COLLAGEN P.I.N.®

User Manual

Caution: Federal law restricts this device to sale by or on the order of a physician.

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SECTION 1: GENERAL INFORMATION

1.1 User Manual

This User Manual provides information about the safe use of the Collagen P.I.N® System. This User Manual should be read in its entirety before using the Collagen P.I.N.® system.

This User Manual must be read and followed by all people who inspect, use, and maintain this device. The User Manual must be available to the user at all times. If the device system is given to a third party, the User Manual must be included.

The User Manual is limited to all information required for safe operation of the device system only. User should refer to additional documents for further information required for safe operation of the device and its components:

- Safety data sheets for disinfectants and cleaning agents
- Provisions on workplace safety and legal requirements for microneedling

The Collagen P.I.N.® microneedling device and accessories are indicated for use as a treatment to improve the appearance of facial acne scars in adults with Fitzpatrick skin types I - III, aged 22 years or older.

1.2 Warning Symbols and Statements Used in This User Manual

DANGER	**DANGER** indicates a hazardous situation which, if not avoided, will result in death or serious injury
WARNING	**WARNING** indicates a hazardous situation which, if not avoided, could result in death or serious injury
CAUTION	**CAUTION** indicates a hazardous situation which, if not avoided, could result in minor or moderate injury
	SHARP HAZARD

The Collagen P.I.N.® is a handheld percutaneous collagen induction therapy device designed for use with a 36 needle array cartridge. The accessories are a battery with electrical cord and BioSheath. Each component and accessory will be explained to clarify how the Collagen P.I.N.® works.

1.3 LIMITATION OF LIABILITY

DO NOT USE the Collagen P.I.N.® device system in any way not exactly described by this User Manual. The use of the Collagen P.I.N.® device system in any way other than that specified in this User Manual has not been tested, and therefore the risks of unspecified use are unknown. This device system is designed for use ONLY by trained clinicians and ONLY in the manner stated in this User Manual. The user of this device system is responsible for following professional guidelines and standards of care for office

cleanliness and hygiene, and for using only sterile materials for patient treatments (see Section 4: Warnings and Precautions and Section 9: Cleaning/Disinfecting the Collagen P.I.N.®). This device system is indicated for use ONLY with sterile, single-use needle cartridges, which must be properly discarded immediately after use (see Section 11: Disposal of Needle Cartridges). Prior to treatment, the patient must be informed of potential treatment risks (see Section 7: Treatment Instructions).

SECTION 2: INDICATIONS / INTENDED USE

Caution: Federal law restricts this device for sale by or on the order of a physician.

The Collagen P.I.N.® microneedling device and accessories are indicated for use as a treatment to improve the appearance of facial acne scars in adults with Fitzpatrick Skin Types I - III, aged 22 years or older.

2.1 User Requirements

The Collagen P.I.N.® may ONLY be utilized by trained clinicians who meet the following minimum requirements:
• Medical training
• Necessary knowledge of microneedling treatments (refer to this User Manual)
• Necessary knowledge of hygiene and safety requirements for treatment (refer to this User Manual)
• Knowledge of all risks and potential side effects of the Collagen P.I.N.® (refer to this User Manual)

2.2 Contraindications

⚠WARNING

Before initiating a treatment with the Collagen P.I.N.® device system, complete a review of the patient's full medical history and any previous aesthetic treatments.

The Collagen P.I.N.® device system should not be used on patients who:
• Have active skin cancer in the treatment area(s)
• Have open wounds, sores, or irritated skin in the treatment area(s)
• Have an allergy to stainless steel or anesthetics
• Have a hemorrhagic (bleeding) disorder or hemostatic (bleeding) dysfunction
• Are pregnant or nursing
• Are currently taking drugs with the ingredient isotretinoin (such as Accutane)
• Have keloid scars
• Are suffering from Sojourns Syndrome
• Have history of eczema
• Have psoriasis and other chronic conditions
• Have a history of actinic (solar) keratosis
• Have a history of herpes simplex infections
• Have diabetes or patients with wound-healing deficiencies
• Are undergoing immunosuppressive therapy
• Have raised moles or warts on targeted area
• Have Fitzpatrick Skin Types IV - VI

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

2.3 Requirements for Safe Use of the Collagen P.I.N.®

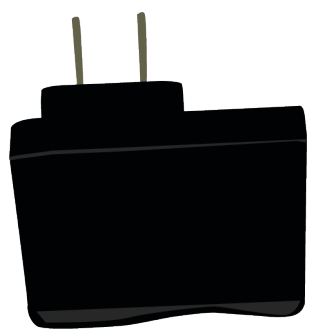
Treatments with the Collagen P.I.N.® device must be administered in a clinical environment. The Collagen P.I.N.® device must be maintained and used as set forth in this User Manual, and all materials used must be sterile and/or cleaned/disinfected in accordance with the instructions herein (see Section 9: Cleaning/Disinfecting the Collagen P.I.N.®). Use of the device system implies that the user has read and understood this entire User Manual, particularly (see Section 4: Warnings and Precautions). The device is indicated for use as a treatment to improve the appearance of facial acne scars in adults with Fitzpatrick Skin Types I - III, aged 22 years or older. Improper use of the device occurs when the user utilizes this device system for any purpose other than its specific intended use, or if the information contained in this User Manual is not specifically adhered to by the user. The user should NOT use any products on a patient's skin other than those listed in this User Manual (see Section 7: Treatment Instructions). This devices system is designed to be placed on a flat surface, and treatments should be done on a patient who is sitting or lying down.

SECTION 3: DEVICE DESCRIPTION

Collagen P.I.N.® System
Device parts your system includes:
(A) Collagen P.I.N.® Handpiece Model # MP1207PT
(B) One USB Wall Adapter
(C) Two rechargeable batteries
(D) One Micro USB Cable

(A)

(B)



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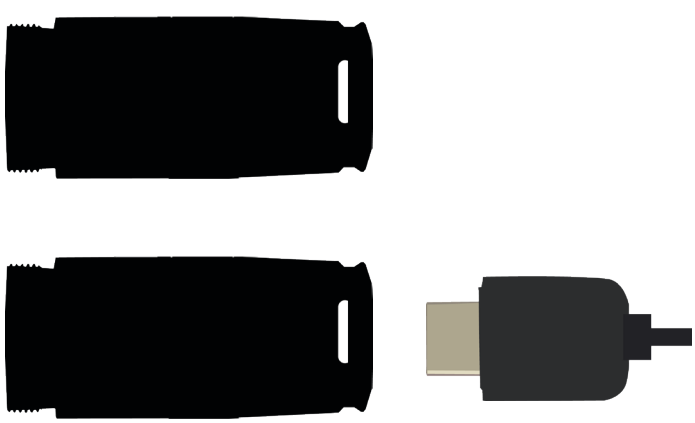


COLLAGEN P.I.N.® TREATMENT SYSTEM

Collagen P.I.N.® 36 Needle Microneedling Cartridge
Product #CP000000
EO (Ethylene Oxide Gas) Sterilized, disposable needle Cartridge individually packaged and labeled. Proprietary needle cartridge. **Cartridges are not to be re-sterilized or reused**

SupraGel™
Product # ITCP2020
SupraGel™ is a hydrogel wound dressing (without drugs and / or biologics) to protect against abrasion and friction during the microneedling procedure. SupraGel™ creates a natural barrier between the skin and the environment to help prevent trans-epidermal water loss. Note the device is NOT intended for transdermal delivery.

