

Profound Matrix®

Matrix Pro® Applicator

Informed Consent

Patient Name _____

Treatment Sites _____

I Duly Authorize _____ to perform treatment.

This form is a written confirmation of the discussion that I have had with _____ or any delegated Provider(s) regarding treatment using the Matrix Pro applicator on the Profound Matrix system. The provider has informed me the users have received appropriate training on the conditions to safely use the device. I have been informed that the procedure delivers short-pulsed radiofrequency (RF) energy to heat the skin in a fractional manner using microneedles resulting in electrocoagulation and hemostasis.

I understand that treatment 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. I understand that a medical consultation, including a diagnostic examination of the skin areas intended for treatment, is recommended. Benefits to treatment cannot be guaranteed, I may be disappointed with the results, some conditions may not respond at all to treatment, and in rare cases, may become worse. The number of treatments vary and multiple treatments may be required. Treatments may not completely improve or prevent future facial skin disorders and no technique can fully prevent all signs of skin aging.

ALTERNATIVE TREATMENTS: Alternative forms of treatment include not undergoing the proposed 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 Matrix Pro applicator may not represent a better alternative to other forms of skin treatment and/or surgery when indicated.

I AM AWARE OF THE FOLLOWING POTENTIAL SIDE EFFECTS, RISKS, AND ADVERSE EFFECTS THAT CAN RANGE FROM MILD TO SERIOUS AND MAY INCLUDE BUT ARE NOT LIMITED TO:

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.

ERYTHEMA: Excessive skin redness of the treated area is common and may occur. It is usually temporary and fades within 1-3 days.

EDEMA: Swelling of the treatment area will likely develop after treatment and is usually transient, fading within a few days (up to 7 days). Edema may present as generalized throughout treatment area, or may present as focal, appearing as palpable-localized imprints from the treatment tip of the Matrix Pro cartridge.

PINPOINT BLEEDING/PETECHIAE: Localized pinpoint bleeding in the treatment area is anticipated. Bleeding may occur from site of needle insertion(s) from administration of injected pain medication and/or the microneedles used during treatment. This usually resolves within a few minutes up to 1-hour post-treatment; while in some cases, petechiae can be transient up to 3-5 days following treatment.

SKIN SENSITIVITY & IRRITATION: Itching, tenderness, warming or burning sensations, or exaggerated responses to hot or cold temperatures may occur. This typically dissipates during the healing process, while in rare cases may be more persistent.

BURN, BLISTERING, CRUSTING, SCABBING, AND/OR INFECTION: Damage to the natural skin texture such as a burn, blister, pustule, acneiform eruption, papules, hive-like response, dryness, crust, and/or scab can occur at the treatment area and can cause infection. Infection is a possibility whenever the skin surface is disrupted and with proper wound care, the risk of infection can be mitigated. Individuals predisposed to Herpes Simplex Virus 1 (HSV-1), or cold sores around the mouth, are at an increased risk of developing the formation of blisters caused by HSV-1 following treatment with an energy-based or laser device. If you have a history of HSV-1 or have had cold sores in the past, please inform your healthcare provider so that they can prescribe the appropriate course of antiviral medication(s). The formation of blisters caused by HSV-1 can also occur among individuals with no known history of HSV-1; and if signs of an infection develop, such as pain, heat, erythema, and/or tingle/twinge sensations, please contact our office at _____.

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PIGMENTARY CHANGES: There is a possibility that the treated area can become either hypopigmented (lighter or white in color) or hyperpigmented (darker in color) when compared to the surrounding skin. Although this is usually temporary, in rare cases, permanent pigmentary changes can occur. Sun avoidance and the use of sun block (SPF 30 or higher) can help minimize the risk, the intensity, and duration of any pigmentary changes.

MEDICATIONS: Please inform your healthcare provider of all medications currently being taken, including both prescription and over-the-counter medications, and vitamins.

