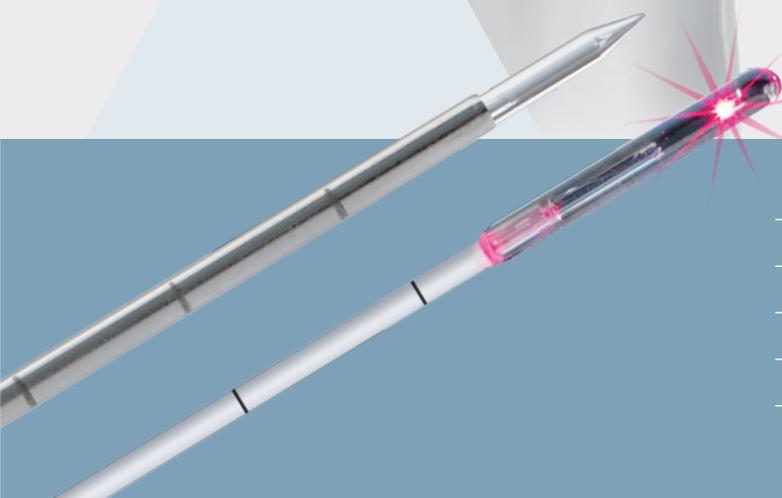


# LHP® FiLaC® SiLaC®

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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> 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<sup>®</sup> laser and fibers**

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

# Literature LHP®

## Kohort Study on 497 patients 2010 - 2016\*

**Patients and methods:** Between November 2010 and November 2016, 497 patients (age  $55 \pm 14$  years) were submitted to laser hemorrhoidoplasty with a 1470 nm diode laser in the centre for minimally invasive proctology in Siegen District Hospital. All operated patients were included in the study. Perioperative clinical and technical data up to 6 weeks and follow-up data up to 6 months were analysed prospectively [...]

**Results:** The mean duration of operation was 14 min ( $\pm 5.2$ ). A mean of 2.7 knots of 2.7 size were treated per patient. **The mean postoperative pain was 2.5/10 (VAS). Long-term symptom relevance was 86%, and patient satisfaction 91%.** There were significant differences in pain on the day of the operation, and the parameters mucopexia, 3 treated segments and energy level  $> 500$  J ( $p < 0.05$ ). Complications were more common when mucopexia was performed, with 3 treated knots and energy consumed per patient  $> 500$  J. The only significant difference was for energy level  $> 500$  J ( $p < 0.05$ ).

**Conclusion:** LHP is a safe, low pain and minimally invasive surgical procedure with long-term good patient acceptance and satisfaction and is suited for routine work. The energy applied should be reduced to a minimum. Complication rates are largely comparable with those of other minimally invasive conventional methods. Additional prospective studies must be performed, particularly in comparison to the Parks method, which gives similar functional results. [...]

**LHP can be performed without any accompanying measures or interventions even if anticoagulation continues with Marcumar or Factor Xa inhibitors.**

\* Laserhemorrhoidoplasty with 1470 nm Diode Laser in the Treatment of Second to Fourth Degree Hemorrhoidal Disease - a Cohort study with 497 Patients  
DDI <https://doi.org/10.1055/s-0043-120449> 2017

## Comparison for LHP vs. Milligan Morgan proved to be superior in terms of pain and speed\*\*

**Results:** Postoperative pain scores (at 12, 18, and 24 hr after surgery) were significantly lower in the laser group compared with the MM group ( $p < .01$ ).

The operative time was also significantly shorter in the laser group than in the MM group ( $33.1 \pm 7.3$  min vs.  $52.6 \pm 15.6$  min,  $p < .001$ ) and intra-operative blood loss were more in the MM group ( $p < .001$ ). One-year follow-up showed comparable results in terms of the resolution of symptoms and sustainable cure.

