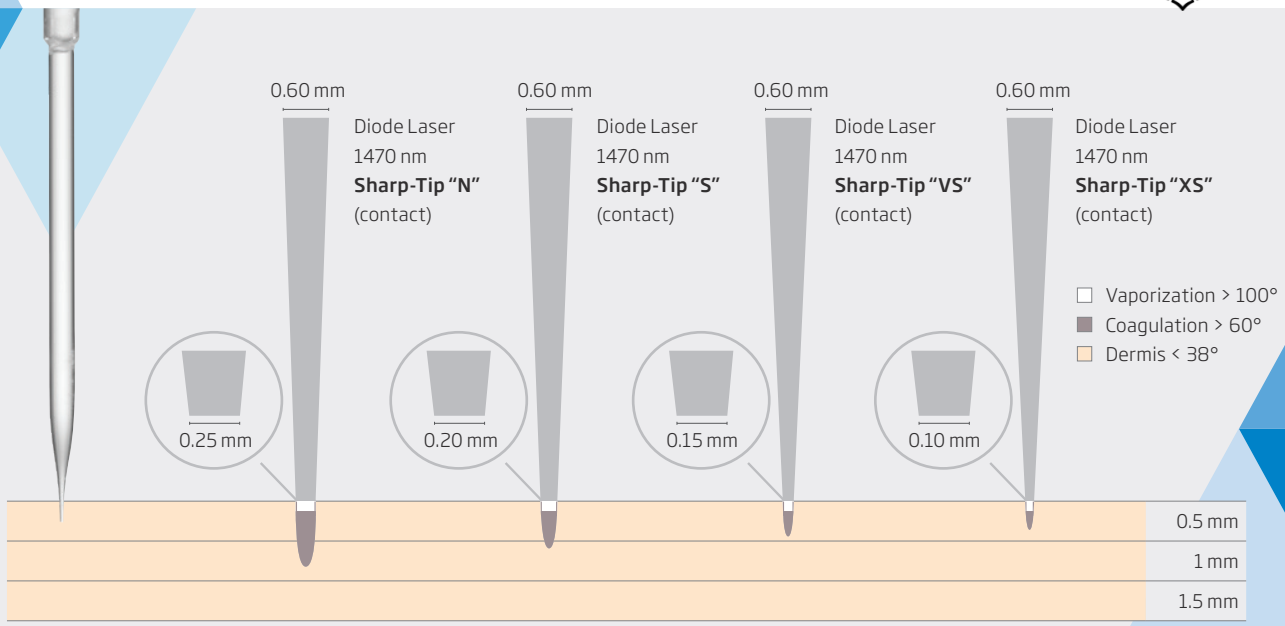
NEEDLE-SHAPED LASER FIBER "SHARP TIP"

especially designed for microsurgical cutting and coagulation



biolitec® laser fibers with precise sharp tips

biolitec® manufactures these high-quality laser fibers in its own production facilities. Your patients will benefit from decades of know-how in the production of high-tech fibers of outstanding quality.

Coagulation
- Precise
- Flat
- Linear

Cutting
- Bloodless
- Carbonization free

High stability and durability

Fibers ("single use")

REF	Product	Length [m]	Fiber ø [µm] / [Fr]	Fiber tip AD ø [mm]
503500500	Bare Fiber 600mic, Sharp Tip N, IC	2.5 ± 0.1m	600	0.25
503500501	Bare Fiber 600mic, Sharp Tip S, IC	2.5 ± 0.1m	600	0.20
503500502	Bare Fiber 600mic, Sharp Tip VS, IC	2.5 ± 0.1m	600	0.15
503500503	Bare Fiber 600mic, Sharp Tip XS, IC	2.5 ± 0.1m	600	0.10

LEONARDO®

Model	**LEONARDO® Mini 1470 nm**	**LEONARDO® DUAL 45**
REF	SL1470nm8W, or: SL980nm+1470nm14W	SL980nm+1470nm45W
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 – CW / 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 cm × 9 cm × 21.5 cm	approx. 28 cm × 37 cm × 9 cm
Weight	900 g	approx. 8.5 kg

All laser sets incl. 3 safety goggles, foot switch, interlock connector, power cord and manual in a carrying case.

biolitec biomedical technology GmbH
Otto-Schott-Str. 15
07745 Jena, Germany
Phone: +49 3641 519 53 0
Fax: +49 3641 519 53 33
info@biolitec.de
www.biolitec.com

All fibers are free of latex and DEHP. Our fibers are single use products (unless otherwise indicated) delivered sterile for immediate use. Manufacturer: CeramOptec GmbH, Germany (unless otherwise specified) Disclaimer: Products might not be available in every country. biolitec® is a registered trademark owned by biolitec.

CE 1984

Technology meets Anatomy

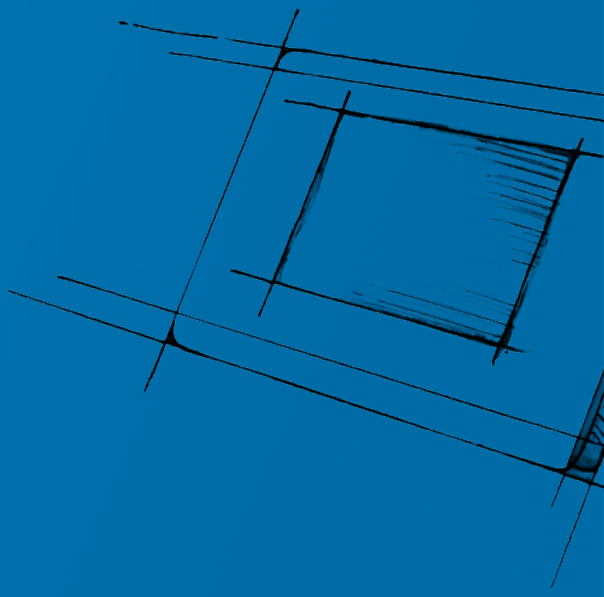
LEONARDO®

Universal and ingenious

- Cutting
- Vaporization
- Tissue shrinking
- Coagulation
- Dual wavelength laser individually selected or blended

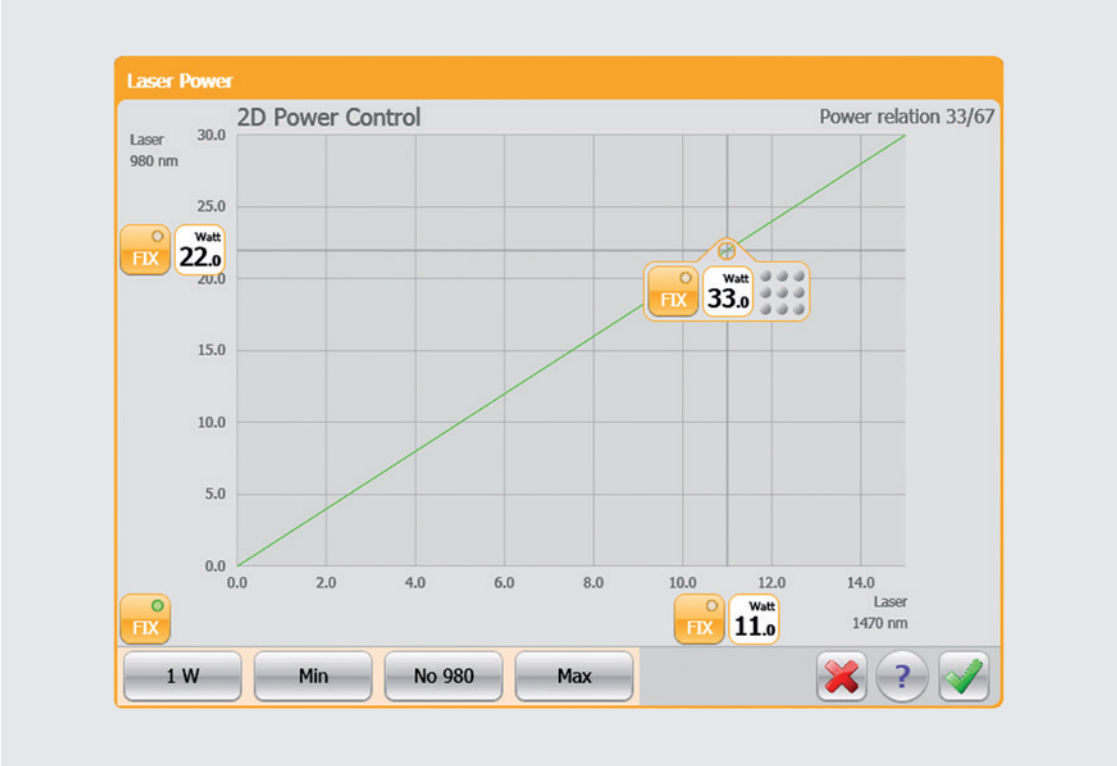
bioLITEC®

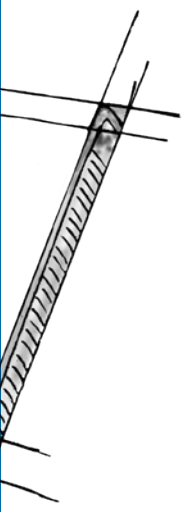
A whole new world of therapeutic applications and clinical results



biolitec® presents the LEONARDO® Laser – the most versatile and universal medical laser in the market today. This highly compact diode laser features the combination of two wavelengths, 980 nm and 1470 nm offering a variety of tissue interactions. Each wavelength can be individually selected or **blended** together to offer the perfect desired tissue effects such as incision, excision, vaporization, hemostasis and coagulation of soft tissue with contact or non-contact delivery options for open and endoscopic procedures. For the first time the clinicians can perform laser surgery selectively, with settings individually tailored to the tissue type and the desired tissue effects and thus corresponding to the therapeutic needs.

