

AOA

**Custom-Made Device
Personalized Medical Device**

**Metal Appliances
Fixed and Removable
Holding, Expanding and
Distalizing
Instructions for Use**

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CUSTOM-MADE DEVICE DESCRIPTION:

Allesee Orthodontic Appliances (AOA), The devices listed in this brochure aid in developing the upper and or lower dental arches by expanding, lengthening, distalizing molars, space regaining or maintaining, correcting oral habits and uprighting teeth.

FIXED APPLIANCES - device is attached to either the upper or lower teeth by the dentist/orthodontist and should only be removed by a dental professional. (Lingual Arch, MCLR, Bonded Retainer, Kiddie Partial, Nance Button, Transpalatal Arch, Band & Loop, Cetlin Lip Bumper, Rapid Palatal Expanders, Quad Expander, Haas, Mini RPE, Fan Exspider, Frozat, Arnold, Dischinger, W-Arch, Bi-Helix, Spring Loaded, Habit Appliances, Pendulum, Pendex, PhD, MDA, Hex and Penguin appliances).

Lingual Arch - is designed to maintain transverse arch width, prevent molar tipping and more. This device is cemented to the patient's teeth.

MCLR - is designed to stabilize the position of the incisors. The mesh pads are located on the lingual of the upper and or lower anterior teeth. The wire is formed to the contour of teeth touching each mesh pad and then soldered to each mesh pad. The dentist or orthodontist adheres the pads with dental composite to the teeth.

Bonded Retainers - are not removable and are designed to prevent movement of your teeth after orthodontic treatment has reached its ideal position. It is bonded to the lingual surface of your teeth.

Kiddie Partial - is designed primarily for young patients who have prematurely lost their anterior teeth. This appliance offers an immediate aesthetic alternative to hold space until the permanent teeth are ready to erupt.

Nance Button - is designed to prevent molars from moving mesially and maintain overall arch length. The design can also be used as an anchorage device when used in conjunction with full brackets. The device is cemented to the patient's teeth.

Transpalatal Arch (TPA) - is primarily designed to maintain transverse width of the upper arch but can also be used to rotate, distalize or perform other movements of the first molars. This device is cemented to the patient's teeth.

Band and Loop - is designed to maintain space mesial or distal to the tooth that is banded to reserve space for a future erupting tooth. It is commonly used during early loss of a primary molar and can help prevent the first molar from tipping and moving mesially. This device is cemented to the patient's teeth.

Cetlin Lip Bumper - is designed to hold the lip muscle away from the anterior teeth and will also distalize the molars. The device is semi-fixed in the patient's mouth by inserting wire into the lip bumper tubes. Secure with elastic bands.

Rapid Palatal Expander, Upper Quad Expander, Lower Expander, DeLuke Bonded Expander, Haas, AOA Mini RPE, Fan Expander, Mayes Frozat, Dischinger Lower Expander, Arnold Expander, W-Arch Expander, and Lower Bi-Helix - are designed to expand the dental arch when the stainless steel wires, coil springs or screws are activated. These devices are fixed into the patient's mouth using stainless steel bands or crowns cemented to the selected posterior teeth.

Spring Loaded Space Regainer - is designed to open or regain space between the selected teeth. This device is fixed in the patient's mouth with bands or crowns cemented onto the tooth.

Vertical Crib, Palatal Thumb Crib, Bluegrass Tongue Trainer, Hayrake-Palatal with Spurs - are designed to help correct over active tongue thrusting and or thumb sucking habits. These devices are fixed into the patient's mouth using stainless steel bands or crowns cemented to the selected posterior teeth.

Hilgers, Pendulum, Pendex, PhD, MDA, Hex and Penguin - are designed to distalize the molars when the wires are activated and inserted into the sheaths. The devices with midline expansion screws will simultaneously widen the dental arch when activated while the helix springs distalize the molars. The helix springs may be activated to rotate molars as well. These devices are fixed into the patient's mouth using stainless steel wire rests, bands or crowns with sheaths and fit on the selected posterior teeth.

REMOVABLE AND SEMI-REMOVABLE APPLIANCES - devices are placed on the teeth and palatal tissue. Removable devices utilize stainless steel wires that are formed into clasps, springs and labial bows. The acrylic secures the wire ends and holds the device in the mouth. (ACCO, Shamey, Nord, Jackson, Schwarz, Sagittal), Semi-Removable devices utilize bands or crowns with a lingual sheath then cemented on the teeth. (Removable Quad, and Wilson™ 3D™ appliances.)

ACCO and Shamey Expanders - are designed to distalize the molars when the wire springs are activated. These devices can be removed from the mouth by the patient.

Nord, Jackson, Schwarz and Sagittal Expanders - are designed to expand or lengthen the dental arch when the stainless steel wires or screws are activated. The devices are placed on or over the teeth and on the palatal tissue and can be removed from the mouth by the patient.

Removable Quad Expander and Wilson™ 3D™ - are designed to expand the dental arch when the stainless steel wires are activated and inserted into the sheaths. The devices are semi-fixed into the patient's mouth using stainless steel wire or bands/crowns with sheaths cemented to the selected posterior teeth. These devices can be removed from the mouth by the patient.

INTENDED USE: Products to be used by orthodontists/dentists/dental laboratories. Products are either removable or non-removable by the patient and are designed for various tooth movements, dental retention and arch development.

