# ellacor® System

# with Micro-Coring® Technology

# ellacor® Operators Manual

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**LBL-00029 Rev H**

# Contents

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# Welcome

The ellacor® System with Micro-Coring® Technology removes unwanted skin on the microscale without evidence of scarring or thermal damage to the tissue. Our specially designed skin-coring mechanism precisely controls location and depth of hollow coring needles to rapidly excise full thickness micro-columns (cores) of the dermal and epidermal tissue. The tissue columns are subsequently removed from the needles via the integrated suction system. The system provides a wide range of skin removal percentages and core excision depths settings to be customized to meet your patients' needs.

The ellacor® System with Micro-Coring® Technology 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.

## Copyright & Patent Information



Patents: www.cytrellis.com/patents

## Ellacor® System with Micro-Coring® Technology

Ellacor® System ships in a crate and includes the following components:

- Handpiece
- System Console
- Footswitch
- Power Cable/Accessories
- Product Information

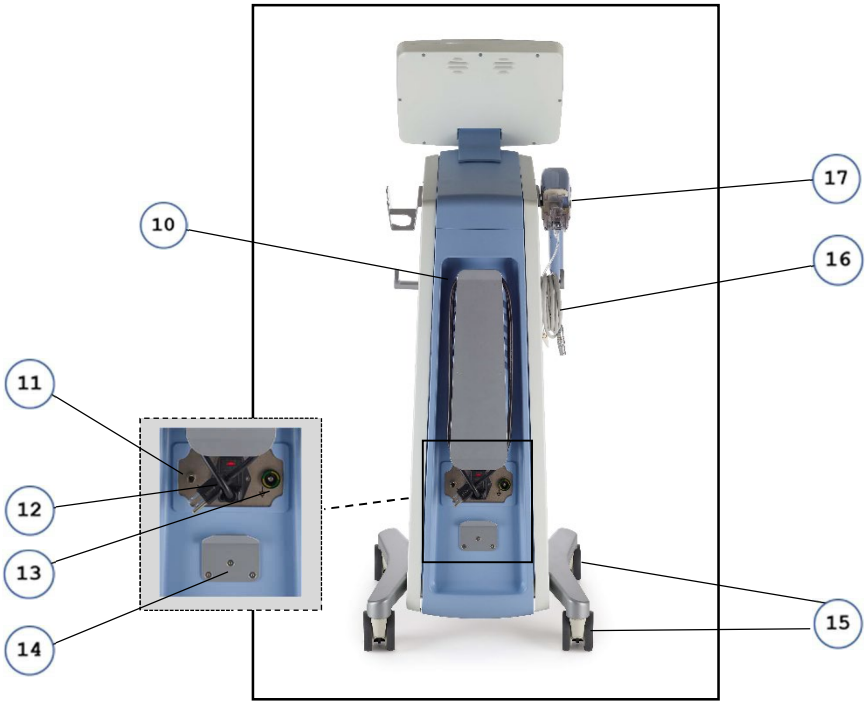
## *Ellacor® System (Front/Left Side View)*

*Figure 1. Ellacor® System Front/Left Side View*


1. **Touchscreen** allows practitioners to select treatment settings and view system status information.
2. **Power Button** turns the System on and off.
3. **Handpiece** positions and actuates the needle(s) of the sterile Single-Use Needle Cartridge into the tissue.
4. **Footswitch** is used to initiate treatment patterns.
5. **Vacuum** (internal component) provides suction to stabilize the treatment area and assist in removing cores of tissue from the needles.
6. **Suction Tubing** (commercially available) is used to connect the vacuum from the Console to the Needle Cartridge.
7. **Handpiece Cable Receptacle** is used to connect the Handpiece to the Console.
8. **Vacuum Filter** (commercially available) collects tissue and bodily fluids from the treatment site to prevent contamination to the system.
9. **Mobile Cart Handle** is used to position the cart.

## *Ellacor® System (Rear/Left Side View)*

*Figure 2. Ellacor® System Rear/Left Side View*




10 **Power Cable Wrap** is used to store the Console Power Cable and Footswitch Cable when the Console is not in use.

11 **Footswitch Cable Receptacle** is used to connect the Footswitch to the Console.

12 **Power Cable Receptacle** is used to connect the System to a power source.

13 **Potential Equalization Conductor** is used to attach third-party tools for grounding.

14 **Footswitch Mount** is used to store the Footswitch when not in use.

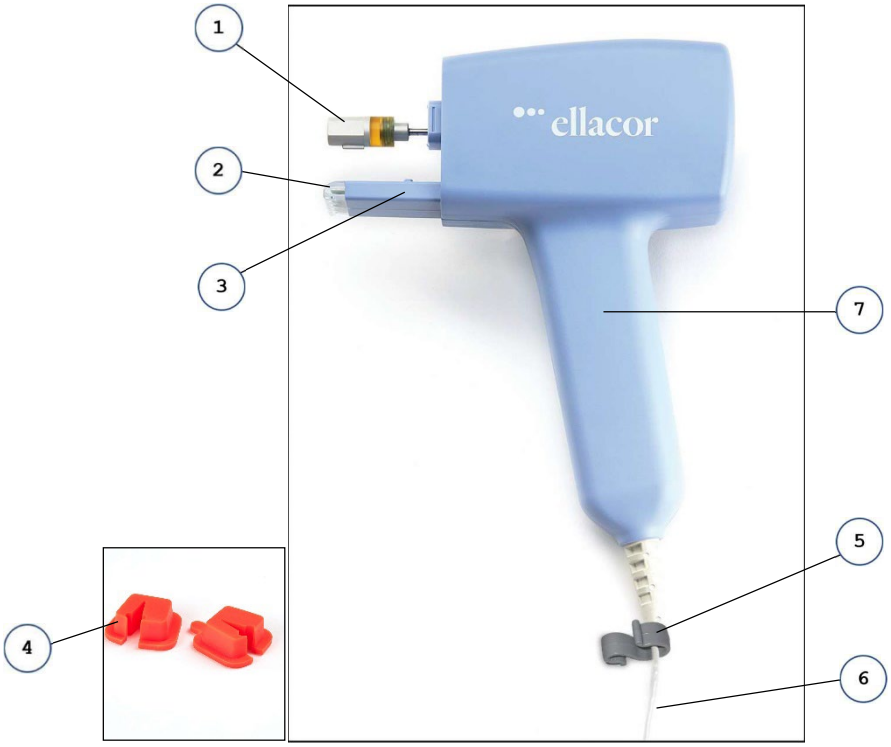
15 **Mobile Cart Wheels** give users the ability to move the System. **Wheel Locking Tabs** secure the Mobile Cart, so it does not move during treatment.

16 **Handpiece Cable Hanger** is provided on both the left and right side of the System Console for stowing the Handpiece Cable.

17 **Handpiece Holster** is provided on both the left and right side of the System Console for stowing the Handpiece.

## *Handpiece*

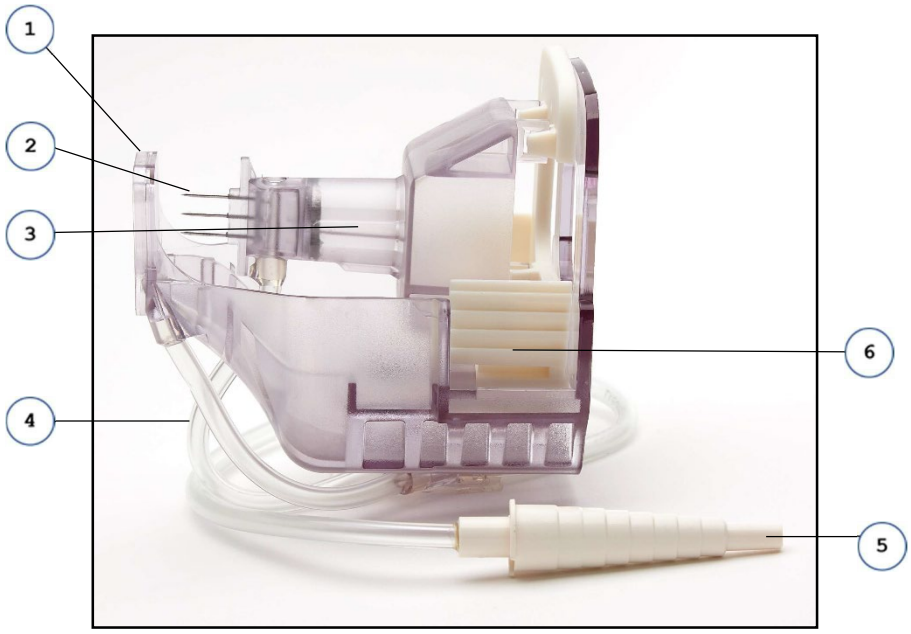
*Figure 3. Ellacor® Handpiece*




1. **Handpiece Actuator** moves the needle(s) to deliver the intended treatment pattern and core depth settings.
2. **Handpiece Light** illuminates the treatment area.
3. **Handpiece Head** is used to align and secure the Needle Cartridge to the Handpiece.
4. **Cleaning Cover** is used to prevent fluid ingress to the Handpiece during the cleaning and disinfecting process.
5. **Tubing Clip** is used to secure the Suction Tubing to the Handpiece Cable.
6. **Handpiece Cable** plugs into the Handpiece Cable Receptacle to provide power to the Handpiece.
7. **Handpiece Grip** provides a location to hold the Handpiece while treating.

## *Single-Use Needle Cartridge*

*Figure 4. Single-Use Needle Cartridge*




1. **Distance Spacer** aligns the position of the treatment pattern and delivers suction to stabilize the treatment area.
2. **Needle(s)** are used to core the treatment area.
3. **Needle Hub** contains the needle(s) and attaches to the Handpiece Actuator.
4. **Needle Cartridge Tubing** provides suction to the Distance Spacer and needle(s).
5. **Needle Cartridge Connector** connects the Suction Tubing to the Needle Cartridge Tubing.
6. **Needle Cartridge Lock** locks the Needle Cartridge to the Handpiece.

## Warranty Information

For specific and detailed warranty information for the ellacor® System, please refer to Cytrellis "Terms and Conditions".

## Ordering Replacement Components

*Table 1. Consumable Components*

| Component | Size | Available From |
|---|---|---|
| Single Use Needle Cartridge[1] | Triple Needle Cartridge (10x10 mm) | Cytrellis |
| Vacuum Filter[1] | 5-micron Vacuum Filter with standard connection for 1/4" diameter Suction Tubing[2] | Medical Supplier |
| Vacuum-rated Suction Tubing[1] | 1/4" (6.35 mm) inner diameter, ≥ 6 ft. (1.83 m) with easy grip ends | Medical Supplier |
| Fuse | 5x20mm, 10 A, 250 VAC fuses. (Type: CER, Slow; Breaking Capacity: 1.5kA) | Local Hardware Store |
| [1]These components must be replaced after each treatment.<br>[2] Filters can also be ordered via the following online resource:<br>https://shippertmedical.com/products/replacement-biofilter | | |

**CAUTION**
US federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the state in which he/she practices to use or order the use of the device; and the method of its application or use.

## Contacting Cytrellis

To reorder Single-Use Needle Cartridges or for other assistance, refer to the website at www.cytrellis.com or contact Cytrellis Customer Service at:

- Phone: (857) 254-1720 or (833) ELLACOR
- Email: customerservice@cytrellis.com

## Equipment Returns

For all equipment returns, contact Cytrellis for a Return Material Authorization (RMA) number, and return instructions.

## End of Life Disposal - Environmental Information

The ellacor® System (Console, Footswitch, Handpiece, and Needle Cartridges) must be disposed of according to local laws and hospital practices. This product is considered medical equipment and must not be disposed of as unsorted municipal waste and must be collected separately. Please contact the manufacturer or other authorized disposal company to decommission your equipment.

## Manual Conventions

While every effort has been made to ensure that the data given in this document is accurate, the information, figures, illustrations, tables, specifications, and schematics contained herein are subject to change without notice.

The following conventions are used in this manual:

- Information that is displayed on the screen appears in the `Courier New` font.
- Buttons to be pressed appear in **BOLD**.
- Web addresses appear in blue font and are underscored.
- Variables, actions are represented within <brackets>. When you see a setting contained in a bracket there are other values that can be used as well.
- And finally, a vertical bar ( | ) is used to separate actions.

## Symbols Used in This Guide

*Table 2. Symbols Used in This Guide*

| Symbol | Definition |
|---|---|
|   | Actions to be performed by the user are distinguished by a number or the STEP text box. |
|  | Supplemental/helpful details are provided in Notes indicated by the information symbol. |
|  | When this symbol appears, cautionary guidance follows. |
|  | When this symbol appears, the information contained in the warning/alert must be followed to avoid harm to either the operator or patient. |

## Built-in Help

The ellacor® System Help Screen displays an image describing how to perform the corresponding task on the Touchscreen when a **Help** button is pressed.

STEP To access the ellacor® System Help Screen, press the **Help** button, shown as a question mark, located next to the corresponding task.

*Figure 5. Sample Help Screen*


STEP To close the ellacor® System Help Screen, press the **CLOSE** button.

# ellacor® System Setup

The ellacor® System with Micro-Coring® Technology is intended for use by qualified personnel in a physician's office, clinic, or hospital and shall not be used near HF Surgical Equipment or the RF shielded room of Magnetic Resonance Imaging (MRI) Equipment. Proper System operation requires the selection of a well-ventilated space in a temperature-controlled environment. The System functions at ambient temperatures between 15°C (59°F) and 30°C (86°F), with controlled relative humidity between 20% and 80% non-condensing.

