Processing (cleaning, disinfection, and sterilization) of cannulas

1 Fundamental points

All cannulas are to be cleaned, disinfected, and sterilized prior to each application; this is required as well for the first use after delivery of the unsterile cannulas (cleaning and disinfection after removal of the protective packaging, sterilization after packaging). An effective cleaning and disinfection is an indispensable requirement for an effective sterilization of the cannulas.

You are responsible for the sterility of the cannulas. Therefore, please ensure that only sufficiently device and product specifically validated procedures will be used for cleaning, disinfection, and sterilization, that the used devices (WD, sterilizer) will be maintained and checked regularly, as well as that the validated parameters will be applied for each cycle.

Additionally, please pay attention to the legal provisions valid for your country as well as to the hygienic instructions of the doctor´s practice or of the hospital. This applies particularly to the different guidelines regarding the inactivation of prions (not relevant for USA).

Please pay attention to the additional and deviating requirements valid for some cannulas as specified in chapter “Specific aspects”.

2 Cleaning and disinfection

2.1 Basics

If possible, an automated procedure (WD (Washer-Disinfector)) should be used for cleaning and disinfection of the cannulas with a Luer-Lock connector (LL). A manual procedure – even in case of application of an ultrasonic bath – should only be used if an automated procedure is not available; in this case, the significantly lower efficiency and reproducibility of a manual procedure has to be considered.

The pre-treatment step is to be performed in both cases.

2.2 Pre-treatment

Please remove coarse impurities of the cannulas directly after application (within a maximum of 2 h).

1. Disassemble the cannulas as possible (see chapter “Specific aspects”).
2. Rinse the cannulas at least 1 min under running water[1] (temperature < 35 °C/95 °F). If applicable (see chapter “Specific aspects”): Rinse all lumens of the cannulas five times by application of a single-use syringe (minimum volume see chapter “Specific aspects”). Sway movable parts several times during pre-cleaning.
3. Remove manually all visible impurities by use of a clean and soft brush (or a clean, soft, and lint-free cloth) only to be for this, in no case metal brushes or steel wool.
   If applicable (see chapter “Specific aspects”): Pull a suitable cleaning wire through the cannula.
4. Rinse again at least 1 min under running water.

1 In case of application of a cleaning and disinfection detergent for this (e.g. in consequence of personnel´s safety) please consider, that this should be aldehyde-free (otherwise fixation of blood impurities), possess a fundamentally approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), be suitable for the disinfection of instruments made of metallic or plastic material, and be compatible with the cannulas (see chapter „material resistance„). Please consider, that a disinfectant used in the pre-treatment step serves only the personnel`s safety, but cannot replace the disinfection step later to be performed after cleaning.

2.3 Automated cleaning/disinfection (WD (Washer-Disinfector))

Pay attention to following points during selection of the WD:

- fundamentally approved efficiency of the WD (for example CE marking according to EN ISO 15883 or DGHM or FDA approval/clearance/registration).
- possibility for an approved program for thermal disinfection (A_0 value > 3000 or – in case of older devices - at least 5 min at 90 °C/194 °F; in case of chemical disinfection danger of remnants of the disinfectant on the cannulas).
- fundamental suitability of the program for the cannulas as well as sufficient rinsing steps in the program.
- post-rinsing only with sterile or low contaminated water (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water.
- only use of filtered air (oil-free, low contamination with microorganisms and particles) for drying.
- regularly maintenance and check/calibration of the WD.

Pay attention to following points during selection of the cleaning detergent:

- fundamental suitability for the cleaning of instruments made of metallic or plastic material.
- only use of detergents, which do not require neutralisation by acid.
- additional application – in case of non-application of a thermal disinfection – of a suitable disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) compatible to the used cleaning detergent.
- compatibility of the used detergents with the cannulas (see chapter „material resistance„).

Rinsing agent must not be used (Use of recommended water quality improves drying and avoids spots).

Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing.

1. Disassemble the cannulas as possible (see chapter “Specific aspects”).
2. Transfer the dismantled cannulas in a small parts basket into the WD (pay attention that the cannulas have no contact). If applicable (see chapter “Specific aspects”): Connect the cannulas by use of the existing LuerLock or of a suitable rinsing adapter to the rinsing port of the WD.
3. Start the program.
4. Remove the cannulas of the WD after end of the program.
5. Check and pack the cannulas immediately after the removal (see chapters „check„, „maintenance„, and “packaging„, if necessary after additional post-drying at a clean place).

