

Preparation Instructions

Preparation (Cleaning, Disinfection and Sterilization) of Products

All products must be cleaned, disinfected and sterilized before each use; this particularly applies to the first use after delivery, as all products are delivered unsterilized (cleaning and disinfection after removing the transport protection packaging; sterilization after packaging). A thorough cleaning and disinfection is an indispensable requirement for effective sterilization.

Please note as part of your responsibility for the sterility of the products during use that

- generally, only suitable equipment and product-specific validated procedures are to be used for cleaning/disinfection and sterilization,
- the equipment used (WD, sterilizer, etc.) are to be regularly maintained and inspected, and
- the validated parameters are to be observed for each cycle.

Please ensure during use that contaminated instruments are collected separately and not placed back into the instrument tray in order to avoid further contamination of the loaded instrument tray. Clean/disinfect the contaminated instruments, then resort them back into the instrument tray and then sterilize the fully loaded instrument tray.

Please also adhere to the legal requirements applicable in your country as well as the hygienic requirements of the medical practice or hospital. This particularly applies to the various requirements (e.g. in Germany according to attachment 7 of KRINKO RKI BfArM recommendation for processing) regarding to an effective prion inactivation (not applicable for the USA).

Remark:

Application of the products is only admitted to qualified professionals.

Processing must performed only by qualified staff in the central sterilization service department of the hospital or in the processing room of the medical practice. Hospital or medical practice are responsible for selection and application of required of protective equipment and hygienic measures.

Please observe differing and/or additional requirements for several products in the "Special Instructions" section.

Cleaning and Disinfection

Principles

For cleaning and disinfection, if possible, an automated procedure [WD (washer-disinfector)] should be used. A manual procedure – even using an ultrasound bath – should only be used according to country specific requirements (e.g. in Germany for critical B products automated procedure binding) and if an automated procedure is not available due to the significantly lower effectiveness and reproducibility.

Pretreatment must be carried out in both cases.

Pretreatment

Immediately after use (within maximum 2 h), large impurities must be removed from the products. If observation of this time is not possible in consequence of duration of application or of

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organizational reasons, it is the responsibility of the user to define and validate measures in order to avoid complete drying of contamination.

- Procedure
1. Disassemble the products as possible.
 2. Rinse the products for at least 1 min under running water (temperature < 35 °C/95 °F). Shift the movable parts back and forth at least three times during the prewash.
If applicable (see "Special Instructions" section):
Rinse all lumina of the products at least three times (aids and minimum volume depend on the cavity to be rinsed).
 3. Insert the disassembled products for the predefined soaking time in the pre-cleaning bath¹ (in an ultrasound bath that is not already activated), so that the products are completely submerged. Ensure that the products do not touch. Support the pre-cleaning by completely brushing all internal and external surfaces (at the beginning of the soaking time, see "Special Instructions" section for aids). The diameter of the brushes to be used for the channel is required to be slightly larger as the inner diameter of the corresponding channel. The length of shaft of the brush must not be shorter as the length of the channel.
Shift the movable parts back and forth at least three times during the pre-cleaning.
If applicable (see "Special Instructions" section):
Rinse all lumina of the products at least three times at the beginning and end of the soaking time (aids and minimum volume depending on the cavity to be rinsed).
 4. Activate the ultrasound for an additional minimum soaking time (but not less than 5 min).
 5. Then remove the products from the pre-cleaning bath and rinse them at least three times thoroughly (for at least 1 minute) with water. Shift the movable parts back and forth at least three times when rinsing.
If applicable (see "Special Instructions" section):
Rinse all lumina of the products at least three times (aids and minimum volume depend on the cavity to be rinsed).

When selecting the cleaning agent¹, ensure that

- it is generally suitable for cleaning invasive medical devices made of metals and plastics,
- the cleaning agent is suitable for ultrasound cleaning (no foam formation),
- the cleaning agent is compatible with the products (see "Material Stability" section).

