




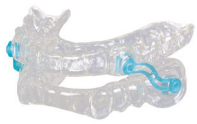














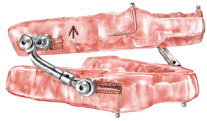


Company		Airway Management Inc	Apex	Dream Systems Dental Sleep Lab	DynaFlex	
Appliance		 dreamTAP w/ AccuTherm	 Kava Dorsal	 OASYS Oral / Nasal Airway System (Optional Tongue Repositioning Buttons)	 Milled Dorsal	 Milled Herbst
Website		www.tapintosleep.com	www.apexsleep.com	www.dreamsystemsdentallab.com	www.dynaflex.com	www.dynaflex.com
Warranty (days)		365 (optional extended 1,095-day)	730	365	1,095	1,095
INDICATIONS	Mild-Moderate OSA	X	X	X	X	X
	Snoring	X	X	X	X	X
	Bruxism					
MATERIALS	Biocompatible Polymer		X	X		
	Cobalt-Chromium Alloys	X		X		
	Ethylene-Vinyl Acetate			X		
	Hard Acrylic		X	X	X	X
	Laminate	X	X	X		
	Thermal Acrylic	X	X	X		
	Other		gluten-free acrylic			
PDAC Verified		X		X (Hinge only)		X
How Does the Oral Appliance Work?		DreamTAP w/ AccuTherm advances and stabilizes the jaw, preventing the tissues of the tongue and airway from collapsing. It corrects any slight tray imperfections during the patient's visit using only warm water.	Kava Dorsal utilizes a mandibular advancement dorsal screw mechanism.	OASYS Simplicity is a simple mandibular advancement with the labial shield. The Standard OASYS with Nasal Dilators improves nasal breathing.	The forward advancement of the lower jaw of this mandibular advancement device helps to gain airway opening.	The forward advancement of the lower jaw helps to gain airway opening.
Fitting Description		DreamTAP w/ AccuTherm has returned to the practice of custom-made devices from models. The AccuTherm liner allows a fit for every patient. All TAP custom products allow patients to fine tune treatment at home. The TAP Custom appliances use a single point of midline adjustment to prevent uneven bilateral adjustment. DreamTAP include 3 hook sizes that allow for a 15 mm range of adjustment with minimal hardware. Posterior stops, mouthshield, and vertical hooks available.	The Kava Dorsal is seated by gently placing the upper arch first, then seating the lower arch in the patient's mouth. Adjust the ball clasp if necessary to properly seat and secure the appliance in place. Engage the dorsal fins to the Kava advancement screw by bringing the lower jaw forward and gently closing down. Check occlusion for desired occlusal contacts.	Upper clear cushion seated first. Lower splint with anterior labial repositioning shield is placed next. MM scale tracks adjustments in 1 mm increments, using the OASYS Wrench for mandibular positioning.	After receiving a set of PVS or good working models, a custom fitted Dorsal is fabricated exactly to the bite registration that is provided by the dentist to the lab. The appliance is returned to the sleep practice, delivered to the patient, and adjusted by a qualified dental sleep clinician.	After receiving a set of PVS/digital/working models, a custom milled Herbst is fabricated exactly to the bite registration. The appliance is returned to the sleep practice, delivered to the patient, and adjusted by a qualified dental sleep clinician.
Adjustment Description		Adjustments are made by the patient with the appliance in the mouth in 1/4 mm increments using an adjustment key. The clinician teaches a home titration schedule. The dreamTAP can also be adjusted during a sleep study by a sleep tech.	Adjusted using an advancement screw and key. The advancement screw can be activated by turning both the left and the right screw in the same upward direction. Each 90-degree activation advances the mandible. 10 activations will advance the mandible 1 mm with a maximum of 70 turns (7 mm) advancement.	The anterior labial shield is on a sliding lock system. Pushing the shield advances the mandible; pulling retrudes. Adjustment 8 -15 mm. Finger adjustment on the nasal dilators and tongue buttons.	The DynaFlex Dorsal has 6 mm of mandibular advancement built into the device. The adjustment ratio is 10:1.	The DynaFlex Milled Herbst has telescoping arms that can advance the mandible up to 5 mm. The advancements are made with a small key that is provided by DynaFlex. A single- or double-collar arm can be provided.
Upper-Lower Connection		Connected by hardware during use.	Not connected.	Not connected.	Not connected.	Connected with stainless steel telescoping arms.
