

## Guideline: Reprocessing of American Orthodontics Instruments

**Manufacturer:** American Orthodontics, [www.americanortho.com](http://www.americanortho.com)

**Devices:** Orthodontic Instruments

### GENERAL INFORMATION

<p><b>Warnings</b></p>	<ul style="list-style-type: none"> <li>• All instruments are to be used only by trained dental professionals and are to be used only for their intended purpose. All instruments are shipped in the non-sterile condition, and should be cleaned and sterilized prior to first use, as well as before each subsequent use.</li> <li>• The instructions provided below have been validated by the manufacturer of the medical device as being capable of preparing a medical device for reuse. It remains the responsibility of the processor to ensure that the processing, as actually performed using equipment, materials and personnel in the processing facility, achieves the desired result. This requires verification and/or validation and routine monitoring of the process.</li> <li>• Single use instruments are intended and manufactured for one use only. They must not be reprocessed.</li> <li>• Do not clean any instruments, sterilization trays or sterilization containers using metal brushes or steel wool.</li> <li>• Do not expose any instruments, cassettes, trays or sterilization containers to temperatures higher than 134°C (273°F). Exposure to higher temperatures is the responsibility of the user.</li> <li>• Chemically dissimilar metals should not be cleaned or sterilized together, as this could result in corrosion or other adverse effects.</li> <li>• All used and contaminated instruments should be handled with puncture- and chemical-resistant protective gloves.</li> <li>• Any repairs made by the user may void the warranty.</li> </ul> <p><i>Information denoted "For Reference Only – Europe" is applicable only for European countries and has not been independently validated by American Orthodontics.</i></p>
<p><b>Limitations on Processing</b></p>	<p>Frequent re-treating has little deleterious effect on the service life of the instrument. The end of the instrument lifetime is determined by wear and damage from use. Instruments shall be disposed of according to office procedure. Do not use any damaged instruments.</p>
<p><b>Selection of Detergents</b></p>	<p>Consider the following during selection of cleaning detergents:</p> <ul style="list-style-type: none"> <li>- suitability for the cleaning of dental instruments</li> <li>- compatibility of the detergents used with the instruments</li> </ul> <p>Observe the instructions of the detergent manufacturer with respect to the concentration and temperature of the cleaning solution. Use detergent manufacturer exposure time if it exceeds recommendations in this guideline.</p> <p>If using a cassette system, follow cassette manufacturer's instructions for loading, exposure time, and other parameters unless a longer exposure time is required by the detergent manufacturer.</p> <p>Powdered cleaners must be dissolved completely in water before immersing the instruments into the solution.</p>

	<p>Detergents containing the following substances must not be used:</p> <ul style="list-style-type: none"> <li>- strong alkalines (&gt; pH 9)</li> <li>- strong acids (&lt; pH 4)</li> <li>- phenols</li> <li>- interhalogenic agents/halogenic hydrocarbons/iodophors</li> <li>- strong oxidizing agents/peroxides</li> <li>- organic solvents</li> </ul>
<p><b>Water Quality</b></p>	<p>Water quality may influence the result of the cleaning and sterilization of the instruments. Corrosion could be caused by high contents of chloride or other minerals in the tap water. If problems with stains and corrosion occur and other reasons can be excluded, it might be necessary to test the tap water quality in your area. The use of completely deionized or distilled water will help to avoid most problems related to water quality.</p> <p>Use only ultra-pure and deionized water (max. 10 germs/ml) as well as low endotoxin contaminated water (max. 0.25 endotoxin units/ml), i.e. aqua purificata for rinsing. Follow the sterilizer equipment manufacturer recommendations for water quality requirements.</p> <p>Instruments must be thoroughly dried immediately after any exposure to water; water droplets remaining on stainless steel can result in surface oxidation (dark or rust-colored spots). If drying with air, use only filtered air.</p> <p>Any local, regional, national, and international standards or regulations pertaining to water quality supersede those described in this guideline.</p>

## INSTRUCTIONS

Instructions for two different instrument cleaning methods are provided in this guideline:

- 1) Manual Cleaning using ultrasonics
- 2) Automated Cleaning

Pre-treatment steps (which can include initial treatment at the point of use and other preparations before cleaning) should be performed for both cleaning methods.

