SkinPen® SkinPen System

The SkinPen System has been used safely and effectively in the following patient populations. Therefore, if you have a history of the following conditions or have taken the following medications, please inform your physician:

- Active acne
- Collagen vascular disease or cardiac abnormalities
- Diabetes
- Glaucoma
- History of recurrent episodes of herpes
- Muscle relaxant
- Persistent hives
- Seizure disorder
- Hypersensitivity to any component
- History of allergy to any component
- Allergies to titanium or steel

Before beginning your treatments please review this important information.

GLOSSARY OF TERMS:

- Acne scar – A rough, scaly patch on your skin that develops from years of exposure to the sun.
- Active acne - Acne where there are currently pustules, cysts or lesions on the skin at the time of evaluation
- Adverse event monitoring at each visit; baseline, day 30, day 60, 1-month post-treatment, and 6-months post-treatment
- Subject safety diaries provided to the subject at each treatment visit (day 1, 30, and 60) and completed for 30 days to record treatment reactions.
- Adverse event monitoring at each visit: day 1, 30, and 60, 1-month post-treatment, and 6-months post-treatment
- Adverse event monitoring at each visit: day 1, 30, and 60, 1-month post-treatment, and 6-months post-treatment

4. CLINICAL STUDY

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

SkinPen® Precision System is a minimally invasive, micro-needling device intended for use by trained aestheticians. The SkinPen® Precision System is comprised of a reusable motor unit designed to be attached to sterile, disposable cartridges that contain 34 microscopic punctures (heads) of varying sizes. When activated and placed properly against the skin, the system can create hundreds to thousands of ‘micro’ punctures in the skin. These punctures heal rapidly, allowing the growth of new skin, and may remodel the appearance of acne scars.

Hemorrhagic – Accompanied by or produced by an escape of blood from a ruptured vessel, especially when bleeding excessively.

One at each clinical visit, digital images were taken of each subject’s facial acne scars. These images were graded by two separate Board Certified Dermatologists after completion of the study using the following assessment tools and timepoints:

Table 5: Acne Scar Assessment Scale

Table 4: Study Endpoints

<table>
<thead>
<tr>
<th>Rating</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>0</td>
<td>No change in appearance of acne scars</td>
</tr>
<tr>
<td>1</td>
<td>Very mild: A single depression is easily noticeable with direct lighting (deep). Most or all of the depressions seen are easily noticeable with direct lighting (deep). Most or all of the depressions seen are only readily apparent with tangential lighting (shallow).</td>
</tr>
<tr>
<td>2</td>
<td>Mild: A few, 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).</td>
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<tr>
<td>3</td>
<td>Moderate: More than half of the depressions are apparent with direct lighting (deep).</td>
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<tr>
<td>4</td>
<td>Severe: All or almost all the lesions can be seen with direct lighting (deep).</td>
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In addition to the clinician graded effectiveness measures, the following patient-reported measures were recorded throughout the study:

- Self-assessed Scar Improvement Scale
- Table 5: Acne Scar Assessment Scale
- Table 6: Self-assessed Scar Improvement Scale

5. Works: The appearance is worse than the original condition.

The photo grading included the following effectiveness assessments:

- Acne Scar Assessment Scale
- Subject Global Aesthetic Improvement Scale completed by subject at baseline, 1-month post-treatment, and 6-months post-treatment
- Safety Endpoint

Primary effectiveness endpoints

A double-blind, randomized, multicenter, controlled trial of the SkinPen Precision System has not been evaluated in the following patient populations:

- Pregnancy or nursing
- Allergy to titanium or steel
- Active acne
- Collagen vascular disease or cardiac abnormalities
- Diabetes
- Male
- Age 40 years or older
- Fitzpatrick Skin Type

Secondary effectiveness endpoints

Adverse event monitoring at each visit: day 1, 30, and 60, 1-month post-treatment, and 6-months post-treatment

Glossary of terms:

- A scar that grows outside the boundaries of the original scar.
- Partially or completely suppressing the immune response of skin.
- Blood thinner
- Anticoagulant

Australian, alive, American Indian, Alaska Native, Asian, Black, or African American, Hispanic or Latino, or those of multiple skin tones (pale to dark skin) were excluded from the SkinPen Precision device (7 male and 13 female), aged 21 years and older from various ethnic groups with multiple skin tones (pale to dark skin). All subjects were treated with the prototype device. Treatments were given on day 1, day 2, day 30, and day 60, with follow-up visits at 1 month and 6 months after the last treatment. Treatments were conducted by trained aesthetician (skin care specialist). The face was cleaned and numbed using anesthetic (lidocaine 1%). During the treatment, the device was instructed to start at 4.5-months post treatment and gradually increase the depth until redness was observed. Following treatment, SkinPen® Lift was applied to prevent the skin from drying-out post procedure.

