Reprocessing instructions for reusable bare fibers

Manufacturer: Light Guide Optics International Ltd

Products: All reusable bare fibers manufactured by Light Guide Optics International Ltd which have articles numbers starting with RBFF, RBFCS, or RTBFCS.

Please note that these medical devices are delivered in sterile or non-sterile condition, depending on the product variation. Therefore, check the device label carefully to determine if the device needs to be subjected to full reprocessing cycle according to the following instructions prior to its first use.

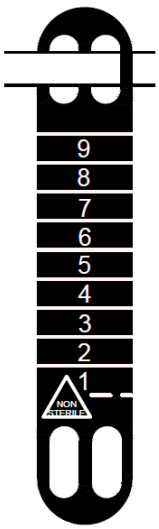
WARNINGS:

In general, cleaning and disinfection should be done immediately after use to avoid drying of blood residues. Such dried contamination is much harder to remove.

Ensure the laser coupling area at the connector remains clean and free of contaminations; it cannot be cleaned and disinfected.

Possibly a high risk of infection after a surgical intervention results from the utilisation at patients for which prion diseases are assumed or detected. In this case the reconditioning is not possible and the product must be disposed of according to the regulations.[1]

Limitations on processing:



The reusable fiber-optic product is designed and tested to withstand ten cycles of application and processing. Every reusable fiber probe is equipped with a plastic marker to record the accumulated number of performed processing cycles. During each device processing cycle, cut the outermost line of the marker from one to nine to record the number of uses. Note that the first dashed line may represent processing for use in case of non-sterile delivery or processing after use in case of sterile delivery.

Dispose any product, which is broken or kinked, and dispose any product, which has a contaminated laser coupling area at its connector, because cleaning and disinfection of the laser coupling area of a connector is not possible.

[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.

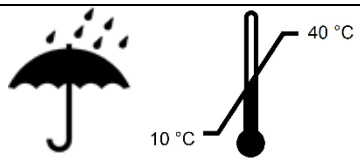
INSTRUCTIONS:

Initial treatment at the point of use:	Attach the protection cap to the connector immediately after disconnecting from the laser port with clean hands or gloves. Ensure the laser coupling area at the connector (protected by the cap) remains clean and free of contaminations; it cannot be cleaned and disinfected. Rinse the product using cold tap water and a soft cloth. Remove all visible superficial residues of blood and tissue. Strip the outermost plastic protective jacket from the distal end on approximately 4 cm using an appropriate fiber stripper. Next, cut the used tip at around 0.5 cm from the jacket. Ideally, scratch the fiber carefully with a cleaving tool or a ceramic blade and pull it apart along the fiber axis. Reconnect to the laser port and verify the beam profile: a symmetric and circular beam profile is desired for optimum energy transfer in the next treatment. In case of asymmetric light output and scattering cut the tip again and verify anew. Attach the protection cap to the connector immediately after disconnecting from the laser port and wind the fiber in a coil. The fiber coil diameter must be at least 20 cm.
Preparation before cleaning:	Ensure the protection cap is attached firmly to the connector and the fiber coil diameter is at least 20 cm.
Cleaning and disinfection, automated:	Equipment: A washer-disinfector complying with the ISO 15883 series and suitable baskets matching the size of the coiled fiber. Cleaning agent: certified cleaning agent for automated cleaning of medical instruments: neodisher mediclean, Dr. Weigert GmbH & Co. KG, Hamburg, Germany 1. Place product in a basket inside the washer-disinfector 2. Select a cycle with at least the following steps and minimum temperature and minimum 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, inspect the product for visual pollution. If necessary, repeat the cycle or perform manual cleaning.

Drying:	No particular requirement as stand-alone process, if part of the automated cleaning and disinfection process. Else, ensure the gaps at the connector are dry.
Function testing:	While the protection cap is attached to the connector, perform a visual inspection along the optical fiber to exclude residual pollution. Repeat the cleaning and disinfection if necessary. Check the fiber and connector for kinks, breaks, corrosion, or wear. The fiber protection jacket must be intact all along the product. Dispose a damaged product. Remove the connector cap and inspect the laser coupling area under 100x magnification, for example with a fiber optic inspection scope. Verify the surface does not have scratches larger than 1 µm or digs larger than 10 µm, and is free of residues from cleaning. Residues can potentially be removed with a lint-free cloth for optics soaked with Isopropyl. Dispose a product, if it does not meet these quality criteria.

Packing:	Wind the fiber in a coil. The fiber coil diameter must be at least 20 cm. Use standardized paper-foil sterile pouches, single or double packed. Use only one item per sterile pouch and make sure its connector protection cap is not attached inside the sterile pouch. The sterile pouch must be large enough to fit the coiled product without putting tension on the seals or on the product.
Sterilization:	Sterilization only permitted with moist heat in a process according to ISO 17665 series. Parameters: at minimum 20 min at 121°C or at minimum 4 min at 132°C When sterilizing several products consider the maximum load of the autoclave
Storage:	 The product must be kept in a dry place and at the temperature range between 10°C and 40°C. Mind the instructions of the packing material.

Instruction for reprocessing compiled in the style of EN ISO 17664:2018 appendix B.

The 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 processing, as actually performed using equipment, materials and personnel in the processing 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.

Please note that potentially existing local requirements for reprocessing must be taken into consideration in any case.

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