The user is responsible for selecting one of the two cleaning methods to perform. Selection should be guided by relevant local, regional, national, and international standards or regulations pertaining to these activities.

Any deviations from the recommended sterilization procedure are the responsibility of the user. A 30 minute (minimum) dry time is recommended; however, use equipment manufacturer's instructions if they exceed the recommendations in this guideline. Flash sterilization procedures must not be used.

<p><b>Initial Treatment at the Point of Use</b></p>	<p>Remove coarse impurities on the instruments immediately after use. Instruments with visible impurities should be pre-treated within two hours of use.</p> <p>Use an enzymatic cleaner or a precleaning product. Observe the instructions of the manufacturer with respect to the concentration and temperature of the cleaning solution.</p> <p>Remove coarse impurities using a soft bristled brush. NEVER use metal brushes or steel wool.</p>
<p><b>Disinfection</b></p> <p><i>For Reference Only – Europe</i></p>	<p><i>Directly after use, instruments may be disinfected by hand in order to reduce the risk of infection for the user. The instruments can be placed in a disinfection solution. Make sure that the instruments are fully immersed in the disinfection solution and that no air bubbles are formed. Follow the instructions of the manufacturer of the disinfection solution.</i></p> <p><i>The disinfectant should:</i></p> <ul style="list-style-type: none"> <li>- be aldehyde-free (otherwise fixation or stabilization of blood contamination can occur),</li> <li>- have a certified proof of efficacy (e.g. VAH/DGHM<sup>1</sup> or FDA approval or CE marking),</li> <li>- be suitable for instrument disinfection</li> </ul> <p style="text-align: center;"><sup>1</sup>German Societies for Hygiene and Microbiology</p>

<b>(1) Cleaning: Manual</b>	<p>If using a cassette system, follow cassette manufacturer's instructions for loading and exposure time unless a longer exposure time is recommended by either the detergent manufacturer or this guideline.</p> <ol style="list-style-type: none"> <li>1. Soak instruments in the cleaning solution for 5 minutes. Ensure that all instruments are sufficiently immersed with no contact between the instruments.</li> <li>2. Sonicate for 15 minutes.</li> <li>3. Remove the instruments from the cleaning solution and rinse them intensively.</li> <li>4. Inspect the instruments. If visible debris remains, repeat steps 1 through 3.</li> </ol>										
<b>(2) Cleaning: Automated</b>	<ol style="list-style-type: none"> <li>1. Place instruments into cassettes or other suitable tray systems compatible with the washer unit. Ensure no contact between the instruments.</li> <li>2. Start the cycle. <ul style="list-style-type: none"> <li><u>Suggested Parameters</u></li> <table border="1" data-bbox="566 698 1275 987"> <tr> <td>1</td> <td>2 min pre-wash</td> </tr> <tr> <td>2</td> <td>2 min wash with enzymatic detergent</td> </tr> <tr> <td>3</td> <td>5 min wash with neutral detergent, minimum 40°C</td> </tr> <tr> <td>4</td> <td>2 min rinse, minimum 40°C</td> </tr> <tr> <td>5</td> <td>30 min dry</td> </tr> </table> <ul style="list-style-type: none"> <li>- Use only cleaning agents recommended for the type of automated washer/disinfector.</li> <li>- Use only washer/disinfectors with approved efficacy (e.g. CE mark, validation according to ISO 15883).</li> <li>- Follow washer/disinfector manufacturer's instructions if longer exposure time and/or higher temperatures are recommended.</li> <li>- Follow detergent manufacturer's instructions if longer exposure time and/or higher temperatures are recommended.</li> </ul> </ul></li> <li>3. Remove the instruments from the automated washer unit after end of the cycle.</li> </ol>	1	2 min pre-wash	2	2 min wash with enzymatic detergent	3	5 min wash with neutral detergent, minimum 40°C	4	2 min rinse, minimum 40°C	5	30 min dry
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<b>Drying</b>	After cleaning, all instruments must be completely dry before packaging for sterilization.										
<b>Maintenance / Inspection / Testing</b>	<p>Inspect all instruments after cleaning for corrosion, damaged surfaces, and impurities. Check for misalignment of instrument tips, loose joints, and other functional issues. Remove damaged instruments from use!</p> <p>If visible debris remains on instruments, repeat the cleaning process.</p> <p>Re-sharpen instruments if necessary. Repeat the cleaning process prior to sterilization of re-sharpened instruments.</p> <p>Hinged instruments must be lubricated with a lubricant suitable for steam sterilization. Only use lubricants specifically formulated for dental and/or surgical instruments, and follow manufacturers' instructions for application. Ensure any excess lubricant is wiped off prior to sterilization.</p>										

