

## Pre-Procedure Recommendations

1. Prior to use review Instructions for Use and User Manual included in the shipment with your Thermi® products.
2. **REQUIRED:** Prior to operating device, attend a clinical in-service(s) provided by Thermi.
3. Review patient history (avoid treatment of pregnant women, active site infection, patients with implantable electrical devices).
4. Confirm signed consent form.
5. Take photos of treatment area based on office protocol.
6. Ensure you have all supplies needed
  - Set up sterile treatment tray or area for procedure
  - See sample injectable RF+ supply List
7. Position patient for anatomical area being treated. Ensure that the position allows the application of the electrode so that it is in full contact with the skin.
8. Ensure hair on treatment area has been significantly reduced or removed prior to treatment.
  - Shaving recommendation one day prior to treatment.
  - Waxing recommendation 5 - 7 days prior to treatment.
  - Laser hair removal recommendation 10-14 days prior to treatment.
9. Prep treatment area by removing all lotions, skincare products and makeup with antibacterial/antimicrobial cleanser per physician's choice such as Hibiclens, chlorhexidine, or isopropyl alcohol, before beginning treatment.
10. Mark treatment area according to office protocol
11. Utilize nerve mapping device (optional): Once positioned, use the external nerve mapping device such as the Xavant STIMPOD device, to map the nerves located in the area of treatment.
  - Place ink marks on the skin to outline the path of the nerve
  - When treating the neck, consider marginal mandibular nerve and buccal nerve
12. **NOTE: ThermiTight RF+ is not intended to be performed on the same day with other procedures on the same area**

### Procedure Set-Up: RF+

1. Position the system in a convenient location so that the procedure screen is visible to the operator. Turn on the black power switch on the back of the console. You will hear a beep; indicator lights will illuminate, and the display will go through a 10 second boot up process from the *logo screen* to *attach probe screen*.

### Connections & Settings

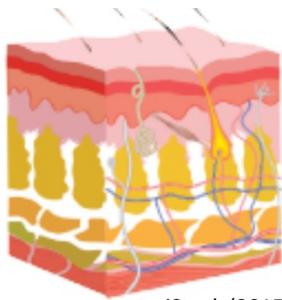
2. Select and connect the disposable grounding pad cord (blue) to the black neutral electrode connection port at the bottom left of the device. Place grounding pad on the patient close to the area being treated, avoid bony prominences and ensure full contact with the skin.
3. Select the ThermiTight® disposable electrode.
4. With the Thermi® logo facing up (12 o'clock position), connect the ThermiTight® electrode to the port located to the right of the grounding pad.



5. Once the electrode is connected, the ThermiTight® option will be automatically highlighted
6. Confirm by pressing the button below the check mark. A blue light will begin flashing in the upper right corner of the generator.
7. Using the soft keys to the right, increase the Set Temperature to the desired starting temperature



### Selecting a temperature for anatomical area to be treated



#### 42-47° C | Epidermis

Thermal induced inflammatory response. Fibroblast stimulation<sup>2</sup>

#### 55-70° C | Dermis & Subcutaneous Tissue

Thermal damage/Fibroblast stimulation/Collagen synthesis<sup>2</sup>

#### 85° C | Nerve Ablation

iStock (2015). Skin Anatomy vector.

Retrieved from <http://www.istockphoto.com/vector/skin-anatomy-gn483754169-25580031>

<sup>2</sup>Dunbar SW, Goldberg DJ. Radiofrequency in Cosmetic Dermatology: An Update. J Drugs Dermatol. 2015 Nov;14(11):1229-38

