



## TAP System Overview 2016

Our story begins in 1994, when a young Dr. Keith Thornton builds his first adjustable mandibular advancement device to treat obstructive sleep apnea. Very successful in his own clinical trials, Dr. Thornton decides to share the device with other dentists and physicians that are looking for an effective OSA treatment that the patients will **actually** use every night.

By 1996, Dr. Thornton completes the onerous tasks to protect his intellectual property and obtain the regulatory clearance to market the device to professionals. The TAP 1 is launched and quickly adopted by the pioneering dentists in the fledgling dental sleep medicine market. It is the first adjustable device that is comfortable and immediately effective for OSA patients. The success of this early device and the overwhelmingly positive response from the DSM dentists changes the course of Dr. Thornton's professional life. Turning an interest in appliance therapy to a vision quest to improve the lives of the millions of our fellow citizens.



Figure 1: TAP 1

Over the next 20 years, Dr. Thornton tirelessly works to constantly improve on the design of the appliance. He also becomes a worldwide leader and spokesperson for the new segment of dentistry called Dental Sleep Medicine. Teaching both dentists and physicians about advantages and practice of oral appliance therapy. He creates both Airway Laboratory and Airway Management to build the appliances and share with the Dental Laboratories and Professionals.

By 2016, Airway Management (AMI) has built a series of TAP appliances. Each one improving on the previous version.



In addition to the core mandibular advancement devices, Dr. Thornton and AMI extend the TAP concept to include an immediate delivery product named the *myTAP* and an advanced product for combination therapy called the *TAP PAP CS*. In 2016, the 5<sup>th</sup> generation TAP appliance is released... **the dreamTAP**.

## Design Principles

Back in 1994, Dr. Thornton established unique design principles for the appliances that have guided all subsequent products. The principles are based on the mission to treat as many patients as possible.

### **Simple. Durable. Patient Friendly.**

These concepts are the foundation for every TAP appliance. The manifestation of these concepts are illustrated as follows:

**Simple:** Single point adjustment and snap-fit trays

**Durable:** Metal injection molded hardware with the finest dental alloys and high strength trays

**Patient Friendly:** Easy to use and low-risk advancement mechanism

Over the years, the TAP appliances have been the subject of over 36 independent peer reviewed studies. Far more than any other appliance. The appliances have consistently been proven to effective judged against CPAP and other MADs. After twenty years of studies, the conclusion is: **It works.**

The academic studies are excellent to prove the design principles but market acceptance by large organizations are another indication of the value of the TAP design in treating OSA. AMI is very proud to supply the Veterans Administration across the country. Every branch of the US Armed Services also uses the TAP appliances to insure our service men and women are getting the finest treatment, are rested and ready to honor their duties. Many of most successful dental laboratories in the USA and abroad manufacture the TAP appliances for their clients. The list is very long.



dreamTAP is the 5<sup>th</sup> generation of the TAP appliance. After years of R&D, the dreamTAP was released in May 2016. For the casual observer, it looks similar to the previous versions of the TAP. But for the dentists treating OSA patients, it is a significant improvement.

The TAP design principles are clearly displayed in the dreamTAP. Single point adjustment, easy for patients or practitioners and snap fit trays are still evident. The durability is increased with the introduction for the first time of Chromium-Cobalt (Cr-Co) dental alloy used in 100% of the hardware.

The most significant and obvious design change is the placement of the hardware. AMI flipped the hardware, so the advancement mechanism is on the mandible and the bars are the maxilla. This was done to maximize the tongue space. All the hardware is now facial to anterior teeth.

Changing the alloy from medical stainless steel to dental Cr-Co, was a difficult engineering task. The advancement mechanism and all the hooks had to be redesigned. They were tested for strength and tolerances as the design was fine tuned. The results have been very encouraging.

