

# 502.C006-B1 Reprocessing of reusable instruments



INNOMED-EUROPE LLC

Alte Steinhäuserstrasse 19 CH-6330 Cham

This manual applies to all reusable instruments of Innomed-Europe LLC, providing instructions on the appropriate reprocessing of reusable instruments in accordance with international standards (EN ISO 17664 <sup>1)</sup>).

<p><b>Warnings:</b></p>	<ol style="list-style-type: none"> <li>1. Instruments made from special plastics or containing aluminum components may be damaged by alkaline (pH &gt;7) detergents and cleaning solutions. Use appropriate neutralizing solutions after cleaning such instruments with alkaline detergents. Then rinse instruments in deionized water.</li> <li>2. The cleaning of long, narrow tubes and blind holes requires special care. Note: Use appropriate brushes to reach every corner. Do not use steel brushes.</li> <li>3. Do not expose instruments with metal components to saline solutions for longer periods – risk of corrosion!</li> <li>4. Wear suitable protective clothing as specified in the instructions for use by the respective manufacturer.</li> </ol>
<p>Restrictions on reprocessing:</p>	<p>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.</p>
<p><b>INSTRUCTIONS:</b></p>	
<p>Storage and transport:</p>	<p>It is recommended to reprocess instruments as soon as possible after use.</p>
<p>Preparation for cleaning:</p>	<p>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. Ultrasound cleaning is suitable for all instruments, but not mandatory.</p>
<p><b>Manual cleaning:</b></p>	<p><b>Cleaning agent:</b> Dr. Weigert – Neodisher MediClean forte or similar (pH 10.5 - 11), recommended: 0.5 vol% (up to 3.0 vol% max.)</p> <p><b>Procedure:</b></p> <ol style="list-style-type: none"> <li>1. Rinse soiled instrument surfaces.</li> <li>2. Use brush to apply cleaning solution to all instrument surfaces. Make sure the articulating instruments are cleaned both in the open and closed positions.</li> </ol> <p>Note: When cleaning long hollow spaces and blind holes, use appropriate brushes to reach every corner. Do not use steel brushes.</p> <ol style="list-style-type: none"> <li>3. Submerge instrument for 15 min. at 40°C.</li> <li>4. Rinse instrument under running water.</li> <li>5. Visual control: in the event of any visual contamination repeat cleaning, starting with step 1.</li> <li>6. Use compressed air for manual drying.</li> </ol>
<p>Disinfection:</p>	<p>93°C for at least 5 min.</p>
<p><b>Automated cleaning and subsequent disinfection:</b></p>	<p><b>Equipment:</b> Miele G7733 or equivalent</p> <p><b>Cleaning agent:</b> Dr. Weigert – Neodisher MediClean forte or similar (pH 10.5 - 11), recommended: 0.2 vol% (up to 1.0 vol% max.)</p> <p><b>Procedure:</b></p>

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	<ol style="list-style-type: none"> <li>1. Heavily soiled or complex instruments like instruments with long and narrow hollow spaces and blind holes need to be pre-cleaned manually until all visible contaminations are removed.</li> <li>2. Articulating instruments need to be placed in the automatic cleaning unit in the open position, allowing water to drain from hollow spaces and blind holes.</li> <li>3. <b>Set cycles:</b> Use cold pre-rinse cycle for at least 2 min., wash at 45°C for at least 3 min. (after warm-up time), neutralize at 37°C for at least 3 min., rinse at 23°C for 1.5 min., rinse with fresh water for 1.5 min.</li> <li>4. Disinfection: 93°C for at least 5 min.</li> <li>5. Remove instruments and check particularly in hollow spaces and blind holes for contamination residues. If necessary, repeat cycle or clean manually.</li> </ol> <p>Alternatively, use equivalent cleaning procedures, automated programs or detergents designed to achieve similar cleaning results.</p>
Drying:	Drying: at 80°C for approx. 30 min.
Maintenance:	<p>If necessary, apply a small amount of high quality surgical lubricant to the instrument articulations.</p> <p>General inspection for defects.</p> <p>Discard defective instruments and blunt cutting edges/blades.</p>
Inspection and performance testing:	<p>Make sure articulating instruments operate smoothly (avoid too much clearance).</p> <p>Check locking mechanism (ratchet wheel) for proper function.</p> <p>Visually inspect all instruments for damage and wear.</p> <p>Cutting edges/blades should be smooth, without notches.</p> <p>Check long, narrow instruments (especially articulating instruments) for damage. If the instruments are part of a larger assembly, check the assembly and all components.</p> <p>Assemble components and follow the respective assembly instructions/surgical technique, if applicable.</p>
Packaging:	<p><b>Per unit:</b> Use standardized sterilization packaging. The pouch needs to be large enough for the instrument to avoid tension on the seal.</p> <p><b>Sets:</b> Sort instruments in their respective trays or place on multi-purpose sterilization trays. Sharp edges/blades need to be protected and 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.</p>
Sterilization:	<p>Vacuum autoclave</p> <ul style="list-style-type: none"> <li><input type="checkbox"/> For at least 18 minutes at 134°C (max. 137°C), 3 bar</li> <li><input type="checkbox"/> For 5 minutes at 134°C, 3 bar (at your own risk, as evidence has shown that it takes at least 18 minutes to render prions harmless).</li> </ul>
Additional information:	<p>Should the indicated cleaning agents not be available, please use a similar detergent and follow the manufacturer's instructions for use. Please read carefully the manufacturer's information and/or carry out physical tests to verify the suitability of the detergent to be used.</p>

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	The individual process steps of automated cleaning/disinfection may take longer, as the water feeding and removal as well as the water heating take extra time.
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### Special Notes:



Please refer to the surgical manual to verify whether an ETO sterilization is required.

**Storage:** Instruments need to be stored in cool and dry environment, protected against unauthorized access.

### References:

- 1) ISO 17664:2004: Sterilization of medical devices - Information to be provided by the manufacturer for the processing of resterilizable medical devices.

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