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Product		 myTAP	 TAP 3 Elite	 ApneaRx	 OASYS Hinge Appliance	 OASYS with Option for Combination Therapy
Website		www.myTAPappliance.com	www.amisleep.com	www.apnearx.com	www.dreamsystemsdentallab.com	www.oasysleep.com
Warranty (days)		90 (30-day satisfaction guarantee)	365 (for parts) (60-day satisfaction guarantee)	30 (guarantee with full refund); 90 (replacement)	365	365
INDICATIONS	Mild to Moderate OSA	X	X	X	X	X
	Severe OSA				X	X
	Snoring	X	X	X	X	X
	Bruxism				X	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.	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 OASYS T-10 Hinges provide 10 mm advancement, holding the lower jaw forward during sleep to open the airway in the back of the throat. Optional nasal dilators and tongue lifters available.	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.
Fitting Description		myTAP can be fit by a clinician or assistant in as little as 15 minutes, allowing you to provide same-day treatment and immediate relief. Defined by accurate molding capabilities, the sleek Precision-Fit trays allow myTAP to fit effortlessly on the teeth while instantly creating a comfortable, low-profile fit. Because they can be reheated and refit, Precision-Fit trays can be adjusted immediately for maximum comfort. The AM Aligner morning repositioner, included with each myTAP, should be fit during the same appointment.	TAP empowers patients to fine-tune treatment at home, as well as work with the clinician to achieve the best results. With a single point of central adjustment, the TAP prevents uneven bilateral adjustment that may create an irregular bite and jaw discomfort. Initial protrusion is set during the fitting process and easily modified. Three different hook sizes allow for greater range of adjustment with minimal hardware. Posterior stops may be added for comfort. With the fixed mechanical hinge and inseparable pivot point, all TAP Custom devices meet Medicare (E0486) requirements to treat OSA.	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 Hinge Appliance is inserted as one piece, placing the upper splint on the upper teeth first and then sliding the lower teeth up into the lower splint.	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.
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 patients to reach their treatment position comfortably.	Adjustment may be made by the patient with the appliance in the mouth in 1/3 mm increments. 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.	Hinges have anterior hex screws for intra-oral advancement. A Hex wrench is used to advance in 1/4 mm and 1/2 mm increments (2 full clockwise turns = 1 mm). Optional nasal dilators and tongue lifters are adjusted with the index fingers and thumbs as needed.	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.
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 reshaping for patients who are having dental work.	Soft thermal plastic and hard acrylic.	Fricke Vitacrylic ThermoFlex hard resin/hard acrylic, Duraloy wires, stainless steel hinges, pivots and screws; ball clasps/arrow clasps, latex-tree elastics.	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.
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 carefully with soft toothbrush and anti-bacterial soap. Let the device dry during the day with the lid of the container left open. A non-alcoholic denture cleaner can be used for 15 minutes.	Brush gently with soft toothbrush and anti-bacterial soap. Use non-alcohol denture cleaner for 15 minutes. Air dry.
Peer-reviewed Study		Not provided (however, technology is based on the custom TAP appliances, which are validated in 32+ peer-reviewed studies)	Hoekema A, Stegenga B, et al. Obstructive sleep apnea therapy. <i>Journal of Dental Research</i> . 2008;87(9): 882-887.	Not provided	Not provided	Not provided

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. Manufacturers were specifically asked to provide FDA-cleared indications only.

Glidewell Laboratories	Great Lakes Orthodontics Ltd		Keller Laboratories	Luco Hybrid OSA Appliance Inc	MicroDental Laboratories
					
