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RELIANT

# PHYSICIANS GUIDE

## Understanding *Fraxel*<sup>™</sup> Laser Treatment

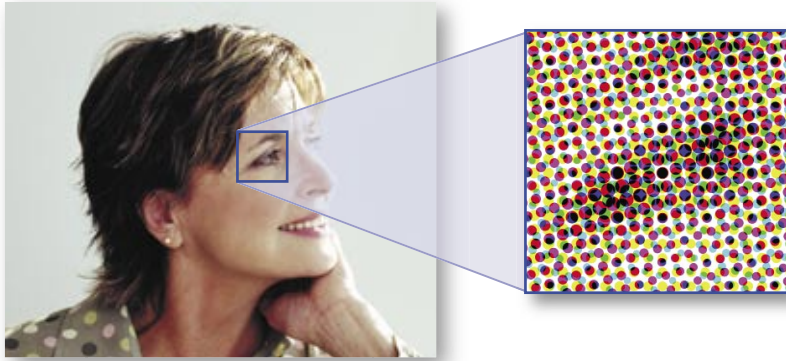


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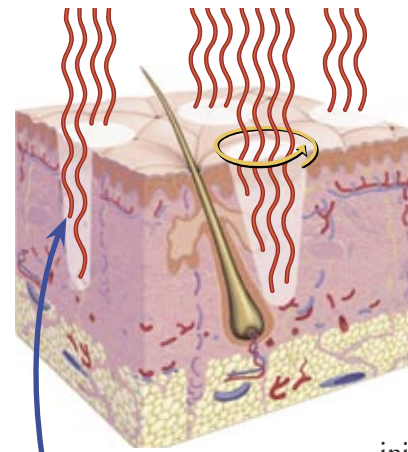
## Think of pixels in a photo when you think of Fraxel™ Laser Treatment (FLT).

If you look at a newsprint photo up close, you'll see that the image is actually comprised of thousands of tiny spots of ink. Similarly, Fraxel Laser Treatment (FLT) produces thousands of tiny treatment zones on skin, known as "microthermal treatment zones" (MTZs) in the emerging science of Fractional™ Photothermolysis.

### New advances in laser skin treatment

Fraxel Laser Treatment is a safe and gradual laser procedure that stimulates the body to replace aged and photo-damaged skin. To date there have been two categories of laser skin rejuvenation—ablative and non-ablative, and both have significant disadvantages. Ablative techniques resurface broad areas of the skin, but carry a high-risk profile, produce problematic side effects and entail prolonged postoperative healing and recovery times. Non-ablative techniques, on the other hand, carry fewer risks, but generally produce only limited clinical improvement.

Fractional Photothermolysis and Fraxel Laser Treatment—an innovative science and a differentiated category of aesthetic medicine—provide the positive results of ablative resurfacing with the much less invasive biological response of non-ablative treatment.

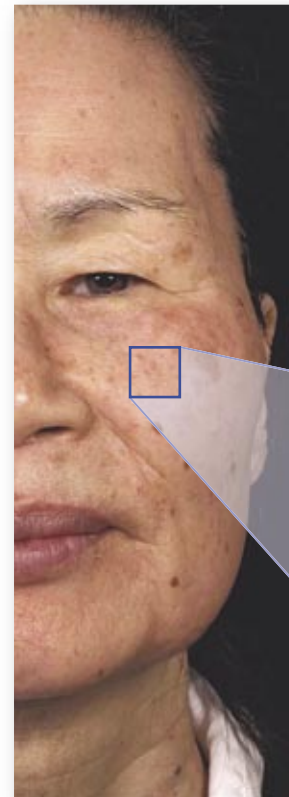


Laser

## How Fractional Photothermolysis Works

Whereas other lasers have a specific target that is differentiated from the rest of the skin, FLT is selectively absorbed by water, which is present in all skin tissue, and treats only a very small fraction of the skin at a time in a process called fractional photothermolysis. This creates a unique wound healing response by sparing healthy tissue. As the size of the injury gets smaller, the wound healing time gets shorter.

Each wound field is typically composed of thousands of individual microthermal zones and surrounding spared tissue units that comprise "nodes" of cutaneous repair. Each node can be expected to expand beyond its own volume to merge with neighboring nodes and affect a large area of skin.



