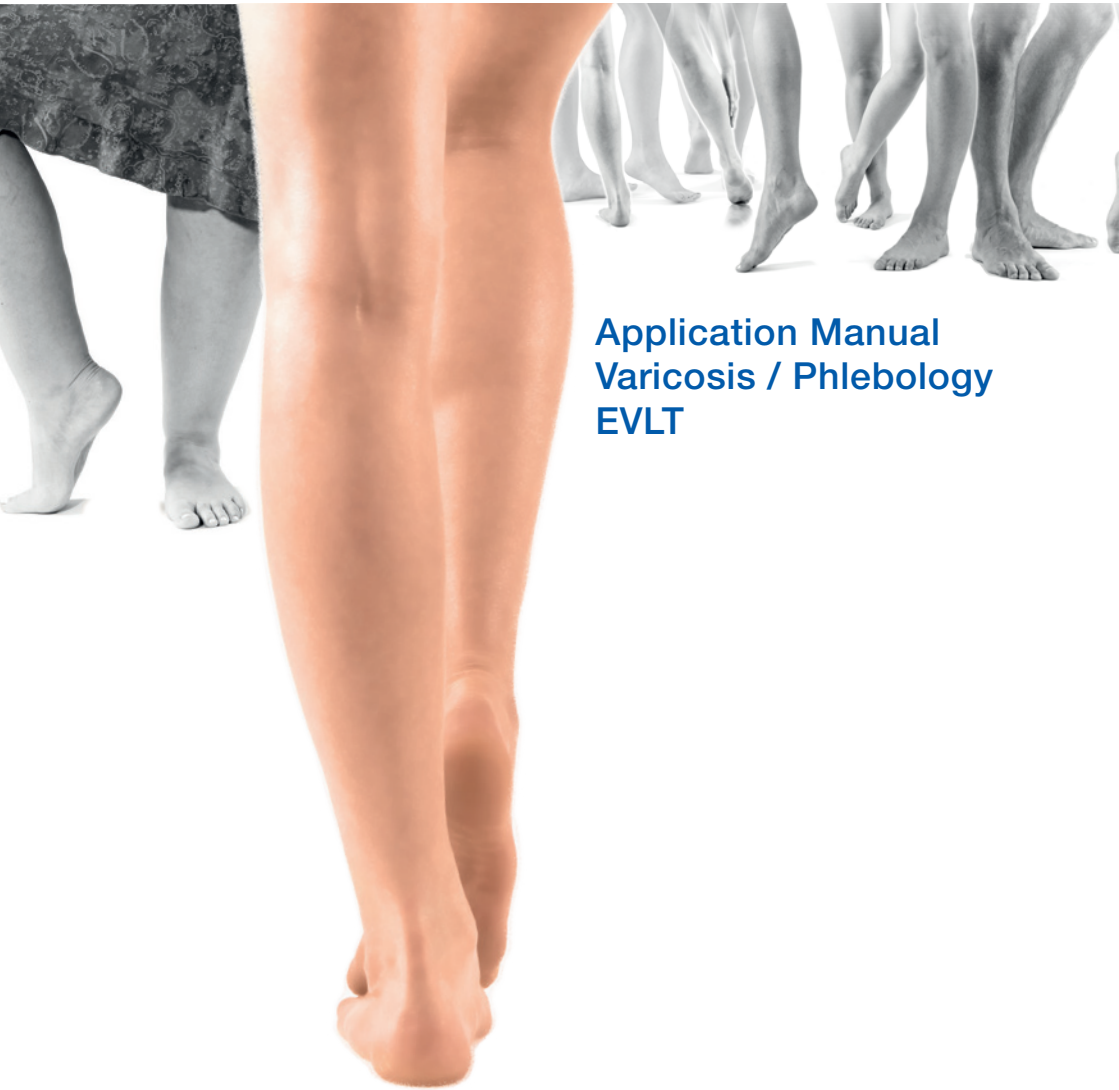
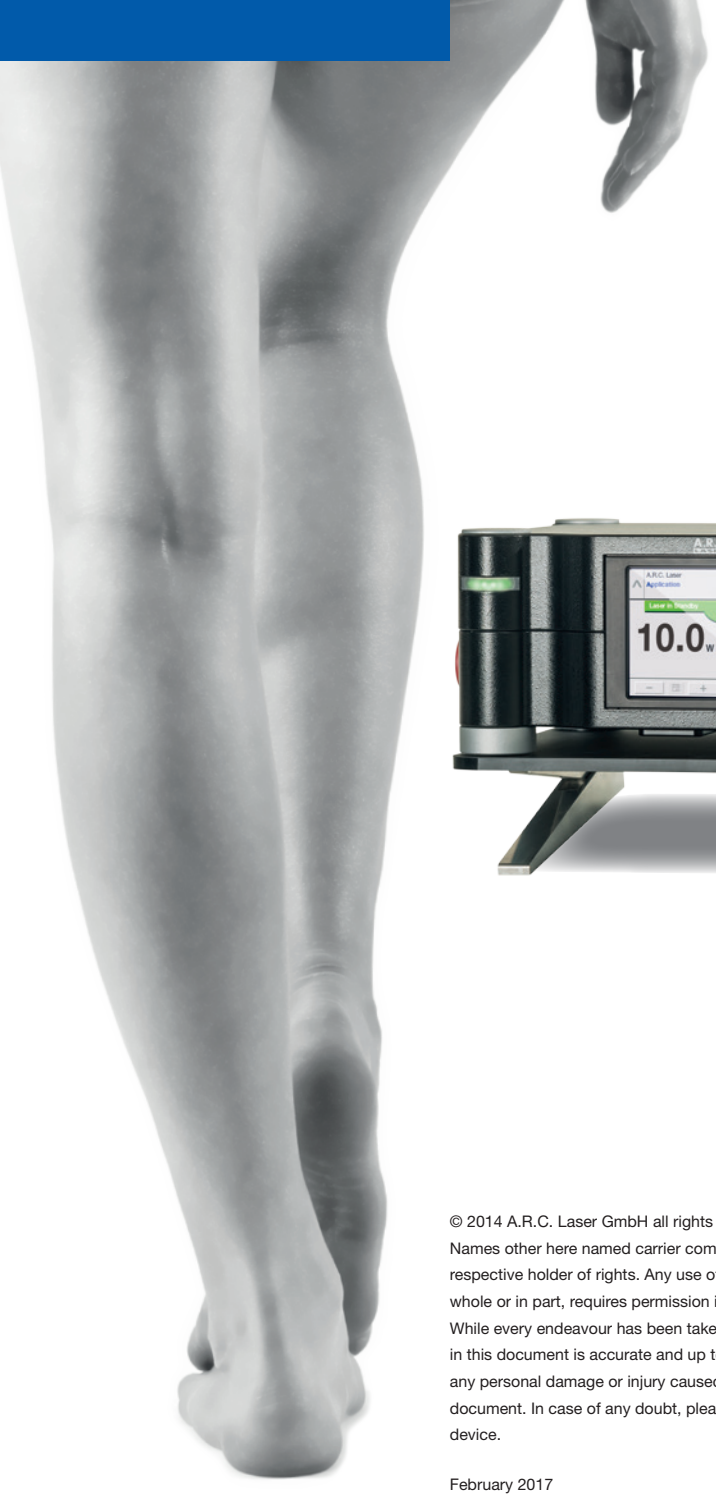
# Diode Laser 1470 nm



