



# **Treatment Guidelines**

## **For use Outside of the US**



**CUTERA®**  
Lasers and Light™

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The Cutera truSculpt™ is a Radio Frequency (RF) device. See the Operator Manual for a complete list of Indications for Use

## **PREREQUISITE**

The truSculpt should only be operated by qualified practitioners who have received appropriate training and have thoroughly read the truSculpt Operator Manual (shipped with system) prior to operating the system.

US federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the state in which they practice to use or order the use of the device.

## **PATIENT ASSESSMENT**

TruSculpt is a medical device. It is important to obtain a complete medical history and signed informed consent. Consult the Operator Manual for additional information, including expected transient events and possible adverse events and set appropriate patient expectations.

## **PATIENT SELECTION**

- Ideal patients are in general good health, with focal areas of concern.
- There are no skin type restrictions for radiofrequency treatments with truSculpt.
- Treatment is contraindicated for patients who are or may be pregnant.
- Do not treat near or over reproductive organs.
- Do not treat over implanted devices, including metallic implants, electronic implants, time-released medical implants and superficially placed body contouring implants.

*For a full list of contraindications, please see the truSculpt Operator Manual.*

## **PRE-TREATMENT PREPARATION**

- Anesthetics should not be used with truSculpt procedures.
  - Patient feedback is necessary to determine optimal treatment levels.
  - Topical anesthetics may damage the RF handpiece electrode.
- Shave treatment area if there is excessive hair.
  - RF handpiece must have full contact with skin.
- Clean treatment area, removing all make-up and/or lotions.
- Pre-treatment photographs are recommended prior to initial treatment for future reference.
- If a patient has been using a self-tanner within the past week, be aware that the tanner may leach onto the RF handpiece electrode during treatment leaving a permanent mark.
- Instruct patient to remove all jewelry, including any body piercings, near treatment area.
- The patient should be hydrated.

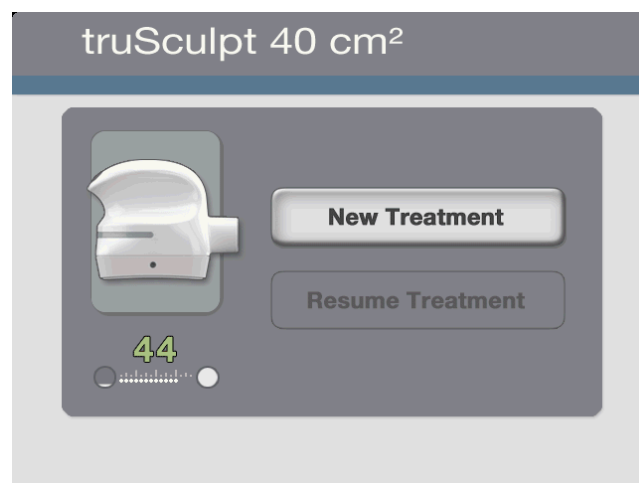
## PATIENT CONSULTATION



- It is important to discuss the treatment process and sensations with the patient prior to the treatment to set the appropriate expectations:
  - The treatment will heat tissue in the treatment area to achieve clinical effects.
  - As the treatment begins, patients feel a gentle warming sensation and, as the real time temperature increases, this heat sensation intensifies.
  - The Target Temperature will be increased in the most comfortable way possible in order to reach maximum clinical effects.
    - The Target Temperature will be increased slowly, allowing the patient to acclimate comfortably to Target Temperature and can be decreased quickly if desired by the patient.
- 2 – 4 treatments are suggested and treatments are typically spaced 4 – 6 weeks apart from each other
- Full results can take up to 8 – 12 weeks to appear.
  - Patients typically report seeing results after the second treatment.

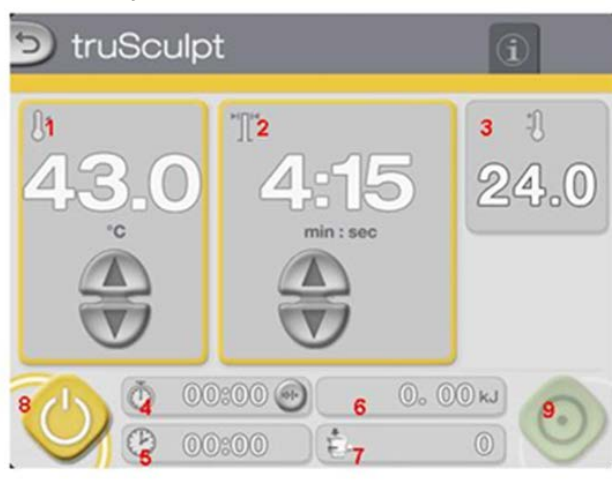
## START UP SCREEN

- Select “New Treatment”.
  - Selecting “New Treatment” will delete any remaining RF time leftover from previous treatment.
  - Each “New Treatment” provides 64 minutes of RF time and 90 minutes of total treatment time.
    - 64 minutes of RF time will result in 16 pulses if using the recommended 4 minute pulse duration.
    - 90 minutes of total treatment time begins when first pulse is activated.
      - This allows for time for patient breaks, repositioning patient, etc.
  - 40 cm<sup>2</sup> Handpiece - 50 “New Treatments”
  - 16 cm<sup>2</sup> Handpiece - 50 “New Treatments”
- Select “Resume Treatment” to continue using RF time from current treatment.
  - If “Resume Treatment” icon is highlighted, there is still RF time remaining.
  - Selecting “Resume Treatment” does not restart 90 minutes of total treatment time or 64 minutes of RF time.

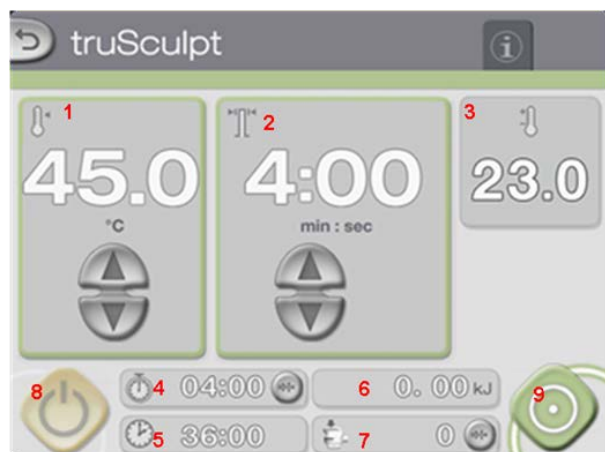




## SELECTING TREATMENT PARAMETERS

### Standby Screen



### Ready Screen



1. **Target Temperature**
  - Adjustable
  - Target temperature for the RF treatment
  - Measured in degrees Celsius
  - Adjustable in ½ degree increments
  - Not the real-time temperature of the patient's skin
2. **Pulse Duration**
  - Adjustable in 15-second intervals
  - Length of each pulse
  - Measured in minutes & seconds
3. **Skin Temperature**
  - Displays the real-time temperature of the patient's skin throughout the treatment
  - Measured in degrees Celsius
4. **RF Pulse Duration Counter**
  - Displays amount of time remaining in current pulse
  - Press  button to reset timer
5. **Total RF Countdown**
  - Displays amount of total RF time available for remainder of treatment
6. **Energy Display**
  - Displays total energy delivered
  - Measured in kJ
7. **Pulse Counter**
  - Displays number of imprints/pulses delivered
  - Press  button to reset
8. **Standby Button**
  - Press to go into Standby Mode
  - RF energy can not be delivered while in Standby Mode
  - Screen background is yellow
9. **Ready Button**
  - Press to go into Ready Mode to begin treatment
  - Start pulse after the "flute" sound
  - Screen background is green

## RETURN PAD

### Before Treatment

- Turn system ON prior to adhering return pad to patient.
- Place return pad on patient BEFORE connecting to neutral electrode cable.
- See Operator Manual for instructions on attaching neutral electrode cable to handpiece connector and disposable return pad.
- Do not place return pad over or near any metallic implants.
- Adhere return pad onto patient's back or on the body at least **10 inches away** from the treatment area.
  - Select a well-vascularized, muscular, and convex site for application.
  - Do not place over scars, inflamed skin, fatty tissue, bony prominences or metal prostheses.
  - Shave all hair from the selected site prior to placing return pad.
  - Remove any excess moisture prior to placing return pad.
- Ensure that there is complete contact with no creases or bubbles.
- Do not substitute with any other manufacturer's return pads.

