Instructions for use
LGO-Bare Fiber reusable

1. Device description

The medical device LGO-Bare Fiber reusable 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 reusable medical device for transmission of laser radiation to the optical fiber probe's distal end. The medical device LGO-Bare Fiber reusable is identified by REF number prefixes "RBF" or "RTBF" followed by a unique alphanumeric sequence. At the distal end of the LGO-Bare Fiber reusable 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:

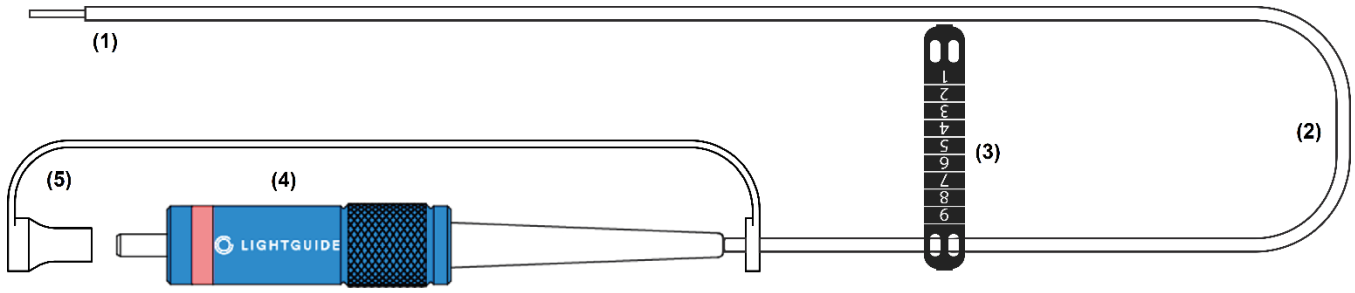


Figure 1 LGO-Bare Fiber reusable
(1) Distal end; (2) Optical fiber; (3) cut-off label; (4) Connector; (5) protection cap

The following variations of LGO-Bare Fiber reusable are available:

Variation	Light emission profile	
Flat distal tip	Frontal, conical in narrow angle	

This medical device is delivered in sterile condition directly for use. It is approved for a total of ten applications with nine corresponding reprocessing cycles (see Section 3 for details on reprocessing).

1.1. Intended purpose and indications

The intended purpose of the LGO-Bare Fiber reusable is to deliver laser energy from a source to the treatment site in laser surgery application.
The LGO-Bare Fiber reusable is indicated in general laser surgery application of different disciplines such as incision, excision, vaporization and coagulation. With the LGO-Bare Fiber reusable 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 reusable 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 reusable 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 reusable as a genuine accessory, the compatibility test with the laser device has already been performed and does not need to be performed again.

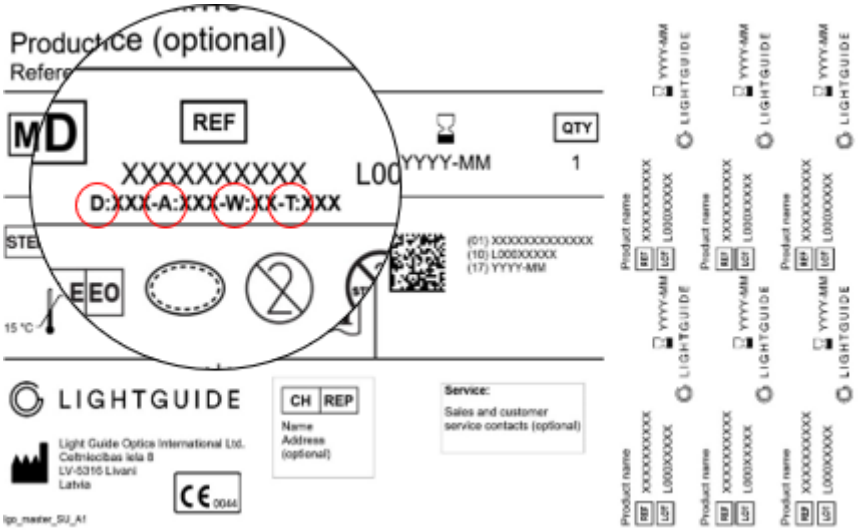


Figure 2 Compatibility code on the device label

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

* Please note that for the reprocessing process different allowed bend radius values apply. (see Section 3)

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.

