

# **AOA**

**Custom-Made Device  
Personalized Medical Device**

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**Splint Appliances  
Instructions for Use**

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**CUSTOM-MADE DEVICE DESCRIPTION:**

**Allesee Orthodontic Appliances (AOA),** These devices are fabricated from dental acrylics, thermal forming plastics, nylon and orthodontic stainless steel/TMA materials. This appliance has been specially made from recent impressions of your patient's teeth. It's been determined that all corrections achieved during your patient's treatment should be retained and appliances for either your upper or lower arch or both have been constructed, to help hold them in their ideal position.

**Splints** - are designed to exert posterior to anterior advancement, lateral pressures from optional expansion device, and mandibular excursions from lower to upper component engagement. All of which are transferred back as reciprocal mechanical forces to the appliance and are intra-oral forces.

Damon™ Retention Splint - is an appliance designed to offer the patient aesthetics while maintaining their finished occlusal bite relationship and tooth position.

**INTENDED USE:** Products to be used by orthodontists/ dentists/dental laboratories. This appliance is most often used for bruxism, intrusion, anterior and posterior advancement. They can also be used for post orthodontic retention to hold teeth in their ideal position and minimize relapse. Some splint appliances are known to treat disc displacement with reduction of the temporomandibular disorder (TMD).

**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 medical devices may contain nickel, chromium, copolyester - PETG (pressure formed material), vinyl - EVA (dual laminate), acrylic (Poly (methyl methacrylate) Allergic reaction to the acrylic, pressure formed, stainless steel/TMA, solder materials. These materials 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 patient appliances containing Stainless Steel 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.
- Parts may be accidentally swallowed or aspirated and may be harmful.
- Crunchy, hard or sticky foods could damage the appliance.

- Device not installed by a Dental Professional may cause harm to patient.

**INSTRUCTIONS FOR USE:**

- Remove device from packaging and clean per office procedures.
- Insert device into patient's mouth and instruct patient to carefully bite down to fully seat device.
- Trim away material that maybe impinging tissue or tooth surfaces.
- Advise patient of wear time.

**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:** Dental Professional to provide.

**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 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 Splints 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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**Rx Only\***

\* For US law only

See symbols glossary at [aolab.com/products/ifu/symbols/glossary](http://aolab.com/products/ifu/symbols/glossary).

# AOA



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