The concentrations, temperatures and soaking times specified by the manufacturer of the cleaning agent or the cleaning/disinfecting agent as well as the specifications for rinsing, must be adhered to. Only use freshly prepared solutions, sterile or low-germ (max. 10 bacteria/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water)² or only with a soft, clean, lint-free cloth (Attention: caution in case of products with rough surfaces, threads, sharp edges or comparable aspects with danger of attachment of particles from the cloth!) and/or filtered air to dry.

¹ If you – e.g. for occupational safety reasons – use a cleaning and disinfecting agent for this, please ensure that this is aldehyde-free (otherwise it would fixate blood contaminants) and has verified effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking), is suitable for disinfecting the products and is compatible with the products (see "Material Stability" section). Please keep in mind that the disinfecting agent used in pretreatment serves only for personal protection and cannot replace the disinfection step to be carried out later after cleaning.

² In case of consideration of a lower water quality as sufficient based on the background of national recommendations (e.g. in Germany KRINKO RKI BfArM recommendation for processing).

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Automated Cleaning/Disinfecting [WD (Cleaning and Disinfection Device)]

When selecting the WD, ensure that

- the WD generally has verified effectiveness (e.g. DGHM or FDA approval/clearance/registration or CE marking in accordance with DIN EN ISO 15883),
- if possible, a tested program for thermal disinfection (A_0 value ≥ 3000 or – for older devices – at least 5 min at 90 °C/194 °F) is used (in chemical disinfection danger of disinfecting agent residues on the products),
- the program used is suitable for the products and contains sufficient rinsing steps (at least three degrading steps after cleaning (respectively neutralization, if applied) or conductance based rinsing control recommended in order to prevent effectively remnants of the detergents),
- for rinsing only sterile (max. 10 bacteria/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water) is used,
- air used for drying is filtered (oil-free, low-bacteria and low-particle) and
- the WD is regularly maintained, inspected, and calibrated.

When selecting the cleaning system, ensure that

- it is generally suitable for cleaning medical instruments made of metals and plastics,
- providing no thermal disinfection is used – a suitable disinfecting agent with verified effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is also used and that it is compatible with the cleaning agent used, and
- the chemicals used are compatible with the products (see “Material Stability” section).

The concentrations, temperatures and soaking times specified by the manufacturer of the cleaning agent and, if applicable, the disinfecting agent as well as specifications for rinsing must be adhered to.

Procedure

1. Disassemble the products as much as possible.
2. Place the disassembled products into the WD. Ensure that the products do not touch.
If applicable (see chapter “Special instructions”):
Enable active rinsing by connecting to the WD rinse port.
3. Start the program.
4. Disconnect the WD (at the appropriate time) and remove the products after the program has completed.
5. Inspect and pack the products as soon as possible after removal (see “Inspection,” “Maintenance” and “Packaging” chapters, possibly after additional drying in a clean area).

The verification of products’ general suitability for effective automated cleaning and disinfecting was provided by an independent, governmentally accredited and recognized (§ 15 (5) MPG) test laboratory using the G 7836 CD washer-disinfector (thermal disinfection, Miele & Cie. GmbH & Co., Gütersloh) and the Neodisher MediClean forte pre-cleaning and cleaning agent (Dr. Weigert GmbH & Co. KG, Hamburg). Here, the procedure described above was taken into consideration.

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Manual cleaning and disinfection

When selecting the cleaning and disinfecting agent, ensure that

- it is generally suitable for cleaning and disinfecting medical instruments made of metals and plastics,
- the cleaning agent is suitable for ultrasound cleaning (no foam formation),
- a disinfecting agent with verified effectiveness (e.g. VAH/DGHM or FDA/EPA approval/clearance/registration or CE marking) is used and that this is compatible with the cleaning agent used, and
- the chemicals used are compatible with the products (see "Material resistance" chapter).

Combined cleaning/disinfecting agents should not be used if possible. Combined cleaning/disinfecting agents can be used only in cases of very low contamination (no visible impurities).