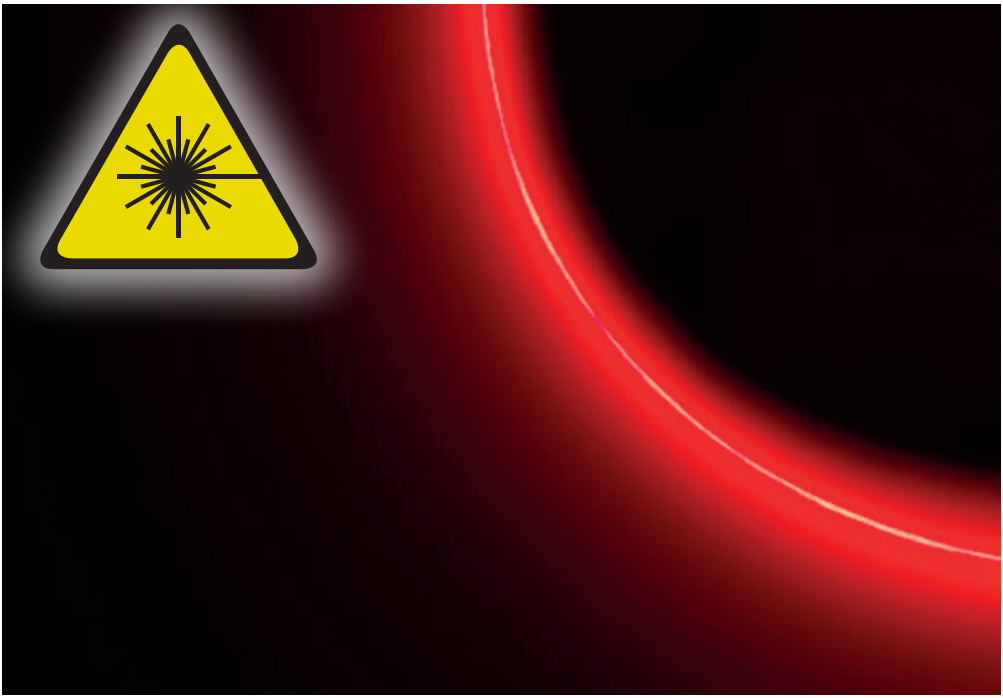
## Application Manual
## Varicosis / Phlebology
## EVLT

A.R.C. LASER
enlighten your surgery.



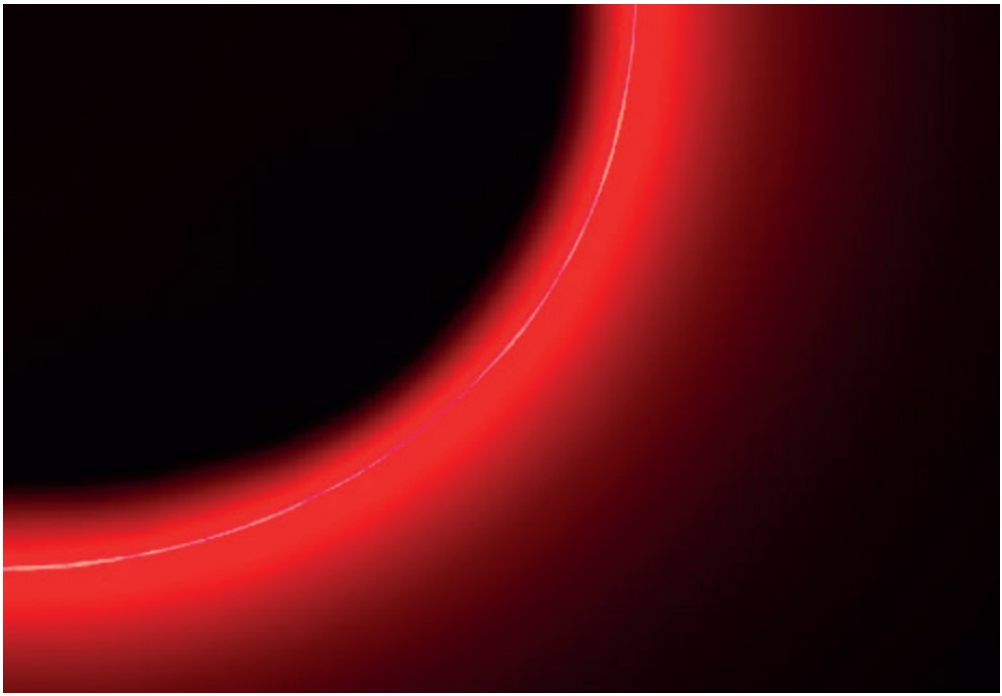



February 2017



## THERAPY INDICATIONS

1. This manual covers the endoveneous treatment of varicose veins approved for use with the laser.
2. Clinical information detailed in this manual is intended to be used by a healthcare professional who posses relevant medical background, as well basic knowledge with medical lasers.
3. In case of any doubt, it is strongly advisable to refer to appropriate literature relevant to the intended use. If no such literature is available, please contact your local A.R.C. Laser representative for support.
4. Laser parameters values are usually detailed with min/max values. These parameters were developed based on the extensive use of the device by healthcare professionals.
5. User is always required to common sense when using these parameters, taking into consideration relevant patient information. Neither the author nor the manufacturer will be liable for a treatment failure caused by misuse of the device.



**BASIC LASER SAFETY INSTRUCTIONS**

Since safety goggles must be worn throughout the procedure, the operator must be aware that his/her vision is temporarily altered (color shades appear differently, contrast may be dimmed, etc.) - this can lead to visual misjudgment. It is than recommended from time to time to turn off the laser, remove the goggles and inspect the treated area without goggles.

In case of any eye injury due to disregard of the eye protection by safety goggles, an ophthalmologist hast to be consulted.

Laser radiation can cause immediate and unwanted tissue damage, therefore it is highly advisable to have within reach burns control measures (such as: ice or cooling pads, topical products, special dressings for burns, etc.).

Laser radiation can cause unwanted Hemostasis and Coagulation damages. The extent strongly depends on the exposure time to the laser's radiation.

Coagulated tissue is not harmful and normally will normally not cause issues. In case of overheating of temperature-sensitive areas, applying immediate local cooling should be done at treatment should be stopped and revaluated.

Laser radiation emitted by the laser can cause serious damage to the patient as well as to the operator and other individuals present near the device. The laser is classified as a Class 4 laser device, this means its laser beam can cause damage when pointed directly or indirectly (reflections) to human tissue.

Most serious injuries may occur, if laser radiation is targeted to the eyes. Even at low level laser power, the eye's retina may suffer serious damage which could lead to blindness. Injury risk level depends on laser wavelength, distance, energy density, power (energy per time) and exposure time.

Discomfort from the heating which is generated by the laser may occur. To avoid this, the user should follow the application parameter guidelines. If possible, cooling can reduce patients discomfort after the treatment.


Laser radiation within the spectrum of 400 nm and 1400 nm poses the highest potential risk to the human eye. The cornea as well as the anterior chamber, the lens and the vitreous body of the eye contain mainly water, while other tissue components (mainly collagen) play a minor role for the laser tissue interaction.

Such radiation has very low absorption index in water, therefore is able to easily penetrate and reach the retina, where it is absorbed by the blood and the retinal pigment epithelium.

Since the WOLF laser emits infrared radiation and given its high intensity, it is absolutely necessary to wear safety goggles at all times while using the device. The infrared laser radiation can also be harmful to the skin and other body parts if not properly used.

In addition, laser radiation can ignite inflammable materials, so such materials should always be stored, or kept away from the treatment room.

