SkinPen®

BY CROWN AESTHETICS

MICRONEEDLING SYSTEM

User Manual/ Instructions for Use

SkinPen® Precision Device
SkinPen® Precision Charger Base

Engineered, Designed & Made in the USA

Inductive Charging

SMART Technology

Patented Reciprocating Mechanism

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1. DEVICE DESCRIPTION

The SkinPen® Precision device consists of a microneedling pen handpiece, and a sterile needle cartridge. The accessories are a charging base and a BioSheath. Each component and accessory will be explained to understand how SkinPen® Precision works.

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

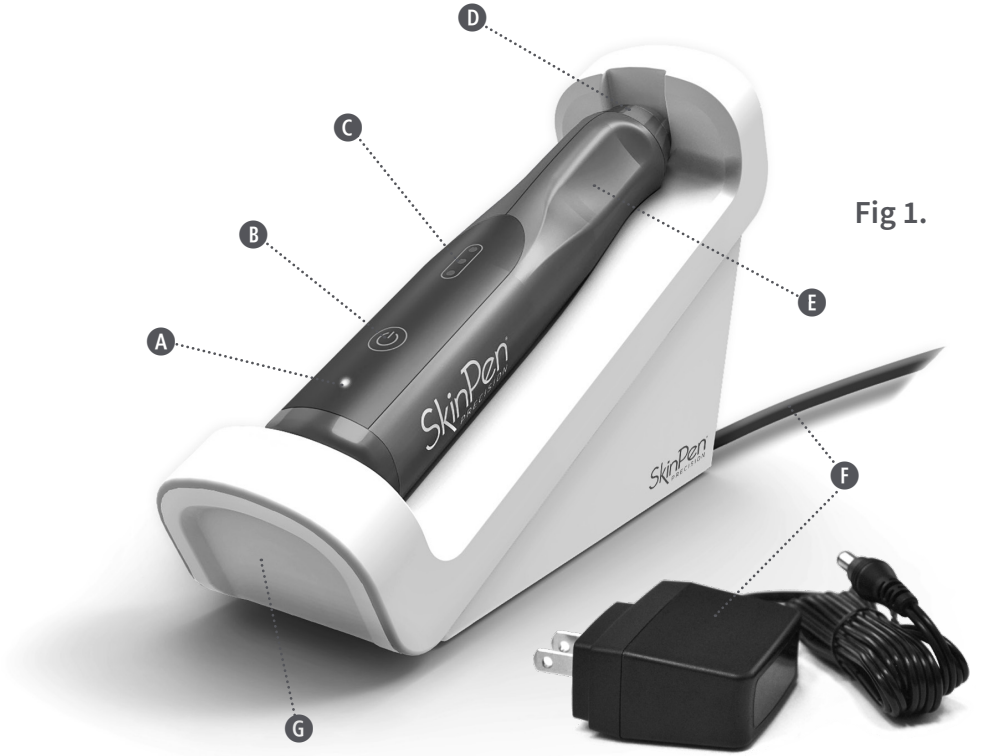


Fig 1.

SKINPEN® PRECISION COMPONENTS

SkinPen® Precision Handpiece - Part #F5SP005 / REF 100

A Power Indicator Light

B Power On/Off Button

C Charge Level Indicator

D Microneedling Connector

E Ergonomic Handle Grip

F Base Charger AC/DC Adapter - Part #F5SP007

G Inductive Charging Base - Part #F5SP006 / REF 101

SKINPEN® PRECISION TREATMENT KIT

INCLUDES:

SKINPEN PRECISION CARTRIDGE

Part #F5SP021 / REF 014

EO (Ethylene Oxide) Sterilized, disposable needle cartridge packaged and labeled individually.

Proprietary needle cartridge. *Cartridges are not to be resterilzed or reused.

The shelf life of this needle cartridge is 2 years from sterilization date.

SKINPEN PRECISION BIOSHEATH

Part #F5SP022

The SkinPen® Precision and needle cartridge interface with a nonsterile and disposable BioSheath to prevent contamination of the SkinPen Precision®.

LIFT HG

Part #F5SP023

Lift HG is a hydrogel wound dressing (without drugs and/or biologics) to protect against abrasion and friction during the microneedling procedure. It may be applied additionally the day of the procedure to prevent the skin from drying out post procedure.

2. INTENDED USE

The SkinPen® Precision system is a microneedling device and accessories intended to be used as a treatment to improve the appearance of wrinkles of the neck for Fitzpatrick skin types II - IV and to improve the appearance of facial acne scars in adults with all Fitzpatrick skin types aged 22 years and older.

3. CONTRAINDICATIONS

The use of the SkinPen Precision 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)

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

4. WARNINGS

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.

Do not use any equipment not designed specifically for SkinPen® Precision as to avoid interference with the device's intended performance.

5. PRECAUTIONS

The SkinPen Precision System has not be evaluated in the following patient populations (i.e. patients with the following conditions or taking the following medications): Actinic (solar) keratosis; active acne; collagen vascular diseases or cardiac abnormalities; diabetes; eczema, psoriasis and other chronic conditions in the treatment area or on other areas of the body; immunosuppressive therapy; history of contact dermatitis; raised moles in the treatment area; rosacea; active bacterial, fungal, or viral (i.e. herpes, warts); keloid scars (a scar that grows outside of the boundaries of an original scar); patients on anticoagulants; scars and stretch marks less than one year old; scleroderma; and wound-healing deficiencies.

PLEASE NOTE: The SkinPen Precision device allows for incremental increase in settings of up to 1.5 mm for acne scars and 2.5 mm for wrinkles on the neck to allow for variability in thickness of the skin. It is essential that the thickness of the patient's skin in each anatomical area to be treated is assessed by a qualified 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 the sensory innervations for the skin of the forehead, mucosa of frontal sinus, and the skin of the upper eyelid) and the temporal, buccal and marginal mandibular branches of the facial nerve (motor nerve that controls facial muscle movement). No adverse events were observed relating to such structures in the SkinPen Precision clinical studies when treating at needle depths up to 1.5 mm (acne scars) and 2.5 mm (wrinkles on the neck). Please refer to Crown provided training module on superficial nerve and vessel facial anatomy for additional information.