ANESTHESIA: May be used during the procedure with the following potential side effects:

- Reactions to include but are not limited to the possibility of an allergic and/or toxic reaction to medication used to numb the areas. You will be questioned about any history of allergies and carefully monitored for signs of an allergic reaction (i.e., itchy red spots on skin, itching, rash, scratchy throat, watery eyes). Prior to treatment, a topical anesthetic cream (e.g., EMLA, BLT) may be applied to the treatment area or a local anesthesia injection may be infiltrated.
- If local anesthesia (pain control) injections are used, it may consist of either a 0.5% - 1.0% lidocaine with epinephrine 1:100,000 - 200,000 (or 3% carbocaine for those who are intolerant of epinephrine) and diluted with sodium bicarbonate and/or bacteriostatic 0.9% sodium chloride to anesthetize the areas and for hemostasis control (cessation of blood flow) prior to treatment. Lower volumes of injectable anesthetic will be administered to start and then increased as needed to achieve effective pain and hemostasis control. Patient weight will be taken (via weight scale in office) during the screening and recorded to calculate the weight-based medication dosage. Manufacturer guidelines of medication must be followed and all prescribing information (i.e., medication name, dosage strength, form, route, quantity, directions for use) is at the discretion of the qualified licensed healthcare professional, to include total safe weight-based dosage limits of medication.
- Additionally, an optional inhaled anxiolytic (anti-anxiety) medication (e.g., Pro-Nox™) may be used. Pro-Nox™ is a commercial device that administers an inhaled mixture of 50% oxygen and 50% nitrous oxide which is used to reduce anxiety and discomfort during in-office procedures, and it can be used in conjunction with local anesthesia. It is inhaled through a disposable mouthpiece and then exhaled. It does not cause people to fall asleep. If you wish you may be treated without anesthesia.

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

INVOLUNTARY MUSCLE FASCICULATIONS (TWITCHING): During treatment, there is a potential for stimulation of nerve(s) and contraction of the muscle(s), and occasionally, these sensations may radiate or be referred (felt) in other parts of the body. This symptom has been reported as transient and is not known to be harmful.

DAMAGED SKIN: Skin that has been previously treated with chemical peels or dermabrasion, damaged by burns, electrolysis (hair removal treatments), or radiation therapy may heal abnormally or slowly following treatment. 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: To include pitted or atrophic scarring, is a possibility whenever the skin surface is disrupted. To minimize the chances of scarring, it is IMPORTANT that all pre- and post-treatment instructions are followed carefully.

TEXTURAL CHANGES/CUTANEOUS INDENTATIONS/VISIBLE SKIN PATTERNS: Textural and/or skin changes may occur because of treatment. The occurrence of this is not predictable.

SUN EXPOSURE & ARTIFICIAL SKIN TANNING: Discontinue and avoid all types of UV exposure and skin tanning, both artificial and outdoors, before, during, and after treatment as this may increase the risk of side effects and adverse events. UV exposure and skin tanning, whether outdoors or artificial, may result in pigmentary changes of the skin, poor healing, and/or scarring. The damaging effects of UV exposure can occur even with the use of sunblock or clothing coverage. Sun avoidance and the use of a total sunblock (SPF 30 or higher) will help minimize the risk, the intensity and duration of side effects. Inform your treatment provider of any UV exposure or skin tanning so your provider can determine when treatment(s) can be performed.

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OTHER REACTIONS:

- **MICROSCOPIC EPITHELIAL NECTROIC DEBRIS (MENDs):** MENDs occurs because of microscopical wounds caused by treatment with the Matrix Pro applicator. They are part of a healing process where treated tissue is working its way out of your body as new skin is created. During this time, the skin may appear and feel dry before peeling and flaking off. This side effect can be observed during and immediately post-treatment.
- **MOTTLING:** Irregular discoloration of the skin observed to be patchy or marbled in appearance is caused by temporary obstruction of blood flow within or near the treatment area. This may occur immediately during treatment or may develop within a few hours following treatment.
- **ECCHYMOsis, PURPURA, HEMATOMA:** A collection of blood that pools outside of blood vessels within the skin forming a swollen lump may form at site of insertion from the Matrix Pro cartridge microneedles or may occur at site of insertion from injection of anesthesia, if used. This may occur immediately during treatment or may develop within hours, becoming more noticeable within 24 - 48 hours following treatment. Depending on size and location, Hematoma's typically resolve within 5 to 7 days but may last for 4 to 6 weeks.
- **LOSS OF SENSATION & NERVE DAMAGE:** Although rare, sensation changes to include but not limited to partial or complete numbness, tingling, and/or nerve pain related to nerve damage may occur. Symptoms may manifest immediately, have delayed onset, may be transient or may last for an unknown duration. Nerve damage can occur from injection of pain medication(s) and/or caused by the Matrix Pro cartridge microneedles used during treatment.