The ability to choose a wavelength mix opens a whole new world of therapeutic applications and improves both the treatment outcomes for the patients and **extends** the clinicians experience and expertise. The LEONARDO® Laser is designed to work in perfect combination with a broad spectrum of special medical fibers and application kits developed by biolitec® and its companies. biolitec® is one of the **world's most** technologically advanced suppliers of fiberoptic products. The biolitec® treatment methods are routinely performed and validated in highly respected medical centers worldwide and are the number one choice for treating a wide variety of diseases and medical conditions.





2D Power Control

LEONARDO®'s intuitive 2D Power Control enables the user to choose a combination of different wavelengths and power settings with a simple touch of the screen.

New Fiber Connector

The new fiber connector facilitates to plug the fiber into the laser. It is equipped with an electronic signature for increased patient safety. It prevents usage beyond the product's lifetime and hazards caused by inserting unsuitable fibers to the laser.

Advantages

Versatile and universal

- Broad spectrum of minimally invasive therapeutic laser applications

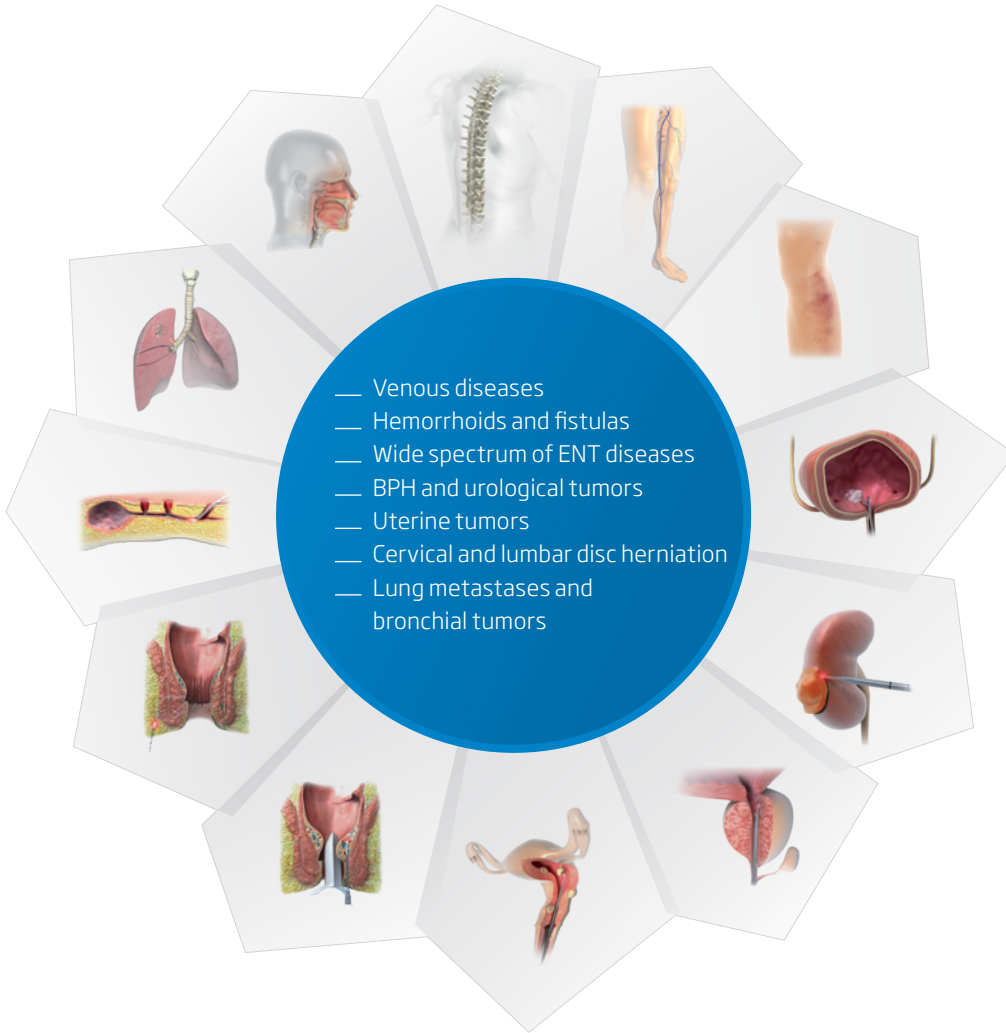
User-Friendly

- Intuitive use with touch screen and fast set-up
- Selection between pre-set modes or individualized settings
- Choice between green or red aiming beam

Economic

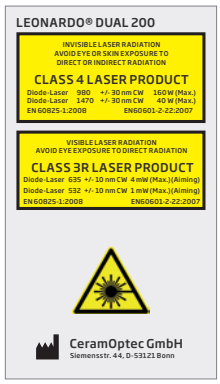
- Two wavelength in one compact and space-saving laser system
- Multidisciplinary use
- Low-maintenance and reliable laser diodes

Special medical fibers and application kits available for minimally invasive laser therapies of:



LEONARDO®

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



Model	**LEONARDO® DUAL 100**
REF	SL980+1470nm100W
Wavelength	980 nm and 1470 nm
Power max.	100 Watt (1470 nm / 15 Watt + 980 nm / 85 Watt) separately adjustable
Fiber diameter	≥ 360 µm
Aiming beam	532 nm and 635 nm, green 1 mW, red 4 mW, user controlled intensity
Treatment mode	CW, Pulse Mode, ELVeS® Signal, ELVeS® Segment, Derma Mode
Pulse duration / -break	0.01 – 60 sec / 0.01 – 60 sec
Power supply	110 - 240 VAC, 50 / 60 Hz, 850 VA
Dimensions (H × W × D)	approx. 28 cm × 37 cm × 9 cm
Weight	approx. 8.5 kg

Model	**LEONARDO® DUAL 200**
REF	SL980+1470nm200W
Wavelength	980 nm and 1470 nm
Power max.	200 Watt (1470 nm / 40 Watt + 980 nm / 160 Watt) separately adjustable
Fiber diameter	≥ 360 µm
Aiming beam	532 nm and 635 nm, green 1 mW, red 4 mW, user controlled intensity
Treatment mode	CW, Pulse Mode, ELVeS® Signal, ELVeS® Segment, Derma Mode
Pulse duration / -break	0.01 – 60 sec / 0.01 – 60 sec
Power supply	110 - 240 VAC, 50 / 60 Hz, 850 VA
Dimensions (H × W × D)	approx. 20 cm × 37 cm × 26 cm
Weight	approx. 15 kg

Why did we name our laser LEONARDO®?

Leonardo was born in Vinci, near Florence, in 1452. He showed early interest in many different subjects and a precocious talent for drawing. During his career he worked for many illustrious men of his age: the Medici family in Florence, Ludovico il Moro and Francesco Sforza in Milan, Louis XII and Francis I of France and many others.
Along with his profession, he applied himself in countless different fields. He studied natural sciences firsthand, discovering new (at that time) phenomena in geology, astronomy, botany, hydraulics, etc. He was a prolific inventor: he produced projects, prototypes and concepts for many applications as the parachute, a surface-supplied diving suit, different artillery pieces, warships, a tank, a rudimentary helicopter, a bicycle and many more. Leonardo da Vinci was also hired as an engineer, mainly for hydraulic and military structures and applications.
His contribution to human anatomy is of the highest importance: at his time anatomy and natural sciences in general were approached in a purely theoretical fashion, by studying the texts of the ancient authors. Da Vinci on the contrary studied the human body through the dissection of corpses (a forbidden practice in that period) and produced illustrations of the different apparatuses, which have been used in anatomy texts until recent times. Due to this extraordinary eclecticism, **Leonardo da Vinci is universally regarded as the epitome of the universal genius.**

biolitec® worldwide

biolitec AG
Vienna, Austria
phone: +43 1 3619 909 50
info@biolitec.de
www.biolitec.com

biolitec biomedical technology GmbH
Jena, Germany
Phone: +49 3641 519 53 0

biolitec Schweiz GmbH
Wollerau, Switzerland
Phone: +41 55 555 30 20

biolitec Italia SRL
Milano, Italy
Phone: +39 02 8423 0633

biolitec T. C. S. V. P. Ltd.
Istanbul, Turkey
Phone: +90 216 574 7456

OOO biolitec Spb
Saint-Petersburg, Russia
Phone: +7 812 4493752

biolitec FZ LLC
Dubai, UAE
Phone: +971 44 29 85 92

biolitec laser science and technology Shanghai Ltd.
Shanghai, China
Phone: +86 21 6308 8856

