

A COMPLETE TREATMENT KIT INCLUDING:

Ringlight radial fiber

Standard fiber

Internal diameter: 600 µm
Capsule diameter: 1,8 mm

Slim fiber

Internal diameter: 400 µm
Capsule diameter: 1,0 mm

Radial emission: 360°

Capsule: atraumatic

Emission angle: 60°

Length: 2,5 m

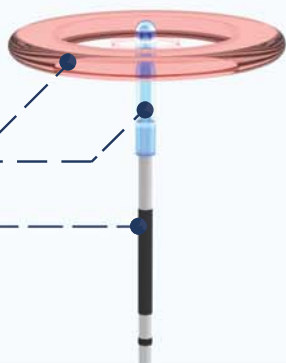
Marking: laser engraving

Connector: SMA 905

Class: IIa

Sterilization: ETO

Use: sterile single use



Complete endovenous 1470 nm kit

Ringlight fiber, standard or slim

Short introducer set 13 cm:

Introducer 4 Fr, 5 Fr or 6 Fr

Guide compatibility:

- Diameter - 0.035

- Guide type - straight / 3 mm J

Sheath:

- Length - 13 cm

Dilatator:

- Length - 20 cm

Guide-wire

Puncture needle 18G



TECHNICAL SPECIFICATIONS OF THE ENDOTHERME™ 1470

Laser: Diode

Wavelength: 1470 nm +/- 10

Power: 15 Watts

Cooling system: Peltier & Air

Emission mode: Continuous or pulsed, 0,1 to 25 sec

Laser class: 4

Device class: IIb [Directive 93/42/CE]

Power supply: 110-230 VAC;

50 to 60 Hz

Weight: 15 kg

Dimensions: H 45cm x L 45cm x l 35cm

Bag

Compatible: Endotherme™ & Exotherme™

Cart

Compatible: Endotherme™ & Exotherme™



For vascular surgeons, vascular doctors, pharmacists, biomedical engineers and operating room staff.

Medical equipment Laser Endotherme™ 1470, Class IIb, CE 0120
Manufacturer: LSO Medical, Biocentre Fleming, Bât D,
280 rue Salvador Allende, 59120 Loos, France

September 2018, Version 7

www.LSOmedical.com

Tel.: +33 (0)3 20 67 90 00

Fax.: +33 (0)3 20 04 46 24

contact@LSOmedical.com

ENDOTHERME™ 1470



LASER AND RADIAL FIRING FIBER FOR THE TREATMENT OF VENOUS INSUFFICIENCY



LSO Medical



LSO Medical
FRANCE

A HIGHLY ADVANCED ENDOTHERMIC TECHNIQUE FOR THE TREATMENT OF VENOUS INCOMPETENCE

The endovenous laser therapy treats **venous reflux disease by removing varicose veins without any anatomic resection**, by using endovenous thermo-occlusion.

This occlusion comes from the endoluminal heat generation produced by the laser. Thermal effect occurs onto the blood flow and the vein wall, leading to parietal modifications (alteration of the endothelium and contraction of collagen), causing the occlusion of the incompetent saphenous vein.

The procedure is carried out in an ambulatory setting. The local tumescent anaesthesia protects the surrounding tissues from the laser thermal effects and by vein compression reduces the blood volume in the vein.

The vein fibrosis is instantly visible (under echo-doppler monitoring), but the complete and long-term occlusion occurs within several weeks.

An effective treatment for :

- Small saphenous veins
- Great saphenous veins
- Perforating veins
- Veins with a diameter from 4mm
- Varicose ulcers

In the CEAP system, varicose veins are classified according to the clinical severity grade ranking from C2 up to C6, the Etiology grade Es or Ep, the anatomy grade As, Ap, or Ad and the Pathophysiology grade Pr or Po.

THE 1470NM ENDOTHERME™ LASER AND THE RINGLIGHT RADIAL FIRING FIBER

A targeted and controlled delivered energy

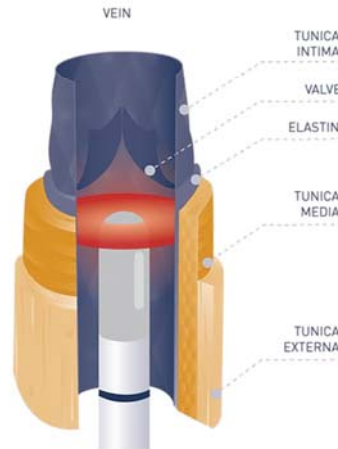
The laser procedure with radial firing fiber ensures a more homogenous, precise and controlled energy delivery.

The volume of the primary light absorption, with a 1470nm laser, leads to a temperature increase focused on the vein wall, not on the outer tissues. The light absorption is higher with a 1470nm. Radial emission leads to an homogeneous destruction of the vein wall exclusively, without any risk of damage to surrounding tissues. Energy delivery is controlled for a long-term occlusion of the incompetent vein.

