Instructions for use
LGO-Bare Fiber single use

1. Device description

The medical device LGO-Bare Fiber single use is a medical grade optical fiber probe for application in various fields of laser surgery, as described in section 1.1. This is an EO-sterilized single-use device for transmission of laser radiation to the optical fiber probe's distal end. The medical device LGO-Bare Fiber single use is identified by REF number prefixes "BF" or "TBF" followed by a unique alphanumeric sequence. At the distal end of the LGO-Bare Fiber Single Use the cladding and coating of the optical fiber are removed on a length of 5 mm which ensures optimum energy transfer to the tissue that is to be treated. The proximal end of this optical fiber probe is equipped with the connector for connecting the optical fiber probe to a suitable medical laser device. The optical fiber probe is shown schematically in Figure 1:

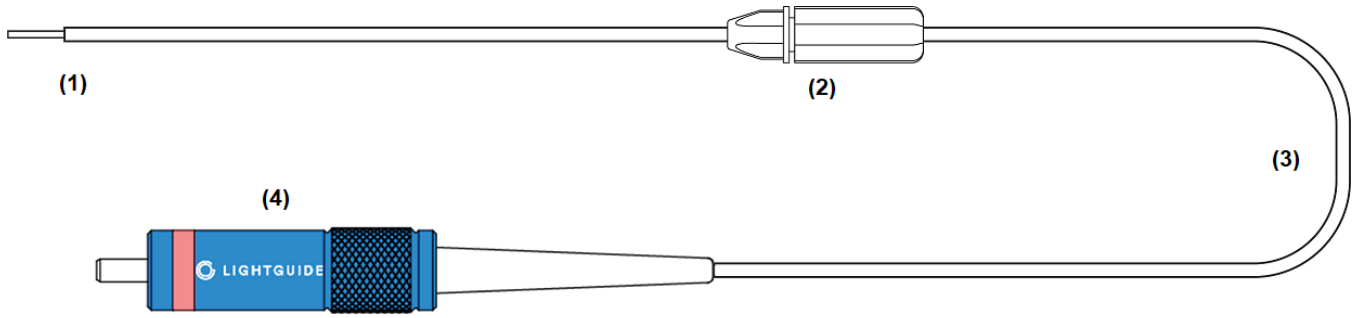
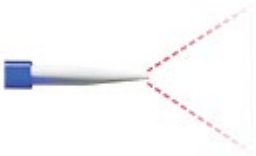


Figure 1 LGO-Bare Fiber single use
(1) Distal end; (2) Optional luer lock adapter; (3) Optical fiber; (4) Connector

The following variations of LGO-Bare Fiber single use are available:

Variation	Light emission profile	
Flat distal tip	Frontal, conical in narrow angle	
Conical distal tip	Frontal, conical in wider angle	
Ball distal tip	Frontal, conical in wider angle	
Spherical distal tip	Frontal, conical in wider angle	
Bent distal tip	Frontal, conical in narrow angle, offset to the direction the fiber tip is bent	

1.1. Intended purpose and indications

The intended purpose of the LGO-Bare Fiber single use is to deliver laser energy from a source to the treatment site in laser surgery application.
The LGO-Bare Fiber single use is indicated in general laser surgery application of different disciplines such as incision, excision, vaporization and coagulation. With the LGO-Bare Fiber single use tissue can be cut out and the open resection surface can be simultaneously sealed by the use of precise coagulation. Moreover, the product can be used for fragmentation of concrement (stones) or for creation of photo-chemical reactions.

1.2. Contra-Indications

The instructions for use of the medical laser device and the corresponding specialist medical literature should be considered for a full outline of contra-indications of the laser surgery or the use of an optical fiber probe as beam delivery system.

1.3. Patient population

No limitations on the target population apply. User should follow clinical guidelines of the treatment.

1.4. Users

In order to ensure correct and save handling, the device may only be utilized by physicians being familiar with the handling of medical laser devices, and with the therapeutic application of sterile medical optical fiber probes.
The current clinical specialist guidelines should be followed, in particular for the selection of the source of laser radiation and laser power. Any off-label use of the LGO-Bare Fiber single use is fully under the user's responsibility. By all means the technical device's compatibility aspects (section 2.1.) must be respected.

1.5. Exclusions

Applications at the central nervous system and the central circulatory system are not allowed.
The use of the optical fiber probe in the vicinity of brackets or implants is not allowed because there is the risk of heating and destruction.

1.6. Potential risks associated with the application

The instructions for use of the medical laser device and the corresponding specialist medical literature should be referred to for a full outline of possible side effects. Possible side effects depend on the medical discipline in which this device is used in.
General side effects can be but are not limited to:

pain, burns / necrosis, swellings, infection, bleeding, bruising / ecchymosis / hematoma, itching, paresthesia (due to injury of adjacent sensory nerves), formation of edema, abscess formation, induration, perforation (in case of application in the vicinity of sensitive areas, such as artery, bowel, …).