6. ELECTRICAL SAFETY WARNINGS

- No modification of this equipment is allowed. Only use included SkinPen® Precision adapter and charger base.
- Do not plug product into outlet with a voltage other than specified on the charger. (90-264 Vac).
- Never force 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 the pen and/or charger base near a sink or where it can fall or be pulled into water.
- This device complies with Part 15 of the FCC Rules. Operation is subject to the following two conditions: (1) this device may not cause harmful interference, and (2) this device must accept any interference received, including interference that may cause undesired operation.
- For your safety from electrical shock, the SkinPen® Precision and/or SkinPen® Precision Charger base should not be opened or disassembled for trouble-shooting purposes. There are no user serviceable parts.
- Do not use any equipment not designed specifically for SkinPen Precision as to avoid interference with the device's intended performance.

- **WARNING:** Use of this equipment adjacent to or stacked with other equipment should be avoided because it could result in improper operation.
- **WARNING:** 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.
- The EMISSIONS characteristics of this equipment make it suitable for use in industrial areas and hospitals (CISPR 11 class A).
- The charger base transmitting frequency is between 110kHz and 205kHz with efficiency around 73%.
- SkinPen Precision & Charger base is suitable for use in industrial areas and hospitals

7. INSTRUCTIONS FOR USE

- Only use this device for the recommended applications. This device should only be used under medical supervision.
- Before administering any treatment, you should become acquainted with the operating procedures for the treatment, as well as the indications, contraindications, warnings, and precautions.

PRE-PROCEDURE PRECAUTIONS

- 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 SkinPen® Precision treatment.
- Wait six months following oral isotretinoin use.
- Although not seen in the clinical study, in Fitzpatrick IV–VI, pigment may darken prior to lightening.

PROCEDURE INSTRUCTIONS

1. Have patient complete consent form.
2. Explain the SkinPen® procedure to the patient and set expectations.
3. Apply single use, non-latex gloves.
4. Cleanse patient's face with a gentle cleansing complex to effectively remove makeup, sunscreen and surface oils.
5. Take "before" pictures of the procedure area.
6. Open the SkinPen® Treatment Kit and remove all contents.
7. Apply the disposable BioSheath to the SkinPen®.
8. Install the cartridge onto SkinPen®.

***NOTE: The cartridge contains a lock-out feature and cannot be re-installed on the SkinPen® Precision device once removed. This safety feature ensures only a sterile single-use application.**

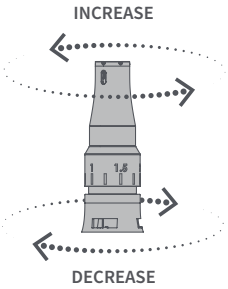
9. If a numbing agent was applied to provide patient comfort, the numbing agent must be removed from the skin with an antiseptic solution prior to the microneedling procedure.
10. Apply a thin layer of Skinfuse® Lift HG to protect the skin against abrasion and friction during the SkinPen® Precision treatment. If the layer is too thick the microneedle cartridge may become clogged.

Please refer to Skinfuse Lift HG instructions for additional details.

Note: if the patient is allergic to any of the following ingredients, which are in the Skinfuse Lift HG hydrogel: purified water, glycerin, carbomer, potassium hydroxide, disodium EDTA, phenoxyethanol, caprylyl glycol, sorbic acid, SkinPen® Precision treatment may not be safe.

11. Ensure the needle is set to "0" before starting a new procedure.
12. Power on by pressing and holding the on/off button on the front of SkinPen® Precision for one second.
13. Adjust needle depth settings on the SkinPen® Precision cartridge. New settings will be indicated by a "click" into place.

Instructions: How to adjust needle length:



- To increase the needle length, adjust on the cartridge according to indicated tick marks on the cartridge. New settings will be indicated by a "click" into place.
- Needle settings should be selected based on patient needs.
- It is recommended to start at a depth setting of 0.25mm.
- Increase by increments of 0.25 mm or 0.5 mm for the desired amount of erythema with a maximum depth of 2.5mm on the face and neck areas.

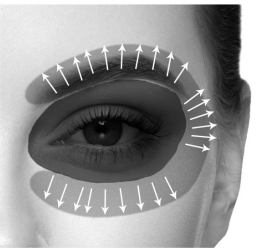
***Lower the setting of the cartridge to 0.25-0.5mm to perform the procedure around the orbital rim.**

- Decrease the needle length by adjusting according to the tick marks on the cartridge. New settings will be indicated by a "click" into place.

14. Select SkinPen® Precision microneedle position based on patient needs. Start at a depth setting of 0.25mm. Increase in increments of 0.25 mm or 0.5mm until desired erythema is reached, with a maximum depth of 1.5 mm on the face and 2.5 mm on the neck areas, under the discretion of the physician. Lower to 0.25-0.5 mm to perform procedure around orbital rim.

Procedure Depth (Suggested Guidelines)
Forehead (0.25-1.0 mm)
Around the Orbital Rim* (0.25-0.5 mm)
Nose (0.25-0.75 mm)
Facial Acne Scars (up to 1.5 mm)
Neck Wrinkles (up to 2.5 mm)

*Note: treatment can be performed around but not within the orbital rim



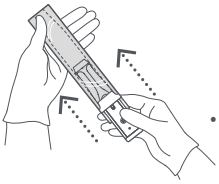
Orbital Rim Guide

- Orbital Rim Treatment area
- Microneedling should not be used within the orbital rim

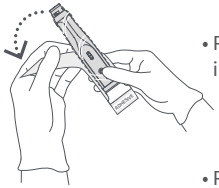
15. When treating the face for Acne Scars divide the face into four quadrants. Start with the right cheek, move to the chin/perioral/nose, then to left cheek, and finish with forehead. When treating the neck region, divide the neck into right and left halves and begin treating at the right jawline, moving downward and across into the left half of the neck and finishing at the left jawline.
16. Hold the skin taut and glide the pen in controlled horizontal motions. Repeat with vertical motions in the same area. Repeat the pattern if the erythema endpoint is not reached. Depth may be increased within guidelines if necessary. Gentle, one-directional circular motions in small targeted areas is acceptable if needed to assist in reaching the erythema endpoint.

    For treatment of facial acne scars, a needle depth of 1.5mm may be used on the face and up to a depth of 2.5mm on the neck under the discretion of the physician.

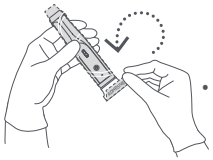
How to apply BioSheath:



- While wearing non-latex gloves, obtain a single use BioSheath and ensure the SkinPen® Precision is clean/disinfected.
- While SkinPen® Precision is powered off, insert the SkinPen® Precision between the white tab and paper backing.

