Before beginning your treatments please review this important information.

Glossary of Terms:
- Actinic keratosis: A rough, scaly patch on your skin that develops from years of exposure to the sun.
- Acne: A condition that causes pimples, whiteheads, blackheads, and cysts to form on the skin.
- Antimicrobials: Substances that kill or inhibit the growth of bacteria, or fungi.
- Beta-carotene: A pigment that is found in some fruits and vegetables, and in the body it is converted to vitamin A.
- Cystic acne: A type of acne that causes pus to form under the skin, leading to the formation of cysts.
- Diastase: An enzyme that is secreted into the mouth to begin the digestion of carbohydrates.
- Exacerbation of acne: An increase in the severity of acne symptoms.
- Fibroblasts: Cells that produce collagen and other proteins that are important for the growth and repair of tissue.
- Forehead: The part of the face between the eyebrows and the hairline.
- Great toe: The largest toe on the foot, located on the front, or volar side.
- Hyperkeratosis: An increase in the thickness of the skin.
- Hyperpigmentation: An increase in the darkness of the skin.
- Irregular: Not straight, smooth, or even.
- Keratinocytes: Cells that make up the outermost layer of the skin.
- Lesion: An area of tissue damage or disease.
- Linear: Shaped like a line or string.
- Malignant: Referring to cancer, which is a disease in which cells grow uncontrollably and can spread to other parts of the body.
- Microblading: A technique used to create eyebrows.
- Papilloma: A small, non-cancerous growth on the skin.
- Physical: Relating to the body or its functions, rather than the mind or emotions.
- Pustules: Small fluid-filled bumps on the skin.
- Scars: Marks left on the skin after an injury has healed.
- Tendon: A strong, fibrous tissue that connects a muscle to a bone.
- Topical: Relating to or applied to the skin.
- Vascular: Relating to blood vessels or the circulatory system.
- Xenon: A rare, colorless, odorless gas that is used in medical equipment.

Safety information was collected throughout the study using subject safety diaries. Safety diaries were provided to the subject at each treatment visit (day 1, day 30, and day 60). The subjects were instructed to record any observations and side effects related to treatment in the safety diary. Common treatment responses are side effects that result from treatment of the subject’s acne and are not adverse events. Adverse events are responses that may be categorized as adverse events when assessed by the investigator at the next visit. Subject safety diaries contained the following potential cutaneous responses: minimal, moderate, severe, or impossible. The informed consent form will be red and flushed similar to a moderate sunburn, skin tightness and mild sensitivity to the touch, redness, burning, tingling, stinging, itching, and/scaling (dryness, exema, shedding, scales, or desquamation), a possibility of developing an infection (an increase in redness, warmth, itching, or pus formation). The duration of open to record the occurrence of new or worsening adverse events up to 6 months post treatment. Adverse events were assessed by the investigator at each subsequent visit.

Side Effect Safety Questionnaire

Three questions were asked to the subjects in the study regarding their level of satisfaction with the treatment. It was included as a secondary endpoint in the study. See separate section in section 6.2.1.1.3.1.

Risks

- What side effects were seen in the clinical study?
  
  Common Treatment Responses:
  - At 6- and 12-month post-treatment visit, no adverse events were observed.
  
  Treatment-related changes in Subject Local Aesthetic Improvement Scale were observed in the subject diaries which were sent home with the subject.

  - Dryness: 8/43 (17%) subjects lasting from 1-4 days
  
  - These responses were reported by 3 subjects with FST II, 3 subjects with FST V, and 1 subject with FST V
  
  - Rough Skin: 2/43 (4%) subjects lasting from 1-2 days
  
  - These responses were reported by 2 subjects with FST II, and 2 subjects with FST V
  
  - Tightness in 2/43 (4%) of subjects lasting from 1-2 days
  
  - These responses were reported by 2 subjects with FST VI
  
  - Redness: 2/43 (4%) subjects lasting from 1-2 days
  
  - These responses were reported by 3 subjects with FST I, 3 subjects with FST V, 3 subjects with FST VI, and 2 subjects with FST VI
  
  - Burning in 1/43 (2%) of subjects lasting from 1-2 days
  
  - These responses were reported by 1 subject with FST I, 1 subject with FST VI, and 2 subjects with FST VI


- What adverse events were seen in the clinical study?

  1 subject reported an insect bite (on the inner right thigh that was determined to be minor) that was unrelated to SkinPen prototype device. 1 subject (1/4) [4%] reported a linear scar (linear red mark), 1 subject (1/4) reported that the forehead and both sides of the face) that was determined to be mild and possibly related to the treatment (SkinPen device). This adverse event may be due to subject exposure to excess sunlight soon after treatment was given for study instructions, yet resolved without any additional complications.

- c. What are other possible adverse events?

