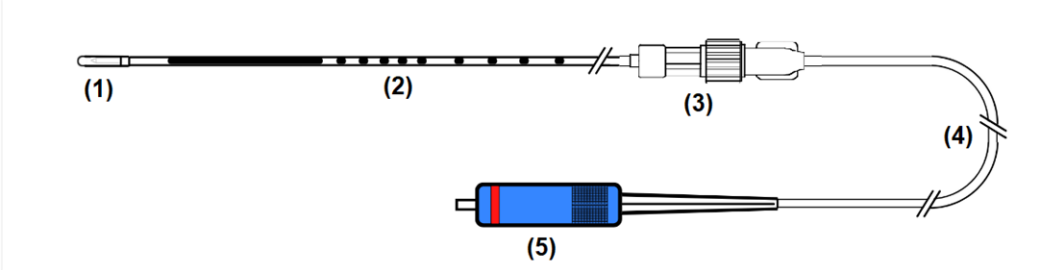
Instructions for use
LGO-Infinity Side Fiber

1. Device description

LGO-Infinity Side Fibers are medical grade optical fiber probes for application in various fields of laser surgery, as described in section 1.1. These are EO sterilized single-use devices for transmission of laser radiation which is emitted laterally at the probe's distal end. For this purpose, the probe's distal end is equipped with a cap made from quartz glass. The probe's proximal end is equipped with the connector for connecting probe to suitable medical laser source. Optical fiber probe is shown in Picture 1:



Picture 1 LGO-Infinity Side fiber probe

(1) Distal end (cap); (2) Fiber marking; (3) Optional luer lock adapter; (4) Optical fiber; (5) Connector

The following LGO-Infinity Side Fibers variations are available:

Variation	Light emission profile	Tip shape
LGO-Infinity Side Fiber	cylindrical 360° all around, approx. 4 mm long 	diameter 1.3 mm to 1.8 mm (depending on variant), rounded
LGO-Infinity Fistula Probe	cylindrical 360° all around, approx. 4 mm long 	diameter 1.6 mm, rounded
LGO-Infinity Hemorrhoid Probe	cylindrical and conical 360° all around, approx. 4 mm long 	diameter 1.8 mm, conical

1.1. Intended purpose and indications

The intended purpose of the LGO-Infinity Side Fiber probes is to deliver laser energy from a source to the treatment site in laser surgery application.

These optical fiber probes are indicated in laser surgery application of different disciplines in minimally invasive soft tissue surgery, such as phlebology, proctology.

1.2. Contra-Indications

Please consider the instructions for use of the medical laser device and the corresponding specialist medical literature 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 this device may only be applied by physicians being familiar with the handling of medical laser devices, and with the therapeutic application of medical laser fibers.

Follow the current clinical specialist guidelines, in particular for the selection of the source of laser radiation and laser power. Any off-label use of the LGO-Infinity Side Fiber product is fully under the user's responsibility.

By all means the technical fiber 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 in the vicinity of brackets or implants are not allowed because there is the risk of heating and destruction.

