Reprocessing (cleaning, disinfection and sterilisation) of products

General principles

All products must be cleaned, disinfected and sterilised before each use; this applies in particular to the first use after delivery, as all products are delivered non-sterile (cleaning and disinfection after removal of the protective transport packaging; sterilisation after packaging). Effective cleaning and disinfection is an indispensable prerequisite for effective sterilisation.

As part of your responsibility for the sterility of the products, observe the following during use,

- ⇨ *that, as a matter of principle, only sufficiently device- and product-specific validated procedures are used for cleaning/disinfection and sterilisation,*
- ⇨ *that the equipment used (WD, steriliser, etc.) is regularly maintained, checked and calibrated, and*
- ⇨ *that the validated parameters are adhered to in each cycle.*

Already during use, make sure that you collect soiled instruments separately and do not put them back into the sterilisation tray in order to avoid greater contamination of the loaded sterilisation tray. Clean / disinfect the soiled instruments, then sort them back into the sterilisation tray and sterilise the fully loaded sterilisation tray.

In addition, observe the legal regulations valid in your country as well as the hygiene regulations of the doctor's practice or hospital. This applies in particular to the different requirements (e.g. in Germany according to Annex 7 of the KRINKO RKI BfArM recommendation for reprocessing) with regard to effective prion inactivation (not applicable to the USA).

Hint:
The products are to be used by trained professionals only.

Reprocessing may only be carried out by trained specialist personnel in the central sterilisation department of the clinic or in the reprocessing room of the doctor's practice. The clinic or doctor's practice is also responsible for the selection and use of the necessary protective equipment and hygiene measures.

Take into account deviating and/or additional specifications for some products in chapter "Special instructions".

Cleaning and disinfection

Basics

If possible, a mechanical process (washer-disinfector) should be used for cleaning and disinfection. A manual process - also using an ultrasonic bath - should only be used if a mechanical process is not available or according to country-specific requirements (e.g. in Germany a mechanical process is mandatory for critical B products) due to the significantly lower effectiveness and reproducibility.

Pre-treatment must be carried out in both cases.

Pre-treatment

Directly after application (within a maximum of 2 h), coarse contamination must be removed from the products. If this time cannot be observed due to the duration of the application or as a result of organisational aspects, the user must determine and validate measures on his own responsibility to prevent the soiling from drying through:

Care should be taken when selecting the cleaning agent1 to be used,

- ✓ *that this is basically suitable for cleaning invasive medical devices made of metals and plastics,*
- ✓ *that the cleaning agent is suitable for ultrasonic cleaning (no foam development),*
- ✓ *that the cleaning agent is compatible with the products (see chapter "Material resistance").*

The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent or detergent and disinfectant, as well as specifications for post-rinsing, must be strictly adhered to. Use only freshly prepared solutions, only sterile or low-germ (max. 10 germs/ml) as well as low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) 2or, for drying, only a soft, clean and lint-free cloth (caution: be careful with products with rough surfaces, threads, sharp edges or similar, on which particles from the cloth can stick!) and/or filtered air.

In addition, take into account the deviating and/or additional specifications for some products in chapter "Special instructions" from the column "Pre-treatment" during the pre-treatment procedure.

Procedure:

