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1 FUNDAMENTAL POINTS

All UNIMED medical devices (hereafter called **devices**) are delivered unsterile and have to be at least cleaned, disinfected, inspected, packaged and sterilized prior to each application (see section 2), including the first use after delivery (cleaning and disinfection after removal of the protective packaging, sterilization after packaging). An effective cleaning and disinfection is an indispensable requirement for a successful sterilization of the devices.

Devices have been validated to be used for a limited period of maximum 1 hour for Hypodermic and Suture Needles (invasive contact) and Adapters and Stopcocks (non-invasive contact).

For the use of Adapters and Stopcocks, the following rules are applicable:

Admissible use	**Non-admissible use**
- A perfusion, administration or infusion fluid into body. - As an accessory of a simple fluid channelling system using gravity.	- Connected to an active medical device. - Channelling and storing blood. - Channelling and storing body liquid.

The user is responsible for the cleanliness, the sterility and the integrity of the devices.

Therefore please ensure:

- Those only specifically installations and products validated procedures are used for cleaning, disinfection and sterilization.
- That the installations used (disinfector, sterilizer) are maintained and checked regularly.
- That the validated parameters are applied for each cycle.

Pay attention to your country's legal dispositions as well as to the internal rules of the doctor´s practice or the hospital concerned. This applies particularly to the different guidelines regarding prion decontamination, which may require the use of alkaline cleaning agents and longer sterilization cycles.

2 PROCESSING

2.1 CLEANING AND DISINFECTION

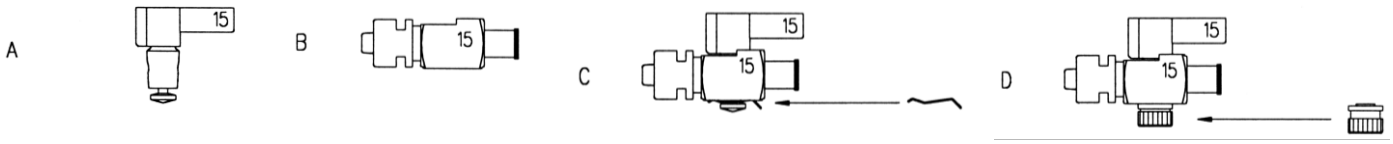
2.1.1 BASICS

If possible, an automated procedure (disinfector) should be used for cleaning and disinfection of the devices. A manual procedure, even one including ultrasound bath, should only be used if an automated procedure is not available. In this case the significantly lower efficiency and reproducibility of the manual procedure has to be considered.

The pre-treatment step has to be performed in all cases.

2.1.2 PREPARATION OF THE STOPCOCK

After each use of the stopcock, remove the key (A) from the body (B) by pulling back the spring clip (C) or by unscrewing the knurled nut (D). Do not interchange keys or bodies. If applicable the numbers on the key and the body of each stopcock must match.



2.1.3 PRE-TREATMENT

Remove coarse impurities on the devices directly after use (within a maximum of 2 h).

For this purpose uses only tap water or a disinfectant solution. The disinfectant should:

- Be aldehyde-free (otherwise there is a risk of fixation of blood impurities).
- Be approved (for example VAH/DGHM or FDA approval or CE marking).
- Be suitable for the disinfection of such devices and be compatible with such devices (see section 2.1.5).

For manual removal of impurities use only a soft brush or clean soft tissue reserved for this usage, in no case a metal brush or steel wool.

Devices with lumen: Rinse all lumen of the devices 5 times with a single-use syringe (minimum volume 10 ml).

The disinfectant used in the pre-treatment step serves only the safety of the personnel and cannot replace the disinfection step to be performed after cleaning.

2.1.4 AUTOMATED CLEANING AND DISINFECTION

Please pay attention to following requirements when selecting a disinfector:

- Approved efficiency of the disinfector (DGHM or FDA approval or CE mark according to EN ISO 15883).
- Availability of an approved program for thermal disinfection (A0 value > 3000 or at least 5 min at 90 °C (~ 194 °F)), (in case of chemical disinfection: danger of remnants of the disinfectant on the devices).
- Fundamental suitability of the program for the devices as well as sufficient rinsing steps in the program.
- Post-rinsing only with sterile water or water with low contamination (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water.

- Use only filtered air for drying.
- The disinfector must be maintained, checked and calibrated according to the manufacturer's instructions.

Please pay attention to following requirements when selecting the cleaning agent:

- Fundamental suitability for the cleaning of devices made of steel and plastic material.
- Except in the case of thermal disinfection, a suitable disinfectant with approved efficiency (for example DGHM or FDA approval or CE marking) compatible with the cleaning agent has to be used.
- Compatibility of the cleaning agents with the devices (see section 2.1.6).

The instructions of the detergent and disinfectant manufacturers regarding concentration and soaking time have to be followed strictly.

