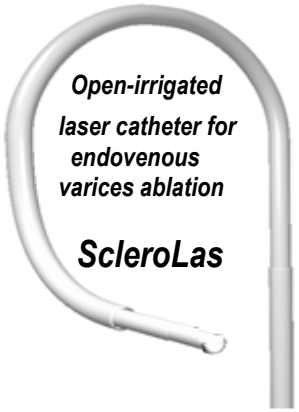
LasCor
Laser Medical Devices



A flexible Laser-Ablation Catheter
Instruction for Use (IFU)
GENERAL DESCRIPTION

The ***ScleroLas*** is an open-irrigated laser ablation catheter designed for **E**ndovenous **L**aser **A**blation (**ELA**). It can be used for ablation of varices by:

- ***Application of 980, 890, 1470nm laser light***
- ***Irrigation with 0.9% heparinized saline.***

For its use the following additional devices are needed:

- ***a 8.5 French steerable sheaths e.g., AGILIS***
- ***a diode laser of above wavelengths***
- ***an irrigation or an infiltration pump***

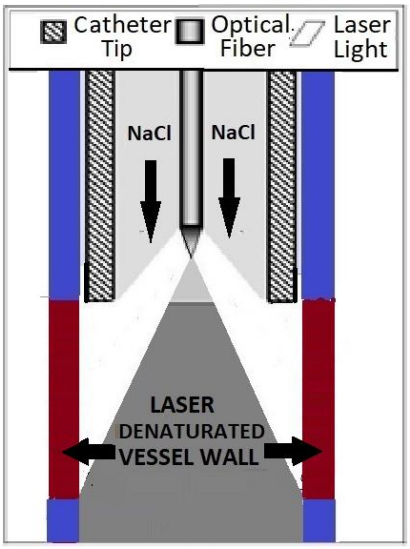
The flexibility of the ***ScleroLas*** and the steerable sheath allow for a safe and quick catheterization of the diseased often tortuous veins, especially leg veins, from the ankles up to the groin. It is a minimally invasive procedure. After tumescent anesthesia the catheter is introduced into the vein through a small incision of the skin under local anesthesia and puncture of the vein (Seldinger technique).

It is a non-contact mode of laser application. The optical fiber is protected within the lumen of the catheter with its tip coaxially positioned at a given distance from the endhole of the catheter.

Continuous saline catheter irrigation at a rate of 10mL/min hinders penetration of blood into the catheter, thrombus formation and burning of the optical fiber is avoided. In addition, with tumescent anesthesia blood is squeezed out of the vein and potential energy absorption by blood is reduced.

During normothermic laser application, the catheter itself is not heated up whereas the walls of veins are thermally denaturated. The laser induced absorptive heating is tissue specific and selective. The laser energy emitted is partly absorbed in the vein wall. Laser energy thermally denaturates collagen, resulting in an inflammation of the vein wall, healing in fibrosis with closure of the vein and further vein resorption and transformation into scar tissue.

Ought to the divergent laser beam of the optical fiber tip circumferential radiation of vessel wall is feasible. Thereby with laser application at 15W/10-15s a vessel wall segment at a length of 5-10mm can be circumferentially irradiated. With repeated laser applications and a stepwise 5.0mm withdrawing of the catheter smoothly contiguous tubular endovenous laser ablation can be achieved at a desired length of venous obliteration.



Scheme showing the divergent laser beam emanated from the optical fiber tip of the laser catheter ***ScleroLas***® with the circumferentially laser denaturated venous vessel wall.

APPLICATIONS

Indications

The ***ScleroLas*** is a laser catheter designed for the treatment of varicose veins to release patient's complaints and discomfort and avoid the risks caused by their varicose veins. In addition, it should improve cosmetic results, and quality of life.