In case of manual cleaning and disinfection with a potential risk of injury and infection observation of measures of employment protection (e.g. protective clothing, protective glasses, gloves, air filtration) according to national requirements (e.g. in Germany TRBA 250) is required.

The concentrations, temperatures and soaking times specified by the manufacturer of the cleaning and disinfecting agent as well as specifications for rinsing, must be adhered to. Only use freshly prepared solutions, sterile or low-germ (max. 10 bacteria/ml) and low-endotoxin (max. 0.25 endotoxin units/ml) water (e.g. purified water/highly purified water)³ or only with a soft, clean, lint-free cloth (Attention: caution in case of products with rough surfaces, threads, sharp edges or comparable aspects with danger of attachment of particles from the cloth!) and/or filtered air to dry.

Procedure

Cleaning

1. Disassemble the products as much as possible.
2. Place the disassemble products for the predefined soaking time in the cleaning bath (in an ultrasound bath that is not already activated), so that the products are completely submerged. Ensure that the products do not touch. Support the cleaning by completely brushing all internal and external surfaces with a soft brush. (Attention: Caution with products with narrow gaps, in which bristles of the brush can get stuck!) The diameter of the brushes to be used for the channel is required to be slightly larger as the inner diameter of the corresponding channel. The length of shaft of the brush must not be shorter as the length of the channel. Shift the movable parts back and forth several times during cleaning. If applicable (see "Special Instructions" section): Rinse all lumina of the products at least five times at the beginning and end of the soaking time (aids and minimum volume depending on the cavity to be rinsed).
3. Activate the ultrasound for an additional minimum exposure time (but not less than 5 min).
4. Then remove the products from the pre-cleaning bath and rinse them at least three times thoroughly (for at least 1 minute) with water. Shift the movable parts back and forth several times when rinsing. If applicable (see chapter "Special instructions"): Rinse all lumina of the products at least five times (aids and minimum volume depend on the cavity to be rinsed).

³ In case of consideration of a lower water quality as sufficient based on the background of national recommendations (e.g. in Germany KRINKO RKI BfArM recommendation for processing).

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5. Inspect the products (see "Inspection" and "Maintenance" chapters).

Disinfection

6. Place the disassembled and inspected products in the disinfection bath for the predefined soaking time so that the products are completely submerged. Ensure that the products do not touch. Shift the movable parts back and forth several times during the disinfection.
If applicable (see "Special Instructions" section): Rinse all lumina of the products at least five times at the beginning and end of the exposure time (aids and minimum volume depending on the cavity to be rinsed).
7. Then remove the products from the disinfection bath and rinse them at least five times thoroughly (for at least 1 minute) with water. Shift the moving parts back and forth several times during the rinse.
If applicable (see chapter "Special instructions"): Rinse all lumina of the products at least five times (aids and minimum volume depend on the cavity to be rinsed).
8. Dry the products with filtered compressed air.
9. Pack the products as soon as possible after removal (see "Packaging" section, possibly after additional drying in a clean area).

The proof of the general suitability of the products for effective manual cleaning and disinfecting was provided by an independent, governmentally accredited and respected (§ 15 (5) German Law for Medical Devices) test laboratory using the Cidezyme/Enzol pre-cleaning and cleaning agent and the Cidex OPA disinfecting agent (Johnson & Johnson GmbH, Norderstedt). Here, the procedure described above was taken into consideration.

Inspections

Check all products after cleaning or cleaning/disinfecting for corrosion, damaged surfaces, chippings, contaminants and stains as well as remove damaged products (numerical restriction of reuse, see "Reusability" section). Any products that are still contaminated must be cleaned again and disinfected.

Maintenance

Reassemble disassembled products.

Instrument oiled or grease may not be used.

Exception (only for specific instruments, see "Special Instructions" section, not for implants):
In the case of oiling joints, ensure that only instrument oils (white oil, without further additives) are used, which – taking into account the maximum applied sterilization temperature – are approved for steam sterilization and have a certified biocompatibility and that only a small amount is applied to the joints.