UNKNOWN RISKS: There is the possibility that additional risk factors and unknown complications ranging from mild to serious may occur. Contact your provider immediately at _____ if you have any concerns about responses to treatment. All complaints will be reported to Candela by your treating provider.

TRAVEL PLANS: Any treatment holds the risk of complications that may prolong healing and delay your return to normal life. Please discuss with the treatment provider upcoming travel plans, scheduled commitments, planned events 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 & OTHER SKIN DISORDERS: Treatment with the Matrix Pro applicator does not offer protection against developing skin cancer or other disorders of the skin in the future.

PATIENT COMPLIANCE: It is essential to follow all pre-and post- treatment instructions carefully. 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 treatment skin care program to enhance healing and results following a treatment with the Matrix Pro applicator.

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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:

- Treatment contraindications
- 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, edema, burning/sensitivities, temporary bruising, blistering, and damage to the natural skin texture. Hyperpigmentation, hypopigmentation, scarring, and loss of sensation may occur. 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 the risk of color change.

I confirm that I do not present with any of the contraindications listed below that would exclude me from receiving treatment and have informed the staff regarding any current or past medical condition(s), disease(s) or medication(s) taken, including confirmation that I am not pregnant or planning to become pregnant, have not given birth less than 3 months ago, and am not breastfeeding.

Contraindications:

- Patients who are less than 18 years of age.
- Patients who have a pacemaker or internal defibrillator, or any other active electrical implant anywhere in their body.
- Patients who have a permanent implant in the treatment area such as metal plates and screws, or an injected chemical substance.
- Patients who have current or history of skin cancer, or current condition of any other type of cancer, or pre-malignant moles.
- Patients who have a history of any kind of cancer.*
- Patients who have severe concurrent conditions, such as cardiac disorders.
- Patients who are pregnant or nursing.
- Patients who have an impaired immune system due to immunosuppressive diseases such as AIDS and HIV, or use of immunosuppressive medications.
- Patients who have a history of diseases stimulated by heat, such as recurrent Herpes Simplex in the treatment area, may be treated only following a prophylactic regimen.
- Patients who have poorly controlled endocrine disorders, such as poorly controlled diabetes.
- Patients who have any active condition in the treatment area, such as sores, psoriasis, eczema, rash, open wounds and severe active inflammatory acne.
- Patients who have a history of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- Patients who have a history of bleeding coagulopathies or use of anticoagulants, aspirin, iron supplement, herbal supplements such as ginkgo, ginseng, garlic or ointment (with the exception of preventive low-dose aspirin*).
- Patients who have had facelift or eyelid surgery (if periorbital treatment is performed) within three months prior to treatment. If the patient exhibits signs of delayed healing response, then a minimum of six months should pass before a Matrix Pro treatment.*
- Patients who have received facial dermabrasion, facial resurfacing, or deep chemical peeling within the last three months if the face is treated. If the patient exhibits signs of delayed healing response, then a minimum of six months should pass before a Matrix Pro treatment.*
- Patients must wait 7-14 days following injections with neuromodulators, 2-4 weeks following injections with natural injectable soft tissue fillers (e.g., Hyaluronic acid) and refer to manufacturer guidelines of the specified product for additional information.
- Patients who have absorbable facial threads within the treatment area, refer to the manufacturer recommendations, within the last two years.

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- Patients who have permanent filler (e.g., silicone) or non-absorbable facial threads within the intended treatment area.
- Patients who use Isotretinoin (Accutane®), systemic corticosteroid therapy or other medication/s where sunlight is contraindicated within six months prior to treatment.*
- Patients who have had any surgical procedure in the treatment area within the last three months or before complete healing. If the patient exhibits signs of delayed healing response, then a minimum of six months should pass before a Matrix Pro treatment.*
- Patients who are treating over a tattoo or permanent makeup.
- Patients who have UV exposed skin and/or excessively tanned skin from the sun, tanning beds or tanning creams within the last four weeks.
- Patients who are unable or unwilling to follow pre- and post-treatment instructions.

