



General Descriptions:

Orthodontic wire devices are used for the leveling and alignment of dental anatomy, in conjunction with a bracket system which is affixed to the teeth of a patient in an orthodontic clinical setting. Orthodontic Wire Devices consist of Arch Wires, Ligature Ties, Retainer Wire, Auxiliaries, and Coil Springs.

Indications For Use:

Orthodontic wire devices are used for the leveling and alignment of dental anatomy, in conjunction with a bracket system in treatment of patients in age from adolescence thru adulthood, based on doctor’s assessment. These devices are intended to be prescribed and used only by Dentists and Orthodontists.

Use of Product:

The dental professional makes a determination on the appropriate devices, material cross sections, and material types, for each unique patient treatment to be performed. The dental professional knows which devices to use at each stage of patient treatment.



Article Number, and Product Description:

Refer to individual product label for article number, and product description.



Indicates the manufacturers batch code so that the batch or lot can be identified.

Information about Material Composition:

For detailed information about material composition, refer to Acme Monaco’s website or sales literature. Website: www.acmemonaco.com



Warning:

Orthodontic wire devices are intended for Single Use Only. Reuse of an Orthodontic wire device may impair product performance and present risk of patient injury.



Warning:

Orthodontic wire devices are sold non-sterile.



Warning:

This product may contain nickel and/or chromium (refer to product specific labeling). A small percentage of the population is known to be allergic to nickel and/or chromium. For patients with known allergies, select devices which will not provoke an allergic response. If an allergic reaction occurs, immediately remove the device.



Warning:

Cancer and Reproductive harm. For more information go to www.P65Warnings.ca.gov

Storage and Handling:

Orthodontic Wire Devices are sold non-sterile in single packs or bulk packaged. No special storage conditions are required. The product can be stored in the provided packaging. Avoid forceful handling of product to prevent distortion and or damage to the product packaging. Where device packaging has been compromised and/or devices are damaged, they are not to be used.



Instructions for Use (IFU) – Orthodontic Wire Devices

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General Information:

There is no information available which would preclude the use of commonly available oral healthcare products.

Chewing of hard foods can cause a device or related appliance to break, come off or loosen.

Some sports may cause damage to an orthodontic wire device and/or related appliance, and which may present a risk of harm in the event of certain sports related injuries. Consult with an orthodontic specialist for recommended safeguards.

Orthodontic Wire Devices have not been evaluated for compatibility in an MRI environment. Always inform MRI or other radiology staff prior to the procedure so that proper action can be taken.

Additional Information: Refer to the Acme Monaco website or sales literature for device configurations, materials, material cross sections, and product performance data. Website: www.acmemonaco.com



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