

## **INFORMED CONSENT FORM:**

## TEMPSURE<sup>TM</sup> WRINKLE, DEEP HEATING AND CELLULITE TREATMENTS

As a customer, it is important for you to understand the expected results and risks of radiofrequency skin treatment with the TempSure<sup>TM</sup> RF System. Please read this document carefully. Before signing this document, please ask your physician, or the consultant providing the RF treatment, about any aspect of this document, or the procedure, that you do not understand.

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

- TempSure<sup>TM</sup> RF System equipment may present a hazard to clients with implantable devices or pacemakers. Please consult qualified medical personnel prior to being treated with radiofrequency equipment.
- Since ongoing feedback by a client 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.
- TempSure<sup>TM</sup> RF System for wrinkle treatment has not been studied for use on pregnant clients, clients 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 are removed from the skin. A common comparison is the static shock you might feel when touching something after dragging your feet across carpeting. I understand that:

- Beard stubble should be thoroughly removed prior to treatment as remaining stubble may accentuate shocks. If the eyelids are to be treated directly, you will 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.
- Wrinkles on 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**

Studies indicate the possible side effects of TempSure<sup>TM</sup> RF System are usually treatment-site related and include mild discomfort during the procedure localized within the treatment area. I understand that:

- Mild swelling and redness may occur which typically goes away within 2 to 24 hours.
- Diligent protection from sun exposure and application of sunscreen 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 wrinkle 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 methat 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.

I understand that the practice of medicine is not an exact science and no results have been guaranteed.

I acknowledge that the results may not meet my expectations. I certify that no guarantees have been made by anyone regarding the procedure(s) that I have requested and authorized. ☐Yes ☐No Initials: \_\_\_ I consent to photographs and digital images being taken and used for medical education, clinical training, professional publications or sales and marketing purposes. No photographs or digital images revealing my identity will be used without my written consent. If my identity is not revealed, these photographs and digital images may be used, shared, and displayed publicly for such stated purposes without my permission.  $\square$  Yes  $\square$  No Initials: Before and after treatment instructions have been discussed with me. The procedure, potential benefits and risks, and alternative treatment options have been explained to my satisfaction.  $\square$ Yes  $\square$ No Initials: I CERTIFY THAT I HAVE READ, FULLY UNDERSTOOD AND RECEIVED A COPY OF THE ABOVE CONSENT AND THAT I HAVE RECEIVED CLEAR EXPLANATIONS REGARDING THE PROVIDED INFORMATION. Client\*: Date Witness:\_\_\_\_\_\_Date\_\_\_\_

\* Parent or legal guardian if patient is under age 18 or unable to authorize consent.