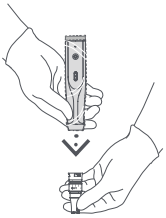


- Push SkinPen® Precision through the BioSheath until the device is snug inside the BioSheath.
- Peel back the protective BioSheath cover by pulling on the Blue tab and white paper backing.

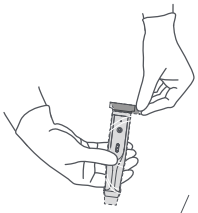


- Remove adhesive backing and seal end. SkinPen® Precision is now protected and ready to use.

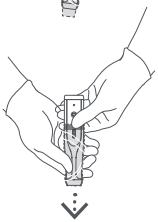
How to remove the BioSheath and clean the SkinPen® Precision Device:



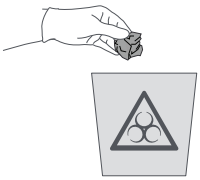
- Hold the SkinPen Precision perpendicular to the floor, or with the cartridge attachment tip pointing downwards. Use one hand to remove the cartridge and dispose of the cartridge in a sharps container.



- Continue to hold the SkinPen Precision device perpendicular to the floor, with the cartridge tip pointed downwards, and pull apart the adhesive strip of the BioSheath.



- Remove the BioSheath by carefully rolling it down the SkinPen Precision to prevent soiling the handpiece.



- Dispose of the BioSheath in a biohazard container. BioSheaths are not intended to be reused.

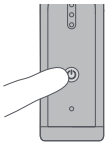
- Disinfection of the SkinPen Precision should be completed with the use of Sani-Cloth HB® wipes or appropriate disinfection method, See section 9-Cleaning of SkinPen Precision and Charger Base.

- After removal of the BioSheath and disinfection with Sani-Cloth HB® wipes or appropriate disinfection method is performed, users' gloves should be removed, hands cleaned, and a new pair of clean gloves worn before proceeding to the next patient.

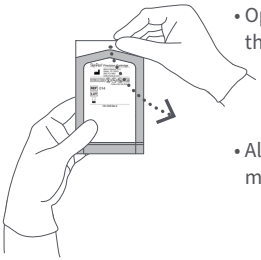
Note: Soiled gloves should always be disposed of in a biohazard container. Do not reuse disposable gloves.

Note: The purpose of a sheath is to provide a covering that helps prevent the transmission of pathogens from one patient to another. SkinPen Precision is intended to be used only with provided BioSheath.

How to install/uninstall disposable SkinPen® Precision cartridge:

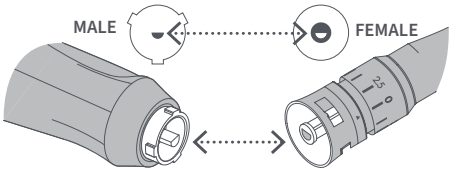


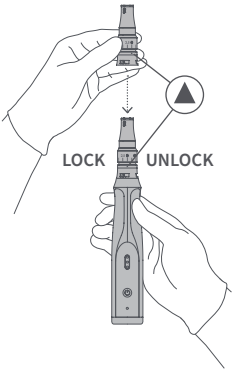
- Ensure SkinPen® Precision is powered off.



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

- Align the lock and key mechanism on the SkinPen® Precision microneedling cartridge and the SkinPen® Precision device.





- Start with the ▲ symbol to the right of the power indicator and rotate the cartridge left to align with the power indicator. The SkinPen® Precision cartridge is now secure.

- To remove the cartridge, rotate until the cartridge is removed.

- The SkinPen® Precision cartridge is designed for single use, with a lock-out feature prohibiting re-installation of the cartridge after use.

- Dispose of used SkinPen® Precision cartridge via a Sharps container.

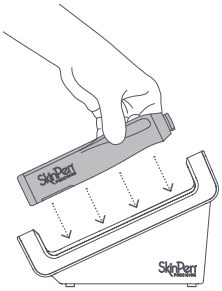
***If a SkinPen® Precision Cartridge becomes inadvertently contaminated before or during installation (ie. Dropped on floor, open/broken package, needles subjected to possible contamination), discard, and obtain new SkinPen® Precision cartridge.**

SKINPEN® PRECISION CHARGING:

Ensure the charger base is plugged into an outlet and the SkinPen® Precision handpiece is placed onto the base with the power button facing up.

IMPORTANT: Keep dry.

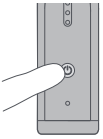
How to charge:



- Inductive charging is used between the SkinPen® Precision charger base and the SkinPen® Precision device.
- Plug the charger base into a live outlet.
- Place the hand-piece into the base with the power button facing out. See "FAQ/Troubleshooting" for additional battery information. Battery charge percentages in "FAQ/ Troubleshooting".

Power:

***Powering ON/OFF should only be done with the SkinPen® Precision device disconnected from the charging base.**



- ON: Press and hold power button for 1 seconds.
- OFF: Press and hold power button for 0.5 seconds.

8. CLEANING OF SKINPEN® PRECISION AND CHARGER BASE

***Ensure SkinPen® Precision device is powered down before cleaning, and SkinPen® Precision charger base is unplugged.**

- The device should be cleaned while holding the SkinPen® Precision facing straight down while wiping the rotary area. Do not clean near the seal.
- Sani-Cloth HB® wipes or an appropriate disinfection method should be used to clean the SkinPen® Precision after each procedure. Sani-Cloth HB® wipes may also be used to clean the SkinPen® Precision Charger Base. Sani-Cloth HB® wipes should be used to carefully wipe the SkinPen® Precision for more than 1 minute, according to their directions for use, found on the Sani-Cloth HB® labeling. Attention should be paid to clean areas such as crevices, seams, and areas around where the SkinPen Precision Cartridge attaches to the device.
- Sani-Cloth HB® DIRECTIONS FOR USE:
  SPECIAL INSTRUCTIONS FOR CLEANING & DECONTAMINATION AGAINST HIV-1 AND HBV OF SURFACES/OBJECTS SOILED WITH BLOOD/BODY FLUIDS:
  - PERSONAL PROTECTION: Specific barrier protection items to be used when handling items soiled with blood or body fluids are disposable latex gloves, gowns, masks, or eye coverings.
  - CLEANING PROCEDURE: Blood and other body fluids must be thoroughly cleaned from surfaces and objects before application of the 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.

