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## Potenza™ Clinical Reference Guide

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## About the Guide

The purpose of the Potenza Clinical Reference Guide is to provide a summary of treatments and techniques when using the Potenza Radiofrequency (RF) Microneedling System. The clinical suggestions contained within this guide are based on current clinical use. However, they do not substitute for the clinical judgment of the practitioner and the individual patient's needs.

Always refer to Potenza Operator Manual for complete safety information when operating the device, including the following sections:

- Equipment Safety
- Device Operation
- Maintenance
- Care and Handling
- Warnings

## About the Potenza™

Microneedling with the Potenza can help to address the most common aesthetic concerns because of the added benefit of advanced radiofrequency technology.

Potenza delivers thermal energy to deeper tissue, causing tissue contraction. The energy/heat also triggers the body to produce collagen and elastin, resulting in skin tightening through soft-tissue coagulation.

## About the Technology

### Potenza Microneedling System

The Potenza RF microneedling system adds the element of radiofrequency energy to the mechanical microneedling procedure. The RF energy is delivered via small needles. In addition to the benefits seen with the micro-injury provided by the microneedles, RF microneedling also delivers RF energy deep into the dermis, further enhancing skin tightening through soft-tissue coagulation. The RF energy heats the underlying layers, causing constriction and tightening of the skin through soft-tissue coagulation, as well as causing the stimulation of collagen and elastin production. Because the RF energy is delivered so deeply, it can produce faster, more dramatic results.

### Intended Use of the Potenza

The Potenza radiofrequency system is intended for use in dermatologic and general surgical procedures for electrocoagulation and hemostasis.

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### Contraindications

Do not use this product on patients listed below:

- Patients with a pacemaker.
- Patients who have previously had a gold-thread skin-rejuvenation treatment.
- Patients with keloid formation propensity.
- Patients with skin infections.

### Cautionary Criteria

Review these criteria when considering treating patients who:

- Have a cut, wound, or infected skin on the area to be treated (but skin eruptions may be treated).
- Are pregnant and/or breastfeeding (aesthetic application).
- Have a metal implant that interferes with the transmission of energy to the electrical field.
- Have any embedded electronic devices that give or receive a signal; the device should be turned off or removed prior to treatment. Always consult with the health care practitioner before turning off a patient's electronic device.
- Have Implantable Cardiac Defibrillators (ICD) or Cardiac Resynchronization Therapy (CRT) devices: treatment may interfere with the functionality of the device and/or damage the electronic implant.
- Have an embedded Implantable Cardioverter Defibrillator (ICD); the patient's cardiologist must be consulted prior to treatment.
- Have electronic implants without first consulting a qualified professional (e.g., cardiologist or the manufacturer of the electronic implant).
- Are allergic to adhesives such as glues on medical tape: they should be alerted that a rash may occur on the neutral electronic monitoring pad (NEM or neutral pad) site, and an over-the-counter preparation may be used to treat the area.
- Are allergic to gold.
- Have an unrealistic expectation of the results: this is not plastic surgery, and all patients should be fully informed of the treatment's expected results.
- Have nerve insensitivity to heat in the treatment area or in the neutral pad placement area.

- Have severe laxity or sagging that causes redundant folds of tissue or hanging skin in the area to be treated: this treatment will be ineffective.
- Have used Accutane (isotretinoin) six to twelve months prior to treatment, as this can thin the skin and make it brittle.
- Have diabetes or diabetic complications.
- Are taking aspirin or are currently taking antiplatelets, thrombolytics, anti-inflammatories or anticoagulants.
- Have a history of bleeding coagulopathies.
- Are allergic to topical anesthetic.
- Studies have not been conducted on the use of the Potenza System on patients with any of the following conditions:
  - Pregnant and breast-feeding women
  - Autoimmune disease
  - Diabetes
  - Herpes simplex
  - Epilepsy
  - HIV
  - Hypertension
  - Dermatitis

## **Precautions**

For all microneedling with fractional RF, treatment is cautioned for patients that meet the following criteria. A doctor's approval should be obtained before treating with the Potenza who:

- Are prone to fever blisters: they should receive a prophylactic antiviral medication regimen prior to treatment.
- Have lesions in the treatment area that have not been evaluated and diagnosed: they should be evaluated prior to the treatment day.
- Have malignant disease including skin malignancies. Precautions should be taken if a person has any other form of a malignant disease (cancer).
- Have used retinoids in the last seven days in the area to be treated: retinoids can create erythema and cause the skin to become heat sensitive.
- Have used any chemical peels in the last two to three months in the treatment area: patients should wait until any remaining erythema or side effects have resolved.
- Have tattoos, permanent makeup, and permanent brows in the treatment area: caution must be used. (The ink used in these applications is unregulated and may have metallic components.)



- Have an autoimmune disease.
- Avoid medications that alter the healing response or hemostasis for three to seven days.
  - Always check with the prescribing physician before stopping any medications.
- Have a history of healing problems.
- Have a neuropathic disorder, impaired skin sensation or diabetic neuropathy.
- Have an Implanted Cardioverter Defibrillator (ICD): the patient's cardiologist must be consulted prior to treatment.
- Have received fillers or neurotoxin injections: patients should wait two weeks before receiving a Potenza treatment.

## **Screening Evaluations**

Not all patients are candidates for this treatment. Please read through this section carefully and present any questions or concerns to the Cynosure Clinical Department, 844-365-5060 or [cynosureclinicalsupport@cynosure.com](mailto:cynosureclinicalsupport@cynosure.com).

All patients who fall into any of the foregoing cautionary criteria shall be informed of the pre- and post-treatment recommendations, as well as any cautions or warnings associated with the criteria prior to beginning treatment.

## **Tissue Guidelines**

- Post-menopausal women may have decreased elasticity in their skin. The results of treatment may be favorable but could potentially not last the same amount of time as they would for non-menopausal women.
- Over time, patients who smoke may see results diminish more quickly than nonsmokers' results. Smokers may also be more sensitive to heat.

## **Patient Pre-treatment Guidelines**

- Keep hydrated by drinking water (at least eight cups daily) or hydrating fluids to improve treatment outcomes.
- Avoid drinking alcohol for 24 hours in advance of treatment.
- For seven days prior to treatment, at the physician's discretion, avoid therapies that may cause erythema (redness) or irritation, such as retinols or products containing isotretinoin or any exfoliating acids.
- Shave visible hair from the treatment area.
- Male beards should be shaved on the day of treatment.
- The same procedure should be followed prior to each visit.

## **Patient Documentation Forms**

Patient documentation is important for tracking the progress of any energy-based treatment. Samples of Consent Forms, Treatment Records and Pre-treatment and Post-treatment Instructions are provided for your convenience in the “Sample Documentation” section of this manual.

Informed Consent forms document the process of accepting and confirming treatment and must be reviewed, understood and signed by the patient prior to treatment. These forms must review the topics discussed during consultation and acknowledge that all questions have been answered and that the patient understands the treatment.

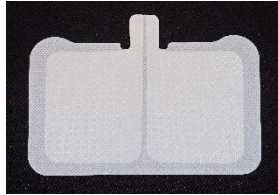
Always review the Pre-treatment and Post-treatment Instructions and confirm that the patient will adhere to such instructions throughout their treatment course. Determine the need for medications or creams to be used pre-treatment and/or throughout the course of treatment.

Treatment Records track treatment information throughout the treatment course, such as fluence, as well as number of pulses used.

### Day of Treatment Guidelines

- Supplies: anesthetic ointment, gauze sponges, ice packs, cool roller, normal saline and medical-grade disposable gloves.
- Take pre and post photos of treatment area.
- Medical history form completed by patient and reviewed by the practitioner.
- Discuss cautions and warnings with the patient to ensure that they are a good candidate for the treatment.
- Discuss the treatment with the patient so they know what to expect, what the discomfort levels may be, how long the treatment will last and the potential side effects.
- Informed consent signed by patient.
- Remove jewelry and any metal such as belts, etc., adjacent to the treatment area.
- Remove electronic devices, any metal items, i.e., keys or coins, from pockets or patient's possession.
- Cleanse the facial area prior to treatment, taking care to remove all makeup, including eye makeup and any lotions or sun block.
- At the patient's request, a topical anesthetic may be applied. (Always apply according to written instructions.)
- If anesthetic is applied topically, have patient wait for 30-45 minutes or per label instructions.
- Thoroughly remove the topical anesthetic before treating.
- Provide final cleansing of the treatment area with alcohol or acetone.
- Ensure that the skin surface is completely dry before treatment.
- For monopolar treatments, a neutral pad is needed.
- Make sure footswitch is connected.
- The practitioner must wear medical-grade, disposable, non-sterile gloves.
- Be sure to place the device into standby mode when not in use.

## Neutral Pad Information and Application



**Neutral Electronic Monitoring Pad**

Neutral electrode pads or ‘NEM pads’ are one-time use, disposable grounding pads.

- To avoid adverse results, the disposable neutral pad must only be used once. Dispose of neutral pad after treatment is completed.
- The neutral pads have dispersive electrodes that direct the displacement current and act as a circuit completion path. This prevents thermal damage to the underlying tissue.
- When treating with monopolar RF, the neutral pad must be used.
- Shave excess hair where neutral pad will be affixed before application.
- Do not cut or modify the neutral pad or its connector in any way.
- The neutral pad should be placed close to the treatment area, i.e., for abdominal treatment, place the neutral pad on lower back; for face treatments, place it on the upper back.
- The neutral pad requires direct skin contact. Consistency in where the neutral pad is placed for each type of treatment will help to maintain more standard energy delivery.
- Select an area that is free of tattoos and has minimal curvature.
- Before attaching the neutral pad, cleanse the skin with 70% isopropyl alcohol. Allow the skin to dry. When attaching the neutral pad, apply it on the flattest surface of the intended site. Firmly press to adhere it to the skin and then smooth it out to ensure that the neutral pad is in full contact with the skin and that there are no wrinkles present on the pad.
- Open clip at end of neutral cable and insert the neutral pad tab; secure by closing the clip over the tab.
- Verify proper neutral pad placement and connections before increasing power.
- Regularly check that the neutral pad cable connections are intact.
- A patient’s report of excessive heat may be an indication that (1) the pad is not in full contact with the skin; (2) there is perspiration under the pad; or (3) the pad is not fully adhered to the skin.
- If you note heavy perspiration under the pad, remove the pad, cleanse the skin with 70% isopropyl alcohol, and dry the skin. Attach a new neutral pad before continuing treatment.

- It is recommended that you check the patient to ensure that no unintended burns have occurred and that the treatment is still safe before continuing.
- If injury is noted, dress the area using a standard protocol of care and apply a new pad to another area before continuing treatment.

**WARNING: To help prevent a patient burn when using a Neutral Pad in Monopolar mode, the patient should be advised to alert the staff should the pad become too hot, or if the patient feels hot spots under the pad. If complaints of heat are made, immediately stop treatment and evaluate the location of the neutral pad. If lifting from skin or patient is diaphoretic, remove pad, assess tissue and treat per protocol if a burn is noted. Dry the area and reapply a new neutral pad to new, adjacent area.**

## Potenza Operation

- Be sure that all cables have been connected into the correct ports before using the device. Connect the handpiece and footswitch. NOTE: the neutral pad will be needed for monopolar treatments only.
- Turn on the device; select the desired mode; select the recommended HP; and attach the tip to the end of the handpiece. Select watts and pulse width. Initiate treatment by sliding or tapping the standby button to treat prompt.