Contraindications

The use of the **Sclero*Las*** is contraindicated in patients with deep vein thrombosis / obliterations, and it may be contraindicated if there is an obstruction in the vessel access. Acute and severe chronic diseases, severe heart failure or coronary disease may also contraindicate the use of the ***ScleroLas.***

Preoperative investigation

Doppler ultrasound and marking on skin of all the veins selected for treatment is performed in standing position. The saphenous vein insufficient segments are marked on the patient`s skin. All straight insufficient segments of veins along the axial reflux of intrafascial parts of saphenous veins and straight extrafascial vein branches, from their proximal to the distal point are to be ablated. In case of need other varicose venous branches can be treated after several months later.

Vein diameters should be measured to calculate the amount of energy required for the vein targeted for ablation. Postphlebitic veins may require more energy for ablation. Relationship of nerves and the skin with the target vein should be analyzed by ultrasound.

SAFETY NOTES

Reuse

The *ScleroLas* is designed for single use only. Cleaning or reuse can result in serious complications. ***LasCor***® will not be responsible for any direct or consequential damages or expenses which result from cleaning or reuse.

Sterilization

Catheters are shipped after ethylene oxide (EO) or after electron ray (E-ray) sterilization. Do not use products from opened or damaged packaging. Under appropriate storage conditions, we guarantee sterility in undamaged packaging until the expiry date (use before date).

External Interference

There is no external interference with the ***ScleroLas.***
Sterile products should be stored at humidity of 45-70% and at temperatures of 18-25°C. They should not be exposed to direct sunlight and must be used before the expiry date on the packaging (DIN 58953).

Side Effects and Complications

Despite correct handling of the ***ScleroLas*** complications may occur such as:

- Vessel spasm and local bleeding with subcutaneous Hematoma
- Perforation of the vein
- Thrombosis due to blood clotting

Catheter Check

During endovenous laser radiation, the ***ScleroLas*** is subjected to a variety of mechanical and thermal strains. If catheter damage is suspected, both the mechanical and optical integrity of the catheter must be verified by visual inspection.

> **!** **This device should be exclusively applied by consultant phlebologists who are trained and experienced in endovenous catheter interventions.**
> **This training should be supervised and certified by an expert in the field of endovascular laser application.**

Laser Safety

The ***ScleroLas*** must be used in compliance with current laser safety regulations. Operators and personnel must have sufficient knowledge about potential hazards and safety measures for medical laser application.

Safety Hazard

Endovenous laser application is performed by means of various invisible continuous wave laser light at various wavelengths including 890, 980, 1470nm. 1470nm laser diodes are most used by the cosmetic industry for treating saphenous veins. Since the traditional laser treatment for varicose veins targets the lining of the blood vessel, it causes blood coagulation, destruction of the vein, bruising and swelling. The 1470nm laser diode targets the water in the vein walls to collapse the walls and ensure complete vein closure. Since 1470nm infrared laser diode is the peak wavelength for water absorption in skin it causes significantly less pain and hence no post-operative bruising and swelling.

Laser safety measures primarily include the prevention of inadvertent laser emission and eye protection for people staying inside the laser area (defined by the area, in which radiation exceeds the authorized value).The ***ScleroLas*** causes a laser area of 1.3 m radius, measured from the catheter tip (calculated according to laser safety regulation DGUV-V 11 for irradiation at 20W over 10s.

Safety hazards are significantly reduced, if laser emission is inhibited on the laser panel whenever the ***ScleroLas*** is handled outside the patient. In this special case, a temporary laser area is caused inside the patient, when the foot switch is enabled. No hazardous radiation can be released into the operating room.

From a practical point of view, laser safety goggles are not necessary. However, laser goggles may be mandatory due to local safety regulations!

To visualize the course of the non-visible laser beam, medical lasers are equipped with a harmless red pilot beam. This beam is suitable to control the radiation characteristics of the ***ScleroLas*** and to study the different beam properties in air and water.

Medical lasers and accessories such as optical fibers or catheters are controlled by a series of hardware switches to avoid inadvertent radiation or radiation under inappropriate conditions.

Before laser application can be started by pressing the laser foot switch, the catheter must have been properly connected and the foot switch must have been enabled on the laser front panel. Make sure to regularly check the functions of the laser safety chain.

RISK MANAGEMENT

A ***ScleroLas*** that is inserted into the patient cannot radiate hazardous laser light into the environment. Laser hazard increases when the connected catheter is handled outside the patient, e.g., during visual inspection of the catheter. Therefore, it is mandatory to enable the laser footswitch only when the ***ScleroLas*** is already placed in the patient's vein, and to inhibit the laser after application.

Never point a connected *ScleroLas* towards a person or reflecting surfaces.
Enable laser radiation only when the *ScleroLas* is positioned inside the vein. Disenable of the laser footswitch:
1. after each laser application, and
2. before removing the catheter from the patient.
Check the laser beam profile only by means of the red pilot beam, never by releasing invisible laser light. Use eye protection that blocks the wavelength used.

Hazards can be also provoked when the ***ScleroLas*** is handled inappropriately, especially when the optical cable is bent around sharp edges or is jammed under wheels or heavy weights.

The conical fiber tip of the ***ScleroLas*** is mounted at a given distance from the end hole in the central lumen of the catheter tip and so it is effectively protected against mechanical forces acting on the catheter during vascular catheterization.

However, it must be strictly avoided to clean its distal end hole by means of sharp objects such as metal pins or cannula, as this might cause fiber breakage. In this case, application of the ***ScleroLas*** would not be safe anymore, and it could endanger patients.

HANDLING

Preparation of the Laser System

Calibration

The ***ScleroLas*** is especially optimized for radiation in an aqueous medium and cannot be calibrated in air. Light transmission is therefore measured by the manufacturer. Only qualitative control of the laser spot must be performed by operators (see chapter "Catheter Control").

Saline Irrigation

Prior to insertion of the catheter its lumen is flushed with saline, and air is completely removed from its lumen. Laser light is applied only during continuous saline irrigation at a flow rate of 10mL/min.

The *ScleroLas* must be irrigated during irradiation and surrounded by an aqueous medium. Laser irradiation without irrigation can destroy the *ScleroLas* and endanger patients.

Preparation of the Patient

After preoperative vein mapping is completed, the patient is placed on the operative table that should be adapted also for Trendelenburg and reversed Trendelenburg position of the patient.

Access to the saphenous vein is achieved under local anesthesia and sterile condition and after cutting down of the skin in the upper thigh where the saphenous junction with the femoral vein is localized by ultrasound. The saphenous vein is supported in a sling, is punctured (Seldinger technique). A guide wire is introduced into the vein and is advanced under ultrasound control down through the varicose vein to the distal end of its insufficient segment.

Alternatively venous access can be achieved by puncture of a leg vein including the ankle vein and the ablation procedure performed along the flow of the venous blood.

In case of need an 8.5F steerable AGILIS™ NxT sheath with dilator is introduced over the guidewire into the vein and is advanced distally to the insufficient vein. Guidewire and dilator are removed and the ***ScleroLas*** is introduced and advanced through the sheath. Its tip is positioned under US control at the endhole or 2-3 mm beyond the endhole of the sheath.

The ***ScleroLas*** is continuously irrigated through its side arm with 0.9% heparinized saline 10mL/min by means of an irrigation / infusion pump.

Stepwise, all insufficient segments of veins, from the distal to the proximal point are ablated. If needed, the remainder varicose branches can be treated after several months.

Precautionary measures:

- Difficulties for the guide wire to pass tortuous veins
- Aneurysmal dilatation of veins that will need higher energy applications
- Post phlebitis veins may need more energy applications and advancement of guide wire may be difficult
- Relationship of nerves with the target vein should be analyzed e.g., by ultrasound.
- To reduce the risk of skin, damage the distance from the target vein to the skin should be ≥5 mm

Anesthesia

With the local tumescent anesthesia (Lidocaine 0.05%):

- Blood is squeezed out of the vein, potential energy absorption by blood is reduced
- A good contact between laser catheter and the vein wall is achieved
- Potential thermal damage of surrounding tissue is reduced

Tumescent Solution Composition:

- Saline solution NaCl 0.9% - 1000 ml
- Lidocaine 2% 0.9% - 25 ml
- Adrenalin 0.01% - 1 ml
- Natrium bicarbonate 8.4% - 12 ml

The faster the cold tumescent solution is administered in the track of the treated vein, the colder it will be during ablation and the better will be its protection for the tissue close to the vein.

Anesthesia in Track of the Target Vein

After positioning the ***ScleroLas*** anesthesia with a cold tumescent solution 4-5°C, in the track of the target vein is performed, preferably with a long needle starting the infiltration at the catheter tip with 8 ml per cm of vein and moving up gradually.

The anesthesia solution application should be mandatorily performed under ultrasound Doppler guidance, continuously monitoring the localization of the needle tip, preventing unguided tumescent solution intravenous application or unnecessary collateral tissue traumatization.

Anesthetic solution substances should not exceed the maximum allowed dose per kg body weight.
For **50kg** weight:
- 350mg Lidocaine = 700 ml of 0.05% tumescent solution

For **70kg** weight:
- 500mg Lidocaine = 1000 ml of 0.05% tumescent solution

If the pilot beam is not visible through skin:
1 Check the laser catheter tip localization under ultrasound guidance.
2 Check for possible laser fiber damage!

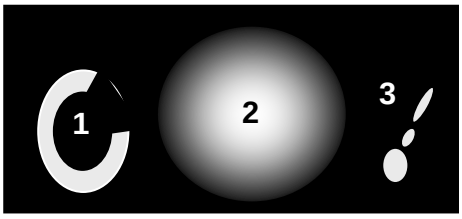
To reduce the number of punctures required for anesthesia it is recommendable to perform tumescent solution infiltration by using a long needle (12 cm),
After tumescent anesthesia, catheter position should be checked by the pilot laser beam.

With a compression bandage smooth spreading of the anesthetic solution around the vein should be performed, squeezing out the blood from the vein, and achieving good contact between the vein wall and the laser catheter. If volume of solution required may exceed the upper limit ablation procedures should be performed on two or more separate days.

Connecting the Catheter

Main functions of the ***ScleroLas*** and its connections to external devices must be checked prior to a clinical application. This mainly includes:

- Integrity and sterility of the packaging
- Catheter irrigation
- Laser spot / beam profile (Pilot beam!)



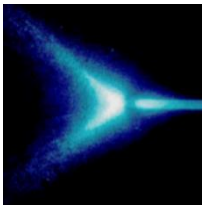
Deteriorated beam profiles:
1. Interrupted ring (tip deformation casts a shadow): ***Reduced effect***, potential overheating of the catheter
2. Diffuse radiation (overheating contamination of the fibre tip) ***Reduced effect***
3. Collimated and partly asymmetrical radiation (due to fibre breakage) **DANGER!** High risk of perforation; increased laser safety hazard.

Thoroughly inspect the packaging and expiry date before opening. Draw the cover sheet off the double sterilization envelope and remove the catheter. For connection of the optical cable, first remove the protective cap from the optical plug.

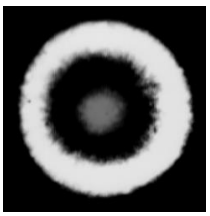
Be sure not to touch or soil the polished proximal end of the optical fiber. Insert the plug into the coupling port of the laser and fully tighten the screwcap until the safety interlock reacts by switching on the pilot laser. Check the course of the optical cable. It should not run next to wheels or across sharp edges. Avoid bending radii below 5 cm. Light should only be radiated from the catheter end hole. Do not use the catheter if light is leaking through cable or catheter body.

Eventually, inspect the laser spot of the ***ScleroLas*** prior to insertion. This test must be performed after irrigation, as the dry catheter radiates a completely different laser beam. Dip the catheter tip into a white cup filled with sterile water or saline. Avoid reflective metal surfaces.

