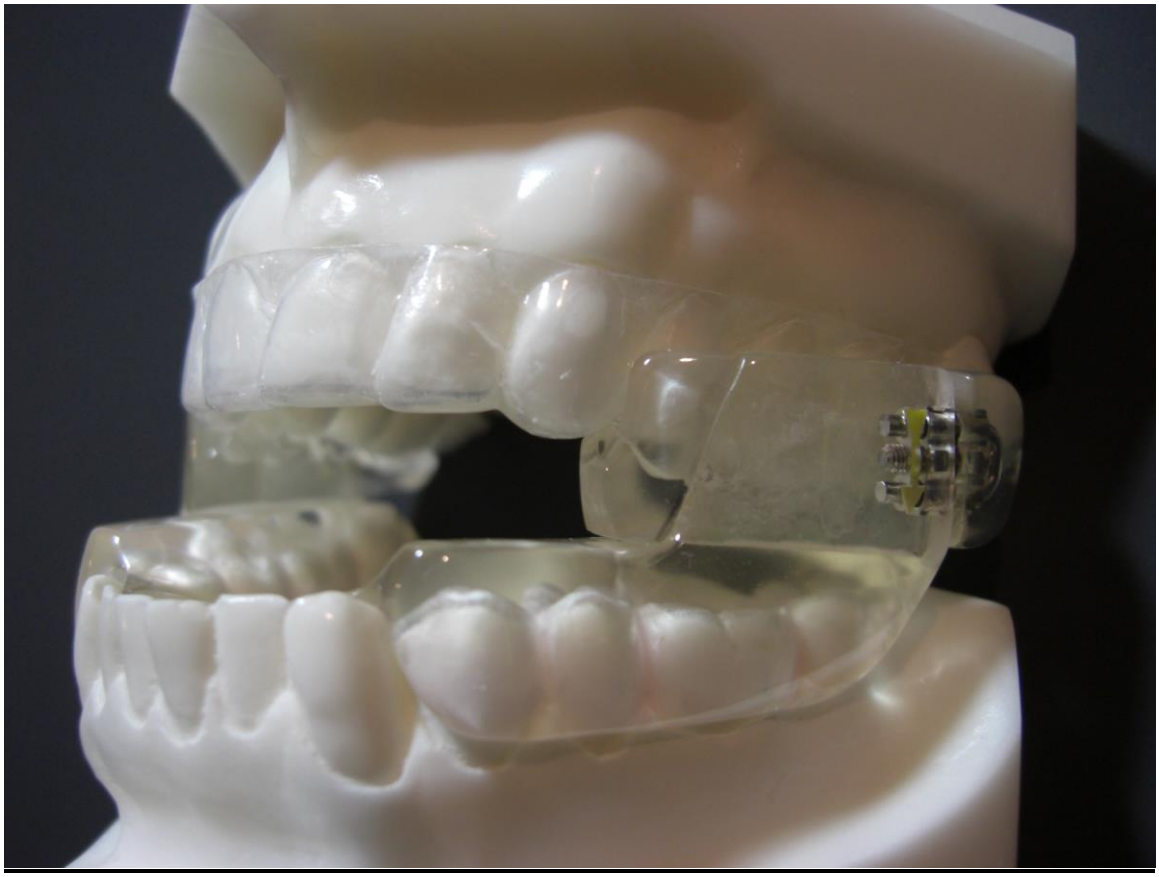
THE MOSES APPLIANCE



Clinical Instruction Booklet

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

TABLE OF CONTENTS

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

PRODUCT DESCRIPTION

The Moses 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 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, the Moses Appliance passively advances the tongue
- There is an open area between the upper and lower cuspids mm vertically that is approximately 6-8 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 the Moses 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 the Moses Appliance potentially reduces the occurrence of snoring and obstructive sleep apnea

