

# SAMPLE

## SkinPen® Patient Consent Form

This verbiage is a suggestion only and should be approved and used to create or incorporate into your own consent form. The below is a reference guide only and should be reviewed by your own legal counsel.

### What is the purpose of this form?

The purpose of this form is to help inform you and to help you decide if you want to have this procedure done to you. You should take part in the procedure only if you want to.

Before you decide if you want to take part in this procedure, it is important that you read the information below. This form may use words you do not understand. Please ask the doctor or the clinic staff to explain any words or procedures that you do not clearly understand.

### Description of the Procedure

The SkinPen® Precision system is a microneedling device and accessories intended to be used as a treatment to improve the appearance of facial acne scars in adults aged 22 years or older.

Microneedling procedures are performed in a minimally-invasive (little to no introduction of the instrument into the body) and precise manner with the use of the sterile needle head. The procedure is normally completed within 30–60 minutes, depending on the required procedure and anatomical site.

### Side Effects

After the procedure, the skin will be red and flushed in appearance, like a moderate sunburn. You may also experience skin tightness and mild sensitivity to touch on certain areas. This will diminish significantly within a few hours following the procedure. Within the next 24 hours, the skin will often appear to have returned to normal. After three days, there is rarely evidence that the procedure has taken place.

### Contraindications

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 stainless steel or anesthetics

- Have a hemorrhagic (bleeding) disorder or hemostatic (bleeding) dysfunction
- Are pregnant or nursing
- Are currently taking drugs with the ingredient isotretinoin (such as Accutane)

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

### Precautions and Warnings

Safety and Effectiveness for settings greater than 1.5 mm has not been evaluated. Universal precautions are necessary during microneedling. Microneedling should not be used within the orbital rim of the eye, such as the eyelids. The SkinPen Precision System has not been evaluated in the following patient populations (i.e. patients with the following conditions or taking the following medications): Actinic (solar) keratosis; active acne; collagen vascular diseases or cardiac abnormalities; diabetes; eczema, psoriasis and other chronic conditions in the treatment area or on other areas of the body; immunosuppressive therapy; history of contact dermatitis; raised moles in the treatment area; rosacea; active bacterial, fungal, or viral infections (i.e. herpes, warts); keloid scars (a scar that grows outside of the boundaries of an original scar); patients on anticoagulants; scars and stretch marks less than one year old; scleroderma; and wound-healing deficiencies.

### Alternative Methods

There may be alternative treatment or procedures to microneedling. Please speak with your doctor to which alternatives may provide similar treatment for your skin condition.

### Patient Consent

I understand that results of microneedling procedures will vary among individuals. I understand that although I may see a change after my first procedure, I may require a series of sessions to obtain my desired outcome.

The procedure and side effects described in this consent have been explained to me including alternative methods, as have the advantages and disadvantages of microneedling.

I have been advised that though good results are expected, the possibility and nature of complications cannot be accurately anticipated, therefore, there can be no

guarantee as expressed or implied either as to the success or other results of the microneedling procedure. I am aware that the microneedling procedure is not permanent and natural degradation may occur over time.

I have read (or it has been read to me) and I understand this consent and I understand the information contained in it.

I have had the opportunity to ask any questions about the microneedling procedure including risks or alternatives, and I acknowledge that all my questions about the procedure have been answered in a satisfactory manner.

This consent form is valid until all or part is revoked by me in writing.

Print Name:

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Signature:

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Date:

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Clinic Name:

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