

Manufacturer: Wagner GmbH Munich **Method:** Re-processing instructions **Symbol:** n.a.

Product(s): SteriSet Sterilization-Containers (all types)

<p>WARNINGS:</p>	<p>When selecting cleaning and disinfection agents and methods, particular attention must be paid to tolerance by aluminium as well as the following points:</p> <ul style="list-style-type: none"> — The selected cleaning agents must be appropriate for the quality of the available water (details: see instructions for use) — Do not use lathering cleaning substances (powder) or abrasive metal brushes or similar — Thorough rinsing must remove all cleaning agent residues — Parts should be thoroughly dried following the cleaning / disinfection, <p>For HOT water (> 60 oC – i.e. for thermal disinfection) preparation the use of fully desalinated water is mandatory (> 60 oC hot tap- or softened water may degrade aluminum).</p> <p>Do only sterilize in standardized vacuum steam cycles (i. e. acc. EN 285)</p>
<p>Limitations on re-processing:</p>	<p>Specifically important when putting NEW containers into service (“wash in”): performing wash/disinfection- and/or sterilization-processes to fast following each other may do harm to “unused” (new) aluminum surfaces. For the first 3 re-processing cycles it is therefore recommended to pause 24 hours between each single step. Later correct re-processing can be performed in the normal cycling routine.</p> <p>The end of the service life is typically influenced by mechanical abuse and damages – which can be identified during the required function control (see instructions for use)</p>

