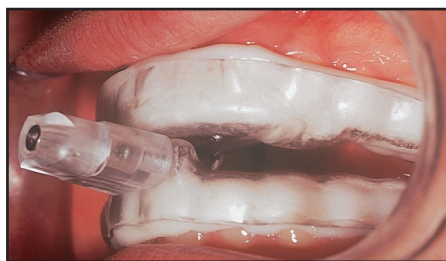


TREATMENT OF SNORING AND SLEEP APNEA USING THE TAP[®] SYSTEM

The Next Generation of Oral Appliance Therapy



The TAP[®] system provides a comprehensive therapy that yields both high clinical success as well as outstanding reports of patient satisfaction.

Practice Potential

Have you wondered why, all of a sudden, your dental patients are asking if there is something you can do to help them with their snoring? People who snore loudly and often may be accustomed to middle of the night elbow thrusts and lots of bad jokes. But snoring is no laughing matter.

Perhaps one in every 10 adults snores and although for most people snoring has no serious medical consequences, for an estimated one in 100 snorers, habitual snoring is the first indication of a potentially life threatening disorder called "Obstructive Sleep Apnea."¹

Recent articles in the medical and dental literature have made it clear that, as a dentist, you can provide a role in the treatment of both Snoring and Obstructive Sleep Apnea through the use of oral appliances. In fact, in response to an overwhelming demand, more

and more dentists are expanding their practices to treat sleep-disordered breathing.

Oral Appliance Therapy

Sleep appliances offer several advantages over other therapy choices. They are inexpensive, non-invasive, easy to fabricate, reversible, and quite well accepted by patients.

Most appliances seem to work in a combination of ways to stabilize the tissues and prevent the airway from collapsing. They reposition and lift the soft palate, bring the tongue forward or lift the hyoid bone. They also seem to increase muscle tone. Specifically, there seems to be an increase in pharyngeal and genioglossus muscle activity.²

Although there are numerous appliances available, a good appliance must have the ability to treat the spectrum of problems ranging from mild snoring to severe apnea. While doing so, it must also: ³

- be retentive.
- be easily adjustable.
- retain the jaw in the most favorable position for breathing.
- assure that the patient's occlusion stays stable.
- establish an appropriate vertical dimension.
- allow mandibular movement.
- protect the health of the TMJ.

One of the best oral appliances available today to treat snoring and apnea is the TAP[®] appliance. The TAP[®] system provides a comprehensive therapy that yields both high clinical success as well as outstanding reports of patient satisfaction.

Clinical Studies

Results from clinical studies provide the best information to help the dentist choose an appliance. Studies show that a good appliance will provide excellent treatment results, maintain a low morbidity rate, and still remain a viable economical alternative to other treatment options.

A study by Pancer and Hoffstein clearly shows that the TAP® meets and exceeds all the criteria set up in these studies to evaluate appliance effectiveness. The results of their study were as follows: ⁴

- a) Excellent Treatment Results - Treatment results are judged on two factors, medical efficacy based on standard polysomnographic outcomes and patient compliance.

This study showed a dramatic reduction in the respiratory disturbance index of severe apneics who used the TAP®. In addition, the polysomnographic results of the TAP® were comparable to CPAP for efficacy and were superior to any other appliance tested.

Their results also showed that patient compliance in all categories, from simple snoring to severe obstructive sleep apnea, was excellent. In fact:

- ✓ 90% of the patients tested wore the appliance every night, all night.
- ✓ 2% of the patients tested wore it as needed for snoring.
- ✓ Only 8% had stopped wearing it due to various reasons.
- ✓ TAP®'s compliance results were far superior to those of CPAP.

- b) Low Morbidity Rate - Although long-term morbidity on oral structures has not been assessed for any appliance, preliminary results for the TAP® show minimal problems. Occlusal changes are rare, though they do occur due to a repositioning of the mandibular condyles in the fossa. ⁴

Neither dysfunction nor other temporomandibular disorders occurred with the use of the TAP®. In another study of 65 patients with

an average of 12 months of use, the TAP® caused no increase in the TMJ Scale. ⁵

- c) Economically Acceptable - Because the TAP® system was engineered to minimize doctor time, auxiliary time, material cost, laboratory fees, follow-up appointments, remakes, and repairs, it has been shown to be a viable economical alternative to other treatment options.

Description of the TAP® system

All medical professionals and many lay individuals who are trained in cardiopulmonary resuscitation, CPR, are familiar with the principles of airway management. A collapsed airway in an unconscious or anesthetized patient is usually managed by establishing a proper head and jaw position.

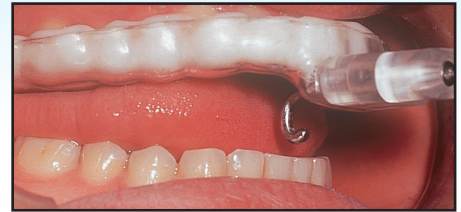
The TAP® appliance was designed with the principles of airway management in mind. Instead of employing existing dental technology for positioning and retention, the TAP® appliance was developed over a period of six years in a sleep lab environment to most effectively meet the demands of airway management while minimizing other dental and medical problems.

Some of the unique functional features of the TAP® appliance are:

1. Individual appliances for each arch - The TAP® is made up of two separate appliances. This allows the patient to easily place each appliance individually in the mouth and adjust the TAP® to the most favorable treatment position.

2. An exact fit that can be easily adjusted - The design of the TAP® incorporates two hard outer polycarbonate shells that are lined with a unique thermoplastic polymer blend,

called ThermAcryl™. ThermAcryl™ has the right balance of flexibility and rigidity to give the TAP® excellent retention without tooth movement.



The TAP® consists of two separate appliances made from polycarbonate shells that are lined with a unique thermoplastic polymer blend, called ThermAcryl™, allowing for ease of placement and excellent retention.

Although initial fabrication of the appliance is accomplished on stone casts of your patient's arches, an even more precise fit is accomplished at delivery by heating the ThermAcryl™ and molding it to the patient's dentition.

If the patient has new dentistry or has a loss of retention, there is no need to remake the entire appliance because a remolding procedure can be performed quickly and easily in one office visit.

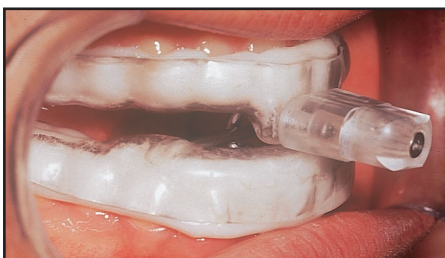
3. A unique hook and screw device - Attached to the upper and lower dual laminate thermoplastic trays is a unique hook and screw device that is used to bring the jaw forward to maintain an open airway. This hook and screw is infinitely adjustable anterior-posteriorly, provides 8 mm of vertical adjustment and a minimum of 25 mm of lateral freedom.

4. Precise Adjustment Mechanism - The TAP® has an adjustment knob that advances the mandible .25 mm with each turn. The patient can vary the position precisely by

counting the turns. This allows both the dentist and the patient to confidently maintain the proper treatment position and yet be able to vary it depending on the patient's symptoms.



A unique hook and screw device is used to bring the jaw forward to maintain an open airway.



The adjustment knob advances the mandible .25 mm with each turn.

5. Infinitely Adjustable - Although the initial trial position of the appliance is set at delivery, the TAP® is infinitely adjustable anteriorly and posteriorly. The dentist is, therefore, not limited to a range of predetermined positions with the TAP®. It can even extend to a point beyond maximum protrusion, which has been shown to improve efficacy.⁶

6. Adjustment in the Mouth - The TAP® is fully adjustable in the patient's mouth by both the dentist and the patient. Since the best treatment position can vary from night to night and can even extend beyond maximum protrusion, the patient has maximum control over his or her therapy with the patient-adjustable feature of the TAP®. This freedom achieves treatment results superior to any other appliance. Furthermore, adjustment does not necessitate an office visit.

This feature also allows titration of the appliance in the sleep lab by a technician or the adjustment at home by the bed partner if the patient's symptoms return while the patient is asleep.

7. Detachable Adjustment Mechanism

- Once the ideal treatment position has been determined, the dentist or patient can elect to remove the adjustable device. In such a case, a locking nut is then applied to fix the hook in one location. If adjustment again becomes necessary, the change can easily be reversed.



Once the ideal treatment position has been determined, the dentist can elect to remove the adjustable device.

8. Anterior contact only - Because the TAP® is designed as two appliances, one for each arch, and is connected with an adjustable hook and rod mechanism, the only contact between the two pieces occurs in the anterior region. There is no posterior contact. This models the normal function of the masticatory system in that the posterior teeth only make contact when the jaw is in a retruded position. In any other position, the posterior teeth are discluded by the anterior teeth. This is commonly known as anterior guidance.

9. "Freeway Space" - The physiologic breathing or rest position of the jaw is down and forward with "freeway space" between the teeth. The disclusion of the appliance's two parts by an anterior ramp maintains this freeway space.

The anterior ramp is similar to the use of an anterior deprogrammer for treating TM disorders. TM symptoms occur with the TAP® only when the posterior regions of the appliances inadvertently touch. In the event that posterior contact occurs after seating, it can easily and quickly be eliminated.



There is no posterior contact between the two pieces of the appliance. This models the normal function of the masticatory system and maintains the freeway space.

10. Attachment for CPAP - A unique universal mount for a CPAP mask bolts to the adjustment mechanism. A CPAP mask can therefore be attached to the TAP®. For the severe apneic, the TAP® reduces the required pressure while providing a leak-free, stable, "strapless" mask system.



A CPAP mask can be attached to the TAP®. This can reduce the required pressure while providing a leak-free, stable, "strapless" mask system.

11. Rugged design - Oral appliances for sleep disordered breathing are worn every night, all night, for years. They must, therefore, be designed to withstand much abuse. The TAP®, with its dual laminate system, has had minimal problems with breakage.

Treatment Procedures

As a general dentist, you should play an active role in screening your patients, treating them in conjunction with other sleep specialists, and providing them with follow-up therapy. Because the etiology of obstructive sleep apnea is multi-factorial and the treatment options are varied, proper diagnosis and treatment are best handled by a team approach.³ The first step, however, is to screen your patients.

1. Screen your patients - The first step in screening your patients is to ask the right questions. Asking your patients the right questions is often all that is necessary to initiate a discussion on snoring and apnea. For example, you may want to ask : Do you snore? Do you wake up feeling tired in the morning? Do you become extremely tired or fall asleep during the day? Do you drink caffeinated beverages throughout the day to help you stay alert? If a patient answers positively to any of these questions, you may then have them fill out a more detailed sleep questionnaire.

The second step in screening your patients is to do a complete intraoral examination. Spend the time to thoroughly evaluate the oropharyngeal airway space, the hypopharyngeal airway space, the size of the tongue, the position of the mandible, the vault of the palate, and the nasal airway. A complete screening examination should also include:

- a) a complete medical history.
- b) a periodontal evaluation.
- c) an orthopedic/TMJ/occlusal examination.
- d) an intraoral habit assessment.
- e) an examination of all the teeth and restorations.
- f) a complete dental radiographic survey (panoramic, full mouth x-rays and a base line lateral

cephalometric survey).
g) diagnostic models.

If you do suspect that a patient may be experiencing apnea episodes, then make sure your patient gets a complete medical work-up and a sleep test. *Remember that a definitive diagnosis of OSA can only be accomplished by a sleep test called a polysomnogram.*

2. Discuss the treatment alternatives - Treatment modalities for snoring and obstructive sleep apnea fall into one of three areas: surgical correction, continuous positive airway pressure known as CPAP, and oral appliance therapy. Although all three try to establish and maintain a patent airway, appliances like the TAP® show the greatest promise for effectively treating the broad range of sleep-disordered breathing. This is the case because it is non-invasive, inexpensive, and reversible. It is also the only appliance that has been clinically shown to be able to treat severe OSA.⁴

3. Take accurate intraoral records - Once you have decided that treatment with a TAP® appliance is appropriate, you must first take accurate impressions of the patient's upper and lower arches. An impression taken with alginate and poured up in yellow stone is more than sufficient. Because the initial trial position of the appliance will be set at delivery, it is not necessary to take an inter-occlusal record.

4. Communicate with the laboratory - Very carefully wrap up your patient's models and send them to the lab along with a lab slip. The initial fabrication of the appliance consisting of two hard outer polycarbonate shells lined with ThermAcryl™ will be accomplished on these stone casts. An even more precise fit will be accomplished at delivery by heating the ThermAcryl™ and molding it to the patient's dentition.

5. Begin the fitting process - Take a few moments to explain the fitting process to your patient. This is very important because you will be placing the appliance in the patient's mouth after heating it up in hot water. It will be necessary to assure them that it is not hot enough to burn them.