## Differences in 1 MHz and 2 MHz and Monopolar and Bipolar Mode

### 1 MHz

Deeper and wider treatment area  
More comfortable

### 2 MHz

Focused targeting  
More aggressive treatment

### Monopolar

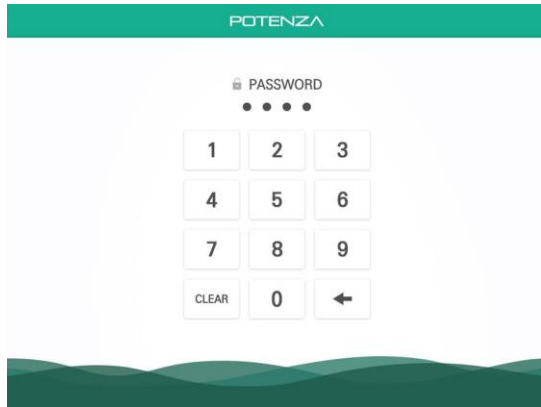
Deep and wide treatment area  
Tissue depth: superficial to deep dermis  
Tissue interaction intent: denaturation  
Suitable for: revitalization and skin tightening  
through soft-tissue coagulation  
Less painful; shorter downtime

### Bipolar

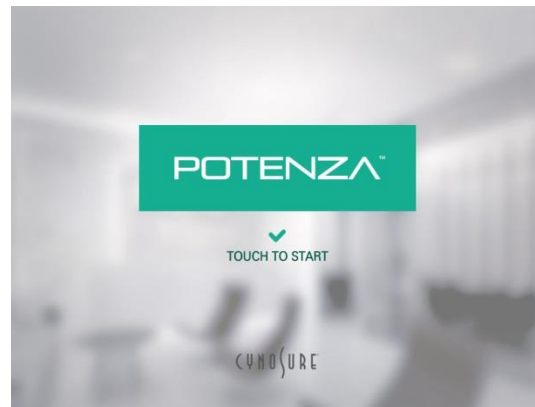
Accurate targeting  
Tissue depth: mid dermis to deep dermis  
Tissue interaction intent: coagulation  
Suitable for: skin tightening  
through soft-tissue coagulation  
More aggressive treatment; longer downtime

## Potenza Treatment Screens

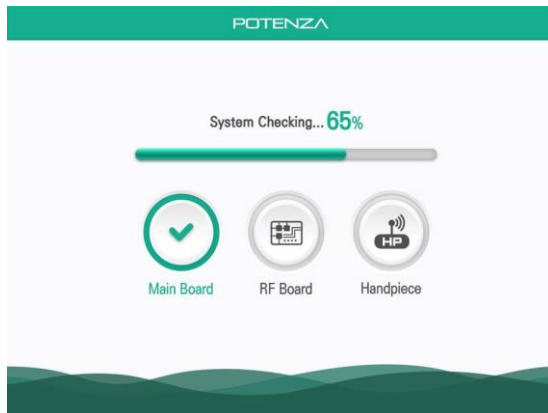
NOTE: The screens shown in this manual may be subject to change due to software upgrades.



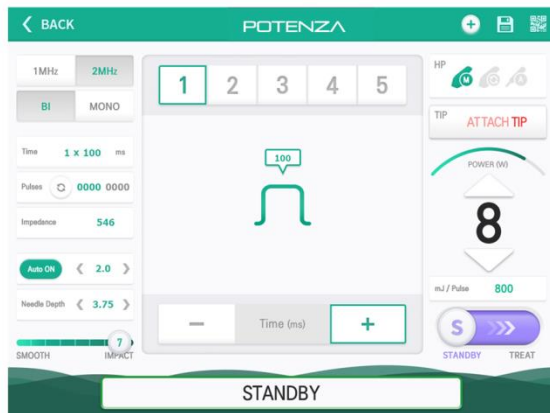
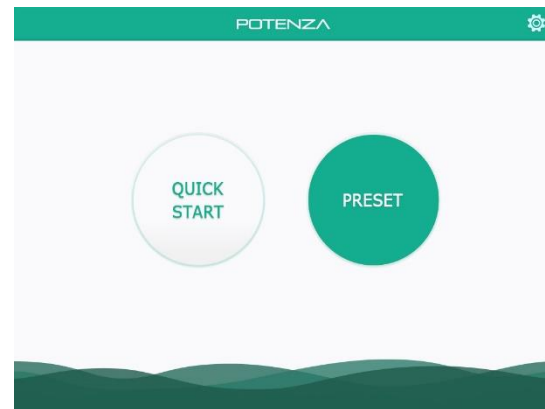
**Enter Password: 1111**



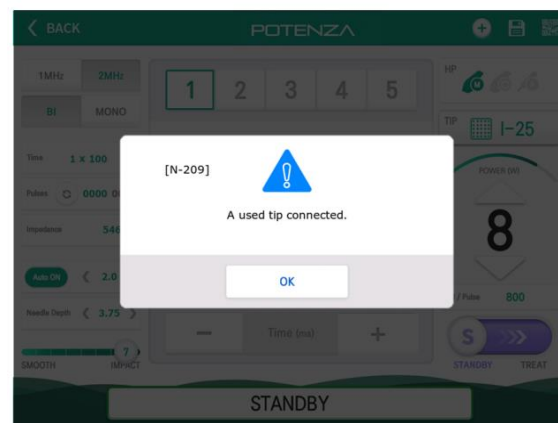
**Press ✓ to Start**



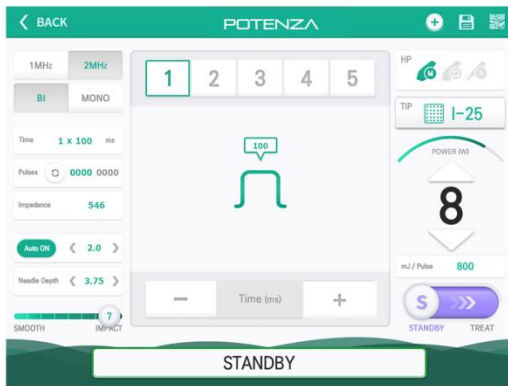
**Device System Check  
Select Quick Start or Preset**



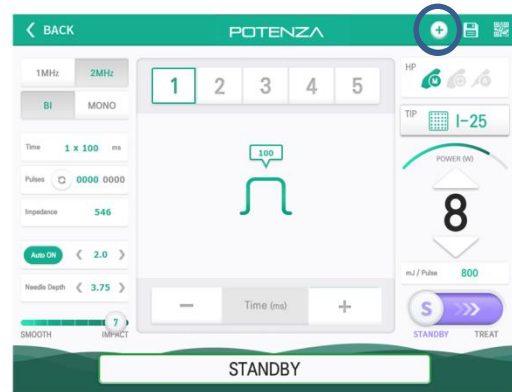
**Treatment Screen: No Tip Attached**



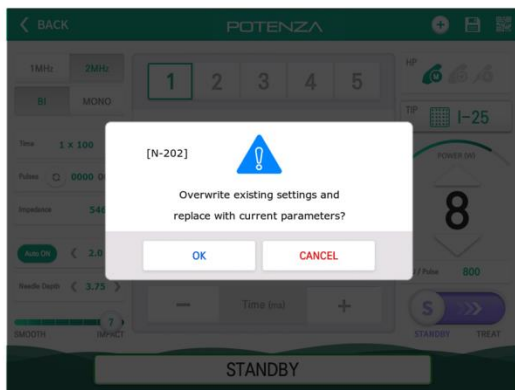
**Warning: Used Tip Attached**



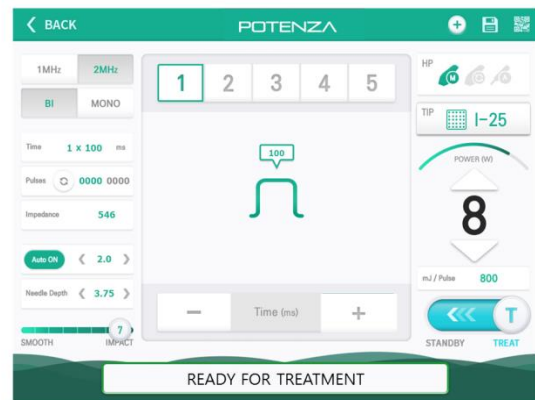
**Settings Selected; Device in Stand By**



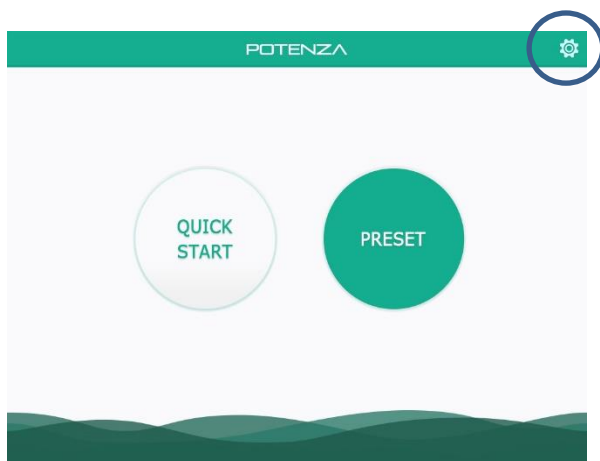
**Zone Selected for Preset; Press +**



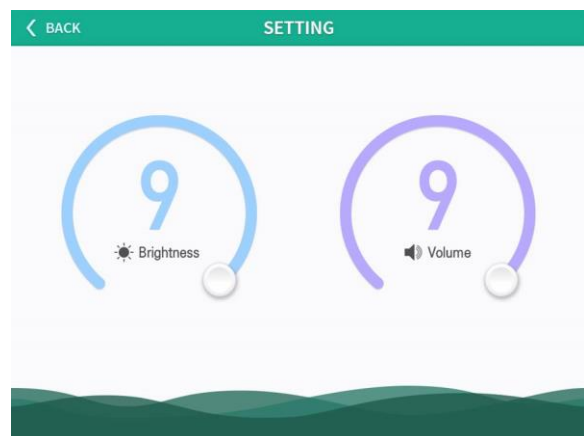
**Select and Name Preset**



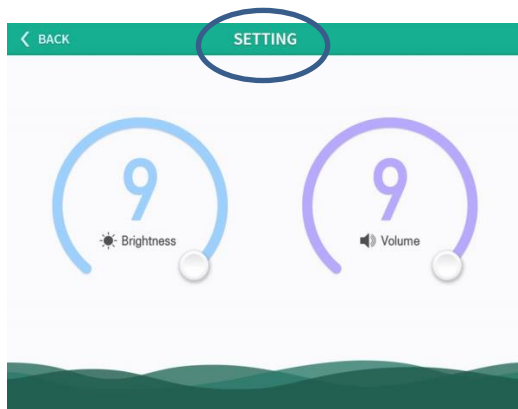
**Preset Selected and Ready for Treatment**



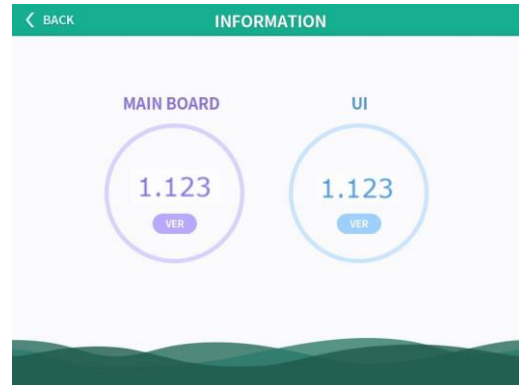
**Press Settings Button**



**Adjust Volume and Brightness**



**Press and Hold Until Screen Advances**



**View Current Software Version**

## Impedance

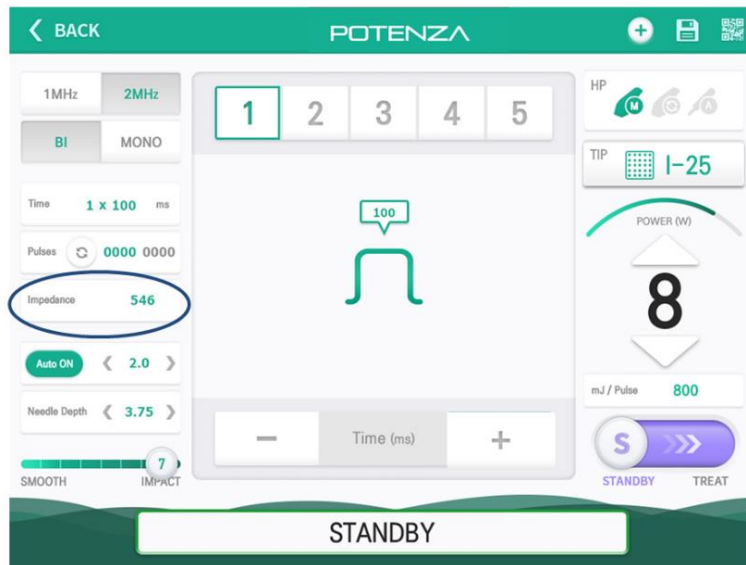
NOTE: Proper Impedance reading during a treatment should be 600 ohms or less. RF energy may be inefficient if the impedance reads more than 600 ohms on the graphic user interface, also known as the 'GUI'.