INSTRUCTIONS																																																																																																																								
<p>Point of use:</p>	<p>After breaking the tamper seal, open BOTH lid latches and lift the lid up VERTICALLY (do not open / lift only one side !)</p>																																																																																																																							
<p>Containment and transportation</p> <p>See also “storage” on next page</p>	<p>Citation DIN 58953-8: Loss of sterility depends less from the storage duration than from external influence or events during storage, transport and handling. There is no generally applicable storage time. DIN 58953-8 Table 1 lists recommendations for storage times of sterile medical devices.</p> <p>Citation DIN 58953-9: Sterile containers should be transported vibration free and always horizontally (other conditions need separate validation)</p>																																																																																																																							
<p>Preparation for Cleaning</p>	<p>Take of lid and disassemble into: outer lid, inner lid and bottom. Process these parts separately (see instructions)</p>																																																																																																																							
<p>Cleaning: Automated</p> <p>Used machine: Belimed WD290 / WD 3xx</p> <p>Note: Alkaline residuals can do harm to aluminum during the thermo disinfection. A optional 2nd clear-rinsing will more safely remove these residuals, therewith increase the compatibility of the process!</p> <p>Used machine: MIELE G 7824</p> <p>Important Note: Alkaline residuals can do harm to aluminum during the thermo disinfection. In the MediClean Forte case listed here (TD done with A0 value of 3000!) only a 2nd clear-rinsing allowed to setup a aluminum compatible process!</p>	<p>The following Dr. Weigert products (Neodisher family) have demonstrated under the listed conditions that validated cleaning / disinfection results can be reached:</p> <table border="1" data-bbox="480 1480 1369 1760"> <thead> <tr> <th>#</th> <th>Step</th> <th>Water</th> <th>T oC</th> <th>t in Min</th> <th>Chemie</th> <th>ml/Liter</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Pre-cleaning</td> <td>Tap</td> <td>25 to 33</td> <td>2</td> <td>--</td> <td>--</td> </tr> <tr> <td>2</td> <td>Cleaning</td> <td>DESAL</td> <td>55</td> <td>10</td> <td>SeptoClean</td> <td>2,0</td> </tr> <tr> <td>3</td> <td>Rinsing</td> <td>DESAL</td> <td>25 to 33</td> <td>2</td> <td>--</td> <td>--</td> </tr> <tr> <td>4</td> <td>Clear-Rinsing</td> <td>DESAL</td> <td>25 to 33</td> <td>2</td> <td>--</td> <td>--</td> </tr> <tr> <td>option</td> <td>opt. repeated Clear-Rinsing</td> <td></td> <td></td> <td></td> <td></td> <td></td> </tr> <tr> <td>5</td> <td>Thermo disinfect. (A0 value 600)</td> <td>DESAL</td> <td>93</td> <td>1</td> <td>--</td> <td>--</td> </tr> <tr> <td>6</td> <td>Drying</td> <td>Hot air</td> <td>130</td> <td>4</td> <td>--</td> <td>--</td> </tr> <tr> <td></td> <td></td> <td>Hot air</td> <td>100</td> <td>6</td> <td>--</td> <td>--</td> </tr> </tbody> </table> <table border="1" data-bbox="480 1794 1369 2051"> <thead> <tr> <th>#</th> <th>Step</th> <th>Water</th> <th>T oC</th> <th>t in Min</th> <th>Chemie</th> <th>ml/Liter</th> </tr> </thead> <tbody> <tr> <td>1</td> <td>Pre-cleaning</td> <td>Tap</td> <td>25 to 33</td> <td>2</td> <td>--</td> <td>--</td> </tr> <tr> <td>2</td> <td>Cleaning</td> <td>DESAL</td> <td>45</td> <td>5</td> <td>MediClean forte</td> <td>3,0</td> </tr> <tr> <td>3</td> <td>Rinsing</td> <td>DESAL</td> <td>25 to 33</td> <td>2</td> <td>--</td> <td>--</td> </tr> <tr> <td>4</td> <td>1 Clear-Rinsing</td> <td>DESAL</td> <td>25 to 33</td> <td>2</td> <td>--</td> <td>--</td> </tr> <tr> <td>5</td> <td>2 Clear-Rinsing</td> <td>DESAL</td> <td>25 to 33</td> <td>2</td> <td>--</td> <td>--</td> </tr> <tr> <td>6</td> <td>Thermo disinfect. (A0 value 3000!)</td> <td>DESAL</td> <td>93</td> <td>5</td> <td>--</td> <td>--</td> </tr> <tr> <td>7</td> <td>Drying</td> <td>Hot air</td> <td>110</td> <td>5</td> <td>--</td> <td>--</td> </tr> </tbody> </table>	#	Step	Water	T oC	t in Min	Chemie	ml/Liter	1	Pre-cleaning	Tap	25 to 33	2	--	--	2	Cleaning	DESAL	55	10	SeptoClean	2,0	3	Rinsing	DESAL	25 to 33	2	--	--	4	Clear-Rinsing	DESAL	25 to 33	2	--	--	option	opt. repeated Clear-Rinsing						5	Thermo disinfect. (A0 value 600)	DESAL	93	1	--	--	6	Drying	Hot air	130	4	--	--			Hot air	100	6	--	--	#	Step	Water	T oC	t in Min	Chemie	ml/Liter	1	Pre-cleaning	Tap	25 to 33	2	--	--	2	Cleaning	DESAL	45	5	MediClean forte	3,0	3	Rinsing	DESAL	25 to 33	2	--	--	4	1 Clear-Rinsing	DESAL	25 to 33	2	--	--	5	2 Clear-Rinsing	DESAL	25 to 33	2	--	--	6	Thermo disinfect. (A0 value 3000!)	DESAL	93	5	--	--	7	Drying	Hot air	110	5	--	--
