



484 S Miller Road, Suite 201, Fairlawn, Ohio 44333 PH 330-801-9069 website: FairlawnAestheticMD.com

### **Instructions**

This is an informed consent document to help inform you about carbon dioxide (CO<sub>2</sub>) laser treatment procedures, risks, and alternative treatments.

It is important that you read this information carefully and completely. Please initial each page at the bottom, indicating you have read the page and sign the consent for the procedure.

Thank you.

### **What is laser skin resurfacing?**

The carbon dioxide laser has been used for more than 25 years for treating the skin. An intense beam of light is emitted that heats and vaporizes skin tissue instantly. Recently developed carbon dioxide can remove the layers of skin, vaporizing the ridges of scars and wrinkles and smoothing out the surface of the skin. In addition, the skin tightens and collagen remodeling occurs, with layers of new collagen replacing sun-damaged collagen.

### **Alternative Treatment**

Alternative forms of treatment include not undergoing the proposed CO<sub>2</sub> laser skin treatment procedure. Other forms of skin treatment (chemical peel) or surgical procedures (dermabrasion or excisional surgery) may be substituted. In certain situations, the CO<sub>2</sub> laser may offer a specific therapeutic advantage over other forms of treatment. Alternatively, CO<sub>2</sub> laser treatment procedures in some situations may not represent a better alternative to other forms of surgery of skin treatment when indicated. Risks and potential complications are associated with alternative forms of treatment that involve skin treatments or surgical procedures.

### **Benefits**

Laser resurfacing may significantly reduce pigment, sun damage, facial wrinkle lines, scars, and acne scarring. The length of time these benefits will last is unknown. Sunspots and brown spots are often removed as well.

### **Contraindications**

No Accutane use in past one year. No use of tetracycline, minocycline, doxycycline, or erythromycin in last month. Any history of vitiligo, scleroderma, collagen disorders, radiation treatment, skin cancer, psoriasis, keloid formation, pregnancy, breastfeeding. Notify your Doctor if you have sleep apnea or any other breathing problems.

### **Risks and discomforts**

There are both risks and complications, both temporary and permanent, associated with all laser treatment procedures of the skin. 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 risk to potential benefit. Although the majority of patients do not experience these complications, make sure you understand the risks, potential complications, and consequences of laser skin treatment.

The most common side effects and complications are explained below.

**Erythema (redness of skin):** the laser-treated areas have a distinctive redness, which is much more vivid than untreated areas. This redness generally will last 3-10 days, depending on the level of energy and density used (discuss with the physician). This redness represents increased blood flow from healing and inflammation, and with new growth of the superficial tissue it fades gradually.

**Inflammation (swelling):** this is common and varies from person to person. Most patients will swell mildly, but in some patients the swelling is more severe. Your skin may feel tight, full, flushed, or swollen following treatment partly from this swelling but also from the tightening effect of the procedure.

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**Hyperpigmentation (increased skin color):** this may occur in those with dark complexions and almost always is temporary. It responds to the use of hydroquinone, UVA protective sunscreens, and topical retinoids post-procedure. Hyperpigmentation may also occur in areas of permanent makeup. Notify the physician if you have permanent makeup.

**Hypopigmentation (decreased skin color):** this has been very uncommon and is usually related to the depth of treatment, although it can occur for unknown reasons even when the procedure has been performed properly. In addition, removing sun-damaged skin can return you to your lighter color similar to areas on your body that have not had long-term sun exposure (i.e., underarms). Delayed hypopigmentation can occur months to years after the procedure and can be permanent.

**Color change:** Laser treatments may also potentially change the natural color of your skin. Skin redness occasionally lasts up to 6 months following CO2 laser skin treatment. There is the possibility of irregular color variations within the skin including areas that are both lighter and darker (as described above). A line of demarcation between untreated skin and skin treated with lasers can occur. Laser treatment procedures may produce visible patterns within the skin. The occurrence of this is not predictable.

**Scarring or Keloids:** scarring is not anticipated as a consequence of this procedure, but any procedure in which the surface of the skin is removed can heal with scarring. This usually occurs because of some secondary factor that interferes with healing, such as infection, irritation, scratching, or poor wound care. It may also occur because of a patient's condition that predisposes to scarring, keloids, or poor wound healing (i.e. diabetes). Scarring from infection, irritation, or scratching does blend and ordinarily disappears in a few months, but some scarring may be permanent if it occurs. Hypertrophic scars or keloids in susceptible people may suddenly appear. Additional treatments may be needed to treat scarring. Most of these respond to injections or special creams. Some scarring could be permanent. Scars may be unattractive and of different color than the surrounding skin.

Notify your physician if you have ever used Accutane, as this can increase your risk for scarring.

**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 (approximately one year) before undergoing CO2 laser skin treatment procedures.

**Burns/Ulcers:** Laser energy can produce temporary or permanent burns/ulcers.

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. Inflammable agents, surgical drapes and tubing, hair, and clothing may be ignited by laser energy. Laser smoke (plume) is noxious to those who come in contact with it. This smoke may represent a possible bio-hazard, although suction is used to collect this smoke/plume.

