KOHLER®
MEDIZINTECHNIK

Important instruction for use and reprocessing of sterilisable medical devices

CE

Procedure	Mechanical, within the cleaning and disinfection apparatus (RDG)
Products	Kohler medical instruments of class 1 Reusable (surgical) instruments in dentistry, which - are one-piece - contain simple hinges or simple moveable parts - in certain cases consist of several replaceable parts
Intended use	Instruments may only be used for their intended purpose in specialist medical fields by properly trained, qualified personnel. The attending doctor or operator is responsible for selection of the instrumentarium for specific applications and operative use, appropriate training and information and adequate experience for handling of the instrumentarium.
WARNINGS	Aluminum-containing instruments are damaged by alkaline (pH> 7) detergents and solutions. When cleaning easily accessible or difficult to access hinges, screws or rivets, a separate pre-cleaning must be carried out, see pre-cleaning. Incorrect handling and care of the instruments as well as misuse or modifications to the instruments can contribute to damage or failure of the instrument, which could result in serious injury to patients or even death. On receipt, check the instrument for possible transport damage and perfect function. Small instruments (e.g. micro mirror, item no. 7407) must be secured by the user to ensure that swallowing or aspiration is excluded, e.g. by using a rubber dam or attaching suture material. Instruments are non-sterile on delivery and must be cleaned and sterilised by the operator before use. Treat all instruments with the necessary care. Every instrument should be checked visually before each use. Check in particular for cracks, fractures, deformation, stiffness – also especially in areas like blades, tips, closures, locks, notches and all moveable parts. If the instrument has been disassembled, ensure perfect functioning and all screws and parts are securely fitted after assembly. There is the possibility of a higher risk of infection if the products are used on patients suspected of having a prion disease (e.g. Creutzfeldt-Jakob disease). In such a case it is at the discretion of the doctor either to dispose of the product or reprocess it in accordance with the national regulations.
Restriction of reprocessing	Due to the product design and the used materials, no defined limit of maximal realizable cycles for the treatment can be settled. The durability of the medical devices will be defined by its function and a gentle handling. Defective products have to pass through the whole process of reconditioning before their return.

INSTRUCTIONS for the reprocessing	
Preparation on the place of action	Immediately after use, remove visible residues from the instruments as completely as possible with a lint-free cloth or disposable cloth. Do not use metal brushes or other surface-damaging abrasives for cleaning, otherwise there is a risk of corrosion. Do not use fixed solutions or hot water (> 40°C), which can cause residues and influence the success of the cleaning. DO NOT place in saline solution (NaCl)! Regarding hygienically safe and material-preserving / value-retaining reprocessing, further information can be found under www.a-k-i.org, AKI Red brochure –Reprocessing of instruments to retain value.

Storage and transport	After use, it is recommended to clean instruments thoroughly and start reprocessing as soon as possible, latest within 6 hours. Store safely in a dry, closed container and transport the instruments to the treatment site to avoid damage to the instruments and contamination to the environment.
Preparation for cleaning	Never put instruments under tension. Instruments with joints must be left open. Disassemble dismountable instruments (especially all silicone ingredients). Narrow-necked instruments and bodies must be pretreated. Inspect the instruments for damage (such as leaks, cracks), and sort out damaged instruments.
Pre-cleaning	<u>For disassembled instruments and easy to clean instruments with easily accessible hinges, screws or rivets:</u> Abrasive dirt has to be removed from the instruments. Do not use fixed solutions or hot water (>40°C), which can cause residues and influence the success of the cleaning. <u>Instruments with poorly accessible hinges, screws or rivets, which cannot be dismantled:</u> Place the instruments into cold water for at least 5 min. If possible, please disperse the instruments and clean them with a soft brush under cold water until no residues can be seen. If the instruments have cavities, boreholes or convolutions you have to flush it with pressure for at least 10 sec. with a water pistol (pulse procedure). Put the instruments for 15 min. in the ultrasonic bath at 40°C with 0,5 % alkaline (enzymatic) cleaner and treat them with ultrasound. Remove the instruments and rinse them with cold water.
Cleaning: automatically	Put the instruments in opened state into a colander on the insertion E 327-06 or MIC E 450 and start the cleaning process by using Cleaning- disinfection device Miele G 7736 CD. 1. 1 min. pre-rinse with cold water 2. Cleanout 3. 3 min. pre-rinse with cold water 4. Cleanout 5. 5 min washing at 55°C with 0,5 % alkaline cleaner (Neodisher Fa. Dr. Weigert, Hamburg), or if you use enzymatic cleaner 0,5 % enzymatic cleaner (Endozime, Fa. Ruhof) 5 min washing at 45°C 6. Cleanout 7. 3 min neutralization with warm tap water (>40°C) and neutralizer (Neodisher Z; Dr. Weigert, Hamburg) 8. Cleanout 9. 2 min in-between flush with warm tap water (>40°C) 10. Cleanout
Disinfection	Execution of the thermal disinfection considering the national requirements in respect of the A0-value (see ISO 15883).
Drying	Drying of the outside of the instruments through the drying cycle of the washer-disinfector (Miele G 7736 CD). If necessary, manual drying can also be achieved using a lint-free cloth or disposable cloth. Cavities of instruments can be dehydrated with sterile blast.
Maintenance	Maintain critical points such as tongs, locks, sliding surfaces for springs after each preparation with white oil / instrument oil Article 9110.
Control and functional check	Visual inspection and functional test (cleanliness, damage, joint instruments smooth, no excessive play, locking mechanisms, no notches on the cutting edges). Check disassembled instruments for cleanliness, assemble and then perform functional test. Worn, corroded, deformed, porous or otherwise damaged instruments or instrument components must be sorted out or replaced. If necessary, repetition of the reprocessing until the instrument is cleaned optically.
Packing	For the sterilisation you have to pack the instruments in packaging according to ISO 11607 and EN 868 standards.

