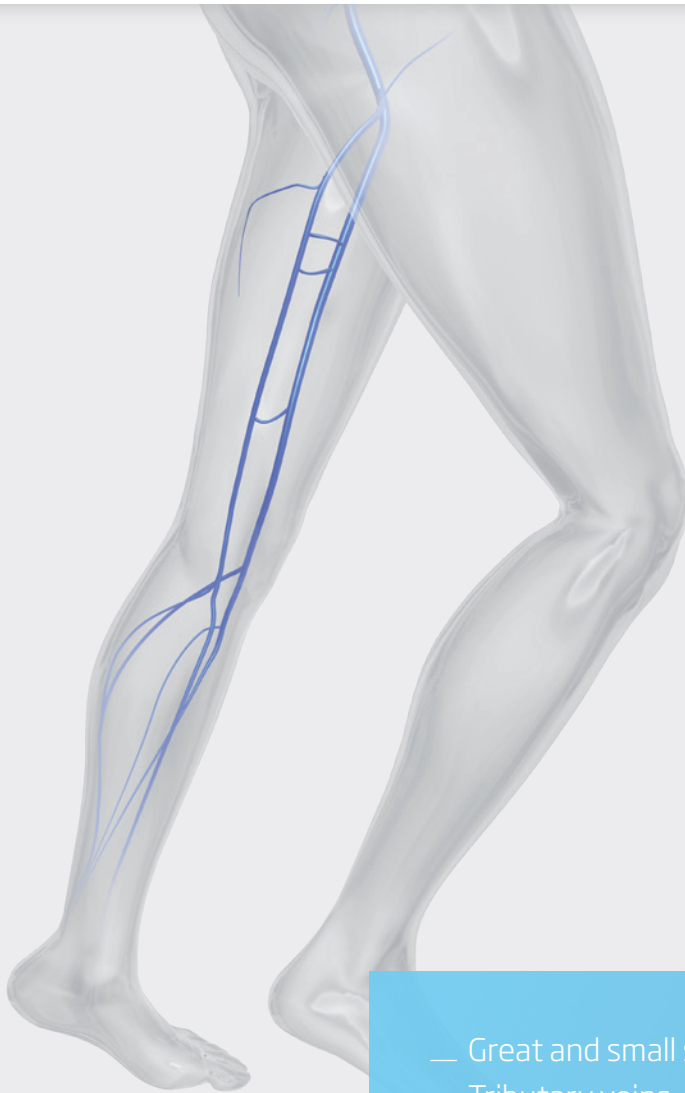
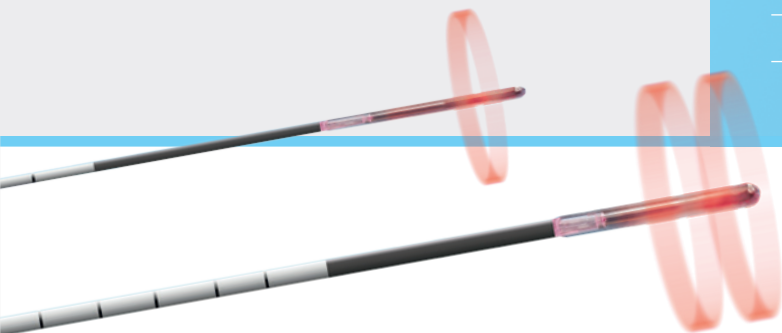


# ELVeS Radial™

Minimally invasive laser therapy of  
venous insufficiency



- Great and small saphenous vein
- Tributary veins
- Laser treatment of telangiectasia
- Laser valvuloplasty



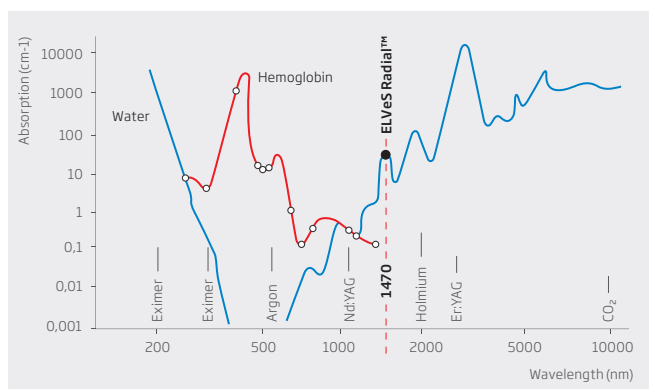
# The ELVeS Radial™ procedure – a unique solution for treatment of venous incompetence

