Instructions for reconditioning

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1. Intention

This instruction serves as a guideline for the reconditioning of Light Guide Optics International Ltd (hereinafter also referred to as LGO) reusable fibre products.

This instruction applies to all versions of LGO reusable fibre products.

This instruction informs the readership on framework conditions of the reconditioning of LGO reusable fibre products. It describes the general fundamentals as well as the procedure of reconditioning, alerts and provides important information on the operational safety of reconditioning. Beyond this, the interested person receives instructions in dealing with LGO reusable fibre products before, during and after the reconditioning.

We strongly recommend that you read this instruction completely before using the LGO reusable fibre products.

LGO reserves the right to update this instruction on the basis of the latest technological, medical or regulatory findings and regulations.

This instruction is included in the scope of delivery of our reusable fibre products, and can be requested free of charge in cases of loss. Please contact us, if you have any questions. You will find the address in the appendix.

Any general deviation from this instruction (such as the application of other sterilisation processes or of procedural modifications in the instruction or mechanical cleaning and disinfection) is the user’s responsibility.

LGO does not accept liability for damages to persons, damages to devices as well as damages to products resulting from the non-compliance with or infringement of the warnings, guidelines, procedures and hints which are described in this instruction.

Furthermore, our general terms and conditions are valid.

2. Delivery

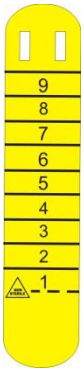
2.1. Non-sterile delivery:

For non-sterile delivered LGO reusable fibre products, the fibre products have to be sterilised or disinfected according to these instructions before the first application. The fibre products have to be reconditioned accordingly to this instruction after every application.

2.2. Sterile delivery:

The fibre product is usable for the first application without pre-treatment.

3. Restriction of the reconditioning



LGO guarantees **ten** cycles of application as well as **ten** cycles of reconditioning.

Every LGO reusable fibre product is equipped either with an electronic RFID tag in the plug and/or with a plastic marker positioned near the proximal fibre end. This indicates the number of performed cycles of reconditioning.

Every performed cycle of reconditioning and utilization can be marked by cutting off of the plastic marker area along the line **beneath** the corresponding cycle number.

The first reconditioning is documented by cutting off along the dashed line. If all numbers are cut off, then the maximal number of guaranteed cycles of reconditioning has been attained.

The dashed line prior to the cycle number **1** serves any longer for the labelling of the performed initial disinfection or initial sterilisation at the non-sterile delivery. Hereafter, nine further cycles of reconditioning still are possible.

4. General information on reconditioning

Caution! *The reconditioning of fibre products and the preparation of the distal end may only take place according to the instructions outlined here.*

Caution! *Fibre products which are contaminated with pathogen agents can be a source of human infections. Thus, the application of such medical devices requires a previous proper reconditioning.* [1]

The usual conditioning comprises the following individual steps:

1. proper preparation / disposal
2. cleaning / disinfection, rinsing and drying
   a) automatic
   b) manual (only permissible in the case of non-availability of a mechanical procedure)
3. testing
   a) cleanliness and intactness

[1] See. § 3 Nr. 14 MPG.

b) technical and functional safety

4. packaging
5. labelling
6. sterilisation

The conditioning finishes with the documented release of the fibre product.

Only persons with the verifiably required expertise and experience as well as structural / technical requirements and means may perform the conditioning. All procedures which are used in the medical products have to be validated[2].

Furthermore, the conditioner has the obligation to guarantee that the reconditioning process including resources, material and staff is suitable to achieve the required results.

5. Other relevant information

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 fibre products. The frequency of use is determined by the specified instruction at the label as well as by the careful treatment of fibre products according to the instructions. Damaged products have to be disposed.

Possibly a high risk of transmission after a surgical intervention results from the utilisation of LGO fibre products and application systems at patients for which prion diseases are assumed or detected.

The reconditioning processes which are prescribed in this case would damage the fibre products in such a manner that a renewed utilization would not be possible. Thus, the LGO fibre products have to be demolished after application in the previously described case according to the regulations.[3]

Information: *In order to avoid TASS (Toxic Anterior Segment Syndrome), great care must be taken to ensure that the applied alkaline or enzymatic cleaning agents or disinfectants are rinsed off or neutralized fully.*

Information: *During pre-cleaning, cleaning and disinfection should be ensured by the process management that there is no fixation of residues, as these affect the cleaning, disinfection and sterilization performance.[4]*

Caution! *Defective products have to pass through the total reconditioning process before sending back for the verification of complaint.*

Caution! *The bending diameter must not be beyond 200mm throughout the entire reconditioning process. A lower deviation of the bending diameter may result in a damage of the LGO fibre products and endanger patients as well as users in the context of the application.*

[2] The validation is the supply of an objective proof that all quality requirements addressed to the process are fulfilled and that the process repeatedly supplies products that meet the given specifications.
[3] 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.
[4] See Bundesgesundheitsblatt 2012; 55: Hygiene requirements in the processing of medical devices“, 2012, p. 1254.

