

myerson ema[®] Oral Appliance

US Patent no. 6,109,265 & Patent Pending



Obstructive Sleep Apnea (OSA)

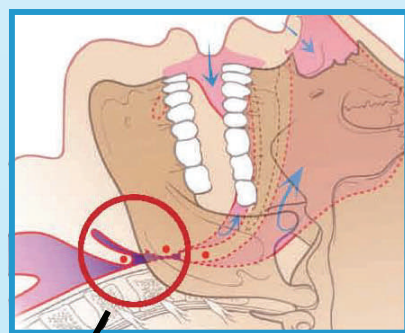
Obstructive sleep apnea (OSA) afflicts over 40 million Americans. Untreated, OSA can lead to heart problems, strokes and excessive daytime sleepiness. Over 100,000* people are killed or injured each year in crashes attributed to a driver who has fallen asleep at the wheel or who was inattentive due to severe drowsiness.

Snoring

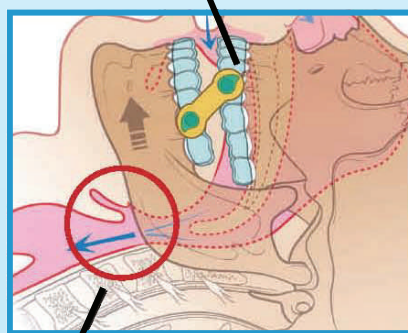
At least 80 million Americans snore (a sign of restricted airflow and impeded breathing during sleep), which can result in excessive daytime sleepiness, cause a higher rate of headaches, adversely affect the sleep quality of the snorer's bed partner, and diminish the overall quality of life.

Treatment of OSA & Snoring

The American Academy of Sleep Medicine (AASM) now recommends oral appliances like the myerson ema appliance as a front line of treatment for snoring and mild to moderate sleep apnea, and in cases where CPAP has not been tolerated. The FDA has approved the myerson ema appliance for the treatment of both obstructive sleep apnea and snoring. This custom oral appliance is available to medical and dental professionals through authorized dental laboratories like Dental Arts Laboratories, Inc.



Closed airway obstructed by soft tissues



Open free flowing airway with the myerson ema appliance

*NHTSA estimate

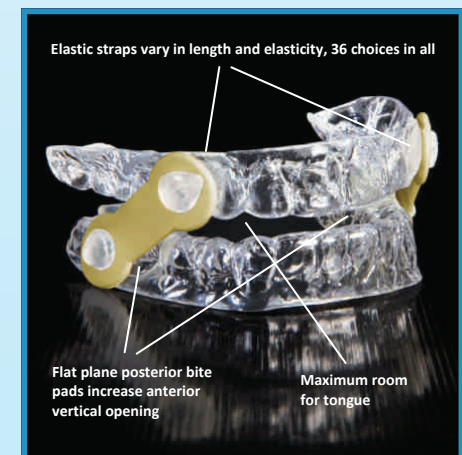
Treatment Protocol

Step 1. Patient Assessment

- Conduct complete patient medical history, which may include the following STOP questionnaire¹:
 - SNORE...**Do you snore loudly?
 - TIRED...**Do you often feel tired, fatigued, or sleepy?
 - OBSERVED...**Has anyone observed you stop breathing during sleep?
 - PRESSURE...**Do you have or are you being treated for high blood pressure?

If a patient answers **“YES”** to two or more questions, then the patient may be at risk for OSA.

- Inform the patient about the design of the ema appliance:
 - The ema appliance uses nine different lengths of elastic straps to gradually and incrementally titrate (i.e. advance) the mandible forward.
 - Four different strengths of elastic straps match the strength of pull to the musculature of the patient.
 - The myerson ema's patented design allows freedom of lateral mandibular movement.
 - Air flow through the oral pharynx is increased either through the advancement of the mandible, the increased vertical opening, or both.
 - Thermoformed custom trays limit tooth movement.



¹ Chung et. al, Anesthesiology. 2008 May;108(5):812-21; also see Barsh, Sleep Breath (2009) 13:1-2

ema is a registered trademark of Frantz Design Inc.

Step 2. Impressions and Bite Registration

- Take upper and lower dental impressions. The extension of the impressions should go to the height of contour of the gingiva on all sides of the teeth.
- Send models and bite registration to an authorized myerson ema dental laboratory like Dental Arts Laboratories, Inc.

