

# INFORMED CONSENT FORM - FRACTORA™

## **Personal Information:**

Name:	Date of Birth:
Address:	
Cell Phone:	Email:

## **Health questionnaire:**

Existing or recent illness	Details:
Hospitalization / surgery	Details:
Medication	Details:
Medicine intolerance	Details:
Aesthetic procedures in the treatment area	Details:

**Medical History** – Please inform physician or assistant prior to treatment if you have any of the following conditions that may make you unsuitable for FRACTORA treatments.

- Pregnancy or nursing
- Under 18 years of age
- Pacemaker or internal defibrillator
- Permanent implant in the treated area such as metal plates and screws, silicone implants or an injected chemical substance
- Current or history of cancer, especially skin cancer, or pre-malignant moles
- Impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications
- Severe concurrent conditions such as cardiac disorders, epilepsy, uncontrolled hypertension, and liver or kidney diseases
- A history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area
- Any active condition in the treatment area, such as sores, psoriasis, eczema and rash as well as excessively/freshly tanned skin
- History of skin disorders such as keloid scarring, abnormal wound healing, as well as very dry and fragile skin
- Any medical condition that might impair skin healing
- Poorly controlled endocrine disorders, such as diabetes or thyroid dysfunction
- Any surgical, invasive, ablative procedure in the treatment area in the last 3 months or before complete healing
- Superficial injection of biological fillers in the last 6 months, or Botox in the last 2 weeks
- Use of Isotretinoin (Accutane®) within 6 months prior to treatment.
- 

## **Specific Informed Consent for FRACTORA™ Treatments**

This form is designed to give you the information you require to make an informed choice of whether or not to undergo treatment with FRACTORA™ technology. If you have any questions before your treatment please feel free to ask.

- I hereby authorize Irina Kouzmina the FRACTORA procedure.
- Technician obtained my medical history and found me eligible for treatment.
  - I have received the following information about the technology:
    - FRACTORA™ technology utilizes fractional radiofrequency (RF) indicated for facial/neck/ chest and back of hands, as well as small body areas.
    - The FRACTORA™ treatment induces ablation, thus improving the appearance of rough texture, fine lines, wrinkles, and depressed scars, such as acne scars along with superficial pigments that will be ablated. The treatment also induces skin rejuvenation by heating of the dermis which stimulates collagen generation and replenishment, as well as closure of superficial fine blood capillaries.
    - The treatment requires anesthesia that involves topical cream, injections, or sedation according to the treatment parameters and the physician discretion.
  - I understand that taking the treatment course is my choice and that I am free to withdraw at any time, without giving any reason.
  - There may be alternative procedures or methods of treatment, such as fractional lasers for ablation (CO<sub>2</sub>) and lasers, IPL or RF based systems for skin rejuvenation. As of today, there are no systems in the market that can address the variety of lesions that FRACTORA does. Details were explained to me.
  - I was told about the possible side effects of the treatment including: local pain, skin redness (erythema), swelling (edema), damage to the natural skin texture (crust, blister, burn), change of skin pigmentation (hyper- or hypo-pigmentation), and scarring. Although these effects are rare and expected to be temporary, redness and swelling may last up to 3 weeks, and are part of a normal reaction to the treatment. Burns and resulting pigmentation change and scarring are rare and may happen in dark skin that is not taken care according to instructions. Tiny scabs appear on the face for a few days as part of a normal healing, however make-up may be applied as soon as 1-3 days after the session to mask them and residual redness. Any adverse reaction should be reported immediately.
  - I understand that the treatment involves a few sessions (1-5), a few weeks apart (3-6 weeks), according to treatment parameters and individual response.
  - I understand that I have to comply with treatment schedule, otherwise results may be compromised.
  - I recognize that during the course of the procedure unforeseen conditions may necessitate different procedures than this above and I authorize the physician or assistants to perform such other procedures if they find them professionally desired.
  - I understand that not everyone is a candidate for this treatment and results may vary. Therefore, there is no guarantee as to the results that may be obtained.
- The procedures to be used to treat my conditions have been explained to me.

Initials: \_\_\_\_\_

1. I have had sufficient opportunity to discuss my condition and treatment. I believe I have adequate knowledge upon which to base an informed consent.
2. Any questions I may have asked have been answered to my satisfaction.
3. I authorize before, during and after the procedure(s) the taking of photographs to be part of my patient profile that may be used for scientific or marketing purposes without disclosing my identity (eyes will be masked in the photographs).

Signature

Date

## FRACTORA POST TREATMENT

Apply post treatment healing ointment or cream such as or other recommended product to treated area 3-4 times per day and in the evening. It is important that you keep the treated areas moist so healing occurs appropriately.

It is normal for your skin to be moderately red, swollen and slightly tender. Redness and swelling may last several days up to 1 weeks depending on your skin response and treatment.

Gently mist your face with cool water with splash of vinegar or soak lightly with a clean white washcloth to treated areas as needed. Do not rub or wipe the cloth over affected areas. Reapply healing ointment to keep the area moist.

On day 2 or 3, 24-72 hours later, you may begin cleansing the area gently with Cetaphil Liquid Cleanser. Please do not use scrubs or exfoliants. Reapply or a gentle moisturizer such as Cetaphil cream to cleansed areas. You may begin using sunblock and makeup if the skin is not bleeding and is not too sensitive.

Do not pick, peel, or scratch the areas treated. Any crusting or scabbing will slough/slide off on its own when the new skin is ready for exposure. Treatment areas such as neck and chest will take longer to heal. Avoid hot showers or steam until all the skin is healed.

You may have some itching in areas as they heal. Do not scratch! You can use hydrocortisone ointment (not cream) to areas that are itching, but only do this if it has at least 24 hours after your procedure.

Use a high factor sunscreen of SPF 30 or greater at all times when exposed to sunlight after day 2-3. This includes driving.

You may return to normal skin care routine after 5-7 days if skin looks normal. Do not apply make up if there are open areas.

Smoking (including second hand smoke) can cause poor or delayed tissue healing and increased risk of infection and other complications.

Avoid AHAs, glycolic acids, Vitamin C, retinoids for 3 to 4 weeks after the skin is healed.