How the laser perform in a specific application is based on laser radiation and tissue interaction, as

the laser radiation may be absorbed, scattered or reflected by the treated area. Air has very little effect on the laser radiation so interaction between air and the laser radiation can be neglected. Reflection do plays a major role with metal, glass and other reflecting surfaces, but not so much when it comes to human tissue.

When emitting laser radiation on human tissue, reflection is minimal but not zero! Although laser radiation may be scattered on a tissue‘s surface, it does not influence much the overall energy absorption. Absorption is mainly derived by the laser radiation physical properties (wavelength). Absorption defines how much of the laser radiation is converted into heat, which causes the desired clinical effects (coagulation / vaporisation).

At low energy densities (large laser beam spot or low laser power), heat gradually built within the tissue. The smaller the beam spot size, or the higher the power, the faster heat will built. Above a certain limit, the tissue can no longer tolerate the amount of absorbed heat, proteins starts to denaturants and coagulation occurs. If continuing to heat up the tissue, the tissue water (intra and extracellular water) will suddenly evaporates (> 300° C). Tissue is fragmented and destroyed - cutting / evaporation is achieved.

| LASER RADIATION & TEMPERATURE EFFECT | |
|---|---|
| TEMPERATURE | EFFECT |
| > 40° C | Enzyme induction, membrane disaggregation, edema |
| 45° – 65° C | Tissue damage, irreversibility depends on irradiation time |
| > 65° C | Coagulation |
| > 100° C | Dehydration |
| > 150° C | Carbonisation |

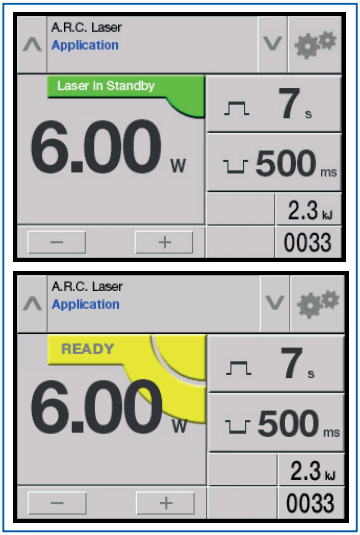
## BASIC LASER SAFETY INSTRUCTIONS

To avoid any injuries it is important
to follow the laser safety instructions:

1. The laser system should only be used by a trained personnel, undergone training by A.R.C. Laser or A.R.C. Laser approved trainer.
2. The room or area, where the laser system is used must be marked with the included warning signs in clear and visible way, to warn against entering the room/area without adequate protection while the laser is in use.
3. The laser system should never be used, in case of a doubt the device or any of its component are faulty. The fiber delivery system should periodically be tested, by aiming the beam to a flat surface (at approx. 5cm distance) and observing the spot shape.
4. The device indicats when the laser is placed on “Ready“ mode. Any person present at the area where laser radiation can occur (laser treatment area / laser room) should wear laser safety goggles, to protect the eyes from laser radiation.

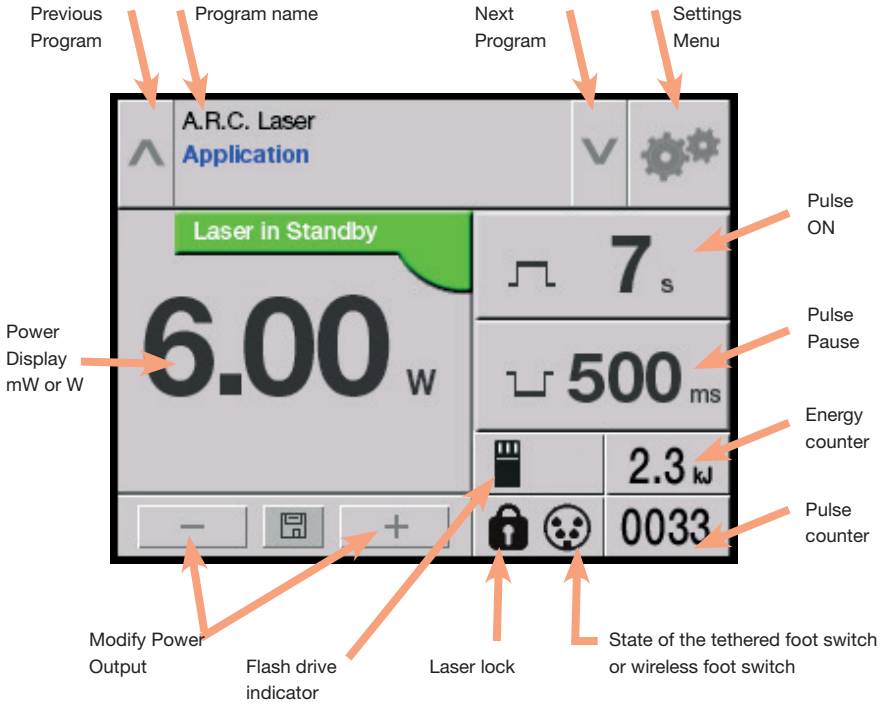

5. The laser device must be used only for its defined application; never irradiate other material / or areas not detailed in the application description.
6. Special care should be taken to avoid irradiating reflecting materials, since reflected laser radiation can still cause serious harm.
7. Always switch off the laser from its „Ready“ mode when not in use; e. g. during long pauses or at the end of the procedure.

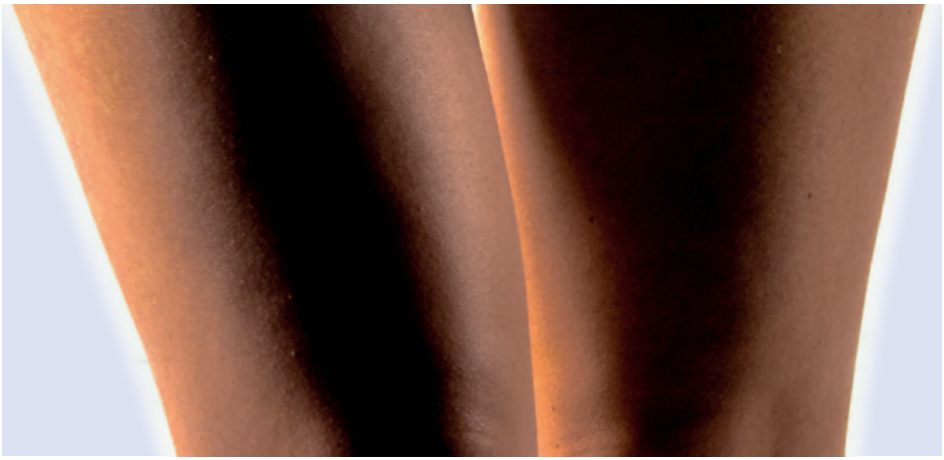
READY-Screen



## WOLF


Emergency Switch. Push to switch off the laser in case of emergency.
Touch Screen
Push Button putting laser into “STAND BY” mode
Red light indicating laser is being emitted
Fiber socket

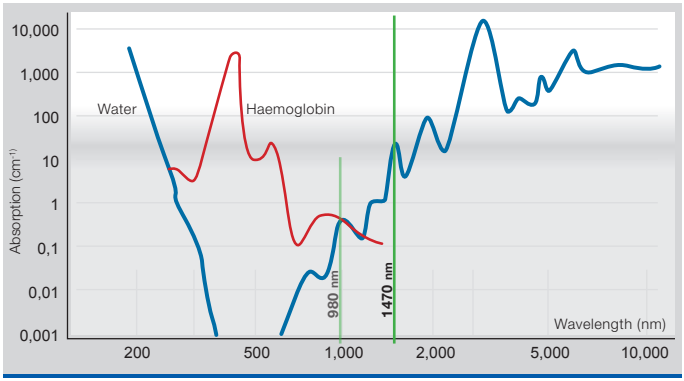

Previous Program
Program name
Next Program
Settings Menu
A.R.C. Laser
Application
Laser in Standby
6.00 W
7 s
500 ms
2.3 kJ
0033
Pulse ON
Pulse Pause
Energy counter
Pulse counter
Power Display mW or W
Modify Power Output
Flash drive indicator
Laser lock
State of the tethered foot switch or wireless foot switch



