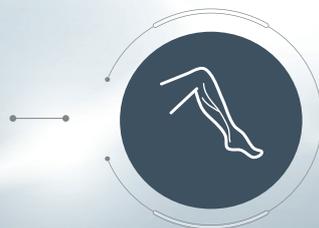


primelase

EXCELLENCE

VASCULARS LESIONS

PROTOCOL



by cocoon medical

Alex
755 nm

Diode
810 nm

Blend
1060 nm
940 nm
810 nm

Yag
1060 nm



Introduction

This protocol aims to assist professionals in the use of the **primelase** excellence device for the treatment of benign vascular lesions and red blemishes on the skin.

It will also complete or reinforce the information provided in the user manual regarding usage instructions, precautions and the necessary warnings required to reduce the risk of physical injury.

All users must read the entirety of the user manual before studying this protocol and using the device.

This treatment should always be carried out under medical supervision.

primelase excellence is a platform that can be used for a diverse array of applications (hair removal, removal of pigmented lesions, rejuvenation, etc.); this protocol, however, focuses on the removal of benign vascular lesions and red blemishes on the skin. Thanks to its high optical power of up to 4,000W and optimal size of 1 cm², the **primelase** excellence platform's 1060 nm applicator has established itself as the best diode laser on the market for treating these pathologies quickly, effectively and safely.

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1. Background

Benign vascular lesions of the skin are treated by dermatology and vascular medicine specialists. These lesions are typically undesirable for the patient due to their colour, size and other factors.

For this 1060 nm high-power diode laser application, **primelase** excellence focuses on the removal of varicules (telangiectasias, also known as spider veins, and venulectasias) and cherry angiomas. Telangiectasias are visible cutaneous vessels with a diameter of 0.1-1 mm, and venulectasias are cutaneous vessels in the lower limbs with dilations above 1 mm.

The following table lists the most common types of benign vascular lesions:

Telangiectasias associated with an incompetent lateral venous system and an incompetent internal saphenous vein

The most common lesion, also known as spider veins
 Found in the lower limbs (thighs and calves)
 Bluish or reddish colouration



Figure 1

Telangiectasias developed following sclerotherapy or varicose vein surgery

Matting or grouping of fine telangiectasias of less than 0.2 mm
 Found in the lower limbs
 Reddish colour



Figure 2

Localised post-traumatic telangiectasias

Appear following mild trauma, mostly around scar tissue
 Reddish colour



Figure 3

Progressive essential telangiectasias

Uncommon
 Found on the calves and feet
 Bluish or bright red in colour, fill rapidly
 after manual pressure is released



Figure 4

Venulectasias

Very common lesion
 Vessels with a diameter greater than 1 mm
 Found in the lower limbs
 Bluish colour



Figure 5

Cherry or senile angiomas

Small punctate skin lesions, 1-5 mm in
 diameter
 Found all over the body, but mostly on the
 face and the upper torso
 Reddish colour



Figure 6

Many invasive techniques exist that are commonly used to remove benign vascular lesions (chemical sclerotherapy, surgery, cauterisation, etc.). Laser is the best non-invasive technique. It has been shown to be an effective and safe method that facilitates the selective removal of red blemishes and dilated vessels, and due to its non-invasive character, it successfully achieves results with minimal side effects. Furthermore, it also prevents the formation of telangiectatic matting and, at the same time, ensures complete coagulation of the vessel, thereby preventing the extravasation of erythrocytes and limiting post-treatment hyperpigmentation¹⁻².

However, the diagnosis of a dermatology or vascular medicine specialist is essential to properly identify lesions that can potentially be treated with this technique, and also to optimise the results.

The 1060 nm, high power (4,000W) diode laser with a 10x10 mm² spot size that is part of the **primelase** excellence platform from **cocoon medical** (Barcelona, Spain) has demonstrated good results for the removal of varicules and cherry angiomas, particularly in lesions made up of larger bluish varicules.

2. Biological effects

The **primelase** excellence platform has a high-power (4,000 W) 1060 nm diode laser applicator that is suitable for treating varicules and cherry angiomas, thanks to working with fluences of up to 120 J/cm² with a spot size of 10x10 mm². This method of removing benign vascular lesions, which is also known as photosclerosis, is based on a biological process called selective photothermolysis³⁻⁷.