biolitec Sdn. Bhd.
Selangor, Malaysia
Phone: +60 3 5569 7158

biolitec India Private Ltd.
Bangalore, India
Phone: +91 265 3201106

PT. Biolitec
Tangerang, Indonesia
Phone: +62 21 537 2994

biolitec Korea Ltd.
Seoul, Republic of Korea
Phone: +82 2 701 4707

Equipos Laser de Uso Medico y Fibra Optica SA de CV
México City, Mexico
Phone: +52 155 55 731800

biolitec BCIE LTDA
São Paulo, Brazil
Phone: +55 11 2093 8602

CeramOptec GmbH
Bonn, Germany
Phone: +49 228 979670

Ceram Optec SIA
Riga, Latvia
Phone: +371 653 25 994

bio LITEC®

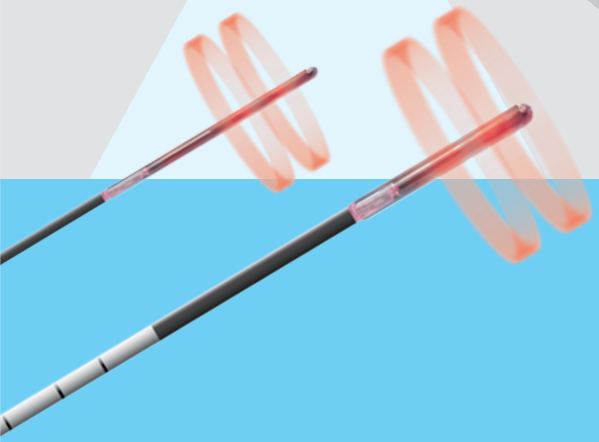
All fibers are free of latex and DEHP. Our fibers are single use products (unless otherwise indicated) delivered sterile for immediate use.

Imprint
biolitec AG
Untere Viaduktgasse 6/9
A-1030 Wien
Phone: +43 1 3619 909 50
www.biolitec.com

ELVeS® Radial®

Minimally invasive laser therapy of venous insufficiency

Safely to the next level



- Vena saphena magna
- Vena saphena parva
- Tributary veins
- Perforator veins
- Recurrences

The ELVeS® Radial® procedure – the unique solution for the treatment of venous insufficiency

THE ORIGINAL RADIAL®

The evolution of laser therapy

As one of the world's leading pioneers in the field of medical laser therapy, biolitec® launched the first medical 1470 nm diode laser in 2006 and the patented Radial® fiber in 2008 and has continued to improve endoluminal laser therapy ever since.

Attain the next level safely with us

2019
1940 nm

2019
ELVeS® Radial® 2ring Pro

2012
ELVeS® Radial® 2ring

2008
ELVeS® Radial®

2006
1470 nm

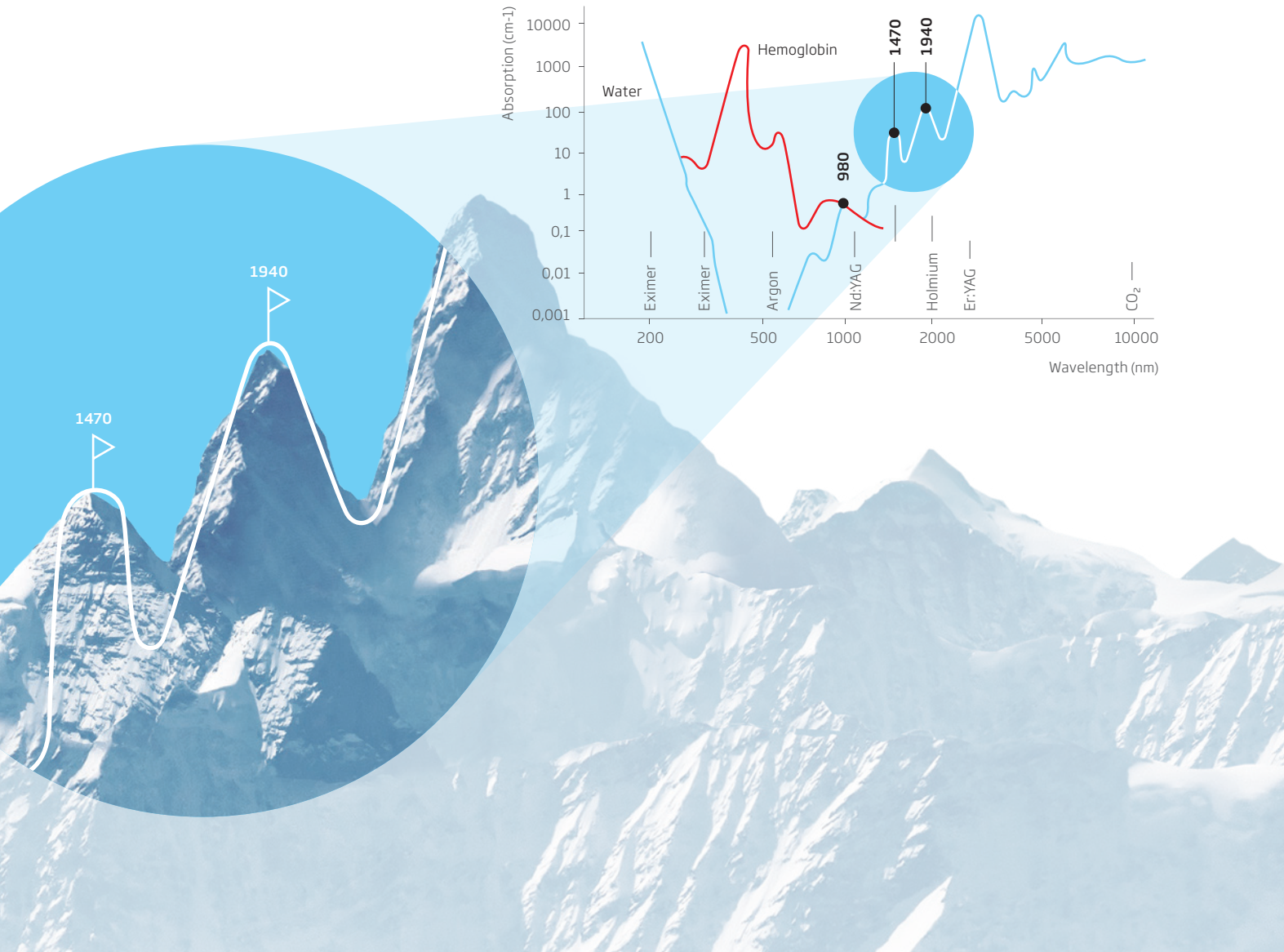
The evolution continues

Present and future call for even more intelligent solutions. Our striving to develop an outstanding system with respect to safety and flexibility for the endoluminal treatment of varicose veins has led us to 2ring technology.

This principle, combined with the safest Fusion® fiber optics, the latest diode laser generation and treatment software, which can also incorporate a pulling device, offers:

- a high degree of standardization of your treatment
- always the right equipment for each of your approaches
- therapy also for complex vascular courses

We are reaching the next peak



ELVeS® Radial® 2ring

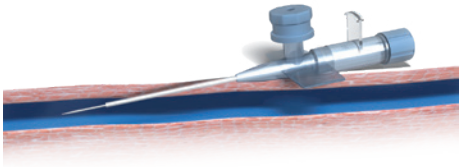
The dual-phase radiation with the ELVeS® Radial® 2ring fiber is the best choice for a perfect result, not only for experienced physicians but also for new users who demand efficient, safe, and easy-to-use technology.

With this laser fiber the energy is split into two rings.
This allows safe closure of the vein with

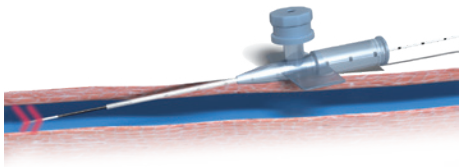
- a low energy density in each ring
- a perfectly centered fiber tip due to the pre-shrinkage effect
- optimal, homogeneous radiation on the vessel wall (even with a large diameter >15 mm)
- a simple retraction technique (possible with the push of a button)

ELVeS® Radial® 2ring slim and ELVeS® Radial® swift 2ring

The great variety of the ELVeS® Radial® family offers you many combinations from direct puncture or the use of introducer sets for tailored treatment of your patients almost without limitations. Due to their very small external diameter of only 1.2 / 1.5 mm the slim or swift fibers are introduced via conventional 16 GA or 14 GA indwelling catheters into the vein, so no complete introducer set is needed. Of course, depending on the findings (e.g., very tortuous veins), several such accesses can be placed or obstacles overcome when using the ELVeS® Radial® Pro-Fiber.



