

# FRAXEL TREATMENT CONSENT

Patient Name \_\_\_\_\_

Date \_\_\_\_\_

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

The nature of the FRAXEL:RESTORE DUAL procedure has been explained to me. Fraxel Dual is a non-ablative fractionated laser. I understand that just as there may be benefits from the procedure (reduction in pigment, sun damage, brown spots, lines, wrinkles acne and other scarring), all procedures involve risk to some degree.

I understand that the following are among the **expected potential 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, temporary or permanent**, 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. Although unlikely, scarring can be permanent if it occurs.

*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

\_\_\_\_\_ Initial that you have read and understand this page.

# FRAXEL TREATMENT CONSENT

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

the sun (sunblock 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 but can be permanent.

*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.

*Delayed healing* --- It may take longer than anticipated for healing to occur after laser treatments. Skin healing may result in thin, easily injured skin. This is different from the normal redness in skin after treatment.

*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.

*Anesthesia* -- Both local and oral anesthesia involve risk. There is the possibility of complications, injury, and even death from all forms of anesthesia and sedation.

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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.

*Patient failure to follow through* --- Patient follow through following a laser skin treatment procedure is important. Post operative instructions concerning appropriate restriction of activity, use of dressings and skin care, and use of sun protection need to be followed in order to avoid potential complications, increased pain, and unsatisfactory 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 12 months, have a predisposition to keloid formation or excessive scarring or have suspicious lesions. No use of tetracycline, minocycline, doxycycline, or erythromycin in last month. Any history of vitiligo, scleroderma, collagen disorders, radiation treatment, skin cancer, psoriasis, keloid formation, pregnancy, breastfeeding.

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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. I understand that results may vary from no result to a great result. 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.*

\_\_\_\_\_ Initial that you have read and understand this page.

# FRAXEL TREATMENT CONSENT

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 IF YOU HAVE ANY OF THE CONTRAINDICATIONS LISTED (BY SIGNING YOU ATTEST TO THE FACT THAT YOU DO NOT HAVE ANY OF THE CONTRAINDICATIONS).

I give permission for any pictures or videotape taken of me may be used for either teaching or publication, if considered appropriate \_\_\_\_\_(YES); \_\_\_\_\_(NO).

I give permission for my pictures to appear in Skin's photo album for other potential patients to view \_\_\_\_\_(YES); \_\_\_\_\_(NO).

*I have read this form and understand it, and I request the performance of the procedure. I acknowledge that no guarantee has been given by anyone as to the results that may be obtained. For the purposes of advancing medical education, I consent to the admittance of assistants and/or observers in the procedure room unless otherwise notified.*

*I understand all risks, temporary or permanent. I am aware of all signs of side effects and complications as listed above (abnormal redness, swelling, blisters, burns, ulcers, and signs of infection) and will call the office and Dr. immediately with any question, concern or signs of problems.*

My signature indicates the following: 1) I have read and understand the information outlined above; 2) I have discussed questions with the physician and/or staff; 3) It has been explained to me in a way that I understand the above treatment, alternatives, and I am aware of the risks, benefits, and alternatives and I am satisfied with the explanation; 4) I have received the pre-treatment and post-treatment information sheets; 5) I am not pregnant and there is no possibility that I could be pregnant and I am not breastfeeding; 6) I understand the risks of the topical, local and oral anesthesia and I consent to taking them; 7) I authorize the physician to perform the mentioned procedures and treatments and any other treatments necessary should unforeseen conditions/complications occur; 8) I acknowledge that no guarantee has been given by anyone as to the results that may be obtained; 9) For the purposes of advancing medical education, I consent to the admittance of assistants and/or observers in the procedure room unless otherwise notified. 10) I know and understand all of the warning signs of problems, side effects, and complication (i.e. burns, ulcers, blisters, signs of infection, redness and swelling, and pain above what is described as expected and any other warning sign) and know to immediately contact Dr. at the office or by cell if I see any of these signs or if I have any questions.

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

Date \_\_\_\_\_

*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, and that the patient should call the office and Dr. immediately with any questions, concerns, or signs of problems (as mentioned above).*

\_\_\_\_\_  
Physician Signature

Date \_\_\_\_\_

\_\_\_\_\_ Initial that you have read and understand this page.