- GENERAL DISINFECTION METHOD: Please dilute bleach according to a concentration outlined by the CDC and EPA. For Clorox bleach (4.5% sodium hypochlorite) dilute 1/3 cup of bleach per gallon of water. Thoroughly wet a paper towel with the diluted bleach solution; the towel should be wet but not dripping. Thoroughly wipe all surfaces of the hand piece for a minimum of 1 minute making sure to keep the surfaces wet with the bleach solution. Allow the hand piece to dry for 10 minutes prior to handling or use. Do not immerse the hand piece in bleach.
- Do not immerse in liquids.
- Do not use solvents to clean device unless specified in the General Disinfection Method.

9. STORAGE

- For optimal performance of your SkinPen Precision®, ensure the device is turned off and store the device in the SkinPen® Precision charging base when not in use.
- If the device is OFF and not connected to the charging base for 30 minutes, the device will generate a “Not on Charger” alert by “beeping” repeatedly at 1 second intervals for 1 minute, and then every 10 minutes after as a reminder to return the SkinPen® Precision to the charger base. Turn off the alert by connecting the SkinPen® Precision to the charger base.

10. DISPOSAL

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

11. WARRANTY

- One year under normal use after its original purchase.
- Warranty extends only to the original purchaser and purchase date.
- Contact Crown Aesthetics Customer Service at 1.888.372.3982 for warranty inquiries.
- Warranty does not cover:
  - Defects due to negligence, alteration, modification, or installation by anyone other than factory authorized personnel.
  - Abuse or misuse.
  - Attempted or actual dismantling, disassembling, service, or repair not specifically authorized by Crown Aesthetics.

12. FAQ/TROUBLESHOOTING

Fault Indications:

- **Motor Speed Fault:**
  LED 1, 3 alternating at 0.25 sec. rate.
  - › The fault indicator will sound as long as the fault persists.
  - › If fault is indicated the motor will stop after 10 sec.
  - › In the case that the motor stops, the indication of the LEDs will continue for an additional 10 seconds before the device powers off.
  - › The fault may be generated by over aggressive needling.
  - › Allow the fault indicator to cease before continuing procedure.
  - › Discontinue use if the motor speed fault results continuously and contact Crown Aesthetics.

- **Over Current Fault:**
  LED 3 flashing at 0.25 sec. rate.
  - › The over current fault will stop the motor and beep for 10 sec.
  - › The fault indication on the LEDs will continue for an additional 10 seconds before the device powers off.
  - › The fault may be generated by over aggressive needling and/or by selecting a needle depth greater than necessary.
  - › Allow the fault indicator to cease before continuing procedure at a lower depth setting or with less aggressive force.

- **Over Temperature Fault:**
  LED 2 flashing at 0.25 sec. rate. Temperature is over 65°C.
  - › The fault will stop the motor and beep for 10 sec.
  - › The fault indication on the LEDs will continue for an additional 10 seconds before the device powers off.
  - › The fault may be generated by over aggressive needling and/or by selecting a needle depth greater than necessary.
  - › Allow the device to cool down before continuing the procedure.

- **Motor Position Fault:**
  LED 1, 2 alternating at 0.25 sec. rate.
  - › If device is unable to stop at the home position then fault is indicated by beeping for 10 sec.
  - › The fault indication on the LEDs will continue for an additional 10 seconds before the device powers off.

If this fault is indicated, use extra caution in removing the disposable cartridge as the needles may not be fully retracted.

Battery percentage indications in Running state:

- **Battery Charged > 70%:**
  LED 1, 2, 3 ON.

- **30% < Battery Charge ≤ 70%:**
  LED 1, 2 ON.

- **15% < Battery Charge ≤30%:**
  LED 1 ON.

- **1% < Battery Charge ≤ 15%:**
  LED 1 flash on/off 1 sec. rate.

- **If the battery charge is <1%** and the user attempts to power on the device, LED 1 will flash at 0.5 second rate for 10 seconds and return to off mode.

Battery Charge Indicator in Charging state:

After 30 minutes of being off the charger the SkinPen® Precision will beep to remind users that it needs to be placed on the charger. This notification may be cleared by either simply powering on the device, or by placing the device on the charger.

- When the SkinPen® Precision is placed on the charger, LED 1, 2, 3 and charger indicator LED will blink sequentially for a second to indicate it is connected with the charger base.
- When the SkinPen® Precision is removed from the charger base the LED's stay solid which indicates the charge level in the battery. They then go off to maintain battery longevity.

- **Battery Charge = 100%:**
  LED 1, 2, 3 OFF to maintain battery longevity.

- **Battery Charge > 90%:**
  LED 1, 2, 3 ON.

- **70% < Battery Charge ≤ 90%:**
  LED 1, 2 ON, LED 3 repeat on/off 1 sec.

- **30% < Battery Charge ≤ 70%:**
  LED 1 ON, LED 2 repeat on/off 1 sec.

- **Battery Charge ≤ 30%:**
  LED 1 repeat on/off 1 sec.

13. SPECIFICATIONS

Technical Information of SkinPen® Precision

Product Name	SkinPen® Precision
SkinPen® Precision Handpiece Model Number	100
SkinPen® Precision Charger Base Model Number	101
Crown Aesthetics FDA Registration #	3016371308
FCC ID	2AGLK-101
Weight and Unit	≤ 5oz /155mm length and max. outer diameter of 34mm
Electrical Requirements	Charger Base Input: 5VDC, 2A max
Output voltage	5W (max)
Charger Time	From 10% charge to 90% charge within 14 hours
Working Time	> 6 hours (under normal use conditions)
Speed	6300RPM – 7700RPM
Needles	• 14 total solid needles • 32 BWG (gauge) • <32 RMS (roughness) • Medical grade Stainless Steel • EU RoHS compliant • Sharpness specification within the Radius 0.005mm (Max) • Maximum extension of the needles from the needle head surface is less than 2.75mm • needle length: 2.5 +/- 0.25mm exposed length • needle geometry: 0.25mm diameter with 1mm conical taper from needle tip • maximum penetration depth: 2.5 ± 0.25 mm • puncture rate: 1470-1797 punctures/sec
Operation	Cordless
AC Adapter	Medical Grade, Universally compatible power requirements: 100-240 VAC at 50-60 Hz
Charger base transmitting frequency	Between 110kHz and 205kHz with efficiency around 73%

14. ENVIRONMENTAL CONDITIONS

Storage and Operating conditions:	Temperature: 17-30°C
	Relative humidity: 30-75% relative humidity non-condensing
	Atmospheric Pressure: 70 -106 kPa
Transportation conditions:	Temperature: -18-60°C
	Relative humidity: 30-85% relative humidity non-condensing

The EMISSIONS characteristics of the SkinPen® Precision & Charger Base make it suitable for use in industrial areas and hospitals (CISPR 11 class A).