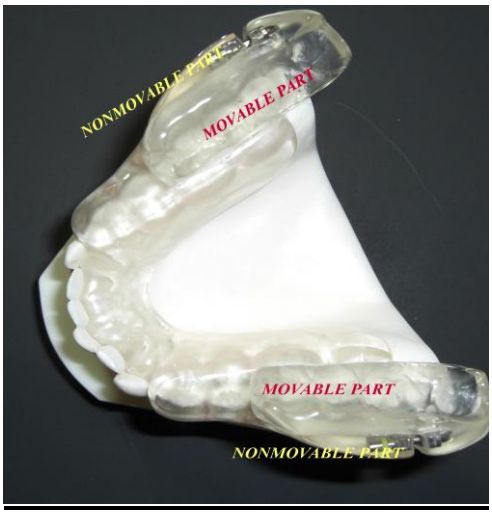
Material Composition

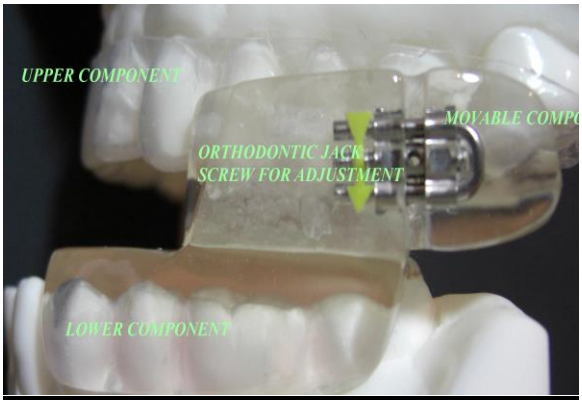
- Lower component – methylmethacrylate
- *Stainless steel orthodontic jack screw*, *making the appliance adjustable anteroposteriorly*
- Upper component – polypropylene/ethylene copolymer

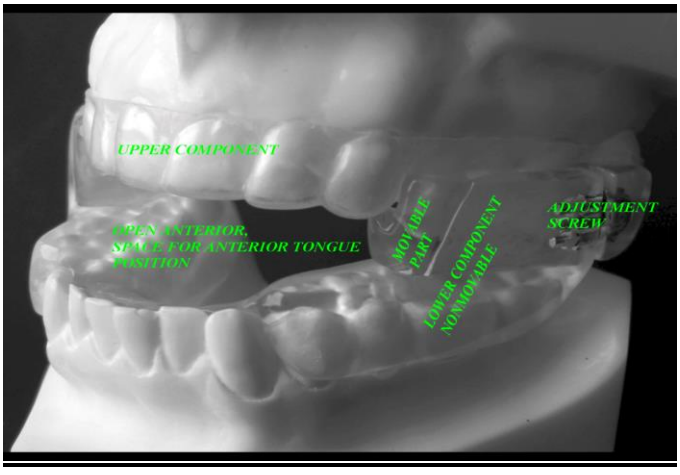
All are materials ADA, CAS, EU and ANSI approved as safe and biocompatible.

NOTE: Read all instructions before using the Moses Appliance.