The laser spot must be visible as a clear-cut continuous ring ("Donut"). An additional spot may be visible in its center that must not be brighter than the ring. Do not use catheters with anomalous laser spots.



The ***ScleroLas*** laser beam: lateral view



Laser beam frontal view

Catheter Insertion

The ***ScleroLas*** is inserted via commercially available steerable guiding sheaths (e.g., AGILIS). Do not use inappropriate introducer sheaths or guiding catheters as they may jeopardize the functions of the ***ScleroLas*** and increase the complication rate!

Procedure

After aseptic skin preparation of the insertion area and sterile covering of the groin, under US guidance the saphenous is localized and skin incision mobilized, hold in a sling and is punctured (Seldinger technique).

Straighten a J-shaped guide wire by its tip deflector and put it on the joining flange of the cannula.

Advance the guide wire through the cannula into the vein and advance it under US control dawn beyond the distal end of the target vein.

Remove the needle, press the vein slightly to minimize bleeding, prevent air embolism, and fix the guide wire.

For insertion of the dilator with the sheath, the proximal part of the guide wire must remain outside the patient over a length of approx. 90 cm.

First, push the dilator into the guide. Then, the dilator and the guide are pushed over the guide wire and are advanced until the distal end of the target vein.

Remove the guide wire and withdraw the dilator while flushing with heparinized saline 0.9%.

Flush the lumen of the sheath with heparinized saline via its side arm.

Flush the ***ScleroLas*** prior to insertion into the sheath to remove air bubbles. Insert the ***ScleroLas*** into the hemostatic valve and push it into the guiding sheath.

Advance the ***ScleroLas*** under continuous flushing with heparinized saline, and, under US control position the catheter with its tip at the endhole of the guide.

Start laser applications by using power settings adapted to the sizes of the target vein.

Create contiguous lesions from the distal to the proximal end of the target vein.

Laser Application

After USD-guided correct positioning of the ***ScleroLas*** in the guiding sheath laser radiation is enabled by means of the button on the laser front panel and radiation can then be released by the foot switch.

The laser is used in the continuous wave irradiation mode at a distal laser power at 15 W with application times adapted to the vein sizes. In general, for a diameter of 5 mm, circumference 16 mm, a radiation length 5-6 mm = irradiated surface 78 mm² at a power of 15W/50s = 10J/mm².

In general, with the compression bandage the catheter is in intimate contact with the vein wall, and continuous saline irrigation creates a clear path for the laser light in front of the catheter endhole. Catheter Irrigation is to be performed via an irrigation pump or perfusion at a rate of 10ml/min.

Laser application at 15W / 50s will result in tubular denaturation of the vein wall at a length of 5-8 mm. After approximately 10 mm withdrawal of the sheath with the catheter laser application is repeated.

By stepwise withdrawal of the sheath together with the catheter after approximately 50 laser applications a 50 cm long vein will be ablated.

To avoid inadvertent release of laser light, triggering by the laser footswitch must be disenabled during catheter insertion and manipulation.

!	**Disenable laser radiation before removing the catheter from the patient.**

Radiation is terminated automatically after the preset pulse duration or by releasing the footswitch. For safety reasons, the laser footswitch should be disenabled immediately after each laser application, no matter if the catheter remains in the patient for further treatments.

Laser radiation may produce a painful sensation of heat or pressure in the leg. In rare cases analgesics may be required.

As mentioned above, prior to ELA, the veins marked by DUS in standing position and selected for treatment may include the following insufficient segments vein:
- The great saphenous vein (GSV)
- Small saphenous vein (SSV)

As well as straight, insufficient intrafascial veins:
- Anterior accessory saphenous vein (AASV)
- Posterior accessory saphenous vein (PASV)
- Superficial accessory saphenous vein (SASV)
- Thigh accessory of SSV/Giacomini vein (VG)
- Extrafascial venous segments
- Perforating veins

All straight insufficient segments of veins, from the proximal to the distal insufficiency point, along the axial reflux are included for planning ELA.
Usually, ELA is done firstly for axial reflux of intrafascial parts of saphenous vein and straight extrafascial vein branches and, secondly, usually after 3 months, varicose vein branches are treated if necessary.

