Informed Consent For Meesha Aesthetics

INTRODUCTION

The Profound system is a minimally invasive device delivering bipolar, non-ablative radiofrequency (RF) energy to the dermal layers of the skin. The treatment applicator inserts an array of micro-needle electrode pairs into the superficial layers of the skin; RF energy is delivered through the distal section of each micro-needle pair during treatment, heating collagen in the skin. Surface cooling is applied during treatment above the area being heated with a cooling assembly integrated within the treatment applicator. Clinical studies suggest the thermal effects of treatment induce a healing response resulting in skin remodeling and the production of collagen, elastin and Hyaluronic acid in the treated skin. The micro-needle electrodes of the Profound system are insulated at the proximal end while leaving the distal end exposed. During treatment, RF current is delivered the exposed lengths of the electrodes in each pair. Energy is delivered directly within the target tissue in a volume largely defined by the geometry of the individual micro-needle pair. The electrode cartridge type and the separation between successive treatment applications determine the spacing between adjacent lesions. The treatment applicator deploys the micro-needle electrodes through the epidermis at a nominal angle of 25° to the skin's surface.

MECHANSIAM OF ACTION

The mechanism for observed clinical improvement following non-ablative RF treatment involves the generation of new dermal volume in the reticular dermis, which is triggered by a strong anabolic response due to the consistent optimal thermal injuries created by the Profound system. Published studies reported post treatment neo-dermal volume, characterized by complete normal structure including hyaluronic acid, collagen, and elastin. Thermal injuries in the reticular dermis create denatured collagen (or shrinkage of the collagen biopolymer). Literature has shown that partially denatured collagen is more effective at inducing a wound healing response than completely denatured collagen. It is also known from thermodynamic research that partial denaturation is obtained when collagen is kept at 67°C for 3-4 sec. In addition, clinical results have been shown to be optimal when Profound settings of 67°C, 3-4 seconds were used. Because of the proprietary real-time temperature feedback embedded in the Profound system, the optimal dermal temperature can be reached and maintained in any skin impedance conditions. Because of the consistency of the technology at reaching the optimal temperature endpoint, high clinical response rate can be expected.

ALTERNATIVE TREATMENT

Certain types of these conditions may be relieved or improved through surgery, which carries with it risks and potential complications. An alternative you shoud consider is to have no treatment at all. Alternative forms of management of the condiditon or conditions being treated may include diet and exercise regimens which may be of benefit in the overall appearance of cellulite.

Please Initial that you DO NOT have any of the following conditions and/ or that you DO NOT wish to be treated in certain body area

____ Pacemaker or internal defibrillator.
____ Active skin infection(s).
____ Collagen vascular disease.
____ Patients with history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
____ Any active condition in the treatment area, such as sores, Psoriasis, eczema, and rash.
____ History of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
____ History of bleeding coagulopathies, or use of anticoagulants.
____ History of hypertrophic scarring.
____ Facial laser resurfacing and deep chemical peeling within the last three months.
____ Any surgical procedure in the treatment area within the last three months or before complete healing.
____ Isotretinoin (Accutane) use in the previous 12 months.
____ As per the practitioner's discretion, refrain from treating any condition, which might make it unsafe for the patient.

Possible Complications and Adverse Effects

Any procedure perforating the skin can cause discomfort, pain, bleeding, infection, swelling, edema, scar formation, permanent marking and pigment alteration. Potential risks which could result from the Profound treatment include discomfort during and after the procedure, pain, infection, scarring, swelling or edema, permanent discoloration, nerve damage, and/or loss of sensation.

Treatment side effects may include:

- Pain during treatment: regional and local anesthetics are recommended to minimize treatment discomfort.
- Bleeding at insertion locations: small beads of blood at insertion points frequently develop several seconds following retraction of the micro-needle electrodes.
- Erythema and redness immediately following treatment: these will typically resolve within several hours.
- Focal edema or induration at treatment sites: focal edema at treatment sites typically develops 2 to 10 minutes follow treatment and can remain visible for 24 to 48 hours. Induration is often palpable for 5 to 10 days following treatment, and has been reported by patients as persisting for 30 days.
- Bruising: all patients develop mild to significant bruising throughout the treatment area. Bruising develops following treatment and is typically most noticeable 24 to 48 hours after treatment. Bruising typically resolves in 5 to 10 days.
- Visibility of insertion locations: small crusts at insertion locations occasionally develop at micro-needle insertion locations and typically slough in 12 to 48 hours for facial skin.
- Generalized swelling: mild to significant swelling throughout the treatment area is expected to develop 6 to 48 hours following treatment. Swelling typically resolves in 3 to 7 days but may persist for up to 20 days.
- Discomfort following treatment: can be none too moderate during the first 24 hours. Aspirin-free analgesics may be taken for discomfort following treatment.
- Discomfort on skin palpation: skin sensitivity/discomfort to firm pressure in the treatment area may persist for 14 to 28 days.
- Itch, twinge and tingle sensations during healing: can begin 5 to 7 days following treatment, becoming infrequent 30 to 45 days following treatment.
- Temporary loss of sensation: Patients have infrequently reported a slight loss of sensation in some regions of the fields infiltrated with local anesthetic and treated. This loss of sensation may persist for 5 to 20 days.
- Pigmentation change: including hypopigmentation, hyperpigmentation and post-inflammatory hyperpigmentation was may occur. Pigmentation change is a potential side effect of treatment and is more likely to occur for Skin Type V and VI patients. Caution is advised when treating these patients.

Patient Name (Printed):_____

Patient Signature: _____