# Fraxel Re:store Dual Post-Care Instructions

## What to Expect After Treatment

Fraxel® Laser Treatment produces after effects. The intensity and duration of your after effects depends on the treatment aggressiveness and your individual healing characteristics. Generally, patients who are treated more aggressively experience more intense and longer lasting after effects; however, some patients who receive a less aggressive treatment may experience after effects of greater-than-expected magnitude, while others receiving more aggressive treatments may experience after effects of less-than-expected magnitude. Notify Skin and Dr. if the severity of your after effects becomes a problem for you (signs of abnormal redness, swelling, blisters, burns, ulcers, signs of infection, or other) or you have any concerns or questions.

## What you may feel and look like:

- Immediately after the treatment, you will experience redness, swelling and sometimes pinpoint bleeding. 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 (crushed ice or frozen peas in a ziplock bag or ice soaked cloths) to the treatment area for 10-20 minutes of every hour (or more) on the day of treatment, until you go to bed. The ice/pea ziplock bags may be put in a pillow case and then on the skin if it is too cold directly on the skin. If given arnica, take it under the tongue “4X4X4” four tablets under the tongue, four times/day for four days.
- Sleep elevated the first night if possible. Use as many pillows as you can tolerate.
- Heat sensation can be intense for the following 2 – 3 hours after the procedure. Occasionally oozing can occur in isolated areas for a few days as well.
- Over the next few days, redness usually worsens. Swelling may be significant and cause some discomfort (continued icing and prescribed skincare will help reduce this).
- You may also notice that your skin appears bronzed or little dark dots will appear on the treated area. 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.
- This dead skin and pigment is a normal result of laser treatment, and should start sloughing off 3 – 4 days after the treatment. Most patients complete this process 5 – 7 days after a treatment on the face. (For off-face areas, such as neck, chest, hands/arms, where healing is slower, the process may take up to 2 weeks.)
- Once the sloughing is complete, you may notice some pinkness over the next few weeks. 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 to minimize the redness once cleared by Dr. , his medical assistant, or nurse.
- Some patients have also experienced itching. White Vinegar soaks (1-2 oz in glass of cold water) will help with the itching and skin sloughing process. Benedryl can be taken if needed (but remember that it might cause drowsiness). Vinegar Soaks will also help with the sloughing process so you can use these even if you don’t itch.
- Flare-up of acne or formations of milia (tiny white bumps on the skin) may occur 2-3 weeks Post-treatment. These symptoms are not unusual and can be easily resolved. Contact our office if this occurs and we will provide you with an anti-biotic prescription if necessary.

## How to Care for Your Skin After Treatment:

Congratulations! You have taken the first step toward more healthy and radiant looking skin by having a Fraxel Re:store® DUAL laser treatment. Now it is important to help your skin heal

quickly and protect your skin investment. Your after treatment skin care regimen is tailored to the treatment you received today. You will need to use the Avene SOS Complete Recovery Kit. Follow the instructions as checked below:

- **Immediately After Treatment.** You will leave the office with the Avene SOS Complete Post-Procedure Recovery Kit, the SkinMedica TNS Recovery Complex, approved sunblock and the Therapearl Facemask (if given). Start with using the Thermal Spring Water Gel and cool with the Water Spray multiple times per day. You should also ICE your skin as much as possible. Also in the kit is the Cicalfate for anti-redness and moisturizing. Use this in addition to the gel, multiple times per day. The night of the procedure, use the Avene Cleansing Lotion to wash the skin and Avene Tolerance Extreme Cream (may be replaced by Avene Skin Recovery Cream) for cooling and moisturizing, also multiple times per day. Starting on the day after the procedure, add the SkinMedica TNS Recovery Complex (on cleansed skin, cleanse with the Avene Cleansing Lotion) twice per day. Follow with Cicalfate and Tolerance Extreme Cream.
- **First Few Days.** Continue cleansing and moisturizing over the next few days (Avene Cicalfate and the Tolerance Extreme Cream). Continue the SkinMedica TNS Recovery Complex. Icing will still help. Once the sloughing starts, please allow your skin to heal and DO NOT scrub, rub, or use exfoliants. Vinegar soaks (1-2 ounces in cold bowl of water, soaked washcloths) can also be used to sooth the skin and clean the skin. It also helps with the skin sloughing. Keep clothing away from treated body parts as much as possible to avoid irritation. Sunblock (from Skin approved SkinMedica or EltaMD) should be applied starting the next day.
- **First Week of Healing.** Keep treated area clean; avoid smoking, excessive alcohol consumption, excessive exercise, perspiring, swimming, or exposing skin to heat and sun.
- **Skin Care Products.** The skin care regimen will be designed with SkinMedica products by Dr. , his medical assistant or nurse.
- **Scrubs, Toners, Glycolic Acid, and Retin A.** Your skin will be sensitive for the first week or so after treatment. 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.
- **Normal Skin Care Regimen.** Once the sloughing is complete, you may resume your routine SkinMedica skin care and make-up products as designed by Dr. , his medical assistant or nurse.
- **Sunblock.** It is very important that you use the SkinMedica or Elta sunblock multiple times during the day to prevent sun damage to the skin. You should avoid direct sun exposure for 2-3 weeks (and as instructed by Dr. or nurse) after the treatment. Apply sunscreen 20 minutes before going outside. Reapply sunscreen every hour. If short, direct sun exposure is necessary, wear a hat and clothing that covers the treated area. Your practice of diligent sunblock use may lower the risk of laser-induced hyperpigmentation (darker color).
- **Moisturizer.** Remember that peeling and/or flaking is normal during the healing process. Therefore, you should continue your Avene moisturization regimen, or else you could develop breakouts.

