Ceramoptec®

Instructions For Use

Gas-, Liquid Cooled Fiber

Variants

**REF 500200525, REF 500201903, REF 500201938,
REF 501200520, REF 501200525, REF 501200550,
REF 503200520, REF 503200525, REF 503200550,
REF 500201903-1, REF 501200525-1 REF FV 600,
REF FV 600L,**

Content

1. INTENDED PURPOSE

The intended purpose of this medical device is to treat patients with light (monochromatic light) of high intensity and a very narrow frequency range.

The used wavelengths can be between 400 nm and 2100 nm. Tissue is irradiated in continuous or pulsed mode using power levels up to 400 W.

2. INTENDED USE

Gas-, Liquid Cooled (GLC) laser fiber was developed to treat healthy or diseased tissue with laser light in contact and non-contact during surgical procedures, including endoscopic procedures.
The light is transmitted from the laser to the patient through a probe with a distal end shaped according to the special treatment requirements.
The distal end can radiate in the following variations: straight, radial, lateral, sectoral, diffuse and asymmetric.
The interaction of laser light with biological matter is determined by its irradiation parameters such as wavelength, power / energy and pulse length.
The exposure time of the laser radiation and the duration of the treatment also determine the laser-tissue reactions.
Laser radiation will be effective in contact and non-contact in hollow spaces, organs, in soft as well as hard tissues.
The laser radiation through the respective probes can penetrate either superficially or to a defined depth,
depending on the surgeon´s choice of the probe and laser wavelengths and the intended use.
Those reactions can be classified in:
Non thermal: Catalysing photomechanical reaction by laser light, change of status and consistency, micro-stimulation
Thermal: Coagulation, hemostasis, vaporization, tightening, denaturation, destruction, carbonization, liquefaction, hyperthermia, resection, excisions, reduction, sealing, fusing, welding and joining, induction and stimulation of healing processes
Ablative: Ablation, widening, channels and passages, cutting, incisions and defined deformation
Optomechanical reactions: Occlusion, destruction and mechanical manipulation

3. INDICATIONS

GLC probes are used in a variety of specialist fields in general laser surgery. These include thorax surgery, pulmonology, urology, visceral surgery and pediatrics, for instance in the ablation of carcinomas or coagulation sealing in cracks in parenchymal tissue.

4. CONTRAINDICATIONS

- These medical probes may not be used in the vicinity of stents that have been inserted, due to the danger of heating or destruction.
- The clinical guidelines for the corresponding treatment must be observed.

5. PATIENT POPULATION/NEEDS

Inclusion criteria:

- Age: > 18 years old
- Gender: all
- Ethnicity: all
- Pre-op rehabilitation time: >4 weeks from prior surgery
- Under drugs: none
- Under photosensitizing medication: none
- Under administered medication of the surgical targeted area: none
- Other inclusion criteria are subject to surgeon's advice and responsibility.
- The inclusion criteria are dependent on the local law as well

6. USER PROFILE/NEEDS

- To ensure proper and secure use of surgical laser systems the Gas-, Liquid Cooled Fiber is only to be used by medically trained specialists who are familiar with the handling of medical laser devices. Security precautions can be learned from the labeling and from the instructions for use of the laser.
- Wearing of laser safety goggles (dependent on wavelength) within the NOHD-security distance (Nominal Ocular Hazard Distance) is unconditionally required. The parameters can be learned from the manual of the respective laser

7. TYPE DESCRIPTION

The GLC fibers are designed for non-contact laser surgery. The fibers are enclosed in a PTFE plastic covering and fitted with a metal nozzle at the distal end. During their application, the fibers must be cooled with gas, air or water. They are equipped with a connector for tumescent pumps for this purpose.
The GLC fiber with SMA905 connector can be connected to different laser models (e.g. solid-state, gas, and diode lasers). However, the beam diameter and numerical aperture of the laser must not exceed the core diameter and numerical aperture of the fiber. Due to the patented connector design, the reusable bare fiber with IC connector can only be connected to the Leonardo laser model from CeramOptec.

