

Master reprocessing instruction

Reprocessing (Cleaning, Disinfection and Sterilization)
of products



REF see AA_200_EN_Article annex list



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1. General Principles

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 reprocessing) regarding to an effective prion inactivation (not applicable for the USA).

Remark:

Application of the products is only admitted to qualified professionals.

Reprocessing must be 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 protective equipment and hygienic measures.

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

2. 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.

3. 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 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 (see specific disassembly/assembly instructions).
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

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(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).

4. 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 (A0 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:

- Disassemble the products as much as possible (see specific disassembly/assembly instructions).
- 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.
- Start the program. **The validated cycle parameters are as follows:**

Step	Description	Medium	Temperature [°C]	Duration [Min.]
1	Pre-rinse	Water	Not tempered (< 30°C)	1
2	Draining	-	-	-
3	Cleaning	Alkaline cleaning detergent: Neodisher MediClean forte (Dr. Weigert GmbH & Co. KG, Hamburg) Concentration: 0.2 – 1% (according to specification Detergent manufacturer)	55° C	10
4	Draining	-	-	-
5	Rinse	Demineralized water	Not tempered (< 30°C)	1
6	Draining	-	-	-
7	Disinfection (thermal)	-	95° C	5
8	Drying	Hot air	100 ° C	25

- Disconnect the WD (at the appropriate time) and remove the products after the program has completed.
- 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.

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. 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 (see specific disassembly/assembly instructions).
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).
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.

6. Inspections / Product life

Any products that are still contaminated must be cleaned again and disinfected.

The products are intended for multiple use. Whereby the end of the product life is usually determined by wear and damage after use.

In order to be able to prove the suitability of the reuse of the products for operational use, they should be checked after each reprocessing in accordance with the specifications of DIN 96298-4. The following characteristics must be checked:

- Cleanliness
- Missing parts
- Breakage
- Deformation
- Surface changes such as corrosion, discoloration, cracks, changes to coatings
- Marking

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The life of the products is finished when

- it can no longer fulfill its intended purpose and thus its function (e.g. breakage or strong deformation)
- traceability is no longer guaranteed (e.g. marking, UDI code no longer readable)
- the surface is damaged in such a way that the product can no longer be used safely (e.g. rust formation, burrs, sharp edges)

If the end of the product's service life has been reached, the products must be marked as no longer functional and sorted out. After reprocessing, the products are to be sent for repair to the manufacturer or for disposal in accordance with hospital practice.

7. Maintenance

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

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.

8. 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)
- 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.

9. 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 ⁷ 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

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)

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 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.

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10. Storage

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

11. 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).

12. 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.

13. Specific aspects (see following pages)

Attention: The following table provides special instructions for certain products within the various geometry groups with regard to additional procedures for pretreatment, manual and mechanical cleaning/disinfection, care, packaging and sterilization. Please refer to the annex „AA_200_EN_Article annex list“ to find out which products have been assigned to which geometry groups. If you cannot find the product in this annex, please contact our service department.

