

1. IDENTIFICATION OF THE COMPANY

Company Name

American Orthodontics
3524 Washington Avenue
Sheboygan, WI 53081

24 HR EMERGENCY TELEPHONE NUMBER

(920) 457-5051

Telephone for Information

(920) 457-5051

2. IDENTIFICATION OF THE PRODUCT

Product Name: Wire Sterilization Package with Indicators

Product Description: Orthodontic Wire Sleeve Packaging

Product Part Number: REF Various Part Numbers

CAUTION: Federal law restricts this device to sale to or on the order of the dentist/orthodontist.

3. INDICATIONS FOR USE, DOMAIN OF USAGE

Wire Sterilization Package with Indicators is intended to be used to enclose and package American Orthodontics' line of Orthodontic Arch Wires. These packages are shipped unsterile and for single-use only. This packaging offers the health provider (trained dental professional and/or Orthodontist) the option of sterilizing the enclosed arch wire using steam or ethylene oxide gas. The indicators will display a visual color change to signify exposure to steam or ethylene oxide gas and distinguish between processed and unprocessed wire.

The enclosed Arch Wires consist of the following models: Stainless Steel Wires, Nickel Titanium (NiTi) Wires, Beta Titanium Wires, Chromium Cobalt (CrCo) Wires, Copper Nickel Titanium (CuNiTi) Wires.

Federal law restricts this device to use by or on the order of a dentist or orthodontist.

4. CONTRAINDICATIONS

American Orthodontics sells products to trained dental professionals and orthodontists. It is the primary responsibility of the dental professional and/or orthodontist to identify any possible contraindications that may preclude the use of American Orthodontics' products. It is also the responsibility of the dental professional and/or orthodontist to determine any pre-starting procedures, as well as working sequence of the medical devices. This will include any sterilization procedures.

5. SIDE EFFECTS

It is the primary responsibility of the dental professional and/or orthodontist to identify any possible risk of injury and/or contraindications that may arise during treatment, relay any possible unwanted side effects to the patient and to individualize treatment accordingly. During treatment, unwanted side effects may include: tooth discolorations, decalcification, root resorption, periodontal complications, allergic reactions, difficulties in oral hygiene maintenance, discomfort and pain.

6. WARNINGS & PRECAUTIONS

- Single-use only, American Orthodontics does not support the re-use of single-use devices.
- Do not use in Dry Heat Sterilizers
- Do not desiccate
- Allow to cool before using enclosed arch wire
- Discard package(s) if chemical indicator has leached into sealed area
- The recommended sterilization cycles are not intended for use with EverWhite wires

7. GENERAL INSTRUCTIONS

- a. The device is to be used on the instruction of, or by a dentist/orthodontist or other licensed practitioner.
- b. Inspect for product damage before and after sterilization.
- c. Select the appropriate cycle and process according to the Sterilization Parameters below.
- d. Remove and allow the Wire Sterilization Package to cool completely. Once cooled, the enclosed archwire is ready for immediate use. **DO NOT STORE**
- e. The chemical process indicator will change accordingly when exposed to the selected process. This distinguishes exposed from unexposed packages.

8. STERILIZATION PARAMETERS

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

- a. Ethylene Oxide [100% E.O.] Gas

1. EO Concentration: 725 mg/L
 2. Exposure Temperature: 130°F (55°C)
 3. Exposure Time: 1 hour
 4. Aeration Time: 8 hours
 5. Upon completion of the process, the EO color indicator will change from Blue to Cocoa Brown.
- b. Steam – Gravity
1. Exposure Temperature: 270°F (132°C)
 2. Exposure Time: 15 minutes
 3. Dry Time: 8 hours
 4. Upon completion of the process, the STEAM color indicator will change from Blue to Black/Brownish Black.

9. STORAGE AND TRANSPORT CONDITIONS

Storage

- Store below 100°F (37.8°C) temperature with less than 60%RH.
- Do not store indicators near sterilants or other chemicals.
- Keep away from UV or light source.

Transport

- Transport with an environmental temperature below 100°F (37.8°C) temperature with less than 60%RH.
- Harsh or rough handling may cause mechanical damage to enclosed wires

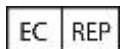
10. DISPOSAL CONSIDERATIONS

American Orthodontics' products are designed and manufactured for single use and, once removed from the patient's mouth, must be disposed of properly. American Orthodontics expressly disclaims any liability for the spread of disease or personal injury caused by reuse. It is the primary responsibility of the dental professional and/or orthodontist to follow applicable laws relating to the disposal of used orthodontic medical devices.

11. WARRANTY LIABILITY

Buyer's remedies with respect to any claim arising out of any defect in any goods or services shall be limited exclusively to the right of repair or replacement of such goods (at the seller's option) or to repayment of the purchase price thereof. In no event shall seller be liable for any consequential or incidental damages including lost profits incurred by buyer with respect to any goods or services furnished by seller. Claims for damage or shortage must be made within 30 days of receipt of order.

12. REGULATORY INFORMATION



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American Orthodontics • 3524 Washington Avenue • Sheboygan, WI 53081 • (920)457-5051



SINGLE USE ONLY



SEE INSTRUCTIONS FOR USE



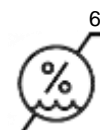
KEEP AWAY FROM SUNLIGHT



NON STERILE



MAY CONTAIN CHROMIUM AND/OR NICKEL.



60%
HUMIDITY LIMITATION



100°F
TEMPERATURE LIMITATION



The information contained in the IFU is believed to be valid and accurate. American Orthodontics, however, makes no warranty, either expressed or implied, as to the completeness of information in all possible conditions. **Reasonable safety precautions must always be observed.**