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, polyethylene, acrylic (Poly (methyl methacrylate) and may cause an allergic reaction to the acrylic, stainless steel/TMA, solder materials. These materials should not be used by 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.
- Crunchy, hard or sticky foods could damage the appliance.
- Device not installed by a Dental Professional may cause harm to patient.

INSTRUCTIONS FOR USE:

All appliances in this category:

- Remove device from packing and clean per office procedure.
- Insert device into patient's mouth and instruct patient to carefully bite down to check for proper occlusion.
- Remind patient to keep device clean. Refer to Daily Care and Maintenance.

ACCO, Shamey Expander, Nord, Jackson, Schwartz and Sagittal Expanders

- Adjust clasping for a secure fit as needed.
- Adjust acrylic by lightly trimming away acrylic that may cause any discomfort or fit issues if needed.

ACCO and Shamey Expander

- Activate wire helix spring(s) to achieve molar distalization as required.
- During each patient visit, re-activate the appliance by adjusting wire helix springs if applicable.

Nord, Jackson, Schwartz and Sagittal Expanders

- Activate expansion screw(s) to achieve desired outcome as required.
- For the Jackson device, activate the lingual wire arch by stretching/pulling the wire out laterally.
- During each patient visit, re-activate the appliance by turning the screws open or re-stretching the Jackson lingual wire if applicable.
- Activate expansion screw(s) to achieve desired outcome if required.
- For the Jackson device activate the lingual wire arch by stretching/pulling the wire out laterally.

- During each patient visit, re-activate the appliance by turning the screws open or re-stretching the Jackson lingual wire if applicable.
- Check that the wire clasps and tighten if needed.
- Check acrylic for cracks and sharp edges, repair or smooth if necessary.

Rapid Palatal Expander, Lower Expander, DeLuke Bonded Expander, Haas Expander, AOA Mini Rapid Palatal

Expander, Fan Expider Expander, Dischinger Lower Expander

- Adjust acrylic/pressure formed material by lightly trimming away acrylic that may cause any discomfort or fit issues if needed.
- Adhere bands/crowns/rests.
- Activate expansion screw(s) as required to achieve desired outcome.
- During each patient visit, re-activate the appliance by turning the screws open if applicable.
- Check acrylic for cracks and sharp edges, repair or smooth if necessary.
- Check bands/crowns for appropriate adhesion.

Removable Quad Expander and Wilson™ 3D™ Appliance

- Adhere bands/crowns.
- Activate wires(s) as required to achieve desired outcome.
- Insert the device into the provided sheaths on the bands/crowns.
- Secure device to sheath with wire tie or elastic bands.
- During each patient visit, re-activate the appliance by removing device from the sheaths and replacing into sheaths if applicable.
- Check bands/crowns for appropriate adhesion.

Hilgers Pendulum, Hilgers Pendex, and Mayes Penguin

- Adjust acrylic by lightly trimming away acrylic that may cause any discomfort or fit issues if needed.
- Adhere bands/crowns/rests.
- The Mayes Penguin, activate the helix coil springs to achieve desired outcome as needed.
- If device contains an expansion screw, active by turning the screw open.
- During each patient visit, re-activate the appliance by recompressing the coil springs or helix springs if applicable.

- Check acrylic for cracks and sharp edges, repair or smooth if necessary.
- Check bands/crowns for appropriate adhesion.

PhD Appliance, Tracy/Hilgers MDA Appliance, Hex Appliance

- Adjust band/crown fit.
- Adhere bands/crowns/rests.
- Activate the helix coil springs as required to achieve desired outcome.
- Activate the expansion screw by turning open.
- During each patient visit, re-activate the appliance helix coils/expansion screws if applicable.
- Check bands/crowns for appropriate adhesion.

Vertical Crib, Palatal Thumb Crib, Bluegrass Tongue Trainer, Hayrake-Palatal with Spurs

- Check band or crown fit, adjust as needed.
- Check crib or roller fit, adjust as necessary.
- Adhere bands/crowns and rests if necessary.
- Check that crib and or roller is functioning properly, adjust if necessary.
- Check bands/crowns for appropriate adhesion.

Spring-Loaded Space Regainer

- Check band or crown fit, adjust as needed.
- Check that coils springs compress enough to seat device, adjust as necessary.
- Check wire ends for sharpness, adjust if necessary.
- Adhere bands/crowns.
- Check that device is functioning properly and check wire ends for sharpness, adjust if necessary.
- Check bands/crowns for appropriate adhesion.

Cetlin Lip Bumper

- If bands are included, adjust as needed.
- Adhere bands/crowns.
- Insert lip bumper as required to achieve desired outcome.
- Adjust wire bow or loops as required to achieve desired outcome.
- Secure lip bumper wire utilizing hooks with ligature ties or elastics.
- During each patient visit, re-activate if applicable.
- Check bands/crowns for appropriate adhesion.

Lingual Arch, Nance Button, Transpalatal Arch, Goshgarian Transpalatal Arch, and Band and Loop Space Maintainer

- Adjust the wires, bands/crowns, and acrylic for the proper fit as needed.
- Prepare tooth surfaces and cement bands/crowns to the selected tooth or teeth.

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: No special storage conditions.

DAILY CARE AND MAINTENANCE: Instruct your patient to brush after each meal by using a soft bristle toothbrush with warm water and a small amount of toothpaste, and rinse. Please remind your patient not to use mouthwash or harsh chemicals as a cleanser, as this may cause damage or discoloration to the appliance.

DISPOSAL: Follow local guidelines.

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