A correctly grounded power connection is required for safe System operation. Therefore, it is mandatory that the AC wall power outlet is correctly grounded and is rated for the electrical load of the system. Follow local electrical codes to ensure proper grounding of the AC wall power outlet.

## Choosing the Best Location for the ellacor® System

The ellacor® System is designed to work with left and right-handed practitioners. When choosing the best site for setting up the ellacor® System, consider the following:

1. Position the console at the desired location, at least 20 cm (8 in) from walls, furniture, or other equipment.
2. Place the unit within 1.75 m (5 ft 9 in) of the AC outlet to be used.
3. Use a floor cable cover to prevent a tripping hazard if the system is located in an area with heavy foot traffic.
4. Ensure that the exhaust vent on the rear of the console is not blocked. Adequate space around the console ensures proper air circulation.

## Connecting the System Components

5. To avoid electrical shock and fire hazards, inspect the Power Cable, Footswitch Cable, and Handpiece Cable to ensure they are not frayed or split.
6. To ensure proper operation, examine the Handpiece and Footswitch for damage. If all the components are in good working order continue with these instructions. If a component is damaged, do not use the System. Contact Cytrellis Biosystems, Inc. for further instructions.

7. Plug the Handpiece Cable into the Handpiece Cable Receptacle on the front of the System Console. The red dot on the Handpiece Cable should always be facing upwards.

*Figure 6. Handpiece Cable Plugged into Handpiece Cable Receptacle*

***NOTE***
If the Handpiece is NOT properly connected, an error displays on the Touchscreen when the system is turned on.

8. Place the Handpiece in the holster on either side of the console and hang the Handpiece Cable on the Cable Hanger.

*Figure 7. Handpiece in Holster*

9. Plug the Footswitch Cable into the Footswitch Cable receptacle on the rear of the System Console. To do so, align the cable and port key features, insert the cable to the port, and spin the locking rings in a clockwise direction.

*Figure 8. Connecting the Footswitch Cable*

10. Insert the receptacle end of the Power Cable into the Power Cable Receptacle on the rear of the System Console and insert the Power Cable plug into an AC wall power outlet that is correctly grounded and is rated for the electrical load of the system.

***CAUTION***
Only use the hospital-grade power cord provided with the System when connecting the console.

11. Position the console at the desired location, at least 20 cm (8 in) away from walls, furniture, or other equipment. Ensure that the exhaust vent on the rear of the console is not blocked. Adequate space around the console ensures proper air circulation.

***WARNING***
To avoid risk of electric shock, this equipment must only be connected to a supply mains with protective earth.

12. Engage the Wheel Locks by pressing down on the Locking Tabs.

# Clinical Applications

The ellacor® System with Micro-Coring® Technology 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.

***CAUTION***
A pertinent medical history should be obtained prior to treating to determine whether the patient is an appropriate candidate for treatment with the ellacor® System with Micro-Coring® Technology.

***NOTE***
This product is not intended for transdermal (under the skin) delivery of topical products such as cosmetics, drugs, or biologics.

## Contraindications

The ellacor® System with Micro-Coring® Technology should not be used for the treatment of:

- Areas of skin with dermatosis, e.g., skin tumors, keloids or in case of predisposition to keloids, solar keratosis, warts, or birthmarks
- The area within the bony orbital rim
- Mucous membranes
- Areas where silicone or synthetic material is implanted

The ellacor® System with Micro-Coring® Technology should not be used on patients that:

- Are pregnant or nursing mothers
- Are suffering from open wounds, sores, or irritated skin in the treatment area
- Have an allergy to stainless steel
- Have an allergy to topical, oral, or injected medications or preparations that may be used during the procedure, such as petrolatum, lidocaine, bupivacaine, chlorhexidine, or povidone-iodine
- Have a history or presence of any clinically significant bleeding disorder
- Have dermatological or autoimmune conditions that may affect the treatment outcome; these may include, but are not limited to: actinic keratosis, raised nevi, rosacea, melasma, active acne, cutaneous papules/nodules, active inflammatory lesions, dermatitis, psoriasis, cellulitis, urticarial folliculitis, acute inflammatory phase of scleroderma, rheumatoid arthritis, eczema, psoriasis, allergic dermatitis, collagen disorders, or lupus

- Have systemic infections or acute local skin infections (as Hepatitis disorders type A, B, C, D, E or F or HIV infection)
- Take a high dose of anti-coagulants or blood-thinning substances, e.g., aspirin, nonsteroidal anti-inflammatory drugs (NSAIDs), warfarin, heparin, acetylsalicylic acid during the previous fourteen (14) days
- Are on courses of chemotherapy, high-dose corticosteroid use, or radiation in the treatment area
- Have undergone plastic surgery of the face within the last twelve (12) months or have any facial surgical scars less than twelve (12) months old
- Have undergone injections of dermal fillers, fat, or botulinum toxin, as well as any minimally invasive/invasive skin treatment in the treatment area during the previous six (6) months
- Have scars less than six (6) months old in the treatment area

## Treatment Precautions

Appropriateness for treatment is based on the clinical assessment of the patient by the treating physician. Use caution when treating patients with the following conditions or taking the following medications:

- History of hyperpigmentation
- Recent exposure to sun or tanning beds with red, peeling, or swollen skin
- Recent trauma or surgery to the treatment area
- Active, chronic, or recurrent infection including bacterial or fungal infections
- Other medications or medical conditions that may interfere with the treatments or that the treatment provider believes may compromise the safety of the patient or the efficacy of the treatments. Refer the patient to their Primary Care Physician (PCP) or other managing health care provider for clearance prior to treatment
- History of or active herpes simplex infection in the treatment area
- Use of topical or oral preparations/medications that may change the skin integrity or prolong healing
- Over the Counter (OTC) and herbal supplements that may increase the risk of bleeding or prolong healing, such as gingko biloba, garlic, ginseng, dong quai, fever few, and fish oil

# Risks and Benefits

Side effects should be discussed with the patient prior to treatment. Proper pre- and post-treatment care reduces the risk of these side effects; however, some conditions may or may not resolve over time. Side effects associated with this procedure may include:

- Erythema – redness
- Ecchymosis – bruising
- Dryness, roughness
- Crusting
- Tenderness
- Bleeding
- Numbness
- Edema – swelling
- Burning
- Tightness/Pulling of Skin
- Pain/Discomfort
- Tingling
- Skin Peeling
- Circular Marks on skin

## *Uncommon Side Effects*

Other side effects not commonly observed with this procedure may include:

- Itching
- Hyper/hypo pigmentation (darkening/lightening of the skin)
- Hematoma (collection of blood under the skin)
- Infection
- Scarring
- Skin irregularities
- Skin necrosis (tissue damage)
- Asymmetrical appearance of the bilaterally treated regions
- Anesthesia toxicity (anesthesia-related complications may include allergic reaction and possibly death)

## *Benefits*

In a study of 51 patients with the ellacor® System with Micro-Coring® Technology, two(2) to three (3) treatments using skin removal percentage (needle density) settings of 6.7 or 7.9% for the face and inferior to the jawline and a 6.7% for the perioral area, with core-depth settings in a range of 2.5mm to 5mm, spaced approximately 30 days apart, showed a significant improvement (≥ 1 grade change) in moderate to severe cheek wrinkles 90 days after treatment. See Appendix B, Safety and Regulatory Information, Clinical Summary on **page 75** for further information.

# Setting up the Treatment Area

At the start of each treatment day, verify that the ellacor® System is properly set up, as instructed in "System Setup" beginning on page 13, and that the items detailed in the “User-Supplied Items” listed below are available.

- Staging User-Supplied Items
- Positioning the System
- Turning on the System
- Preparing the System for Use

## Staging User-Supplied Items

The following items are supplied by the user.

### *Standard Facility Supplied Items*

- Disposable cosmetic marker or pencils
- Surgical bonnets and hair bands
- Dental rolls
- Tongue depressors
- Biohazard trash bags
- Sharps container with a wide mouth that can accept Single-Use Needle Cartridge
- Small treatment table, mayo stand, or equivalent
- Small drape for mayo stand

### *Treatment Specific User-Supplied Items*

These single-use consumables are used once and never used on multiple patients.

- Vacuum-rated Suction Tubing - ¼ inch diameter (6.35 mm), > 6 ft. (1.83 m)
- Vacuum Filter (5-micron with standard connection for 1/4" inch internal diameter suction tubing)
- Personal protective equipment for provider and assisting staff as per site standard policy
- Sterile water (chilled)
- Sterile towels for blood management
- Soft bristle toothbrush (for cleaning)
- 70% Isopropyl Alcohol (Isopropanol) solution and/or wipes
- Clean wipes (for cleaning and disinfection)
- Clean Soft Cloth (for cleaning)
- Gloves

## Positioning the System

When positioning the ellacor® System, make sure the Footswitch can be reached and the Handpiece can be moved freely. Make sure the exhaust vent on the rear of the console is not blocked. Adequate space around the console ensures proper air circulation.

1. Disengage the wheel locks by pulling up on the locking tabs.

*Figure 9. Locking Tabs*

*Wheel Locked (Tab Down)*

*Wheel Unlocked (Tab Up)*

2. Use the Handle on the front of the System Console to push the console to the desired location.

***WARNING***
Maintain a separation distance of at least 20 cm (8 in) between the System Console and the body of the user or nearby persons.

3. Engage the wheel locks by pressing down on the locking tabs.

## Turning on the System

Before turning on the system, verify that the system components are properly connected and that the main Power Cable is connected to an appropriate wall power outlet.

4. Press the **POWER** button on the front of the System Console just below the Touchscreen to turn on the system.

***NOTE***
The Power Cable is the main means of power disconnection for the System.

5. When the System has powered up, a **Start** button appears:

*Figure 10. Startup Screen*


6. Press the **Start** button on the Touchscreen.

***CAUTION***
Shortly after the **Start** button is pressed, the handpiece shaft will move.

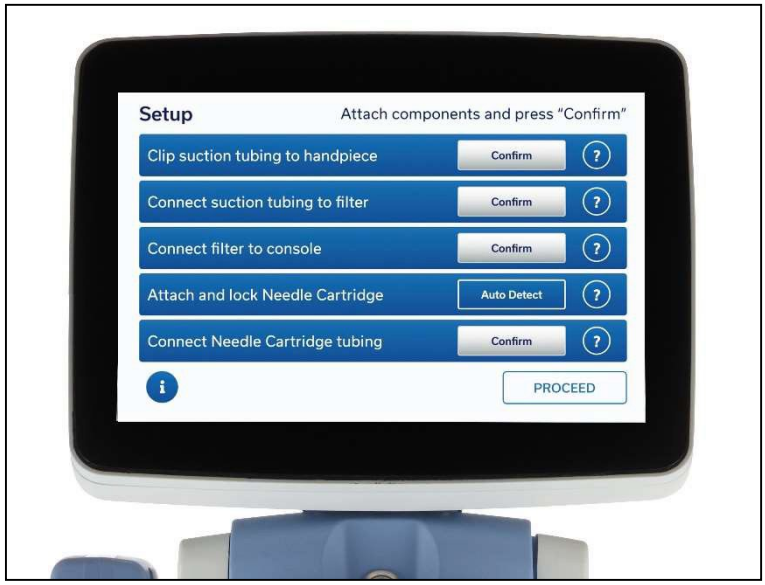
**NOTE**
Do not disconnect the Handpiece while powered. The Handpiece is powered on when the **Start** button is pressed and remains powered through the Patient Profile screen, Setup screen, Treatment screen in Standby and Ready modes, and on the Treatment Complete screen prior to unlatching the Needle Cartridge. The Handpiece should not be removed at any of these times

7. The Handpiece initializes and conducts a self-test. It repositions the mount for the needle hub to the loading position. When the self-test completes, the Patient Profile screen appears:

*Figure 11. Patient Profile Screen*


8. Enter the Patient Profile information as appropriate. Once complete, press **PROCEED** to continue to the Setup screen:

*Figure 12. Setup Screen*



# Preparing the System for Use

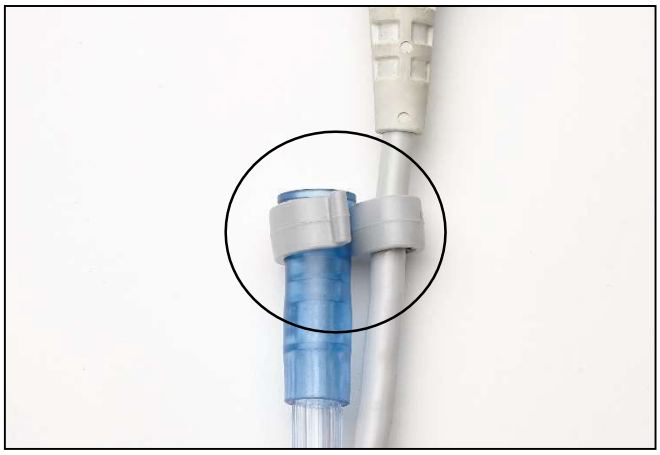
Setup screen guides the practitioner through the steps for treatment setup, including:

- Attaching the Suction Tubing to the Handpiece Cable,
- Attaching the Suction Tubing to the Vacuum Filter,
- Attaching the Vacuum Filter to the Console, and
- Installing and locking the Single-Use Needle Cartridge onto the Handpiece.

## *Attaching the Suction Tubing to the Handpiece Cable*

9. Secure the Suction Tubing to the Handpiece Cable using the Tubing Clip.

*Figure 13. Securing the Suction Tubing to the Handpiece Cable*

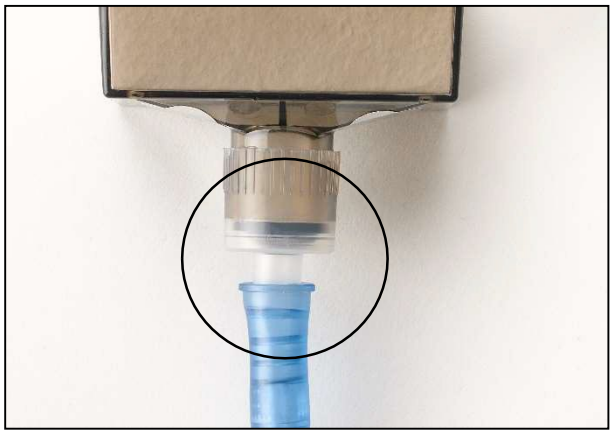


10. Validate the tubing is secure by pressing the **Confirm** button to the right of the "`Clip suction tubing to handpiece`" label.

## *Attaching the Suction Tubing to the Vacuum Filter*

11. Attach the other end of the Suction Tubing to the Vacuum Filter.

*Figure 14. Attaching the Suction Tubing to the Vacuum Filter*



12. Validate the connection on the Touchscreen by pressing the **Confirm** button to the right of the "`Connect suction tubing to filter`" label.

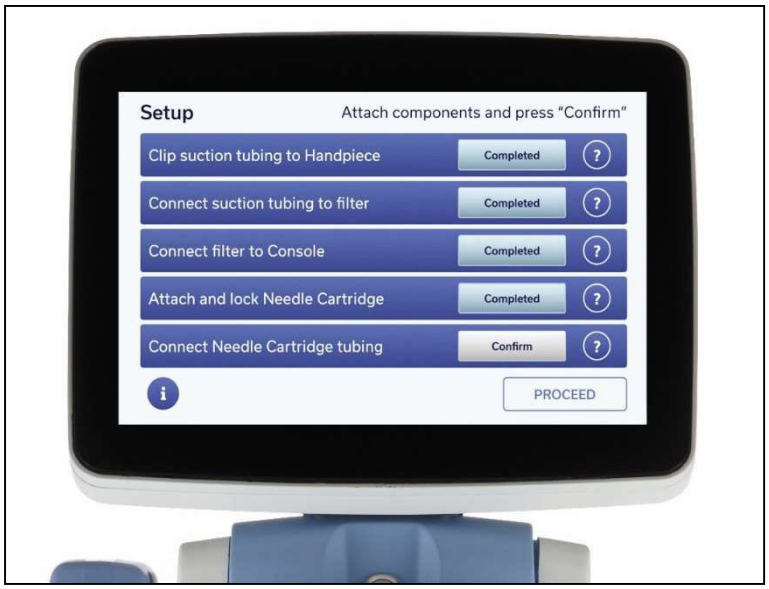
## *Attaching the Vacuum Filter to the Console*

13. Attach the Vacuum Filter to the Console.

*Figure 15. Vacuum Filter Attached to Console*

14. Validate the connection on the Touchscreen by pressing the **Confirm** button to the right of the "`Connect filter to console`" label.

*Figure 16. Setup Screen (Tubing and Filter Installed)*



## *Installing and Locking the Single-Use Needle Cartridge onto the Handpiece*

15. Select the appropriate Needle Cartridge:

*Figure 17. Single-Use Needle Cartridge*


***CAUTION***
The System is designed for use only with the Cytrellis® Needle Cartridge.

16. Inspect all sterile packaging to ensure that it is not damaged and that the expiration date on the label has not passed.

***WARNING***
Discard the Needle Cartridge immediately if the needles have been damaged or suspected of being damaged.

17. While wearing gloves, open the sterile package for the individually wrapped Needle Cartridge and remove the protector from the Needle Cartridge.

*Figure 18. Removing the Needle Cartridge Protector*

18. Unwrap the Handpiece Cord to allow for movement, then remove the Handpiece from the Holster. Insert the Handpiece Head into the Needle Cartridge slot until an audible snap is heard, as shown below:

*Figure 19. Inserting the Handpiece into the Needle Cartridge*

19. Carefully lift the Handpiece and Needle Cartridge from the packaging, ensuring that the Needle Cartridge is attached to the Handpiece.

20. To ensure the Handpiece is fully inserted into the Needle Cartridge, pull the cartridge towards the Handpiece so that it is flush. There should be no gap between the components.

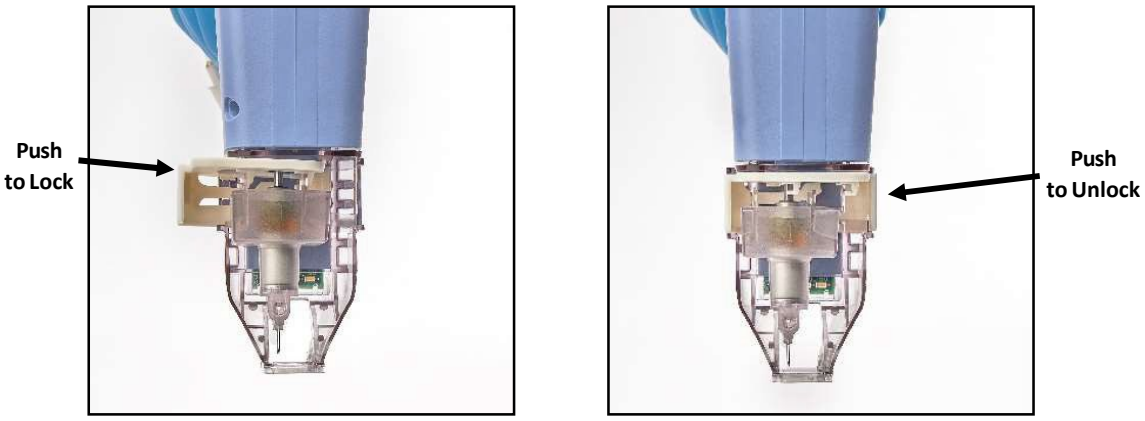
*Figure 20. Installing the Needle Cartridge (Flush with the Handpiece)*

***WARNING***

Follow OSHA guidelines on needle sticks and sharps injury prevention and your office procedures to avoid needle sticks while handling the Needle Cartridge.

21. Once the Needle Cartridge has been fully inserted, lock the Needle Cartridge by pushing the Needle Cartridge Lock into the locked position. When the lock has been fully engaged, the user will hear a single click.

*Figure 21. Locking/Unlocking the Needle Cartridge on the Handpiece*



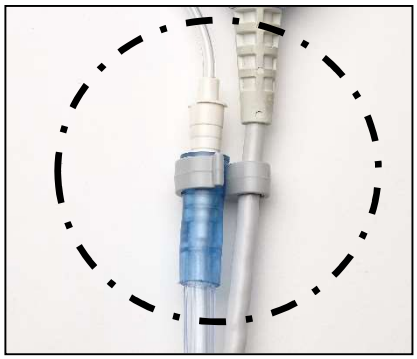

*Needle Cartridge Unlocked* *Needle Cartridge Locked*

22. After properly locking the new Needle Cartridge onto the Handpiece, the system automatically changes the Needle Cartridge Status to "`Completed`".

23. Review the Setup Screen to confirm the Needle Cartridge Status says "`Completed`". If the Needle Cartridge Status does not say "`Completed`", try unlocking and relocking the Needle Cartridge to fully engage the Lock.

24. Connect the Needle Cartridge Tubing Connector to the open end of the Suction Tubing.

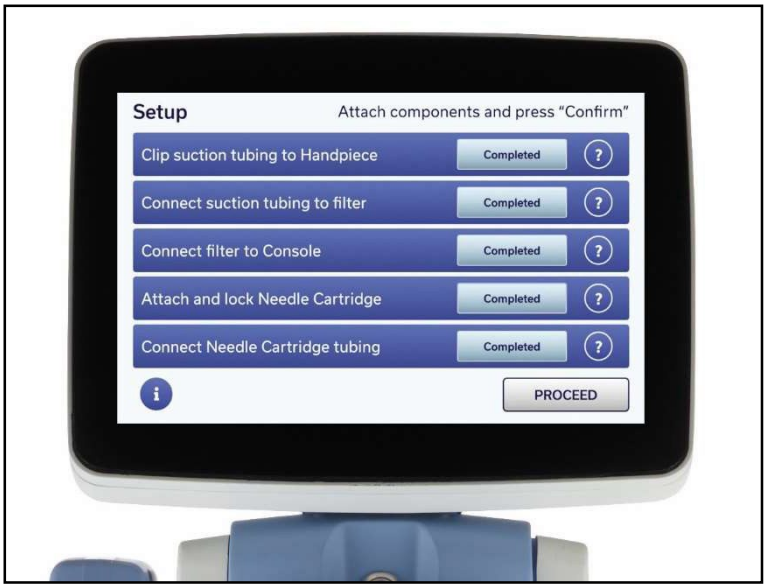
*Figure 22. Connecting the Needle Cartridge Tubing to the Suction Tubing*



25. Validate the Suction Tubing connection on the Touchscreen by pressing the **Confirm** button to the right of the "`Connect needle cartridge tubing`" label.

26. After all actions on the Setup screen are "`Completed`", press the **PROCEED** button in the lower right-hand corner to advance to the Treatment screen and select the treatment parameters.

*Figure 23. Setup Screen (Validation)*




27. Set the Handpiece and the other end of the Tubing down on the small treatment table or place in the Handpiece Holster.

***CAUTION***

- After installing the Needle Cartridge, keep the end of the Distant Spacer free from contact with any surfaces. Do not let the Handpiece fall while completing setup.
- Take care not to pinch or disrupt the Tubing when positioning the Handpiece.

***WARNING***

Discard the Needle Cartridge immediately if the needles have been damaged or suspected of being damaged.

## *Treatment Screen*

The Treatment Screen displays on the Touchscreen after the **PROCEED** button is pressed on the Setup Screen.

*Figure 24. Treatment Screen (Standby Mode)*


From the Treatment Screen, you can:

- Toggle between Standby and Ready modes (system status)
- Select <Skin Removal Percentage> and <Core Depth> setting
- View the Needle Cartridge type and `Total Core Count`
- Complete the treatment session and go to the Treatment Complete screen

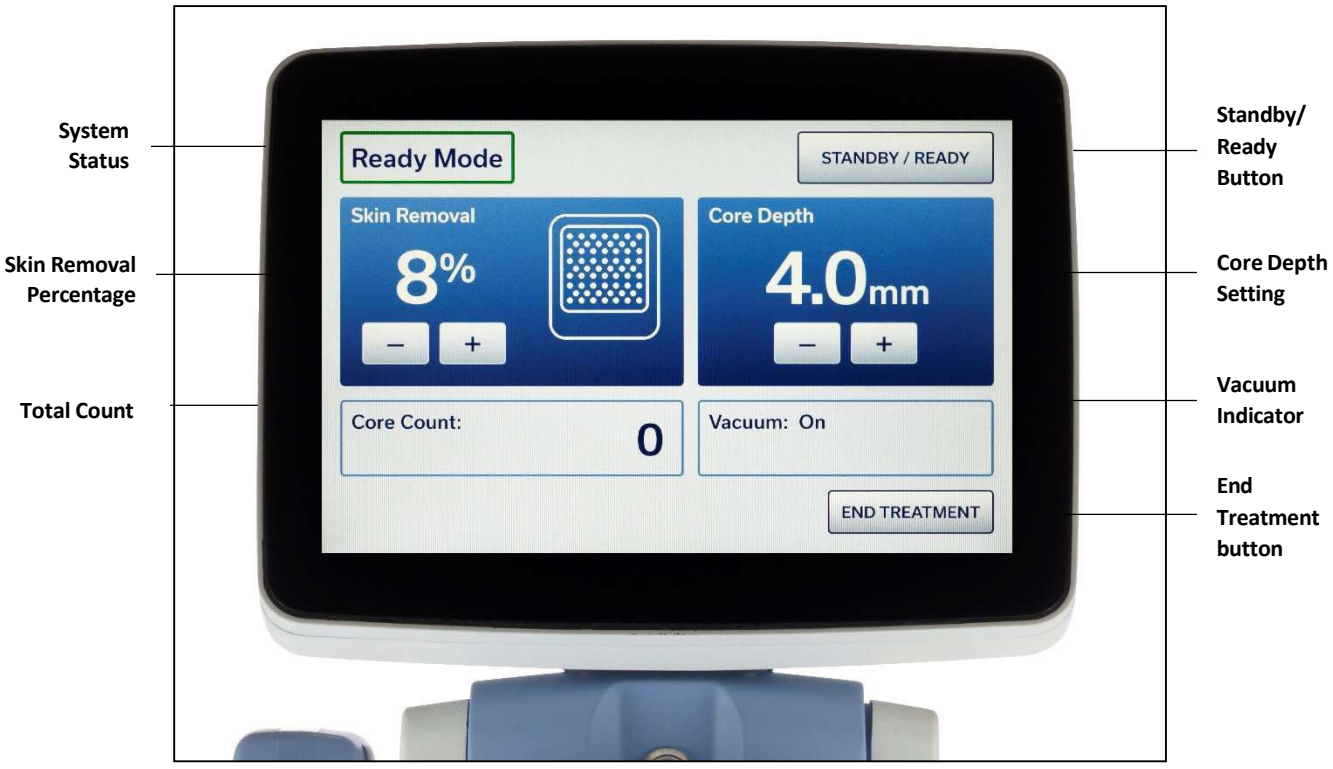
## *Toggling Between Standby and Ready Modes*

The System status (`Standby` or `Ready`) displays on the Treatment Screen at all times to alert you to the current mode.

