Reprocessing instructions
Cleaning and steam autoclave
for reusable handpieces and their accessory parts

Manufacturer:	Light Guide Optics International Ltd
Products:	All reusable handpieces and their accessory parts manufactured by Light Guide Optics International Ltd which have got articles numbers starting with HAP or CAN.

Please note that these medical devices are delivered in non-sterile condition and therefore have to be subjected to the full reprocessing cycle according to the following instructions prior to the first use and any subsequent use.

WARNINGS: 	Particular attention is required when cleaning long and tight cannulas. 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. Possibly a high risk of transmission 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 reprocessing:	Frequent reprocessing has got little impact on these products. 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, see section “function testing” and must be replaced, if necessary.

[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.

INSTRUCTIONS:

Point of use:	See warnings
Preparation for decontamination:	The products must be decomposed into the individual parts so that all openings and threads are easily accessible. Hollow spaces must be rinsed using cold tap water. Obvious pollution on the external surface must be removed with a disposable paper towel.
Cleaning and disinfection, automated:	Equipment: certified washer/disinfection appliance with rinse connector for female Luer-Lock connector: Miele G 7836 CD with mobile injector unit for Luer-Lock connector, Miele & Cie. KG., Gütersloh, Germany Cleaning agent: certified cleaning agent for automated cleaning of medical instruments: neodisher mediclean, Dr. Weigert GmbH & Co. KG, Hamburg, Germany Place products in the washer and secure the rinse connectors Select cycle with the following minimum duration and temperatures:

cleaning	55°C	10 minutes
disinfection	93°C	10 minutes
final rinse	not critical	2 minutes
drying	90°C	15 minutes

Upon removal from the washer inspect the products for visual pollution. If necessary, repeat the cycle or perform manual cleaning.

Cleaning, manual:

Equipment: running water, brush, syringe with thread for female Luer-Lock connector: REF 4606728V, B.Braun Melsungen AG, Melsungen, Germany

Cleaning agent: certified cleaning agent for manual cleaning of medical instruments: Cidezyme (REF 2258), Johnson & Johnson GmbH, Neuss, Germany

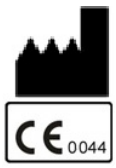
1. Immerse the products in cold water for at minimum five minutes.
2. Use a brush to remove any pollution, also in the area of the threads and openings as far as accessible.
3. Rinse every hollow space at minimum five times with each 10 ml of cleaning solution with the help of a syringe with Luer-Lock connector.
4. Immerse the products in cleaning solution for at minimum five minutes.
5. Again, rinse every hollow space at minimum five times with each 10 ml of cleaning solution with the help of a syringe with Luer-Lock connector.
6. Rinse the products thoroughly under running water. Also rinse every hollow space using a syringe with Luer-Lock connector. Hold the products such that the water runs out.

Disinfection, manual:	Equipment: sterile, deionized water, syringe with thread for female Luer-Lock connector: REF 4606728V, B.Braun Melsungen AG, Melsungen, Germany Disinfection agent: certified disinfection agent for medical instruments: Cidex OPA (REF 20391), Johnson & Johnson GmbH, Neuss, Germany 1. Rinse every hollow space at minimum five times with each 10 ml of disinfection agent with the help of a syringe with Luer-Lock connector. 2. Immerse the products in disinfection agent for at minimum 12 minutes. 3. Again, rinse every hollow space at minimum five times with each 10 ml of disinfection agent with the help of a syringe with Luer-Lock connector. 4. Rinse the products thoroughly externally at minimum three times with each 10 ml of sterile, deionized water. Then rinse every hollow space at minimum twice with the help of a syringe with Luer-Lock connector. 5. Dry the products using filtered sterile pressurized air. 6. Inspect the products for visual contaminations. If necessary, repeat the entire cleaning cycle.
Function testing:	Perform visual inspection for damage and wear, check the thread for free movement.
Packing:	Use standardized paper-foil sterile pouches, single or double packed. Use only one item per sterile pouch. The sterile pouch must be large enough to fit the product without putting tension on the seals.
Sterilization:	Equipment: vacuum autoclave (fractional vacuum process) Parameters: at minimum 20 min at 121°C or at minimum 4 min at 134°C, when sterilizing several products consider the maximum load of the autoclave
Storage:	No particular requirements for the products. Mind the instructions of the packing material.

Instruction for reprocessing compiled in the style of DIN EN ISO 17664:2004 appendix B.

The instructions provided above have been validated by the medical device manufacturer as being capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires 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.



Light Guide Optics International Ltd.
Celtniecibas Street 8
LV-5316 Livani
Latvia

Light Guide Optics Sales and Customer Service:
LightGuideOptics Germany GmbH
Tel. +49 2225 70953 0
Fax +49 2225 70953 20
E-Mail info@lgoptics.de
Release of this version on: 2020-06-29