This device complies with Industry Canada's license-exempt RSS. Operation is subject to the following two conditions: (1) This device may not cause interference; (2) This device must accept any interference, including interference that may cause undesired operation of the device.

This user manual is valid for SkinPen Precision® handpiece, the SkinPen® Precision Charger Base (with AC adapter), SkinPen® Precision BioSheath and SkinPen® Precision Treatment Kit.

This user manual is published by Crown Aesthetics. Crown Aesthetics 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 this manual.

Declaration of Conformity

Crown Aesthetics declares that the SkinPen® Precision and SkinPen® Precision charger base complies with the following normative documents:

IEC 62133, IEC 60601-1, IEC 60601-1-2, IEC 62366, ISO 14971:2012,
IEC 62304, MDD 93/42/EEC, RoHS, IEC 60601-1-6, IEC 60529, ISO 10993-1.

This device complies with Part 15 of the FCC Rules.

We Crown Aesthetics accept not having the ETL Mark on the SkinPen® Precision device label, but our product is 60601 certified.

Conforms to AAMI STD ES 60601-1, Certified to CSA STD C22.2 #60601-1.

This device is classified as Class IIa per MDD 93/42/EEC.

15. CLINICAL STUDY SUMMARY – ACNE SCARS

A clinical study was conducted to support the safety and effectiveness of the SkinPen Precision System for the treatment of acne scars on the face.

The study was conducted at a single center and included treatments on day 1, day 30, and day 60, with follow-up visits at 1 month and 6 months after the final (day 60) treatment. Treatments were conducted by a trained aesthetician (skin care specialist). The face was cleaned and numbed prior to treatment. A thin layer of Skinfuse Lift HG was applied prior to treatment to protect against abrasion and friction during the procedure. The aestheticians were instructed to start at the lowest depth setting and gradually increase the depth until erythema was observed, with a maximum depth of 1.5mm. The instructions included a precaution that microneedling was used around but not within the orbital rim. The face was divided into quadrants for treatment to ensure that all acne scars were treated. Following treatment, Skinfuse Lift HG was applied to prevent the skin from drying out post procedure.

A total of 41 subjects completed the study. Only 20 of these subjects were treated with the SkinPen Precision System. The other 21 subjects were treated with a prototype device. There are technological differences between the SkinPen Precision System and the prototype device, including a greater number of needles in the SkinPen Precision cartridge and faster motor speed in the SkinPen Precision device, which may affect the device effectiveness results. Therefore, the safety assessments collected for both treatment groups are included in the summary below. However, for the effectiveness results, only the data for the SkinPen Precision group was considered.

Subjects enrolled in the study included both men (31.7%) and women (68.3%) over the age of 21. The study included 11/41 subjects with Fitzpatrick Skin Type (FST) V and VI.

Table 1: Summary of Demographic Information

	SkinPen Precision System		All Subjects	
N	20		41	
Age (years)				
Mean (standard deviation)	43.8 (12.7)		44 (11.9)	
Minimum, Median, Maximum	23, 48, 60		21, 46, 60	
	N	(%)	N	(%)
Sex				
Male	7	35	13	31.7
Female	13	65	28	68.3
Ethnicity				
Hispanic or Latino	6	30	13	31.7
Not Hispanic or Latino	14	70	28	68.3
Race				
American Indian or Alaska Native	1	5	2	4.9
Asian	3	15	9	22.0
Black or African American	6	30	10	24.4
White	10	50	20	48.8
Fitzpatrick Skin Type				
II	2	10	3	7.3
III	4	20	10	24.4
IV	7	35	17	41.5
V	4	20	7	17.1
VI	3	15	4	9.8

At each clinical visit, digital images were taken of each subject's facial acne scars. On day 1, day 30, and day 60, imaging was performed prior to treatment. A total of 3 full-face images were collected. Images were also collected at the 1 month and 6 month follow-up visit. These images were graded by two separate Board Certified Dermatologists after completion of the study using the following assessment tools and timepoints [Table 2]. Details of each of these assessment tools are provided below in Tables 3-5. The results of the study are provided in Tables 6-10.

Table 2: Study Endpoints

Primary effectiveness endpoints	Acne Scar Assessment Scale graded by two blinded dermatologists using photographs taken at baseline, day 30, day 60, 1-month post-treatment, and 6-months post-treatment
	Clinician's Global Aesthetic Improvement Assessment graded by two blinded dermatologists using photographs taken at 1-month post-treatment, and 6-months post-treatment
Secondary effectiveness endpoints	Self-assessed Scar Improvement Scale completed by subjects at baseline, 1-month post-treatment, and 6-months post-treatment
	Subject Global Aesthetic Improvement Scale completed by subjects at baseline, 1-month post-treatment, and 6-months post-treatment
	Patient Satisfaction Questionnaire completed by subjects at 1-month post-treatment and 6-months post-treatment
Safety Endpoint	Subject safety diaries provided to the subject at each treatment visit (day 1, 30, and 60) and completed for 30 days to record treatment responses
	Adverse event monitoring at each visit; baseline, day 30, day 60, 1-month post-treatment, and 6-months post-treatment

The photo grading included the following effectiveness assessments:

- Acne Scar Assessment Scale[1]

Table 3: Acne Scar Assessment Scale

Grade	Term	Description
0	Clear	No depressions are seen in the treatment area. Macular discoloration may be seen.
1	Very mild	A single depression is easily noticeable with direct lighting (deep). Most or all of the depressions seen are only readily apparent with tangential lighting (shallow).
2	Mild	A few to several, but less than half of all the depressions are easily noticeable with direct lighting (deep). Most of the depressions seen are only readily apparent with tangential lighting (shallow).
3	Moderate	More than half of the depressions are apparent with direct lighting (deep).
4	Severe	All or almost all the lesions can be seen with direct lighting (deep).