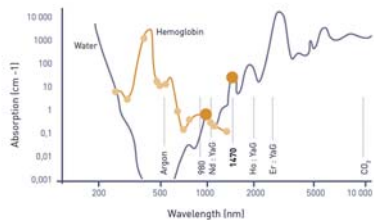
The Ringlight radial firing fiber, with the encapsulated tip, smooth and atraumatic, avoids perforations of the vein wall when the fiber is introduced.

The energy delivery required to produce the vein occlusion is lower than for a 980nm laser use.

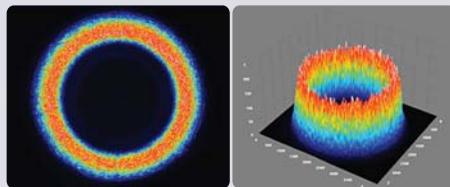
This optimised energy delivery and the design of the fiber improve the patient post-op comfort. Post-operative pain, hematoma and complications are limited.**



Anatomy of the vein wall, radial firing fiber and light emission



Homogeneous, targeted and standardized radial laser emission



Measurement of luminous flux [W/cm²] emitted by a standard Ringlight fiber

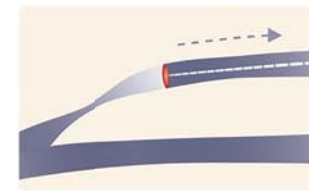
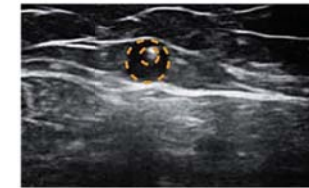
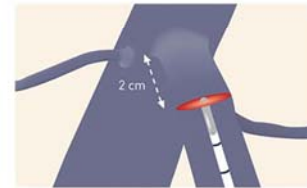
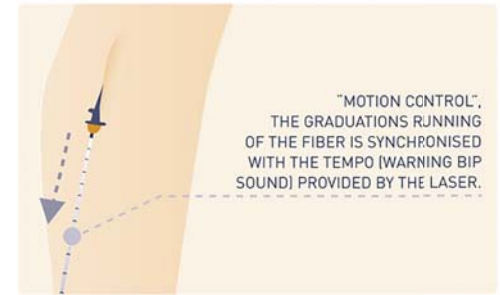
A standardised configuration and a controlled withdrawal

The withdrawal of the fiber during the laser shot is a key step in the procedure. An adequate control of the continuous or point-by-point removal of the fiber, is required to deliver the right dosimetry.

The graduated Ringlight radial firing fiber and the configuration of the Endotherme™ laser allow a standardised removal of the fiber in a continuous laser shooting.

- Determination of the LEED (Linear Endovenous Energy Density) to be delivered, (e.g. : 70 J/cm of treated vein)
- These settings are saved in the laser device,
 - An audio warning predefined on the laser settings allows the adjustment of the speed during the withdrawal of the fiber: the fiber has to be removed from 1 graduation (1 cm) at each sound warning.
 - The use of the **Osypilot®** is an alternative technique to this removal method. This light ruler guides the physician when retracting the fiber in a continuous laser shooting by following the speed of the diodes running lights.

The withdrawal of the laser fiber is controlled thanks to the sound signal of the laser or the Osypilot®, and is no longer operator-dependent.



- * Positioning of the fiber, from 1 to 2cm from the saphenofemoral junction (to preserve the tributary veins) under ultrasound guiding.
- * Vein before tumescence. (small circle : fiber, large circle: vein wall).
- * Vein after tumescence: the vein is compressed by the tumescent liquid, the surrounding tissues are protected. (small circle : fiber and the vein around with spasm, large circle: tumescent volume).
- * Withdrawal of the fiber while delivering the laser energy: the vein collapses, leading to its occlusion along the entire length of the vein and the elimination of the venous reflux.

LIGHT TREATMENT, MONITORING THROUGH ENERGY

What science says:

A calorie (4.18 Joules) enables a rise of temperature of one gram water by one Celsius degree. The amount of energy needed for the destruction of the vein should therefore be adjusted to the vein volume being heated.

Considering that Energy [J] = Power [W] x Exposure Time [s], the tissue destruction induced by thermal effect results from the combination of energy power actually delivered into the tissue and from its exposure time (and not only from power emission and from the reached temperature).

What LSO Medical is proposing:

The Endotherme™ 1470 laser device ensures the delivery of energy level by radiation without any contact fiber-vein.

The Endotherme™ 1470 laser device guarantees treatment efficiency through standardization of the procedure:

- By measuring and ensuring the energy delivered into the tissue, in real time.
- By controlling exposure times by way of a standardized protocol for withdrawal.