AOA

Custom-Made Device
Personalized Medical Device

Removable Class II Corrector Devices Instructions for Use

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CUSTOM-MADE DEVICE DESCRIPTION:
Allesee Orthodontic Appliances (AOA), Removable Class II Corrector Devices are primarily fabricated from dental acrylics and cobalt chrome or orthodontic stainless steel/TMA materials and customized for each specific patient and are intended to aid in the correction and treatment of Class II orthodontic malocclusions and obtaining Class I orthodontic occlusion.

Activator - The upper wire is formed into a labial bow with loops against the upper anterior teeth. An expansion screw may be added to widen the dental arches. All wires and expansion screws are held in position with lingual and palatal acrylic. The lower lingual acrylic then forces the mandible into a dental Class I position as the teeth come into occlusion.

Bionator - The upper wire is formed into a labial bow with loops against the upper anterior teeth, an anterior lingual U-shaped wire, and an upper wire palatal loop. An expansion screw may

be added to widen the dental arches. All wires and expansion screws are then held in position with lingual acrylic. The lower lingual acrylic then forces the mandible into a dental Class I position as the teeth come into occlusion.

Frankel - The wires are formed on, in-between and over the teeth of the dental arches, labial and lingual. All wire ends/tails are then held in position with acrylic buccal shields, a lingual arch and lip pads. The lower lingual acrylic then guides the mandible into a dental Class I position as the teeth come into occlusion.

Orthopedic Corrector - is used for correcting the upper and lower jaw relationship. The upper wire is formed into a labial bow with loops against the upper anterior teeth, an anterior lingual U-shaped wire, and an upper wire palatal loop. Expansion screws are placed to widen and lengthen the dental arches. All wires and expansion screws are then held in position with lingual acrylic. The lower lingual acrylic then forces the mandible into a dental Class I position as the teeth come into occlusion.

Twin Block™ - The upper and lower wires are formed into a labial bow with loops, ball clasps against the upper anterior teeth or in the interproximals. Wire clasps are placed between the interproximals in the posteriors for retention purposes. Expansion screws may be requested to widen and lengthen the dental arches. All wires are then held in position with acrylic. The upper and lower occlusal wedges of acrylic guide the mandible into a dental Class I position as the teeth come into occlusion.

INTENDED USE: Products to be used by orthodontists/dentists/dental laboratories to aid in the correction of dental Class II malocclusions and in obtaining a Class I orthodontic occlusion.

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 vary by the determination of the dentist/orthodontist, usually 6 months to a year.

WARNINGS:
Some of these medical devices may contain nickel, chromium, acrylic (Poly (methyl methacrylate), allergic reaction to the acrylic, pressure formed, stainless steel/TMA, polypropylene, menzanium, iron, aluminum, solder materials. In rare instances some patient's 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 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. Solder joints/wire may deteriorate leaving a sharp edge that may cut the mouth.
- Crunchy, hard or sticky foods could damage the appliance.
- Device not installed by a Dental Professional may cause harm to patient.

INSTRUCTIONS FOR USE:
Activator (ACT), Frankel (FR), Bionator (BIO), Orthopedic Corrector (OC), and Twin Block™ (TB).
- Remove device from packaging and clean per office procedure.
- Insert device into patient's mouth and instruct patient to carefully bite into teeth and position their jaw into a protrusive position.
- Adjust clasping as needed for a secure fit.
- Adjust acrylic by lightly trimming away acrylic that may cause any discomfort such as lower lingual undercuts (ACT, BIO, FR, OC) tight anterior capping (BIO/OC/ACT), buccal shields (FR), lip pads (FR).
- Devices that include screws, activate as required to achieve desired outcome.

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: 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: Advise your patient to store appliance in carrying case. Store in a clean, dust-free place. Store in a dry, cool place at room temperature.

DISPOSAL: Follow local guidelines.

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

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EC REP

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Rx Only*
* For US law only

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

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