

PATIENT SELECTION FOR TRAINING DAY

Patients should have indications that are FDA approved for your device.

- When consulting with your patients, please inform them that a Lutronic Nurse Educator from Lutronic will be in the room instructing the facility staff and answering any questions from the staff and doctors. They should also be informed that most of these indications are not a “one time” treatment.
- The patients should be given the Consent Form to read and have their questions answered prior to signing the form (see sample form at the end of this document).
- The History and Physical form should be completed at this time to be sure that the patient is a good candidate for treatment and there are no allergies or contraindications (see sample form at the end of this document).
- Pre-treatment photographs should be taken if desired.
- Pre-instructions and Post-instructions should be explained to the patient and any family members that will be involved with the post treatment care. At this time any questions should be answered thoroughly so that on the treatment day the patient will arrive relaxed, comfortable and prepared.
- Medications:
 - If any oral pain meds are given, it is suggested that all patients have someone available to drive them home, and that all prescriptions be filled prior to treatment day.
 - If anti-viral medications have been prescribed by the doctor, it is advised to start the medication the day before treatment.
 - Aspirin or any other anticoagulant products should be discontinued at least 1-2 days prior to treatment.
 - Any required post-treatment skin products should be available so that the patient can go home immediately after their treatment.



PATIENTS THAT ARE NOT GOOD CANDIDATES ARE

- Those who would be unrealistic about their results
- Non-compliant
- Allergic to topical anesthetics
- Have collagen vascular disease or immunodeficiency, history of keloid formation, skin conditions and/or skin diseases
- Are pregnant or are breastfeeding
- Have any type of infection
- We emphatically discourage scheduling paying patients for training day, as it is difficult to freely discuss important topics in front of a patient who has paid for this time and treatment



PATIENT TREATMENTS ON IN-SERVICE DAY

- **Please refer to the above Patient Selection and Preparation criteria, as well as to the Contraindications for Treatment**
- Make sure to complete a full medical assessment of the patient. Check for contraindications and make sure the indications are appropriate for the Lutronic system being used
- No paying patients should be treated during training. Staff, family or friends are ideal patients as this allows for more open conversation and guidance
- **Any staff** that will assist in treatment, treat patients or consult with patients should attend the In-service. **Remember, it is essential that the supervising physician attends the training session!**

CONTRAINDICATIONS FOR TREATMENT

Patients who have had prior problems with radiofrequency therapy should be carefully screened before treatment. Additionally, persons known to form skin keloids may be more prone to scarring after any skin trauma, including RF treatment.

Treatment of Wrinkles with the INFINI RF system should NOT be attempted in patients with:

- Active infection in the treatment area
- Active infection or a history of herpes simplex in the area to be treated
- Use of oral Isotretinoin (e.g., Accutane, others) within the preceding 6 months
- History of keloid formations
- Bleeding disorders or use of anticoagulants before the washout period, per package insert, and at the physician's discretion
- Patient with personal history of melanoma must first pass a skin screening (of area to be treated) by a licensed dermatologist prior to treatment
- Dysplastic nevi in the area to be treated
- History of collagen, vascular or immunosuppressive disorders
- Significant concurrent skin conditions affecting areas to be treated or any inflammatory skin conditions
- Active cold sores (unless pre-treated with anti-viral), open lacerations or abrasions on the area to be treated
- History of immune deficiency (including HIV infection or AIDS)
- Chronic or cutaneous viral, fungal or bacterial infections in the treatment area
- Uncontrolled diabetic complications or other severe medical complications
- Uncontrolled hypertension
- Patients with implanted pacemaker or defibrillator
- Patients with implanted metal pins or prosthetic joints
- Patients with gold allergies
- Patients that are pregnant

PREPARING THE TREATMENT ROOM

- Adjustable treatment table and stool
- Adequate lighting
- Camera for before and after documentation
- No use of mobile telephones or similar appliances, and no persons with pacemakers or defibrillators should be in the room while the INFINI system is in use.
- Documentation forms (included in this In-service Guide)
 - Patient History and Physical Forms
 - Informed Consent Forms

SUPPLY CHECKLIST

- Topical Anesthetic Cream
- 4 x 4 and 2 x 2 gauze pads
- INFINI disposable treatment tips
- Sani-cloths or Cavicide to clean the handpieces between patients
- Cleanser or toner to clean the treatment area
- Towels/washcloths
- Cold packs or ice should be available for cooling robust tissue reaction
- Aloe Vera gel, anti-burn and anti-inflammatory ointment or creams should also be available. Hydrocortisone is discouraged due to side effect of hirsutism and epidermal atrophy.
- Epinephrine soaked swabs for possible pinpoint bleeding
- Surgical gloves

PATIENT TREATMENT – BEFORE, DURING AND AFTER

PRE-TREATMENT

- Cleanse the treatment area
- Apply topical anesthetic cream and incubate according to product manufacturer's instructions.
- Remove anesthetic cream thoroughly and cleanse.
- Clean the treatment area one more time with alcohol.