Catheter Control

Whenever suspecting a reduced catheter performance or a malfunction, the ***ScleroLas®*** should be inspected. This includes its general appearance and the shape of the laser beam profile. Post-application laser beam inspection is analogous to the initial catheter check after unpacking.

Connections

Laser

In general, the ***ScleroLas*** is connected to a 1470 nm diode laser via a flexible optical fiber provided with a FSMA connector at its proximal end.

As light transmission and radiation characteristics of the catheter depend on the laser model, use only the medical Lasers approved for endovenous laser treatment.

There is no electrical connection between the laser and the patient or the working field. Damages of the Laser or the patient by using a Cardioverter of Defibrillator can be ruled out.

EXCLUSION OF LIABILITY

The ***ScleroLas*** is used in the thoroughly aggressive environment of the human body. Moreover, the needed flexibility and the very small diameter of the catheter invariably result in limited reliability.

Despite the greatest possible care taken in development, choice of components, assembly, and final control prior to delivery, the ***ScleroLas*** can become damaged by negligent handling or other influences, during or after introduction.

As a result, we do not assure or guarantee in any way that a disturbance or discontinuation of function will not occur, nor that the human body will not reject the introduced catheter, nor that there will be no medical complications, including myocardial perforation, because of introducing the catheter.

Since the accessories can become damaged by negligent handling or other influences before, during or after introduction, we do not assure or guarantee in any way that a disturbance or discontinuation of function will not occur.

However, in cases of defects found prior to its use the no contaminated catheter can be replaced by the manufacturer, provided the catheter is sent back with documents describing the defect found.
The ***ScleroLas®*** is sold in "as is" condition. No responsibility will be assumed for any deficiencies that are not immediately declared upon delivery of the goods. The purchaser assumes the total risk related to the quality and function of the catheter and accessories when they are put into use.

LasCor® assumes no responsibility whatsoever for any loss, damage, or injury, be it directly or indirectly related to the catheter or accessories or determined to be subsequent damage resulting from the use thereof.

Consequently, ***LasCor®*** does not and will not assume any expenses incurred by the purchaser or a third party, ensuing from the use, malfunction or total failure of any catheter or accessories.

This exclusion encompasses physician's fees, costs of hospitalization, costs incurred by using medicinal products, any secondary expenses, and all subsequent damages.

Let it be known that no institution, organization, or individual has ever been empowered or in any other manner obtained the right to issue any notification deviating from the above or to make any guaranty in the name of ***LasCor®***.

NOTE

After its use the catheter is biologically contaminated and must be disposed according to the local regulations. The catheter does not contain toxic components that would need special measures.

!	**The *ScleroLas* is for single use only. Resterilization and reuse of the catheter would jeopardize its function and endanger the patient.**

TECHNICAL DATA: *ScleroLas*

Body size 8 F Useable length 115 cm Total Length: 3 m
Optical fiber Core 400 µm Numerical aperture: 0.22
Distal beam divergence fiber in water 70°
Distributor Y-Form Luer-Lock female
Laser-connector FSMA

Catalogue No: V 004-115-XXX
UDI-DI: 4260691560047
Packaging: carton box with one sterile set
Delivery box: with 10 single carton boxes

SYMBOLS

This medical product is labelled according to **DIN EN ISO 15223-1:2022-02** by using the following graphical symbols:

MD	**Medical Device**
	Manufacturer
LOT	**Lot number**
	Date of manufacturing
STERILE EO	**Sterile, sterilization method**
	For single use only
	Regard operating manual
	To be used until
CE 0481	

ANNEXES
1. Patient Information
2. Patient's Statement and Written Informed Consent

!	**The patient information sheet must be handed out to and must be signed by the patient together with the informed written consent.**

3. Fax Template: Post Market Clinical Follow-up is compelling after the use of the catheter.

Version:2023-02-08
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Patient Information
Endovenous Laser Catheter Ablation of Leg Varices

What it's all about?

