

TAP FAQ

Tap is the only FDA approved oral appliance proven effective for the treatment of mild to moderate obstructive sleep apnea.

Sleep Apnea: is the temporary cessation of breathing 10 seconds or more during sleep.

The Obstructive Sleep Apnea cycle

The person falls asleep, the mandible relaxes and the tongue falls to the back of the mouth (the soft tissue in the rear of the throat collapses and closes). The airway becomes partially blocked and person starts to snore. The partially blocked airway collapses and due to a vacuum effect from the lungs, the airway stays closed. With a lack of oxygen the brain starts to awake, coming out of deep sleep. The person adjusts the mandible, gasping for breath. This cycle continues throughout the night up to 50 times an hour.

Describing the TAP3 Appliance

The device is made of two clear horseshoe shaped interocclusal trays that hook together holding the mandible in a protrusive position. The position of the guards is adjustable using a TAP key.

What is the difference from TAP1 and TAP2?

- TAP1 had all the hardware outside of the plastic trays. It allowed a large range of lateral motion and the hardware contained nickel
- TAP2 the hardware was embedded in the plastic trays. It reduced the range of lateral motion. It is not as easy to titrate.
- **TAP3 modified: This is what Keller will be using.** Hardware is medical grade stainless steel with no Nickel. Less interference with the tongue. Range of lateral motion increased.

How does the TAP work?

By holding the mandible forward, the TAP maintains a clear airway to reduce snoring and improve breathing.

What are the indications?

Used as antisnoring device
FDA Approved for Obstructive Sleep Apnea
Adults
Nickel-Free

What are the contraindications?

Any condition in which the patient would have loose teeth or dental work including dentures
Central Sleep Apnea
Under 18 years old
Monomer Allergies

What is Central Sleep Apnea?

Loss of respiratory function due to dysfunction in the thalamus area of the brain that fails to signal the muscles to breath

TAP Research and Studies

- **Patients prefer oral appliances 20/1 over CPAP** American Academy of Sleep Medicine website www.aasmnet.org
- **More than 94% of patients using the appliance have stopped snoring.** **The TAP appears to be an effective treatment alternative for selected patients with snoring and varying degrees of sleep apnea, including those with severe obstructive sleep apnea.** Chest Magazine 1999; 116:1511-1518 Evaluation of Variable Mandibular Advancement Appliance for Treatment of Snoring and Sleep Apnea conducted by Jeffre Pancer, DDS, Salem Al-Faifi MD, Mohamet Al Al-Faifi and Victor Hoffstein, PhD, MD .
- **The device costs about as much as a CPAP device and it has a higher level of patient acceptance. 9 out of 10 patients wear the TAP all night, every night.** Internal Medicine News, August 2002, Vol 35, No.15 Oral Device Muzzles Obstructive Sleep Apnea and Snoring in a 2 Year Study by Jack Gerschman PhD.
- **Research shows it is the most successful obstructive sleep apnea treatment available.** Chest 1999; vol 116, pages 1501-1503 “Treatment of Sleep Apnea” by Peretz Lavie, Ph

Describe the materials used in fabricating the tap:

The outer layer of the TAP device is made using a durable hard polymer known as the thermalblend layer. The inner later is made using a triple laminate rubbery material known as the durasoft layer. The nickel free hardware is anchored between the layers.

What is the hardware made of?

A nickel-free medical grade stainless steel

What is the National Dentex FDA registration number: 3003643785

What do I do with the FDA sticker?

Doctors should attach the sticker to the patient’s paper in the permanent file. Any replacement parts will come with a sticker also and should be attached to the original paperwork in the permanent file.

Risk Factors of Sleep Apnea

Upper Airway Anatomy
Endocrine abnormalities (problems with the thyroid)
Alcohol or sedative use
Smoking
Male
Obesity
Nasal congestion
Genetics (physical characteristics that are passed on)

Shape of patient's head & neck

Sleep Apnea results in

Restless sleep
Daytime drowsiness
increased blood pressure
increased likelihood of heart attacks/strokes
Changes in behavior and relationships
Morning headaches
Depression
Impotence
Marital / relationship strain
Poor memory
Gastroesophageal reflux

How do you care for the device?

Each morning wash using a soft toothbrush and anti-bacterial soap. Rinse and dry.
Every two weeks you may use an ultrasonic or denture cleaner to clean thoroughly do not soak for more than 15 minutes.