- In Standby mode, the Footswitch is disabled, and the Vacuum system and Handpiece light are deactivated.
- In Ready mode, the Footswitch is enabled, and the Vacuum system and Handpiece Light are activated. Once the System is in Ready mode, treatment can be initiated by pressing the Footswitch.

***NOTE***
When in Ready mode, if the Footswitch is not pressed for five minutes, the System automatically goes into Standby mode.

*Figure 25. Treatment Screen (Ready Mode)*



## *Selecting the Skin Removal Percentage and Core Depth Setting*

### Skin Removal Percentage

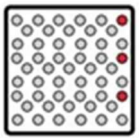
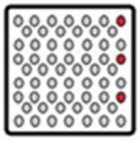
Skin removal percentage is defined as the percentage of tissue removed. See the table for the available <skin removal percentage> settings.

***NOTE***
The red dots in the treatment pattern below signify the needle mechanism's starting point as the needles move from left to right to complete the treatment pattern.

STEP To select the <skin removal percentage>, press the **–** and **+** buttons under the Skin Removal display.

The corresponding <skin removal percentage> and treatment pattern automatically appears on the treatment screen [see Figure 25. Treatment Screen (Standby Mode)].

*Table 3. Skin Removal Percentages by Needle Cartridge Type*

| Triple-Needle Cartridge (10x10 mm window) | |
|---|---|
| **Skin Removal %** | **Pattern** |
| 1% |  |
| 3% |  |
| 5% |  |
| 7% |  |
| 8% |  |

### Core Depth Setting

Core depth setting is defined as the depth of the core removed by the ellacor® System with Micro-Coring® Technology, measured in millimeters. The core depth may be affected by the quality of the skin being treated. For thin, fragile skin, adjust the <core depth> setting to a lower number (e.g., 3.0); test and evaluate the treatment pattern for efficient coring; and adjust the <core depth> setting as needed. For thicker, fibrotic skin, adjust the <core depth> setting to a larger number (e.g., 4.0); test and evaluate the treatment pattern for efficient coring; and adjust the <core depth> setting as needed. The <core depth> setting can be set from 0.0 to 4.0, in 0.5 increments.


To select the <core depth> setting, press the **–** and **+** buttons under the Core Depth Setting display. [see Figure 25. Treatment Screen (Standby Mode)].

## *Viewing the Total Core Count*

The total number of tissue cores excised for all Needle Cartridges used during the current treatment session is displayed on the Treatment Screen. The `Core Count` is also displayed on the Treatment Complete screen. Pressing the **END TREATMENT** button on the Treatment Screen resets the `Core Count` and deactivates the current Needle Cartridge to prevent cross-contamination.

***NOTE***
Maximum number of cores that can be removed by the Triple-Needle Cartridge is 24,000.

# Treatment Instructions

## *Treatment Instructions*

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*

1. Ensure that the patient is wearing a hair band or hair net. Clean the patient skin with suitable cleansing wipe to remove all traces of make-up.

2. Using office protocol, determine the appropriate pain management technique.

***CAUTION***

A pertinent medical history should be obtained when assessing the risks and benefits of various pain management techniques. Follow the recommended manufacturer's instructions for proper use of the desired pain management method.

3. Make the patient comfortable. The patient should be positioned on the treatment bed, with the patient's head in a horizontal position.

4. Press the **STANDBY/READY** button on the Treatment Screen to go to `Ready` mode.

***CAUTION***

- To prolong needle function, do not apply downward pressure with the treatment window during treatment.
- Using gauze pads, even those classified as non-shedding, during the procedure may cause the Needle Cartridge to clog. Use sterile towels for blood management instead.

5. Select the appropriate <skin removal percentage> and <core depth> setting, as described in the previous section, to deliver the best treatment for the patient. Please see schematic below for recommended starting <core depth> settings. The <core depth> setting can be increased or decreased by 0.5mm increments to achieve maximum coring and ensure patient safety.

6. To ensure patient safety, consider the dermal and subcutaneous fat thickness of the patient as well as location of nerves and blood vessels when selecting the coring depth setting. Refer to the schematic below of front and side views of the face including nerves, blood vessels and anatomical areas as well as core depth setting guidance. Descriptive explanations are also provided. Do NOT apply downward pressure on the handpiece during treatment to avoid compressing the tissue.

**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**

## Maximum Depth Setting

- 2.5 mm; perioral area
- 3.0 mm; jawline, upper cheek
- 4.0 mm; mid to lower cheek

## Arteries:

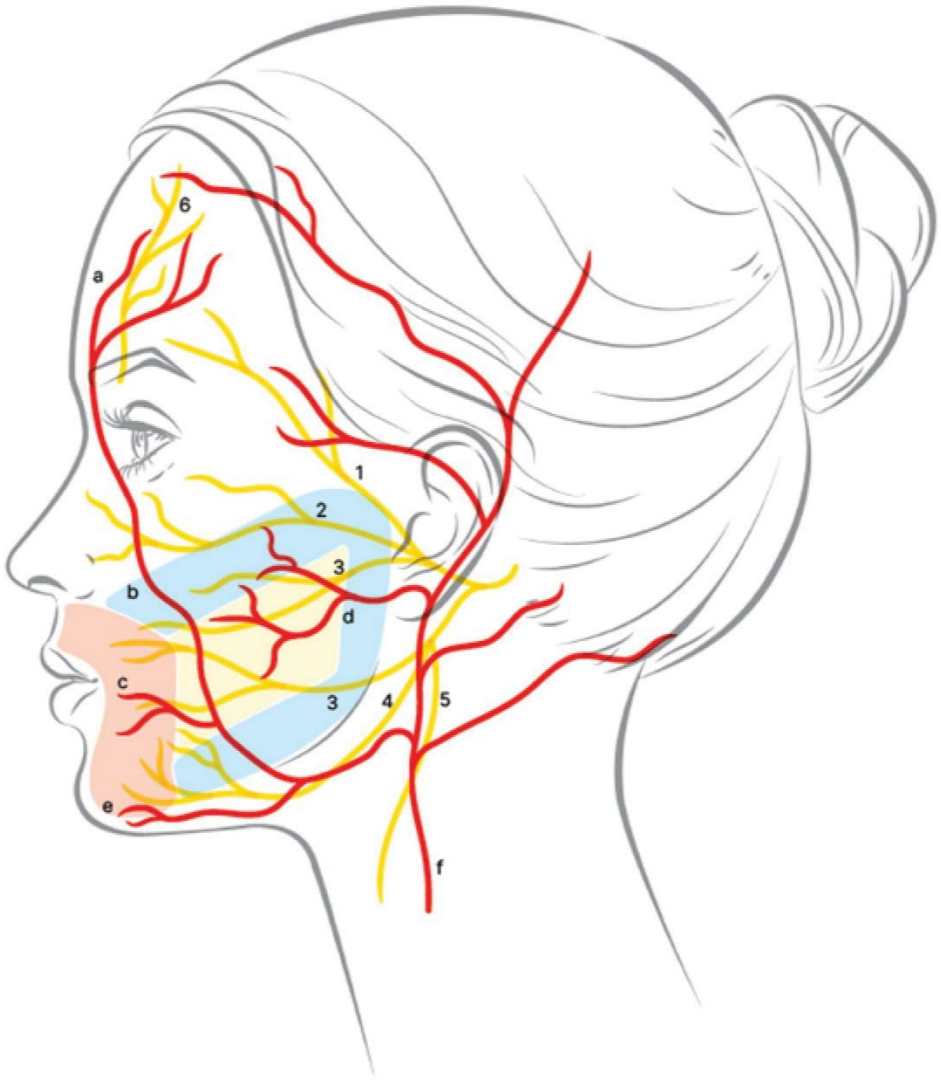
*(letters)*

a. Supraorbital
b. Lateral Nasal
c. Inferior Labial
d. Transverse
e. Submental
f. Carotid

## Nerves:

*(numbers)*

1. Temporal
2. Zygomatic
3. Buccal
4. Mandibular
5. Cervical
6. Supraorbital



## Maximum Depth Setting

- 2.5 mm; perioral area
- 3.0 mm; jawline, upper cheek
- 4.0 mm; mid to lower cheek

## Arteries:

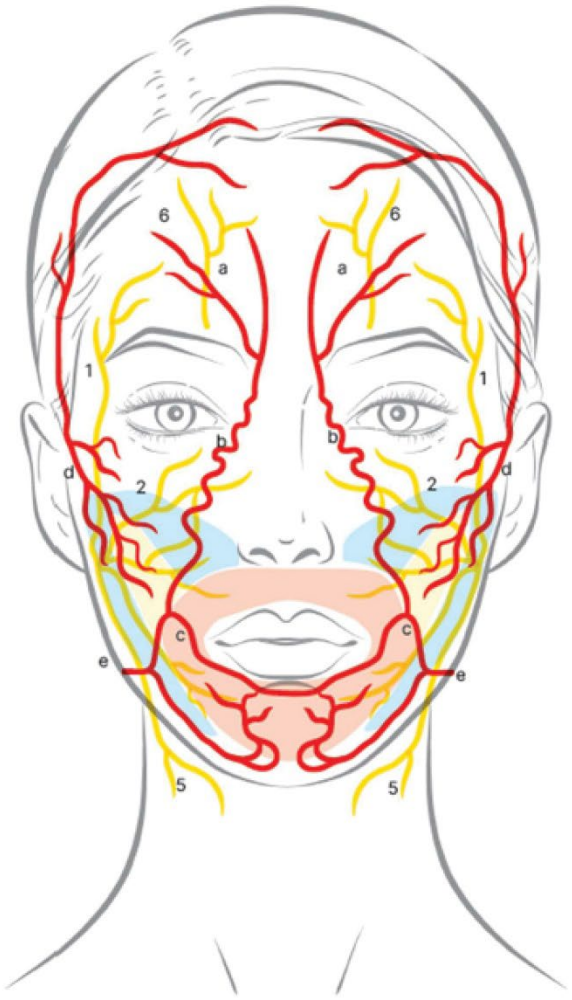
*(letters)*

a. Supraorbital
b. Lateral Nasal
c. Inferior Labial
d. Transverse
e. Submental

## Nerves:

*(numbers)*

1. Temporal
2. Zygomatic
3. Buccal
4. Mandibular
5. Cervical
6. Supraorbital

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**Trigeminal nerve branches**

- The Supraorbital Nerve is located on average 25.32mm from the facial midline at the medial brow

- The Infraorbital Nerve is located on average 29.57mm from the facial midline. The distance from the infraorbital rim is on average 8.8mm.

- The Mental Nerve is located 25.55mm from the facial midline. The mental foramen is located between the first and second premolar, or at the second premolar.

**Facial nerve branches**

- The Frontal Nerve is located is located along Pitanguy's Line, which is defined as running from 0.5 cm below the tragus to 1.5 cm above the lateral eyebrow.

- The mean horizontal distance of the zygomatic branch as it emerges from the anterior border of the parotid gland and the tragus is 30.71 mm, whereas the mean vertical distance of the zygomatic branch from the midpoint between the tragus and the lateral palpebral commissure is 19.29 mm.

- The Buccal Nerves course below a line drawn from tragus to ala nasi.

- In proximity to the treatment area, the Marginal Mandibular Nerve the runs, on average, 3.6 mm superior to the point at which the facial artery reaches the inferior border of the mandible, and 10.9 mm superior to the vertical line that extends from the commissure of lip to the inferior border of the mandible.

**Arteries**

- The Facial Artery is located is located 19 mm ± 5.5 from the oral commissure, 31 mm ± 6.8 from the mandibular angle, 92 mm ± 8.0 from the lateral canthus.

- The Angular Artery runs along the nasolabial fold 6.7 ± 4.4 mm from the nasal ala.

- The Superficial Temporal artery is located 16.68+/-0.35 mm at the front of the tragus.

7. Hold the skin taut and place the Needle Cartridge on the area of the skin to be treated.

8. When the Needle Cartridge is correctly placed on the skin, the suction air flow is no longer audible at the treatment window, be careful not to break the suction. Use this technique to ensure optimal skin surface interaction with the needles. Do *NOT* apply downward pressure while needles are moving to prevent damage to the needles.

***NOTE***

- Retract/stretch loose skin if necessary, taking care to keep fingers out of the treatment window area.
- Suction may be difficult to achieve on smaller and bony areas. In these areas, position the window on the skin and activate the Footswitch, but do *NOT* apply downward pressure.

***CAUTION***

Verify that the treatment parameters are correct before pressing the Footswitch.

9. Press and hold the Footswitch down to deliver the treatment pattern. The treatment will be applied according to the <skin removal percentage> selected. The pattern will be applied starting in the current location of the needles.

***WARNING***

- Keep hands and fingers away from the treatment window at all times while the needle is activated.
- Do NOT continue use of the System if the power goes out. If the System experiences a sudden loss of power, the needles may remain extended beyond the distance spacer. Take precautions against needle sticks. Avoid coming in contact with the treatment area of the distance spacer when the Handpiece is unpowered.