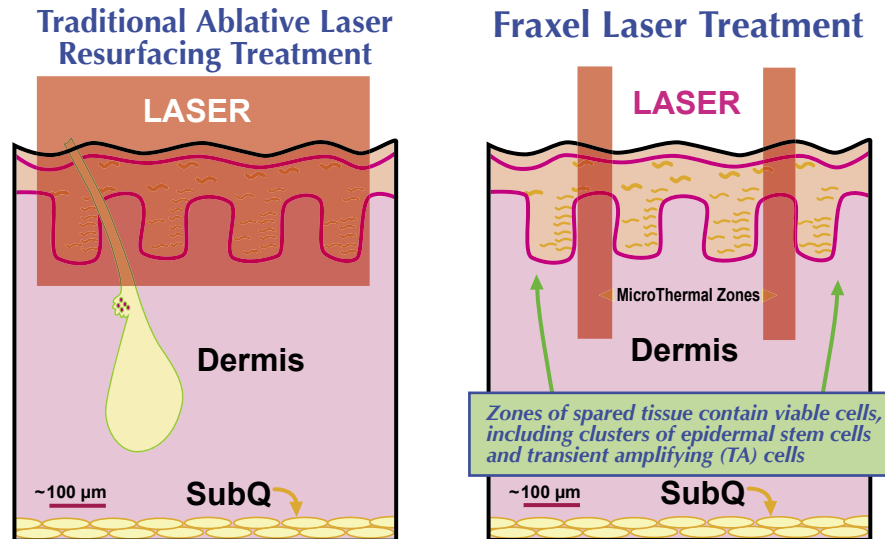
Patient 24 hours after first treatment

Microscopic view of MTZs

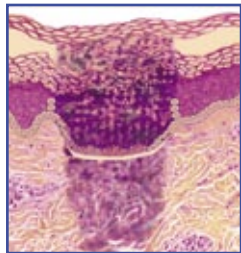


## Wound response

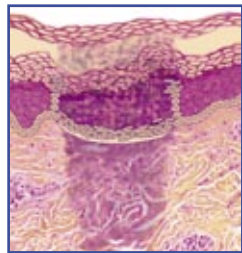
The wound healing response differs from previous techniques because the areas of epidermal tissue that are spared between treatment zones contain viable cells, including both epidermal stem cells and transient amplifying (TA) cell populations. The speed of re-epithelialization is directly proportional to the number and density of TA and stem cells. Thus, re-epithelialization of treatment zones proceeds rapidly, with little or none of the side effects (such as lengthy downtime, pain, fluid drainage and prolonged edema) observed after traditional resurfacing procedures.



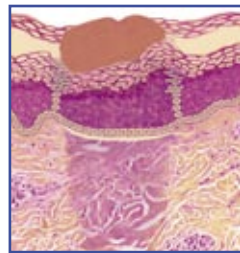
**MENDs** Each laser hit produces a 30-70 micron plug of Microscopic Epidermal Necrotic Debris (MEND).



*Within 1 hour, MTZ wounds heal by movement of keratinocytes at the deep and lateral margins of the epidermal defect.*

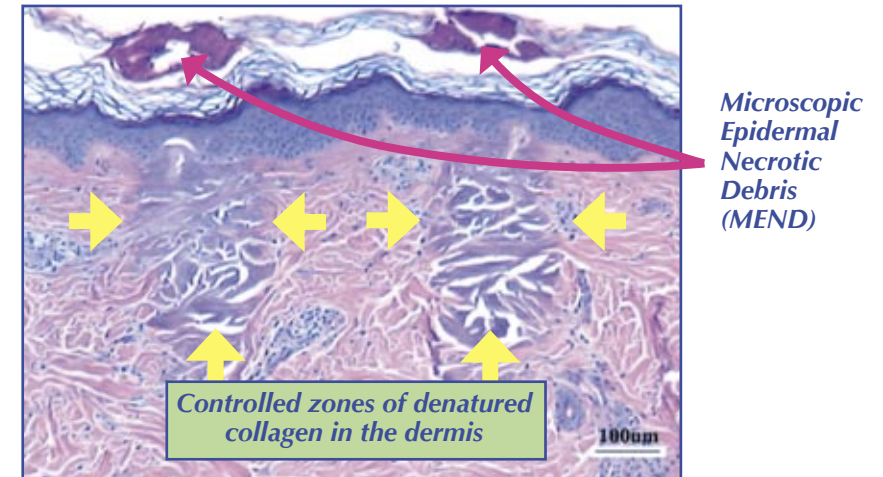


*By 12 hours, viable cells at the wound margins have encircled necrotic debris and epidermal pigment to begin MEND formation.*