## **A brief history of evolution**

Venous reflux disease is a common condition. Up to 55 % of women and 45 % of men suffer from symptoms such as fatigue, pain and swelling of lower limbs. Primary causes include congenital connective tissue weakness, hormonal changes and long periods of standing and sitting. Impaired veins can be more than just a cosmetic problem. Left untreated, venous reflux disease can progress to skin changes, discoloration, inflammation and even venous ulcer.

As a global pioneer in laser technique, biolitec® introduced the first medical 1470 nm diode laser in 2006 to improve the outcome of endoluminal laser use.

# Why 1470 nm?



The absorption coefficient of water at 1470 nm is significantly higher than in the wavelength range of 810 – 1064 nm which results in much better control of the laser energy applied.

“ The ELVeS Radial™ procedure minimizes any post-operative inflammatory pain and bruising, due to a 40 times or greater absorption coefficient in water compared to 810 nm – 980 nm lasers targeting hemoglobin. Incompetent veins treated with ELVeS Radial™ showed a 30 – 40 % reduction in vein diameter one day after the procedure as well as highest occlusion rates in a D1, D10, D30, 6 and 12 months follow-up. Dr. Uldis Maurins, Riga, Latvia ”

## Why radial?

Along with the 1470 nm laser biolitec®'s next remarkable innovation was the ELVeS Radial™ fiber in 2008. This atraumatic radial emitting fiber probe, in conjunction with our 1470 nm laser source for optimized energy control, formed the ideal combination for Endovenous Thermal Ablation and is considered the new state-of-the-art technology allowing for minimally invasive endoluminal treatment of venous reflux disease. The ELVeS Radial™ fiber applies energy safer and more accurately than any other fiber type in the endovenous market.

The patented radial (360°) energy emission ensures homogenous photothermal destruction of the vein wall, allowing immediate closure of the vein. By avoiding perforation of the vein wall and associated thermal irritation of the surrounding tissue, post-operative pain is minimized, as are ecchymosis and other side-effects. A micro-puncture kit is used to insert the ELVeS Radial™ fiber (atraumatic fiber tip) directly into and along the vein in a fast and safe one-step procedure. Optimal monitoring and positioning of the fiber tip is possible thanks to excellent ultrasound visibility. The ELVeS Radial™ fiber is equipped with safety markings for optimal control of the pullback process in conjunction with our ELVeS® signal software.

“ Short and intermediate term results of EVLA of the SSV with the 1470 nm diode laser and Radial fiber appears to be highly safe and effective in the elimination vein reflux. T King MD, Venous Research Foundation, Illinois – USA, IUA World Congress, 2010, Buenos Aires (Argentina) ”

No doubt that Endovenous Laser Ablation will lead the thermal techniques in elimination of saphenous reflux. Can treatment outcomes be improved? In medicine nothing can be 100 % effective and we are already at a very high rate of success with saphenous ablation.” John Mauriello MD, FACPh, (USA), IUA World Congress 2010, Buenos Aires (Argentina) ”

The Original  
by biolitec®

# Evolution continues

Unique FUSION®  
technology by biolitec®

The ELVeS Radial™ silica glass fiber caps by biolitec® are fused to the fiber instead of merely glued.

The presence and the future demand for even more intelligent solutions. Our effort to achieve a unique system in terms of safety and flexibility for the endoluminal treatment of varicose veins has led to our new 2ring™ fiber technology.

## ELVeS Radial 2ring™

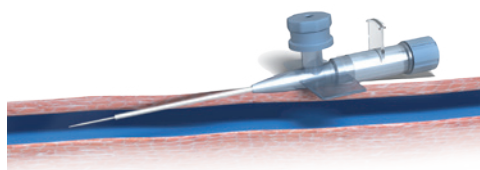
The 2-phase radiation with ELVeS Radial 2ring™ is the best choice for a perfect outcome, not only for experienced physicians, but also for beginners who ask for an efficient, safe and easy-to-use technique.