Impedance is a measurement of resistance within the tissue. Potenza provides real-time impedance monitoring that helps achieve and maintain optimal therapeutic RF delivery. Potenza also makes instant adjustments for optimal energy delivery.

If the impedance reading is more than 600 ohms:

1. Confirm that the tissue is properly hydrated.
2. Assure that the tip is flush (perpendicular) on the skin.
3. Increase or decrease the pressure of the tip on the tissue.
4. Increase the depth of the needle by 0.25 mm increments.
5. Switch from monopolar to bipolar mode.
6. Choose a tip with a greater number of needles (e.g., from 16 to 25).
7. Keep the tissue taut and increase the impact of the needles.





## Tip and Handpiece Selection

In Quick Start Mode, handpiece, tips and treatment parameters need to be appropriately selected for each area, according to the purpose of treatment. Please refer to Skin Depth table. Desired settings may be saved in the Preset option. (For more in-depth information on Presets, consult the Potenza Operator Manual.

Select the Motor (M) handpiece icon on the top right of GUI screen when using any multi-needle tip:

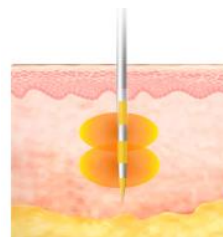
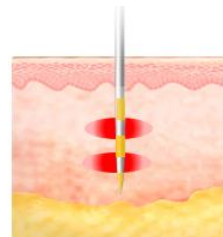
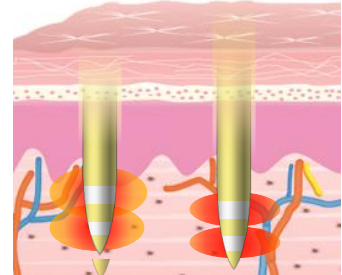


## Motorized Needle Tips

### Treating with Semi-Insulated RF Needles (S-Tips)

- For use with the motor handpiece.
- S-Tips are single use, semi-insulated electrode needles.
- Two areas (each 0.25 mm) of the electrode are uninsulated.
- Allow for simultaneous treatment of epidermis and dermis.
  - This allows for two horizontal areas of coagulation in one pass.
  - 25% overlap may be performed utilizing the single pass method.
- S-Tips can be used in bipolar or monopolar modes.
  - S-Tips are pre-loaded with a 1000 pulse count per tip.
- Treating with higher watts (W) and a shorter pulse width (PW):
  - Provides a focused delivery of energy (heat) at two depths.
  - Creates focused areas of heat diffusion with higher temperatures.
- Treating with lower watts (W) and a longer pulse width (PW):
  - Creates larger areas of energy diffusion.
  - Works at a lower temperature.
  - When treating with the S- tips, treat at a depth of 1.5 mm or deeper, especially when utilizing monopolar mode.
  - To induce coagulation at four different depths, a 0.25 mm difference of depth between the first and the second pass is needed.
  - When a two-pass approach is used, it is not recommended to perform a 25% overlap. 25% overlap should only be used when performing a single pass.

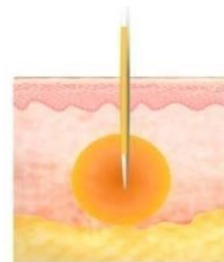
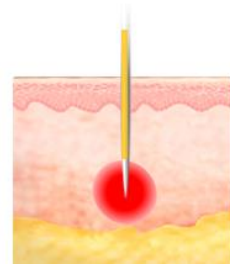
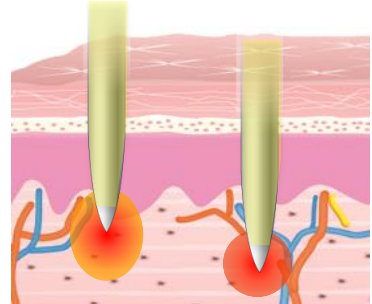
Use **Semi-Insulated** needle tips for increased coverage in a single insertion.



## Treating with the Insulated RF Needles (I-Tips)

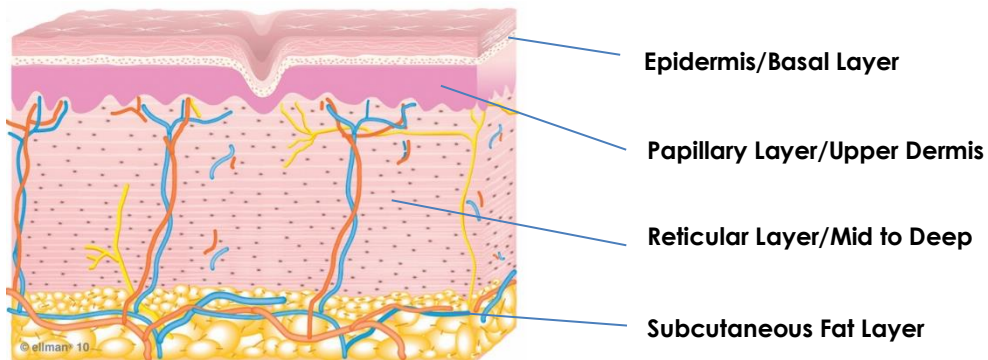
- Use with the motor handpiece.
- Insulated tips are single use and have insulation on the length of the needle shaft down to the end of the tip, which is uninsulated.
- The tip (0.3 mm) of the electrode needle is uninsulated.
- Perfect for precise, lateral energy delivery at any depth in bipolar or monopolar mode.
- I-Tips are pre-loaded with a 1000 pulse count per tip.
- Easily maintains impedance readings below 600 ohms.
- Treating with higher watts (W) and a shorter pulse width (PW):
  - Provides a focused delivery of energy (heat) at a set depth.
  - Creates focused areas of heat diffusion with higher temperatures.
- Treating with lower watts (W) and a longer pulse width (PW)
  - Creates larger areas of heat diffusion (energy)
  - At a lower temperature
- Less risk of skin surface side effects.
- Direct energy delivery to the dermis.

**Use Insulated** needles for deep (bipolar) treatments and targeted areas at superficial (monopolar) depths



# Tissue Anatomy

## Skin Layers



## Progressive Characteristics of Aging:

### Early Signs of Aging: 20s-30s

Tissue depth 0.50 mm to 0.75 mm:

- Fine facial lines
- Dullness
- Enlarged pores
- Freckles or light-brown benign pigmented areas

### Advanced Signs of Aging: 40+

Tissue depth 0.75 mm to 1.50 mm:

- Tissue laxity
- Fine facial lines
- Skin textural changes

Tissue depth 1.50 mm to 2.0+ mm:

- Deeper etched facial lines
- Facial folds
- Drooping and sagging tissue
- Fibrotic tissue

### Skin Blemishes

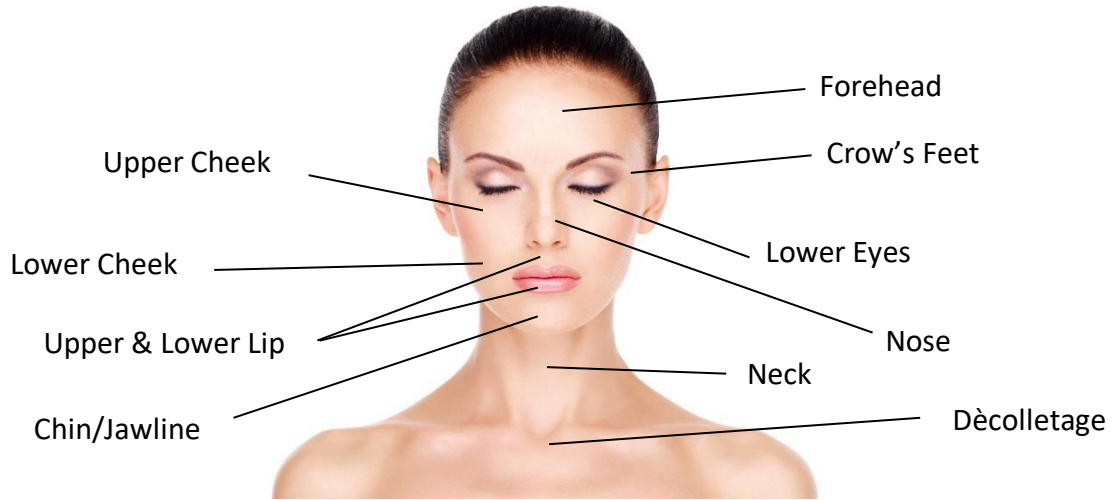
Depth 1.50 mm.

### Abdominal Tissue

Tissue Depth: 1.75 mm to 4.00 mm.

- Laxity

## Treatment Areas



Abdomen (not shown)

## Skin Depth

Area	Average Thickness (mm)	Max Thickness* (mm)
Forehead <sup>1</sup>	1.27	2.19
Crows Feet <sup>1</sup>	1.29	2.95
Lateral Brow <sup>1</sup>	1.20	2.53
Lower Eyelid Tear Trough <sup>1</sup>	1.27	2.21
Nose <sup>1</sup>	1.55	2.60
Chin <sup>1</sup>	1.21	2.05
Upper Cheek/Cheek Bone <sup>1</sup>	1.09	1.93
Mid/Lower Cheek <sup>1</sup>	1.34	2.21
Upper Lip <sup>1</sup>	1.50	2.75
Jowl Area/Jawline <sup>1</sup>	1.03	2.24
Lateral Neck <sup>1</sup>	1.47	2.74
Medial Neck <sup>1</sup>	1.28	2.42
Dècolletage	2.00	2.00
Abdomen <sup>2, 3</sup>	2.24	3.20

\*Max thickness for all areas except abdomen calculated from mean and standard deviations to encompass 95% of the sample population.

1) Chopra K, Calva D, Sosin M, et al. A Comprehensive Examination of Topographic Thickness of Skin in the Human Face. *Aesthetic Surgery Journal*. 2015;35(8):1007-1013. doi:10.1093/asj/sjv079.

2) Jain S, Pandey K, Lahoti A, Rao P. Evaluation of skin and subcutaneous tissue thickness at insulin injection sites in Indian, insulin naïve, type-2 diabetic adult population. *Indian Journal of Endocrinology and Metabolism*. 2013;17(5):864-870. doi:10.4103/2230-8210.117249.













