

MOSES ALPHA 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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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

INDICATIONS: Moses Alpha Appliance is intended for use on adult patients as an aid for the reduction and/or alleviation of snoring and obstructive sleep apnea. Advancement of the mandible and tongue prevents collapse of the patient's tongue on the soft palate and/or oropharyngeal airway.

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. Moses Alpha Appliance is also contraindicated for patients who have central apnea, severe respiratory disorders, or are under eighteen years of age.

PRODUCT DESCRIPTION

Moses Alpha 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 Moses Alpha Appliance are as follows:

- A lower acrylic component, custom 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, Moses Alpha Appliance passively advances the tongue.
- There is an open area between the upper and lower cusps mm vertically that is approximately 3-8 mm vertically. This open area is to facilitate a forward tongue position against the lips.
- Opening and closing movements are permitted with the appliance in place.
- The open anterior design of Moses Alpha Appliance and the prescribed patient exercises facilitate more forward tongue posture in the mouth.
- By deterring collapse of the tongue on the airway when the patient is asleep Moses Alpha Appliance potentially reduces the occurrence of snoring and obstructive sleep apnea

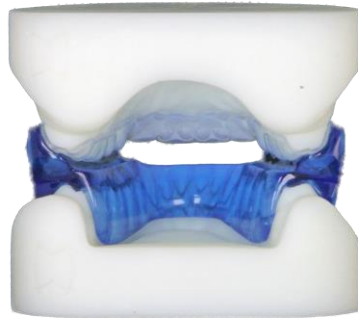
Material Composition

- Lower component – methylmethacrylate
- Upper component – polypropylene/ethylene copolymer

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

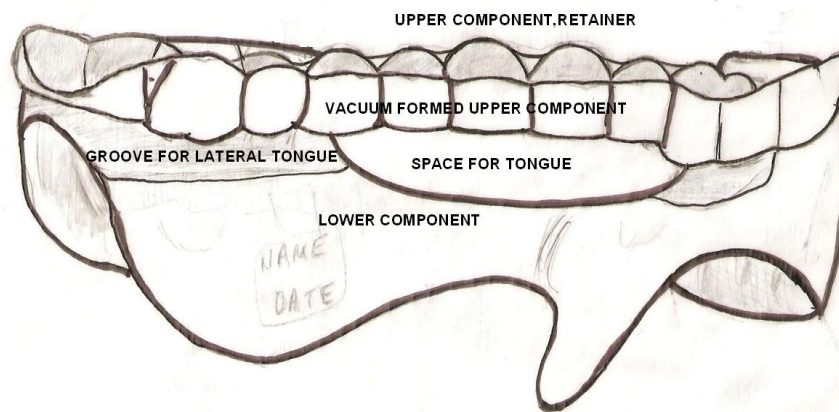
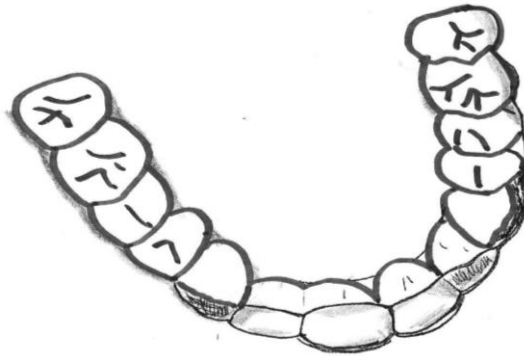
NOTE: Read all instructions before using Moses Alpha Appliance.

PHOTOS OF MOSES ALPHA APPLIANCE



LABELLED DIAGRAMS AND PHOTOS OF MOSES ALPHA APPLIANCE

VACUUM FORMED UPPER COMPONENT



WARNINGS

- This device is intended to reduce or alleviate night-time snoring and obstructive sleep apnea (OSA). If symptoms of breathing difficulty or other respiratory disorders exist or persist with or without use of Moses Alpha Appliance you should contact your doctor immediately.
- You may experience soreness or discomfort in your jaw or teeth. If the discomfort persists, you should contact your doctor.
- In the morning you may sense a change in your bite. This sensation should disappear within one hour. If it continues for more than two hours, you should chew a piece of sugarless gum for 15-30 minutes or until your back teeth are meeting. If you cannot get back to your old bite and experience pain or discomfort trying, contact your doctor.
- Under normal circumstances you should **not** experience obstruction of oral breathing with Moses Alpha Appliance in your mouth. If you do experience breathing difficulty with Moses Alpha Appliance in place, consult with your sleep physician.
- You should return to the doctor who fit you for your Moses Alpha Appliance every six months for a re-evaluation. If the appliance becomes loose, damaged or does not fit properly at any time, contact your doctor for an appointment.