At this wavelength (1060 nm), the laser penetrates into the dermis, where the blood vessels and the target chromophore, haemoglobin, are located. Our therapeutic target, therefore, is haemoglobin. Selective photothermolysis involves the energy of the laser being absorbed by the target chromophore, which experiences greater optical absorption of said wavelength than the surrounding tissue⁷⁻⁹. During the pulse, the energy emitted by the laser is absorbed and converted into heat, which increases the temperature of the target chromophore. The heat is initially confined to the chromophore before gradually dissipating to the surrounding tissue, which is at a lower temperature. Despite this, the tissue's rate of energy conduction is relatively slow, so the temperature in the target chromophore is greater, while the surrounding tissue does not experience a significant increase in temperature¹⁰.

The basis of laser photosclerosis is the transformation of haemoglobin into methemoglobin, which has an absorption coefficient that is 3-4 times greater than that of haemoglobin¹⁰. The heat produced by the absorption of the laser causes the photocoagulation of blood when its temperature exceeds 70°C. The heat is transmitted to the walls of the varicule causing its epithelial cells to denature, which results in damage and inflammation and prevents recanalisation¹¹⁻¹². With time, the tissue repairs itself, the culmination of which is the disappearance of the varicule.

Another important factor to consider is the duration of the laser pulse. The **primelase** excellence platform's 1060 nm, 4,000W diode laser enables high-energy and short-duration pulses to be achieved due to its high power, which is unique in the market and essential for limiting the thermal damage to the varicule without affecting the adjacent dermis¹³. The laser pulse must be of a duration that is shorter than the thermal relaxation time of the varicules if the photosclerosis is to be effective, this can be achieved with **primelase** excellence.

3. Diagnosing the status of the patient

Before performing the **primelase** excellence treatment, an appointment should be made with the dermatologist and/or the vascular medicine specialist where they will carry out an assessment of the lesions and analyse the medical history of the patient. Performing Doppler echocardiography is recommended to assess the blood flow that circulates through the varicules that will be treated; this allows the realistic expectations for the treatment to be evaluated. Before performing any laser treatment, it must be observed if there is reflux by perforator, reticular or incompetent varicose veins. If this is the case, surgical or sclerotherapy treatment should be used first, and the remaining lesions can be treated with a laser during a second phase. The ideal patient for the removal of varicules and/or cherry angiomas is someone with light skin.

The primary indicators of the success of the treatment are:

- In varicules, achieving one of the two possible end-points:

- Spasm: an immediate clearing of the vessel occurs.
- Thrombosis: the vessel darkens.
- In cherry angiomas, achieving the end-point:
 - The cherry angioma darkens to a purple/grey colour.

During this first visit an initial evaluation will be performed and the medical history of the patient will be covered, along with information related to: potential alternative therapies, contraindications, realistic expectations for the treatment, potential side effects and complications of the treatment. In addition, the informed consent of the patient will also be obtained.

During the initial evaluation the medical practitioner must take into account:

- The colour of the skin (classification of the phototype according to the Fitzpatrick scale)
- The characteristics of the lesion: colour, diameter, reflux spots
- The anatomical location
- The existence of a history of herpes

When analysing the patient's medical history the medical practitioner must take into account:

- When the lesion appeared
- Age of onset
- History of pregnancies
- Hormonal treatments
- Family history
- Whether a prior treatment has been used to remove the lesion
- The potential existence of a herpes simplex infection
- The presence of pain, cramps or a sensation of fatigue in the legs
- History of hypertrophic scarring or keloids
- Recent exposure to the sun or UVA
- Toxic and pharmacological records

The patient must be informed of potential therapeutic alternatives:

- Sclerotherapy: this is performed by injecting a chemical product into the telangiectasias or reticular veins. The most commonly used chemical in Spain is polidocanol, which comes in different concentrations and as a foam. This product triggers a chemical reaction in the vessel that leads to endoluminal inflammation, which in turn results in closure and sclerosis. Multiple sessions are sometimes required to achieve the desired result.
- Surgery: in the majority of cases, veins are removed through consecutive small punctures in the skin. In more serious cases, like varicose veins, endoscopic surgery will be required.
- The 755 nm alexandrite laser, 595 nm pulsed dye laser and 1064 nm Nd: YAG laser have all demonstrated efficacy for the removal of benign vascular lesions.