3) Gibney MA, Arce CH, Byron KJ, Hirsch LJ. Skin and subcutaneous adipose layer thickness in adults with diabetes at sites used for insulin injections: implications for needle length recommendations. *Current Medical Research and Opinion*. 2010;26(6):1519-1530. doi:10.1185/03007995.2010.481203

## Treatment Recommendations

NOTE: Refer to the Skin Depth table to select the appropriate treatment depth for the desired treatment area.

- Always secure the NEM pad to the patient when using the Monopolar mode or single needle tips.
- Be sure to check the RF mode (Monopolar/Bipolar) before initiating treatment.
- Generally, aged tissue is thinner, and younger tissue is thicker; set depth accordingly.
- Before starting a full treatment, always perform two to three test spots at the selected sites.
- For the I-tips and S-tips, apply 3-4 test spots using higher watts with a shorter pulse width, such as 20 W and 50 ms.
- For the I-tips and S-tips, apply 3-4 test spots with lower watts with a longer pulse width, i.e., 6 W and 150 ms.
- For the I-tips and S-tips, adjust settings as needed.
  - Appropriate clinical end point should result in mild tissue edema, mild erythema, and trace pinpoint bleeding.
  - Tissue that reacts with severe edema, erythema, or pinpoint bleeding indicates settings are too aggressive and should be decreased.
  - Reapply test spots until appropriate tissue reaction is achieved.
- For the CP-21 tip, apply 3-4 test spots at 23W and 110ms. Adjust settings as needed.
  - Appropriate clinical end point should result in more moderate tissue edema, erythema, and trace pinpoint bleeding.
  - Tissue that reacts with severe edema, erythema, or pinpoint bleeding indicates settings are too aggressive and should be decreased.
  - Reapply test spots until appropriate tissue reaction is achieved.
- Select and use the setting most preferred by the patient.
- Deliver one to two pulses to the tissue and note pain score.
- Pain scores of  $\leq 4$  out of 10 are acceptable and tolerable.
- Keep in mind that pain scores are highly subjective and can vary between anatomical sites and areas of thinner or thicker tissues.
- Also note that the pain sensation stems mostly from the mechanical needles and less so from the RF dose.
- Begin facial treatments on the lateral cheek: this helps acclimate the patient to the procedure sensation.
- When treating facial tissue, be sure to decrease the depth of needle penetration for areas with thinner tissue, i.e., eye area or forehead.
- A minimum of 300-500 pulses is recommended for each pass when treating the face.
- Increase the needle depth for areas with thicker tissue, i.e., mid cheek or abdomen.

## Treatment Tip Types

Tip ID	TIP Image (not to scale)	Number of Needles	Depth	Treatment Area
<b>S-25</b>  25 Semi Insulated		25	0.5 mm to 4.0 mm 0.25 mm increments	8 mm x 8 mm
<b>I-25</b>  25 Insulated		25	0.5 mm to 4.0 mm 0.25 mm increments	8 mm x 8 mm
<b>S-49</b>  49 Semi Insulated		49	0.5 mm to 4.0 mm 0.25 mm increments	8 mm x 8 mm
<b>I-49</b>  49 Insulated		49	0.5 mm to 4.0 mm 0.25 mm increments	8 mm x 8 mm
<b>AI-15</b>  1 Insulated		1	1.5 mm fixed	1 point
<b>CP-21</b>  21 Cushion Plus		21	0.5 – 2.5 mm 0.25 mm increments	Ø 5.4

## Attaching the Microneedle Tips



A. Insert the tip onto the end of the handpiece, twisted 20 degrees counterclockwise from the center.



B. To secure tip, turn it clockwise until it clicks.



C. Before the treatment, check that the tip is properly connected to the handpiece.

## Test Spots

Test Spots are recommended prior to treatment to determine patient suitability and tolerability to treatment. Darker skin may require 48-72 hours for the test spot to be assessed. Utilize the Pain Scale in the Appendix when assessing the patient's tolerance. A reported score of four (4) or lower is appropriate.

When treating with the I-tips and S-tips, start with three to four (3-4) pulses using 20W/50ms and appropriate needle depth on one area (preauricular) and document client's comfort score. On the contralateral side (preauricular) use 6W/150ms with appropriate needle depth delivering three to four (3-4) pulses and documenting the comfort score. Never apply test spots or initiate full treatment at the mid face area. Start treatment at the outer cheek area.

When treating with the CP-21 tip, start with three to four (3-4) pulses using 23W/110ms and appropriate needle depth on one area (preauricular). Observe the endpoint tissue response and document the client's comfort score. Tissue that reacts with severe edema, erythema, or pinpoint bleeding indicates settings are too aggressive and should be decreased. Adjust settings appropriately. Never apply test spots or initiate full treatment at the mid face area. Start treatment at the outer cheek area.

A moderate power setting (W) and shorter pulse duration (ms) seem to be well tolerated by most clients. Others prefer a lower power setting (W) and longer pulse width (ms). Use the setting that is best suited by the client to perform the desired treatment. Adjust the power (W) or pulse width (ms) as needed. Take care to decrease or increase needle depths that correspond with depth of the tissue being treated, especially when treating the facial area. If immediate or severe swelling, scabbing, crusting or burns presents, decrease settings and re-evaluate tissue.

The expected outcome of test spots includes mild to moderate edema and erythema, and minimal pinpoint bleeding.



## Treatment Intervals and Sessions

<b>S-25</b> <b>S-49</b> <b>Skin Tightening</b> <b>Though Soft-</b> <b>Tissue</b> <b>Coagulation</b>	<ul style="list-style-type: none"><li>• 3-5 Sessions</li><li>• 4-6 week treatment intervals</li><li>• 1 Stacking</li><li>• 1-2 Passes</li></ul>
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<b>I-25</b> <b>I-49</b> <b>Revitalization</b>	<ul style="list-style-type: none"><li>• 3-5 Sessions</li><li>• 4-6 week treatment intervals</li><li>• 1 Stacking</li><li>• 1-2 Passes</li></ul>
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Patients may notice some improvement after the first or second treatment. More significant results occur after two to three treatments, spaced approximately four to six weeks apart. Skin will continue to improve during the next 6 to 12 months post treatment. Patients are encouraged to follow a skin care regimen suitable for their age and specific problems. RF microneedling results will vary from patient to patient. For the CP-21 Tip, refer to Chapter 5.

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## Chapter 4 I Tip and S Tip on Motor Handpiece

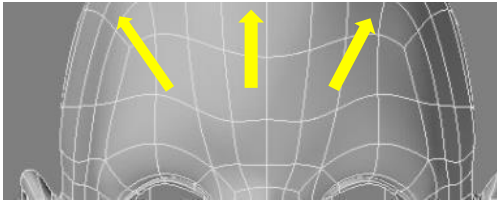
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### Treatment Procedure

- Patient should fill out a Medical History Intake Form and sign the informed consent.
- Discuss the procedure with the patient; provide pre-treatment and post-treatment instructions.
- Remove all make up, lotions and jewelry from the treatment area. The treatment must be performed on clean, dry, intact skin.
- Topical anesthetic may be used at the discretion of the treating physician. Make sure after the designated time, the topical cream is removed, and the skin is cleansed with alcohol or acetone prior to treatment.
- Refer to the Multilayer Techniques tables in this Clinical Reference Guide.
- Select the appropriate needle tip according to the treatment type and treatment area.
- Attach the tip into the handpiece.
- If monopolar mode is used, attach to neutral pad between the shoulder blades for facial/neck treatments and lower back for abdominal treatment. To ensure good contact, cleanse the area with 70% isopropyl alcohol to remove any lotions or body oils.
- Set the frequency (MHz), RF mode (bipolar or monopolar), needle depth and power (W), following the recommendations found within the Multilayer Techniques tables.
- Perform test spots as recommended.
- Clinicians may perform one to two extra passes on problematic lines or other target areas for better clinical results, depending on patient tolerance and skin condition.
- It is recommended that the needle depth should be set to 0.5 mm to 0.75 mm for areas where the skin is thin or close to the bone (forehead, cheekbones, around the eyes, etc.). If the needle is set too deep for these areas, bruising or erythema may occur.
- When treating the periocular area, even if the needle depth is less than 1.5 mm, bruising may occur if a blood vessel is penetrated.
- When performing the treatment on the nose, with your free hand, use a tongue depressor to support nose tissue so that there is no space between the tip and the skin of the nose. The needles **must** be inserted perpendicular to the skin.
- Depending on the treatment mode, the recommended needle penetration depth and settings are set differently for each zone.
- All Potenza tips are disposable and cannot be reused.
- Treatment should be initiated at the outer cheek area, working towards the center of the face.
- For enhanced needle insertion, with fingers, stretch tissue taut before delivering treatment.
- Follow the Directional Guidelines to optimize the treatment.

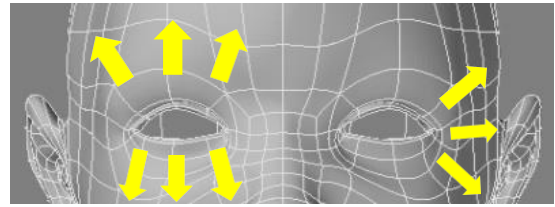
## Directional Guidelines

### 1. Forehead



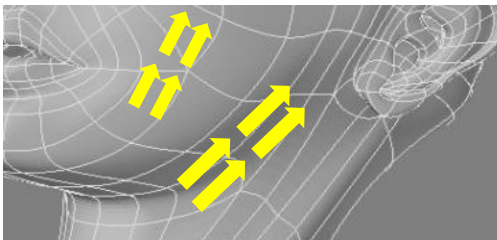
Gently pull the tissue upward on the forehead.

### 2. Around the Eyes



Gently pull the skin outward from the eyes.

### 3. Cheek and Jawline



### 4. Neck



Gently pull the tissue in the direction of the arrows. Deliver the RF energy moving in the same direction. Do not treat over the vocal cords or large blood vessels.

It is good practice to never treat directly over neck structures like the trachea or thyroid areas with any device. That tissue can still be treated by gently pulling the tissue off the structure and then applying the energy.

**NOTE:** If a patient complains of severe pain during treatment, the operator should stop treatment immediately and consult with a physician.

**NOTE:** If immediate and severe swelling of the skin occurs during treatment, stop the treatment immediately.

**NOTE:** If a burn occurs on skin surface during treatment, stop treatment immediately and provide appropriate care to the area.

**NOTE:** If an adverse event or unanticipated results or side effects occur, please report the issue to [cynosureclinicalsupport@cynosure.com](mailto:cynosureclinicalsupport@cynosure.com) or call 844-365-5060.

## Treatment Protocol

- Always use a new, sterilized, single-use, disposable tip.
- Check the packaging for damage and a valid expiration date before use; never use an expired tip or one from a damaged package.
- Apply moderate handpiece pressure before delivering RF energy to the tissue.
- Needles are designed to smoothly and swiftly pierce the skin.
- Always hold handpiece perpendicular to the skin.
- Typical treatments start with the deepest pass first, followed by shallower passes. When adjusting your depths, it is advised to change by .25mm increments within the treatment zone. Determine tissue depths by referencing the Skin Depth table.
- Skin thickness varies considerably from person to person and from one area to another.
- Depth settings should be adjusted to stay within the dermis, except when specifically targeting deeper tissue.
- With each pulse, always wait for the needles to completely retract before lifting the handpiece off the skin.
- Use gauze moistened with normal saline or sterile water to remove any pinpoint bleeding after completing each pass in each region.
- Allow adequate time, one to two minutes, before applying an additional pass to same area.
- For patient's comfort, provide dental rolls or gauze moistened with water when treating over dental appliances or implants. Use a tongue depressor to isolate the areas of treatment, i.e., the nose.