Packaging

Sort the cleaned and disinfected products into the corresponding sterilization tray.
Please pack the products or the sterilization trays in sterilization containers or very large products in single-use sterilization packaging (single or double packaging) in accordance with the following requirements (material/process):

- DIN EN ISO/ANSI AAMI ISO 11607 (for USA: FDA clearance)

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- suitable for steam sterilization (temperature stability up to at least 138 °C (280 °F) sufficient steam permeability)
- sufficient to protect the products or sterilization packaging from mechanical damage
- undergo regular maintenance according to the manufacturer's specifications (sterilization containers)
- do not exceed a maximum weight of 10 kg per package/contents of the sterilization container.

Sterilization

For sterilization, only the following sterilization methods may be used; other sterilization methods are not allowed.

Steam sterilization

- Fractionated vacuum procedure^{4, 5} (with sufficient product drying⁶)
- Steam sterilizer in accordance with DIN EN 13060/DIN EN 285 or ANSI AAMI ST79 (for USA: FDA clearance)
- Validated in accordance with DIN EN ISO 17665 (valid IQ/OQ (commissioning) and product-specific performance assessment (PQ))
- maximum sterilization temperature 134 °C (273 °F; plus tolerance in accordance with DIN EN ISO 17665)
- Sterilization time (exposure time at sterilization temperature):

Country	Fractionated vacuum procedure	Gravity displacement
Germany	at least 5 min ⁷ at 134 °C (273 °F)	not recommended ⁵
USA	at least 4 min at 132 °C (270 °F), drying time at least 20 min ⁴	not recommended ⁵
France	at least 5 min at 134 °C (273 °F) if required for prion inactivation sterilization time 18 min	not recommended ⁵
other countries	at least 5 min ⁷ at 132 °C (270 °F) / 134 °C (273 °F)	not recommended ⁵

Verification of the general suitability of the products for effective steam sterilization was provided by an independent, governmentally accredited and respected (§ 15 (5) MPG) test laboratory using the HST 6x6x6 steam sterilizer (Zirbus technology GmbH, Bad Grund) and using the fractionated vacuum procedure, as well as the instrument oil LAWTON MEDOIL. Here, the typical conditions in the clinic and medical practice and the procedure described above were taken into consideration.

The flash sterilization procedure is generally not permitted.

Do not use dry head sterilization, radiation sterilization, formaldehyde or ethylene oxide sterilization, or plasma sterilization.

Storage

After sterilization, the products must be stored dry and free of dust in the sterilization packaging.

⁴ at least three vacuum steps

⁵ The use of the less effective gravity displacement is only permitted if the fractionated vacuum procedure is not available. It requires significantly longer sterilization times and must be validated by the user for each specific product, device, procedure and parameter.

⁶ The actual required drying time depends directly on the parameters, which are the sole responsibility of the user (loading configuration and density, sterilizer status) and must, therefore, be determined by the user. Nonetheless, drying time should not be under 20 min.

⁷ or 18 min (prion inactivation, not relevant for the USA)

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Material Stability

When selecting the cleaning and disinfection agents, please ensure that they do not contain the following components:

- Organic, mineral and oxidizing acids (minimum permitted pH value 5.5)
- Alkalis/strong alkalis (neutral/enzymatic (max. permitted pH 8.5, mandatory requirement for products made of aluminum or other alkali-sensitive materials, see "Special Instructions" section) or alkaline cleaner (max. permitted pH 11, mandatory requirement for products with intended application in prion-critical areas, e.g. in accordance with Annex 7 of KRINKO RKI BfArM recommendation for treatment) recommended)
- Organic solvents (e.g. alcohols, ethers, ketones, benzines)
- Oxidizing agents (e.g. hydrogen peroxides)
- Halogens (chlorine, iodine, bromine)
- Aromatic/halogenated hydrocarbons

Never clean products, sterilization trays or sterilization containers with metal brushes or steel wool.

All products, sterilization trays and sterilization containers can only be exposed to temperatures under 138 °C (280 °F).