### During Treatment

- If patient reports discomfort or heat in return pad area, pause treatment and verify that return pad has full contact and is adhered properly to skin with no wrinkles or bubbles.
- Periodically check the return pad throughout the treatment to ensure that it maintains full contact with the patient's skin.
- If return pad becomes loose or needs to be replaced, it should only be replaced when system is in standby mode.
- Disconnect neutral electrode cable from return pad prior to removing return pad from patient.



### CAUTION

- Do not relocate the return pad after initial application.
- Do not reuse a return pad.
- Do not use damaged return pads.

### After Treatment

- Detach neutral electrode cable from return pad **before** removing return pad from patient.
- Remove return pad gently after treatment (do not rip off).
- Discard used return pad after each treatment.



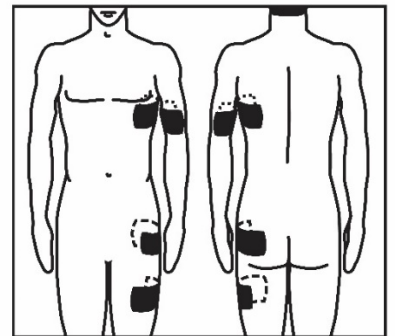
### NOTE

*The return pad uses a moderate strength adhesive to ensure good electrical contact. It is not uncommon for patients (especially those with sensitive skin) to develop mild redness in response to removing the return pad. If redness develops, it will typically be in the shape of the tape margin surrounding the electrodes and will typically resolve within a few days.*

### Proper return pad cable connection & placement



*It is important that the electrode cable is NOT attached to the return pad while removing or adhering to the patient.*



*Correct placement locations for return pads*

## HANDPIECE INSPECTION

Prior to every treatment, and periodically throughout the procedure, inspect handpiece carefully for any scratches/imperfections/defects to RF electrode.

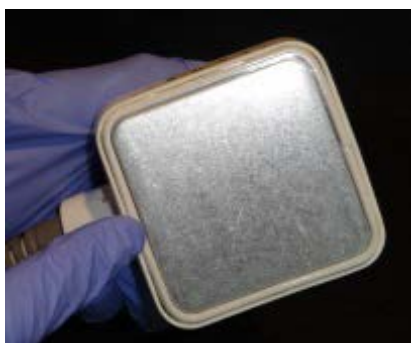


### CAUTION

DO NOT use truSculpt handpiece if there are any scratches/imperfections/defects on RF electrode.  
Contact Cutera Service at (415) 657-5500.

### Example of suitable handpieces

Silver or white coating with no imperfections, marks or scratches.



### Example of damaged handpieces. Do not use.

Scratches, imperfections or brown/grey marks on the coating



## RECOMENDED TREATMENT PARAMETERS

*The recommended parameters are provided as a guide and are based on practitioner feedback.*

The goal is for patients to be treated at the highest temperature that they can comfortably tolerate.

### Target Temperature & Pulse Duration

- Start treating the area with the most subcutaneous fat thickness first as these treatment areas are typically easier for the patient to tolerate.
- The recommended Pulse Duration for each imprint is 4 minutes unless otherwise indicated.
- Start at low Target Temperature (43.0°C) for first imprint of the treatment session.
  - Pre-treatment anxiety may make first imprints more painful.
  - Once the patient is familiar with treatment sensation, they may be able to tolerate a higher starting Target Temperature for subsequent imprints.
- During the first imprint explain to the patient that as their real time temperature reaches 40-41°C, the imprint may feel more uncomfortable due the system ramping up to reach the Target Temperature.
  - Patients typically report the intensity leveling off or diminishing slightly as Target Temperature is reached.
- Watch the patient's real time temperature during the treatment. Once the patient's real time temperature has reached the Target Temperature, increase the Target Temperature by 0.5°C. Continue this process until the maximum comfortably tolerated temperature (typically 45°C) has been reached.
  - Continue to adjust Target Temperature during the imprint based on patient feedback as maximum tolerable temperature may vary with anatomical location or subcutaneous fat thickness.
    - If discomfort is too high for patient to tolerate, lower temperature in steps of 0.5°C during imprint until patient can tolerate the treatment.
  - The last 30 seconds of an imprint can be the most intense, work with the patient to distract them or have the patient count down the last few seconds to help deal with the discomfort.
- If patient can't reach 45°C in a specific area, retreat that area again after the other imprints have been delivered.
- If the patient is having difficulty with the procedure and can't reach the Target Temperature of 45°C on any imprint, increase the pulse duration for all imprints to 5 minute and treat to a lower Target Temperature.
- Patients report being able to reach higher Target Temperatures when distracted. Following are strategies that some physicians have found useful to help patients reach higher Target Temperatures. Use these or other methods to help patients work through the discomfort:
  - Engage patient in a conversation.
  - Have patient play with their tablet or smart phone.
  - Have patient hold and squeeze a stress ball.

