

INSTRUCTIONS FOR USE – POWERSCOPE

This IFU is applicable to all current and previous generations of this product.

1. IDENTIFICATION OF THE COMPANY

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2. IDENTIFICATION OF THE PRODUCT

Product Name: PowerScope

Product Description: Orthodontic Class II Correction Device

3. INTENDED PURPOSE/INDICATIONS FOR USE

Intended to operate together with other orthodontic devices to apply forces to teeth. Under the supervision of a trained dental professional or orthodontist, this may result in changes to the position of teeth.

American Orthodontics' devices are indicated for the treatment of malocclusions and craniofacial abnormalities as diagnosed by trained dental professionals and/or orthodontists.

4. PERFORMANCE CHARACTERISTICS

The PowerScope appliance is a device installed wire-to-wire with the attachments placed mesial to the first molar in the maxillary arch and distal to the canine of the mandibular arch.

During normal use, the PowerScope device exerts a distal force on the maxillary molars. This may result in changes to the position of teeth and/or the mandible under supervised treatment by the clinician.

5. CONTRAINDICATIONS

American Orthodontics sells products to trained dental professionals and orthodontists. It is the primary responsibility of the dental professional and/or orthodontist to identify any possible contraindications that may preclude the use of American Orthodontics' products. It is also the responsibility of the dental professional and/or orthodontist to determine any pre-starting procedures, as well as the working sequence of the medical devices.

If a patient has known allergies or hypersensitivity to any material in this product, its use is not recommended or should only occur under strict medical supervision. Even under normal conditions, reactions of the immune system (allergies) or other side effects cannot be completely ruled out.

6. WARNINGS & PRECAUTIONS

- PowerScope is a single use only device.
- PowerScope contains nickel and should not be installed on patients with allergies or sensitivities to nickel.
- PowerScope can only be sold to trained dental professionals or orthodontists.
- PowerScope should not be installed on patients undergoing MR scans.
- PowerScope should be removed if it becomes disassembled or broken to avoid cuts or harm to the mouth.
- PowerScope parts that become loose may be swallowed or inhaled.
- PowerScope appliances that are not installed or supervised correctly may cause damage to teeth.
- Sores may occur from the device rubbing against the mouth.
- If oral health is not maintained properly by the user, gum infection or tooth decay may occur.

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7. IDENTIFICATION

- The left PowerScope is designated by an “L” ID mark.
- The right PowerScope is designated by an “R” ID mark.
- The “OPEN” with directional arrow designates loosening direction (reverse thread) on the right appliance only. (Figure A)
 - o NOTE: Both screws are tightened by turning distally and loosened turning mesially.
- Three activation lines spaced 2mm apart indicate the level of activation (Full, Partial, and None). (Figure B)



Figure A

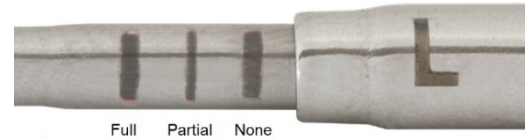


Figure B

8. INSTRUCTIONS

1. PowerScope is delivered as a one-size-fits-all appliance with two options for installation.
 - a. Intraoral installation uses an open channel attachment nut as shown in Figure C.
 - b. Extraoral installation uses a closed channel attachment nut as shown in Figure C.

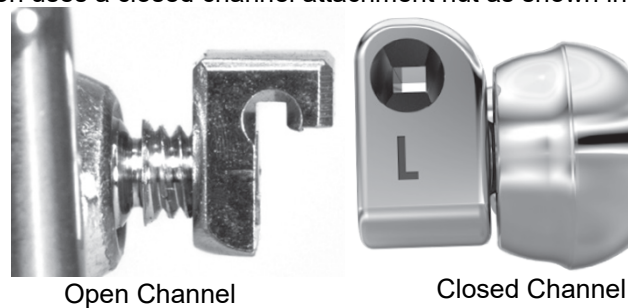


Figure C

2. The PowerScope appliance connects to the orthodontic system with attachments placed mesial to the first molar in the maxillary arch and distal to the canine of the mandibular arch.
3. The use of stainless-steel arch wires is recommended. To ensure best results, use 0.017 × 0.025 wire with 0.018 slots, or 0.019 × 0.025 wire with 0.022 slots.