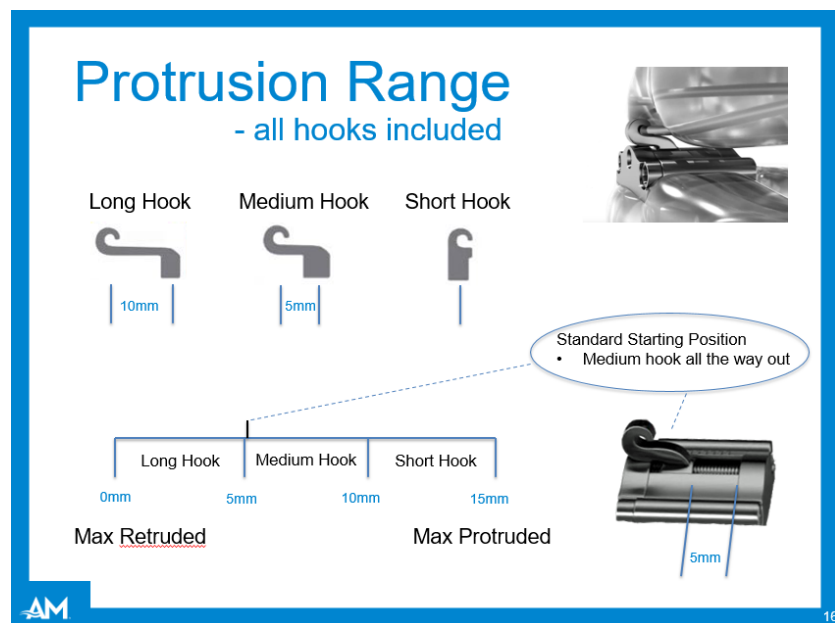


The new Cr-Co hardware is nickel (Ni) and beryllium (Be) free. Universally accepted as the finest non-precious dental alloy, it eliminates any allergic reactions to nickel. There is no ferrous metal, which is present in stainless steel, to discolor the device. Which solves another annoying issue for the practitioner. The higher tolerance and friction coefficient of the Cr-Co, combined with a new nylon washer in the assembly insures that the hook will not retrace during use. This has been a complaint for some of the previous TAP designs using SS.

The dreamTAP is a very flexible treatment tool. Dimensionally, the lateral excursion in the anterior can be designed and built from about 4mm to about 15mm. Airway Labs uses the standard of the width of the two centrals or about 15mm.

The vertical height between the trays has been reduced to about 5mm. This is the space needed for the hardware. The dentist can prescribe the appliance with up to 15mm of vertical opening as determined by his/her preference.

One of the biggest advantages of the dreamTAP is the enormous 15mm of horizontal protrusion range. The screw mechanism has a range of 5mm, as shown in the figure. You can extend this range with three hooks included with the appliance.



Airway Labs provides all three hooks with every case. The standard build is to use the medium hook initially and place the hook at the most retracted screw position. This way the appliance can be advanced a full 5mm before you would need to use the short hook. If the starting position turns out to be too far advanced, the long hook allows the practitioner to retard the starting position by 5mm.

Bottom line is the dreamTAP has the largest range of any oral appliance to treat OSA. The dreamTAP is NOT technique sensitive. It is very flexible to insure that wherever your starting position is, the dreamTAP can be adjusted in the practice to fit the patient's needs.

## Medicare vs Quick Release

Like all the of the TAP appliances, dreamTAP has received approval by PDAC (Pricing, Data, Analysis and Coding) and therefore are accepted for reimbursement by Medicare. Unfortunately, the only other PDAC approved device is the Herbst, the bilateral orthodontic appliance modified for DSM.

The dreamTAP meets the requirements of PDAC by creating a hook design that is hinged and cannot be easily unhinged by the user. We use a 1.3mm bar to create the hinge with the hook. You must engage the hook on the side of the bar, where the diameter is reduced to accept the 1mm opening in the hook.

AMI has been asked by our clients to create an optional version that allows the patients to quickly unhook while wearing the appliance. The optional bar design has been created with the dreamTAP to allow for this. We can this the “Quick Release” version, which can be used with every other insurance carrier besides Medicare.



Quick Release dreamTAP uses a 0.8mm Cr-Co bar to engage the hook. The patient simply advances the mandible about 1.5mm to release the hook, while wearing the appliance. This eliminates any concerns about being “locked” in with the appliance and makes it easier to insert and remove.

The practitioner only needs to order the version desired on the prescription. No extra cost.

## TL vs ThermAcryl and other tray options

Most veteran appreciate the all the options that the professional can utilize to customize the TAP for the patient. One of the biggest is the two current tray options.