As a consequence of use of the LGO-Bare Fiber reusable on patients who have or are suspected to have a prion disease there may possibly arise an increased risk of infection after the treatment. The reprocessing procedure, which is prescribed in Section 3, might not be effective for these cases and the contaminated LGO-Bare Fiber reusable should be disposed in accordance with legal regulations.

2.3. Application guidelines

Depending on the specific application it is indicated to use the LGO-Bare Fiber reusable 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.

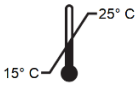
Laser pyrolysis products (gas, steam, particles, infectious aerosols, etc.), which are created during the treatment, should be removed using a suction system above the treatment area. Gas embolisms can arise from using flushing gas.

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.
 (optional)	Indicates the entity distributing the medical device into the locale (Distributor).
CE 0044	CE marking of conformity

3. Reprocessing of LGO-Bare Fiber reusable

3.1. General

Instructions for reprocessing are compiled according to the requirements of EN ISO 17664-1:2021. The structure of the Instructions for reprocessing provided in section 3.4. is according to Annex B of this standard.
Please note that potentially existing local requirements for reprocessing must be taken into consideration in any case.

3.2. Warnings on reprocessing

Ensure compliance with all applicable safety protocols and guidelines, including the use of personal protective equipment (PPE) such as gloves, masks, and protective eyewear, to minimize the risk of exposure to potentially hazardous materials during the reprocessing procedure.
Initial packaging materials (sterile pouches, optional tray) are not suitable for reuse and should be disposed of.
A high risk of infection is possible after a surgical intervention results from the utilization of the product on the patients for which prion diseases are assumed or detected. In these cases the reprocessing is not possible and the product must be disposed of according to the regulations.[1]
Cleaning and disinfection should be done immediately after use to avoid drying of blood and tissue residues. Dried contamination is much harder to remove.
It should be ensured that the laser coupling area of the connector remains clean and free of contamination as it cannot be cleaned and disinfected.

3.3. Limitations on reprocessing

Any product, which is broken or kinked or has a contaminated laser coupling area at its connector should be disposed.
The reusable fiber-optic product is designed and tested to withstand 9 (nine) cycles of reprocessing. Every reusable fiber probe is equipped with a plastic cut-off label marker (see Fig.1. position (3)) to record the accumulated number of performed reprocessing cycles. During each device reprocessing cycle, the outermost line of the marker from one to nine should be cut to record the number of reprocessing cycles (see Fig.3).

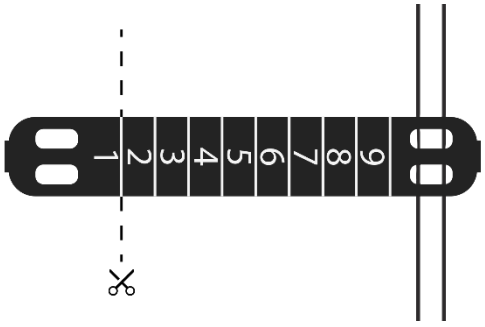


Figure 3 Cut-off plastic label marker

For any additional reprocessing cycles or deviating from manufacturer’s instructions only the user is responsible.

[1] See German Bundesgesundheitsblatt 1998; 41, Final report of the Task-force vCJK at RKI, supplement 7: Measurements to minimize the risk of transmission of CJK/vCJK by medical devices to the „Hygiene requirements in the processing of medical devices“ p. 279-285.

