

# Fraxel re:store<sup>®</sup> DUAL Laser Treatment Patient Consent Form



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

The nature of the Fraxel re:store DUAL 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 re:store DUAL 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.

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I understand that the following are among the **possible risks or complications** associated with the Fraxel re:store DUAL 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.

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*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.

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*Contraindications* — Fraxel re:store DUAL 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.

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*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 further agree that any pictures or videotape taken of me may be used for either teaching or publication, if considered appropriate; **unless I notify the doctor in writing that he or she is not to use these photographs prior to publication.** \_\_\_\_\_ Initials

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

_____	_____	_____
Patient Name (please print)	Patient Signature	Date
_____	_____	_____
Witness Name (please print)	Witness Signature	Date