- a) Wet your hands before starting the fitting process.
- b) Place the lower appliance (the appliance with the lingual bar) in a water bath that is heated to 160 degrees for a few minutes to soften the ThermAcryl™ lining material. As soon as the ThermAcryl™ material becomes clear, it is ready to place in the patient's mouth. **DO NOT LEAVE THE APPLIANCE IN THE WATER BATH TOO LONG!** Doing so will cause the hard plastic outer shell to warp.
- c) Once the ThermAcryl™ in the lower unit is clear, position it over the teeth and, using your fingers, push the appliance on the teeth starting from the back and working your way forward. Some of the ThermAcryl™ will express out of the tray.
- d) Leave the tray in place for approximately 30 to 45 seconds then remove the lower appliance from the mouth by the hard material making sure not to touch the soft lining material as it will distort.
- e) Next, trim away all the thermocryl material beyond the edge of the hard shell with curved tissue scissors, making sure to clear the material away from the gingival tissues. Then remove any rough edges by burnishing the edge of the appliance with a wet finger.

- f) Replace the lower appliance in the patient's mouth and allow it to continue to set up. Do not leave the appliance in the mouth too long as there is a 1% shrinkage rate. During this process have the patient take it in and out a few times before the lining material completely hardens. Doing so will prevent the appliance from engaging an undercut and locking in place.
- g) Repeat the same process (steps a. through f.) for the upper unit. When seating the upper, make sure to press down (especially in the posterior region) with even pressure, trying not to rock the appliance.
- h) Once both units are properly fitted and trimmed, allow them to bench cure (run under cold water) for a few minutes until the ThermAcryl™ becomes completely white.
- i) Next, have the patient place both units in his or her mouth by placing the lower first, then the upper. The appliance must be tight, but not uncomfortably so, equal in all areas, and comfortable to the tongue. Make sure the patient removes the units. If any of these criteria are not met, reheat, refit, cool and try again until it is perfect and the patient says it is comfortable. When the appliance is made correctly, it should "snap" onto the teeth and not be uncomfortable.
- j) Now, with both units in the patient's mouth, have the patient close and relax to establish a normal breathing position (lips together, teeth apart). This does not have to be exact, just a position that is easy to find, and neither forward nor backward. This position, will be your starting point.
- k) Place the hook in an engaged position by twisting the front piece clockwise until the hook is engaged with the lingual bar. In order to engage the hook under the lingual bar, the patient must move the lower jaw forward, up, then back to a rest position. Be sure that the patient understands this procedure very clearly.
- l) Next, have the patient posture forward to his or her maximum protrusive position and turn the adjusting knob until the hook is once again engaged with the lingual bar in this position. Continue to turn the adjustment knob until the patient tells you that it is uncomfortable. This position represents the patient's maximum protrusive position and is a border position. Remove the appliance from the patient's mouth and cut off the excess screw. Then turn the adjustment knob back to the point where the patient can once again wear the appliance comfortably. The appliance is now ready to be adjusted.
- m) It is extremely important that there be a minimum of 1 mm of space bilaterally in the posterior areas at all times, in all positions. This will lessen the likelihood of TMJ symptoms. The only contact should be in the anterior area.
- 6. Adjusting the Appliance** - Do not adjust the appliance for the first few days. Instead, keep the patient in the initial position until the patient has completely accommodated to the appliance and everything associated with it (increased saliva flow, bulk in the mouth, and a change in the swallowing pattern).
- a) If the patient is still uncomfortable, turn the screw backward one turn at a time until the appliance feels comfortable.
- b) Once the patient is comfortable, have him or her slowly and patiently turn the front screw mechanism one-half turn per night until the desired effect is achieved.
- c) Instruct the patient not to advance the lower jaw forward too far, or too fast. If this happens, muscle soreness can occur, and the patient may end up rejecting the appliance. Advance the jaw only as far as needed.
- 7. Follow-up Visits** - While the self-adjusting feature of this appliance allows the patient to maximize the treatment benefit while at home, some follow-up appointments are still necessary. Unless the patient is having problems adjusting to the appliance, the first follow-up appointment is usually not necessary until three weeks later. At this appointment, the following questions should be answered: ³
- Are you able to sleep with the appliance?
 - Is it comfortable?
 - Are your teeth sore in the morning? If so, for how long?
 - Is your bite different in the morning?
 - Does your jaw hurt? When? For how long?
 - Did your bed partner hear you snore? Was it as loud as usual?
 - Was any gasping or choking observed?
 - Did you appear to stop breathing at any time?
 - Does your breathing appear to be different in any manner than prior to the appliance placement?
 - Did you wake up often?
 - Do you feel more refreshed in the morning?

