



# SkinPen®

Microneedling System

## User Manual

SkinPen® Precision Device  
SkinPen® Precision Charger Base

Engineered, Designed  
& Made in the USA

Inductive Charging

SMARTTechnology

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.



### SkinPen® Precision Components

- A SkinPen Precision Handpiece – Part #10130010 / 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 #10130012
- G Inductive Charging Base – Part #10130011 / REF 101

# SKINPEN® PRECISION TREATMENT KIT



## INCLUDES:

### SkinPen Precision Cartridge

Part #10230010 / REF014

EO (Ethylene Oxide) Sterilized, disposable needle cartridge packaged and labeled individually. Proprietary needle cartridge. \*Cartridges are not to be resterilized or reused.



### SkinPen Precision BioSheath

Part #10130001

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



### LIFT HG

Part #11720001

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 facial acne scars in adults aged 22 years or 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

Safety and Effectiveness for setting greater than 1.5 mm has not been evaluated.

The SkinPen Precision System has not been 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 2.5 mm to allow for the variability in thickness of healthy skin and acne scar tissue. However, the device has not been clinically evaluated at cartridge settings of greater than 1.5 mm. 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 at needle depths greater than 1.5mm. 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 study when treating at needle depth of up to 1.5 mm. Please refer to Bellus provided training module on superficial nerve and vessel facial anatomy for additional information.

## 6. ELECTRICAL SAFETY WARNINGS

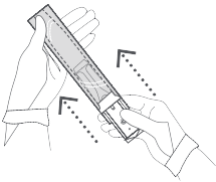
- No modification of this equipment is allowed. Only use included SkinPen® Precision adapter and charger base.
- Do not plug product into outlet with a voltage other than specified on the charger. (90–264 Vac).
- Never force plug into an outlet if it does not easily fit into the outlet, discontinue use.
- Discontinue use if product appears damaged in anyway.
- 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

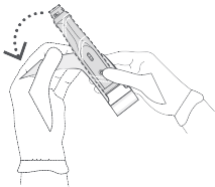
- Only use this device for the recommended applications. This device should only be used under medical supervision.
- Before administering any treatment, you should become acquainted with the operating procedures for the treatment, as well as the indications, contraindications, warnings, and precautions.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

### How to apply BioSheath:

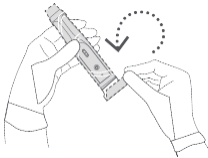
- While wearing non-latex gloves, obtain a single use BioSheath and ensure the SkinPen® Precision is clean/disinfected.



- While SkinPen® Precision is powered off, insert the SkinPen® Precision between the white tab and paper backing.



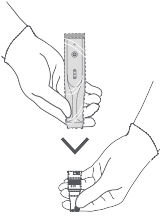
- Push SkinPen® Precision through the BioSheath until the device is snug inside the BioSheath.



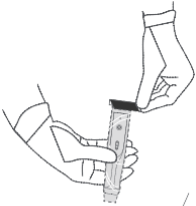
- Peel back the protective BioSheath cover by pulling on the Blue tab and white paper backing.
- Remove adhesive backing and seal end. SkinPen® Precision is now protected and ready to use.



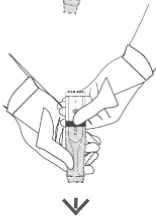
## How to remove the BioSheath and clean the SkinPen Precision Device:



- 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.

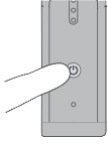
- Disinfection of the SkinPen Precision should be completed with the use of Sani-Cloth HB Wipes, See section 9– Cleaning of SkinPen Precision and Charger Base.

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

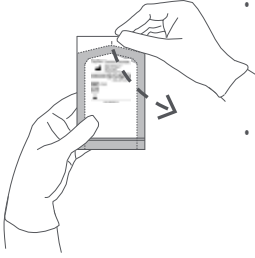
**Note:** Soiled gloves should always be disposed of in a biohazard container. Do not reuse disposable gloves.

**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.

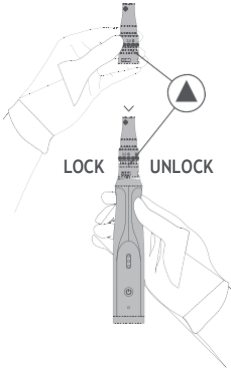
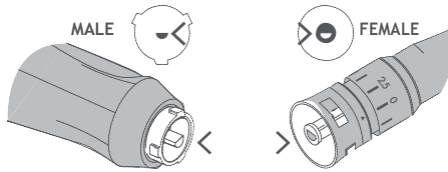
## How to install/uninstall disposable SkinPen® Precision cartridge:



- 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.

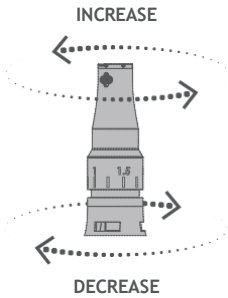
- Dispose of used SkinPen® Precision cartridge via a Sharps container.