2. CONTROINDICATIONS

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

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 84 subjects, 26 of which were exclusive to the SkinPen Precision device (13 male and 13 female), aged 21 years and older from various ethnic groups: 15 white; 12 black; 10 Asian; 5 Hispanic or Latino; 3 American Indian or Alaska Native; 2 African American; and 1 of multiple skin tones (pale to dark skin). All subjects were treated with the prototype device. Treatments were given on day 1, day 2, day 30, and day 60, with follow-up visits at 1 month and 6 months after the last treatment. Treatments were conducted by trained aesthetician (skin care specialist). The face was cleaned and numbed using anesthetic (lidocaine 1%). During the treatment, the device was instructed to start at 4.5-months post treatment and gradually increase the depth until redness was observed. Following treatment, SkinPen® Lift was applied to prevent the skin from drying-out post procedure.

- Vesicle
- A small blister on the skin
- Under the skin

The SkinPen® Precision System has been used safely and effectively in the following patient populations. Therefore, if you have a history of the following conditions or have taken the following medications, please inform your physician:

- Acne scar – A rough, scaly patch on your skin that develops from years of exposure to the sun.
- Active acne - Acne where there are currently pustules, cysts or lesions on the skin at the time of evaluation
- Adverse event monitoring at each visit; baseline, day 30, day 60, 1-month post-treatment, and 6-months post-treatment
- Subject safety diaries provided to the subject at each treatment visit (day 1, 30, and 60) and completed for 30 days to record treatment reactions.
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Table 5: Acne Scar Assessment Scale

Table 4: Study Endpoints

Primary effectiveness endpoints

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

The aesthetician would evaluate the scars they did not know which treatment or time point was represented in each photo. Details of each of these analyses are provided below in Tables 5-7. The results of the study are provided in Tables 8-9.
Subjects reported using the Patient Satisfaction Questionnaire:

Treatment with SkinPen Precision produced an improvement in SGAIS scores

Table 9: Change from Baseline for Photo Grading of Acne Scar Assessment

1 subject reported an insect/bug bite on the inner right thigh that was

• These responses were reported by 1 subject with FST III, 1 subject with FST VI,

• Burning in 4/41 (9%) of subjects lasting 1-3 days

• Rough Skin in 3/41 (7%) of subjects lasting from 1-2 days

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

Common Treatment Responses:

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

b. Does microneedling with the SkinPen® Precision hurt?

c. When should I call my doctor?

8. WHEN TO CALL YOUR DOCTOR?

b. Allergic reactions to the test material (s). Rare allergic reactions can consist

5. BEFORE TREATMENT INFORMATION

a. What happens in the office before the SkinPen® Precision treatment?

a. When should I call my doctor?

7. AFTER TREATMENT INFORMATION

a. What should I do if I have additional questions?

6. TREATMENT DESCRIPTION

a. What happens during the treatment?

Table 12: Results of Patient Satisfaction Questionnaire – Question 3

Table 10: Results of Patient Satisfaction Questionnaire - Question 1

Table 11: Results of Patient Satisfaction Questionnaire – Question 2

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

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

Table: Time Point N Subject Time Point N Mean Standard Treatment

Time Point N Subject

Time Point N Mean Standard Treatment

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Time Point N Mean Standard Treatment

Subjects reported using the Self-assessed Scar Improvement Scale:

Treatment with SkinPen Precision produced an improvement in SGRAS scores at 5-month post-treatment and 6-month post-treatment. At 1-month post-

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Subjects reported using the Subject Global Aesthetic Improvement Scale

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The SkinPen® Precision treatment may cause some minor discomfort during after

While individual results may vary, in the clinical study, the results were evaluated

The SkinPen® Precision treatment may cause some minor discomfort during after

different options for pain management will be discussed, and if pretreatment

Be sure to call your doctor if you:

You may be cautioned to avoid sun exposure and stop topical retinoid therapy 24

A layer of Skinfuse Lift HG is applied to the treatment area to protect the skin

You will be cleaned and then prepared with isopropyl alcohol or other antiseptic

In the informed consent process: skin will be red and flushed similar to a moderate

u. Two subjects reported no change. The mean value for the population was = 2.85

The investigator will review the informed consent process and conduct any

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For further questions and information, please call Bellus Medical

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2. Allergic reactions to the test material (s). Rare allergic reactions can consist

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