

Custom-Made Device Personalized Medical Device

Jet Appliances Instructions for Use

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CUSTOM-MADE DEVICE DESCRIPTION:

Allesee Orthodontic Appliances (AOA), Jet appliances are primarily metal based, are customized for each specific patient and provides expansion, distalization, or tooth movements in an uprighting or mesial direction. (Uprighter, Mesial, Spring, and Distal).

Distal Jet - is designed to distalize or move the molars when the wires or coil springs 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. This device is fixed into the patient's mouth using stainless steel wire, rests, bands or crowns fit on the selected posterior teeth.

Molar Uprighter - is designed to correct tipped molars caused by prematurely missing or extracted teeth. The device is fixed into the patient's mouth using stainless steel bands or crowns cemented to the selected posterior teeth on the upper or lower arches.

Spring Jet - is designed to expand the dental arch when the stainless steel wires, coil springs or screws are activated. The device is fixed into the patient's mouth using stainless steel bands or crowns cemented to the selected posterior teeth.

INTENDED USE: Products to be used by orthodontists/dentists/ dental laboratories. These products are for arch development.

INDICATIONS FOR USE: The appliance is worn by the patient on the dental arches as prescribed by the treating dentist/ orthodontist. This product is placed inside the patient's mouth by the Dental Professional and cannot be removed by the patient. It is designed for various tooth movements and arch development. The duration of wear will range by the determination of the dentist/orthodontist.



WARNINGS:

Some of these medical devices may contain nickel, chromium, 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 Jet Appliances containing metal, screws, wires or springs 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.
- Crunchy, hard or sticky foods could damage the appliance.

PRECAUTIONS (CON'T):

- Device not installed by a Dental Professional may cause harm to patient.
- Overtightening screws can compromise the overall effectiveness of the product and desired tooth movement.
- The screw should not be turned more than 60° 90° past initial contact with the bayonet director tube. Adequate positional retention of the tube in the activation lock will then be achieved and no crushing of the tube will occur.

INSTRUCTIONS FOR USE:

All Jet appliances - Remove device from packaging and clean per office procedure.

Jet Appliances

- Remove separators and excess debris from the interproximal area.
- Check the fit by placing the appliance in the mouth prior to cementation.
- Mix the cement, load the bands, and cement the appliance. per cement manufacturer's instructions.
- Continue to the applicable section for the instruction of your patient's appliance.

Uprighter Jet Appliance

- Remove the stabilizing power chain, prior to activation.
- Activate the appliance by compressing the coil spring with the activation lock. Additional activation is generally prescribed in 4-6 week intervals, when needed.
- For bilateral cases, it's suggested to activate the appliance in an alternating sequence. (One side, during one visit the other during the next). Activating both sides may cause undesirable loss in anchorage.
- Remove appliance, bond, band or place the retainer after completed.

Mesial Jet Appliance

- Ligate the activation arm firmly into the molar sheath.
- Activate the appliance by compressing the coil spring with the activation lock. Additional activation is generally prescribed in 4-6 week intervals, when needed.
- For bilateral cases, it's suggested to activate the appliance in an alternating sequence. (one side, during one visit, the other during the next). Activating both sides could cause loss in anchorage.

• Remove appliance, bond, band or place the retainer once the space is closed.

Spring Jet Appliance

- Remove the stabilizing power chain.
- Note: Spring Jets may be delivered either loaded or unloaded. Loaded = spring is compressed, Unloaded = spring is not compressed. A heavy ligature wire is used to bring the two halves of the appliance together as one unit.
- Activate the appliance by compressing the coil spring with the activation lock. Additional activation is generally prescribed in 4-6 week intervals, when needed.
- Once desired expansion is achieved, release some tension on the spring, tighten the lock and leave the spring jet in place to maintain correction.

Distal Jet Appliance

- Check passive fit of directors and bayonets adjust if necessary.
- Prior to activation, remove the stabilizing power chain.
- Activate the appliance by compressing the coil spring with the activation lock. Additional activation is generally prescribed in 4-6 week intervals, when needed.
- Once complete, convert Distal Jet to a retainer.
 - a. Peel the spring from the appliance with a plier.
- b. Slide the lock firmly next to the stop and tighten the screw.
- c. Squeeze the end of the lock tight onto the bayonet wire.
- Note: This will prevent the appliance from loosening.
- d. Alternative option is to tie the lock and bayonet wire/molar sheath together with a steel ligature or thread or elastic chain.

Note: Appliance designs requesting locking wires or a Bowman Modification will not use stabilizing power chains to assist in delivery.

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.

DISPOSAL: Follow local guidelines.

DAILY CARE AND MAINTENANCE: Follow instructions provided by your Dental Professional.

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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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