Informed Consent for TempSure® Wrinkle and Dry Eye Treatments

Patient Name: _____ Date: _____

As a patient, it is important for you to understand the expected results and risks of radiofrequency skin treatment with the TempSure™ RF System. Please read this document carefully. Before signing this document, please ask the provider performing your RF treatment about any aspect of this document or the procedure that you do not understand.

TempSure™ RF System equipment may present a hazard to patients with implantable devices or pacemakers. Please consult qualified medical personnel prior to being treated with radiofrequency equipment.

Since ongoing feedback by the 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 TempSure™ RF System.

The TempSure™ RF System has not been studied for use on pregnant clients, patients with autoimmune disease, diabetes or herpes simplex.

TempSure™ RF System

TempSure™ RF System has been cleared by the FDA for the nonablative treatment of mild to moderate facial wrinkles and rhytids on skin phototypes I-VI. All clients are different and exact results of this cosmetic procedure and treatments cannot be predicted or guaranteed. Our studies indicate that greater than 85% of clients still have observable results six months after treatment.

FDA Approval

The treatment of meibomian gland disease and dry eye with the TempSure™ device is not FDA approved, and we provide treatment off label. “Off label” refers to using a product that is FDA approved for a particular indication for some other medical purpose.

Prior to Treatment

Beard stubble should be thoroughly removed prior to treatment as remaining stubble may accentuate patient discomfort.

If the eyelids are to be treated directly, you will have plastic, non-conductive eye shields 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 or injury.

Slight discomfort may be experienced while undergoing treatment. Typically, the discomfort is mild and temporary 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 and reduce the risk of complications.

After Treatment

Mild swelling and redness may occur which typically goes away within 2 to 24 hours.

Diligent protection from sun exposure and application of sunscreen (SPF 45 or higher) for two to three weeks after treatment will minimize pigmentation changes.

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

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

It has been explained to me that this is a dry eye and 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. Dry eye treatment alternatives include: artificial tears, warm compresses, medicated drops, and thermal pulsation. 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 my provider. 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 TempSure™ RF System.

Patient Name: _____

Signature: _____ Date: _____