

Informed Consent

Laser Resurfacing Procedures of the Skin

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INSTRUCTIONS

This is an informed consent document that has been prepared to help inform you about laser resurfacing procedures of the skin, potential 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 a laser. In some situations, laser treatments may be performed at the same time as 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 or surgical procedures.

INHERENT RISKS OF LASER RESURFACING PROCEDURES OF SKIN

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 is 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 relevant consequences of laser resurfacing procedures of skin.

SPECIFIC RISKS OF LASER RESURFACING PROCEDURES OF SKIN

Infection:

Although infection following laser skin resurfacing is unusual, bacterial, fungal, and viral infections can occur. **Herpes simplex virus** skin infections can occur following a laser treatment. This applies to both individuals with a history of Herpes simplex virus infections (typically presenting as "cold sores") 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 infection from this virus. Should an infection occur, additional treatment including antibiotics, hospitalization, or additional surgery may be necessary.

Burns:

Laser energy can produce burns that can lead to scarring. 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 several days to weeks depending on the treatment and your skin type, but may occasionally persist for 6 months or longer following laser skin resurfacing. Be sure to discuss the likely duration of redness with your plastic surgeon. There is a 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. If you have ever taken Accutane[®], you should discuss this with your surgeon. 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 skin treatment procedures.

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.

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. If you have ever had such treatment, you should inform your surgeon.

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 tell your surgeon of any other infections, such as ingrown toenails, insect bites, tooth abscesses, or urinary tract infections that you may have. Infections in other parts of the body, may lead to an infection in the operated area.

Scarring:

All surgery leaves scars, some more visible than others. Although good wound healing after a surgical procedure is expected, abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of 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.

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.

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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.

Pain:

You will experience pain after your procedure. Pain of varying intensity and duration may occur and persist after procedure. Chronic pain may occur very infrequently.

Allergic Reactions:

In rare cases, local allergies to tape, 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 possible. 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 now regularly take. Provide your surgeon with a list of medications and supplements you are currently taking.

Asymmetry:

Symmetrical body appearance may not result after surgery. Factors such as skin tone, fatty deposits, skeletal prominence, and muscle tone may contribute to normal asymmetry in body features. Most patients have differences between the right and left side of their bodies before any surgery is performed. Additional surgery may be necessary to attempt to diminish asymmetry.

Unsatisfactory Result:

Although good results are expected, there is no guarantee or warranty expressed or implied, regarding 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 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 procedure. You may be disappointed with the results of the treatment. 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. Follow your surgeon's direction regarding stopping any medications before your laser treatment.

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

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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 procedure 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 treatment can be timed accordingly. There are no guarantees that you will be able to resume all activities in the desired time frame. 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 <u>not</u> related to your procedure.

Jewelry:

Jewelry should not be brought with you at the time of your procedure.

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 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 TREATMENTS NECESSARY

There are many variable conditions that may influence the long-term result of treatments. It is unknown how your tissue may respond or how wounds will heal. Secondary treatments may be necessary. The practice of medicine 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 procedure. You and your surgeon will discuss the options available should additional procedures 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 to follow the skin care instructions provided by your surgeon.

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 complications such as 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.

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___ 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 treatment 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 understand that for my safety, the surgery, if possible, may be delayed.

Smoking may have such a negative effect on your treatment that a urine or blood test just before your procedure may be done which will prove the presence of nicotine. If positive, your treatment may be cancelled and your procedure, 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 a substantive risk for respiratory arrest and death when they take narcotic pain medications following treatment. This is an important consideration when evaluating the safety of procedures in terms of very serious complications, including death, that relate to pre-existing medical conditions.

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.

COMMUNICATION ACKNOWLEDGEMENT – CONSENT

There are many ways to communicate with you. It is important to keep appointments and let us know if problems or issues arise. Methods of communication include telephone, text, pager, answering service if available, email, and regular mail. If an emergency arises, keep us alerted to your progress so we may aid in any necessary treatments. Please do not leave a message after hours or on weekends on the office answering machine if any urgent or emergent situation exists, as there will be a delay in retrieving such messages. All attempts will be made to preserve your privacy in accordance with HIPAA rules.

Please confirm below all acceptable ways of communicating with you:

____ Telephone Home(-

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Work (Cell (Text	-	-))	
Pager – Answering Service if available Email – with up to date email address (Regular Mail and Delivery			@)

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 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. James Anthony and such assistants as may be selected to perform Laser Resurfacing Procedures of Skin.

I have received the following information sheet: Laser Resurfacing Procedures of Skin.

- I recognize that during the course of the operation and medical treatment or anesthesia, unforeseen conditions may 2. 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.
- I consent to the administration of such anesthetics considered necessary or advisable. I understand that all forms of 3. anesthesia involve risk and the possibility of complications, injury, and sometimes death.
- I understand what my surgeon can and cannot do, and understand there are no warranties or guarantees, implied or 4. specific, about my outcome. I have had the opportunity to explain my goals and understand which desired outcomes are realistic and which are not. All of my questions have been answered, and I understand the inherent (specific) risks to the procedures I seek, as well as those additional risks and complications, benefits, and alternatives. Understanding all of this, I elect to proceed.
- I consent to be photographed or televised before, during, and after the operation(s) or procedure(s) to be performed, 5. including appropriate portions of my body, for medical, scientific, or educational purposes, provided my identity is not revealed by the pictures.
- For purposes of advancing medical education, I consent to the admittance of observers to the operating room. 6.
- I consent to the disposal of any tissue, medical devices, or body parts that may be removed. 7.
- 8. I authorize the release of my Social Security number to appropriate agencies for legal reporting and medical-device registration, if applicable.
- I understand that the surgeons' fees are separate from the anesthesia and hospital charges, and the fees are 9. agreeable to me. If a secondary procedure is necessary, further expenditure will be required.
- 10. I realize that not having the operation is an option. I opt out of having this procedure _____.
- 11. 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 (1-11). I AM SATISFIED WITH THE EXPLANATION.

Patient or Person Authorized to Sign for Patient

Date/Time Witness