

Fraxel® DUAL 1550/1927 Laser Treatment Patient Consent Form

Doctor/Practice Address Phone

Patient Name _____ Date of Birth _____

Do not sign this form without reading and understanding its contents.

The nature of the Fraxel DUAL 1550/1927 procedure has been explained to me. I understand that just as there may be benefits from the procedure, all procedures involve risk to some degree.

I understand that the following are among the **expected side effects** of the Fraxel DUAL 1550/1927 procedure:

Discomfort — Most people will feel some heat-related discomfort (pain) associated with the treatment. This discomfort is usually temporary during the procedure and localized within the treatment area. A small number of patients have reported tenderness in the treatment area lasting up to several weeks.

Redness and Swelling — Laser treatment will cause varying degrees of redness and swelling in the treatment area. These common side effects last from several days to a couple of weeks, depending upon the aggressiveness of the treatments.

Itching — This can occur as part of the normal wound healing process or may occur as part of infection, poor wound healing or contact dermatitis.

Acne or Milia Formation — A flare-up of acne or formation of milia (tiny white bumps or small cysts on the skin) may occur. These symptoms usually resolve completely.

Herpes Simplex Reactivation — Herpes Simplex Virus (cold sore) eruption may result in rare cases in a treated area that has previously been infected with the virus.

I understand that the following are among the **possible risks or complications** associated with the Fraxel DUAL 1550/1927 procedure:

Bleeding; Oozing; Crusting — Aggressive treatment may cause pin point bleeding, petechiae (small red dots under the skin surface), and/or oozing. Crusting or scabbing may form if the clear fluid or blood dries.

Blisters; Burns; Scabbing — Heating in the upper layers of the skin may cause blisters or burns and subsequent scab formation. Steam from the heating may produce a separation between the upper and middle layers of the skin resulting in blister formation. The blisters usually disappear within 2-4 days. A scab may be present after a blister forms, but typically will disappear during the natural wound healing process of the skin.

Scarring — Scarring is a possibility due to the disruption to the skin's surface and/or abnormal healing. Scars, which can be permanent, may be raised or depressed, and scarring could lead to loss of pigment ("hypopigmentation") in the scarred area.

Pigment Changes — During the healing phase, the treated area may appear to be darker. This is called PIH, post inflammatory hyperpigmentation. You may have experienced this type of reaction before and noticed it with minor cuts or abrasions. PIH occurs as a part of the normal skin reaction to injury. The skin functions become hyperactive during the healing process, including cells that produce pigment. PIH occurs more frequently with darker colored skin, after sun exposure to the treatment area, or with patients who already have a tan. To reduce the risk of PIH, the treated area must be protected from exposure to

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the sun (sunscreen for 6 months after treatment); however, in some patients, increased skin coloring may occur even if the area has been protected from the sun. This pigmentation usually fades in 3 to 6 months.

Hypopigmentation — In some patients who experience pigment changes, the treated area loses pigmentation (hypopigmentation) and becomes a lighter color than the surrounding skin. This type of reaction may also be permanent.

Infection — If blisters or bleeding are present, an infection of the wound is possible. Scarring and associated pigment changes may result from an infection.

Eye Injury — Eye injuries may result from numbing cream getting into the eyes. Your eyes will be covered with protective goggles during treatment and should remain closed during the treatment. The laser could cause direct eye injury in the absence of these precautions.

Efficacy — Because all individuals are different, it is not possible to completely predict who will benefit from the procedure. Some patients will have very noticeable improvement, while others may have little or no improvement. A series of treatments is usually needed for maximum results.

Contraindications — Fraxel DUAL 1550/1927 cannot be performed on patients who are currently undergoing or have had Accutane treatment within the past six months, have a predisposition to keloid formation or excessive scarring or have suspicious lesions.

I am aware that other unexpected risks or complications may occur and that no guarantees or promises have been made to me concerning the results of the procedure. It has also been explained that during the course of the proposed procedure, unforeseen conditions may be revealed requiring performance of additional procedures. My questions regarding this treatment, its alternatives, its complications and risks have been answered by my doctor and/or his or her staff.

DO NOT SIGN THIS FORM UNLESS YOU HAVE READ IT AND BELIEVE THAT YOU UNDERSTAND IT. ASK ANY QUESTIONS YOU MIGHT HAVE BEFORE SIGNING THIS FORM. DO NOT SIGN THIS FORM IF YOU HAVE TAKEN MEDICATIONS WHICH MAY IMPAIR YOUR MENTAL ABILITIES OR IF YOU FEEL RUSHED OR UNDER PRESSURE.

I have read this form and understand it, and I request the performance of the procedure.