Collagen P.I.N.® BioSheath
Product #CP000000
The Collagen P.I.N.® and needle cartridge interface with a nonsterile and disposable BioSheath to prevent contamination of the Collagen P.I.N. ®

⚠WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation. Use of accessories other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation. To avoid interference with the device's intended performance, do not use any equipment not designed specifically for Collagen P.I.N.® Microneedling should not be used within the orbital rim of the eye, such as the eyelids.

The Collagen P.I.N.® System has not been evaluated in the any of the following patient populations (i.e. patients with the following conditions or taking the following medications): Those with active acne, psoriasis, eczema, rosacea, actinic (solar) keratosis, diabetes, scleroderma, keloid scars (scars that grow outside the boundaries of an original scar), those with other chronic conditions in the treatment area or on other areas of the body, those with an active bacterial, fungal, or viral infection (i.e. herpes, warts), those with raised moles in the treatment area, those going through immunosuppressive therapy, those suffering from collagen vascular diseases or cardiac abnormalities, those with a history of contact dermatitis, those on anticoagulant therapy, those with scars and stretch marks less than one year old, and those with wound healing deficiencies.

SECTION 4: WARNINGS AND PRECAUTIONS

Caution: Federal law restricts this device to sale by or on the order of a physician.

4.1 Operating Precautions

- This device system should ONLY be used by trained clinicians with proper medical training
- All treatments MUST be administered in an environment suitable for medical treatments
- Before using the device system, ensure the device handpiece is “OFF,” and perform a visual check the system for any signs of damage. Do NOT use the device if there are any obvious signs of damage. Do NOT handle a faulty needle cartridge, as there is risk of sharps injury. Contact Customer Service at 877-746-4407 if your device system is damaged. Use of any part of a damaged device system could lead to harm to the user or patient.
- Clean the device before and after each use by following the instructions in Section 9: Cleaning/ Disinfecting the Collagen P.I.N. ®. Ensure the device is “OFF” prior to cleaning the device. Do NOT use the handpiece that is contaminated with bodily fluids or any other substances. Do NOT place the device system on any surface that is not sterile. Do NOT use the device without the BioSheath cover.
- Do NOT use the device without applying disposable nitrile, latex or non-latex gloves prior to use.
- Do NOT use a needle cartridge if its sterile packaging is damaged or if it is past the use-by date listed on the packaging. The sterility of the needle cartridge is only guaranteed if the packaging has not been damaged.
- Do NOT use a sterile needle cartridge on more than one patient, as re-use can lead to the transmission of bloodborne pathogens from one patient to another. Dispose of the needle cartridge immediately after use, and ONLY dispose of the needle cartridges in an approved biohazard sharps container.

4.2 Electrical Safety Warnings and Risk of Sharps Injury

⚠WARNING

The Collagen P.I.N.® device system is an electrical device, which could present the risk of electrical shock to the user. All users should review this User Manual carefully to ensure maximum safety during use of the device system.

- Do NOT attempt to disassemble or repair the device system.
- No modification of this equipment is allowed. There are no user serviceable parts available for this device.
- Do not use the device with any equipment or accessories that are not included with the Collagen P.I.N.® System as to avoid interference with the device’s intended performance.
- Do not plug product into an outlet with a voltage other than what is specified on the charger adapter. (100- 240Vac)
- NEVER use the Collagen P.I.N.® system if you think it has been immersed in water or exposed to liquids of any type with the exception of cleaning solutions contained in this User Manual (see Section 9: Cleaning/Disinfecting the Collagen PI.N.®).
- Never force a plug into an outlet if it does not easily fit into the outlet, discontinue use.
- Discontinue use if product appears damaged in any way.
- Do not use or charge if cord or plug is damaged.

• Keep cord away from heated surfaces.
• Do not store any part of the device system near a sink or where it can fall or be pulled into water.
• The emission characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR11 class A).

WARNING

The Collagen P.I.N.® microneedling device comes with safety needle cartridges, which under certain circumstances pose the risk of a sharps injury. Injuries from contaminated needles in safety needle cartridges may lead to the transmission of diseases. Please read this User Manual thoroughly and follow
directions stated to assure maximum safety during operation.

- Do NOT attempt to attach or remove the safety needle cartridge to or from the handpiece while the device is ON. The safety needle cartridges may ONLY be attached and removed when the handpiece is switched OFF. Failure to follow this precaution may lead to a sharps injury.
- Do NOT touch the needles and tip of the cartridge at any time. Contact with the needles may lead to a sharps injury or contamination.
- Use ONLY original safety needle cartridges for the device that fit your Collagen P.I.N.® handpiece.
- NEVER depress the needle plunger so that the needles are exposed outside of the needle cartridge.
- ALWAYS dispose of used or contaminated safety needle cartridges in a suitable sharps container immediately after use. Follow local guidelines for disposal of sharps containers.
- Before switching on the handpiece motor, ALWAYS hold the handpiece firmly.
- ALWAYS dial to “0” on the depth gauge to ensure retraction when inserting or removing a needle cartridge.
- Needle cartridges are designed for single use only – discard needle cartridge immediately after use!
- Open the sterile needle cartridge packaging at the “PEEL” mark

WARNING

Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.

Use of components other than those specified or provided by the manufacturer of this equipment could result in increased electromagnetic emissions or decreased electromagnetic immunity of this equipment and result in improper operation.

SECTION 5: UPON RECEIPT OF YOUR COLLAGEN P.I.N. ® MICRONEEDLING SYSTEM

WARNING

DAMAGE CAUSED BY CONDENSATION: If the device is exposed to high differences in temperature (e.g. during shipment) condensation may form on the inside and cause damage to electronic components, which under certain circumstances could present an electrical shock hazard to the user.

- After unpacking your Collagen P.I.N.® and before first time use, make sure that the device has reached ambient temperature.
- Store and use the device ONLY at an ambient temperature of +62°F to +86°F and at a relative humidity of 30% to 75%.

WARNING

DAMAGE TO THE PRODUCT FROM DROPPING: Dropping the handpiece or any accessory/component could cause damage. If you do drop the handpiece or any accessory/component, complete a visual inspection. If the handpiece or any of the accessories/components show visible signs of damage or are not working properly, contact Induction Therapies, LLC at 877-746-4407.

5.1 Initial Setup

WARNING

RISK OF SHORT CIRCUIT AND ELECTRIC SHOCK: In the event of visible damage to cords or cord connections, there is a risk of electric shock and damage to electronic components. Do not connect or use damaged cords. If cords are damaged contact Induction Therapies, LLC at 877-746-4407.

WARNING

TRIP HAZARD FROM CORDS: If cords are not laid properly, this could cause a tripping hazard and cause or risk injury.

- Unpack the Collagen P.I.N.® system from its outer shipping container.
- Contact Induction Therapies, LLC at 877-746-4407 immediately if you observe any missing parts or components.
- Carry out a visual inspection of the equipment.
- Do NOT use the device if you observe visible signs of damage.
- Lay charging cord carefully to avoid a tripping hazard. Do NOT allow the charging cord to twist or curve.