Silent Nite sl	Herbst Appliance	MPowRx Snoring and Sleep Apnea Appliance	ClearDream	The Luco Hybrid OSA Appliance	MicroO ₂ Sleep Device
www.glidewell dental.com	www.greatlakesortho.com	www.greatlakesortho.com	www.kellerlab.com	www.lucohybridosa.com	www.micro2sleepdevice.com
182 (if the failure is due to defects in materials or workmanship)	90 (metal component); 365 (body material)	N/A	365	1,695	730
	X	X	X	X	X
				X	
X	X	X	X	X	X
	X				
X	X		X	X	X
		X			
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 ClearDream maintains an open airway using titratable posterior hardware on the upper arch, which determines the amount the mandible and pharyngeal tissue are held forward.	Mandibular advancement moves the tongue and jaw forward opening and maintaining the airway. Vertical wing design prevents retrusion when sleeping.	MicroO ₂ utilizes vertically mated buccal posts to advance and hold the mandible forward to open the airway.
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 ClearDream is custom fabricated from full arch upper and lower casts, scans, impressions. Immerse in warm tap water for 10 seconds to moisten before seating. Insert upper and lower arch separately, ensuring a gentle, but snug fit. Next, reinsert the appliance, starting with the upper, and have the patient protrude until they can engage the mandibular "fins" against the maxillary buccal pads. Inspect the bite relationship.	Very simple to insert, no lingual acrylic. Retained by four small ball clasps per appliance.	The MicroO 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.
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.	Small increments using advancement shims, or up to 5 mm with a 1 mm retrusion using telescopic hardware.	Non-custom, non-adjustable.	Titrate with provided adjustment key, which fits into screws on each side of the ClearDream's maxillary arch. To advance mandible forward, move key either up or down as guided by the arrow to turn the expansion screw allowing for titration in as small as 0.1 mm increments with a total range of 5.5 mms. To move mandible backwards, move key in the opposite direction to the arrow.	Titration is by two orthodontic screws that are turned with a key (wire). Adjustable in 1/4 mm adjustments up to 6 mm.	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.
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).	Standard hard acrylic and soft version, but can be made of Variflex, a thermo-active option.	Elastomer.	Keller's clinically unbreakable Clear 450 Acrylic. Available with a thermo-adaptive lining for ease of insertion and increased patient comfort.	Chrome cobalt, methyl methacrylate, stainless steel.	Pre-polymerized, milled polymethylmethacrylate (PMMA).
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.	Clean after each use with mild soap and water. Store dry. Do not use toothpaste, alcohol, or alcohol-based products.	Clean with liquid soap and a soft toothbrush.	Clean daily using a soft toothbrush with mild toothpaste or mild detergent. Do not soak. Store in dry container.
Not provided	Journal of Sleep 2006	Sleep Breath 2008	Not provided	Not provided	Case report to be published in Dental Sleep Practice, Summer 2015, p 24-27.

Company		Myerson	OravanOSA	Quali-Som LLC	ResMed	SML-Space Maintainers Laboratories
Product		 Myerson EMA	 Oravan	 TheraSom Cast	 Narval CC	 Lamberg-Sleep Well Appliance
Website		www.myersontooth.com	www.oravansa.com	www.quali-som.com	www.resmed.com/narval	www.smlglobal.com
Warranty (days)		N/A	730	1,825	1,095	1,095
INDICATIONS	Mild to Moderate OSA	X	X	X	X	X
	Severe OSA	X		X		X
	Snoring	X	X	X	X	X
	Bruxism	X		X		X
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.	The device opens the patient's airway through advancement of the mandible and holding the jaw in a forward position. The true open anterior design of the device encourages natural protrusion of the tongue and maximum patient comfort.	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.	It advances the mandible by holding it in a protrusive position.
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.	The Oravan is custom fitted to each patient by a professional sleep dentist by taking impressions and a bite registration. The Oravan's separate top and bottom acrylic pieces allow patients complete comfort and the freedom to open and close their mouth and lips, speak clearly, yawn, and drink. As a result of the no anterior coverage, less clinical chair time is required, and the Oravan will not interfere with any anterior dental cosmetic work.	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.	The dentist seats the upper and lower appliance separately to determine: a snug and secure fit, patient comfort, and the ability of the patient to easily insert and remove the appliance. Adams clasps adjust to achieve optimal comfort and retention.
Adjustment Description		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 Oravan can be titrated by inserting the titration key into the adjustment mechanism that is located on the posterior maxillary component of the device. Each turn in the direction of the arrow moves the appliance forward 0.1 mm.	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 0.5 mm increments.	Each patient receives his/her own box of inserts, which includes a sequence of numbered protrusive elements that advance the mandible in 0.5 mm increments. The patient simply pops out the insert on the upper member and replaces it with the following insert in the numbered sequence.
Materials		Completely metal free; the custom trays are made from a proprietary thermoplastic and the straps from a latex-free polymer.	Acrylic.	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.	Special SML brand sleep appliance acrylic.
Recommended Cleaning		Clean appliance in tepid water with a toothbrush and toothpaste or soak it in a denture cleaning solution; no mouthwash.	Clean with cold water and a soft toothbrush every morning. If one wishes to use toothpaste to clean the Oravan, brush lightly and thoroughly rinse. Shake dry and store the device in its container until the next use.	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 recommended. Rinse in lukewarm water; clean 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 storage box.	Clean once daily with OAP anti-microbial dental appliance cleaner.
Peer-reviewed Study		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):215-227.	Not provided	Not provided	Not provided