  Although not seen in the clinical study, patients may experience reactivation of herpes simplex infections (such as cold sores); warts; keloid scars; patients on anticoagulants; the body; immunosuppressive therapy; history of contact dermatitis; raised moles in the area that resolves over time, or no change in their acne scars.

- What will a SkinPen Precision Treatment accomplish, and what did the clinical study achieve?

  The study doctors reported using the Acne Scar Assessment Scale: Results of the photo grading indicated a significant improvement in acne scar assessment over the 6-month post-treatment period when compared with baseline with 51% (21/42) of subjects showing improvement at 6-months post-treatment when compared with baseline. At 12-month post-treatment, the remaining 9 subjects (46%) reported no change in score when compared to baseline. The visual improvements seen in the grading results were considered to be clinically relevant.

  Table 7: Subject Global Aesthetic Improvement Scale: Table 5: Summary of Demographic Information

<table>
<thead>
<tr>
<th>SkinPen Precision System</th>
<th>All Subjects</th>
</tr>
</thead>
<tbody>
<tr>
<td>N</td>
<td>20</td>
</tr>
<tr>
<td>Age (years)</td>
<td></td>
</tr>
<tr>
<td>Mean (Standard deviation)</td>
<td>43.8 (12.7)</td>
</tr>
<tr>
<td>Minimum, Maximum</td>
<td>21, 66</td>
</tr>
</tbody>
</table>

  Table 6: Self-assessed Scar Improvement Scale

<table>
<thead>
<tr>
<th>Subject Local Aesthetic Improvement Scale</th>
</tr>
</thead>
<tbody>
<tr>
<td>Description</td>
</tr>
<tr>
<td>1  -No change in appearance of acne scars</td>
</tr>
<tr>
<td>2  -5%-10% improvement in appearance of acne scars</td>
</tr>
<tr>
<td>3  -11%-25% improvement in appearance of acne scars</td>
</tr>
<tr>
<td>4  -26%-40% improvement in appearance of acne scars</td>
</tr>
<tr>
<td>5  &gt;40% improvement in appearance of acne scars</td>
</tr>
</tbody>
</table>

  Table 8: Results of Acne Scar Assessment Scale for SkinPen System

<table>
<thead>
<tr>
<th>Time Point</th>
<th>N</th>
<th>Subject Improved (%)</th>
<th>Subject Worsened (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>20</td>
<td>3.65 (0.2)</td>
<td>3.65 (0.2)</td>
</tr>
<tr>
<td>Day 30</td>
<td>20</td>
<td>2.74 (0.5)</td>
<td>2.74 (0.5)</td>
</tr>
<tr>
<td>Day 60</td>
<td>20</td>
<td>2.78 (0.55)</td>
<td>2.78 (0.55)</td>
</tr>
<tr>
<td>1-Month Post-Treatment</td>
<td>20</td>
<td>2.75 (0.45)</td>
<td>2.75 (0.45)</td>
</tr>
<tr>
<td>3-Month Post-Treatment</td>
<td>20</td>
<td>3.63 (0.58)</td>
<td>2.51 (0.58)</td>
</tr>
<tr>
<td>6-Month Post-Treatment</td>
<td>20</td>
<td>5.55 (0.8)</td>
<td>3.00 (0.8)</td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th>Time Point</th>
<th>N</th>
<th>Subject Improved (%)</th>
<th>Subject Worsened (%)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Day 1</td>
<td>20</td>
<td>3.65 (0.2)</td>
<td>3.65 (0.2)</td>
</tr>
<tr>
<td>Day 30</td>
<td>20</td>
<td>2.74 (0.5)</td>
<td>2.74 (0.5)</td>
</tr>
<tr>
<td>Day 60</td>
<td>20</td>
<td>2.78 (0.55)</td>
<td>2.78 (0.55)</td>
</tr>
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<td>1-Month Post-Treatment</td>
<td>20</td>
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<td>6-Month Post-Treatment</td>
<td>20</td>
<td>5.55 (0.8)</td>
<td>3.00 (0.8)</td>
</tr>
</tbody>
</table>
Subjects were informed of the following common treatment responses in the informed consent process: skin will be red and flushed similar to a moderate sunburn for at least 24 hours; skin tightness and mild sensitivity to touch; the skin may feel dry, burning, stinging, itching, and/or scaling/dryness, edema (swelling), tenderness/discomfort, a gap in definition, redness, and/or a history of hives, and itching.

NOTE: If you are allergic or sensitive to any of the following ingredients which are in the SkinPen® device, such as polyethylene oxide, polypropylene glycol, dimethyl sulfoxide, water, or fragrance, please consult your physician prior to treatment.

5. CLINICAL STUDY – WRINKLES

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 wrinkles on the neck.