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EN

Geometric aspects			Specific/additional procedure in case of						
Worst case type	Specific geometric aspects	Rinsing volume	Brushes	Pretreatment	Manual cleaning/ disinfection	Automated cleaning/ disinfection	Maintenance/ packaging	Sterilization	Recommended classification according to KRIN- KO/RKI/BfArM guidance (only Germany, with respect to intended use)
AA	segmented products with longer/narrow ringlike cannulation dismantling for cleaning/disinfection possible direct connection not possible	50 ml (single-use sy- ringe) / rinsing pistol	standard brushes	dismantle brush inside and outside rinse at least 5times inside and outside	dismantled brush inside and outside rinse at least 5times inside and outside	dismantled use rinsing lance for cannulated parts standard basket for other parts	assemble loosely lubricate threads and inner shaft	loosely mounted lubricated	Critical C
	tube shaft products with self-closing jaw without LuerLock or rinsing port no dismantling possible	-	standard brushes	brush outside least 5times during soaking and rinsing	brush outside least 5times during soaking and rinsing	jaw in open position	lubricate joint	lubricated	Critical C
	segmented products with longer/narrow ringlike cannulation dismantling for cleaning/disinfection possible direct connection not possible	50 ml (single-use syringe) / rinsing pistol	standard brushes long brush (length > 320 mm, diameter approx. 6 mm)	dismantle brush inside and outside rinse at least 5times inside and outside	dismantled brush inside and outside rinse at least 5times inside and outside	dismantled use rinsing lance for cannulated parts standard basket for other parts	assemble again no lubricated admitted	mounted	Critical C
	segmented products with longer/extre- mely narrow ringlike cannulation dismantling for cleaning/disinfection possible direct connection not possible	5 ml (single-use syringe)	standard brushes long brush (length > 320 mm, diameter approx. 4 mm)	dismantle (and dispose protective tube for the tips) brush outside rinse at least 5times inside and outside	dismantled brush inside and outside rinse at least 5times inside and outside	dismantled apply rinsing tube to the flush port small pieces basket for cleaning wire	assemble again (only rinsing wire, not protective cap for flush port) no lubrication admitted	mounted (only rinsing wire, not protective cap for flush port)	Critical C

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Geometric aspects		Specific/additional procedure in case of							
Worst case type	Specific geometric aspects	Rinsing volume	Brushes	Pretreatment	Manual cleaning/ disinfection	Automated cleaning/ disinfection	Maintenance/ packaging	Sterilization	Recommended classification according to KRIN-KO/RKI/BfArM guidance (only Germany, with respect to intended use)
AB	uncoated flexible shaft products no flush port no dismantling possible	-	standard brushes	brush outside articulate jaw at least 5times forwards and backwards during soaking and rinsing	brush outside articulate jaw at least 5times forwards and backwards during soaking and rinsing	in standard basket	loop moved backwards no lubrication admitted	standard	Critical B
	coated flexible shaft products with flush port (LuerLock) with cap for closure of LuerLock no dismantling possible	10 ml (single-use syringe)	standard brushes	open cap on flush port brush outside rinse inside at least 5times move loop at least 5times forwards and backwards during soaking and rinsing	cap on flush port opened brush outside rinse inside at least 5times move loop at least 5times forwards and backwards during soaking and rinsing	connect to rinsing port loop moved forwards	loop moved backwards cap on flush port opened no lubrication admitted	cap on flush port opened loop moved backwards	Critical B
AD	flexible tube shaft products with flush port (LuerLock) with protective cap no dismantling possible	10 ml (single-use syringe)	standard brushes	brush outside rinse inside at least 5times (flush port) articulate joint at least 5times during soaking and rinsing	brush outside rinse inside at least 5times (flush port) articulate joint at least 5times during soaking and rinsing	connect to rinsing port	lubricate joint cap on flush port opened apply protective cap	cap on flush port opened protection cap applied jaw closed	Critical C
	tube shaft products with LuerLock no dismantling possible	10 ml (single-use syringe)	standard brushes	brush outside rinse inside at least 5times articulate joint at least 5times during soaking and rinsing	brush outside rinse inside at least 5times articulate joint at least 5times during soaking and rinsing	connect to rinsing port jaw in open position	lubricate joint open Luer-Lock close jaw	lubricated protection cap opened jaw closed	Critical C