[1] Jwala Karnik, Leslie Baumann, Suzanne Bruce, Valerie Callender, Steven Cohen, Pearl Grimes, John Joseph, Ava Shamban, James Spencer, Ruth Tedaldi, William Philip Werschler, Stacy R. Smith, "A double-blind, randomized, multicenter, controlled trial of suspended polymethylmethacrylate microspheres for the correction of atrophic facial acne scars" Journal of the American Academy of Dermatology 71(1):77-83 (2014).

In addition to the clinician graded effectiveness measures, the following patient-reported measures were recorded throughout the study:

- Self-assessed Scar Improvement Scale

Table 4: Self-assessed Scar Improvement Scale

Rating	Description
-1	Exacerbation of Acne Scars
0	No change in appearance of acne scars
1	1% - 25% improvement in appearance of acne scars
2	25% - 50% improvement in appearance of acne scars
3	50% - 75% improvement in appearance of acne scars
4	75% - 99% improvement in appearance of acne scars

- Subject Global Aesthetic Improvement Scale

Table 5: Subject Global Aesthetic Improvement Scale

Rating	Description
1	**Very Much Improved:** Optimal cosmetic result.
2	**Much Improved:** Marked improvement in appearance from the initial condition, but not completely optimal.
3	**Improved:** Obvious improvement in appearance from initial condition.
4	**No Change:** The appearance is essentially the same as the original condition.
5	**Worse:** The appearance is worse than the original condition.

- Patient Satisfaction Questionnaire

  Three questions were asked to the subjects in the study regarding their level of satisfaction with the treatment. It was included as a secondary endpoint in the study. See individual questions and results in the section below.

  Safety information was collected throughout the study using subject safety diaries. Safety diaries were provided to the subject at each treatment visit (day 1, 30, and 60). The subject was instructed to record any observations related to treatment including common treatment responses. Common treatment responses are side effects that result from treatment which resolve on the order of days. Common treatment responses that persist may be categorized as adverse events when assessed by the investigator at the next visit.

  Subjects were informed of the following potential common treatment responses in the informed consent process: skin will be red and flushed similar to a moderate sunburn, skin tightness and mild sensitivity to the touch, redness, burning, tingling, stinging, itching, and/or scaling/dryness, edema (swelling), tenderness/discomfort, a possibility of developing an infection (an increase in redness, warmth, itching, or pus formation). The diaries included space for daily recording of observations for the 30 days in between treatment visits. Adverse events were assessed by the investigator at each subsequent visit.

Results:

Safety:

At the 6-month post-treatment visit, no adverse events persisted.

The following common treatment responses were reported in the subject safety diaries which were sent home with the subject:

- Dryness in 5/41 (12%) subjects lasting from 1-6 days
  - o These responses were reported by 3 subjects with FST III, 1 subject with FST VI, and 1 subject with FST V
- Rough Skin in 3/41 (7%) of subjects lasting from 1-2 days
  - o These responses were reported by 1 subject with FST III, and 2 subjects with FST V
- Tightness in 2/41 (4%) of subjects lasting from 1-2 days
  - o These responses were reported by 2 subjects with FST VI
- Redness, Itching, Peeling Discomfort and Tenderness in 13/41 (31%) of subjects lasting 1-3 days
  - o These responses were reported by 6 subjects with FST III, 2 subjects with FST VI, 3 subjects with FST V, and 2 subjects with FST VI
- Burning in 4/41 (9%) of subjects lasting 1-3 days
  - o These responses were reported by 1 subject with FST III, 1 subject with FST VI, and 2 subjects with FST V

Over the course of the study, 1 subject reported an arthropod bite on the inner right thigh that was determined to be moderate and unlikely related to SkinPen prototype device. 1 subject (1/41, 2.4%) experienced an AE (skin striae [linear marks, ridges, or grooves] on the forehead and both sides of the face) that was determined to be mild and possibly related to use of the SkinPen Precision System. This AE was thought to be due to subject exposure to excess sunlight soon after treatment which was against study instructions, yet resolved without any additional complications.

Effectiveness:

Acne Scar Assessment Scale:

Results of photo grading using the Acne Scar Assessment Scale demonstrated that at baseline the mean population score was mild at 2.80. Following the three treatments and 6 months of follow-up, the mean population score was reported as mild at 2.35.

The evaluation by the blinded assessors indicated that seven subjects (7/20, 35%) had a 1-grade reduction in the Acne Scar Assessment Scale at 6-months post-treatment compared to baseline. The seven subjects reporting a 1-grade reduction included 1 subject with FST II, 2 subjects with FST III, 1 subject with FST IV, 2 subjects with FST V, and 1 subject with FST VI.

In addition, 4 subjects (20%) showed an improvement greater than 0 but less than 1 on the Acne Scar Assessment Scale, giving a total of 55% (11/20) of subjects showing improvement at 6-months post-treatment when compared with baseline. At 6-months post-treatment, the remaining 9 subjects (45%) reported no change in score when compared to baseline. The visual improvements seen in the photo grading results were considered to be clinically meaningful.

Table 6: Results of Photo Grading of Acne Scar Assessment Scale for SkinPen Precision System

Time Point	N	Mean	Standard Deviation	Minimum	Median	Maximum
Baseline	20	2.80	0.52	2.00	3.00	4.00
Day 30	20	2.78	0.57	2.00	2.75	4.00
Day 60	20	2.70	0.55	2.00	2.50	3.50
1-Month Post-Treatment	20	2.68	0.49	2.00	2.50	3.50
6-Months Post-Treatment	20	2.35	0.69	1.50	2.50	3.50

Table 7: Change from Baseline for Photo Grading of Acne Scar Assessment Scale for SkinPen Precision System

Time Point	N	Subject Improved (%)	Subject Worsened (%)	Mean Change	Standard Deviation for Change	Mean Change (%)
Day 30	20	30.0	20.0	-0.03	0.50	-0.9
Day 60	20	35.0	20.0	-0.10	0.50	-3.6
1-Month Post-Treatment	20	40.0	20.0	-0.13	0.58	-4.5
6-Months Post-Treatment	20	55.0	0.0	-0.45	0.46	-16.1

Self-assessed Scar Improvement Scale:

Treatment with SkinPen Precision produced an improvement in SASIS scores at 1 month post-treatment and 6-months post-treatment. At 1-month post-treatment, 17 (85%) subjects reported some percentage of improvement in the appearance of their acne scars, with 3 (15%) subjects reporting no change. At 6-months post-treatment, 18 (90%) subjects reported some percentage of improvement in the appearance of their acne scars, with 2 (10%) subjects reporting no change. The mean value for the population was = 1.65 and 1.70, at 1-month post-treatment and 6-months post-treatment respectively (1%-25% improvement in appearance of acne scars) when compared with a score of 0 (no change in appearance of acne scars). No subjects reported a negative score (i.e., exacerbation of acne scars) at either post-treatment timepoint.