<b>Packaging</b>	<p>Ensure all instruments are completely dry before packaging for sterilization.</p> <p>Use of a cassette system, sterilization pouches/wrap, or other suitable sterilization containers is recommended according to ISO 11607-1 (EN 686-2). Appropriate sterilization packaging should be:</p> <ul style="list-style-type: none"> <li>- suitable for steam sterilization (temperature resistance up to at least 141 °C (286 °F), sufficient steam permeability)</li> <li>- sufficiently protective of the instruments and the sterilization packaging against mechanical damage</li> <li>- maintained regularly according to the manufacturers' instructions</li> <li>- in conformance with FDA regulations (for US applications)</li> </ul> <p>If using a cassette system, follow cassette manufacturer's instructions for loading and wrapping of the cassette.</p>
<b>Sterilization</b>	<ul style="list-style-type: none"> <li>- Use a steam sterilizer according to local, regional, national, or international standards as applicable. This may include: DIN EN ISO/ANSI AAMI ISO 17665, DIN EN 13060, DIN EN 285.</li> <li>- Ensure equipment/process is validated according to local, regional, national, or international standards.</li> <li>- Follow sterilizer manufacturers' instructions with respect to routine inspection and regular maintenance.</li> <li>- Abide by any special instructions provided by the sterilizer equipment manufacturer.</li> <li>- Sterilizers with an automatic drying program are recommended, as the sterilized items must be completely dried after sterilization and before handling.</li> </ul>

**Minimum cycle times for gravity-displacement steam sterilization cycles**

Item	Exposure time at 121°C (250°F)	Drying times
Wrapped instruments	30 minutes	Minimum 30 minutes

**Minimum cycle times for dynamic-air-removal steam sterilization cycles**

Item	Exposure time at 132°C (270°F)	Drying times
Wrapped instruments	4 minutes	Minimum 30 minutes

<b>Storage</b>	<p>Store instruments in a dry and dust free place in the clean section of the instrument processing area after sterilization. Sterilization can only be maintained if the instruments remain packaged or wrapped - impermeable to micro-organisms - following validated instructions developed by the packaging manufacturer.</p>
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**Additional Information**

Aluminium Instruments	<p>Do not clean or sterilize with stainless steel instruments or in contact with stainless steel cassettes; adverse chemical reaction may result. Do not clean in an ultrasonic unit. After soaking, use a soft-bristled nylon brush for one minute to clean contaminated areas while still immersed in the cleaning solution.</p>
Hinged Instruments Debond Instrument	<p>Process in an open state and lubricate prior to sterilization.</p>
Mouth Mirrors	<p>To avoid scratches on the mirror surface from other pointed instruments, reprocess in an instrument tray with instrument rails.</p>

## Annex

### Examples of Country Specific Regulations

Procedures for cleaning, disinfection, and sterilization must adhere to any local, regional, national, and international standards or regulations pertaining to these activities. Below are examples of both general guidance documents and country specific regulations. This list is not intended to be exhaustive and should be used for reference only; the user is solely responsible for identifying applicable standards.

#### General:

[Instrument Reprocessing: Reprocessing of Instruments to Retain Value](#)

[Instrument Reprocessing in Dental Practices: How to do it right](#)

#### United States of America:

[CDC Guideline for Disinfection and Sterilization in Healthcare Facilities \(2008\)](#)

[CDC Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care](#)

#### United Kingdom:

[UK Department of Health: Decontamination in primary care dental practices](#)

#### Canada:

[Public Health Ontario: Best Practices for Cleaning, Disinfection & Sterilization of Medical Equipment/Devices](#)

#### Germany:

[Hygiene Requirements for the Reprocessing of Medical Devices \(2012\)](#)