Dr. James B. Lowe – Plastic Surgery LOWER EXTREMITY (LEG, FOOT, TOE) SURGERY INFORMATION SHEET AND INFORMED CONSENT

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you of lower extremity surgery, its risks, as well as 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/ hand surgeon and agreed upon by you.

GENERAL INFORMATION

The lower extremity involves the area from the hip to the ends of the toes. Lower extremity surgery is performed to treat diseases such as tumors, chronic pain, broken bones, or other acute and chronic injuries. Your particular lower extremity problem will be discussed with you in some detail during your consultation. It is important to note before undergoing any procedure of the lower extremity surgery is associated with some risks and potential complications. Dr. James Lowe is a fully trained surgeon who is board certified in Plastic Surgery, General Surgery, and Hand and Microsurgery. Lower extremity surgery often requires the expertise of not only a surgeon but Physical Therapist to maximize recovery. Often patients with extensive trauma or surgery will need to see a Therapist for several months to adequately recover. It should also be noted that one of the most important parts of lower extremity surgery is patient compliance and participation in recovery.

Diagnostic studies such as X-rays, MRI's, or electro-diagnostic studies will often allow your surgeon the ability to determine the extent, position, and clinical course of a patient's lower extremity disease. These studies may be performed after a period of observation or conservative management. Such studies can allow your physician the ability to optimize your care and recovery before and after lower extremity surgery. Lower extremity surgery can usually be performed under local or regional anesthetic. Tourniquets are often utilized to prevent bleeding and to increase surgeon's visibility. Most lower extremity surgery can be performed as out-patient surgery where patients are allowed to go home on the same day. For more substantial surgery patients may be asked to stay at the hospital over night or longer in some cases.

Lower extremity surgery involves some risks and unknowns. Often these issues do not become completely clear until after surgery. One of the major risks to lower extremity surgery is injury to adjacent structures such as vessels or nerves. Often incisions will need to be extended or lengthened to increase safety or exposure. Patients often underestimate the difficulty of their surgical recovery, and they usually require the assistance of family and other medical sub-specialties. Significant lower extremity surgery almost always requires the help of a therapist. Some of the risks and potential complications of lower extremity surgery are listed below.

ALTERNATIVE TREATMENTS

Alternative treatment consists of not undergoing Lower Extremity Surgery. There is the possibility of loss of function if not repaired. Risks and potential complications are associated with alternative forms of surgical treatment.

RISKS OF LOWER EXTREMITY SURGERY

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

Bleeding- It is possible, though unusual, to experience a bleeding episode during or after surgery. Intraoperative blood transfusions may be required. Should post-operative bleeding occur, it may require an emergency treatment to drain the accumulated blood or blood transfusion. Do not take any aspirin or antiinflammatory medications for ten days before surgery, as this may increase the risk of bleeding. Non-

prescription "herbs" and dietary supplements can increase the risk of surgical bleeding. If blood transfusions are needed to treat blood loss, there is a risk of blood related infections such as hepatitis and the HIV (AIDS). Heparin medications that are used to prevent blood clots in veins can produce bleeding and decreased blood platelets.

<u>Infection</u>- Infections after lower extremity surgery may occur. Additional treatment may be required. There is the possibility of repair failure or scarring from an infection. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary.

<u>Change in Skin Sensation</u>- A diminished (or loss) of skin sensitivity in the area may occur and not totally resolve after upper extremity surgery.

Failure of Surgery- Lower extremity surgery is not always successful. Tissues may be repaired and may then rupture or fail to properly heal. If a tumor or mass is removed it may return requiring re-excision or another operation. Joint surgery may not heal properly requiring another operation or a significant change in the surgical plan. On occasion further surgery may not be beneficial. It is important that you follow all post-operative instructions concerning protecting the nerve repair from damage.

Loss of Parts or all of the Lower Extremity- Patients undergoing surgery to salvage or save parts or the entire lower extremity are usually aware that surgery may not always be successful. The surgeon should be able to give you a rough estimate of the overall success rate for re-vascularization or re-plantation procedures. It should be noted that attempts at these surgical procedures does not imply surgical success in any way.

Skin Contour Irregularities- Contour irregularities and depressions may occur after lower extremity surgery. Visible and palpable wrinkling of skin can occur. Residual skin irregularities at the ends of the incisions or "dog ears" are always a possibility and may require additional surgery. This may improve with time, or it can be surgically corrected.

<u>Skin Discoloration / Swelling-</u> Some bruising and swelling normally occurs following surgery. 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.

<u>Scarring</u>- All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur both 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. There is the possibility of visible marks in the skin from sutures. Scars may limit motion and function. In some cases scars may require surgical revision or treatment.

<u>Scarring to Deeper Structures</u>- Injuries to the lower extremity may result in significant scarring in joints or soft tissue that effect function. Injury from the surgery itself can occur within the wound or in nearby structures that prevent the return of maximal function. Additional surgery may not be successful in repairing injuries or allowing return of normal function. When deeper tissues are injured during surgery from scarring, function may be affected permanently and pain may result.

<u>Inability to Restore Function</u>- Certain lower extremity injuries never recover completely from the insult. Not all damaged structures can be surgically repaired. Injuries to other soft tissues and bone may prevent adequate nerve function despite a successful repair or release. Loss of soft tissues in the area may require other reconstructive surgical operations. Some injuries may be so severe that there is no reasonable expectation of return of function. Complications involving other parts of the body may occur after lower extremity surgery. When tissue is harvested to repair an area of injury this will result in some permanent loss of function or sensation in the area of the tissue harvest.

