

AOA

Custom-Made Device
Personalized Medical Device



3D Metal Printed
Appliances
Instructions for Use

DISCLAIMER OF LIABILITY: This product is part of an overall concept and may only be used in conjunction with the associated original products according to the instructions and recommendation of (ORMCO/AOA). Non-recommended use of products made by third parties in conjunction with (ORMCO/AOA) products will void any warranty or other obligation, express or implied, of (ORMCO/AOA). The user of (ORMCO/AOA) products has the duty to determine whether or not any product is suitable for the particular patient and circumstances. (ORMCO/AOA) disclaims any liability, express or implied, and shall have no responsibility for any direct, indirect, punitive or other damages, arising out of or in connection with any errors in professional judgment or practice in the use of (ORMCO/AOA) products. The user is also obliged to study the latest developments in regard to this (AOA) product and its applications regularly. In cases of doubt, the user has to contact (ORMCO/AOA). Since the utilization of this product is under the control of the user, it is his/her responsibility. (ORMCO/AOA) does not assume any liability whatsoever for damage arising thereof. Please note that some products detailed in this Instructions for Use may not be regulatory cleared, released or licensed for sale in all markets.

CUSTOM-MADE DEVICE DESCRIPTION:

Allesee Orthodontic Appliances (AOA), The devices listed aid in developing the upper and or lower dental arches by expanding or maintaining their ideal position.

3D PRINTED FIXED APPLIANCES (Lingual Arch, Bonded Retainer, Nance Button, Trans-Palatal Arch, Band & Loop, Rapid Palatal Expanders, & Haas) - These devices are permanently attached to either the upper or lower teeth by the dentist/orthodontist and should only be removed by a dental professional. Refer to the Suggested Bonding Protocol in this IFU.

Appliance's bands or crowns will be 3D printed out of cobalt chrome and will not extend interproximally and subgingival to cover the tooth, as no separators are necessary.

NOTE: 3D Metal printed portions of the appliances are not adjustable. If you would like to adjust the appliance chairside, order additional components in stainless steel or acrylic, i.e. Lingual Arch, Nance Button, TPA, Face Mask Hooks, .018 Single Buccal Tubes, .022 Single Buccal Tubes, Screws, Clasps, Labial Bow, etc.

Lingual Arch - is designed to maintain transverse arch width, prevent molar tipping and more. This device is cemented to the patient's teeth.

Nance Button - is designed to prevent molars from moving mesially and maintain overall arch length. The design can also be used as an anchorage device when used in conjunction with full brackets. The device is cemented to the patient's teeth.

Trans-Palatal Arch (TPA) - is primarily designed to maintain transverse width of the upper arch but can also be used to rotate, distalize or perform other movements of the first molars. This device is cemented to the patient's teeth.

Band and Loop - is designed to maintain space mesial or distal to the tooth that is banded to reserve space for a future erupting tooth. It is commonly used during early loss of a primary molar and can help prevent the first molar from tipping and moving mesially. This device is cemented to the patient's teeth.

Rapid Palatal Expander & Haas - are designed to expand the dental arch when the stainless steel wires, coil springs or screws are activated. These devices are fixed into the patient's mouth using stainless steel bands or crowns cemented to the selected posterior teeth.

3D PRINTED REMOVABLE APPLIANCES (Hawley Retainers)

- device can be inserted and removed by the patient.

Hawley Retainers - are still the most frequently used device for after treatment for retention for both upper and lower arches. 3D printed cobalt chrome palate.

INTENDED USE: Products to be used by orthodontists/dentists/dental laboratories. Fixed appliances are designed for various tooth movements, dental retention and arch development. A removable appliance is intended for post-orthodontic retention to hold teeth in their ideal position and minimize relapse.

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.



WARNINGS: Some of these products require add-ons which may contain nickel, cobalt chrome, stainless steel, solder materials or acrylic (Poly (methyl methacrylate)). These materials should not be used by individuals with known allergic sensitivity to these materials.



