

Pre-Procedure

1. Prior to use review Instructions for Use (User Manual) shipped with your Thermi[®] products.
2. Review patient history.
3. Confirm signed consent form.
4. Take photos of the treatment area per office photography protocol.
 - Before photos should feature the treatment area at rest and in all phases of motion.
 - Consider taking a short video (5-7 seconds) of the complete rest – motion – rest cycle.
5. Remove make up and lotions from treatment area.
6. Apply grounding pad close to area being treated, avoid bony prominences and ensure full contact with the skin.
7. Position patient in anatomical position for body area treated.
8. Once positioned, use an 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 from proximal to distal.
9. Set up sterile treatment tray or area for procedure.
 - See InjectableRF[®] Recommended Supply List for reference.
10. Prep the procedure area using sterile technique per office protocol (example: betadine, hibiclens, chlorhexidine).

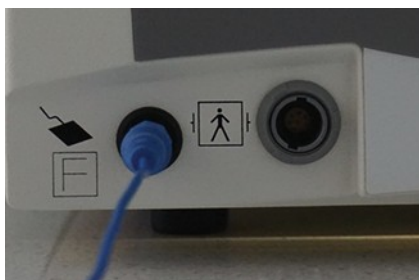
THERMiRase® Recommended InjectableRF® Procedural Guidelines: Nerve Ablation

Procedure Set-Up

1. System: Position the system in a convenient location, so that the procedure screen and monitor are 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 zone.

Connections

- A. Grounding Pad: Connect the 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.



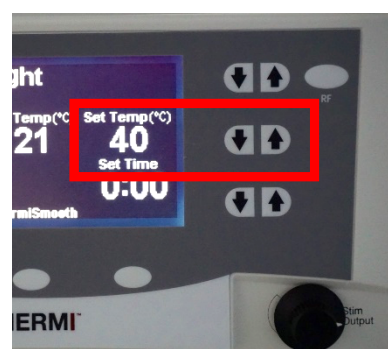
2. Once the desired electrode has been selected
Connect white plug end of cable to free end of AC-SN-DUS, See Above (pic 3)

Optional Extension Handle



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 performing.
- 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:

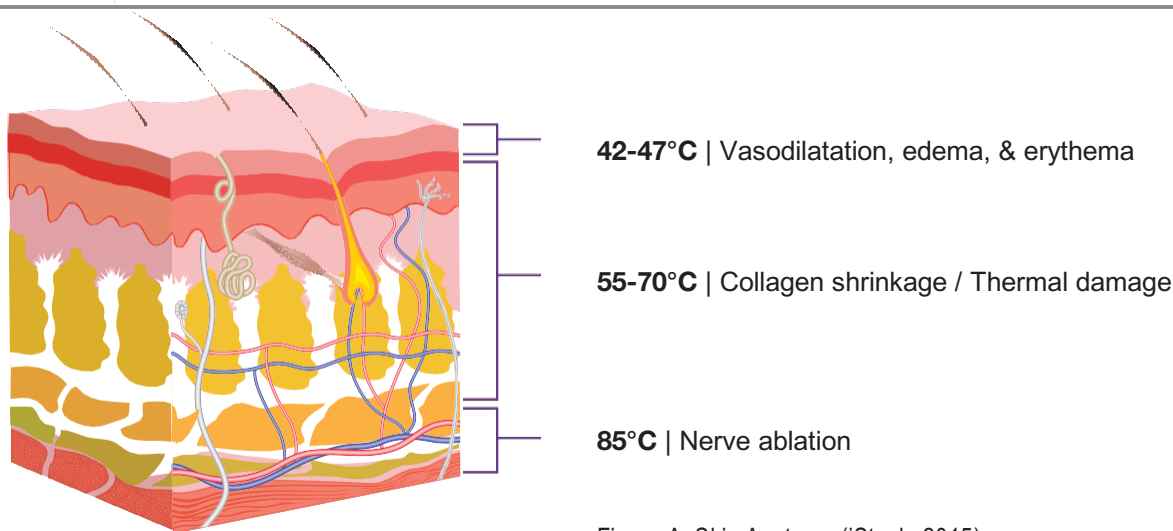


Figure A. Skin Anatomy (iStock, 2015)

Procedure Guidelines and Techniques

1. Inject local anesthesia into skin at the RF Electrode insertion site.
 - This should be at least 1cm lateral of first ablation target on nerve
 - Recommend 1% Lidocaine with epinephrine
2. Use 18 Gauge needle or physician preferred needle to create an opening at the electrode insertion site.
3. On sterile field fill 1cc leur lock syringe with suggested infusion anesthetic
 - Recommend 4% plain Lidocaine
4. Attach the 1cc leur lock syringe to back of selected injectable RF electrode.
5. Prime cannula until fluid is seen at opening on tip of the electrode.
6. With energy off insert electrode into electrode insertion site.
7. Electrical stimulation is activated by pressing the **black** stim knob on the lower right of the Thermi® RF control unit and select "Stim Motor".
 - Adjust stimulation current to 0.3v, by turning the black knob clockwise slowly, the cannula is then slowly inserted along the path of mapped nerve until muscle contraction is observed
 - Adjust voltage as low as possible to achieve minimal muscle contraction.
 - Withdraw cannula along mapped nerve course until stimulation stops.
 - Slowly advance until proximal stimulation reappears.
 - Push black stim knob on lower right to return to application selection screen.
8. Deliver 0.2cc of Infusion anesthetic through cannula to target area.
 - Wait 1-2 minutes to allow anesthesia to take effect.
 - For subsequent ablations, inject 0.1cc of Infusion anesthetic wait 1 minute.

