Medical Microneedling Consent Form

PATIENT NAME _____

I Duly Authorize Yana Skin and Beauty to perform treatment.

This form is a written confirmation of the discussion that I have had with **the named Provider** to perform treatment with the Exceed microneedling device. I hereby authorize **the named Provider** or a delegated person by the named Provider to treat facial wrinkles of the glabellar region, periorbital lines, and cheek folds or to improve the appearance facial acne scars. The procedure involves creating tiny, microscopic punctures in the epidermal and dermal layers of the skin using sterile stainless-steel needles which then stimulates nucleogenesis. I understand this device will not prevent me from developing or re-developing facial wrinkles and facial acne scars. Although this device is successful in most cases, no guarantees can be made. I understand I may not experience complete clearance, and that it may take multiple treatments. Some conditions may not respond at all, and in rare cases, may become worse. I understand that clinical results may vary depending on individual factors, including but not limited to medical history, skin type, Patient compliance with pre- and post-treatment instructions, and individual response to treatment.

ALTERNATIVE TREATMENTS- Alternative forms of treatment include not undergoing the proposed medical microneedling treatment. Other forms of skin treatments such as chemical peels, laser and/or light-based treatments, surgical procedures, dermabrasion, or resurfacing may be substituted. In certain situations, treatment with the Exceed microneedling device may offer a specific therapeutic advantage over other forms of treatment. Alternatively, treatment with the Exceed microneedling device in some situations may not represent a better alternative to other forms of surgery or skin treatment when indicated. Risks and potential complications are associated with alternative forms of treatment that involve skin resurfacing(s) or surgical procedures.

I am aware of the following possible experiences, side effects, risks:

PAIN & DISCOMFORT - The level of pain and discomfort varies with a person's tolerance, and both may be experienced during treatment with gradual cessation of pain after treatment. In a clinical study using the Exceed microneedling device, subjects reported that they experienced moderate to moderate-severe pain.

REDNESS & SWELLING - Short term redness (erythema) or swelling (edema) of the treated area is common and may occur. An urticarial (hive-like) reaction may occur as well. In the clinical study using the Exceed microneedling device, subjects experienced a non-persistent inflammatory response, erythema and edema in the first one to six days after treatment.

PINPOINT BLEEDING - Localized pinpoint bleeding in the treatment area resolving within 24 hours.

SKIN SENSITIVITY & IRRITATION – Itching, tenderness, warming, or exaggerated responses to hot or cold temperatures may occur. This typically resolves during the healing process, which should clear after 8 days. In rare situations it may be chronic.

INFECTION - Infection is a possibility whenever the skin surface is disrupted, though proper wound care should prevent this. Individuals predisposed to herpes simplex labialis (HSL) are at an increased risk of developing the formation of blisters caused by HSL. Prophylactic anti-viral is recommended for patients with a history of HSL. If signs of an infection develop, such as pain, heat, or surrounding redness, please contact our office. **Herpes simplex virus infections (cold sores)** around the mouth can occur/reoccur following a laser treatment. This applies to both individuals with a history of Herpes simplex virus infections and individuals with no known history of Herpes simplex virus infections in the mouth area. If you had cold sores in the past, please let your provider know as specific medications can be prescribed and taken both prior to and following the procedure to suppress an infection from this virus.

MEDICATIONS - Please inform your provider of any and all medications currently being taken.

PIGMENT CHANGES - There is a possibility that the treated area can become either hypopigmented (lighter or white) or hyperpigmented (darker) in color compared to the surrounding skin. This is usually temporary but can be permanent. The Exceed microneedling device has not been studied in Patients with FST IV-VI.

ACCUTANE (Isotretinoin) - Accutane is a prescription medication used to treat certain skin diseases. If you have ever taken Accutane, you should discuss this with your treatment provider. This drug may impair the ability of skin to heal following treatments for a variable amount of time even after the Patient has ceased taking it. Individuals who have taken this drug are advised to allow their skin adequate time to recover from Accutane before undergoing skin treatment procedures.

EPIDERMAL CRUSTING - During the healing phase, small pinpoint crusts, flaking, or peeling may appear in place of each microscopic puncture. It is important not to pick or disturb the crusts as they heal. They may require medical attention if sensitivity or redness occurs. Crusts will typically slough off in 1-3 weeks after treatment.

PUSTULES & MILIA - Formation of small pustules and milia within the first days after treatment may occur.

VISIBLE SKIN PATTERNS - the Exceed microneedling device may produce visible patterns within the skin. The occurrence of this is not predictable.

DAMAGED SKIN - Skin that has been previously treated with chemical peels or dermabrasion, or damaged by burns, electrolysis (hair removal treatments), or radiation therapy may heal abnormally or slowly following treatment by microneedling. The occurrence of this is not predictable. Additional treatment may be necessary. If you have ever had such treatments, you should inform your treatment provider.

SCARRING - Scarring is a rare occurrence, but it is a possibility whenever the skin surface is disrupted. To minimize the chances of scarring, it is IMPORTANT that you follow all post-treatment instructions carefully.

TEXTURAL CHANGES/CUTANEOUS INDENTATIONS - Textural and/or skin changes may occur because of treatment.