Reusability

With proper care, the products can be reused if they are undamaged and uncontaminated. Each additional use or using damaged and/or contaminated products is the user's responsibility.

If disregarded, any liability is excluded.

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Specific aspects

Geometric aspects			material		specific/additional procedure in case of				maintenance/ packaging	sterilization
worst case type	specific geometric aspects	rinsing volume	brushes	cleaning/ disinfection pretreatment	manual cleaning/ disinfection	automated cleaning/ disinfection				
Aa1	Products with longer/narrower ring-shaped lumen without rinsing connection Disassembly for cleaning/disinfection possible	50 ml (single-use syringe / rinsing pistol)	standard brushes	Disassembled Brush inside and outside Rinse the lumen at least five times	disassembled Brush inside and outside Rinse the lumen at least five times	Disassembled Rinsing the lumen with a rinsing lance Small parts in small parts basket	assemble loosely lubricate threads and inner shaft	standard		
Aa2	Product with longer/narrower ring-shaped lumen without rinsing connection No disassembly for cleaning/disinfection possible	-	standard brushes	Brush outside Open and close the joints at least five times Joints are in the open position during ultrasound	Not permissible	joints in open position	lubricate joints	standard		
Aa3	Product with longer/narrower ring-shaped lumen without rinsing connection Disassembly for cleaning/disinfection possible	50 ml (single-use syringe / rinsing pistol)	standard brushes long brush (length > 320 mm, diameter approx. 6 mm)	Not permissible	Not permissible	Not permissible	assemble again lubrication not admitted	standard		
Aa4	Product with longer/narrower ring-shaped lumen with rinsing connection (olive) Disassembly for cleaning/disinfection possible	5 ml (single-use syringe)	standard brushes	Disassembled (cleaning wire and protective cap) Brush outside Flush the lumen at least five times via the rinsing connection	Disassembled (rinsing wire and protective cap) Brush outside Flush the lumen at least five times via the rinsing connection	Disassembled connect to rinsing port Small parts in small parts basket	assemble again (only rinsing wire, not protective cap) lubrication not admitted	standard		
Ab1	Products with longer/lower ring-shaped lumen (flexible) without rinsing connection Disassembly for cleaning/disinfection not possible	-	standard brushes	Brush outside Open and close the joints at least five times Joints are in the open position during ultrasound	Not permissible	joints in open position	Lubricate joints Jaw closed	standard		
Ab3	coated flexible shaft products with rinsing connection (LuerLock) with cap for closure of LuerLock Disassembly for cleaning/disinfection not possible	10 ml (single-use syringe)	standard brushes	open cap on rinsing connection brush outside rinse the lumen at least five times move loop at least five times forwards and backwards during soaking and rinsing	Not permissible	connect to rinsing port loop moved forwards	lubrication not admitted loop moved backwards cap on rinsing port opened	standard		

