Informed Consent for Microneedle Radiofrequency

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

Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Age: \_\_\_ Gender: \_\_\_\_\_\_\_\_\_\_\_\_\_\_

Address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Machine Used-

Treatment Area

I \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_,(the patient) or representative of patient \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, have (initial next to appropriate response option below).

* Read
* Been explained this consent form in \_\_\_\_\_\_\_\_\_\_\_\_\_(name of language) which I fully understand, and understand the information provided about \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_(full name of procedure) given below in this consent form.

Brief description of procedure:

Microneedle radiofrequency involves insertion of fine electrodes mechanically into the skin followed by the discharge of small amount of radio frequency energy at the desired depth. This leads to stimulation of new collagen production and restructuring of old collagen bundles in the skin.

Multiple sessions may be required based on the severity of the skin condition. Skin may continue to improve till 3 months-6 months after a treatment. Even after multiple sessions, the complete eradication of the skin problem may not happen, and maintenance sessions may be required for maintaining the improvement.

Strict sun protection is added for a few days after the procedure to avoid any adverse effects of the treatment.

Intended benefits:

Reduction of acne scars, other scars, photo ageing, stretch marks, skin laxity, improvement of skin texture, wrinkles, and fine lines.

I understand that all procedures carry certain risks. The potential risks and complications from the procedure are:

1. Pain-the stinging or burning sensation from the procedure can produce a moderate amount of discomfort. An anesthetic crème will typically be used to minimize discomfort.
2. Redness-redness resembling a sunburn can occur in the treated area. The redness will typically subside in 1 to 7 days but could last longer.
3. Swelling-treatment may cause swelling which subsides in 1 to 7 days and can be minimized with the application of cool water compresses.
4. Skin darkening-darkening of the skin rarely occurs in the treated areas and will usually fade within 1 to 6 months. This reaction is more common when treated areas are exposed to the sun. It is extremely important to protect the treated area from sun exposure with a hat and sunscreen for 6 weeks after treatment and carefully adhere to all post-treatment instructions.
5. Blisters or scabs-blistering is uncommon but can develop with treatment. Blisters will go away within 2 to 5 days and may be followed by a scab. The scab will disappear during the natural wound healing process of the skin. During this time, the area should not be manipulated or picked, which can lead to scarring.
6. Infection-swelling, crusting, pain, or fever could indicate an infection or reactivation of cold sores or fever blisters. This may require the use of oral antibiotics and/or antiviral agents prescribed by your physician.
7. Acneiform eruptions-breakouts from acne have been reported to occur after treatment with laser resurfacing procedure. Careful adherence to all advised post-procedure instructions will help reduce the possibility of this occurrence.
8. Lesion persistence or failure to respond-some skin conditions may not improve or go away completely despite the best efforts made by the aesthetician. No guarantee can be made regarding any individual’s response to treatment.
9. Additional side effects-there are risks associated with any procedure. Since it is impossible to state every risk or complication that may occur as a result of treatment, the possible risks and complications listed here may be incomplete. There may be risks or complications associated with this treatment that are not yet reported in the literature.

The treatment in contraindicated in patients currently taking anti-coagulants, active skin infection, compromised immune system, impaired healing (e.g. keloid scar formers), pregnancy, and pacemaker

I have been explained the implications of not undergoing this procedure and the alternative methods of treatment like medical treatment, fractional lasers, chemical peels, dermabrasion, micro needling, and botulinum toxin and fillers.

COST AND PAYMENT POLICY:

I have been explained about the cost of each session which is \_\_\_\_\_\_\_\_\_\_\_\_.

I am going to pay per session/package basis. Package if opted for includes minimum number of sessions and I must pay accordingly if any additional sessions or treatments are required.

I am now aware of the intended benefits, possible risks and complications, and available alternatives to the said procedure. I am also aware that results of any procedure can vary from patient to patient and I declare that no guarantees have been made to me regarding success of this procedure. I am aware that while most patients have an uneventful procedure and recovery, few cases may be associated with complications. I am aware of the common risks and complications associated with this procedure and understand that it is not possible to list all possible risks and complications of any procedure.

I also understand that sometimes a planned procedure may need to be postponed or cancelled if patients clinical condition demands or due to any unforeseen technical reason. I am also aware that I can withdraw my consent at any point of time at my own risk and consequences, by submitting withdrawal in writing.

I understand that if medical exigencies demand, further or alternative procedural measures may need to be carried out and, in such case, there may be differences in the planned and actual procedure.

I am now also aware that during this procedure, the aesthetician may seek consultation/assistance from relevant specialists if the need arises.

I agree to observing, photography(still/video/televising) of the procedure (including my diagnosis/reports pathology, radiology, etc.) for academic/medical/medico-legal purposes provided my identity is not revealed by such acts. I also agree to my clinical details being shared for scientific or advertisement purposes if my identity is not disclosed.

I am also aware of the expected course after the procedure and the post procedural care to be taken.

I declare that I have received and fully understand the information provided in this consent form, that I have been given an opportunity to ask questions relating to my alignment, the procedure being performed, its risks, consequences, alternatives, potential complications and intended benefits and recovery and that all my questions have been answered to my entire satisfaction and there are no misconceptions or false hopes in my mind. I further declare that all fields (of this form) requiring insertion or completion were filled out in my presence at the time of my signing this form.

For the above mentioned procedure that I have been made aware of, I give consent voluntarily to Jaalah McCullough for carrying out the said procedure on ( )myself or ( ) my above named patient being fully aware of the nature, potential risks and complications, intended benefits and possible alternative.

I, above named patient, named patient representative (circle appropriate) do further hereby declare that I am above 18 years of age as of the date of signing this form, mentally sound and giving consent without any fear, threat, or false misconception.

Patient/Client\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Patient/Client Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date/Time of Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Surrogate/Guardian Name (if applicable) \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Surrogate/Guardian Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Relationship to Patient/Client \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Reason for Surrogate or Guardian Consent\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Date/Time of Signature\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

I, Jaalah McCullough, Aesthetician, have explained the nature, potential risks and complications, intended benefits, expected post-procedure cause and possible alternatives to the planned procedure to the patient/patient representative. I am confident he/she has understood the information fully as described in this document.

Consent obtained by \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

 Jaalah McCullough

Date/Time\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_