The fundamental suitability of the cannulas for an effective automated cleaning and disinfection was demonstrated by an independent accredited test laboratory by application of the WD G 7836 CD, Miele & Cie. GmbH & Co., Gütersloh, (thermal disinfection) and the cleaning detergent Neodisher medizym (Dr. Weigert GmbH & Co. KG, Hamburg) considering to the specified procedure.

2.4 Manual cleaning and disinfection

Pay attention to following points during selection of the cleaning and disinfection detergents:

- fundamental suitability for the cleaning and disinfection of instruments made of metallic or plastic material.
- in case of application of an ultrasonic bath: suitability of the cleaning detergent for ultrasonic cleaning (no foam development).
- application of a disinfectant with approved efficiency (for example VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) compatible with the used cleaning detergent.
- compatibility of the used detergents with the cannulas (see chapter „material resistance„).

Combined cleaning/disinfection detergents should not be used.

Only in case of extremely low contamination (no visible impurities) combined cleaning/disinfection could be used.

Pay attention to the instructions of the detergent manufacturers regarding concentration, temperature and soaking time as well as post-rinsing. Please use only freshly prepared solutions as well as only sterile or low contaminated water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), for example purified/highly purified water, and a soft, clean, and lint-free cloth and/or filtered air for drying, respectively.

Cleaning

1. Disassemble the cannulas as possible (see chapter “Specific aspects”).
2. Soak the dismantled cannulas for the given soaking time in the cleaning solution so that the cannulas are sufficiently covered. Pay attention that there is no contact between the cannulas. Assist cleaning by careful brushing with a soft brush or with ultrasonic treatment. Sway movable parts several times during cleaning.
   If applicable (see chapter “Specific aspects”): Rinse all lumens of the cannulas at least five times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume see chapter “Specific aspects”) and of the existing LuerLock or of a suitable rinsing adapter.
3. Then, remove the cannulas of the cleaning solution and post-rinse them at least three times intensively (at least 1 min) with water.
   If applicable (see chapter “Specific aspects”): Rinse all lumens of the cannulas at least five times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume see chapter “Specific aspects”) and of the existing LuerLock or of a suitable rinsing adapter.
4. Check the cannulas (see chapters „check„ and „maintenance„).

Disinfection

5. Soak the dismantled cannulas for the given soaking time in the disinfectant solution so that the cannulas are sufficiently covered. Pay attention that there is no contact between the cannulas. Sway movable parts several times during cleaning.
   If applicable (see chapter “Specific aspects”): Rinse all lumens of the cannulas at least five times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume see chapter “Specific aspects”) and of the existing LuerLock or of a suitable rinsing adapter.
6. Then, remove the cannulas of the disinfectant solution and post-rinse them at least five times intensively (at least 1 min) with water.
   If applicable (see chapter “Specific aspects”): Rinse all lumens of the cannulas at least five times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume see chapter “Specific aspects”) and of the existing LuerLock or of a suitable rinsing adapter.
7. Dry and pack the cannulas immediately after the removal (see chapter „packaging„, if necessary after additional post-drying at a clean place).

The fundamental suitability of the cannulas for an effective cleaning and disinfection was demonstrated by an independent accredited test laboratory by application of the cleaning detergent Cidezyme/Enzol and the disinfectant Cidex OPA (Johnson & Johnson GmbH, Norderstedt) considering the specified procedure.

3 Check

Check all cannulas after cleaning or cleaning/disinfection, respectively, on corrosion, damaged surfaces, and impurities. Do not further use damaged cannulas (for limitation of the numbers of re-use cycles see chapter „reusability„). Still dirty cannulas are to be cleaned and disinfected again.

Particularly, if nickel plated surface is damaged by scratches, cannulas have to be rejected.

4 Maintenance

Assemble dismanteled cannulas if permitted (see chapter “Specific aspects”). Please notice, that some cannulas have to be packed and sterilized only in dismanteled condition. Cleaning wires must not be inserted during sterilisazion.

Instrument oils must not be used.

5 Packaging

Please insert the cleaned and disinfected cannulas in the corresponding sterilization trays. Packaging without sterilization box is not recommended (danger of damage of the sterilization packaging or of injury).

