

## **Pre-Procedure Recommendations**

- 1. Prior to use review Instructions for Use (User Manual) shipped with your Thermi<sup>®</sup> products.
- 2. Review patient history.
- 3. Confirm signed consent form.
- 4. Take photos of the treatment areas per office photography protocol.
- 5. Remove make up and lotions from treatment area.
- 6. Mark treatment area according to office protocol.
- 7. Position patient properly for body area being treated.
- 8. 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.
- 9. Set up sterile treatment tray or area for procedure.
  - See InjectableRF<sup>®</sup> Recommended Supply List for reference.
- 10. Prep the procedure area using sterile technique per office protocol (example: betadine, hibiclens, chlorhexidine).



# THERMITIGHT® Recommended InjectableRF® Procedural Guidelines

## Procedure Set-Up: ARVATI<sup>™</sup>

- 1. Position the system in a convenient location so that the generator 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 the attach probe screen.
- 2. Position FLIR<sup>®</sup> 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  $\geq$
  - V-10-10-18-B-G2  $\geq$
  - V-15-10-18-B-G2  $\geq$
  - V-20-10-16-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.
- 7. Confirm by pressing the button below the check mark. A blue light will begin flashing in the upper right corner of the generator.



- ARVATI select treatment
- 8. Using the soft keys to the right, increase the Set Temperature to the desired starting temperature for the dermal/subcutaneous area you are treating. (Fig. A Pg.3)



THERM



THERMItight<sup>®</sup> Recommended InjectableRF® Procedural Guidelines

## 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

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

- 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 pg. 5: Avoiding Nerve Injuries)

## **Recommended Procedure Guidelines and Techniques**

- 1. Divide treatment area into sections.
  - For example, a neck should be divided into 3 sections: left, right, medial.
- 2. Inject local anesthesia into skin at the RF Electrode insertion site.
  - Recommend 1% Lidocaine withepinephrine.
- 3. Use 18 Gauge needle (or physician preference) to create an opening in the skin.
- 4. Infuse infiltration fluid peroffice protocol
  - Recommend 30- 40 cc of infiltration fluid per 8 x 8 cm square body area using a blunt standard infiltration cannula.
  - Fluid should be warmed to 40°-45°C just before infiltration.
- 5. With energy off, insert the Injectable RF electrode under the skin to the distal portion of first pass.
- 6. Gently press then release the foot pedal (or RF ON/OFF button) to start radiofrequency emission.
  - The flashing blue light on the upperright of the display will become solid and the device will give an audible beep every five seconds to indicate that RF energy is on and being delivered through the active tip of the InjectableRF electrode.
  - To pause RF emission, press then 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.





THERMITIGHT® Recommended InjectableRF® Procedural Guidelines

## **Recommended Procedure Guidelines and Techniques (continued)**

- 7. When the ACTUAL subdermal tissue temperature (displayed on the Thermi generator) reaches physician selected SET temperature, slowly begin withdrawing the electrode. *There will be a double beep the first time the actual subdermaltemp meets (SET) temp and the running timer will begin.*
- 8. Withdraw the electrode ½ to 1cm and again allow ACTUAL subdermal temp to reach the 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.



#### 1. Displayed on the Thermi generator screen:

 The ACTUAL dermal / subcutaneous temperature should be maintained within 3 degrees of the SET temperature as you withdraw your pass.



#### 2. Visualized via the FLIR camera and monitor:

- The epidermal surface temperature target is between 42°-47°C across the entire treatment area.
- The entire treatment area appears an even uniform color.







## THERMItight<sup>®</sup> Recommended InjectableRF® Procedural Guidelines

## **Pearls**

- If epidermal surface temperature does not reach 42-47°C consider:
  - Placing your passes closer together or slightly overlap them.
  - Adjusting your subdermal plane.
  - Increasing your subdermal (SET) temperature in1-2 degree increments.
- Always be aware of epidermal surface temperature on the monitor (displayed in the upper left corner).
  - Recommend having cool saline soaked 4x4 gauze available for dabbing a "hot spot" when the epidermal surface temperature reaches 47°C or above.
- If epidermal surface temperature reaches 47°C or above, dab with 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 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.
- To avoid nerve injuries:
  - Map nerves such as the marginal mandibular nerve with an external nerve mapping device such as the Xavant STIMPOD.
  - Infuse additional infiltrate over and around the nerve area to create a cushion from the deeper structures.
  - Consider a lower sub-dermal SET temperature in the area. (example: 55°C)
  - Consider staying > 5mm away from the mapped nerve.

## **Post-Procedure**

- Entry sites may be cleaned and dressed if necessary.
- Compression garments can be used at physician's discretion.
- 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-anatomygm483754169-25580031

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

