

Morpheus8V applicator is a fractional device with programmable penetration depth and energy delivery. Fractional RF energy is delivered through bipolar arrays of micropin electrodes providing sub-epithelial remodeling. Simultaneously, directional RF energy generates bulk sub-necrotic heat in the treated area.

TYPICAL TREATMENT PARAMETERS

- Depth – 1mm, 2mm, 3mm.
- RF Energy – range is from 5 to 60. For 1mm depth range is 5-30

Treatment Areas	Depth	RF Energy Level	Number of Passes
Vaginal Canal	1 – 3 mm	20 - 40	1 – 2 for each depth
Introitus	1 – 2 mm	15 – 20	1 – 2 for each depth

PRE-TREATMENT

- 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.
- Discuss pre- and pos-treatment recommendations.
- Hair should be shaved - not waxed or chemically removed - in the treatment area 2-4 days prior treatment. Remove any jewelry in the treatment area
- The patient should empty the bladder prior to the procedure.
- Position the patient in on the treatment table in a dorsal lithotomy position to provide adequate access to the treatment area.
- Thoroughly clean the treatment area (vulva, vaginal canal, introitus) with disinfecting solution. Ensure that the treatment area is clean and dry from all residue prior to beginning the procedure.
- Perform an exam of the treatment area immediately prior to the procedure to visualize the area that is going to be treated

TREATMENT PROCEDURE

- Prior to the treatment inspect the handpiece and disposable for visible damage.
- Attach the sterile disposable, single use tip to the handpiece before entering the treatment screen to allow calibration. Select parameters according to the table above.
- Slowly insert Morpheus8V handpiece into the vaginal canal up to the depth of 9 cm (according to the cm markings on the handpiece). Small amount of clear ultrasound gel should may be used to allow a more comfortable insertion into introitus.
- Ensure a full contact of the tip with the tissue with slight pressure, before applying the first pulse.
- Press the footswitch to release a pulse. Do not move or reposition the handpiece until pulse LED indicator is switched off and actuator returns to the initial position.
- Continue applying pulses in a circular fashion at the same depth by rotating the handpiece 45° between each pulse (8 pulses) until a full 360° rotation has been completed.
- Retract the handpiece 1 cm and repeat. Continue treatment until 3cm mark is visible.

- Additional passes may be applied per physician discretion.
- For the introitus area reduce the energy according to patient comfort. Topical anesthetics creams might be applied to reduce discomfort.
- A tingling heat sensation may be felt during and after the treatment.

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, unusual discharge or any other unusual or untoward symptoms.
- The detachable tip should be disposed.
- The handpiece should be cleaned from the gel and disinfected by 70% alcohol.

TREATMENT SCHEDULE

- The number of treatment sessions depends on the individual patient and treatment aggressiveness and may vary from 1-5 sessions. Treatments are typically repeated every 3-6 weeks.
- It is recommended to schedule follow-up session 2-3 days after the treatment to ensure safe healing process.
- Treatment should be concluded when the results are satisfactory to the patient or according to the physician's discretion. Generally, 3-5 sessions are needed for mild to moderate depth settings. It is not typical to perform more than five consecutive sessions however more sessions can be performed as per physician discretion. In some instances, 1-2 sessions may be sufficient.