

INFORMED CONSENT – LASER RESURFACING PROCEDURES OF SKIN

INSTRUCTIONS

This informed-consent document has been prepared to help inform you about laser resurfacing procedures of skin, 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 for surgery as proposed by your plastic surgeon and agreed upon by you.

GENERAL INFORMATION

Lasers have been used by plastic surgeons as a surgical instrument for many years. Laser energy can be used to cut, vaporize, or selectively remove skin and deeper tissues. There are many different methods for the surgical use of lasers. Conditions such as wrinkles, sun damaged skin, scars and some types of skin lesions/disorders may be treated with the CO₂ and Erbium laser. Certain surgical procedures may use the CO₂ laser as a cutting instrument. In some situations, laser treatments may be performed at the time of other surgical procedures.

Skin treatment programs may be used both before and after laser skin treatments in order to enhance the results.

ALTERNATIVE TREATMENTS

Alternative forms of treatment include not undergoing the proposed laser skin resurfacing procedure. Other forms of skin treatment (chemical peel) or surgical procedures (dermabrasion or excisional surgery) may be substituted. In certain situations, the laser may offer a specific therapeutic advantage over other forms of treatment. Alternatively, laser resurfacing procedures in some situations may not represent a better alternative to other forms of surgery or skin treatment when indicated. Risks and potential complications are associated with alternative forms of treatment that involve skin resurfacing (s) or surgical procedures.

RISKS OF LASER RESURFACING PROCEDURES OF SKIN

Every 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. Risks involve both items that specifically relate to the use of laser energy as a form of surgical therapy and to the specific procedure performed. An individual's choice to undergo a 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 all possible consequences of laser skin resurfacing.

Infection- Although infection following laser skin resurfacing is unusual, bacterial, fungal, and viral infections can occur. **Herpes simplex virus** infections around the mouth can occur following a laser treatment. This applies to both individuals with a history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. Specific medications must be prescribed and taken both prior to and following the laser treatment procedure in order to suppress an infection from this virus. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary.

Scarring- Although good wound healing after a procedure is expected, abnormal scars may occur within the skin and deeper tissues. In rare cases, keloid scars may result. 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.

Burns- Laser energy can produce burns. Adjacent structures including the eyes may be injured or permanently damaged by the laser beam. Burns are rare, yet represent the effect of heat produced within the tissues by laser energy. Additional treatment may be necessary to treat laser burns.

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Color Change- Laser resurfacing may potentially change the natural color of your skin. Skin redness usually lasts 1-3 months and occasionally 6 months following laser skin resurfacing. There is the possibility of irregular color variations within the skin including areas that are both lighter and darker. A line of demarcation between normal skin and skin treated with lasers can occur.

Accutane (Isotretinoin)- Accutane is a prescription medication used to treat certain skin diseases. This drug may impair the ability of skin to heal following treatments or surgery for a variable amount of time even after the patient has ceased taking it. Individuals who have taken this drug are advised to allow their skin adequate time to recover from Accutane before undergoing laser skin treatment procedures.

Fire- Inflammable agents, surgical drapes and tubing, hair, and clothing may be ignited by laser energy. Laser energy used in the presence of supplemental oxygen increases the potential hazard of fire. Some anesthetic gases may support combustion.

Laser Smoke (Plume)- Laser smoke is noxious to those who come in contact with it. This smoke may represent a possible biohazard.

Bleeding- Bleeding is rare following laser skin resurfacing procedures. Do not take any aspirin or anti-inflammatory medications for ten days before or after your procedure, 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. Should bleeding occur, additional treatment may be necessary.

Skin Tissue Pathology- Laser energy directed at skin lesions may potentially vaporize the lesion. Laboratory examination of the tissue specimen may not be possible.

Visible Skin Patterns- Laser resurfacing procedures may produce visible patterns within the skin. The occurrence of this is not predictable.

Distortion of Anatomic Features- Laser skin resurfacing can produce distortion of the appearance of the eyelids, mouth, and other visible anatomic landmarks. The occurrence of this is not predictable. Should this occur, additional treatment including surgery may be necessary.

Skin Discoloration / Swelling- Some swelling normally occurs following a laser skin resurfacing. 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 and, in rare situations, may be permanent.

Change in Skin Sensation- It is common to experience diminished (or loss) of skin sensation in areas that have had surgery. Diminished (or complete loss of skin sensation) may not totally resolve.

Damaged Skin- Skin that has been previously treated with chemical peels or dermabrasion, or damaged by burns, electrolysis (hair removal treatments), or radiation therapy may heal abnormally or slowly following treatment by lasers or other surgical techniques. The occurrence of this is not predictable. Additional treatment may be necessary.

Skin Contour Irregularities- Contour irregularities and depressions may occur after surgery. Visible and palpable wrinkling of skin can occur. Residual skin irregularities are always a possibility and may require additional surgery. This may improve with time, or it can be surgically corrected.

Pain- You will experience pain after your surgery. Pain of varying intensity and duration may occur and persist after surgery. Very infrequently, chronic pain may occur after laser skin resurfacing procedures. Some individuals who have a history of allergies may be prone to chronic skin discomfort after laser resurfacing procedures.

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Allergic Reactions- 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.

Lack of Permanent Results- Laser or other resurfacing treatments may not completely improve or prevent future skin disorders, lesions, or wrinkles. No technique can reverse the signs of skin aging. Additional surgical procedures may be necessary to further tighten loose skin.

Delayed Healing- Wound disruption or delayed wound healing is possible. Some areas of the skin may not heal normally and may take a long time to heal. Skin healing may result in thin, easily injured skin. This is different from the normal redness in skin after a laser resurfacing. Some areas of skin may die, requiring frequent dressing changes or further surgery to remove the non-healed tissue. **Smokers have a greater risk of skin loss and wound healing complications.**

Surgical Anesthesia- Both local and general anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of surgical anesthesia and sedation.

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 where on the body surgery is being performed. Injury to deeper structures may be temporary or 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.

Unsatisfactory Result- 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 a poor result from laser resurfacing. This would include risks such as unacceptable visible deformities, skin slough, loss of function, poor healing, wound disruption, permanent color changes in the skin and loss of sensation. It may be necessary to perform additional surgery to attempt to improve your results.

Seroma- Fluid accumulations infrequently occur in between the skin and the underlying tissues. Should this problem occur, it may require additional procedures for drainage of fluid.

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.

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 and fat emboli can be life threatening or fatal in some circumstances. Air travel, 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.

Unknown Risks- There is the possibility that additional risk factors of laser skin resurfacing may be discovered. The risks of performing skin tightening surgery and laser resurfacing is unknown in terms of

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the combination effect of the two procedures and potential complications, depending on the area treated. Skin slough, delayed healing and poor surgical outcome may occur.

ADDITIONAL ADVISORIES

Long-Term Results- Subsequent alterations in appearance may occur as the result of aging, weight loss or gain, sun exposure, pregnancy, menopause, or other circumstances not related to laser resurfacing. Laser resurfacing surgery does not arrest the aging process or produce permanent tightening of the skin. Future surgery or other treatments may be necessary to maintain the results of laser resurfacing.

Skin Cancer / Skin Disorders- Laser skin resurfacing procedures may not offer protection against developing skin cancer or skin disorders in the future.

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.

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, 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 smoke exposure causing surgical complications.

_____ I am a smoker or use tobacco / nicotine products. I understand the risk of surgical complications due to smoking or use of nicotine products.

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

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.

Medications- 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 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.

ADDITIONAL TREATMENT OR SURGERY NECESSARY

There are many variable conditions which influence the long term result of laser skin resurfacing. Even though risks and complications occur infrequently, the risks cited are the ones that are particularly

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associated with these procedures. Other complications and risks can occur but are even more uncommon. Should complications occur, additional surgery or other treatments may be necessary. 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.

PATIENT COMPLIANCE

Follow all physician instructions carefully; this is essential for the success of your outcome. Postoperative instructions concerning appropriate restriction of activity, use of dressings, and use of sun protection must be followed in order to avoid potential complications, increased pain, and unsatisfactory result. Your physician may recommend that you utilize a long-term skin care program to enhance healing following a laser skin resurfacing. 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 health insurance companies exclude coverage for cosmetic surgical operations such as laser skin resurfacing or any complications that might occur from surgery. Please carefully review your health insurance subscriber-information pamphlet or contact your insurance company for a detailed explanation of their policies. **Most insurance plans exclude coverage for secondary or revisionary surgery.**

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.**

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.

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CONSENT FOR SURGERY / PROCEDURE or TREATMENT

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

LASER SKIN RESURFACING SURGERY

I have received the following information sheet:

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2. I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may necessitate different procedures than those above. I therefore authorize the above physician and assistants or designees to perform such other procedures that are in the exercise of his or her professional judgment necessary and desirable. The authority granted under this paragraph shall include all conditions that require treatment and are not known to my physician at the time the procedure is begun.
3. I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of anesthesia involve risk and the possibility of complications, injury, and sometimes death.
4. I acknowledge that no guarantee or representation has been given by anyone as to the results that may be obtained.
5. I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes, provided my identity is not revealed by the pictures.
6. For purposes of advancing medical education, I consent to the admittance of observers to the operating room.
7. I consent to the disposal of any tissue, medical devices or body parts which may be removed.
8. I consent to the utilization of blood products should they be deemed necessary by my surgeon and/or his/her appointees, and I am aware that there are potential significant risks to my health with their utilization.
9. I authorize the release of my Social Security number 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.
12. IT HAS BEEN EXPLAINED TO ME IN A WAY THAT I UNDERSTAND:
 - a. THE ABOVE TREATMENT OR PROCEDURE TO BE UNDERTAKEN
 - b. THERE MAY BE ALTERNATIVE PROCEDURES OR METHODS OF TREATMENT
 - c. THERE ARE RISKS TO THE PROCEDURE OR TREATMENT PROPOSED

I CONSENT TO THE TREATMENT OR PROCEDURE AND THE ABOVE LISTED ITEMS (1-12). I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date _____ Witness _____