










**Important Instruction for
Use & Reprocessing of
Sterilisable Medical
Devices**
















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CE / CE 0483

Procedure	Mechanical, within the cleaning and disinfection apparatus (RDG)
Products	<p>Kohler medical instruments of class 1</p> <p>Reusable (surgical & non-surgical) instruments in dentistry, which</p> <ul style="list-style-type: none"> - are one-piece - contain simple hinges or simple moveable parts - in certain cases consist of several replaceable parts -
Intended use Indication Contraindication	<p>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. There are no known contraindications.</p> <p>Application - Limited to the dental area</p>
Warnings	<p>Aluminum-containing instruments or trays are damaged by alkaline (pH > 7) detergents and solutions.</p> <p>When cleaning easily accessible or difficult to access hinges, screws or rivets, a separate pre-cleaning must be carried out, see pre-cleaning.</p> <p>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.</p> <p>Instruments are non-sterile on delivery and must be cleaned and sterilised by the operator before use.</p> <p>Treat all instruments with the necessary care. Every instrument should be checked visually /functional 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.</p> <p>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.</p> <p>Small instruments (e.g. micro mirror) 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.</p> <p>Serious incidents related to the device must be reported to the manufacturer and the competent authority of the Member State in which the user or patient is located.</p>
Restriction of reprocessing	<p>The durability of medical devices is determined by their function and gentle handling.</p> <p>Due to the product design and the used materials, at least 50 reprocessing cycles can be verified based on the parameters below.</p> <p>In addition, you can also use Kohler Dental instruments for longer on your own responsibility if the visual and functional inspection does not reveal any abnormalities. Defective products have to pass through the whole process of reconditioning before their return.</p>

INSTRUCTIONS for the Reprocessing	
Preparation on the Place of Action 	<p>Immediately after use, remove visible residues from the instruments as completely as possible with a lint-free cloth or disposable cloth. Remove coarse dirt from the instruments immediately after use.</p> <p>Do not use metal brushes or other surface-damaging abrasives for cleaning, otherwise there is a risk of corrosion.</p> <p>Do not use fixed solutions or hot water (> 40°C), which can cause residues and influence the success of the cleaning.</p> <p>Caution: DO NOT place in saline solution (NaCl)!</p> <p>Regarding hygienically safe and material-preserving / value-retaining reprocessing, further information can be found under http://www.a-k-i.org, AKI Brochures PDF-Shop-> Yellow or red brochure Instrument Reprocessing</p>
Storage and Transport  	<p>After use, it is recommended to clean instruments thoroughly and start reprocessing as soon as possible. Avoid allowing any residues to dry.</p> <p>Instruments must be stored in dry, closed dust-protected containers without major temperature fluctuations.</p> <p>Safe transport of the the instruments to the treatment site must always be ensured to avoid damage to the instruments and contamination to the environment or persons.</p>
Preparation for Cleaning	<p>Never store instruments under tension. Instruments with joints must be left open.</p> <p>Disassemble dismountable instruments and/or remove attachments. Narrow-necked instruments and bodies must be pretreated e.g., with a suitable cleaning brush (soft bristles).</p> <p>Inspect the instruments for damage (such as leaks, cracks), and sort out damaged instruments.</p>
Pre-Cleaning 	<p>Place the instruments into cold water for at least 5 min. If possible, disassemble 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 flush with pressure for at least 10 sec. with a water pistol (pulsed procedure).</p> <p>Put the instruments for 15 min. in the ultrasonic bath at < 40°C with 0,5 % alkaline cleaner (e.g. Dr. Weigert neodisher Mediclean forte) and treat them with ultrasound. Remove instruments and rinse with cold tap water for at least 10 seconds.</p> <p>Caution: Do not use ultrasound for micro mirrors!</p>
Cleaning Automatically 	<p>Put the instruments in an open state into a colander on the insertion and start the cleaning process by using a qualified cleaning and disinfection device.</p> <ol style="list-style-type: none"> 1. 1 min. pre-rinse with cold tap water (<40°C) 2. Empty 3. Pre-rinse for 3 minutes with cold tap water (<40°C) 4. Empty 5. Clean for 10 minutes at 55°C with a 0.5% alkaline cleaning agent solution (e.g., Dr. Weigert neodisher Mediclean forte universal cleaner) in deionized water 6. Cleanout 7. 3 min neutralization with cold tap water (<40°C) and 0,1 % neutralizer (e.g. Neodisher Z, Dr. Weigert, Hamburg) 8. Cleanout 9. 2 min in-between flush with cold deionized water (<40°C) 10. Cleanout <p>Caution: Do not use ultrasound for micro mirrors!</p>
Disinfection	<p>Execution of the thermal disinfection with deionized considering the national requirements in respect of the A0-value.</p> <p>An A0 value of 3000 is recommended.</p> <p>This is achieved at 90 °C for 5 minutes (see also ISO 15883-1).</p>