1. *Disassemble the products as much as possible (see specific disassembly/assembly instructions).*
2. *Rinse the products for at least 1 min under running water (temperature < 35 °C/95 °F). Move moving parts back and forth at least three times during pre-rinsing. If applicable (see chapter "Special instructions"):*
   Rinse all lumina of the products at least three times (auxiliaries and minimum volume depend on the cavity to be rinsed).
3. *Place the disassembled products in a sufficiently large pre-cleaning bath (in an ultrasonic bath that has not yet been activated) for the specified exposure time so that the products are completely covered. Make sure that the products do not touch each other. Support the pre-cleaning by completely brushing all inner and outer surfaces (at the beginning of the soaking time, for aids see chapter "Special instructions"). (Attention: Be careful with products with narrow gaps where bristles of the brush can get stuck! The brushes for the channels must be slightly larger than the respective channel inner diameter; the shaft length of the brush must be at least as long as the channel.*
   Move moving parts back and forth at least three times during pre-cleaning.
   If applicable (see chapter "Special instructions"):
   Rinse all lumina of the products at least three times at the beginning or end of the exposure time (auxiliaries and minimum volume depend on the cavity to be rinsed).
4. *Activate the ultrasound for a renewed minimum exposure time (but not less than 5 min).*
5. *Then remove the products from the pre-cleaning bath and rinse them thoroughly with water at least three times (at least 1 min). Move moving parts back and forth at least three times when rinsing. If applicable (see chapter "Special instructions"):*
   Rinse all lumina of the products at least three times (auxiliaries and minimum volume depend on the cavity to be rinsed). see chapter "Special instructions" as well as the columns "Rinsing volume" and "Brushing").

[1] *If you use a cleaning agent and disinfectant for this purpose - e.g. for reasons of occupational safety - please take into account that it should be aldehyde-free (otherwise fixation of blood contamination), have a tested efficacy (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), be suitable for disinfecting the products and be compatible with the products (see chapter "Material resistance"). Please note that the disinfectant used during pre-treatment is only for personal protection and cannot replace the disinfection step to be carried out later - after cleaning has been completed.*

[2] *If you consider a lower water quality to be sufficient against the background of national recommendations (e.g. in Germany KRINKO/RKI/BfArM recommendation on treatment), this is your sole responsibility.*

Mechanical cleaning/disinfection (RDG = washer-disinfector)

When selecting the WD, pay attention to the following,

- *that the washer-disinfector has been tested for effectiveness (e.g. DGHM or FDA approval/clearance/registration or CE marking according to DIN EN ISO 15883),*
- *that, if possible, a tested programme for thermal disinfection (A0 value > 3000 or - for older units - at least 5 min at 90 °C/194 °F) is used (in the case of chemical disinfection, there is a risk of disinfectant residues on the products),*
- *that the programme used is suitable for the products and contains sufficient rinse cycles (at least three depleting steps after cleaning (or neutralisation, if applied) or conductivity control recommended to effectively prevent detergent residues)),*
- *that only sterile or low-germ (max. 10 germs/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water)[3] is used for rinsing,*
- *that the air used for drying is filtered (oil-free, low in germs and particles) and*

- *that the WD is regularly maintained, checked and calibrated.*

When selecting the cleaning agent system to be used, pay attention to this,

- *that this is basically suitable for cleaning invasive medical devices made of metals and plastics,*
- *that - if thermal disinfection is not used - a suitable disinfectant with tested efficacy (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is also used and that this is compatible with the cleaning agent used, and*
- *that the chemicals used are compatible with the products (see chapter "Material resistance").*

The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agent and, if applicable, disinfectant, as well as the instructions for rinsing must be strictly adhered to.

In addition, take into account deviating and/or additional specifications for some products in chapter "Special instructions" from the column "Mechanical cleaning/disinfection" when carrying out mechanical cleaning/disinfection.

Procedure:

1. *Disassemble the products as much as possible (see specific disassembly/assembly instructions).*
2. *Place the disassembled products in the washer-disinfector. Make sure that the products do not touch each other.*
   If applicable (see chapter "Special instructions"):
   Enable active flushing by connecting to the flushing connection of the WD.
3. *Start the programme.*
   Validated cycle parameters

