

**CONSENT FORM  
AGREEMENT TO BE IN A RESEARCH STUDY**

**PROTOCOL NUMBER AND TITLE OF STUDY:** [REDACTED] “A Proof of Concept Study to evaluate the efficacy and tolerability of Microneedling with SkinPen in female and male Subjects with facial Acne Vulgaris, ages 22 through 45”

**NAME OF PERSON IN CHARGE OF THE RESEARCH STUDY (STUDY DOCTOR/INVESTIGATOR):**

[REDACTED]

**TELEPHONE NUMBER(S), DAYTIME:  
AFTER HOURS:**

[REDACTED]

**INTRODUCTION:**

You are deciding if you would like to volunteer for a research study. You must read and sign this form before you agree to take part in this study. This form will give you more information about this study. Please ask as many questions as you need to before you decide if you want to be in the study. Do not sign this form if you have any questions that have not been answered.

The Physician is the Principal Investigator at Crown Laboratories, the company that owns the SkinPen Microneedling Device.

**PURPOSE OF STUDY:**

This proof of concept study is being conducted in order to assess the efficacy and tolerability of microneedling in treating Acne Vulgaris on the face.

**DURATION OF STUDY:**

Approximately 5 months. Duration of study may be subject to change by Sponsor/Investigator-see below.

**DESCRIPTION OF PROCEDURE:**

Subjects will be pre-screened by [REDACTED] a recruitment service provider and Crown laboratories Research Staff. A total of 15 Subjects aged 22 to 45 with Investigator’s Global Assessment(IGA) score between 1 and 3 on the face are expected to complete this study. All Subjects will be completing a total of 4 clinic Visits. There will be 3 Microneedling Treatment Visits (Baseline/Visit 1, Visit 2 and Visit 3) and 1 Follow Up Visit(Visit 4). All Subjects will be completing diaries between visits to capture any adverse events. During Study Visits, the Investigator or designee will obtain photographs. You will be given instructions on usage of post microneedling products. All female Participants will undergo a pregnancy screen.

**Baseline: Visit 1**

1. You will be given an IRB-approved informed consent form (ICF) to read and sign. You will have all study related questions answered by the Investigator or a designated staff, and if you agree, you will sign 1 copy of the ICF. You will receive a copy, and the original will be kept in the study file.
2. You will be screened by the Investigator or a qualified designee for qualification criteria.
3. Standard photography using a [REDACTED] camera will be performed.
4. You will participate in pregnancy screening procedures, if applicable.
5. If applicable, if you arrive having not removed all make-up, you will be required to remove the make-up at the clinic and wait at least 15 minutes prior to other procedures.
6. A numbing cream will be applied to the face for at least 20-30 minutes before a trained Clinical Research Coordinator or the Investigator will treat your face from hairline to jawline with the SkinPen Precision System following instructions in IFU. A trained Clinical Research Coordinator or the Investigator will treat the face at depths of up to 1.5mm. Treatment depth will be recorded for each treatment at every visit.
7. You will be provided with a safety diary and trained on compliance.
8. You will be offered the SkinFuse regimen including cleanser, sunscreen, and moisturizer, and trained on proper use. It is up to your discretion if you will utilize this regimen.
9. Next visit to be scheduled

This visit will last approximately 3 hours

**Day 30: Visit 2**

1. You will return to the clinic for evaluation at Day 30 (+/-5 days).
2. Standard photography using a [REDACTED] camera will be performed.
3. After acclimation, the lesion count and IGA will be completed prior to treatment.
4. A numbing cream will be applied to the face for at least 20-30 minutes before a trained Clinical Research Coordinator or the Investigator will treat your face from hairline to jawline with the SkinPen Precision System following instructions in IFU. A trained Clinical Research Coordinator or the Investigator will treat the face at depths of up to 1.5mm. Treatment depth will be recorded for each you at every visit.
5. The safety diary will be reviewed, and a new diary will be dispensed to you.
6. Any adverse events will be reviewed.
7. If applicable, your SkinFuse regimen use will be reviewed
8. Next visit will be scheduled

This visit will last approximately 2 hours

**Day 60: Visit 3**

All the procedures completed at Visit 2 (above) will be done at this Visit.

