Reprocessing Instructions

Item number: reusable surgical instruments

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Important details

Read the Operating Instructions carefully before use and save it in an easily accessible form for the end user or the technical staff.

Please go through the warning instructions marked with this icon. Inappropriate handling of the products can lead to serious injuries to the patient, the users or third parties.

Section	Title		Description
10	Intended Use and Areas of Application		The instruments may be handled by suitably trained qualified personnel exclusively for the intended purpose in the specified medical departments. The attending doctor or the user is responsible for the choice of the instrument for specific practices or surgical use and also has to account for the appropriate training and adequate expertise in using the equipments
20	Precautionary measures and Warning Instructions	⚠ Note!	The reusable surgical equipments were meant to be used only for surgical purposes and should not be used for any other application. Inappropriate handling and maintenance as well as use for purposes other than the intended use can lead to premature wear and tear of the surgical instruments.
		⚠ Handling of brand-new instruments	New instruments , before its initial use, must be run through the complete conditioning cycle. Protective caps and protective nets must be removed completely in case of sharp-edged instruments
		⚠ Impairment of function	Surgical instruments corrode and their functioning is hampered when they come in contact with aggressive substances. Hence it is absolutely necessary to follow the preparation and sterilization instruction.
		⚠ Operations conditions	Proper care and correct maintenance of the afore-mentioned products is absolutely essential to ensure th eir proper and safe operations. Further, it is advisable to do a functional testing and visual inspection before each application. Hence we advise you to refer to the corresponding sections in this operations manual.
		⚠ Possibility of re-procesing	In view of the reprocessing of medical products that are used in the case of patients or suspects of Creutzfeldt-Jacob diesease (CJK) or its variant (vCJK) , the requirements mentioned in the respective Appendix of the Guideline for Hospital Hygiene and Infection Prevention and the publications in the Bundesgesundheitsblatt (Health Office Gazette) are to be fully complied with. The medical products that are used for this patient group are to be safely disposed off through incineration (European Waste Catalog - EAK 180103). Dry heat, ethanol, formal dehyde and glutaraldehyde have a fixing but not a deactivating effect on the TSE- pathogens. Of all the existing sterilization procedures that are available, only steam sterilization (esp. at 134°C, 18 minutes) has shown limited effect.
		⚠ Storage	There are no specific requirements with respect to the storage of the products before sterilization. However, we recommend that medical products be stored in a clean and dry environment.
30	Liability and Warranty		The instruments may be handled by suitably trained qualified personnel exclusively for the intended purpose in the specified medical departments. The attending doctor or the user is responsible for the choice of the instrument for specific practices or surgical use and also