(*) Indicated conditions may be treated at the discretion of – and under the full responsibility of the medical director/physician, although not recommended.

I certify that I have been given the opportunity to ask questions and they have been answered satisfactorily. I understand the procedure, I have read and fully understand the contents of this consent form and accept any risks associated with the procedure.

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 PROFOUND MATRIX SYSTEM, MATRIX PRO APPLICATOR AND THAT THE DISCLOSURES REFERRED TO HEREIN WERE MADE TO ME.

Patient Name (Printed): _____

Patient Signature: _____ **Date:** _____

Witness Name (Printed): _____

Witness Signature: _____ **Date:** _____

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Sublative™ RF Applicator

Informed Consent

Patient Name _____

Treatment Sites _____

I Duly Authorize _____ to perform treatment.

This form is a written confirmation of the discussion that I have had with _____ or any delegated Provider(s) regarding treatment using the Sublative RF applicator on the Profound Matrix system. The provider has informed me the users have received appropriate training on the conditions to safely use the device. I have been informed that the procedure delivers bipolar RF energy to the skin in a fractional manner, via an array of multi-electrode pins. This results in a widely diffuse impact mainly in the dermis, with low epidermal disruption to achieve fibroblast stimulation and dermal remodeling, for a more compact and organized dermal matrix, and an even/homogenous epidermal skin surface.

I understand that treatment 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. I understand that a medical consultation, including a diagnostic examination of the skin areas intended for treatment, is recommended. Benefits to treatment cannot be guaranteed, I may be disappointed with the results, some conditions may not respond at all to treatment, and in rare cases, may become worse. The number of treatments vary, and multiple treatments may be required. Treatments may not completely improve or prevent future facial skin disorders and no technique can fully prevent all signs of skin aging.

ALTERNATIVE TREATMENTS: Alternative forms of treatment include not undergoing the proposed 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 Sublative RF applicator may not represent a better alternative to other forms of skin treatment and/or surgery when indicated.

I AM AWARE OF THE FOLLOWING POTENTIAL SIDE EFFECTS, RISKS, AND ADVERSE EFFECTS THAT CAN RANGE FROM MILD TO SERIOUS AND MAY INCLUDE BUT ARE NOT LIMITED TO:

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.

ERYTHEMA: Excessive skin redness of the treated area is common and may occur. It is usually temporary and fades within 1-3 days.

EDEMA: Swelling of the treatment area will likely develop after treatment and is usually transient, fading within a few days (up to 7 days). Edema may present as generalized throughout treatment area, or may present as focal, appearing as palpable-localized imprints from the treatment tip of the Sublative™ iD tip.

PINPOINT BLEEDING/PETECHIAE: Localized pinpoint bleeding and/or petechiae (brown-purple spots due to bleeding underneath the skin) in the treatment area may occur and may be observed as imprints from the treatment tip of the Sublative™ iD tip. In rare cases, ecchymosis or purpura can occur. These side effects can be treatment technique and treatment area dependent. Symptoms usually resolve within a few minutes up to 1- hour post-treatment; while in some cases, can be transient lasting several days following treatment.

SKIN SENSITIVITY & IRRITATION: Itching, tenderness, warming or burning sensations, or exaggerated responses to hot or cold temperatures may occur. This typically dissipates during the healing process, while in rare cases may be more persistent.

BURN, BLISTERING, CRUSTING, SCABBING, AND/OR INFECTION: Damage to the natural skin texture such as a burn, blister, pustule, acneiform eruption, crust, folliculitis, dryness, and/or scab can occur at the treatment area and can cause infection. Infection is a possibility whenever the skin surface is disrupted and with proper wound care, the risk of infection can be mitigated. Individuals predisposed to Herpes Simplex Virus 1 (HSV-1), or cold sores around the mouth, are at an increased risk of developing the formation of blisters caused by HSV-1 following treatment with an energy-based or laser device. If you have a history of HSV-1 or have had cold sores in the past, please inform your healthcare provider so that they can prescribe the appropriate course of antiviral medication(s). The formation of blisters caused by HSV-1 can also occur among individuals with no known history of HSV-1; and if signs of an infection develop, such as pain, heat, erythema, and/or tingle/twinge sensations, please contact our office at _____.