What should the doctor send?

Rx
Full upper and lower PVS impressions
Construction bite showing 60% protrusive position

What is the warranty included with this device?

60 day customer satisfaction
1 year on parts (free repair)

Lab Fee: \$319

Lab working Days: 3 days; KY 6 days; KC 4 days

Insurance

- Keller is only providing applicable MEDICAL insurance codes.
- Oral orthotic devices are for treatment of a medical disease & thus, dental codes usually won't apply.
- Virtually all insurance providers will require a sleep study before submittal of coverage for oral appliance is considered.
- CPAP is still the "gold standard." Oral appliances are a relatively new treatment option.
- In the majority of instances, most insurance providers will require a patient to first undergo treatment via CPAP (still the most accepted form of treatment for OSD) & only cover TAP after patient has proven to be intolerant of it.
- To increase likelihood of coverage, patient should obtain copy of "Medical Policy Guidelines." Oftentimes it will state that for orthotic appliance to be covered, the patient must either have more than 5 apnea-related events per hour & 2 other possible apnea-related symptoms (high blood pressure, stroke, etc).
- Dr / Pt should confirm that their policy covers "durable medical equipment." This is usually submitted under code E0486. This is the same code used when submitting items for coverage such as crutches, wheelchairs, & CPAP.
- In many instances, policies will state that "orthotic devices" are not covered. This usually refers to podiatry (foot) orthotic devices such as prosthetic limbs. If this is the case, a copy of the policy pertaining to Obstructive Sleep Apnea should be requested. If "oral orthotics" are not specifically excluded in this portion of the policy, the argument can be made (often successfully) that the appliance should be covered.
- Informing the claims personnel that you have a CPT code will expedite the process.

Recommended Insurance Codes

Diagnostic Code 327.23 Obstructive Sleep Apnea
E0486 Oral Appliance to Treat Sleep Apnea
70355 Panoramic X-Ray of Jaws
95806 Sleep Study Unattended
99205 New Comprehensive Exam / Evaluation

Glossary

Apnea - The cessation of breathing for at least 10 seconds - A drop in the body's oxygen level of 3% or more. Results in complete stoppage of airflow or diminished airflow.

Central Sleep Apnea - Loss of respiratory effort resulting in episodes of apnea. Caused by a dysfunction in the thalamus area of the brain (part of brain that relays the need to breathe). Typically treated with various drugs or CPAP.

Construction Bite - A bite registration that records the relationship between the maxilla and mandible when patient's mandible is protruded to adequately open airway yet still allow patient comfort. This is typically approximately 60% of the patient's maximum protrusion.

Hypopnea – breathing that is shallower or slower than normal – literally: under breathing.

Mixed Sleep Apnea - Sleep disorder consisting of both central & obstructive sleep apneas.

Mild Sleep Apnea - 5 to 15 episodes of apnea or reduced airflow to lungs every hour with 86% or more oxygen saturation in the blood. Symptoms may include sufferer falling asleep during activities that require little attention such as reading or watching television.

Moderate Sleep Apnea - 15 to 30 episodes of apnea or reduced airflow to the lungs with 80-85% oxygen saturation. Symptoms may include patient falling asleep at inappropriate times such as during classes or meetings.

Obstructive Sleep Apnea - Sleep disorder occurring when the patient's upper airway is obstructed, usually when the soft tissue in the rear of the throat collapses, yet they continue to have respiratory effort. Most common form. Treated by the TAP 3.

Polysomnography - Sleep study

Respiratory Effort Related Arousals (RERA) – An arousal from sleep that follows a 10 second or longer sequence of breaths that are characterized by increasing respiratory effort. Considered in RDI totals.

Respiratory Disturbance Index (RDI) - Apnea + Hypopnea + RERA's. The number of sleep disorder-related breathing events per hour resulting in arousal from sleep.

Severe Sleep Apnea - More than 30 episodes of apnea or reduced airflow to the lungs every hour with no more than 79% oxygen saturation. May cause sufferer to experience drowsiness during activities that require active attention such as eating, driving, or participating in social functions.

Snoring - Noise produced by excessive soft tissue obstructs the airway & vibrates when breathing.

Titrate - To adjust in small, measured increments (turning TAP key to adjust mandibular protrusion)