Procedure Guidelines and Techniques (continued)

9. Select ThermiRase® operation mode on generator.
10. Recommend set temperature to 85°C *to treat most nerves*.
 - When treating the angular nerve or areas with “thin skin”, recommend set temperature to 65°C .
11. Press the foot pedal to start the 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 that the RF energy is on and being delivered through the active tip of the Injectable RF electrode.
12. When actual temperature reaches set temperature, the timer will count down for one minute and automatically stop at the end of the treatment cycle.
 - Monitor the external skin temperature with the FLIR® camera at all times.
 - If the temperature exceeds 45°C, pause the energy and/or apply cool saline gauze to area.
13. Advance electrode to next ablation target on nerve and repeat steps 7-12.

Recommended Treatment Parameters

1. The set temp must be held for 1 minute in order to ablate the nerve at that point.
2. The treatment is complete when the muscles no longer contract or the desired decrease in muscle contraction has been achieved.

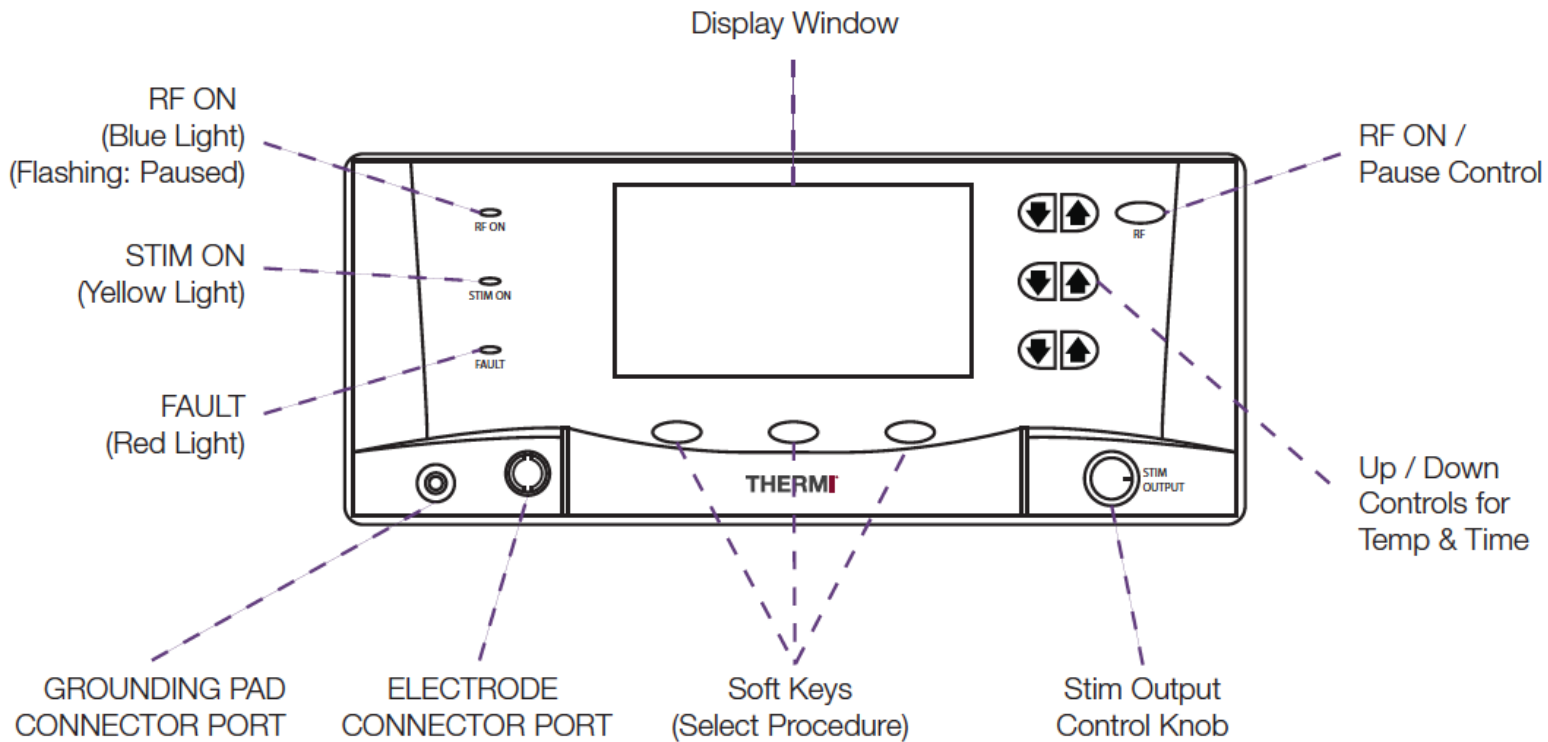
Pearls

- After verifying proper placement of Injectable RF electrode with Thermi® generator Stim Motor function avoid moving out of position.
- Some nerves will require multiple ablation targets along its course to achieve desired results.
- Injectable RF Electrode should be in the OFF or PAUSED mode when entering and exiting an entry point.
- Avoid tenting the skin.
- Avoid catching the dermis with the Injectable RF Electrode (appears as a pucker in the skin).
- Avoid hitting the distal skin with the tip of the Injectable RF Electrode.
- 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 your surface skin temperature on the monitor (Max in the upper left corner).
- Recommend having a cool saline soaked 4x4 gauze available for dabbing a “hot spot” when the skin temp reaches 45°C .

Post-Procedure

- Entry sites may be cleaned and dressed if necessary.
- For head and neck procedures, elevate head while sleeping for the first 72 hours post procedure to minimize swelling.
- Treatment area may experience minor swelling immediately post-procedure.

Thermi[®] RF Generator



References

iStock (2015). Skin Anatomy vector. Retrieved from
<http://www.istockphoto.com/vector/skin-anatomy-gm483754169-25580031>