Drying	<p>Drying of the outside of the instruments through the drying cycle of the washer-disinfector (example RDG setting: 20 minutes at 110°C).</p> <p>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.</p>															
Maintenance	<p>Maintain critical points such as joints, locks, sliding surfaces for springs after each preparation with medically approved instrument oil. Do not use maintenance oils/greases on rubber and latex items, as this will cause swelling.</p>															
Control and functional Check 	<p>Visual inspection and functional test (cleanliness, damage, joint instruments smooth, no looseness, locking mechanisms, no notches on the cutting edges). Check disassembled instruments for cleanliness, assemble and then perform functional test; a cutting test, if necessary. Worn, corroded, deformed, porous or otherwise damaged instruments or instrument components must be sorted out or replaced.</p> <p>If necessary, repetition of the reprocessing until the instrument is cleaned optically.</p>															
Packing	<p>For the sterilisation you have to pack the instruments in packaging according to ISO 11607 (-1 international) and the current valid versions of the DIN EN 868 standards.</p>															
Sterilisation	<p>Sterilisation of the products with the fractionated pre-vacuum method (according to ISO 13060 / EN 285 / ISO 17665) considering the national requirements of each country.</p> <p>3 pre-vacuum phases with a pressure of at least 60 millibar</p> <p>The following parameters are available for selection; other methods are not permitted. Example 2 is a method validated by Kohler; examples 1, 3, and 4 are possible alternatives that can be used at your own responsibility.</p> <table border="1" style="width: 100%; border-collapse: collapse; text-align: center;"> <thead> <tr> <th></th> <th>Example 1</th> <th>Example 2</th> <th>Example 3</th> <th>Example 4</th> </tr> </thead> <tbody> <tr> <td>Sterilisation Time</td> <td>5 min</td> <td>4 min</td> <td>18 min</td> <td>3 min</td> </tr> <tr> <td>Sterilisation Temperature</td> <td>134 °C</td> <td>132 °C</td> <td>134 °C</td> <td>134 °C</td> </tr> </tbody> </table> <p>Drying time: at least 20 min</p>		Example 1	Example 2	Example 3	Example 4	Sterilisation Time	5 min	4 min	18 min	3 min	Sterilisation Temperature	134 °C	132 °C	134 °C	134 °C
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Storage 	<p>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.</p>															
Disposal	<p>Observe your local and national laws, guidelines, standards and regulations for disposal and ensure that parts are not contaminated during disposal. Please do not dispose of in normal household waste.</p>															
Exceptions	<p>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, Dr. Weigert, Hamburg www.neodisher.de)</p> <table style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 30%;">Item-No.</td> <td>Description</td> </tr> <tr> <td>6129</td> <td>Hammer 200 g / 25 mm</td> </tr> </table>	Item-No.	Description	6129	Hammer 200 g / 25 mm											
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Symbols	<p> European CE Mark</p> <p> Manufacturer</p> <p> Follow instructions for use</p> <p> Distribution Partner</p> <p> Importer</p> <p> Medical Device</p> <p> UDI Number (Unique Device Identifier)</p> <p> EC-REP</p> <p> Prescription required (USA)</p> <p> Date of Manufacture</p> <p> LOT/Batch Number</p> <p> Item/Order Number</p> <p> Attention: Observe accompanying documents</p> <p> Indication for non-sterile product</p> <p> Autoclavable at the specified temperature</p> <p> Store in a dry place</p> <p> Protect from sunlight</p>
Contact with the Manufacturer 	<p>Kohler Medizintechnik GmbH Bodenseedallee 14-16 D-78333 Stockach Tel.: +49 7771 64999-0 Fax: +49 7771 64999-50 E-mail: info@kohler-dental.de Website: www.kohler-dental.de</p> <p>SRN: DE-MF-000006989</p>
Other	<p>Additional information regarding cleaning, sterilization, and care of instruments can be found on our website.</p> 