thrombosis (DVT) and Pulmonary Embolus (PE) with every surgical procedure. It varies with the risk factors below. The higher the risk factors, the greater the risk and the more involved you must be in both understanding these risks and, when permitted by your physician, walking and moving your legs. There may also be leg stockings, squeezing active leg devices, and possibly medicines to help lower your risk.

There are many conditions that may increase or affect risks of clotting. Inform your doctor about any past or present history of any of the following:

- Past History of Blood Clots
- Family History of Blood Clots
- Birth Control Pills
- Hormone Stimulating Drugs
- Swollen Legs
- History of Cancer
- Large Dose of Vitamins
- Varicose Veins
- Past Illnesses of the Heart, Liver, Lung, or Gastrointestinal Tract.

CONSENT for SURGERY/PROCEDURE or TREATMENT

1. I hereby authorize Dr. James Anthony and assistants that may be selected to perform **Cutaneous/local flap**.
I have received the following information sheet: **Cutaneous/local flap**.
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 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 understand what my surgeon can and cannot do, and understand there are no warranties or guarantees, implied or specific regarding my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All my questions have been answered, and I understand the inherent (specific) risks of the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
5. I consent to being 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 am aware that there are potential significant risks to my health with the utilization of blood products, and I consent to their utilization should they be deemed necessary by my surgeon and/or his/her appointees.
9. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
10. I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
11. I realize that not having the operation is an option. I opt out of having this procedure _____.
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/Time _____ Witness _____