

Stacey Folk, MD
303-321-6608
www.FolkPlasticSurgery.com

Non-invasive Skin Tightening and Smoothing Procedure Consent Form

As a patient, it is important for you to understand the expected results and risks of radiofrequency skin treatment with the *ThermiRF* System. Please read this document carefully. Before signing this document, please ask your physician, or the consultant providing the *ThermiSmooth* treatment, about any aspect of this document, or the *ThermiSmooth* procedure, that you do not understand.

The *ThermiRF* System equipment may present a hazard to patients with implantable devices, such as but not limited to pacemakers, imbedded defibrillators, and Cochlear ear implant. Please consult qualified medical personnel prior to being treated with radiofrequency equipment.

Since ongoing feedback by a patient during a procedure is required, if you have nerve insensitivity to heat anywhere in the treatment area, you should not be treated with the *ThermiRF* System.

The *ThermiSmooth* treatment uses the *ThermiRF* equipment and is unstudied and unknown for pregnant patients, patients with autoimmune disease, diabetes, or herpes simplex.

During Treatment

You may feel an electric shock similar to a static discharge in a dry environment when the electrode makes contact or is removed from the skin. A common comparison is the static shock you might feel when touching something after dragging your feet across carpeting. Beard stubble should be thoroughly removed prior to treatment as remaining stubble may accentuate shocks. If the eyelids are to be treated directly, please have plastic, non-conductive eyeshields covering your eyes.

All jewelry and makeup, including lotions, eyeliner and eye shadow should be removed from the treatment area prior to treatment.

Cut, wounded or infected skin should not be treated as this could promote infection and injury.

Slight discomfort may be experienced while undergoing treatment. Typically the discomfort is mild and temporary during the procedure and localized within the treatment area. During the treatment you should feel warmth and heat and provide ongoing feedback to the individual performing the treatment. Therefore no anesthetic (local, oral, or systemic) should be used prior to or during the treatment. Additionally, if you have nerve insensitivity to heat anywhere in the treatment area, you should not be treated. Inadequate or impaired feedback may lead to burns or injury. Ongoing feedback should be provided by you to the individual performing the treatment to avoid excessive discomfort.

After Treatment

Possible side effects of the *ThermiSmooth* treatment are usually treatment-site related and include mild discomfort during the procedure localized within the treatment area. Mild swelling and redness may occur which typically goes away within 2 to 24 hours.

Diligent protection from sun exposure and application of sunscreen after treatment will minimize pigmentation changes.

A regimen to moisturize and soothe skin for one week post-treatment is recommended.

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There is the possibility that additional risk factors of radiofrequency skin treatments may be discovered. The results of performing *ThermiSmooth* treatments in combination with other treatments is unstudied and unknown.

It has been explained to me that this is a cosmetic procedure and not covered by insurance. It has been explained to me that more than one treatment may be recommended to achieve the best results and that there are other treatment options such as microdermabrasion, chemical peels, filler injections, or no treatment at all. As mentioned before, there is no guarantee of results and no refund of payments for the procedure will be made.

My signature below signifies that all of my questions have been answered by the physician or consultant. I understand the risks, complications, expected results, and expense of the treatments. I have read and understand this document and give my consent to receive treatment with the *ThermiRF* radio frequency system.

Patient Name _____ Signature _____ Date _____

Physician Name _____ Signature _____ Date _____