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PIGMENTARY CHANGES: There is a possibility that the treated area can become either hypopigmented (lighter or white in color) or hyperpigmented (darker in color) when compared to the surrounding skin. Although this is usually temporary, in rare cases, permanent pigmentary changes can occur. Sun avoidance and the use of sun block (SPF 30 or higher) can help minimize the risk, the intensity, and duration of any pigmentary changes.

MEDICATIONS: Please inform your healthcare provider of all medications currently being taken, including both prescription and over-the-counter medications, and vitamins.

ANESTHESIA: May be used during the procedure with the following potential side effects:

- Reactions to include but are not limited to the possibility of an allergic and/or toxic reaction to pain medication used to numb the areas. You will be questioned about any history of allergies and carefully monitored for signs of an allergic reaction (i.e., itchy red spots on skin, itching, rash, scratchy throat, watery eyes). Prior to treatment, a topical anesthetic cream (e.g., EMLA, BLT) may be applied to the treatment area. Manufacturer guidelines of medication must be followed and all prescribing information (i.e., medication name, dosage strength, form, route, quantity, directions for use) is at the discretion of the qualified licensed healthcare professional, to include total safe weight-based dosage limits of medication.
- Additionally, an optional inhaled anxiolytic (anti-anxiety) medication (e.g., Pro-Nox™) may be used. Pro-Nox™ is a commercial device that administers an inhaled mixture of 50% oxygen and 50% nitrous oxide which is used to reduce anxiety and discomfort during in-office procedures, and it can be used in conjunction with local anesthesia. It is inhaled through a disposable mouthpiece and then exhaled. It does not cause people to fall asleep. If you wish you may be treated without anesthesia.

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

DAMAGED SKIN: Skin that has been previously treated with chemical peels or dermabrasion, damaged by burns, electrolysis (hair removal treatments), or radiation therapy may heal abnormally or slowly following treatment. 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: To include pitted or atrophic scarring, is a possibility whenever the skin surface is disrupted. To minimize the chances of scarring, it is IMPORTANT that all pre- and post-treatment instructions are followed carefully.

TEXTURAL CHANGES/CUTANEOUS INDENTATIONS/VISIBLE SKIN PATTERNS: Textural and/or skin changes may occur because of treatment.

SUN EXPOSURE & ARTIFICIAL SKIN TANNING: Discontinue and avoid all types of UV exposure and skin tanning, both artificial and outdoors, before, during, and after treatment as this may increase the risk of side effects and adverse events. UV exposure and skin tanning, whether outdoors or artificial, may result in pigmentary changes of the skin, poor healing, and/or scarring. The damaging effects of UV exposure can occur even with the use of sunblock or clothing coverage. Sun avoidance and the use of a total sunblock (SPF 30 or higher) will help minimize the risk, the intensity and duration of side effects. Inform your treatment provider of any UV exposure or skin tanning so your provider can determine when treatment(s) can be performed.

OTHER REACTIONS:

- **MICROSCOPIC EPITHELIAL NECTROIC DEBRIS (MENDs):** MENDs occurs because of microscopical wounds caused by treatment with the Sublative RF applicator. They are part of a healing process where treated tissue is working its way out of your body as new skin is created. During this time, the skin may appear and feel dry before peeling and flaking off. This side effect can be observed during and immediately post-treatment.
- **MOTTLING:** Irregular discoloration of the skin observed to be patchy or marbled in appearance is caused by temporary obstruction of blood flow within or near the treatment area. This may occur immediately during treatment or may develop within a few hours following treatment.
- **LOSS OF SENSATION & NERVE DAMAGE:** Although rare, sensation changes to include but not limited to partial or complete numbness, tingling, and/or nerve pain related to nerve damage may occur. Symptoms may manifest immediately, have delayed onset, may be transient or may last for an unknown duration.