Introduction
Endovenous Laser Ablation (**ELA**) of varicose veins is a minimally invasive catheter procedure that thermally denaturates the vein wall, resulting in an inflammation, then fibrosis, and finally a closure of the vein, with further vein resorption and transformation into scar tissue. ELA allows achieving a complete transformation of the treated vein into scar tissue, and to close its lumen permanently.

Preparing for the Ablation Procedure
You will probably undergo the treatment in an outpatient hospital unit. Several routine laboratory tests will be performed prior to the intervention including an ECG, blood tests, and ultrasound doppler (**USD**) mapping of your varicose veins scheduled for ELA. The doctor performing the ablation procedure will review your medical history and examine you. You may be seen by the doctor at the office several days before the procedure. The doctor will explain the ablation technique, its purpose, potential benefits, and possible risks. This is a good time to ask questions and to share any feelings or concerns you may have about the ablation intervention.

You will be asked to sign a consent form, a document that allows drugs to be injected directly into the vein if necessary. To help you relax, you will be given a sedative if necessary. For your comfort, empty your bladder as completely as possible before the procedure starts.

Once pre-operative vein mapping and catheter check are completed, and the laser energy required is calculated, you will be placed on the operating table which is adapted for Trendelenburg positions. The equipment in the lab includes the ***CardioVascLas®*** laser ablation system and various other instruments and devices. The lab team generally includes the phlebologist with special training, and two assistants. After being positioned on the table, you will be covered with sterile sheets. The staff will be wearing sterile gowns and gloves, and protective glasses. The skin where the catheter will be inserted is cleansed thoroughly. A local anaesthetic is injected into the skin with a tiny needle to numb the area.

During the Ablation Procedure
A small incision is made in the skin and a needle is used to puncture the exposed vein. Under visual control a guidewire is introduced into the vein and is advanced under USD control down to the distal end of the target vein. Subsequently, a steerable introducer sheath e.g., AGILIS is advanced over the wire. Guidewire and the dilator of the sheath are replaced by the catheter ***ScleroLas*** provided with an optical fibre mounted coaxially in its inner lumen that can transmit laser light. The catheter is filled with saline prior to insertion and is then connected via its sidearm to the irrigation pump and is flushed continuously through its central lumen during the procedure. Under USD control the ***ScleroLas*** is introduced and advanced in the long sheath and is positioned with its tip at the endhole or 1-2 mm beyond the endhole of the sheath.

After final USD positioning of ***ScleroLas,*** anaesthesia with a cold tumescent solution in the track of the vein is performed. You will feel discomfort during puncture through the skin, rather than during anaesthetic infiltration or laser application. For a smooth spreading of anaesthetic solution around the vein a compression bandage will be applied, thus squeezing out the blood from the vein and achieving good contact between the vein wall and laser catheter. Perivenous tumescent solution will also protect sensitive structures such as nerves and skin from damage during laser application.

Eventually, the laser generator is activated, and the adequate energy is delivered. The laser light is selectively denaturating the vein wall while perivenous structures are spared from overheating. The laser catheter itself is not heated up. The 5-8 mm long irradiated vein segment per each application will result in a smoothly continuous denaturation of the vein wall along its entire irradiated length. By radiation of a venous segment of 5-8mm at 15W/10s and a stepwise 5-8 mm withdrawal the average time required for a 40cm vein ablation is up to 10 minutes.

Finally, the catheter is removed, the doctor will close the incision with a few stitches and a dressing with a light pressure will be applied onto the wound. You can leave operating room und after final instruction from your doctor you can leave the hospital. The compression bandage applied around the leg during the procedure is maintained the whole day; it can be removed when you go to bed or according to the instructions of your doctor.

