

## ELLACOR® SYSTEM WITH MICRO-CORING® TECHNOLOGY

**INDICATIONS FOR USE** - The ellacor System is indicated for use by medical professionals for the treatment of moderate and severe wrinkles in the mid and lower face in adults aged 22 years or older with Fitzpatrick skin types I-IV. This system uses specifically designed hollow coring needles that, when inserted into the tissue, excise cores in the size of the inner needle diameter. The tissue cores are subsequently removed from the needle and evacuated by suction. This product is not intended for transdermal delivery of topical products such as cosmetics, drugs or biologics. Use of other modalities/topicals post procedure may result in prolonged healing and have not been studied for efficacy and safety with ellacor.

## LOCAL ANESTHESIA RECOMMENDATION

### Supplies

- 1% Lidocaine with Epinephrine (1:100,000)
- 8.4% Sodium Bicarbonate
- Topical anesthetic (BLT 20/10/4% recommended)
- 3 or 5 cc syringes
- 18g Needles to draw up anesthetic
- Alcohol prep pads & gauze
- Provider choice of germicidal cleanser (i.e. Hibiclens, alcohol bath, Chlorhexidine)
- Needles: 30G, 4mm for Injections

## ANESTHESIA PROTOCOL OVERVIEW

1. **Skin Prep:** Use germicidal cleanser (e.g., Hibiclens, alcohol, Chlorhexidine) to remove all makeup and skincare products.
2. **Topical Anesthetic:** Apply and leave on for 30 minutes.
3. **Lidocaine Toxicity Calculation:** Perform weight-based calculation for max lidocaine dosage.
4. **Remove Anesthetic:** Clean skin again after removing topical anesthetic.
5. **Nerve Block (Optional):** Administer 1cc per mental/orbital block.
6. **Lidocaine Prep:** Mix 1% lidocaine with epi 1:100,000 and sodium bicarbonate (9:1 ratio).
7. **Syringe Fill:** Prepare 3 cc or 5 cc syringes based on weight calculation and treatment area size.
8. **Injection:** Perform lidocaine injections
9. **Pain Testing:** Use 30G needle to test for sensitivity and add more anesthesia as needed.

**DISCLAIMER:** The recommendations provided regarding local anesthetic use are intended for informational purposes only. It is the sole responsibility and discretion of the treating physician to determine the appropriate anesthetic, dosage, and administration method for each patient, ensuring safety and efficacy based on individual patient needs and clinical judgement.

## SUPPLIES NEEDED PER TREATMENT

- Vacuum-rated suction tubing - 3/16 inch diameter (6.35mm), >6ft. (1.83m)
- Vacuum filter (5-micron with standard connection for 1/4" internal diameter suction tubing)
- Personal protective equipment for staff per office policy
- Sterile water (chilled)
- Sterile towels for blood management
- Soft bristle toothbrush (for cleaning device)
- 70% Isopropyl alcohol solution and/or wipes (for cleaning device)
- Clean soft cloth (for cleaning device)
- Gloves

## PRE-PROCEDURE PATIENT CHECKLIST

Ensure that patients receive a comprehensive packet with Pre-Procedure and Post-Procedure care instructions.

Ensure skin is fully healed from all facial treatments, including but not limited to surgery, laser, microdermabrasion, and chemical or mechanical peels.

### 2 Weeks Before the Procedure:

- **Avoid Blood Thinners:** Do not take blood-thinning agents such as aspirin, ibuprofen, herbal medications, or supplements like grapeseed extract, Vitamin E, or fish oil.
- **Consult with Physician:** If taking any of these under medical supervision, consult your physician.
- **Sun and Tanning Bed Exposure:** Avoid sun exposure and tanning beds to prevent red, peeling, or swollen skin.
- **Avoid Skin Treatments:** Refrain from invasive and minimally invasive skin treatments in the area to be treated.

### 1 Day Before the Procedure:

- **Facial Hair:** Shave excessive facial hair.

