You have choosen a high-quality product by purchasing this product. To avoid damage/harm to patients, users and third parties please read and follow the instructions hereunder.

Intended use

Our reusable surgical instruments are intended for transient use for surgical invasive procedures for:

- manually cutting, drilling, sawing, scratching, scraping, clamping, retracting, clipping or similar like seizing/grasping, ligating, dilating, spreading and palpating, etc., without a connection to an active device.
- Reusable surgical instruments are hand-manipulated/operated by surgeons/users.
- Reusable surgical instruments can be cleaned, disinfected, controlled and sterilized for repeated use in surgery if the process for sterile reuse is performed in accordance with the instructions stipulated hereunder.
- Higher risk of injuries may occur from reusable surgical instruments having pointed or cutting tips/working ends being designed for their intended use.
- Reusable surgical instruments are mostly manufactured from stainless steel that is **electrically guiding** and can therefore be transmitting high frequency energy.
- It is **not** allowed to use these reusable stainless instruments with active devices such as RF units.
- These reusable surgical instruments are **not** for use of the central nervous system and central circulatory system.
- In case you received knowledge from undesirable side effects or related notifiable adverse incidents we kindly ask you to inform us.

Checking of incoming goods

Inspect incoming goods for transport damages that might have caused quality defects.
Claims for damages can only be filed if the transport company or the vendor are informed immediately.

Preparation (Cleaning, Disinfection and Sterilization) of Products

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 processing) regarding to an effective prion inactivation.

Remark:

Application of the products is only admitted to qualified professionals.

Processing 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 of protective equipment and hygienic measures.

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 (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 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).

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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.

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)[3] 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 (see specific disassembly/assembly instructions).
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 (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.

[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).

[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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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.

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).It is not allowed to reuse defective products. Any products that are still contaminated must be cleaned again and disinfected. If inscriptions/markings on instruments are no longer readable they must be rejected.

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.

Products returned to the manufacturer for repair must undergo the complete process of cleaning, disinfection and sterilization. A protocol confirming this must be added.

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
- 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
- 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]
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.*

[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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The flash sterilization procedure is generally not permitted.

Do not use dry heat 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.

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.

Label - Symbol of label

LOT	**Batch number**
CE	**European CE-mark**
	Manufacturer

NON STERILE	**Non sterile**
	Read instruction manual!

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