Installation using Open Channel Attachment Nut

NOTE: Installation using open channel attachment nut can be done after the installation of the arch wire.

1. Engage the magnetic sleeve onto the driver by holding the Hex Head Driver over the magnet with conical chamfer slot facing up. As the driver nears the opening, the magnetic sleeve will seat itself on the driver tip. (Figure D)

NOTE: PowerScopes from the single patient kits are pre-installed with Open Channel Nuts. If the nuts are pre-installed, proceed to step 3.

2. **Screw the open channel nuts on to PowerScope device. Take care to install the correct “left” or “right” nuts based on the patient’s left or right side.**
3. Use the driver to slightly back out both screws on the PowerScope arm to ensure the wire channel is fully open. (Figure E)
 - o Turn screw mesial to loosen.

NOTE: Prior to installation, the use of a thread adhesive is recommended to address any concerns of the screw loosening or backing out.

4. Using the driver provided, engage the maxillary attachment nut and place mesial to the first maxillary molar.
5. Approach the arch wire at a 45° degree angle with the attachment nut.
6. Rotate the attachment while applying downward force until you feel it properly seat into place. (Figure F)
7. Once the attachment nut is properly seated on the wire, engage the screw. Placing a finger on top of the attachment nut while tightening will help stabilize the mechanism.

- o **NOTE:** The screw does not pinch the wire when installed but rather acts as a fourth wall to capture the wire when engaged.



Figure D

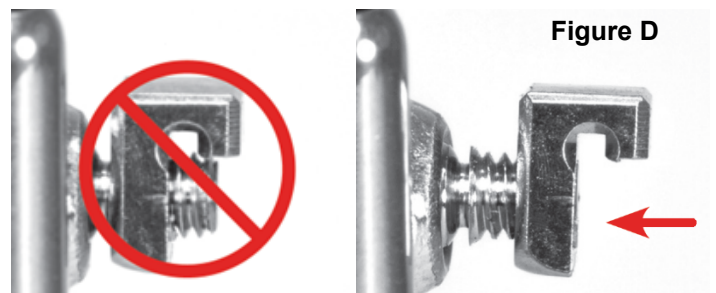


Figure E

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8. Engage mandibular attachment nut using the driver and place distal to the mandibular canine on the arch wire.
9. Repeat steps #4-6 until mandibular attachment nut is fully seated.
10. Repeat steps #2-8 on opposite side.
11. Once installed, activate appliance (continue to the Device Activation instructions).

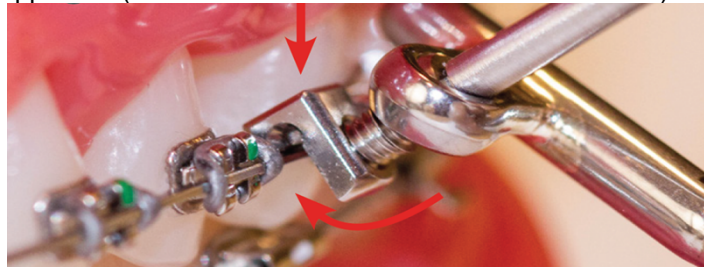


Figure F

Installation using Closed Channel Attachment Nut

NOTE: Installation using the closed channel attachment nut must be done prior to the installation of the arch wire.

1. Engage the magnetic sleeve onto the driver by holding the Hex Head Driver over the magnet with conical chamfer slot facing up. As the driver nears the opening, the magnetic sleeve will seat itself on the driver tip.

NOTE: Prior to installation, the use of a thread adhesive is recommended to address any concerns of the screw loosening or backing out.

2. Slide the left attachment nut on to the patient left side of the maxillary arch wire. Repeat with the right attachment nut on the patient right side.

- **NOTE:** Left and Right closed channel attachment nuts are labeled mesially with an “L” and “R” respectively. (Figure G)

3. Size and cut the distal ends of the maxillary arch wire once the nuts are placed.

4. Feed the wire into the patient's upper molar tubes and ligate the maxillary brackets on the wire. Ensure the nuts are located mesial to the first molar.

5. On the mandibular arch wire, repeat steps #2-4, making sure nuts are located distal to the canines. (Figure H)

6. Remove the left side PowerScope arm from packaging **and, if applicable, remove any pre-installed open channel nuts.**

7. Attach the posterior of the PowerScope arm to the maxillary closed channel nut by turning screws distally until tight.