3.4. Instructions for reprocessing

Initial treatment at the point of use:

1) The protection cap should be put on the connector immediately after disconnecting the latter from the laser port. It is to be ensured that the laser coupling area of the connector (protected by the cap) remains clean and free of contamination as it cannot be cleaned and disinfected.
2) The product should be rinsed using cold tap water and a soft cloth. All visible superficial residues of blood and tissue should be removed by cleaning the area of application lengthwise several times. If the residues cannot be removed, the contaminated part of the fiber up to the distal end must be cut-off (see point 3) below for details). Ensure that the remaining length of the optical fiber is sufficient for the next treatment. Otherwise the medical device should be disposed of according to the regulations.
3) The used fiber tip should be cut at around 4 cm from the distal tip. Ideally, the fiber should be carefully scratched with a cleaving tool or a ceramic blade and pulled apart along the fiber axis.
4) The outermost plastic protective jacket and cladding should be stripped off for the length of approximately 0.5 cm from the distal end by using a fiber stripper of suitable size which matches the quartz glass portion of the optical fiber.
5) The optical fiber probe should be reconnected to the laser and the beam profile at the distal tip should be verified: a symmetric and circular beam profile is desired for optimum energy transfer in the next treatment. In case of asymmetric light output or scattering, the fiber's tip should be cut and verified anew. In case there is light leakage in any other part of the medical device, it should be verified if the affected part of fiber can be cut-off ensuring the remaining length of the medical device is sufficient for the next treatment or the medical device should be disposed of according to the regulations.
6) The protection cap should be put on the connector immediately after disconnecting the latter from the laser port and the fiber should be wound in a coil with diameter of at least 20 cm.

Preparation before cleaning:

It should be ensured that the protection cap is attached firmly on the connector and diameter of the fiber coil is at least 20 cm.

Cleaning and disinfection, automated:

Equipment: A washer-disinfector complying with the requirements of ISO 15883 series and suitable baskets matching the size of the coiled fiber. Instructions for use of the washer-disinfector should be followed.

Cleaning agent: Certified cleaning agent for automated cleaning of medical instruments: **neodisher MediClean forte** manufactured by Dr. Weigert GmbH & Co. KG, Hamburg, Germany. Instructions for use from Dr. Weigert GmbH & Co. KG for safe and correct utilization of cleaning agent neodisher MediClean forte should be followed.

Process:

1) The product should be placed in a basket inside the washer-disinfector,
2) A cycle with at least the following steps and minimum temperature and minimum duration should be selected:

Action	Temperature	Duration
cleaning	50°C	6 minutes
rinsing	not critical	5 minutes
disinfection	93°C	6 minutes
drying	not critical	15 minutes

3) Upon removal from the washer-disinfector, the product should be inspected for visual pollution. If necessary, the cycle should be repeated, or manual cleaning should be performed.

Drying:	Not required as stand-alone process, if it is a part of the automated cleaning and disinfection process. Else, it should be ensured that the gaps at the connector are dry.
Function testing:	While the protection cap is attached on the connector, a visual inspection along the optical fiber to exclude residual pollution should be performed. The cleaning and disinfection should be repeated if necessary. The fiber and connector should be checked for kinks, breaks, corrosion, or wear. The fiber protection jacket should be intact all along the product. The protection cap should be removed and the laser coupling area should be inspected under 100x magnification, for example, with a fiber optic inspection scope. It should be verified that the laser coupling surface does not have scratches larger than 1 µm or digs larger than 10 µm and is free of residues from cleaning. Potentially residues might be removed with a lint-free wipe for optics soaked with high purity isopropyl alcohol. If any irregularities are detected, the product should be disposed of. After the functional testing is successfully passed, the outermost line of the plastic marker from one to nine should be cut to record the number of reprocessing cycles (see Fig. 3).
Packaging:	The fiber should be wound in a coil with diameter at least 20 cm. Standardized paper-foil sterile barrier systems, single or double, should be used for packaging. The sterile pouch should be suitable to fit the coiled product without putting tension on the seals or on the product. Only one item should be placed in a sterile pouch. Ensure that the protection cap is taken off the connector, before placing the probe into sterile pouch.
Sterilization:	Only sterilization with moist heat in a process according to ISO 17665 series is permitted. Instructions for use of the sterilizer should be followed. Allowed parameters: a) 20 – 21 minutes at 121°C, or b) 4 – 21 minutes at 132°C – 134°C. When sterilizing several products, the maximum load of the autoclave should be considered.
Storage:	The product should be stored in a dry place, protected from light sources and at the temperature range between 15°C and 25°C.

The reprocessing instructions provided above have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the reprocessing, as actually performed using equipment, materials and personnel in the reprocessing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process. Likewise, any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.

4. 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.

5. 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/.

6. 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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