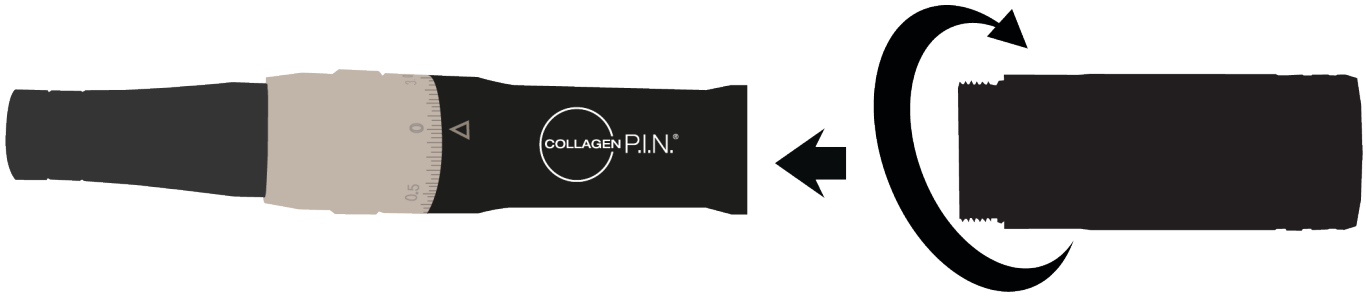
SECTION 6: ASSEMBLY AND USE OF THE COLLAGEN P.I.N. ® SYSTEM

WARNING

THIS DEVICE IS ONLY TO BE USED UNDER THE SUPERVISION OF A LICENSED TRAINED CLINICIAN AND ONLY FOR THE SPECIFIC INDICATIONS FOR USE LISTED IN THIS USER MANUAL

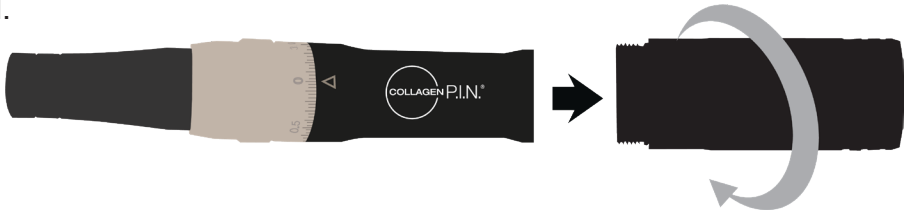
6.1 Assembling the Collagen P.I.N. ® Device

To assemble the Collagen P.I.N. ® handpiece with the battery, twist the battery clockwise (see below) until the threads catch and it fits snugly into the larger opening at the bottom of the Collagen P.I.N. ® handpiece.



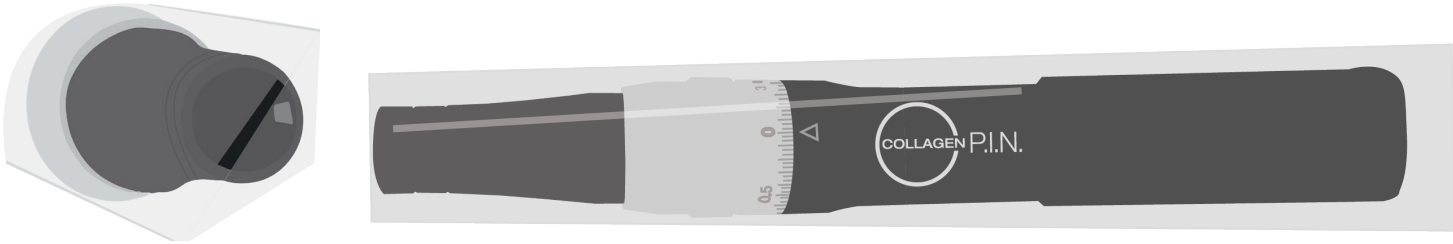
6.2 Removing the Battery

Ensure the Collagen P.I.N. ® Device has been properly cleaned and disinfected before removing the battery (see Section 9: Cleaning/Disinfecting the Collagen P.I.N.®). Ensure the device is powered off. Grasp the Collagen P.I.N. ® Handpiece firmly at the logo and twist the battery counterclockwise until fully removed.



6.3 Applying the BioSheath

Ensure the Collagen P.I.N. ® is powered off. While wearing disposable nitrile, latex or non-latex gloves, ensure the Collagen P.I.N. ® is clean/disinfected. Obtain a single use BioSheath from the Collagen P.I.N. ® Device System. With the Collagen P.I.N. ® powered off, insert the device into the large end opening of the BioSheath and ensure the entire device is fully covered. Position the device within the sleeve so that the tip is at the edge of the small opening/slit.



NOTE: The purpose of the BioSheath is to provide a disposable barrier that helps prevent cross contamination. The Collagen P.I.N.® device is intended to be used ONLY with provided BioSheath.

6.4 Removing the BioSheath

Ensure the Collagen P.I.N.® is powered off. Hold the Collagen P.I.N.® device perpendicular to the floor, or with the tip pointing downwards. Remove the BioSheath by carefully rolling it down the Collagen P.I.N. ® device to prevent soiling the Handpiece.

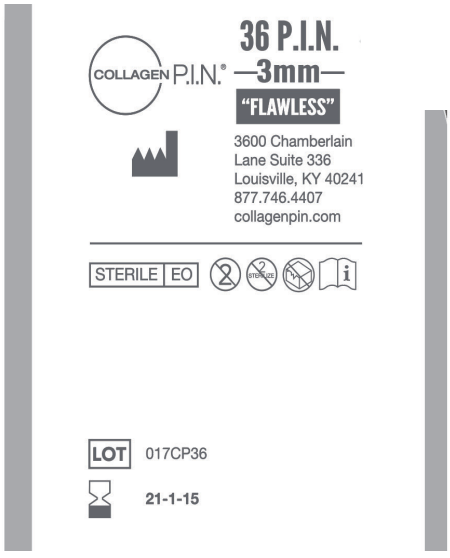
DISPOSE OF THE BIOSHEATH IN A BIOHAZARD CONTAINER.

- Collagen P.I.N. ® BioSheaths are designed for single use ONLY.
- Disinfection of the Collagen P.I.N. ® device should be completed after each use (see Section 9:Cleaning/Disinfecting the Collagen P.I.N.®).
- After removal of the BioSheath and disinfection of the device (see Section 9: Cleaning/Disinfecting the Collagen P.I.N.®) is performed, user's gloves should be removed, hands cleaned, and a new pair of clean gloves applied before proceeding to the next patient.

6.5 Installing the Needle Cartridge

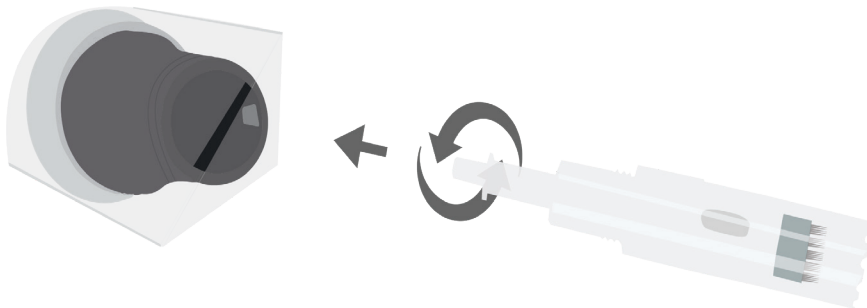
Ensure the Collagen P.I.N. ® is powered off. Do NOT attempt to attach a needle cartridge while the device is on, as it could lead to a sharps injury

- Obtain a single use needle cartridge from the provided needle pack in your Collagen P.I.N. ® device system.
- Do NOT touch the needles or tip of the needle cartridge at any time as it could lead to a sharps injury or contamination of the needles.
- Use ONLY needle cartridges that are specifically designed for use with the Collagen P.I.N® device system.