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Worst case type	Specific geometric aspects	Rinsing volume	Brushes	Pretreatment	Manual cleaning/ disinfection	Automated cleaning/ disinfection			
B	products with longer/ narrow cavity with flush port for rinsing tubes	50 ml (single-use sy- ringe) / rinsing pistol	standard brushes flexible long brush (length $\geq$ 700 mm, dia- meter approx. 4 mm)	brush inside and outside rinse inside at least 5times	brush inside and outside rinse inside at least 5times	apply rinsing tube to the olive	no lubrication admitted	standard	Critical C
	products with longer/ narrow cavity with Luer-Lock with trumpet valve	50 ml (single-use sy- ringe) / rinsing pistol additional closed screw cap	standard brushes	rinse at least 5times inside with pressed trumpet valve dismantle the trumpet valve brush inside and outside rinse at least 5times inside and outside close the lateral openings caused by dismantling of the trumpet valve by the closed screw cap and one additional screw cap and rinse inside again	dismantled brush inside and outside rinse at least 5times inside and outside rinse at least 5times and outside close the lateral openings caused by dismantling of the trumpet valve by the closed screw cap and one additional screw cap and rinse inside again	close the lateral openings caused by dismantling of the trumpet valve by the closed screw cap and one additional screw cap and connect to rinsing port small pieces basket for inner parts of trumpet valve	assemble again (wi- thout protective cap) lubricate trumpet valve	mounted (without protective cap!) lubricated	Critical C
	small cannula-like pro- ducts, with LuerLock	5 ml (single-use syringe)	standard brushes	brush carefully outside rinse inside at least 5times	brush carefully outside rinse inside at least 5times	connect to rinsing port	assemble again no lubrication admitted	standard	Critical C

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C	segmented products with longer/narrow cannulation dismantling for cleaning/disinfection possible direct connection not possible	50 ml (single-use syringe) / rinsing pistol	standard brushes long brush (length > 510 mm, diameter approx. 4 mm)	dismantle brush inside and outside rinse at least 5times inside and outside	dismantled brush inside and outside rinse at least 5times inside and outside	dismantled standard basket small pieces basket for threaded bush	assemble again lubricate threads and inner shaft	mounted lubricated	Critical C
	segmented products with longer/narrow ringlike cannulation dismantling for cleaning/disinfection possible direct connection not possible	-	standard brushes	dismantle brush inside and outside rinse at least 5times inside and outside	dismantled brush inside and outside rinse at least 5times inside and outside	dismantled small pieces basket	assemble nearly closed, but still a little bit loosely lubricate threads	nearly closed, but still a little bit loosely mounted lubricated	Critical C
D*	products with longer/ narrow cavity with tube olive	50 ml (single-use syringe) / rinsing pistol	standard brushes flexible long brush (length ≥ 700 mm, diameter approx. 4 mm)	brush inside and outside rinse inside at least 5times	brush inside and outside rinse inside at least 5times	apply rinsing tube to the olive	no lubrication admitted	standard	Critical C

*For BUNELL / RALK hand drills (article number: 40-918-00 / 40-919-00 / 40-919-01) see additional reprocessing instruction [AZ_150_EN_Hand drills](#)

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Geometric aspects			Specific/additional procedure in case of						
Worst case type	Specific geometric aspects	Rinsing volume	Brushes	Pretreatment	Manual cleaning/ disinfection	Automated cleaning/ disinfection	Maintenance/ packaging	Sterilization	Recommended classification according to KRIN-KO/RKI/BfArM guidance (only Germany, with respect to intended use)
EA	segmented products with blind cavities	10 ml (single-use syringe) with fitted extra long cannula (for post-rinsing of the blind cavity)	standard brushes	dismantle brush outside (do not brush inside!) back-rinse inside at least 5 times	dismantled in small pieces basket	in small pieces basket	assemble loosely lubricate thread	loosely mounted lubricated	Critical C
	products with narrow blind cavities and Luer/olive	10 ml (single use syringe)	standard brushes	brush outside (do not brush inside!) rinse at least 5times inside	brush outside (do not brush inside!) rinse at least 5times inside	apply rinsing tube to the olive	no lubrication admitted	standard	Critical C
EB	products with ringlike revolute joint without possibility for rinsing	-	standard brushes	brush outside articulate grip at least 5times during soaking and rinsing	brush outside articulate grip at least 5times during soaking and rinsing	standard basket	lubricate revolute joint	revolute joint lubricated	Critical A

