Ceramoptec

a company of biolitec® AG

Instructions for use

LHP® Procedure Kit

Varianten

REF 501100220	LHP® Procedure Kit
REF 503100220	LHP® Procedure Kit, IC

Manufacturer
CeramOptec GmbH
A company of biolitec® AG
Siemensstr. 44 – 53121 Bonn – Germany
Phone +49 228 97967 0

Components

1	HeLP® LHP®-Fiber, Conical glass Tip, Adj. Luer, ID or HeLP® LHP®-Fiber, Conical glass Tip, Adj. Luer, IC	REF 501100200 or REF 503100200
2	LHP® cannula	REF AB2594
3	LHP®proctoscope	REF AB2536

Indication

1) The HeLP® LHP®-Fiber (LHP=LaserHaemorrhoidoPlasty) has been designed for the coagulation and vaporisation of tissue in the haemorrhoidal cushion, for 2-3 degree haemorrhoids which are pathological and therefore require treatment. It can be operated with the following laser systems:

   980 nm laser systems with connector (numerical aperture of between 0.22 and 0.37)
   1470 nm laser systems with connector (numerical aperture of between 0.22 and0.37)

   The HeLP® LHP®-Fiber (501100200) is a part of the ID concept of the biolitec® group companies. The HeLP® LHP®-Fiber (503100200) with IC connector could be used due to its patent connector design only with the laser model Leonardo of the company CeramOptec. This concept ensures the compatibility of the probe and the used laser device by means of automatic fiber recognition.

2) The LHP® cannula serves the guiding and fixation of the fiber tip. This necessitates you screwing the blue Luer lock adapter of the fiber with the Luer lock connection of the cannula before operating. Verify the silica/glass tip sticking out of the cannula for approximately 8-10 mm by pushing or pulling the fibre backwards of the Luer lock adapter. Afterwards tighten the Luer lock adapter to fix the fiber in position.

3) The enclosed LHP® proctoscope can be used for both inspection and treatment purposes as it enables an access to be made to the anal canal and thereby treat the sphincter with care, this therefore being an alternative to conventional spreaders.
   The fenstered so called gull flap was designed and manufactured with "seagull wings", which enable a rotation to be carried out inside the anal canal as easily as possible. It is a diversified medical product which enables the anal channel to be progressively dilated to a far-reaching extent due to its diameter and size: length 93 mm, diameter 31 mm. Ideal for haemorrhoid excision by Milligan Morgan and by Ferguson, laser-haemorrhoid excision, sphincterotomie, anastomosis, classical and laser fistula excision.

User profile

In order to ensure a correct and safe use, the Bare Fiber single-use is only to be used by medically trained specialists who are familiar with the handling of medical laser devices.

Accessory available as an option

Dual Luer lock hand piece REF 400100100

This hand piece can be used between the LHP® cannula and the HeLP® LHP®-Fiber as an option. This is carried out by the LHP® cannula being placed on the front of the hand piece by the Luer lock adapter before the HeLP® LHP®-Fiber is fed through the hand piece in reverse and than being locked in position at the Luer lock connection on the back of the hand piece, using the blue Luer lock adapter. Verify the silica/glass tip sticking out of the cannula for approximately 8-10 mm by pushing or pulling the fibre backwards of the Luer lock adapter. Afterwards tighten the Luer lock adapter to fix the fibre in position

Handling

Preparation

- Check the packaging and the sterile packaging for signs of damage
- Remove the products from the packaging
- Inspect the products for signs of damage before commencing with the treatment

