

# Reprocessing Instructions according ISO 17664:2004 Tweezers (Date: 10-07-01)



**Steiner**  
PINZETTEN

<b>Process:</b>			
<b>Products:</b>	Steiner-Pinzetten GmbH, Engen / Germany Different forceps for surgical and dental use Article Number: 100-xx x to 900-xxx		
<b>ADICE:</b>	Reprocessing procedures have only limited implications to a surgical instrument. The limitation of the numbers of reprocessing procedures is therefore determined by the function / wear of the device.  In case of damage the device should be reprocessed before sending back to the manufacture for repair.		
<b>Reprocessing Instructions</b>			
<b>Preparation at the point of use:</b>	Remove gross soiling by submerge the instrument into cold water (<40°C) immediately after use. Don't use a fixation detergent or hot water (>40°C) as this can cause the fixation of residua which may influence the result of the reprocessing process.		
<b>Transportation:</b>	Safe storage and transportation in a closed container to the reprocessing area to avoid any damage an contamination to the environment.		
<b>Preparation for Decontamination:</b>	No special requirements.		
<b>Pre-Cleaning:</b>	No special requirements.		
<b>Cleaning:</b>	<table border="0"> <tr> <td style="vertical-align: top;"> <p><b>Automated cleaning:</b> Put the instruments on a tray in an open state. Put the tray in the washer disinfectant and start the cycle:</p> <ol style="list-style-type: none"> <li>1. 1 min pre-cleaning with cold water</li> <li>2. draining</li> <li>3. 3 min pre-cleaning with cold water</li> <li>4. draining</li> <li>5. 5 min cleaning at 55°C with 0,5 % alkaline detergent</li> <li>6. draining</li> <li>7. 3 min neutralisation with warm water (&gt;40°C) an neutralizer</li> <li>8. draining</li> <li>9. 2 min rinse with warm water (&gt;40°C)</li> <li>10. draining</li> </ol> <p>Special instructions of the manufacturer of the automated washing machine have to be followed.</p> </td> <td style="vertical-align: top;"> <p><b>Automated cleaning:</b> Put the instruments on a tray in an open state. Put the tray in the washer disinfectant and start the cycle:</p> <ol style="list-style-type: none"> <li>1. 1 min pre-cleaning with cold water</li> <li>2. draining</li> <li>3. 3 min pre-cleaning with cold water</li> <li>4. draining</li> <li>5. 5 min cleaning at 45°C with 0,5 % enzymatic detergent</li> <li>6. draining</li> <li>7. 3 min neutralisation with warm water (&gt;40°C)</li> <li>8. draining</li> <li>9. 2 min rinse with warm water (&gt;40°C)</li> <li>10. draining</li> </ol> <p>Special instructions of the manufacturer of the automated washing machine have to be followed.</p> </td> </tr> </table>	<p><b>Automated cleaning:</b> Put the instruments on a tray in an open state. Put the tray in the washer disinfectant and start the cycle:</p> <ol style="list-style-type: none"> <li>1. 1 min pre-cleaning with cold water</li> <li>2. draining</li> <li>3. 3 min pre-cleaning with cold water</li> <li>4. draining</li> <li>5. 5 min cleaning at 55°C with 0,5 % alkaline detergent</li> <li>6. draining</li> <li>7. 3 min neutralisation with warm water (&gt;40°C) an neutralizer</li> <li>8. draining</li> <li>9. 2 min rinse with warm water (&gt;40°C)</li> <li>10. draining</li> </ol> <p>Special instructions of the manufacturer of the automated washing machine have to be followed.</p>	<p><b>Automated cleaning:</b> Put the instruments on a tray in an open state. Put the tray in the washer disinfectant and start the cycle:</p> <ol style="list-style-type: none"> <li>1. 1 min pre-cleaning with cold water</li> <li>2. draining</li> <li>3. 3 min pre-cleaning with cold water</li> <li>4. draining</li> <li>5. 5 min cleaning at 45°C with 0,5 % enzymatic detergent</li> <li>6. draining</li> <li>7. 3 min neutralisation with warm water (&gt;40°C)</li> <li>8. draining</li> <li>9. 2 min rinse with warm water (&gt;40°C)</li> <li>10. draining</li> </ol> <p>Special instructions of the manufacturer of the automated washing machine have to be followed.</p>
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<b>Disinfection:</b>	Automated Disinfection: Automated Thermal Disinfection in washer/disinfectant under consideration of national requirements in regards to A <sub>0</sub> -Value (see EN 15883).		
<b>Drying:</b>	Automated Drying: Drying of outside of instrument through drying cycle of washer/disinfectant. If needed, additional manual drying can be performed through lint free towel. Insufflate cavities of instruments by using sterile compressed air.		
<b>Functional Testing, Maintenance:</b>	Visual inspection for cleanliness and functional testing according to instructions of use. If necessary perform reprocessing process again until the instruments are visibly clean.		
<b>Packaging:</b>	Appropriate packaging for sterilization according ISP 11607 and EN 868.		
<b>Sterilization:</b>	Sterilization of instruments by applying a fractionated pre-vacuum process (according ISO 13060 / ISO 17665) under consideration of the respective country requirements.  Parameters for the pre-vacuum cycle: 3 prevacuum phases with at least 60 milli bar. Heat up to a minimum sterilization temperature of 132°-134°C; maximum temperature 137°C Minimum Holding time: 3 min Drying time: Minimum 10 min		
<b>Storage:</b>	Storage of sterilized instruments in a dry, clean and dust free environment at modest temperatures of 5°C to 40°C.		
<b>Reprocessing validation study information</b>	The following testing test devices, materials & machines have been used in this validation study; Detergent: Neodisher FA; Dr. Weigert; Hamburg Endozone AW Triple plus Ruhof; USA Neutralizer: Neodisher Z; Dr. Weigert, Hamburg Washer / Disinfectant: Miele G 7735 CD Instrument Rack: Miele E 327-06  Details: Cleaning: See report SMP 12407011007 Sterilization: See report SMP 12207022307		
<b>Additional Instruction:</b>	If the described chemistry and machines are not available, it is the duty of the user to validate his process.		
It is the duty of the user to ensure that the reprocessing processes including resources, materials and personnel are capable to reach the required results. State of the art and often national law requiring these processes and included resources to be validated and maintained properly. For manual processing the instructions have to be followed accordingly. The user is responsible für the result of manual cleaning, which has to be of equal value than automated cleaning.			