1.6. Potential risks associated with the application

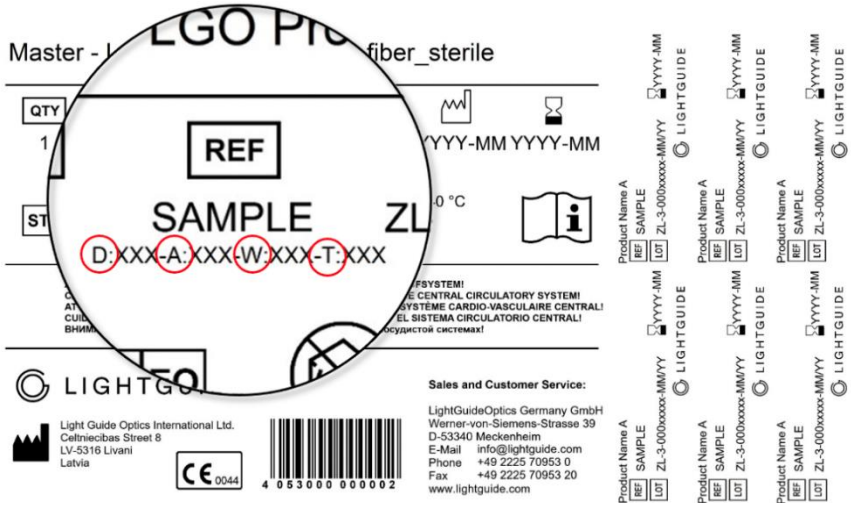
Please refer to the instructions for use of the medical laser device and the corresponding specialist medical literature for a full outline of possible side effects. Possible side effects depend on the medical discipline in which this device is used in. Side effects can be but are not limited to: bruising / ecchymosis / hematoma, paresthesia, thrombosis, pulmonary embolism, induration, burn / necrosis, formation of edema, phlebitis, bleeding, itching, perianal thrombosis, urinary retention, abscess formation, major forms of incontinence, or anismus.

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 LGO-Infinity Side Fiber compatibility with the laser device must be checked. If a laser manufacturer offers the LGO-Infinity Side Fiber product as a genuine accessory product, the compatibility test with the laser device has already been performed and does not need to be performed again.



Picture 2 REF compatibility code

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 10 W.

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

2.2. Precautions

Check the sterile packaging for integrity. Do not use the product if the packaging is damaged or unintentionally opened before use.

The product should be removed from the sterile barrier system and optional plate with special care to avoid product damage.

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-Infinity Side Fiber products must never be bent too tight during the procedure:

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

When using the device in conjunction with an introducer sheath, a cannula, 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.

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 product must not be used if any part of product is damaged or broken.

After connection to the laser device the aiming beam must be visible as laterally 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 product. If these conditions are not fulfilled, the product shall not be used.

The LGO-Infinity Side Fibers may not be operated exposed to air.

Overheating of the quartz glass cap at the tip of the optical fiber is to be prevented:

- the laser power has to be selected appropriately,
- When the laser is active, the optical fiber tip should always be kept in steady motion in the target tissue.

2.3. Application guidelines

Depending on the specific application it is indicated to use the LGO-Infinity Side Fiber probe in conjunction with an introducer sheath, a cannula, a handpiece, or an endoscopic instrument to safely position the tip of the optical fiber probe, hence the laser beam. Details for safe positioning of the optical fiber tip are provided in Section 3. 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. Make use of imaging techniques such as ultrasound for applications in soft tissue when the fiber tip cannot be observed visually to ensure correct positioning and alignment towards the target tissue. Depending on the indication, a continuous irrigation and clear view of the tissue to be treated is only maintained with an endoscopic instrument

Typical treatment parameters and laser settings depend on the individual case. Please consult the specialist medical literature. For direct tissue contact, typical recommended powers are 3 W to 10 W, depending on the laser wavelength used and the associated laser-tissue interaction.

Always start with low power and adjust the laser settings depending on the course of the treatment while observing the effects on the tissue.

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 quartz glass cap. To remove adhered tissues from fiber tip, the fiber should be carefully pulled out of the body, and after some seconds of cool down time tissues can be removed by carefully rubbing of the tissue with a sterile moist swab.

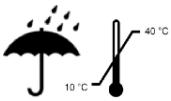
Laser pyrolysis products (gas, steam, particles, infectious aerosols, etc.), which are created during the treatment, should be removed using a suction system above the treatment area.

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 quartz cap. 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.