Application instructions

- The HeLP® LHP®-Fiber has an outer diameter of 1.80 mm and a distal length of 18 mm and a rigid silica glass cap; the end is in the form of a tip.
- Approx. 8-10 mm of this tip has to be visible distal outside the cannula. If this should not be the case, loosen the fixation adapter and push the fiber tip out of the cannula respectively. Now lock the fixation adapter back in place.
- This tip is used to feed the fiber up to the base of the pathologically enlarged haemorrhoidal node, so that the shrinking/radiation respectively can be commenced from here.
- Now use the pilot beam and digital controls to position the tip in order to ensure that it is in the centre of the node and parallel to the anal canal, so as to avoid a radiation of the Musculus sphincter ani internus or the mucosa.
- Always pull the fiber back so that it is straight. It is imperative to avoid lateral pressure to the fiber tip as there is a risk of the fiber breaking.
- A sclerosing and haemostasis of the perforation point can be achieved by positioning the laser fiber and then activating the laser for 1-2 seconds in order to perforate the mucosa.
- Each time you have treated a node, inspect the tip for soiling.
- The use of a higher laser performance can result in tissue being burnt into the silica cap in addition to the fiber tip being irreversibly destroyed. The cap is to be carefully observed during treatment. Should there be signs of damage, the laser is to be deactivated in addition to the HeLP® LHP®-Fiber being removed and subjected to a visual inspection.
- In the improbable event of a part or the entire distal silica glass cap being lost, this can be removed using suitable surgical forceps.

CAUTION: The use of irrigation gas, with endoscopic or interstitial procedures in particular, may cause gas embolisms.
CAUTION: Laser pyrolysis products (gases, vapors, particles, and infectious aerosols) resulting from the treatment are to be extracted using suction systems above the laser zone.
CAUTION: Recommended power levels can be found in the user manual of the laser device.
When using the bare fiber with a hand piece, the catch on the hand piece must be released first, then the distal end of the bare fiber must be inserted and re-engaged after adjusting the length. The hand pieces are delivered in an un-sterile condition and must be sterilized before each use as per description in their user manual.

Possible laser treatment risks

Possible laser treatment risks are swelling, haemorrhaging, infections and possible nerve damage. It is also possible that an incorrect or excessive setting of the laser power can cause damage to the targeted tissue. Complete information on possible adverse reactions is included in the instructions for use for the laser device in question and the corresponding medical literature.

Recommended maximum power parameters

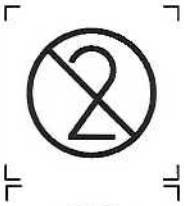
980 nm:	Do not operate the HeLP® LHP®-Fiber with more than 20W cw
1470 nm:	Do not operate the HeLP® LHP®-Fiber with more than 10W cw

Preparation and sterilization

All components of the Kit (pos. 1-3) are sterilised with EtO and are sterile in unpacked and undamaged condition of the package.

In order to avoid the risk of infection and injury, these fibers are only to be used once and if the sterile packaging is undamaged.

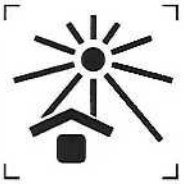
Safety instructions



Do not reuse: The medical device is intended for the utilization with a single patient during a single treatment.

Do not use if the packaging is damaged: The medical device is not to be used in case of a damaged or open packaging.

Sterilized with ethylene oxide: The medical device was sterilized with ethylene oxide.



Keep away from sunlight: The medical device needs protection from light sources.

Store in a dry place: The medical device must be protected from moisture.

Mind the instructions: It is necessary for the user to consult the instructions for use.

Manufacturer: Indicates the manufacturer of the medical device according to the guidelines 90/385/EWG, 93/42/EWG and 98/79/EG.

Expiration date: Indicates the date after which the medical device must no longer be used.

Batch code: Indicates the batch number of the manufacturer so that the batch can be identified.