			has to account for the appropriate training and adequate expertise in using the equipments Similarly, the manufacturer does not undertake any liability for damages that can be attributed to repairs or maintenance carried out by unauthorized persons/offices.
40	Obligation to report		All serious incidents occurring in the context of the product must be notified immediately to the manufacturer and the concerned authority in the member country in which the user and/or the patient resides.
50	NON STERILE Sterility in Delivery Status		The medical products are delivered in a non-sterile sate and are to be reprocessed and sterilized by the user before the first use and before each subsequent use according to the following instruction.
60	Limitations of Reprocessing, Disposal		Frequent reprocessing has very little effect on the surgical instruments. The product life is normally dependent on the wear and tear and the damage caused due to use of the instrument. On expiry of the product life, please ensure that you bring the surgical instruments into a proper system of disposal or reuse/recycling. The national stipulation and the waste disposal guidelines are to be followed!
70	Reprocessing		See the following points
80	⚠ Warning Instructions		• The tap water that is to be used must meet the requirements of potable (drinking) water quality. • Before cleaning, loosen and dismantle the products to the maximum extent possible. • Loosened and dismantled products are to be assembled again before sterilization.
90	⚠ Place of Installation		Gross contamination, residues, for e.g. of hemostasis, skin disinfection and lube agents as well as caustic medicines should be removed, as far as possible, before putting the instruments away. Any pre-cleaning that is needed must be done immediately after use. Gross contamination must be rinsed or wiped off. Before dry disposal, the instruments should not be cleaned or stored with physiological saline. Wherever possible, dry disposal (humidified , closed system) is to be preferred. Prevent drying of the residue on the instruments! Long waiting periods till the time of reprocessing (for e.g. overnight or over the weekend) are to be prevented in both the cases of disposal types (< 6 hours).
100	⚠ Transport		After their use, the instruments are to be stored without any disinfectant or other additional fluids and transported to the ZSVA. The products must be immediately dried and stored after their usage. This means that the products are to be transported in closed moist containers from the place of use to the reprocessing iste so that there is no drying of the product.
110	Pre-cleaning	Manual pre-cleaning	• The product must be dismantled and loosened to the maximum extent possible. • Rinse under flowing tap water (potable quality) till they are visually clean. • If necessary the residual impurities are to be removed using a soft brush. • Lumens and other parts that are difficult to access (hollow spaces, undercuts, sack holes, edges, joints, etc) are to be rinsed for at least 60 seconds using a water pistol. • Movable parts on the instruments are to be moved back and forth at least three times. • The lumens are to be handled using a brush whose diameter and length are a little more than the diameter and length of the lumen. Go through the lumens at least thrice with the brush. • If it is not possible to clean the lumen with a brush due to the small diameter of the lumens, then the lumens must be rinsed with a 50 ml one-time-use syringe. Potable tap water (<40°C) is to be used for the purpose.

<table>
<tr><td>120</td><td></td><td>Ultra-sound cleaning</td><td>Place the product in an ultra-sound bath (<40°C) with a mildly alkaline cleaning agent; acoustic irradiation time of at least 20 minutes at a frequency of approx. 35 kHz.

Use a cleaning agent that is suitable for ultra-sound cleaning. Follow the instructions of the manufacturer of the cleaning agent.
Place the instruments in such a way that all
Surfaces
Hollow areas
Lumens
Orifices
are covered. The instruments should not be touched. No acoustic shadows should be formed.