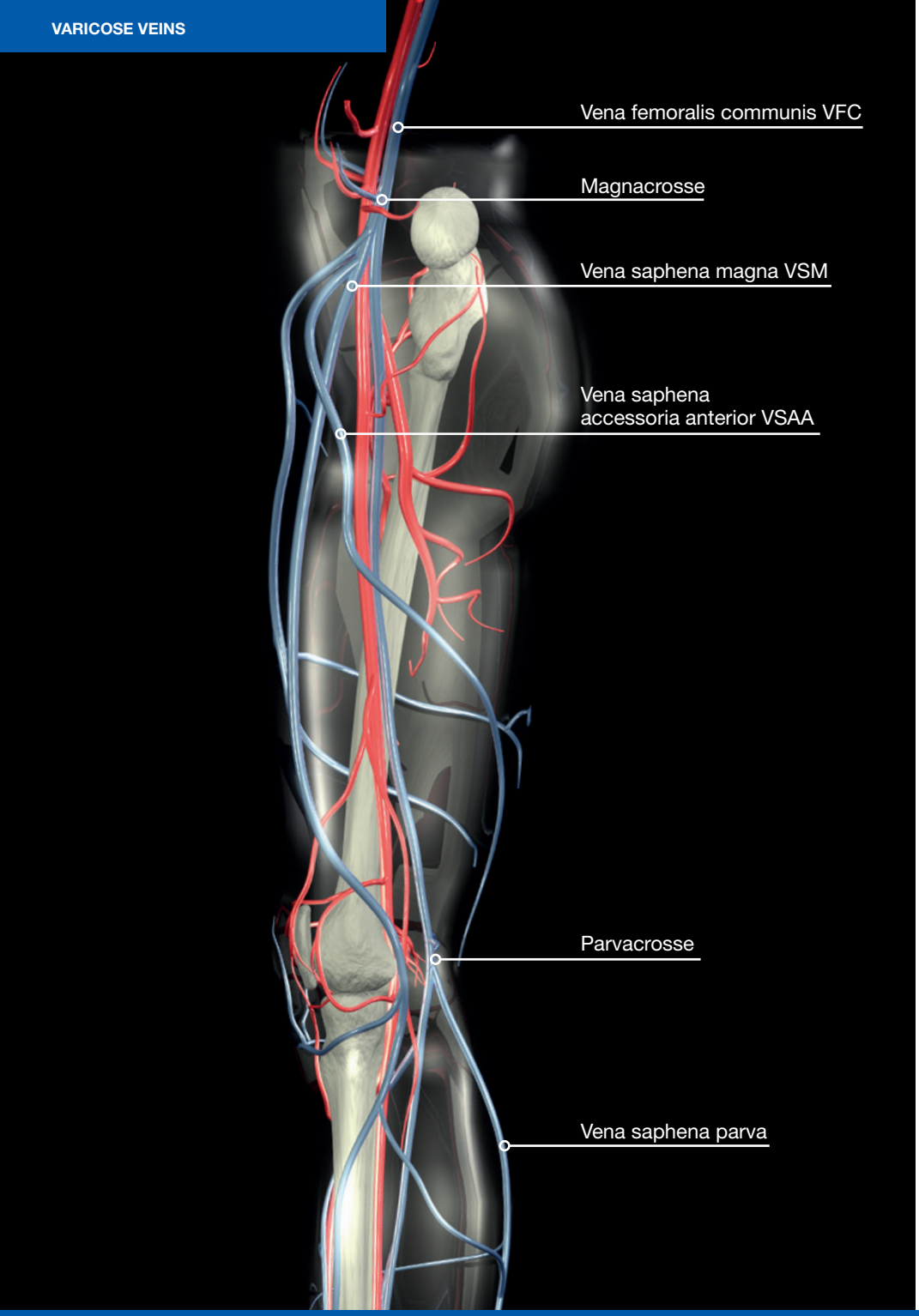
## 1470 nm – STATE OF THE ART

**In endovenous laser therapy of varicose veins, the laser radiation is brought to the dysfunctional target segment inside the vein via a fiber to cause thermal damage of the venous tissue.**

The advantage of an endovenous laser therapy with 1470 nm is that the absorption coefficient of water is 55 to 60 times higher at this wavelength than at 980 nm. Thus, a precise application of laser radiation into the vein wall can be performed. Furthermore, the treatment requires less total energy and shows lower heat generation. Due to the use of 1470 nm, the patient comfort is increased, whereas postoperative pain and haematoma are demonstrably reduced.




The laser radiation of 1470 nm is not within the visible range. Therefore make sure that every person in the area, that may be impacted by laser radiation, is wearing laser safety goggles throughout the entire treatment.


Vena femoralis communis VFC
Magnacrosse
Vena saphena magna VSM
Vena saphena
accessoria anterior VSAA
Parvacrosse
Vena saphena parva

# VARICOSE VEINS

## DEFINITION

Varicose veins are enlarged and tortuous vessels of the superficial venous system, which underlie a chronic venous insufficiency (CVI) with a resulting venous hypertension.

## PATHOGENESIS

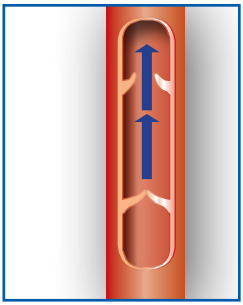
Varicose veins are caused by blood, which remains in the vessel if the vein walls are weak, the neighboring tissue builds up less pressure or sufficient movement of legs is missing. The veins are stretched until the venous valves can no longer fully perform their closure function and the flow is reversed, which is called reflux (following the gravity, blood flows in the direction of the foot instead of the heart). The blood sinks and further dilates the already enlarged vessel walls. If it is the case that a hypertension is present, the venous dysfunction is deteriorating continuously. This phenomenon continuous downwards more and more quickly due to increasing local enlargement, which breaks down other adjacent valves. If some valves, which are connected in series, can no longer work well, the total superficial venous system falls down.

## FACTS

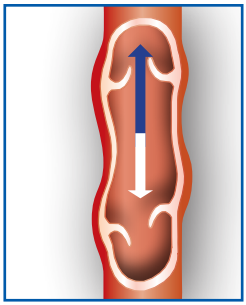
In Europe and the USA, 25 % of women and 15 % of men suffer from venous insufficiency of lower limbs. In 70 – 80 % of the patients suffering from varicose veins, the great saphenous vein (GSV) is insufficient. Here, the venous reflux results from the functional loss of the sapheno-femoral-junction. The small saphenous vein (SSV) is affected less commonly in about 10 % of the patients, but the symptoms are equally severe. The reflux of the SSV is caused by the functional loss of the sapheno-popliteal-junction. The reflux of the anterior accessory saphenous vein (AASV) occur at 10 % of the patients. Another reason of the venous reflux is the functional loss of the perforating veins. [Literature 3].

All 4 causes of reflux can be treated with the endovenous laser therapy.