Table 1: Variants

REF	Item Name	$Ø_{Core}$ [µm]	$Ø_{exter.}$ [µm]	$Ø_{Glass-cap}$ [µm]	NA	Length [m]	Connector/ ID*
500200525	GLC 180 Gas-, Liquid Cooled Fiber	565	1800	n.a.	0,26/0,37	3	SMA905/ No
500201903	GLC 180 Gas-, Liquid Cooled Fiber, Sharplan connector	565	1800	n.a.	0,26/0,37	3	SMA905/ No
500201903-1	Gas Cooled Fiber GLC-0180 SH Sharplan connector			n.a.			
500201938	Ceralas GLC-0210 DL length: 4m	565	2100	n.a.	0,26/0,37	4	SMA905/ No
501200520	GLC 180 Gas-, Liquid Cooled Fiber, Broncho, ID 3x3h	565	1800	n.a.	0,26/0,37	3	SMA905/ Yes 3x3h
501200525	GLC 180 Gas-, Liquid Cooled Fiber, ID 1x6h	565	1800	n.a.	0,26/0,37	3	SMA905/ Yes 1x6h
501200525-1	GLC 180 Gas-, Liquid Cooled Fiber, ID 1x6h, TESL			n.a.			
501200550	GLC 180 Gas-Liquid Cooled Fiber, 3.5m, ID 1x6h	565	1800	n.a.	0,26/0,37	3.5	SMA905/ Yes 1x6h
503200520	GLC 180 Gas-, Liquid Cooled Fiber, Broncho, IC 3x3h	565	860	n.a.	0.26/0.37	3	IC/ Yes 3x3h
503200525	GLC 180 Gas-, Liquid Cooled Fiber, IC 1x6h	565	1800	n.a.	0,26/0,37	3	IC/ Yes 1x6h
503200550	GLC 180 Gas-Liquid Cooled Fiber, 3.5m, IC 1x6h	565	1800	n.a.	0,26/0,37	3.5	IC/ Yes 1x6h

FV 600	Fibre 600 m — OH- - vent.-L:3,00m-Dia1,8mm	565	1800	n.a.	0,26/0,37	3	SMA905/ No
FV 600L	Fibre 600 m vent. - L:3,00 m Dia 1,8 mm	565	1800	n.a.	0,26/0,37	3	SMA905/ No

*The Gas-, Liquid Cooled Fibers marked with "Yes" are components of the Biolitec corporate group's ID concept. This concept uses automatic fiber recognition to ensure the compatibility of the probe for the intended CeramOptec GmbH laser equipment. The fibers come with a defined service life. During the usage cycle, the user is informed two times about the remaining service life, once at 30 min. and once at 10 min. prior to expiration. This ID concept does not apply when using lasers from manufacturers other than CeramOptec GmbH or for older models that do not feature RFID equipment

8. ACCESSORIES

The GLC with SMA905 connector could be used with different laser types (for example solid-state laser, gas laser and diode laser). Therefore, the values for beam diameter and the numeric aperture of the laser and additional to this the core diameter and the numeric aperture of the probe must be inside the range. The GLC with IC connector could be used due to its patent connector design only with the laser model Leonardo of the company CeramOptec.

Protective laser eyewear used in accordance with the usage instructions is imperative for laser applications.

A tumescent pump is necessary for cooling the GLC fibers. Below is an example of a pump that is suitable for use.

REF CeramOptec	Manufacturer	Product
MP0002	Nouvag	Infusion Pump DP20
400100200	Nouvag	Infusion Pump DP30

For endoscopic applications, i.e. such as in pulmonology, flexible or rigid endoscopes can be used. The working channel of the instrument should have a rating of no less than 7 on the French scale.

9. HANDLING

9.1 PREPARATION

- Mind the expiry date on the packaging.
- Inspect packaging and sterile packaging for signs of damage of all components.
- This product is made from quartz glass and it must be handled with special care and attention.
- Remove the products from the packaging. Take care not to damage the fiber.
- Inspect the products for damages prior to the treatment.

⚠ **CAUTION:** *All personnel in the treatment room must be wearing protective glasses (EN 207) with the proper rating for the wavelength being used.*

9.2 TREATMENT

- Mind the guidelines for the handling of sterile products.
- The functionality of the laser probe must be tested using the pilot beam of the corresponding laser prior to using the probe for the first time.
- The metal nozzle on the distal fiber end must be inspected to ensure that it is undamaged and intact.

Description of treatment process:

1. Remove the GLC fiber from the sterile packaging and visually inspect it to ensure that it is undamaged.
2. Remove the black cap from the blue connection and screw/ Click the fiber clockwise onto the laser device and ensure that no axial play remains.
3. For endoscopic procedures, insert the fiber into a suitable, sterile endoscope. The distal end should protrude completely out of the instrument.
4. Connect the fiber with the infusion pump using the proximal end's Luer taper system connector and ensure that the gas, air or water flushing function is working properly.
5. Put on the protective laser eyewear in accordance with the laser's instructions for use.
6. Test the functionality of the fiber with the assistance of the corresponding laser's pilot beam.
7. The laser is only to be activated with a correctly positioned fiber tip and only after the tissue to receive treatment has been inspected and precise aim has been taken.
8. The laser energy must be set to correspond with medical applications and must be adjusted in accordance with continuous observation of its effect on the tissue.
9. The fibers can be cleaned during treatment using hydrogen peroxide or a sterile compress doused in sterilized water.

