Instructions for use
LGO-Dual Luer Lock Handpiece

1. LGO-Dual Luer Lock Handpiece

The LGO-Dual Luer Lock Handpiece is designed as accessory part for medical optical fibers for precise alignment of the fiber tip onto the tissue to be treated. It can hold optical fibers up to a maximum outer diameter of up to approx. 2.5 mm. It is delivered in non-sterile condition. Prior to the first and each subsequent application a reprocessing cycle including sterilization according to section 3 must be conducted.

On both sides the LGO-Dual Luer Lock Handpiece is equipped with Luer Lock connectors (1 x male, 1 x female). They are designed for fixation of the medical optical fiber using a squeeze adapter (Tuohy Borst or equivalent) and / or for connection of additional accessory parts such as LGO-Cannula.

1.1. Field of application and exceptions

The indication is derived from the used medical optical fiber, which the LGO-Dual Luer Lock Handpiece is combined with as an accessory part. Please consult the instructions for use of the respective medical probe.

Surgically invasive procedures are excluded. Additional exclusions are derived from the used medical optical fiber. Please consult the instructions for use of the respective medical probe.

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 physicians 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, of the used medical probe and the corresponding specialist medical literature for a full outline of possible side effects.

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, please contact your technical service or supplier and dispense with the treatment until the problem has been solved fully.

2.1. Application guidelines

a) Mount the optical fiber into the reprocessed and sterilized LGO-Dual Luer Lock Handpiece:
   - Open the squeeze adapter on the optical fiber and insert the fiber from proximal to distal through the handpiece until is protrudes at the distal end.
   - Adjust the medical optical fiber such that the tip protrudes by minimum 5 mm from the handpiece to avoid any heating of the handpiece. In case the handpiece is used in conjunction with a cannula for the same reason the fiber tip must protrude minimum 5 mm from the cannula.
   - Fix the squeeze adapter.
   - Confirm that the fiber is fixed by gentile, straight pulling on the proximal end of the medical optical fiber and check the position of the tip again.

b) Use on the patient:
   - Move the medical optical fiber with the LGO-Dual Luer Lock Handpiece slowly towards tissue to be treated, without contact to the tissue.

- Use the handpiece and the aiming beam to adjust the medical optical fiber to the tissue to be treated. Do not start the laser before having identified the tissue to be treated and having aligned the optical fiber correctly.
- Start the treatment. For new alignments and for correcting the position use only the aiming beam and to not activate the laser.

c) After the treatment:

- Separate the Medical optical fiber, squeeze adapter and any additional accessory parts such as the LGO-Cannula from the LGO-Dual Luer Lock Handpiece and dispose of or reprocess separately.
- Perform the reprocessing and sterilization of the LGO-Dual Luer Lock Handpiece according to section 3.

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.

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. Please consult the instructions for use of the respective medical probe.

2.3. Symbol explanation

Non-sterile: Indicates a medical device which was not subjected to a sterilization process.

Caution: Indicates the need for the user to consult the instructions for use regarding important and safety related content such as warnings and precautions.

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

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

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

3. Reprocessing of the LGO-Dual Luer Lock Handpiece

Effective cleaning and disinfection are essential preconditions for an effective sterilization. The instructions for reprocessing are the basis of the reprocessing procedure for the LGO-Dual Luer Lock Handpiece. This instruction is included with every delivery and can be requested free of charge in case of loss. The reprocessing of the product may only take place according to the instructions outlined there. In case of deviations there can be no sterility assumed for the product.

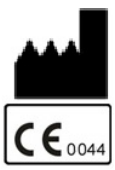
Because of the design of the product and the used materials LGO does not define a limit for the lifetime of the LGO-Dual Luer Lock Handpiece. The end of the life time is typically determined by damage and wear resulting from use, e.g. of the thread. During the course of each subsequent reprocessing cycle the product must be inspected for its function and must be replaced, if necessary. For details consult the instructions for reprocessing.

4. 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 product.

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-Dual Luer Lock Handpiece nor in terms of possible side effects using LGO-Dual Luer Lock Handpiece in the medical laser treatment.



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