- Open the cartridge package by holding it right-side up and pulling back the protective covering at the sealed chevron.

Insert and thread the needle cartridge at the tip of the device, so that a small bit of the BioSheath is caught within the threads (about 2-3mm). Allow a small portion of the BioSheath to thread into the device with the needle cartridge, providing an additional seal and added stability for BioSheath effectiveness. Collagen P.I.N. ® is now protected and ready for use.



Note: If a Collagen P.I.N.® cartridge becomes inadvertently contaminated before or during installation (i.e. dropped on the floor, open/broken package, needles subjected to any possible contamination) DISCARD and obtain a new Collagen P.I.N. ® cartridge.

6.6 Removing the Needle Cartridge

Ensure the Collagen P.I.N. ® is powered off.

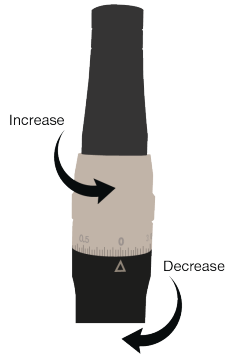
- Hold the Collagen P.I.N. ® device perpendicular to the floor, or with the needle cartridge tip pointing downwards.
- To remove the cartridge, rotate the cartridge counterclockwise until the cartridge is removed.

Collagen P.I.N. ® Needle Cartridges are designed for single use ONLY. Dispose of used needle cartridges in an approved biohazard sharps container.

Note: Soiled gloves should always be disposed of in a biohazard container. Do not reuse disposable gloves.

6.7 Adjusting Needle Depth

⚠WARNING



Hold the Collagen P.I.N.® device perpendicular to the floor, or with the tip pointing downwards.

- To increase needle depth, grasp the Collagen P.I.N.® handpiece firmly at the logo, and rotate the silver collar clockwise according to indicated tick marks featured on the silver dial (depth gauge) of the Collagen P.I.N.® handpiece.
- Use the "△" symbol located below the depth gauge to locate desired depth based on the patient needs.
- It is recommended to start at a depth of 0 - 0.1 mm.
- Increase by increments of 0.1 mm to achieve the desired amount of erythema for the patient's Fitzpatrick skin type with a maximum recommended depth of 3.0 mm on the face.
- Decrease the needle depth by rotating the silver collar counterclockwise according to the depth gauge on the Collagen P.I.N.® handpiece.

NOTE: Treatment can be performed around but not within the orbital rim (see Section 7: Treatment Instructions).

6.8 Powering the Collagen P.I.N.® Device ON/OFF with Battery

ON: Press and hold the power button at the base of the Collagen P.I.N.® device for 1-2 seconds.
OFF: Press and hold the power button at the base of the Collagen P.I.N.® device for 1-2 seconds.

SECTION 7: TREATMENT INSTRUCTIONS

⚠CAUTION

7.1 Pre-Procedure Precautions

- Perform a full review of the patient's medical history to ensure that he or she is a good candidate for microneedling treatment.
- Carefully review Section 2.2: Contraindications prior to treatment and do NOT treat a patient who exhibits symptoms of any of the listed conditions.
- Avoid excessive sun exposure/burns 24 hours prior to procedure.

• Discontinue use of topical retinoids 24 hours prior to procedure.
• Avoid treatment on patients with active breakouts or open lesions.
• Allow at least 24 hours after autoimmune therapies before a Collagen P.I.N.® treatment.
• Wait six months following oral isotretinoin use.

7.2 Treatment Preparation

⚠WARNING

1. Have the patient first complete a consent form.
2. Explain the Collagen P.I.N.® procedure to the patient and set expectations.
3. Apply single use, disposable nitrile, latex or non-latex gloves.
4. With the patient's consent, take a picture of the treatment area before starting the procedure.
5. Clean skin thoroughly and then swab with an antiseptic solution prior to applying numbing agent.
6. Ensure the Collagen P.I.N.® and components/accessories are properly cleaned prior to use (see Section 9: Cleaning/Disinfecting the Collagen P.I.N.®).
7. Apply the disposable Biosheath to the Collagen P.I.N.® (see Section 6.3: Applying the BioSheath).
8. Install the safety needle cartridge into the Collagen P.I.N.® handpiece (see Section 6.5: Installing the Needle Cartridge)
9. If a numbing agent was applied to provide patient comfort, the numbing agent must first be removed from the skin before starting the procedure. Re-cleanse the patient's face to effectively remove all numbing agent and apply an antiseptic solution prior to the procedure.
10. Apply a thing layer of SupraGel™ to protect the skin against abrasion and friction during the Collagen P.I.N.® treatment.
11. Ensure the needle is set to "0" before starting a new procedure.
12. Do NOT use the device when the charging cord is plugged into it.
13. Power the device ON by pressing and holding the ON/OFF button at the end of the Collagen P.I.N.® battery for two seconds (see Section 6.8 Powering the Collagen P.I.N.® device ON/OFF with Battery).
14. Prior to treatment, remove all makeup and other debris from the skin's surface with Induction Therapies' Cleanse-IT or a comparable gentle cleanser (non-comedogenic and free of parabens, fragrance, alpha hydroxy acid (AHA),beta hydroxy acid (BHA), and retinoids). If a numbing agent is applied to provide patient comfort, follow the recommended manufacturer's instruction for incubation time. After the recommended incubation time, remove the anesthetic cream with water-soaked gauze and prep the treatment areas with alcohol or hypochlorous acid immediately prior to treatment. Adjust needle depth settings on the Collagen P.I.N.® to the desired depth based on patient.

7.3 Procedure Instructions

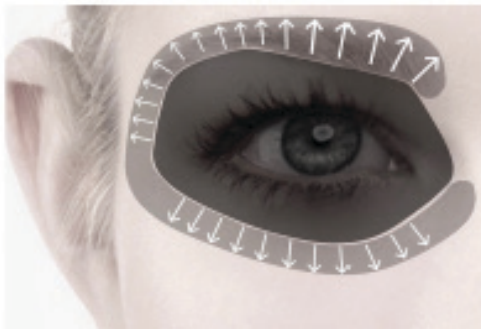
1. Apply SupraGel™ to the scars to facilitate the gliding action of the Collagen P.I.N.® microneedling device during treatment.
2. Utilize gentle traction of the skin with one hand while simultaneously applying the microneedling tip perpendicular to the scar(s) with the other hand to ensure the smooth delivery of microneedles into the skin.
3. A combination of horizontal, vertical and oblique device passes over the treatment areas (a range of 4- 10 passes) may be utilized until uniform pinpoint bleeding is observed.

(Continued Next Page)

Procedure Depth (Suggested Guidelines)

WARNING *Lower the depth gauge setting of the cartridge to 0.1-0.5mm to perform the procedure around the orbital rim.

