

502.C006-C2 Processing of reusable Instruments (EN)



These instructions apply to all reusable instruments of Atesos medical AG. The instructions are intended to ensure the proper processing during refurbishment of reusable instruments in accordance with international standards (DIN EN ISO 17664 ¹⁾).

Warnings:	<ul style="list-style-type: none"> - Instruments with aluminium or special plastic components may be damaged by alkaline (pH > 7) detergents and solutions. After alkaline cleaning, suitable neutralizing solutions should be used with such instruments. Then rinse with deionized water. - When cleaning long narrow cannulas and blind holes special attention is required. Use suitable brushes to reach any point. - Do not use metal brushes - Instruments with metal components may not be stored for a longer period in saline solutions - risk of corrosion! - At temperatures above 137 °C, the instruments can be damaged - Use protective clothing according to the manufacturer's instructions for the agents used.
Limitation in the Processing:	Frequent processing has small effect on the instruments. The end of the service life is usually determined by wear and damage caused by the application.
Instructions:	
Initial treatment at the place of use:	<ul style="list-style-type: none"> - Disassemble contaminated instruments - Wipe clean and, if necessary, rinse with cold water - Place instruments in cleaning trays - It is recommended to start refurbishment as soon as possible after application
Preparation before cleaning:	<ul style="list-style-type: none"> - Disassemble all demountable instruments for cleaning. - For more complex instruments, which must be specially disassembled for cleaning, instructions are provided in the product-specific surgical techniques and product descriptions (disassembly / assembly instructions). - Pre-rinse the instruments manually <ul style="list-style-type: none"> • Alkaline detergent pH value ≤ 12 for dosage refer to manufacturer's instructions. • Insert at approx. 40 °C for 15 min • Clean with a soft brush • Rinse with deionized water - Ultrasonic cleaning according to the instructions of the equipment manufacturer is permitted for all instruments but not mandatory. Instruments that cannot be cleaned with ultrasound are described in the product-specific surgical techniques and product descriptions.
Cleaning by machine	<p>Equipment: Cleaning disinfector (CDI) according to DIN EN ISO15883</p> <p>Alkaline detergent: pH value ≤ 12, for dosage refer to manufacturer's instructions</p> <p><i>As example, the machine cleaning cycle used for validation: (Miele G7733):</i></p> <ol style="list-style-type: none"> 1. Cold pre-rinse for at least 2 Min. 2. Wash at 45 °C for at least 3 Min. (heating time not included) 3. Neutralize at 37 °C for at least 3 Min. 4. Rinse with fresh water at 23 °C for at least 1.5 Min. 5. Disinfection at 93°C for at least 5 Min. <p><i>The individual process steps for mechanical cleaning / disinfection may deviate.</i></p>

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Cleaning manually	<p>Alkaline cleaning agents: pH value ≤ 12, for dosage refer to manufacturer's instructions</p> <p>Process:</p> <ol style="list-style-type: none"> 1. Clean the instrument manually at about 45 °C 2. Rinse the instrument under running deionized water. 3. Visual control: no dirt should be detectible anymore, otherwise start at point 1 again
Disinfection:	<ul style="list-style-type: none"> - CDI according to DIN EN ISO15883 - The thermal disinfection should be preferred. - Observe minimum values according to DIN EN ISO15883 eq. 93°C/ at least 5 min.
Drying:	If possible in CDI according to DIN EN ISO 15883 or at approx. 80 °C for approx. 0.5 hrs. For drying in case of manual cleaning, medical compressed air should be used.
Maintenance, inspection and functional testing:	<ul style="list-style-type: none"> - Let the instrument cool down to room temperature - If necessary, apply a small amount of high quality physiologically acceptable surgical lubricating oil to the joints. - Basic inspection for defects. - Sort out defective instruments and dulled edges. Cutting edges should have no nicks or deformation and should be even. - Check instruments with joints for ease of movement (avoid too much play). - Locking mechanisms (locking wheel) should be checked for their function. - Check long, narrow instruments (especially joint instruments) for damage. If instruments are part of a larger assembly, these must be checked with the affiliated components. - Where mounting is necessary: perform this, if necessary with the help of specific installation instructions / surgical technique.
Packaging:	<p>Individually: Use a qualified packaging material. The bag must be big enough for the instrument so that the seal is not under tension.</p> <p>Sets: Place the instruments in designated trays or place them on general-purpose sterilization trays. The blades must be protected and the weight must not exceed the maximum weight per tray according to local laws. A suitable procedure must be used to package the trays.</p>
Sterilization:	<p>Process: Use a validated process according to DIN EN ISO 17665-1 (Sterilization of health care products - Moist heat) e.g. fractionated vacuum process</p> <ul style="list-style-type: none"> - At least 18 minutes at 134°C and 3 bar (max. 137°C) - 5 minutes at 134°C and 3 bar (residual risk of non-deactivated prions)
Storage:	Instruments should be stored in a cool and dry place protected against unauthorized access.
Transport:	Pay attention to suitable transport devices and facilities.
Additional Information:	<p>Machine cleaning is preferable to manual cleaning.</p> <p>Detergent used for validation: Dr. Weigert – neodisher ‚MediClean forte‘ pH 10.5 – 10.8 (in demineralized water). When using other detergent, manufacturer's instructions should be observed and their suitability and effectiveness should be checked.</p> <p>In case of deviating local or national instructions, it is up to the user to validate the procedure accordingly.</p>

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Reference:



In case another reprocessing procedure is required, refer to the product-specific surgical technique / reprocessing instructions.

Literature:

- 1) DIN EN ISO 17664: Processing of health care products - Information to be provided by the medical device manufacturer for the processing of medical devices

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