

**ROD J. ROHRICH, M.D.**  
**PLASTIC SURGERY**

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**MICRONEEDLING CONSENT FOR TREATMENT**

**Description of Microneedling Procedure**

The SkinPen FDA approved Microneedling device is used for Microneedling the skin also known as Collagen Induction Therapy (hereinafter referred to as “Procedure(s)” or “Microneedling” or “Microneedling treatment” or “Micropen treatment”), is an elective procedure that is intended to allow for controlled induction of the skin’s self-repair mechanism by creating micro “injuries” in the skin which triggers new collagen synthesis. The intended result is smoother, firmer and younger looking skin. Skin needling procedures are performed in a safe and precise manner with the use of the sterile SkinPen FDA approved Microneedling needle head. The procedure is normally completed within 30-60 minutes depending on the required treatment and anatomical site.

**Effects of Microneedling Procedures**

After the Microneedling procedure, the skin will be red and flushed in appearance in a similar way to a moderate sunburn. You may also experience skin tightness and mild sensitivity to touch on the area being treated. It is anticipated that the skin’s redness will diminish greatly after 24 hours following the treatment. There may be peeling of the skin in some people in certain areas of the face which were treated. Generally, after 3 days the skin will return to a near-normal appearance.

Short term pinkness or redness of the skin where the treatment is performed is common. Swelling of the area is uncommon but can last 2-3+ days.

**Precautions and Warnings of Microneedling**

Precautions must be taken in the following conditions and circumstances: discontinue auto-immune therapies or retinoid (Retin-A) or other forms of skin treatment 24 hours prior to procedures under care and directions of a physician; active acne, rosacea or other inflammatory condition; open wounds; facial outbreaks such as herpes simplex where medications must be taken per doctor’s instructions; metal allergies or skin allergies; skin medications that would affect the characteristics of the skin 2 months prior to the treatment; facelift or eye lift surgery in the last year; dermabrasion, remodeling, deep chemical peels or any surgical procedure on the treatment area within previous 3 months; Botox, Collagen, fat or other methods of augmentations with injected materials in the treatment area in past 6 months; sunburned skin in last 2 weeks or someone who has excessively tanned in past 2 weeks; Fitzpatrick skin types V-VI.

Topical lidocaine and tetracaine is used with microneedling and will be contra-indicated if you have a known allergy to lidocaine. An undetected allergy to lidocaine or tetracaine could cause itching, shortness of breath, swelling or respiratory distress.

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**Contraindications for Microneedling**

Keloid scars; history of eczema, psoriasis and other chronic conditions; history of actinic (solar) keratosis; history of Herpes Simplex infections; history of hemophilia; history of diabetes; the presence of raised moles, warts on the targeted area. Absolute contraindications include; scleroderma, collagen vascular diseases or cardiac abnormalities; use of Accutane in prior 6 months; blood clotting problems; active bacterial or fungal infection; facial melanosis; malignant tumors, immunosuppression; use of blood thinners or prednisone; pregnant or nursing women; corticosteroids within two weeks of procedure, chronic liver disease, porphyria or other skin diseases.

**Risks of Microneedling**

*Inherent Risks of Microneedling*

Every procedure involves a certain amount of risk and it is important that you understand the risks involved with Microneedling. An individual's choice to undergo Microneedling is based upon the comparison of the risk to potential benefit. Although the following potential complications have not been observed in the majority of patients, you should discuss each of them with your medical provider to make sure you understand the risk, potential complications, and consequences Microneedling.

*Specific Risks of Microneedling*

**Bleeding.** It is possible, though unusual, that you may have problems with bleeding during a Microneedling treatment. Should post-procedure bleeding occur, it will usually only consist of a few drops or pinpoint areas. Accumulations of blood under the skin may cause a bruise or *hematoma*. The occurrence of this is not predictable.

**Infection.** Infection is possible, although unusual after Microneedling treatment. Should an infection occur, additional treatment, including antibiotics, could be necessary.

**Scarring.** No scarring is to be expected from Microneedling treatment. Scars have been observed in Micropen rollers which we do not use and are not the same as the FDA approved SkinPen.

**Damage to Deeper Structures.** Deeper structures such as blood vessels and muscles are rarely damaged during the course of a Microneedling treatment. If this does occur, the injury may be temporary or permanent.

**Bruising and Puffiness.** There is a possibility of bruising (hematomas), puffiness, itching, warmth, pain or other symptoms at the site of the Microneedling.

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***Nerve Injury.*** It is unusual to experience injuries to the motor or sensory nerves Microneedling treatment(s). However, if they occur, injury to the motor or sensory nerves may cause temporary or permanent loss of facial movements and feeling. Such injuries may improve over time. Injury to sensory nerves of the face, neck and ear regions may cause temporary or more rarely permanent numbness. Painful nerve scarring is very rare.

***Needle Shock.*** Needle shock from Microneedling treatments is a rare event. Needle shock is a reaction to the needling that is typically immediate and may include such symptoms as malaise, perspiration, nausea, fainting, or loss of consciousness in extreme situations. In the event this happens, the Microneedling is immediately discontinued until recovery. Needle shock is a rare complication during and after Microneedling treatment.

***Unsatisfactory Result.*** Although good results are anticipated, there is no guarantee or warranty express or implied, of the results that may be obtained from Microneedling treatment(s). Some patients do not achieve their desired goals or results, notwithstanding proper procedures being followed by the medical provider, relating to the Microneedling treatment(s). You may be disappointed with the Microneedling treatment(s). It may be possible but by no means a certainty to improve your results with additional treatments.

