Instructions for use
LGO-Bare Fiber Reusable

1. LGO-Bare Fiber Reusable

The LGO-Bare Fiber Reusable is an optical fiber for medical application in various fields of laser surgery. The LGO-Bare Fiber Reusable is supplied in sterile or non-sterile condition, depending on the product variation. Only the product variations which are supplied sterile are suitable for immediate for the first use without preconditioning. LGO guarantees ten application and ten reprocessing cycles (see section3). For any additional reprocessing cycles only the user is responsible.

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 to ensure optimum energy transfer to the tissue that is to be treated. The proximal end the LGO-Bare Fiber Reusable is equipped with an SMA-905 connector or a custom special connector for connection to suitable medical laser devices. Prior to the treatment the compatibility must be checked.

1.1. Field of application and exceptions

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 be 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.

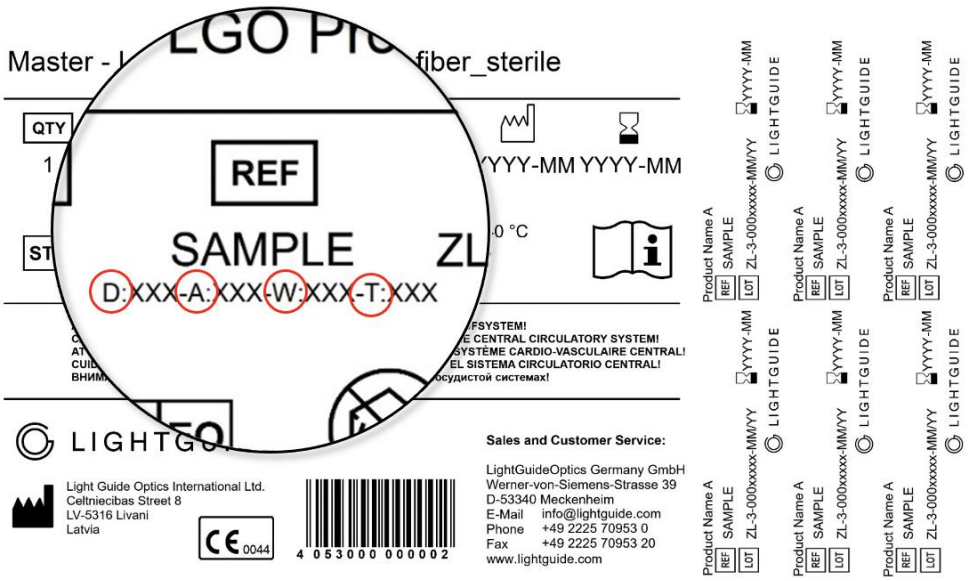
Surgeries in the vicinity of brackets or implants are excluded because there is the risk of heating and destruction.

Follow current clinical guidelines. Applications at the central nervous system and the central circulatory system are not allowed. In order to ensure correct and save handling this device may only be applied by surgeons being familiar with the handling of medical laser devices, and with the therapeutic application of laser fiber probes.

1.2. Potential risks associated with the procedure

Please refer to the instructions for use of the medical laser device and the corresponding specialist medical literature for a full outline of possible side effects. Possible side effects can be but are not limited to: burns, swellings, bleeding, pain, infection, paraesthesia due to injury of adjacent sensory nerves, perforation in case of application in the vicinity of sensitive areas (artery, bowel, …). Moreover, unintended reactions of the treated tissue can be caused because of wrong (for example too high) laser settings.

1.3. Compatibility check



REF code sample

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

The connector of the optical fiber must match the laser device. The connector type of the optical fiber is given in the label as parameter T. Examples are:

- SMA: SMA-905 connector (IEC 60874-2)
- SC: SC connector (IEC 61754-4)
- CC: Customer connector (depends on the laser device)
  Verify that the port of the laser device can accept it. In case of a customer connector (CC) mind the Instructions for Use of the laser device, which may specify further requirements on the optical fiber probe. Moreover, there are certain laser devices which additionally require a valid RFID tag or code for activation.

Maximum Power
The maximum laser power setting for all product variations is 100 W unless there is a dedicated labelling on the product.

In the case of doubt, contact your technical service or supplier and dispense with the treatment until the problem has been solved fully.

2. Application guidelines and safety rules

Prior to the start of the laser treatment, all necessary instructions for use of the equipment employed must be read and fully understood. In the case of doubt, contact your technical service or supplier and dispense with the treatment until the problem has been solved fully.