Subject Global Aesthetic Improvement Scale:

Treatment with SkinPen Precision produced an improvement in SGAIS scores at 1 month post-treatment and 6 months post-treatment. At 1-month post-treatment, 7 (35%) subjects reported much improved, 9 (45%) subjects reported improved, and 4 (20%) subjects reported no change. At 6-months post-treatment, 2 (10%) subjects reported very much improved, 8 (40%) subjects reported much improved, 8 (40%) subjects reported improved, and 2 (10%) subjects reported no change. The mean value for the population was = 2.85 and 2.50, at 1-month post-treatment and 6-months post-treatment respectively (improved) when compared with a score of 4 (no change). No subjects reported a score of 5 (worse) at either post treatment timepoint.

Patient Satisfaction Questionnaire:

The results of the patient satisfaction questionnaire for all subjects indicated that a greater proportion of subjects selected favorable responses regarding treatments at 1 month and 6 months post-treatment for the following inquiries:

• Question 1: Do you notice any improvement in how your acne scars look in the treated area?

Table 8: Results of Patient Satisfaction Questionnaire - Question 1

Time Point	Yes [N (%)]	No [N, (%)]
1-Month Post-Treatment	16 (80.0)	4 (20.0)
6-Months Post-Treatment	18 (90.0)	2 (10.0)

• Question 2: How would you characterize your satisfaction with the treatment?

Table 9: Results of Patient Satisfaction Questionnaire – Question 2

Time Point	Extremely Satisfied [N (%)]	Satisfied [N (%)]	Slightly Satisfied [N (%)]	Neither Satisfied nor Dissatisfied [N (%)]	Slightly Dissatisfied [N (%)]	Dissatisfied [N (%)]	Very Dissatisfied [N (%)]
1-Month Post-Treatment	3 (15.0)	9 (45.0)	5 (25.0)	3 (15.0)	0 (0.0)	0 (0.0)	0 (0.0)
6-Months Post-Treatment	3 (15.0)	9 (45.0)	5 (25.0)	1 (5.0)	1 (5.0)	1 (5.0)	0 (0.0)

• Question 3: Would you recommend this treatment to your friends and family members?

Table 10: Results of Patient Satisfaction Questionnaire – Question 3

Time Point	Yes [N (%)]	No [N, (%)]
1-Month Post-Treatment	18 (90.0)	2 (10.0)
6-Months Post-Treatment	18 (90.0)	2 (10.0)

16. CLINICAL STUDY SUMMARY – WRINKLES

A clinical study was conducted to support the safety and effectiveness of the SkinPen Precision System for the treatment of wrinkles on the neck.

The single center study was conducted on a total of 35 subjects (2 male and 33 female), aged 44 years and older from various ethnic groups with multiple skin tones (pale to dark skin). Treatments were given on day 1, day 30, day 60, and day 90 with follow-up visits at 1 month and 3 months after the last treatment. Under direct supervision of a licensed Physician, treatments were conducted by a trained aesthetician (skin care specialist). The face and neck was cleaned and numbed prior to treatment. A thin layer of Skinfuse Lift HG was applied prior to treatment area to protect against abrasion and friction during the procedure. The aestheticians were instructed to treat at depths of up to 2.5 mm. Following treatment, Skinfuse Lift HG was applied to prevent the skin from drying out post procedure.

Table 11: Summary of Demographic Information Per Protocol

	SkinPen Precision System	
N	32	
Age (years)		
Mean (standard deviation)	56.3 (5.0)	
Minimum, Median, Maximum	44, 56.5, 65	
	N	(%)
Sex		
Male	2	6.3
Female	30	93.8
Ethnicity		
Hispanic or Latino	4	12.5
Not Hispanic or Latino	28	87.5
Race		
Other	4	12.5
White or Caucasian	28	87.5
Fitzpatrick Skin Type		
II	24	75.0
III	4	12.5
IV	4	12.5

At each clinical visit, digital images were taken of each subject's wrinkles on the neck. These images were graded by two separate independent blinded Board Certified Physicians after completion of the study using the following assessment tools and timepoints [Tables 12-15]. The results of the study are provided in Tables 16-20.

Table 12: Study Endpoints

Primary Effectiveness Endpoints	G. Lemperle Wrinkle Scale graded by two blinded graders using photographs taken at day 1 and 3-months post-treatment
Secondary Effectiveness Endpoint	Clinician's Global Aesthetic Improvement Assessment graded by two blinded graders using photographs taken at day 1 and 3-months post-treatment
	Subject Global Aesthetic Improvement Scale completed by subjects at 1-month post-treatment, and 3-months post-treatment
	Patient Satisfaction Questionnaire completed by subjects at 1-month post-treatment and 3-months post-treatment
Safety Endpoint	Subject safety diaries provided to the subject at each treatment visit (day 1, 30, 60 and 90) and completed for 30 days to record treatment responses
	Adverse event monitoring at each visit; day 1, day 30, day 60, day 90, 1-month post-treatment and 3 months post-treatment

Subjects had wrinkling assessed on the neck using the G. Lemperle Wrinkle Assessment Scale.

Table 13: Assessment of Wrinkling – G. Lemperle Wrinkle Scale

Class	Description
0	No wrinkles
1	Just perceptible wrinkle
2	Shallow wrinkles
3	Moderately deep wrinkle
4	Deep wrinkle, well-defined edges
5	Very deep wrinkle, redundant fold

At 1 month post-treatment and 3 months post-treatment, subjects also participated in the following procedures:

- Clinician's Global Aesthetic Improvement Scale

Table 14: Clinician's Global Aesthetic Improvement Scale (CGAIS)

Rating	Description
1	**Very Much Improved:** Optimal cosmetic result in this subject.
2	**Much Improved:** Marked improvement in appearance from the initial condition, but not completely optimal for this subject.
3	**Improved:** Obvious improvement in appearance from initial condition, but a re-treatment is indicated.
4	**No Change:** The appearance is essentially the same as the original condition.
5	**Worse:** The appearance is worse than the original condition.