The easiest to deliver is the TL version. This version utilizes a 1.8mm thick polycarbonate that is dual-durometer, hard on the outside and soft on the inside. The tray is thermoformed over your models and creates the snap-fit retention TAP is famous for. Easily adjusted for minor fit issues, this is our most popular tray by far. It’s quick to deliver and comfortable for the patient.

The ThermAcryl version uses a 2mm hard PMMA tray that is lined with our heat moldable acrylic called ThermAcryl. It’s a little more complex to deliver, as there is more customization available to the dentist. Since the material can flow into every undercut, it can allow for higher retention. Which is useful for short teeth or other challenging situations. It’s also very easy to modify, should the patient require new restorative treatments in the future. Can be relined to extend the life of the appliance.

Posterior stops can be added either by the laboratory or in the practice. AMI recommends that if these are going to be used, wait until the patient has reached an ideal protrusion position before adding.



## Future Options

We are currently working on several new options for our clients. The most anticipated is the ability to add compliance tracking to the appliances. We have partnered with Braebon to add the Dentitrac compliance device to any of our appliances. This will allow the professional to “read” the Dentitrac and prove compliance with the treatment. As insurers and government regulators attempt to increase compliance for OSA, this recording device will be extremely useful and possibly required in the future.



We also are introducing a mouth shield to encourage nasal breathing, which can be added to the dreamTAP and is now available for the myTAP.

Blue colored trays will be an option in the 4<sup>th</sup> quarter of 2016 as supply becomes available.

## Combination Treatment

Most studies have shown the TAP appliances to be very effective in the entire sleep disordered breathing range from simple snoring to moderate obstructive sleep apnea. To treat severe OSA, Airway Management has designed an add-on product to connect a dreamTAP (or TAP 3 / TAP 3 Elite) to a nasal pillow. We call it the TAP PAP CS

This allows the professional to combine oral appliance therapy with a CPAP device. For most patients, using the TAP PAP CS will permit the patient to reduce the pressure on the CPAP by opening the airway first with the TAP appliance. The result is higher compliance with the treatment.

Many DSM dentists use the TAP PAP CS to help bridge the gap between the MD and DDS/DMD. It allows the dentist to discuss oral appliance therapy with the MD with a collaborative tangible device. Helping to create a positive working relationship between the two branches of medicine needed to treat OSA.



TAP PAP CS w/dreamTAP

## Grow your DSM practice

Airway Management has supported dental practices for 20 years with the most effective and trusted appliances available. AMI now has two demonstration kits to help grow your DSM practice. Both kits are subsidized by AMI at less than half the cost of the actual appliances. The goal is to get more patients to accept oral appliance treatment for SDB.

### 1) Organic Growth

We know that the majority of adults either are afflicted or sleep with someone afflicted with sleep disordered breathing. This means that the normal dental practice has a large percentage of patients that need treatment. The simplest method to reach these patients and get the conversation started is with demo models in the waiting room.

Airway Management has created a beautiful counter display including a myTAP and a dreamTAP on blue translucent models. With a small footprint of 5 ½" x 8 ½", it can fit every practice. These are actual appliances that can be picked up by your patients. If they snore or have sleep apnea, they will start the discussion.



### 2) Referral Growth

All DSM practices are depended on prescriptions from MDs. The key is building a trust relationship between the referring MD and your DSM practice. The TAP PAP CS demo kit is a great tool to build those relationships. Instead of simply pitting the oral appliance against the CPAP, as is normally done, this device allows the best of both treatments. By using the TAP PAP CS as the discussion point with your MD, both treatments can be recognized and supported. This creates a non-confrontational environment for your meeting.

Many DSM practitioners report increased referrals from the MDs by utilizing the TAP PAP CS as the center point in developing the relationship.



## Summary

Airway Management is extremely proud to be part of the solution for 20 + years. As a medical device manufacturer, we strive to continually improve our products. Your feedback is very important to guiding the future of the TAP. We believe that the dreamTAP is the most flexible, effective and trusted device on the market. We've got a long way to go, but together we can make oral appliance therapy available to everyone and improve the lives of millions.