Caution! *The plug protective cap has to be attached after application. The proximal end (protected by the plug protective cap) does not undergo any cleaning and disinfection. The plug protective cap has to be removed before any sterilization.*

Caution! *LGO reusable fibre products consist of glass-like materials. Extreme temperature fluctuations inevitably result in material cracking. Thus, the fixed temperature parameters as well as the sequence of processes have to be met by all means.*

Information: *Light Guide Optics International reserves the right to make modifications based on new technologies and findings.*

6. Fundamentals of reconditioning

All LGO reusable fibre products have to be cleaned, disinfected and sterilised prior to any use. This is not only valid for the first-time utilisation of sterilely delivered products.

Caution! *Effective cleaning and disinfection are essential preconditions for an effective sterilization.*

Caution! *Due to the substantially higher reproducibility, always a mechanical procedure should be used for the cleaning and disinfection.* [5]

Caution! *Automated thermal cleaning and disinfection procedures are primarily from chemical or chemo-thermal method to use because of the more reliable efficiency for reprocessing.* [6]

This instruction describes validated procedures for the cleaning / disinfection and sterilisation of LGO reusable fibre products.

Please note in this connection that the equipment-specifically as well as product-specifically validated procedures and the parameters predefined in this instruction have to be met at each cycle. More detailed information on the validation are given in the appendix, top 11.2 (validation data) according to the type of reconditioning procedure.

Please bear in mind fundamentally that the applied devices (disinfector, sterilizer) have to be maintained and tested regularly. Please consult the specific user's instruction and servicing instruction.

All valid legal regulations as well as the valid hygiene rules of the conditioner (hospital or clinic) have to be met furthermore.

[5] See „Bundesgesundheitsblatt" 55: Hygiene requirements during conditioning of medical devices, 2012, page 1250.
[6] See „Bundesgesundheitsblatt" 55: Hygiene requirements during conditioning of medical devices, 2012, page 1254.

Information: *Due to the intended application and the type of construction of the LGO reusable products, LGO recommends the classification of their products as „critical A“ (without special requirements in regard to the conditioning).*[7]

7. Reconditioning

7.1. Proper preparation / disposal

7.1.1. Preparation on site and transport

Caution! *Never disconnect the fiber product with contaminated gloves from the laser device. A contamination of the coupling region with the ferrule protected by the protective cap must be absolutely avoided. Dispose contaminated fiber products, because the reprocessing of the coupling region is not possible.*

Caution! *The plug protective cap has to be attached on the ferrule directly after the separation of the fibre product from the laser equipment.*

Caution! *In order to prevent damages at the LGO reusable fibre products during the process of transportation as well as to prevent environmental contaminations the fibres only have to be transported within a suitably closed container.*

7.1.1.1. Manual pre-cleaning

Caution! *The proximal end (protected by the plug protective cap) is not subjected to cleaning and disinfection.*

Caution! *To avoid the fixation of proteins, use in the precleaning none of the following active substances: aldehyde, alcohol and peracetic acid.*

In this context, the use temperature of the cleaning and disinfectant solution up to 45°C may be allowed.

Immediately after application, coarse contaminants of the fibre products have to be removed under surgical conditions.

Procedure:

1. Clean the fibre product several times lengthwise in the field of application with a clean lint-free cloth and remove visible residues of blood and tissues.
2. Then use cold running water or a disinfectant solution in order to remove adhering residues of blood and tissue. In this connection, rinse the plug with the attached protective cap very intensively.

[7] See above; table 1 risk evaluation and classification of medical devices prior to conditioning, page 1248.

Information: *Use only soft brushes or clean lint-free clothes to remove manually the soiling. Don't use hard objects such as surgical instruments or metal brushes even for stubborn soiling.*

7.1.1.2. Preparation of the distal fibre end

During or after the manual pre-cleaning, the distal end of the LGO reusable fibre product has to be conditioned newly. If possible, perform the preparation in the OP or under surgical conditions because the fibre has to be tested subsequently by means of the laser device. Pay particular attention to ensure that the proximal fibre end as well as the laser device is not contaminated during the process of cleaning. If your surgical processes enable the preparation, perform the preparation directly after application and cleaning process with the still connected fibre product.

Proposed procedure:

1. Clean the fibre product several times lengthwise in the field of application with a clean and lint-free cloth and remove visible residues of blood and tissues.
2. Remove the outer plastic sheath as well as the silicon layer (if present at the product) from the fibre for a length of approximately 40mm using an appropriate stripper.
3. Break off (cut off) the used fibre approximately 5mm below the sheath end by means of the tool for fibre conditioning or a ceramics cutter. For this purpose, scratch the light conductor carefully and break it off at the cut surface by pulling in the longitudinal direction of the fibre.
4. Examine the beam pattern by means of the pilot beam of the laser (steady round without scattering). Repeat the process of preparation in the case of too high light scattering.
5. Separate the fibre product from the laser after the successful preparation, and directly attach the plug protective cap to the ferrule in order to protect the proximal fibre end.

7.2. Automated cleaning / disinfection, rinsing and drying

7.2.1. General information on the application of cleaning / disinfection devices

- The device has to comply with the requirements of EN ISO 15883/AAMI ST15883. The device also has to exhibit a proven efficacy.
- The device should hold an approved program for thermal disinfection in conformity with EN ISO 15883/AAMI ST15883 (A0 value > 3,000).
- The program used has to be suitable for the instruments and has to enclose a sufficient number of rinsing cycles.
- Use only sterile, deionized water to final rinse.
- Make sure that the air used for drying is filtered.

7.2.2. General information on the applied cleaning agent or disinfectant, respectively

- In principle, the cleaning agent has to be suitable for the cleaning of instruments consisting of metal and plastics.
- Unless thermal disinfection is used – make sure, that a suitable disinfectant with proven efficacy (such as DGHM/VAH or FDA certification or CE marking) is applied and that this disinfectant is compatible with the used cleaning agent.
- If an alkaline cleaning agent is used, an adequate neutralisation has to be performed in accordance with the information received from the chemicals producer.
- Make sure that the used chemicals are compatible with the instruments.

Caution! *The concentrations of the cleaning agent and disinfectant as specified by the producer have to be met.*

Caution! *The user is responsible for a deviation from this instruction (such as other sterilisation processes or deviations in the manual or automated cleaning and disinfection).It is the responsibility of the user to validate his process correspondingly. LGO will accept no liability for damage to products resulting from non-conformities with the present instruction. By virtue of different microbiological contaminations due to particles and residues in the cleaning / disinfection device, the clinic has to guarantee on its own authority the prescribed maintenance of the cleaning / disinfection device inclusive the corresponding filters in order to guarantee that not only contaminated solutions come in contact with LGO fibre products. The listed temperature parameters as well as cycle parameters do not damage the product.*

7.3. Machine workflow

Caution! *During the entire process of automatic reconditioning, the bending diameter must not be beyond 200mm. A shortfall of the bending diameter may result in a damage of the LGO fibre product and endanger patients as well as users in the course of application.*

Caution! *The proximal end (protected by the plug protective cap) will not be cleaned and protected.*

7.3.1. Thermal reconditioning

The program Vario-TD is validated for the thermal reconditioning of LGO reusable fibre producs.[8] Please clean the fibres in accordance with the procedure described below. The process sequence is binding and shall not be modified:

1. Fold up the fibres circularly with a diameter of at least 200mm.
2. Position maximal three fibres one about the other in a separate basket of instruments (steel box) or a similar object and fix this basket of instruments with an appropriate subject (grid) in order to avoid the change of the position of the fibres by the water pressure during cleaning and to avoid a possible damage of the fibres.
3. Position the basket of instruments in the cleaning device at an appropriate location.
4. Start the program.

Procedure (parameter):

	operation	**temperature (°C)**	**length (minimum in minutes)**	**cleaning agent**
1	pre-rinsing	5-26	5	
2	cleaning	50-55	5	yes
3	intermediate rinsing	25-30	5	
4	disinfection	90-136	5	
5	drying	15-135	5	

1. Remove the fibres from the cleaning device and disinfection device at the end of the program.
2. Test the fiber products in accordance with point 7.5. (Testing) of this instruction.

