

<b>Inspection Instructions</b>	
<b>Initial Receipt:</b>	<p>You have purchased a high quality medical instrument. To guarantee its ongoing proper function and safety, please observe the instructions in this document. Unless otherwise noted, Delasco instruments are supplied non-sterile. Therefore, initial cleaning and sterilization is required prior to the instrument's first use.</p> <p><u>Initial Inspection:</u> Carefully examine each instrument for breaks, cracks or malfunctions before use. Check critical places such as blades, stops, locks, points and all movable parts. Do not use damaged instruments. In case of damage, please contact the manufacturer.</p>
<b>Ongoing Use:</b>	<p><u>Ongoing Inspection:</u> The useful life of a surgical instrument depends on several factors, including the method of use, reprocessing, and storage of the device. Prior to each use, inspect the device for damage and proper functioning. Look for discoloration, excessive wear, cracks, and other signs of damage. If the instrument is damaged, please contact the manufacturer.</p>
<b>Reprocessing Instructions</b>	
<b>Preparation at the Point of Use:</b>	Remove gross soiling by submerging the instrument in water (<40°C) immediately after use. Do not use a fixating detergent or hot water (>40°C) as this can cause fixation of the residue, which may impact the effectiveness of reprocessing.
<b>Transportation:</b>	Carefully store and transport the instrument in a closed container to the reprocessing area to avoid damage and contamination to the surrounding environment.
<b>Preparation for Decontamination:</b>	Open and/or disassemble instruments to expose surface areas to the decontamination process. Apply enzymatic cleanser (recommended).
<b>Pre-Cleaning:</b>	<p>Perform the following manual or automated pre-cleaning procedure:</p> <p><u>Manual Cleaning:</u> Immerse the instrument in cold water for at least 5 minutes. Brush the instruments under cold tap water until all visible residues are removed. If possible, dismantle the instruments and brush again under cold tap water. Flush inner lumens, threads, and holes with a water jet pistol for a minimum of 10 seconds in the pulsed mode and brush again.</p> <p>Next, immerse the instrument in an ultrasonic bath with neutral detergent and treat with ultrasound for 15 minutes at 40°C/35KHz. Take the instrument out of the bath and rinse with tap water again.</p> <p><u>Automated Cleaning:</u> Place the instruments in an opened or completely disassembled state on an instrument tray. Place the tray on an instrument rack in the washer disinfecter, following the instructions from the machine manufacturer. See appendix A for more information.</p>
<b>Disinfection:</b>	<p><u>Automated Disinfection:</u> Perform automated thermal disinfection in a washer/disinfecter in compliance with national requirements for A<sub>0</sub>-Value (see ISO 15883).</p>
<b>Drying:</b>	<p><u>Automated Drying:</u> The outer surface of the instrument should be completely dry after the washer/disinfecter's drying cycle. If necessary, use a lint free towel to perform additional manual drying. Insufflate cavities of instruments by using sterile compressed air.</p>
<b>Functional Testing, Maintenance:</b>	Visually inspect for cleanliness. If acceptable, assemble the instrument and perform functional testing. If necessary, reprocess again until the instruments are visibly clean.
<b>Packaging:</b>	Use appropriate packaging for sterilization according to ISO 11607 and EN 868.
<b>Sterilization (Pre-Vacuum):</b>	<p>Sterilize the instruments by applying a fractionated pre-vacuum process (according to EN 13060 / ISO 17665) in compliance with the respective country requirements.</p> <p>Parameters for the pre-vacuum cycle:</p> <ul style="list-style-type: none"> <li>• 3 pre-vacuum phases with at least 60 millibar</li> <li>• Heat to a minimum temperature of 134°C (273°F); maximum temperature of 137°C (279°F)</li> <li>• Pressure: 3 bar</li> <li>• Minimum Holding time: 5 min</li> <li>• Minimum Drying time: 10 min</li> </ul>

<b>Sterilization (Gravity):</b>	<p>Use the standard in ANSI/AAMI ST79:2010/A4:2013, "Comprehensive guide to steam sterilization and sterility assurance in health care facilities," which recommends the following cycle times:</p> <table border="1" data-bbox="451 310 1398 401"> <thead> <tr> <th>Item</th> <th>Exposure Time at 121°C (250°F)</th> <th>Exposure Time at 132°C (270°F)</th> <th>Drying Time</th> </tr> </thead> <tbody> <tr> <td>Wrapped Instruments</td> <td>30 minutes</td> <td>15 minutes</td> <td>15-30 minutes</td> </tr> </tbody> </table> <p>We recommend that you also refer to your internal procedures for steam sterilization, and to the cleaning and sterilizing equipment manufacturer's instructions.</p>	Item	Exposure Time at 121°C (250°F)	Exposure Time at 132°C (270°F)	Drying Time	Wrapped Instruments	30 minutes	15 minutes	15-30 minutes
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Wrapped Instruments	30 minutes	15 minutes	15-30 minutes						
<b>Storage:</b>	<p>Store sterilized instruments in a dry, clean and dust free environment at moderate temperatures of 5°C to 40°C.</p>								
<b>Reprocessing validation study information:</b>	<p>The following test devices, materials, and machines were used in the validation study:</p> <p>Tap water: Drinking water quality (&lt;100 CFU)          Deionized water: Deionized and distilled (RhymaPharm/BBraun)          Water jet pistol: Selecta          Brushes: Hand brush, instrument-cleaning brush with synthetic bristles, cleaning brush with nylon bristles for MIC instruments (interlock 09098), tooth brush.</p> <p>Ultrasonic bath: Sonorex RK 1028H (Bandelin)          Washer/Disinfector: Miele 7735 CD          Detergent: Neodisher FA; Dr. Weigert; Hamburg          Neutralizer: Neodisher Z; Dr. Weigert; Hamburg          Instrument rack: Miele E 327-06          Key Hole Surgery Rack: Miele E 450          Sterilizers: Selectomat S3000, Varioclav 400E, Vaculab 969 S3000, KS 666-2ED</p>								
<b>Additional Instructions:</b>	<p>If the described chemistry and machines are not available, the user is responsible for validating the processes used. Before sterilization, stainless steel instruments should be lubricated with a suitable medical grade instrument lubricant, suitable for steam sterilization, according to the manufacturer's instructions. Moveable parts and articulations should be lubricated sufficiently.</p> <p>The user is responsible for ensuring that the reprocessing procedures, resources, materials, and personnel are qualified to achieve the required results. All resources must be validated and maintained properly.</p>								
<b>Repair and Warranty Limitations:</b>	<p>Do not attempt to make repairs yourself. Repairs done by third parties will void the warranty. If returning your instrument for repairs, the device must be cleaned and sterilized.</p>								
<b>Appendix A:</b>	<p>Delasco's instrument sterilization process was validated using the Miele 7735 CD Washer/Disinfector, using the following automated pre-cleaning cycle:</p> <ol style="list-style-type: none"> <li>1. 1 min. pre-cleaning with cold water</li> <li>2. Drain</li> <li>3. 3 min. pre-cleaning with cold water</li> <li>4. Drain</li> <li>5. 5 min. cleaning at 55°C with 0.5% alkaline detergent</li> <li>6. Drain</li> <li>7. 3 min. neutralization with warm water (&gt;40°C) and neutralizer</li> <li>8. Drain</li> <li>9. 2 min. rinse with warm water (&gt;40°C)</li> <li>10. Drain</li> </ol>								