

PROPOSED LABELING FOR THE DEVICE

THE MOSES ELITE APPLIANCE



Clinician Instruction Booklet

Caution: *Federal (U.S.) law restricts this device to sale by or on the written order of a licensed physician or dentist*

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INDICATIONS FOR USE

The Moses Elite appliance is intended for use on adult patients 18 years of age and older as an aid for the reduction and/or alleviation of mild to moderate snoring and obstructive sleep apnea.

IMPORTANT SAFEGUARDS

SAVE THESE INSTRUCTIONS

The following words in this manual have special significance:

WARNING: means there is a possibility of injury to your self

NOTE: indicates points of particular interest for more efficient and convenient operation

CONTRINDICATIONS: This device is contraindicated for patients with loose teeth, loose dental work, numerous missing teeth, dentures or other oral conditions that would be adversely affected by wearing an intraoral dental device which maintains the jaws in a protrusive jaw position. The Moses Elite appliance is also contraindicated for patients who have central apnea, severe respiratory disorders, or are under eighteen years of age.

PRODUCT DESCRIPTION

The Moses Elite appliance is a dental device in the category of mandibular advancement device. It is laboratory fabricated to the patient's mouth based on individual impressions of the patient's dental arches and a specific formula for registering the prescribed bite. It is fit to the patient by a trained dentist.

The device characteristics of The Moses Elite appliance are as follows:

- A lower acrylic and vinyl component, customized processed to fit over the mandibular teeth
- An upper heat-formed retainer that fits over all maxillary teeth
- The prescribed protrusive jaw position is maintained by the labial flanges and by impressions of the upper arch retainer processed into the lower component
- By supporting the mandible in a protrusive jaw position, The Moses Elite appliance passively advances the tongue
- There is an open area between the upper and lower cuspids that is approximately 2-8 mm vertically.
- This open area enables a forward tongue position against the lips. If the mouth is closed, the patient is nasally competent and nose breathing during sleep.
- This open area facilitates mouth breathing if the patient is nasally incompetent and sleeps with their mouth open.
- Opening and closing movements are permitted with the appliance in place
- By deterring collapse of the tongue on the airway when the patient is asleep The Moses Elite appliance treats mild to moderate obstructive sleep apnea.

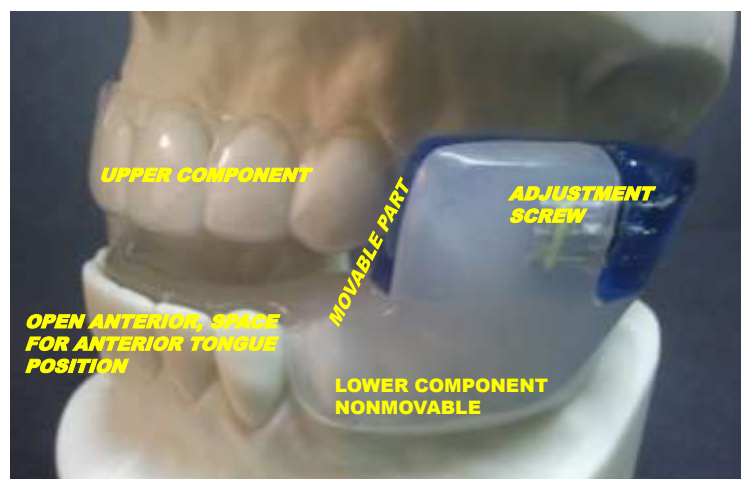
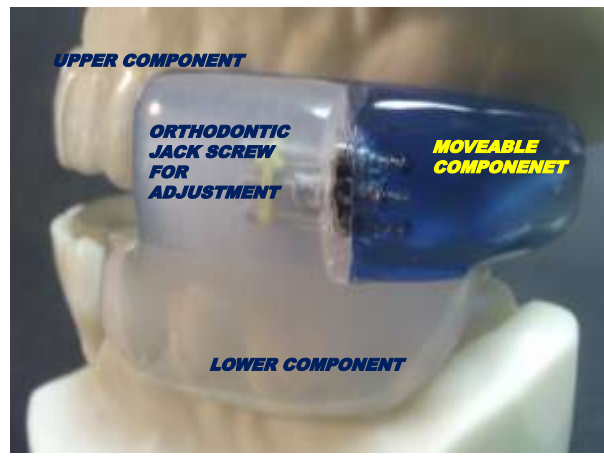
Material Composition

- Lower component – polymethylmethacrylate and ethylene propylene
- *Stainless steel orthodontic jack screw, making the appliance adjustable anteroposteriorly*
- Upper component – polypropylene/ethylene copolymer

All are materials ADA, CAS, EU and ANSI approved as safe and biocompatible.

NOTE: Read all instructions before using The Moses Elite appliance.