*24 hours after treatment, MENDs are found within the stratum corneum while epidermal and dermal repair continues.*

Individual MENDs are not clinically noticeable, but for example, 2,000 MENDs per square centimeter of treated tissue give the skin a bronze appearance for about three to fourteen days depending on treatment energy and spacing of the microthermal zones. The MENDs naturally exfoliate as shown in the 16-day post in vivo histology below.



## Intact Barrier Function

The stratum corneum, which prevents water loss and acts as a protective barrier, remains intact after FLT, significantly reducing the risk of infection. One reason the stratum corneum is not damaged by the laser is because it contains relatively very little water. The laser light passes through the stratum corneum like a window, thermally denaturing the epidermis and penetrating well into the dermis.

## Typical Treatment Plan

Before treatment, you and your patient can discuss which areas are appropriate for treatment, what kind of response can be anticipated, what to expect after treatment, and at what intervals ongoing treatments should be scheduled. By sparing healthy tissue, FLT can also be used on delicate skin areas that require soft tissue coagulation such as the neck, chest, and hands.

Clinical studies suggest that an effective treatment regime is 3 to 5 sessions, spaced about 5 to 14 days apart. Each treatment session targets about 20% of the skin's surface, depending on the treatment level selected. Results are immediate and progressive; optimal cosmetic improvement is usually visible in 3-6 months.

## Procedure

Fraxel Laser Treatment can be performed in your office using only topical anesthesia. The following are the steps involved in treatment.

**1. Wash** The treatment area will be thoroughly cleansed prior to the procedure using a mild, gently abrasive skin cleanser.



**2. OptiGuide™ Blue** An FDA certified water-soluble tint is applied to the treatment area to highlight the contours of the skin. This allows the laser's Intelligent Optical Tracking System™ to detect contact with the skin and to adjust the treatment pattern with respect to hand piece velocity. The OptiGuide Blue is washed off after treatment.

**3. Topical Anesthesia** A lipid based topical anesthetic ointment is applied to the skin prior to treatment. This serves to numb the skin and avoid any prickling or heat sensation that may be felt during this procedure. After about 45 minutes, when the patient's sensitivity to the cold of an ice cube is reduced to a low level, the contact treatment may begin, directly through the anesthetic ointment.

### 4. How the Fraxel Pattern is Laid Down

A complete procedure consists of a series of horizontal and vertical passes with the laser. The physician simply slides the robotic hand piece over the skin. Each pass consists of overlapping strokes.

By treating through the anesthetic ointment, the physician can follow the progress of the laser's track to determine the area that has been treated. Additionally, mild erythema is also a clinical endpoint.

Typical treatment densities are about 2000 MTZs per cm<sup>2</sup>; somewhat lower densities are appropriate at higher treatment energies, depending on the physician's clinical judgment.

## The Fraxel™ SR Laser in Action

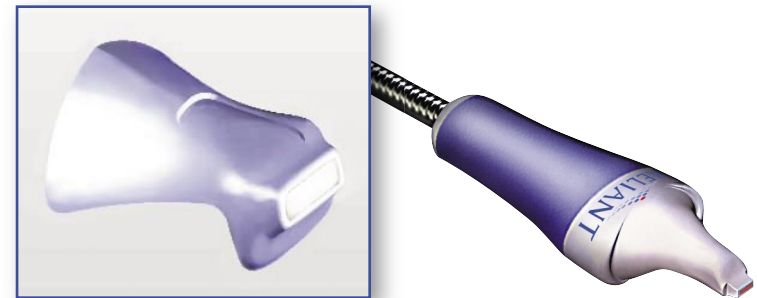
The mid-infrared wavelength of the Fraxel Laser allows deeper penetration into the tissue, without the bulk injury observed with ablative laser techniques. The Fraxel SR device is designed to ensure proper levels of treatment at all times.



