

Pre-Procedure Recommendations

1. Prior to use, review Instructions for Use and User Manual included in the shipment with your Thermi® products.
2. Attend a clinical in-service provided by Thermi.
3. Review patient history.
 - Current negative pap smear.
 - Pelvic exam within 1 year.
 - Negative for pregnancy
 - Negative for infection/wounds (including, but not limited to: Herpes Simplex Virus, lesions or abrasions, UTI or Yeast).
 - No metal IUD in place.
 - No implantable electrical devices (including, but not limited to: pacemakers, nerve stimulators).
4. Confirm signed consent form.
5. 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
6. Have patient empty bladder prior to positioning for treatment.
7. Take photos of treatment area based on office protocol.
8. Ensure you have all supplies needed including a clear ultrasonic water-based gel (i.e. Parker Labs Aquasonic Gel or equivalent).
 - Do not use gel containing color or glycerin.
 - Do not use any oil-based conductive medium.
9. Position patient in lithotomy position. Ensure that the position allows you to apply the electrode to treatment area with firm, even pressure.

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 ThermiVa® disposable electrode.
4. With the Thermi® logo facing up (12 o'clock position), connect the ThermiVa® electrode to the port located to the right of the grounding pad.



5. Once the electrode is connected, the ThermiVa® 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 37 degrees Celsius



Recommended Procedure Guidelines and Techniques

Vaginal Canal

1. Apply moderate amount of warmed water based ultrasonic gel to electrode.
2. With energy **off**, introduce the ThermiVa RF+ electrode into the vaginal canal until resistance is met to measure depth of the vagina.
3. Note maximum length of the vaginal canal, then withdraw the electrode 2-3 cm from cervix. This will be your maximum treatment depth.
4. Select desired 'set' temperature
 - Recommend starting 'set' temperature at 37 degrees Celsius
5. Place electrode in full contact with tissue, apply moderate amount of pressure
6. Gently press then release the foot pedal (or RF ON/OFF button) to start radiofrequency emission and begin moving electrode. The running timer starts upon RF emission.
 - The flashing blue light on the upper right of the display will become solid and the device will give an audible beep every 5 seconds to indicate that the energy is on and being delivered through the active tip of the ThermiVa RF+ electrode.
 - To pause RF emission, 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 of the soft key.
7. Increase temperature in increments of 1-2 degrees Celsius per patient tolerance, (suggested temperature is 40-41 degrees Celsius).
8. Apply RF energy to the entire area needed for desired result.
9. Apply additional gel as needed to ensure electrode glides on tissue for patient comfort and adequate conduction.

Labia Majora/Labia Minora

1. Apply moderate amount of warmed water based ultrasonic gel to procedure area.
2. Select desired 'set' temperature.
 - Recommend starting 'set' temperature at 37 degrees Celsius
3. With energy off, place electrode in full contact with the skin and apply a moderate amount of pressure.
4. Gently press then release the foot pedal (or RF ON/OFF button) to start radiofrequency emission and begin moving electrode. The running timer starts upon RF emission.
 - The flashing blue light on the upper right of the display will become solid and the device will give an audible beep every 5 seconds to indicate that the energy is on and being delivered through the active tip of the ThermiVa RF+ electrode.
 - To pause RF emission, 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 of the soft key.
5. Apply RF energy unilaterally, dividing the left and right side.
6. Increase temperature in increments of 1-2 degrees Celsius per patient tolerance (suggested temperature is 40-41 degrees Celsius).
7. Apply additional gel as needed to ensure electrode glides on tissue for patient comfort and adequate conduction.

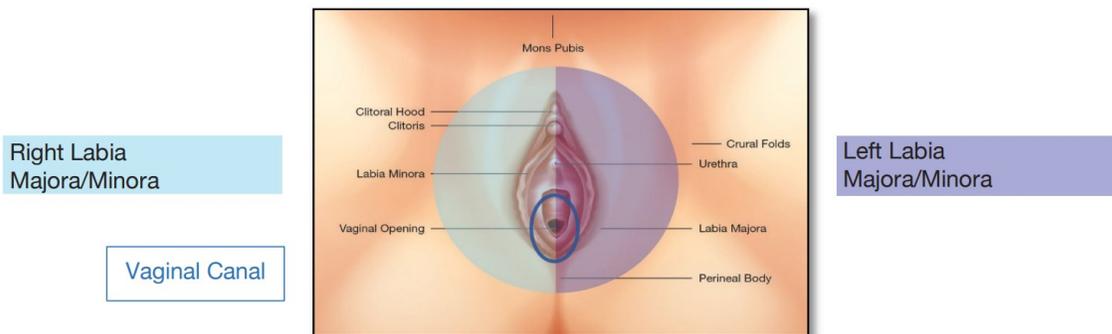
Recommended Treatment Parameters

Vaginal Canal

1. Suggested total procedure time for **internal tissue is 12-20 minutes**, excluding warm-up time.
2. Target temperature is between 40-42 degrees Celsius.
3. Actual temperature should be maintained within 3 degrees of (SET) temperature.
 - This is managed by controlled slow movement of the electrode.

Labia Majora/Labia Minora

1. Suggested total procedure time for **external tissue is 12-20 minutes**, excluding warm-up time.
2. Target temperature is between 40-42 degrees Celsius
3. Erythema should be visualized on external tissue.
4. Actual temperature should be maintained withing 3 degrees of (SET) temperature.



Pearls

- Request patient feedback on temperature tolerance and comfort.
- Always keep electrode moving.
- Keep active tip of the electrode in full contact with the tissue at all times.
- Avoid withdrawing electrode from contact with tissue while the energy is on.
- Vary depth and lines of sweeping motion making a different path each time.
- Avoid contact with the cervix during application.
- Avoid applying RF energy near the urethral opening.
- Recommend three treatment sessions separated at one-month intervals.

Post-Procedure

- Cleanse the skin to remove excess ultrasonic gel.
- Patient may experience warmth and mild pink to redness of skin.
- Procedure area may experience minor swelling immediately post-procedure.