NOTE: Decrease energy setting (W) if severe edema is evident within minutes after energy delivery or the entire square footprint of the needle tip is visible on the tissue.

NOTE: If the patient develops hyper- or hypopigmentation post treatment, treatment should be discontinued, and the side effects should be treated.

# Multilayer Techniques Using Monopolar and Bipolar Modes

## Recommended Parameters Treating with I-Tips Revitalization Using the I-Tips

Always note and document the mJ/pulse before initiating treatment.

Test spots are recommended prior to treatment to determine patient suitability.

The following parameters are suggested starting settings and may be adjusted based on the physician's discretion, test spot results, the patient's skin condition (including its hydration and tissue thickness), and the location of the area being treated.

Moderate to severe skin conditions may take a series of treatments to achieve an optimal outcome; results may be seen several weeks to months after the final treatment.

**Frequency (MHz), pulse width (ms), and power (W), may all be adjusted based on patient's comfort scores.**

### PASS 1

#### PASS 1

**The goal is to deliver approximately 800-1000mJ/pulse.  
The total mJ/pulse will be displayed on the bottom right corner of the screen.**

Treat the deeper dermis using the Bipolar mode.

- Bipolar may be more uncomfortable in the upper dermis.

Start by using the highest power (W) and a short pulse width (ms). 20W/50ms will deliver 1000 mJ/pulse.

- If tolerated, continue to treat all remaining areas in the \*deeper dermis.

To use a lower power with a longer pulse width (ms), try 6W/150ms to deliver 900 mJ/pulse.

- If tolerated, continue treating the remainder of treatment areas in the \*deeper dermis.

If needed, continue to adjust power (W) or pulse width (ms) as long as the total equals 800-1000 mJ/pulse.

Take care to decrease or increase needle depths to correspond with depth of the tissue being treated.

**Treating at power greater than 30 watts or 1000 mJ/pulse puts the patient at a risk for adverse events and is not recommended.**

Pass	Target	*Depth (mm)	Mode	Frequency	Power	Pulses & PW	Impact	mJ/Pulse
Pass 1	Deeper Dermis	1.5-2.0+	Bipolar	1-2 MHz	6-20W	1 Pulse 50-150 ms	3-4*	800-1000

## Recommended Parameters Treating with I-Tips Revitalization Using the I-Tips

### PASS 2

#### PASS 2

**The goal is to deliver 450-800 mJ/pulse for the second pass.  
The total mJ/pulse will be displayed on the bottom right corner of the screen.**

Treat in Monopolar mode.

Start by using the highest power (W) and the shortest pulse width (ms). 20W/40ms will deliver 800 mJ/pulse.

- If tolerated, continue to treat all remaining areas in the \*\*upper dermis.

To use lower power (W) with a longer pulse width (ms), try 5W/100ms which equals 500 mJ/pulse.

- If tolerated, continue treating the remainder of treatment area in the \*\*upper dermis.

If needed, continue to adjust power (W) or pulse width (ms) as long as the total equals 450-800 mJ/pulse.

No more than a 10% overlap is recommended.

Choose lower impact settings (3-4) for tissue less than 1.5 mm, i.e., eyes, forehead, etc.

Take care to decrease or increase needle depths to correspond with depth of the tissue being treated.

**Treating at power greater than 30 watts or 1000 mJ/pulse puts the patient at a risk for adverse events and is not recommended.**

Pass	Target	**Depth (mm)	Mode	Frequency	Power	Pulses & PW	Impact	mJ/Pulse
<b>Pass 2</b>	Upper Dermis	0.75-1.0	Monopolar	1 MHz	5-20 W	1 Pulse 40-100 ms	3 -4	450-800

## Recommended Parameters Treating with the S-Tips

### Deep Tissue Tightening (as a Result of Soft Tissue Coagulation) Using the S-Tips

Always note and document the mJ/pulse before initiating treatment.

Test spots are recommended prior to treatment to determine patient suitability.

The following parameters are suggested starting settings and may be adjusted based on the physician's discretion, test spot results, the patient's skin condition (including its hydration and tissue thickness), and the location of the area being treated.

Moderate to severe skin conditions may take a series of treatments to achieve an optimal outcome; results may be seen several weeks to months after the final treatment.

**Frequency (MHz), pulse width (ms), and power (W), may all be adjusted based on patient's comfort scores.**

#### PASS 1

##### PASS 1

**The goal is to deliver approximately 800-1000mJ/pulse.**

**The total mJ/pulse will be displayed on the bottom right hand corner of the screen.**

Treat the \*deeper dermis using the Monopolar mode.

Start by using the highest power (W) and the shortest pulse width (ms). 20W/50ms will deliver 1000mJ/pulse.

- If tolerated, continue to treat all remaining areas in the \*deeper dermis.

To use lower power (W) with a longer pulse width (ms), try 6W/150ms to deliver 900mJ/pulse.

- If tolerated, continue treating the remainder of treatment areas in the \*deeper dermis.

If needed, continue to adjust power (W) or pulse width (ms) as the total equals 800-1000mJ/pulse.

Consider treating the neck and abdominal areas with the S-Tip delivering one dense pass with ~25% overlap at an appropriate depth and energy. This method helps to prevent long healing times and associated textural irregularities.

Take care to decrease or increase needle depths to correspond with depth of the tissue being treated.

**Treating at power greater than 30 watts or 1000 mJ/pulse puts the patient at a risk for adverse events and is not recommended.**

Pass	Target	*Depth (mm)	Mode	Frequency	Power	Pulses & PW	Impact	mJ/Pulse
Pass 1	Deeper Dermis	1.75-3.0+	Monopolar	1-2 MHz	6-20W	1 Pulse 50-150 ms	4-7	800-1000



## Recommended Parameters Treating with the S-Tips

### Deep Tissue Tightening (as a Result of Soft Tissue Coagulation) Using the S-Tips

The second pass is optional and is recommended when no overlap was performed in Pass 1.

#### PASS 2

<p style="text-align: center;"><b>PASS 2</b></p> <p style="text-align: center;"><b>Deep Tissue Tightening**</b></p> <p style="text-align: center;"><b>The goal is to deliver approximately 450-800mJ/pulse.</b></p> <p style="text-align: center;"><b>The total mJ/pulse will be displayed on the bottom right hand corner of the screen.</b></p> <p>Treat the **mid dermis using the Bipolar mode.</p> <p>Start by using the highest power (W) and the shortest pulse width (ms). 20W/40ms will deliver 800mJ/pulse.</p> <ul style="list-style-type: none"> <li>• If tolerated, continue to treat all remaining areas in the **mid dermis.</li> </ul> <p>To use a longer pulse width with lower power, try 5W/100ms which equals 500mJ/pulse.</p> <ul style="list-style-type: none"> <li>• If tolerated, continue to treat all remaining areas in the **mid dermis.</li> </ul> <p>If needed, continue to adjust power (W) or pulse width (ms) as long as the total equals 450-800mJ/pulse.</p> <p>Take care to decrease or increase needle depths to correspond with depth of the tissue being treated.</p> <p><b>Treating at power greater than 30 watts or 1000mJ/pulse puts the patient at risk for adverse events and is not recommended.</b></p>								
Pass	Target	Depth (mm)	Mode	Frequency	Power	Pulses & PW	Impact	mJ/Pulse
<b>Pass 2</b>	Mid Dermis	1.5-1.75	Bipolar	1 MHz	5-20W	1 Pulse 40-100 ms	4-7	450-800

## **Expected Outcomes**

### **Results May Include**

- Improvement of early signs of aging.
- Brightening of damaged skin.
- Tighter, firmer-looking skin through soft-tissue coagulation.
- Faster healing times than the traditional microneedling (non-RF) treatments.
- Younger, healthier-looking skin.
- Smoother complexion within several days and gradual improvement over the course of several weeks to several months.
- Long-lasting results with a short, in-office procedure.
- Minimal downtime with either procedure (single or multiple needle).
- Quick return to daily routine.
- Potenza stimulating the body's self-healing by initiating the wound-healing process.

# Chapter 5 Cushion Plus (CP-21) Tip on Motor Handpiece

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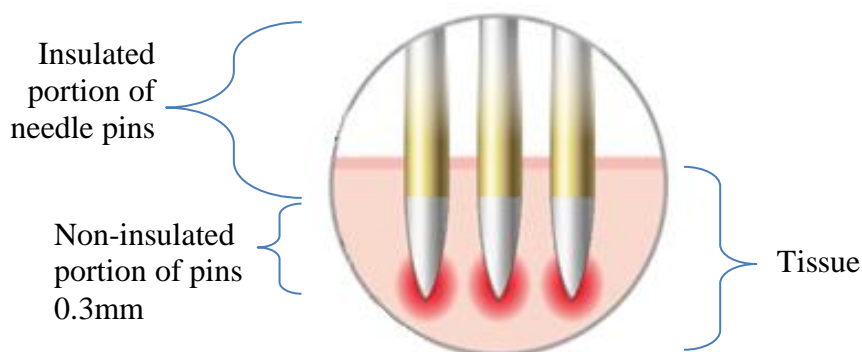
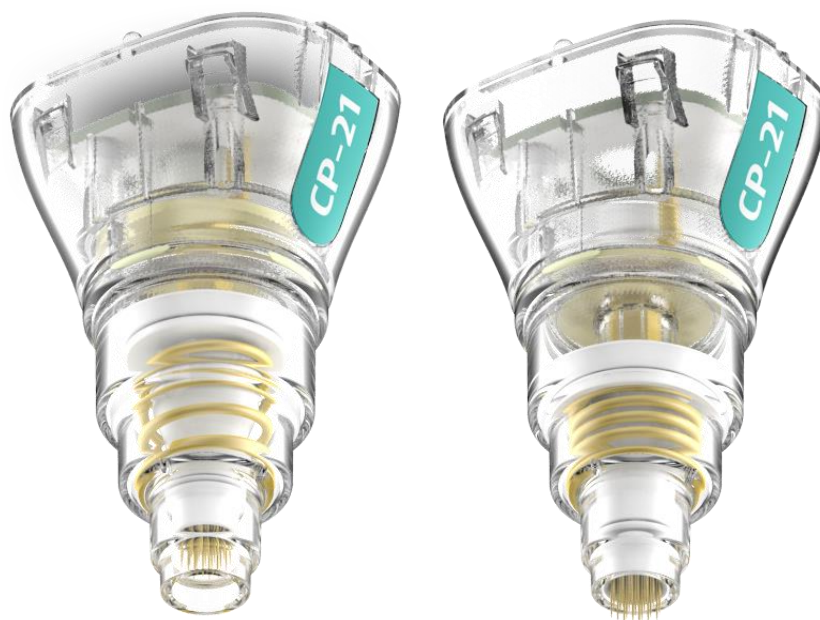
## Cushion Plus (CP-21) Tip for Monopolar Mode

The Cushion Plus (CP-21) is an adjustable, single use, insulated tip with a total of 21 (twenty-one) needles. The Cushion Plus (CP-21) needle tip principle of operation is the piston mechanism. This method of action results in enhanced tissue engagement as illustrated below and described on the following pages.

The CP-21 tip is designed with two spaces where the volume changes as the needles move.

The movement of the needles within the spaces creates negative and positive pressure resulting in tissue being pulled into the needle tip chamber, and an emitted puff of air. This puff of air towards the skin with each pulse also enhances the penetration of topicals into the skin.

The CP-21 tip is designed for treating at a higher mJ/pulse and impact. These parameters should not be used with the I-tips or S-tips.



