SkinPen® Treatment Kit

Glossary of Terms:
- Actinic keratosis - A rough, scaly patch on your skin that develops from years of exposure to the sun.
- Active acne - Acne where you currently have pus, cysts or lesions on the skin at the time of evaluation.
- Active lesion - A lesion that has pus or a non-blanching bulla as part of the lesion.
- Anticonvulsive - Blood thinner
- Care: Clinical judgment - Awareness/blood vessel structure or function.
- Contact dermatitis - A rash that occurs at the site of exposure to a substance capable of producing an irritant skin response.
- Diabetes - A disease in which your blood glucose, or blood sugar levels, are too high because your body does not make enough insulin or cannot use insulin effectively.
- Fitzpatrick skin types - A theoretical classification system for human skin color that groups people into categories based on their ability to burn or tan.
- Global r.m. - The portion of the skin that outshines the border of the eye socket.
- Lower limit of normal is the lowest point where a value may be found within normal limits.
- Perianal - A common skin condition that can cause pain in the rectum when passed.
- Prednisone - A number of rare disorders that involves the hardening and tightening of the skin and the connective tissue beneath it.
- Sequela - Any complications that follow a medical illness or event.
- Self-effect - An expected result of a medication or treatment that is used in an approved manner.
- Subject - All subjects are divided on the skin.

1. Product Description

A. What is it, and how does it work?

SkinPen® Precision System is a minimally invasive, micro-needling device designed for use on the skin. It is composed of a reusable motor-driven device to be attached to a disposable cartridge that contains needles. The cartridges are disposable in order to prevent infection transmission. When activated, the needles penetrate the skin, creating thousands of microinjections in the skin’s outer layer. As these needles burrow, the epidermal turnover process begins. SkinPen®’s precision-pointed cartridge design mimics the extravasation of fluid into the dermal wire that allows for rebuilding and healing, helping to prevent potential cross-contamination of the solution between users. It is for personal use only.

B. Who is a candidate?

The SkinPen® Precision System is intended to be used as a treatment to improve the appearance of facial scars in adults aged 12 years or older. The SkinPen® Precision System is contraindicated for use on the following areas of skin:
- Areas of active cold sores, herpes simplex (herpes zoster) or shingles.
- Wounds, ulcers, scars or wounds that are unhealed.
- Areas of active acne or acne scars.
- Areas with eczema, psoriasis, or other chronic conditions of the skin or other areas of the body.

2. Conditions of Use

A. Are there any reasons why I should not receive a SkinPen® Precision treatment?

The SkinPen® Precision System has not been evaluated in the following patient populations:
- Patients with a history of a theoretical condition of the following conditions or who have taken the following medications, please let your doctor know, as treatment with the SkinPen® Precision System may not be appropriate for you:
  - Diabetes (insulin or oral medications)
  - Ulcerative colitis
  - Ovarian cancer
  - Nephrotic syndrome
  - Lupus
  - HIV infection
  - Other connective tissue diseases

B. Who is a candidate?

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3. Precautions

A. What precautions should my doctor advise me about?

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4. Clinical Study

A. How was the product studied?

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 single center study was conducted on a total of 40 subjects, 20 of which were exclusively for this clinical study (18 males and 2 females), aged 12 to 59 years. The 20 study participants were treated with a SkinPen® Precision device, 10 males and 10 females, aged 12 to 59 years and were divided into two groups.

B. Study endpoints:

Primary 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 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.

C. Safety endpoints

- Subject safety diaries provided to the subject at each treatment visit (day 30, day 60, and 6-months post-treatment).
- Adverse event monitoring at each visit; baseline, day 30, day 60, 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.
- Adverse event monitoring at each visit; baseline, day 30, day 60, 1-month post-treatment, and 6-months post-treatment.

In addition to the clinical grade of effectiveness measures, the following patient-reported measures were included in the study:
- Acne Scar Improvement Scale.
| Time Point         | N | Quality Satisfactory | N (% | Quality Satisfactory | N (% | Quality Satisfactory | N (% | Quality Satisfactory | N (% | Quality Satisfactory | N (%) |
|------------------|---|----------------------|--|---------------------|--|---------------------|--|---------------------|--|---------------------|--|---------------------|
| 1-Month Post-Treatment | 16 (80.0) | N | 4 (20.0) | 8 (40.0) | 4 (20.0) | 2 (10.0) |
| 6-Months Post-Treatment | 18 (90.0) | N | 2 (10.0) | 0 (0.0) | 0 (0.0) | 0 (0.0) |

**Question 1:** Do you notice any improvement in how your acne scars look in the treatment area? **Question 2:** How would you characterize your satisfaction with the treatment? **Question 3:** Would you recommend this treatment to your friends and family?

| Time Point         | N | Slightly Dissatisfied | N (% | Dissatisfied | N (% | Very Dissatisfied | N (%) |
|------------------|---|----------------------|--|------------|--|-----------------|--|---------|
| 1-Month Post-Treatment | 0 (0.0) | Slightly Dissatisfied | 0 (0.0) | Dissatisfied | 1 (5.0) | Very Dissatisfied | 0 (0.0) |
| 6-Months Post-Treatment | 1 (5.0) | Slightly Dissatisfied | 1 (5.0) | Dissatisfied | 0 (0.0) | Very Dissatisfied | 0 (0.0) |

**DEFINITION OF TREATMENT IMPERFECTIONS**

- Acne scars
- Post-inflammatory hyperpigmentation
- Pigmented lesions
- Redness
- Erythema
- Ridges

**DEFINITION OF TREATMENT IMPROVEMENT**

- Improvement: Apathy reduction or elimination, with or without dyschromia.
- Improvement: Improvement in erythema reduction.
- Improvement: Improvement in post-inflammatory hyperpigmentation reduction.
- Improvement: Improvement in redness.
- Improvement: Improvement in erythema.
- Improvement: Improvement in ridges.

**APPLICATION OF TREATMENT IMPROVEMENT**

- Baseline
- Day 30
- Day 60
- 1-Month Post-Treatment
- 6-Months Post-Treatment

**DIFFERENCES IN TREATMENT IMPROVEMENTS**

1. **Satisfaction**
2. **Improvement**
3. **Definitive Improvement**
4. **Adverse Events**
5. **Data Analysis**
6. **Conclusion**