Forehead (0.1mm - 1.0mm)	Nose (0.1mm - 0.5mm)
Around the Orbital Rim (0.1mm - 0.5mm)	Remaining Facial Area (up to 3.0mm)



■ Microneedling **SHOULD NOT** be used **WITHIN** the Orbital Rim

■ Orbital Rim treatment area

PLEASE NOTE: The Collagen P.I.N.® device allows for incremental increase in settings of up to 3.0 mm to allow for variability in the thickness of healthy skin, acne scars, and other scar tissue. As there are fine structures (i.e. nerve branches and accompanying blood vessels) that run under the skin and are essential to proper tissue function, it is not recommended to treat facial acne scars at needle depths greater than 1.5 mm unless the trained clinician determines it is appropriate to do so. It is essential that the thickness of the patient's skin in each anatomical area to be treated is assessed by a trained clinician to address any potential risk of injuring these structures. Such structures include (but are not limited to) the supra orbital nerve (the terminal branch of the frontal nerve that provides sensory innervations in the forehead, mucosa of frontal sinus, and the skin of the upper eyelid) and the temporal, buccal, and marginal madibular branches of the facial nerve (motor nerve that controls facial muscle movement).

WARNING

AGAIN: MICRONEEDLING SHOULD NOT BE USED WITHIN THE ORBITAL RIM OR AREAS AROUND THE EYES, SUCH AS THE EYELIDS.

IMPORTANT: Microchannels created during the procedure may remain open for up to 24 hours. These channels could still be permeable to topicals applied for as long as 48-72 hours post treatment. **Be sure to ONLY use the products recommended or provided by a trained clinician post-procedure.**

NOTE: This product is not intended for transdermal (under the skin) delivery of cosmetics, drugs, or biologics. Unexpected complications may occur when products not proven safe for use with microneedling procedures are used.

SECTION 8: POST PROCEDURE INSTRUCTIONS

CAUTION

The following are post-treatment recommendations which have been provided to your skin care professional. We do not recommend deviating from the below protocol and are not responsible for any adverse effects a Collagen P.I.N.® user may experience if and when this protocol is not followed by you and/or your skin care professional.

• Gauze soaked in ice water may be applied to the treated areas to remove excess SupraGel™ and

achieve hemostasis.

- Advise patient to avoid sweaty exercise and sun exposure for 72 hours post-procedure.
- It is recommended to avoid other scar treatments for 30 days following the Collagen P.I.N.® treatment.
- Schedule next appointment after at least 4 weeks.
- Take “after” pictures before next appointment.
- Apply Induction Therapies’ Block-IT™ sunscreen and Skin Renewal Hydrator moisturizer, or a comparable 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 post treatment.

8.1 Day of Treatment

Immediately following the treatment:

- Pat down the entire treated area with sterile damp gauze.
- Then apply a layer of moisturizer (provided by your skincare professional) after the procedure.
- We recommend not wearing makeup products until 5 days post-treatment. However, if necessary, you may use ONLY mineral-based foundation powders. If you are unsure as to whether a powder is mineral-based, ask your skin care provider before using it.

⚠CAUTION

DO NOT USE ANY GLYCOLIC ACIDS, RETINOIDS, OR PH LOWERING SKIN CARE PRODUCTS UNTIL AT LEAST FIVE (5) DAYS AFTER YOUR TREATMENT. IF YOU ARE UNSURE ABOUT THE INGREDIENTS OF ANY PRODUCT, ASK YOUR SKIN CARE PROFESSIONAL BEFORE USING THE PRODUCT. IT IS HIGHLY RECOMMENDED NOT TO USE PRODUCTS CONTAINING PARABENS UNTIL DAY 5 POST-MICRONEEDLING*

*Unexpected complications may occur when products not proven safe for use with micro needling are applied post-procedure.

SECTION 9: CLEANING/DISINFECTING THE COLLAGEN P.I.N.®

⚠CAUTION **⚠WARNING**

Personal Protection Required: When handling items soiled with blood or bodily fluids, always wear disposable nitrile, latex or non-latex gloves, gowns, masks, or eye coverings.

Perform the manual cleaning procedure as follows:

1. Ensure the Collagen P.I.N.® device is powered off.
2. The device should be cleaned while holding the Collagen P.I.N.® device facing straight down.
3. Remove the needle cartridge from the Collagen P.I.N.® handpiece and dispose of the needle cartridge appropriately (see Section 6.6: Removing the Needle Cartridge).
4. Thoroughly wipe the surface of the Collagen P.I.N.® using sterile gauze pads dampened with 70%isopropyl alcohol (IPA). Pay special attention to cracks, crevices, seams, and hard to reach areas.
5. Using Metrex CaviWipes Disinfecting Towelettes or similar disinfecting wipe, wipe the handpiece to remove potential contaminants. Be sure to wipe the handpiece continuously for a minimum of 2 minutes. Pay special attention to seams, cracks, crevices, and hard to reach areas.
6. Additional wipes may be used to help remove excess soil.
7. Use a fresh Metrex CaviWipes Disinfecting Towelette or similar disinfecting wipe to thoroughly wet the surface of the handpiece and let it remain visibly wet for 2 minutes. Use additional wipes, if needed, to assure the device is continuously wet for the required 2 minutes.

Special Instructions for cleaning and decontamination against HIV-1 and HBV of surfaces/objects soiled with blood/body fluids:

- CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleansed from surfaces and objects before applying disinfectant.
- DISPOSAL OF INFECTIOUS MATERIALS: Blood and other body fluids should be autoclaved and disposed of according to federal, state, and local regulations for infectious waste disposal.
- CONTACT TIME: Leave surfaces wet for 30 seconds and 10 minutes for HIV-1 and HBV, respectively. Use the 10-minute contact time to mitigate other viruses, bacteria and fungi listed on the label.
- Do not immerse device or accessories/component in liquids.
- Do not use solvents to clean device or accessories/components.

NOTE: Soiled gloves and wipes should always be disposed of in a biohazard container. Do not reuse disposable gloves or wipes.

NOTE: The purpose of the BioSheath is to provide a disposable barrier to help prevent crosscontamination.
The Collagen P.I.N.® device is intended to be used ONLY with the provided BioSheath.

SECTION 10: DEVICE STORAGE

- Always clean / disinfect the Collagen P.I.N.® handpiece prior to storage (see Section 9:Cleaning/Disinfecting the Collagen P.I.N.®)
- Ensure the battery has been removed and that the Collagen P.I.N.® handpiece is dry.
- For optimal Collagen P.I.N.® performance, ensure the device is powered off and stored inside the Collagen P.I.N.® device System when not in use.
- This device is not autoclavable.

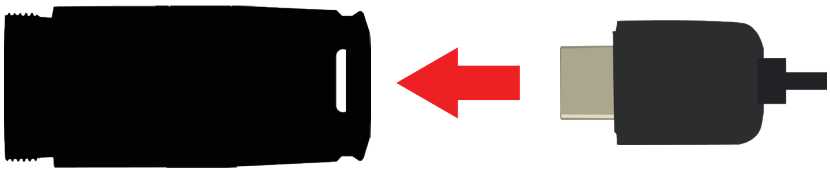
• SECTION 11: DISPOSAL OF COLLAGIN P.I.N.® AND ACCESSORIES/COMPONENTS

- Dispose of cartridges / needle tips as medical waste via a designated biohazard container.
- Properly dispose of all items in accordance with local regulations.
- You must dispose of Collagen P.I.N.® and all other Collagen P.I.N.® components properly and according to federal, state, and local laws and regulations. Because Collagen P.I.N.® contains electronic components and a Lithium-Ion rechargeable battery, Collagen P.I.N.® must be disposed of separately from household waste. When Collagen P.I.N.® reaches its end of life, contact local authorities for proper disposal and recycling options.

