


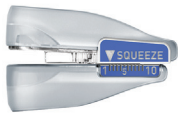


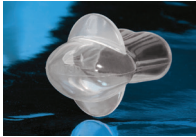



















Company		Advanced Brain Monitoring	Airway Management Inc		Apnea Sciences	Distar LLC
Product Name		 Apnea Guard	 myTAP	 TAP	 ApneaRx	 Adjustable TheraSnore
Website		www.advanced-sleep.com	mytapappliance.com, amisleep.com	www.amisleep.com	www.apnearx.com	www.distar.com
Warranty		None	30-day satisfaction guarantee, 90-day warranty	1 year parts and workmanship, 60-day patient satisfaction guarantee	30-day guarantee with full refund; 90-day replacement	1 year
FDA 510(k) Clearance		Yes	Yes	Yes	Yes	Yes
INDICATIONS	Mild to Moderate OSA	X	X	X	X	
	Severe OSA					
	Snoring	X	X	X	X	X
	Bruxism			X		
	Other					
TYPE	Custom			X		
	Noncustom	X	X			
	Boil and Bite		X		X	X
How Does the Oral Appliance Work?		Serves as inexpensive temporary or titration appliance for up to 30 nights. Provides 1 mm increment adjustments, three vertical sizes, and predicted 70% advancement.	The myTAP advances and stabilizes the mandible preventing the soft tissues of the throat and tongue from collapsing into the airway. It's based on the original TAP, which is well validated in 30+ independent peer review studies.	E0486 code verified by Medicare, the TAP stabilizes the lower jaw in the appropriate protrusive position, preventing airway collapse and tongue blockage while keeping the jaw closed during sleep. The TAP has a full range of adjustment beyond maximum protrusion on into maximum passive protrusion.	Advances the mandible in precisely marked 1 mm increments.	Advances the mandible by gently holding it in a protrusive position. Patient has complete vertical and lateral freedom of movement and is not "locked" into the appliance.
Fitting Description		Fitted by patient with assistance of a trained healthcare professional within 15 minutes. First, the lower tray is fitted using predetermined amounts of retention material, followed by fitting of upper tray.	myTAP is in a category of its own—"Precision Fit"—that allows for accurate molding capabilities, which eliminates the need for a bite registration and lab fabrication. It's an immediate treatment solution. When heated, the trays can be widened or narrowed to fit any arch size. It also features thin trays that create a comfortable low profile snoring appliance.	The TAP 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. Submerge 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.	Custom fit in the doctor's office in less than 40 minutes. Three different arch sizes are available and 5 precise adjustment settings available. A heat-and-fit design customized for each individual patient; minimal trimming needed for patient comfort.
Adjustment Description		Neutral, maximum, and 70% advancement, and bite registration established with Apnea Guard inserted. Optimal jaw-forward positioning established by titration study, transferable to custom appliances fabricated by a knowledgeable dental lab.	myTAP is a midline advancement oral appliance that is unique to all TAP designs. The adjustment mechanism is attached to the lower tray and threaded through the adjustment post of the upper tray. A dial is screwed onto the end of the threaded adjustment mechanism allowing the patient to control the treatment position. With its incremental advancement (1/3 mm per half turn) capabilities and its wide range of adjustment (20 mm total), the myTAP incorporates Airway Management Inc's existing custom technology.	Adjustment may be made by the patient with the TAP 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 may also be easily adjusted in the sleep lab by the sleep tech during a study.	Simple patent-pending adjustment mechanism is unaided by external accessories (screws, bands, etc). Provides marked 1 mm adjustment and locking capability with a 10 mm range.	Easily adjusted by separating two halves of the appliance and following the number guide along the side to the appropriate protrusion setting. Appliance snaps into place with desired setting via a locking mechanism.
Materials		Biocompatible plastic trays that adjust and accommodate a full range of arch widths. Protrusive ranges are lined with heavy-set polyvinyl siloxane retention material customized to the patient's teeth.	The myTAP is an all-plastic design. The trays are made from a plastic that when heated becomes 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 refitted.	Hardware material is surgical grade stainless steel. The trays have two hard layers of a durable polymer and the 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 reshaping for patients who have dental work.	Soft thermal plastic and hard acrylic.	Soft thermal plastic and hard acrylic.
Recommended Cleaning and Maintenance		Clean daily by rinsing with cold water and a soft toothbrush.	With regular toothbrush and cool water	After use, clean with a toothbrush, cool water, and antibacterial soap. The TAP can be soaked weekly in a diluted peroxide solution for 5 minutes.	Clean daily with soft toothbrush and toothpaste.	Brush appliance after each use to remove any debris; clean every 2 days using OrthoFresh cold water cleaner.
Published, Peer-reviewed Validation Articles		Yes	No	Yes	No	Yes