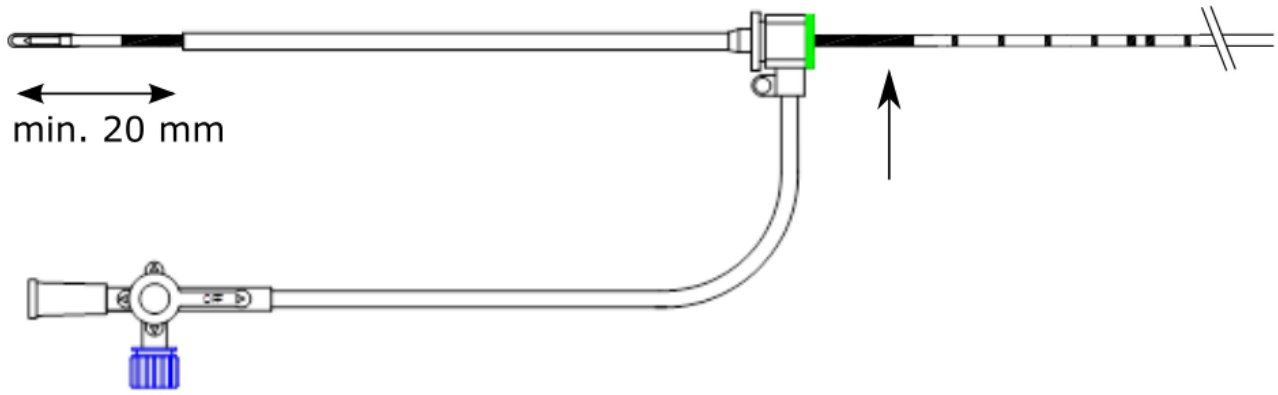
2.4. Symbol explanation

	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 or unintentionally opened before use.
	The product has been sterilized with ethylene oxide (EO).
	Do not reuse. This product is intended for use with a single patient during a single treatment. Sterility and function cannot be guaranteed for reuse.
	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: Indicates the manufacturer of the medical device according to directives 90/385/EEC, 93/42/EEC and 98/79/EC, and regulation 2017/745/EU.
	Batch code: Indicates the batch number of the manufacturer so that the batch can be identified.

3. Application of the LGO-Infinity Side Fiber products with an Introducer Set or other cannulas and instruments

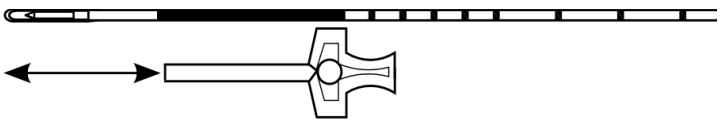
During application of the LGO-Infinity Side Fiber products with an Introducer Set, cannulas and instruments the user must ensure that the quartz glass cap of the optical fiber (distal end) fits through the working channel smoothly and always protrudes completely during the treatment.

For some product variations of LGO-Infinity Side Fiber a suitable Introducer Set is available from LIGHTGUIDE. In this combination, a dedicated marker (long solid bar) will appear on the proximal side of the catheter sheath when leaving about 20 mm of space at the tip and indicating that the catheter must be removed before continuing. The final long solid bar marker indicates that the fiber tip approaches the surface and laser emission must be stopped (see Pic.3).



Picture 3 Fiber positioning in catheter

For the use of the LGO-Infinity Side Fibers in cannulas, marking lines are applied at intervals of 5 mm and 10 mm (see Pic.4). Prior to treatment make yourself familiar with the selected cannula for safe removal of the canula.



Picture 4 Fiber positioning in cannula

LGO-Infinity Hemorrhoid Probe has a squeeze Luer Lock adapters which can be used for fixing the fiber to a handpiece or accessory. Prior to the treatment make yourself familiar with the instrument and the position of the optical fiber probe inside it.

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

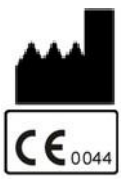
In an unlikely situation of a failure of our product resulting in serious incident, incident report should be sent to Light Guide Optics Sales and Customer Service. If necessary, our complaint submission template is available at https://www.lightguide.com/forms/.

6. Disclaimer

Light Guide Optics International Ltd does not accept any reliability for personal injuries as well as for damages of the laser device due to an inappropriate handling and storage of the LGO-Infinity Side Fiber.

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 does not accept any responsibility neither in terms of the application of the LGO-Infinity Side Fiber nor in terms of possible side effects of the medical laser treatment with this laser fiber probe.



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