Step	*Designation*	*Medium*	*Temperature [°C]*	*Duration [min.]*
1	*Pre-rinse*	*Water*	*Not tempered (< 30°C)*	*1*
2	*Empty*	*-*	*-*	*-*
3	*Clean*	*Alkaline cleaning agent: Neodisher MediClean forte (Dr. Weigert GmbH & Co. KG, Hamburg)* *Concentration: 0.2 - 1% (according to detergent manufacturer)*	*55*	*10*
4	*Empty*	*-*	*-*	*-*
5	*Sinks*	*Deionised water*	*Not tempered (< 30°C)*	*1*
6	*Empty*	*-*	*-*	*-*
7	*Disinfection (thermal)*	*-*	*95*	*5*
8	*Drying*	*Hot air*	*100*	*25*

[3] *If you consider a lower water quality to be sufficient against the background of national recommendations (e.g. KRINKO/RKI/BfArM recommendation on treatment), this is your sole responsibility.*

4. *Deconnect (if necessary) and remove the products from the WD at the end of the programme.*
5. *Check and pack the products as soon as possible after removal (see chapter "Checking", "Maintenance" and "Packing", if necessary after additional post-drying in a clean place).*

Proof of the fundamental suitability of the products for effective machine cleaning and disinfection was provided by an independent, officially accredited and recognised (§ 15 (5) MPG) test laboratory using the RDG G 7836 CD (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the pre-cleaning and cleaning agent Neodisher MediClean forte (Dr. Weigert GmbH & Co. KG, Hamburg). The procedure described above was taken into account.

Manual cleaning and disinfection

Care should be taken when selecting the cleaning agents and disinfectants to be used,

- *that these are basically suitable for cleaning or disinfecting invasive medical devices made of metals and plastics,*
- *that the cleaning agent is suitable for ultrasonic cleaning (no foam development),*
- *that a disinfectant with tested efficacy (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is used and that it is compatible with the cleaning agent used, and*
- *that the chemicals used are compatible with the products (see chapter "Material resistance").*

Combined detergents/disinfectants should not be used if possible. Only in cases of very low contamination (no visible contamination) can combined cleaning/disinfection agents be used.

During manual cleaning, disinfection with a possible risk of injury and infection, further occupational health and safety measures (e.g. protective clothing, safety goggles, gloves; room air filtration) must be observed according to national regulations (e.g. in Germany TRBA 250).

The concentrations, temperatures and exposure times specified by the manufacturer of the cleaning agents and disinfectants as well as specifications for post-rinsing must be strictly adhered to. Use only freshly prepared solutions, only sterile or low-germ (max. 10 germs/ml) as well as low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water)3 or, for drying, only a soft, clean and lint-free cloth (caution: be careful with products with rough surfaces, threads, sharp edges or similar, on which particles from the cloth can stick!) and/or filtered air.

When carrying out manual cleaning/disinfection, also take into account the deviating and/or additional specifications for some products in chapter "Special instructions" from the column "Manual cleaning/disinfection".

Cleaning procedure:

1. *If applicable, disassemble the products as much as possible (see specific disassembly/assembly instructions).*
2. *Place the disassembled products in a sufficiently large cleaning bath (in an ultrasonic bath that has not yet been activated) for the specified exposure time so that the products are completely covered. Make sure that the products do not touch each other. Support the cleaning by completely brushing all inner and outer surfaces with a soft brush (Attention: Be careful with products with narrow gaps where bristles of the brush can get stuck!). The brushes for the ducts must be slightly larger than the respective duct inner diameter; the shaft length of the brush must be at least as long as the duct.*
   Move moving parts back and forth several times during cleaning.
   If applicable (see chapter "Special instructions"): Rinse all lumina of the products at least five times at the beginning or end of the exposure time (auxiliaries and minimum volume depend on the cavity to be rinsed).
3. *Activate the ultrasound for a renewed minimum exposure time (but not less than 5 min).*

4. *Then remove the products from the cleaning bath and rinse them thoroughly with water at least three times (at least 1 min). Move moving parts back and forth several times when rinsing.*
   If applicable (see chapter "Special instructions"): Rinse all lumina of the products at least five times (auxiliaries and minimum volume depend on the cavity to be rinsed).
5. *Check the products (see chapter "Checking and maintenance").*