### Unique tracking system in hand piece

The hand piece of the Fraxel SR features an Intelligent Optical Tracking System in the laser unit, which ensures that the laser creates a consistent treatment zone pattern. The device self-adjusts to velocity and ensures a constant pattern density of microthermal spots. Further, the laser will not fire unless the optical hand piece is in contact with skin and there is relative motion between the skin and the hand piece. Of course, proper safety procedure requires that the foot pedal should never be engaged unless the laser is in contact with the skin and treatment is intended.

The laser hand piece features two unique disposable tips to facilitate treatment. The large tip treats an area of 15 millimeters; the smaller tip treats an area of 7 mm, allowing you to reach small areas.



## SAFETY FEATURES

- Tracks speed of application and matches the number of MTZs laid down. Prevents over-treatment.
- Stops firing if removed from skin.
- Early trials indicate it is safe for most skin types.

## Before and After Images



**Patient 2: untreated side**



**Patient 1: Above—before treatment, below—1 month after 4th treatment**

**Patient 1: Detail of forehead before treatment and 1 month after 4th treatment**



**Patient 2: treated side one week after 4th session**



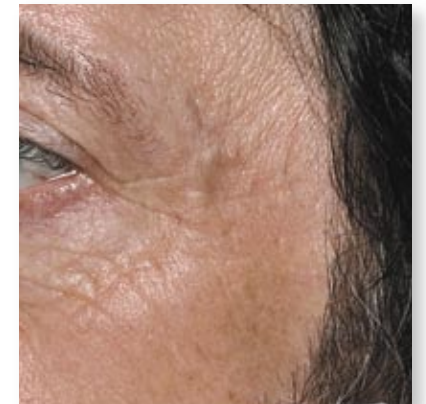
**Patient 2: treated side before**



**Patient 2: treated side one week after 4th session showing skin flaking**



**Patient 3: before treatment**



**Patient 3: after 4th treatment of lateral periorbital area only**

## What can your patient expect after treatment?

When used with topical anesthetic ointment, there is no need for systemic pain medicine either during or following treatment because there is minimal discomfort. There is a mild sunburn sensation for about an hour and then virtually no discomfort after that. The skin will have a pinkish tone for 5-7 days, which is a normal sign that the skin is healing, there's new collagen growth, and good blood circulation. Swelling is minimal and generally resolves in 2 to 3 days.



### Patient can apply make-up soon after treatment.

Because FLT spares the stratum corneum, the skin is strong enough immediately after the procedure to apply topical agents, cosmetics or for men to even shave. Typically patients find they can go back to work after treatment or the next day.

### New skin develops immediately.

Within 24 hours, re-epithelialization is complete, with preservation of barrier function.

**Bronzing:** The bronze appearance created by the MENDs lasts for anywhere between 3 and 14 days, depending on the treatment level and density of the microthermal zones.

**Flaking:** The MENDs naturally exfoliate as the reorganized epidermal skin replaces the dead tissue. Flaking is similar to that of minor sunburn, but without the associated pain.



3 days Post-treatment    7 days Post-treatment    11 days Post-treatment    14 days Post-treatment    21 days Post-treatment

## Questions and Answers

### Is the Fraxel Laser FDA cleared?

The Reliant Laser was recently cleared by the FDA for dermatological conditions requiring soft tissue coagulation with CO2 as the predicate device. It is pending 510k clearance for photocoagulation and regeneration of soft tissue for treatment of wrinkles.

### How many treatments are necessary?

Depending on the nature of the patient's skin condition, a series of 3-5 treatments, spaced four to seven days apart has been found to be effective. It is also an option to treat at longer intervals. Each treatment session addresses approximately 20% of the skin surface. Results are immediate and progressive; optimal cosmetic improvement is usually visible in 3-6 months.

### Is there any skin discoloration or pigment changes associated with treatment?

Based on clinical research to date, there is no evidence or indication of hyper- or hypo-pigmentation. Because this procedure spares islands of healthy tissue, lasting pigment change hasn't been observed.

### What kind of anesthesia is used?

A lipid base topical anesthesia is recommended. Many patients may not need it for small treatment areas.

### What kind of aftercare is recommended?

Applying hypoallergenic moisturizer can help with some of the bronzing and flaking symptoms. Make-up can be applied immediately to cover the blush of the skin's natural healing process. Avoiding sun exposure is always a smart policy.