

## **INFORMED CONSENT –NON-ABLATIVE LASER RESURFACING PROCEDURES OF THE SKIN**

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# 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 CO<sub>2</sub> and Erbium laser. Certain surgical procedures may use the CO<sub>2</sub> 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. Should an infection occur, additional treatment including antibiotics may be necessary.

**Scarring-** Although good wound healing after a procedure is expected, abnormal scars may occur within the skin and deeper tissues. Scars may be unattractive and of different color than the surrounding skin tone. Scars may be asymmetrical (appear different on the right and left side of the body).

**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 can last up to 2 weeks after a non-ablative laser skin resurfacing treatment. There is the possibility of irregular color variations within the skin including areas that are both lighter and darker.

**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 (typically 1 year) 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.

**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.

**Bruising**- It is very common to develop petechiae (broken blood vessels) after non-ablative skin resurfacing. This side effect is temporary, but may last up to 2 weeks after laser treatment.

**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 most common pattern in the skin will be one of a circular shape, which mimics the tip of the laser head. Inside this circular shape may also appear a grid like pattern. Both of these phenomenon are temporary side effects of the laser treatment and may last up to 4 weeks post treatment. 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.

**Skin Discoloration / Swelling**- Some swelling normally occurs following laser skin resurfacing. The skin in or near the treatment site can appear either lighter or darker than surrounding skin. Swelling can last up to 2 weeks following a non-ablative laser resurfacing treatment.

**Change in Skin Sensation**- It is common to experience a temporary diminished (or loss) of skin sensation in areas that have had laser treatment.

**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 laser treatment. Visible and palpable wrinkling of skin can occur. Residual skin irregularities are always a possibility and may require additional treatment.

**Skin Drainage**- It is not common to have a significant amount of skin drainage after non-ablative laser skin resurfacing. It is however common to experience milia (small white heads in the skin) after a laser resurfacing treatment. Milia can appear patchy and rough in texture. This side effect usually resolves itself within 2 weeks.

**Pain**- You may experience pain after laser treatment. This can generally be alleviated with Acetaminophen (Tylenol).

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**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 laser treatments may be necessary to receive the most optimal results.

**Delayed Healing-** Wound disruption or delayed wound healing is possible. Some areas of the skin may take longer than others to heal. Skin healing may result in thin, easily injured skin. This is different from the normal redness in skin after laser resurfacing. **Smokers have a greater risk of skin loss and wound healing complications.**

**Surgical Anesthesia-** Local anesthesia is usually required for non-ablative laser skin resurfacing in the form of a topical anesthetic cream. This anesthetic is typically applied to the affected area for up to one hour prior to the laser treatment. There is the possibility of complications from all forms of surgical anesthesia and sedation.

**Skin Sensitivity-** Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur after surgery. This usually resolves during the healing process.

**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, poor healing, wound disruption, permanent color changes in the skin and loss of sensation.

**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 can lead to illness, and may require further medical treatment.

**Unknown Risks-** There is the possibility that additional risk factors of laser skin resurfacing may be discovered. 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 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.

**Sun Exposure-** It is extremely important that direct sun exposure and the use of artificial tanning products be avoided for 4 weeks before and for 4 weeks after non-ablative laser resurfacing treatment. If you plan on sun tanning within this time frame of your scheduled laser treatment, please advise our office so we can reschedule your procedure.

#### **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.

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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 physician, prior to treatment, 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 procedures, 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. .

### **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 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 laser treatment and subsequent care. Physical activity that increases your pulse or heart rate may cause additional bruising and swelling. It is important that you participate in follow-up care, return for aftercare, and promote your recovery after laser treatment.

### **HEALTH INSURANCE**

Most health insurance companies exclude coverage for cosmetic surgical operations such as laser skin resurfacing or any complications that might occur from treatment. 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 treatment.**

### **FINANCIAL RESPONSIBILITIES**

The cost of laser skin resurfacing may involve several charges for the services provided. 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 treatment. **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

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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. Few 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.

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\_\_\_\_\_  
Patient or Person Authorized to Sign for Patient

Date \_\_\_\_\_