Dream Systems LLC	Glidewell Laboratories		Great Lakes Orthodontics Ltd		Modern Dental Laboratory USA
 OASYS Oral/Nasal Airway System with Removable CPAP Pro	 aveoTSD Tongue Stabilizing Device	 Silent Nite sl	 Herbst Appliance	 MPowRx Snoring and Sleep Apnea Appliance	 The Moses
www.oasysleep.com	www.getaveo.com	www.glidewell dental.com	www.greatlakesortho.com	www.greatlakesortho.com	www.themoses.com
1 year	6-month replacement warranty from the date of purchase for product defects determined to be caused by the manufacturer	6 months if the failure is due to defects in materials or workmanship	90 day for metal component; 1 year for body material	N/A	2 years
Yes	Yes	Yes	Yes	Yes	2 years
X			X	X	X
X					
X	X	X	X	X	X
X			X		
Nasal Dilator, Tongue Repositioning					
X		X	X		X
	X			X	
The device is adjustable and repositions the mandible to open the throat, with tongue lifter buttons to train and position the tongue forward. Nasal Dilators improve breathing through the nose.	The aveoTSD works by gently suctioning onto the tip of the tongue, preventing it from falling back into the throat and obstructing the airway.	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.	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.	The Moses incorporates all three necessary attributes of a successful therapy: tongue management, mandibular advancement, and patient compliance.
The upper Biocryl Splint is placed first. The lower Variflex Splint is seated on the lower teeth and the lips are pulled over the Labial Shield and Nasal Dilators.	Push the tongue gently into the aveoTSD until it touches the sides of the device. Squeeze the bulb to draw the tongue into the device until it is firmly attached.	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.	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 Moses is custom fabricated in laboratory with ISO 9001:2008 and ISO 13485 certifications. Use The Moses Bite Shims for proper bite registration and follow the video instructions at www.themoses.com/bite.
The anterior shield is on a sliding/locking system, with mm guides. Pushing on shield increases protrusion. The Nasal and Tongue Buttons are adjusted with pliers and/or finger pressure.	The device requires no adjustment. Small, medium, and large sizes are available. For patients with longer than average tongues, 4 mm/7 mm Uni-Spacers can be clipped onto the device for extra titration.	Slide-Link connectors attach to the upper and lower trays. These connectors come in five lengths (21-25 mm) and are easily interchangeable by the patient if the lower jaw needs repositioning.	0.25 mm adjustment with telescopic hardware, or 1 mm using advancement shims with the standard hardware option.	Non-custom, non-adjustable.	The jaw relationship established by the bite registration will be the exact jaw position of the fabricated Moses. Titrate The Moses by activating the bilateral expansion screw mechanisms with the key provided. Eight turns = 1.0 mm.
Upper 1.5 mm Biocryl retainer/splint; lower Variflex thermoplastic splint, with Biocryl ice shield, onlays, and buttons; stainless steel wire with welded corners for sliding bars; Duraloy wire for nasal dilators and tongue buttons; stainless steel locks.	The aveoTSD is made of 0.4 mm thick soft medical-grade silicone.	The upper tray of the Silent Nite sl is made of a soft polyurethane inner layer and a hard copolyester outer layer that are BPA-free. Depending on retention, the lower tray is made from this same dual-layered material or all hard copolyester.	Standard hard acrylic but can be made of Veriflex, a thermal-reactive option.	Thermoplastic elastomer	Hard acrylic and Essix C+ upper retainer
Brush gently with soft toothbrush and antibacterial soap/mild toothpaste. Use non-alcohol denture cleaner for 15 minutes.	The aveoTSD should be rinsed under hot water daily and washed thoroughly once a week using a denture cleaning solution.	Rinse well with water before and after use and store dry. Clean appliance with soap and warm water only.	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.	Use a denture cleaner, such as 3-minute Polident, and clean daily.
Yes	Yes	No	Yes	Yes	Yes

Company		Myerson	ResMed	SML – Space Maintainers Laboratories		
Product Name		 Myerson EMA	 Narval CC	 Adjustable Dorsal	 Full Breath Solution	 Lamberg Sleep Well
Website		www.myersontooth.com	www.resmed.com/narval	smlsleep.com	smlsleep.com	smlsleep.com
Warranty		n/a	3 years	1 year (materials and workmanship)	1 year (material and workmanship)	1 year (materials and workmanship)
FDA 510(k) Clearance		Yes	Yes	Yes	Yes	Yes
INDICATIONS	Mild to Moderate OSA	X	X	X	X	X
	Severe OSA					
	Snoring	X	X	X	X	X
	Bruxism			X	X	
	Other					
TYPE	Custom	X	X	X	X	X
	Noncustom					
	Boil and Bite					
How Does the Oral Appliance Work?		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.	Narval CC is the first and only computer-aided design/computer-aided manufacturing (CAD/CAM) appliance on the market; patented articulation along the occlusal plane maintains lower jaw in a forward position promoting physiological breathing during sleep.	Uses precision-milled upper and lower occlusal appliances to open the vertical relationship, with buccal “dorsal” fins to hold the mandible forward and allows for the desirable degree of lateral movement. Suitable for all dentitions.	Lower single-arch appliance with proprioceptive tongue control with no mandibular advancement	This appliance advances the mandible in .5 mm increments and opens the vertical in 3 mm increments. The lower jaw has freedom of movement along the arc of opening/closing.
Fitting Description		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.	Narval CC uses CAD technology to suit the complex dental anatomy of individual patients; does not load incisors and the innate lateral flexibility eliminates “locked-in” sensation, patients can easily talk and drink.	It is only necessary to verify that the upper and lower appliances seat fully and the vertical and AP position is correct. Patient should wear the appliance for several days, after which time mandible advancement is performed via Adjustment Key if necessary (expansion screws on upper portion of the appliance).	Chair side fitting similar to fitting a bruxism splint. If patient is comfortable with appliance, schedule recall in 1 week. If patient experiences a gag reflex and/or swallowing inhibition, “tail” will have to be modified. If problem persists, trans-lingual bar must be “arched up.”	Appliance does not require special fitting at delivery visit. It is only necessary to verify that the upper and lower members seat fully.
Adjustment Description		The EMA appliance uses four different strengths of elastic straps in nine different lengths to gradually titrate the mandible. The shorter or stronger the strap, the further the mandible is advanced.	Narval CC is easy to titrate and highly adjustable with connecting rods that allow for 15 mm of protrusive range at 1 mm increments. The dentist/patient can simply select a shorter connecting rod until optimal advancement is achieved.	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 expansion screw from bar to bar advances the mandible approximately one-quarter millimeter (.25 mm).	Appliance may be modified with adding acrylic to the “tail”	A series of “inserts” slide into the upper appliance to increase the amount of mandibular protrusion (up to 9 mm) in .5 mm increments. Vertical adjustment can also be achieved with a vertical “insert.”
Materials		The EMA appliance is completely metal free. The custom trays are made from a proprietary thermoplastic and the straps from a latex-free polymer.	Narval CC is made of a highly resilient and durable biocompatible polymer material and then manufactured through selective laser sintering to allow the device to be strong yet supple as well as flexible yet highly resilient. Narval is metal-free, flexible, and lightweight.	Available in Dual Laminate, All Acrylic, and Thermoplastic (Talon)	Available in Dual Laminate, All Acrylic, and Thermoplastic (Talon)	Hard polycarbonate and hard acrylic
Recommended Cleaning and Maintenance		Clean appliance in tepid water with a toothbrush and toothpaste or soak it in a denture cleaning solution; no mouthwash.	Clean Narval CC daily in lukewarm water with a soft brush and a mild soap/baking soda. Rinse, dry, and store in case provided. Twice weekly, use the Sonic Cleaner provided with an effervescent antibacterial tablet.	Use OAP Dental Appliance Cleaner, which is an anti-fungal, anti-viral, anti-bacterial, and anti-germicide. Simply spray, brush, and rinse—a 1-minute procedure.	Use OAP Dental Appliance Cleaner, which is an anti-fungal, anti-viral, anti-bacterial, and anti-germicide. Simply spray, brush, and rinse—a 1-minute procedure.	Use OAP Dental Appliance Cleaner, which is an anti-fungal, anti-viral, anti-bacterial, and anti-germicide. Simply spray, brush, and rinse—a 1-minute procedure.
Published, Peer-reviewed Validation Articles		Yes	Yes	No	No	No

SML – Space Maintainers Laboratories	SomnoMed		Strong Dental		
					
ZQuiet Pro-Plus	SomnoDent Flex	SomnoDent G2	The Standard SUAD Device	The SUE 2G (Second Generation)	The SUAD B-H (Basic Herbst)
smlsleep.com	www.somnomed.com	www.somnomed.com	www.strongdental.com	www.strongdental.com	www.strongdental.com
1 year (material and workmanship)	3 years	3 years	5-year limited	5-year limited	2-year limited
Yes	Yes	Yes	Yes	Yes	Yes
X	X	X	X	X	X
X	X	X	X	X	X
X	X	X	X	X	X
Consists of two custom acrylic orthotics (one for the maxillary arch and one for the mandibular), a buccal cam mechanism (apposing fin and buttress) that maintains the orthotics in the proper AP relationship. Upon request, the maxillary orthotic can be made with an Omega Loop for patients who suffer from frequent headaches due to appliance use.	The SomnoDent Flex, made with proprietary SMH BFlex, is a premium comfort, patient specific device worn during sleep to treat mild to moderate sleep apnea.	The SomnoDent G2 is an easy to calibrate, standard metal-free customized device worn during sleep to treat mild to moderate sleep apnea.	The Standard SUAD stabilizes the lower jaw in the required protrusive position to effectively treat snoring and OSA.	The SUE 2G stabilizes the lower jaw in the required protrusive position to effectively treat snoring and OSA. The design of the SUE 2G allows for an increase in tongue space and airflow volume.	The SUAD B-H stabilizes the lower jaw in the required protrusive position to effectively treat snoring and OSA.
Seat appliance and check for patient comfort	SomnoDent Flex comprises upper and lower dental trays with a patented fin-coupling component, allowing normal mouth opening and closing.	SomnoDent G2 comprises upper and lower dental trays with a patented fin-coupling component, allowing normal mouth opening and closing.	The SUAD Device is manufactured exclusively by Strong Dental and delivered by the dentist. After placing appliance in warm tap water for approximately 1 minute, the appliance is inserted onto the patient's dentition and checked for fit and proper occlusal contact. Adjustments made if necessary. Optional occlusal contacts are available.	The SUE 2G is manufactured exclusively by Strong Dental and delivered by the dentist. Its occlusal surface mimics the Morning Repositioner (bite deprogrammer), reducing the likelihood of jaw discomfort.	The SUAD B-H is manufactured exclusively by Strong Dental and delivered by the dentist. After placing appliance in warm tap water for approximately 1 minute, the appliance is inserted onto the patient's dentition and checked for fit.
It is adjustable in .25 mm increments (by patient or doctor). A total of 6 mm of anterior movement is possible.	The SomnoDent Flex achieves mandibular advancement by means of bilateral adjustment screws located on the upper maxillary splint. As the screw mechanisms are titrated, they engage with the wings or fins on the lower splint to advance the mandible. The adjustment mechanism allows the mandibular protrusion to be adjusted in the range of -0.5 mm to +5.5 mm from the preset level for a total of 6 mm.	Provides patients with an easy to use modular adjustment system, which allows instant and accurate measurement. The device has a small coupling mechanism, is slim-line and more posteriorly located. The adjustment clips allow the mandibular protrusion to be adjusted in the range of -2.0 mm to +8.0 mm from the preset level for a total of 10 mm.	Unique tube and rod mechanism, virtually unlimited in protrusive advancement. Standard Herbst arms advanced using friction fit or metal spacers. Telescopic Herbst arms are available and advanced using key.	Unique tube and rod mechanism, virtually unlimited in protrusive advancement. Same arm options as SUAD Device and SUAD B-H. Vertical adjustment can be realized by building discluding elements with acrylic.	Unique tube and rod mechanism, virtually unlimited in protrusive advancement. Standard Herbst arms advanced using friction fit or metal spacers. Telescopic Herbst arms are available and advanced using key.
Available in Dual Laminate, All Acrylic, and Thermoplastic (Talon)	SMH BFlex, a soft polymer that is heat-cured, packed, and pressed utilizing a chemical formula that facilitates soft to hard polymer bonding at the layers. Surgical grade stainless steel adjustment mechanism.	Soft Liner: Made from SMH BFlex, a soft polymer that is heat-cured, packed, and pressed utilizing an exclusive chemical formula that facilitates soft to hard polymer bonding at the layers. Ball Clasps: Made from the highest quality acrylic that will not discolor. Both options feature durable polycarbonate adjustment winglets and clips.	Choice of base material (softer dual laminate or firmer solid thermoflex). Choice of advancement arms. All metal components are made with 300 series medical grade stainless steel.	To reduce the bulk of the appliance and allow more tongue space, all SUE 2Gs are fabricated out of solid thermoflex material. All metal components are made with 300 series medical grade stainless steel and the casted framework is made using chromium cobalt.	Choice of base material (softer dual laminate or firmer solid thermoflex). Choice of advancement arms. All metal components are made with 300 series medical grade stainless steel.
Use OAP Dental Appliance Cleaner, which is an anti-fungal, anti-viral, anti-bacterial, and anti-germicide. Simply spray, brush, and rinse—a 1-minute procedure.	Rinse daily in cold or lukewarm water and clean with a soft toothbrush and a mild detergent, such as liquid soap. Always store in a container of clean water when not in use.	Rinse daily in cold or lukewarm water and clean with a soft toothbrush and a mild detergent, such as liquid soap. Always store in a container of clean water when not in use.	Brush daily, after use, with a soft toothbrush and toothpaste. Soak daily in Polident solution (partial retainer 3 minutes or 5 minutes).	Brush daily, after use, with a soft toothbrush and toothpaste. Soak daily in Polident solution (partial retainer 3 minutes or 5 minutes).	Brush daily, after use, with a soft toothbrush and toothpaste. Soak daily in Polident solution (partial retainer 3 minutes or 5 minutes).
No	Yes	Yes	No	No	No