The patient will be informed of the contraindications of the treatment:

- Immunosuppression
- Psychiatric conditions
- Recent sun exposure <15 days
- Isotretinoin treatment in the last 6 months
- History of hyper or hypopigmentation
- Active herpes simplex virus infection
- Healing alterations
- Active or recent malignant pathology (cancer), within the 5 years, use of anticancer drugs.
- Vitiligo
- Psoriasis
- Treatments that involve medications which increase light sensitivity
- A history of keloid formation
- A history of livedo reticularis
- The use of anticoagulants
- The presence of a dysplastic nevus in the treatment area
- A history of bleeding disorders
- A history of vascular and collagen disorders
- The presence of tattoos in the treatment area
- A history of immunodeficiency
- A history of erythema ab igne
- Photosensitivity disorders
- A sensation of irritation, itching or burning during or after the treatment
- Burns and/or scabs in the treatment area
- Pregnancy
- Ulcers
- Diabetes
- Vasculitis

The precautions that must be taken before beginning the treatment will be covered:

- With thick spider veins, it is advisable to ensure that the circulation is not affected. So it is advisable to perform an ultrasound scan and/or a Doppler scan before the treatment.
- Avoid sunbathing or UVA treatments for at least 15 days before and after the treatment.
- In patients over 70 years old, or with a history of herpes, or those who are immunosuppressed, it is essential to use an anti-herpetic prophylaxis with acycloguanosine 48-72 hours prior to treatment.

The patient will be informed of the possible side effects:

- Exercise precaution with tanned or dark-skinned patients of phototypes IV-VI, as there is a significant risk of causing changes to pigmentation, hypopigmentation in particular.
- Treating patients with phototypes IV-VI also increases the risk of the appearance of scars due to epidermal damage.
- The appearance of purple discolouration and punctate haemorrhages in the treatment area is a sign that the energy density used is too high and is increasing the risk of the appearance of undesirable effects.
- Permanent or long-lasting reduction of hair in the treatment area.
- Oedema and erythema
- Scabs
- Temporary changes to pigmentation (hyper or hypopigmentation)

The patient will be informed of possible complications:

- Dyschromia (alterations to pigmentation, hyper or hypo)
- Prolonged erythema
- Infection
- Contact dermatitis due to creams or bandages
- Blisters
- Keloids or bad healing
- Infection
- Pruritus
- Formation of a cord (collapsed vein), detectable by touch

The patient will be further informed that, depending on the type of lesion, the dermatologist may consider the need to perform several sessions (typically 1-2 sessions), which will be carried out every 6-8 weeks.

4. Parameters

The suggested parameters for the treatment are listed in table 1. These parameters are based on the clinical experience of doctors who treat benign vascular lesions. The specialists must use their clinical knowledge and experience when determining the parameters for the treatment, as they must be adjusted in accordance with:

- The type of lesion (shape, colour, density, etc.)
- The patient's skin type or the presence of a tan
- Observation of the end-point during or immediately following the treatment

In the case of varicules, the minimum dose of effective energy must always be aimed for. A fluence of 80 J/cm² is used initially, and then gradually increased until the desired end-point is achieved. When treating varicules, NEVER perform two consecutive shots on the same point. If the selected fluence is too low, treat other areas first to allow said point to cool down and then return later to discharge another shot with the indicated fluence. Using excessively high fluences may cause thermal damage and scarring.

In the case of cherry angiomas, the minimum effective energy dose must always be aimed for. A fluence of 20 J/cm² is used initially, and then gradually increased until the desired end-point is achieved. When treating cherry angiomas, 4 consecutive shots must be performed on the same point. Using excessively high fluences may cause thermal damage and scarring.