***NOTE***

To terminate treatment without powering down the system, simply release the Footswitch.

10. When the ellacor® System has completed the treatment pattern, the Vacuum will disengage, and the needles will stop moving. Lift the Needle Cartridge from the skin and assess the cored area. The cored area should be visually distinct (with lines/edges indicating where the treatment had been applied) and a clean center with no evident debris.

11. If coring was not achieved, review the treatment settings and technique. Increase the <core depth> setting or hold the skin tauter around the treatment area and repeat the pattern.

12. Repeat steps 5 through 9 until the desired level of coring is achieved. To remove blood and maintain visibility of the treatment area, use a sterile towel dampened in chilled sterile water.

13. Move onto the adjacent area to be cored. Hold the skin taut, place the Needle Cartridge on the area of the skin to be treated, gently pull up on the Handpiece being careful not to break the suction, and then press the Footswitch to deliver the coring pattern. Repeat this step for each area to be cored until the entire treatment area has been cored. (Visualize one row/column of cores across the treatment area to provide a well-aligned treatment pattern.)

***NOTE***

To interrupt treatment at any time, simply release the Footswitch. The system remains in `Ready` mode unless you press the **STANDBY/READY** button to go to `Standby` mode. To continue treatment from `Ready` mode, press the Footswitch. To continue treatment from `Standby` mode, press the **STANDBY/READY** button to `Ready` mode, and then press the Footswitch.

14. After all areas have been treated, wipe the face with chilled sterile water and sterile towel to remove any debris. Apply a light film of petrolatum to the treatment area.

15. Instruct patient on post care treatment and possible side effects:

    a. Cleanse the treated area twice daily with water and mild facial cleanser. Do not scrub or vigorously rub face
    b. Apply light film of petrolatum at least twice daily for 7 days
    c. After skin has healed (no open wounds and holes have closed), apply a broad-spectrum sunscreen daily and refrain from direct sun exposure
    d. Refrain from the following activities until skin is fully healed (no open wounds and holes have closed):
        i. Shaving
        ii. Using tanning beds and sunless tanning cream
        iii. Direct sun exposure
        iv. Scrubbing, scratching and/or picking at the treated area
        v. Contact sports or any other activity that could cause injury to the treated area
        vi. Submerging the treated area in pools, whirlpools, lakes, oceans or rivers
        vii. Activities that result in overheating, such as long exposure to hot baths, spas, or excessive exercise

16. After completing the treatment session, press the **END TREATMENT** button on the Treatment Screen.

17. When the validation screen appears, choose one of the following:

- Press the **END TREATMENT** button to go to the Treatment Complete Screen.
- Press the **CANCEL - RETURN** button to return to the previous screen.

*Figure 26. End Treatment Validation Screen*


*Figure 27. Treatment Complete Screen*

## Replacing the Needle Cartridge During Treatment

18. Press the **STANDBY/READY** button to go to Standby mode.

***CAUTION***

The Needle Cartridge can only be removed from the Handpiece when the system is in `Standby` mode. If you attempt to unlock the Needle Cartridge when the system is in `Ready` mode, a notification pop-up window displays on the Touchscreen to alert you to re-lock the Needle Cartridge. After re-locking the Needle Cartridge, the system goes to `Standby` mode, enabling you to remove the Needle Cartridge.

19. Disconnect the Suction Tubing from the Needle Cartridge Tubing Connector and place the Tubing onto your work area.

20. Remove and dispose of the Needle Cartridge, as instructed in “Post-Treatment Clean-up Instruction” on page 43.

21. Install the new Needle Cartridge, as instructed in “Installing and Locking the Single-Use Needle Cartridge onto the Handpiece” on page 26.

22. Reconnect the Suction Tubing to the Needle Cartridge Tubing Connector.

23. Verify that the new Needle Cartridge is properly installed by confirming the status on the Setup Screen, then press the **Proceed** button to go to the Treatment Screen.

***WARNING***

Discard the Needle Cartridge immediately if the needles have been damaged or are suspected of being damaged.

24. Resume the treatment session.

# Post-Treatment Clean-Up Instructions

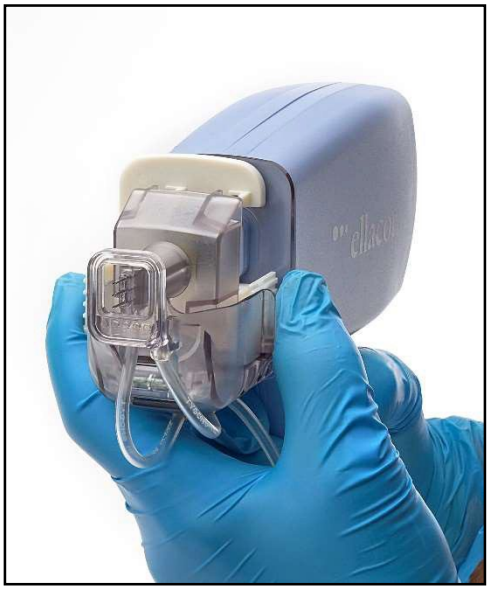
After completing the treatment session and pressing the **End Treatment** button on the Treatment Screen, the Treatment Complete screen displays. The Treatment Complete screen guides you through the steps for removing the single-use treatment components, as described below.

*Figure 28. Example Treatment Complete Screen*


1. Disconnect the Needle Cartridge Connector from the Suction Tubing.

2. Push the Needle Cartridge Locking Tab to the unlock position.

*Figure 29. Push Out Locking Tab*

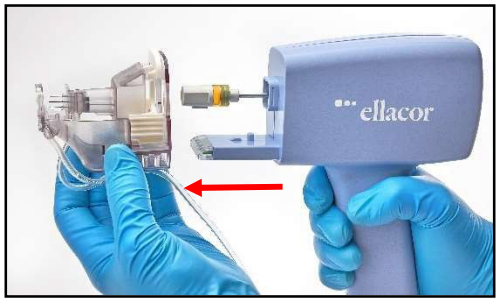


3. Pull the Needle Cartridge straight off the end of the Handpiece. Use a quick and firm motion to avoid damaging the Handpiece.

***WARNING***

Follow OSHA guidelines on needle sticks and sharps injury prevention and your office procedures to avoid needle sticks while handling the Needle Cartridge.

*Figure 30. Pull Needle Cartridge Off Handpiece*




4. Dispose of the Needle Cartridge in a wide mouth sharps container and per facility protocol.

5. Disconnect the Suction Tubing from the Tubing Clip.

6. Disconnect the Vacuum Filter from the System Console and dispose of the Suction Tubing and Vacuum Filter in a biohazard bin per facility protocol.

7. Proceed to clean and disinfect the Handpiece as instructed below in "Post-Treatment Clean-Up".

# Post-Treatment Clean-Up

STEP Disconnect the Handpiece from the System Console prior to completing the cleaning and disinfection steps.

*Table 4. Routine User Maintenance Activities*

| Action | Frequency |
|---|---|
| Clean the Handpiece | Between patient use |
| Disinfect the Handpiece | Between patient use |
| Clean the System Console (including the display, holster, and any contaminated surfaces) | As needed |

## *Cleaning the Handpiece*

These steps remove any debris, soil or bodily fluids which may be present on the handpiece prior to disinfection. A toothbrush dampened with warm tap water and 70% isopropyl alcohol wipes are needed to complete these steps.

***WARNING***
Perform all cleaning and disinfection steps in an appropriate room separate from the patient. Personal protective equipment (PPE) must be worn by personnel performing the reprocessing.

8. Immediately after use, install the Handpiece Cleaning Cover onto the front of the Handpiece as shown.

***NOTE***
The Handpiece Cleaning Cover is intended to prevent water ingress during cleaning.

*Figure 31. Installing the Handpiece Cleaning Cover*

*Handpiece without Cleaning Cover*

*Handpiece with Cleaning Cover Installed*

9. Thoroughly clean the Handpiece surface using a soft bristled Toothbrush.

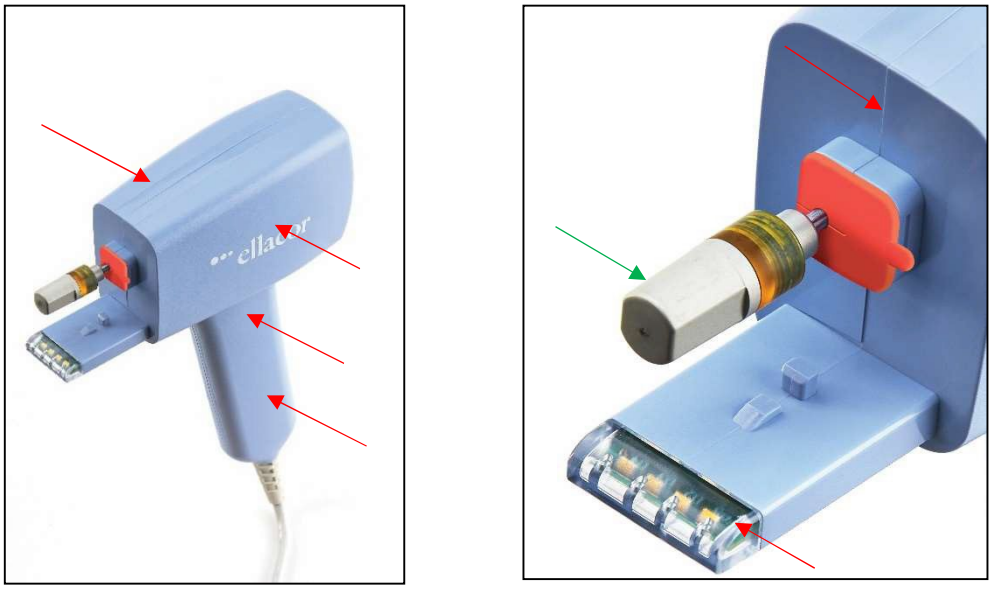
   a. Wet the Toothbrush with warm tap water.
   b. Shake off the excess water.
   c. Gently brush the outer surfaces of the Handpiece, paying particular attention to the crevices and seams of the Handpiece shell. See diagram in Figure 33 for surfaces requiring cleaning with the soft bristled toothbrush.

***CAUTION***
- Do NOT submerge in water or autoclave the Handpiece.
- Do NOT use the wet brush on the Handpiece Actuator

10. Dampen a clean wipe with warm tap water, and thoroughly wipe the Handpiece Actuator for at least 30 seconds. Discard the wipe. Repeat this step until all visible soil is removed.

***CAUTION***
Ensure that the wipe is damp, not wet.

*Figure 32. Handpiece Surfaces to be Cleaned*



*Red arrows indicate surfaces that require brushing; step 9, green arrow indicates the Handpiece Actuator surface to wipe per step 10.*

11. Dampen a clean wipe with warm tap water, and thoroughly wipe all surfaces of the Handpiece for at least 30 seconds. Discard the wipe.

***CAUTION***
Ensure that the wipe is damp, not wet.

12. With an unaided eye, visually examine the surface to ensure that all adherent soil has been removed. Repeat the cleaning process if necessary.

13. Dampen another clean wipe with 70% isopropyl alcohol (isopropanol), and thoroughly wipe all surfaces of the Handpiece for at least 30 seconds.

14. Allow the Handpiece to dry completely before disinfection by either air-drying or drying with a sterile lint-free tissue.

## *Disinfecting the Handpiece*

These steps significantly reduce any remaining bacterial and vegetative organisms not removed during the cleaning procedure. Multiple 70% isopropyl alcohol wipes are needed to complete these steps.

15. After cleaning the Handpiece, wipe the Handpiece with a clean wipe dampened with 70% isopropyl alcohol (isopropanol). Discard the wipe.

16. Dampen another clean wipe with 70% isopropyl alcohol (isopropanol) and wipe the Handpiece thoroughly for five (5) minutes.

17. Follow this cleaning with an additional eight (8) minutes of continuous contact of the wipe with the surfaces being cleaned. Additional wipes should be used as needed to ensure the Handpiece is continuously contacted with a wet 70% isopropyl alcohol (isopropanol) wipe.

18. Allow Handpiece to dry completely before use by either air-drying or drying with a sterile lint-free tissue.

19. Remove and dispose of Cleaning Cover.

***NOTE***
The Handpiece Cleaning Cover is a single-use component and intended to be discarded after disinfection.

## *Cleaning the System Console*

STEP Wipe the external surfaces of the System Console for at least 30 seconds with a clean wipe dampened with 70% isopropyl alcohol (isopropanol). Dry with a clean cloth or allow to air dry.

***WARNING***
Do NOT attempt to gain access to any internal components, electrical shock may result.

***CAUTION***
Do not spray or pour cleaning agents directly onto the System Console, as damage may occur.

## *Cleaning the Touchscreen Display*

STEP Apply an alcohol-based cleaner to a soft cloth and wipe the Touchscreen display for at least 30 seconds. Allow to air dry.

***CAUTION***
Do not spray or pour cleaning agents directly onto the Touchscreen, as damage may occur.

## Turning Off the System

Users can turn the system off using the physical **POWER** button on the front of the Console or the **POWER OFF** button on the Treatment Complete screen.

20. To turn the system off, choose one of the following:

    - Press the physical **POWER** button on the front of the System Console.
    - Press the **POWER OFF** button on the Treatment Complete screen.
    - If the Touchscreen becomes nonresponsive, press and hold the physical **POWER** button on the front of the System Console.