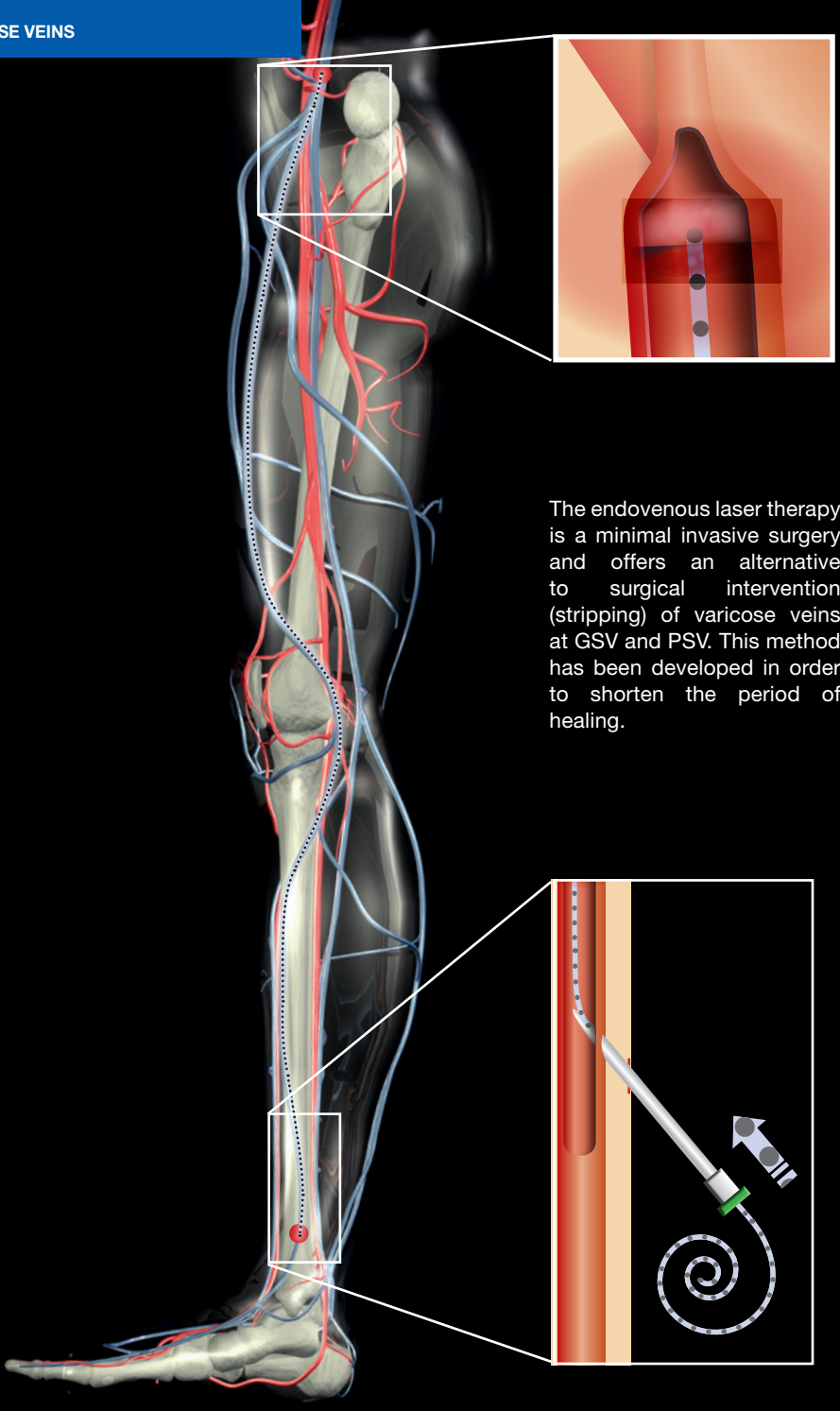
Varicose vein



The venous valves prevent a reflux of the blood on its way back to the heart.



Varicose veins occur when the vein walls are overstretched and the venous valves can no longer fully perform their closure function.



The endovenous laser therapy is a minimal invasive surgery and offers an alternative to surgical intervention (stripping) of varicose veins at GSV and PSV. This method has been developed in order to shorten the period of healing.

# ENDOVENOUS LASER THERAPY (EVLT)

## THE MECHANISM OF ACTION

The mechanism of endovenous laser therapy is based on the thermal destruction of venous tissue. In this process, the laser radiation is transferred via the fiber to the dysfunctional segment inside the vein. Within the penetration area of the laser beam, heat is generated by direct absorption of laser energy and the inside vein wall intentionally irreversible damaged. The vein closes, hardens and completely disappears within a few month (6 – 9) or is reduced, respectively, rebuilt to connective tissue by the body. [Literature 3]

Among endovenous thermo ablation processes, EVLT offers following advantages in comparison to radio frequency ablation:

- Access via puncture due to small fiber dimension
- Focused and specific heat input into the vessel wall
- Lower heat input into surrounding tissue
- Fewer pain during surgery
- Fewer postoperative pain
- Clearly cheaper applicators
- Enhanced fiber positioning based on aiming beam function

## INDICATION AND CONTRAINDICATION

**Indication:**

- Normalization / improvement of venous hemodynamics
- Improvement / removal of banking up in the legs or long-term edemas
- Healing / reduction of rate of recurrence of venous ulcers and other forms of trophic disorders
- Prevention of further complications ( e.g. varicose phlebitis)

**Relative Contraindication:**

- Severe general disease
- Dysfunction of homeostasis
- Arterial occlusive disease stage III and IV according to Fontaine
- Pregnancy
- Severe diabetic polyneuropathy
- Neoplasm / severe consuming diseases
- Heart failure stage NYHA > II – III

**Absolute Contraindication:**

- Acute phlebothrombosis, patients having an elevated risk of thrombosis
- Hemodynamically relevant collateral function of vein segments

[Literature 4]


A.R.C.
LASER
A.R.C. Laser
Application
Laser in Standby
10.0 W
7 s
500 ms
2.3 J
0033
1470

## THE EQUIPMENT

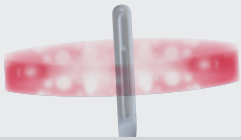
### DIODE LASER WOLF

- WOLF 1470 nm, 10 W
  U.C. Universal Centering

### A.R.C. APPLICATORS

Slim Fiber
- Donut-Fiber 400 µm, 1,0 mm (LL28061s)

Standard Fiber
- Donut-Fiber 600 µm, 1,8 mm (LL28060s)



### INTRODUCER SET

- 6 French Introducer Set (ZU01067s)

### PVC

For a simplified vein access:

- Usage **without** Introducer-Set ZU01069s for Slim Fiber (16G PVC)

**ULTRASOUND SCANNER + STERILE SLEEVE**

**TUMESCENCE ANAESTHESIA**

**STERILE SURGERY ENVIRONMENT**

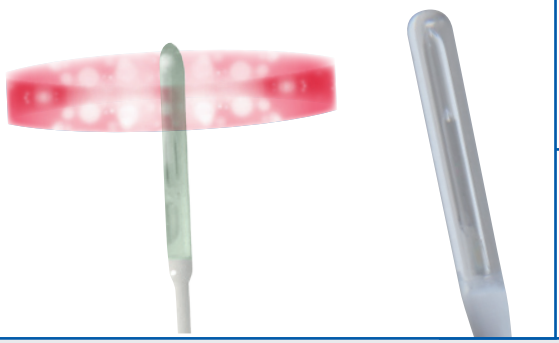
## A.R.C. APPLICATORS

Due to the special radiation characteristics of the A.R.C. fibers combined with the wavelength of 1470 nm, the applied energy is more homogeneously and effectively spread. They enhance patient comfort and reduce post-operative pain, hematoma and other side effects. Furthermore, the risk of vein perforations and ulcerations, which can possibly be caused by using conventional bare fibers, can be reduced by these applicators.

