

Cytrellis® Dermal Micro-Coring® System

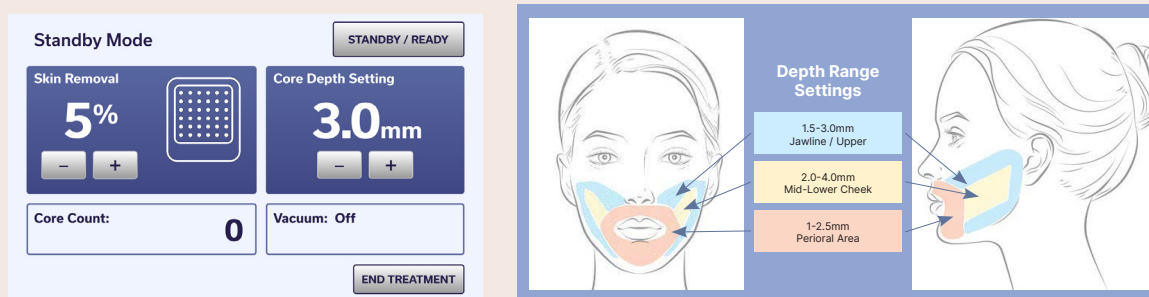
INDICATIONS FOR USE - The Cytrellis Dermal Micro-Coring System is indicated for use by medical professionals for the treatment of moderate and severe wrinkles in the mid and lower face in adults aged 22 years or older with Fitzpatrick skin types I-IV. This system uses specifically designed hollow coring needles that, when inserted into the tissue, excise cores in the size of the inner needle diameter. The tissue cores are subsequently removed from the needle and evacuated by suction.

This product is not intended for transdermal delivery of topical products such as cosmetics, drugs or biologics. Use of other modalities/topicals post procedure may result in prolonged healing and have not been studied for efficacy and safety with ellacor.

Procedure Settings

- Skin Removal Percentage – 1%, 3%, 5%, 7%, and 8%
 - **NOTE:** HIGHER SKIN REMOVAL PERCENTAGE = MORE AGGRESSIVE TREATMENT
- Treatment Window Size – 10mm X 10mm
- Core Depth – 0.0 - 4.0mm and adjustable in 0.5 mm increments
 - **NOTE:** CONSIDER ANATOMICAL AREA TO BE TREATED

The goal of the treatment is to obtain full thickness cores at the minimum treatment depth required for each anatomical area. Required treatment depths to achieve this goal will vary by patient. Keep in mind that increased density and depth settings correlate with more downtime for the patient.



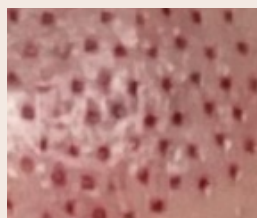
1% 9 cores	3% 24 cores	5% 36 cores	7% 51 cores	8% 60 cores

Coring Best Practices

A core (micro-core) is a column of skin removed by each needle and is comprised of epidermal and dermal tissue.

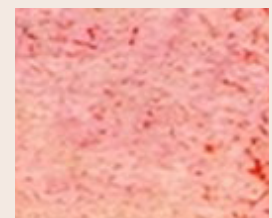
Good Coring

- Consistent hole sizes
- Mild bleeding
- Holes are open



Poor Coring

- Inconsistent hole sizes
- Faint bleeding
- Holes are barely visible



IMPORTANT

- **DO NOT impede tubing on handpiece.**
- **DO NOT apply forceful downward pressure.**
- **DO NOT TOUCH needle cartridge tubing while treating patient.**
- Avoid overlapping.
- Avoid treating/treat with caution over bone and curved body areas.

Methods of Anesthesia

- In the pivotal study, investigators used various anesthetic techniques at their discretion to ensure patient comfort and to minimize pain and bleeding.
- Local infiltration was used for all subjects in the study but any additional methods such as topical anesthesia and oral treatments varied by subject.
- Lidocaine (1-2%), sodium bicarbonate and epinephrine were mostly used, and volumes were determined according to patient weight and drug manufacturer guidelines.

