

# AGNES Radio-Frequency Micro-Insulated Needling Device

# INFORMED CONSENT

#### **INTRODUCTION**

The concept of RF micro-needling is based on the skin's natural ability to repair itself when it suffers physical damage such as cuts, burns, abrasions or other injuries. Immediately after an injury to the skin, our body begins the healing process, triggering new collagen synthesis. The AGNES is a radio-frequency micro-needling device that intentionally creates superficial "micro-injuries" to the layer of the skin, active acne, or Syringoma inducing the healing process including new collagen production.

#### ABOUT THE PROCEDURE

This procedure is performed by a trained healthcare professional, physician, or physician assistant, who is licensed to practice medicine in the State of California. The AGNES procedure is performed in a safe and precise manner with a single-use sterile micro-insulated needle. The treatment session usually takes about 30-60 minutes, depending on the area(s) being treated. After the procedure, the treatment area(s) will be red, with mild swelling and/or bruising, and your skin might feel tight and sensitive to the touch. Although these symptoms may take four to fourteen days to resolve completely, they will be diminished significantly within a couple of days after the treatment.

#### ALTERNATIVE TREATMENT

Alternative treatments to micro-needling may include the use of routine skin care, oral and/or topical prescription and/or non-prescription medications, microdermabrasion, dermaplaning, laser treatments, and even cosmetic/plastic surgery. Each of these alternatives carry their own inherent risks and benefits. However, since this treatment is elective and is done for cosmetic purpose only, no treatment at all should also be considered a viable alternative.

#### RISK OF RF AGNES MICRO-NEEDLING

Although the majority of patients do not experience any complications with micro-needling, it is important for you to understand that risks do exist. The micro-needling procedure is minimally invasive, utilizing a set of micro-needles to inflict multiple, tiny, puncture/lacerations to the skin layer. Because micro-needling penetrates the skin, it inherently carries health risks, including but not limited to those listed below. You should discuss any and all health concerns with the attending health care provider PRIOR to signing this consent form.

#### **INFECTION**

Infection is unusual. However, viral, bacterial, and fungal infections can occur anytime the integrity of the skin is compromised. Should infection occur, you must contact or return to our office immediately, as additional treatment will likely be necessary.

# PIGMENT/COLOR CHANGE

Because of dermal penetration of the AGNES procedure, failure to follow post treatment instructions can put you at risk for hyperpigmentation. You MUST avoid sun exposure for a 1 to 2 weeks after the



treatment. You should also wear a daily SPF facial moisturizer, which your doctor or esthetician can recommend. Lastly, avoid picking and/or peeling the skin during healing period.

#### **SCARRING**

Although normal healing after the procedure is expected, abnormal scars may occur in both skin and deeper tissues. In rare cases, thickened or keloid scars may result. Scars may be unattractive and of different color than surrounding skin. Additional treatments may be needed to treat scarring.

#### PAIN

There may be a very slight burning, scratchy, and irritated sensation to the skin. This is usually temporary and is gone within a few days after treatment. A sudden reappearance of redness or pain is a sign of infection and you should notify our office immediately.

# PERSISTENT REDNESS, ITCHING, AND/OR SWELLING

Itching, redness, and swelling are normal parts of the healing process. These symptoms rarely persists longer than 24 hours. However, treatments received less than 4 weeks apart may induce prolonged symptoms.

#### ALLERGIC REACTION

An allergic reaction from AGNES RF micro-insulated needling procedure is nearly impossible. However, it can cause you to be hypersensitive to any products used on the face since the procedure increases the penetration of topical substances. If an allergic reaction were to occur, you must contact our office immediately, as it may require further treatment.

#### LACK OF PERMANENT RESULT

The AGNES RF micro-insulated needling procedure will not completely or permanently improve skin texture, tone, elasticity, scars, minimize fine lines, wrinkles, eye-bag tones, and any other indications including Acne and Syringoma. It is important that your expectations should be realistic and understand the procedure has its limitations. Additional procedures may be necessary to achieve desired effect.

# **UNSATISFACTORY RESULT**

There is a possibility of a poor result from AGNES RF micro-insulated needling procedure like other cosmetic procedures. You may be disappointed with the final results.

# CONTRAINDICATIONS TO MICRO-NEEDLING

Although it is impossible to list every potential risk and complication, the followings are recognized as the known contraindications to AGNES RF micro-insulated needling procedure. Furthermore, it is your responsibility to fully and accurately disclose all medical history PRIOR to the initial treatment, as well as provide any necessary updates at all future treatment sessions. If you have any of the condition listed below, you should bring it to the attention of your doctor PRIOR to signing this consent form.

- Blood Thinner Medications
- o Cardiac Disease / Cardiac Pace Maker
- Chemotherapy or Radiation



- Collagen Vascular Disease
- o Hemophilia / Bleeding Disorder
- Skin Cancer
- Uncontrolled Diabetes
- Vascular Lesions (Hemangioma)

# AGNES Radio-Frequency Micro-Insulated Needling Device ACKNOWLEDGEMENT

My signature below acknowledges that I have read and understand the content of this informed consent. I have been given substantial opportunity to ask questions, all of which have been answered in a satisfactory manner. I understand that results can vary and that no guarantee, neither expressed nor implied, has been or will be, given to me regarding my results. I am aware of the risks and benefits associated with the AGNES Micro-needling procedure, as well as available alternative treatments. I understand that AGNES RF micro-needling is an elective procedure, performed solely for cosmetic purposes, and is not critical to my health. On my own free will, I am requesting and providing my informed consent, to undergo AGNES RF Micro-Insulated Needling treatment(s) at the office located at

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I assume all risks as my own and agree to hold harmless, AGNES RF USA, LLC. their providers, estheticians, and any other staff member, affiliate, or independent contractor. I hereby release them from any liability, both seen and unforeseen, now and forever.

Patient Signature Print Name Date

Parent/Guardian Co-Signature Print Name Date