## TRUSCULPT COMFORT SCALE

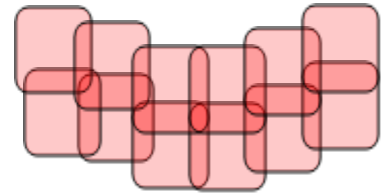
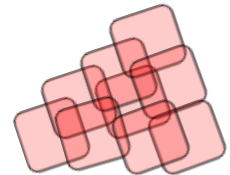
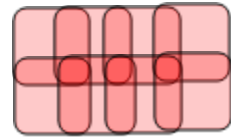




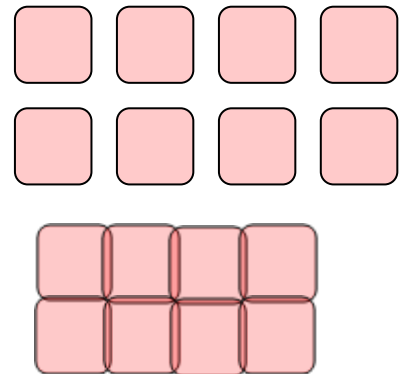
## DETERMINE TREATMENT AREA

- Ensure the RF electrode is placed so that it contacts only tissue intended to be treated.
- Outline treatment area boundaries with a white eyeliner pencil and formulate a plan for positioning treatment imprints within treatment area.
  - Color eyeliner pencils or markers can leach onto the RF handpiece electrode during treatment leaving a permanent mark.
  - Do not treat areas where complete contact of full electrode surface cannot be ensured.
- Ensure there is a minimum of 1 cm thickness of soft tissue in treatment area to allow for current delivered through skin to disperse.
  - Do not treat over hard structures including bone or cartilage unless there is at least 1 cm thickness of soft tissue between electrode and hard structure.
- Do not treat over implanted devices, including metallic implants, electronic implants, time-released medical implants and superficially placed body contouring implants.
- Do not treat over any wounds.
- Align imprints with an overlap of 20% - 50%.
  - Areas of concern can be treated with extra pulses, however a full second pass is not recommended.
- Ensure treatment area is dry prior to each imprint and handpiece is in full contact with skin.
  - Ensure skin is wiped dry prior to all imprints.
  - Focal sweating under treatment applicator and on surrounding skin during treatment is common.
  - Dab (do not wipe) RF electrode gently with cotton ball or gauze to ensure it is fully dry prior to each imprint.
  - Do NOT use paper towels, Kleenex or any abrasives on RF electrode.
  - Consider using a small fan in treatment room to keep skin dry during treatment.

### Examples of correct RF Handpiece Placement with 20%-50% overlap



### Example of incorrect RF Handpiece Placement



## TREATMENT TECHNIQUE

- Use gloves when touching patient's skin.
  - If the practitioner is grounded (touching metal or other conductive surface) and touching the patient's skin with no gloves, a secondary return path for current flow may occur.
- Place handpiece so that electrode is oriented to natural contour of body.
  - Curvature indicator on side of handpiece is helpful when orienting handpiece to body.
- Ensure handpiece is in full contact with skin during entire imprint.
  - Do not tilt, move or slide handpiece during RF delivery.
  - Apply only sufficient pressure to ensure full contact of handpiece on skin.
    - It may be necessary to push surrounding skin towards edges or into concavity of handpiece to ensure full contact.
    - Excessive pressure may diminish treatment effects and cause additional patient discomfort.
  - If handpiece is fully lifted off the skin during treatment, RF energy will cease and an error code will appear.
- To start a treatment, depress handpiece on/off button then release. Treatment will begin after RF contact is verified.
- Patient should feel a uniform heat sensation during RF pulse.
  - Treatment should be moderately uncomfortable, but not unbearable.



