



Reprocessing and Sterilization Instructions For all Extremity Medical Reusable Instruments and Surgical Kits

Limitations on reprocessing:	Repeated processing has minimal effect on these instruments. End of life is normally determined by wear and damage due to use.								
Instructions									
Point of use:	Warning: The following Extremity Medical instruments are intended for single use - guide wires, cannulated drills, and cleaning brushes. Before being used for the first time and each use thereafter, the instructions outlined below should be followed to ensure safe handling of biologically contaminated instruments.								
Containment and transportation:	It is recommended that instruments are reprocessed as soon as reasonably practical following use.								
Preparation for cleaning:	Where instruments interface with other devices, disassemble prior to cleaning. Remove excess soil with a clean, disposable, absorbent Kimwipe or equivalent.								
Cleaning (Automated):	<p>Equipment: Washer Disinfectant/Decontaminator (Hydrim L110W) and detergent (HIP Cleaning Solution L110W) or equivalent.</p> <ul style="list-style-type: none"> Alcohol wipe the instruments then place in instrument washer for cleaning - load instruments in such a way that the parts can drain. The following Heavy Duty Cycle will be selected (at a minimum): <table border="1" style="margin-left: 40px;"> <tr> <td>Cold prewash</td> <td>< 45° C (113° F)</td> </tr> <tr> <td>Wash</td> <td>50° C (122° F) for 9 minutes</td> </tr> <tr> <td>Rinse</td> <td>60° C (140° F)</td> </tr> <tr> <td>Dry</td> <td>20 minutes</td> </tr> </table> <ul style="list-style-type: none"> When unloading, check instruments for complete removal of any debris. If necessary, repeat cycle or use manual cleaning. 	Cold prewash	< 45° C (113° F)	Wash	50° C (122° F) for 9 minutes	Rinse	60° C (140° F)	Dry	20 minutes
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Cleaning (Manual):	<p>Warning: Movable components and blind holes require particular attention during cleaning.</p> <p>Preparation of Cleaning Agents (Recommended):</p> <ul style="list-style-type: none"> Add 60 mL of Endozime® AW Plus to 3.8 L of water, (1:64 dilution). Add 8.0 mL of Vesphene® IIse to 992.0 mL of sterile water. <p>Manual Cleaning Instructions:</p> <ul style="list-style-type: none"> Alcohol wipe the instruments. Bathe the instruments in the Endozime® AW Plus solution for 20 minutes; where appropriate, the instrument shall be rotated and briskly moved in bath to promote flushing. Where appropriate, a large syringe or pulsating water jet may be used to thoroughly flush all channels and lumens with the solution. Scrub the instruments with a soft brush. Rinse the instruments in cold water. Submerge the samples in Vesphene® IIse solution and sonicate for 15 min at 40° C (104° F). Scrub the instruments with a soft brush. Rinse the instruments in deionized water. Pat dry the instruments with a clean, disposable, absorbent Kimwipe or equivalent. If necessary, repeat manual cleaning cycle. 								
Disinfection:	<p>Disinfection solution (Vesphene® IIse 8% or equivalent) may be used in accordance with the label instructions.</p> <p>If automated cleaning is employed, a final rinse at 60° C for 20 minutes may be used to affect thermal disinfection.</p>								



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Maintenance:	<p>Warning: The use of damaged instruments may increase the risk of tissue trauma, infection and length of procedures. Do not attempt to repair any Extremity Medical instrument.</p> <p>If your Extremity Medical instrument requires repair or maintenance, return the instrument in the Extremity Medical box or other sturdy box with adequate packaging material to protect the instrument. Send the packaged instrument to:</p> <p style="text-align: center;">Extremity Medical, LLC. 300 Interpace Parkway Suite 410 Parsippany, NJ 07054 Attn: Extremity Medical Technical Services</p> <p><u>Note:</u> Instruments returned to Extremity Medical must have a statement which testifies that each instrument has been thoroughly cleaned and disinfected. Failure to supply evidence of cleaning and disinfection will result in a cleaning charge and delayed processing of your instrument repair.</p>												
Inspection and Function Testing:	<p>All instruments: Visually inspect for damage and wear. Where instruments interface with other devices, inspect to ensure that the interface is not damaged.</p> <p>Check for misalignment, burrs, bent or fractured tips. Mechanically test the working parts to verify that each instrument functions correctly. Remove stained, discolored or damaged instruments.</p>												
Packaging:	<p>Instruments may be loaded into dedicated instrument trays, or in general-purpose trays. Wrap the trays using an appropriate method.</p>												
Storage:	<p>Extremity Medical instruments must be completely dry before storing and must be handled with care to prevent damage. Store in designated trays and in areas which provide protection from dust, insects, chemical vapors and extreme changes in temperature and humidity.</p>												
Sterilization:	<p>Warning: Extremity Medical does not recommend that the instruments be sterilized by Flash, EtO or Chemical sterilization. When sterilizing multiple instruments in one autoclave cycle, ensure that the sterilizer's maximum load is not exceeded.</p> <p>To achieve a sterility assurance level of SAL 10⁻⁶, Extremity Medical recommends the following parameters:</p> <table border="1" style="margin-left: auto; margin-right: auto;"> <thead> <tr> <th style="text-align: left;">Sterilizer Type</th> <th style="text-align: center;">Pre-Vacuum</th> <th style="text-align: center;">Gravity</th> </tr> </thead> <tbody> <tr> <td>Minimum Temp.</td> <td colspan="2" style="text-align: center;">132° C (270° F)</td> </tr> <tr> <td>Exposure*</td> <td style="text-align: center;">4 min</td> <td style="text-align: center;">15 min</td> </tr> <tr> <td>Dry Time</td> <td colspan="2" style="text-align: center;">20 minutes</td> </tr> </tbody> </table> <p><small>*Extremity Medical has validated the above sterilization cycles and has the data on file. The validated sterilization parameters meet the minimum requirements per AAMI ST79. Other sterilization cycles may also be suitable; however individuals or hospitals not using the recommended method are advised to validate any alternative method using appropriate laboratory techniques.</small></p> <p>Extremity Medical recommends following the recommendations of AAMI Guideline For Steam Sterilization ST79 which includes: physical monitoring of the cycle, including a chemical indicator external and internal of the package, and monitoring of every load with a Biological Indicator and/or Class 5 Integrating Indicator.</p>	Sterilizer Type	Pre-Vacuum	Gravity	Minimum Temp.	132° C (270° F)		Exposure*	4 min	15 min	Dry Time	20 minutes	
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The instructions provided above have been validated by Extremity Medical as capable of preparing a medical device for re-use. It remains the responsibility of the processor to ensure that the processing as actually performed using equipment, materials and personnel in the processing facility achieve the desired result. This requires validation and routine monitoring of the process. Likewise, a deviation by the processor from the instructions provided should be properly evaluated for the effectiveness and potential adverse consequences.



Extremity Medical, LLC
300 Interpace Parkway, Suite 410
Parsippany, NJ 07054
USA
+(1) 973 588 8980



MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany