SkinPen®
PRECISION

User Manual

SkinPen® Model #100
SkinPen® Charger Base Model #101

Engineered
& Designed
in the USA

Made in the USA

Inductive Charging

SMART Technology

Patented
Reciprocating
Mechanism

Table of Contents

1. DEVICE DESCRIPTION

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

Fig 1.

SkinPen® Precision Key Components

A Power Indicator

B Power On/Off Button

C Charge Level Indicator

D Microneedling Connector

E Ergononic Handle Grip

F Base Charger AC/DC Adapter

G Inductive Charging Base

SKINPEN® TREATMENT KIT

INCLUDES:

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

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

LIFT HG
Lift HG is a hydrogel wound dressing without drugs and/or a biologic to protect against abrasion and friction during the microneedling procedure.

RESCUE Calming Complex
Key ingredients assist in reducing the risk of prolonged inflammation post-procedure.

NUMB Topical Analgesic
Skinfuse® NUMB is a OTC 5g individual pre-procedure packet (4% lidocaine) that will provide patient comfort during the procedure by topically numbing the area receiving the microneedling procedure. The single-use packet reduces the risk of cross-contamination.

2. INTENDED USE

SkinPen® Precision is a microneedling device to improve the appearance of fine lines, wrinkles, and scars on the face and body. Rx Only.

3. CONTRAINDICATIONS

The use of SkinPen® Precision should not be used on patients with active skin cancer or active bacterial, fungal or viral (i.e. herpes, warts) skin infections in the treatment area(s).

4. WARNINGS

SkinPen® Precision has not been evaluated in the following patient populations, and as such, precautions should be taken when determining whether to treat patients with a history of the following conditions: Eczema, psoriasis, and other chronic conditions in the treatment area; herpes simplex infections; keloid scars; patients on anticoagulants; scars and stretch marks less than one year old; scleroderma; and wound-healing deficiencies.

5. PRECAUTIONS

Universal precautions are necessary during microneedling. Microneedling should not be used within the orbital rim, such as the eyelids. Special care needs to be exercised on patients with the following conditions or on the following medications: Actinic (solar) keratosis; active acne; allergies to stainless steel; collagen vascular diseases or cardiac abnormalities; diabetes; eczema, psoriasis and other chronic conditions on other areas of the body; immunosuppressive therapy; irritated skin in the treatment area; history of contact dermatitis; hemorrhagic disorder or hemostatic dysfunction; isotretinoin drugs, pregnancy or nursing; open wounds or sores; irritated skin; raised moles in the treatment area; and rosacea.

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. (90-264Vac).
- 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

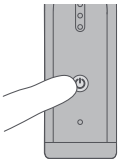
interference received, including interference that may cause undesired operation.

- 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.

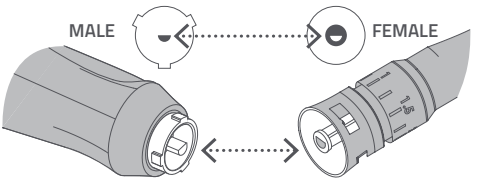
7. INTENDED USE

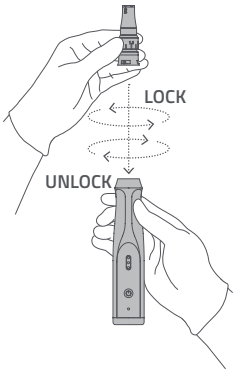
- Only use this device for the recommended applications. This device should only be used under medical supervision.
- Before administering any treatment, you should become acquainted with the operating procedures for the treatment, as well as the indications, contraindications, warnings, and precautions. Consult other resources (ie. IFU) for additional information regarding the application of microneedling therapy.

How to install/uninstall disposable SkinPen cartridge:



- Ensure SkinPen® Precision is powered off.
- Align the lock and key mechanism on the SkinPen® Precision microneedling cartridge and the SkinPen® Precision device.





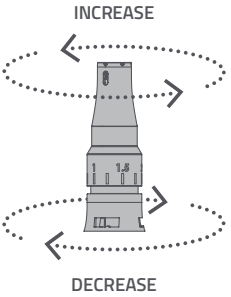
- Rotate counterclockwise onto the SkinPen® Precision until secure.
- To remove the cartridge rotate clockwise until the cartridge is removed.
- The SkinPen® Precision cartridge is designed for single use, with a lock-out feature prohibiting re-installation of the cartridge after use.