Procedure:

1) Disassemble the devices as far as possible. The components of several devices should not be interchanged. If applicable, the numbers on the components should match.
2) Transfer the disassembled devices into the disinfector. Ensure that the devices have no contact. If applicable: Connect the devices to the rinsing ports of the disinfector.
3) Start the program.
4) Disconnect and remove the devices from the disinfector after the end of the program.
5) Check the devices (see sections 2.2 and 2.3).
6) Pack the devices immediately after checking (see section 2.4) if necessary after additional post-drying in a clean place.

Example:

Parameters of the automated cleaning and disinfection program D-V-MEDICLEA905, based on the program DES-VAR-TD (Miele) and the cleaner/disinfector G 7836 CD (Miele):

- *Pre-rinsing:* *1 min at 10 ± 2 °C (~ 50 °F)*
- *Cleaning:* *5 min at 45 ± 2 °C (~ 113 °F), with cleaning agent Neodisher Mediclean WE 404333 (Chemische Fabrik Dr. Weigert), concentration 0.2% (2 ml/l)*
- *Post-rinsing:* *2 min at 10 ± 2 °C (~ 50 °F)*
- *Thermic disinfection:* *5 min at 90 ± 2 °C (~ 194 °F)*

2.1.5 MANUAL CLEANING AND DISINFECTION

Please pay attention to following requirements when selecting the cleaning and disinfection agents:

- Fundamental suitability for the cleaning and disinfection of devices made of steel or plastic material.
- In case of application of an ultrasonic bath: suitability of the cleaning agent for ultrasonic cleaning (no foam development), (for example: Cidezyme, REF 2258 (Johnsson & Johnson Medical Ltd), concentration 1.6%, soaking time 5 min).
- Application of a disinfectant with approved efficiency (for example DGHM or FDA approval or CE marking) and compatible with the cleaning detergent, (for example Cidex OPA, REF 20391 (Johnson & Johnson Medical Ltd), solution ready for use, soaking time 12 min).
- Compatibility of the cleaning and disinfection agents with the devices (see section 2.1.6).

Combined cleaning/disinfection agents should not be used, if possible. Only in case of extremely low contamination (no visible impurities) can a combined cleaning/disinfection agent be used.

The instructions of the manufacturers of the cleaning and disinfectant agents regarding concentration and soaking time have to be followed strictly.

Use only freshly prepared solutions as well as only sterile water or water with low contamination (max. 10 germs/ml, max. 0.25 endotoxin units/ml), for example purified/highly purified water and filtered air for drying.

Cleaning procedure:

1) Disassemble the devices as far as possible. The components of several devices should not be interchanged. If applicable the numbers on the components should match.
2) Soak the disassembled devices for the given soaking time in the cleaning solution so that the devices are sufficiently covered (if necessary assisted by ultrasonic treatment or careful brushing with a soft brush). Ensure there is no contact between the devices.
   Rinse all lumen of the devices 5 times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume 10 ml).
3) Remove the devices from the cleaning solution and post-rinse them at least 3 times with water.
   Rinse all lumen of the devices 5 times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume 10 ml).

Disinfection procedure:

1) Soak the disassembled devices for the given soaking time in the disinfectant solution so that the devices are sufficiently covered. Ensure there is no contact between the devices.
   Rinse all lumen of the devices 5 times at the beginning and at the end of the soaking time with a single-use syringe (minimum volume 10 ml).
2) Remove the devices from the cleaning solution and post-rinse them at least 3 times with water.
   Rinse all lumen of the devices 5 times at the beginning and at the end of the soaking time with a single-use syringe (minimum volume 10 ml).
3) Dry the devices by blowing off/blowing through with filtered compressed air.
4) Check the devices (see sections 2.2 and 2.3).
5) Pack the devices immediately after checking (see section 2.4) if necessary after additional post-drying in a clean place.

2.1.6 MATERIAL RESISTANCE

The cleaning or disinfection agents shall not contain the following substances:

- Organic, mineral, and oxidizing acids (minimum admitted pH-value 5,5).
- Strong lyes (maximum admitted pH-value 10, neutral/enzymatic or weak alkaline cleaner recommended).
- Organic solvents (for example: acetone, ether, alcohol, benzene).
- Oxidizing agents (for example: peroxide).
- Halogens (chlorine, iodine, bromine) or aromated, halogenated hydrocarbons.

Do not clean any devices with metal brushes or steel wool.

Do not expose devices without stopcocks to temperatures above 141 °C (~ 286 °F).

Do not expose devices with stopcocks to temperatures above 180 °C (~ 356 °F).

2.2 INSPECTION

After cleaning and disinfection, check all devices for the following elements:

- No corrosion.
- No damaged surfaces and tip.
- No impurities.
- Patency of lumen (e.g., by introduction of an appropriate mandrel).
- Waterproof of the lumen and stopcock (e.g., by doing a visual leak test using a syringe).
- Free motion of the moving and rotating element.

Do not use devices if any of these elements are failing during the inspection (see section 4). Insufficiently cleaned devices have to be cleaned and disinfected again.