Microneedling with the Cushion Plus (CP-21) Tip creates channels in the dermis. These artificial wounds induce tissue tightening through soft tissue coagulation.

The insulated needles protect the epidermis and minimize downtime.

The Cushion Plus (CP-21) Tip in Monopolar / 1MHz mode results in:

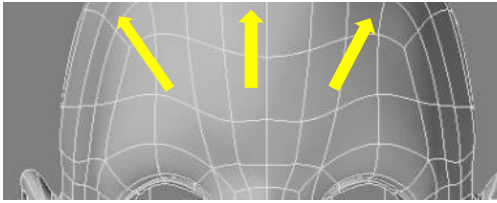
- Less pain
- Less downtime (approx. 2-3 days)
- Deep and wide RF delivery
- Decreased side effects
- Enhanced tissue engagement
- Enhances topical penetration

## CP-21 Treatment Procedure

- Patient should fill out a Medical History Intake Form and sign the informed consent.
- Discuss the procedure with the patient; provide pre-treatment and post-treatment instructions.
- Remove all make up, lotions and jewelry from the treatment area. The treatment must be performed on clean, dry, intact skin.
- Topical anesthetic may be used at the discretion of the treating physician. Make sure after the designated time, the topical cream is removed, and the skin is cleansed with alcohol or acetone prior to treatment.
- Treating with topicals is at the discretion of the treating physician.
- Refer to the Multilayer Techniques tables as well as the CP-21 Treatment Protocol in this Clinical Reference Guide.
- Select the CP-21 tip and attach the tip into the handpiece.
- Attach a neutral pad between the shoulder blades for facial/neck treatments. To ensure good contact, cleanse the tissue at the neutral pad placement area with 70% isopropyl alcohol to remove any lotions or body oils.
- Set the frequency (1 MHz), RF mode to monopolar, needle depth and power (W), following the recommendations found within the Multilayer Techniques tables.
- Perform test spots as is recommended.
- Clinicians may perform one to two extra passes on problematic lines or other target areas for better clinical results, depending on patient tolerance and skin condition.
- It is recommended that the needle depth should be set to 0.5 mm to 0.75 mm for areas where the skin is thin or close to the bone (forehead, cheekbones, around the eyes, etc.). If the needle is set too deep for these areas, bruising or erythema may occur.
- When treating the periocular area, even if the needle depth is less than 1.5 mm, bruising may occur if a blood vessel is penetrated.
- When performing the treatment on the nose, with your free hand, use a tongue depressor to support nose tissue so that there is no space between the tip and the skin of the nose. The needles **must** be inserted perpendicular to the skin.
- The recommended needle penetration depth and settings are set differently for each zone.
- All Potenza tips are disposable and cannot be reused.
- Treatment should be initiated at the outer cheek area, working towards the center of the face.
- For enhanced needle insertion, with fingers, stretch tissue taut before delivering treatment.
- Follow the Directional Guidelines to optimize the treatment.

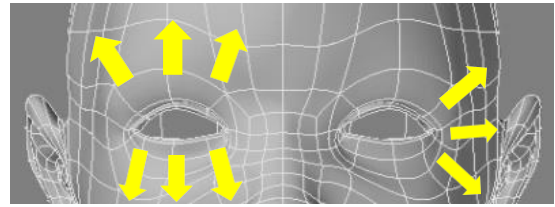
## Directional Guidelines

### 4. Forehead



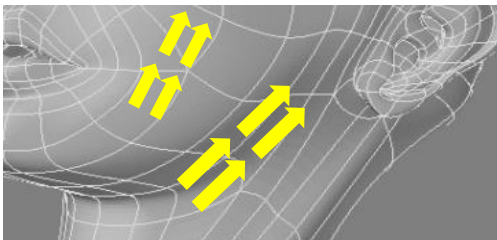
Gently pull the tissue upward on the forehead.

### 5. Around the Eyes



Gently pull the skin outward from the eyes.

### 6. Cheek and Jawline



### 4. Neck



7. Gently pull the tissue in the direction of the arrows. Deliver the RF energy moving in the same direction. Do not treat over the vocal cords or large blood vessels.
8. It is good practice to never treat directly over neck structures like the trachea or thyroid areas with any device. That tissue can still be treated by gently pulling the tissue off the structure and then applying the energy.
9. NOTE: If a patient complains of severe pain during treatment, the operator should stop treatment immediately and consult with a physician.
10. NOTE: If immediate and severe swelling of the skin occurs during treatment, stop the treatment immediately.
11. NOTE: If a burn occurs on skin surface during treatment, stop treatment immediately and provide appropriate care to the area.
12. NOTE: If an adverse event or unanticipated results or side effects occur, please report the issue to [cynosureclinicalsupport@cynosure.com](mailto:cynosureclinicalsupport@cynosure.com) or call 844-365-5060.


## CP-21 Treatment Protocol

- Always use a new, sterilized, single-use, disposable tip.
- Check the packaging for damage and a valid expiration date before use; never use an expired tip or one from a damaged package.
- Apply moderate handpiece pressure before delivering RF energy to the tissue.
- Needles are designed to smoothly and swiftly pierce the skin.
- Always hold handpiece perpendicular to the skin.
- Typical treatments start with the deepest pass first, followed by shallower passes. When adjusting your depths, it is advised to change by .25mm increments within the treatment zone. Determine tissue depths by referencing the Skin Depth table.
- Skin thickness varies considerably from person to person and from one area to another.
- Depth settings should be adjusted to stay within the dermis, except when specifically targeting deeper tissue.
- With each pulse, always wait for the needles to completely retract before lifting the handpiece off the skin.
- Use gauze moistened with normal saline or sterile water to remove any pinpoint bleeding after completing each pass in each region.
- Allow adequate time, one to two minutes, before applying an additional pass to same area.
- For patient's comfort, provide dental rolls or gauze moistened with water when treating over dental appliances or implants. Use a tongue depressor to isolate the areas of treatment, i.e., the nose.

NOTE: Decrease energy setting (W) if severe edema is evident within minutes after energy delivery or the entire square footprint of the needle tip is visible on the tissue.

NOTE: If the patient develops hyper- or hypopigmentation post treatment, treatment should be discontinued, and the side effects should be treated.

## CP-21 Recommended Parameters

Tip	Icon	Mode	Frequency	Depth (mm)	Method of Action	Hand Piece
CP-21		Monopolar	1 MHz	0.5 – 2.5 mm	Enhanced Tissue Engagement	Motor

- The penetration depth of the needle is set differently according to the treatment site, skin condition, and thickness.
- When performing the procedure near the bone such as on the forehead, decrease the depth of needle penetration.
- The CP-21 only operates in the monopolar mode. A neutral (NEM) pad must be placed on the patient's back. If not, the RF energy will not flow.
- The CP-21 tip is designed for treating at a higher mJ/pulse. These parameters should not be used with the I-tips or S-tips.
- When performing stacking, the tip should be twisted at 30-degree and 60-degree intervals. 90-degrees is not recommended due to the needle insertion being the same as the original pulse.

## Treatment Interval and Session

WEEK	1	2	3	4	5	6	7	8	9
<b>CP-21 Enhanced Tissue Engagement</b>	<b>TX</b>	No TX	No TX	No TX	<b>TX</b>	No TX	No TX	No TX	<b>TX</b>
	<ul style="list-style-type: none"> <li>• 3-5 treatments</li> <li>• 4-6 weeks treatment intervals</li> <li>• If stacking: 1-2 passes of stacked pulses, with 30° rotation and no more than 25% overlap row to row.</li> <li>• If not stacking: 1-3 passes.</li> </ul>								

Patients may notice some improvement after the first or second treatment. More significant results occur after two to three treatments, spaced approximately four to six weeks apart. Skin will continue to improve during the next 6 to 12 months post treatment. Patients are encouraged to follow a skin care regimen suitable for their age and specific problems. RF microneedling results will vary from patient to patient.

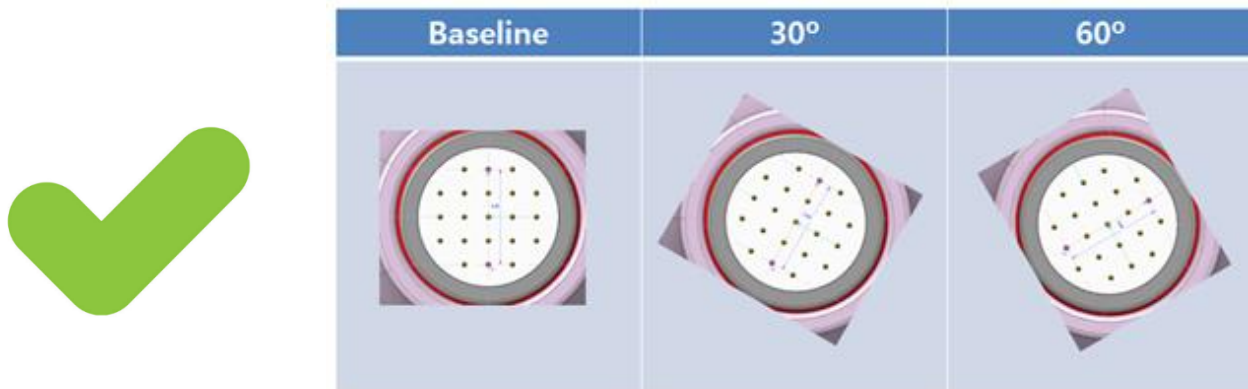


## CP-21 Recommended Needle Tip Rotation

### CORRECT:

Illustrated below is the correct way (Baseline, 30-degrees, and 60-degrees) to rotate the CP-21 Cushion Needle Tip when administering stacking passes.

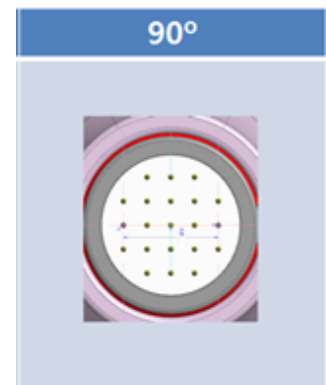
When performing stacking, the tip should be twisted at 30-degree and 60-degree intervals.



### INCORRECT:

Illustrated below is the incorrect way (90-degrees) to rotate the CP-21 Cushion Needle Tip when administering stacking passes.

90 degrees is not recommended due to the needle insertion being the same as the original pulse.



## Recommended Parameters with the Cushion Plus (CP-21) Tip

Always note and document the mJ/pulse before initiating treatment.

Test spots are recommended prior to treatment to determine patient suitability.

The following parameters are suggested starting settings and may be adjusted based on the physician's discretion, test spot results, the patient's skin condition (including hydration and tissue age, and thickness), and the location of the area being treated.

Moderate to severe skin conditions may take a series of treatments to achieve an optimal outcome; results may be seen in several weeks to months after the final treatment.

Aged skin will react differently. Older patients experience longer erythema and edema. If this continues for a length of time, the skin may become dull. For older patients, reduce energy and administer more stacking.

**Frequency (MHz), pulse width (ms), and power (W), may be adjusted based on the patient's comfort scores and tissue reaction.**

### PASS 1

PASS 1								
The CP-21 tip can only be operated in Monopolar mode. A NEM pad is required for treatment. Impact and speed of the needles can be adjusted per physician discretion and patient condition.								
Take care to decrease or increase needle depths to correspond with depth of the tissue being treated.								
The CP-21 tip is designed for treating at a higher mJ/pulse.								
<b>Treating at power greater than 30 watts or 2530 mJ/pulse puts patient at a risk for adverse events and is not recommended.</b>								
<b>These parameters should not be used with the I-tips or S-tips.</b>								
Pass	Target	Depth (mm)	Mode	Frequency	Power	Pulses & PW	Impact	mJ/Pulse
Pass 1	Deeper Dermis	1.5-2.0+	Monopolar	1 MHz	23 W	1 Pulse 110 ms	7	≈ 2530

## PASS 2 & 3 (Optional)

### PASS 2 & 3

The CP-21 tip can only be operated in Monopolar mode. A NEM pad is required for treatment. Impact and speed of the needles can be adjusted per physician discretion and patient condition.

