**GLYCOHYDROGEL: Term**

Glucosamine: A sugar, levels are too high

**Acutane** - A carbohydrate that induces sensitivity to a medication or treatment

Anesthetic: A substance that induces insensitivity to pain, a numbing agent

Antioxidant: Blood thinning

Cardiovascular abnormality – Abnormal heart/blood vessel structure or function

Contraindication: A medical condition or situation that contraindicates the use of a medication

Diabetes: A disease in which the body does not process glucose, or blood sugar, levels are too high.

Eczema – A condition that makes your skin red and itchy.

 Fitzpatrick Skin Types: A number of skin types for individuals

Hormone: Abnormal blood/blood vessel structure or function

Immunosuppressive: A process or compound that suppresses the immune response of an individual

Inflammatory: A condition that affects your skin and sometimes your eyes. It causes redness and pimpls

Scleroderma: A number of rare diseases that involve the hardening and tightening of the skin and connective tissue

Sequela: Any complications that follow a medical illness or event

Side effect: An unexpected reaction to a medication or treatment that is used in an approved manner

Skin strad: A linear mark, slight mark, or groove

Transdermal – Under the skin

Vein: A small blood vessel on the skin

**1. PRODUCT DESCRIPTION**

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

The SkinPen Precision System is a minimally invasive, micro-needling device intended for use on the facial skin. The SkinPen Precision System is comprised of a reusable motor unit designed to be attached to sterile, disposable cartridges that contain 14 micro-needles (750 µm in diameter) on a removable handle that, when activated and placed properly against the skin can create hundreds to thousands of microscopic punctures in the skin’s outer layers. As these punctures heal, the remaining process works to improve the appearance of the area with acne scars. The SkinPen Precision System’s patented-pending cartridge design inhibits the entrance of fluid into the device which allows both biologic and photoactive ingredients help to prevent potential cross-contamination of the motor unit between uses. It is for use by a physician or other qualified healthcare professional only.

**b. Who is candidates?**

The SkinPen Precision System is intended to be used as a treatment to improve the appearance of facial acne scars in adults aged 22 years or older. The SkinPen Precision System’s clinical study was conducted in 21 adult women and men ranging from light to very dark skin Fitzpatrick skin type I to VI. Clinical study was conducted on adult men and women of various skin colors. Clinical study was conducted on adults aged 22 years or older. The SkinPen Precision System is not intended for use on children, pregnant, or nursing women.

**2. CONTRAINDICATIONS**

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

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 products or anesthetics

- Have a hematoma (bleeding disorder or hemorrhagic bleeding) dysphagia, pre-pro or nursing

- Are currently taking drugs with the ingredient isotretinoin (such as Acutane)

NOTE: This product is not intended for transgender (under the skin) delivery of topical products such as cosmetics, drugs, or biologics.

**3. PRECAUTIONS**

**a. What precautions should my doctor advise me about?**

The SkinPen Precision System should not be used in the following patients’ population:

- If you have a history of the following conditions or have taken the following medications, please let your doctor know, as treatment with the SkinPen Precision System may not be indicated for the following dermatologic conditions:
  - Keratosis; active acne; collagen vascular diseases or cardiac abnormalities.
  - Active acne
  - Pregnancy or nursing
  - Allergic reaction to any of the ingredients: Carbomer, potassium hydroxide, disodium EDTA, Phenoxyethanol, Caprylyl glycol, and Isotretinoin (such as Accutane)

**b. Are there any precautions I should be aware of?**

The following precautions are to be considered:

- This procedure is not intended for use in the following conditions or have taken the following medications:
  - Keratosis; active acne; collagen vascular diseases or cardiac abnormalities.
  - Active acne
  - Pregnancy or nursing
  - Allergic reaction to any of the ingredients: Carbomer, potassium hydroxide, disodium EDTA, Phenoxyethanol, Caprylyl glycol, and Isotretinoin (such as Accutane)

- Avoid using any of the following products 48 hours prior to treatment:
  - Non-comedogenic oil
  - Sunscreen
  - Makeup
  - Lip Balm
  - Any other products that may interfere with the healing process

- Avoid taking any of the following medications 48 hours prior to treatment:
  - Antibiotics
  - Oral contraceptives
  - Blood thinning medications

- Avoid taking any of the following medications 48 hours prior to treatment:
  - Non-comedogenic oil
  - Sunscreen
  - Makeup
  - Lip Balm
  - Any other products that may interfere with the healing process

- Avoid taking any of the following medications 48 hours prior to treatment:
  - Antibiotics
  - Oral contraceptives
  - Blood thinning medications

**4. CLINICAL STUDY**

**a. How was the product studied?**

A clinical study was conducted to study the safety and effectiveness of the SkinPen Precision System from the Fitzpatrick skin type I to VI. The single center study was conducted on a total of 43 subjects, 20 of which were included to the SkinPen Precision device 7 male and 33 female), aged 21 years and older from various ethnic groups with multiple skin tones (pale to dark). The device was used for one treatment session. Treatments were given on day 1, day 30, Day 60, and Day 60, with follow-up visits at 1, 3, 6, and 12 months.

SkinPen treatments were conducted by a trained aesthetician (skin care specialist). The device was used for one treatment session. Treatments were given on day 1, day 30, Day 60, and Day 60, with follow-up visits at 1, 3, 6, and 12 months.

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

The appearance is worse than the original condition.

**c. When can I expect results?**

In addition to the clinician graded effectiveness assessments, the following patient-reported measures were recorded throughout the study.

- **Self-Assessed Scar Score Improvement Scale**

**5. Self-Assessed Scar Score Improvement Scale**

**Rating Description**

- **No**
  - Erosion of Acne Scars

- **Very Good**
  - Improvement in appearance of acne scars

- **Excellent**
  - Marked improvement in appearance of acne scars

- **Moderate**
  - Improvement in appearance of acne scars
Question 1: Do I notice any improvement in how my acne scars look in the mirror?

Question 2: How would you characterize your satisfaction with the results of the SkinPen Precision treatment?

Question 1: Do I notice any improvement in how my acne scars look in the mirror?

Question 2: How would you characterize your satisfaction with the results of the SkinPen Precision treatment?