

AOA

**Custom-Made Device
Personalized Medical Device**

**Finishing/
Retention 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 DESCRIPTION:

Allesee Orthodontic Appliances (AOA), These devices are fabricated from dental acrylics, and orthodontic medical grade stainless steel, cobalt chrome and 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 their upper or lower arch or both have been constructed, to help hold them in their ideal position.

Removable Appliances - device can be inserted and removed by the patient. (Hawleys, Spring Retainers, Invisible Retainers, and Prezurv™)

Hawley Retainer - is still the most common device used after treatment for retention for both upper and lower arches. With our vast array of labial bows, clasping and acrylic options, this appliance can be uniquely crafted for both you and your patient's needs. Additional features can also be added to aid in specific tooth movements.

Spring Retainer - is a commonly used device for after treatment retention and minor tooth correction on both upper and lower arches. With our vast array of labial bow clasping and acrylic options, this appliance can be uniquely crafted for both you and your patient's needs.

Invisible Retainer - is designed to offer the patient a combination of comfort and aesthetics while maintaining their finished tooth position.

Prezurv™ - is designed to prevent relapse and maintain a beautiful smile. Due to extended wear, retainers fatigue and begin to lose their shape. The Prezurv™ system provides multiple sets of retainers to assure teeth stay in their optimal position. Patients worry less about lost, broken or discolored retainers.

INTENDED USE: Products to be used by orthodontists/dentists/dental laboratories. Most common for post-orthodontic retention to hold teeth in their ideal position and minimize relapse. Some appliances in this category may include minor tooth correction.

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 appliances contain nickel, chromium, plastics, copolyester - PETG (pressure formed material), polyliquid acetate, vinyl - EVA (dual laminate) and acrylic (Poly (methyl methacrylate). Allergic reaction to the acrylic, pressure formed, stainless steel/TMA, solder materials. In rare instances some patients may be allergic. These materials should not be used for individuals with known allergic sensitivity to these acrylics and/or metals. In rare instances patient's with hereditary angioedema (HAE), a genetic disorder, may experience rapid local swelling of subcutaneous tissues including the larynx. HAE may be triggered by mild stimuli including dental procedures.



Single Patient Use - Risk of cross-contamination.



Magnetic Resonance (MR) Safety Information: Please advise your patient Hawley and Spring Retainers with wires, screws or springs must be removed before 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:

Hawley Retainer & Spring 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 acrylic by lightly trimming away acrylic that may cause bite interference or discomfort as needed.
- Devices that include screws or springs, activate to achieve desired outcome .
- Advise patient of wear time.

Invisible Retainer and Prezurv™

- 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 may be impinging tissue or tooth surfaces as needed.
- Prezurv™ devices maybe changed out every 3 to 6 months per year if necessary.
- 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
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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* For US law only

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

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