Procedure to be followed after ultra-sound cleaning:
At the end, the products must be rinsed for at least 1 minute under flowing water. Lumens and other parts that are difficult to access (hollow spaces, undercuts, sack holes, edges, joints, etc) are to be rinsed for at least 60 seconds using a water pistol.
Moving parts are to be moved back and forth at least thrice and the lumens are to be treated with a brush whose diamter and length are a little bigger than the diameter and length of the lumens. Go through the lumens at least thrice with the brush.
If it is not possible to clean the lumen with a brush due to the small diameter of the lumens, then the lumens must be rinsed with a 50 ml one-time-use syringe. Potable tap water (<40°C) is to be used for the purpose.
After the pre-cleaning, visually inspect the friction surface and check for dirt/impurities.</td></tr>
<tr><td>130</td><td colspan="2">Preparing for decontamination</td><td>The product must be sent in an open and/or loosened state for the next reprocessing steps.
Double joints must be brought to an open state with the help of a fixture. (Handle)springs must be exhibited.
Product s must be arranged in such a way that there should be no rinse shadows. The product must be reprocessed in suitable sieve baskets or drainage bowl (select the size according to the product). The product must be fixed in the cleaning basket at a minimum distance from other products. There should be no overlapping of products; this will prevent damage to the products during the cleaning process. The quantity and type of loading in the instrument trays selected for the cleaning is to be done in such a way that the cleaning result is not hampered. Instruments are to be arranged in such a way that water can flow out of the lumen. Products that come with luer lock or some other similar lock must be connected using the same.</td></tr>
<tr><td>140</td><td>Mechanical Cleaning/ Disinfection</td><td>Automatic cleaning process</td><td>(Washing machine, RDG according to EN ISO 15883):
<table>
<tr><th>Step</th><th>Parameter</th><th></th></tr>
<tr><td>Pre-rinsing</td><td>Rinse temperature</td><td>Cold tap water (potable water quality)</td></tr>
<tr><td></td><td>Exposure time</td><td>60 sec</td></tr>
<tr><td>Pre-rinsing</td><td>Rinse temperature</td><td>Cold tap water (potable water quality)</td></tr>
<tr><td></td><td>Exposure time</td><td>180 sec</td></tr>
<tr><td>Clean</td><td>Cleaning temperature</td><td>55°C</td></tr>
<tr><td></td><td>Exposure time</td><td>min. 300 sec</td></tr>
<tr><td></td><td>Clearning medium</td><td>mildly alkaline cleaning agent</td></tr>
<tr><td></td><td>Concentration ratio</td><td>0.5 %</td></tr>
<tr><td>Neutralize</td><td>Rinse temperature</td><td>Cold demineralized water</td></tr>
<tr><td></td><td>Exposure time</td><td>180 sec</td></tr>
<tr><td></td><td>Neutralization agent</td><td>acidic neutralization agent</td></tr>
<tr><td></td><td>Concentration ratio</td><td>0.1 %</td></tr>
<tr><td>Re-rinsing</td><td>Rinse temperature</td><td>Cold demineralized water</td></tr>
<tr><td></td><td>Exposure time</td><td>120 sec</td></tr>
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The special instructions of the manufacturer of the automatic cleaning machine and the cleaning agent are to be followed. Use a cleaning agent that is suitable for a RDG.</td></tr>
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150		Automatic disinfection	Automatic thermal disinfection in cleaning and disinfection device taking into account the national requirements of A) value, for e.g. AO value 3000: • Disinfection for at least 300 secs with demineralized water 93°C
160		Automatic drying	Automatic drying according to the automatic drying procedure of the cleaning and disinfection device for at least 30 minutes (at 60°C in the rinsing chamber). If needed: manual drying with a fuzzle-free cloth if there is any wetness found on the product.
170	Inspections/Tests		The instruments must be macroscopically clean after each cleaning - that is they must be free from any visible dirty. • Stained instruments (corrosion, decoloring) are to be sorted out immediately and treated separately. • Dirty or contaminated instruments must be again subjected to reprocessing. • If any mistakes or damages occur, then the instruments must be sorted out immediately. • The frictional surface must be examined for dirt and stains using a 10x magnification. • The following components must be checked extra carefully: ○ All movable parts (joints, etc.) ○ Locks ○ Cuts
180	Maintaining the Instrument Pool		**This reprocessing step is only applicable to the instruments with joints or locking (scissors, clamps, etc.) or those with smooth metallic surfaces (rib shears, punch/cutter, etc.)** These instruments must be treated with steam-sterilizable care products with paraffin oil base. Let the instruments cool down to room temperature. Reassemble the dismantled product. "Care" means applying instrument oil or instrument milk (emulsion of white oil in water) to the instruments. The paraffin oil must correspond to the applicable pharmacopoeia and should be physiologically harmless according to the "Deutsches Arzneibuch" (German Pharmacopoeia, 10th edition (DAB10) and or "European Pharmacopoeia" (Ph. Eur) or the "United States Pharmacopoeia (USP)". The care agents prevent the friction of metal on metal and keep the instruments usable. Product with laser-lettering can get bubbles when treated with cleaning agents containing phosphoric acid or hydrofluoric acid . This can lead to the disruption or loss of the coding function. Basically, surgical instruments must be subject to a permanent maintenance and care before doing a functional test. Care agents must not lead to a 'sticking' of the joints during use due to an additive effect.
190	Packaging		If the product has not been subject to the Care step and is still in a dismantled/ loosened state, then the product must first be reassembled. The instrument is packed and sealed in a packaging or sterilization tray that is suitable for the respective instrument according to DIN EN ISO 11607 and/or DIN EN 868. The packaging must comply with the following requirements: • Suitable for steam sterilization (temperature resistance up to min. 138 °C (280 °F), adequate steam permeability) • Adequate protection of products and/or sterilization packaging to protect against mechanical damage • Regular maintenance according to the manufacturer's specifications (sterilization container) • A maximum weight of 10 kg for each packaging/content should not be exceeded.