**Fast learning curve: "Furthermore, laser technique is easy to use and instruct, with a learning curve of three to five proctored cases for surgeons and surgical assistants."**

\*\* A Randomized Controlled Trial Comparing Laser Intra-Hemorrhoidal Coagulation and Milligan-Morgan Hemorrhoidectomy Mohammad Naderan, MD et al Journal of Investigative Surgery 2016

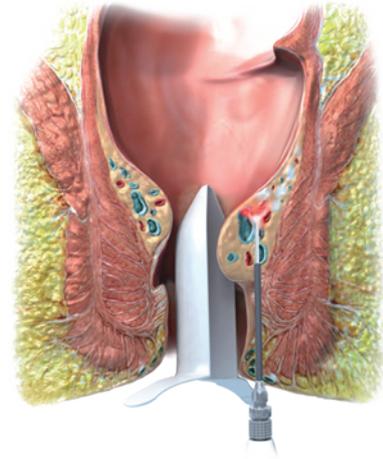
## Comparison for LHP vs. open surgical hemorrhoidectomy proved to be superior in terms of pain and speed\*\*\*

**Significant differences between laser hemorrhoidoplasty and open surgical procedure were observed in operative time and early postoperative pain.** There was a statistically significant difference between the two groups regarding the early postoperative period: 1 week, 2 weeks, 3 weeks and 1 month after respective procedure ( $p < 0.01$ ). The procedure time for LHP was 15.94 min vs. 26.76 min for open surgery

( $p < 0.01$ ). Laser hemorrhoidoplasty is satisfactory for symptomatic hemorrhoidal patients with III or IV stage.

\*\*\* Laser Hemorrhoidoplasty Procedure vs Open Surgical Hemorrhoidectomy: a Trial Comparing 2 Treatments for Hemorrhoids of Third and Fourth Degree  
Halit Maloku et al; ACTA INFORM MED. 2014 DEC 22(6): 365-367

# Laser Hemorrhoido Plasty (LHP<sup>®</sup>)



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 2<sup>nd</sup> and 3<sup>rd</sup> 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.

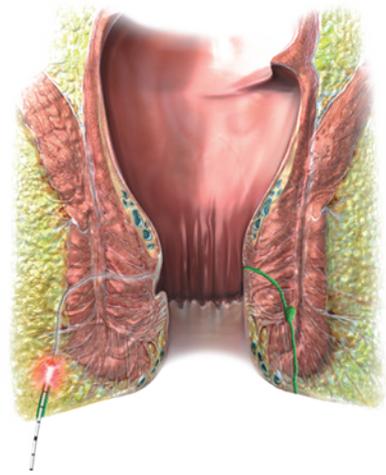
- Tissue reduction in the hemorrhoidal node
- Closure of the arteries entering the CCR feeding the hemorrhoidal cushion
- Maximum preservation of muscle, anal canal lining, and mucosa
- Restoration of the natural anatomical structure

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<sup>®</sup> 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.

- No incisions
- No excisions
- No open wounds



# Fistula-tract Laser Closure (FiLaC®)

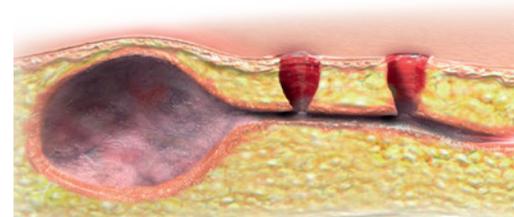


Anal fistula treatment: In order to eliminate the fistula tract as gently as possible, the flexible, radially emitting laser fiber is inserted from the outside and positioned exactly by using the pilot beam. Defined energy is being emitted into the fistula. The epithelialized tissue is being destroyed 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 disturbances 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<sub>2</sub>O<sub>2</sub>)
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\*

**Background:** There are limited data available concerning endofistular therapies for fistula-in-ano, with our group reporting the first preliminary outcomes of the use of the radial fibre Fistula laser Closing (FiLaC®) device.

**Methods:** The aim of this study was to assess a cohort of anal fistulae managed with laser ablation plus definitive flap closure of the internal fistula opening over a long-term follow-up. Factors governing primary healing success and secondary healing success (i.e. success after one or two operations) were determined.

**Results:** The study analysed 117 patients over a median follow-up period of 25.4 months (range 6–60 months) with 13 patients (11.1%) having Crohn's-related fistulae.

**No incontinence to solid and liquid stool was reported. [...]**

The primary healing rate was 75/117 (64.1%) overall, and 63.5% for cryptoglandular fistulae versus 69.2% for Crohn's fistulae respectively. Of the 42 patients who failed FiLaC® 31 underwent a second operation ("Re-FiLaC®", fistulectomy

with sphincter reconstruction or fistulotomy). The secondary healing rate, defined as healing of the fistula at the end of the study period, was 103/117 (88.0%) overall and 85.5% for cryptoglandular fistulae versus 92.3% for Crohn's fistulae. A significantly higher primary success rate was observed for intersphincteric-type fistulae with primary and secondary outcome unaffected by age, gender, presence of Crohn's disease, number of prior surgeries and the type of flap designed to close the internal fistula opening.