Introduction into the vein



Placement of the catheter

Applications

ELVeS® Radial® procedures*

- Vena saphena magna
- Vena saphena parva
- Tributary veins
- Perforator veins
- Recurrences
- Ulcus cruris venosum

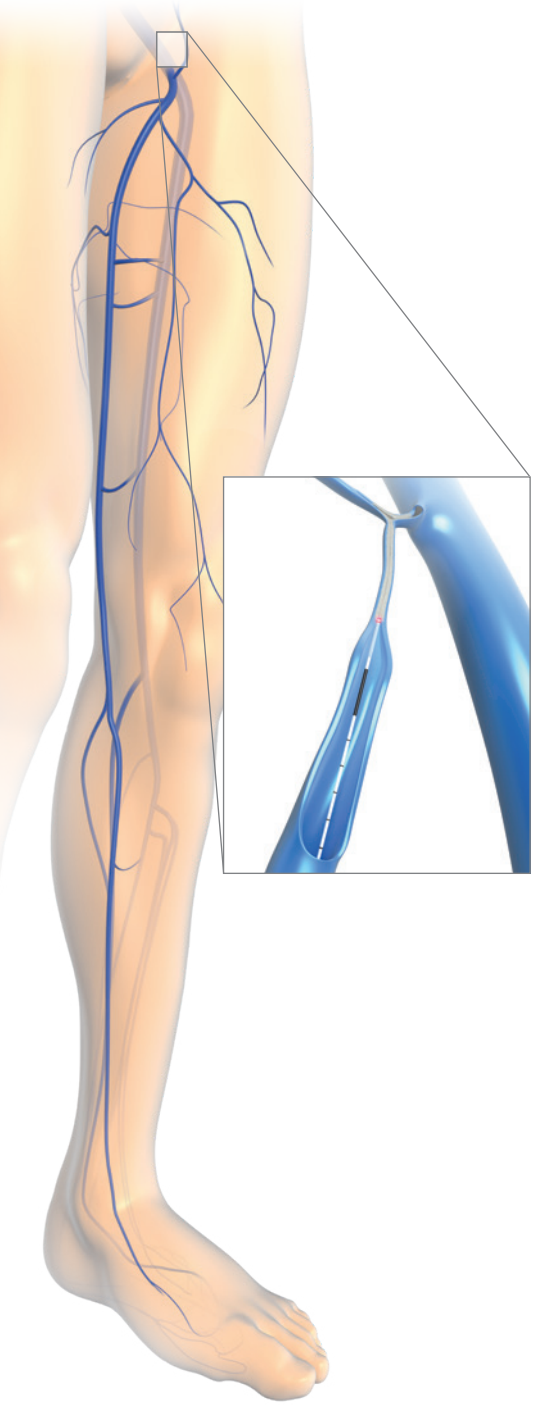
* for use with 1470 nm and 1940 nm only.

ELVeS® Radial® Original Quality

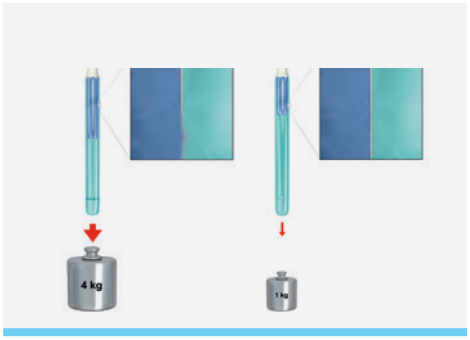
Why Fusion®?

Because quality matters

Due to of its high quality standards, biolitec® has understood from the beginning what is important when it comes to safety. For this reason, all of biolitec®'s distal quartz glass caps and laser fibers are fused to one another with the help of Fusion® technology. Simple gluing does meet the current standard for these products (DIN EN ISO 10555-1, Annex B), but not the high demands of modern minimally invasive laser medicine. biolitec® has developed the Fusion® process and thus set the standards worldwide.



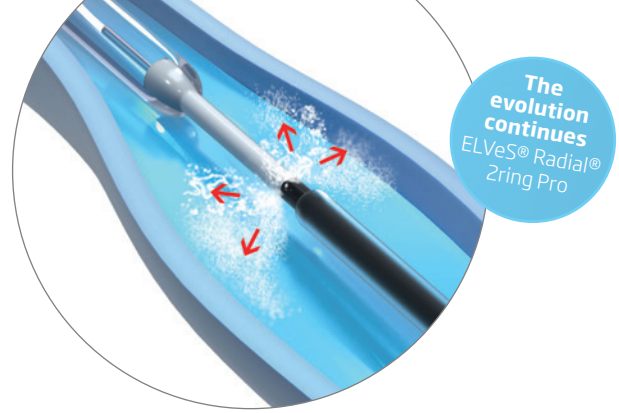
On the right side is a sketch of the tensile forces that a catheter must meet according to the standard. On the left, however, one sees the tensile strength, attained as a minimum by Fusion®-technology (internal biolitec® tests).



ELVeS® Radial® 2ring – the procedure

The ELVeS® Radial® 2ring procedure is usually performed on an outpatient basis under local anesthesia and with ultrasound monitoring. After the percutaneous puncture of the vena saphena, the ELVeS® Radial® 2ring fiber is advanced to the saphenofemoral junction.

The laser treatment is performed along the insufficient vein segment; the ELVeS® Radial® 2ring fiber is continuously withdrawn during the process. The entire treatment lasts approx. 30 – 40 minutes depending on the findings. Shortly thereafter, the patient can resume his normal activities. With the ELVeS® Radial® 2ring procedure, bilateral treatments or combined treatments of the vena saphena magna and the vena saphena parva can be performed in a single session.



Simple and Safe – The All-Round Solution with the Integrated Safety Concept

The ELVeS® Radial® 2ring process is the optimal solution for effective and careful endovenous laser therapy and sets new standards for patients and users. Performing endovenous laser therapy has never been easier. Thanks to the homogeneous laser radiation made possible by an exclusive and patented distal design, the ELVeS® Radial® 2ring procedure minimizes the risk of vein perforation and ensures high echogenic visibility. The 1470 nm laser energy is preferably absorbed by the intracellular water of the vein wall. The induced irreversible photothermic process leads to complete closure of the treated vein. The ELVeS®-Signal software mode guides the user through the procedure. The laser energy can be applied in an individual dose to any vein diameter without having to treat individual sections a second time, as is the case with other products.

The recently introduced 1940 nm diode laser with 10 watts output power even offers slightly higher water absorption compared to the established 1470 nm wavelength. It thus offers the possibility of treating even more controlled superficial (extrafascial) vein segments and, according to initial findings, leads to a faster resorption of the treated vein segments. In combination with the 2ring fiber and a fiber pullback device, this leads to unrivalled homogeneity of your treatment, all this with the push of a button, or you can continue to "handle it yourself".

The ELVeS® Radial® 2ring procedure is ...

- fast
- safe
- homogeneous
- effective
- evidence-based

NEW
LEONARDO®
Mini 1470 nm –
Now with
12 watts

LEONARDO®

Model	**LEONARDO® Mini 1470**	**LEONARDO® 1470**	**LEONARDO® 1940**
REF	SL1470nm12W	SL1470nm15W	SL1940nm10W
Wavelength	1470 nm	1470 nm	1940 nm
Power	12 Watt	15 Watt	10 Watt
Fiber diameter	≥ 360 µm	≥ 360 µm	≥ 360 µm
Aiming beam	635 nm, max. 4 mW	532 nm und 635 nm, green 1 mW, red 4 mW, user controlled intensity	635 nm, red 4 mW, user controlled intensity
Treatment mode	CW, Pulse Mode, ELVeS® Signal	CW, Pulse Mode, ELVeS® Signal, ELVeS® Segment, Derma Mode	CW, Pulse Mode, ELVeS® Signal, ELVeS® Segment
Impulslänge / - break	0.01 – 180 sec / 0.01 – 180 sec	0.01 – 60 sec / 0.01 – 60 sec	0.01 – 60sec / 0.01 – 60 sec
Power supply	110 – 240 VAC, 50 – 60 Hz (12 VDC @ 100 W)	110 – 240 VAC, 50 / 60 Hz, 450 VA	110 – 240 VAC, 50 / 60 Hz, 450 VA
Batteries	Li-ion Batterien	–	–
Dimensions (H × B × T)	6.0 cm × 9.0 cm × 21.5 cm	ca. 28 cm × 37 cm × 9 cm	ca. 28 cm × 37 cm × 9 cm
Weight	900 g	approx. 8.5 kg	approx. 8.5 kg

All laser sets incl. 3 safety goggles, foot switch, interlock connector, power cord and manual in a carrying case.