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<tr><td>200</td><td colspan="2">Sterilization</td><td>Sterilization of the product using the factional pre-vacuum process (according to DIN EN ISO 17665-1) taking into account the respective national requirements. The sterilization of the product must take place in suitable sterilization packaging.
Sterilization is to be carried out using a fractioned pre-vacuum procedure with the help of the following parameters:

<table><tr><th>Country</th><th>Fractioned pre-vacuum procedure</th></tr><tr><td>Germany</td><td>≥ 5 min. at 134°C (273° F)</td></tr><tr><td>USA</td><td>≥ 4 min. at 132°C (269,6°F), Drying in vacuum for at least 20 minutes</td></tr></table>
The operating instructions of the Autoclave manufacturer and the recommended guidelines for the maximum loading with items to be sterilized must be followed. The Autoclave must be installed, maintained, validated and calibrated according to the specifications.</td></tr>
<tr><td>210</td><td colspan="2">⚠ Additional information</td><td>The re-processor is responsible for ensuring the actual reprocessing is carried out using proper equipment, materials and staff in the reprocessing setup and the same leads to the desired results. To achieve this, it is generally necessary to validate and monitor the procedural routine and the equipment that is used.</td></tr>
<tr><td rowspan="2">220</td><td rowspan="2">Service, Repairs and Returns</td><td>⚠ Service and Repairs</td><td>Do not independently carry out any repairs or changes to the product. There are exclusive authorized persons of the manufacturer responsible and ear-marked for the same. Should you have any complaints or instructions about our products,, we would request you to please get in touch with us.</td></tr>
<tr><td>⚠ Returns</td><td>Defective or non-compliant products must be subject to the entire reprocessing procedure before returning them for repairs/ service. Decontamination proofs are to be attached.</td></tr>
<tr><td>230</td><td colspan="2">Storage and transport</td><td>• Protect against mechanical damage.
• Store in a dry and dust-free state.
• Store and transport in safe containers/ packaging.
• Handle with utmost care - do not throw or let the product fall.
Sterilization packaging (for e.g. according to DIN EN 868, ISO 11607) is to be used for subsequent transport and storage.</td></tr>
<tr><td>240</td><td colspan="2">Instructions for inspection</td><td>Before each use, the instrument is to be checked for breakage, crack, deformation, damage and proper functioning. Worn off, corroded, deformed, porous instruments or those damaged in some other way must be sorted out.
The following assemblies must be checked extra carefully:
• Cuts
• Closures
• Locks
• movable parts such as joints etc.
The stainless steels used for the manufacturing of instruments (non-rusting, stainless steel) form certain specific passive layers as protective layers due to their alloy composition. These steels are only partially resistant to attack from chloride ions and aggressive media and liquids! In addition to the efforts that have been undertaken by the manufacturer for the choice of the correct materials and their processing, it is necessary that surgical instruments are subject to proper care and maintenance by the user and are also subject to correct reprocessing.</td></tr>
<tr><td>250</td><td colspan="2">Material resistance</td><td>While selecting the cleaning agent and disinfectant, pay attention to ensure that they do not contain the following substances:
• organic and mineral acids and oxidizing acids (minimum permissible pH value of 5.5)
• Lyes/ strong lyes (neutral/ enzymatic substances (max. permissible pH value of 8.5) are necessary for products made of aluminium or other alkali-sensitive materials; see chapter "Special Instructions") or alkaline cleaning agents (max. permissible value pH 11 are absolutely essential and recommended for products that are proposed to be used in prion critical areas for e.g. according to Appendix 7 of "KRINKO RKI BfArM recommedatio for reprocessing .</td></tr>
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		• organic solvents (for e.g. alcohols, ether , ketones, petrols) • Oxidization agents (for e.g. hydrogen peroxide) • Halogens (chlorine, iodine, bromine) • Aromatic/ halogenized hydrocarbons