Sterilisation	Sterilisation of the products with the fractionated pre-vacuum method (according to ISO 13060 / ISO 17665) considering the national requirements of each country. 3 pre-vacuum phases with a pressure of at least 60 millibar Heating to a sterilisation temperature of at least 134°C; max.137°C Shortest holding time: 4 min Drying time: at least 10 min
Stocking	Storage of the sterilised instruments in a dry, clean and dust-free environment, no storage nearby any chemical products. Avoid temperature fluctuations and direct sunlight. Storage at moderate temperatures from 5°C to 40°C.
Disposal	Observe your local and national laws, guidelines, standards and regulations for disposal and ensure that parts are not contaminated during disposal.
Exceptions	Due to technical reasons the below-mentioned instruments are partially produced of aluminium. Therefore please do not put them either into the thermo-disinfector or into the ultrasonic bath. Please also use only disinfectant which can be used for instruments with aluminium (for example: neodisher® Septo MED of Dr. Weigert, Hamburg, www.neodisher.de) Item-no. Description 6129 Hammer 200 g / 25 mm 5265- 5268 Alu-norm-tray,bottom 28x18 cm 5271- 5274 Alu-norm-tray, lid 18x14 cm Due to technical reasons the below-mentioned instruments contain chromed component parts. Therefore please do not put them either into the thermo-disinfector or into ultrasonic bath. Please also use only disinfectant which can be used for instruments with aluminium (for example: neodisher® Septo MED von Dr. Weigert, Hamburg, www.neodisher.de) Item-no. Description 6555 Syringe 1,8 ml with 2 corniches - handle S-form 6555-ASP Cartridge Syringe 1,8 ml with 2 corniches self aspirating syringe 6556 Syringe 2,2 ml with 2 corniches - handle S-form 6556- ASP Cartridge Syringe2,2 ml with 2 corniches self aspirating syringe 6557 Water syringe aspirating HUNT 10ml 6557-K Canula for water syringe HUNT 6557 4515-CC Mouth mirror Rhodium 4 ENDOBLACK (Ø 22 mm) 6412-CC Mikro mouth mirror Rhodium ENDOBLACK (Ø 3 mm) 6413-CC Mikro mouth mirror Rhodium ENDOBLACK (Ø 5 mm) 6414- CC Mikro mouth mirror Rhodium ENDOBLACK (3x6 mm) 4516-CC Mouth mirror Rhodium 5 ENDOBLACK (Ø 24mm)
Contact with the manufacturer	Kohdent Roland Kohler Medizintechnik GmbH & Co. KG Bodenseeallee 14-16 D-78333 Stockach Tel.: +49 7771 64999-0 Fax: +49 7771 64999-50 E-mail: info@kohler-medizintechnik.de Website: www.kohler-medizintechnik.de

We refer to our instructions which you can find in our catalogue respecting cleaning, sterilisation and care of the instruments.
The instructions above have been validated by Kohler, based on the current version ISO 17664, for the preparation of a medical device for reuse as SUITABLE.

It is the responsibility of the processor to ensure that the treatment actually carried out with the equipment, materials and personnel used in the treatment facility achieves the desired results. This usually requires validation and routine monitoring of the process. Likewise, any deviation from the instructions provided by the preparer should be carefully evaluated for its effectiveness and possible adverse consequences.

Serious incidents related to the instrument must be reported to the manufacturer and authorities of the Member State where the user or the patient is established.