Disinfection procedure:

6. *Place the disassembled, cleaned and checked products in the disinfection bath for the specified exposure time so that the products are completely covered. Make sure that the products do not touch each other. Move moving parts back and forth several times during disinfection. If applicable (see chapter "Special instructions"): Rinse all lumina of the products at least five times at the beginning or at the end of the exposure time (auxiliary agents and minimum volume depend on the cavity to be rinsed).*
7. *Then remove the products from the disinfection bath and rinse them thoroughly with water at least five times (at least 1 min). Move moving parts back and forth several times when rinsing.*
   If applicable (see chapter "Special instructions"): Rinse all lumina of the products at least five times (auxiliaries and minimum volume depend on the cavity to be rinsed).
8. *Dry the products by blowing them off with filtered compressed air.*
9. *Pack the products as soon as possible after removal (see chapter "Packaging", if necessary.*
   after additional post-drying in a clean place).

Proof of the basic suitability of the products for effective manual cleaning and disinfection was provided by an independent, officially accredited and recognised (§ 15 (5) MPG) test laboratory using the pre-cleaning and cleaning agent Cidezyme/Enzol and the disinfectant Cidex OPA (Johnson & Johnson GmbH, Norderstedt). The procedure described above was taken into account.

Control

After cleaning or cleaning/disinfection, check all products for corrosion, damaged surfaces, chipping, soiling and discolouration and discard damaged products (see chapter "Reusability" for the number of reusable products). Products that are still dirty must be cleaned and disinfected again.

Maintenance

Reassemble disassembled products (see specific disassembly/assembly instructions).

Instrument oils or grease must not be used. Exception (only for special instruments, see chapter "Special instructions", not for implants) In the case of oiling joints, make sure that only instrument oils (white oil, without further additives) are used which - taking into account the maximum sterilisation temperature applied - are approved for steam sterilisation and have a tested biocompatibility, and that only a small amount is applied to the joints.

Packing

Sort the cleaned and disinfected products into the corresponding sterilisation tray.

Please pack the products or the sterilisation trays in sterilisation containers or very large products in single-use sterilisation packaging (single or double packaging) that meet the following requirements (material/process):

- *DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)*
- *suitable for steam sterilisation (temperature resistance up to at least 138 °C (280 °F) sufficient steam permeability)*
- *Sufficient protection of the products or sterilisation packaging against mechanical damage.*
- *Regular maintenance according to the manufacturer's specifications (sterilisation container)*
- *A maximum weight of 10 kg per package/content of the sterilisation container must not be exceeded.*

Sterilisation

Only the sterilisation methods listed below may be used for sterilisation; other sterilisation methods are not permitted.

Steam sterilisation

- *fractionated vacuum process[4] , [5](with sufficient product drying[6])*
- *Steam steriliser according to DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)*
- *validated according to DIN EN ISO 17665 (valid IQ/OQ (picking) and product-specific performance assessment (PQ)) -*
- *Maximum sterilisation temperature 134 °C (273 °F; plus tolerance according to DIN EN ISO 17665)*
- *- Sterilisation time (exposure time at the sterilisation temperature):*

Country	*fractionated vacuum process*
Germany	*min. 5 min7 at 134 °C (273 °F)*
USA	*min. 4 min at 132 °C (270 °F), drying time min. 20 min5*
France	*min. 5 min7 at 134 °C (273 °F)* *if required for prion inactivation Sterilisation time 18 min*
other countries	*min. 5 min7 at 132 °C (270 °F) / 134 °C (273 °F)*

Procedure: *Steam sterilisation*

Place the packaged product in the steam steriliser.
Start the sterilisation programme
Remove the product from the steam steriliser at the end of the programme.

Also, do not use gravitational sterilisation, flash sterilisation, hot air sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation, or plasma sterilisation.

