502.C006-C3
Reprocessing of reusable instruments

This manual applies to all reusable instruments of Innomed-Europe GmbH, providing instructions on the appropriate reprocessing of reusable instruments in accordance with international standards (DIN EN ISO 17664-1 [1]).

Warnings:	1. Instruments with components made from aluminum or special plastics may be damaged by alkaline (pH >7) cleaning agents and solutions. Use appropriate neutralizing solutions after cleaning such instruments with alkaline detergents. Then rinse instruments in deionized water. 2. The cleaning of long, narrow tubes and blind holes requires special care. Use appropriate brushes to reach every corner. 3. Do not use any metal brushes. 4. Do not expose instruments with metal components to saline solutions for longer periods – risk of corrosion! 5. Instruments may get damaged at temperatures above 137°. 6. Wear suitable protective clothing as specified in the instructions for use by the respective manufacturer.
Limitations on reprocessing:	Frequent reprocessing has a minor impact on these instruments. The end of the product service life is normally determined by the degree of wear and damage from use.
INSTRUCTIONS:	
Initial treatment at the point of use	- Disassemble contaminated instruments. - Wipe clean and rinse with cool water if necessary. - Place instruments in baskets suitable for cleaning. - It is recommended to reprocess instruments as soon as possible after use.
Preparation before cleaning:	- Disassemble all demountable instruments for cleaning. - For more complex instruments which require special disassembly techniques for cleaning, please refer to the respective disassembly and assembly instructions, specified in the product specific surgical manuals and product descriptions. - Pre-rinse the instruments by hand • Use alkaline cleaning agents with a pH value ≤12 - for dosage follow manufacturer's instructions. • Immerse at 40°C for 15 min. • Clean with soft brush. • Rinse with deionized water. - Ultrasonic cleaning in accordance with the device manufacturer's instructions is permitted for all instruments but is not mandatory. Instruments that are not suitable for ultrasonic cleaning are described in the corresponding surgical techniques and product descriptions.
Automated cleaning:	**Equipment:** Washer/Disinfector according to DIN EN ISO15883 **Alkaline cleaning agent:** pH value ≤12 - for dosage follow manufacturer's instructions *Example of an automated cleaning cycle used for validation (Miele G7733):* *1. Cold rinse for at least 2 min* *2. Wash at 45°C for at least 3 min (heat-up time not included)*

	3. Neutralize at 37°C for at least 3 min *4. Rinse with fresh water at 23°C for 1.5 min* *5. Disinfect at 93°C for at least 5 min.* *The individual process steps for automated cleaning/disinfection may vary.*
Manual cleaning:	**Alkaline cleaning agent:** pH value ≤12 - for dosage follow manufacturer's instructions **Procedure**: 1. Manually clean the instrument at approx. 45°C. 2. Rinse the instrument under running deionized water. 3. Visual inspection: in the event of any visual contamination repeat the cleaning, starting with step 1.
Disinfection:	Use washer/disinfector according to DIN EN ISO15883. Thermal disinfection is preferable. Adhere to the minimum values as per DIN EN ISO15883, e. g. 93°C for at least 5 min
Drying:	If possible, use washer/disinfector in accordance with DIN EN ISO15883 or dry at approx. 80°C for approx. 0.5 h. Use medical compressed air for manual drying.
Maintenance, inspection and functional testing:	- Allow the instrument to cool down to room temperature. - If necessary, apply a small amount of high quality physiologically harmless surgical lubricant to the instrument articulations. - Perform a general inspection for defects. - Discard defective instruments and blunt cutting edges/blades. Cutting edges/blades should be even, without notches or deformation. - Make sure articulating instruments operate smoothly (avoid too much clearance). - Check locking mechanism (ratchet wheel) for proper function. - Check long, narrow instruments (especially articulating instruments) for damage. If the instruments are part of a larger assembly, check the assembly and all components. - If applicable, assemble components and follow the respective assembly instructions/surgical technique. - Check all instruments at risk of wear. If necessary, replace or return them to the manufacturer for reworking.
Packaging:	**Individual packaging**: Use appropriate packaging material. The pouch needs to be large enough for the instrument to avoid tension on the seal. **Sets**: Sort instruments in their respective trays or place on multi-purpose sterilization trays. Sharp edges/blades need to be protected. The maximum weight per tray as per local applicable regulations must not be exceeded. The trays need to be appropriately wrapped using suitable packaging methods.
Sterilization:	**Process**: Use a validated process, e. g. a fractioned vacuum process according to DIN EN ISO 17665-1 (Sterilization of health care products - Moist heat). • At least 18 minutes at 134°C (max. 137°C), 3 bar • 5 minutes at 134°C, 3 bar (residual risk of non-deactivated prions)
Storage:	Instruments need to be stored in cool and dry environment, protected against unauthorized access.
Transport:	Ensure suitable transportation equipment and facilities.

Additional information:	Automated cleaning is preferable to manual cleaning. Detergent used for validation: Dr. Weigert – neodisher "MediClean forte" pH 10.5 – 10.8 (in demineralized water). If other cleaning agents are used, verify their suitability and effectiveness and follow the manufacturer's instructions. In the event of deviating local or national directives, the user is responsible for validating the procedure accordingly.
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Special Notes:

Refer to the product manual to verify whether another reprocessing procedure is required.

References:

[1)] DIN EN ISO 17664-1: Processing of healthcare products – Information to be provided by the manufacturer for the processing of medical devices.

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