Patient Information

What is ellacor® with Micro-Coring® Technology?

Ellacor with Micro-Coring Technology removes unwanted skin without surgery or thermal energy to treat moderate and severe wrinkles in the mid and lower face in adults aged 22 years or older with Fitzpatrick skin types I-IV. The proprietary system precisely controls needle location and depth to remove tiny columns of skin. A medical professional will determine the proper amount of skin removal for your treatment needs. Afterwards, your skin will begin to heal through your body's natural process, resulting in visibly reduced moderate and severe cheek wrinkles.

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

About the Procedure

A typical treatment regimen includes up to 3 sessions of the mid and lower face (see Figure 1).

As assessed and determined by your physician, depth settings up to 4 mm are used, with skin removal in density up to 8% (percent of skin removed per 1 cm^2)

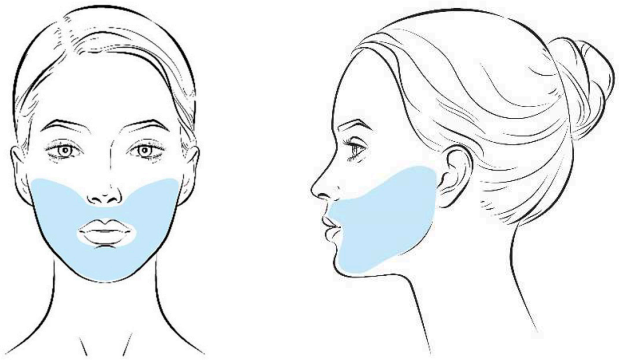

Figure 1 – Typical Treatment Area

Glossary

Acute – Severe but short in duration

Anti-coagulant – A substance that prevents or reduces the clotting of blood

Autoimmune Condition – A condition where the immune system is overactive causing it to attack the body's healthy cells

Dermatological Condition – A condition of the skin

Hematoma – A collection of blood under the skin, appears in the form of bruising

Hyperpigmentation – Darkening of the skin from its natural color

Hypopigmentation – Lightening of the skin from its natural color

Necrosis – Damage of the tissue

Nonsteroidal anti-inflammatory drug (NSAIDs) – Drugs that reduce pain and inflammation (e.g. Aspirin, Ibuprofen)

Systemic – Affecting the entire body

Contraindications

(Specific situations in which the treatment should not be used because it may be harmful.)
Please tell your treatment provider if you have any of the following:

- Tendency for scarring
- Current or potential skin cancer in the treatment area
- Pregnancy and nursing mothers
- Open wounds, sores, or irritated skin in the treatment area
- Allergy to stainless steel
- Allergy to local anesthesia or topical creams such as petrolatum
- History or presence of bleeding disorders

Skin or autoimmune conditions that may affect the treatment outcome; these may include, but are not limited to:

- actinic keratosis
- active acne
- rosacea
- cutaneous papules/nodules
- raised nevi
- dermatitis
- melasma
- psoriasis
- active inflammatory lesions
- cellulitis
- urticarial folliculitis
- lupus
- rheumatoid arthritis
- eczema
- collagen disorders
- acute inflammatory phase of Scleroderma
- dermatitis/allergic dermatitis
- Systemic infections or severe skin infections in the treatment area
- Taken high-dose anti-coagulants or blood-thinning substances (e.g. aspirin) or nonsteroidal anti-inflammatory drugs (NSAIDs) (e.g. Advil) during the previous fourteen (14) days.
- On courses of chemotherapy, radiation, or high-dose corticosteroid use in the treatment area.
- Silicone or synthetic material implanted in the face.
- Received injections of dermal fillers, fat, or botulinum toxin, as well as any cuts or openings made in the treatment area during the previous six (6) months.

Risks and Benefits

Your medical professional will discuss the following side effects with you 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
- Edema – swelling
- Ecchymosis – bruising
- Burning
- Dryness, roughness
- Tightness/pulling of skin
- Crusting
- Pain/discomfort
- Tenderness
- Tingling
- Bleeding
- Skin peeling
- Numbness
- Circular marks on skin

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

- Itching
- Hyper/hypo pigmentation
- Hematoma
- Infection
- Scarring
- Skin irregularities
- Skin necrosis
- Uneven appearance of the treated regions (left and right sides of face)
- Anesthesia toxicity (complications may include allergic reaction and possibly death)

NOTE: Structures including nerves and blood vessels run under the skin. These are essential for tissue function and may be damaged during treatment.

In the pivotal clinical study, 51 patients received up to 3 treatments with ellacor with Micro-Coring technology, approximately 30 days apart. Depending on patient baseline characteristics, the treating physician determined the density and depths to be used for optimal outcomes. All patients showed a significant improvement (greater or equal to 1 average grade change) in moderate and severe cheek wrinkles 90 days after their final treatment.

Post-Treatment Care

- Cleanse the treated area twice daily with water and mild facial cleanser and then gently pat the area dry with a clean towel; do not scrub or vigorously rub your face.
- Use a fresh clean towel each day or use paper towels to dry face; do not share your towel with family members.
- Apply light film of lanolin-free petrolatum (or as prescribed by your provider) at least twice daily for 7 days or until the area has healed; you may apply more often as needed.
- After skin has healed (no open wounds and holes have closed), apply a broad-spectrum sunscreen daily and refrain from direct sun exposure.

Refrain from the following activities until skin is fully healed (no open wounds and holes have closed):

- Shaving.
- Using tanning beds and sunless tanning cream.
- Scrubbing, scratching and/or picking at the treated area.
- Contact sports or any activity that could cause injury to the treated area.
- Submerging the treated area in pools, whirlpools, lakes, oceans or rivers.
- Activities that result in overheating, such as long exposure to hot baths, spas or excessive exercise.
- Contact your medical professional if you notice unusual redness, tenderness or other signs of concern, such as infection or fever.

Things to Discuss with Your Medical Professional

Appropriateness for treatment is based on a clinical assessment by your medical professional. Please let them know if you have any of the following conditions or are taking any of 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.

If you have any questions or concerns regarding this treatment or post treatment effects, please contact your medical professional or call Cytrellis Biosystems at (857) 254-1720 or (833) ELLACOR.

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

Patents: www.cytrellis.com/patents

Manufactured By:

Cytrellis Biosystems, Inc.
34 Commerce Way
Woburn, MA 01801 USA
T: (847) 254-1720

Patient results and experience may vary. The ellacor® 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.