

WESTSIDE AESTHETICS

ThermCool TC Non-Ablative Radiofrequency System Informed Consent

This form is designed to provide you with the information you need to make an informed decision on whether or not to have the Thermage performed. If you have any questions or do not understand any part of this consent, please do not hesitate to ask us.

I, (Patient Name) _____
have requested Thermage performance on the following area(s):

Forehead Cheeks Jowls Neck Other

If other please specify _____

A member of Dr. Alexander Rivkin staff has explained the nature of my condition, the nature of the procedure and its alternative treatments, and the benefits to be reasonably expected compared with alternative approaches. This document is a written confirmation of this discussion.

Texture Change/Surface Irregularities: Thermage has received a low incidence (reported less than 0.2% of the total estimated number of treatments) or reports citing the development of focal "surface irregularities." Such reports have been received for treatments that have been performed in the forehead, and mid/lower face areas. These surface irregularities have been variously described as "small dents in the surface of the skin," (localized) and "rippling," "ridging," or "waffle patterns" (covering a larger surface area). Frequently these irregularities are not present immediately post-treatment but show up later (1 or more months post-treatment). In a few cases these symptoms have resolved over the course of time. In some cases, the treating physician has elected to use soft tissue fillers (e.g. collagen, fat injections, etc.).

Burns; Blisters; Scabbing; Scarring: The procedure may produce heating in the upper layers of the skin, causing burns and subsequent blister and scab formation. Burns have been reported at a rate less than 0.3%. There is a small chance of scar formation (rare). Scars may be raised or slightly depressed.

Pigment Changes: Thermage has received a few reports of focal pigmentation changes post-treatment (reported less than 0.05%). These have primarily been reports of hyperpigmentation (reports of hypopigmentation are rare). Cases of hyperpigmentation have usually resolved over the course of time (within several months). Cases of hyper-and hypo-pigmentation have typically been associated with a burn.

Bruising: In very rare cases, the treatment may cause bruising, which typically dissipates within several days. Bruising may be more typically associated with the use of some anesthetic agents (e.g. nerve blocks).

Erythema/Blanching: The treated area may become temporarily red (erythema) or white (blanching). Erythema typically resolves within a few hours however, on rare occasions, has been seen to last longer (up to several weeks); blanching typically resolves within twenty-four hours.

Swelling (edema): The treated area may swell. Swelling typically resolves in three to five days or less but can persist up to several weeks.

Pain: Most people will feel some heat-related discomfort (pain) with the treatment. This discomfort is usually temporary during the procedure and localized within the treatment area. A small

number of patients have reported transient aching in the treatment area (lasting up to several weeks). In addition, a small number of patients have reported headaches following forehead treatment.

Altered Sensation: Thermage has received a low incidence (reported less than 0.1% of the total estimated number of treatments) of reports of focal, transient altered sensation, variously described as "numbness," "tingling" or "temporary paralysis." These cases have typically resolved in a short period of time but in a few cases have persisted up to several weeks. Reports have been received with respect to patients treated in the forehead, mid/lower face and neck areas.

PLEASE INITIAL:

INT: _____ I do not have diabetes, autoimmune disorder, or history of cold sores.

INT: _____ I am not pregnant, planning pregnancy and I am not breastfeeding.

INT: _____ I understand that this office has a no refund policy for all cosmetic treatments performed.

INT: _____ I understand all procedures involve risks to some degree and have no guarantee. Because all individuals are different, it is not possible to completely predict who will benefit from treatment with the ThermoCool device. No guarantees or promises can be made concerning the results of the treatment. Some patients will have very noticeable improvement, while others may have little or no improvement. It is possible that additional treatments may be needed to achieve the desired end result.

Herpes Simplex: Herpes simplex eruption may result in rare cases in a treated area that has previously been infected with the virus. This reactivation can be avoided by taking an Anti-viral prior to the procedure.

Off-label Use: The ThermoCool System has been studied by Thermage in US clinical trials for face treatment. The system is currently cleared by the US Food & Drug Administration only for this indication. All other areas of deployment, such as other areas of the body, are thus considered "off-label" and "investigational." Thermage is aware of studies that have been conducted internationally for off label uses. This body of knowledge, along with the information gained during the initial period of commercial use, is extensive, but not yet sufficient to allow Thermage to determine additional risks that may accompany the use of the ThermoCool procedure in such off-label, investigational areas.

Allergic Reaction: There is a possibility of an allergic reaction to materials used during the Thermage procedure. For example, an allergic reaction to the anesthesia, to the ink used for marking the skin or any other drugs or substances used during the ThermoCool procedure.

Photographs: If Pre and Post-Operative photos and/or videos are taken of the treatment for record purposes, I understand that these photos will be the property of Dr. Alexander Rivkin. I understand that these photos may be used for diagnostic, educational, advertising, or record keeping purposes.

By my signature, I acknowledge that I have read the foregoing informed consent form and have been adequately informed of the expected benefits of this treatment, risks of this treatment, alternative methods of treatment, and the risks of not treating my condition. I hereby consent to this procedure.

Patient's Signature _____ Date _____

Technician Signature _____ Date _____