

THERMIrase® Recommended InjectableRF® Procedural Guidelines: Nerve Ablation

Pre-Procedure Recommendations

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.
 - Pre-treatment 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. Position patient in proper position for body area treated.
7. 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.
8. Set up sterile treatment tray or area for procedure.
 - See InjectableRF® Recommended Supply List for reference.
9. Prep the procedure area using sterile technique per office protocol (example: betadine, hibiclens, chlorhexidine).

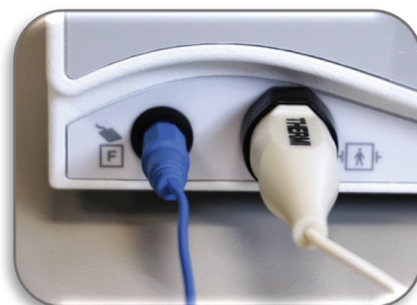
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Procedure Set-Up ARVATI™

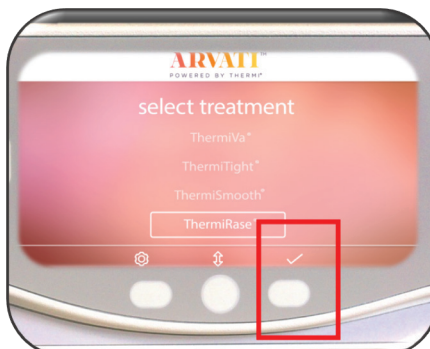
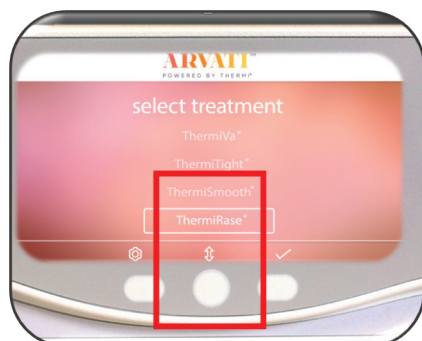
1. Position the system in a convenient location so that the procedure screen and monitor are visible to the operator. Turn on the black power switch on the back of the console. You will hear a beep; indicator lights will illuminate, and the display will go through a 10 second boot-up process from the *logo screen* to *attach probe screen*.
2. Position FLIR® camera with the treatment area centered on the monitor and visualization beyond the treatment zone. (The FLIR camera monitors the epidermal surface temperature and displays it on the monitor.)

Connections & Settings

3. 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.
4. Select the desired length of the InjectableRF electrode. To extend the handle for comfort, screw the black textured handle (optional) to the back of the electrode.
➤ V-5-5-20-B-G2
5. With the Thermi® logo facing up (12 o'clock position), connect the InjectableRF electrode to the port located to the right of the grounding pad.



6. Once the electrode is connected, the ThermiTight® option will be automatically highlighted. Use the middle soft key to scroll down to ThermiRase®.
7. Confirm by pressing the button below the check mark. A blue light will begin flashing in the upper right corner of the generator.
8. Using the soft keys to the right, increase the Set Temperature to the desired starting temperature for nerve ablation. (Fig. A Pg. 3)



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Selecting a temperature for anatomical area to be treated:

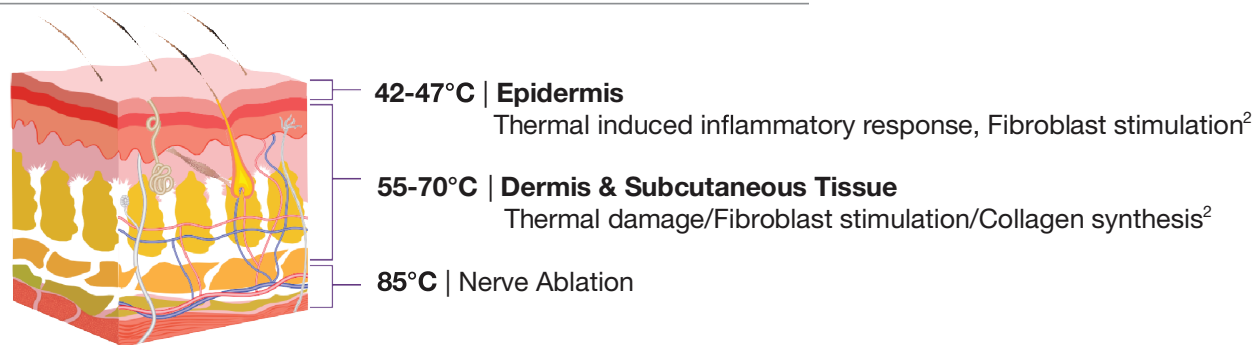


Figure A Skin Anatomy (iStock, 2015)

²Dunbar SW, Goldberg DJ. Cosmetic dermatology: An Update. J Drug Dermatol 2015;14(11):1229–1238.

- Recommend set temperature to 85°C to treat most nerves.
- When treating the angular nerve or areas with “thin skin” recommended temperature 65°C.

Recommended Procedure Guidelines and Techniques

1. Inject local anesthesia into skin at the RF Electrode insertion site.
 - This should be at least 1cm lateral of the first ablation target on the nerve.
 - Recommend 1% Lidocaine with epinephrine.
2. Use 18 Gauge needle (or physician preference) to create an opening in the skin.
3. On sterile field fill the 1cc luer lock syringe with suggested infusion anesthetic.
 - Recommend 4% plain Lidocaine.
4. Attach the 1cc luer lock syringe to the back of the selected InjectableRF electrode.
5. Prime cannula until fluid is seen at opening on tip of the electrode.
6. With energy off insert the Injectable RF electrode under the skin.
 - Electrical stimulation mode on the generator is entered by pressing middle soft key ‘stim’.
 - Adjust stimulation voltage to 0.3v by pressing either set of +/- soft keys.
 - A yellow light will illuminate on the front panel above “stim” when delivering stimulation voltage.
 - The cannula is then slowly inserted along the path of the mapped nerve until muscle contraction is observed.
 - Adjust voltage as low as possible to achieve minimal muscle contraction.
 - Withdraw cannula along the mapped nerve course until stimulation stops.
 - Slowly advance until proximal stimulation reappears.
 - Press x to end stimulation or back arrow button to return to TherMiRase screen.
7. 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 and wait 1 minute.

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Recommended Procedure Guidelines and Techniques (continued)

8. Gently press then release the foot pedal (or RF ON/OFF button) to start the radiofrequency emission.
 - The flashing 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 that the RF energy is on and being delivered through the active tip of the Injectable RF electrode.
9. 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.
 - If it is necessary to pause RF emission before timer is up, press and release the foot pedal (or RF ON/OFF button). The blue light will again begin to flash, and the return arrow will appear above the bottom left soft key.
10. Advance electrode to next ablation target on nerve and repeat steps 6-9.

Recommended Treatment Parameters

1. The set temp must be held for one 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 InjectableRF 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.
- RF Generator MUST be in the OFF or PAUSED mode when the InjectableRF Electrode is entering and exiting the skin.
- Avoid tenting the skin.
- Avoid catching the dermis with the InjectableRF electrode (appears as a pucker in the skin).
- Avoid hitting the distal skin with the tip of the InjectableRF 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 epidermal surface temperature on the monitor (displayed in the upper left corner).
 - Recommend having a cool saline soaked 4x4 gauze available for dabbing a “hot spot” when the skin surface temperature reaches 45°C or above. (Visualized on the monitor via the FLIR camera.)

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.

References

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

²Dunbar SW, Goldberg DJ. Cosmetic dermatology: An Update. J Drug Dermatol 2015;14(11):1229–1238.