**Conclusions:** There is a moderate primary success rate using first-up FiLaC® treatment. If FiLaC® fails, secondary success with repeat FiLaC® or other approaches was high.

**The minimally invasive FiLaC® approach may therefore represent a sensible first-line treatment option for anal fistula repair.**

\* Five years of experience with the FiLaC® laser for fistula-in-ano management: long-term follow-up from a single institution. A. Wilhelm, A. Fiebig, M. Krawczak; Tech Coloproctol 2017

## 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).

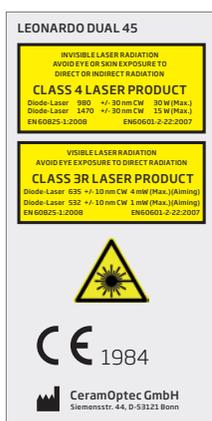
**Conclusion:** The Sinus Laser Therapy (SiLaC) proved to be a safe and effective procedure to treat patients suffering from pilonidal sinuses. Clinical results showed low morbidity and recurrence rates comparable to the published literature for other modern techniques.

\*\* 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	SL1470nm8W	SL980 + 1470nm14W	SL980 + 1470nm45W
Wavelength	1470 nm	980 nm and 1470 nm	980 nm and 1470 nm
Power	8 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 – 60 sec. / 0.01 – 60 sec.	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 (7.2 VDC @ 36 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

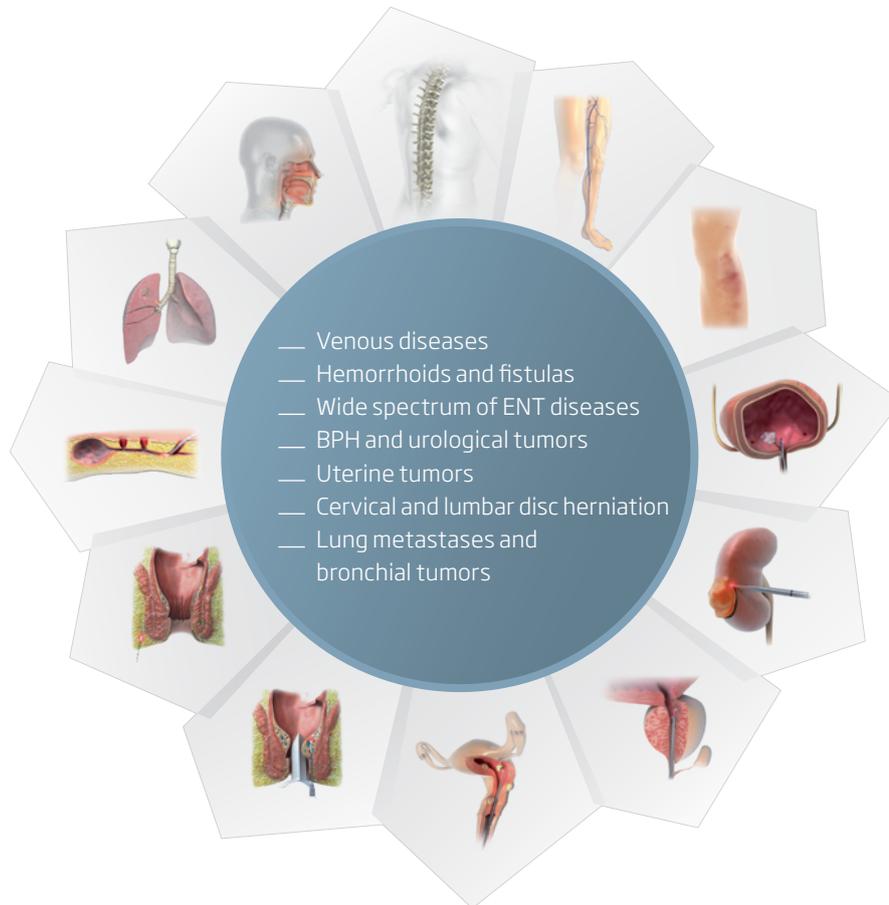
## Accessories

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



# Contact us

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



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

### **Imprint**

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