

Guideline: Sterilization of American Orthodontics Band Assemblies

Basic Concepts

American Orthodontics does not require bands and their attachments to be sterilized before use; the decision to sterilize is made solely by the user of this product.

Procedures for cleaning, disinfection, and sterilization must adhere to any local, regional, national, and international standards or regulations pertaining to these activities.

Bands and their attachments are single-use only. American Orthodontics does not support the re-use of single-use devices. All bands and attachments are shipped in the non-sterile condition.

Cleaning

Instructions for two different 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.

(1) Ultrasonic Cleaning

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

(2) Automatic Cleaning using Automated Washer Unit

1. Place band assemblies 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 band assemblies from the automated washer unit after end of the cycle.

Packaging for Sterilization

Use of 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 devices and the sterilization packaging against mechanical damage
- maintained regularly according to the manufacturers' instructions

Devices 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.

It is the responsibility of the user to ensure that the sterilization process, as it is actually performed, achieves the desired results.

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
Band assemblies	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
Band assemblies	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.