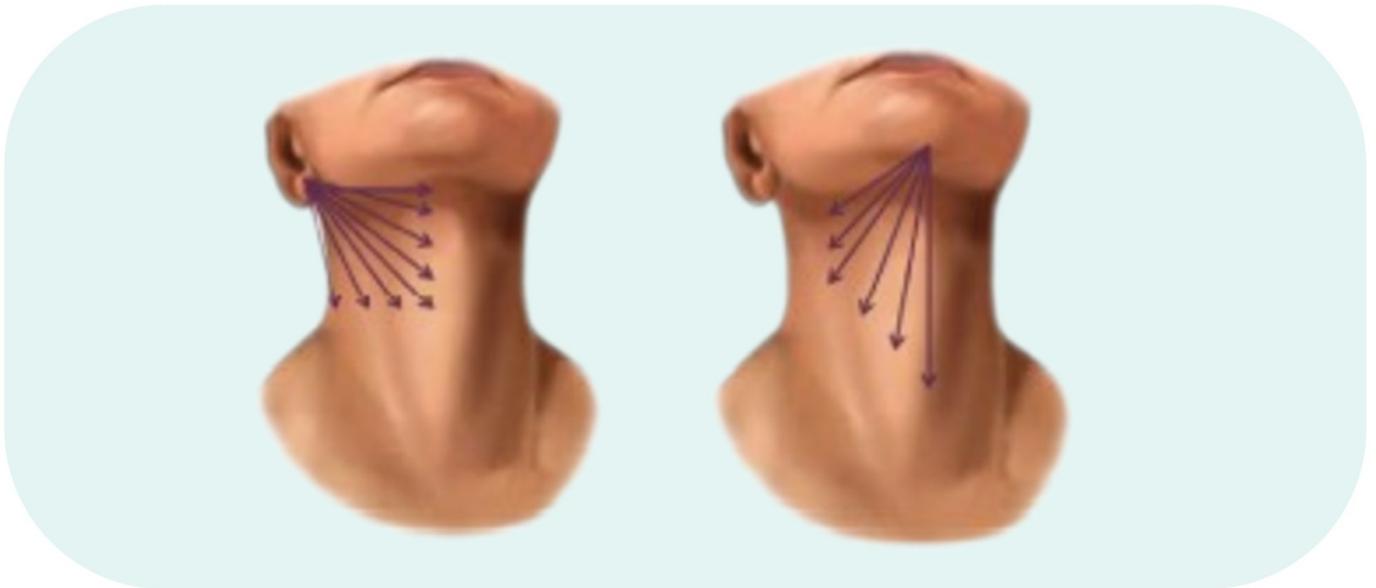
- Recommend selecting set subdermal temperature depending on area being treated and desired result, as indicated by figure above.
- Evaluate patient skin thickness and integrity.
- Consider a lower sub-dermal set temperature in the area around and above the marginal mandibular nerve (see Pearls Section on page 6: Avoiding Nerve injuries)

### Recommended Procedure Guidelines and Techniques

1. Divide treatment area into sections. For example, divide the neck into 3 sections, *left right and medial*.
2. Inject local anesthesia into skin at the RF+ electrode insertion site.
  - Consider 1% Lidocaine with epinephrine
3. Use 18 gauge needle or physician preferred needle to create an opening at the electrode insertion site.
4. Infuse infiltration fluid per clinic standard practice. Consider 30-40cc of infiltration fluid per 8 x 8 cm square body area using a blunt standard infiltration cannula. Fluid may be warmed to 40-41 degrees Celsius just before infiltration. **Please note that the selection of infiltration fluid components is based on the physician's preference. Additionally, it is the physician's responsibility to ensure proficiency in administering tumescent anesthesia.**
5. With energy off, insert the Injectable RF+ electrode to the distal portion of first pass.
6. Press foot pedal (or start button) to start radiofrequency emission.
  - The blue light on the upper right of the display will become solid and the device will give an audible beep every five seconds to indicate RF energy is on and being delivered through the active tip of the injectable RF+ electrode.
  - To pause RF emission, press then release the foot pedal (or RF ON/OFF button). The