TREATMENT

- ALWAYS perform Test Spots before full treatment commences
- Once clinical endpoint has been achieved safely, full treatment can be continued
- Frequent checks of patient comfort and tip cleanliness will be made throughout treatment

TREATMENT TECHNIQUE SUMMARY

- Set the desired LEVEL, TIME, AND NEEDLE DEPTH
- Use gentle contact with the tip to the skin surface. The needles are designed to smoothly and swiftly pierce the skin.
- The depth and size of the coagulation zone is adjustable by level or time
- Treatment with one pass is considered the standard treatment.
- Additional passes can be performed where no erythema is observed.
- After a standard treatment, 1-2 passes can be added on problematic areas for better clinical result.
- Using the "pinch technique" provides patient comfort.
- Use lower setting with shallow needle depth.
- Do not use a needle depth of more than 1.5mm on bony areas.
- For better pain control, start treatment in areas of thick skin, then treat thin and sensitive areas.

IMMEDIATELY POST-TREATMENT

- Apply cool compresses to the treated area if desired.
- Apply aloe gel or cooling cream as desired.
- Application of an antibiotic cream and a moisturizing spray is recommended.
- Provide patient with post-treatment instructions.
- Adjunctive light-emitting diode (LED) phototherapy can have very beneficial effects.
- Pinpoint bleeding may occur following microneedling of the skin. To control this, swab any such areas with epinephrine.

POST-TREATMENT PATIENT INSTRUCTIONS

- Postoperative stinging can be alleviated by the application of ice packs or gauze soaked in cold water
- The treated area should be gently washed at least twice daily with mild soap and water
- A crust may form over the treated lesion. Do not rub or forcefully remove the crust, allow crusts to fall off naturally. If a crust is forcefully removed, scarring may occur
- Once the crust has fallen off, immediately start to use sunblock (UVA/B, >SPF30, PA++) on the treated area
- Sunblock should be applied at least 1 hour before going outdoors. Sunblock should be re-applied after going into water and at intervals according to product instructions. Sunblock should be used in treatment area for at least 6 weeks
- Apply a post-treatment moisturizer per physician's recommendation.

EXPECTED SKIN REACTIONS AND RESULTS

- 1 day Post-Treatment: Redness and transient edema, skin begins to turn to a condition similar to before treatment.
- 3 days - 1 week Post-Treatment: Brighter skin tone and significant reduction in sebum secretion in oily skin types.
- 1 month Post-Treatment: Improvement of fine wrinkles and skin laxity.
- 1-3 months Post-Treatment: Continuous improvement of fine wrinkles, pores size, scars and skin laxity.

ADVERSE EVENTS

Expected Sequelae

- Pruritus may occur in rare cases. Contact dermatitis or irritant dermatitis may occur in some cases. Infection at the treatment site can happen with poor hygiene, scratching, or picking
- Irritation, itching, burning or tight sensation. This can be resolved with post-care cooling; LED phototherapy may also help.
- Edema: Transient edema (1 – 2 mm) may be noted in treated areas after treatment. However it will spontaneously resolve after 1~2 days; LED phototherapy may also help.
- Pinpoint Bleeding: Pinpoint bleeding may occur following microneedling of the skin. To control this, swab any such areas with epinephrine.
- A crust may form over the treated lesion. Do not rub or forcefully remove the crust, allow crusts to fall off naturally after a few days. If a crust is forcefully removed, scarring may occur

ADVERSE EVENTS

- Infection at the treatment site: Occasional infections can occur. If not treated promptly, these could result in scarring.
- As with the use of any RF system, scarring is a possibility, but rare.

CLOSING

Thank you for taking the time to prepare for your In-service day. We at Lutronic want to make your training experience a happy one.

Please remember that since lasers are prescriptive devices the Medical Director of the facility must be present for the didactic and at least part of the treatment portions of the training. It is also recommended that the Laser Safety Officer is given the Operator Manual and/or attends the didactic portion of the treatment so appropriate protocols can be formulated for your facility.

Please feel free to contact Lutronic Service, Administration, Sales, or Clinical at 1-888-588-7644 if you have any questions or concerns.

POST-TREATMENT INSTRUCTIONS

- Postoperative stinging can be alleviated by the application of ice packs wrapped in sterile gauze or gauze soaked in cold water
- The treated area should be gently washed at least twice daily with mild soap and water
- A crust may form over the treated lesion. Do not rub or forcefully remove the crust, allow crusts to fall off naturally. If a crust is forcefully removed, scarring may occur
- Once the crust has fallen off, immediately start to use sun block on the treated area
- Sunblock (UVA/B, >SPF30, PA++) should be applied at least 1 hour before going outdoors. Sunblock should be re-applied after going into water and at intervals according to product instructions. Sunblock should be used in treatment area for at least 6 weeks
- Apply a post-treatment moisturizer per physician's recommendation.

EXPECTED SKIN REACTIONS AND RESULTS

- 1 day Post-Treatment: Redness and transient edema, skin begins to turn to a condition similar to before treatment.
- 3 days - 1 week Post-Treatment: Brighter skin tone and significant reduction in sebum secretion in oily skin types.
- 1 month Post-Treatment: Improvement of fine wrinkles and skin laxity.
- 1-3 months Post-Treatment: Continuous improvement of fine wrinkles, pores size, scars and skin laxity.