LABELLED PHOTOS OF THE MOSES ELITE APPLIANCE



THE MOSES ELITE APPLIANCE, FRONT AND BACK VIEWS



WARNINGS

- This device is intended for use on adult patients 18 years of age and older as an aid for the reduction and/or alleviation of snoring and mild to moderate obstructive sleep apnea. If symptoms of breathing difficulty or other respiratory disorders exist or persist with or without use of The Moses Elite appliance patient should contact you immediately.
- Patient may experience soreness or discomfort in their jaw or teeth. If the discomfort persists, the patient should contact you.
- In the morning the patient may sense a change in their bite. This sensation should disappear within one hour. If it continues for more than two hours, instruct patient to chew a piece of sugarless gum for 15-30 minutes or until their back teeth are meeting. If they cannot get back to their old bite and experience pain or discomfort trying, they should contact you.
- Under normal circumstances the patient should **not** experience obstruction of oral breathing with The Moses Elite appliance in their mouth. If the patient experiences breathing difficulty with The Moses Elite appliance in place, the patient should consult their sleep physician.
- The patient should return to you, the dentist who fit the Moses Elite appliance every six months for a re-evaluation. If the appliance becomes loose, damaged or does not fit properly at any time, the patient should contact you.

POSSIBLE SIDE EFFECTS

There are possible side effects associated with use of The Moses Elite appliance. These side effects are not common. If the patient experiences any of the following side effects they should contact you, the doctor who prescribed The Moses Elite appliance.

- Slight tooth or gingival discomfort, due to pressure from the appliance
- Excessive salivation initially. This will improve as the patient becomes accustomed to wearing The Moses Elite appliance.
- Slight jaw soreness or tightness initially that will ease with wearing the appliance
- Morning sensation of bite change. This will subside between 30 minutes and 2 hours after The Moses Elite appliance is removed. If this perceived bite change persists longer, chewing a piece of sugarless gum will usually correct this problem. If it does not, the patient should contact you, the doctor who prescribed and fitted The Moses Elite appliance.
- Removing The Moses Elite appliance while the patient is asleep. This usually stops after an adjustment period.
- Movement of teeth. Both the upper and lower are retainers. This would be an unusual response. Should it occur, the patient should contact you, the prescribing doctor.
- Permanent bite change. This should not occur with a timely call to you, the prescribing doctor when the patient first notices this symptom.
- Allergic or toxic reaction to the materials in the appliance. If this occurs, the patient should discontinue use and call you, the prescribing doctor immediately.

Prior to prescribing The Moses Elite appliance to a patient, the dentist should consider the medical history of the patient including history of asthma, breathing or respiratory disorders or other relevant health problems. If a concern exists, the patient should be referred to the appropriate healthcare provider before prescribing the device.

ORAL APPLIANCE PROTOCOL

I) Medical Assessment

- A) Dentist/other, on the basis of a screening refers patient to sleep specialist
- B) Consultation, objective testing and diagnosis by a sleep specialist
- C) CPAP is usually tried and the patient has experienced CPAP failure or is CPAP intolerant
- D) Patient has mild to moderate obstructive sleep apnea and an oral appliance is indicated in the expert opinion of the sleep expert
- E) Referral for oral appliance – written referral letter to dentist with diagnosis expressed as part of a treatment plan, plus interpretation and summary printout of sleep study.

II) Dental Assessment

- A) History – medical and dental
- B) Examination by dentist
- C) Consultation and treatment plan
- D) Possible referral to original referrer or other medical specialist
- E) Written report

(III) Clinical Standards

The American Academy of Sleep Medicine has established as criteria for oral appliances to define successful treatment of obstructive sleep apnea syndrome:

- A) post-treatment Apnea-Hypopnea Index (AHI) 10 or below
- B) post-treatment AHI reduced by at least 50% from baseline AHI
- C) both criteria are met

- (IV) Clinical procedure
 - A) Baseline objective testing - polysomnogram
 - B) Appliance design, fabrication, delivery
 - C) Patient signs informed consent, given appliance instructions and patient exercise regimen
 - D) Appliance adjustments
 - E) Completion of treatment, written letter to sleep specialist explaining results, and recommendation for follow-up polysomnogram

- (V) Periodic Evaluation
 - A) Six month recalls for two years following appliance fabrication to check effectiveness, fit, TMJ status and check for possible tooth shifting or bite change
 - B) Annual recall after two year period
 - C) A caries screening is recommended at all recalls

If neither clinical standard for success as described in (III) above is met and The Moses Elite has been fully adjusted, the patient protocol is as follows:

- 1) The old disinfected bite registration with the midlines and protrusive positions marked on the anterior segment is broken apart so the posterior segments are detached
- 2) The anterior segment is inserted and the patient is asked to protrude the lower jaw as far as possible without causing pain. If greater protrusion is possible or greater vertical dimension is possible (1mm or more), a new position is recorded. A new lower component is then made from the old polyvinyl impressions and the new bite.

CLINICIAN NOTES:

VERTICAL: The correct vertical position at which The Moses Elite appliance should be made is the maximum height the patient can tolerate and still comfortably close the lips. This usually does not change.