Patient Signature

Date of Birth

I have informed the patient of the available alternatives to treatment and of the potential risks and complications that may occur as a result of this treatment

Physician Signature

Date

Nurse or Medical Assistant

Date



How to Care for Your Skin After Fraxel® Treatment

Your treatment was performed by: _____ For problems or questions, call: _____

Congratulations! You have taken the first step toward more healthy and radiant looking skin by having a *Fraxel re:store™* treatment. Now it is important to help your skin heal quickly and protect your skin investment.

- **Fraxel Deep Hydration Masks (first 48 hours) and Fraxel Green Tea Infusion Masks (days 3-7).** Use these masks up to a few times each day for soothing cool comfort and moisture. To use the masks, follow the instructions on the package label. (These masks can be purchased from your Fraxel physician).
- **Skin Care Products.** All of your skin care products should be non-irritating and non-clogging for the first week or so after Fraxel Laser Treatment. Examples of brands that offer very gentle and inexpensive products that are ideal to use: Aveeno®, Dove®, Neutrogena®, and Cetaphil®, etc.
- **Sunscreen.** The American Academy of Dermatology believes that proper and repeated sunscreen application is very important. Your sunscreen should have a sun protection factor (SPF) of 30 or more and offer broadband protection (UVA and UVB). First apply the sunscreen 20 minutes before going outside, and then apply it again, immediately before going out. After that, reapply your sunscreen every 2 hours. If direct sun exposure is necessary, wear a hat and clothing that covers the treated area. It is very important to use this regimen during the healing period and you should then make it part of your normal routine. You will probably find that you use about 1 bottle of sunscreen per month, rather than the 1 bottle per year that most people use.
- **Moisturizer.** Remember that peeling and/or flaking is normal during the healing process. Therefore, the product should be non-irritating and non-clogging, else you could develop breakouts. During the healing period your normal moisturizer may be too occlusive, so consider products from the brands listed above. Instead of using 2 separate products, use moisturizers that contain SPF30 or more. Reapply whenever your skin feels dry.
- **Scrubs, Toners, Glycolic Acid, and Retin A.** Your skin will be sensitive for the first week or so after treatment, so do not use products that will cause irritation during this time. Do not use abrasive scrubs, toners, or products that contain glycolic acids or Retin A. *Be sure to read all of the skincare product labels.*
- **Bleaching Creams.** Discontinue use of your bleaching cream while your skin is tender. Restart your bleaching cream on: _____
- **Cold Sores.** For your history of cold sores, take the following medication as instructed below.

- **Resume your normal skin care regimen when your skin has fully healed.**



What to Expect After Treatment

Fraxel® Laser Treatment produces side-effects. The intensity and duration of your side effects depends on the treatment aggressiveness your individual healing characteristics. Generally, patients who are treated more aggressively experience more intense side-effects that last longer. However, some patients have greater than "expected" reactions to less aggressive treatments and others have fewer side-effects to aggressive treatments than would ordinarily be expected. Notify your physician if the severity of your side-effects becomes a problem for you.

- **Swelling.** You will notice most of the swelling on the first morning after treatment, particularly under the eyes. Swelling usually lasts two to three days. To minimize swelling do the following:
 - ✓ Apply cold compresses to the treatment area for 10 minutes of every hour on the day of treatment, until you go to bed.
 - ✓ Sleep elevated the first night. Use as many pillows as you can tolerate.
- **Redness.** Most redness resolves during the first week after treatment, but a rosy "glow" can remain for several weeks. If you wish, you can apply makeup immediately after treatment to minimize the redness.
- **Dry skin.** Your skin may feel dry, peel, or flake. You may notice a "sandpaper" texture a few days after treatment. This is the treated tissue working its way out of your body as new fresh skin is regenerated.
- **Bronzing, Crusting and Small Dark Dots.** Fraxel Laser Treatment causes destruction to microscopic cylinders of skin which then exfoliates during the healing process. In individuals with heavily pigmented skin, or in areas where sun damage has produced pigmented lesions, these microscopic wounds, known as MENDs, contain large amounts of melanin. Because there are so many MENDs, they can make the skin look bronzed, or small areas appear crusted (do not try to scratch them off). When high energies are used to produce deep and wide lesions, the MENDs can sometimes be seen as individual dark dots. On the face, the MENDs will shed within 7-10 days. Off the face, it may take as long as 3 weeks for the MENDs to shed.
- **Raw Skin.** If you develop areas of raw skin post treatment, keep them moist with something like Aquaphor® or Bacitracin®. You do not need to apply band-aids, but keep the areas moist and *do not pick at them*. They will heal very rapidly on their own and without problems.

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