












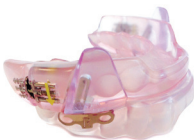




Company		Airway Management Inc		Apnea Sciences	Dream Systems LLC	Glidewell Laboratories
Product		 myTAP	 TAP 3 Elite	 ApneaRx	 OASYS with Option for Combination Therapy	 Silent Nite sl
Website		www.myTAPappliance.com	www.amisleep.com	www.apnearx.com	www.oasysleep.com	www.glidewell dental.com
Warranty (days)		90 (30-day satisfaction guarantee)	365 (for parts) (60-day satisfaction guarantee)	30 (guarantee with full refund); 90 (replacement)	365	182 (if the failure is due to defects in materials or workmanship)
INDICATIONS	Mild to Moderate OSA	X	X	X	X	
	Severe OSA				X	
	Snoring	X	X	X	X	X
	Bruxism				X	
TYPE	Custom		X		X	X
	Noncustom	X				
	Boil and Bite	X		X		
How Does the Oral Appliance Work?		The myTAP advances and stabilizes the mandible, preventing the soft tissues of the throat and tongue from collapsing into the airway.	E0486 code verified by Medicare, the TAP 3 Elite advances and stabilizes the jaw, preventing the tissues of the throat and tongue from collapsing into the airway.	Advances the mandible in precisely marked 1 mm increments.	The device repositions the mandible, the nasal dilators improve nasal breathing, and the tongue buttons improve tongue position, plus a removable bracket can be added for combination therapy with CPAP.	Silent Nite sl works by positioning the lower jaw forward using special S-shaped connectors that are attached to upper and lower trays, which increases the volumetric capacity of the airway.
Fitting Description		The myTAP is fit in an easy 15-20 minute appointment. To fit the trays, drop the upper tray in boiling water for 60 seconds, remove the tray with a pair of tongs, and let cool for 20 seconds. Place the upper tray over the patient's teeth and let cool for 4 minutes. Repeat this process with the lower tray. During this appointment, the AM Aligner morning repositioner, which is included with each myTAP, will be fit as well with a similar process.	The TAP 3 Elite is fabricated in a licensed dental laboratory and fitted by a clinician. The upper and lower trays are adjusted for retention and fit. Initial protrusion is set during the fitting process and can be easily modified. Posterior stops may be added for comfort if necessary.	Fitting takes less than 10 minutes. Emerge in boiled water for 90 seconds. Dip into cup of tap water for 3 seconds to cool off. Place in patient's mouth to custom mold for 30 seconds.	The Oasys Upper splint is placed. The lower splint with anterior shield is seated. If combination therapy is required, the appliance is retrofitted to include a removable bracket.	It is custom thermoformed in the laboratory from the patient's models. A bite registration taken with the Slide-Link protrusion gauge is used to determine protrusive position and align the device.
Adjustment Description		The myTAP is a midline advancement oral appliance adjustable by the patient. The adjustment dial allows the patient to control the treatment position. With its incremental advancement (1/4 mm per half turn) capabilities and its wide range of adjustment (20 mm total), the myTAP allows the patient to reach their treatment position comfortably.	Adjustment of the TAP 3 Elite may be made by the patient with the appliance in the mouth. An anterior dial with one point of adjustment prevents unequal torque. The clinician teaches a home titration schedule, which engages the patient in the therapy process. The TAP 3 Elite may also be easily adjusted in a sleep lab by the sleep tech during a study.	Simple patented adjustment mechanism is unaided by external accessories (screws, bands, etc). Provides 1 mm adjustment and locking capability with a 10 mm range.	The anterior shield is on a sliding/locking system, with mm guides. Pushing on the shield increases protrusion/pulling reduces. Finger adjustment is used for the nasal and lingual buttons.	Slide-Link connectors attach to the upper and lower trays. These connectors come in six lengths (21-26 mm) and are easily interchangeable by the patient if the lower jaw needs repositioning.
Materials		All-plastic design: a patented ThermAcryl material over molded onto a polycarbonate tray. The patented trays, when heated, become soft and can be molded to the teeth at the time of fitting. If reheated, the trays will return to their original shape and can be refit.	Surgical grade stainless steel hardware; the trays have two hard layers of a durable polymer and inner lining is one of two types designated by the clinician. Triple Laminate is the most popular, using DuraSoft, which enables retention by comfortably gripping the teeth. ThermAcryl is the other option, which softens when heated to allow "snapping" and re-shaping for patients who are having dental work.	Soft thermal plastic and hard acrylic.	Upper: 1.5 mm/2 mm Vacuform splint; lower: ThermoFlex hard splint, with hard acrylic shield, onlays, and buttons; stainless steel wire, ball clasps, locks; Duraloy wire for the nasal dilators and tongue buttons, plastic bracket and medical-grade nasal CPAP mask.	Upper tray: soft polyurethane inner layer and a hard copolyester outer layer, which are BPA-free. Lower tray: this same dual-layered material or all hard copolyester (depending on retention).
Recommended Cleaning		The myTAP should be cleaned thoroughly after each use with a regular soft toothbrush and warm water. Weekly (or less as needed), clean the trays with warm water, mild soap, and a toothbrush. Always rinse thoroughly and allow to air dry before storing in the container.	Clean thoroughly after each use with a regular soft toothbrush, mild soap, and cool water. Always rinse thoroughly and allow to air dry before storing in the container. The TAP 3 Elite can be soaked weekly in a diluted peroxide solution for 5 minutes if needed	Clean daily with soft toothbrush and toothpaste.	Brush gently with soft toothbrush and anti-bacterial soap. Use non-alcohol denture cleaner for 15 minutes. Air dry.	Rinse well with water before and after use and store dry. Clean appliance with soap and warm water only.
Published, Peer-reviewed Validation Articles		No (however, the myTAP's technology is based on the custom TAP appliances, which have been validated in over 32 independent peer-reviewed studies)	Yes	No (in process)	Yes	No

Great Lakes Orthodontics Ltd	MicroDental Laboratories	Myerson	Quali-Som LLC	ResMed	
<div></div> <div>Herbst Appliance</div> <div>www.greatlakesortho.com</div>	<div></div> <div>MPowRx Snoring and Sleep Apnea Appliance</div> <div>www.greatlakesortho.com</div>	<div></div> <div>MicrO₂</div> <div>www.microdental.com</div>	<div></div> <div>Myerson EMA</div> <div>www.myersonstooth.com</div>	<div></div> <div>TheraSom Cast</div> <div>www.quali-som.com</div>	<div></div> <div>Narval CC</div> <div>www.resmed.com/narval</div>
90 (metal component); 365 (body material)	N/A	730	N/A	1,825	1,095
X	X	X	X	X	X
		X		X	
X	X	X	X	X	X
X			X		
X		X	X	X	X
	X				
It works by repositioning and holding the mandible in a more protrusive position, thereby holding the tongue forward and airway open.	It repositions the tongue forward instead of relying on the alveolar ridge or dentition to stay in place. No impression needed.	MicrO ₂ utilizes vertically mated buccal posts to advance and hold the mandible forward to open the airway.	EMA uses interchangeable elastic straps and posterior bite pads attached to thermoformed custom trays to allow gradual advancement of the mandible and increased vertical opening until treatment is successful.	The TheraSom Cast works by moderate mandibular advancement coupled with increased lingual and protrusive space, thus increasing the opening of the airway at the back of the throat.	Narval CC uses an optimized articulation method that maintains the mandible in an advanced position, opening the upper airway to enable effective treatment.