LABELLED DIAGRAMS AND PHOTOS OF THE MOSES APPLIANCE

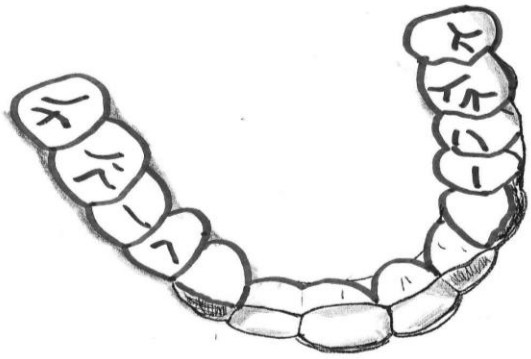


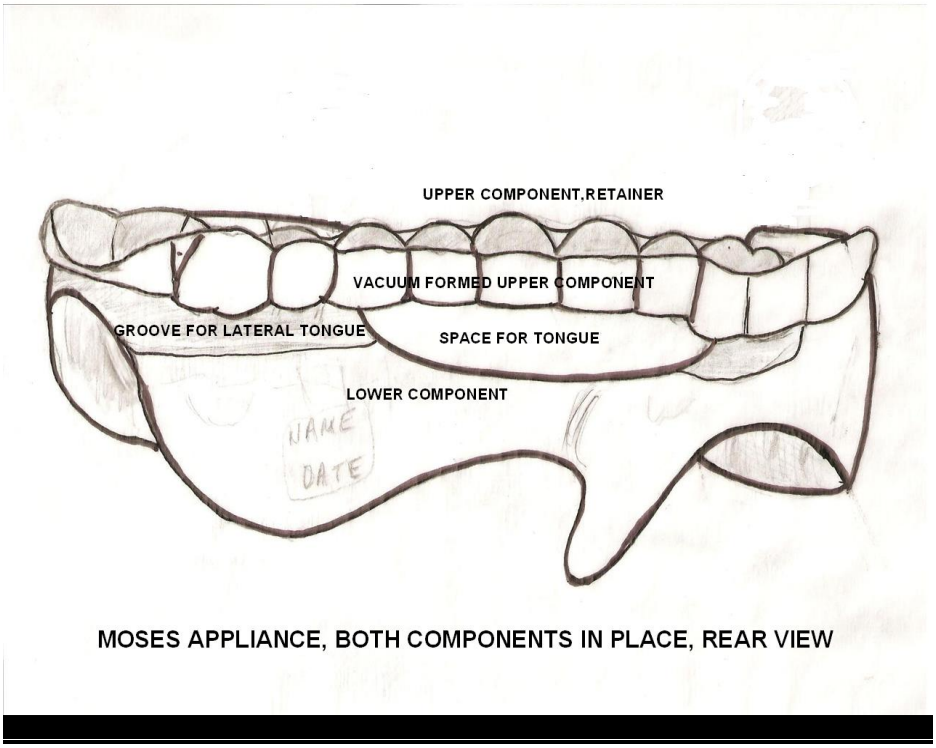




LABELLED DIAGRAMS AND PHOTOS OF THE MOSES APPLIANCE

VACUUM FORMED UPPER COMPONENT





MOSES APPLIANCE, BOTH COMPONENTS IN PLACE, REAR VIEW

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 the Moses 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 you're 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 the Moses Appliance in your mouth. If you do experience breathing difficulty with the Moses Appliance in place, consult with your sleep physician.
- You should return to the doctor who fit you for your Moses 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 the Moses 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 Appliance.

- Slight tooth or gingival discomfort due to pressure form the appliance.
- Excessive salivation initially. This will improve as you become accustomed to wearing the Moses 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 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 the Moses Appliance.
- Removing the Moses 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 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 the Moses Appliance
3. Notice that when the Moses Appliance is in place you can drink without removing the appliance.
4. When you remove the Moses 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 the Moses Appliance if it is not stored properly.**

HOMECARE INSTRUCTIONS

Each morning after use, clean your Moses Appliance with a denture cleanser. The recommended cleanser for the Moses 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 Appliance and clean it professionally in the ultrasonic cleaner.

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

NOTE: Leaving your Moses 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 Appliance.

WARNING: Eating or drinking high sugar foods before inserting your Moses 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.

DAILY PATIENT EXERCISES

PATIENT INSTRUCTIONS FOR USE OF A "MOSES"

These exercises should be started 15 – 20 minutes before bed time.

- Insert the Moses Appliance in your mouth, upper component first, lower component second.
- Spread lip balm heavily on your lips
- Can you comfortably close (seal) your lips with the appliance in place? Sleeping with your lips together is important.
- With your lips closed create and maintain a suction in your mouth.
- Confirm that you feel your tongue being pulled forward into the space between the upper and lower.
- Feel the tip of your tongue touching your lips.
- Experience the sensation of your tongue on the plastic retainer covering the edge of your upper front teeth.
- Notice the feeling of your tongue against the cut edge of the upper retainer behind the front teeth.
- Experience the suction holding your tongue against the roof of your mouth and feel the rugae (or ridges).
- Push your tongue against the palatal rugae for three seconds. Now create additional suction of your tongue against palatal rugae. Hold suction for three seconds. Push – suck, push –
- suck for a total of three cycles.
- Note the feeling of your tongue against the edges of your lower front teeth.
- Feel the bottom of your tongue resting on the plastic appliance behind your lower front teeth.
- Take note of feeling the sides of your tongue in the groove created between the upper retainer and the lower back teeth.
- Repeat this series of exercises two to three times before going to sleep and try and maintain the suction and do deep breathing as you fall asleep.

Guimaraes KC, Drager LF, Genta PR, Marcondes BF, Lorenzi-Filho G. Effects of oropharyngeal exercises on patients with moderate obstructive sleep apnea syndrome. Am J Respir Crit Care Med Vol 179. pp 962-966, 2009

PALATAL RUGAE

The mucosa of the hard palate in humans is characterized by dense, stratified squamous epithelium arranged in two to eight lateral thickened ridges called rugae. The rugae facilitate food transport through the oral cavity, affect proper positioning of the tongue in the roof of the mouth, aid the tongue in crushing food, proprioception and swallowing and have immunoreactive properties. In children habitual palatal positioning of the tongue facilitates normal maxillary development, nasal breathing, proper swallowing and creates room for the teeth to erupt into proper occlusion.