    The treatment is terminated (if in progress) by pressing the **POWER OFF** button on the Touchscreen.

***CAUTION***
When the Power Cable is connected to the wall outlet, some internal circuits remain energized. To de-energize all internal circuits, unplug the Power Cable from the wall outlet.

*Figure 33. Power Off Screen*

21. When the validation screen appears, choose one of the following:

- Press the **YES - POWER OFF** button to turn off the system.
- Press the **NO - RETURN** button to return to the previous screen.

*Figure 34. Power Off Validation Screen*

## Disconnecting the System Components

22. Verify that the System is turned off, as described in the previous section.

23. Place the Handpiece in the Holster and wrap the Handpiece Cable on the Handpiece Cable Hanger.

*Figure 35. Handpiece in Holster; Cable on Cable Hanger*

24. Disconnect the Power Cable plug from the electrical outlet and wrap the Power Cable around the Cable Wrap on the rear of the System Console.

25. Disconnect the Footswitch Cable, place the cable inside the Footswitch housing or on the Power Cable Wrap on the back of the system, and store the Footswitch on the Footswitch Mount on the rear of the System Console.

*Figure 36. Footswitch Mount*

*Before View*

*After View*

## Moving the System

26. Disconnect the System components (See “Disconnecting the System Components” above).
27. Disengage the Wheel Locks by pulling up on the Locking Tabs.
28. Use the Handle on the front of the System Console to push the Console to the desired location.
29. Engage the Wheel Locks by pressing down on the Locking Tabs.

# Maintenance

## System Maintenance

All maintenance of the ellacor® System with Micro-Coring® Technology must be performed by trained Cytrellis personnel to maintain the warranty.

# Appendix A System Specifications

*Table 5. System Specifications*

| | |
|---|---|
| **Physical Characteristics** | |
| Needle type | 22 Gauge hypodermic coring needle, type 304 stainless steel |
| Needle geometry | Ground to 10° tip angle resulting in 2 cutting surfaces and 2 tips |
| Needle length | 6.0 mm |
| Maximum penetration depth | 5.0 mm (corresponds to 4.0 mm core depth setting) |
| Needle depth tolerance | ± 0.5 mm |
| Maximum puncture rate | 12 Hz |
| System console weight | 42 kg (92.6 lb) |
| System console size (H x W x D) | 45.7 cm x 45.7 cm x 106.7 cm (18 in x 18 in x 42 in) |
| Power cable length | 1.83 m (6 ft) |
| Handpiece weight | 550 g (1.2 lb) |
| Handpiece size (H x W x D) | 20.3 cm x 21.6 cm x 6.4 cm (8 in x 8 1/2 in x 2 1/2 in) |
| Handpiece cable length | 2 m (6 ft 6 in) |
| Footswitch weight | 1.2 kg (2.6 lb) |
| Footswitch size (H x W x D) | 12.0 cm x 15.0 cm x 14.2 cm (4 3/4 in x 5 15/16 in x 5 9/16 in) |
| Footswitch cable length | 2.67 m (8 ft 9 in) |
| Max. vacuum pressure | 100 kPa |
| Cartridge box size (H x W x D) | 8.8cm x 26.5cm x 16.7cm (3 7/16 in x 10 7/16 in x 6 9/16 in) |
| **Electrical Requirements** | |
| Voltage | ~100-240 VAC |
| Frequency | 50-60 Hz |
| Current | 8.5 A |
| **Environmental Requirements (Operating)** | |
| Maximum altitude | 2,000 m (6562 ft) |
| Temperature range | 15 °C - 30 °C (59 °F - 86 °F) |
| Maximum humidity | 20% - 80% non-condensing |
| Atmospheric Pressure | 70 kPa - 106 kPa |
| **Environmental Requirements (Non-operating)** | |
| Maximum altitude | Standard commercial shipping altitude |
| Temperature range | 5 °C - 40 °C (41 °F - 104 °F) |
| Maximum humidity | 10% - 90% non-condensing |
| Atmospheric Pressure | 70 kPa - 106 kPa |
| **Protection Classifications** | |
| Type | Class I ME Equipment |
| Degree | Type B |
| Applied part | Handpiece<br>Single-Use Needle Cartridge |
| IPX rating | System console: IP32<br>Handpiece (with Single-Use Needle Cartridge installed): IP22 |

# Appendix B Safety and Regulatory Compliance

## General Safety and Regulatory Information

The ellacor® System with Micro-Coring® Technology is a precision medical instrument. The System has undergone extensive testing. To protect operating personnel and patients, this manual should be read thoroughly and understood before operation.

Cytrellis does not make recommendations regarding the practice of medicine. Treatment parameters are provided as a guide. Individual treatments should be based on clinical training and clinical observation of appropriate clinical endpoints.

## Electrical Hazards

*Table 6. Electrical Hazards*

| Symbol | Definition |
|---|---|
|  | ***WARNING***<br>• Do NOT attempt to perform maintenance other than that which is outlined in this manual.<br>• Do NOT attempt to gain access to any internal components, as electrical shock may result.<br>• Maintenance should only be performed when the system is turned off and disconnected from the power source.<br>• To avoid risk of electric shock, this equipment must only be connected to a supply main with protective earth. |
|  | ***CAUTION***<br>• Only an authorized Cytrellis service representative should perform service on the system or directed by Cytrellis service representative.<br>• The system is grounded through the grounding conductor in the power cord. Grounding is essential for safe operation. |

# Additional Safety Considerations

*Table 7. Additional Safety Considerations*

| Symbol | Definition |
|---|---|
|  | ***WARNING***<br>• During a power loss, the needles may remain extended beyond the distance spacer. Take precautions against needle sticks. Avoid contacting the treatment area of the distance spacer when the Handpiece is unpowered.<br>• Do NOT re-use single-use parts (Needle Cartridge, Suction Tubing, or Vacuum Filter) for multiple patients.<br>• Do NOT store the Needle Cartridge boxes in direct sunlight. UV lights can cause damage to the sterile packaging.<br>• Follow OSHA guidelines on needle sticks and sharps injury prevention and your office procedures to avoid needle sticks while handling the Needle Cartridge.<br>• Keep hands and fingers away from the Handpiece and Needle Cartridge to avoid moving parts hazards.<br>• Do NOT locate System so that it is difficult to access power supply cord. |
|  | ***CAUTION***<br>• No modification of the System is allowed.<br>• Do NOT use any other manufacturer's Needle Cartridge with the System. It is designed for use with the Cytrellis® Needle Cartridges only.<br>• Do NOT submerge in water or autoclave the Handpiece.<br>• Do NOT spray or pour cleaning agents directly onto the System Console or Touchscreen, as damage may occur.<br>• No untrained or unqualified personnel shall use the System at any time. The System is intended solely for licensed practitioners trained in its proper use.<br>• The Handpiece is a fragile instrument and must not be dropped. If a Handpiece is dropped, carefully examine the Handpiece for any physical damage prior to use.<br>• Verify that the treatment parameters are correct before pressing the Footswitch.<br>• Use the Potential Equalization Conductor to bring other equipment to the same case potential as the System. |
|  | ***NOTE***<br>• To prolong needle function, do NOT apply downward pressure with the treatment window when coring. |

# Regulatory Compliance Safety Features

## *Needle Penetration Hard-stop*

The proprietary Micro-Coring® Technology is designed to provide needle penetration depth control for a core depth setting from 0.0 to 4.0 mm. In addition, the ellacor® System has an emergency mechanical stop to prevent the needle tips from extending more than 6.75 mm (1/4 in) beyond the end of the Distance Spacer.

## *Electrical Fault Detection Circuitry*

If the System detects a fault condition, an error message displays on the Touchscreen and the system enters a safe state. Some fault conditions are user clearable. Refer to “Error Codes, Messages & Troubleshooting” for additional information.

## *Location and Definition of Regulatory and Other System Labels*

As required by national and international regulatory agencies, appropriate regulatory compliance labels have been mounted in the locations specified in the “Label Symbols” section on the following page. All treatment room staff should be familiar with the location and meaning of these labels.

# Label Symbols

*Table 8. Label Symbols*

| Symbol | Standard Reference | Description | Location |
|---|---|---|---|
|  | BS EN ISO 15223-1 | Catalogue number | Console, Footswitch, Handpiece, and Single-Use Needle Cartridge labels |
|  | BS EN ISO 15223-1 | Batch Code | Single-Use Needle Cartridge labels |
|  | BS EN ISO 15223-1 | Serial number | Console, Footswitch, and Handpiece labels |
|  | BS EN ISO 15223-1 | Date of manufacture | Console, Footswitch, and Handpiece labels |
|  | BS EN ISO 15223-1 | Manufacturer | Console, Footswitch, Handpiece, and Single-Use Needle Cartridge labels |
|  | IEC 60601-1 | Refer to Operator's Manual | Console, Footswitch, and Handpiece labels |
|  | BS EN ISO 15223-1 | Caution | Console, Footswitch and Handpiece labels |
|  | IEC 60601-1 | Type B applied part | Handpiece and Single-Use Needle Cartridge labels |
|  | N/A | Quantity | Single-Use Needle Cartridge labels |
|  | 21 CFR 801.109 | US federal law restricts this device to sale by or on the order of a practitioner licensed by the law of the state in which he/she practices to use or order the use of the device. | Console, Footswitch, Handpiece, and Single-Use Needle Cartridge labels |

*Table 8. Label Symbols (continued)*

| Symbol | Standard Reference | Description | Location |
|---|---|---|---|
|  | BS EN ISO 15223-1 | Use-by Date | Single-Use Needle Cartridge label |
|  | BS EN ISO 15223-1 | Do not reuse | Single-Use Needle Cartridge label |
|   | BS EN ISO 15223-1 | Sterilized using irradiation | Single-Use Needle Cartridge label |
|  | IEC 60601-1 | Equipotentiality | Console |
|  | IEC 60601-1 | Protective earth (ground) | Console |
|  | BS EN ISO 15223-1 | Consult instructions for use | Single-Use Needle Cartridge label |
|  | BS EN ISO 15223-1 | Keep away from sunlight | Single-Use Needle Cartridge label |
|  | BS EN ISO 15223-1 | Humidity limitation | Single-Use Needle Cartridge label |
|  | BS EN ISO 15223-1 | Temperature limitation | Single-Use Needle Cartridge label |
|  | BS EN ISO 15223-1 | Atmospheric pressure limitation | Single-Use Needle Cartridge label |
|   | ASTM F2503-20 | Known to pose hazards in all MR environments | Console label |
|  | N/A | Footswitch attachment point | Console |
|  | N/A | Accesses Service Screen | Console label |

# FCC Information

NFC Device
FCC ID: 2AUPV-830-00013
Model: 830-00013

Contains Cellular Module:
FCC ID: XPY2AGQN4NNN
Model: MTQN-MNG1-B02.R1 (SARA-R410M) (Manufactured by Multi-Tech Systems, Inc.)

This device complies with Part 15 of the FCC Rules. Operation is subject to the following conditions:

1. This device may not cause harmful interference, and
2. This device must accept any interference received, including interference that may cause undesired operation.

Changes and Modifications not expressly approved by Cytrellis can void your authority to operate this equipment under Federal Communications Commission's rules.

## *User Steps to Access FCC Electronic Labeling*

1. From the Startup Screen, press the information icon in the bottom left corner.

*Figure 37. Startup Screen*

2. The FCC Electronic Label is shown on the left side of the screen.

*Figure 38. System Information Screen*

# Wireless Technologies

***WARNING***
Other equipment could interfere with the communication of this device, even if the other equipment complies with CISPR8 emission requirements.

## *Near Field Communication (NFC) Device*

The ellacor® System with Micro-Coring® Technology is equipped with an NFC tag reader for interfacing with the Cytrellis® Needle Cartridge. This feature allows the system to ensure that Needle Cartridges are compatible with the system. Needle Cartridge configuration data is read from the Needle Cartridge when it is loaded onto the Handpiece. After use, the Needle Cartridge is automatically disabled by the system to prevent reuse of the cartridge. All data is encrypted to ensure its integrity.

The NFC device meets the requirements of ETSI EN 300 330 V2.1.1 (2017-02) - Short Range Devices (SRD); Radio Equipment in the Frequency Range 9 kHz to 25 MHz and Inductive Loop Systems in the Frequency Range 9 kHz to 30 MHz; Harmonized Standard Covering the Essential Requirements of Article 3.2 of Directive 2014/53/EU.NFC applications must fall entirely within the frequency bands for short range devices from 9 kHz to 30 MHz.

The NFC device utilized within the System is designed to operate at 13.56 MHz at an estimated power of less than 500 nanowatts within the range of 8mm or less. The targeted location for relevant operation is fixed by the Needle Cartridge and its installation onto the Handpiece. Distances greater than 8 mm do not provide enough energy to operate the NFC tag in the Needle Cartridge. Quality of service does not apply for the operation of the NFC device.

NFC functions and commands are designed specifically to operate with selected Cytrellis NFC tags that have been properly formatted. Data is loaded and stored on command and integrity is confirmed through error statuses, fault codes, cyclic redundancy checks, and AES encryption within the device and within the system. Operation of the NFC device only occurs when requested by a triggering event. When the System is running a treatment pattern, the NFC device is turned off.

While the NFC device is designed and configured to read and verify a single NFC tag at a time, care should be taken to ensure that limited RF devices are operating in close proximity to the handpiece during use. Other transmitters may interfere with NFC operation.