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

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

Additional SkinPen® Precision Cartridge Instructions:

How to adjust needle length:

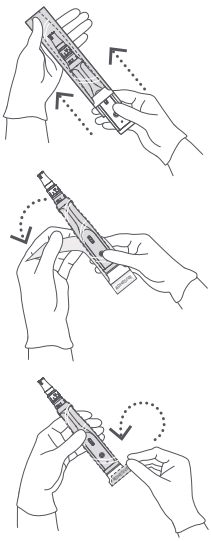


- To increase the needle length, adjust on the cartridge according to indicated tick marks on the cartridge. New settings will be indicated by a "click" into place.
- Needle settings should be selected based on patient needs.
- It is recommended to start at a depth setting of 0.25mm.
- If even erythema (redness) is not seen, gradually increase the depth to a maximum of 1.5mm on the face and up to 2.5mm on the body.

***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.

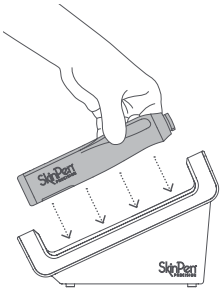
How to apply BioSheath:



- 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.

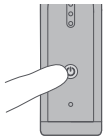
- To remove BioSheath simply peel off of the SkinPen® Precision and *discard appropriately.

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:



- ON: Press and hold power button for 2 seconds.
- OFF: Press and hold power button for 2 seconds.

8. PROCEDURE INSTRUCTIONS, POST-PROCEDURE INSTRUCTIONS, POST-PROCEDURE CARE

- For Procedure, Post-Procedure instructions, and Post-Procedure Care refer to SkinPen® IFU Rev.V1.0.

9. CLEANING OF SKINPEN PRECISION AND CHARGER BASE

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

- Sani-Cloth® wipes may be used to clean SkinPen® Precision after each procedure. Sani-Cloth® wipes may also be used to clean the SkinPen® Precision Charger Base.
- Do not immerse in liquids.
- Do not use solvents to clean device.

10. STORAGE

- For optimal performance of you SkinPen® Precision, ensure the device is turned off and store the device in the SkinPen® Precision charging base when not in use.

11. 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 battery, SkinPen® Precision must be disposed of separately from household waste. When SkinPen® Precision reaches its end of life, contact local authorities to learn bout disposal and recycling options.

12. WARRANTY

- One year under normal use after its original purchase.
- Warranty extends only to the original purchaser and purchase date.
- Contact Bellus Medical, LLC 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 Bellus Medical, LLC.

13. FAQ/TROUBLESHOOTING

Fault Indications:

- **Motor Speed Fault:**
  LED 1, 3 alternating at 0.25 sec. rate.
  › Device will turn off and fault is indicated by beeping for 10 sec.

- **Over Current Fault:**
  LED 3 flashing at 0.25 sec. rate.
  › Device will turn off and fault is indicated by beeping for 10 sec.

- **Over Temperature Fault:**
  LED 2 flashing at 0.25 sec. rate.
  Temperature is over 65°C.
  › Device will turn off and fault is indicated by beeping for 10 sec.

- **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.

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, LED1 will flash at 0.5 second rate for 10 seconds and return to off mode.

Battery Charge Indicator in Charging state:

- 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.

14. SPECIFICATIONS

Technical Information of SkinPen® Precision

Product Name	SkinPen® Precision
SkinPen® Precision Model Number	100
SkinPen® Charger Base Model Number	101
Bellus Medical FDA Registration #	# 3010392991
Weight and Unit	5oz / 155mm length and max. outer diameter of 34mm
Electrical Requirements	Input voltage: 4.2V
Output voltage:	5V battery
Charger Time	From 10% charge to 90% charge within 12 hours
Working Time	> 6 hours (under normal use conditions)
Speed	6300RPM – 7700RPM
Needles	14 pin, 32g, Stainless Steel
Operation	Cordless
AC Adapter	Medical Grade, 5VDC +/- 5%, 1A minimum, 59" length

15. ENVIRONMENTAL CONDITIONS

Operating conditions:	Temperature: 15-30°C Relative humidity: 30-75% relative humidity non-condensing
Transportation conditions:	Temperature: -20-60°C Relative humidity: 10-98% relative humidity non-condensing

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

Refer to the SkinPen® Precision Instructions For Use for additional information on the Procedure Instructions.

This user manual is published by Bellus Medical, LLC. Bellus Medical, 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 this manual.

SkinPen® Precision Rev.V1.0

Declaration of Conformity
Bellus Medical, LLC. Declares that the SkinPen® Precision and SkinPen® Precision charger base complies with the following normative documents:

IEC 62133, IEC 60601-1, IEC60601-1-2, IEC 60601-1, IEC 62366, ISO 14971:2012, IEC 62304, ISO:13485:2003, MDD 93/42/EEC, RoHS, ISO15223:2012, IEC 60601-1-6, IEC 60529, IEC 62304, ISO 10993-1, ISTA-2A, IEC 62133, UN 38.3

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.

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