Fibers

REF	Product	PU*	length [m]	ø fiber tip [mm]	CI**
503100150	ELVeS Radial slim Fiber, IC	10	2.5	1.25	4 Fr
503100100	ELVeS Radial Fiber, IC	10	2.5	1.85	6 Fr
503100140	ELVeS Radial swift Fiber, IC	10	2.5	1.5	5 Fr
503100142	ELVeS Radial swift 2ring Fiber, IC	10	2.5	1.5	5 Fr
503100170	ELVeS Radial 2ring Fiber, IC	10	2.5	1.85	6 Fr
503100155	ELVeS Radial 2ring slim Fiber, IC	10	2.5	1.25	4 Fr
503100145	ELVeS Radial 2ring Pro Fiber, IC	10	2.5	1.85	6 Fr

Kits

503100160	ELVeS Radial slim Kit / Venflon, IC	10	2.5	1.25
503100130	ELVeS Radial Kit 6F, IC	10	2.5	1.85
503100141	ELVeS Radial swift Kit, IC	10	2.5	1.5
503100143	ELVeS Radial swift 2ring Kit, IC	10	2.5	1.5
503100185	ELVeS Radial 2ring Kit 6F	10	2.5	1.85
503100156	ELVeS Radial slim 2ring Kit, IC	10	2.5	1.25
503100146	ELVeS Radial 2ring Pro Fiber Kit, IC	10	2.5	1.85

* Packaging unit ** compatible introducers

Contact us

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

biolitec® worldwide

biolitec Holding GmbH & Co KG
Vienna, Austria
phone: +43 1 3619 909 50
info@biolitec.de
www.biolitec.com

biolitec biomedical technology GmbH
Jena, Germany
Phone: +49 3641 519 53 0

biolitec Schweiz GmbH
Wollerau, Switzerland
Phone: +41 55 555 30 20

biolitec España
Madrid, Spain
Phone: +34 91 9910857

biolitec Italia SRL
Milano, Italy
Phone: +39 02 8423 0633

biolitec Tıbbi Cihazları Ltd. Şti.
Istanbul, Turkey
Phone: +90 216 574 7456

OOO biolitec Spb
Saint-Petersburg, Russia
Phone: +7 812 4493752

biolitec FZ LLC
Dubai, UAE
Phone: +971 44 29 85 92

biolitec laser science and technology Shanghai Ltd.
Shanghai, China
Phone: +86 21 6308 8856

biolitec Sdn. Bhd.
Selangor, Malaysia
Phone: +60 3 5569 7158

biolitec India Private Ltd.
Bangalore, India
Phone: +91 93275 11005

PT. Biolitec
Tangerang, Indonesia
Phone: +62 21 295 57 419

biolitec Korea Ltd.
Seoul, Republic of Korea
Phone: +82 2 701 4707

Equipos Laser de Uso Médico y Fibra Óptica SA de CV
(Biolitec Mexico & Latín América)
Phone: +52 (55) 5573 1800

Biolitec Biotecnologia Comércio, Importação, Exportação LTDA
São Paulo, Brazil
Phone: +55 11 2093 8602

CeramOptec GmbH
Bonn, Germany
Phone: +49 228 979670

Ceram Optec SIA
Riga, Latvia
Phone: +371 653 25 994

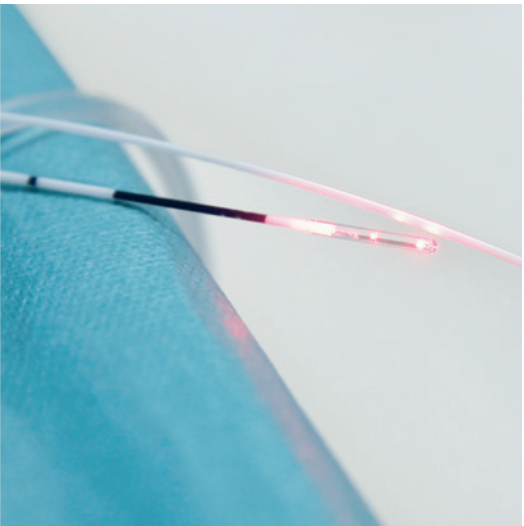
bio LITEC®

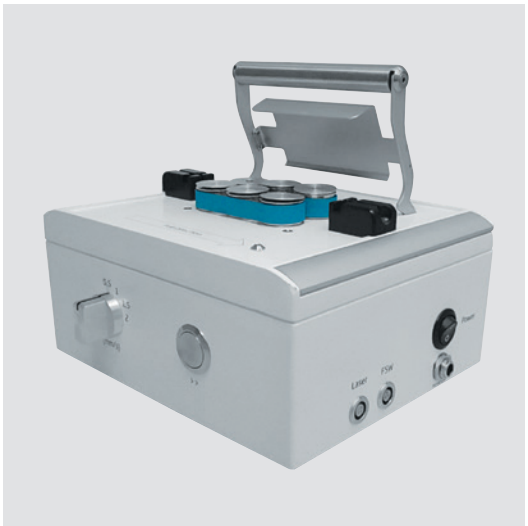
All fibers are free of latex and DEHP. Our fibers are single use products (unless otherwise indicated) delivered sterile for immediate use.

Imprint
biolitec Holding GmbH & Co KG
Untere Viaduktgasse 6/9
A-1030 Wien
Phone: +43 1 3619 909 50
www.biolitec.com

ELVeS® Accessories

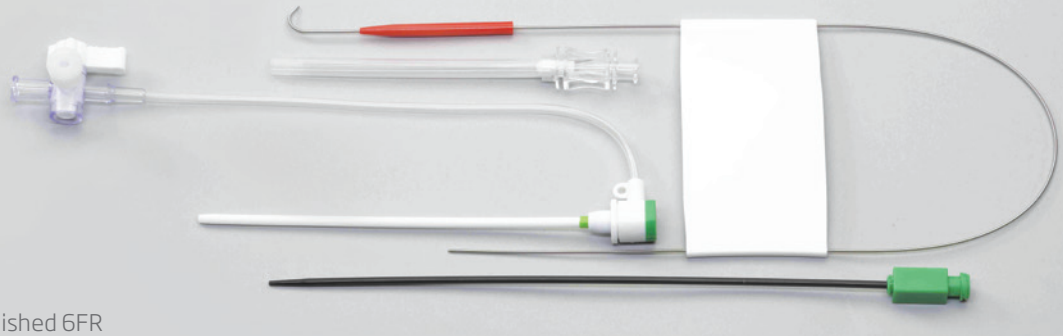
all from one source





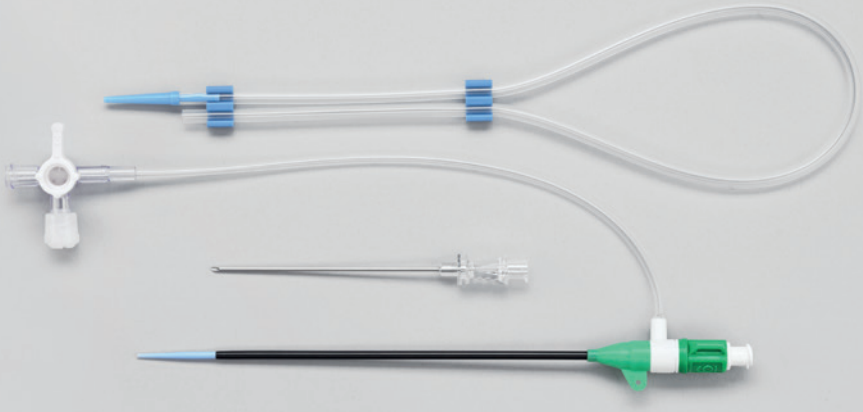
What else can we offer you?

Additional to the established ELVeS® Radial® fibers and kits biolitec® offers a large variety of further components which might make life easier for you.



Introducer Set, 6F
AB2522

Our worldwide established 6FR Introducer Set for the ELVeS® Radial® or ELVeS® 2ring fibers.



Introducer Set, 6F Bioteq
AB5317

Our alternative to the standard (AB2522) with slimmer guide wire and shorter dilator.

In case of a complex anatomical access or vein course the 4FR Introducer set (AB5331) helps you to enable the placement of the slim fiber family.

US Cover with sterile gel
AB2882

The safe and convenient ultrasound cover with 240 cm length and sterile gel.

Go2ring slim 16G
AB2805

Our 16GA catheter with extended length of 50 mm for the fast placement of slim fibres.

TLA Needle
AB2581

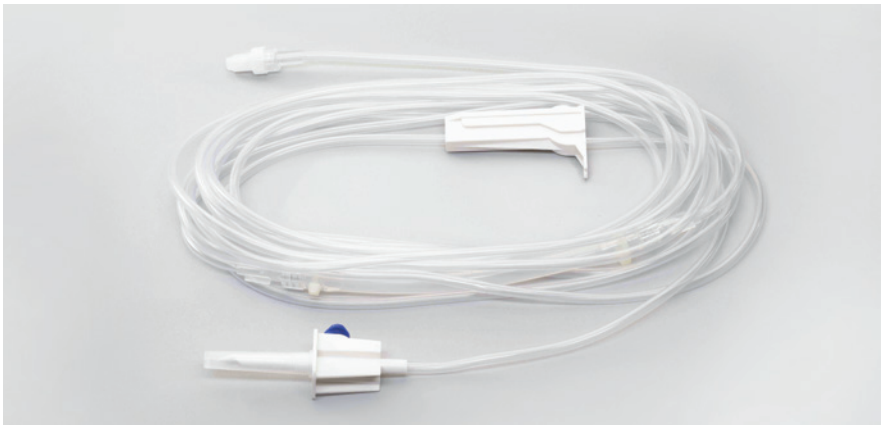
Tumescence needle extralong 120 mm in practicle pack of 100.

