

FormaV provides non-invasive, gentle RF heating for internal and external contraction. Temperature regulated and uniform RF heating is applied for gentle thermal muscle stimulation, relaxation and blood circulation.

## **BASIC PARAMETERS CONSIDERATION**

- Plenty of ultrasound gel to be applied
  - Gel to be applied directly to all 3 electrodes on FormaV tip.
  - Pre-warm the gel by covering the tip electrodes completely and applying RF for a few seconds.
  - Inserting gel manually into the vaginal canal may be helpful in cases of moderate to severe atrophy.
- Temperature cut-off as high as tolerable. In general, higher cutoff temperature yields best results.
- Power level to be set according to patient tolerance.
- Position the probe at the end of the canal without RF to determine the penetration depth for repeated insertion. Reaching the cervix is felt by both the patient and the operator.

## **FORMAV TYPICAL TREATMENT PARAMETERS**

Vaginal Treatment Zone (cm <sup>2</sup> )	RF Energy Level	Cut-Off Temperature [°C]	Gel
10-20	20-35	As high as tolerable Starting at 40°C	Thick Layer

Adjust parameters according to patient tolerance and skin response and increase them gradually.

## **PRE-TREATMENT**

- Clean hand piece tip with alcohol 70% for at least 30 seconds and repeat as necessary. Leave it for complete drying.
- Inspect all components of the handpiece for visible damage.
- Review patient intake, indications, contraindications, inform the patient about treatment schedule, typical treatment results and possible side effects and discomfort. Instruct the patient about the safety warnings.
- The patient should discontinue any irritant topical agents for 2-3 days prior to treatment and if medically permitted, anticoagulants should be stopped 1-2 weeks prior treatment.
- Physician prescribed Acyclovir or Valacyclovir for prophylaxis prior to treatment.
- Hair should be shaved - not waxed or chemically removed - in the treatment area 2-4 days prior treatment.
- The patient should empty the bladder prior to the procedure.
- Perform an exam of the treatment area immediately prior to the procedure to visualize the area that is going to be treated
- Clean the treatment area with Chlorhexidine or 70% rubbing alcohol. Ensure that the treatment area is clean and dry from all residue prior to beginning the procedure.

## **TREATMENT PROCEDURE**

- Make sure that the hand piece for the treatment (FormaV) corresponds to the interface.
- Apply clear ultrasound gel (not oil) to the tip electrodes or insert into the vaginal canal to determine the depth according to the cm markings on the handpiece.
- Ensure a full contact of the electrodes with the skin with slight pressure, then press footswitch.
- Move the handpiece back and forth along the canal or in circular movements across, with gentle pressure over the treatment area to reach uniform heating. Movement should be constant and its amplitude should be at least double handpiece spot size to avoid hot spots.
- Continue to treat the full area in this fashion. Always start with a low setting level to check the patient's tolerance to the treatment parameters. Increase settings gradually.
- Move the handpiece back and forth or in circular movements across, with gentle pressure over the treatment area to reach uniform heating. Movement should be constant, and its amplitude should be at least double handpiece spot size to avoid hot spots.
- Apply multiple passes to maintain the desired temperature during at least 10 min per zone.
- However, when there is excessive tissue reaction, stop treatment. For excessive heat sensation, you may increase the movement speed, reduce the RF power and lastly, reduce the cut-off temperature. If this does not help stop the treatment.
- Outside genitalia may be treated with the same probe, using a similar technique to Forma. Each treatment zone – left or right external genitalia covered with gel – is treated with constant gentle movement for 10-20 minutes.

## **POST-TREATMENT**

- The patient should empty the bladder immediately post procedure.
- Patient should avoid very hot water for at least 2 days after the treatment.
- Patient should avoid mechanical contact with the treated area for at least 2 days.
- After each treatment session, the patient should be advised to contact the physician if there is any indication of infection, excessive swelling, redness, pain, or any other unusual or untoward symptoms.
- The handpiece should be cleaned from the gel and disinfected by 70% alcohol.
- The tip should be disposed of.

## **TREATMENT SCHEDULE**

- The number of treatment sessions depends on the individual patient and is typically 2-3 sessions, every 2-4 weeks but can vary according to patient response.
- Treatment time internally and externally up to 30 minutes may reduce the number of sessions to 1-2, but depends on skin response and patient tolerance.
- Treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion.