



THERMiTight[®]

Recommended Transdermal RF Procedural Guidelines

Pre-Procedure Recommendations

- 1. Prior to use review instructions** for Use and the User Manual shipped with your Thermi[®] device.
 - 1. Attend a clinical in-service** provided by Thermi
 - 2. Review patient history**
 - *(avoid treatment of pregnant women, active site infection, patients with implantable electrical devices).*
 - 3. Confirm** signed consent form.
 - 4. Take photos of treatment area** based on office protocol.
 - 5. Position patient properly** for body area being treated.
 - 6. Ensure you have all supplies** needed.
 - Set up sterile treatment tray or area for procedure
 - See injectable RF Recommended Supply List for reference
 - 7. Position Patient:** Position patient for anatomical area being treated. Ensure that the position allows you to apply the electrode so that it is in full contact with the skin.
 - 8. Prep treatment area** by removing all lotions, skincare products and makeup with antibacterial/antimicrobial cleanser such as Betadine, Hibiclens or Chlorhexidine.
 - 9. Mark treatment** area according to office protocol.
 - 10. 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.*
 - 11. NOTE: THERMiTight is not intended to be performed on the same day with other procedures on the same day**

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, the blue light on the upper left of the machine will flash and the display will show procedure settings. Position FLIR camera with the treatment area centered on the monitor and visualization beyond the treatment area.

Connections

A. Disposable Grounding Pad cord (blue) to the black neutral electrode connection port at the bottom left.

B. Connect SJM-AC-PN-ADAP Black Extension Cable. Ensure that the arrows are at the 12 o'clock position before connecting to the Thermi Radiofrequency generator. DO NOT twist the connector

C. Connect the gray end of the AC-SN-DUS adapter cable to the gray end of the extension cable. The black arrows should meet at each connection. DO NOT twist



2. Once the desired electrode has been selected, screw black textured handle to back of electrode to close opening. Connect white plug end of cable to free end of AC-SN-DUS. See above (pic 3)



Settings

A. Press the white button in the lower right corner that corresponds with the 'Start' on the front display panel (the blue light on the upper left corner will illuminate and flash).

B. The display will have three options ThermiTight, ThermiRase, and ThermiSmooth. Press the corresponding button below for the Thermi treatment you are

C. Using the middle set of arrows, increase the Set Temp to desired starting subdermal temperature (fig. A/Pg. 3)



Selecting a temperature for anatomical area to be treated

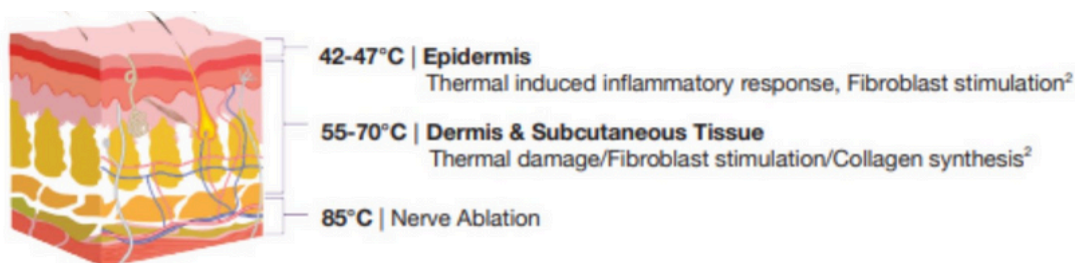
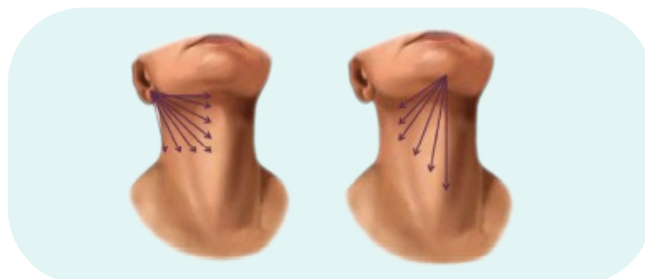


Figure A Skin Anatomy (iStock, 2015)
²Dunbar SW, Goldberg DJ. Cosmetic dermatology: An Update. J Drug Dermatol 2015;14(11):1229-1238.

Recommended Procedure Guidelines and Techniques

1. Divide treatment area into sections. For example, a neck is divided into 3 sections.
2. Inject local anesthesia into skin at the RF Electrode insertion site.
 - Recommend 1% Lidocaine with epinephrine
3. Use 18 Guage needle or physician preferred needle to create an opening at the electrode insertion site.
4. Infuse infiltration fluid per clinic standard practice. Recommend 30-40cc of infiltration fluid per 8x8 cm square body area using a blunt standard infiltration cannula. Fluid should be warmed to 40-45 degrees C just before infiltration.
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 left 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.
7. When the ACTUAL sub dermal tissue temperature displayed on the Thermi Generator Screen reaches physician selected SET temperature, slowly begin withdrawing the electrode.
 - Withdraw the electrode 1/2 to 1 cm 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 42-43 degrees Celsius across the entire treatment area. **IMPORTANT:** *The cursor must follow each sub-dermal pass while the surface temperatures maintain the 42-43 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 temperatures reach 42 degrees Celsius.*
3. Displayed on the Thermi Generator Screen: The ACTUAL (ACT) temperature (Subdermal) should be maintained within 3 degrees of the (SET) temperature as you withdraw your pass.

Pearls

- If surface tissue temperature of the skin does not reach 42-43 degrees Celsius, place your passes closer together or slightly overlap them or consider adjusting your subdermal plane more superficially.
- If surface tissue temperature of the skin reach 44 degrees Celsius, dab with a cold compress and space your passes further apart. Consider a lower set temperature, or adjust your 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 saline soaked on a 4x4 gauze available for dabbing a “hot spot” when the surface skin temperature reaches 44 degrees Celsius.
- Avoiding 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 55 degrees Celsius).
 - 4) Consider staying >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.

Generator Information

