

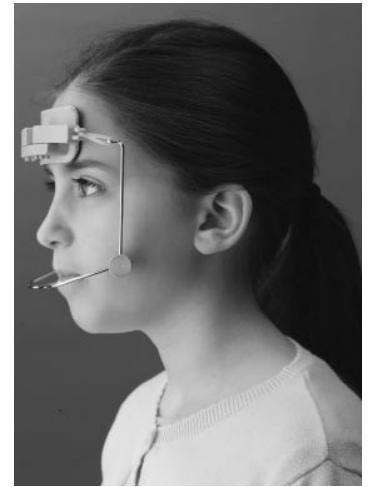


# The Keles Face Mask

Manufactured exclusively by Great Lakes Orthodontics

## Clinical Instructions

The Keles Face Mask, an effective device to correct Class III malocclusion, overcomes the adverse effects and limitations of current designs by rotating the maxilla in a downward and forward direction, which assists in correcting anterior open bites. This is accomplished using a design that produces forces above the center of resistance of the maxilla and parallel to the Frankfort horizontal plane. In addition, the extraoral headgear design provides two independent adjustments (forehead width and horizontal/vertical dimensions) that allow this device to be customized to each patient.



XKFM  
Patent Pending

## Clinical Application

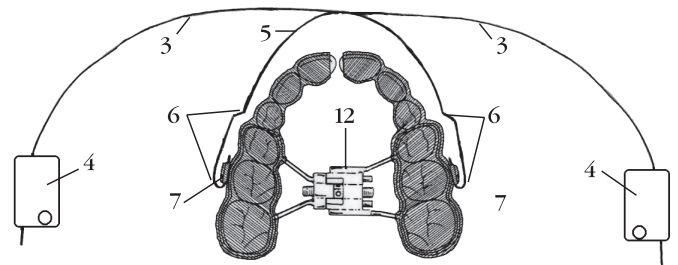
### Intraoral Adjustment

Intraorally (**Figure 1**), the Keles Face Mask connects to the teeth via a banded or bonded acrylic splint (rapid palatal expander-RPE) appliance (**12**). The intraoral appliance (RPE) is secured to the patient's dentition with an adhesive (i.e. fluoride releasing glass ionomer cement-3M/Unitek) by the clinician.

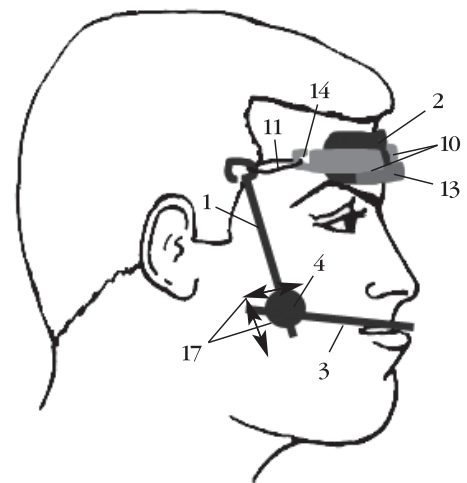
The "U" shaped intraoral bow (**5**), which is connected to the front horizontal bar (**3**), is positioned 10mm in front of the anterior dentition. The intraoral portion of the facebow is bent (**6**) by the clinician to insert through the distal end of tubes (**7**) on the right and left sides of the dental appliance.

### Extraoral Adjustment

The extraoral wire framework (**Figure 2**) consists of two main parts, the vertical bar (**1**) with distal hooks that attach to the forehead rest (**2**) via elastic elements (**11**), and a front horizontal bar (**3**). The horizontal bar extends backwards towards the ear. From there, adjustment blocks (**4**) provide customization to each patient joining the horizontal to vertical bars. Allen screws are used to fix the location of the adjustment blocks.



**Figure 1** Intraoral RPE appliance with Keles Face Mask. (3) Horizontal bar. (4) Adjustment blocks. (5) Intraoral bow. (6) Chairside bends to customize intraoral bow to tubes of RPE appliance. (7) Tubes to connect RPE appliance to Keles Face Mask. (12) RPE appliance.



**Figure 2** Extraoral components of Keles Face Mask on patient. (1) Vertical bar with elastic hook. (2, 10, 13, 14) Adjustable forehead components. (3) Horizontal bar. (4,17) Adjustment blocks with Allen screw locks and activation movement. (11) Elastic elements.