**Day 120(2Months post last procedure): Visit 4**

1. You will return to the clinic for a follow-up evaluation 2 months post last microneedling treatment(+/- 5 days)
2. Standard Photography using a [REDACTED] camera will be performed
3. Lesion Count Assessment and IGA will be performed.
4. Any adverse events will be reviewed.

5. The safety diary will be reviewed
6. You will complete the Patient Satisfaction Questionnaire

**REQUIREMENTS:**

You must report for all scheduled appointments; avoid direct sun exposure and tanning beds; should not use any other facial skin treatment products, apply any other products, or otherwise tamper with the skin on the face.

**IF YOU GET A TAN IF YOU ARE NON-COMPLIANT WITH THE REQUIREMENTS OF THE STUDY, YOU WILL BE DISMISSED.**

List of products for post treatment usage:

- Purify Cleansing Complex
- Reclaim Hydrating Support
- Shield SPF 30

**Could your participation end early?** There are several reasons why the researchers may need to end your participation in the study (early withdrawal). Some reasons are:

- The researcher believes that it is not in your best interest to stay in the study.
- You become ineligible to participate.
- Your condition changes and you need treatment that is not allowed while you are taking part in the study.
- You do not follow instructions from the researchers.
- The study is stopped.

**ANTICIPATED RISKS AND POSSIBLE SIDE EFFECTS:**

Because of your participation in this study, you are at risk for the following side effects. You should discuss these with the researchers and your regular health care provider.

The SkinPen Precision System may cause some, all, or none of the side-effects listed below:

- red/flushed appearance, similar to a moderate sunburn
- skin tightness
- mild sensitivity to touch

Supporting products used during the study may cause some minor side-effects such as:

- subjective sensations (such as itching, burning, stinging and/or tingling)
- scalding/dryness
- redness
- edema
- and tenderness/discomfort

Photography

You may be uncomfortable with sitting still for an extended period of time or from turning your body in various positions. You may be sensitive to the bright lights, which can sometimes cause headaches, irritation of the eyes, discomfort, after-effects such as seeing spots, and in rare cases, could stimulate a migraine headache or epileptic seizure.

Photos will only be identified by a unique subject identification number that contains no personal identifying information.

Loss of Confidentiality

Any time information is collected; there is a potential risk for loss of confidentiality. Every effort will be made to keep your information confidential; however, this cannot be guaranteed.

Risks to Sperm, Embryo, Fetus or Breast-fed Infant

**Males:** Being in this research may damage your sperm, which could cause harm to a child that you may father while on this study. If you take part in this study and are sexually active, you must agree to use a medically-acceptable form of birth control. Medically-acceptable forms of birth control include:

- (1) surgical sterilization (vasectomy), or
- (2) a condom used with a spermicide (a substance that kills sperm).

**Females:** If you are part of this study while pregnant or breast-feeding an infant, it is possible that you may expose the unborn child or infant to risks. For that reason, pregnant and breast-feeding females cannot participate in the study. If you take part in this study and you are sexually active, you and any person that you have sex with must use medically-acceptable birth control (contraceptives) during the study. Medically-acceptable birth control (contraceptives) includes:

- (1) surgical sterilization (such as hysterectomy or “tubes tied”),
- (2) approved hormonal contraceptives ( such as birth control pills, patch or ring; Depo-Provera, Implanon),
- (3) barrier methods (such as condom or diaphragm) used with a spermicide (a substance that kills sperm), or
- (4) an intrauterine device (IUD).

If you do become pregnant during this study, you must tell the researchers immediately.

Other Risks

There may possibly be other side effects that are unknown at this time. If you are concerned about other, unknown side effects, please discuss this with the researchers.

**COMPENSATION:**

[REDACTED]

You will be paid per completed visit as follows:

<b>Visit</b>			)
Baseline/Visit 1			
Visit 2			
Visit 3			
Visit 4			

[REDACTED]

\*In the event that the study is changed by the Sponsor (for example, cancellation of study or number and/or duration of the visits), the payment schedule may be changed to reflect this alteration in study design.