[8] See point 11 (Appendix)

7.3.2. Chemical reconditioning

Caution! *In case of chemical disinfection there is the* danger of remnants of disinfectants in cavities as well as on the surface of the instruments.

Caution! Extreme differences in temperature and rapid temperature changes between cleaning cycles and flushing cycles have to be avoided by all means.

A chemical-thermal recondition process is validated for LGO reusable fibre products as an alternative to the thermal reconditioning.[9] A maximal temperature of 55 °C may not be exceeded during the entire program sequence. Please clean the fibres following the procedure described hereafter. The procedure is obligatory and must not be modified:

1. Fold up the fibres circularly with a diameter of at least 200mm.
2. Position maximal three fibres one about the other in a separate basket of instruments (steel box) or a similar object and fix this basket of instruments with an appropriate subject (grid) in order to avoid the change of the position of the fibres by the water pressure during cleaning and to avoid a possible damage of the fibres.
3. Position the basket of instruments in the cleaning / disinfection device at an appropriate location.
4. Start the program.

Procedure (parameter):

	operation	**temperature (°C)**	**length (minimum in minutes)**	**cleaning / disinfection agent**
1	pre-rinsing	8-12	1	
2	cleaning	45-55	5	yes
3	intermediate rinsing	25-30	5	
4	disinfection	53-55	5	yes
5	final rinsing	8-12	2	
6	drying	15-135	5	

1. Remove the fibres from the cleaning / disinfection device at the end of the program.
2. Test the fibre products in accordance with point **Error! Reference source not found.** (Testing).

Information: *If necessary, one may redry by means of a lint-free, sterile cloth. If necessary, grooves and cavities in the plug area have to be blown out with sterile-filtered compressed air (<4 bar) and thereby redried.*

[9] See point 11 (Appendix).

7.4. Manual workflow

Caution! *Due to the fundamentally reduced efficiency and reproducibility of the manual workflow, the manual workflow only is permissible in the case of non-availability of an automated process!*

Caution! *If an ultrasonic cleaning device is used, one has to ensure within the selection of the used cleaning agent and disinfectant that the cleaning agent is suitable for ultrasonic cleaning, and that there is no foam development during the cleaning procedure.*

Caution! *Combined cleaning agents and disinfectants should not be used as far as possible. Only in case of extremely low contamination (no visible impurities) combined cleaning agents and disinfectants can be used.*

Caution! The concentration and reaction times prescribed by the manufacturer of the cleaning agents and disinfectants must be strictly observed*. Use only freshly prepared solutions, only sterile or low-germ (max. 10 germs/ml) as well as low-endotoxin (max. 0.25 units of endotoxin /ml) water (such as purified water / highly purified water, the FDA recommends deionized or reverse-osmosis filtered Water) or only filtered air for drying, respectively.*

Caution! *During the entire process of machine reconditioning, the bending diameter must not be beyond 200mm. A shortfall of the bending diameter may result in a damage of the LGO fibre product and endanger patients as well as users in the course of application.*

Caution! *The proximal end (protected by the plug protective cap) is not subjected to cleaning and disinfection.*

7.4.1. Manual cleaning and disinfection

In order to recondition LGO Reusable fibre products in particular cases without an availability of an automated procedure, a manual reconditioning procedure is validated by the manufacturer.[10]

Please clean the fibres following the procedure described hereafter.

The procedure is obligatory and must not be modified:

7.4.1.1. Cleaning procedure:

1. Fold up the fibres circularly with a diameter of at least **200mm** and fix the fibre in this position by striking the distal end.
2. Dip now the fixed fibre for at least **five minutes** in cold (**5-20 °C**) freshly distilled or deionised water.
3. Remove blood residues or cellular residues by means of a soft brush or a sterile, lint-free cloth. On this occasion, work thoroughly and carefully in the plug area. Move **multiple** mobile plug elements and devote special care to dents and grooves.
4. Flush the plug area by means of a syringe at least **five times** with **10mL** rinsing solution.
5. Insert the fibre product for at least **five times** into the rinsing solution.
6. Flush the plug area once more by means of a syringe at least **five times** with **10mL** rinsing solution.

[10] see point 11 (Appendix).

7. Remove the fibre product from the cleaning bath and flush it at least **three times** for a time period of **15 seconds** thoroughly by means of a water pistol and sterile, deionised water. Use at least one flushing cycle (**15 seconds**) for the plug, and thereby hold the fibre product downwards so that the water can run off.
8. Control whether the fibre product is cleaned successfully. Repeat the purification if visible impurities still are present at the product!