- How do you feel the rest of the day?
- Do you have any other comments or concerns?

Once the patient is subjectively doing better, (i.e. excessive daytime sleepiness is gone, he or she is feeling great, energy level is back, and there is no snoring at night), the next step is to send the patient home with a pulse oximetry unit. Pulse oximetry is an easy way to evaluate the true effectiveness of the appliance by seeing if the patient is remaining oxygen saturated throughout the night.

Finally, if your patient is suffering from OSA and you are treating him or her with an appliance, it is appropriate for the patient to have a follow-up polysomnogram to evaluate the effectiveness of the appliance.

8. Explain the Home Care - Remind the patient to follow the home care instructions carefully. This will help the life span of the ThermAcryl™.

9. Future Recall Appointments, Relining the Appliance and Setting the Appliance in a Final Position - If the patient has new dentistry or has a loss of retention, there is no need to remake the entire appliance because a remolding procedure can be performed quickly and easily in one office visit. Regardless, the ThermAcryl™ will usually have to be relined within 12-17 months. To reline the appliance:

- Heat the appliance in a water bath that is heated to 160 degrees only until the ThermAcryl™ turns clear. If the appliance becomes too hot, it will warp.
- Remove the ThermAcryl™ with a spatula and let the appliance cool down.

- Heat some fresh ThermAcryl™ in a ceramic coffee mug until it becomes completely clear.
- Lightly flame the inner surfaces of the tray with a hand torch. Be careful, as too much heat will warp the tray.
- Fill the tray with hot ThermAcryl™.
- To reseat on patient's teeth, dip the filled tray quickly in cool water while the ThermAcryl™ is still warm. This will prevent the ThermAcryl™ from sticking to the patient's dental work and from delaminating from the tray. Then seat the appliance in the same manner as described earlier in step 5.
- Remove the Appliance and trim any excess ThermAcryl™ with 1" curved tissue scissors. Then burnish any burrs or rough edges and smooth with a wet finger.
- Allow the appliance to bench cool and then check the fit. Once cool, the appliance should snap into place and fit tightly.

10. You can remove the front assembly and lock it in position by attaching a Locator Nut - Once the patient is getting good results and needs no more adjustments, you can remove the front assembly and lock it in position by attaching a Locator Nut:

- Mark with a black sharpie where the hook is positioned in the locator.
- Using a 5/64" Allen wrench, remove the plastic front piece by twisting it to one side and exposing the screws. Unscrew the screws that are attaching the front assembly of the appliance.

- Once the screws are removed, twist the plastic front assembly counter-clockwise from the hook. Screw in the locator nut until it is lined up with the locator and check that the hook is at the position marked.
- Cut off the excess threaded wire with a burr or a cutting tool so that it is flush with the locator nut.
- Using a .050 Allen wrench, screw in the two screws through the locator nut and into the locator. The screws should be smooth enough for the patient's mouth, but they may be smoothed further with a rubber wheel or covered with acrylic. The hook may also be held in place with acrylic if desired.

Home Care Instructions for your T.A.P. Appliance:

Teeth should always be brushed and flossed well before inserting the appliance in the mouth.

In the morning, the oral appliance should be rinsed thoroughly with warm water. **DO NOT USE HOT WATER!**

A soft toothbrush should be used to clean the appliance. It should not be scrubbed too hard as the lining material can be scratched.

Make sure that the appliance is stored dry. It may help to leave the container open so that the appliance can dry thoroughly.

The oral appliance should be disinfected every 3 days with a cap full of bleach, diluted in water. Leave it in for 8 hours, then rinse thoroughly. **Remember this needs to be done only every 3rd day.** Soaking the appliance all day, every day will cause the material to become dry and brittle. If the

ThermAcryl™ has to be replaced earlier than 12 months, your patient may be soaking the appliance more than every third day.

If an odor or bad taste develops, have your patient rinse the appliance in mouthwash.

Important Caution!!! The lining of the appliance is a heat-sensitive material. Be very careful to store it in a cool, dry place. Do not leave it where the temperature may reach or exceed 120-140 degrees. This may cause distortion of the lining material and alter the fit of the appliance. (DO NOT PUT THE APPLIANCE IN THE GLOVE COMPARTMENT OF A CAR OR THE CARGO HOLD OF AN AIRPLANE!)