1. In order to ensure a correct and safe handling of surgical laser systems, the LHP® kit is only to be used by physicians who are familiar with the handling of medical laser devices.
2. The general rules and instructions concerning the handling of laser beams have validity. Safety measures are to be found on the labels and in the instructions for use.
3. **CAUTION**: the probes are only to be used under surgery conditions. Inspect the sterile packaging in order to ensure that it is not damaged. Probes from packaging which is already open or is damaged, are not sterile and are therefore not to be used. Check the use-by date.
4. Remove the probe from the packaging and carry out a visual inspection. You should especially ensure that the distal end is undamaged and that the laser-connector is clean.
5. Insert the connector into the laser optics input and turn the cap nut clockwise (SMA905) or push it (IC) as far as it will go. The fiber is correctly connected if there is no longer any axial play and the fiber cannot be rotated.
6. **CAUTION**: do not use a laser probe if it has a damaged distal end or a damaged connector.
7. **CAUTION**: this is a fiber which can only be used once. It is not to be reused as it cannot be cleaned or disinfected for a second use.
8. Special care is to be taken when handling medical laser probes. Impacts or strong bending can cause damage to these and impair there function.
9. It is imperative that laser protection goggles (wavelength-related) are worn within the NOHD safety distance (Nominal Ocular Hazard Distance). The parameters are included in the manual for the laser concerned.
   Before using the laser probe for the first time, the treating physician is to familiarise himself with the resulting tissue effects and start with a low power rating (1-5 W). When doing so, it is to be ensured that the red pilot laser beam exits at the distal point of the fibre. Do not use the fiber if there is no light leaving the distal end although pilot beam is active.
   Do not use the fiber if a significant part of the pilot beam exits the fiber on the way between the laser optics and the distal end. Danger of broken fiber!
10. Before inserting the fiber into the tissue, rotate the fixation adapter on the back of the cannula clockwise again so that it is absolutely tight, thus preventing the fiber from slipping when making the incision. You can check that this has been correctly carried out by holding the LHP® cannula (or the optional hand piece should one exist) in one hand and carefully pulling the fiber back with the other hand. This should be rather difficult. Do not use the HeLP® LHP®-Fiber if it should be possible to move it slightly!
    CAUTION: heavily scarred tissue can result in the HeLP® LHP®-Fiber being pushed into the cannula when penetrating the tissue. This is to be corrected by the fiber being pushed forward out of the cannula and the Luer lock adapter being locked in place again (also see "Handling").
11. Only trigger the laser if the fiber tip is localized and you have exactly targeted and examined the tissue which is to be treated.
12. Check the distal end for residues and damage. Blood and tissue residues or damage could result in overheating and the fiber tip being subjected to changes. This has a direct effect on the power intensity of the laser beam, as well as on the achieved therapeutic tissue effect in addition to it being a risk for the patient which cannot be disregarded.
13. Tissue adhesions are to be removed. In order for this to be carried out, the laser MUST be in standby mode. During a treatment of haemorrhoids, the cleaning is to be carried out by means of a swab which has been moistened with sterile water being applied in a distal wiping motion.
    CAUTION: do not activate the laser during cleaning and allow the distal end of the fiber to cool down before.
14. **CAUTION**: perforations can occur when carrying out laser treatment close to sensitive areas (arteries, the bowels). The laser treatment is only to be carried out for a duration which is required in order to achieve a coagulation or vaporisation effect.
15. **CAUTION**: do not hold any flammable materials in the laser beam.
16. Contaminated disposable materials are to be disposed of in accordance with the valid regulations.
17. Defective contaminated merchandise is only to be returned after it has been disinfected.

Disposal

The fibers must be disposed of in observance of the contamination of the product and in accordance with the local legal provisions.

Complaints

CeramOptec GmbH only supplies defect-free products that have been appropriately tested. In the event of a product complaint, contaminated goods may only be returned in a cleaned, disinfected state.

Liability and warranty

CeramOptec GmbH assumes no liability for damages to persons or equipment resulting from the improper handling or storage of the product.
CeramOptec GmbH cannot be held liable for incidental damages, subsequent damages, losses and costs directly or indirectly connected with the use this product.

CeramOptec GmbH assumes no liability whatsoever for indirect damages or subsequent damages resulting from:

- Usage of the product not compliant with its intended use
- Improper usage, application or handling
- Improper preparation and sterilization
- Improper maintenance and repairs

Non-compliance with the product's Instructions for Use

Manufacturer

CeramOptec GmbH
a company of biolitec® AG

Siemensstrasse 44 - 53121 Bonn – Germany
Fon: +49 (228) 97 967 – 0 - Fax: +49 (228) 97 967 99
info@ceramoptec.de - www.ceramoptec.com - www.biolitec.de

Document: CO_IFU_LHP-Kit-E_F
Date of release: 09.10.2013