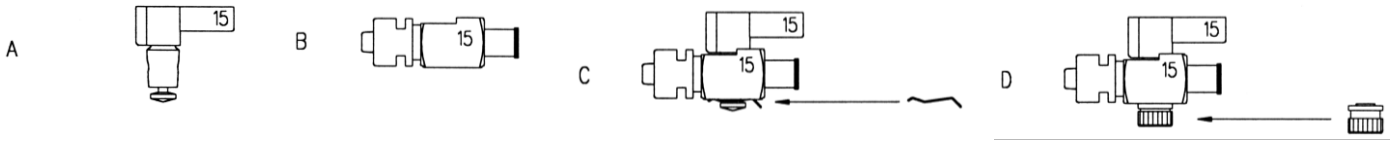
Reassemble the devices. The components of several devices should not be interchanged. If applicable the numbers on the components should match.

2.3 GREASING OF STOPCOCKS

Lubrication is essential after every cleaning.

Apply a light film of DOW CORNING High-Vacuum Silicone Grease to the keys. No other grease can be used without new validation of the dry heat sterilization process.

Reassemble the stopcocks with the original handle (A) and body (B). The components of several stopcocks should not be interchanged. If applicable the numbers on key and body should match. Slide the spring clip (C) into place or tighten the knurled nut (D). By bending of the clip the traction on the key can be adjusted (Please note: if the clip is bent too much, the key will be hard to turn; if the clip is too flat, the stopcock could leak).



2.4 PACKAGING

2.4.1 PACKAGING OF NEEDLES AND ADAPTORS

Please insert the cleaned and disinfected devices into single-use sterilization packaging (single or double packaging), which meet the following requirements:

- Compliant to standard EN ISO 11607.
- Suitable for steam sterilization (temperature resistance up to at least 141 °C (~ 286 °F), sufficient steam permeability).
- Sufficient protection of the devices as well as of the sterilization packaging against mechanical damage.

2.4.2 PACKAGING OF STOPCOCKS

Please insert the cleaned and disinfected stopcocks into single-use sterilization packaging, which meet the following requirements:

- Compliant to standard EN ISO 11607.
- Suitable for dry heat sterilization (temperature resistance up to at least 180 °C (~ 356 °F), sufficient air permeability), (Example: Transparent pouches Ref.-Nr. 68090550 from Brömeda Amcor Flexibles GmbH).
- Sufficient protection of the stopcocks as well as of the sterilization packaging against mechanical damage.

2.5 STERILIZATION

2.5.1 STERILIZATION OF NEEDLES AND ADAPTORS

Please use the listed sterilization procedure. Other sterilization procedures can be applied, however the sterilization personnel is fully responsible for their validation and application.

Steam sterilization:

- Fractionated vacuum procedure or gravity procedure (1) (with sufficient product drying).
- Steam sterilizer according:
  - Small sterilizer: EN 13060
  - Big sterilizer: EN 285.
- Sterilization validation according to the standard EN ISO 17665-1.
- Sterilization temperature: maximum 138 °C (~ 280 °F) plus tolerance
- Sterilization time (exposure time at the sterilization temperature) of at least 20 min at 121 °C (~ 250 °F).
  - Fractionated vacuum procedure: at least 20 minutes at 121 °C (~ 250 °F)
    or at least 3 minutes [2)] at least at 132/134 °C (~ 270 °F)
  - Gravity procedure: at least 5 minutes [2)] at least at 134 °C (~ 273 °F)

[(1)] *A gravity procedure should only be used if a fractionated vacuum procedure is not available and may require longer exposure times.*

[(2)] *Respectively 18 minutes (prion inactivation).*

2.5.2 STERILIZATION OF STOPCOCKS

For the sterilization of the stopcocks only the following dry heat sterilization procedure can be used. Because of the necessary greasing of the stopcocks all other sterilization procedures are excluded.

Stopcocks with markings or any other identification applied by the customer cannot be sterilized by dry heat.

Dry heat sterilization:

- Dry heat sterilization procedure with active air circulation, temperature-driven start of exposure and independent recording of the effective sterilization temperature.
- Dry heat sterilization compliant to the standard EN ISO 20857.
- Sterilization validation according to the standard EN ISO 20857.
- Sterilization temperature: maximum 175 °C (~ 347 °F) plus tolerance of maximum 5 °C.
- Time of exposure (at sterilization temperature)
  - A least 60 minute at 160 °C (~ 320 °F)

The sterilization personnel are fully responsible for the suitability and validation of the dry heat sterilization equipment used.

3 STORAGE

After sterilization it is recommended to store the devices in the sterilization packaging in a dry and dust-free place. This storage must be done on furniture preventing any damages to the sterile packaging.

4 REUSABILITY

As long as devices respect all requirements of the processing (see section 2) and they are cleaned and then sterilized by using a validated method (per this procedure or a method owned by the user), the devices can be re-used as long as they are compliant to the following 3 elements:

1) The device must pass all inspection criteria as required by this instruction (see section 2.2).
2) Using the device for a maximum of 10 years after having been purchased.
3) A maximum of 50 sterilization cycles (see section 2.5) applied to the device.

Users are responsible to ensure being compliant to this instruction and its requirements through their management system (or equivalent).