[4] *At least three vacuum steps*
[5] *The use of the less effective gravitation process is only permissible if the fractionated vacuum process is not available, requires significantly longer sterilisation times and must be validated by the user for specific products, devices, processes and parameters.*
[6] *The actual drying time required depends directly on parameters that are the sole responsibility of the user (load configuration and density, steriliser condition, ...) and must therefore be determined by the user. Nevertheless, drying times of 20 min should not be undercut.*

Proof of the basic suitability of the products for effective steam sterilisation was provided by an independent, officially accredited and recognised (§ 15 (5) MPG) test laboratory using the HST 6x6x6 steam steriliser (Zirbus technology GmbH, Bad Grund) and employing the fractionated vacuum process as well as LAWTON MEDOIL (oiling of the joints and friction surfaces). Typical conditions in clinics and medical practices as well as the procedure described above were taken into account.

The flash sterilisation procedure is generally not permissible.

Also, do not use hot air sterilisation, radiation sterilisation, formaldehyde or ethylene oxide sterilisation, or plasma sterilisation.

Storage

After sterilisation, the products must be stored in the sterilisation packaging in a dry and dust-free place.

Material resistance

When selecting cleaning agents and disinfectants, make sure that the following ingredients are not included:

- *organic, mineral and oxidising acids (minimum permissible pH value 5.5)*
- *Lyes/strong alkalis (neutral/enzymatic (max. permissible pH 8.5, mandatory for products made of aluminium or other alkali-sensitive materials, see chapter "Special instructions") or alkaline cleaner (max. permissible pH 11, mandatory for products intended for use in prion-critical areas, e.g. in accordance with the [7]KRINKO RKI BfArM recommendation for reprocessing) recommended).*
- *Organic solvents (e.g. alcohols, ethers, ketones, benzines)*
- *Oxidising agents (e.g. hydrogen peroxides)*
- *Halogens (chlorine, iodine, bromine)*
- *aromatic/halogenated hydrocarbons*

Never clean all products, sterilisation trays and sterilisation containers with metal brushes or steel wool.

All products, sterilisation trays and sterilisation containers must only be exposed to temperatures not higher than 138 °C (280 °F).

Reusability

The products can be reused - with appropriate care and provided they are undamaged and uncontaminated; any further use or use of damaged and/or contaminated products is the responsibility of the user.

In case of disregard, any liability is excluded.

[7] or extended sterilisation time (e.g. 18 min) for prion inactivation according to national requirements (not relevant for the USA).

Special notes (see following pages)

Worst Case (Code)	Geometric features	Flushing volume	Brush	Special/additional procedure for			Packing	Sterilisation	Maximum permissible number of cycl	Classification recommendation according to KRINKO/RKI/BfArM recommendation (only Germany, if used as directed)
				Pre-treatment	manual cleaning/ Disinfection	Mechanical cleaning/ Disinfection				
Aa1	Products with longer/closer Ringlumen (Standard) Dismantling for Cleaning/disinfection possible Direct connection not possible	50 ml (disposable syringe) with attached cannula (for backwash of the Blind lumens)	Standard brushes	disassembled, five times rinse inside, brush outside and inside	disassembled, rinse five times inside, outside and Brush inside	Disassembled Fit the outer pipe onto the flushing mandrel, insert the small parts into the outer pipe. Small parts basket Standard basket for others Parts	Loosely assemble Inner shaft and Lubricate thread	Loosely mounted Lubricated	Tbd which After the final results validation were evaluated	Tbd After the final results of the validation were evaluated
Aa2	Products with longer/closer Ringlumen (Standard) without Luer Lock and Flushing connection No disassembly possible	-	Standard brushes	disassembled brush outside and inside, rinse by immersion and removal	disassembled outside and inside Brush, rinse by submerging and removing.	Standard	Lubricate joint	Lubricated	Tbd which After the final results validation were evaluated	Tbd After the final results of the validation were evaluated
Aa3	Products with longer/closer Ringlumen (Standard) Direct connection not possible	50 ml (disposable syringe) Rinsing gun	Standard brushes Long brush (length>320mm, diameter approx. 6 mm)	Dismantle open and close five times, for ultrasonic Inserting the handle in the open position	Dismantled open and close five times, insert in open position for ultrasound treatment	Standard Dismantled	again assemble No lubrication permitted	mounted	Tbd which After the final results validation were evaluated	Tbd After the final results of the validation were evaluated

