

# Informed Consent for TempSure<sup>TM</sup> Wrinkle, Tissue Heating, and Cellulite Treatments

Client Name:			
Date:			

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

TempSure System equipment may present a hazard to clients with implanted 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 System.

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

TempSure System treatments have not been studied for use on pregnant clients, clients with autoimmune disease, diabetes, or herpes simplex.

#### **TempSure System**

TempSure System has been cleared by the FDA for the following:

**NOTE**: All clients are different and exact results of this cosmetic procedure and treatments cannot be predicted or guaranteed.

- Non-ablative treatment of mild to moderate facial wrinkles and rhytids.
- Elevating tissue temperature for selected medical conditions such as temporary relief of pain, muscle spasms, and increase in local circulation.
- Temporary reduction in the appearance of cellulite.

## **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. 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 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.

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

### **After Treatment**

Studies indicate the possible side effects of TempSure System are usually treatment-site related and include mild discomfort during the procedure localized within the treatment area. 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 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. 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 the treatment provider or consultant. 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 System.

Client Name		
Signature		
Date		
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Practitioner Name		
Cianatura		
Signature		
Data		
Date		



# MEDICAL HISTORY FORM

	Last Name:		First Name:		
	Address:				
	City:	State:	Zip Code:		
	Telephone: Home:	Work:	Cell:		
	Date of Birth:	Sex: Fema	e Male		
	Family Doctor:		Phone:	_	
	Pharmacy:		Phone:	_	
	Emergency Contact:		Phone:	_	
Wh	nich body area/areas or condition would you	like treated?			
Ple	ease answer all of the following questions  Do you have ANY current or chronic me	edical illnesses?		YES	NC
	Disclose any history of heat urticaria, dic immunosuppression, blood disorders, ca conditions that significantly compromise disorders, or <u>any</u> other condition or illnes	ncer, bacterial or vire the healing respons	al infections, medical		
	Please List:				
2.	Do you have <b>ANY</b> current or chronic skin conditions?				
	Also disclose any history of vitiligo, eczer diseases affecting collagen including Ehor any other skin condition.				
	Please List:				
3.	Are you currently under a doctor's care	? If so, for what reaso	on?		
4.	Do you take/use <b>ANY</b> medications (pres herbal or natural supplements, on a reg Please List:	ular or daily basis?	escriptions), vitamins,		
5.	Are there any topical products (both muse on your skin on a regular or daily ba		dical) that you		
	Please List				

6.	Do you take/use ANY systemic/oral steroids (e.g., prednisone, dexamethasone)?	YE	S NO
7.	Do you have <b>ANY</b> allergies to medications, foods, latex or other substances?		
0	Please List:	_	_
8. 9.	(For women) are you or could you be pregnant? (For women) are menstrual periods regular, or have you		
<i>y</i> .	ever been diagnosed with Polycystic Ovarian Disorder?		
10.	Do you have a history of herpes I or II in the area to be treated?		
11.	Do you have a history of keloid scarring or hypertrophic scar formation?		
12.	Do you have a history of light induced seizures?		
13.	Do you have any open sores or lesions?		
14.	Do you have any history of radiation therapy in the area to be treated?		
15.	In the last six (6) months, have you used any of the following:		
	anticoagulants or blood-thinning medications; photosensitizing medications; or anti-		
	inflammatory or blood thinning medications? Please List product name and date last used:		
	rieuse List prodoct name and date last osea.		
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16.	In the last three (3) months, have you used any of the following products: glycolic acid or otheralphahydroxy or betahydroxyacid acid products;		
	exfoliating or resurfacing products or treatments?		
	Please List product name and date last used:		
	riedse List product marite and date last used.		
17.	Do you have or have you ever had any permanent make-up, tattoos, implants,		
	or fillers, including, but not limited to, collagen, autologous fat, Restylane®, etc.?		
	If yes, please list locations on or in the body and dates:		
18.	Do you have or have you ever had any Botulinums, such as Botox® or Dysport®?		
	If yes, please list locations on or in the body and dates:		
19.	Have you taken Accutane® (or products containing isotretinoin) in the last 12 months?		
20.	Have you taken Tretinoin (like Retin-A®, Renova®) in the last 6 months?		
21.	Have you had any unprotected sun exposure, used tanning creams (including		
21.	sunless tanning lotions) or tanning beds or lamps in the last 4-6 weeks?		
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	Signature:Date:		
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