

## Informed Consent for TempSure® Wrinkle and Cellulite Treatments

Patient Name: \_\_\_\_\_ Date: \_\_\_\_\_

*Please read this document carefully. Before signing this document, please ask your physician, or the consultant providing the RF (Radiofrequency) treatment, about any aspect of this document, or the procedure, that you do not understand.*

### **TempSure™ RF System**

TempSure™ RF System has been cleared by the FDA for the non-ablative 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. Three consecutive treatments 3 weeks apart are recommended for best results of wrinkle treatment. For cellulite treatment, treatments are recommended once a week for 3 consecutive treatments. Additional “re-touch” treatments are also suggested. Our studies indicate that greater than 85% of clients still have observable results six months after treatment.

### **Contraindications:**

The following are contraindications to the use of TempSure™ RF System equipment. If you have any of the following conditions, we will not be able to approve TempSure RF treatment for you.

1. Implantable devices or pacemakers.
2. Nerve insensitivity to heat anywhere in the treatment area
3. Pregnancy – no studies have been done
4. Autoimmune disease – no studies have been done
5. Uncontrolled Diabetes- no studies have been done
6. Active Herpes Simplex – no studies have been done
7. Any wound on treatment area will need to heal completely for a month before TempSure RF treatment.
8. Alcohol and drug intoxication- impairs ability to give accurate feedback to medical assistant or physician.
9. Use of regular pain killers, tranquilizers or any medications causing drowsiness or altered mental status should be avoided the morning of the treatment.
10. Use of blood thinners is a relative contraindication.

### **Before Treatment:**

1. All jewelry and makeup, including lotions, eyeliner and eye shadow should be removed from the treatment area prior to treatment.
2. Beard stubble should be thoroughly removed prior to treatment as remaining stubble may accentuate shocks.
3. Drink at least 80 oz. of water the day before and the day of the treatment.

### **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. If the eyelids are to be treated directly, you will have plastic, non-conductive eye shields covering your eyes.

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 will feel warmth and heat. The skin temperature is automatically determined by the temperature sensor at the tip of the probe. For benefits to be achieved, skin temperature has to reach 39° C and sustained for at least 3 minutes. Thirty nine degrees centigrade is the temperature considered as high grade fever; it is generally tolerable. For best results, the medical assistant will try to raise the temperature to 41°C. **You will be asked to provide ongoing feedback** to the individual performing the treatment. Feel free to let the medical assistant/physician know if discomfort is reaching intolerable level. There will be **no anesthetic** (local, oral, or systemic) used prior to or during the treatment. Additionally, if you have nerve sensitivity to heat anywhere in the treatment area, you should not be treated. Inadequate or impaired feedback may lead to burns or injury. To reiterate ongoing feedback should be provided by you to the individual performing the treatment to avoid excessive discomfort.

**After Treatment:**

1. Studies indicate the possible side effects of TempSure™ RF System are usually treatment-site related and include mild discomfort during the procedure.
2. Mild swelling and redness may occur which typically goes away within 2 to 24 hours.
3. Photo-sensitive pigmentation may occur. Diligent protection from sun exposure and application of sunscreen for two to three weeks after treatment will minimize pigmentation changes.
4. A regimen to moisturize and soothe skin for one week post-treatment is recommended.
5. Drink a minimum of 80 oz. of water a day. Adequate hydration always promotes healthy skin with fewer wrinkles and less eye bags.

There is the possibility that additional side effects of radiofrequency skin treatments may be discovered in the future. The use of RF wrinkle treatments in combination with other treatments is unstudied and unknown.

**Disclaimer and Consent Form:**

1. It has been explained to me that this is a cosmetic procedure and not covered by insurance.
2. 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.
3. As mentioned before, there is no guarantee of results and therefore no refund of payments for the procedure will be made.
4. While my physician and the staff will take reasonable precautions to ensure my safety, I am willing to assume the risks of treatment whether known or unknown.

*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 understood this document and give my consent to receive treatment with the TempSure™ RF System.*

Client Name \_\_\_\_\_

Date of Birth \_\_\_\_\_

Signature \_\_\_\_\_

Date Signed \_\_\_\_\_

Practitioner Name \_\_\_\_\_

Signature \_\_\_\_\_

Date Signed \_\_\_\_\_