Yag ^{1060nm} M 10x10 | 1060nm



Skin Phototype (Fitzpatrick I-IV)	Lesion	Fluence (J/cm ²)	Pulse Duration (ms) AUTO*	Frequency (Hz)	Treatment
I-IV	Telangiectasias or spider veins (thickness <1 mm)	80-120	33-74	1	1 pulse With contact and gel
	Venulectasias (thickness >1 mm)	100-120	50-74	1	1 pulse With contact and gel
	Cherry angiomas	20-30	6-9	1	4 consecutive pulses With contact and gel

*AUTO: Minimum pulse duration based on the selected fluence

5. Step by step: varicules (telangiectasias and venulectasias)

General clarifications:

For very sensitive patients, the application of EMLA anaesthetic cream along with occlusion with osmotic film may be recommended. The patient will be instructed to apply the cream 90 minutes prior to the scheduled treatment time. However, the use of anaesthetics is generally not recommended as they cause vasoconstriction and may limit the effectiveness of the treatment.

Treatment procedure:

- Cleanse, degrease and disinfect the treatment area.
- If there is hair, shave the treatment area. If the patient does not want to be shaved, inform the patient that the hair could be burned by the laser.
- Demarcate the treatment area. (Figure 7)



Figure 7. Demarcation of the treatment area

- The patient, medical practitioner and the staff must wear appropriate protective eyewear.
- Select the parameters on the treatment screen. Begin the treatment with the lowest recommended energy levels and evaluate the response of the patient. (Figure 8)



Figure 8. primelase excellence screen

- The use of a gel is recommended to facilitate the movement of the head of the applicator across the skin and to minimise energy loss (figure 9). It is not advisable to cool the area with packs prior to treatment, as this may lower the temperature of the vessels making photothermal coagulation difficult to achieve.



Figure 9. Spread gel over the area to be treated

- Rest the head of the laser applicator on the skin for 1-3 seconds to cool the skin, then perform a shot. (Figure 10)



Figure 10. The head of the applicator resting on the skin, ready for shooting

- The applicator must make contact with the skin in order to cool the epidermis, but no pressure should be applied. Pressure could potentially push the blood out of the target veins, thereby reducing the amount of oxyhaemoglobin that is available to absorb the laser energy.
- The shots must juxtapose one another. Do not use dynamic mode or overlap the area where shots are discharged.
- Treating veins in a distal to proximal direction is recommended to redirect the blood to healthier veins of the vascular system.
- In cases where it is necessary, cooling with the sapphire crystal can be used to ease pain in the treatment areas or to prevent pain in sensitive areas. To do this, simply pass the head of the applicator over the area in circular motions for 2-3 seconds.

- Verification that one of the two potential end-points has been reached:

- Spasm: an immediate clearing of the vessel occurs. (Figure 11)



Figure 11. Spider vein before (left) and immediately after the treatment (right), showing the lightening of the vessel

- Thrombosis: the vessel darkens. (Figure 12)



Figure 12. Spider vein before (left) and immediately after the treatment (right), showing the darkening of the vessel

- Inflammation: transient inflammation is present following the emptying or darkening of the vessel, this will disappear over the following days. (Figure 13)



Figure 13. Spider vein before (left) and immediately after the treatment (right), showing the inflammation of the vessel

6. Step by step: cherry angiomas

General clarifications:

For very sensitive patients, the application of EMLA anaesthetic cream along with occlusion with osmotic film may be recommended. The patient will be instructed to apply the cream 90 minutes prior to the scheduled treatment time. However, the use of anaesthetics is generally not recommended as they cause vasoconstriction and may limit the effectiveness of the treatment.

Treatment procedure:

- Clean, degrease and disinfect the skin. (Figure 14)



Figure 14. Cherry angiomas ready to be treated

- If there is hair, shave the treatment area.
- Demarcate the treatment area. (Figure 15)



Figure 15. Mark the cherry angiomas with a white pencil

- The patient, medical practitioner and the staff must wear appropriate protective eyewear.
- Select the parameters on the treatment screen. Begin the treatment with the lowest recommended energy levels and evaluate the response of the patient. (Figure 16)



Figure 16. primelase screen

- The use of a gel to minimise energy loss is recommended (figure 17). It is not advisable to cool the area with packs prior to treatment, as this may lower the temperature of the vessels making photothermal coagulation difficult to achieve.