Supporting Study		Hoekema A, Stegenga B, et al. Obstructive sleep apnea therapy. <i>J Dent Res.</i> 2008;87(9):882-7. More studies at tapintosleep.com/dentist/peer-reviewed-studies	Not provided	Shrivastava D, Bixby JK, Livornese DS, et al. Efficacy of oral appliance therapy in the treatment of severe OSA in CPAP-resistant cases. <i>Sleep Vigilance.</i> 2018.	Not provided	Not provided

Company	Glidewell	Great Lakes Dental Technologies	Luco Hybrid OSA Appliance Inc	OravanOSA	Oventus Medical	Panthera Dental
Appliance		 Telescopic Herbst Sleep Appliance in Hard Acrylic	 The Luco Hybrid OSA Appliance	 Oravan Herbst	 O ₂ Vent Optima	 Panthera D-SAD
Website	glidewell dental.com/services/dental-sleep-medicine/silent-nite-sl	www.greatlakesdentaltech.com	www.lucohybridosa.com	www.oravansa.com	www.o2vent.com	www.pantherasleep.com
Warranty (days)	180	90 (metal); 730 (body)	1,695	365	1,095	1,095
INDICATIONS	Mild-Moderate OSA	X	X	X	X	X
	Snoring	X	X	X	X	X
	Bruxism			X		
MATERIALS	Biocompatible Polymer	X			X	X
	Cobalt-Chromium Alloys			X		
	Ethylene-Vinyl Acetate	X				
	Hard Acrylic		X	X	X	
	Laminate					
	Thermal Acrylic	X				
	Other				stainless steel	
PDAC Verified		X		X	X	
How Does the Oral Appliance Work?	Mandibular advancement appliance. Connectors on right and left buccal side will pull the mandible in protrusion to open up the airway. 6 adjustable settings.	By repositioning and holding the mandible in a more protrusive position, it holds the tongue forward and the airway open. (The Herbst is a registered trademark of Dentaaurum Inc.)	Uses a patented forward bite to activate the masseter inhibitory reflex to treat sleep bruxism while managing OSA and UARS symptoms. The only FDA cleared treatment of sleep apnea with concurrent sleep bruxism.	The device opens the patient's airway through advancement of the mandible using an adjustable telescopic Herbst mechanism. Like the Oravan device, Oravan Herbst has a truly open anterior design, encouraging natural protrusion of the tongue.	An adjustable dual mechanism stabilizes jaw position and advances the mandible to reduce airway collapse, still enabling opening of the mouth. It allows for breathing through an air channel to bypass obstructions in the nose. Lips maintain a seal around the device extension.	Custom-made by computer, the D-SAD holds the lower jaw in a forward position, increasing the space behind the tongue, which facilitates airflow and eliminates snoring. The jaw advancement also prevents the obstruction responsible for OSA.
Fitting Description	Both upper and lower trays will be tugging on each other to get adequate mandibular advancement, so it needs to be snug and not too passive.	The standard hard acrylic snaps into place. When requested, retention clasps can be added.	No lingual acrylic to adjust; 2 ball clasps per sextant. Only 2 contacts of occlusion with the forward bite.	The Oravan Herbst is custom fitted to each patient by a dentist who takes impressions and bite registration. No anterior coverage means it will not interfere with anterior dental cosmetic work.	Custom fit by a dentist following physical or digital intraoral impressions and bite registration. Dental models scanned and the device and protrusive position designed based on bite registration. Device is 3-D printed in biocompatible nylon.	Compatible with intraoral scanning technology or regular dental impressions. Each case is designed on a proprietary software so retention can be adjusted individually. The D-SAD could be designed for horizontal protrusion as well as vertical.
Adjustment Description	May need to switch out the 6 different connectors to get ample advancement of the mandible to open the airway.	Small increments using advancement shims, or up to 5 mm with a 1 mm retrusion using telescopic hardware.	Titration is by 2 orthodontic screws that are turned with a key (wire). Adjustable in 0.25 mm adjustments up to 6 mm.	Insert the key into the adjustment mechanism located on the anterior mandibular component of the device. Can be advanced in small increments up to 5 mm.	Connector bands attach to custom placed lugs on each side of the upper and lower trays. Adjustable bands in 9 lengths (13-21 mm) allow for 6 mm protrusion, 2 mm retrusion, in increments of 1 mm.	A patented locking mechanism means rods can be replaced for titration. The rods will not disengage during sleep nor elongate. Rods in 0.5 mm increments and lengths from 18 mm to 36 mm.
