



AOA

Custom-Made Devices
Personalized Medical Device

**3D Printed
Fixed Class II
Corrector Devices
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), Fixed Class II Corrector Devices are fabricated primarily using stainless steel and silver alloy brazing material and customized for each specific patient to treat malocclusions.

3D PRINTED FIXED APPLIANCES (Lingual Arch, Trans-Palatal Arch, & Rapid Palatal Expanders) - 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, TPA, RPE, Bands and Crowns.

Herbst™* is a fixed appliance designed to aid in correction of an overbite. Mechanisms are guides to show you where to bite. The appliance helps guide the patient's front-to-back bite relationship.

MARA™ (Mandibular Anterior Repositioning Appliance) is a fixed bite advancer appliance designed to aid in the correction of an overbite. The patient is guided by the appliance to habitually hold the jaw in a Class I relationship by essentially forcing the patient to bite forward in front of the device elbow.

HERBST & MARA INTENDED USE: Products to be used by orthodontists/dentists/dental laboratories. Products to be used during orthodontic treatment to correct Class II malocclusions and obtain a Class I orthodontic occlusion.

HERBST & MARA INDICATIONS FOR USE: The appliances are intended to be worn by the patient on the dental arch(s) as prescribed by the treating dentist/orthodontist. The duration of wear will range by the determination of the dentist/orthodontist, usually 24 hours per day for 6 - 24 months.

Lingual Arch - is designed to maintain transverse arch width, prevent molar tipping and more. This 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.

Rapid Palatal Expander - 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.

*Herbst™ is a registered trademark of Dentaureum GmbH & Co. KG

FIXED APPLIANCES INTENDED USE: Products to be used by orthodontists/dentists/dental laboratories. Fixed appliances (Lingual Arch, Trans-Palatal Arch (TPA), & Rapid Palatal Expanders) are designed for various tooth movements, dental retention, and arch development.

FIXED APPLIANCES 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: This product may contain nickel, chromium, cobalt chrome, acrylic(Poly(Methyl Methacrylate)) and should not be used for 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.
- If crowns are not seated properly, the tubes/pistons (Herbst), may bind, and elbows/arms (MARA) will not contract properly and may cause no advancement or locking on the axles.
- Solder joints may deteriorate leaving a sharp edge that may cut the mouth.
- Ensure lower cantilever arms and elbows are adjusted to avoid tissue impingement.
- Crunchy, hard or sticky foods could damage the appliance.
- Device not installed by a Dental Professional may cause harm to patient.

INSTRUCTIONS FOR USE: Herbst™ and MARA™

- Remove device from packaging and clean per office procedure.
- NOTE: For narrow maxillary arches it may be necessary to expand prior to placing mechanisms.
- Fit and bond crowns or bands. (For reference, see the Suggested Bonding Protocol in this IFU.)
- If desired, bond the end of the extended lingual arch or occlusal rests (if fabricated to extend beyond the lower crowns or bands) to the teeth using standard preparation procedures and bonding adhesives.

Herbst:

Standard Mechanism:

- Attach the prepared and shortened rods and tubes.
- Re-check the length of the rods and adjust as needed to prevent the rods from injuring the patient when the bite is closed firmly.
- Use caution when asking the patient to bite down firmly until you are satisfied that the rods are not too long and that they will not injure the patient when the bite is firmly closed.
- Re-check the length of the rods to ensure that they will not emerge from the tubes when the bite is fully open during lateral excursions.

Telescoping Mechanism:

- Attach the laboratory sized mechanism.
- Check the amount of mandibular advancement, adjust as needed by adding or removing "C" shims.
- Use caution when asking the patient to bite down as not to injure the patient when the bite is firmly closed.
- Check to make sure the patient can move freely during lateral excursions.

Flip-Lock® Mechanism:**

- Attach the laboratory sized mechanism by sliding the piston into the tube (Red = left piston or tube & Green = right piston or tube). With the colored dot facing out & distal, slide the tube socket on to the upper ball hinge.
- Flip the assembly toward the teeth.
- Place the piston socket over the lower ball hinge with the colored dot facing outward. It may be necessary to lightly

****Flip-Lock®** is a registered trademark of TP Orthodontics.

- crimp down the lower rod hinge to keep the piston secure.
- Check the amount of mandibular advancement, adjust as needed by adding or removing “C” shims.
- Use caution when asking the patient to bite down as not to injure the patient when the bite is firmly closed.

MARA:

- Verify that the elbows and shim spacer(s) are attached to the hook on the crowns or bands.
- Use an elastic “O” or ligature wire to secure via the elbow hook.
- Make sure that the elbow length and distal ends are not too long as to irritate the tissue, adjust as necessary.
- Add or remove round shims from the elbow to adjust the mandible position.
- Instruct the patient to bite forward to engage the elbow to the arm stopping point.
- Use caution when asking the patient to bite forward so not to bite past or bite on the arm.

INSTRUCTIONS FOR USE: 3D Metal Printed Appliances

All appliances in this category:

- Remove device from packaging 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:

- 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, & Trans-Palatal Arch:

- Prepare tooth surfaces and cement bands/crowns to the selected tooth or teeth.

AOA SUGGESTED BONDING PROTOCOL*

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

- Prophyl 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: 6 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: You may need to occasionally adjust these appliances.

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: Follow instructions provided by your Dental Professional.

DISPOSAL: Follow local guidelines.

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

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