

## Sample Informed Consent

### Ellipse IPL and Nd:YAG – Treatment of Vascular & Pigmented Lesions & Permanent Hair Reduction

Patient name \_\_\_\_\_

Treatment sites \_\_\_\_\_

I duly authorize \_\_\_\_\_ to perform \_\_\_\_\_ treatment.

I understand that the Ellipse IPL and Nd:YAG technologies are used for treatment of vascular and/or pigmented lesions, removal of or lightening the appearance of facial redness including rosacea, port wine stains, hemangiomas, angioma, spider angioma, Poikiloderma of Civatte, acne, and/or benign cutaneous lesions, and/or permanent reduction of unwanted hair by using a narrowband (400-950nm) optical technology (or Nd:YAG 1064nm laser technology for vascular treatment). I understand the procedure involves careful selection of wavelengths and pulse durations to effectively target and destroy the pigment, vessel or hair while minimizing absorption by surrounding skin structures and I am consenting to be a patient receiving \_\_\_\_\_ (specify procedure).

I understand that this handpiece will not prevent me from developing or re-developing vascular and/or pigmented lesions and/or unwanted hair and although this handpiece is effective in most cases, no guarantees can be made. I understand that I may not experience complete clearance and that it may take multiple treatments. I understand that 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/post treatment instructions, and individual response to treatment.

**ALTERNATIVE TREATMENTS** - Alternative forms of treatment include not undergoing the proposed laser procedure. Other forms of skin treatments such as other laser and light based treatments, sclerotherapy, topicals and skin care and chemical peels may be substituted. In certain situations, the optical technology may offer a specific therapeutic advantage over other forms of treatment. Risks and potential complications are associated with alternative forms of treatment that involve vascular and benign pigmented lesion removal.

I understand that there is a possibility of short-term effects such as:

**PAIN & DISCOMFORT** - The level of pain and discomfort varies with a person's tolerance, and both may be experienced during treatment.

**BURNS** - Optical technology can produce burns. Adjacent structures including the eyes may be injured or permanently damaged by the optical energy. Burns are rare, yet represent the effect of heat produced within the tissues by laser energy. Additional treatment may be necessary to treat optical technology burns.

**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.

**PURPURA/BRUISING** - Purpura (bruising) may occur and is a transient phenomenon that usually resolves with time.

**HEMOSIDERIN STAINING** - (Iron leaking into tissue from blood breakdown) may occur and usually resolves over time, but it may be permanent.

**SKIN SENSITIVITY** - Itching, tenderness, or exaggerated responses to hot or cold temperatures may occur. This typically resolves during the healing process, but in rare situations it may be chronic.

**WOUND HEALING** - Treatment can result in burning, blistering, or bleeding of the treated areas resulting in a wound. If this occurs, please contact our office.

**INFECTION** - Infection is a possibility whenever the skin surface is disrupted, though proper wound care should prevent this. If signs of an infection develop, such as pain, heat or surrounding redness, please contact our office at \_\_\_\_\_. **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.

**PIGMENT CHANGES (Skin color)** - 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.

**FIRE** - Inflammable agents, surgical drapes and tubing, hair, and clothing may be ignited by laser energy. Laser energy used in the presence of supplemental oxygen increases the potential hazard of fire. Some anesthetic gases may support combustion.

**EPIDERMAL CRUSTING** - Pigmented lesions may crust or scab as part of the healing process. 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 1-3 weeks after treatment.

**LASER SMOKE (Plume)** - Laser smoke is noxious to those who come in contact with it. This smoke may represent a possible biohazard.

**SKIN TISSUE PATHOLOGY** - Laser energy directed at skin lesions may potentially vaporize the lesion. Laboratory examination of the tissue specimen may not be possible.

**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 lasers. 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.

**UNDESIRABLE HAIR REDUCTION** - Hair reduction may occur at treatment sites. This is typically temporary but can be permanent.

**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.

**EYE EXPOSURE** - Eye injury is possible from laser procedures. Protective eyewear (shields or goggles) will be provided. It is important to keep these on always during the treatment to protect your eyes from injury.

**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 clear your vascular and/or pigmented lesions and/or permanent reduction of unwanted hair is unknown.

**LACK OF PERMANENT RESULTS** - Ellipse IPL or Nd:YAG treatments or other skin treatments may not completely improve or prevent future skin lesions, or hair growth. No technique can reverse the signs of skin aging. You may be required to continue with a skin care maintenance program after an Ellipse IPL or Nd:YAG procedure.

**OTHER** - You may be disappointed with the results of the Ellipse IPL or Nd:YAG treatment. It may be necessary to perform additional Ellipse IPL treatments to improve your results.

**UNKNOWN RISKS** - There is the possibility that additional risk factors of Ellipse IPL or Nd:YAG treatments 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** - Ellipse IPL or Nd:YAG and skin treatment procedures do 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 activity.

**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/or results following an Ellipse IPL or Nd: YAG treatment.

**Disclaimer**

Informed consent documents are used to communicate information about the proposed surgical treatment of a disease or condition along with disclosure of 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.

I certify that I have been fully informed of the nature and purpose of the procedure, expected outcomes and possible complications, and I understand that no guarantee can be given as to the final result obtained. I am fully aware that my condition is of cosmetic concern and that the decision to proceed is based solely on my expressed desire to do so.

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

I consent to the taking of photographs and authorize their anonymous use for the purposes of medical audit, education and promotion.

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.

Patient Name (Printed) \_\_\_\_\_

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

Witness Name (Printed) \_\_\_\_\_

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