Aa4	Products with longer/closer Ringlumen (Standard) Dismantling for Cleaning/disinfection possible Direct connection not possible	5 ml (disposable syringe)	Standard brushes Long brush (length>320mm, diameter approx. 4 mm)	Dismantle five times inside flush, outside, move wire eyelet back and forth five times	Rinse inside five times, outside, wire eyelet back and forth five times	Standard Disassembled	Refit (only flush wire, not protective cap) for flushing connection) No lubrication permitted	mounted (only rins not Wire, for Protective cap Flushing connection)	Tbd whi After ch final results the validation were evaluated	Tbd After the final results of the validation were evaluated
From1	Products with longer/lower ring lumen (Standard, not rinsable	-	Standard brushes	Brush outside open and close five times, for ultrasonic action in Insert in open position	open and close five times, at Ultrasound action in Insert in open position	At Standard cor b	Loop shifted backwards No lubrication permitted	Standard	Tbd whi After ch final results the validation were evaluated	Tbd After the final results of the validation were evaluated
Ab3	Coated, flexible Shaft products with flushing connection (Luer Lock) with Closure cap for Luer Lock No disassembly possible	10 ml (disposable syringe)	Standard brushes	Open cap on the flushing connection Flush brush outside inside at least 5 times Loop at least Move 5 times forward and backward during soaking and rinse	Cap on Flushing connection open Brush outside inside at least 5 Rinse Loop at least 5 times Shift forward and backward during soak and rinse	Connection to Flush connection Loop move forward	Move loop backwards Cap on Flushing connection open no lubrication permitted	Cap on Flushing connection open Loop backwards move	tbd whi ch After the final results validation were evaluated	Tbd After the final results of the validation were evaluated
Ad1	Products with longer/closer Ringlumen With flushing connection (LuerLock) With protective cap	10 ml (disposable syringe)	Standard brushes	open and close five times, for ultrasonic action in Insert in open position	open and close five times, with Ultrasound action in Insert in open position	Connection to Rinse connection ss	Standard procedure Lubricate joint Cap on Open the rinsing hose Apply protective cap	Standard procedure Protective cap applied Cap on Open the rinsing hose Mouth parts closed	Tbd whi After ch final results the validation were evaluated	Tbd After the final results of the validation were evaluated

	No disassembly possible									
Ad2	*Tube shank Products with LuerLock No disassembly possible*	*10 ml (disposable syringe)*	*Standard brushes*	*outside brush inside Rinse at least 5 times Move the joint five times while soaking and Sinks*	*outside brush inside at least 5 Rinse times Move the joint five times while soaking and Sinks*	*Connection to Flush connection Mouthpiece in open position*	*Lubricate joints Close open Luer-Lock jaws*	*lubricated protective cap open Mouth part closed*	*tbd which After final results the validation were evaluated*	*tbd After the final results of the validation were evaluated*
B1	*Products with longer/lower single lumen with flush connection for flush pipes*	*50 ml (disposable syringe) / Flushing gun*	*Standard brushes flexible long Brush (length ≥ 700 mm, Diameter approx. 4 mm*	*Brush inside and outside Inside at least Rinse 5 times*	*inside and outside brush inside at least 5 Rinse times*	*Rinse lye applied to olive*	*No lubrication permitted*	*Standard*	*tbd which After final results the validation were evaluated*	*tbd After the final results of the validation were evaluated*