Contraindications and concerns

In order to best treat the patient and achieve maximum success, it is imperative for the dentist to have a firm understanding of the complex process of sleep and sleep disorders.

Some of the common side effects that you see with the use of sleep appliances are, excessive salivation, discomfort in the teeth, a dry mouth, and tissue irritation from mouth breathing.

As with other dental sleep appliances, temporary disharmonies in the bite and some pain in the joints can occur with the TAP®. TM symptoms, however, occur with the TAP® only when the posterior regions of the appliances inadvertently touch. In the event that posterior contact occurs after seating, it can easily and quickly be eliminated.

The best treatment position can vary from night to night and can even extend beyond maximum protrusion. Because of the patient-adjustable feature of the TAP, the

patient can have maximum control over his or her therapy. At home, even the bed partner can adjust the appliance if the patient's symptoms return while he or she is asleep. This freedom achieves treatment results superior to any other appliance.

Allowing the appliance to cool in the mouth enhances retention. If removal becomes difficult, the patient can hold warm water in his or her mouth for a few minutes to loosen the material. To reduce the amount of retention in the mouth, the dentist or patient can remove and replace the appliance several times while it cools.

LAB FEES:

To keep the appliance economical for both the doctor and the patient, the TAP® system was engineered to minimize doctor time, auxiliary time, material cost, laboratory fees, follow-up appointments, remakes, and repairs. The lab fee for this appliance is \$210, making it an excellent economical alternative to all other treatment options.

SUPPLY LIST:

One of the exceptional attributes of this appliance is the need for minimal supplies to complete the treatment. Some of the supplies we recommend are:

- ☐ Alginate*
- ☐ Mixing bowl and spatula*
- ☐ High quality stone for working casts - do not use plaster
- ☐ Hot water bath*
- ☐ Gloves
- ☐ Acrylic burrs to adjust the trays*
- ☐ 1" curved tissue scissors*
- ☐ Articulation paper
- ☐ ThermAcryl™
- ☐ Ceramic coffee mug*
- ☐ Hand torch
- ☐ Black sharpie
- ☐ 5/64" Allen wrench
- ☐ .050 Allen wrench
- ☐ Screening and exam forms*

- ☐ Patient information pamphlets*
- ☐ American Sleep Disorders Association patient pamphlets
- ☐ Sleep Apnea protocol information

*Available from Success Essentials

CUSTOMARY FEES:

For a new therapy to be instituted in a dental office, it must be as profitable as the customary dental procedures provided by that office. Also, the patient must believe that the value of the therapy is at least as great as the fee. Fees for treating obstructive sleep apnea range between \$500 to \$2500. This variation in fees is dependent upon the number of appointments needed to accomplish a positive result. This fee should include your examination, clinical work-up and all the appliances. Out of office services such as sleep studies, tomograms/ceph x-rays, and any medical consultations or procedures are not included.

INCOME POTENTIAL:

Statistics show that one out of every ten people in your practice snores. But, if you don't find a way of telling your patients that you can help them, how are they going to know? Here are a few simple marketing ideas to help you reach your existing patients and bring new ones into the practice.

1. Place brochures on Snoring and OSA in your waiting room - We have created excellent patient pamphlets for this purpose. By reading these pamphlets, your patients will learn that you can help them with their sleep problem.
2. Revise initial patient screening form - Asking your patients the right questions can trigger a discussion on snoring and apnea. For example, asking your patient

if they dream is the type of question that most patients do not expect to be asked by their dentist. Most patients will then ask you why you want to know.

3. Send out a newsletter - Newsletters are an excellent tool to keep your patients informed on what's new in your practice. Please feel free to use the information in this Practice Building Bulletin to create your letter.
4. Work in a team approach - Referring patients to a physician or a sleep diagnostic center, indicates your desire to make sure that your patients get the best care possible. It is this level of knowledge and expertise that will have sleep specialists willingly referring patients back to you for appliance therapy.

When it comes to treating Snoring and Apnea, as soon as you successfully treat one patient, more will be at your door. There are thousands of people just looking for someone to help them out. Treating just one patient per month can add up to \$6000-\$30,000 a year to your gross income.

By Keith Thornton D.D.S.,
Rob Veis D.D.S.

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