**Splitting the laser power in two phases leads to an effective closure of the vein with**

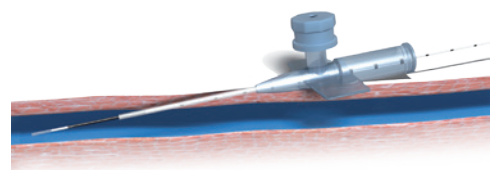
- Less energy density of each ring
- Perfect centration of the fiber tip by pre-shrinking effect
- Optimal homogenous radiation to the vessel wall even for large diameter >15 mm
- Easier pullback technique

## ELVeS Radial slim™

Designed to treat superficial venous reflux on perforator veins and small saphenous veins. More complicated anatomies and recurrences from stripping can also be handled effortlessly with ELVeS Radial slim™ just by placing the ELVeS Radial slim™ fiber via a 16G catheter.



Placing the catheter



Entering the vein

- The ELVeS Radial™ fibers are part of our FUSION® product line, allowing for utmost safety during laser treatment. The FUSION® technology employs a unique process that - instead of merely gluing - safely and firmly fuses the silica glass cap to the fiber to resist even highest temperatures and mechanical strains. Detachment of the cap inside the vein during treatment and an associated emergency surgery are nearly impossible.

## Applications

**ELVeS Radial™ procedure\***

- Great saphenous vein
- Small saphenous vein
- Accessory veins
- Perforating veins
- Recurrences
- Ulcus cruris

\* Only to be used with 1470 nm

Evolution continues  
ELVeS Radial  
2ring™

New  
for small  
veins

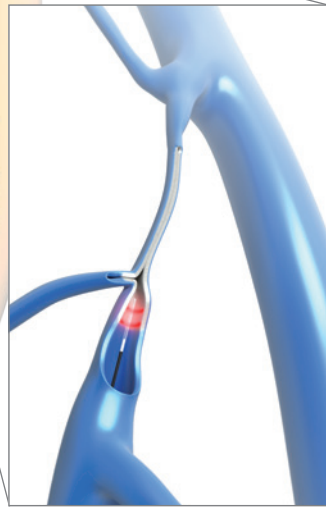
In addition to this the Laser use can be tapped to the full potential by the following two applications:

#### **Internal laser valvuloplasty**

- This vein repair approach represents an important step in development to further optimize the laser treatment of sickened veins. Task and target is to repair the insufficient valves.
- Controlled laser energy is applied internally to narrow the expanded vein and to restrict the gap between the valvular cusps. This can help experts to focus on restoring the vein's function by repairing the defect venous valves rather than removing it completely. Doing so the whole vein can be preserved.
- Internal laser valvuloplasty represents a smooth alternative method, specially with regard to the surgical treatment of the saphenous vein varicosis.

#### **Transdermal laser treatment of telangiectasia**

- Easy transcutaneous application
- Very low side effects
- Handpiece with different spot sizes according target vessels



# ELVeS Radial 2ring™ procedure – how does it work?

The ELVeS Radial 2ring™ procedure is performed on an outpatient basis under ultrasound guidance and Tumescent Local Anesthesia (TLA). However, some centers prefer to work without TLA using a sensory femoral nerve block or a mild sedation with some reported advantages (see below). Following percutaneous entry into the saphenous vein, the ELVeS Radial 2ring™ fiber is advanced towards the saphena-femoral junction. The laser procedure is carried out along the entire length of the incompetent vein under continuous pull back of the ELVeS Radial 2ring™ fiber. The complete treatment takes about 30 minutes; patients can return to normal activities immediately. Bi-lateral ELVeS Radial 2ring™ treatments or combined GSV and SSV procedures can be performed during the same session.

“ We use ELVeS Radial™ and perform procedures without tumescent anaesthesia and our favourite protocol is the use of the quick Sensory Femoral Nerve Block. This gives a better US image enabling real time visualization of the vein closure, which improves results as we can respond according to the individual anatomy. Patients report none or little discomfort and less post procedure pain and side effects. JHG Ferreira MD, Phlebology Unit at Sao Lucas Hospital, Pontiac Catholic University (PUCRS) – Brazil, IUA World Congress 2010, Buenos Aires (Argentina) ”

“Technology  
meets Anatomy”

A blue laser device with a long, thin, silver needle-like tip. A red laser beam is visible at the tip. A circular badge in the upper right corner contains the text "Evolution continues ELVeS Radial 2ring™".

