

FRACTEL™ Laser Procedure Informed Consent Form

Patient Name (print)

Today's Date

This consent form may contain words that you do not understand. Please ask the doctor or the staff to explain any words or information that you do not clearly understand.

You will be treated with the FRACTEL™ laser, which is used for dermatological procedures requiring soft tissue coagulation. The treatment will be for the following indications:

- Peri-orbital (around the eyes) wrinkles, and
- Pigmented lesions, specifically _____
- Melasma
- Skin Resurfacing
- Acne Scars
- Surgical Scars

Explanation of Procedure

The procedure requires multiple treatments over a period of one to two months. Photographs will be taken at each visit. These photos may be used for publication or presentation in a scientific journal or lecture; however, your identity will remain confidential. You will be asked to remove any makeup you are wearing. You will be interviewed to obtain information regarding your medical history and a clinical examination will be conducted to assess your skin type and to determine if you are a good candidate for this treatment. Prior to treatment, the area to be treated will be anesthetized with a topical numbing cream. Following your treatment, you may experience swelling and redness, similar to a mild-sunburn, for the first several days. Light peeling of the skin may also occur.

Risk and Discomfort

Risk and discomfort involved with this laser treatment include, but are not limited to:

- **Pain** - Some people may feel some pain with this treatment, similar to snapping the skin with a rubber band.
- **Reddening** – Laser treatment will cause a reddening of the area. The reddening will go away in one to two weeks.
- **Swelling** – Laser treatment may cause swelling, which will usually go away in one week or less.
- **Pigment Changes** – Although extremely rare, the treated area may heal with increased pigmentation (increased skin coloring). This occurs most often with darker colored skin and after exposure of the area to sun. You may have experienced this type of reaction before and noticed it with minor cuts or abrasions. The treated area must be protected from exposure to the sun (sunscreen for 4 weeks after treatment) to minimize the changes of too much pigmentation (increased skin coloring). However, in some subjects, increased skin coloring may occur even if the area has been protected from the sun. These spots usually fade in three to six months. In some cases, the pigment change is permanent. During pregnancy, areas of increased pigmentation frequently appear spontaneously. For this reason, laser therapy is not recommended during pregnancy.

In some subjects who experience pigment alteration, the treated area loses pigmentation and becomes a lighter color than the surrounding skin. This type of reaction tends to gradually fade away and 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 is a possibility because of the disruption of the skin’s surface. Compliance with aftercare is crucial for the prevention of scarring.
- **Bleeding** – The laser treatment may cause some pinpoint bleeding which will probably stop within a few minutes without any lasting effect. The bleeding may not reach the upper level of the skin and may result in a dark reddening of the skin. The red color will darken to purple and purple-yellow and will disappear in one to two weeks.
- **Blistering** – The laser procedure may produce heating in the upper layers of the skin resulting in steam formation. The steam may produce a separation between upper and middle layers of the skin resulting in blister formation. The blisters will go away within two to four days.
- **Scabbing** – A scab may be present after a blister forms. The scabbing will disappear during the natural wound healing process of the skin.
- **Infection** – If a blister or bleeding is present, an infection of the wound is possible. Any blistering or bleeding must be dressed with an antibiotic ointment and covered. An infection could last seven to ten days and could lead to scarring.

It is important to follow all post-treatment instructions carefully.

Consent

I, the undersigned, have read and understand the information contained within this consent form. My signature on the last page of this consent form indicates that I have read and understand the information in the consent. I hereby release the laser center, technician, and physician from all liability associated with this procedure. 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.

Patient Name (print)

Patient Signature

Date

Name of Person Conducting Informed Consent (print)

Signature of Person Conducting Informed Consent Discussion

Date