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UNKNOWN RISKS: There is the possibility that additional risk factors and unknown complications ranging from mild to serious may occur. Contact your provider immediately at _____ if you have any concerns about responses to treatment. All complaints will be reported to Candela by your treating provider.

TRAVEL PLANS: Any treatment holds the risk of complications that may prolong healing and delay your return to normal life. Please discuss with the treatment provider upcoming travel plans, scheduled commitments, planned events 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 & OTHER SKIN DISORDERS: Treatment with the Sublative RF applicator does not offer protection against developing skin cancer or other disorders of the skin in the future.

PATIENT COMPLIANCE: It is essential to follow all pre-and post- treatment instructions carefully. 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 treatment skin care program to enhance healing and results following a treatment with the Sublative RF applicator.

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:

- Treatment contraindications
- 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, edema, burning/sensitivities, and damage to natural skin texture. Hyperpigmentation, hypopigmentation, and scarring may occur. 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 the risk of color change.

I confirm that I do not present with any of the contraindications listed below that would exclude me from receiving treatment and have informed the staff regarding any current or past medical condition(s), disease(s) or medication(s) taken, including confirmation that I am not pregnant or planning to become pregnant, have not given birth less than 3 months ago, and am not breastfeeding.

Contraindications:

- Patients who are less than 18 years of age.
- Patients who have a pacemaker or internal defibrillator, or any other active electrical implant anywhere in the body.
- Patients who have a permanent implant in the treated area such as metal plates and screws, or an injected chemical substance.
- Patients who have a current or history of skin cancer, or current condition of any other type of cancer, or pre-malignant moles.
- Patients who have a history of any kind of cancer.*
- Patients who have severe concurrent medical conditions, such as cardiac disorders.
- Patients who are pregnant or nursing.
- Patients who have an impaired immune system due to immunosuppressive diseases such as AIDS and HIV, and/or use of immunosuppressive medications.

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- Patients who have a history of diseases stimulated by heat, such as recurrent Herpes Simplex virus in the treatment area, may be treated only following a prophylactic regimen.
- Patients who have poorly controlled endocrine disorders, such as poorly controlled diabetes.
- Patients who have any active condition in the treatment area, such as skin sores, psoriasis, eczema, and rash.
- Patients who have a history of skin disorders, keloids, abnormal wound healing, as well as very dry and fragile skin.
- Patients who have a history of bleeding coagulopathies and/or use of anticoagulants, with the exception of preventive low-dose aspirin medication.
- Patients who had a face lift or eyelid surgery (if periorbital treatment is performed) within three months prior to treatment. If the patient exhibits signs of delayed healing response, then a minimum of six months should pass before performing a Sublative RF treatment.*
- Patients who have facial dermabrasion, facial resurfacing, or deep chemical peeling within the last three months if the face is treated. If the patient exhibits signs of delayed healing response, then a minimum of six months should pass before a Sublative RF treatment.*
- 7-14 days following injections with neuromodulators, 2-4 weeks following injections with natural injectable soft tissue fillers (e.g., Hyaluronic acid) and refer to the manufacturer guidelines of the specified product for additional information.
- Patients who use of Isotretinoin (Accutane®) within 6 months prior to treatment.*
- Patients who have had any surgical procedure in the treatment area within the last three months or before complete healing. If the patient exhibits signs of delayed healing response, then a minimum of six months should pass before Sublative RF treatment.*
- Patients who are treating over tattoo or permanent makeup.
- Patients who have excessively tanned skin from sun, tanning beds or tanning creams within the last 2-4 weeks.

(*) Indicated conditions may be treated at the discretion of – and under the full responsibility of the medical director/physician, although not recommended.

I certify that I have been given the opportunity to ask questions and they have been answered satisfactorily. I understand the procedure, I have read and fully understand the contents of this consent form and accept any risks associated with the procedure.

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 PROFOUND MATRIX SYSTEM, SUBLATIVE RF APPLICATOR AND THAT THE DISCLOSURES REFERRED TO HEREIN WERE MADE TO ME.

Patient Name (Printed): _____

Patient Signature: _____ **Date:** _____

Witness Name (Printed): _____

Witness Signature: _____ **Date:** _____