7.4.1.2. Disinfection procedure:

1. Flush the plug area by means of a syringe at least **five times** with **10mL** disinfectant solution.
2. Immerse the fibre product for at least **12 minutes** in the disinfectant solution.
3. Flush the plug area once more by means of a syringe at least **five times** with **10mL** cleaning solution.
4. Remove the fibre product from the disinfection bath and flush it at least **three times** for a time period of nearly **15 seconds** thoroughly with a water pistol and sterile, deionised water. Use at least one flushing cycle (**15 seconds**) for the plug, and thereby hold the fibre product downwards so that the water can run off.
5. Control whether the fibre product is cleaned successfully. Repeat the entire cleaning and disinfection procedure, even if there are visible impurities at the product!
6. Dry the product with sterile filtrated compressed air.
7. Test the fiber products in accordance with point 7.5. (Testing).

7.5. Testing

7.5.1. Macroscopic visual inspection

Test the LGO fibre product after cleaning and disinfection against corrosion, damaged surfaces, splintered materials and contaminations.

Dispose of the damaged fibre products.

7.5.2. Microscopic inspection

Remove the plug protective cap.

Control the proximal fibre end area at the plug at 100-fold resolution with a microscope (fiberscope).

The proximal fibre end area as well as the distal fibre abutting face may not exhibit scratches, residues or discolorations due to cleaning agents or disinfectants, respectively. Cleaning residues can be removed by means of a sterile, lint-free cloth as well as 2-propanol**.**

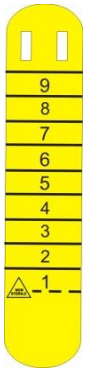
Dispose of the damaged fibre products.

8. Labelling of the reconditioning process / packaging

Caution! *The bending diameter must not be beyond 150 mm. A shortfall of the bending diameter may result in a damage of the LGO fibre product and endanger patients as well as users in the course of application.*

Caution! *Never pack up the LGO reusable fibre products with attached plug protective caps.*

8.1. Process of labelling and packaging:



1. Label the performed cycle of reconditioning by cutting off of the next cycle number of the plastic marker on the left side of this page. For that purpose use a sterile scissors.
2. Remove the plug protective cap (if attached).
3. Fold up the fibres circularly with a diameter of at least 150mm and fix the fibre in this position by striking the distal end.
4. Pack up the fibre products in suitable disposable sterilisation packages (single and double wrapping) corresponding to the following requirements:
    - ISO/ANSI AAMI ISO 11607
      Suitable for seam sterilisation (temperature resistance up to at least 134 °C (273 °F), sufficient vapour permeability).
    - Suitable for Ethylene oxide (EO) sterilisation (temperature resistance up to at least 60 °C (140 °F), sufficient gas and vapour permeability).
    - Sufficient protection of fibre products or sterilisation packages, respectively, against mechanical damages.

9. Sterilisation/Release

Caution! *A sterilisation with attached plug protective cap is not permitted.*

Information: The times and temperatures specified are minimum requirements below which these values must not fall. If processing reasons require a derivation downwards, this deviation should be validated by the user. An exceedance of the times and temperatures specified fundamentally is possible. However, longer sterilization times result in an enhanced material loading and thus to a premature aging of the products. Only cleaned and disinfected products should be sterilised. Other sterilisation processes (such as hot air sterilisation, formaldehyde sterilisation, radiation sterilisation and low temperature – plasma - sterilisation) are performed outside of the responsibility of the manufacturer. Consider the respective applicable standards in this case. Verify the suitability and the principal efficiency of the process (where required, inclusive residue studies of the sterilisation agent) under consideration of the technical properties as well as the specific product geometry within the framework of a validation process.

9.1. Steam sterilisation

The steam sterilisation is subject to the following criteria:

- fractionated vacuum process
- steam sterilizer according to EN 13060-2004, EN 285, AAMI/ANSI ST55, respectively
- validated according to ISO/ANSI AAMI ISO 17665 (valid commissioning and product-specific performance evaluation)
- maximal sterilization temperature 134 °C (273 °F); (in addition tolerance according to EN ISO/ANSI AAMI ISO 17665)
- sterilisation time (exposition time at the sterilisation temperature) at least 20min at a temperature of 121 °C (250 °F) or alternatively at least 5min at a temperature of 134 °C (273°F)

9.2. Ethylene oxide (EO) sterilisation

Use an excess pressure process (with sufficient product drying) under consideration of the following criteria:

- EO sterilizer according to EN 1422, ASME, cGMP, ANSI/AAMI/ISO 11135-94, FDA, NFPA 560, NFPA 70 and USNEC

- Validated according to EN ISO/ANSI AAMI ISO 11135 (valid IQ/OQ commissioning and product-specific performance evaluation (PQ))
- maximal sterilisation temperature 50°C (122°F; in addition tolerance according to EN ISO/ANSI AAMI ISO 11135
- sterilisation time (exposition time at the sterilisation time) at least 120min at a temperature of 45°C (113°F)
- Residual amount of EO according to ISO/ANSI AAMI ISO 10993-7

10. Storage

After sterilisation the LGO reusable fibre products have to be stored in a sterilisation packaging within a dry and dust-free environment at temperatures between 10 °C and 40 °C.

11. Appendix

11.1. Material resistance

When selecting the cleaning agents and disinfectants, please pay attention, that the following components are not included:

- organic, mineral and oxidizing acids (maximum permissible pH value 11, neutral / enzymatic cleaner recommended)
- strong alkaline solutions
- organic solutions (such as alcohols, ether, ketones, gasolines)
- oxidation agents (such as hydrogen peroxides)
- halogenes (chlorine, iodine, bromine)
- aromatic / halogenated hydrocarbons
- salts of heavy metals

11.2. Data of validation

11.2.1. Thermal reconditioning

validated by:	Medical Device Services, Dr. Rossberger GmbH 82205 Gilching
test no.:	132361-10
used cleaning agent:	neodisher mediclean, Dr. Weigert GmbH & Co. KG, Hamburg
used cleaning / disinfection devices:	Miele G 7836 CD, Miele & Cie. GmbH & Co., Gütersloh
program:	D-V-MEDICLEAN[11]

[11] Based on the DES-VAR-TD procedure developed by Miele under worst case conditions.

Parameter:

operation	temperature (°C)	length (minutes)	cleaning agent
cleaning	50	5	0,2% (33ml/L)
thermal disinfection	90	5	

11.2.2. Chemical reconditioning

validated by:	Medical Device Services, Dr. Rossberger GmbH 82205 Gilching
test no.:	074104-10-B
used cleaning agent (1):	neodisher medizym, Dr. Weigert GmbH & Co. KG, Hamburg
used disinfectant (2)	neodisher Septo DN, Dr. Weigert GmbH & Co. KG, Hamburg
used cleaning / disinfection device:	Miele G 7836 CD, Miele & Cie. GmbH & Co., Gütersloh
program:	MEDIZYM-SEPTODN[12]

Parameter:

operation	temperature (°C)	length (minutes)	Cleaning agent
pre-rinsing	10 +/- 2	1	
cleaning	45 +/- 2	5	(1) 0.2 % (2ml/L)
disinfection	55 +/- 2	5	(2) 1.0 % (10ml/L)
final rinsing	10 +/- 2	2	

11.2.3. Manual cleaning and disinfection

validated by:	Medical Device Services, Dr. Rossberger GmbH 82205 Gilching
test no.:	074104-10-A
used cleaning agent (1):	Cidezyme, Artikel Nr. 2258, Johnson&Johnson Medical Ltd, Gargrave, Skipton
used disinfectant (2)	Cidex OPA, Artikel Nr. 20391, Johnson&Johnson Medical Ltd, Gargrave, Skipton

[12] Based on the CHEM_DESIN process developed by MIELE under worst case conditions.

Parameter:

operation	**temperature (°C)**	**length**	**cleaning agent**
pre-cleaning product	5-20		running water
pre-cleaning plug	5-20	5 times	syringe (10ml)
cleaning product	5-20	5 minutes	(1) cleaning solution 1.6 % (V/V)
cleaning plug	5-20	5 times	(1) syringe (10ml) with cleaning solution 1.6 % (V/V)
rinsing	5-20	3 times	Sterile, deionised water
disinfection product	5-20	12 minutes	(2) disinfection solution
disinfection plug	5-20	5 times	(2) syringe (10ml) with disinfection solution
final rinsing	5-20	3 times	Sterile, deionised water

11.2.4. Steam sterilisation

validated by:	Medical Device Services, Dr. Rossberger GmbH 82205 Gilching
test no:	074105-10

11.2.5. Ethylene oxide (EO) sterilisation

validated by:	Medical Device Services, Dr. Rossberger GmbH 82205 Gilching
test no:	074106-10

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