Figure 17. Spread gel over the area to be treated

- Rest the head of the diode laser applicator on the skin for 1-3 seconds to cool the skin, then perform four consecutive shots without lifting the head of the applicator away from the skin. The applicator must be in contact with the skin in order to cool the epidermis, but pressure should not be applied. (Figure 18)



Figure 18. The head of the applicator resting on the skin, ready for shooting

- In cases where it is necessary, cooling with the sapphire crystal can be used to ease pain in the treatment areas or to prevent pain in sensitive areas. To do this, simply pass the head of the applicator over the area in circular motions for 2-3 seconds.
- Verification that the end-point has been reached. (Figure 19)
 - The cherry angioma darkens to a purple/grey colour.



Figure 19. Cherry angiomas immediately after the treatment

- If, after 1 minute, an end-point cannot be observed, discharge another shot.

7. Post-treatment

Varicules:

Erythema and inflammation of the treated vascular route will be present, the duration of which will vary depending on the size of the vessel and the parameters used.

A lightening or an initial darkening will be present. Lightening of the lesion occurs between 4-8 weeks after laser therapy.

Cherry angiomas:

The lesion will gradually darken during the 24-48 hours following the treatment, until a scab forms which may be present until 7-21 days after the treatment.

The lesion will typically be resolved at the 21-30 day mark, resulting in the lightening of the pigment.

Post-treatment recommendations

Varicules:

- Washing and applying vitamin K or topical iron chelating agents is recommended during the first 15 days.
- Sun exposure must be avoided during the first 4-6 weeks following treatment and an SPF 50 sunscreen must be used to avoid hyperpigmentation.
- The use of a pentosan polysulfate sodium cream on the lesion is recommended from the 3rd day following the treatment and for a period of 1 week to assist the reabsorption of the cord that forms in thick varicose veins.

Cherry angiomas:

- 1% hydrocortisone creams can be used to prevent inflammatory reactions.

- Washing the area with a neutral soap and applying antibiotic, e.g. Plasimine (mupirocin), or antiseptic cream, e.g. Diprogenta or Cicalfate (copper and zinc salts), as indicated is recommended for the first 15 days.
- Sun exposure must be avoided from day one and an SPF 50 sunscreen must be used to avoid hyperpigmentation.
- The use of moisturisers is generally not advised when the scab is still present as they may moisten it, avoiding this will help the skin to regenerate.
- Revitalising creams can be used once the scab has fallen off.

Post-treatment assessment visit

The success of the treatment is assessed through the observation of the lightening of the telangiectasias and/or cherry angiomas in the first session’s control visit and also at the time of discharge. At the control visit, the dermatologist may consider the need to perform several sessions (typically 3-5), which will be carried out every 6-8 weeks, depending on the patient.

GRADE	CRITERIA	PERCENTAGE: Lightening
-1	Worsens. Post-inflammatory hyperpigmentation occurs	0
0	No change	0
1	Minimal lightening	1-25%
2	Moderate lightening	26-75%
3	Pronounced lightening	76-100%

Table 2: Treatment evaluation test

8. Final results

The efficacy and safety of primelase excellence treatments have been demonstrated. As is shown in the figures, the telangiectasias and cherry angiomas disappear after the treatment, thereby achieving the removal of the lesions that are undesirable for the patient. The final results of the treatment can be seen in the following photographs.

The before and after results of the treatment on thick varicules or varicose veins can be seen in the following photographs. (Figure 20)



Figure 20. Thick spider veins or varicose veins before (left) and after the treatment (right)

The before and after results of the treatment on fine varicules or telangiectasias can be seen in the following photographs. (Figure 21 and 22)



Figure 21 and 22. Fine varicules or telangiectasias before (left) and after the treatment (right)

The before and after results of the treatment on ruby points or cherry angiomas can be seen in the following photographs. (Figure 23)



Figure 23. Ruby points or cherry angiomas before (left) and after the treatment (right)

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