
AOA

Archwire Extender Instructions for Use



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PRODUCT DESCRIPTION:

Allesee Orthodontic Appliances (AOA), Removable archwire tubes that attach to the patient's bonded (or welded) buccal molar bracket. The extenders act as an extension to the molar buccal tubes encasing the archwire up to 6 mm mesial of the fixed tube. This helps prevent the archwire from disengaging during early arch expansion and development. They are used bilaterally and are removed without needing to debond.

INTENDED USE: Archwire tube extension of the buccal fixed molar attachment. A dentist/orthodontist will attach to the existing molar bracket by sliding the wire into the archwire tube.

INDICATIONS FOR USE: The appliance is worn by the patient on the dental arches as prescribed by the treating dentist/orthodontist. The duration of wear will range by the determination of the dentist/orthodontist.

CONTRAINDICATIONS: There are no contraindications for this device.



WARNINGS:

This product contains nickel and stainless steel. In rare instances some patients may be allergic. These materials should not be used for individuals with known allergic sensitivity to these metals.



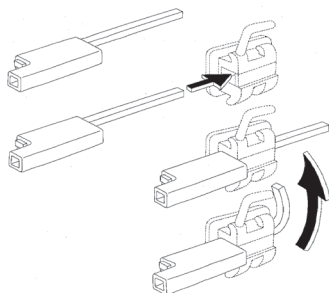
Single Patient Use - Risk of cross-contamination.



Magnetic Resonance (MR) Safety Information: Please advise your patient the Archwire Extender part must be removed prior to entering the MRI environment.

PRECAUTIONS:

- Non-sterile device.
- Patient may deliberately or accidentally bite incorrectly and cause the device to function improperly.
- Sores may develop from rubbing on tissue.
- Crunchy, hard or sticky foods could damage the appliance.
- The device could be fractured, swallowed or aspirated.
- Device not installed by a Dental Professional may cause harm to patient.



INSTRUCTIONS FOR USE:

- Step 1. Clean accessory per established office procedures (NOTE: Archwire Extender Accessory has not been tested for sterilizing procedures.)
- Step 2. Insert Archwire Extender into molar buccal tube until extender tube contacts mesial of attached buccal tube.
- Step 3. Bend distal wire upward to securely hold Archwire Extender in place. (Do not apply excess pulling force to wire.)
- Step 4. Inspect end of wire for sharp edges, adjust if necessary.

WARRANTY: 3 months

ORAL HYGIENE: It is very important for your patient to brush their teeth and pay extra attention to dental hygiene during this time.

PATIENT VISIT INSTRUCTIONS: Routine review and adjustments may be required.

REPORTING SERIOUS INCIDENTS:

User and Patient Notice - If a serious incident occurs with this medical device, report it to the manufacturer and to the competent medical authority for the user/patient's country.

STORAGE AND HANDLING: No special storage conditions.

DISPOSAL: Follow local guidelines.

DAILY CARE AND MAINTENANCE: Follow instructions provided by your Dental Professional.

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Rx Only*

* For US law only

See symbols glossary at aolab.com/products/ifu/symbols-glossary.

AOA



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