Please pack the sterilization trays in single-use sterilization packagings (single or double packaging) and/or sterilization containers, which fulfill the following requirements (material/process):

- EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)
- suitable for steam sterilization (temperature resistance up to at least 142 °C (288 °F), sufficient steam permeability)
- sufficient protection of the cannulas as well as of the sterilization packagings to mechanical damage

6 Sterilization

Please use for sterilization only the listed sterilization procedures; other sterilization procedures must not be applied.

Steam sterilization

- fractionated vacuum/dynamic air removal procedure[2, 3] (with sufficient product drying[4])
- steam sterilizer according to EN 13060/EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- validated according to EN ISO 17665 (valid IQ/OQ (commissioning) and product specific performance qualification (PQ))
- maximum sterilization temperature 138 °C (280 °F; plus tolerance according to EN ISO 17665)
- sterilization time (exposure time at the sterilization temperature) at least 5 min[5] at 132 °C (270 °F)/134 °C (273 °F)

2 at least three vacuum steps

3 The less effective gravity displacement procedure must not be used.

4 The effectively required drying time depends directly on parameters in sole responsibility of the user (load configuration and density, sterilizer conditions, ...) and by this is to be determined by the user. Nevertheless, drying times less than 20 min must not be applied.

5 respectively 18 min (inactivation of prions, not relevant for USA)

The fundamental suitability of the cannulas for an effective steam sterilization was demonstrated by an independent accredited test laboratory by application of the steam sterilizer HST 6x6x6 (Zirbus technology GmbH, Bad Grund) and the fractionated vacuum/dynamic air removal procedure. For this, typical conditions in clinic and doctor´s practice as well as the specified procedure were considered.

The flash sterilization procedure must not be used.

Do not use dry heat sterilization, radiation sterilization, formaldehyde and ethylene oxide sterilization, as well as plasma sterilization.

7 Storage

Please store the cannulas after sterilization in the sterilization packagings at a dry and dust-free place.

8 Material resistance

Please take care that the listed substances are not ingredients of the cleaning or disinfection detergent:

- organic, mineral, and oxidizing acids (minimum admitted pH-value 6.5)
- stronger lyes (maximum admitted pH-value 10.2, neutral/enzymatic or weak alkaline cleaner recommended)
- organic solvents (for example: acetone, ether, alcohol, benzine)
- oxidizing agents (for example: peroxide)
- halogens (chlorine, iodine, bromine)
- aromatic, halogenated hydrocarbons

Please do not clean any cannulas, sterilization trays, and sterilization containers by use of metal brushes or steel wool.

Please do not expose any cannulas, sterilization trays, and sterilization containers to temperatures higher than 142 °C (288 °F)!

9 Reusability

The cannulas can be processed up to 50 times and reused up to 10 times – in case of adequate care and if they are undamaged and clean. The user is responsible for each further use as well as for the use of damaged and dirty cannulas (no liability in case of disregard).

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Specific aspects

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<tr><td>all simple cannulas with luer-lock connector (LL) without mandrin</td><td rowspan="4">10 ml (single-use syringe)</td><td rowspan="2">cleaning wire</td><td colspan="2" rowspan="2">five-times rinsing inside, brushing outside, pulling through of the cleaning wire</td><td>in the open small parts basket, connected to the rinsing port of the WD by application of the LL</td><td rowspan="4">lubrication not admitted</td><td rowspan="2">standard procedure

cleaning wire must not be inserted</td><td rowspan="4">50</td><td rowspan="4">10</td><td rowspan="4">critical B</td></tr>
<tr><td>cannulas with luer connector (L)</td><td>-</td></tr>
<tr><td>all cannulas with luer-lock connector (LL) with mandrin</td><td>-</td><td colspan="2">five-times rinsing inside, brushing outside, pulling through of the mandrin or of the inner cannula through the handle</td><td>in the open small parts basket, connected to the rinsing port of the WD by application of the LL</td><td>standard procedure

dismantled</td></tr>
<tr><td>sternal puncture needle Klima-Rosegger</td><td>tooth brush

long interdental brush with outer diameter 8 mm (e.g. Curaprox LS635G)</td><td colspan="2">five-times rinsing inside, pulling of the mandrin through the handle, brushing outside (tooth brush) and inside (inner side of the front piece with interdental brush)</td><td>mandrin, arresting disk and front piece in the closed small parts basket; handle connected to the rinsing port of the WD by application of the LL, in the open small parts basket</td><td>standard procedure

in the mounted, but loosened state</td></tr>
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