***WARNING***
Other equipment with RF emitters including RFID readers could interfere with the operation of this device. To prevent interference, ensure that other such equipment is not operated within 30 cm of the ellacor® System with Micro-Coring® Technology.

Any errors triggered due to interference with the NFC should result in an Error 201 or 202 on the System Screen. Refer to the Troubleshooting Guidance in Appendix C for details on how to proceed if an error occurs.

## *Wireless and Cellular Module*

The ellacor® System with Micro-Coring® Technology is also equipped with cellular communication capabilities. This allows performance data to be wirelessly transmitted to Cytrellis in a secure fashion for the purposes of ensuring optimal system operation, monitoring for potential service issues, and helping you better utilize your system. Data stored by the System relates to each procedure including parameter settings, core counts, error codes, and performance data. No patient-identifying data is used, stored, or transmitted by the system. Any data transmitted from the system is done utilizing encrypted connections to a secure server accessible only to authorized Cytrellis personnel. Data transmission is done via secure cellular communications and does not require WiFi or other network connection configured at the installation site.

Data transmission happens automatically without the need for the operator to enable this feature. Data from a completed procedure is stored prior to System shutdown. In order to ensure that your data is properly stored, do not unplug the system until it has completely powered down. Stored data will be transmitted the next time that the System powers up. Once transmission of data is complete the System powers down the module to a standby mode. A failure to connect to the wireless network will timeout and allow the System to startup normally. Other transmitters operating in the vicinity of the System during data transmission may prevent data from being properly transmitted.

Wireless communication depends on cellular network availability. Coverage may not be available everywhere and varies by network coverage and service levels. Please be aware that within the cellular network, the availability and quality of the service may be affected by terrain, buildings, and the weather. Data might not be transmitted if the system is used outside of the country or region of purchase. Coverage is not required for the system to operate safely and effectively.

The cellular module meets requirements of IEC60601-1-2 and FCC Part 15 Class B.

The cellular module may utilize the AT&T network for 4G LTE frequency and bands as noted:

*Table 10. AT&T Operating Frequencies & Bands*

| Frequency (MHz) | Bands |
|---|---|
| 700 | Band 12,13,29 |
| 850 | Band 5 |
| 1700/2100 | Band 4 |
| 1900 | Band 2 |
| 2600 | Band 30 |

The cellular module may utilize the Verizon Wireless network for 4G LTE frequency and bands as noted:

*Table 11. Verizon Operating Frequencies & Bands*

| . Frequency (MHz) | Bands |
|---|---|
| 700 | Band 13 |
| 1700/2100 | Band 4 |
| 1900 | Band 2 |

# Electromagnetic Compatibility

The ellacor® System with Micro-Coring® Technology design complies with IEC 60601-1-2 (Edition 4.0) requirements for electromagnetic compatibility (EMC) with other devices. Like other electrical medical equipment, the System requires special precautions to ensure EMC with other electrical medical devices and must be installed and operated according to the EMC information provided in this manual. Consult the tables on the following pages for guidance in placing the System.

***WARNING***

- Do NOT use cables or accessories other than those provided with the System, as this may result in increased electromagnetic emissions or decreased immunity to such emissions.
- Do NOT use the System adjacent to or stacked with other equipment, before verifying normal operations under the configuration in which it will be used prior to use.
- Portable and mobile RF communications equipment (including peripherals such as antenna cables and external cables) should be used no closer than 30 cm (12 inches) to any part of the System, including cables specified by the manufacturer. Otherwise, degradation in the performance of this equipment could result.

The following table describes the basic safety and essential performance specifications defined for the System. The right-most column includes the error condition that the operator would expect to see due to any potential, unforeseen electromagnetic disturbances that result in the loss or degradation of the corresponding specification. Refer to the Troubleshooting Guidance in Appendix C for details on operator actions in response to the error condition created.

*Table 12. Basic Safety and Essential Performance for the System*

| Basic Safety and Essential Performance | | |
|---|---|---|
| **Characteristic** | **Specification** | **Possible Error Condition(s)** |
| **Z Position**: Core depth determined by the distance the needle extends away from the handheld | No greater than 6.75 mm tip depth | The maximum needle penetration depth is not affected, lost, or degraded by EM disturbances. |
| | No greater than 0.5 mm deeper than the chosen set point | Handpiece will stop and a system Error 64 will appear. |
| **X Position**: Core position within the spacer flange in the side-to-side direction (perpendicular to the handle) | No overlapping holes | Handpiece will stop and a system Error 2 or 10 will appear. |

*Table 12. Basic Safety and Essential Performance for the System*

| Basic Safety and Essential Performance | | |
|---|---|---|
| **Y Position**: Core position within the spacer flange in the side-to-side direction (parallel to the handle) | No overlapping holes | Handpiece will stop and a system Error 4 or 12 will appear. |
| **Vacuum Pressure**: Amount of pressure at the spacer flange applied by the vacuum | Vacuum control is within 20% of expected pressure | Vacuum pressure outside of expected range will result in a vacuum notification on the screen as well as reduced suction on the distance spacer treatment window. |
| **Consumable Configuration**: Data on RFID tag, which communicates needle position, manufacturing date, and whether the consumable has been used. | No undetected read or write errors. | System will prevent start of treatment and a system Error 201, 202, 204, or 206 will appear. |

*Table 13. Guidance and Manufacturer's Declaration: Electromagnetic Emissions*

| Guidance and Manufacturer's Declaration: Electromagnetic Emissions | | |
|---|---|---|
| The ellacor® System with Micro-Coring® Technology is intended for use in the electromagnetic environment specified below. The customer or the user of the System should ensure that it is used in such an environment. | | |
| Emissions Test | Compliance | Electromagnetic Environment: Guidance |
| RF emissions CISPR 11 | Group 1<br>Class B | The System uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment. |
| RF emissions CISPR 11 | Group 1<br>Class B | The System is suitable for use in professional healthcare and clinical environments. The System is not intended to be used in the operating room (i.e., near electrosurgical equipment) or in the shield room of MRI equipment. |
| Harmonic emissions IEC 61000-3-2 | Complies | |
| Voltage Fluctuations/flicker emissions IEC 61000-3-3 | Complies | Warning: This equipment/system is intended for use by healthcare professionals only. This equipment/system may cause radio interference or may disrupt the operation of nearby equipment. It may be necessary to take mitigation measures, such as re-orienting or relocating the System or shielding the location. |

*Table 14. Electromagnetic Immunity*

| Guidance and Manufacturer's Declaration: Electromagnetic Immunity | | | |
|---|---|---|---|
| The ellacor® System with Micro-Coring® Technology is intended for use in the electromagnetic environment specified below. The customer or the user of the System should ensure that it is used in such environment. | | | |
| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment: Guidance. |
| Electrostatic Discharge (ESD) IEC 61000-4-2 | ±8kV contact<br>±15kV air | ±8kV contact<br>±15kV air | Floor should be wood, concrete, or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30-60%. |
| Electrical fast transient/burst IEC 61000-4-4 | ±2kVAC lines<br>±1kV I/O lines | ±2kV AC lines<br>±1kV I/O lines | Mains power quality should be that of a typical commercial or hospital environment. |
| Surge IEC 61000-4-5 | ±1kV line to line<br>±2kV line to P.E. | ±1kV line to line<br>±2kV line to P.E. | Mains power quality should be that of a typical commercial or hospital environment. |
| Voltage dips, short interruptions, and voltage variations on power supply input lines IEC 61000-4-11 | 0% UT .5 cycle<br>0% UT 1 cycle<br>70% UT 25 cycles<br>0% UT 250 cycles | 0% UT .5 cycle<br>0% UT 1 cycle<br>70% UT 25 cycles<br>0% UT 250 cycles | Mains power quality should be that of a typical commercial or hospital environment. If the user of the ellacor® System requires continued operation during power mains interruptions, it is recommended that the ellacor® System be powered from an uninterruptible power supply or a battery. |
| Power frequency (50/60 Hz) magnetic field IEC 61000-4-8<br>RFID magnetic field immunity IEC 61000-4-39 | 30 A/m<br>65 A/m<br>7.5 A/m | 30 A/m<br>134.2 kHz @ 2.1kHz PM<br>13.56 MHz @ 50 kHz PM | Power-frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment. |
| **NOTE:** UT is the AC mains voltage prior to application of the test level. | | | |

*Table 15. Electromagnetic Immunity (Cont'd)*

| Guidance and Manufacturer's Declaration: Electromagnetic Immunity | | | |
|---|---|---|---|
| The ellacor® System with Micro-Coring® Technology is intended for use in the electromagnetic environment specified below. The customer or the user of the System should ensure that it is used in such an environment. | | | |
| Immunity Test | IEC 60601 Test Level | Compliance Level | Electromagnetic Environment: Guidance |
| Conducted RF<br>IEC 61000-4-6 | 0.15 - 80 MHz<br>3 Vrms & 6 Vrms in ISM bands 80% AM modulation @ 1 kHz AC Mains | 0.15 - 80 MHz<br>3 Vrms & 6 Vrms in ISM bands 80% AM modulation @ 1 kHz AC Mains | Portable and mobile RF communications equipment should be used no closer to any part of the System, including its cables, then the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended Separation Distance<br>$d = 1.17 \sqrt{P}$<br>$d = 1.17 \sqrt{P}$ 80MHz to 800MHz<br>$d = 2.33 \sqrt{P}$ 800MHz to 2.5GHz<br>where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and d is the recommended separation distance in meters (m). Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey(a), should be less than the compliance level in each frequency range(b).<br>Interference may occur in the vicinity of equipment marked with the following symbol:  |
| Radiated RF<br><br>IEC 61000-4-3<br>Proximity field from RF wireless communications equipment<br>IEC 61000-4-3 | 80 MHz - 2.7 GHz<br><br>3 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation<br><br>10 V/m, PM @ 217 Hz | 80 MHz - 2.7 GHz<br><br>3 V/m 80% @ 1 kHz Spot frequencies 385MHz – 5.750 GHz Pulse Modulation<br><br>3100 MHz to 4990 MHz | |
| **NOTE 1:** At 80 MHz and 800 MHz, the higher frequency range applies.<br>**NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. | | | |
| Field strengths from fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobiles radios, amateur radio, AM and FM radio broadcast, and TV broadcast, cannot be predicted theoretically with accuracy. To assess the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the ellacor® System with Micro-Coring® Technology is used exceeds the applicable RF compliance level above, the ellacor® System with Micro-Coring® Technology should be observed to verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as reorienting or relocating the System.<br>Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3V/m. | | | |

*Table 16. Separation Guidance from Portable and Mobile RF Communications Equipment*

| **Recommended Separation Distances Between Portable and Mobile RF Communications Equipment and the ellacor® System with Micro-Coring® Technology** | | | |
|---|---|---|---|
| The ellacor® System with Micro-Coring® Technology is intended for use in an electromagnetic environment in which radiated RF disturbances are controlled. The user of the System can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the System as recommended below, according to the maximum output power of the communications equipment. | | | |
| Rated maximum output power (W) of transmitter | Separation distance (m) according to frequency of transmitter | | |
| | 150 kHz to 80 MHz<br>$d = 1.17 \sqrt{P}$ | 80 MHz to 800 MHz<br>$d = 1.17 \sqrt{P}$ | 800 MHz to 2.5 GHz<br>$d = 2.33 \sqrt{P}$ |
| 0.01 | 0.12 | 0.12 | 0.23 |
| 0.1 | 0.37 | 0.37 | 0.74 |
| 1 | 1.17 | 1.17 | 2.33 |
| 10 | 3.70 | 3.70 | 7.37 |
| 100 | 11.70 | 11.70 | 23.30 |
| For transmitters rated at a maximum output power not listed above, the recommended separation distance (d) in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where P is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer. | | | |
| **NOTE 1:** At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.<br>**NOTE 2:** These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects, and people. | | | |

# Clinical Summary

A clinical study was conducted to support the safety and effectiveness of the ellacor® System with Micro-Coring® Technology for the treatment of moderate to severe cheek wrinkles in adults aged 22 years or older with Fitzpatrick skin types I-IV.

The objective of the study was to assess the effectiveness of the proposed device in reducing the signs of skin aging as measured by the improvement in wrinkles after at least two (2), but no more than three (3) standardized treatment sessions and to assess the safety of the proposed device as measured by the number of adverse events.

The multicenter study was conducted at four (4) sites in the United States. Subjects were treated at least two (2) times, but no more than (3) times, approximately 30 days apart, with the final assessment 90 days after the last treatment.

Professional clinical portrait photographs were taken of the subject at Day 0, Day 30, Day 60 and Day 90. Day 30, Day 60 and Day 90 photos were taken for each treatment.*

Treatments were performed by licensed medical professionals.

Prior to treatment the subject was injected with local anesthetic, per the site's procedure(s). A Triple Needle Cartridge and densities of 6.7% and 7.9% (percent of skin removed per 1 $cm^2$) were used. The operator started the treatment at a core-depth setting of 3 mm but could increase or decrease the core-depth setting in increments of 0.5 mm for a range of 2.5 to 5 mm to achieve maximum coring and ensure subject safety. Following the treatment, Aquaphor was applied to the treated areas.

**Demographics:**
Fifty-one (51) subjects completed the study. The average age of the subjects was 62.9 years. The subject population was predominantly female (98%). The study included subjects with Fitzpatrick skin types I to IV.

