COLLAGEN P.I.N.®

PATIENT GUIDE

What is the Collagen P.I.N.?

The Collagen P.I.N.® is a microneedling device that is indicated as a treatment to improve the appearance of facial acne scars in adults with Fitzpatrick skin types I, II, and III, aged 22 years and older. Microneedling devices use one or more needles to mechanically puncture and injure skin tissue for aesthetic use.

How many treatments will I need?

Induction Therapies recommends four Collagen P.I.N.® treatments spaced four weeks apart.

What happens during treatment?

Your trained clinician will clean the area to be treated and may apply a topical numbing agent. Next, your trained clinician will install a sterile disposable needle cartridge with 36 microneedles. Your trained clinician will then power the device ON to begin treatment and will glide the device across your skin while the device mechanically pushes the microneedles inside the cartridge in and out to puncture the skin. Your trained clinician will determine an effective depth best suited for your skin and your desired outcomes.

Side Effects:

Microneedling is an in-office treatment with little-to-no downtime. Following the procedure, your skin will be red and flushed in appearance, similar to a sunburn. You may also experience skin tightness, mild sensitivity, a mild burning sensation, and pinpoint bruising on the treatment area. Your skin may be sensitive to exposure to sunlight for several days. We recommend using Induction Therapies' *Cleanse-IT* gentle cleanser, *Block-IT* sunscreen, and *Skin Renewal Hydrator*, or a comparable gentle cleanser (non-comedogenic and free of parabens, fragrance, alpha hydroxy acid (AHA), beta hydroxy acid (BHA), tretinoin, benzoyl peroxide, adapalene, and retinoids), sunscreen (SPF 30, active ingredient of Zinc Oxide, non-comedogenic, and free of fragrance and parabens), and moisturizer (non-comedogenic, Squalane-based, and free of fragrance or parabens), for at least four days following the procedure.

Contraindications:

Prior to treatment with the Collagen P.I.N.®, disclose your full medical history and any previous aesthetic treatments to your trained clinician. The use of the Collagen P.I.N.® device system should not be used on individuals who:

- Are currently taking drugs with the ingredient isotretinoin (such as Accutane)
- Have permanent fillers or implants within the treatment area
- Have diabetes or patients with woundhealing deficiencies
- Have active skin cancer in the treatment area
- Have an allergy to stainless steel or anesthetics
- Have psoriasis and other chronic conditions
- Have keloid scars
- Are pregnant or nursing
- Have open wounds, sores, infection, or irritated skin in the treatment area
- Have a hemorrhagic (bleeding) disorder or hemostatic (bleeding) dysfunction
- Have raised moles or warts on the treatment area
- Are undergoing immunosuppressive therapy
- Have a history of herpes simplex infections
- Have history of eczema
- Are suffering from Sojourns Syndrome
- Have a history of actinic (solar) keratosis

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Induction Therapies, LLC
1920 Stanley Gault Parkway, Suite 200
Louisville, Kentucky 40223

www.InductionTherapies.com
Phone: 877.746.4407
Fax: 855.856.1424

Prohibited Medications and Treatments:

If you have used any of the following medications or treatments, you should refrain from treatment with the Collagen P.I.N.® within the times indicated below:

- NSAIDS, ASA at dosage over 81mg/day, fish oil, or greater than 30,000 IU/day oral vitamin E should not be used within 7 days prior to or 14 days after treatment
- Prescription strength topical retinoids should not be used in treatment area within 14 days prior to treatment
- Anti-coagulation/anti-platelet therapies should not be undergone within 14 days prior to or 14 days after treatment
- Anti-wrinkle or skin lightening devices, topical or systemic medications known to affect skin aging or dyschromia should not be used in treatment area within 14 days prior to treatment
- Exposure to any investigational drug or device should not be undergone within 30 days prior to treatment
- Botulinum toxin injections should not be used in treatment area within 3 months prior to treatment
- Prescription strength lightening devices should not be used in treatment area within 3 months prior to treatment
- Chemical treatments should not be used in treatment area within 3 months prior to treatment
- Deep chemical peels or surgical dermabrasion should not be undergone within 6 months prior to treatment
- Systemic retinoids should not be used within 6 months prior to treatment
- Laser/light therapies should not be used in treatment area within 6 months prior to treatment
- Non-invasive skin-tightening, mesotherapy, and fat injections should not be used in treatment area within 12 months prior to treatment
- Bioresorbable fillers in the treatment area should not be used within 12 months prior to treatment

