

SkinPen[®] Instructions for Use

with SkinPen[®] + Skinfuse[®] Treatment Kit

OVERVIEW

SkinPen[®] is an automated, non-surgical microneedling technology device designed for use by licensed healthcare practitioners or individuals directed by practitioners. The device incorporates a sterile microneedle cartridge and Bio-Sheath for single use only.

INTENDED USE

SkinPen Microneedling System and SkinPen+SkinFuse Treatment kit are a system that utilizes Collagen Induction Therapy to treat Melasma, acne and surgical scars.

CONTRAINDICATIONS

The use of SkinPen[®] should not be used on patients with active skin cancer or active bacterial, fungal or viral (i.e. herpes, warts) skin infections in the procedure area(s). NOTE: This product is not intended for transdermal (under the skin) delivery of cosmetics.

WARNINGS

SkinPen[®] 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 procedure area; herpes simplex infections; keloid scars; patients on anticoagulants; scars and stretch marks less than one year old; scleroderma; and wound-healing deficiencies.

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 patient 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 procedure 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 procedure area; and rosacea.

CHARGE SKINPEN[®]

1. Ensure charger base is plugged into outlet and place SkinPen[®], with the power button facing out, onto the charger base.

IMPORTANT: Keep dry.

PRE-PROCEDURE PRECAUTIONS

1. Avoid sun exposure/burns 24 hours prior to procedure.
2. Discontinue use of retinoids 24 hours prior to procedure.
3. Avoid procedure on patients with active breakouts or open lesions.
4. Allow at least 24 hours after autoimmune therapies before using SkinPen[®].
5. Wait six months following isotretinoin use.
6. 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. First, apply the disposable Bio-Sheath to the SkinPen.
8. Install the cartridge onto SkinPen[®].

***The cartridge contains a lock-out feature and may not be re-applied to SkinPen[®] once removed, ensuring a sterile single use application.**

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

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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[®] for two seconds.
13. Adjust needle depth settings on the SkinPen[®] cartridge. New settings will be indicated by a “click” into place.
14. Select SkinPen[®] microneedle position based on patient needs. 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 2.5 on the body. Lower to 0.25-0.5 mm to perform procedure around orbital rim.
15. 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.
16. For wrinkles and fine lines, 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.
17. For scar tissue, such as acne scars, a needle depth of 1.5 mm should be used on the face and up to 2.0 mm on the body.

NOTE: Microneedling should not be used within the orbital rim, such as the eyelids.

IMPORTANT: Microchannels created during the procedure may remain open up to 24 hours.

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

POST-PROCEDURE INSTRUCTIONS

1. Gently use sterile gauze to pat down the affected area.
2. Apply Skinfuse[®] LIFT HG after the procedure.
3. Skinfuse[®] RESCUE cosmetic calming complex may be applied the day after the procedure as needed to help soothe and calm the skin.
4. Advise patient to avoid sweaty exercise and sun exposure for 72 hours post-procedure.
5. Schedule next appointment at 4 weeks.
6. Take “after” pictures before next appointment.

CLEANING & STORAGE INSTRUCTIONS

Following the Procedure:

1. Remove the cartridge by rotating until it releases.
2. Always dispose of needle tips in a sharps container.
3. Remove Bio-Sheath.
4. Sani-Cloth[®] germicidal disposable wipes may be used to clean/disinfect the SkinPen[®] after every procedure.

For additional information refer to the SkinPen User Manual PN. 16130015 | Rev. B