## PROCEDURE PARAMETERS

### Skin Removal % (Density)

- Determine density setting based on skin condition, downtime, expectations
- Higher density settings = more aggressive treatment and greater downtime for patient

### Core Depth Setting


- Recommended depths are anatomy specific and take underlying bony and soft tissue areas into account
- Start with recommended depth for each region and reduce depth by 0.5mm if:
  - Patient has thin skin or prominent bones
  - A needle alert is triggered at recommended depth for a region

**Standby Mode** STANDBY / READY

**Skin Removal**

5%

-
+



**Core Depth Setting**

3.0mm

-
+

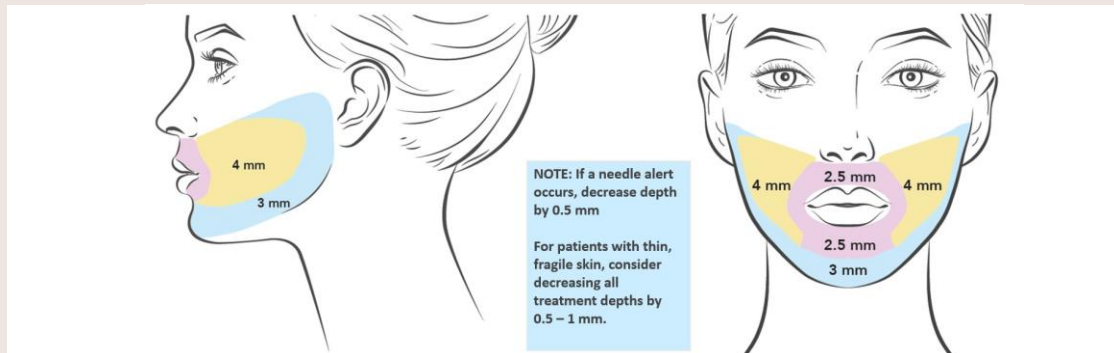
Core Count: 0

Vacuum: Off

END TREATMENT

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

## CORE DEPTH SETTINGS RECOMMENDATION



## PROCEDURE PROTOCOL

### Step 1: Mid/Lower Cheek

- Begin at 4 mm core depth.
- Target soft tissue, starting at the nasolabial fold and treating in columns down to just above the jawline.
- Continue laterally towards the preauricular area, avoiding bony regions.

### Step 2: Preauricular Area & Jawline

- Adjust to 3 mm core depth.
- Treat the bony area starting from the alar crease under the zygoma, treating laterally to the preauricular area.
- Treat the preauricular area down to the jawline, then along the jawline to the chin.

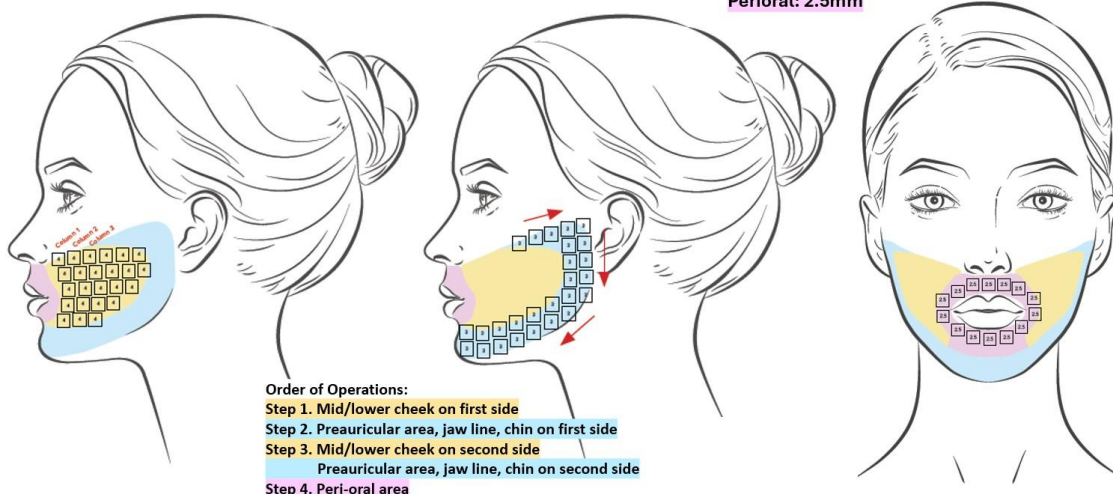
### Step 3: Opposite Side

- Repeat Steps 1 and 2 on the other side of face.

### Step 4: Chin & Perioral Area

- Set core depth to 3 mm and treat the chin.
- Set core depth to 2.5 mm and treat the peri oral area.