The single-center study was conducted on a total of 15 subjects (male and female), aged 44 years and older from various ethnic groups with multiple skin tones (pale to dark skin). Treatment was administered on the day 1, day 10, day 60, and day 90 with follow-up visits at 1 month and 3 months after the last treatment. Under direct supervision of a licensed Physician, treatments were conducted by a trained aesthetician (skin care specialist). The face and neck was cleaned and numbed prior to treatment. At the end of the day, SkinPen LR was applied prior to treatment and protein found in friction during the procedure. The aesthetician was instructed to treat at depths of up to 2.5 mm. Following treatment, Skinfuse LR was applied to prevent the skin from drying out post procedure.

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

Common Treatment Responses on the face and neck:
- Dryness in 7/32 (22%) subjects lasting from 1-3 days
- Redness in 3/32 (9.4%) subjects lasting from 1-3 days
- Tingling in 2/32 (6.3%) subjects lasting from 1-3 days
- Scaling/dryness in 6/32 (19%) subjects lasting from 1-3 days

3. Patient Satisfaction Questionnaire

Subjects reported using the Subject Global Aesthetic Improvement Scale:
- Excellent improvement in appearance at the initiation of treatment, but not completely optimal
- Marked improvement in appearance at the initiation of treatment
- Significant improvement in appearance at the initiation of treatment
- Moderate improvement in appearance at the initiation of treatment
- Slight improvement in appearance at the initiation of treatment
- No improvement in appearance at the initiation of treatment

4. What adverse events were seen in the clinical study?

A total of 3 subjects reported adverse events, which were treated in a series of 4 treatments spaced 4 weeks apart. It is recommended to avoid other facial aesthetic treatments the month following your SkinPen Precision treatment.

5. After Treatment Information

A. What should I expect following the treatment?

Possible treatment responses include redness, rough skin, tightness, redness, itching, peeling, discomfort, tenderness, and burning. These conditions may resolve over time with gentle care.

Although not seen in the clinical study for acne scars, you may experience reactivation of herpes simplex virus (cold sore), pigment changes that include lighter or darker skin in the treated area, and/or no change in their acne scars.

B. Will I need more than one treatment to achieve my desired results for treatment of acne scars?

You should discuss treatment goals with your doctor. In the clinical study patients were treated in a series of 3 treatments spaced 4 weeks apart. It is recommended to avoid other facial aesthetic treatments the month following your SkinPen Precision treatment.

C. What is the potential for treatment of acne scars?

You should discuss treatment goals with your doctor. In the clinical study subjects were treated in a series of 4 treatments spaced 4 weeks apart. It is recommended to avoid other facial aesthetic treatments the month following your SkinPen Precision treatment.

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

You should discuss treatment goals with your doctor. In the clinical study patients were treated in a series of 4 treatments spaced 4 weeks apart. It is recommended to avoid other facial aesthetic treatments the month following your SkinPen Precision treatment.

E. How often should I have a re-treatment?

You should discuss treatment goals with your doctor. In the clinical study patients were treated in a series of 4 treatments spaced 4 weeks apart. It is recommended to avoid other facial aesthetic treatments the month following your SkinPen Precision treatment.

F. Will I need more than one treatment to achieve my desired results for treatment of acne scars?

You should discuss treatment goals with your doctor. In the clinical study patients were treated in a series of 4 treatments spaced 4 weeks apart. It is recommended to avoid other facial aesthetic treatments the month following your SkinPen Precision treatment.

G. Can I re-treat the same area?

You should discuss treatment goals with your doctor. In the clinical study patients were treated in a series of 4 treatments spaced 4 weeks apart. It is recommended to avoid other facial aesthetic treatments the month following your SkinPen Precision treatment.

H. Can I use any other facial aesthetic treatments the month following your SkinPen Precision treatment?

You should discuss treatment goals with your doctor. In the clinical study patients were treated in a series of 4 treatments spaced 4 weeks apart. It is recommended to avoid other facial aesthetic treatments the month following your SkinPen Precision treatment.

I. Can I use any other facial aesthetic treatments the month following your SkinPen Precision treatment?

You should discuss treatment goals with your doctor. In the clinical study patients were treated in a series of 4 treatments spaced 4 weeks apart. It is recommended to avoid other facial aesthetic treatments the month following your SkinPen Precision treatment.

J. Can I use any other facial aesthetic treatments the month following your SkinPen Precision treatment?

You should discuss treatment goals with your doctor. In the clinical study patients were treated in a series of 4 treatments spaced 4 weeks apart. It is recommended to avoid other facial aesthetic treatments the month following your SkinPen Precision treatment.

K. Can I use any other facial aesthetic treatments the month following your SkinPen Precision treatment?

You should discuss treatment goals with your doctor. In the clinical study patients were treated in a series of 4 treatments spaced 4 weeks apart. It is recommended to avoid other facial aesthetic treatments the month following your SkinPen Precision treatment.

L. Can I use any other facial aesthetic treatments the month following your SkinPen Precision treatment?