

AOA

**Custom-Made Devices
Personalized Medical Device**

**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.

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™ is a registered trademark of Dentaaurum, Inc.

INTENDED USE: Products to be used during orthodontic treatment to correct Class II malocclusions and obtain a Class I orthodontic occlusion.

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.



WARNINGS:

This product contains nickel and chromium and 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: All removable mechanisms must be removed prior to entering the MRI environment (telescoping mechanisms, screws, extenders, elbows, rods and sleeves).

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 intraorally using a standard crown or band adhesive.
- 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 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.

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.

DISPOSAL: Follow local guidelines.

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

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* For US law only

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

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