# INSTRUCTIONS FOR USE – Protraction Facemask

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

## 1. IDENTIFICATION OF THE COMPANY

| | | |
|---|---|---|
| | American Orthodontics<br>3524 Washington Avenue<br>Sheboygan, WI 53081 USA | **24 HR EMERGENCY TELEPHONE NUMBER**<br>+1 920 457 5051 |
| EC REP | MT Promedt Consulting GmbH<br>**Ernst-Heckel-Straße 7**<br>66386 St. Ingbert<br>Germany | **Telephone for Information**<br>+1 920 457 5051 |
| CE | www.americanortho.com/resources/instructionsfor-use/ | |

## 2. IDENTIFICATION OF THE PRODUCT

**Product Name: Protraction Facemask**
**Product Description: Orthodontic Class III Correction Device**

## 3. INDICATIONS FOR USE

Protraction Facemask is to be prescribed only by licensed dental professional and/or orthodontic professionals to patients during orthodontic treatment.
Protraction Facemasks are used during orthodontic treatment to correct Class III malocclusions in patients by attaching elastics intraorally from the facemask bar to either bracket or band hook on the upper arch.
Protraction Facemask is indicated for repeated use in patients during orthodontic treatment Class III malocclusion correcting.

## 4. CONTRAINDICATIONS & SIDE EFFECTS

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 working sequence of the medical devices.

If a patient has known allergies against or hypersensitivities towards a component of this product, we recommend not to use it or to do so only under strict medical supervision. The clinician should consider known interactions and cross reactions of the product with other materials already in the patient's mouth before using the product. With proper use of this medical device, unwanted side-effects are extremely rare. Reactions of the immune system (allergies) or local discomfort, however, cannot be ruled out completely.

## 5. WARNINGS & PRECAUTIONS

Extreme care should be taken to avoid hitting or pulling the appliance while being worn.
This product contains traces of Nickel, Chromium, and Styrene, chemicals know to the State of California to cause cancer.
Other residual risks include soft tissue soreness, root resorption, and tooth shifting after treatment.
Protraction Facemasks are used during orthodontic treatment to correct Class III malocclusions in patients. Patients should follow the licensed dental and/or orthodontic professional's prescribed time worn.

## 6. INSTRUCTIONS

1. Remove product from packaging.
2. Position the forehead rest near the center of the patient's forehead and tighten the hexagon screw. The metallic support will oscillate for better adaptation and comfort.
3. Place the chin cup on the patient's chin and tighten the hexagon screw to the desired fit.
4. Adjust the crossbar by loosening the hexagon screw and sliding the bar along the vertical main frame. Once the desired position is achieved, tighten the crossbar with the hexagon wrench. The crossbar can also be reversed and placed on the outside of the metal frame for additional elastic force.
5. Elastics can then be placed on both sides of the crossbar and attached intraorally to either bracket or band hook.

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## 7. DISPOSAL

Discard faulty and/or defective facemasks, for example: facemasks with rough, broken, and/or protruding corners or edges. Handle with care for safe use

Disposal of Discarded Product and Packaging:

Ensure safe and proper disposal of used/ discarded product and packaging to avoid adverse effects to environment. The disposal should be in accordance to local law in the country of use.

## 8. SERIOUS INCIDENT REPORTING

If, during the use of this device or as a result of its use, a serious incident has occurred or a product performance issue has been observed, please report it to the manufacturer and/or its authorized representative or your local affiliate, and to your national authority.

## 9. REGULATORY INFORMATION

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| | MANUFACTURER | STERILE | NOT STERILIZED |
| EC REP | EC REP | MD | MEDICAL DEVICE |
| CE | CE MARK | REF | REF NUMBER |
| ℞ ONLY | RX ONLY | LOT | LOT NUMBER |
| Cr Ni | Warning: Product contains chromium-nickel; keep away from patients with a nickel allergy | | CONSULT INSTRUCTIONS FOR USE |