



# Headgear

## **Intended Use**

Intended to be used in orthodontic treatment of natural teeth.

## **Indications for Use**

Head Gear devices are strictly intended for orthodontic treatment. Treatment as well as any additional procedures should be defined by the appropriate clinician.

## **Contraindications**

Head Gear devices are contraindicated for use outside of orthodontics and not by licensed orthodontists.

## **⚠ Warnings**

Instruct patients to never wear headgear while running, playing sports or engaging in other vigorous activities. Headgear should only be worn during inactive periods, such as reading or television time, homework or sleeping. Never pull, or let anyone else pull on the headgear. Your facebow and headgear are not toys. If worn or removed carelessly, they can cause cuts to the inside of the mouth, poke the face, or cause serious injuries to the eyes, including loss of vision. It's important that all directions for safe use of your headgear be followed carefully

## **Precautions**

Not properly utilizing head gear devices, as dictated by the instructions, can lead to unintended effects on the orthodontic treatment.

## **Adverse Reactions**

No known adverse reactions.

## **Step-by-Step Patient Instruction**

### **PUTTING ON HEADGEAR**

1. On headgear with the neck-strap latch, unlatch the headgear so that the two halves hang freely from each of the outer facebow arms. Hold the facebow so that it is right side up, and position the inner wire arms inside the mouth.

2. Pointing the inner wire arms upward slightly, get one facebow arm, then the other just started in the tubes on the upper molar bands.
3. With both arms barely inserted in the tubes, simultaneously raise the front part of the facebow and push it gently until both inner arms slide back and into the tubes. The facebow is now properly in place.
4. Bring neckpad around to the back of the neck. Insert facebow arms into plastic strap in desired position.

#### REMOVING THE HEADGEAR

1. Hold the facebow firmly in place with one hand. Do not pull it, or attempt to pull it out of your mouth.
2. Unlatch the headgear from facebow by removing facebow arms from plastic strap. On headgear models with the neck-strap latch, unlatch by pinching the clasp until it releases.
3. Slowly remove the facebow from the molar tubes as follows:
4. Place the thumb and first finger of both hands on the thick, front part of the facebow. Do not use just one hand or grasp the facebow on the outer arms.
5. Gently wiggle the facebow side to side and pull slowly toward the front. Do not wiggle the facebow up and down, or you might loosen the bands cemented to the teeth.
6. Store the entire headgear in the case provided.

#### **Warranty and Limited Remedy**

1. Manufacturer warrants that this product is free from defects in materials and manufacture
2. Manufacturer's sole obligation and customer's sole remedy in the event of a claimed defect shall be limited to replacement of merchandise or refund of the purchase price. All implied warranties, including implied warranties of merchantability or fitness for any particular purpose or use are disclaimed.

#### **Limitation of Liability**

3. Except where prohibited by law, Manufacturer will not be liable for any loss or damages arising from this product, whether direct, indirect, special, incidental, or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability. This limitation does not apply to third party personal injury claims.



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