Very few adjustments are required. The hard acrylic snaps into place. When requested, retention clasps can be added.	Comfortable, secure fit. Maintains shape and one size fits most.	The MicrO ₂ consists of a series of incrementally advanced full arches that are uniquely lingual-less and metal free. Dentists must provide MicroDental Lab with patient impressions or digital scans along with a repositioning or neuromuscular bite registration and prescribed advancements. Dentists and patients alike experience easy and fast insertion due to the accuracy of the digital design and milling process.	Fit the upper and lower appliances without the elastic straps to check for comfort and to make sure there is no gingival impingement. Check the posterior bite pads for even occlusion.	The TheraSom Cast is fit by a professional in about 30 minutes, and is done in the same way a dentist fits a cast partial. The protrusion is achieved using a spring attached to each hook on the maxillary portion of the appliance and then to one of four corresponding hooks on the mandibular portion.	Narval is a computer-aided design and computer-aided manufacturing (CAD/CAM) MRD device, and each device is fitted specifically to the patient by their dentist. The dentist will take an impression—just like they would for any dental procedure—and will define the initial amount of protrusion required. The lateral flexibility allows patients to talk and drink while wearing the device.
0.25 mm adjustment with telescopic hardware, or 1 mm using advancement shims with the standard hardware option.	Non-custom, non-adjustable.	Adjustments are accomplished by simply removing an arch and inserting the next arch in the series of advancement arches. No screws, mechanisms, or elastics required.	The EMA appliance uses 4 different strengths of elastic straps in 9 different lengths to gradually titrate the mandible. The shorter or stronger the strap, the further the mandible is advanced.	The TheraSom Cast is adjusted in 1.25 mm increments by attaching one of three springs of different lengths to the hook on the maxillary portion and from there to one of the four hooks on the mandibular portion. It is not necessary to move the mandible forward so far that the patient experiences any discomfort.	If patients are still experiencing symptoms at first follow-up, the dentist will adjust fit by replacing the flexible, non-metal connecting rods to adjust fit. Narval CC is easy to titrate and highly adjustable with connecting rods that allow for 15 mm of protrusive range at .5 mm increments.
Standard hard acrylic, but can be made of Veriflex, a thermal-reactive option.	Elastomer.	Pre-polymerized, milled polymethylmethacrylate (PMMA).	Completely metal free; the custom trays are made from a proprietary thermoplastic and the straps from a latex-free polymer.	Vitalium, a dental alloy that has been in use for over 60 years; stainless steel springs.	A flexible, lightweight polymer that is CAD/CAM custom-made for a patient's mouth.
Use of DentaSOAK is recommended along with toothbrush and toothpaste daily. Must be stored dry.	Use of DentaSOAK is recommended along with toothbrush and toothpaste daily. Must be stored dry.	Clean daily using a soft toothbrush with mild toothpaste or mild detergent. Do not soak. Store in dry container.	Clean appliance in tepid water with a toothbrush and toothpaste or soak it in a denture cleaning solution; no mouthwash.	Clean each morning using a firm toothbrush and can also be cleaned by soaking it in an over the counter denture cleaner. It's even possible to put the appliance into the dishwasher.	Daily cleaning is recommended to maintain the lifetime of the appliance. Rinse the device in lukewarm water; clean the device with a soft, clean toothbrush. (Do not use the same toothbrush used to brush teeth, as toothpaste can damage the device.) Rinse in lukewarm water, and dry with a clean paper towel before putting it back in the storage box.
Yes	Yes	Yes	Yes	No	Yes

Company		Respire Medical	SML—Space Maintainers Laboratories	SomnoMed Inc	Strong Dental	Tomed Dr. Toussaint GmbH
Product		 Respire Blue Series	 Lamberg—Sleep Well Appliance	 SomnoDent Fusion	 SUAD Family of Premium Oral Sleep Appliances	 SomnoGuard AP
Website		www.respiremedical.com	www.smlglobal.com	www.somnomed.com	www.strongdental.com	www.tomedcare.com
Warranty (days)		365	1,095	1,095	365 (acrylic); 1,825 (metal)	365 (against manufacturer's defects)
INDICATIONS	Mild to Moderate OSA	X	X	X	X	X
	Severe OSA		X		X	
	Snoring	X	X		X	X
	Bruxism		X		X	
TYPE	Custom	X	X	X	X	
	Noncustom					
	Boil and Bite					X
How Does the Oral Appliance Work?		The device opens the patient's airway by advancing the jaw and the associated tissues.	It advances the mandible by holding it in a protrusive position.	It advances the mandible to open the airway and hold the jaw in position.	Our durable appliances can withstand heavy bruxers while protruding the mandible forward and opening the obstructed airway to effectively treat snoring and obstructive sleep apnea.	The 2-part SomnoGuard AP repositions the lower jaw forward and thereby prevents the collapse of the upper airway. With the device in place, the upper airway is wider and the patient can breathe more easily without snoring.