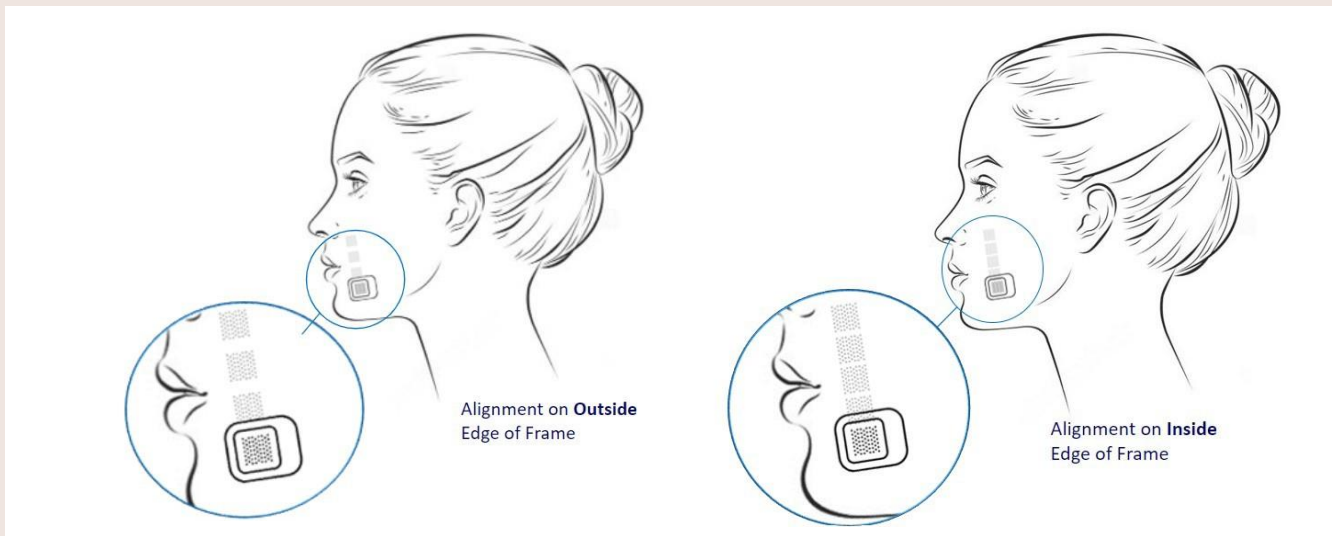
Mid/Lower Cheek: 4.0mm  
Preauricular / Jaw Line / Chin: 3.0mm  
Perioral: 2.5mm



## PATTERN ALIGNMENT

### Pattern Alignment: Steps to Lay consecutive Patterns across different treatment areas

- Align outside/inside edge of treatment frame against previous treatment pattern for wider/tighter spacing.
- Lay patterns in accordance with the anatomical guidelines provided in Steps 1-4



## PROCEDURE PROTOCOL: WHAT NOT TO DO

### AVOID the following techniques for coring application:

- Use of bite blocks, tongue depressors, etc. for counter pressure inside of cheek or perioral area
- Applying excessive or uneven pressure on handpiece during treatment – allow weight of the handpiece to rest on the skin
- Tilting the handpiece – hold the handpiece perpendicular to treatment surface
- Post treatment core extraction (with vacuum, tweezers, aggressive scrubbing, etc.)

### AVOID the following techniques for skin presentation:

- Excessive skin stretching either by hand or with further injection of anesthesia/tumescent
- Use of gauze or linting towels – lint free surgical towels are provided in consumable kits
- Excessive scrubbing with towels

## POST PROCEDURE CARE

### Immediate Care

- Always take post procedure photos of the entire treated area.
- Continue gentle compression with cold, damp, sterile towels to control bleeding.
- Provider choice of moist after-care product (e.g. observed best practices with exosomes, Alastin Skin Nectar, Epidermal Repair, growth factors, etc.) **Do not use petroleum-based products directly on the open wound.**
- Recommended use: Gently apply the healing product over the entire treatment area
- Apply wound dressing (Tegaderm) over treated area for first 12 hours

### Home Care

- Gently wash the treated area twice daily with water and a mild cleanser (e.g. CeraVe Facial Cleanser), clean towel to pat dry.
- Be gentle with skin, do not scrub or vigorously rub or wipe face.
- Follow each cleansing with topical healing skincare product per provider, keeping skin moist while healing.
- After skin has healed, (no open wounds and holes have closed), use a broad-spectrum sunscreen >30 SPF and avoid direct and prolonged sun exposure for 1 month post treatment.

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

- Shaving
- Makeup and skincare products
- Using tanning beds and sunless tanning creams.
- Scrubbing, scratching and/or picking at the treated area.
- Submerging the treated areas in pools, whirlpools, lakes, oceans or rivers.
- Contact sports or any other activity that could cause injury to the treated area.
- 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.
- After skin has healed, use a broad-spectrum sunscreen >30 SPF and avoid direct and prolonged sun exposure for 1 month post treatment.