⚠ **ATTENTION:** *The laser may not be activated when cleaning and the distal end of the fiber must be in a cooled state.*

9. GENERAL POTENTIAL RISKS AND SIDE-EFFECTS

Potential risks of laser treatment can be swelling, bleeding, infections and the damage of nerves. Furthermore, false or too intense settings of the laser power can cause burn on the focused tissue. A full demonstration of potential side-effects can be learned from the instruction of the used laser and from correspondent medical specialist literature.

10. STORAGE

Storageconditions:
The premises where sterile products are stored in / or handled should be maintained in accordance with following requirements:

- Keep storage container clean, dry and in good condition.
- Protect from daylight or direct sunlight.
- Storage temperature: + 15 °C - + 25°C
- Do not open protecting packaging until the point of use of the product.
- Do not store nearby: Chemicals, Detergents.

For further information regarding the storage conditions the WHO guidelines for the storage of medicines and other health commodities is highly recommended.

11. SAFETY INSTRUCTIONS

- General regulations and instructions for the use of laser radiation apply. Security precautions can be learned from the labeling and from the instructions for use of the laser.
- Wearing of laser safety goggles (dependent on wavelength) within the NOHD-security distance (Nominal Ocular Hazard Distance) is unconditionally required. The parameters can be learned from the manual of the respective laser.

ATTENTION: *Probes are only to be used under OR-conditions. The sterile packaging has to be inspected for intactness. Probes from opened, open or damaged packing are not sterile and must not be used. Mind the expiry date.*

ATTENTION: *Never use a laser probe with a damaged distal end or a damaged laser connector.*

CAUTION: *In the unlikely event that the metal nozzle breaks off and remains inside the body, clinical measures must be undertaken.*

CAUTION: *The product may only be used with especially authorized accessories (for example, catheters, introducer needles etc.) specified by the manufacturer or in collaboration with a co-manufacturer. Violations may lead to errors in function of the product, for example, by damage to the surface by severe bending or breakage of the fiber due to damage to the end face.*

CAUTION: *GLC probes must be flushed with gas, medical air or water during use in order to prevent damages to the fiber. Oxygen may not be used under any circumstances, since it can result in rapid heating and uncontrolled burning!*

CAUTION: *The uninterrupted flow of the flushing agent must be ensured and monitored prior to and during the treatment. Products with insufficient flow may not be used, since they do not guarantee sufficient cooling.*

⚠ **WARNING:** *Deficient flow of the flushing agent, tissue residue on the distal end and damages to the nozzle can result in overheating and possible burning of the distal end and pose significant danger to the patient.*

CAUTION: *Gas embolisms can occur when using flushing gas, particularly in endoscopic or interstitial procedures. The laser pyrolysis products emerging as a result of the treatment (gases, vapors, particles and infectious aerosols) must be captured with appropriate extraction systems above the laser zone.*

CAUTION: *Laser treatment close to sensible areas (arteries, intestines) may cause perforations. Laser radiation should only continue for the required period of time for reaching the coagulation or vaporization effect.*

⚠ **WARNING:** *Before and during the treatment to avoid damage of the laser fiber cause by impact, tensile or extreme bending of the fiber. The fiber must not be bend to a diameter below 13 cm.*

If in doubt, please ask for help by the responsible medical products adviser.

12. REPROCESSING

The GLC fibers are designed for one-time use only and are delivered in sterile condition. Additional preparation and sterilization are not permitted.

13. WARNING NOTICE

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.

Temperature limitation: Indicates the temperature limits to which the medical device can be safely exposed.

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.

14. DISPOSAL

The fibers must be disposed of in observance of the contamination of the product and in accordance with the local legal provisions of contaminated single-use material (residue of patients' material respectively).

15. 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, preferably in the original packaging.

16. WARRANTY

CeramOptec GmbH guarantees that its products are manufactured with the greatest possible care.

It should be noted that due to biological differences in patients, no product is always absolutely effective under all circumstances.

CeramOptec GmbH has no influence on the use of its products, the patient diagnosis, or the handling of its products once they leave the company. For this reason, CeramOptec GmbH can guarantee neither the effectiveness nor complication-free use of its products. Therefore, CeramOptec GmbH accepts no liability or responsibility for damages or costs arising in association with the use of its products. CeramOptec GmbH disclaims all responsibilities for personal injuries or equipment damage resulting from the improper use or storage of the product. CeramOptec GmbH cannot be held liable for incidental or consequential damages, losses, or costs directly or indirectly related to the use of this product.

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CeramOptec GmbH reserves the right to make product modifications without notice.

17. MANUFACTURER

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