**Effectiveness – Physician Reported Outcomes:**
A blinded assessment by three (3) independent evaluators was performed. The evaluators assessed before and 90-day post treatment* photographs of the subject's cheek area for improvement using the Lemperle Wrinkle Severity Scale (LWSS). When assessed at depth settings of up to 5mm, the mean change from baseline for the LWSS was 1.3 [95% CI: 1.22, 1.42]. The lower limit of the 95% confidence interval for the mean change is greater than 1.0, indicating that these data support the primary endpoint conclusion of 1 point or greater improvement. When the treatment was performed at up to 4mm, the LWSS change was 1.1.

**Safety – Physician Reported Outcomes:**
No Serious Adverse Events were reported. Nine (9) adverse events were reported in five (5) subjects. Of the nine, four (4) were considered Adverse Device Effects (ADEs). The ADEs were Black eye (bruising (1), cheek numbness (1), redness (1), and track marks on cheek (1). The ADEs were mild to moderate in severity and did not require intervention. All ADEs were anticipated risks of the device/treatment as listed in the device labeling.

*NOTE: Due to the COVID-19 pandemic subject photographs were taken at Day 150 or Day 180 per protocol amendment.

# Appendix C Error Codes, Messages, & Troubleshooting

If the System detects an error, the Error Screen displays on the Touchscreen. Some errors serve as a notification and are clearable by pressing the Continue button on the screen. Other errors indicate what action must be taken before the error can be cleared. If the error is successfully cleared, pressing the Continue button will allow the sequence of activities to resume. If an error cannot be cleared or if an error persists or reappears, refer to the troubleshooting guidance provided in Table 18.

*Table 17. Error Code Key*

| | |
|---|---|
| **Error Number** | Unique numerical value assigned to errors to facilitate troubleshooting. |
| **Error Message** | A description/explanation of the error. For alerts that require end-user action, the next step is included in the Error Message. |
| **Troubleshooting Guidance** | A set of sequential actions for the end-user to perform with the potential to eliminate the cause of the error. |

*Table 18. Error Code, Messages, & Troubleshooting Guidance*

| Error Number | Error Message | Troubleshooting Guidance |
|---|---|---|
| 1, 2, 4, 9, 10, 12, or 24 | **Actuation Error**<br>Clear area around Needle Cartridge. | 1) Clear area around Needle Cartridge. Ensure there are no obstructions preventing normal travel of the needles.<br>2) Press **Continue** to restart the Handpiece.<br>3) If problem persists, power cycle the Console (NOTE: Needle Cartridge will become expired if the Console is turned off).<br>4) If problem persists, record error code and contact Cytrellis Customer Service. |
| 8 | **Handpiece Not Powered**<br>Confirm that the Handpiece cable is attached to Console. | 1) Disconnect the Handpiece cable from the front of the Console and reconnect.<br>2) Press **Continue**.<br>3) If problem persists, power cycle the Console (NOTE: Needle Cartridge will become expired if the Console is turned off).<br>4) If problem persists, record error code and contact Cytrellis Customer Service. |

*Table 18. Error Code, Messages, & Troubleshooting Guidance*

| Error Number | Error Message | Troubleshooting Guidance |
|---|---|---|
| 32 or 65 | **Needle Alert**<br>**Needle Damage Will Occur**<br>Decrease core depth setting or adjust treatment technique. | 1) Check coring for precise holes, a full clean pattern should be visible. If not, replace Needle Cartridge.<br>2) Decrease <core depth> setting to prevent recurrence of this warning. Assess if the depth setting is appropriate for the treatment area.<br>3) Assess treatment technique to ensure minimal pressure is applied to the treatment area.<br>4) Clear area around the Needle Cartridge as needed. Ensure there are no obstructions preventing normal travel of the needles.<br>5) If problem persists, record error code and contact Cytrellis Customer Service. |
| 64 or 66 | **Actuation Error**<br>Clear area around Needle Cartridge | 1) Clear area around Needle Cartridge. Ensure there are no obstructions preventing normal travel of the needles.<br>2) Press **Continue**.<br>3) If problem persists, replace the Needle Cartridge.<br>4) If problem persists, record error code and contact Cytrellis Customer Service. |
| 101 | **Vacuum Pressure Error**<br>Confirm all tubing connections from Console to Handpiece. | 1) Check that Needle Cartridge tubing is connected to the suction tubing.<br>2) Check that suction tubing is connected to the filter.<br>3) Check that the filter is connected to the Console.<br>4) If problem persists, power cycle the Console (NOTE: Needle Cartridge will become expired if the Console is turned off).<br>5) If problem persists, record error code and contact Cytrellis Customer Service. |

*Table 18. Error Code, Messages, & Troubleshooting Guidance*

| Error Number | Error Message | Troubleshooting Guidance |
|---|---|---|
| 102 | **Vacuum Pressure Error**<br>Confirm tubing is not clogged or pinched. | 1) When the system is sitting idle, blood may coagulate in tubing and filter resulting in blockages. Check that suction can be achieved at the treatment area.<br>2) If there is no suction, check for the following:<br>a. Suction tubing kinks<br>b. Blockages in the Needle Cartridge tubing and suction tubing<br>c. Filter clogging<br>3) Replace the Needle Cartridge, suction tubing or filter as needed.<br>4) If problem persists, power cycle the Console (NOTE: Needle Cartridge will become expired if the Console is turned off).<br>5) If problem persists, record error code and contact Cytrellis Customer Service. |
| 103 or 104 | **Console Temperature Error**<br>Confirm adequate ventilation around the Console. | 1) Verify that the treatment room is within the specified operating environmental conditions listed in Appendix A.<br>2) Verify that there is adequate space around the Console to allow for proper air circulation, reposition the Console, as necessary.<br>3) Press **Continue**. To resume treatment, press **Enable Treatment**.<br>4) If problem persists, power off the Console and allow it to cool for 5 minutes (NOTE: Needle Cartridge will be expired if the Console is turned off).<br>5) Restart the Console and proceed through the setup screens.<br>6) If problem persists, record error code and contact Cytrellis Customer Service. |
| 105 | **Handpiece Temperature Error**<br>Verify that the treatment room is within the specified operating environmental conditions. | 1) Verify that the treatment room is within the specified operating environmental conditions listed in Appendix A.<br>2) Press **Continue**. To resume treatment, press **Enable Treatment**.<br>3) If problem persists, unplug the Handpiece, record error code and contact Cytrellis Customer Service |

*Table 18. Error Code, Messages, & Troubleshooting Guidance*

| Error Number | Error Message | Troubleshooting Guidance |
|---|---|---|
| 106 | **Maximum Core Count Exceeded**<br>Install new Needle Cartridge. | 1) Remove and discard Needle Cartridge (NOTE: The Needle Cartridge has been deactivated after reaching its maximum number of excised cores; 24,000 for the Triple Needle Cartridge and 8,000 for the Single Needle Cartridge).<br>2) Install a new Needle Cartridge.<br>3) Press **Enable Treatment**.<br>4) If problem persists, record error code and contact Cytrellis Customer Service. |
| 107 | **Handpiece Setup Error**<br>Clear area around Needle Cartridge. | 1) Clear area around Needle Cartridge. Ensure there are no obstructions preventing normal travel of the needles.<br>2) Press **Continue** to restart the Handpiece.<br>3) If problem persists, power cycle the Console (NOTE: Needle Cartridge will be expired if the Console is turned off).<br>4) If problem persists, record error code and contact Cytrellis Customer Service. |
| 108 | **Needle Cartridge Unlock Detected**<br>Not Allowed While in Treatment Mode<br>Re-lock Needle Cartridge - then press **Continue**.<br>Needle Cartridge can be removed when in Standby Mode | 1) Do not unlock the Needle Cartridge when in Treatment Mode.<br>2) To resume the treatment with the same Needle Cartridge, re-lock the Needle Cartridge and press **Continue**.<br>3) If trying to replace the Needle Cartridge, Re-lock the Needle Cartridge, press **Continue**, then enter Standby Mode before removing the Needle Cartridge.<br>4) If problem persists, record error code and contact Cytrellis Customer Service. |
| 109 | **Footswitch Down**<br>Release Footswitch before entering Treatment Mode. | 1) Verify Footswitch is not pressed when trying to enter Treatment Mode.<br>2) If problem persists, record error code and contact Cytrellis Customer Service. |
| 110 or 113 | **Console Communications Error**<br>Press **Continue** to retry. If problem persists, hold power button until device shuts off. Then restart. | 1) Press **Continue** to retry.<br>2) If problem persists, power cycle the Console (NOTE: Needle Cartridge will be expired if the Console is turned off).<br>3) If problem persists, record error code and contact Cytrellis Customer Service. |

*Table 18. Error Code, Messages, & Troubleshooting Guidance*

| Error Number | Error Message | Troubleshooting Guidance |
|---|---|---|
| 111 | **Handpiece Error**<br>Confirm that the Handpiece cable is attached to Console. | 1) Disconnect the Handpiece cable from the front of the Console and reconnect.<br>2) Press **Continue**.<br>3) If problem persists, power cycle the Console (NOTE: Needle Cartridge will be expired if the Console is turned off).<br>4) If problem persists, record error code and contact Cytrellis Customer Service. |
| 112 or 207 | **Needle Deactivation**<br>Needle Cartridge has been deactivated due to potential needle damage.<br>Install new Needle Cartridge. | 1) Remove and discard Needle Cartridge (NOTE: Needle Cartridge has been deactivated to prevent treating with potentially damaged needles).<br>2) Install a new Needle Cartridge.<br>3) Press **Enable Treatment**.<br>4) Decrease <core depth> setting to prevent recurrence of this warning. Assess if the core depth setting is appropriate for the treatment area.<br>5) Assess treatment technique to ensure minimal pressure is applied to the treatment area.<br>6) If problem persists, record error code and call Cytrellis customer service. |
| 128 | **Handpiece Communications Error**<br>Press continue to retry.<br>If problem persists, hold power button until device shuts off; then restart. | 1) Disconnect the Handpiece cable from the front of the Console and reconnect.<br>2) Press **Continue**.<br>3) If problem persists, power cycle the Console (NOTE: Needle Cartridge will become expired if the Console is turned off).<br>4) If problem persists, record error code and contact Cytrellis Customer Service. |
| 201 or 202 | **Defective Needle Cartridge**<br>Unlock and re-lock Needle Cartridge.<br>If problem persists, install new Needle Cartridge. | 1) Unlock and re-lock Needle Cartridge.<br>2) If problem persists, replace Needle Cartridge with a new one.<br>3) If problem persists, record error code and contact Cytrellis Customer Service. |
| 203 | **Used Needle Cartridge**<br>Install new Needle Cartridge. | 1) Remove and discard Needle Cartridge (NOTE: Needle Cartridges are single-use only).<br>2) Install a new Needle Cartridge.<br>3) Press **Enable Treatment**.<br>4) For more information, record error code and contact Cytrellis Customer Service. |

*Table 18. Error Code, Messages, & Troubleshooting Guidance*

| Error Number | Error Message | Troubleshooting Guidance |
|---|---|---|
| 204, 206, or 218 | **Defective Needle Cartridge**<br>Install new Needle Cartridge. | 1) Remove Needle Cartridge.<br>2) Install a new Needle Cartridge.<br>3) Press **Enable Treatment**.<br>4) Retain defective Needle Cartridge and packaging (if available), record error code and contact Cytrellis Customer Service. |
| 205 | **Needle Cartridge Attached but Unlocked**<br>Lock or remove Needle Cartridge. | 1) Lock the Needle Cartridge.<br>2) Press **Continue**.<br>3) If problem persists, unlock and relock the Needle Cartridge.<br>4) Press **Continue**.<br>5) If problem persists, record error code and contact Cytrellis Customer Service. |
| 208 | **Idle too long**<br>Resume treatment soon | 1) Check that suction can be achieved at the treatment area before resuming. Replace Needle Cartridge, suction tubing, and filter as needed.<br>2) The Needle Cartridge will expire if treatment is not resumed soon.<br>3) For more information, record error code and contact Cytrellis Customer Service. |
| 209 | **Idle too long**<br>Remove Needle Cartridge. | 1) Remove and discard Needle Cartridge (NOTE: Due to inactivity, the Needle Cartridge has been deactivated).<br>2) Install a new Needle Cartridge.<br>3) Press **Enable Treatment**.<br>4) Check that suction can be achieved at the treatment area before resuming. Replace the suction tubing and filter as needed.<br>5) For more information, record error code and contact Cytrellis Customer Service |
| 210 | **System Paused**<br>Press **Continue** to use system.<br>Press **Power Off** to turn off system. | 1) System paused due to inactivity. Press **Continue** to restart the Handpiece.<br>2) For more information, record error code and contact Cytrellis Customer Service. |
| 211 | Fewer than 50 patterns remain at current density | 1) This is a notification that the Needle Cartridge is approaching its maximum number of excised cores and will need to be replaced to continue treatment.<br>2) For more information, record error code and contact Cytrellis Customer Service. |

*Table 18. Error Code, Messages, & Troubleshooting Guidance*

| Error Number | Error Message | Troubleshooting Guidance |
|---|---|---|
| 301 or 302 | **Power on Self-Test Failed**<br>Press **Continue** to retry. | 1) Press **Continue** to retry.<br>2) If problem persists, hold the power button down for 3 seconds until the system turns off and back on.<br>3) If problem persists, record error code and contact Cytrellis Customer Service. |

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