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<p>Cleaning: Manual</p> <p>Note: Chemical residuals can do harm to aluminum during the following thermo disinfection or sterilization, therefore it is mandatory to safely remove these residuals !</p>	<p>Use only aluminum compatible, ph-neutral cleaners together with soft brushes or towels to clean the soiled surface - and thoroughly remove residual cleaner at the end. Example: product „Shining NE“ (available from: Wagner GmbH):</p> <ol style="list-style-type: none"> Put max. 3ml per 50 cm² surface of Shining NE on a soft, wet towel, then rub in gently (in circles) into the soiled surface Have the cleaner rest on the surface for 3-5 minutes (in case only slightly soiled surfaces) respectively 15 minutes (heavily soiled surfaces) Thoroughly remove the cleaner by rinsing the treated surface with tap water or better (finally) distilled water Wipe surfaces dry with soft, lint free towel 											
<p>Disinfection:</p> <p>Note: Residual chemical disinfectants can do harm to aluminum during the following sterilization. It is therefore mandatory to safely remove any residuals !</p>	<p>Aside from the requirement for proven effectiveness (effective disinfectants are listed i.e. on the “Desinfektionsmittel-Liste” of RKI or DGHM), there are also requirements for material compatibility of used agents.</p> <p>NOTE: Even if material compatibility is claimed, it is important to know that this is no “general” compatibility under all circumstances: since compatibility will always depend from the used water quality, mixing ratio/dosation, exposure time and -temperature or possibly harmful effects from mixing with various different agents, the agents manufacturers instructions on how to achieve aluminium compatibility must be obeyed.</p>											
<p>Drying:</p>	<p>If drying is part of the automatic cleaning process (hot air), 134 oC should not be exceeded. Surfaces can always be dried by use of a soft, lint free towel.</p>											
<p>Maintenance, Inspection and Function Testing</p>	<p>Between cleaning / disinfection and a new use (filling), the sterile container should undergo a thorough function control as specified in the instructions for use.</p>											
<p>Packing:</p>	<p>Sterilization containers themselves ARE a packaging for medical devices to be sterilized, stored and transported. When used as intended they do not need a outer wrap or additional protection.</p>											
<p>Sterilization:</p>	<p>SteriSet containers are suitable for use in steam sterilizers using fractionated pre-vacuum or fractionated circulation cycles. Used sterilizers shall be built, installed and operated in accordance with recognized standards (i. e. like DIN 58946 ("large sterilizers") or EN 285).</p> <p>If this is not the case, it is absolutely essential that the sterilization procedure which shall be used is validated in accordance with the latest technical standards, as it may otherwise not be possible to guarantee the attainment of sterility.</p> <p>In generally: respect the instructions for use with their warnings resp. explanations.</p> <p>Hot-air sterilization, gravity or circulation procedures and also formaldehyde or ethylene oxide sterilization or other substitute procedures for the sterilization of thermo labile products such as plasma sterilization or peroxide sterilization <u>may not be used.</u></p>											
<p>Storage:</p> <p>See DIN 58953-8 Table 1</p> <p>Note 7.1.2 states what “protected” means a) in closed systems like cupboards b) In open shelves if room complies to DIN 1946-4.2008-12 “room class II”</p>	<table border="1"> <thead> <tr> <th>Kind of packaging</th> <th>Storage “un-protected”^a</th> <th>Storage “protected” (acc. 7.1.2)</th> </tr> </thead> <tbody> <tr> <td>Sterile barrier system</td> <td>Use as soon as possible^b (Should be avoided for storage)</td> <td>6 months, yet not longer then expiration date</td> </tr> <tr> <td>Packaging system (combination of sterile barrier system and protective packaging)</td> <td>5 years if not the manufacturer defines a earlier expiration date</td> <td></td> </tr> </tbody> </table>	Kind of packaging	Storage “un-protected” ^a	Storage “protected” (acc. 7.1.2)	Sterile barrier system	Use as soon as possible ^b (Should be avoided for storage)	6 months, yet not longer then expiration date	Packaging system (combination of sterile barrier system and protective packaging)	5 years if not the manufacturer defines a earlier expiration date		<p>^a In open shelves in rooms which do not comply to DIN 1946-4.2008-12 “room class II”</p> <p>^b “as soon as possible” is understood as use of the product within max. 2 days / 48 hours.</p>	
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<p>Additional Information:</p>	<p>www.wagner-steriset.de -> see there i. e. headline „FAQs/Info“, or downloads under headline “Catalogs” (where also the INSTRUCTIONS for use are available as PDF)</p>											
<p>Manufacturer contact:</p>	<p>Wagner GmbH Fabrik f. med. Geraete, Schulstr. 16a, D-80634 Muenchen, P: +49 (89) 1211010 F: +49 (89) 133099 info@wagner-sterilsysteme.de</p>											

The instructions provided above have been validated by the medical device manufacturer as being 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 any deviation by the processor from the instructions provided should be properly evaluated for effectiveness and potential adverse consequences.