



## Instructions for Cleaning and Sterilization of Premier Reusable Hand Instruments and Trachea Tubes

The following instructions are for all Premier reusable hand instruments, unless stated otherwise with the packaging of the product. All reusable devices are supplied non-sterile and should be cleaned and sterilized before first use and after each subsequent use. These instructions are intended for use only by persons with the required specialist knowledge and training.

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| <b>WARNINGS</b>                        | <ul style="list-style-type: none"> <li>• Follow instructions and warnings as issued by manufacturers of any decontaminants, disinfectants and cleaning agents used. Wherever possible avoid use of mineral acids and harsh, abrasive agents.</li> <li>• Do not use chemical sterilants with caustic ingredients such as surgical scrub solutions, povidone-iodine solutions, bleach, peroxide solutions, Virox 3, Sporox and Cidex PA. Do not use garment or surface disinfectants.</li> <li>• Do not autoclave with dissimilar metals as this may cause a reaction and lead to rust or discoloration.</li> <li>• No part of the process shall exceed 140° C.</li> <li>• When reprocessing medical devices, handle with care, wearing protective clothing and face visors or goggles where appropriate.</li> </ul> |
| <b>INSTRUCTIONS</b>                    |  |
| <b>FROM POINT OF USE</b>               | <ul style="list-style-type: none"> <li>• If possible, soiled devices should be placed in a holding solution (combined disinfectant/enzyme solution) immediately after use and prior to cleaning.</li> </ul>  |
| <b>PREPARATION FOR DECONTAMINATION</b> | <ul style="list-style-type: none"> <li>• Clean all devices as soon as it is reasonably practical to do so.</li> </ul>  |
| <b>CLEANING:<br/>MANUAL</b>            | <ul style="list-style-type: none"> <li>• Multicomponent devices should be disassembled before cleaning.</li> <li>• Using a sink dedicated for instrument cleaning (not used for hand washing), rinse excess soil from the device (water temperature &lt;35° C).</li> <li>• Keeping the device submerged, with a brush, apply cleaning solution to all surfaces. Pay particular attention working ends. Always brush away from the body. Do not use a wire brush.</li> <li>• Rinse the device thoroughly with clean water, so that the water reaches all parts of the device, then carefully hand dry.</li> </ul>   |

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| <b>CLEANING:<br/>AUTOMATED</b>             | <ul style="list-style-type: none"> <li>• Use only medical or dental washer-disinfector machines and cleaning agents (do not use household dishwasher or cleaning agents) following the manufacturers’ instructions for use, warnings and recommended cycles.</li> <li>• Load devices carefully, ensure any delicate parts of the device are not liable to damage during the loading procedure.</li> </ul> <p><b>Premier recommends the following automatic washer-disinfector cycle:<br/>Pre-wash 28 °C for 4 minutes, Wash at 50 °C for 8 minutes, Rinse at 50°C for 4 minutes, Thermal Disinfection at 90°C – 95°C for 1 minute, Drying for 25 minutes.</b></p>   |
| <b>CLEANING: INSPECTION</b>                | <ul style="list-style-type: none"> <li>• After cleaning, check <i>all</i> surfaces for complete removal of soil.</li> <li>• If any soil is still visible, return the device for repeat cleaning.</li> </ul>   |
| <b>INSPECTION AND<br/>FUNCTION TESTING</b> | <ul style="list-style-type: none"> <li>• Visually inspect and check all devices for damage and wear.</li> <li>• Remove for repair or replacement any damaged product.</li> </ul>  |
| <b>RECOMMENDED<br/>PACKAGING</b>           | <ul style="list-style-type: none"> <li>• Ensure all devices are dry before packaged</li> <li>• To ensure proper packaging that will maintain the integrity of sterilization, consult the packaging manufacturers’ instructions for use (IFU) and follow the sterilization standards and guidelines from the Association for the Advancement of Medical Instrumentation (AAMI)</li> </ul>  |
| <b>STERILIZATION</b>                       | <ul style="list-style-type: none"> <li>• Multicomponent devices should be disassembled before sterilization.</li> <li>• <b>Always follow the instructions of the autoclave manufacturer.</b></li> <li>• When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer manufacturer’s stated maximum load is not exceeded.</li> <li>• Ensure all devices are dry before sterilization. If the devices cannot be dried prior to sterilization, then use distilled/deionized water in the final-rinse stage of cleaning.</li> </ul> <p><b>Premier instruments have been validated using a pulsed pre-vacuum sterilization process (dynamic air removal steam sterilization)<br/>For wrapped packages - sterilizing temperature 134°C ± 2°C (273°F),<br/>Sterilizing time 5 minutes. 30 minutes of drying time.<sup>1,2,3, 4</sup></b></p> |
| <b>STORAGE</b>                             | <ul style="list-style-type: none"> <li>• Ensure all packaged devices are dry before storage. Store in dry, clean conditions at ambient room temperature.</li> </ul>   |

1) ANSI/AAMI ST77:2006/(R) 2010. Containment devices for reusable medical device sterilization  
2) ANSI/AAMI ST79:2010 and A1:2010 and A2:2011 and A3:2012. Comprehensive guide to steam sterilization and sterility assurance in health care facilities  
3) AAMI TIR12:2010. Designing, testing and labeling reusable medical devices for reprocessing in health care facilities: A guide for medical device manufacturers. s  
4) Full report available on request

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