PROTRUSIVE: The correct horizontal bite position is the maximum painless position the patient can maintain. This position is different than "maximum comfortable protrusive". Patients will often assume a comfortable position that is less than the maximum painless protrusive. When the bite is being recorded the patient generates muscle forces to hold the bite material in place while it sets.

Once the material is set or when the appliance is inserted that much muscle force is not generated. The appliance holds the patient's jaws in position.

MIDLINE DETERMINATION: The recorded bite is usually based on the upper incisor midline over the lower incisor midline. An alternative is upper arch centered directly over the lower arch. Often these are the same. When both alternatives do not coincide, the patient's comfort decides the choice. If the patient complains of unilateral pain on wearing The Moses Elite appliance, it may be necessary to re-record the bite and remake the lower component in a corrected lateral position.

IMPRESSION TECHNIQUE FOR THE MOSES ELITE APPLIANCE

1. **SEND IMPRESSIONS**, NOT MODELS. Impressions are needed so the lab can make separate models for the upper vacuum-formed retainer and the device itself
2. Take full extension impressions into maxillary anterior vestibule and mandibular sublingual area
 - a. Full mandibular lingual extension is necessary because we want to enable our device to discourage low tongue position, and stimulate a high tongue position in the roof of the mouth
 - b. Dentaurum, O-trays are preferred. Enlarging the retention holes in the impression tray and use of rubber base adhesive is also recommended
3. Use of a polyvinyl rubber such as Discus Splash is strongly recommended for impressions.
4. **THE BITE** – Wooden tongue depressors (usually 6" x ¾") are recommended for anterior arch positioning in the bite registration. Cut them with scissors into 2-2.5 inch segments. 3, 4, or 5 (on rare occasion 6) segments are used. Cut and further trim with a scissors so the wooden tongue depressors fit the anterior arch form.
5. The trimmed tongue depressors are placed for try-in between upper and lower teeth in the area of the incisors to the bicuspid and must not interfere with lip closure
6. The correct number of tongue blades is the maximum number the patient can fit, close on and comfortably seal the lips – in an **UNSTRAINED** lip closure. *Check lip muscles and mentalis and query the patient.* "Can you comfortably keep your lips together or is that a strain to keep your lips closed?"
7. With the first mixing tip on the bite registration extruder gun
 - a. Tack 2 tongue blades together with a dot of bite registration paste between them
 - b. Spread bite registration paste on the surface of one blade and insert behind the edge of the maxillary incisors.
 - c. Immediately tack the remaining blades together with small dots of bite registration material, spread bite registration material all over one surface insert on mandibular incisors.
 - d. Instruct the patient to bite into an edge-to-edge bite
8. Mark the midlines with a wax pencil.
9. Instruct the patient to slide the mandible forward to the maximum protrusive position that is not painful. *Using the words, "maximum comfortable protrusive" does not imply the same thing and they do not usually stretch as far.*

10. Mark a line on the tongue blades between the upper and lower segments in this position.
11. With the patient looking in a mirror instruct them to hold that exact position for 1 ½ minutes.
12. Extrude the bite registration paste, using a new mixing tip, between the posterior segments and overlap the front segment to hold everything together in a rigid one piece bite.
13. Trim the bite registration with a sharp scalpel removing what was soft tissue. Leave only the impressions of hard tissue in the bite.
14. Discus Dental's Vanilla Mousse is highly recommended as the bite registration material.
15. A good desk scissors is the appropriate tool to cut and trim the wooden tongue depressors in step 4.

CLINICIAN ADJUSTMENT OF THE MOSES ELITE APPLIANCE

Laboratory fabrication of The Moses Elite appliance involves a preliminary step to block out all undercuts (both hard and soft tissue before the acrylic is processed on the lower component. Usually The Moses Elite inserts immediately but occasionally slight adjustment is needed. A colored, disclosing indicator such as Pascal Occlude[®] is sprayed on the interior surfaces where The Moses Elite would contact teeth and tissue. Where there is interference the colored indicator spray shows clear from having been rubbed off. Interferences are removed with a small egg-shaped carbide bur on a slow speed handpiece. It is very important that patients be able to easily and smoothly insert and remove The Moses Elite by themselves. Patients should be carefully queried to make sure the appliance is not irritating their soft tissue before they leave and instructed to come in immediately for adjustment if they develop a sore spot.

The Moses Elite appliance is adjustable by the doctor for anterior mandibular movement. The appliance has two jack screws built in – one on each side. They must both be adjusted together for anterior movement. Each turn of the jack screw from bar to bar advances the mandible approximately 1/4 millimeter. Six additional millimeters of anterior movement is possible.

The starting bite position for The Moses Elite appliance is the maximum comfortable protrusive jaw position. It is recommended that patient comfort be a consideration in further anterior adjustment. As the patient wears The Moses Elite appliance tight muscles may lengthen and ligaments may stretch. The appliance should never be adjusted to a position in which the patient is uncomfortable either wearing it or in the morning after awakening. Results of advancing the mandible anteriorly beyond the initial bite position should be monitored by objective measurement – a full polysomnographic study at a sleep lab.