

Guideline: Reprocessing of American Orthodontics Instruments

Basic Concepts

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.

The user is solely responsible for the sterility of the instruments. With this in mind, the user must establish and validate their own cleaning and sterilization procedures. Procedures for cleaning, disinfection, and sterilization must adhere to any local, regional, national, and international standards or regulations pertaining to these activities. All equipment used in the cleaning and sterilization procedures must be maintained and checked regularly for proper operation. Validated procedures must be followed for every cleaning and sterilization cycle.

Single use instruments are intended and manufactured for one use only. They must not be reprocessed.

Additional guidelines on reprocessing instruments in orthodontic (dental) practices can be found as follows:
[CDC Guideline for Disinfection and Sterilization in Healthcare Facilities \(2008\)](#)
[CDC Summary of Infection Prevention Practices in Dental Settings: Basic Expectations for Safe Care](#)
[UK Department of Health & Social Care: Decontamination in primary care dental practices](#)
[Public Health Ontario: Best Practices for Cleaning, Disinfection & Sterilization of Medical Equipment/Devices](#)
[AKI: Instrument reprocessing in Dental Practices](#)

This guideline is applicable to instruments listed in Appendix A.

General Precautions

Do not clean any instruments, sterilization trays or sterilization containers using metal brushes or steel wool.

Do not expose any instruments, cassettes, trays or sterilization containers to temperatures higher than 141 °C (286 °F). Exposure to higher temperatures is the responsibility of the user.

All used and contaminated instruments should be handled with puncture and chemical resistant protective gloves.

Selection of Detergents

Consider the following during selection of cleaning detergents:

- suitability for the cleaning of dental instruments
- compatibility of the detergents used with the instruments

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.

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.

Powdered cleaners must be dissolved completely in water before immersing the instruments into the solution.

Detergents containing the following substances must not be used:

- strong alkalines (> pH 9)
- strong acids (< pH 4)
- phenols
- interhalogenic agents/halogenic hydrocarbons/iodophors
- strong oxidizing agents/peroxides
- organic solvents

Water Quality

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.

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.

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). Use only filtered air for drying.

Any local, regional, national, and international standards or regulations pertaining to water quality supersede those described in this guideline.

Specific Precautions

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

Chemically dissimilar metals should not be cleaned or sterilized together, as this could result in corrosion or other adverse effects.

Instrument Reprocessing Steps

Cleaning

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

- 1) Ultrasonic Cleaning
- 2) Automatic Cleaning using Automated Washer Unit

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

Pre-treatment steps should be performed for both methods.

Pre-treatment

Remove coarse impurities on the instruments immediately after application (within a maximum of two hours). Instruments with visible impurities should be pre-treated within two hours of use.

Use an enzymatic cleaner, such as Hu-Friedy Enzymax, or a precleaning product such as Enzymax Spray Gel. Observe the instructions of the manufacturer with respect to the concentration and temperature of the cleaning solution.

Remove coarse impurities using a soft bristled brush. NEVER use metal brushes or steel wool.

(1) Ultrasonic Cleaning

If using a cassette system, follow cassette manufacturer's instructions for loading and exposure time unless a longer exposure time is recommended by the detergent manufacturer or this guideline.

1. Soak instruments in the cleaning solution for 5 minutes. Ensure that all instruments are sufficiently immersed with no contact between the instruments.
2. Sonicate for 15 minutes.
3. Remove the instruments from the cleaning solution and rinse them intensively.
4. Inspect the instruments. If visible debris remains, repeat steps 1 through 3.

(2) Automatic Cleaning using Automated Washer Unit

1. Place instruments into cassettes or other suitable tray systems compatible with the washer unit.
2. Start the cycle. Program should include the following sequence at a minimum: pre-wash, wash 1, wash 2, rinse, dry.
3. Remove the instruments from the automated washer unit after end of the cycle.

Inspection

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!

If visible debris remains on instruments, repeat the cleaning process.

Re-sharpen instruments if necessary. Repeat the cleaning process prior to sterilization of re-sharpened instruments.

Lubrication

Hinged instruments must be lubricated with a lubricant suitable for steam sterilization, such as DSX Medic 365 Instrument Lubricant or Hu-Friedy Instrument Lubricant Spray. 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.

Packaging for Sterilization

Use of a cassette system, sterilization pouches or other suitable sterilization containers is recommended. Such containers should be:

- FDA approved
- suitable for steam sterilization (temperature resistance up to at least 141 °C (286 °F), sufficient steam permeability)
- sufficiently protective of the instruments and the sterilization packaging against mechanical damage
- maintained regularly according to the manufacturers' instructions

Instruments must be completely dry prior to sterilization.

Sterilization

Use only the recommended sterilization procedure listed below. Any deviations from this 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.

Steam Sterilization

- Use a steam sterilizer according to ANSI/AAMI ST55 or ANSI/AAMI ST8.
- Ensure equipment/process is validated according to ANSI/AAMI ST79 (valid IQ/OQ and product specific performance qualification (PQ)).
- Follow sterilizer manufacturers' instructions with respect to routine inspection and regular maintenance.
- Abide by any special instructions provided by the sterilizer equipment manufacturer.
- Sterilizers with an automatic drying program are recommended, as the sterilized items must be completely dried after sterilization and before handling.

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

Restrictions

- Flash sterilization procedures must not be used.
- Do not use radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization, dry heat sterilization, or plasma sterilization.

Storage

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 standards developed by the user.

Appendix A

This document applies to the instruments listed below:

001-017380	001-023352	001-100	010-751
001-017381	001-023353	001-100A	010-771
001-017382	001-023354	001-100F	010-772
001-017383	001-023355	001-100M	010-773
001-017384	001-000HW	001-101	010-775
001-017385	001-001	001-101S	010-775M
001-017386	001-002	001-102	010-775N
001-017387	001-006	001-2104	010-776
001-017388	001-016	001-222	010-8015
001-017389	001-016L	001-250C	100-208
001-017390	001-026	001-505	100-302
001-017391	001-051	001-506	100-550
001-017392	001-E110	001-800S	100-700
001-017393	001-E111	010-008	678-901C
001-017394	001-E113	010-009	678-901EX
001-017395	001-E139	010-010	678-903
001-017396	001-E140	010-011	861-210
001-017397	001-E158	010-012	
001-017398	001-E158L	010-013	
001-017403	001-E200	010-014	
001-017404	001-E346RT	010-015	
001-017405	001-E347	010-145	
001-017406	001-E347L	010-255	
001-017407	001-E810S	010-255S	
001-023349	007-001	010-300	
001-023350	100-109	010-301	
001-023351	100-111	010-500	