2.1. Application guidelines

It can be applicable to use the LGO-Bare Fiber Reusable in conjunction with a handpiece or endoscope. 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 bended working channels prior to the treatment it is to be evaluated carefully if the probe can be inserted without friction.

The tissue to be treated should always be visible to see the aiming beam and to monitor the effect of the laser radiation. 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. During the course of the treatment the distal end must be checked for tissue residues and damages. Tissue adhesion reduces the amount of laser power which is available for the treatment and causes the probe to heat up, which shortens its lifetime. Potential adhesion of tissue should be removed after some seconds of cool down time without or with only little laser power by carful rubbing at tissue. Burnt-in tissue must be removed carefully with a sterile moist swab.

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

Typical treatment parameters and laser settings depend on the individual case. Please consult the specialist medical literature. Always start with low power and adjust the laser settings depending on the course of the treatment while observing the effects on the tissue.

2.2. Warnings ⚠

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

When using a handpiece or endoscope, make sure that the LGO-Bare Fiber Reusable can be inserted into the working channel smoothly and always protrudes from the instrument during the treatment.

The general instructions and information with regard to a safe handling with laser radiation have to be applied (including eye protection). Safety relevant information has to be extracted from the labelling of the laser devices and their reference manuals.

The handling of medical laser probes requires an enhanced care. Laser probes could be damaged by stresses, impacts or high-grade torsions. Such damages impact the functionality and/or appropriate operation/treatment. The

LGO-Bare Fiber Reusable 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 radii apply. They can be taken from the instructions for reconditioning.

After connection to the laser device the aiming beam must be visible as a frontal emitting spot. If this is not the case the product must not be used.

After the treatment the LGO-Bare Fiber Reusable must be inspected for damages. In the unlikely event of the fiber tip breaking off and remaining in the body (or if this is considered possible) respective clinical measures are to be taken.

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 this case[1], damages the optical fiber in a way that any further application is impossible. Consequently, the LGO-Bare Fiber Reusable is to be disposed in accordance with legal regulations in such case.

[1] See 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.

2.3. Symbol explanation

The product must be kept in a dry place and at the given temperature range.

Prior to use check the packaging for damage. Do not use if the packaging is damaged.

The product has been sterilized with ethylene oxide (EO).

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

Expiration date: Indicates the date after which the medical device must not be used.

Manufacturer: Symbol indicates the manufacturer of the medical device according to the guidelines 90/385/EEC, 93/42/EEC and 98/79/EC.

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

3. Reprocessing of the LGO-Reusable Bare Fiber

3.1. Preparation of the distal fiber end

As required the distal end of the LGO-Bare Fiber Reusable must be prepared anew. This must be done at minimum after the treatment is over and before reprocessing. Afterwards, the optical fiber must be inspected with the help of the aiming beam of the laser device.

Suggested course of the procedure:

1. Clean the fiber product several times lengthwise in the area of application with a clean and lint-free cloth and remove visible residues of blood and tissue.
2. Remove the outer cladding and coating from the fiber on length of approx. 40 mm using an appropriate stripper.
3. Break off (cut off) the used fiber approx. 5 mm below the end of the remaining fiber coating by means of the tool for fiber conditioning or a ceramics cutter. For this purpose, scratch the optical fiber carefully and break it off at the cut surface by pulling in the longitudinal direction of the fiber.
4. Using the aiming beam of the laser device examine the emission pattern. The beam profile must be homogeneously round without scattering. If this is not the case the preparation procedure must be repeated.

3.2. Reprocessing for reuse

Effective cleaning and disinfection are essential preconditions for an effective sterilization. The instructions for reconditioning are the basis of the reconditioning procedure for LGO Reusable fiber products. This instruction is included in the scope of delivery of our reusable fiber products, and can be requested free of charge in case of loss. The reconditioning of the product and the preparation of the distal end may only take place according to the instructions outlined there. In case of deviations there can be no sterility assumed for the product.

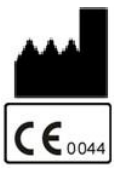
Based on the product design and the materials used, the manufacturer does not specify a definite limit for the period of application of LGO reusable fiber products. The frequency of use is determined by the specified instruction at the label as well as by the careful treatment of fiber products according to the instructions. For any additional reprocessing cycles only the user is responsible.

4. Disclaimer

Light Guide Optics International Ltd is not liable for personal injuries as well as for damages of the laser device due to an inappropriate handling and storage of the LGO-Bare Fiber Reusable.

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 these products.

Light Guide Optics International Ltd is not liable in terms of application of the LGO-Bare Fiber Reusable and in terms of possible side effects of the medical laser treatment with the laser fiber probes.



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