



PROFILE™ CLEARSCAN™ 1.064-μM LASER MODULE: VASCULAR LESION PROTOCOL

The following protocol is a safe start guide based upon the clinical observations of experienced physicians.

Introduction

Vascular lesions can be treated with a 1064-nm wavelength through selective absorption by blood in the target vessel. This process was described as early as 1968 using ruby (694 nm) and Nd:YAG (1064 nm) lasers (Solomon et al., J Inv Derm, 1968, 50:141-146). The absorption converts laser light into heat energy, which raises the temperature of blood within vessels. With appropriate selection of fluence and pulse width the temperature of the blood will be high enough to alter and damage the vessel wall resulting in the elimination of the vessel.

The 1064-nm laser energy is capable of deep penetration and selective coagulation without damage to the epidermis. The PROFILE can deliver enough energy or fluence to effectively coagulate vessels, and has variable pulse widths for treating a range of vessel sizes.

Surface Cooling

Cooling is essential to vascular lesion treatment because higher fluence settings yielding more damage to targeted vessels can be used if the skin surface is cooled. In addition, collateral dermal damage is prevented, and patient discomfort is reduced.

Although absorption of the 1064-nm wavelength in melanin is minimal, some epidermal cooling is beneficial. The amount of cooling required will vary depending upon the patient's skin type. Lighter skin types require less cooling, and darker skin types require more cooling. The Profile ClearScan contact cooling plate insures that the epidermis is adequately protected from overheating regardless of skin type.

When the 1064-nm wavelength is used to treat blood vessels, there is a tremendous amount of heat build-up in the vessel from the laser pulse. The heat dissipates upward towards the skin surface. Surface cooling before, during and immediately after laser

treatment, or after the light is converted to heat, can quench heat from the surface and protect the epidermis from undesirable heating.

IMPORTANT: Treating with dirty lenses, high fluence or overlapping laser pulses may lead to undesirable outcomes including blisters, scarring and skin pigmentation changes due to overheating tissue. Attention to technique and conservative treatment will avoid these problems. This guide is not intended as a replacement for clinical training, preceptorship or supervised experience. Please follow the instructions in the Operator's Manual for this system.

1. PRE-TREATMENT CONSIDERATIONS

1.1. PATIENT EXAMINATION

Veins and telangiectasias should be classified prior to treatment according to vessel diameter and depth, which can be assessed by micrometer, dermatoscope, venoscope, or a Duplex ultrasound. A pre-treatment photo should be taken to assist in evaluating the effectiveness of the treatment.

CAUTION: Treatment of veins is not recommended around tattoos or the use of self-tanning products. Tattoo ink and chemical tanning products may absorb laser energy resulting in a color change in tattoo ink or a risk of epidermal damage.

1.2. SITE PREP

Shave the area to be treated. Cleanse the area with mild soap and water followed by an alcohol swab to thoroughly remove any residue from lotions, makeup or shaving. Remove the alcohol with a gauze and plain water leaving the surface of the skin slightly moist.

CAUTION: Hair in the treatment area may be singed by the laser, resulting in secondary heating of the skin.

1.3. HANDPIECE CLEANING

The laser output lens and the contact cooling plate should be gently cleaned between procedures with a cotton-tipped applicator or a 4 x 4 gauze slightly moistened with alcohol.

CAUTION: A dirty laser lens or cooling plate shield may lead to an inaccurate delivery of laser energy due to scattering or absorption of the laser beam.

1.4. EYE PROTECTION

Always use eye protection for the patient, the operator and anyone in the laser treatment room during the treatment. Laser safety glasses with an OD5+ for

use with the 1064nm laser wavelength should be worn. When working in the facial area, patients should wear external, matte-finish metal eye shields. If patient is lying flat, they should ALWAYS wear either goggles or totally opaque external eye shields. The use of glasses especially in that position puts them at an ocular risk.

CAUTION: Treating within the patient's orbital rim may cause retinal damage or blindness.

