

AOA

**Custom-Made Devices
Personalized Medical Device**

**Aligners
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), These appliances have been specially made from recent impressions of your patient's teeth. The appliances are activated each time the patient firmly seats the aligner over their teeth. While the amount of movement each appliance can produce is measured on fractions of millimeters, the force will be noticeable and may result in some temporary minor discomfort.

Aligners are made from a "plastic" type material that can be heated and formed onto the patient's dental cast. The purpose or function of the appliance is to achieve alignment or straightening of your patient's teeth to a more ideal position. These appliances should be worn in sequential order.

INTENDED USE: Products to be used by orthodontists/dentists/dental laboratories to move teeth to a more desired position. The appliances are activated each time the patient firmly seats the aligner over their teeth. While the amount of movement each appliance can produce is measured in fractions of millimeters, the force will be noticeable and may result in some temporary minor discomfort.

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.

CONTRAINDICATIONS: There are no contraindications for this device.



WARNINGS:

This product contains Polyliquid Acetate Co-Polymer. In rare instances some patients may be allergic. In rare instances patients 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: Not applicable.

PRECAUTIONS:

- Non-sterile device.
- Patient may deliberately or accidentally bite incorrectly and cause the device to function improperly.
- Sores may develop from rubbing on tissue.
- Crunchy, hard or sticky foods could damage the appliance.
- The device could be fractured, swallowed or aspirated.
- Device not installed by a Dental Professional may cause harm to patient.
- Remind your patient that trays may cause attachments to come loose or fall off and require replacement. Parts can be swallowed or aspirated.

INSTRUCTIONS FOR USE:

Red, White, Blue (RWB), Simpli5™, Refinements, Attachments, IPR and Installation of Aligners

- Prepare patients teeth for use of retention attachments if required.
- Remove attachment tray from packaging and clean per office protocol.
- Trial fit attachment tray for proper fit.
- Fill tray reservoirs with preferred light cure composite.
- Carefully fit tray over teeth.
- Light cure composite per manufacturer's instructions.
- Remove attachment tray, clean and store in the event the composite attachment breaks off.
- Perform interproximal reduction (IPR) if necessary, as indicated on the "Strip Card" enclosed with the appliances.
NOTE: All attachments must be removed upon completion of treatment.

RWB

- Remove the 1st aligner from packaging and clean per office protocol.
- Carefully fit aligner tray with Red dot, over teeth.
- In approximately 3 weeks deliver aligner tray with White dot
- Follow instructions for 1st aligner and continue through sequence of aligners.
- Additional IPR may be necessary.
- Install RWB into patient's mouth.

Simpli5™

- Remove the 1st aligner from packaging and clean per office protocol.
- Carefully fit aligner tray with one Blue dot over teeth.
- In approximately 3 weeks deliver aligner with two Blue dots.
- Follow instructions for 1st aligner and follow through sequence of aligners.
- Additional IPR may be necessary.
- Install Simpli5™ into patient's mouth.

Refinements

- Remove the 1st refinement aligner from packaging and clean per office protocol.
- Carefully fit aligner tray with one Yellow dot over teeth.
- In approximately 3 weeks deliver aligner with two Yellow dots.
- Follow instructions for first refinement and follow through with the rest of the sequence of aligners.
- Additional IPR may be necessary.
- Install Refinement into patient's mouth.

WARRANTY: RWB - 3 months, Simpli5 - 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: 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 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 OF ALIGNERS: Instruct your patient Aligners should be cleaned after each meal, by using a soft bristle toothbrush with 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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Distribution Facility:
Ormco PTY LTD
Unit 6, 12 Mars Road
Lane Cove West, NSW 2066
Australia



Kerr Italia S.r.l., Via Passanti, 174
84018 Scafati (SA), Italy



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* For US law only

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

AOA



AOA
13931 Spring Street
Sturtevant, WI 53177
USA