B2	Products with longer/lower single lumen and Luer/LuerLock With trumpets Valve	50 ml (disposable syringe) / Flushing gun additional closed screw cap	Standard brushes	Open the valve five times and Rinse through (connection via hose connection), brush outside and inside, dismantle the trumpet valve, the lateral Openings created by dismantling the trumpet Valve through the closed screw cap and a additional Screw cap causes close and inwards rinse again	Disassemble, Brush the outside and inside, open the valve five times and close flush (connection via Hose connection uss), the lateral Openings created by Disassembly of the trumpet Valve through the closed screw cap and an additional screw cap are caused, close and rinse out again towards the inside	the side openings, which can be opened by dismantling the trumpet Valves through the closed e Close the screw cap and an additional screw cap and connect it to the flushing connection. connect , Small parts baskets for internal parts of the trumpet v entils	reassemble (without Protective cap) Lubricate trumpet valve	mounted (without protective cap!) lubricated	Tbd wh After ich final results the validation were evaluated	Tbd After the final results of the validation were evaluated
B4	Products with longer/lower single lumen Luer/LuerLock	5 ml (disposable syringe)	Standard brushes	five times inside flush, connection via LuerLock), brush outside	flush five times inside, connection via LuerLock), brush outside	Connection via LuerLock	again assemble No lubrication permitted	Standard	Tbd After the final results of the validation were evaluated	Tbd After the final results of the validation were evaluated
C1	Products with very short/wide Ring lumen without LuerLock Dismantling for Cleaning/disinfection possible Direct connection not possible	50 ml (disposable syringe) /flush gun	Standard brushes Long brush (length > 510 mm: diameter approx. 4mm)	Dismantle five times inside flush, Brush inside and outside	Dismantled rinse five times inside, brush outside	Dismantled Standard cor b, Throw-over sleeve se in the Small parts cor b	again assemble Threads and inner shafts lubricate	Mounted Lubricated	Tbd After the final results of the validation were evaluated	Tbd After the final results of the validation were evaluated

C4	segmented Products with longer/narrow ring-shaped cannulas Dismantling for Cleaning/disinfection possible Direct connection not possible	-	Standard brushes	Disassemble Brush inside and outside Rinse at least 5 times	Disassembled inside and Brush outside inside and outside at least 5 Rinse times	Disassembled Basket for small parts	almost closed, but still a little loose mounted lubricate thread	almost closed, but still a little loosely mounted lubricated	Tbd After the final results of the validation were evaluated	tbd After the final results of the validation were evaluated
D2	Products with longer/lower single lumen With flushing hose olive	50 ml (disposable syringe) / Flushing gun	Standard brushes flexible long Brush (length ≥ 700 mm, Diameter approx. 4 mm	Brush inside and outside Inside at least Rinse 5 times	inside and outside brush inside at least 5 Rinse times	Apply rinsing water to olive	No lubrication permitted	Standard	Tbd After the final results of the validation were evaluated	tbd After the final results of the validation were evaluated
Ea2	Products with small cavities without LuerLock	10 ml (disposable syringe) with attached extra-long cannula (for backwashing of the Blind lumens)	Standard brushes	disassembled, backwash five times on the inside, brush on the outside (not on the inside). brush!)	disassembled, five times inside backwash, outside and Brush inside	Dismantled, put over rinsing hose (hose connection)S tandard basket	Loosely assemble Lubricate thread	Loosely mounted Lubricated	Tbd After the final results of the validation were evaluated	Tbd After the final results of the validation were evaluated
Ea3	Products with very narrow cavities without LuerLock, minimally open	10 ml (disposable syringe)	Standard brushes	five times inside flush, Brush outside (not inside brush!)	rinse five times inside, brush outside	Putting the rinsing hose on (hose connection)	No lubrication permitted	Standard	Tbd After the final results of the validation were evaluated	Tbd After the final results of the validation were evaluated
Eb2	Products with very short/wide ring-shaped Blind lumen without LuerLock	-	Standard brushes	brush outside, turn handle five times	brush outside, turn handle five times	Standard cor b	Lubricate spiral joint	Spiral joint lubricated	Tbd After the final results of the validation were evaluated	Tbd After the final results of the validation were evaluated