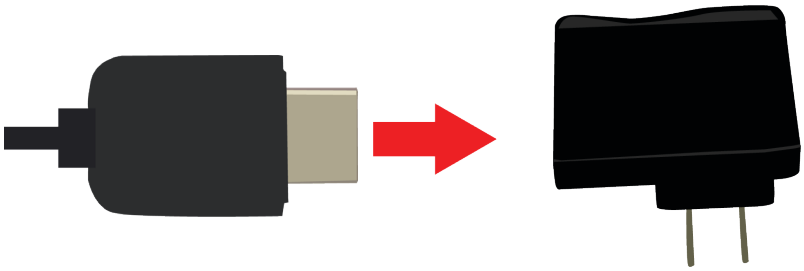
SECTION 12: COLLAGEN P.I.N.® BATTERY CHARGING

Ensure the charging cord is properly connected to the USB Wall Adapter and that the USB Wall Adapter is correctly plugged into an appropriate electrical outlet (see Section 12: Collagen P.I.N.® Battery Charging).

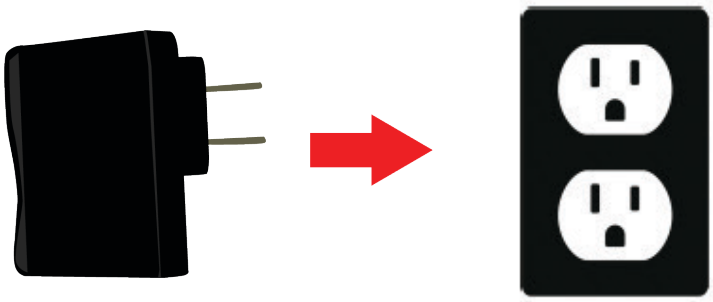
- Plug the battery charging cord into the battery.



- Then plug the USB end of the cord into the USB wall adapter.



- Then plug the wall adapter into an approved electrical outlet.



- If not fully charged, the light on the end of the battery will turn blue when plugged in. This indicate that the battery is charging
- Once the battery is fully charged, the blue light will turn off. Unplug the battery from the wall adapter at that time.
- Use Caution to not overcharge the battery. Once the blue light extinguishes, the battery is fully charged and should be disconnected from wall plug.
- Charging can take anywhere from 30 – 90 minutes on average depending on the life remaining in the battery once connected to the charger.

IMPORTANT: Keep dry. To better maintain the life of your battery, make sure you disconnect the charging cord once the battery is fully charged.
IMPORTANT: Do NOT use device when the charging cord is plugged into it.

SECTION 13: RISK- BENEFIT DETERMINATION (NON-CLINICAL AND CLINICAL DATA

Non-clinical data demonstrates the safety and effectiveness of the use of the Collagen P.I.N.® microneedling device. Bench performance testing demonstrated that there was no leakage or backflow while using the single use sterile 36 needle array cartridge, confirming that there is no risk of cross-contamination with use of the device. Bench performance testing further demonstrated that the maximum depth of needle penetration on pig skin was less than 3.0mm.

Induction Therapies sponsored a clinical study to evaluate the safety and effectiveness of Collagen P.I.N. as treatment to improve the appearance of facial acne scars in adults with Fitzpatrick Skin Types I -III, aged 22 years and older. The clinical study was a nonsignificant risk, open-label, prospective, single-arm, two-site study in fifty subjects (n=50).The safety data from the subjects with facial acne scars (n = 25), as well the safety data from the subjects with nonfacial surgical or traumatic scars (n= 25), were used to demonstrate Collagen P.I.N.'s substantial equivalence for use in treating facial acne scars in the intended patient population.

Study Subjects

Eligible subjects were males or females at least 22 years of age of any race who had facial acne scars rated as mild to moderate (Grade 15 to 180) per the Échelle d'évaluation clinique des cicatrices d'acné (ECCA) acne scar scale or one non-facial surgical or traumatic scar that was mild to moderate (score of 1 to 10) based on the Vancouver Scar Scale (VSS). The scars had to be amenable to microneedling and not have been treated with any alternative treatment modality within 6 months of the first study visit. Fifty subjects (n=50) were enrolled in the study (25 with facial acne scars and 25 with nonfacial scars). One site treated all of the facial acne scars and the other site treated all of the non-facial surgical and traumatic scars. All of the subjects provided informed consent and met the study entry criteria.

All 25 subjects with facial scars were female, the majority were white (64%), and the mean age was 39.5 years (range 24 to 60). Among the 25 subjects with non-facial scars, the majority were female (84%) and white (80%), and the mean age was 46.4 years (range 22 to 68). The planned distribution by Fitzpatrick skin type (at least 20% types IV to VI and 10% types V or VI) was met as: (1) 40% of subjects treated for facial acne were types were types IV to VI and 32% were types V or VI; (b) 32% of subjects treated for non-facial scars were types IV to VI and 12% were types V or VI.

Forty seven of the subjects (94%) completed the study and 3 (6%) discontinued early. One subject discontinued due to transportation issues, another subject discontinued due to personal issues associated with starting a new job, and the third subject discontinued due to a family emergency that required the subject being out of state indefinitely. No subject discontinued the study due to an AE.

Study Treatment

After washing the subject's skin in the treatment area with Induction Therapies' Cleanse-It and applying DMC Medical Ltd.'s SupraGel to it, the investigators set the initial treatment depth by rotating the dial on the handpiece which has a scale from 0.0 mm to 3.0 mm in 0.1 mm increments. The investigator glided the tip perpendicular to the skin using a cross hatch motion (using horizontal and vertical movements) in the treatment area while applying gentle traction to the surrounding area. They gradually increased the needle depth until pinpoint bleeding was observed. Subjects were instructed to use Induction Therapies' Block-IT, which is a sunscreen, and Induction Therapies' Skin Renewal Hydrator after the treatment.

Subjects were treated with Collagen P.I.N. at Visit 1 (Day 1), Visit 2 (Day 30), Visit 3 (Day 60), and Visit 4 (Day 90). They were assessed for final efficacy and safety outcomes at Visit 5 (Day 150). The mean number of treatments for subjects with facial acne scars was 3.7 of the planned 4 treatments. The maximum depth ranged from 2.2 to 3.0 mm overall. All of the subjects with non-facial scarring received the four planned treatments. The maximum treatment depth ranged from 1.0 to 2.5 mm overall, with the mean ranging from 2.06 to 2.36 mm.

