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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. I certify that I have been fully informed of the nature and purpose of the procedure, expected outcomes and possible complications, and I understand that no guarantee can be given as to the final result obtained. I am fully aware that my condition is of cosmetic concern and that the decision to proceed is based solely on my expressed desire to do so. I confirm that I have informed the staff regarding any current or past medical condition, disease or medication taken.
4. I assume full liability for any adverse effects that may result from the administration of the proposed treatment. I waive any claim in law or equity for redress of any grievance that I may have concerning or resulting from the procedure, except as that claim pertains to negligent administration of this procedure.
5. I knowingly and willingly give my consent for TempSure RF treatment. I have had ample opportunity to discuss the nature, the risks and benefits, and the reasoning for the treatments. I understand that medical treatment is an evolving art and that treatment results are not guaranteed or may result in unexpected adverse events. While my doctor and the staff will take reasonable precautions to ensure my safety, I am willing to assume the risks of treatment whether known or unknown.

6. Acknowledging the above, and weighing the risks versus the significant potential benefits, I give consent to Dr. Eileen C. Comia and her staff to administer the treatment to me. I will not hold responsible Dr. Eileen C. Comia, Advance Biomedical Treatment Center, or any of the center's staff or any other person associated with the medical intervention, for the physical and/or behavior problems as well as any injury to myself, and/or any form of emotional distress experienced by me.

I understand that treatment with this system involves a series of treatments and the fee structure has been fully explained to me.

I consent to the taking of photographs and authorize their anonymous use for the purposes of medical audit, education and promotion.

I certify that I have been given the opportunity to ask questions and that I have read and fully understand the contents of this consent form.

Printed Name _____

Patient Signature _____ Date signed _____

Practitioner Signature _____