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Geometric aspects			material		specific/additional procedure in case of				sterilization
worst case type	specific geometric aspects	rinsing volume	brushes	cleaning/ disinfection pretreatment	manual cleaning/ disinfection	automated cleaning/ disinfection	maintenance/ packaging		
Ad1	Products with longer/narrower ring-shaped lumen with rinsing connection (LuerLock) with protective cap (rinsing connection) Disassembly for cleaning/disinfection not possible	10 ml (single-use syringe)	standard brushes	Brush outside Open the protective cap Open and close the joints at least five times Joints are in the open position during ultrasound Flush the lumen at least five times via the rinsing connection	Brush outside Open the protective cap Open and close the joints at least five times Joints are in the open position during ultrasound Rinse the lumen at least five times via the rinsing connection	connect to rinsing port joints in open position	lubricate joint jaw closed cap on rinsing port opened apply protective cap to the working end	standard	
Ad2	Products with longer/narrower ring-shaped lumen with rinsing connection (LuerLock) with protective cap (rinsing connection) Disassembly for cleaning/disinfection not possible	10 ml (single-use syringe)	standard brushes	Open the protective cap Open and close the joints at least five times Joints are in the open position during ultrasound Rinse the lumen at least five times via the rinsing connection	Open the protective cap Open and close the joints at least five times Joints are in the open position during ultrasound Rinse the lumen at least five times via the rinsing connection	connect to rinsing port joints in open position	lubricate joint jaw closed cap on rinsing port opened	standard	
B1	Product with longer/narrower circular lumen with rinsing connection (olive) Disassembly for cleaning/disinfection not possible	50 ml (single-use syringe / rinsing pistol)	standard brushes flexible long brush (length ≥ 700 mm, diameter approx. 4 mm)	brush inside and outside rinse lumen at least five times via the rinsing connection	brush inside and outside rinse lumen at least five times via the rinsing connection	connect to rinsing port	no lubrication admitted	standard	
B2	Product with longer/narrower circular lumen with rinsing connection (Luer-Lock or olive) Disassembly for cleaning/disinfection possible	50 ml (single-use syringe / rinsing pistol)	standard brushes	Rinse the lumen at least five times via the rinsing connection with the trumpet valve depressed Disassemble the trumpet valve Brush inside and outside Rinse the lumen at least five times via the rinsing connection Close the side openings with protective caps Rinse the lumen at least five times via the rinsing connection and fitted protective caps	disassembled Brush inside and outside Rinse the lumen at least five times via the rinsing connection Close the side openings with protective caps Rinse the lumen at least five times via the rinsing connection and fitted sealing caps	Disassembled Close the side openings with protective caps connect to rinsing port Small parts basket for disassembled parts	assemble again (without protective cap) lubricate trumpet valve	standard	
B4	Product with longer/ very narrow circular lumen with rinsing connection (LuerLock) Disassembly for cleaning/disinfection not possible	5 ml (single-use syringe)	standard brushes	brush carefully outside rinse lumen at least five times via rinsing connection	brush carefully outside rinse lumen at least five times via rinsing connection	connect to rinsing port	no lubrication admitted	standard	
C1	Products with longer/narrower ring-shaped lumen without rinsing connection Disassembly for cleaning/disinfection possible	50 ml (single-use syringe / rinsing pistol)	standard brushes long brush (length > 510 mm, diameter approx. 4 mm)	Disassembled brush inside and outside rinse lumen at least five times	Disassembled brush inside and outside rinse lumen at least five times	Disassembled Small parts basket for disassembled parts	assemble again lubricate threads and inner shaft	standard	