A total of 3 passes can be performed. Continue to monitor for suitable patient endpoint to determine the number of passes performed.

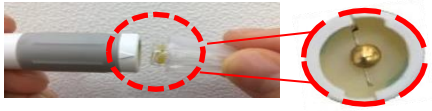
Take care to decrease or increase needle depths to correspond with depth of the tissue being treated.

**Treating at power great than 30 watts or 2530 mJ/pulse puts patient at a risk for adverse events and is not recommended.**

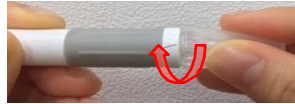
Pass	Target	Depth (mm)	Mode	Frequency	Power	Pulses & PW	Impact	mJ/Pulse
<b>Pass 2 &amp; 3</b>	Upper Dermis	0.5-1.25	Monopolar	1 MHz	5 W	1 Pulse 40 ms	7	≈ 200

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### Single Needle Tip Fastening



Fix the tip to the groove at the end of the handpiece.



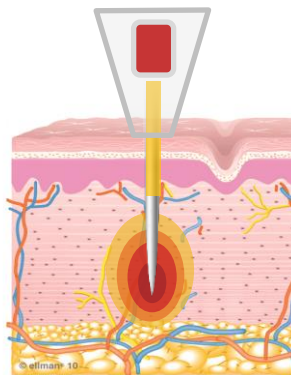
Rotate the tip clockwise to secure it.



Remove the cap before treatment.

NOTE: Impedance readings may be high (over 600) but this does not affect the treatment.

### AC Handpiece



### Single-Needle Tip (AI-15)

## Treating with a Single-Needle Tip

The AI-15 tip is a single use needle tip for use on the AC handpiece.

**WARNING:** If the needle insertions are too close together, energy can overlap, causing skin damage.

### Pre-treatment

- Remove any flaking skin.
- Apply anesthetic cream for approximately 30 minutes, depending on the Rx.

### Treatment

- Perform one-needle treatment.
- Insert the single needle tip into the blemish at a right angle to the skin. Deliver 1-6 (one to six) pulses of energy.
- Apply energy only to the blemish.
- If there is bleeding, control the bleeding and treat other areas. Once the bleeding stops, continue the treatment.
- Cleanse the area with normal saline solution.
- Apply cold compresses.

### Post-treatment

- Apply soothing mask.
- Apply sunblock.

Indication	Tip	Watts	Number of Treatments	Treatment Interval
Blemishes (Large)	AI-15	7-9	3-5	≈4 weeks
Blemishes (Small)	AI-15	5-6	3-5	≈4 weeks

### AC Handpiece Treatment Pearls:

- Only Monopolar RF can be utilized with the AC handpiece.
  - NEM pad is required for all single needle treatments.
  - RF energy is being delivered from only one pin.
  - The size of the coagulation zone in the tissue will be larger.
  - There is an insulated area of 0.3 mm at the top portion of each single needle.
- The rest of the needle (1.2 mm) is uninsulated and an active zone.

### Post-treatment Instructions

- Do not scrub or exfoliate the skin.
- Wash the area with warm water and a mild cleanser.
- Do not apply liquid makeup for 24 hours; mineral makeup is acceptable after the erythema resolves. Be sure to apply makeup with clean brushes to avoid spreading bacteria to the treated area.
- If erythema after treatment persists, use an ice pack or cool compresses at home; always use a protective barrier, such as a face cloth, between the skin and the ice pack.
- Before touching your face or applying facial products, be sure to wash your hands well: there are micro-pathways opened into the dermis and hands will introduce bacteria.
- If skin feels tight or dry, apply moisturizing cream as often as desired.
- If you currently have skin breakouts, you may find that the condition may temporarily worsen due to inflammation or edema.
- Do not pick at treated tissue, doing so may result in hyper- or hypopigmentation.
- Avoid ultraviolet rays and apply sunblock >30 SPF UV A/B daily.
- Avoid alcohol consumption if possible.
- For 24 hours, refrain from cardio exercise or activities that increase the body temperature and cause perspiration, i.e., hot yoga, saunas, etc.
- Contact your practitioner if any problems develop: concerns regarding rash, itching, erythema, etc., for more than 24 hours.

### Expected Side Effects

- Erythema (redness) may occur after the treatment, lasting a few hours and up to three days.
- Tissue may be edematous (swollen) for a few hours up to several days.
- Pinpoint bleeding on the surface of the skin can be expected with deeper treatments. Bleeding is temporary and is typically resolved by the end of the patient's visit.
- Overtreated tissue may heal with small areas of micro crusting or scabbing.
- Burning sensation: patients may feel uncomfortable temporarily while receiving treatment.
- Temporary tingling which typically resolves within 48 hours.

## **Adverse Effects**

### **Infection**

- All Potenza tips are sterilized, but there is a risk of bacterial infection.
- The practitioner must wear new, medical-grade, disposable, non-sterile gloves during the treatment and keep the treatment site clean.

### **Pigmentation**

- Be aware that during the treatment, if the needle is not fully inserted or if after the treatment artificial exfoliation occurs, it may cause hyper- or hypopigmentation.
- Treat carefully, allowing the needles to fully retract before moving to the next area.

NOTE: During the treatment if the needles have not retracted fully and you move the tip, they may cause microscopic tissue tearing and interruption of the RF energy flow.

### **Textural Irregularities**

- Treating too deeply and performing too many passes at high energies may cause tissue textural changes, especially on the neck area.

### **Folliculitis**

- During the treatment, temporary folliculitis may be caused by thermal stimulation of the hair follicles.
- The heat stimulus applied to the hair follicles may temporarily increase sebum secretion immediately after the treatment.



## Photography Guidelines

Taking before and after patient photographs is recommended. Note that consistency is essential in positioning of the patient, the camera and the lighting.

To help ensure photographic consistency:

- The same person should take all photographs.
- The same camera, lens, lighting, and settings should be used with all patients.
- Take photographs in an area without windows or other bright light sources. If this isn't possible, consider using blackout shades and turning off lights.
- Ensure that the patient has signed a photography release form.
- When taking post-treatment photos, have pre-treatment photos available for reference to ensure consistency.

If patient has difficulty in maintaining a neutral expression while their face is photographed, ask them to take a deep breath. While exhaling through the mouth instruct them to close their eyes. Then slowly, open eyes looking straight ahead. This resets the patient's countenance.

### Camera Positioning

- Set up two light sources in front of the patient.
- Set up a neutral, non-reflective background, i.e., blue or black.
- Position the patient.
- Take all photos in the portrait setting, not landscape.
- The camera should be set on a tripod for height uniformity.
- At follow up visits, have baseline photographs available to ensure consistent positioning.
- The flash should be in the same position for all photos.



### Patient Positioning

- No makeup, hair pulled back, relaxed and without facial expressions.
- A black drape or smock over the patient's clothes (no turtlenecks or visible jewelry).
- Adjust the chair for patient's height (measure height at pre-photo sitting).
- Hands flat and resting on table or thighs.
- Position the face the same for all pre and post photos, with chin centered.
- No expression: eyes, mouth, eyebrows, etc.
- Photo shots: front, left 90°; right 90°; left 45°; and right 45°.

## **How to Store and Maintain the Potenza Device**

- After each treatment, it is recommended that you immediately wipe off any visible debris with a dampened paper towel/gauze.
- Then gently clean the device, including the touch screen, cables, handpiece, handle etc., with a soft paper towel or gauze pad that has been dampened with 70% isopropyl alcohol.
- Wipe the screen and equipment surface gently with a soft pad with a non-corrosive cleaning solution such as alcohol on it.
- Wipe the machine once more with a clean, dry cloth or gauze pad.
- Tips are sterile and disposable and cannot be reused; they must be discarded in a biohazard-compliant sharps container.
- Move the device to a secure and dry storage area.

Provided are samples of forms and useful information, including informed consent, pre- and post-treatment instructions, Five Steps to Treatment, and treatment form. A pain scale has also been included for reference during test spots and treatments.

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**Potenza Microneedling/Hemostasis and Electrocoagulation**

Patient Name: \_\_\_\_\_

Date: \_\_\_\_\_

As a patient, it is important for you to understand the expected results and risks of radiofrequency microneedling treatment with the Potenza Microneedling System. Please read this document carefully. Before signing this document, please ask your physician, or the consultant providing the RF treatment, about any aspect of this document or the procedure that you do not understand.

Potenza System equipment may present a hazard to patients with implantable devices.

Please consult qualified medical personnel prior to being treated with radiofrequency equipment. Since ongoing feedback by a patient during a procedure is required, if there is nerve insensitivity to heat anywhere in the treatment area, the patient should not be treated with the Potenza System. All patients should be free of infection prior to application. Infection can further increase the risk of scarring; therefore, proper wound care is important in the prevention of infection. If signs of infection such as pain, heat, blisters or surrounding redness develop following application, call the provider's office immediately.

Potenza treatments have not been studied for use on pregnant patients, patients with autoimmune disease, diabetes or herpes simplex.

**Potenza System**

The application will involve applying low level heat to the tissue using radiofrequency for therapeutic purposes.

NOTE: All patients are different and exact results of this cosmetic procedure and treatments cannot be predicted or guaranteed.

**During Treatment**

All jewelry and lotions should be removed from the treatment area prior to treatment.

The procedure should not be performed on cut, wounded or infected skin as this could promote infection and injury. Although uncommon, burns can occur.

Slight discomfort may be experienced while undergoing treatment. Typically, the discomfort is mild and temporary during the procedure and localized within the treatment area. During the treatment, you should provide ongoing feedback to the individual performing the treatment. Additionally, if you have nerve insensitivity to heat anywhere in the treatment area, you should not be treated. Inadequate or impaired feedback may lead to burns or injury. Ongoing feedback should be provided by the patient to the individual performing the treatment to avoid excessive discomfort.

## After Treatment

Studies indicate the possible side effects of Potenza System are usually treatment-site related and include mild discomfort during the procedure, localized within the treatment area. Mild swelling and redness may occur, which typically goes away within 2 to 24 hours.

A regimen to moisturize and soothe the external skin posttreatment is recommended.

There is the possibility that additional risk factors of radiofrequency skin treatments may be discovered. The results of performing RF tissue-heating treatments in combination with other treatments is unstudied and unknown.

It has been explained to me that this is a cosmetic procedure and not covered by insurance. It has been explained to me that more than one treatment may be recommended to achieve the best results. As mentioned before, there is no guarantee of results and no refund of payments for the procedure will be made.

My signature below signifies that all of my questions have been answered by the physician or consultant. I understand the risks, complications, expected results, and expense of the treatments. I have read and understand this document and give my consent to receive treatment with the Potenza System.

Patient Name (Print)\_\_\_\_\_

Signature\_\_\_\_\_

Date\_\_\_\_\_

Practitioner Name (Print)\_\_\_\_\_

Signature\_\_\_\_\_

Date\_\_\_\_\_

## **Sample Form      Pre-treatment Guidelines**

- Keep hydrated by drinking water (at least eight cups daily) or hydrating fluids to improve treatment outcomes.
- Avoid drinking alcohol for 24 hours in advance of treatment.
- For three to seven days prior to treatment, at the physician's discretion, avoid therapies that may cause erythema (redness) or irritation, such as retinols or products containing isotretinoin and any exfoliating acid preparations.
- Shave visible hair from the treatment area.
- Male beards should be shaved on the day of treatment.
- The same procedure should be followed prior to each visit.

