

Anne M. Nickodem, M.D., F.A.C.S.

Aesthetic, Breast and Reconstructive Surgery



INFORMED CONSENT – LASER RESURFACING PROCEDURES OF SKIN

INSTRUCTIONS

This is an informed-consent document that has been prepared to help inform you concerning laser resurfacing procedures of skin, the associated 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 treatment 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 CO₂ laser skin treatments in order to enhance results.

ALTERNATIVE TREATMENT

Laser resurfacing of the skin is an elective procedure. Alternative treatment would consist of not undergoing the procedure. Other forms of skin treatment (e.g. chemical peel, dermabrasion, 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.

RISKS OF LASER RESURFACING PROCEDURES OF SKIN

Every treatment 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 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 resurfacing of skin.

Bleeding: It is possible, though unusual, to experience a bleeding episode during or after treatment. Should post-treatment bleeding occur, it may require emergency treatment to drain accumulated blood or blood transfusion. Intra-operative blood transfusion may also be required. Aspirin, anti-inflammatory medications, non-prescription "herbs", and dietary supplements can increase the risk of bleeding. If blood transfusions are needed to treat blood loss, there is a risk of blood related infections such as hepatitis and the Human Immunodeficiency Virus (the virus that causes AIDS).

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Patient Initials

01/07/08 version

Suite 340
3299 Woodburn Road
Annandale, VA 22003
(703) 560-8711
(703) 560-8725 FAX

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Infection: Infection is unusual after treatment, but bacterial, fungal, and viral infections can occur. If you have a history of **Herpes simplex virus** infections around the mouth, it is possible that an infection can recur following laser resurfacing treatments. Specific medications must be prescribed prior to the laser treatment procedure in order to suppress an infection from this virus. Should an infection occur, additional treatment including antibiotics, hospitalization, or surgery may be necessary.

Change in skin sensation: It is possible to experience diminished (or loss) of skin sensation in areas that have had treatment. Diminished (or complete loss of skin sensation) may not totally resolve.

Skin Sensitivity: Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after treatment. Usually this resolve during healing, but in rare situations it may be chronic.

Scarring: Although good wound healing after a laser treatment is expected, abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of different color than surrounding skin. Scar appearance may also vary within the same scar, exhibit contour variations and "bunching" due to the amount of excess skin. Scars may be asymmetrical (appear different between right and left side of the body). Additional treatments including surgery may be necessary to treat abnormal scarring.

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

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 treatment. 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 laser treatment can occur, due to the healthier appearance of laser-treated skin.

Accutane (isotretinoin)- Accutane is a prescription medication used to treat certain skin diseases. This drug may impair the ability of the 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. Wet towels are placed around the area to be treated.

Laser smoke (plume)- Laser smoke is noxious to those who come in contact with it. This smoke ay represent a possible bio-hazard.

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 treatment procedures may produce visible patterns within the skin. The occurrence of this is no predictable.

Distortion of anatomic features- Laser skin treatments 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. The occurrence of this is not predictable. Additional treatment may be necessary.

Skin cancer/skin disorders- Laser skin resurfacing procedures may not offer protection again developing skin cancers or skin disorders in the future.

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Pain- Very infrequently, chronic pain may occur after laser skin resurfacing procedures.

Delayed healing- It may take longer than anticipated for healing to occur after laser treatments. Skin healing may result in thin, easily injured skin. This is different from the normal redness in skin after a laser treatment. **Smokers have a greater risk of skin healing complications.**

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 to drugs used during treatment and prescription medications. Allergic reactions may require additional treatment.

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 skin treatment. Laser or other resurfacing treatments may not completely improve and will not prevent future skin wrinkling. None of these techniques can reverse the signs of skin aging. Additional surgical procedures may be necessary to further tighten loose skin.

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

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

Unsatisfactory result- Although good results are expected, there is no guarantee or warranty expressed or implied, on the results that may be obtained. You may be disappointed with the results of laser skin resurfacing. This would include risks such as unacceptable visible deformities, skin slough, loss of function, and permanent color changes in the skin. Additional treatment may be required to improve results.

Summary of Side Effects and Complications of Laser Resurfacing:

- **MILD:** persistent erythema, transient edema, milia formation, acne flare, contact dermatitis, delayed hyperpigmentation or hypopigmentation, post-operative swelling, petechiae
- **MODERATE:** Transient hyperpigmentation, local Herpes-Simplex virus reactivation, superficial bacterial or fungal activation
- **SEVERE:** hypertrophic scarring, disseminated infection, ectropion

ADDITIONAL ADVISORIES:

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 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 nicotine products. I understand the risk of second-hand smoke exposure causing treatment complications.

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

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.

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Mental Health Disorders and Elective Treatment- It is important that all patients seeking to undergo elective treatment have realistic expectations that focus on improvement rather than perfection.

Complications or less than satisfactory results are sometimes unavoidable, may require additional treatment and often are stressful. Please openly discuss with your surgeon, prior to procedure, 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 treatment, 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 treatment, 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.

ADDITIONAL TREATMENT NECESSARY

Should complications occur, additional treatments may be necessary. Secondary treatment may be necessary to obtain optimal results. Even though risks and complications occur infrequently, the risks cited are particularly associated with laser resurfacing procedures of skin. Other complications and risks can occur but are even more uncommon. 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. With laser resurfacing treatment, it may not be possible to achieve optimal results with a single procedure. This may require multiple treatment sessions to produce a final outcome.

PATIENT COMPLIANCE

Follow all physician instructions carefully; this is essential for the success of your outcome. It is important that the treated skin areas 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-treatment function depends on both treatment and subsequent care. Physical activity that increases your pulse or heart rate may cause bruising, swelling, fluid accumulation around implants and the need for return to treatment. It is wise to refrain from intimate physical activities after treatment 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 treatment.

HEALTH INSURANCE

Most health insurance companies exclude coverage for cosmetic treatment procedures or any complications that might occur from treatment. Please carefully review your health insurance subscriber-information or contact your insurance company for a detailed explanation of their policies. **Most insurance plans exclude coverage for secondary or revisionary treatment.**

FINANCIAL RESPONSIBILITIES

The cost of treatment involves several charges for the services provided. The total includes fees charged by your surgeon, the cost of supplies, anesthesia, laboratory tests, and possible outpatient hospital charges, depending on where the treatment is performed. Depending on whether the cost of treatment 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 treatment. Secondary treatment or other charges involved with revision treatment will also be your responsibility. **In signing the consent for this 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.**

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DISCLAIMER

Informed-consent documents are used to communicate information about the proposed treatment of a disease or condition along with disclosure of risks and alternative forms of treatment(s), including no treatment. 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 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.

**INFORMED CONSENT – LASER RESURFACING PROCEDURES OF SKIN
CONSENT FOR SURGERY / PROCEDURE or TREATMENT**

1. I hereby authorize Dr. _____ and such assistants as may be selected to perform the following procedure or treatment: **Laser Resurfacing of Skin**

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 _____