Step 3. Delivery of myerson ema Appliance to Patient

- Fit the upper and lower appliances without the ema elastic straps to check for comfort and to make sure there is no gingival impingement. The ema may feel snug to the patient for the first five to ten minutes. Remove upper and lower appliance.
- Wet two ema elastic straps of the same color and length, then attach each to the lower appliance, rotating the strap on the button hook to seat. The ema logo on the strap should be facing the appliance. Repeat procedure to attach straps to upper appliance.
- Seat the upper appliance first and have the patient move the mandible forward while pushing down on the anterior portion of the lower appliance until it snaps into place. Question the patient for comfort of the appliance on the teeth as well as TMJ comfort.
- Check the posterior bite pads for even occlusion. If either side is high, conservatively grind the high side until both sides occlude evenly in the protruded position with straps in place.
- To avoid unnecessary office visits, you may send extra straps with the patient to use in advancing the mandible further or to replace stretched out straps.
- Instruct the patient to chew sugar free gum every morning after wearing the appliance to help return condyles to normal position.

Step 4. Patient Follow Up

- Instruct your patient to call the office the day after the first night of wearing the appliance. Side effects may include clenching, sore anterior teeth, TMJ sensitivity and increased saliva flow. These symptoms should abate significantly or disappear completely within ten days. If mild TMJ discomfort is reported, replace existing straps on the appliance with softer or longer straps.
- If the patient has discomfort in one TMJ, adjust the bite pads as necessary (pain usually is on the side where the pad is high).
- If the patient experiences pain in both TMJs, he or she should discontinue wearing the appliance and contact your office.
- If one or two teeth are sore after wearing the appliance, it may be necessary to relieve the interior problem areas with an acrylic bur.

Step 5. Titration (Advancement) and Vertical

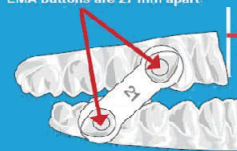
- If an elastic strap is 1/8 of an inch longer than a new strap or the hole becomes oval, then it should be replaced with a new strap of the same color and length.
- If the patient reports that there has been no significant lessening of apneic episodes or snoring, **AND** if the patient feels the mandible could be moved further forward without TMJ pain, then this may be addressed in one of three ways:
 - 1) Replace the present straps with new straps **of the same color that are one size shorter.**
 - 2) Replace the present straps with new, firmer straps **of a different color that are one size longer.**
 - 3) Increase the anterior vertical opening by adding up to 3 or 4 mm of acrylic or composite to the occlusal surfaces of the mandibular bite pads.

Each EMA elastic strap comes in 4 different strengths, indicated by color.



EMA* STRAP LENGTH	DISTANCE BETWEEN EMA BUTTONS	
	27 mm	25 mm
21 mm	6 mm	4 mm
20 mm	7 mm	5 mm
19 mm	8 mm	6 mm
18 mm	9 mm	7 mm
17 mm	10 mm	8 mm
16 mm	11 mm	9 mm
15 mm	12 mm	10 mm
14 mm	13 mm	
13 mm	14 mm	

EMA buttons are 27 mm apart*



6 mm advancement



10 mm advancement



14 mm advancement

Each of the four colors of elastic straps comes in nine lengths. The shorter the ema elastic strap, the further the mandible is advanced.

*myerson recommends a button distance of 27 mm unless the patient can only advance 9 mm or fewer in which case 25 mm distance is recommended.

Important: Patients diagnosed with OSA will require a sleep study after you and the patient feel adequate treatment has occurred. The disappearance of subjective signs does not always translate to a successful treatment, especially with a diagnosis of OSA.

Patients should consult their medical doctor and dentist to evaluate their condition to determine if a dental device is suitable for them. The patient's medical history, including a history of asthma, breathing or respiratory disorders, or other relevant health problems, should be considered in determining whether this device is appropriate. An oral appliance may be contraindicated if any of the following apply to the patient: central sleep apnea, severe respiratory disorders, a history of TMJ problems, loose teeth or advanced periodontal disease, or if the patient is under the age of 18. Patients should be aware that use of the oral appliance may cause tooth movement or changes in dental occlusion, gingival or dental soreness, pain or soreness to the temporomandibular joint, obstruction of oral breathing and excessive salivation. The information provided herein is general and does not constitute advice in any specific patient case.

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