8. Repeat steps 6 and 7 for the right side.

9. Attach the anterior of the PowerScope arm to the mandibular closed channel nut.

- **NOTE:** If utilizing open channel nuts on the mandibular wire, follow steps in the Installation using Open Channel Attachment Nut section.

10. Once installed, activate appliance (continue to the Device Activation instructions).

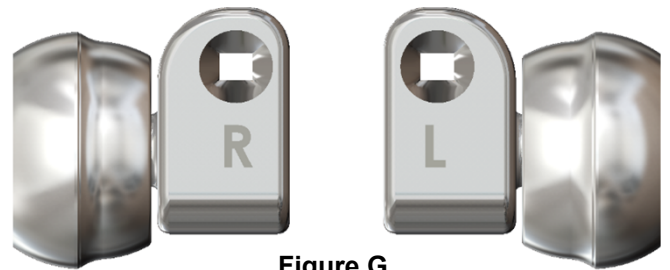


Figure G

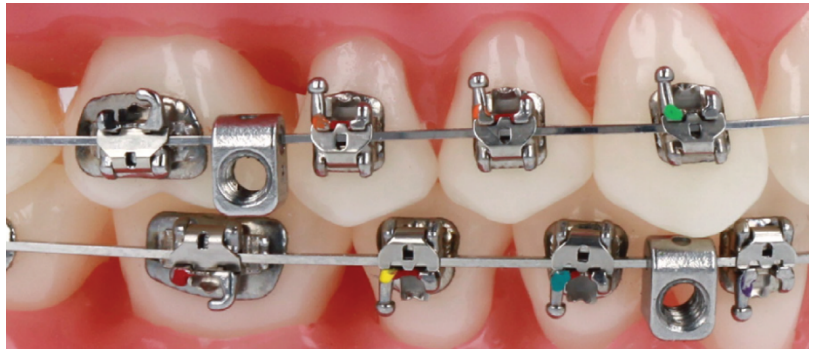


Figure H

Device Activation

NOTE: Crimpable shims may be used as needed for the activation of the appliance during treatment. (Figure I)

1. Determine the appropriate shim size(s) needed (1mm, 2mm, or 3mm) and set aside.
2. Using a Mathieu or Weingart Instrument, grab one of the shims.
3. Have the patient open their mouth to expose the rod. Slightly crimp the selected shim(s) onto the rod next to the anterior nut. **CAUTION:** Avoid overactivation of the PowerScope appliance.
4. Repeat this process on the opposite side PowerScope.
 - **NOTE:** Lengths of shims from side to side may be different as determined by the doctor.

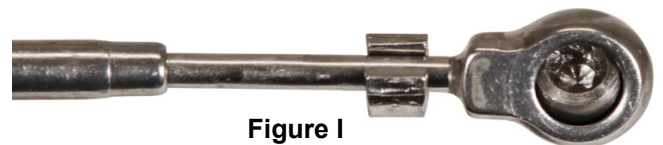


Figure I



Figure J – Installed device before adding shims

9. STORAGE

There are no storage or transport conditions that negatively affect the product or medical device except for harsh or rough handling which may cause mechanical damage.

10. DISPOSAL

PowerScope Appliances are single use only devices. Dispose of immediately after first use. Disposal should follow local, state, and/or federal guidelines.

11. SERIOUS INCIDENT REPORTING SECTION

If a serious incident occurs during the use of this device, or as a result of its use, please report it to the manufacturer and/or the competent authority of the country where the user and/or patient is located.

12. PAPER COPY REQUEST

A paper copy of this IFU can be provided upon request. To request, please reach out to the American Orthodontics team at regulatory@americanortho.com.

13. REGULATORY INFORMATION

	MANUFACTURER		MANUFACTURED DATE
	EC REP		NOT STERILIZED
	CE MARK		RX ONLY
	MEDICAL DEVICE		MR UNSAFE
	REF NUMBER		LOT NUMBER
	INTENDED FOR SINGLE USE ONLY; DO NOT REUSE		CONSULT ELECTRONIC INSTRUCTIONS FOR USE
	WARNING: PRODUCT CONTAINS CHROMIUM-NICKEL; KEEP AWAY FROM PATIENTS WITH A NICKEL ALLERGY		