Evolution  
continues  
ELVeS Radial  
2ring™

# Safe and simple – the all-around solution with a built-in safety concept

The ELVeS Radial 2ring™ procedure offers the optimum treatment solution for an effective and gentle endovenous laser therapy and is setting new standards for patients and users. Performing an endovenous laser therapy has never been more convenient. Delivering homogenous laser emission based on a unique and patented distal design, ELVeS Radial 2ring™ minimizes the risk of vein perforations and assures high echogenic visibility. The 1470 nm laser energy is preferentially absorbed in the intracellular water of the vein wall and in the water content of blood. The irreversible photo-thermal process induced by the laser energy results in a complete occlusion of the treated vein. The ELVeS® signal software mode guides the user throughout the procedure. Individually addressable energy deposition to any length of the vein without having to retreat certain sections as with other products.

#### The ELVeS Radial 2ring™ procedure is ...

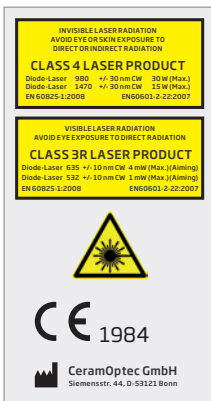
- Fast
- Safe
- Homogenous
- Effective
- Evidence-based

“With the available results and patient/physician preferences it can be said that conventional high ligation plus stripping of the incompetent saphenous vein is no longer the gold standard treatment choice. Suat Doganci and Ufuk Demirkilic, Vascular Surgery Published online 04, April, 2012 ISBN 978-953-51-0328-8”





## LEONARDO®



Model	LEONARDO® Mini 1470 nm	LEONARDO® DUAL 45
REF	SL1470nm8W	SL980+1470nm45W
Wavelength	1470 nm	980 nm and 1470 nm
Power	8 W (1470 nm)	max. 45 Watt (1470 nm / 15 Watt + 980 nm / 30 Watt) separately adjustable
Fiber diameter	≥ 360 µm	≥ 360 µm
Aiming beam	635 nm, max. 4 mW	532 nm and 635 nm, green 1 mW, red 4 mW, user controlled intensity
Treatment mode	CW, Pulse Mode (optional), ELVeS® Signal	CW, Pulse Mode, ELVeS® Signal, ELVeS® Segment, Derma Mode
Pulse duration /-break	0.01 – 60 sec. / 0.01 – 60 sec.	0.01 – 60 sec / 0.01 – 60 sec
Power supply	110 - 240 VAC, 50 - 60 Hz (7.2 VDC @ 36 W)	110 - 240 VAC, 50 / 60 Hz, 450 VA
Batteries	Li-ion batteries	-
Dimensions (H × W × D)	6.0 cm × 9.0 cm × 21.5 cm	approx. 28 cm × 37 cm × 9 cm
Weight	900 g	approx. 8.5 kg

Alle Lasersets umfassen 3 Schutzbrillen, einen Fußschalter, ein Türschalter-Interlock, ein Stromkabel und ein Handbuch in einem Tragekoffer.

## Fibers\*

REF	Product	PU **	length [m]	ø fiber tip [mm]	Cl***
503100150	ELVeS Radial slim™ Fiber, IC	5	2.5	1.3	4 Fr
503100100	ELVeS Radial™ Fiber, IC	5	2.5	1.85	6 Fr
503100170	ELVeS Radial 2ring™ Fiber, IC	5	2.5	1.85	6 Fr

## Kits\*

503100160	ELVeS Radial slim™ Kit / Venflon™, IC	5	2.5	1.3
503100130	ELVeS Radial™ Kit 6F, IC	5	2.5	1.85
503100185	ELVeS Radial 2ring™ Kit 6F	5	2.5	1.85

## Handpieces

503200980	Derma Set Change Optic 0.6/1.0/1.5 mm, IC (5y)	1
503200981	Derma Set Change Optic 1.0 mm, IC (5y)	1

\* Only to be used with 1470 nm \*\* Packaging unit \*\*\* Compatible introducer

# Contact us

to learn more about a whole new world  
of minimally invasive laser therapies



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DEHP. Our fibers are single use products  
(unless otherwise indicated) delivered  
sterile for immediate use.