Fa1	Products with very complex lumen (instruments)	-	Standard brushes	Open and close the outer brushes five times. action in Insert in open position	open and close five times, at Ultrasound action in Insert in open position	Standard cor b, in Insert in open position	in open Position Lubricate the Joint	in open position Joint lubricated	Tbd After the final results of the validation were evaluated	Tbd After the final results of the validation were evaluated
Fa3	Products with very complex lumen (instruments)	-	Standard brushes	Open and close the outer brushes five times. Inserting the handle in the open position	open and close five times, at Ultrasound Inserting the handle in the open position	Standard cor b, in Insert in open position	in open Position Lubricate the Joint	in open position Joint lubricated	Tbd After the final results of the validation were evaluated	Tbd After the final results of the validation were evaluated
Fa4	segmented Products with longer/extremely narrow ring-shaped Cannulas and complex mechanism within Dismantling for Cleaning/disinfection possible Direct connection not possible	50 ml (disposable syringe) / Flushing gun	Standard brushes long brushes (length> 510 mm, diameter approx. 4 and 5 mm)	Disassemble Brush inside and outside Rinse at least 5 times	Disassembled Brush inside and outside inside and outside at least 5 Rinse times	Disassembled Use You take up the cistern lance for cannulated parts Standard cor b for others Parts	Reassemble lubricate all moving parts	Mounted (not drawer and cone part) Lubricated	Tbd After the final results of the validation were evaluated	tbd After the final results of the validation were evaluated
G1	Products with Joint, dismountable	-	Standard brushes Long brush (length >400 mm; diameter approx. 12 mm)	disassembled, handle tubes with running water flush, Open and close the joint five times, at Ultrasound treatment joint in open Insert position	disassembled, joint, open and close five times, at Ultrasound treatment Joint in Insert in open position	Standard basket, disassembled, joint in Insert in open position	assemble (handlebars) the joints lubricate	Mounted Lubricated	Tbd After the final results of the validation were evaluated	Tbd After the final results of the validation were evaluated

G4	Products with Joint / Thread	-	Standard brushes	Outside and in the Brush gaps Open and close five times, for ultrasound treatment joint in open position. Insert position	Outside and in the gaps brushes open and close five times, at Ultrasound treatment Joint in Insert in open position	Standard basket b, insert joint in open position	not complete closed Lubricate the joints and the Thread of the Spindle	not completely closed	Tbd After the final results of the validation were evaluated	Tbd After the final results of the validation were evaluated
G6	Self-closing joint instruments	-	Standard brushes	Brush inside and outside, Open and close five times, for ultrasound treatment joint in open position. Insert position (if no Locking device present, Hinge through rubber band/stainless steel wire loop e to keep the handles open)	Brush inside and outside, open and close five times, at Ultrasound treatment Joint in Insert in open position (if No locking device available, Joint through rubber band/steel wire loop open around the handles keep open)	Standard basket b, insert joint in open position (if there is no locking device, insert joint by Rubber band /Stainless steel wire loop to hold the handles open).	in slightly opened Position the joints lubricate	in slightly opened Position Joints lubricated	Tbd After the final results of the validation were evaluated	Tbd After the final results of the validation were evaluated
G7, G8	Shaker Dismountable	-	Standard brushes	Dismantle Brush inside and outside Crank at least five Move times during the Soaking and Sinks	Dismantled inside and brush outside crank at least five Move times during the Soaking and Sinks	Standard cor b Dismantled	Lubrication not permitted	Mounted	Tbd After the final results of the validation were evaluated	tbd After the final results of the validation were evaluated

H	*No special notes*	*No special notes*	*No special notes*	*No special notes*	*No special notes*	*No special notes*	*No special notes*	*No special notes*	*No special notes*	*No special notes*