### CAUTION

*If at any time patient complains of sharp pain, scratching sensation or excessive discomfort, or if an audible sound is heard from the handpiece, pause treatment and observe patient's skin for any signs of epidermal damage (skin that turns white/grey, edematous, blanches, etc.).*

- *Stop treatment and contact Cutera Service at (415) 657-5500 if any epidermal damage is observed.*
- *If no epidermal damage is observed, ensure skin is dry.*

- After imprint is completed:
  - Wipe skin dry.
  - Dab RF electrode with cotton balls if moist or wet.
    - Do NOT use paper towels, Kleenex or abrasives.
  - Move handpiece to adjacent area.
- Moderate hyperemia should appear after each imprint (redness of treatment area) and typically resolves within a few hours.

## Correct Treatment Example



## Incorrect Treatment Example



## Dabbing RF Electrode



## TREATING THE SUBMENTUM AREA

- Only the 16cm<sup>2</sup> handpiece is recommended for submentum treatments.
  - Always place handpiece horizontally, never vertically, on patient's submentum
- Submentum treatments must be limited to patients with sufficient submentum tissue area to accommodate the full size of the treatment applicator without extending to touch the neck skin.
- Ensure that there is a minimum of 1 cm thickness of soft tissue in treatment area to allow for current delivered through skin to disperse.
  - NEVER treat over hard structures including bone or cartilage unless there is at least 1 cm thickness of soft tissue between electrode and hard structure.
  - Take extra care to ensure that the lower edge of the electrode does not touch neck skin over the thyroid cartilage or trachea as this may result in a skin injury.
  - Treatment of neck skin over the thyroid cartilage or trachea is contraindicated.
- Outline the treatment area boundaries with a white eyeliner pencil to ensure correct placement of the handpiece.
  - Color eyeliner pencils or markers can leach onto the RF handpiece electrode during treatment leaving a permanent mark.
- Imprint Placement
  - First imprint should be located directly under the chin.
  - Place imprints with 20 – 50% overlap under the jaw line.
  - Always place the handpiece horizontally, NEVER vertically on the patient's submentum.
  - It is better to have the handpiece higher towards the chin or jaw line than lower towards the neck where there is a higher risk of adverse event.
  - The RF electrode may extend beyond the jawline if the practitioner ensures that the entire RF electrode is dry prior to the imprint.
    - If the RF electrode is wet prior to imprint, this could lead to an adverse event.
- Ensure that the concave electrode is oriented to the natural contour of the treatment area.
  - The practitioner may need to gently push the surrounding skin into the concavity of the handpiece to ensure full contact.
  - The practitioner must be wearing gloves when contacting the patient's skin to ensure that they do not offer a parallel current return path.
- Ensure that patient's jaw remains still (no talking or chewing) during the treatment.
- Make sure the handpiece is placed with only sufficient force to ensure good contact, excessive pressure increases the risk of an adverse event and may reduce perfusion or diminish treatment effects.
  - Excessive pressure may also cause additional patient discomfort.
- It is important to remember to wipe the skin and dab the RF electrode dry in between each imprint.
- Patients typically receive 3-5 pulses.

### Correct Treatment Example

Treatment is within the submentum area



### Incorrect Treatment Example

Treatment is outside the submentum area



## TRUGLIDE ROLLER PROTOCOL

- If desired, use truGlide roller to massage entire treatment area prior to and/or following RF treatment.
- Massage entire treatment area thoroughly with truGlide roller.
- Use moderate pressure to ensure desired smoothing is achieved.
- Massage entire area for 5-10 minutes, or until desired improvement is reached.

truGlide Roller



## SYSTEM CARE

- Disconnect then dispose of return pads after each treatment.
- Clean RF electrode with alcohol, gently dabbing with cotton balls or gauze.
  - Using anything but alcohol can potentially damage the RF handpiece electrode.
  - Do NOT use abrasives such as sani-cloth, paper towels or Kleenex on the RF electrode.
- Disinfect plastic covering of handpiece and cord with a damp cloth and mild detergent or a sani-cloth.
- See Operator Manual for detailed information on system care and maintenance.



## POST TREATMENT CARE

- Moderate hyperemia (redness in treatment area) is expected and typically resolves within a few hours.
- Mild edema (swelling) and tenderness may develop and typically resolves within 24 hours.
- Patient should contact doctor's office if the following occur:
  - Blister, crusting or skin burns
  - Tenderness, redness or swelling persisting beyond 24 hours
  - Nodules or lumps in treatment area
    - May develop up to 72 hours post-treatment
- For maximum results, 2 - 4 treatments spaced 4 - 6 weeks apart is recommended.

Hyperemia example