1.5. PATIENT POSITIONING

Patients should lie flat during treatment and be positioned to allow the handpiece to be held near perpendicular to the tissue plane. When treating facial areas, the handpiece should be positioned so that the laser points away from delicate structures such as the eye, nasal cavity and ears. Protect the teeth if working near the lips.

2. SETTING TREATMENT PARAMETERS

2.1. COOLING

The chiller should be set between 0°C to 20°C. The recommended setting is 10°C.

2.2. SET FLUENCE AND PULSE WIDTH

CAUTION: If blanching of the surrounding skin occurs, decrease joules or increase cooling as blanching of the skin may lead to blistering.

Larger vessels will accept longer pulse durations. Longer pulse durations result in lower epidermal heating because some of the laser energy absorbed in the epidermis is lost due to diffusion over longer time periods.

USING THE 6-mm HANDPIECE:

Fluence should be 90 – 120 J/cm². If using 3-mm handpiece the fluence requirement will need to be increased to 150 -250 J/cm² to compensate for scattering loss.

Vessel Size	Pulse Width msec
< 0.2 mm	10
0.2 mm	15
0.3 mm	20
0.4 mm	25
0.5 mm	30
0.6 mm	35
0.7 mm	40
0.8 mm	45
0.9 mm	50
1.0 mm	60
1.3 mm	70
1.6 mm	90
2.0 mm	100
2.3 mm	120
2.6 mm	140
3.0 mm	160

3. TREATMENT TECHNIQUE

3.1. ANESTHESIA –

Cooling plate relieves discomfort. Do not use injectable local anesthesia. Topical anesthetic is usually ineffective

3.2. Check the **COOLING PLATE** temperature before and during treatment.

Use colorless gel to insure good contact, adequate cooling and optical coupling to tissue. About 1 cc of gel in the center of the bottom surface of the cooling plate should spread to a thin film when placed in contact with skin.

3.3. TREATMENT TECHNIQUE

- 3.1.1 **Handpiece position.** After selecting the treatment parameters, place the contact cooler over the treatment site. Position the handpiece with good contact between the cooling plate and skin. Wait one or two seconds to allow the treatment area to cool

down. If using the separate cooling plate and handpiece, keep the distal end of the handpiece in contact with the upper surface of the cooling plate.

Note: Use little to no positive pressure of the cooling plate on the skin surface to avoid blanching of vessels.

- 1.1.1 **Pulse placement.** Place consecutive pulses 2-3 mm apart, and wait to observe vessel and vessel response. Pulses should be applied slightly apart from one another (approximately 2–3 mm). Skip areas are permitted- complete linear treatment of the vein is not necessary.
- 1.1.2 **Repeating treatment.** Do not treat repeatedly in the same area. Move the laser handpiece from one area to another to allow the epidermal and dermal tissues to return to a more stable temperature and reduce patient discomfort. Do not immediately retreat static vessels, wait 2 to 3 minutes between passes. Most vessels will require 3 passes.

CAUTION: Overlapping pulses may lead to excessive heat build-up which can result in blisters, scarring or hyperpigmentation. Proper pulse spacing will avoid this. DO NOT STACK PULSES.

3.4. CLINICAL ENDPOINTS

- Vessels may disappear, darken, lighten or appear unchanged but fade with time, variations depend on the depth, diameter and oxygenation of the vessel.
- Blurring of the vessel margins.
- If prolonged blanching of the skin is seen, decrease fluence (J/cm^2) or increase cooling parameters (blanching may lead to blistering).
- If a second pass is needed, fluence may be increased by $10 J/cm^2$
- Contraction, disappearance, lightening or darkening of the vessel will become apparent within 15 seconds after the laser treatment.
- Slight amount of hyperemia in the treated vessel area.
- Urticaria may be visible after 1-2 minutes.

3.4.1. Vessel stasis:

When purging (gently rubbing the vessel) after treatment and the vessel neither disappears nor back fills, then the vessel is static and does not have blood flowing through it. This is a definite endpoint and further treatments are not necessary.