Upper-Lower Sections Connection	Connected	Connected (telescopic hardware); others not	Not connected	Connected	Connected	Connected
Supporting Study	Borrie F, Keightley A, Blacker S, Serrant P. Mandibular advancement appliances for treating sleep apnoea/hypopnoea syndrome. <i>Evid Based Dent.</i> 2013 Mar;14(1):27-8.	Not provided	Not provided	Sutherland K, et al; on behalf of the ORANGE Registry. Oral appliance treatment for obstructive sleep apnea: an update. <i>J Clin Sleep Med.</i> 2014;10(2):215-27.	Not provided	Not provided

Company		ProSomnus Sleep Technologies			Quiesco Health	SICAT GmbH & Co KG
Appliance						
		ProSomnus [IA] Iterative Advancement Sleep and Snore Device	ProSomnus [CA] LP Continuous Advancement Sleep and Snore Device	ProSomnus [PH] Precision Herbst Style Sleep and Snore Device	The Silencer with Halstrom Hinge	OPTISLEEP
Website		www.prosomnus.com	www.prosomnus.com	www.prosomnus.com	www.the-silencer.com	www.optisleep.com
Warranty (days)		1,095	1,095	1,095; 1,825 (Medicare patients)	1,825 (hinge); body varies	730
INDICATIONS	Mild-Moderate OSA	X	X	X	X	X
	Snoring	X	X	X	X	X
	Bruxism					
MATERIALS	Biocompatible Polymer					X
	Cobalt-Chromium Alloys					
	Ethylene-Vinyl Acetate					
	Hard Acrylic				X	X
	Laminate					
	Thermal Acrylic				X	
	Other	control-cured polymethylmethacrylate	control-cured polymethylmethacrylate	control-cured polymethylmethacrylate	ivocap acrylic-elastomer	
PDAC Verified				X		
How Does the Oral Appliance Work?		ProSomnus [IA] utilizes vertically mated buccal posts to advance and hold the mandible forward to open the airway.	ProSomnus [CA] advances the arch using a split 90° post with embedded expansion screw. Total available range of 12.0 mm, 11.0 mm for advancement and -1.0 mm retrusion from original bite position.	The ProSomnus [PH] uses a continuous advancement protocol. Upper arch connects via Herbst Arm to lower arch with an adjustment nut.	Airway patency achieved through incremental advancement combined with vertical adjustability and lateral movement.	The airway is kept open by protrusion of the mandible with a 2-part appliance. It allows for lateral movement and mouth opening.
Fitting Description		The dentist typically inserts and confirms the fit and comfort of each arch independently and then together. Patients are instructed to place the device arches in as a single unit. Experience fast insertion due to the accuracy of the digital design and precision manufacturing.	The dentist typically inserts and confirms the fit and comfort of each arch independently and then together. Patients are instructed to place the device arches in as a single unit. Experience fast insertion due to the accuracy of the digital design and precision manufacturing.	The dentist typically inserts and confirms the fit and comfort of each arch independently and then together. Patients are instructed to place the device arches in as a single unit. Experience fast insertion due to the accuracy of the digital design and precision manufacturing.	Standard.	The dentist inserts the OPTISLEEP and confirms fit, comfort, and mandible position.
Adjustment Description		Remove an arch and insert the next arch in the series of advancement arches. Combinations of arches add up to a new titration increment. No screws, mechanisms, or elastics required. Unlimited Advancement Arches can be ordered one at a time until satisfied.	Includes 1 upper [CA] LP arch; 1 lower (L0) arch; 1 lower (L3) arch; linguless anterior coverage; full posterior coverage; tapered posts; flat plane splint design with lingual and labial anatomical scalloping. Device starting position is set at bite when delivered. When the advancement is completed using the initial upper [CA] LP arch, the patient can swap in the lower (L3) arch. Note: Both the ProSomnus [CA] and [CA] LP Sleep and Snore Devices can be adjusted within a 12.0 mm total titration range.	Uses a continuous advancement protocol. Upper arch connects via a Herbst Arm to the lower arch with an adjustment nut allowing for small incremental adjustments in a range from -1.0 mm to 6.0 mm.	Advancement through a range of 10 mm, adjustable in 1 mm increments. Vertically adjustable through changing connecting stylus pin.	Adjustments are done by changing the connectors, which are provided together with the OPTISLEEP. There are 10 pairs in total, providing an incremental range from 1.0 mm to 10.0 mm.
