

# Informed Consent for TempSure™ 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\_\_\_\_\_

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

Signature\_\_\_\_\_

Date\_\_\_\_\_

# Marketing Consent for TempSure™ Wrinkle, Tissue Heating, and Cellulite Treatments

## CLIENT INFORMATION CONSENT AND RELEASE

DATE: \_\_\_\_\_

Cynosure, Inc. has requested permission to use information and images from your TempSure treatment procedure(s), which includes and is not limited to, my personal health information related to the procedure (e.g. age, gender, skin type, treatment regimen, etc.) as well as procedure and client descriptions (e.g. portrait, picture, likeness; and my voice). Any or all of which may be used in a recording, videotape, television production or reproduction, sound track recording, film strip, still photograph, medical research, product development, training or other written materials or articles for publication purposes, including use on website(s) supported by Cynosure, Inc. Such information and images will become a part of my personal health records and, under certain circumstances, may be shared or given to third parties as a part of my health records. I will have the ability to review and access such information and images as a part of my health records and provide corrections to errors I believe exist. Beyond this, I acknowledge that I have no rights, title or interest in the information and images, including claim of copyrights.

I consent to photographs and videos being taken only with the consent of my practitioner, and under such conditions and at such times as may be approved by my practitioner. I agree that the photographs and videos shall be taken by my practitioner or by a photographer approved by my practitioner.

I hereby grant to Cynosure, Inc., its successors, assigns, and anyone acting under its authority or permission, the right to make originals, copies or derivative works of the information and items referred to in this Consent Form, where appropriate and to use for any lawful purpose (including publicity and other trade purposes) throughout the world and reproduce at any time in any form or manner and to copyright any form or manner capturing the information and items referred to in this Consent Form.

I hereby release Cynosure, Inc. and its successors from any claim, which I might otherwise have as a result of any such use, copyright or publication.

Client name (please print)

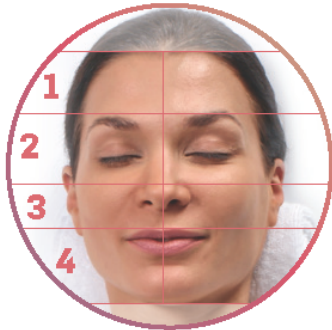
\_\_\_\_\_

Signature

\_\_\_\_\_

Date \_\_\_\_\_

# TempSure™ Wrinkle Treatment Form



TREATMENT AREAS

# TempSure™ *Envi*

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

Gender: \_\_\_\_\_ Date: \_\_\_\_\_

### DAY 1

### DAY 2

### DAY 3

<b>1</b>	Handpiece Size:	mm		mm		mm		mm	
		L	R	L	R	L	R	L	R
	Time:								
	Generator Setting:								
	Skin Temperature:								
<b>2</b>	Handpiece Size:	mm		mm		mm		mm	
		L	R	L	R	L	R	L	R
	Time:								
	Generator Setting:								
	Skin Temperature:								
<b>3</b>	Handpiece Size:	mm		mm		mm		mm	
		L	R	L	R	L	R	L	R
	Time:								
	Generator Setting:								
	Skin Temperature:								
<b>4</b>	Handpiece Size:	mm		mm		mm		mm	
		L	R	L	R	L	R	L	R
	Time:								
	Generator Setting:								
	Skin Temperature:								

Notes: \_\_\_\_\_

---

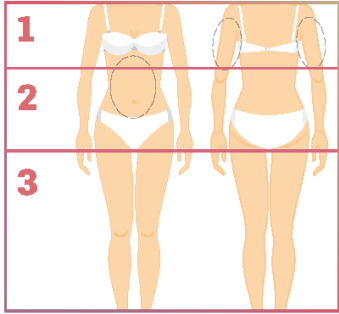


---



---

# TempSure™ Tissue Heating Treatment Profile



TREATMENT AREAS

# TempSure™ *Envi*

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

Gender: \_\_\_\_\_ Date: \_\_\_\_\_

## DAY 1

## DAY 2

## DAY 3

**1**

Handpiece Size:  
Time:  
Generator Setting:  
Skin Temperature:

	FRONT	BACK		FRONT	BACK		FRONT	BACK
Handpiece Size:	mm	mm		mm	mm		mm	mm
Time:								
Generator Setting:								
Skin Temperature:								

**2**

Handpiece Size:  
Time:  
Generator Setting:  
Skin Temperature:

	FRONT	BACK		FRONT	BACK		FRONT	BACK
Handpiece Size:	mm	mm		mm	mm		mm	mm
Time:								
Generator Setting:								
Skin Temperature:								

**3**

Handpiece Size:  
Time:  
Generator Setting:  
Skin Temperature:

	FRONT	BACK		FRONT	BACK		FRONT	BACK
Handpiece Size:	mm	mm		mm	mm		mm	mm
Time:								
Generator Setting:								
Skin Temperature:								

Notes: \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_  
 \_\_\_\_\_