Other Precautions

The safety or effectiveness of Collagen P.I.N.® in individuals with the following traits, diseases, or conditions has not been tested:

- Persons under the age of 22 years
- Known sensitivity to local anesthetics of the amide type, history of multiple severe allergies, history of anaphylactic shock
- Acute or chronic skin disease, inflammation or related conditions, cancerous or precancerous lesions, or infection near the treatment area
- History of active or inactive systemic granulomatous diseases or connective tissue disease
- Scars treated with any alternative treatment modality within 6 months prior to treatment
- Known history of clinically significant skin pigmentation disorders
- Scars aged less than 6 months
- Clinically significant active skin disease within the treatment area within 6 months prior to treatment
- Severe or cystic active and clinically significant facial acne on treatment area, or hypertrophic scars or keloid formation on the area to be treated
- Susceptible to or known history of keloid formation, hypertrophic scarring, scar related disease, or delayed healing activity
- Undergoing, or planning to undergo, radiation or ultrasound therapy near the treatment area
- Malignancy (excluding non-melanoma skin cancer) within the past 3 years
- An uncontrolled systemic disease

Clinical Study Summary

Induction Therapies sponsored a study to test the safety and effectiveness of Collagen P.I.N.® in improving the appearance of facial acne scars and non-facial surgical and traumatic scars in adults with all Fitzpatrick skin types aged 22 years or older. One doctor treated acne scars on 25 patients' faces. Another doctor treated non-facial scars (the chest, stomach, legs, and arms) of 25 different patients.

Each doctor washed their patient's scar with Induction Therapies' *Cleanse-IT* and applied DMC Medical Ltd.'s *SupraGel* to the scar area. Next, the doctor decided how deep the Collagen P.I.N.®'s needles needed to go into the patient's skin to treat the scar. The doctor then set the dial on the device's handpiece to that depth. The doctor moved the tip of that handpiece with the exposed needles over the scar while applying gentle pressure to the skin around it and slowly increasing the depth of the needles up to its 3.0 mm maximum. The doctor stopped the treatment when very small drops of blood (the size of the head of a pin) appeared at the spots where the needles pierced the skin.

Twenty three patients with facial acne scars and 25 patients with non-facial surgical or traumatic scars received all four of the planned treatments. The doctor who treated the 23 patients with facial acne scars found that the appearance of all of those patients' scars improved. The doctor who treated the 25 patients with non-facial surgical or traumatic scars found that all of those patients' scars improved.

Two other doctors, who are called observers, graded all of those patients' scars based on photographs taken after each treatment. One of those observers found that the appearance of scars in 47.8% of patients with facial acne scars and 64.0% of patients with non-facial surgical or traumatic scars, improved after four treatments. The other observer found that the appearance of scars in 60.9% patients with facial acne scars and 24.0% of patients with non-facial surgical or traumatic scars improved after four treatment. At the end of the study, 91.3% of the 23 patients with facial acne scars and 68% of the 25 patients with non-facial surgical or traumatic scars reported being satisfied or very satisfied with their results.

No serious or unexpected adverse events occurred during the study. No patient had to stop participating in the study due to adverse events. The study showed that the Collagen P.I.N.® improved the appearance of mild to moderate facial acne scars and non-facial surgical and traumatic scars in adults with Fitzpatrick skin types I, II, and III aged 22 years or older. The study also showed that this treatment was well-tolerated.

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