

SkinPen® Precision Patient Consent Form

What is the purpose of this form?

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

SkinPen® Precision, the first-to-market and U.S Food and Drug Administration-cleared microneedling device clinically-proven solution to safely and effectively improve the appearance of facial acne scars for people age 22 and above. The SkinPen also improves the appearance of wrinkles on the neck.

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 on the face. 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.

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.



The logo for SkinPen, featuring the brand name in a large, blue, sans-serif font. Below the brand name, the text "BY CROWN AESTHETICS" is written in a smaller, blue, sans-serif font.

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

Print Name: _____

Signature: _____

Date: _____

Clinic Name: PARAGON PHYSICAL MEDICINE

Please circle yes or no to the following questions:

1. Are you at least 22 years of age?
YES NO
2. Are you allergic to tetracaine, lidocaine, or benzocaine?
YES NO
3. Any allergies to stainless steel or anesthetics?
YES NO
4. Has it been at least 6 months since you have used any drugs with the active ingredient isotretinoin (like Accutane)?
YES NO
5. Is there any chance you could be pregnant or nursing?
YES NO
6. Have you been diagnosed with any bleeding disorders/ dysfunctions?
YES NO
7. Are you taking any blood thinners on a daily basis?
YES NO
8. Do you have any open sores, wounds, irritated skin, or cysts within the treatment area?
YES NO
9. Do you have any active infections, viral issues (including herpes) within the treatment area?
YES NO
10. Are you taking any immunosuppressants?
YES NO
11. Are there any scars or stretchmarks within the treatment area that are less than a year old?
YES NO
12. Do you have active skin cancer in the treatment area?
YES NO
13. Have you ever been diagnosed with cancer of any kind?
YES NO

*If YES, have you been diagnosed as clear for at least a year by an oncologist? _____

What are your goals for treatment with the skin pen? _____



Paragon Physical Medicine/Chaffee Chiropractic Clinic Inc
242 E Milltown Rd, Wooster, OH 44691, (330)345-4440

PATIENT INFORMATION

First Name _____ MI _____ Last Name _____ Date ____/____/____

Address _____ City _____ ST _____ Zip _____

Home Phone# _____ Work# _____ Cell# _____

Email _____ Social Security _____

Birth Date ____/____/____ Age _____ Gender: Male Female

Family Physician and Clinic: _____

Do we have permission to discuss this case with another family member Y or N Whom: _____

Whom may we thank for referring you to our office _____

Person financially responsible for this account _____

Spouse _____ Your Employer _____

Phone# _____ Phone# _____

Address _____ Address _____

DOB _____ SS# _____ Emergency Contact _____

Place of Emp _____ Relation & Phone# _____

Email _____

INSURANCE INFORMATION

Ins. Co. Name _____

Policy#: _____

Group#: _____

Subscriber's Name: _____

Subscriber's Birth Date: _____

Subscriber's SS#: _____

Insured Add: _____

Employer of Insured: _____

Secondary Ins. _____

Policy#: _____

Group#: _____

Subscriber's Name: _____

Subscriber's Birth Date: _____

Subscriber's SS #: _____

Insured Add: _____

Employer of Insured: _____

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NOTICE OF PRIVACY PRACTICES

THIS NOTICE DESCRIBES HOW MEDICAL INFORMATION ABOUT YOU MAY BE USED AND DISCLOSED AND HOW YOU CAN GET ACCESS TO THIS INFORMATION. PLEASE REVIEW IT CAREFULLY.

Uses and Disclosures: We will use and disclose elements of your Protected Health Information (PHI) in the following ways:

- Without your signed authorization
- Chiropractic treatment
- Payment (cash, insurance, worker's compensation, personal injury)
- When release is required by law, including in judicial settings and to health oversight regulatory agency and law enforcement
- In emergency situations or to avert serious health/safety situations
- To medical examiners, coroner or funeral directors to aid in identifying you or to help them in performing their duties.

Special Cases

To contact you about appointment reminders, treatment alternatives and other health related benefits and services

Other

All other uses and disclosures by us will require us to obtain from you a written authorization in addition to any other permission you will provide us.

Your Rights

Restrictions: To request restricted access to all or part of the PHI, write specific information on your patient information and contact our insurance department. We are not required to grant your request.