POSSIBLE SIDE EFFECTS

There are possible side effects associated with use of Moses Alpha Appliance. These side effects are not common. If you experience any of the following side effects you should contact you're the doctor who prescribed your Moses Alpha Appliance.

- Slight tooth or gingival discomfort due to pressure form the appliance.
- Excessive salivation initially. This will improve as you become accustomed to wearing Moses Alpha 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 Moses Alpha 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, contact the doctor who prescribed and fitted Moses Alpha Appliance.
- Removing Moses Alpha Appliance while you are 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, contact the prescribing doctor.
- Permanent bite change. This should not occur with a timely call to the prescribing doctor when you first notice this symptom.
- Allergic or toxic reaction to the materials in the appliance. If this occurs, discontinue use and call your prescribing doctor immediately.

DIRECTIONS FOR DAILY USE

Inspect your Moses Alpha Appliance each day prior to use. If you notice any cracks or chips, contact your prescribing doctor.

1. Place the upper component in your mouth first. Use your thumbs to firmly snap it over your upper teeth.
2. Insert the lower component, slide your lower jaw forward until you have engaged both arches in Moses Alpha Appliance
3. Notice that when Moses Alpha Appliance is in place you can drink without removing the appliance.
4. When you remove Moses Alpha Appliance in the morning, remove the lower component first.

WARNING: When the appliance is not in your mouth it should be stored dry in its container and kept in a drawer or medicine cabinet.

If you have pets (dogs or cats) it is a near certainty that they will chew up Moses Alpha Appliance if it is not stored properly.

HEMOCARE INSTRUCTIONS

Each morning after use, clean your Moses Alpha Appliance with a denture cleanser. The recommended cleanser for Moses Alpha Appliance is **Kleenite**. Efferdent, Polident and store brand cleansers are not as good but acceptable.

When you visit your prescribing doctor for your six month appliance check, it is recommended that you bring the appliance with you so the doctor can check your Moses Alpha Appliance and clean it professionally in the ultrasonic cleaner.

You should leave your Moses Alpha Appliance in the denture cleanser for 10 – 15 minutes. Rinse it off and store it dry in its container.

NOTE: Leaving your Moses Alpha Appliance in the denture cleanser for longer periods will not clean it better but may cause it to pick up a yellow discoloration. Discoloration may occur but does not affect the quality or performance of your Moses Alpha Appliance.

WARNING: Eating or drinking high sugar foods before inserting your Moses Alpha Appliance could cause tooth decay and damage your teeth. Should you do this, always brush, floss and rinse before inserting your appliance for the night.

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 CPAP intolerant
 - D) 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

- (IV) Clinical procedure
 - A) Baseline objective testing with an FDA approved Class II ambulatory PSG or other equivalent approved device such as Stardust®, Watch PAT 100®, or MediByte®
 - B) Appliance design, fabrication, delivery and objective testing
 - C) Patient signs informed consent, given appliance instructions and patient exercise regimen
 - D) Appliance adjustments and objective testing
 - E) Completion of treatment, written letter to sleep specialist explaining results with print out of final tests, and recommendation for follow-up PSG

- (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

If neither clinical standard for success as described in (III) above is met, the patient protocol is as follows:

- 1) A new bite is registered
- 2) A new lower component is made

CLINICIAN NOTES:

VERTICAL The correct vertical position at which Moses Alpha 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.

LATERAL 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 Moses Alpha Appliance, it may be necessary to re-record the bite and remake the lower component in a corrected lateral position.

IMPRESSION TECHNIQUE FOR MOSES ALPHA

1. **SEND IMPRESSIONS.** 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. Digital or PVS impressions can be used
3. **THE BITE** – Use 3, 4, or 5 bite shims (on rare occasion 6).
4. The bite shims 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.
5. The correct number of bite shims 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?”
6. Position the bite shims in the desired position and extrude bite registration material to record the bite.
7. Trim the bite registration with a sharp scalpel removing what was soft tissue. Leave only the impressions of hard tissue in the bite.