<u>Surgical Anesthesia</u>- 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.

<u>Delayed Healing</u>- Wound disruption or delayed wound healing is possible. Depending on the type of surgery performed, complete healing may be prolonged. Areas of skin may die. This may require frequent dressing changes or further surgery to remove the non-healed tissue. **Smokers have a greater risk of skin**Page 2 of 6

Patient Initials

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loss and wound healing complications.

<u>Damage to Associated Structures</u>- Structures such as nerves, blood vessels, bones and soft tissues may be damaged during surgery. The potential for this to occur varies with the type of surgical technique utilized. Additional surgery may be necessary should this problem occur. Injury to associated structures may be temporary or permanent.

<u>Additional Incisions Necessary</u>- Soft tissues may retract. It may be necessary to extend the original wound beyond to area anticipated or make new incisions to make full repairs to nerves, tendons, joints, or blood vessels. Further incisions will be required where tissue grafts are harvested.

<u>Allergic Reactions-</u> In rare cases, local allergies to tape, suture materials and glues, blood products, topical preparations or injected agents have been reported. Serious systemic reactions including shock (anaphylaxis) may occur to drugs used during surgery and prescription medications. Allergic reactions may require additional treatment.

<u>Pain-</u> You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after upper extremity surgery. Chronic pain may occur very infrequently from nerves becoming trapped in scar tissue. A more serious chronic pain (i.e. RSD) can occur when performing surgery on extremities and trunks particularly around nerves that may be permanent or require other interventions.

<u>Shock</u>- 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.

<u>Cardiac and Pulmonary Complications-</u> 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 and fat 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.

ADDITIONAL ADVISORIES

<u>Unsatisfactory Result-</u> Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. There is the possibility of an unsatisfactory result from the lower extremity surgery. This would include risks such as skin and soft tissue loss, wound disruption, chronic pain, loss of hand function, visible deformities, poor healing, and loss of sensation. There is the possibility that hand function after repair surgery may not be adequate for return to your regular occupation. It may be necessary to perform additional surgery to attempt to improve your results.

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

<u>Medications</u>- There are many 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. 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.

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 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 nicot	ine products. I understand the risk of second-hand
smoke exposure causing surgical complications.	
Lam a amakar ar uga tahagaa / nigatina	products. Lunderstand the risk of surgical complications
	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

Should complications occur, additional surgery or other treatments may be necessary. Secondary surgery may be necessary to obtain optimal results. Even though risks and complications occur infrequently, the risks cited are particularly associated with peripheral nerve 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

Lower extremity surgery may be vulnerable to breakage or injury until healing has occurred. Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the surgical incisions are <u>not</u> subjected to excessive force, swelling, abrasion, or motion during the time of healing. Personal and vocational activity needs to be restricted. Protective dressings and splints should <u>not</u> be removed unless instructed by your plastic surgeon. Successful restoration of function depends on both surgery and subsequent hand rehabilitation. 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 and hand rehabilitation, return for aftercare, and promote your recovery after surgery.

HEALTH INSURANCE

Depending on your particular health insurance plan, lower extremity surgery may be considered a covered benefit. 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 revision surgery**.

FINANCIAL RESPONSIBILITIES

The cost of surgery involves several charges for the services provided. The total includes fees charged by your doctor, the cost of surgical supplies, anesthesia, laboratory tests, and outpatient hospital charges, depending on where the surgery is performed. Additional charges may include hand rehabilitation therapy after surgery. 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 injury or surgery. Secondary surgery or hospital day-surgery charges involved with revision surgery would also be your responsibility. Health insurance may not completely cover the costs of surgery and rehabilitation. You may require more hand rehabilitation services than your insurance plan covers. In signing the consent for this surgery/procedure, you acknowledge that your 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 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 before signing the consent on the next page.

CONSENT FOR SURGERY / DROCEDURE or TREATMENT

	CONSENT FOR SURGERT / FRC	CLOCKE OF TREATMENT	
1.	I hereby authorize DrLowe to perform the following procedure or treatment:	and such assistants as may be selected	
	LOWER EXTREMITY (LEG, FOOT, TOE) SURGERY		
	I have received the following information sheet:		
	INFORMED CONSENT – LOWER EXTREMITY (LEG	, FOOT, TOE) SURGERY	
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 cooperating room.	nsent to the admittance of observers to the	
7.	I consent to the disposal of any tissue, medical devices	s 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 medical-device registration, if applicable.	to appropriate agencies for legal reporting and	
10.	. I understand that the surgeons' fees are separate from fees are agreeable to me. If a secondary procedure is required.		
11.	. I realize that not having the operation is an option.		
12.	a. THE ABOVE TREATMENT OR PROCEDURE TO b. THERE MAY BE ALTERNATIVE PROCEDURES C. THERE ARE RISKS TO THE PROCEDURE OR T	BE UNDERTAKEN OR METHODS OF TREATMENT	
	I CONSENT TO THE TREATMENT OR PROCEDURE AM SATISFIED WITH THE EXPLANATION.	AND THE ABOVE LISTED ITEMS (1-12). I	
	Patient or Person Authorized to Sign for Patient		

Witness

Date