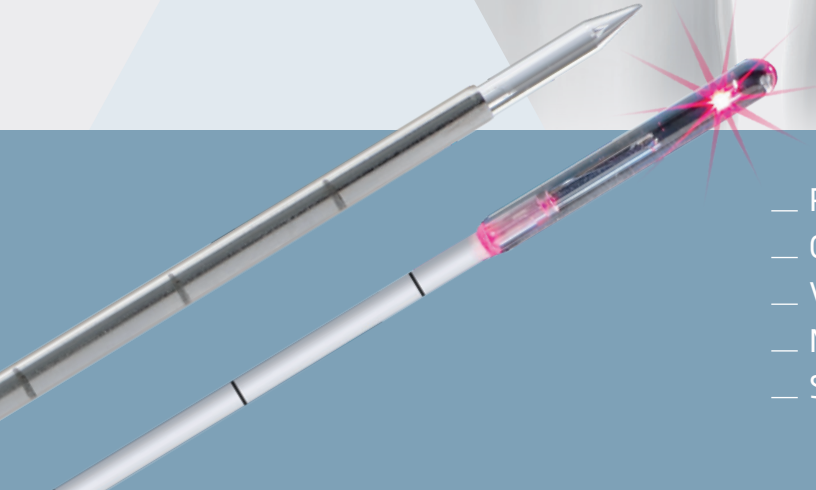
# LHP® FiLaC® SiLaC®

## 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

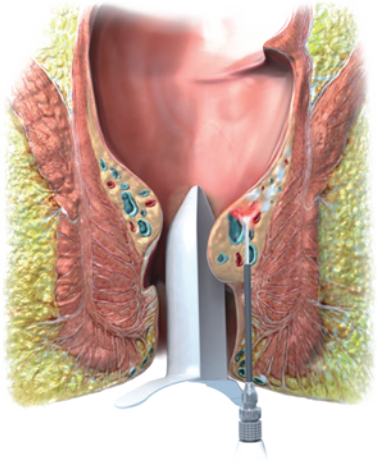
**Postoperative results after treatment of hemorrhoidal disease: Laser hemorrhoidoplasty, a minimally invasive treatment for symptomatic hemorrhoids****

**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.

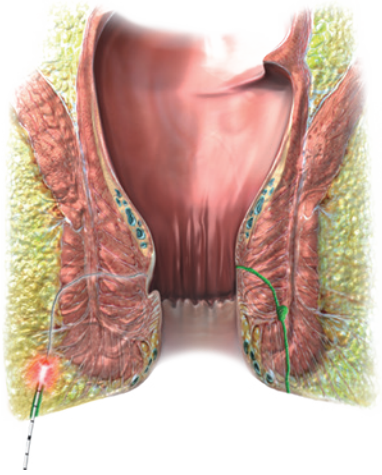
- Tissue reduction in the hemorrhoidal node
- Closure of the arteries entering the CCR feeding the hemorrhoidal cushion
- Maximum preservation of muscle, anal canal lining, and mucosa
- Restoration of the natural anatomical structure

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®)

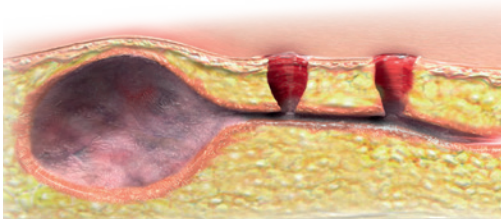


Anal fistula treatment: In order to eliminate the fistula tract as gently as possible, the flexible, radially emitting laser fiber is inserted from the outside and positioned exactly by using the pilot beam. Defined energy is being emitted into the fistula . The epithelialized tissue is being destroyed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

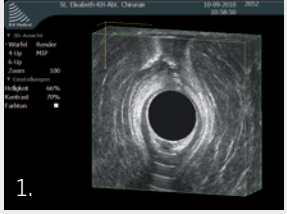
# Sinus Pilonidalis treatment

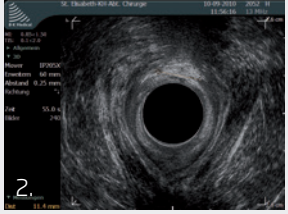


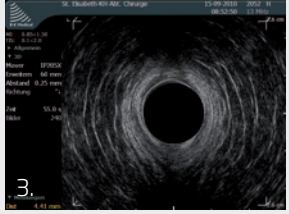
SiLaC® in the treatment of sinus pilonidalis enables you to destroy the pits and the communicating subcutaneous tract in a controlled manner. Using the laser fiber means preservation of the Rima Ani surface and avoidance of wound healing disturbancies to a very high extend known from open excision and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

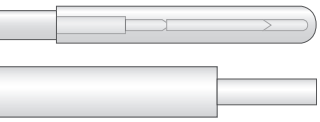
# Our products

## 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



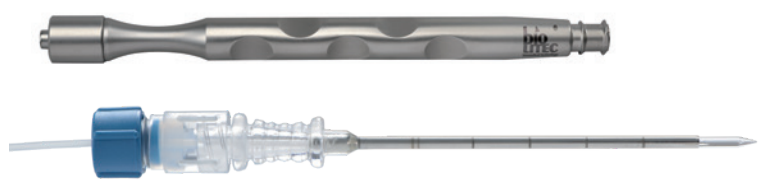
| REF | Product | PU [Packaging unit] | length [m] | ø fiber [mm] |
|---|---|---|---|---|
| 503100250 | FiLaC® Fistula Probe, IC | 10 | 2.6 | 1.85 |
| 503200740 | Bare Fiber 600 µm, Flat Tip, IC | 10 | 2.6 | 0.96 |

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


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bio LITEC®

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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