

## FRAXEL RE:STORE TREATMENT INFORMED CONSENT

### **Procedure Description**

The elective procedure for which you are consenting is called Fraxel Laser Treatment™. The Fraxel® 1550nm laser utilizes a scanning device to apply highly concentrated tiny laser pulses to your skin and create thousands of microscopic wounds. This treatment is termed “fractional” because only a fraction of the skin is treated, leaving the remainder of untreated skin to speed the healing process. Because only a portion of the skin is treated in a single session, Fraxel Treatment is performed as a series of treatments.

This laser has been market-cleared by the FDA for the following indications: dermatologic procedures requiring coagulation of soft tissue; skin resurfacing; non cancerous pigmented lesions associated with sun damage and aging; actinic keratoses; melasma; periorbital wrinkles; acne scars and surgical scars.

The procedure will be performed as follows. After you use a gentle cleanser to remove your makeup, we will take pre treatment photographs. Then topical anesthesia (numbing cream) will be applied and stay on for approximately one hour. The topical anesthesia will be removed immediately prior to the procedure and you will lie down on a treatment table. Your eyes will be covered to protect them from the laser beam. As the laser handpiece glides over your skin, the laser will discharge hundreds of tiny pulses that will feel like rubber bands snapping against your skin. Cold air will blow onto your skin to help improve comfort. The actual treatment will take between 20 and 40 minutes, depending on the size and location of the treatment area.

**Side-Effects** are temporary and are a normal occurrence with Fraxel Laser Treatment. Factors that affect the intensity and duration of the side-effects include: a) treatment aggressiveness; b) treatment depth; c) medications that you are taking and skin care products that you are using; and d) your unique healing characteristics. You will be given specific instructions on how to minimize the side-effects and care for your skin while it heals.

Immediately after the treatment, you will feel a **sunburn sensation** that will improve over the next few hours.

**Redness and swelling** are the most common side-effects. Most of the redness and swelling will go away over the first one to two days after treatment. The remaining redness will gradually disappear over the next 1 to 2 weeks. All swelling is usually gone by the end of the first week.

**Peeling, flaking, dry skin, itching and milia** (tiny pimples) are also common and will resolve over one to two weeks.

A **bronzed skin appearance** may occur and occasionally **small brown dots** will be visible on the skin surface. Both occur because brown pigment is being eliminated from the skin and will disappear over 1-2 weeks.

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Please Print Full Name Legibly

Patient Signature

Today's Date:  
DD/MM/YYYY

Dr. Matta

**Pin-point bleeding** or **tiny red spots under the skin** can occur. Both will resolve without treatment and will not affect the final treatment outcome.

**Temporary breakouts** can occur.

**Benefits/ Risks/Uncertainties** - The benefits of FLT are short-term and long-term. The microscopic heat-induced wounds stimulate regeneration in the upper layer of the skin (epidermis) and longer-term collagen regeneration (remodeling) in the middle layer of the skin (dermis). Once the surface of the skin is healed, your skin will feel smoother and you should notice a lightening in the brown spots/areas. The effect of the laser treatment on smoothness and pigment will be more noticeable with further treatments. Healing in the dermis takes 3-6 months. Dermal remodeling is responsible for the reduction in wrinkles. All medical /cosmetic procedures involve risk and Fraxel Laser Treatment is no exception.

**Pigment Changes** – Although pigment changes can occur in anyone, patients with darker skin or on hormone treatment or with hormone imbalance have a higher risk. Hyperpigmentation (too much pigment) can result from this treatment, as it can from any laser treatment, infection, or trauma to the skin. You may have noticed this type of reaction before with minor cuts or abrasions. This risk increases greatly with sun exposure while the skin is healing. Therefore, you must protect the treated area from direct exposure to the sun and SPF 30+ broad spectrum sunscreen throughout the series and for at least 4 weeks after the last Fraxel Treatment. Despite these precautions, it is possible for the changes in skin coloring to still occur. Areas of increased color usually fade in three to six months, but in rare cases, can be permanent. During pregnancy, areas of increased pigmentation frequently appear spontaneously. For this reason, Fraxel Treatments are not recommended during pregnancy.

Occasionally, treated areas lose pigmentation (color) and become lighter than the surrounding skin. This type of reaction tends to gradually fade away and should return to normal over a period of two to four months.

**Scarring** – There is a small chance of skin scarring, including abnormal raised scars. Scarring generally occurs when the skin's surface has been disrupted and followed by abnormal healing/infection.

**Blistering and Scabbing** – This incidence of blistering, followed by scabbing is low. It can occur when steam formation causes the upper layers of the skin to separate. If a blister occurs, you must keep the area moist with antibiotic ointment and protect the wound with a bandage. The blisters should go away with in two to four days. Do not pick at scabs, if they form. The scabbing will disappear during the natural wound healing process. In rare instances, blistering and scabbing can lead to scarring. Contact our office if you are concerned.

**Infection** – Infection is a possibility after any laser procedure and the risk increases if a blister forms or bleeding occurs. Any blistering or bleeding must be dressed with an antibiotic ointment and covered. Infections, if they occur can lead to scarring. Notify our office immediately if you think you have a skin infection.

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**Questions**

Do not sign this consent form unless you have had a chance to ask questions and have received satisfactory answers to all of your questions.

**Initial HERE**



**Consent for treatment:**

\_\_\_\_\_ I, the undersigned, have read and I understand the information contained within this consent form.

\_\_\_\_\_ My signature on each page of this consent form indicates that I have read and understand the information in the consent. Further, my signature below indicates my consent to the treatment described and my agreement to comply with the requirements placed on me by this consent form.

\_\_\_\_\_ I understand that any treatment provided may or may not meet my expectations.

\_\_\_\_\_ I understand and agree that there is no compensation or refund of monies paid in any event.

\_\_\_\_\_ I consent to the taking of photographs and authorize their anonymous use for the purposes of medical audit, education and promotion.

\_\_\_\_\_  
Please Print Full Name Legibly

\_\_\_\_\_  
Patient Signature

\_\_\_\_\_  
Today's Date:  
DD/MM/YYYY

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Dr. Matta