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Geometric aspects		material		specific/additional procedure in case of cleaning/ disinfection				maintenance/ packaging	sterilization
worst case type	specific geometric aspects	rinsing volume	brushes	pretreatment	manual cleaning/ disinfection	automated cleaning/ disinfection			
C4	Product with longer/ very narrow ringlike lumen with rinsing connection disassembly for cleaning/disinfection possible	-	standard brushes	not admitted	not admitted	not admitted	assemble loosely lubricate thread	standard	
D2	products with longer/ Inarrower ring-shaped lumen with rinsing connection (olive) Disassembly for cleaning/disinfection not possible	50 ml (single-use syringe/ rinsing pistol)	standard brushes flexible long brush (length ≥ 700 mm, diameter approx. 4 mm)	Brush inside and outside Rinse the lumen at least five times via the rinsing connection	Brush inside and outside Rinse the lumen at least five times via the rinsing connection	connect to rinsing port	no lubrication admitted	standard	
Ea2	Product with circular blind lumens without rinsing connection Disassembly for cleaning/disinfection possible	10 ml (single-use syringe with fitted extra long cannula (for post-rinsing of the blind cavity)	standard brushes	disassembled Brush outside Do not brush inside Back-rinse the lumen at least five times	disassembled Brush outside Do not brush inside Back-rinse the lumen at least five times	Disassembled Small parts basket for disassembled parts	assemble loosely lubricate thread	standard	
Ea3	Product with narrow circular blind lumens with rinsing connection (olive) disassembly for cleaning/disinfection not possible	10 ml (single use syringe)	standard brushes	Brush outside Do not brush inside Rinse lumen at least five times via rinsing connection	Brush outside Do not brush inside Rinse lumen at least five times via rinsing connection	connect to rinsing port	no lubrication admitted	standard	
Eb2	Product with narrow ring-shaped blind lumen (handle with swivel joint) without rinsing connection Disassembly for cleaning/disinfection not possible	-	standard brushes	brush outside articulate grip at least five times	brush outside articulate grip at least five times	standard	lubricate grip	standard	
Fa1	Products with complex lumen (sliding stem) without rinsing connection disassembly for cleaning/disinfection not possible	-	standard brushes	Brush outside Open and close the joints at least five times Joints are in the open position during ultrasound	Brush outside Open and close the joints at least five times Joints are in the open position during ultrasound	Insert joints in opened position	lubricate joints in opened position	standard	
Fa3	Products with complex lumen (sliding stem) without rinsing connection disassembly for cleaning/disinfection not possible	-	standard brushes	Brush outside Open and close the joints at least five times Joints are in the open position during ultrasound	Brush outside Open and close the joints at least five times Joints are in the open position during ultrasound	Insert joints in opened position	lubricate joints in opened position	standard	
Fa4	Product with longer/ extremely narrow ring-shaped lumen (tube shaft) and complex mechanism inside without rinsing connection Disassembly for cleaning/disinfection possible	50 ml (single-use syringe/ rinsing pistol)	standard brushes long brushes (length > 510 mm, diameter approx. 4 and 5 mm)	disassembled Brush inside and outside Rinse the lumen at least five times	disassembled Brush inside and outside Rinse the lumen at least five times	Disassembled Rinsing the lumen with a rinsing lance	assembled (not loading and cone part) Lubricate all moving parts	standard	

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Geometric aspects		material		specific/additional procedure in case of				maintenance/ packaging	sterilization
worst case type	specific geometric aspects	rinsing volume	brushes	cleaning/ disinfection pretreatment	manual cleaning/ disinfection	automated cleaning/ disinfection			
G1	Products with hinge and longer circular lumen Without rinsing connection Disassembly for cleaning/disinfection possible	-	standard brushes long brushes (length > 400 mm, diameter approx. 12 mm)	Disassemble (handle tubes) Brush outside and inside Rinse lumen at least five times (handle tubes) Open and close joint at least five times Joints are in open position during ultrasound	Disassemble (handle tubes) Brush outside and inside Rinse lumen at least five times (handle tubes) Open and close joint at least five times Joints are in open position during ultrasound	Disassembled (handle tubes) insert joints in opened position	assemble (handle tubes) lubricate the joints	standard	
G4	Product with multiple joints and open thread Without rinsing connection disassembly for cleaning/disinfection not possible	-	standard brushes	Open and close joints (incl. locking mechanism) at least five times Brush outside and between the gaps Joints are in open position during ultrasound	Open and close joints (incl. locking mechanism) at least five times Brush outside and between the gaps Joints are in open position during ultrasound	insert joints in opened position	Lubricate joints and threads Joint not fully closed	standard	
G6	Product with joint (double transmission) self-closing (with locking) without rinsing connection disassembly for cleaning/disinfection not possible	-	standard brushes	Open and close joints (incl. locking mechanism) at least five times Brush on outside and between gaps Joints are in open position during ultrasound	Open and close joints (incl. locking mechanism) at least five times Brush on outside and between gaps Joints are in open position during ultrasound	insert joints in opened position	Lubricate the joints Joint not fully closed	standard	
G7	Retractor without rinsing connection Disassembly for cleaning/disinfection possible	-	standard brushes	disassembled Brush outside and inside Turn crank at least five times	disassembled Brush outside and inside Turn crank at least five times	disassembled	assembled lubrication not admitted	standard	
G8	Retractor without rinsing connection Disassembly for cleaning/disinfection possible	-	standard brushes	disassembled Brush outside and inside Turn crank at least five times	disassembled Brush outside and inside Turn crank at least five times	disassembled	assembled lubrication not admitted	standard	