### DONUT FIBER

The energy of the Donut fiber is emitted radially and homogeneously in a defined area at the fiber tip (360°). This enables a direct power input into the vessel wall (A-C).

(A) Radial radiation characteristics

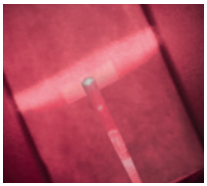


(B)

front view onto the fiber

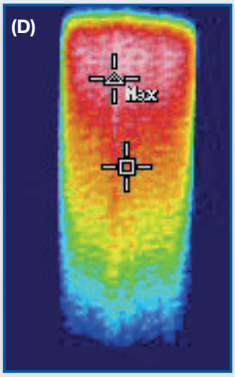
(C)

side view to the fiber



### THERMAL IMAGEERY SHOW THE ADVANTAGE OF THE A.R.C. LASER DONUT FIBER

(D)



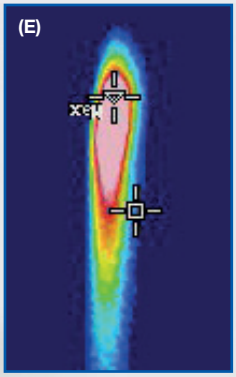

**BENEFITS OF A DONUT FIBER (D)**

- radial radiation characteristics
- homogeneous energy delivery directly to the vein wall (temperatures 100 to 200°C)
- radial radiation avoids perforation and minimises complications and side effects

**DO NOT USE A BARE FIBER (E):**

The linear radiation creates a hot fiber tip with restricted energy diffusion, so the energy cummulates in one single spot at the fiber tip, which leads to complications.

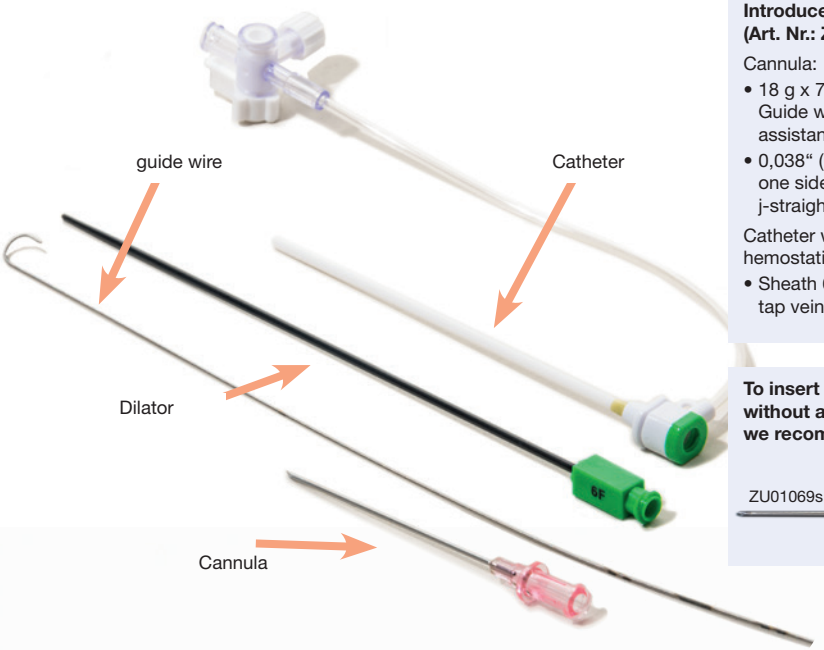
(E)



A.R.C. fibers for endovenous laser therapy are available as follows:

| FIBER DIMENSIONS | |
|---|---|
| Vein diameter: | Donut-Fiber |
| small – medium | 400 µm, ∅ 1 mm (LL28061s) |
| medium – large | 600 µm, ∅ 1,8 mm (LL28060s) |

**INTRODUCER SET**




**Introducer Set (Art. Nr.: ZU01067s)**

Cannula:

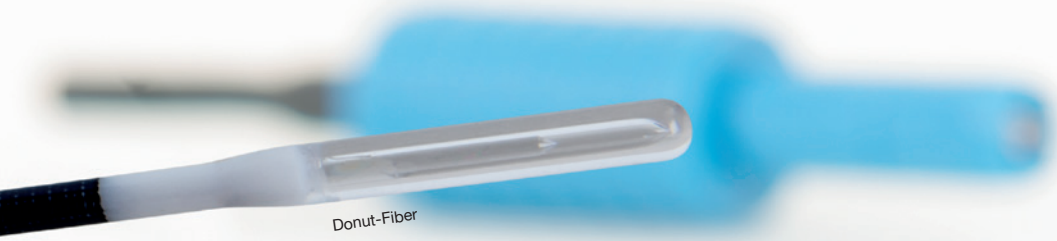
- 18 g x 70 mm cannula Guide wire with insertion assistance:
- 0,038“ (0,9 mm) x 50 cm, one sided Soft-J-Tip and j-straightener

Catheter with hemostatic valve:

- Sheath 6 FR with 3 way tap vein dilator

**To insert the slim fiber without an Introducer Set we recommend a PVC like:**

ZU01069s



# THE EVLT TREATMENT

The treatment takes 30 to 45 minutes on average (laser treatment about 10 to 15 minutes) and can be carried out as an outpatient procedure.

Since it is a minimally invasive surgery, please pay attention to sterility throughout the entire treatment.

The laser radiation of 1470 nm is not within the visible range. Therefore make sure that every person in the area, that may be impacted by laser radiation, is wearing laser safety goggles throughout the entire treatment.

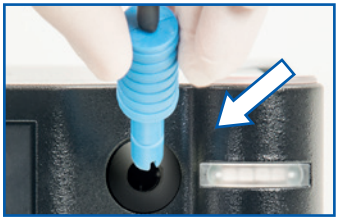
**LASER PREPARATION**

Before starting the treatment, check the proper function of the laser as well as the completeness and condition of all accessories. This applies in particular to the integrity of the fiber.
Turn on the laser. Connect the fiber to the laser and set the laser to “Ready Mode”. Check if the aiming beam is clearly visible at the distal end of the fiber. If necessary, increase the aiming beam intensity to the maximum value.

Do not continue neither the laser check up nor the treatment if you notice a damage of the laser fiber.

**CONNECTING THE FIBER TO LASER**

Ensure a tight fit of the fiber. The fiber is correctly and fully connected to the laser if you can hear a > click <.



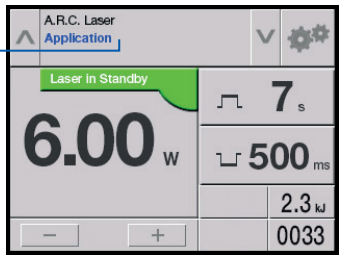
## LASERPARAMETER

Adjust the patient-specific laser parameters on the WOLF diode laser. A.R.C. Laser provides preset parameters as follows ( cf. Treatment parameters):

Veins - 400 µm DonutFiber

Veins - 600 µm DonutFiber

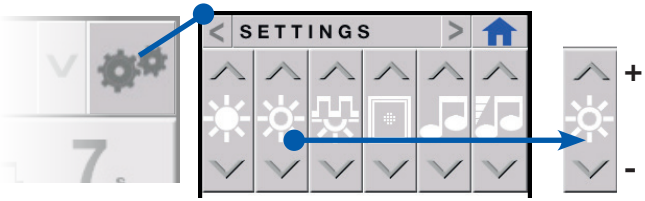
These values are for orientation and can always be adapted to your special needs.