Study Endpoints and Statistical Analyses

Collagen P.I.N.'s efficacy was evaluated based on the following:

- Clinician Global Aesthetic Improvement Assessment (CGAIS): a 5-point scale from 1 (Very Much Improved) to 5 (Worse). The CGAIS was assessed in two ways:, i.e., live by the Investigator pre-treatment at Day 30, Day 60, Day 90 (pre-treatment), and Day 150 using pretreatment photographs as the baseline. In addition, CGAIS was graded by a panel of 2 board-certified dermatologists (non-investigators) after the final visit using photographs taken pre-treatment at each visit. CGAIS success was the proportion of subjects for whom the appearance of their scars improved, i.e., grade 1-3.
- Self-Assessed Scar Improvement Scale (SSIS): 6-point scale from -1 (Exacerbation of Scars)to 4 (75% to 99% improvement in appearance of acne scars).
- Subject Global Aesthetic Improvement Assessment (SGAIS): 5-point scale from 1 (Very Much Improved) to 5 (Worse).
- Subject Satisfaction: 5-point scale from 1 (Very Satisfied) to 5 (Very dissatisfied).

The primary population for efficacy analyses was the modified intent-to-treat ("mITT") population, which consisted of all subjects who received at least one study treatment and provided at least one post-treatment evaluation (n=48). The primary efficacy endpoint was CGAIS success in the mITT population.

The safety of Collagen P.I.N. was evaluated based on:

- Adverse Events (AEs), including treatment-emergent AEs ("TEAEs") and treatment-related AEs(TRAEs), serious adverse events ("SAEs"), unexpected adverse device effects ("UADEs"), and for TRAE by severity and relationship to study treatment.
- Investigator Tolerability Assessments on a scale of zero (none) to three (severe) of dryness,roughness of skin, tightness, erythema, and edema prior to each study treatment and 15minutes following each treatment. The Investigator also asked the subject about itching and burning prior to and 15 minutes after treatment.
- Common Treatment Responses (CTR Diary) - the subjects recorded the following responses that typically occur following microneedling treatment in their CTR Diaries: redness, tightness,rough skin, dryness, tenderness, itching, burning, discomfort, and peeling.

Study Results

Collagen P.I.N. improved the appearance of mild to moderate facial acne scars and non-facial surgical or traumatic scars as assessed by the CGAIS (both Investigator and non-Investigator assessments), SSIS, SGAIS, and subject satisfaction. The primary efficacy endpoint of the proportion of subjects with CGAIS success at Visit 5 (Day 150) in the mITT population based on live assessment by the Investigator was 100% for subjects with facial acne scars (n=23) and 96% for subjects with non-facial traumatic or surgical scars (n=25), with no subjects in either group experiencing a worsening of their scars.

The proportion of subjects with CGAIS success at Visit 5 in the mITT population graded by non- investigators 1 and 2, which was the other primary efficacy endpoint, was 47.8% and 60.9% for subjects with facial acne scars and 64.0% and 24.0% for subjects with non-facial scars.

The proportion of subjects in the mITT population who reported at least a 25% improvement in the appearance of treated scars on the SSIS was 91.3% at Visit 5 (Day 150) for subjects with facial acne scars and 68% for subjects with non-facial scars. The proportion of subjects in the mITT population who reported at least improvement on the SGAIS increased to 82.6% at Visit 5 (Day 150) for subjects with facial acne scars and 84% for subjects with non-facial scars. The proportion of subjects reporting that they were satisfied or very

satisfied increased to 91.3% at Visit 5 for subjects with facial acne scars and 68% for subjects with nonfacial scars. The increase in the proportion of subjects reporting improvement on the SSIS and on SGAIS are consistent with the CGAIS success assessed by the Investigator at Visit 5. The increase in subject satisfaction over time supports the investigator's CGAIS results.

Of the 50 treated subjects, 11 (22%) experienced one or more TEAEs during the study. Eleven of the 25 subjects with facial acne scars (44%) had a total of 12 TEAEs and none of the 25 subjects with non-facial scars had a TEAE. Six of the 25 subjects with facial scars (24%) experienced one or more TRAEs during the study. The only TRAE was post-inflammatory pigment change; all of those events were mild or moderate and all 6 subjects who experienced TRAEs had Fitzpatrick skin type IV to VI. No SAEs and no UADEs were reported during the study and no subjects had study treatment temporarily or permanently discontinued due to AEs.

All of the treatment tolerability assessments were reported as none or mild pre-treatment by at least 96% of subjects on Days 1, 30, 60, and 90. Post-treatment assessments of dryness, roughness of skin, itching, and burning were reported as none or mild for at least 94% of subjects. Tightness was assessed as none or mild post-treatment for 60% to 84% of subjects, moderate for up to 38% of subjects (Day 90), and severe for 2% on Day 90. Erythema was reported post-treatment as none or mild for 34% to 64% of subjects, moderate for up to 58% of subjects (Day 1), and severe for up to 11% (Day 30). Edema was reported post-treatment as none or mild for 62% to 78% of subjects, moderate for up to 38% of subjects (Day 60), and severe for up to 4% (Day 90).

A similar pattern was observed across most of the Common Treatment Responses ("CTRs"). From Day 1 to Day 7 after each visit, the proportion of subjects reporting none to mild CTRs generally increased, reaching 85% to 100% at Day 7. The severity of rough skin and peeling tended to increase for a few days before decreasing.

Conclusions

The results of this open-label study have shown that the Collagen P.I.N. improved the appearance of mild to moderate facial acne scars and non-facial surgical or traumatic scars and was well-tolerated.

SECTION 14. TROUBLESHOOTING

WARNING CAUTION

Needles are not moving	Power device motor off. Make sure depth gauge is set to 0mm. Remove needle cartridge and re-insert, making sure cartridge is seated and threaded properly. Check that the battery is fully charged. If same results occur call 877-746-4407 for further assistance.
Motor is not running	Make sure battery is properly attached and fully charged. Press and hold the battery "power on" button for 1-2 seconds. If same results occur, call 877-746-4407 for further assistance.

WARNING

When troubleshooting the Collagen P.I.N. ® device, use caution when removing the disposable needle cartridges as they may not be fully retracted.

SECTION 15: SPECIFICATIONS

Product Name	Collagen P.I.N.® Handpiece
Model #	MP1207PT
FDA Registration #	3010893595
Material	Aluminum, Plastic, Silicone, Stainless Steel
Weight and Unit	3.5oz / 157mm length and max. outer diameter of 21mm
Electrical Requirements	Input: 5VDC, 2A max
Output Voltage	5W (max)
Device Operation	7000-9000 RPM
Working Time	3-4 hours cordless
Charging Time	30-90 Minutes
Needles:	36 needle array cartridge - 35 SWG Gauge 0 - 3.0 mm Penetration Medical Grade stainless steel

SECTION 16: Electromagnetic Compatibility of Collagen P.I.N.

Suitable Environments for Collagen P.I.N. Use/Exposure

The suitable use environments for Collagen P.I.N. (Percutaneous Induction Needling) microneedling system are Med Spas, Skin Clinics, Dermatologist's Offices, Plastic Surgeon's Offices, or other facilities with a licensed medical director.

⚠WARNING

Operating Conditions:
- Temperature: 17-30° C
- Relative Humidity: 30-75%
- Atmospheric Pressure: 75-100 kPa

Transportation Conditions:
- Temperature: -29°C - +50°C
- Relative Humidity: 0 - 70%

Collagen P.I.N. should be used in the described suitable use/exposure environment, and maintained per directions for use to ensure the device remains safe and performs as intended with regard to EM disturbances throughout the expected service life.