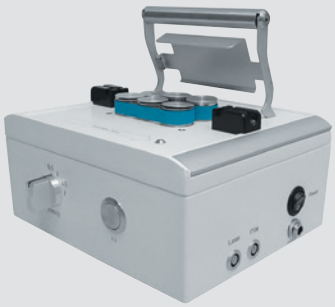
Nouvag pump
400100200

The efficient and low-noise-level pump from Nouvag for tumescence application.

Tubing set for infiltration
MP0009

Tube for infiltrationpump (Nouvag DP20 and DP30) to facilitate deposition of tumescence solution.





ELVeS® smart, Pullback device, Set
L-ELVesSmart-Set

The new fiber pullback device for continuous and homogenous withdrawal of all ELVeS® Radial® fibers during the endovenous laser ablation of varicose veins in conjunction with the ELVeS® Signal Software.

ELVeS Accessories

REF	Produktname	PU *
AB2522	Introducer Set 6F	5
AB5317	Sheath 6Fr x 11 cm with 18G needle & 0.035 "wire	10
AB5331	Sheath 4Fr x 11 cm with 20G x 38 mm needle & 0.025 "wire	10
AB2882	Ultrasound Cover 15 / 240 cm with sterile gel	20
AB2604	Ultrasound Gel, 20 ml, sterile	48
AB2805	Go2ring slim 16G IV catheter	50
AB2581	Needle OD 0.80 x 120 mm (green) 21G	100
400100200	Dispenser DP 30 incl. Footpedal Vario	1
MP0009	Tubing set disposable, Nouvag pump DP20 / DP30 compatible	10
L-ELVeS® Smart-Set	ELVeS® smart, Pullback device, Set	1
AB5244	Uprobe-L5C Linear Doppler probe	1

* Packaging unit

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

biolitec® worldwide

biolitec AG
Vienna, Austria
phone: +43 1 3619 909 50
info@biolitec.de
www.biolitec.com

biolitec biomedical technology GmbH
Jena, Germany
Phone: +49 3641 519 53 0

biolitec Schweiz GmbH
Wollerau, Switzerland
Phone: +41 55 555 30 20

biolitec España
Madrid, Spain
Phone: +34 91 9910857

biolitec Italia SRL
Milano, Italy
Phone: +39 02 8423 0633

biolitec Tıbbi Cihazları Ltd. Şti.
Istanbul, Turkey
Phone: +90 216 574 7456

OOO biolitec Spb
Saint-Petersburg, Russia
Phone: +7 812 4493752

biolitec FZ LLC
Dubai, UAE
Phone: +971 44 29 85 92

biolitec laser science and technology Shanghai Ltd.
Shanghai, China
Phone: +86 21 6308 8856

biolitec Sdn. Bhd.
Selangor, Malaysia
Phone: +60 3 5569 7158

biolitec India Private Ltd.
Bangalore, India
Phone: +91 265 3201106

PT. Biolitec
Tangerang, Indonesia
Phone: +62 21 537 2994

biolitec Korea Ltd.
Seoul, Republic of Korea
Phone: +82 2 701 4707

Equipos Laser de Uso Medico y Fibra Optica SA de CV
México City, Mexico
Phone: +52 155 55 731800

biolitec BCIE LTDA
São Paulo, Brazil
Phone: +55 11 2093 8602

CeramOptec GmbH
Bonn, Germany
Phone: +49 228 979670

Ceram Optec SIA
Riga, Latvia
Phone: +371 653 25 994

bioLITEC®

All fibers are free of latex and DEHP. Our fibers are single use products (unless otherwise indicated) delivered sterile for immediate use.

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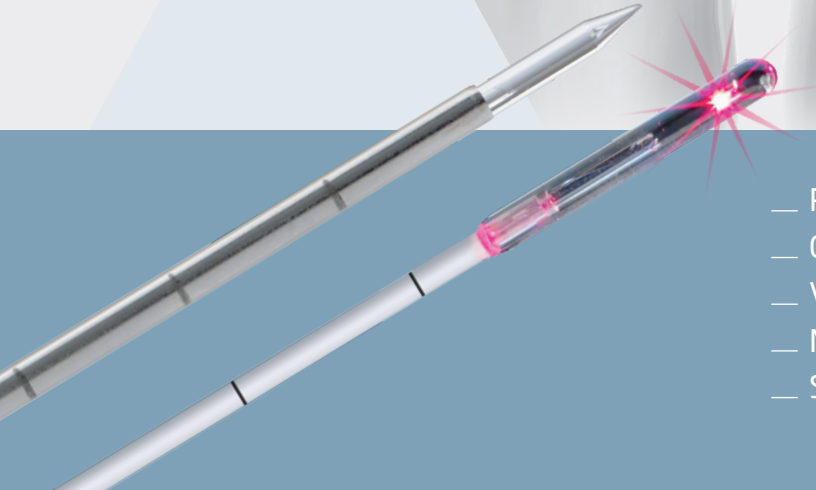
biolitec AG
Untere Viaduktgasse 6/9
A-1030 Wien
Phone: +43 1 3619 909 50
www.biolitec.com

LHP® FiLaC® SiLaC®

Minimally invasive laser therapies of hemorrhoids, fistulas and sinus pilonidalis



- Painless
- Controlled hemorrhoidal shrinkage
- Very good hemostasis
- Maximized preservation of continence
- Small wound sizes

Our laser solutions in coloproctology

LHP® for Hemorrhoids
(LaserHemorrhoidoPlasty)

This approach is used for the treatment of advanced hemorrhoids under appropriate anesthesia. The energy of the laser is inserted centrally into the hemorrhoidal node. By this technique the hemorrhoid can be treated according to its size without causing any damage to the anoderm or mucosa.

FiLaC® for Anal fistulas
(Fistula-tract Laser Closure)

The aim is to gently remove the fistula tract without damaging the sphincter. Thus, any parts of the muscle are preserved to a maximum and incontinence is avoided. Furthermore the FiLaC procedure offers a minimally invasive approach which can be performed in just a few minutes as the laser action replaces the excision.

SiLaC® for Sinus pilonidalis
(Sinus Laser ablation of the Cyst)

The ideal treatment to heal the sinus tract, preserve the overlying skin and prevent recurrence. Simple and minimally invasive in order to shorten hospital stay and the period off – work or school – to reduce pain and post-operative care with the best esthetic result.

To complete the broad range of application there are other possible proctological applications of the biolitec® laser and fibers

- Condylomata
- Fissures
- Stenosis (endoscopic)
- Removal of polyps
- Skin tags

Literatur LHP®

Comparative study in 121 patients LHP vs. excision vs. mucopexy*

Comparison of the outcomes of laser hemorrhoidoplasty (LHP®), hemorrhoidectomy (EH), and mucopexy (MP). **Methods:** A randomized, parallel, double-blind, prospective study of patients with symptomatic 2nd and 3rd degree hemorrhoids. Interventions according to computer randomization sequence, patient blinding, operator blinding, and reviewer blinding. Follow-up at 1 and 6 weeks and 1 year. **Outcome measures:** Recurrence of symptoms requiring treatment, intensity and duration of pain after surgery, quality of life, fecal incontinence, and patient assessment of treatment. **Results:** LHP® lasted 15 minutes, MP lasted 16 minutes, and EH lasted 29 minutes. The recurrence rate was 0 % after EH, 10 % after LHP®, and 22 % after MP. LHP® and MP were less painful than EH. **Mean postoperative pain intensity during defecation after LHP 3.8, after MP 4.0 and after EH 6.4.**

Patients after LHP® returned to regular activity significantly faster than after MP and after EH. Patients rated LHP® better than EH and MP. **Conclusions: Laser hemorrhoidoplasty is a safe, minimally invasive option for hemorrhoids,** more effective than MP and less effective than EH. **Patients rate this technique better than the other two.**

* Results of the double-blind randomized controlled trial comparing laser hemorrhoidoplasty with sutured mucopexy and excisional hemorrhoidectomy
International Journal of Colorectal Disease
https://doi.org/10.1007/s00384-019-03460-6

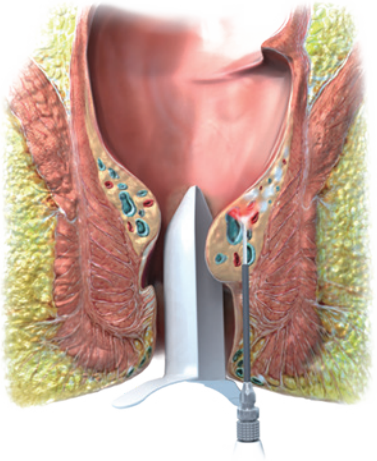
Postoperative results after treatment of hemorrhoidal disease: Laser hemorrhoidoplasty, a minimally invasive treatment for symptomatic hemorrhoids**

Results: Laser hemorrhoidoplasty (LHP) is a minimal invasive procedure for HD treatment determining the shrinkage of the hemorrhoidal piles by diode laser. 50 consecutive patients with hemorrhoids II - III grade were enrolled in the study and underwent LHP® treatment with a 1470 nm diode laser. Surgical time, postoperative pain and complications, resolution of symptoms, and duration of return to daily activity were prospectively evaluated. Recurrence of hemorrhoidal prolapse or symptoms at a follow-up of at least 6 months was evaluated. **No significant intraoperative complications occurred. Postoperative pain** (12, 18 and 24 hours postoperatively) evaluated by visual analog scale (VAS) **was extremely low (mean 2)**. All treated patients returned to daily activity two days after surgery. At a mean follow-up of 8.6 months, we reported a recurrence rate of 0 %. The LHP® showed great efficacy in selected patients.