Confidential Communication: To receive correspondence of confidential information by alternate means or location, contact our insurance or front desk department.

Access: To inspect or receive copies of your PHI, you must sign a consent form.

Amendments: To request changes made to your PHI, contact our insurance department. We are not required to grant your request.

Accounting: To receive an accounting of the disclosures by us of your PHI in the six years prior to your request, contact our insurance department.

This Notice: To get updates or reissue of this notice, contact our front desk department.

Complaints: Complaints to Paragon Physical Medicine/Chaffee Chiropractic Clinic Inc or the U.S. Department of Health & Human Services. If you feel your privacy rights have been violated, register your complaint in writing to Dr. Bryce Chaffee. The law forbids us from taking retaliatory action against you if you complain.

Our Duties

We are required by law to maintain the privacy of your PHI. We must abide by the terms of this notice or any update of this notice.

Privacy Contact: For more information about our privacy practices, please contact this clinic at:

PPM/Chaffee Chiropractic Clinic Inc, 242 East Milltown Road, Wooster, Ohio 44691, (330) 345-4440

Effective date: April 14, 2003

I acknowledge receipt of this notice:

_____/_____/_____
_____/_____/_____
Patient or Authorized Signature **Printed Name** **DOB** **Date**

If you are signing as the patient's representative:

Patient's Printed Name

Relationship to Patient

**ASSIGNMENT OF HEALTH PLAN BENEFITS AND RIGHTS
AS WELL AS AN
APPOINTMENT AND/OR DESIGNATION AS MY PERSONAL REPRESENTATIVE AND AN ERISA/PPACA REPRESENTATIVE AND BENEFICIARY**

I understand and agree that (regardless of whatever health insurance or medical benefits I have), I am ultimately responsible to pay **Paragon Physical Medicine/CHAFFEE CHIROPRACTIC CLINIC INC, DR BRYCE CHAFFEE, DR TAMI CHAFFEE, CHRISTINA COOK, CNP** as well as all employees, employers, representatives, and agents thereof, (hereinafter collectively referred to as "Healthcare Provider") the balance due on my account for any professional services rendered and for any supplies, tests, or medications provided. I hereby authorize payment of, and assign my rights to, any health insurance or medical plan benefits directly to Healthcare Provider for any and all medical/healthcare services, supplies, tests, treatments, and/or medications that **have been or will be** rendered or provided; as well as designating and appointing Healthcare Provider as my beneficiary under all health insurance or medical plans which I may have benefits under. I hereby authorize the release of any health status, conditions, symptoms or treatment information contained in your records that is needed to file and process insurance or medical plan claims, to pursue appeals on any denied or partially paid claims, for legal pursuit as to any unpaid or partially paid claims, or to pursue any other remedies necessary in connection with same. I hereby assign directly to Healthcare Provider all rights to payment, benefits, and all other legal rights under, or pursuant to, any health plan (including, but not limited to, any ERISA governed plan/insurance contract, PPACA governed plan/insurance contract) rights that I (or my child, spouse, or dependent) may have under my/our applicable health plan(s) or health insurance policy(ies). I also hereby appoint and designate that Healthcare Provider can act on my/our behalf, as my/our Personal Representative, ERISA Representative, and PPACA Representative as to any claim determination, to request any relevant claim or plan information from the applicable health plan or insurer, to file and pursue appeals and/or legal action (including in my name and on my behalf) to obtain and/or protect benefits and/or payments that are due (or have been previously paid) to either Healthcare Provider, myself, and/or my family members as a result of services rendered by Healthcare Provider, and to pursue any and all remedies to which I/we may be entitled, including the use of legal action against the health plan, the insurer, or any administrator. I hereby also declare that Healthcare Provider is my/our beneficiary regarding my/our health plan as contemplated by both ERISA and PPACA, and that Healthcare Provider can pursue any and all rights that I/we may have under state and/or federal law regarding my/our health plan. This assignment, appointment, and designation will remain in effect unless revoked by me in writing. *It is my intent that the effective date of this document shall relate back to include all services, supplies, test, treatments, or medications that have been previously provided by Healthcare Provider.* A photocopy or scan or this document is to be considered as valid and as enforceable as the original.

Signed this _____ day of _____, 20 ____.

X _____ DOB ____/____/_____
(patient signature)

X _____
(signature of Guardian if applicable)

X _____
(please print patient name)