ALLERGIC REACTIONS- In some cases, local allergies to products used during or after treatment such as adhesive, numbing agents, topical preparations and topical post-care have been reported. Systemic reactions which are more serious may occur to drugs used during the procedure. Allergic reactions may require additional treatment.

SUN EXPOSURE/ TANNING BEDS/ ARTIFICIAL TANNING - May increase risk of side effects and adverse events. It has been advised that you discontinue and avoid UV exposure and artificial tanning before, during, and after your treatment and recommended that you discontinue this practice all together as the effects of the sun are damaging to the skin. A broad spectrum (UVA/UVB) sunscreen should be used to prevent further pigmentation. Exposing the treated areas to sun may result in increased scarring, color changes, and poor healing. Patients who tan, either outdoors or in a salon, should inform their treatment provider and either delay their treatment or avoid UV exposure until your provider says it is safe to resume. The damaging effects of UV exposure occurs even with the use of sunscreen or clothing coverage.

TREATMENTS - The number of treatments vary but multiple treatments are always required. The number of treatments needed to improve and reduce your facial wrinkling and/or facial acne scars is unknown.

LACK OF PERMANENT RESULTS - the Exceed microneedling treatment or other skin treatments may not completely improve or prevent future facial skin disorders, lesions, wrinkles, and/or acne scarring. No technique can reverse the signs of skin aging. Additional treatments with the Exceed microneedling device may be necessary to further improve facial wrinkling and/or facial acne scars. You may be required to continue with additional skin care maintenance programs. You may be disappointed with the results of an Exceed microneedling treatment.

OTHER RARE RISKS - Persistent inflammatory response, hematoma, erythema, and edema lasting longer than 5 days. Fever within first 3 days after treatment, and headache within first two days after treatment.

UNKNOWN RISKS - There is the possibility that additional risk factors of Exceed microneedling treatment may be discovered.

ADDITIONAL ADVISORIES

TRAVEL PLANS - Any treatment holds the risk of complications that may delay healing and delay your return to normal life. Please let the treatment provider know of any travel plans, important commitments already scheduled or planned, or time demands that are important to you, so that appropriate timing of your treatment can occur. There are no guarantees that you will be able to resume all activities in the desired time frame.

SKIN CANCER/SKIN DISORDERS - Treatment with the Exceed microneedling device does not offer protection against developing skin cancer or skin disorders in the future.

BODY PIERCINGS - Individuals who currently wear body-piercing jewelry in the treated region are advised that an infection could develop from this treatment.

MENTAL HEALTH DISORDERS AND ELECTIVE PROCEDURES - It is important that all Patients seeking to undergo elective treatments have realistic expectations that focus on improvement rather than perfection. Complications or less than satisfactory results are sometimes unavoidable, may require additional treatments, and can be stressful. Please openly discuss with your treatment provider, prior to the treatment, 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 procedures, effects on mental health cannot be accurately predicted.

PATIENT COMPLIANCE - Follow all pre-and post-instructions carefully; this is essential for the success of your outcome. Post-treatment instructions concerning appropriate restriction of activity, use of post-treatment care and use of sun protection must be followed to avoid potential complications, increased pain, and unsatisfactory results. Your treatment provider may recommend that you utilize a long-term skin care and/or post care program to enhance healing and results following a treatment with the Exceed microneedling device.

DISCLAIMER

Informed consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure or risks and alternative forms of treatment(s). The informed consent process attempts to define principles of risk disclosure that should generally meet the needs of most Patients in most circumstances. However, informed consent documents should not be considered all-inclusive in defining other methods of care and risks encountered. Your treatment provider may provide you with additional or different information, which is based on all the facts in your particular case and the state of medical and device knowledge. Informed consent documents are not intended to define or serve as the standard of care. Standards of care are determined based on all facts involved in an individual case and are subject to change as scientific knowledge and technology advance and as practice patterns evolve.

The following points have been discussed with me:

- The potential benefits and limitations of the proposed procedure, including the possibility that the procedure may not work for me.
- The possible alternative treatments include topical medications or skin care, chemical peels, other laser or light therapies, or no treatment at all.
- The probability of success.
- The reasonably anticipated consequences if the procedure is not performed.
- The most likely possible complications/risks involved with the proposed procedure.
- Post treatment instructions.
- Short term effects may include reddening, mild burning, temporary bruising, or blistering. Hyperpigmentation and hypopigmentation have also been noted after treatment. These conditions usually resolve within 3-6 months, but permanent color change is a rare risk. Avoiding sun exposure before, during, and after treatment reduces risk of color change.

I confirm that I have informed the staff regarding any current or past medical condition, disease or medication taken. I certify that I have

been given the opportunity to ask questions and that I have read and fully understand the contents of this consent form.

ACKNOWLEDGEMENT & RELEASE

BY MY SIGNATURE BELOW, I CERTIFY THAT I HAVE READ AND FULLY UNDERSTAND THE CONTENTS OF THIS CONSENT FORM FOR TREATMENT WITH THE MICRONEEDLING DEVICE AND THAT THE DISCLOSURES REFERRED TO HEREIN WERE MADE TO ME.

PATIENT SIGNATURE:_____ **DATE:** _____

WITNESS SIGNATURE: _____ **DATE:** _____