Fitting Description		The upper and lower components are not connected, so this freedom allows the patient to place one component at a time. This also allows the patient to open and close their mouth during the night, which should increase patient acceptance and comfort. The device can be prescribed only by a doctor and should take only a few minutes to insert.	The dentist seats the upper and lower appliance separately to determine: a snug and secure fit of each appliance, overall patient comfort, and the ability of the patient to easily insert and remove the appliance. Adams clasps can be readily adjusted to achieve optimal comfort and retention. While the initial fitting of the appliance takes no more than a couple of minutes, it is appropriate to schedule 10 minutes for the delivery visit to accommodate patient instructions as well as for scheduling of follow-up visits.	The patient will be fitted for the device by a qualified dental sleep professional. The dentist will make a model of the patient's teeth and take a protrusive bite registration.	The Standard SUAD is manufactured exclusively by Strong Dental and delivered to the patient by the dentist. After placing the appliance in warm water for approximately 1 minute, the appliance is inserted onto the patient's dentition and verified for fit and proper occlusal contact. Adjustments will be made if necessary and optional occlusal contacts are available.	Fitting can be done by doctors or their trained staff in approximately 15 minutes. No special accessories needed apart from a boiling water bath, a small pair of scissors, and gripping tongs.
Adjustment Description		We provide an adjustment key to advance the screw inside of the device. This, in turn, advances the jaw. There is an arrow inside of the device indicating which direction to turn the screw and we can also provide videos to show this.	Each patient receives his/her own box of inserts, which includes a sequence of numbered protrusive elements that advance the mandible in .5 mm increments. The patient simply pops out the insert on the upper member and replaces it with the following insert in the numbered sequence.	The SomnoDent Fusion is advanced in 1 mm increments by changing the wings on the lower device or more precisely by adjusting the screw in 0.1 mm increments using the screw on the top device. The SomnoDent Fusion offers a custom 8.5 mm range of calibration, reducing the need for device resets.	Our appliances encompass a unique tube and rod mechanism, which makes them virtually unlimited in protrusive advancement. Standard Herbst arms are advanced using a nylon friction fit or metal spacers (for heavy bruxers). Telescopic (one-piece) Herbst arms are also available and advanced using the key included.	The lower jaw can be infinitely repositioned forward (titration) by any degree up to about 10 mm by an adjusting screw inserted into the screw guide of the lower jaw tray. Adjustments are quickly and easily made outside of the mouth. Protrusion changes can be done by doctors or the instructed patients themselves.
Materials		Acrylic.	Special SML brand sleep appliance acrylic.	Acrylic.	Choice of base material (soft dual-laminate or firmer solid thermoflex), advancement arms, and color. Metal components: 300 series medical-grade stainless steel; casted framework: chromium cobalt.	Rigid tray walls: rigid polycarbonate; lining: soft thermal copolymer; stainless steel adjusting screws.
Recommended Cleaning		Clean with soap and water every morning. It's recommended to use a denture/retainer cleaner once a week.	Clean once daily with OAP anti-microbial dental appliance cleaner.	Clean the device every morning after removing it from the mouth using a soft toothbrush, but never use toothpaste as it contains abrasives. SomnoMed recommends using SomTabs for daily cleaning of a SomnoDent device.	The appliance is to be brushed daily after each use with a soft toothbrush and toothpaste. We also recommend soaking it on a daily basis in Polident solution for 3-5 minutes.	Clean daily with soft toothbrush and mild liquid soap or a liquid denture cleaner. Rinse and let the device dry in the open air.
Published, Peer-reviewed Validation Articles		Yes	Yes	Yes	No	Yes