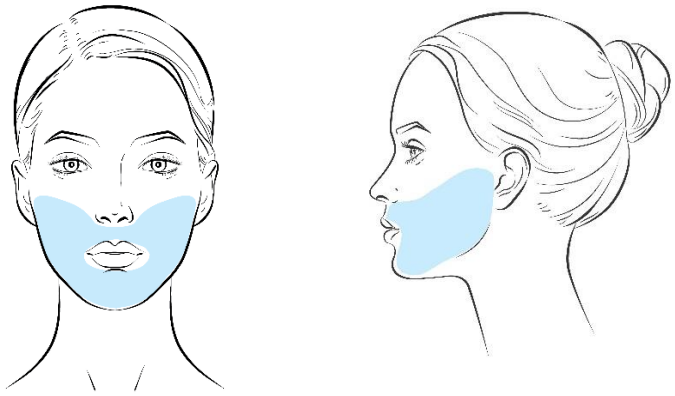
TREATMENT CONSENT FORM

Patient's Name:	**Date of Birth:** **Age:**
Telephone:	**Email:**

You are scheduled for treatment(s) using the ellacor® System with Micro-Coring™ Technology. This system removes unwanted skin without surgery or thermal energy to treat moderate and severe wrinkles in the mid-to-lower face in adults aged 22 years or older with Fitzpatrick skin types I-IV. (The Fitzpatrick skin type scale depends on the amount of melanin pigment in your skin.) This 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.

NOTE: The system is <u>not</u> intended for transdermal (under the skin) delivery of topical products such as cosmetics, drugs, or biologics.

A typical treatment regimen includes 2-3 sessions, (30-days apart depending on your body's own natural healing process), to the mid and lower face (see diagram). Your treatment provider will determine the number of sessions for your treatment.



Typical Treatment Area

What you can expect:

In the clinical trial for the ellacor System with Micro-Coring Technology, patients felt comfortable going out in public after an average downtime of 3 days. Some patients may feel comfortable going out in public sooner than three days, whereas other patients may prefer a longer recovery time. Every patient heals differently; mild to moderate side effects may still be present after this time, particularly redness and bruising.

Your treatment provider will discuss the following potential 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:

- *Redness* may appear for up to two weeks or more after treatment. At 30 days, physicians reported redness in less than 20% of patients. Initial:____

- *Bruising, swelling, tightness, tingling, discomfort, dryness, skin peeling and circular marks on skin* can occur in the treated area and may appear for up to two weeks or more after treatment. Initial:____

- Other changes including *tenderness to the touch/ skin sensitivity or discomfort* may occur in the treated area. Initial:____

- *Burning, bleeding, roughness, itching, crusting, skin irregularities, hypo/hyperpigmentation* have also been reported. Initial:____

- Other side effects not commonly observed: *Hematoma, infection, scarring, skin necrosis; uneven appearance of treated regions, anesthesia toxicity, anesthesia-related complications may include allergic reaction and possible death*. Structures including nerves and blood vessels run under the skin. These are essential for tissue function and may be damaged during treatment. Initials:____

- Patient experiences vary. Some patients may experience a delayed onset of the previously mentioned symptoms. **Contact your treatment provider <u>immediately</u> if any unusual side effects occur or if symptoms worsen over time.** Initial:____

- Your skin will begin to heal through your body's natural process. Visibly reduced moderate to severe cheek wrinkles may be appreciated within 6 weeks post-treatment**,** although some patients may not experience any visible change. Patient results vary. Initial:____

- Additional treatments may be needed to reach your desired outcome. Initial:____

- **I understand that these and other unknown side effects may also occur. Initial:____**

Do you have any of the following?

- Tendency for scarring
- Current or potential cancer in the treatment area
- Pregnancy or nursing mother
- 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 disorder
- Systematic infections or severe skin infections in the treatment area
- Ingestion of high-doses of anti-coagulants or blood-thinning substances (e.g., aspirin) or nonsteroidal anti-inflammatory drugs (NSAIDS) (e.g., Advil) during the previous 14 days
- Ongoing courses of chemotherapy, radiation, or high-dose corticosteroid use in the treatment area
- Silicone or synthetic materials implanted in the face
- Received injections or dermal fillers, fat, or botulinum toxin, as well as any cuts or openings made in the treatment area during the previous six (6) months
- 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 scars less than six (6) months old in the treatment area
- Skin or autoimmune conditions that may affect the treatment outcome; these may include, but are not limited to the following:

actinic keratosis
active acne
rosacea
cutaneous papules/nodules
raised nevi
dermatitis
melasma
psoriasis
active inflammatorylesions
cellulitis
urticarial folliculitis
lupus
rheumatoid arthritis
eczema
psoriasis
collagen disorders
acute inflammatory phase of scleroderma

These specific situations are contraindications. If you answered YES or have any of the above, please inform and discuss with your treatment provider prior to treatment. Treatment may be harmful and should not be used.

Appropriateness for treatment is based on a clinical assessment. Please answer whether you currently have or have had any of the following conditions or are taking any of the following medications:

- History of hyperpigmentation ☐ YES ☐ NO
- Recent exposure to sun or tanning beds with red, peeling, or swollen skin ☐ YES ☐ NO
- Recent trauma or surgery to the treatment area ☐ YES ☐ NO
- Active, chronic, or recurrent infection including bacterial or fungal infections ☐ YES ☐ NO
- History of active herpes simplex infection in the treatment area ☐ YES ☐ NO
- Use of topical or oral preparations/medications that may change the skin integrity or prolong healing ☐ YES ☐ NO
- 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 ☐ YES ☐ NO
- Other medications or medical conditions that may interfere with the treatment ☐ YES ☐ NO

If you answered YES to any of the questions above, please discuss with your treatment provider prior to your treatment. It may be necessary to obtain clearance from your Primary Care Physician or other managing healthcare provider prior to treatment.

Day of Treatment – The skin on your face, chin, and neck should be free of makeup, lotions, and other skin care products. It is important to tell your treatment provider about any products used in the treatment area on the day of treatment.

Post Treatment Care – Refrain from the following activities until your skin has fully healed and has no open wounds and holes have closed: *Shaving, waxing, makeup and skin care products, using tanning beds and sunless tanning creams; scrubbing, scratching and/or picking at the treated area(s); contact sports or any activity that could cause injury to the treated site; submerging the treated area in water such as pools, whirlpools, oceans, etc.; and activities that result in overheating, such as long exposure to hot baths, spas, or excessive exercise.* Speak with your treatment provider who may have additional post treatment care.

Photographs will be obtained for medical records. If pictures are used for education and marketing purposes, all identifying marks will be cropped or removed. Initial:____

As with most medical procedures, there are risks and side effects. These have been explained to me in detail. Initial:____

The ellacor System does not collect patient identifying data; only patient gender, patient age range, treatment settings, date and time of each treatment.

I have read the above information, and I give my consent to be treated with the ellacor System by Dr. *[insert physician name]* and *[his/her]* designated staff.

Print Name:_____ **Signature:**_____ **Date:**_____

Witness:_____ **Date:**_____