Upper-Lower Connection		Not connected	Not connected	Connected	Connected	Connected
Supporting Study		Hu J, et al. Case report: The Micro, Sleep Device. <i>DSP</i> . Summer 2015:24-7. Remmers JE, et al. Clinical study: a feedback-controlled mandibular positioner identifies individuals with sleep apnea who will respond to oral appliance therapy. <i>JCSM</i> . 2017;13(7). Vranjes N, et al. Assessment of potential tooth movement and bite changes with a hard-acrylic sleep appliance: A 2-year clinical study. <i>J Dent Sleep Med</i> . 2019;6(2).	Seltzer N, et al. Case report: Using a precision milled, continuous advancement, oral appliance with symmetric titration to treat all severity levels of obstructive sleep apnea. <i>DSP</i> . Spring 2019:22-4.	Not provided	Raphaelson MA, et al. Oral appliance therapy for obstructive sleep apnea syndrome: progressive mandibular advancement during polysomnography. <i>Cranio</i> . 1998;16(1):44-50.	Not provided

Company		SML-Space Maintainers Laboratories	SomnoMed Inc	Tomed GmbH	True Function Laboratory	Whole You
Appliance		 Clear Sleep Appliance	 SomnoDent Avant	 SomnoGuard SP Pro	 TrueDorsal	 Respire Pink Micro
Website		www.smlglobal.com	www.somnomed.com	www.tomed.com	www.truefunction.com	www.wholeyou.com
Warranty (days)		365-730	1,095	730; body varies	730	365
INDICATIONS	Mild-Moderate OSA	X	X	X	X	X
	Snoring	X	X	X	X	X
	Bruxism					
MATERIALS	Biocompatible Polymer	X	X	X		
	Cobalt-Chromium Alloys					
	Ethylene-Vinyl Acetate				X	
	Hard Acrylic	X		X	X	X
	Laminate	X			X	X
	Thermal Acrylic					
	Other		control cured acrylic	stainless steel	milled PMMA	
PDAC Verified						
How Does the Oral Appliance Work?		Two BPA-free trays allow for lateral movement and maximum room for the tongue while advancing the mandible forward.	The device functions as a mandibular repositioner, which acts to increase the patient's pharyngeal space during sleep.	A 2-piece, adjustable mandibular advancement device with a connector on each side, it repositions the lower jaw forward and so prevents collapse of the upper airway.	The upper splint has bilateral adjustable components made with orthodontic expansion screws that engage with the lower splint to advance the mandible.	With shorter Herbst arms, the Respire Pink Micro increases comfort due to its smaller size. It minimizes contact of the hinge on the lip area and reduces irritation on cheeks. A thin chrome framework version is also available.
Fitting Description		The appliance is seated by placing the upper and lower portions together. First seat the upper portion, then guide the lower portion and seat with finger pressure.	The device consists of two trays customized to fit over the upper and lower teeth, and the lower tray is held in a protrusive position by an advancement mechanism consisting of a strap attached to an upper anterior guide and two lower fixing elements.	Dental impression of the upper and lower jaw. Construction bite registration and definition of the initial protrusion for the lower jaw. For the thermoforming technique, thermoforming discs with a thickness of ~2 mm and a pressure forming unit are necessary. The attachment points for the metal knobs and wires are in the lower jaw in the molar region and in the upper jaw in the canine region.	Place the upper tray in the patient's mouth and press it up into place with your thumbs. Place the lower tray into the patient's mouth and press down both sides using index fingers to ensure the fit on the teeth. Once both trays are securely positioned, engage the fins by bringing the lower jaw forward. Removal: Remove the lower tray by using your thumbs to pull the tray up and out. Using thumbs and index fingers, pull upper tray down and out.	Place upper component (marked with both arrows on the side of the device) onto upper teeth by hand. Press up to ensure plate is seated securely and fits comfortably. Place lower component onto lower teeth by hand. Press down on both sides to ensure plate is seated securely and fits comfortably. Close the mouth once the upper and lower components are seated firmly. Ensure device's flat planes are in even contact throughout the arch.
Adjustment Description		The Clear Sleep provides up to 7 mm of advancement and uses a series of connector straps that can be interchanged to move the mandible forward in 1 mm increments.	SomnoDent Avant is adjusted by switching out the strap for another strap with a different length.	Two connectors of equal length connect the upper with the lower jaw tray. The lower jaw advancement can be infinitely adjusted from -3 to +7 mm (and more) by turning the screws between the connectors with the spanner. Connectors without screw in different sizes are also available.	The dentist can advance the TrueDorsal using the orthodontic expansion key enclosed with the device. A patient can also advance the device, if needed, under the care of the dentist. Full 360° turn = 0.8 mm. ¼ turn (every time a new hole appears) = 0.2 mm. Maximum advancement is = 6 mm.	The micro arm will advance up to 3 mm. For further titration, unscrew the fixing element on the upper device using the hex key, turn the adjustable component on the Herbst arm back to the starting point (zero turns). Using the key, connect the Herbst arm to the anterior fixing element on the upper device for up to additional 3 mm of advancement Maximum protrusion is 3 mm = 48 quarter turns. Do not titrate over 3 mm.
Upper-Lower Connection		Connected	Connection of the upper and lower tray by a strap attached to an upper anterior guide; adjustable with a range, by increments of 1 mm, from - 1.0 mm to +8.0 mm; design features both lateral movement and vertical opening.	Connected	Not connected	Connected
Supporting Study		Not provided	Not provided	Not provided	Not provided	Not provided