The major advantages were low postoperative pain, the presence of mildly significant perianal wounds, no special anal hygiene measures, and **low operative time**. Thus, LHP® leading to negligible postoperative discomfort can be considered as a painless and minimally invasive technique in the treatment of HD.

** Postoperative discomfort and pain in the management of hemorrhoidal disease: laser hemorrhoidoplasty, a minimal invasive treatment of symptomatic hemorrhoids
Updates in Surgery
https://doi.org/10.1007/s13304-019-00694-5

Laser Hemorrhoido Plasty (LHP®)



If reduction of the hemorrhoidal cushion is indicated (no matter if it is segmental or circular), this therapy will provide you with an improved patient outcome especially regarding pain and recovery compared to conventional surgical proceeding for 2nd and 3rd degree hemorrhoids. Under proper local or general anesthesia, the controlled laser energy deposition obliterates the nodes from the inside and preserves the mucosa and sphincter structures to an extremely high degree.

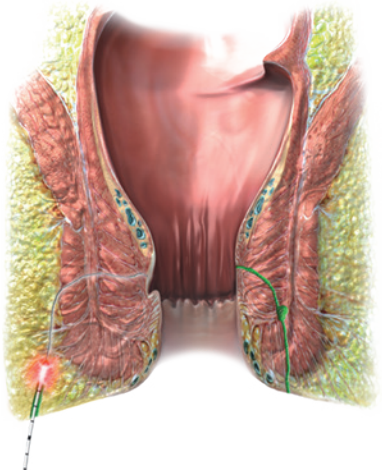
- Tissue reduction in the hemorrhoidal node
- Closure of the arteries entering the CCR feeding the hemorrhoidal cushion
- Maximum preservation of muscle, anal canal lining, and mucosa
- Restoration of the natural anatomical structure

The controlled emission of laser energy, which is applied submucosally, causes the hemorrhoidal mass to shrink. In addition, fibrotic reconstruction generates new connective tissue, which ensures that the mucosa adheres to the underlying tissue. This also prevents the occurrence or recurrence of a prolapse. LHP® is not associated with any risk of stenosis. Healing is excellent because, unlike conventional surgeries, there are no incisions or stitches. Access into the hemorrhoid is achieved by entering through a small perianal port. By this approach no wounds are generated in the area of the anoderm or mucosa. As a result, the patient experiences less post-operative pain and can return to normal activities within a shorter space of time.

In the anal canal

- No incisions
- No excisions
- No open wounds

Fistula-tract Laser Closure (FiLaC®)

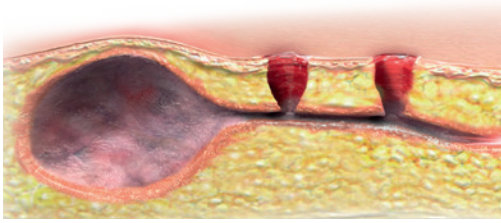


Anal fistula treatment: In order to eliminate the fistula tract as gently as possible, the flexible, radially emitting laser fiber is inserted from the outside and positioned exactly by using the pilot beam. Defined energy is being emitted into the fistula . The epithelialized tissue is being destroyed in a controlled way and the fistula tract collapses to a very high degree. This also supports and accelerates the healing process. The inner ostium can easily be closed by direct sutures to keep tensions low in the mucous membrane.

Features:

- Good control
- No excision or splitting
- Independent on the length of the fistula tract
- Flexible fiber also allows use in convoluted tract
- Can be executed in only a few minutes
- Can be combined with other forms of therapy for closing the ostium

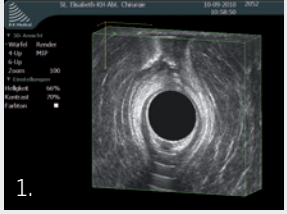
Sinus Pilonidalis treatment

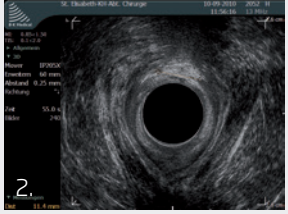


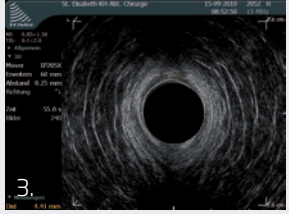
SiLaC® in the treatment of sinus pilonidalis enables you to destroy the pits and the communicating subcutaneous tract in a controlled manner. Using the laser fiber means preservation of the Rima Ani surface and avoidance of wound healing disturbancies to a very high extend known from open excision and at the same time offers a high rate of success.

FiLaC® fiber

Both procedures are realized by using the FiLaC® fiber. This applies energy to the pathway of the fistula extent. The 360° "ringlight" energy emission ensures homogenous photothermal destruction of the fistula tract, allowing safe closure. The efficient radiation concept of the FiLaC® fiber makes optimal use of the laser energy applied. Optimal monitoring of the fiber tip is possible thanks to its excellent ultrasound visibility (if applied). The rugged fiber design is superior to other light guides through its patented Fusion® technique.







1. 3-D ultrasound illustration of a trans-sphincteric anal fistula at 12 o'clock (contrast enhancement via H_2O_2)
2. Ultrasound image directly after advancement flap. In the area of the former inner opening in the musculus sphincter ani internus strong echo-reactions can be seen due to the applied laser energy. The protecting flap can be seen as isoechoic zone beneath.
3. Ultrasound image 5 days post-op. In the treated area the hyperechoic regions are vanished and form a hypoechoic district. The dimensions correlate to the original fistula tract and display the entrance depth of the laser. It also shows the safe application of the laser and short term wound healing by courtesy of Dr. med. A. Wilhelm.

Literature FiLaC® for Anal fistulas*

Meta-Analysis FiLaC®*

Background: Fistula laser closure (FiLaC®) is a novel sphincter-sparing technique for the treatment of anal fistulas. The aim of this study was to evaluate the safety and efficacy of the FiLaC® procedure. Methods Databases such as PubMed/ Medline, Scopus, Web of Science, and Embase were searched for FiLaC® articles. All studies, including case series and comparative studies, reporting the results of FiLaC® in the treatment of fistula were included. The endpoints were the cure rates of fistula closure with laser, postoperative complications including incontinence, technical aspects of the procedure, and failure to cure.
Results: Seven studies were included. There were a total of 454 patients, 69.1 % of whom had a transsphincteric anal fistula and 35 % of whom had previous surgery (multiple times). The median operation time was 18.3 minutes (range 6 – 32 minutes). With a median follow-up of 23.7 months, the average primary healing rate was 67.3 % and the overall success rate for FiLaC® reuse was 69.7 %. The average complication rate was 4 %. These were minor complications, and the weighted mean of the of the impact on continence was 1 % in the form of minor stool smearing.
Conclusions: FiLaC® can be considered an effective and safe sphincter-sparing technique for the treatment of anal fistulas with an acceptable low complication rate.

* A systematic review and meta-analysis of the safety and efficacy of fistula laser closure, Techniques in Coloproctology, https://doi.org/10.1007/s10151-020-02165-1

Literature SiLaC® for Sinus pilonidalis**

Background: Various surgical techniques are available for the management of pilonidal sinus, but there is still controversy concerning the optimal surgical approach. The aim of our study was to evaluate the safety, efficacy and clinical outcome of the laser procedure for the treatment of pilonidal sinus.

Patients and Methods: Patients suffering from pilonidal sinus were operated with the sinus laser method in our Institute. It was applied under local anaesthesia after a small skin incision of 0.5 – 1 cm and careful cleaning of the sinus tracts with a curette. A radial emitting fiber connected to a diode laser set at the wavelength of 1470 nm was then introduced into the tracts. The laser energy was delivered in continuous mode.

Results: Two-hundred and thirty-seven (237) patients suffering from pilonidal sinus were operated using the sinus laser procedure in our referral Institute and prospectively evaluated (183 males, median age 24 years, range 14 – 58). **A high healing rate was observed after the first session (90.3 %, 214 of 237) with a median healing time of 47 days (range 30 – 70 days).** A second treatment was offered for patients failing in the first session and was successful in 78.3 % (18/23). The procedure duration ranged between 20 and 30 minutes and had limited morbidity (wound infection in 7.2 %, 17 of 237).

Conclusion: The Sinus Laser Therapy (SiLaC) proved to be a safe and effective procedure to treat patients suffering from pilonidal sinuses. Clinical results showed low morbidity and recurrence rates comparable to the published literature for other modern techniques.