- **Bleaching Creams.** Discontinue use of your bleaching cream while your skin is tender. Restart your bleaching cream and other SkinMedica products when instructed to do so by Dr. , his medical assistant or nurse.
- **Resume your normal skin care regimen:** When your skin has fully healed and instructed to do so by Dr. and your skin health professional.
- **Cold Sores.** If you have a history of cold sores, you will need to take Valtrex as prescribed by Dr..
- **Abnormal Healing.** If you notice any blisters, cuts, bruises, crusting/scabs, areas of raw skin, ulcerations, active bleeding, increased discomfort or pain, pigment changes (lighter or darker than usual complexion), or any other problems, please contact Skin and Dr. at the office or on his cell immediately.
- **Questions/Concerns.** Post-treatment healing varies from patient to patient. If you have any questions or concerns, please contact at or Dr. on his cell phone at.
- **Extras:** You may shower later that day or the next day and wash hair, but avoid excessively hot water. It would be best to take a bath so you do not let too much water pressure touch your face for the first day or two. Advil (ibuprofen) 600mg three times per day or Aleve 500 mg two times per day may be taken as an anti-inflammatory to help decrease discomfort and swelling.
- **Waxing:** You should not do any waxing of the treated area until 4 weeks after treatment.

Other Instructions: \_\_\_\_\_

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I understand the above instructions. I understand the risks and signs of side effects and complications such as severe redness, swelling, blistering, burns, ulcers, pain, or signs of infection and I will call the office and Dr. immediately if I have any questions or concerns.

**Initial** \_\_\_\_\_

## Fraxel Re:store Dual Pre-Care Instructions

### Contraindications:

- No Accutane use in the past one year.
- Any history of vitiligo, scleroderma, collagen disorders, radiation treatment, skin cancer, psoriasis, keloid, pregnancy, breastfeeding.

### Pre-Care Instructions:

- Notify us if you have a history of developing cold sores (herpes infections), facial sores, or any other type of infection. Also notify us if you have permanent makeup.
- Minimize sun exposure and use daily sunblock containing zinc oxide. Discuss with Dr. Seiler how long you must be completely out of the sun and off of self tanner before treatment.
- Fill your prescription and begin taking the antiviral (Valtrex or other) the day before the procedure. If you have a long ride home, bring a cooler of ice for afterwards.
- Purchase small bottle of vinegar for vinegar soaks. Also purchase small cotton washcloths and wash them in unscented, powder detergent using an extra rinse cycle. Do not use fabric softener or dryer sheets on anything that will come in contact with your face or hands. This includes bed sheets, pillowcases, washcloths, and towels.
- Maintain a healthy diet. Come in for procedure without makeup and in comfortable clothes.
- Stop Retin A two weeks before and bleaching creams 3 days before.
- Avoid waxing for 1 week before and 4 weeks after treatment.
- Begin taking arnica “4X4X4” four tablets under tongue four times per day for four days prior to procedure (and four days after).

### Morning of the procedure:

Eat a solid meal. Cleanse face and do not wear makeup or perfume to treatment. Dress in comfortable clothes with a loose fitting, low cut shirt. If you have long hair, wear it in a ponytail away from face and neck.

### Medication Protocol:

**Valtrex** – 1 daily starting day before procedure. **Keflex/Clinda** (if given) twice/day starting day before. **Diflucan** (if given) take one the day before procedure. If given Valium, pain tablet, phenergan, take one of each on way to procedure and bring rest. (Must have a driver if taking valium, pain tablet, phenergan).