After the Ablation Procedure

The next morning, prior to leave the bed, you put on support stockings. Unless a second ELA procedure is already scheduled for the next day, your physician will inform you about the date of the first postoperative visit for removal of the local bandage with the suture stiches from the wound. You will not need any additional therapy in the postoperative period.

If the treatment is successful, your varicose veins were ablated with minimal risk of side effects and complications, by using minimally invasive, 1–2-hour outpatient procedure, with minimal bruising and pain, and often impressive cosmetic result; and you can follow your regular activities in the same day.

In general, monitoring of outcome is performed in the outpatient clinic 7-14 days after ELA. If the treated vein is not or only incomplete occluded ELA can be repeated, alternative therapies considered before clinical recurrence has developed.

Possible Complications after ELA

Post ablation superficial thrombus extension induced by endovenous heat may occur. Complete USD investigation of the deep venous system must be performed to search for deep vein thrombosis (**DVT**) because the thrombus may extend to the saphenous junction:

- up to the deep vein level (only monitoring with an interval of 2 weeks without medication),
- in the deep vein with narrowing up to 50%,
- with narrowing more than 50%, and,
- complete occlusion of the deep vein

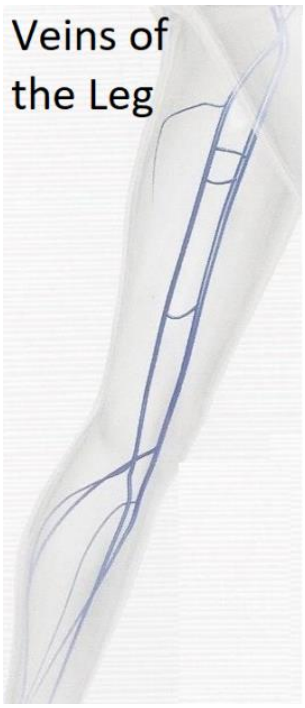
For DVT therapeutic anticoagulation according to the advice of your doctor is needed until full resorption of DVT that usually takes 4-5 weeks. DVT after novel ELA with its unique catheter radiation system and its venous access by ligation of the saphenous vein junction to the deep vein is less than 1% and has substantially reduced recurrences.

A second postoperative visit is usually done 3 months after ELA by USD for the target vein, for possible DVT, for evaluation of clinical, anatomical, and cosmetic outcome after ELA and, whether you need any additional therapy for varicose veins. A next visit is recommended after a year or when you have new complaints.

Alternate Therapies to ELA

The following alternative therapies of the great saphenous vein are nowadays available:

1. *Vein surgery and stripping – the classical treatment*
2. *Radiofrequency ablation - heat destruction with current*
3. *Foam sclerotherapy*
4. *Glue injection*
5. *EVLA by using lase catheters with ring-shaped radiation.*



Don’t hesitate and ask your doctor if you need more information or if some of the above is still unclear to you or if you would like to know more about the procedure, possible complications, and risks. Your doctor will give you further information.

Patient's Statement and Written Informed Consent

Signature File in accord with 21 CFR 50 with the Patients Statement

I had detailed discussion(s) with my doctor (print):_____

Concerning my questions, problems, concerns and doubts of the laser ablation procedure and the possible complications and risks. I have received a complete file of **Patient Information** (two pages) and I have no further questions.

Herewith I agree with the proposed endovenous laser ablation procedure, with the emergency interventions, necessary for the treatment of possible complications, and with the follow-up controls or studies.
I do not give my consent for the laser catheter ablation because (comment): …… …… …… …… …… …… ……

↑

Delete what not applicable.

Patient: _____ _____ _____

Name (print) Date Signature

Investigator: _____ _____ _____

Name (print) Date Signature

Post Market Clinical Follow-up (PMCF) for
Endovenous Laser Catheter Ablation

Please Fax to +49 (0)89 759 5770 ***ScleroLas catalogue number*** **V 004-115-XXX**

Patient ID: Hospital / Health Unit:

Diagnosis: Physician (print):_____

If no events, please mark with **X** here O Signature_____

Or describe events ……

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