Specific side effects in case of application in blood vessels can be but are not limited to:

phlebitis, pulmonary embolism, thrombosis.

Specific side effects in case of application in gynecology, urology and proctology can be but are not limited to:

urinary retention, anismus, major forms of incontinence, perianal thrombosis.

2. Application and safety rules

Prior to the start of the laser treatment, all necessary instructions for use of the utilized equipment must be read and fully understood. In the case of doubt, please contact your technical service or supplier and dispense with the use until the doubts have been dispelled.

2.1. Compatibility check

The compatibility of the LGO-Bare Fiber single use with the laser device must be checked. Information is provided on the device label (see Fig. 2). If the manufacturer of the laser device offers the LGO-Bare Fiber as a genuine accessory, the compatibility test with the laser device has already been performed and does not need to be performed again.

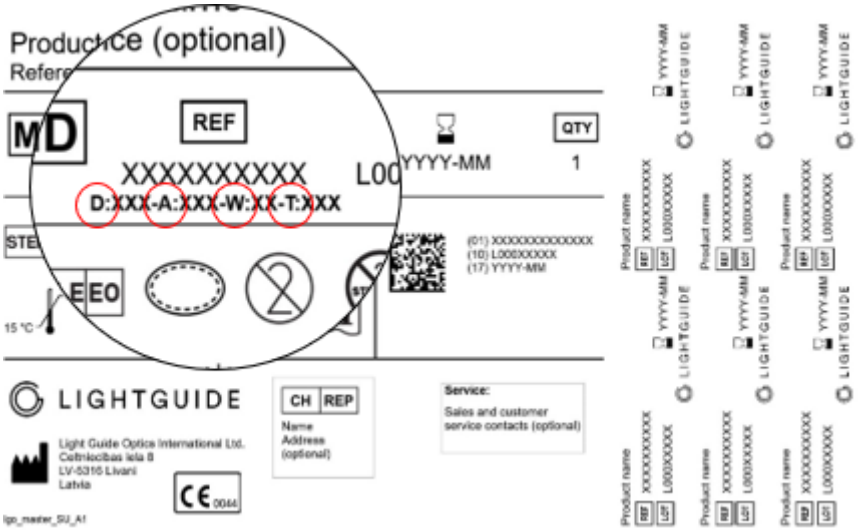


Figure 2 Compatibility code on the device label

D parameter - Beam diameter

The laser device in use must not have a beam diameter larger than the core diameter of the optical fiber. The core diameter of the optical fiber is given in units of microns.

A parameter - Numerical Aperture

The numerical aperture (NA) of the laser device in use must not exceed the value of parameter “A”.

W parameter - Wavelength

The wavelength range of the optical fiber is specified in the label:

- UV: 200 - 1000 nm
- IR: 400 - 2200 nm

T parameter - Type of connector

Verify that the port of laser device is compatible with the connector of the optical fiber probe. Mind the Instructions for Use of the laser device, which may specify further requirements on the optical fiber probe.
The connector type of the optical fiber is given in the label as parameter T. Examples are:

- SMA: SMA-905 connector (IEC 61754-22)
- SC: SC connector (IEC 61754-4)
- NC: A proprietary connector (matches only selected laser devices marked as such)
- CC: Customer connector (matches only selected laser devices)

Maximum Power

The maximum laser power setting for all product variations is 100 W.

In the case of doubt, your technical service or supplier should be contacted and the treatment dispensed until the problem has been solved fully.

2.2. Precautions

The sterile packaging should be checked for integrity. The device should not be used if the packaging is damaged or unintentionally opened before use.

The device should be removed from the sterile packaging and optional tray with special care to avoid damage of the device.

The handling of medical optical fiber probes requires an enhanced care. The optical fiber probes could be damaged by stresses, impacts or high-grade torsions. Such damages impact the functionality and/ or appropriate operation/ treatment.
The optical fiber probes must never be bent too tightly during the procedure:

Core diameter	Allowed bend radius
≤ 400 µm	≥ 21 mm
≤ 600 µm	≥ 31 mm
≤ 1000 µm	≥ 51 mm

When the device will be used in conjunction with a handpiece or an endoscopic instrument the diameter of its working channel must be chosen such that the optical fiber probe can be smoothly inserted into the working channel and always protrudes from the instrument during the treatment.

The general instructions and information regarding a safe handling with laser radiation have to be followed (including eye protection, according to the selected laser wavelength and power). Safety relevant information has to be extracted from the labelling and the instructions for use of the medical laser device.