## **TREATMENT SCHEDULE**

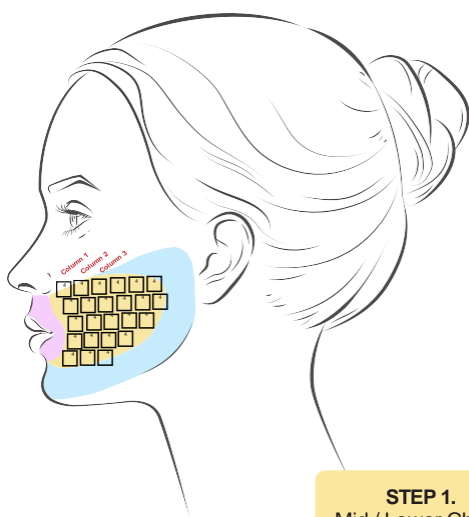
- Patients in the pivotal trial were treated up to 3 times. Retreatment was performed at 30 days for those that required more than 1 treatment. Treatments can be spaced further apart if more time is needed for healing.
- Before subsequent treatments, ensure that micro-cores have fully closed and healed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

## PROCEDURE PROTOCOL STEPS

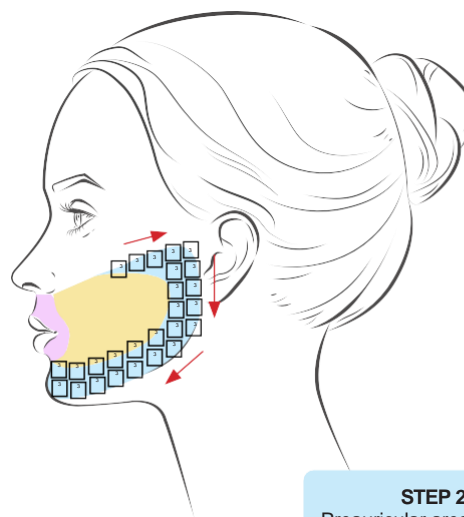
Mid / Lower Cheek:  
4.0mm

Preauricular /Jawline /  
Chin: 3.0mm

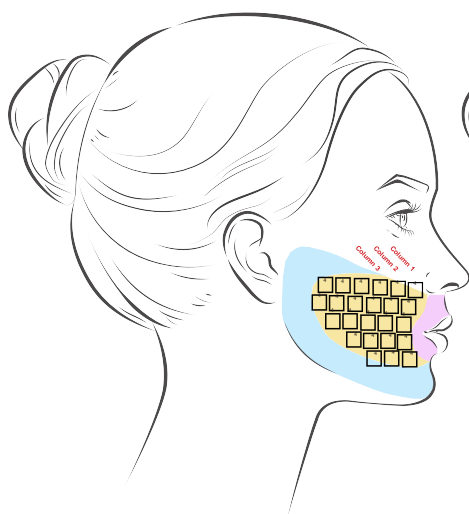
Perioral: 2.5mm



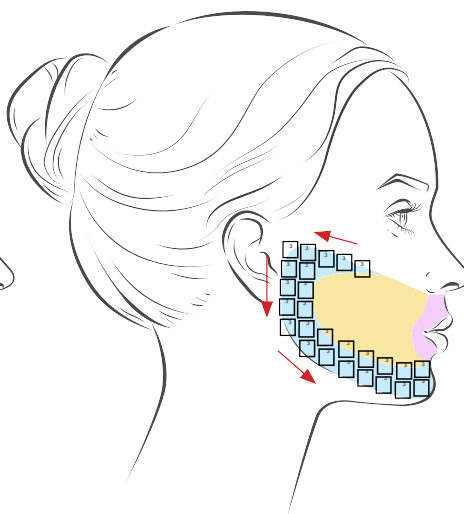
**STEP 1.**  
Mid / Lower Cheek  
on first side



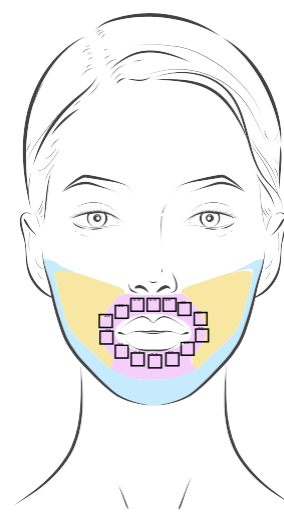
**STEP 2.**  
Preauricular area, Jawline,  
Chin on first side