## AIMING BEAM INTENSITY

The aiming beam intensity should be set to maximum.

In the sub menu „Settings“ you can adjust the aiming beam intensity. The value of 100 % represents the maximum value.




## TREATMENT PARAMETERS

The treatment can be performed in a continuous (cw) or pulsed (pulse duration / pulse pause) mode.
With the cw mode a faster treatment is possible but it requires an accurate and continuous pullback of the fiber. The pulsed mode allows the user a little more time and prevents overheating in case the fiber is not moved for a short time (e. g. for repositioning your hand on the fiber).

The treatment parameters for varicose leg veins base on experience values and are summarized in the following table.
Energy inputs of 40 to 60 J per cm vein are well accepted. This value is suited for the GSV and has to be decreased as the fiber is pulled back to smaller diameter veins (e. g. for the lower leg).

| TREATMENT PARAMETERS FOR VARICOUS LEG VEINS | | | | |
|---|---|---|---|---|
| Vein diameter: | Power [W] | Linear Endoveneous Energy Density (LEED) [J/cm] for the individual vein | Pulse Duration [s] | Pulse Pause [ms] |
| Veins - 400 µm DonutFiber | 6 to 7 | 42 to 49 | 7 | 500 |
| Veins - 600 µm DonutFiber | 6 to 9 | 56 to 63 | 7 | 500 |

## PATIENT PREPARATION

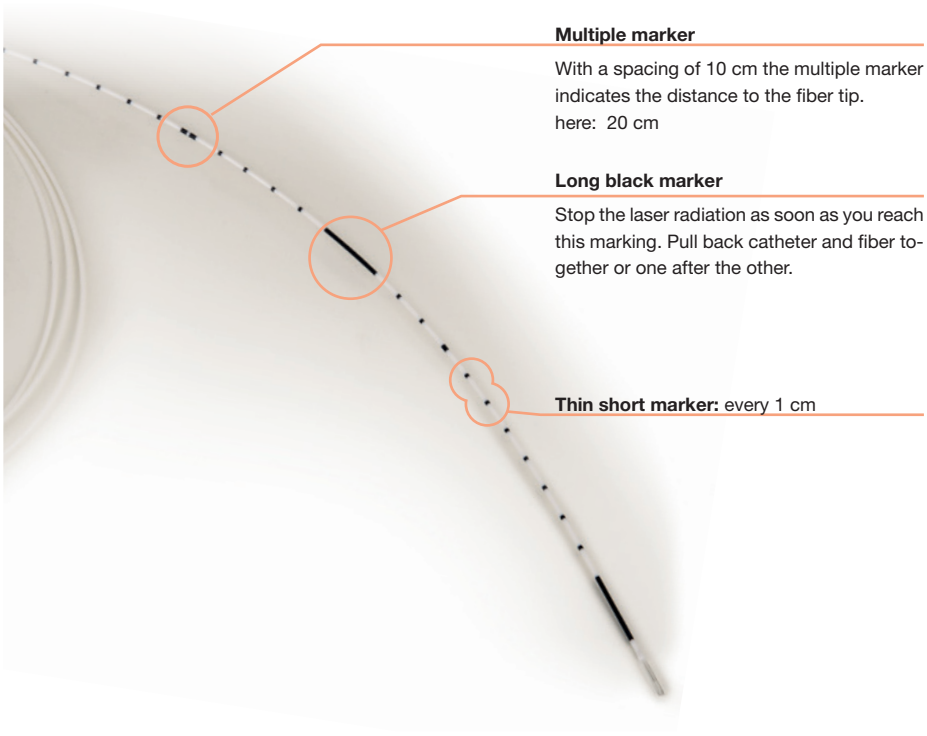
- The patient should be instructed not to take aspirin or non steroidal anti-inflammatory drugs (NSAIDs; e. g. Ibuprofen, Advil, Motrin, Aleve, Naproxen) to reduce haematoma and bleedings.
- The survey of clinical history and signing the informed consent is necessary.
- A physical examination of the standing patient using Doppler sonography is performed to identify the insufficient origin. There follows a marking on the patient‘s skin over the respective target segment.
- The extremity, which will be treated, has to be disinfected and the blood volume in the vein has to be minimized through Trendelenburg position, manual compression or subcutaneous infiltration with tumescence solution into the vein surroundings.

The blood volume in the vein has different effects on the EVLT-effect and, therefore, should be reduced as far as possible in advance.

- Perform tumescence anaesthesia (250 – 500 ml in about 7-10 insertions spread over the leg) along the vein.

## APPLICATION AIDS

The fiber is marked to faciliate your application.



**Multiple marker**

With a spacing of 10 cm the multiple marker indicates the distance to the fiber tip.
here: 20 cm

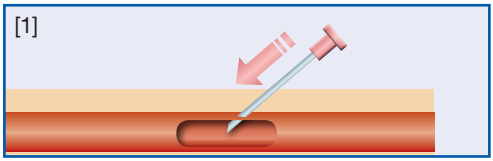
**Long black marker**

Stop the laser radiation as soon as you reach this marking. Pull back catheter and fiber together or one after the other.

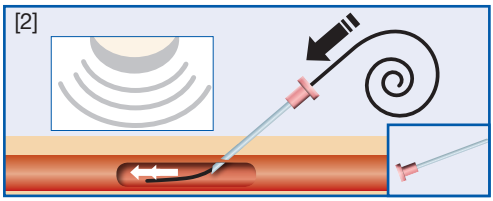
**Thin short marker:** every 1 cm

## ACCESS TO VEIN THROUGH SELDINGER TECHNIQUE

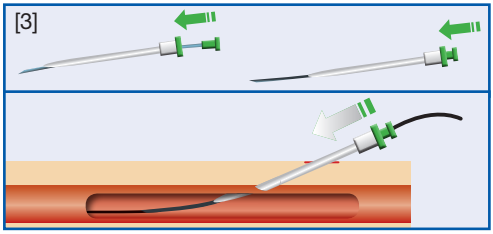
1. **Puncture the Vein**
   After localizing the vein, which is to be treated, by using ultrasound, the venepuncture follows.



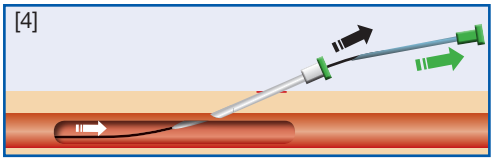

2. **Insert the Guide Wire**
   Under ultrasound guidance, the guide wire is now inserted into the vein through the cannula. The cannula can then be removed after the guide wire is inserted as desired.



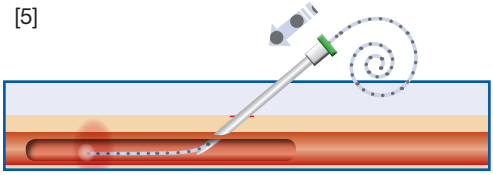

3. **Insert the Catheter**
   First, insert the dilator into the catheter and tighten it. Second, slide the catheter together with the dilator over the guide wire into the vein. If necessary, an incision can be made to facilitate the insertion of the catheter.



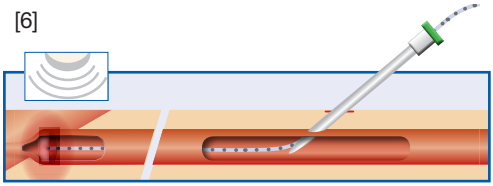

4. **Remove Guide Wire and Dilator**
   After positioning the catheter correctly, loose the dilator and remove the guide wire along with the dilator in one step.