- Subject's Global Aesthetic Improvement Scale

Table 15: Subject Global Aesthetic Improvement Scale

Rating	Description
1	**Very Much Improved:** Optimal cosmetic result.
2	**Much Improved:** Marked improvement in appearance from the initial condition, but not completely optimal.
3	**Improved:** Obvious improvement in appearance from initial condition.
4	**No Change:** The appearance is essentially the same as the original condition.
5	**Worse:** The appearance is worse than the original condition.

- Patient Satisfaction Questionnaire

  Subjects completed a Sponsor-provided questionnaire regarding improvement in wrinkles, satisfaction with the treatment and willingness to recommend the treatment to friends and family members.

Results:

Safety:

a. What side effects were seen in the clinical study?

Common Treatment Responses on the face and neck:

Common Treatment responses of dryness, redness, burning sensation and itchiness which lasted the duration of 1-3 days. Reactions of tenderness and peeling/flaking occurred for the duration of 1-7 days.

The following common treatment responses were reported in the subject safety diaries which were sent home with the subject:

- Dryness in 7/32 (22%) subjects lasting from 1-3 days
  - o These responses were reported by 6 subjects with FST II, 1 subject with FST IV
- Redness in 2/32 (6%) subjects lasting from 1-3 days
  - o These responses were reported by 2 subjects, 1 subject with FST II, 1 subject with FST IV
- Itching in 1/32 (3%) subjects with FST II, lasting from 1-2 days
- Peeling was reported in 8/32 (22%) of subjects lasting 1-3 days
  - o These responses were reported by 8 subjects, 5 subjects with FST II, 1 subject with FST III, 2 subjects with FST IV
- Tenderness that lasted 1-4 days in 1/32 (3%) of Subjects , with FST II
- Burning in 2/32 (6%) of subjects lasting 1-3 days
  - o These responses were reported by 2 subjects with FST IV

b. What adverse events were seen in the clinical study?

At the 3-month post-treatment visit, no adverse events were seen.

No adverse events related to the SkinPen Precision treatment were observed on the face or neck during the study.

c. What are other possible adverse events?

Although not seen in the clinical study, patients may experience red and flushed skin, skin tightness and mild sensitivity to touch (such as itching, burning, stinging, tingling), scaling/dryness, redness, edema and tenderness/discomfort.

Benefits:

What will a SkinPen Precision Treatment accomplish, and what did the clinical study show?

The study doctors reported using the G. Lemperle Wrinkle Scale:

Results of the photo grading indicated a significant improvement in wrinkles on the neck area assessment at 3 months post- treatment.

Table 16: Results of Photo Grading of G. Lemperle Wrinkle Scale for SkinPen Precision System

Detail	Time Point	N	Mean	Standard Deviation	Min	Median	Max
Neck	Day 1	32	3.31	0.74	2.00	3.25	5.00
	3 Mo. Post-Treatment	32	2.45	0.93	1.00	2.00	4.50

Table 17: Change from Baseline for Photo Grading of G. Lemperle Wrinkle Scale for SkinPen Precision System

Detail	Time Point	N	Subjects graded as having a ≥1 grade improvement
Neck	3 Mo. Post-Treatment	32	16 (50%)

Clinician's Global Aesthetic Improvement Assessment:

Treatment with SkinPen Precision produced an improvement in CGAIS scores at 3 months post-treatment. At three-months post-treatment evaluation, 31.5% of subjects received a '3: improved' grading and 57% received a grading of '4: no change' relative to pre-treatment. Four subjects (11.5%) received a grading of '2: much improved'.

Subjects reported using the Subject Global Aesthetic Improvement Scale:

Treatment with SkinPen Precision produced an improvement in Subject GAIS scores at 3-months post-treatment. At 3-months post-treatment, 22 (68.8%) subjects reported some percentage of improvement in the appearance of their wrinkles, with 10 (31.3%) subjects reporting no change.

Subjects reported using the Patient Satisfaction Questionnaire:

The results of the patient satisfaction questionnaire for all subjects indicated that a greater number of subjects selected favorable responses regarding treatments at 1 month and 3 months post-treatment for the following inquiries

- Question 1: Do you notice any improvement in how your fine lines and wrinkles look in the treated area?

Table 18: Results of Patient Satisfaction Questionnaire - Question 1

Time Point	Yes [N (%)]	No [N, (%)]
1-Month Post-Treatment	30 (93.8)	2 (6.3)
3-Months Post-Treatment	23 (71.9)	9(28.1)

- Question 2: How would you characterize your satisfaction with the treatment?

Table 19: Results of Patient Satisfaction Questionnaire – Question 2

Time Point	N	Favorable (+) N (%)	Unfavorable (-) N (%)	Neutral N (%)
1 Month Post-Treatment	32	28 (87.5)	3 (9.4)	1 (3.1)
3 Months Post-Treatment	32	24 (75.0)	6 (18.8)	2 (6.3)

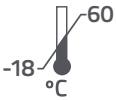
- Question 3: Would you recommend this treatment to your friends and family members?

Table 20: Results of Patient Satisfaction Questionnaire – Question 3

Time Point	Yes [N (%)]	No [N, (%)]
1-Month Post-Treatment	25 (80.6)	6 (19.4)
3-Months Post-Treatment	21 (65.6)	11 (34.4)

Subjects were informed of the following potential common treatment responses in the informed consent process: skin will be red and flushed similar to a moderate sunburn, skin tightness and mild sensitivity to the touch, redness, burning, tingling, stinging, itching, and/or scaling/dryness, edema (swelling), tenderness/ discomfort, a possibility of developing an infection (an increase in redness, warmth, itching, or pus formation). The diaries included space for daily recording of observations for the 30 days in between treatment visits. Adverse events were assessed by the investigator at each subsequent visit.

SYMBOL LEGEND

Manufacturer's trade name and address		Manufacturer's catalouge code	
Serial Number		Batch code	
Authorized Representative in the European Community		CE mark	
Do not re-sterilize		Do not re-use	
Sterilized using ethylene oxide		Consult Instructions for Use	
Caution		Do not use if package is damaged	
Temperature shipment limits		Humidity limitation	
Keep dry		Not for general waste	
This device includes RF transmitters		Direct Current	
Positive Polarity		Use-by date	

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