A variety of specialized innervation has been found in the stratified squamous epithelium and the connective tissue beneath the rugae of the hard palate. Sensory nerve fibers are found most abundantly in the first or most anterior rugae and in progressively decreasing numbers in posterior rugae. Several varieties of receptors categorized together as lamellated corpuscles have been reported. Specifically, Ruffini Corpuscles, Meissner's Corpuscles, Pacinian Corpuscles and Merkel cells have all been demonstrated in the tissue of the *rugae palatini.* Each type has been shown to provide distinct proprioceptive feedback for sensorimotor control. An important role of these specialized nerve cells in monitoring position of the tongue is suggested in current literature.

Merkel Cells are distinctive neural cells that are abundantly distributed in the dermal layer or the palatal rugae. They are low-threshold, slowly-adapting mechanoreceptors that respond to touch and pressure. They have been shown to participate in immunoreactive responses, secrete neuropeptides resulting in glutamate release. They are also thought to have a functional role in hormone regulation.

Meissner Corpuscles have at least three types of innervative function. They are rapidly-adapting low threshold mechanoreceptors as well as nociceptors. Their immunoreactive nerve endings are thought to be involved in pain mediation and inflammatory responses.

Pacinian Corpuscles, located subcutaneously below the palatal rugae, have been shown to be rapidly-adapting mechanoreceptors of tactile perception during mastication and swallowing.

Ruffini Corpuscles, also located subcutaneously, have been shown to be slowly-adaptive receptors, involved in stretching and immunoreactive responses.

Immunoreactivity is a characteristic of autonomic nerves and involved in reflex regulation of airway smooth muscle tone. Autonomic nerves mediate both contraction and relaxation of the smooth muscles of the airway. Parasympathetic/cholinergic nerves mediate smooth muscle contraction and sympathetic/adrenergic nerves mediate smooth muscle relaxation. Dysfunction or dysregulation involving the autonomic function of these specialized nerve endings may contribute to pathogenesis of obstructive airway disease.

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) 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 (1mm or more) the new position is recorded by extruding new bite registration paste into the posterior segment and overlapped anterior to the cuspids to achieve a one piece bite registration. 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 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 the Moses Appliance, it may be necessary to re-record the bite and remake the lower component in a corrected lateral position.

EVALUATION OF TREATMENT

AMBULATORY PSG (AMB-PSG) TESTING IS STRONGLY RECOMMENDED

Numerous devices are available that are FDA approved Class III polysomnographic recorders. They are compact ambulatory devices designed to aid in the detection of sleep disorders such as apnea, snoring and upper airway resistance in adult patients. Data collection occurs in the patient's natural surroundings instead of the stressful environment of a sleep laboratory. Patients are given verbal instructions in the office, and then connect the device to themselves at night with the aid of a diagrammed instruction sheet.

The AMB-PSG should record up to eight channels of information at one time. The patient however, typically connects six sensors that record all eight channels of data:

1. Nasal/oral cannula – airflow, airflow resistance (snoring via a pressure transducer)
2. Chest belt – respiratory effort
3. Abdominal effort – respiratory effort
4. Body position monitor – supine, right, left, prone or standing
5. Finger monitor – pulse rate, blood oxygen
6. Microphone – snoring loudness

The microphone is connected into the auxiliary channel.

At the initial visit, the patient is given complete instructions on how to set up the AMB-PSG and then they take the device home for a night to establish baseline measurements of the physiological parameters mentioned. After each oral appliance adjustment the patient again sleeps with the AMB-PSG to establish consistent data on the effect of the adjustment and the effect of the appliance. Between adjustment and testing there is typically a two week adjustment period.

The standards strived for with oral appliance therapy are those recommended as being apnea-free by the American Academy of Sleep Medicine. The use of the AMB-PSG, disposable supplies, downloading of the data and interpretation by the clinician are included in the fee for the oral appliance during the initial adjustment phase of treatment. Regular six month recall visits are recommended for all patients using a Moses Appliance. The cost of the AMB-PSG re-evaluation at recall exams is not included in the initial fee quoted for the Moses Appliance.

IMPRESSION TECHNIQUE FOR A "MOSES"

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 –** Use 3, 4, or 5 (on rare occasion 6). Cut and trim with a scissors 6"x3/4" wooden tongue depressors to fit the anterior arch form
5. The trimmed tongue depressors are placed for try-in between uppers and lower teeth in the area of the incisors to the bicuspids 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 APPLIANCE

The Moses 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 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 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 – either a full polysomnographic study at a sleep lab or an ambulatory PSG.