Company		Tomed Dr. Toussaint GmbH	
Product Name		 SomnoGuard AP	 SomnoGuard SP Soft
Website		www.tomedcare.com	www.tomedcare.com
Warranty		1 year against manufacturer's defects	1 year against manufacturer's defects
FDA 510(k) Clearance		Yes	Yes
INDICATIONS	Mild to Moderate OSA	X	X
	Severe OSA		
	Snoring	X	X
	Bruxism		
	Other		
TYPE	Custom		
	Noncustom		
	Boil and Bite	X	X
How Does the Oral Appliance Work?		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.	The 2-part SomnoGuard SP Soft 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		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.	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		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.	Two connectors of equal length combine laterally the upper and lower jaw trays and enable the advancement of the lower jaw from approximately -3 mm to +10 mm. This type of mandibular positioner also can be worn by retrognathic bite patients. Adjustments are quickly and easily made outside of the mouth. Protrusion changes can be done by doctors or the instructed patients themselves.
Materials		Rigid polycarbonate (rigid tray walls), soft thermal copolymer (lining), stainless steel adjusting screws	Rigid polycarbonate (rigid tray walls), soft thermal copolymer (lining), semi-rigid plastic (connectors)
Recommended Cleaning and Maintenance		Clean daily with soft toothbrush and mild liquid soap or a liquid denture cleaner. Rinse and let the device dry in the open air.	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	No

Information for this guide based on data submitted by product manufacturers. Sleep Review strives for accuracy in all data but cannot be held responsible for claims made by manufacturers.