***Allergic Reactions.*** An allergic reaction although not common is possible with the use of local anesthetic which may include swelling, itchy, bruising, local discomfort, redness or itching. In rare cases, a severe allergic reaction to anesthetics may cause shortness of breath, respiratory distress or seizures.

***Delayed Healing.*** Microneedling treatment(s) uses micro-injury to the skin to build collagen. This process may be delayed based on your own body's collagen production. Collagen production can take longer in older patients and due to external factors, such as diet, sun exposure and lack of sleep can delay collagen synthesis, therefore, delaying or minimizing the effect of Microneedling treatment(s).

***Mental Health Disorders and Elective Treatments.*** It is important that all patients seeking to undergo elective treatments, including Microneedling treatment(s), have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are possible, may require additional treatments and are often stressful. Please discuss any questions you have with your medical provider, prior to Microneedling treatment, including any history that you may have of significant emotional depression or mental health disorders. Although many individuals may benefit psychologically from the results of elective Microneedling treatment(s), effects on mental health cannot be accurately predicted.

***Long Term Effects.*** Subsequent alterations in facial appearance may occur as the result of the normal process of aging, weight loss or gain, sun exposure, or other circumstances not related to Microneedling treatment(s). Microneedling treatment does not arrest the aging process or

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produce permanent tightening of the face and neck. Microneedling treatment(s), or other treatments, may be necessary to maintain the positive results of Microneedling treatment(s).

**The Use of Anesthesia**

Local anesthesia is used to reduce pain during Microneedling. A topical numbing cream containing lidocaine and tetracaine is applied to the face 15-30 minutes prior to the procedure. This will create a feeling of numbness in the face or areas it is applied to that can last hours after the procedure. This will create a feeling of numbness in the face or areas it is applied to that can last hours after the procedure.

An allergic reaction although not common is possible with the use of the described anesthesia above. An allergic reaction may cause itching and redness locally to the skin or in system reactions, including, local discomfort, swelling, bruising, wheezing, systemic itching, shortness of breath, respiratory distress or seizures.

**Informed Consent for Microneedling**

I have reviewed this Informed Consent Form and I understand the risks and potential benefits of Microneedling treatment(s), hereinafter, the “Procedure” or the “Treatment.” I have been given the opportunity and have had all of my questions answered by my Physician and/or Medical Provider. I understand that I have the right to consent to or refuse the proposed Treatment at any time prior to its performance and have elected to proceed with the Procedure and my signature below shall evidence my consent, approval, and authorization to proceed. I understand that positive results are not guaranteed. I further understand that negative complications could occur. I do not expect the medical provider to anticipate and or explain all possible risks and complications. I rely on the medical provider to exercise their professional judgment during the course of treatment with regard to this Procedure. I understand that the Treatment or recommendation provided to me as a patient are not mutually exclusive from any treatment or advice that I may receive now, or in the future, from another licensed health care provider. I have read and understood all of the above foregoing information and have been informed, to my satisfaction, of potential side effects and risks that may be associated with the Procedure.

I understand that results will vary among individuals. I understand that I may not see a change after my first treatment and that even after a series of sessions, I may not experience my desired outcome. The procedure contraindications and warnings have been explained to me including alternative methods; as have the advantages and disadvantages. I am advised that though good results are expected, the possibility and nature of complications cannot be accurately anticipated and that, therefore, there can be no guarantee as expressed or implied either as to the success or other results of the treatment.

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I understand that Microneedling is an “Elective” procedure that I am voluntarily electing to do and not covered by insurance and payment is required in full for all treatments at the time of service. I am aware that any positive effects of Microneedling treatment(s) are not permanent as natural degradation or aging will occur over time. I understand all the possible side effects of the anesthesia used in Microneedling.

I consent to the administration of local anesthetics as may be considered necessary by the medical provider in charge of my care. I understand the risks of local anesthesia. I state that 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 treatment including risks or alternatives and acknowledge that all my questions about the procedure have been answered in a satisfactory manner.

I give permission to my medical provider at Dallas Plastic Surgery Institute to perform the Procedure and will hold him/her and his/her staff harmless from any liability resulting from the proper administration of Microneedling treatment(s). I have fully and accurately disclosed all known allergies, prescription drugs, my physical condition and products I am currently ingesting or using topically. I understand the Procedure and accept the risks. Further, I do not hold the Physicians or medical providers at Dallas Plastic Surgery Institute responsible for any negative effects of the Treatment which could be the result of my physical conditions that were present, but not disclosed to my Physician and/or Medical Staff at the time of the Procedure.

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THIS CONSENT FORM IS VALID UNTIL ALL OR PART IS REVOKED BY ME IN WRITING.

My Signature below evidences and confirms that:

1. I understand I certify that I have read and fully understand, the above paragraphs and that I have had sufficient opportunity for discussion to have any questions answered by the medical provider.
2. The procedure(s) has been adequately explained to me by the medical provider.
3. I have received all the information and explanation I desire concerning this Procedure(s).
4. I hereby authorize and consent to the Procedure(s).
5. I certify that I am a competent adult of at least 18 years of age and sign this Informed Consent of my own free will.

Patient Name \_\_\_\_\_ Patient Signature \_\_\_\_\_ Date \_\_\_\_\_

Witness Name \_\_\_\_\_ Witness Signature \_\_\_\_\_ Date \_\_\_\_\_

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