Single Patient Use - Risk of cross-contamination.



Magnetic Resonance (MR) Safety Information: Please advise your patient these appliances 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 parts rubbing on tissue.
- Screws or small parts may come loose and be swallowed.
- Crunchy, hard or sticky foods could damage the appliance.
- Device not installed by a Dental Professional may cause harm to patient.

INSTRUCTIONS FOR USE:

All appliances in this category:

- Remove device from packing and clean per office procedure.
- Insert device into patient's mouth and instruct patient to carefully bite down to check for proper occlusion.
- Remind patient to keep device clean. Refer to Daily Care and Maintenance.

Rapid Palatal Expander & Haas Expander

- Adjust acrylic material by lightly trimming away acrylic that may cause any discomfort or fit issues if needed.
- Adhere bands/crowns/rests.
- Activate expansion screw(s) as required to achieve desired outcome.
- During each patient visit, re-activate the appliance by turning the screws open if applicable.
- Check acrylic for cracks and sharp edges, repair or smooth if necessary.
- Check bands/crowns for appropriate adhesion.

Lingual Arch, Nance Button, Trans-Palatal Arch, and Band and Loop

- Adjust the wires, bands/crowns, and acrylic for the proper fit as needed.
- Prepare tooth surfaces and cement bands/crowns to the selected tooth or teeth.

Hawley Retainer

- Remove device from packaging and clean per office procedures.
- Insert device into patient's mouth and instruct patient to carefully bite down to check for occlusal interferences with wire and acrylic.
- Adjust labial wire for a secure fit as needed.
- Adjust clasping for a secure fit as needed.
- Adjust device by lightly trimming away metal that may cause bite interference or discomfort as needed.
- Advise patient of wear time.

AOA SUGGESTED BONDING PROTOCOL*

Note: When using additional products check manufacturer's instructions for use.

- Prophy or polish the buccal and lingual surfaces of the tooth. Apply etching material to the buccal and lingual surfaces covering the area normally occupied by a buccal tube. Etch bonding site for 10 seconds then rinse with water for 5 seconds followed by air drying. Apply a thin layer of single-paste band cement on the entire inside surface of band making sure all surfaces are coated. If there is any excess paste around the band edge after seating, light cure for one second about 5mm away from the band. The excess can then be removed in putty form.
- Using an LED curing light apply light in a circular fashion over the entire occlusal surface for a period of 40 seconds. During this process the light tip may remain in contact with the occlusal surface for maximum penetration.

REMOVAL OF 3D PRINTED METAL APPLIANCES*

- Using a band removing plier (or tool of your choice), place the plastic rest on the occlusal surface of the tooth not covered by the band.
- Engage the gingival margin of the printed band and close the pliers firmly removing the band from the tooth.
- Excess cement can be removed from the tooth with a scaler or with a 24 fluted finishing bur. Be careful not to contact the enamel surface.

* Dr. Mark Coreil is a paid consultant for Ormco/AOA Corporation. The suggested bonding protocol was provided by Dr. Coreil. Ormco/AOA are medical device manufacturers and do not dispense medical advice. Clinicians should use their own professional judgment in treating their patients.

WARRANTY: Product will be warrantied for 12 months for fixed appliances and 2 years for removable appliances. This only applies to defective appliances, not lost or misplaced appliances.

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: You may need to occasionally adjust these appliances. See note on page 3. Dental Professional is to provide patient instructions.

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.

DAILY CARE AND MAINTENANCE: Instruct your patient to brush after each meal by using a soft bristle toothbrush with warm water and a small amount of toothpaste, and rinse. Please remind your patient not to use mouthwash or harsh chemicals as a cleanser, as this may cause damage or discoloration to the appliance. Removable Hawley Retainers should be cleaned after each meal, rinsed and returned to the mouth.

DISPOSAL: Follow local guidelines.

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* For US law only

See symbols glossary at aolab.com/productsifu/symbols glossary.

AOA



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