Master reprocessing instruction

Reprocessing (Cleaning, Disinfection and Sterilization)
of products



see AA_200_Article annex list



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EN

Geometric aspects		Specific/additional procedure in case of							
Worst case type	Specific geometric aspects	Rinsing volume	Brushes	Pretreatment	Manual cleaning/ disinfection	Automated cleaning/ disinfection	Maintenance/ packaging	Sterilization	Recommended classification according to KRIN-KO/RKI/BfArM guidance (only Germany, with respect to intended use)
FA	tube sliding shaft instruments no dismantling possible	-	standard brushes	brush outside open and close at least 5times during soaking and rinsing for ultrasonic treatment joint in opened position	brush outside open and close at least 5times during soaking and rinsing for ultrasonic treatment joint in opened position	standard basket joint in opened position	in opened position lubricate the joint	in opened position joint lubricated	Critical B
	Sliding shaft instruments no dismantling possible	-	standard brushes	brush outside open and close at least 5times during soaking and rinsing for ultrasonic treatment joint in opened position	brush outside open and close at least 5times during soaking and rinsing for ultrasonic treatment joint in opened position	standard basket joint in opened position	in opened position lubricate the joint	in opened position joint lubricated	Critical B
	segmented products with longer/extremely narrow ringlike cannulation and complex mechanism inside dismantling for cleaning/disinfection possible direct connection not possible	50 ml (single-use syringe) / rinsing pistol	standard brushes long brushes (length > 510 mm, diameter approx. 4 and 5 mm)	dismantle brush inside and outside rinse at least 5times inside and outside	dismantled brush inside and outside rinse at least 5times inside and outside	dismantled use rinsing lance for cannulated parts standard basket for other parts	assemble again lubricate all moveable parts	mounted (not loader and conus part) lubricated	Critical B

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Worst case type	Specific geometric aspects	Rinsing volume	Brushes	Pretreatment	Manual cleaning/ disinfection	Automated cleaning/ disinfection	Maintenance/ packaging	Sterilization	Recommended classification according to KRIN- KO/RKI/BfArM guidance (only Germany, with respect to intended use)
G	instruments with joints dismantling possible	-	standard brushes long brushes (length > 400 mm, diameter approx. 12 mm)	dismantle (removal of the grip tubes) brush outside and inside open and close at least 5times (including lock) during soaking and rinsing soak grip tubes by dipping and taking out for ultrasonic treatment joints in half opened position	dismantled(grip tubes removed) brush outside and inside open and close at least 5times (including lock) during soaking and rinsing soak grip tubes by dipping and taking out for ultrasonic treatment joints in half opened position	standard basket joints in half opened position	assemble (grip tubes) lubricate the joints	mounted lubricated	Critical B
	retractors with several joints and open threads	-	standard brushes	brush outside and in the gaps open and close at least 5times (including lock) during soaking and rinsing for ultrasonic treatment joints in half opened position	brush outside and in the gaps open and close at least 5times (including lock) during soaking and rinsing for ultrasonic treatment joints in half opened position	standard basket joints in half opened position	not completely closed lubricate the joints and the thread of the spindle	not completely closed	Critical B
	instruments with joints self-closing (with lock)	-	standard brushes	brush inside and outside open and close at least 5times (including lock) during soaking and rinsing for ultrasonic treatment joint in half opened position	brush inside and outside open and close at least 5times (including lock) during soaking and rinsing for ultrasonic treatment joint in half opened position	standard basket joint in half opened position	in slightly opened position lubricate the joints	in slightly opened position joints lubricated	Critical B
	spreader dismountable	-	standard brushes	dismantle brush inside and outside articulate crank at least 5times during soaking and rinsing	dismantled brush inside and outside articulate crank at least 5times during soaking and rinsing	standard basket dismantled	lubrication not admitted	mounted	Critical B