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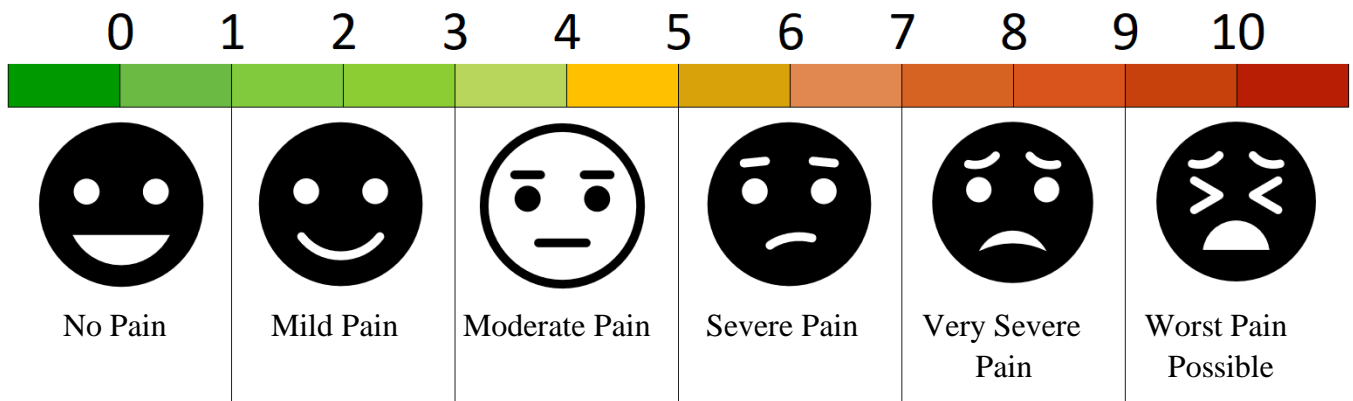


## Sample Form

## Post-treatment Instructions

- Do not scrub or exfoliate the skin.
- Wash the area with warm water and a mild cleanser.
- Do not apply liquid makeup for 24 hours; mineral makeup is acceptable after the erythema resolves. Be sure to apply makeup with clean brushes to avoid spreading bacteria to the treated area.
- If erythema after treatment persists, use an ice pack or cool compresses at home, but always use a protective barrier, such as a face cloth, between the skin and the ice pack.
- Always wash your hands thoroughly before touching your face: there are micro-pathways opened into the dermis and hands will introduce bacteria.
- If skin feels tight or dry, apply moisturizing cream frequently.
- If you currently have skin breakouts, you may find that the condition may temporarily worsen due to inflammation or edema.
- Do not pick at treated tissue: doing so may result in hyper- or hypopigmentation.
- Avoid ultraviolet rays and apply sunblock >30 SPF UV A/B daily.
- Avoid alcohol consumption if possible.
- For 24 hours, refrain from high intensity aerobic exercise or activities that increase the body temperature like saunas, hot tubs, steam showers or exercise (i.e., jogging, weight training, kickboxing, etc.).
- Call your practitioner if any problems develop: concerns regarding rash, itching, erythema, etc., for more than 24 hours.

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A patient score of 4 or less is an indication of an acceptable comfort level for test spots and treatment.

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## Five Steps For Treatment

Refer to the Potenza Clinical Reference Guide parameter tables for more detailed guidance such as tissue cleansing and administering Test Spots.

Impedance readings must be maintained at  $\approx 600$  ohms or less for optimal results.

Step 1 Indication (For depth of needles, refer to Step 1 Chart)	Step 2 Suggested Tip		Step 3 Frequency (MHz)	Step 4 Monopolar / Bipolar	Step 5 # of Passes
Revitalization	I-25 I-49	 	<input checked="" type="checkbox"/> 1 MHz <input checked="" type="checkbox"/> 2 MHz	<input checked="" type="checkbox"/> Bipolar <input checked="" type="checkbox"/> Monopolar	1-2
Deep Tissue Tightening through Soft- Tissue Coagulation	S-25 S-49	 	<input checked="" type="checkbox"/> 1 MHz <input checked="" type="checkbox"/> 2 MHz	<input checked="" type="checkbox"/> Bipolar <input checked="" type="checkbox"/> Monopolar	1-2
Skin Blemishes	AI-15		<input checked="" type="checkbox"/> 1 MHz <input type="checkbox"/> 2 MHz	<input type="checkbox"/> Bipolar <input checked="" type="checkbox"/> Monopolar	1 -6 Pulses of Energy per Blemish
Enhanced Tissue Engagement	CP-21		<input checked="" type="checkbox"/> 1 MHz	<input checked="" type="checkbox"/> Monopolar	1-3

**Step 1. Indication.** Use the chart below to determine the treatment areas and appropriate needle depth. Care should be taken to identify any tissue concerns i.e., condition, age, location, and hydration. The needle depths are an approximation, and the treatment provider should always use best clinical judgement.

*Step 1 Chart Approximate Tissue Treatment Depths in mm				
Forehead	Crow's Feet	Below Eyes Festoons	Nose/Chin	Cheek Cheek Bone
Thin 0.25-0.5 Med 0.5-0.75 Thick 1.25-2.0	Thin 0.75-1.0 Med 1.25-1.50 Thick 1.5-2.0	0.05-0.75	Thin 0.5-1.0 Med 1.0-1.5 Thick 1.5-2.5	Upper 0.75-2.0 Mid/lower 1.0-2.0 Cheekbone 1.0-1.75
Upper Lip	Jawline	Neck	Abdomen	Skin Blemishes
Thin 0.25-0.75 Med 0.75-1.50 Thick 1.75-2.75	Thin 0.75-1.0 Med 1.25--1.75 Thick 1.75-2.25	Lower 1.0-1.5 Medial 1.25-2.0 Lateral 1.25-2.50	1.5 – 4.0+	1.2-1.8

**Step 2. Tip selection.** Selecting a tip with fewer needles will result in a lower density but higher RF energy per pin, with less mechanical injury to the tissue. Selecting tips with more needles will disburse the energy over the multiple pins resulting in less energy per pin but with a greater mechanical density of injury to the tissue. The semi-insulated tips (S-tip) have two uninsulated areas that will deliver energy at two different depths within the tissue. When using the insulated tips (I-tip), the energy will flow from the tip into the tissue delivering the energy precisely at the selected needle depth. The CP-21 tip enhances permeability of the topical into the skin and is intended for enhanced tissue engagement.

**Step 3. Choose frequency of wave formation:** Choose 1 MHz or 2 MHz. Typically, 1 MHz is more comfortable and provides a wider and deeper delivery. The wave formation is wider, and the energy is delivered at a slower frequency than 2 MHz. Treating at 2 MHz may produce a more aggressive sensation as the wave form is closer together and the delivery to the tissue is more focused.

**Step 4. Choose monopolar or bipolar mode.** Bipolar mode is a more superficial delivery of energy as the RF passes from positive (+) pole to negative (-) pole on the needle tips. The area of heat delivery is more concentrated and can be uncomfortable when used in the upper dermis of the facial tissue. Monopolar mode allows energy to travel from the source (Tip) to the NEM pad creating a deeper, wider, and more diffused pattern of heat distribution. Refer to the Clinical Reference Guide parameter tables for recommended modes.

**Step 5. Determine the number of passes per area.** Facial tissue— 1-3 passes with  $\approx$ 300-500 pulses per pass will equal approximately 1000 pulses. Smaller faces and youthful tissue will require less pulses. Use any remaining pulses by providing another pass to target areas i.e., periocular, upper lip, jaw line or pre-jowl area. Deeper tissue treatment, i.e., abdomen, neck, and pre-jowl areas may receive one dense pass (25% overlap from row to row only) when using the S-tips. Treat blemishes with a single needle tip with 1-6 pulses of RF energy.

## Sample Form

## Treatment Record

Patient Name \_\_\_\_\_ DOB: \_\_\_\_\_ Date: \_\_\_\_\_

Allergies: \_\_\_\_\_

Implanted devices/metals discussed: ☐ Yes ☐ No ☐ N/A

☐ 1<sup>st</sup> Treatment ☐ 2<sup>nd</sup> Treatment ☐ 3<sup>rd</sup> Treatment Other: \_\_\_\_\_

Neutral Pad Connected? Yes ☐ No ☐ Location: \_\_\_\_\_

TX Location	Tip ID	Frequency (MHz)	Polarity	Auto (Hz) (0.2 -3.0)	HP	Depth (0.5-4.0 or N/A)	Power (W)	Pulse Width	Impact (1-7)
		<input type="checkbox"/> 1 MHz <input type="checkbox"/> 2 MHz	<input type="checkbox"/> Bi <input type="checkbox"/> Mono	<input type="checkbox"/> On <input type="checkbox"/> Off	<input type="checkbox"/> AC <input type="checkbox"/> Motor				
		<input type="checkbox"/> 1 MHz <input type="checkbox"/> 2 MHz	<input type="checkbox"/> Bi <input type="checkbox"/> Mono	<input type="checkbox"/> On <input type="checkbox"/> Off	<input type="checkbox"/> AC <input type="checkbox"/> Motor				
		<input type="checkbox"/> 1 MHz <input type="checkbox"/> 2 MHz	<input type="checkbox"/> Bi <input type="checkbox"/> Mono	<input type="checkbox"/> On <input type="checkbox"/> Off	<input type="checkbox"/> AC <input type="checkbox"/> Motor				
		<input type="checkbox"/> 1 MHz <input type="checkbox"/> 2 MHz	<input type="checkbox"/> Bi <input type="checkbox"/> Mono	<input type="checkbox"/> On <input type="checkbox"/> Off	<input type="checkbox"/> AC <input type="checkbox"/> Motor				
		<input type="checkbox"/> 1 MHz <input type="checkbox"/> 2 MHz	<input type="checkbox"/> Bi <input type="checkbox"/> Mono	<input type="checkbox"/> On <input type="checkbox"/> Off	<input type="checkbox"/> AC <input type="checkbox"/> Motor				
		<input type="checkbox"/> 1 MHz <input type="checkbox"/> 2 MHz	<input type="checkbox"/> Bi <input type="checkbox"/> Mono	<input type="checkbox"/> On <input type="checkbox"/> Off	<input type="checkbox"/> AC <input type="checkbox"/> Motor				
		<input type="checkbox"/> 1 MHz <input type="checkbox"/> 2 MHz	<input type="checkbox"/> Bi <input type="checkbox"/> Mono	<input type="checkbox"/> On <input type="checkbox"/> Off	<input type="checkbox"/> AC <input type="checkbox"/> Motor				
		<input type="checkbox"/> 1 MHz <input type="checkbox"/> 2 MHz	<input type="checkbox"/> Bi <input type="checkbox"/> Mono	<input type="checkbox"/> On <input type="checkbox"/> Off	<input type="checkbox"/> AC <input type="checkbox"/> Motor				
		<input type="checkbox"/> 1 MHz <input type="checkbox"/> 2 MHz	<input type="checkbox"/> Bi <input type="checkbox"/> Mono	<input type="checkbox"/> On <input type="checkbox"/> Off	<input type="checkbox"/> AC <input type="checkbox"/> Motor				

Comments: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Patient's tissue response: \_\_\_\_\_

\_\_\_\_\_

\_\_\_\_\_

Post care reviewed: ☐ Yes ☐ No

Clinician's Signature \_\_\_\_\_ Date \_\_\_\_\_

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