MR UNSAFE - Not for Use in Magnetic Resonance Environments

The emissions characteristics of the Collagen P.I.N. make it suitable for use in industrial areas and hospitals (CISPR 11 Class A).

This user manual is valid for The Collagen P.I.N.® as described under Section 3: Device Description. This user manual is published by Induction Therapies, LLC. Induction Therapies, LLC does not guarantee its contents and reserves the right to improve and amend it at any time without prior notice. Amendments will, however, be published in a new edition of the User Manual.

Accessories and Other Equipment with which has been Determined to be Compatible

The Collagen P.I.N. components listed below have undergone Basic Safety and Essential Performance validation, per IEC 60601-1-2.

- USB Wall Adapter
- Micro-USB Charging Cable
- Rechargeable Lithium-Ion Battery Cells

Impact of EM Disturbance on Device Performance / Function

Collagen P.I.N. has been assessed for the following electromagnetic disturbances, and their potential impact to users of the device.

Disturbance	Potential Effect on Function or Performance
Electromagnetic Energy	
Line Voltage	No potential effect on function or performance.
Contact with accessible energized parts.	Harm to user or operator through static discharge.
Electric Fields	Static discharge cause damage to the electronic component.
Magnetic Fields	Treatment is delayed or incomplete. Or other devices could be damaged.
Radiation Energy	
Ionizing Radiation	No potential effect on function or performance.
Non-Ionizing Radiation	No potential effect on function or performance.
Thermal Energy	
High Temperature	The device emits heat. May cause a warm feeling to contacting site of user. No harm.
Battery Overcharge	May cause a warm feeling to contacting site of user. No harm. The device cannot start.
Low Temperature	No potential effect on function or performance.

Emission and Immunity Compliance - Collagen P.I.N.

Collagen P.I.N. achieved “compliance” for all emission and immunity tests, indicating no loss of basic safety and essential performance.

Test	Result
Emission	
Emission Test - Line	*1 - Compliant*
Emission Test - Neutral	*1 - Compliant*
Radiated Emission, 50 Hz	*1 - Compliant*
Radiated Emission, Battery	*1 - Compliant*
Harmonic Current Emission	*1 - Compliant*
Flicker Emission	*1 - Compliant*
Voltage Fluctuation	*1 - Compliant*
Electrostatic Discharge - Indirect	*1 - Compliant*
Electrostatic Discharge – Direct	*1 - Compliant*
Electrostatic Discharge – Air Discharges	*1 - Compliant*
Immunity	
Radiofrequency Disturbance	*1 - Compliant*
Electrical Fast Transients	*1 - Compliant*
Surges	*1 - Compliant*
Continuous Conducted Disturbance	*1 - Compliant*
Power-Frequency Magnetic Fields	*1 - Compliant*
Voltage Dips & Interruptions	*1 - Compliant*

Deviation & Allowances from Referenced Performance Standards

There were no deviations, or allowances, specified for Collagen P.I.N.’s testing against the below referenced standards:

- IEC 60601-1; General Requirements for Basic Safety & Essential Performance
- IEC 60601-1-2; General Requirements for Basic Safety & Essential Performance
- IEC 62366-1; Applicability of Usability Engineering to Medical Devices

Electromagnetic Emission Testing		
Med Spa, Skin Clinic, Dermatologist's Office, Plastic Surgeon's Office, or other facility with licensed medical director.		
Emissions Test	**Compliance**	**EMC Guidance**
RF emissions Conducted Emission CISPR 11	Classification: Group 2 Class A Complies	No EMC-specific guidance.
RF emissions Radiated Emissions CISPR 11	Class A Complies	No EMC-specific guidance.
Harmonic Current Emissions IEC 61000-3-2	Class A Complies	No EMC-specific guidance.
Voltage Fluctuations/ Flicker emissions IEC 61000-3-3	Complies	No EMC-specific guidance.

Electromagnetic Immunity Testing			
Med Spa, Skin Clinic, Dermatologist's Office, Plastic Surgeon's Office, or other facility with licensed medical director.			
Immunity Test	**Test Level**	**Compliance Level**	**EMC Guidance**
Electrostatic Discharge (ESD) IEC 61000-4-2	± 8 kV Contact ± 2kV, ± 4kV, ± 8k, ± 15 kV Air	± 8 kV Contact ± 2kV, ± 4kV, ± 8k, ± 15 kV Air	No EMC-specific guidance for use environment.
Radiated RF Electromagnetic Field IEC 61000-4-3	80 – 1000 (MHz) 3 V/m 80% AM (1 kHz) 1000 – 2700 (MHz) 3 V/m 80% AM (1 kHz) 5100 – 5800 (MHz) 9 V/m Pulse, 217 Hz	80 – 1000 (MHz) 3 V/m 80% AM (1 kHz) 1000 – 2700 (MHz) 3 V/m 80% AM (1 kHz) 5100 – 5800 (MHz) 9 V/m Pulse, 217 Hz	No EMC-specific guidance for use environment.
Electrical Fast Transients IEC 61000-4-4	± 2 kV at 100 kHz repetition frequency for power supply lines ±1 kV at 100 kHz repetition frequency for input/output lines	± 2 kV at 100 kHz repetition frequency for power supply lines ±1 kV at 100 kHz repetition frequency for input/output lines	No EMC-specific guidance for use environment
Surges IEC 61000-4-5	Input AC Port ± 1.0 kV (line to line) (1.2μS x 50μS Voltage, 8μS x 20μS Current)	Input AC Port ± 1.0 kV (line to line) (1.2μS x 50μS Voltage, 8μS x 20μS Current)	No EMC-specific guidance for use environment
Continuous Conducted RF IEC 61000-4-6	0.150 – 80 MHz 3 Vrms 80% AM at 1Khz 0.150 – 80 MHz (ISM) 6 Vrms 80% AM at 1Khz	0.150 – 80 MHz 3 Vrms 80% AM at 1Khz 0.150 – 80 MHz (ISM) 6 Vrms 80% AM at 1Khz	No EMC-specific guidance for use environment.
Power Frequency Magnetic Field IEC 61000-4-8	50 (Hz) 30 A/m	50 (Hz) 30 A/m	No EMC-specific guidance for use environment.
Voltage Dips, Short Interruptions and Voltage Variations IEC 61000-4-11	0 % UT for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle at 0° 70 % UT for 25/30 cycles at 0° 0 % UT for 250/300 cycles	0 % UT for 0.5 cycles at 0°, 45°, 90°, 135°, 180°, 225°, 270° and 315° 0 % UT; 1 cycle at 0° 70 % UT for 25/30 cycles at 0° 0 % UT for 250/300 cycles	No EMC-specific guidance for use environment.

SECTION 17: SYMBOL LEGEND

Manufacturer's trade name and address		Manufacturer's catalog code	REF
Serial Number	SN	Batch code	LOT
Do not re-sterilize		Do not re-use	
Sterilized using ethylene oxide gas	STERILE EO	Consult Instructions for Use	
Caution		Do not use if package is damaged	
Temperature shipment limits	15 30 °C	Humidity limitation	%
Keep dry	IP30	Not for general waste	
Device type B, meaning that the device offers protection against electric shocks and leakage currents.		Direct Current	
Positive Polarity		Use-by date	
Follow Instructions for use		Date of Manufacture	
Sharps Hazard		Warning	WARNING

Distributed By:
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STD-0300-1 Rev. B