Supplies Needed Per Treatment

- Vacuum-rated suction tubing - 1/4-inch diameter (6.35mm), >6ft. (1.83m)
- Vacuum filter (5-micron with standard connection for 1/4" internal diameter suction tubing)
- Personal protective equipment for staff per office policy
- Sterile water (chilled)
- Sterile towels for blood management
- Soft bristle toothbrush (for cleaning device)
- 70% Isopropyl alcohol solution and/or wipes (for cleaning device)
- Clean soft cloth (for cleaning device)
- Gloves
- Tongue depressor and/or dental guard
- Petrolatum

Pre-Treatment

- After patient profile and setup screens completed, attach all tubing and refer to on-screen tutorial if needed.
- Check that tubing is routed correctly. Suction is often blocked by tubing being kinked or improperly routed.
- Install and lock single use cartridge onto handpiece.
- Inspect cartridge for any visible damage and proceed to treatment screen.
- Select skin removal percentage and depth setting. The red dots in the treatment pattern signify the starting point as the needles move from right to left to complete the treatment pattern.
- The maximum core count for each cartridge is 24,000.

Treatment Procedure

- **DO NOT impede tubing on handpiece.**
- **DO NOT apply forceful downward pressure.**
- **DO NOT use gauze pads. Use only lint-free sterile towels.**
- Ensure hair is out of the treatment field and cleanse skin with a suitable cleanser. Shave any visible hair.
- When performing treatment, move the hand piece to the adjacent area with overlap of flange only.
(See image to the right.)

Visible flange footprint



Treatment Procedure Continued

- For nerve and blood vessel schematics, please refer to the Operators Manual.
- Hold the skin taut and place the needle cartridge on the area of skin to be treated. When the needle cartridge is correctly placed on the skin, the suction air flow is no longer audible at the treatment window. Apply minimal pressure until the skin begins to pillow in the treatment area.
- DO NOT apply downward pressure while needles are moving.
- Press and hold footswitch down to deliver treatment pattern. When completed, the vacuum will disengage and the needles will stop moving. Lift the needle cartridge from the skin and assess the cored area. The cores should be distinct (see visual on first page) with a clean center and no debris.
- **If coring not achieved**, review settings and technique. Increase depth setting or if anatomical area assessed is correct for depth, hold skin tauter and repeat pattern next to area already treated but DO NOT OVERLAP ALREADY TREATED AREA. Use tongue depressor inside cheek or mouth guard on perioral area for counter pressure.
- If a needle alert is triggered, relax pressure or reduce treatment depth because you run the risk of damaging the needles.
- Repeat treatment pattern to cover area in mid to lower face. To remove blood and maintain visibility use a sterile towel dampened in chilled sterile water.
- After all areas have been treated, wipe face with chilled sterile water and sterile towel and apply thin film of petrolatum.

Post-Treatment

- Cleanse the treated area twice daily with water and mild facial cleanser without scrubbing or vigorously rubbing.
- Apply a light film of petrolatum at least twice daily for seven days.
- After skin has healed (no open wounds and cores have closed), apply a sunscreen and refrain from direct sun exposure
- Refrain from shaving, sunbeds and sunless tanning creams, direct sun exposure, scrubbing, scratching or picking treated area, submerging in pools, whirlpools, lakes oceans or rivers, or activities that result in overheating such as hot baths, spas or excessive exercise until skin has fully healed (cores closed).

Treatment Schedule

- Patients in the pivotal trial were treated up to 3 times. Retreatment was performed at 30 days for those that required more than 1 treatment. Treatments can be spaced further apart if more time is needed for healing.
- Before subsequent treatments, ensure that micro-cores have fully closed and healed and that any adverse events have been resolved.

Tips

- For thin, fragile skin, consider decreasing percentage skin removal and/or core depth. For thicker fibrotic skin, consider increasing core depth settings.
- The goal is to obtain full cores (micro-cores) at the minimum required depth. Start at a lower depth setting and only increase if depth is not achieving good coring.
- Always hold skin taut in treatment area.
- To minimize bleeding that may obscure the treatment area, begin treatment in the lower area of the face and works upwards to mid-face.
- Downtime will vary by patient and settings.
- Begin treatment moving from right to left to achieve tighter patterns being careful not to overlap.