**STEP 3.**  
Mid / Lower Cheek  
on second side

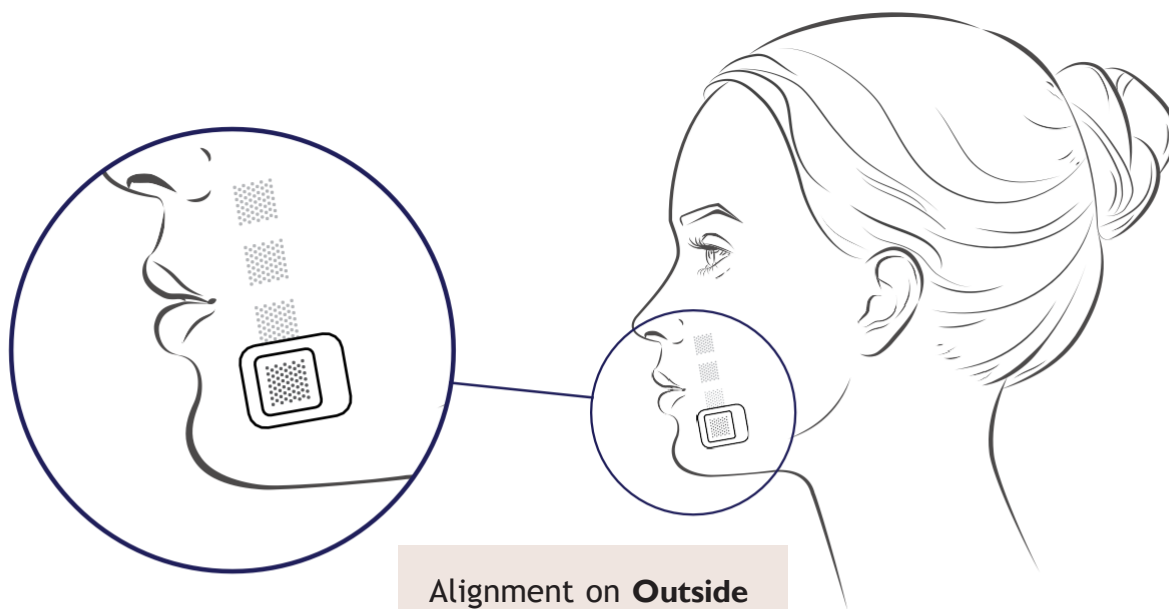


Preauricular area, Jawline,  
Chin on second side

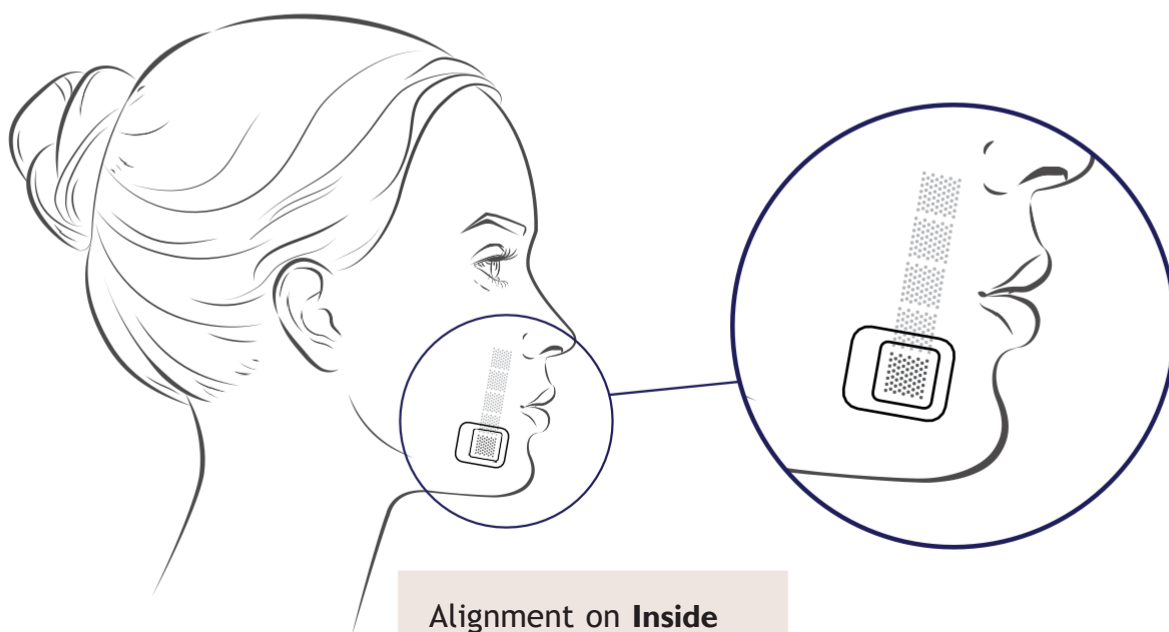


**STEP 4.**  
Perioral area

## PATTERN ALIGNMENT



Alignment on **Outside**  
Edge of Frame



Alignment on **Inside**  
Edge of Frame