Special attention should be paid to the cleanliness of the connector and the integrity of the distal end. The device must not be used if any part of the device is damaged or broken.

After connection to the laser device the aiming beam must be visible as emitted light. The specific light emission pattern (see Section 1) must be visible. There must not be light leakage in any other part of the device. If these conditions are not fulfilled, the device shall not be used.

2.3. Application guidelines

Depending on the specific application it is indicated to use the LGO-Bare Fiber single use in conjunction with a handpiece or an endoscopic instrument to safely position the tip of the optical fiber probe, hence the laser beam. In this case it is important that the optical fiber can be inserted smoothly into the working channel and always protrudes from the instrument during the treatment. In particular with bent working channels prior to the treatment it is to be evaluated carefully if the probe can be inserted without friction.

In cases when the tip of the optical fiber probe is not visible, the aiming beam and the tissue to be treated should always be monitored in order to be able to track the effect of the laser radiation. Imaging techniques such as ultrasound should be used for applications in soft tissue when the optical fiber probe's tip cannot be observed visually to ensure correct positioning and alignment towards the target tissue. Depending on the indication an endoscopic instrument should be used to maintain continuous irrigation and clear view of the tissue to be treated.

Typical treatment parameters and laser settings depend on the individual case. The specialist medical literature should be consulted. The treatment should always start with low power and the laser settings should be adjusted depending on the course of the treatment while observing the effects on the tissue.

For application in contact surgery, guide the distal end of the fiber across the tissue surface without applying pressure. Lateral pressure is to be avoided.

Tissue adhesion reduces the amount of laser power which is available for the treatment and causes the probe to heat up, leading to wear of the distal tip. To remove adhered tissues from the tip of optical fiber probe, the optical fiber probe should be carefully pulled out of the body, and after cooling down of the optical fiber probe tissue could be removed by carefully rubbing of the tissue with a sterile moist swab.

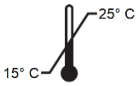
Laser pyrolysis products (gas, steam, particles, infectious aerosols, etc.), which are created during the treatment, should be removed using a suction system above the treatment area. Gas embolisms can arise from using flushing gas.

The laser treatment should be limited to a period of time that is strictly necessary for the therapeutic effect.

Information on patient care and follow-up resulting from literature must be observed in order to avert or minimize unwanted side effects of laser treatment.

After the treatment the optical fiber probe must be inspected for damage particularly at the distal end. In the unlikely event of any component breaking off the optical fiber probe and remaining in the body (or if this is considered possible) respective clinical measures should be taken.

2.4. Symbol explanation

	Indicates the device is a medical device.
	Indicates the device's catalogue number.
	Manufacturer: Indicates the manufacturer of the medical device according to directive 93/42/EEC and regulation 2017/745/EU.
	Expiration date: Indicates the date after which the medical device must not be used.
	Batch code: Indicates the manufacturer's batch code so that the batch or lot can be identified.
	The device must be stored in a dry place.
	The device must be stored at the given temperature range.
	Indicates a medical device that needs protection from light sources.
	The device has been sterilized with ethylene oxide (EO).
	Indicates a single sterile barrier system with protective packaging inside.
	Indicates a single sterile barrier system.
	Mind the instructions. It is necessary for the user to consult the instructions for use prior to use.
	Prior to use check the packaging for damage. The medical device should not be used if the packaging is damaged or unintentionally opened before use.
	Do not reuse. This device is intended for use with a single patient during a single treatment. Sterility and function cannot be guaranteed for reuse.
	Indicates a medical device that is not to be re-sterilized.
 (optional)	Indicates the entity distributing the medical device into the locale (Distributor).
CE 0044	CE marking of conformity

3. Disposal

The use of the medical device may result in biological risk. Medical devices have to be used and disposed of in accordance with local legal regulations and accepted practice.

4. Complaints

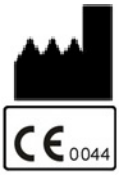
In an unlikely situation of a failure of the device resulting in serious incident, an incident report should be sent to Light Guide Optics Sales and Customer Service. If necessary, our complaint submission template is available at https://www.lightguide.com/forms/.

5. Disclaimer

Light Guide Optics International Ltd does not accept any reliability for personal injuries as well as for damages of the medical laser device due to an inappropriate handling and storage of the optical fiber probe.

Light Guide Optics International Ltd cannot be held responsible for indirect damages or consequential damages, losses and expenses with respect to a direct or indirect application of the medical device.

Light Guide Optics International Ltd does not accept any responsibility neither in terms of the application of the device nor in terms of possible side effects of the medical laser treatment with the optical fiber probe.



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