3.4.2. Vessel purging:

Some vessels will disappear after purging post treatment. Purge blood that

is trapped. If treatment is successful it will not backfill. This is another common endpoint where no further treatments are necessary.

4. POST-TREATMENT CONSIDERATIONS

4.1. Topical treatments to reduce erythema may be applied at the discretion of the physician. Cool compresses can be applied for patient comfort. Any skin breakdown or blistering should be treated with a topical antibiotic ointment to prevent infection. Immediate clinical responses to be noted include percentage of vein closure, loss of vein margins, clotting, blanching, erythema, edema, purpura,

4.2. Compression stockings may be used at the clinician's discretion.

4.3. The treated area should be evaluated and documented in the patient's chart. urticaria, patient's tolerance of the procedure or other reactions.

4.4. Re-examination and or re-treatment can be scheduled at 4 weeks.

4.5. EYE PROTECTION

If patient is lying flat, they should ALWAYS wear either goggles or totally opaque external eye shields. The use of glasses especially in that position puts them at an ocular risk.

PROFILE™ CLEARSCAN™ 1.064-μm LASER MODULE: VASCULAR LESION PROTOCOL SUMMARY

1. PRE-TREATMENT:

- Clean the area to be treated, and shave if necessary.
- Remove any topical anesthesia completely.
- Clean the laser lens and cooling plate.
- Avoid tattooed areas; do not treat skin with self-tanning preparations.
- Always use eye protection for the patient, the operator and anyone in the laser treatment room.
- Position patients lying flat with the handpiece held perpendicular to the skin surface.

2. SETTING TREATMENT PARAMETERS:

- Set according to the size and depth of the vessel.
- The chiller should be set to 10°C.

USING THE 6-mm HANDPIECE

Fluence should be 90 – 120 J/cm². (150 – 250 J/cm² for 3-mm handpiece.)

Vessel Size	Pulse Width msec
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0.9 mm	50
1.0 mm	60
1.3 mm	70
1.6 mm	90
2.0 mm	100
2.3 mm	120
2.6 mm	140
3.0 mm	160

3. Treatment Techniques:

- Apply a very thin layer of colorless gel to the skin.

- Position the handpiece with good contact between the cooling plate and skin. Wait one or two seconds to allow the treatment area to cool.
- Do not apply pressure and blanch vessels with cooling plate.
- Place consecutive pulses 2-3 mm apart, and wait to observe vessel and vessel response.
- Pulses should be placed slightly apart from one another (2-3 mm).
- Observe the treated area for several minutes before deciding to treat again or increase fluence.

4. Clinical Endpoints:

- Vessels may disappear, darken, lighten or appear unchanged but fade over time, variations depend on the depth, diameter and oxygenation of the vessel.
- Blurring of the vessel margins.
- If blanching of the skin is seen, decrease fluence (J/cm^2) or increase cooling parameters (blanching may lead to blistering).
- If a second pass is needed, fluence may be increased by $10 J/cm^2$
- Contraction, disappearance, lightening or darkening of the vessel will become apparent 15 seconds after the laser treatment.
- Slight amount of hyperemia in the treated vessel area.
- Urticaria may be visible after 1-2 minutes.

5. POST-TREATMENT CONSIDERATIONS:

- Apply topical treatments as needed.
- Compression stockings as directed by the physician.
- Document treatment in patient's chart.
- Re-treat as needed in 4+weeks.

CAUTION:

Treatment of veins is not recommended around tattoos or the use of self-tanning products. Tattoo ink and chemical tanning products may absorb laser energy resulting in a color change in tattoo ink or a risk of epidermal damage.

Treating within the patient's orbital rim may cause retinal damage or blindness.

Hair in the treatment area may be singed by the laser, resulting in secondary heating of the skin.

A dirty laser lens or cooling plate shield may lead to an inaccurate delivery of laser energy due to scattering or absorption of the laser beam.

If blanching occurs, decrease joules or increase cooling as blanching leads to blistering.

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