

# Guidelines: 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 appropriate, 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 each and 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:

<http://www.a-k-i.org/index.php?id=12&L=1>

[http://www.publichealthontario.ca/en/eRepository/PIDAC\\_Cleaning\\_Disinfection\\_and\\_Sterilization\\_2013.pdf](http://www.publichealthontario.ca/en/eRepository/PIDAC_Cleaning_Disinfection_and_Sterilization_2013.pdf)

<https://www.gov.uk/government/publications/decontamination-in-primary-care-dental-practices>

<https://www.cdc.gov/oralhealth/infectioncontrol/guidelines/>

<https://www.cdc.gov/infectioncontrol/guidelines/disinfection/index.html>

This document applies only to metallic hand instruments except for those noted in Appendix A; non-metallic instruments and/or inserts are not covered by this document.

## General Precautions

Detergents or disinfectants 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

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.

Water quality may influence the result of the cleaning and disinfection 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.

Instruments must be thoroughly dried immediately after sterilization; water droplets remaining on stainless steel will result in surface oxidation (dark or rust-colored spots).

### Specific Precautions

Carbon Steel Instruments	Clean and sterilize separately. Do not clean or sterilize with stainless steel instruments. After cleaning and prior to sterilization, coat the instruments with 2% sodium nitrite (Proclave® protective emulsion) after washing and drying but before moist heat sterilization.
Aluminium Instruments	Do not clean or sterilize with stainless steel instruments. Do not clean in an ultrasonic unit.
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. Clean and sterilize in a completely disassembled state.

## Instrument Reprocessing Steps

### Cleaning

#### Basics

All assembled instruments must be disassembled before reprocessing and pre-treated per the process below. Remove pads from Luno 001-017395 and 001-017397 Pliers and Masterline 001-E347 and 001-E347L Pliers, remove tips from Luno 001-017405 Pliers, and disassemble tips, screws, and blades from Masterline 001-E346RT and 001-109/001-111 Pliers before cleaning/disinfection/sterilization.

#### Protection of Staff Members:

All used and contaminated instruments must be handled with protective gloves. Contaminated instruments must be cleaned as early as possible in the reprocessing process in order to maximize safety for staff members.

#### Pre-treatment

Remove coarse impurities on the instruments immediately after application (within a maximum of 2 hours). Instruments with visible impurities should be pre-treated within two hours of use.

Use an enzymatic cleaner, such as Hu-Friedy Enzymax. When using an enzymatic cleaner, pre-soak for 3-5 minutes at 32°C. For other cleaning agents and disinfectants the instructions of the manufacturer must be observed.

For manual removal of coarse impurities use only a soft brush or a long handled soft brush; NEVER use metal brushes or steel wool.

If applicable: Rinse all lumens of the instruments five times with a single-use syringe (minimum volume 50 ml) or a suitable rinsing adapter.

#### Manual and Ultrasonic Cleaning

Consider the following during selection of the cleaning detergents:

- suitability for the cleaning of dental instruments
- compatibility of the detergents used with the instruments (reference General Precautions)

Observe the instructions of the manufacturer with respect to the concentration, exposure time, and temperature of the cleaning solution. Powdered cleaners must be dissolved completely in water before immersing the instruments into the solution.

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 (highly purified water acc. Pharmacopeia) for rinsing.

Use only filtered air for drying.

## Cleaning (Cont.)

### Manual Cleaning

Procedure:

1. Completely disassemble the instruments, if applicable.
2. Soak the disassembled instruments for the recommended soaking time in the cleaning solution and make sure that the instruments are sufficiently immersed.  
If applicable: Rinse all lumens of the instruments five times at the beginning and at the end of the soaking time with a single-use syringe (minimum volume 50 ml) or a suitable rinsing adapter.
3. Remove the instruments from the cleaning solution and post rinse them extensively with ultra-pure and de-ionized water (i.e. aqua purificata).
4. Inspect the instruments to ensure no visible debris remains.

### Ultrasonic Cleaning

The use of a cassette system is recommended.

Procedure:

1. Completely disassemble the instruments if applicable. Soak the disassembled instruments for the recommended soaking time in the cleaning solution, and make sure that the instruments are sufficiently immersed. Use the processing time recommended by the manufacturer of the detergent and/or the cassette system.  
Note: There should not be any contact between the instruments.  
If applicable: Rinse all lumens of the instruments five times at the beginning and at the end of the soaking time by application of a single-use syringe (minimum volume 50 ml).
2. If using a cassette system, follow the manufacturer's recommendation for ultrasonic cleaning time unless a longer exposure time is required by the manufacturer of the detergent. Do not overload the ultrasonic cleaning unit.
3. Remove the instruments from the cleaning solution and post rinse them intensively with ultra-pure and de-ionized water (i.e. aqua purificata) for best results.
4. Inspect the instruments to ensure no visible debris remains.

### Inspection

Inspect all instruments after the cleaning and rinsing step for corrosion, damaged surfaces, and impurities. Check for misalignment of instrument tips, loose joints, and other functional issues. Do not further use damaged instruments. If visible debris remains on instruments, repeat the cleaning process. Resharpen instruments if necessary. Completely remove any residues from the sharpening process, such as metal residue or sharpening oil.

### 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.

### 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

## Sterilization

Use only the recommended sterilization procedure listed below. Any deviations from this procedure are the sole responsibility of the user. A 30 minute (minimum) dry time is recommended; however, defer to the manufacturer's instructions for the equipment used if they contain an alternative drying time.

### 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 (commissioning) and product specific performance qualification (PQ)).
- When using a specific sterilizer, consult only that manufacturer's recommendations.

#### 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

### Inspection and Maintenance Recommendations for Steam Sterilizers

- The manufacturers' instructions with respect to routine inspection and the regular maintenance of the sterilizer must be observed.
- The sterilizer must be cleaned on a regular basis.
- Only ultra-pure and deionized water (i.e. aqua purificata) should be used.
- The sterilized items must be completely dried after sterilization and before handling. Sterilizers with an automatic drying program are recommended.

### Restrictions

- Flash sterilization procedures must not be used.
- Do not use radiation sterilization, formaldehyde sterilization, ethylene oxide sterilization, or plasma sterilization.
- The use of dry heat sterilization is the responsibility of the user.

### 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.

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## Appendix A

This document does not apply to the instruments listed below:

001-501            DONTRIX GAUGE  
001-502            FORCE GAUGE