Call us if you have any questions or concerns.

# Fraxel Preop

Patient: \_\_\_\_\_

Date: \_\_\_\_\_

Allergies/sensitivities/type of reaction: \_\_\_\_\_

Chronic medical conditions: no yes, list: \_\_\_\_\_

Known blood borne infection? no yes, describe: \_\_\_\_\_

Current anticoagulants or medications, herbals that can affect coagulation? no yes, list: \_\_\_\_\_

Using products with glycolic acid or retinols? no yes, describe: \_\_\_\_\_

Previous history of cold sores? no yes

Previous face lift? no yes, when: \_\_\_\_\_

Previous resurfacing? no CO<sub>2</sub> Er:YAG Other \_\_\_\_\_

When? \_\_\_\_\_

Previous history of fillers? no yes explain: \_\_\_\_\_

Previous history of melasma/PIH? no yes, explain: \_\_\_\_\_

Does patient exhibit evidence of melasma, PIH, sun exposure, self tanner? no yes, explain: \_\_\_\_\_

Are there telangiectasias, vascular malformations present? no yes, explain: \_\_\_\_\_

Previous history of keloid formation? no yes

Isotretinoin (or Accutane<sup>®</sup>) use within last 6 months? no yes

Are any lesions suspicious for cancer? no yes (This is an absolute treatment contraindication)

Circle as appropriate: Fitzpatrick Skin Type I II III IV V VI

Glogau Photoaging I II III IV

Fitzpatrick Wrinkle Score MILD 1 2 3 MODERATE 4 5 6 SEVERE 7 8 9

Treatment Indication: \_\_\_\_\_

**Pre treatment regimens/instructions:** check and describe, if instituted.

HSV \_\_\_\_\_

Bleaching agent \_\_\_\_\_

Stop Hydroquinone \_\_\_\_\_ prior to procedure

Stop products containing glycolic acid, retinols, and retinoids \_\_\_\_\_ prior to procedure.

Procedure explained

Written instructions given to patient.

Rx given: Valtrex Diflucan Clinda Valium Demerol Phenegran Arnica

Other: \_\_\_\_\_

\_\_\_ Patient has been shown before and after pictures \_\_\_ Patient has a make-up consult scheduled

\_\_\_ Patient has a ride home someone to stay for the day of the procedure to assist with aftercare

\_\_\_ Patient understands all RBAC, and understands what side effects or complications to call about

Provider signature \_\_\_\_\_ Date \_\_\_\_\_

# FRAXEL TREATMENT RECORD

Patient Name \_\_\_\_\_ Date \_\_\_\_\_

Fitzpatrick skin Type:

- I Always burns, never tans
- II Always burns, sometimes tans
- III Sometimes burns, always tans
- IV Rarely burns, always tans
- V Brown, moderately pigmented skin (Hispanic)
- VI Black skin

Safety:  Door secured with Laser Warning  Consent Signed  Eye protection

Image Performed  Pre-Procedure Pictures Taken  Ride home and can stay with patient

CC: \_\_\_\_\_

Reviewed side effects, possible benefits and patient expectation of treatment  Yes

Skin prepped; Anesthetics used:  No  Yes, \_\_\_\_\_ applied @ \_\_\_\_\_

Anesthetic wiped off completely:  Yes Treatment started @ \_\_\_\_\_

Other anesthesia:

Area	Wavelength	Energy (mJ)	TL Coverage	No. of Passes	Deviation / Notes	kJ	Pain Level (0-10)	Tx Time (min)

Cryo @ \_\_\_\_\_ Applied to area during TX:  No  Yes Tx Duration: \_\_\_\_\_ min

Immediate Responses

- Erythema \_\_\_\_\_
- Edema \_\_\_\_\_
- Petechiae \_\_\_\_\_
- Laser Cuts \_\_\_\_\_
- Other (describe) \_\_\_\_\_

Immediate Post care: Ice, Avene Complete Kit \_\_\_\_\_

Standard home care instruction given/reviewed:  No  Yes Patient Satisfied: Yes No

Special Instructions: \_\_\_\_\_

Patient informed of all possible side effects and complications (redness, swelling, blister, burn, sign of infection, other) and patient knows to contact office and Dr. immediately with questions concerns and given instruction sheet YES

Physician Signature \_\_\_\_\_ Date \_\_\_\_\_