**\*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.**

## Additional SkinPen® Precision Cartridge Instructions:

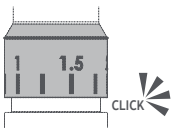
### How to adjust needle length:



- 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 0.25 mm.
- Increase by increments of 0.25 mm or 0.5 mm for the desired amount of erythema with a maximum depth of 1.5 mm on the face.



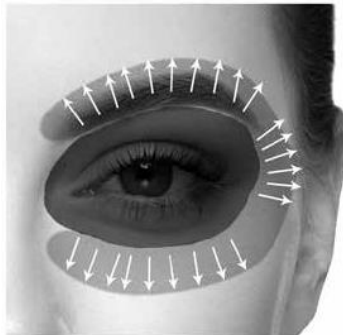
**\*Lower the setting of the cartridge to 0.25-0.5 mm to perform the procedure around the orbital rim.**



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

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

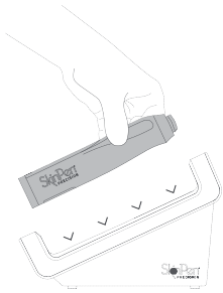
\*Note: treatment can be performed around but not within the orbital rim



#### Orbital Rim Guide

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

## How to charge:

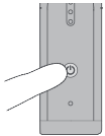


- Inductive charging is used between the SkinPen® Precision charger base and the SkinPen® Precision device.
- Plug the charger base into a live outlet.
- Place the hand-piece into the base with the power button facing out. See “FAQ/Troubleshooting” for additional battery information. Battery charge percentages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



- For additional information refer to SkinPen® Precision IFU.

## 9. 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 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® wipes 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® wipes 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.

- Do not immerse in liquids.
- Do not use solvents to clean device.

## 10. 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.

## 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 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.

## 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.

- › 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 Bellus Medical.



- **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 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.



## 14. SPECIFICATIONS

### Technical Information of SkinPen Precision®

|                                     |   |
|-------------------------------------|---|
| Product Name                        | SkinPen Precision®  |
| SkinPen® Precision Handpiece        |   |
| Model Number                        | 100   |
| SkinPen® Precision Charger Base     |   |
| Model Number                        | 101   |
| Bellus Medical FDA Registration #   | 3010392991  |
| FCC ID                              | 2AGLK-101   |
| Weight and Unit                     | ≤ 5oz/155mm length and<br>max. outer diameter of 34mm   |
| Electrical Requirements             | Charger Base Input: 5VDC, 2A max  |
| Output voltage:                     | 5W (max)  |
| Charger Time                        | From 10% charge to 90%<br>Charge within 14 hours  |
| Working Time                        | > 6 hours<br>(under normal use conditions)  |
| Speed                               | 6300RPM – 7700RPM   |
| Needles                             | <ul style="list-style-type: none"><li>• 14 total solid needles</li><li>• 32 BWG (gauge)</li><li>• &lt;32 RMS (roughness)</li><li>• Medical grade Stainless Steel</li><li>• EU RoHS compliant</li><li>• Sharpness specification within the<br/>Radius 0.005mm (Max)</li><li>• Maximum extension of the needles<br/>from the needle head surface is less<br/>than 2.7mm</li></ul> |
| Operation                           | Cordless  |
| AC Adapter                          | Medical Grade, Universally<br>compatible power requirements:<br>100–240 VAC at 50–60 Hz   |
| Charger base transmitting frequency | Between 110kHz and 205kHz<br>with efficiency around 73%   |

## 15. ENVIRONMENTAL CONDITIONS

|                            |  |
|----------------------------|--|
| Operating conditions:      | Temperature: 17–30°C<br>Relative humidity: 30–75%<br>relative humidity non-condensing<br>Atmospheric Pressure: 70 –106 kPa |
| Transportation conditions: | Temperature: –20–60°C<br>Relative humidity: 10–98%<br>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.

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.

### Declaration of Conformity

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













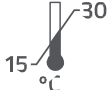
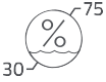






IEC 62133, IEC 60601–1, IEC 60601–1–2, IEC 62366, ISO 14971:2012, IEC 62304, MDD 93/42/EEC, RoHS, IEC 60601–1–6, IEC 60529, ISO 10993–1.

This device complies with Part 15 of the FCC Rules.

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

Conforms to AAMI STDES 60601–1, Certified to CSA STD C22.2 #60601–1.

# SYMBOL LEGEND

|   |   |   |   |
|---|---|---|---|
| Manufacturer's trade name and address               |    | Manufacturer's catalogue code   |    |
| Serial Number                                       |    | Batch code  |    |
| Authorized Representative in the European Community |    | CE mark (made in compliance with 93/42EEC Directive on class I medical devices) |    |
| 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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www.skinpen.com  
www.bellusmedical.com  
10330010 | Rev. A

ETL CLASSIFIED



Intertek  
5005341