## Direction of Force Application

An important aspect of the Keles Face Mask involves the direction of force application (**Figure 3**). The level of force application is positioned above the center of resistance (**8**) of the maxilla and parallel to the Frankfort horizontal plane (**9**). This force-moment system design of the Keles Face Mask eliminates the adverse effects of conventional face masks such as molar extrusion, downward and backward rotation of the mandible, lower facial height increase, as well as unknown effects on the TMJ.

A fully adjustable forehead assembly (**Figure 4**) is customized to the patient, by the clinician, providing a horizontal force at the forehead region. This assembly consists of a forehead pad (**2**) and a series of referencing slots (**10**) designed to receive the pin locks (**15**) of two adjustment blocks (**13**). Forehead adjustments are accomplished by selecting the best position for the adjustable forehead component pin locks in the desired referencing slots. **Do not snap pins in place before final position is determined.** The hooks (**14**) of the forehead component should be positioned wide enough to prevent elastics (**11**) from irritating forehead tissues. The hooks of the forehead pad should be approximately 3cm anterior to the hook on the vertical wire (**1**) of the facebow. To reposition forehead component *after* locking component pins in place, pinch the locking tips together and push upwards.

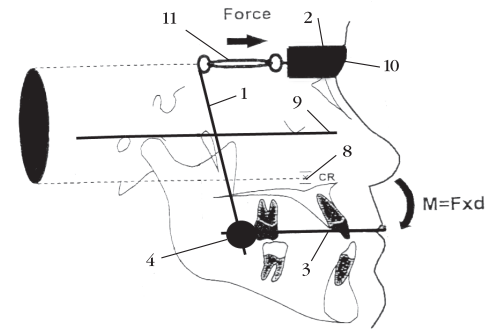
Elastic elements (**11**) (1/2" x 16 oz.), generating approximately 300-800 grams of force, connect the hooks (**14**) of the head pad assembly to the vertical hooks (**1**) on the wire facebow near the area of the temporal bone. This provides the force necessary for treatment. **DO NOT lock arms in place until correct position is established.** Prior to connecting elastics, make sure the screw of the adjustment blocks (**4**) are firmly holding the vertical (**1**) and horizontal (**3**) bars on right and left sides of the patient. **Once final alignment is achieved, cut excess bar ends protruding through the adjustment blocks.** Cut the bars flush with the block using a diamond wheel and smooth metal areas with a rubber disc.

## Appliance Management

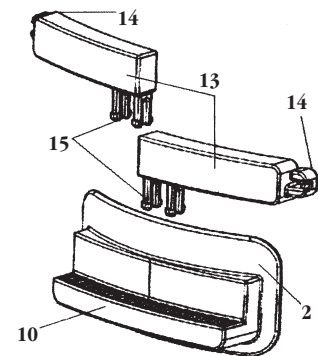
The intraoral appliance is activated ¼ turn (one activation) twice daily for the first 5 days. The patient will then wear the Keles Face Mask for at least 14 hours daily, including sleep for the next six months.

Patients should secure the Keles Face Mask into the tubes of the intraoral appliance first, and then connect the forehead unit to the hook on the vertical bars with the elastics. To remove the mask, patients are instructed to disengage one side of the elastic band on the forehead rest from the vertical wire bar. Holding the horizontal bar, push it back into the mouth until the bow is disengaged from the tube on the molar band, approx. ¼ inch. Lower the facebow and remove from mouth.

After six months, records are taken (cephalometric x-ray, intraoral & extraoral photographs). Based on the amount of correction that has occurred, treatment is terminated or continued until desired correction is accomplished.



**Figure 3** Direction of Force Application (1) Vertical bar with elastic hook. (2, 10) Adjustable forehead components. (3) Horizontal bar. (4) Adjustment blocks with Allen screw locks. (8) Center of resistance of maxilla. (9) Frankfort horizontal plane. (11) Elastic elements.



**Figure 4** Adjustable forehead pad of Keles Face Mask. (2) Forehead pad that is referenced to the patients forehead. (10) Series of referencing slots designed to receive the pin locks of the adjustable forehead component. (13) Adjustable forehead component with pin locks and elastic hooks. (14) Elastic hooks. (15) Pin locks.



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