** A new minimally invasive treatment of pilonidal sinus disease with the use of diode laser – A prospective large series of patients; Colorectal Disease©
Alkiviades F. Pappas, Dimitrios K. Christodoulou;
https://doi.org/10.1111/codi.14285

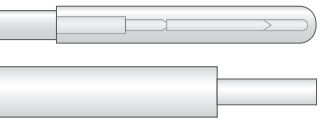
Our products

LEONARDO®

Model	**LEONARDO® Mini 1470 nm**	**LEONARDO® Mini Dual**	**LEONARDO® DUAL 45**
REF	SL1470nm12W	SL980 + 1470nm14W	SL980 + 1470nm45W
Wavelength	1470 nm	980 nm and 1470 nm	980 nm and 1470 nm
Power	12 W (1470 nm)	10 W (980 nm) / 4 W (1470 nm)	max. 45 Watt (1470 nm / 15 Watt + 980 nm / 30 Watt) separately adjustable
Fiber diameter	≥ 360 µm	≥ 360 µm	≥ 360 µm
Aiming beam	635 nm, max. 4 mW	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 (optional)	CW, Pulse Mode, ELVeS® Signal, ELVeS® Segment, Derma Mode
Pulse duration / -break	0.01 – 180 sec. / 0.01 – 180 sec.	0.01 – 180 sec. / 0.01 – 180 sec.	0.01 – 60 sec / 0.01 – 60 sec
Power supply	110 – 240 VAC, 50 - 60 Hz (12 VDC @ 100 W)	110 – 240 VAC, 50 – 60 Hz (12 VDC @ 65 W)	110 – 240 VAC, 50 / 60 Hz, 450 VA
Batteries	Li-ion batteries	Li-ion batteries	–
Dimensions (H × W × D)	6.0 cm × 9.0 cm × 21.5 cm	6.0 cm × 9.0 cm × 21.5 cm	approx. 28 cm × 37 cm × 9 cm
Weight	900 g	900 g	approx. 8.5 kg

All laser sets incl. 3 safety goggles, foot switch, interlock connector, power cord and manual in a carrying case.

Fibers



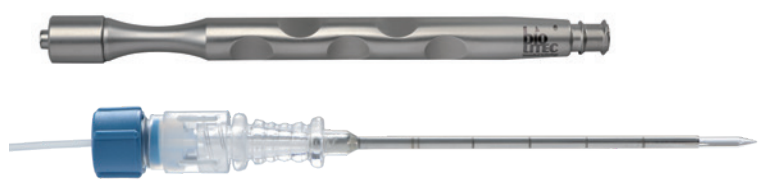
REF	Product	PU [Packaging unit]	length [m]	ø fiber [mm]
503100250	FiLaC® Fistula Probe, IC	10	2.6	1.85
503200740	Bare Fiber 600 µm, Flat Tip, IC	10	2.6	0.96

Kits

503100220	LHP® Procedure Kit, IC	5	2.6	1.85
503100255	FiLaC® Fistula Kit, IC	5	2.6	1.85

Accessories

REF	Product	PU [Packaging unit]
400100100	Universal Dual Luer Handpiece	1
LA1371	Laser Safety goggles 950 – 1010 L4 + 1470 L2 (FULL), transparent	1



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biolitec Holding GmbH & Co KG
Vienna, Austria
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www.biolitec.com

biolitec biomedical technology GmbH
Jena, Germany
Phone: +49 3641 519 53 0

biolitec Schweiz GmbH
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biolitec España
Madrid, Spain
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biolitec Italia SRL
Milano, Italy
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biolitec Tıbbi Cihazları Ltd. Şti.
Istanbul, Turkey
Phone: +90 216 574 7456

OOO biolitec Spb
Saint-Petersburg, Russia
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biolitec FZ LLC
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biolitec laser science and technology Shanghai Ltd.
Shanghai, China
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biolitec Sdn. Bhd.
Selangor, Malaysia
Phone: +60 3 5569 7158

biolitec India Private Ltd.
Bangalore, India
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Equipos Laser de Uso Médico y Fibra Óptica SA de CV
(Biolitec Mexico & Latín América)
Phone: +52 (55) 5573 1800

Biolitec Biotecnologia Comércio, Importação, Exportação LTDA
São Paulo, Brazil
Phone: +55 11 2093 8602

CeramOptec GmbH
Bonn, Germany
Phone: +49 228 979670

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Treatment mode	CW, Pulse Mode (optional), ELVeS® Signal	CW, Pulse Mode (optional)	CW, Pulse Mode, ELVeS® Signal, ELVeS® Segment, Derma Mode
Pulse duration / -break	0.01 – 180 sec. / 0.01 – 180 sec.	0.01 – 180 sec. / 0.01 – 180 sec.	0.01 – 60 sec / 0.01 – 60 sec
Power supply	110 – 240 VAC, 50 - 60 Hz (12 VDC @ 100 W)	110 – 240 VAC, 50 – 60 Hz (12 VDC @ 65 W)	110 – 240 VAC, 50 / 60 Hz, 450 VA
Batteries	Li-ion batteries	Li-ion batteries	–
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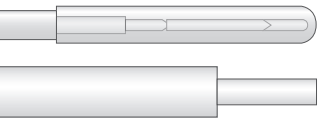
Fibers



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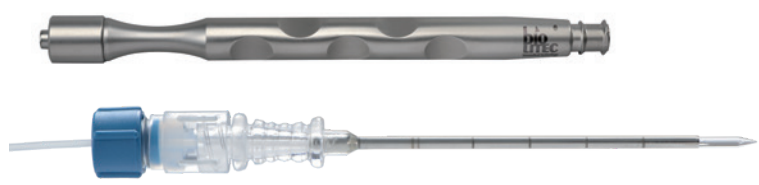
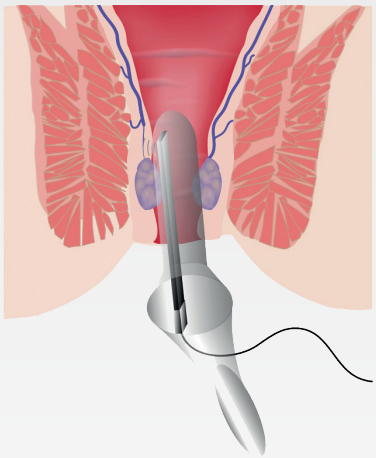




HeLP®

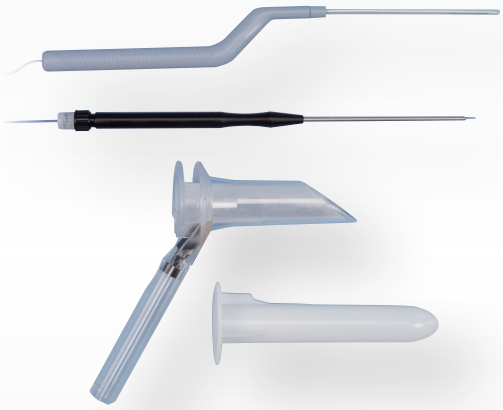
(Hemorrhoid Laser Procedure) – ambulatory for hemorrhoids

The perfect solution for patients fearing invasive painful surgical or semisurgical techniques in this delicate matter. This Hemorrhoid Laser Procedure, called HeLP®, is biolitec's innovation for painless treatment of hemorrhoids. The HeLP® Doppler probe identifies the branches of the superior hemorrhoidal arteries above the dentate line whereas the special HeLP® handpiece photocoagulates and closes the superior hemorrhoidal arteries. It is an ambulatory approach and serves you with a fast outpatient procedure.

It is surely the simplest among other techniques and does not comprise tissue removal, but only the closing of the artery, with no internal sture or stitches. Using the HeLP® Kit with disposable guidance Doppler probes and selective laser energy delivered by fiber optic handpiece, the hemorrhoidal arteries above the hemorrhoidal cushions are identified and treated accordingly.

The Benefits of HeLP®:

- Specially developed for simple and safe out-patient treatment of hemorrhoids
- Enables the use of a minimally invasive surgical procedure that is effective and precise
- Minimal side-effects and discomfort post treatment
- Faster post-operative recovery than surgical methods
- Anaesthesia or analgesia generally not required
- Excellent short- and long-term results
- Clinically proven, with high levels of patient acceptance and satisfaction



LITERATURE

Patients and methods: Terminal branches of the superior hemorrhoidal artery in the anal canal, if precisely identified through a Doppler signal, can be closed with the use of this laser. A specially designed proctoscope allows introducing a Doppler probe whose function is to identify hemorrhoidal arteries. Above the dentate line, the terminal branches of the superior hemorrhoidal artery are recognized through a clockwise rotation of the proctoscope and progressively photocoagulated through a laser optic fiber. The procedure does not require anesthesia and can be performed as an ambulatory treatment.

Results: Thirty patients (16 men) with second to third grade symptomatic hemorrhoids have been treated with the described technique. The procedure proved to be successful at 3 months' follow-up in 92% of cases. No major adverse effects or complications were reported. In two cases surgical hemostasis was necessary. Minor pain that required medication was reported in three cases.

Conclusions: The hemorrhoidal laser procedure (HeLP®) represents a new nonexcisional, mini-invasive treatment for patients suffering from second and third degree hemorrhoids without severe mucosal prolapse. Thermal occlusion of the hemorrhoidal arteries causes a progressive shrinkage of hemorrhoidal cushions. The procedure does not require anesthesia.

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