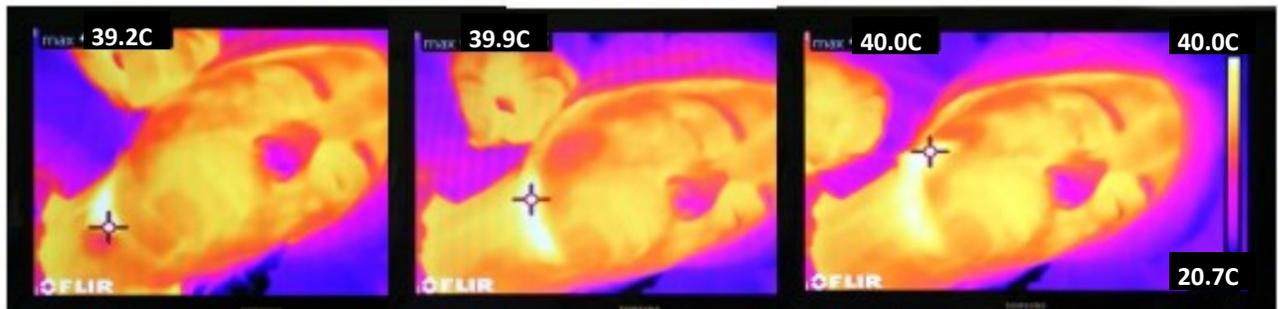
### Recommended Procedure Guidelines and Techniques (continued)

7. When the ACTUAL subdermal tissue temperature displayed on the ThermiRF+ generator screen reaches physician selected SET temperature, slowly begin withdrawing the electrode.
  - Withdraw the electrode 1/2 to 1cm and again allow ACTUAL temp to reach SET temp.
  - Continue withdrawing in this manner until entire pass has reached physician selected SET temperature.
  - The goal is to keep the ACTUAL temp within 3 degrees of set temp as you withdraw.
  - Repeat with a fanning technique until entire area has been treated and reaches the recommended treatment parameters



### Recommended Treatment Parameters

1. Visualized via the FLIR camera and monitor: The surface skin temperature should reach between 40-41 degrees Celsius across the entire treatment area. **IMPORTANT: The cursor must follow each subdermal pass while the surface temperatures maintain the 40-41 degrees Celsius range throughout.**
2. Visualized via the FLIR camera and monitor: The entire area treated should appear an even uniform color. **IMPORTANT: If you are treating the superficial subdermal plane, the color change will graduate to bright white as the surface temperature reach 40 degrees Celsius.**



3. Displayed on the Thermi RF+ generator screen: The ACTUAL (ACT) temperature (subdermal) should be maintained within 3 degrees of the (SET) temperature as you withdraw your pass.

NOTE: Consider starting out with SET temperature at 55 then graduating up to 60 as more experience is achieved.



## Pearls

**NOTE: THERMITight is not intended to be performed on the same day with procedures on the same area.**

- If surface tissue temperature of the skin does not reach 39-40°C, consider placing passes closer together or slightly overlap or adjusting the subdermal plan more superficially.
- If surface tissue temperature of the skin reaches 42° C, dab with a cold compress and space your passes further apart. Consider a lower set temperature, or adjust the electrode to a deeper subdermal plane.
- The RF+ Generator MUST be in the OFF or Paused mode when the Injectable RF Electrode is entering and exiting the entry point.
- Avoid tenting the skin or hitting the distal skin with the tip of the InjectableRF electrode.
- Avoid catching the dermis with the InjectableRF electrode (appears as a pucker in the skin).
- Verify by viewing the monitor, that the FLIR camera has COMPLETE VISUALIZATION of the area being treated before starting each new area.
- Always be aware of the surface skin temperature on the monitor (Max in the upper left corner).
- Recommend having cool sterile saline soaked on a 4x4 gauze available for dabbing a “hot spot” when the surface skin temperature reaches 42° C.
- Avoid nerve injuries: 1) Map nerves such as the marginal mandibular nerve with an external nerve mapping device such as the Xavant STIMPOD. 2) Infuse additional infiltrate over and around the nerve area to create a cushion from the deeper structures. 3) Consider a lower sub-dermal set temperature (example 50 degrees Celsius). 4) Stay >5mm away from the mapped nerve.

## Post Procedure

- Entry sites should be cleaned and dressed as per physician preference.
- Compression garments may be used at the physician’s discretion.
- For head and neck procedures, elevate the head while sleeping for the first 72 hours post procedure to minimize swelling.
- Treatment area may experience minor swelling immediately post-procedure.

## References

iStock (2015). Skin Anatomy vector.

Retrieved from <http://www.istockphoto.com/vector/skin-anatomy-gn483754169-25580031>

<sup>2</sup>Dunbar SW, Goldberg DJ. Radiofrequency in Cosmetic Dermatology: An Update. J Drugs Dermatol. 2015 Nov;14(11):1229-38