SomnoMed Inc	SomnoMed Inc	Somnowell Inc	Tomed Dr. Toussaint GmbH	Whole You Inc
				
SomnoDent Herbst Advance with Compliance Recorder	SomnoDent Fusion	Somnowell Chrome	SomnoGuard AP	Whole You Sleep Appliance Respire Blue
www.somnomed.com	www.somnomed.com	www.somnowell.com/en-us	www.tomedcare.com	www.wholeyou.com
365 (non-Medicare); 1,095 (Medicare)	1,095	2,555	365 (against manufacturer's defects)	365
X	X	X	X	X
		X	X	X
X	X	X	X	X
			X	
The first oral device with compliance recording (only can be offered by SomnoMed in its oral devices), it advances the mandible to open the airway and hold the jaw in position.	It advances the mandible to open the airway and hold the jaw in position.	It holds the jaw forward in a non-laterally displaced position using an adjustable telescopic Herbst mechanism. The chrome cobalt frameworks act as anchorage.	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 device opens the patient's airway by advancing the jaw and the associated tissues.
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 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 dentist will take accurate records to include dental impressions and a forward postured non-laterally displaced bite. Additionally, the dentist will take a Facebow registration so the technician can mount the records on a jaw simulator (semi-adjustable articulator), so the Somnowell Chrome should work in harmony with the patient's jaw joints.	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.	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.
Herbst Advance can easily be adjusted in 0.1 mm increments by utilizing our provided titration key; you can easily gauge protrusive movement by using our proprietary visual indicator, giving you and your patients total control of their treatment. With an 8 mm range of calibration, even when starting patients with a conservative protrusive registration you can offer your patients continuous therapeutic efficacy.	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.	The telescopic Herbst arms have a fine adjustment/titration facility. This is achieved by turning the adjustment nut. Adjustment of up to 5 mm is possible. The frameworks can have minor adjustments made by the dentist.	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.	An adjustment key is provided to advance the screw inside of the device. This, in turn, advances the jaw in 0.2 mm increments, and up to 6 mm in full advancement. There is an arrow inside of the device indicating which direction to turn the screw and videos to show this can be provided.
Acrylic.	Acrylic.	Chrome cobalt and stainless steel.	Rigid tray walls: rigid polycarbonate; lining: soft thermal copolymer; stainless steel adjusting screws.	Acrylic.
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.	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.	Scrub under clean water with a toothbrush. Dishwasher safe.	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 with soap and water every morning. It's recommended to use a denture/retainer cleaner once a week.
Not provided	SomnoMed SomnoDent Fusion Obstructive Sleep Apnea Device. <i>Dental Product Shopper</i> 2015. 9(6):72-3.	Ash SP, Smith AM. Chrome cobalt mandibular advancement appliances for managing snoring and obstructive sleep apnoea. <i>Journal of Orthodontics</i> . 2004;31:295-299.	Banhiran W, Kittiphumwong P, Assanasen P, Chongkolwattana C, Metheetrairut C. Adjustable thermo-plastic mandibular advancement device for obstructive sleep apnea: outcomes and practicability. <i>Laryngoscope</i> . 2014 Oct;124(10): 2427-32.	Not provided