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

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 bath[1] (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 agent[1], 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).

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.

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).

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)

- 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 drying[6])
- 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)

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.

Specific aspects

Geometric aspects		rinsing volume	brushes	specific/additional procedure in case of			maintenance/ packaging	sterilization	maximum admitted cycle number	recommended classification according to KRINKO/RKI/BfArM guidance (only Germany, with respect to intended use)
worst case type	specific geometric aspects			pretreatment	manual cleaning/ disinfection	automated cleaning/ disinfection				
Aa1	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	dismantle brush inside and outside rinse at least 5times inside and outside	Not permissible	dismantled use rinsing lance for cannulated parts standard basket for other parts	assemble loosely lubricate threads and inner shaft	loosely mounted lubricated	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
Aa2	tube shaft products with self-closijng jaw without LuerLock or rinsing port no dismantling possible	-	standard brushes	brush outside least 5times during soaking and rinsing	Not permissible	jaw in open position	lubricate joint	lubricated	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
Aa3	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	Not permissible	dismantled use rinsing lance for cannulated parts standard basket for other parts	assemble again no lubricated admitted	mounted	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
Aa4	segmented products with longer/extremely 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	Not permissible	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)	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
Ab1	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	Not permissible	in standard basket	loop moved backwards no lubrication admitted	standard	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated

Ab3	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	Not permissible	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	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
Ad1	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	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
Ad2	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	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
B1	products with longer/narrow cavity with flush port for rinsing tubes	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	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
B2	products with longer/narrow cavity with Luer-Lock with trumpet valve	50 ml (single-use syringe) / 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	assemble again (without protective cap) lubricate trumpet valve	mounted (without protective cap!) lubricated	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated

						of trumpet valve				
B4	small cannula-like products, 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	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
C1	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	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
C4	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	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
D2	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	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
Ea2	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 brush outside (do not brush inside!) back-rinse inside at least 5 times	dismantled in small pieces basket	assemble loosely lubricate thread	loosely mounted lubricated	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated

Ea3	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	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
Eb2	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	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
Fa1	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	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
Fa3	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	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
Fa4	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	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
G1	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	dismanted(grip tubes removed) brush outside and inside open and close at least 5times (including lock)	standard basket joints in half opened position	assemble (grip tubes) lubricate the joints	mounted lubricated	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated

				(including lock) during soaking and rinsing soak grip tubes by dipping and taking out for ultrasonic treatment joints in half opened position	during soaking and rinsing soak grip tubes by dipping and taking out for ultrasonic treatment joints in half opened position					
G4	rectractors 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	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
G6	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	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated
G7, G8	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	tbd after the final results of the validation has been evaluated	tbd after the final results of the validation has been evaluated

Distributor

Posting	
QM-folder:	Dokumente
Save location EDP:	I:/Daten/QM-System/QM-Daten/ Dokumente PDF
Internet	https://reuchlen.com/

Standards & laws:
EN ISO 17664:2018
EN ISO 17665
EN ISO 14971

Other applicable documents:
Matrix Produktübersicht Aufbereitung
DM QM Interpretation of the results of Validation Report 182669-10-A_Annex2
DM QM Interpretation of the results of Validation Report 182669-10-C
DM QM Interpretation of the results of Validation Report 182670-10-C and182670-10-E
DM QM Interpretation of the results of Validation Report 182670-10-D
DM QM Interpretation of the results of Validation Report 182671-10
DM QM Interpretation of the results of Validation Report 182669-10-B Table 2
DM QM Interpretation of the results of Validation Report 182669-10-B Table 3
DM QM Notes and decisions about Validation Project A01 EN ISO 17664

Creation & Approval

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