**Bleeding:** Bleeding is rare following CO2 laser skin treatment procedures. 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.

**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 treatments 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. The occurrence of this is not predictable. Should this occur, additional treatments including surgery may be necessary.



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**Skin cancer/skin disorders:** CO2 laser skin treatment procedures may not offer protection against developing skin cancer or skin disorders in the future.

**Pain:** Very infrequently, chronic pain may occur after CO2 laser skin treatment.

**Allergic reactions:** In rare cases, local allergies to tape or preservatives used in cosmetics or topical preparations have been reported. Systemic reactions which are more serious may result from drugs used during the procedure and prescription medicines. Allergic reactions may require additional treatment. Allergic reactions or irritations to some of the medications or creams may develop. An increased sensitivity to wind and sun may occur but is usually temporary and clears as the skin heals.

**If you have had a cold sore or herpes outbreak, notify your physician, as laser treatment can reactivate it.**

**Drug side effects:** The drugs that may be administered can have the following general side effects:  
**Retin-A, Renova (or other topical vitamin A creams):** sensitivity to sunlight, including sunlamps, mild skin irritation, or dryness.

**Hydroquinones or bleaching creams:** mild skin irritation, itching, burning sensation.

**Valtrex or acyclovir (antivirals):** headaches, nausea, allergic reaction

**Keflex (or other antibiotic):** dizziness, headache, nausea, rash, allergic reaction, or other

**Narcotic pain medicine:** lightheadedness, dizziness, sedation, nausea, vomiting, or other

**Valium:** dizziness, lightheadedness, sedation, respiratory depression

**Patient failure to follow through:** Patient follow through following a laser skin treatment procedure is important. Postoperative instructions concerning appropriate restriction of activity, use of dressings and skin care, and use of sun protection need to be followed in order to avoid potential complications, increased pain, and unsatisfactory results.

**Unsatisfactory result:** There is a possibility of an unsatisfactory result from these procedures. CO2 laser treatment procedures may result in unacceptable visible deformities, skin slough, loss of function, and permanent color changes in the skin. You may rarely be disappointed with the final result. It is possible that you may derive no benefits from the procedure. Whereas this procedure is effective in most cases, no guarantees can be made that a specific patient will benefit from treatment. This procedure may not completely improve or prevent future skin disorders, lesions, or wrinkles. No technique can reverse the signs of aging permanently. Do not sign this form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

**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 treatment.

**Unknown risks:** There is the possibility that additional risk factors of CO2 laser skin treatments may be discovered. The results of performing skin tightening surgery and CO2 laser treatments is unknown in terms of the combination effect of the two procedures and potential complications, depending on the area treated.

**Anesthesia:** Both local and oral anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of anesthesia and sedation. Notify your Doctor if you have sleep apnea or any other breathing problems.

**Additional treatment or surgery necessary:** There are many variable conditions which influence the long term result of CO2 laser skin treatments. 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.

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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.

**Financial responsibilities:** The cost of CO2 laser skin treatment involves several charges for the services provided. This includes fees charged by your physician, the cost of some pre- and post-procedure skin care, medications, supplies, laser equipment and personnel, and other costs. It is unlikely that cosmetic procedure costs would be covered by an insurance plan. Even if there is some insurance coverage, you will be responsible for necessary co- payments, deductibles, and charges not covered. Additional costs may occur should complications develop. Secondary surgery or treatment charges involved would also be your responsibility.

**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 treatments. 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 physician 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 or your questions answered before signing the consent page. Please initial each page of this document.**

**Consent**

My signature indicates the following: 1) I have read and understand the information outlined above; 2) I have discussed questions with the physician and/or staff; 3) It has been explained to me in a way that I understand the above treatment, alternatives, and I am aware of the risks, benefits, and alternatives and I am satisfied with the explanation; 4) I have received the pre- treatment and post-treatment information sheets; 5) I am not pregnant and there is no possibility that I could be pregnant and I am not breastfeeding; 6) I understand the risks of the topical, local and oral anesthesia and I consent to taking them; 7) I authorize the physician to perform the mentioned procedures and treatments and any other treatments necessary should unforeseen conditions/complications occur; 8) I acknowledge that no guarantee has been given by anyone as to the results that may be obtained; 9) For the purposes of advancing medical education, I consent to the admittance of assistants and/or observers in the procedure room unless otherwise notified. 10) I know and understand all of the warning signs of problems, side effects, and complication (i.e. burns, ulcers, blisters, signs of infection, redness and swelling above what is described as expected and any other warning sign) and know to immediately contact your Doctor at the office or by cell if I see any of these signs or if I have any questions.

I give permission for any pictures or videotape taken of me may be used for either teaching or publication, if considered appropriate \_\_\_\_\_(YES); \_\_\_\_\_(NO).

I give permission for my pictures to appear in Doctor's photo album for other potential patients to view \_\_ (YES); \_\_ (NO).

\_\_\_\_\_  
Signature of the Patient

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Physician

\_\_\_\_\_  
Date