5. **Insert the Fiber**
   Entering the fiber through the catheter in the target vein and switch the laser into READY-mode so that the aiming beam is visible.



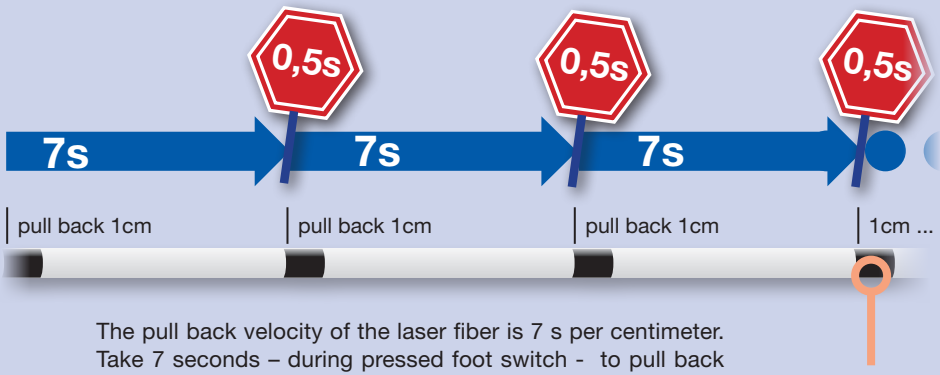

6. **Positioning the Fiber**
   Push the fiber until it reaches the target segment. The correct position of the fiber has to be verified with ultrasound. The red light of the aiming beam should be visible through the skin.




Make sure that the aiming beam intensity is set to maximum. Nevertheless, if you cannot see the aiming beam, the correct position of the fiber has to be verified with ultrasound.

## FIBER HANDLING

The cw-mode enables a faster treatment but it requires an accurate and continuous pullback of the fiber. The pulsed mode allows the user a little more time and prevents overheating in case the fiber is not moved for a short time (e. g. for repositioning your hand at the fiber).




The pull back velocity of the laser fiber is 7 s per centimeter. Take 7 seconds – during pressed foot switch - to pull back the fiber slowly and uniformly 1 cm. The laser beeping signals the application time.
Once the laser becomes silent, the interval ends and you can use the break of 0,5 s to readjust your hand placement.

the fiber marks in black have a distance of 1 cm

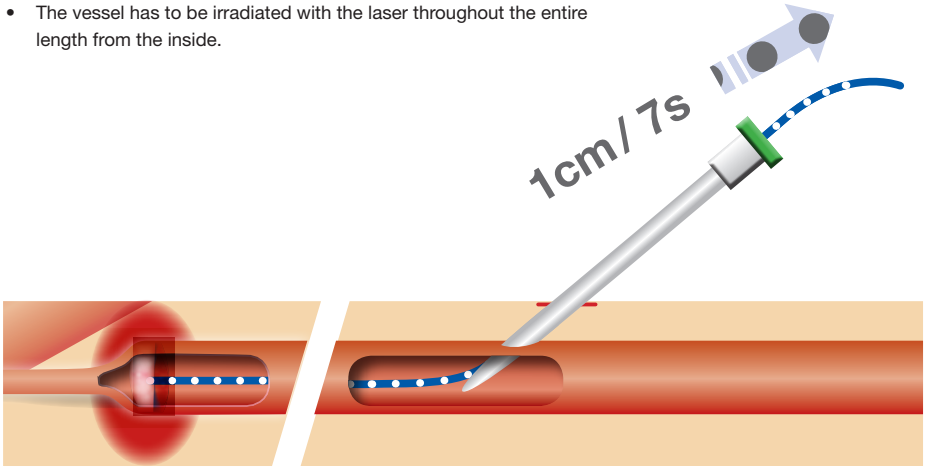
If the pull back velocity is to slow, perforations of the vascular wall are possible!

Be aware of the total input energy. The absorbed dose should not be above 3,5 kJ for one leg. A too high dosage could result in thermal injuries.

## LASER COAGULATION

Make sure that you will not apply the laser radiation too close to the sapheno-femoral-junction (connection between GSV and femoral vein). This could cause a deep vein thrombosis.

- Pull back slowly and uniformly with a pull back velocity of 7 s per cm.
- Do not stop at the same position for a long time when releasing laser radiation.
- Avoid to irradiate the same area with one laser pulse.
- The vessel has to be irradiated with the laser throughout the entire length from the inside.




Take care that you stop laser radiation before reaching the catheter. Stop the laser radiation immediately if you reach the marking at 15 cm in front of the fiber tip. The fiber can now be pulled back together with the catheter.

### COMPRESSION

- After the EVLT treatment the treated leg should be tightly wrapped with eccentric compresses until the first checkup.
- In the next three weeks the patient should wear compression stockings (class 2 or 3) for the entire leg.

### MEDICATION

- To prevent thromboembolic complications, low molecular weight heparin can be prescribed for at least 8 days.

### MOBILIZATION

- Immediately after the treatment the patient can resume normal everyday activities (walking, climbing stairs, etc.).
- An early and regular physical exercise is important, especially movement in ankle joints.
- The patient should avoid sporting or intense physical activities for 8 to 14 days.

### CHECKUP

The treated vein should be examined using ultrasound at the following intervals:

- 24 h after EVLT treatment
- 6 weeks after EVLT treatment

**PICTURE CREDITS**

- [1-5]; [7-10] [12-13] [15fff] A.R.C. Laser.
- [6] [11] [14] istockphoto.com

**LITERATURE REFERENCES**


- [1] Doganci, S., and U. Demirkilic. „Comparison of 980 nm laser and bare-tip fibre with 1470 nm laser and radial fibre in the treatment of great saphenous vein varicosities: a prospective randomised clinical trial.“ European Journal of Vascular and Endovascular Surgery 40.2 (2010): 254-259.
- [2] Schwarz, Thomas, et al. „Endovenous laser ablation of varicose veins with the 1470-nm diode laser.“ Journal of vascular surgery 51.6 (2010): 1474-1478.
- [3] Raulin, Christian, and S. Karsai. Lasertherapie der Haut. Springer DE, 2013.
- [4] Rabe, Eberhard, and Horst-Eberhard Gerlach, eds. Praktische Phlebologie: Empfehlungen zur differenzierten Diagnostik und Therapie phlebologischer Krankheitsbilder; 69 Tabellen. Georg Thieme Verlag, 2006.
- Pannier, F., E. Rabe, and U. Maurins. „First results with a new 1470-nm diode laser for endovenous ablation of incompetent saphenous veins.“ Phlebology 24.1 (2009): 26-30.
- Pannier, F., et al. „Endovenous laser ablation of great saphenous veins using a 1470 nm diode laser and the radial fibre–follow-up after six months.“ Phlebology 26.1 (2011): 35-39.
- Almeida, Jose, et al. „Saphenous laser ablation at 1470 nm targets the vein wall, not blood.“ Vascular and endovascular surgery 43.5 (2009): 467-472.
- Poluektova, Anna A., et al. „Some controversies in endovenous laser ablation of varicose veins addressed by optical–thermal mathematical modeling.“ Lasers in medical science (2013): 1-12.

# Diode Laser
# 1470 nm


Distributor:

A.R.C. Laser GmbH
Bessemerstraße 14
D-90411 Nürnberg
Germany

+49 (0) 911 217 79-0
+49 (0) 911 217 79 99
info@arclaser.de
www.arclaser.de

A.R.C. LASER
enlighten your surgery.


02/2017