

dreamTAP[®]

Patient Instruction for Use

 **AIRWAY**
MANAGEMENT

TAP SLEEP CARE
tapintosleep.com

Important Safeguards

SAVE THESE INSTRUCTIONS

The following words in this manual have special significance.

Warning:

- Means there is a possibility of injury.

Note:

- Indicates point of particular interest for more efficient and convenient operation.

Indications:

- The dream Thornton Adjustable Positioner (dreamTAP®) is intended to reduce or alleviate nighttime snoring and sleep related breathing disorders including obstructive sleep apnea (OSA). The appliance is for adult patients to be used when sleeping at home or in a sleep laboratory and is for single patient use.

Contraindications:

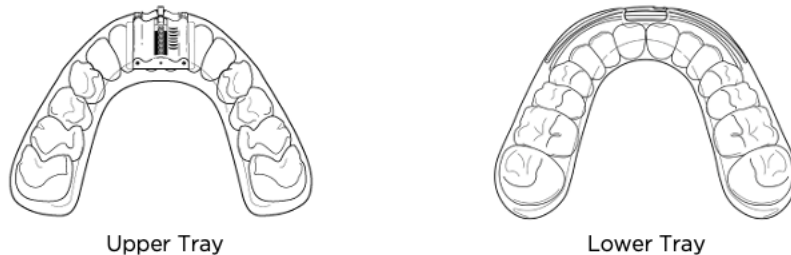
- This device is contraindicated for patients with loose teeth, loose dental work, dentures, or other oral conditions which would be adversely affected by wearing dental appliances. In addition, the appliance is contraindicated for patients who have central sleep apnea, have severe respiratory disorders or are under 18 years of age. Severe Class 2 or severe Class 3 malocclusion may require a custom splint.

Introduction

The dreamTAP[®] is an oral device intended to reduce or alleviate nighttime snoring and obstructive sleep apnea (OSA).

The dreamTAP device consists of an Upper Tray that fits over the upper teeth and Lower Tray that fits over the lower teeth. A hook mechanism attached to the Lower Tray fits onto a bar attached to the Upper Tray and positions the lower jaw forward, preventing the soft tissue of the throat from collapsing and obstructive the airway. The Adjustment Key of the dreamTAP permits the patient to adjust the protrusion of his/her lower jaw to the most effective and comfortable position.

Note: Failure to follow these instructions may compromise the performance and safety of the dreamTAP.



The dreamTAP is supplied with a notched bar design to prevent the hook from disengaging. Any adverse events that might occur due to altering the appliance is the responsibility of the person performing the alteration.

Linings: The device is fabricated on the dental casts of individual patients. The outer layer of the dreamTAP trays is Polyethyleneterephthalat-Glycol Copolyester (PET-G). There is a choice of three unique linings.

The first and second lining options, ThermAcryl and AccuTherm, are thermoplastic material which softens when heated and molded to the patient's teeth at the time of delivery. These linings are unique because they can be reheated and re-molded to the patient if the patient has had any dental work, like a crown.

Note: ThermAcryl and AccuTherm are heat sensitive linings and may deform if subjected to temperatures greater than 160°F. If it is heated above 160°F the impressions of your teeth in the tray will deform and your dreamTAP will no longer fit.

The third lining, Triple Laminate (TL), consists of a dual laminate material that features hard and soft linings (typically PETG and Polyurethane).

Each dreamTAP package contains:

1. An Upper and Lower Tray
2. Instructions for Use
3. Storage Case
4. AM Aligner
5. Adjustment Key

Directions for Daily Use

Instruct your patient in the daily use of the dreamTAP appliance. Also give your patient a copy of the Patient Instruction Booklet.

1. The patient should brush his/her teeth and floss well before inserting the dreamTAP.
2. Instruct the patient to inspect the device prior to each use. If there is any material separation, material degradation or damaged parts, the patient should discontinue use and contact you, the prescriber.
3. Tell the patient to engage the Hook of the Lower Tray with the bar of the Upper Tray before placing the trays in his/her mouth. The patient should make sure the Hook is not dialed too far back that he/she cannot comfortably snap the trays over his/her teeth while engaged. The patient should use his/her thumbs to push the tray from the bottom to snap it over the upper teeth. Repeat the same process on the lower tray.
4. The patient should gently relax once the dreamTAP is in his/her mouth.
5. After use, the patient can remove either the Upper or Lower tray by gently opening the mouth while the Hook is engaged. At the same time, the patient can lift up on the Lower Tray or pull down on the Upper Tray to loosen either tray and remove.

Warning: dreamTAP trays should never be worn separately. The patient should always wear both trays when using the appliance.

Operating the Adjustment Key

Note: Operating the Adjustment Key is written from the perspective of the patient with the dreamTAP is in his/her mouth. Always adjust your appliance when looking in the mirror.

1. To pull your lower jaw forward with the appliance in the mouth, turn the Adjustment Key clockwise (towards your right ear).
2. To return the lower jaw to the starting position with the appliance in your mouth, turn the Adjustment Key counterclockwise (towards your left ear).

Note: One turn of the key is 180 degrees or .25 mm.

Homecare Instructions

Warning: It is imperative to use the AM Aligner each day to reduce the risk of permanent bite change.

- Each morning after use, thoroughly clean your dreamTAP appliance using a regular soft toothbrush, tooth paste and cool water. Do not use hot water.
- Rinse thoroughly and dry your appliance completely before storing in the container. It may help to leave the container open to ensure that your dreamTAP dries thoroughly. Please store your appliance out of reach of pets and small children.

Note: Using hydrogen peroxide will cause the plastic materials of the appliance to deteriorate more rapidly or delaminate more easily. The best way to keep the dreamTAP appliance clean is to brush it each morning after use.

Warning: The dreamTAP should be stored in a cool dry place. The appliance is made from sensitive materials and should not be stored where temperatures exceed 120°F, such as in the glove compartment of a car or the cargo hold of an airplane. Do not clean the appliance in hot or boiling water, nor to soak it in bleach or hydrogen peroxide which will cause the trays to distort or the lining to become brittle and delaminate.

Warning: Do not disassemble any of the dreamTAP hardware. The dreamTAP is a medical device and the patient must not tamper with it other than following specific instructions in the patient instruction booklet.

Return to your prescriber at least yearly for examination and assessment to ensure that the dreamTAP is not damaged and is still treating your snoring or sleep apnea.

Warnings and Possible Side Effects

Note: Read all instructions before using the dreamTAP.

Warnings:

- This device is intended to reduce or alleviate nighttime snoring and obstructive Sleep apnea (OSA). If symptoms, breathing difficulties or other respiratory disorders exist or persist, with or without the device, the patient should contact the prescriber immediately.
- The dreamTAP should only be used as directed. Do NOT misuse the product.
- You may experience soreness or discomfort in your jaw or teeth. If discomfort persists, you should contact the prescriber.
- In the morning, you may sense a change in your bite. This change should disappear as the day progresses. If it continues with no change, you should contact the prescriber.
- US Federal Law restricts this device to sale by prescription only.
- Do NOT use if you have braces.
- Do NOT use if you have not seen a dentist in the last 12 months or are under active treatment.
- Do NOT use if you have loose teeth, loose crowns, or loose fillings.
- Do NOT use if you have temporary crowns, removable dentures, or bridges.
- You may experience obstruction of oral breathing with any oral appliance in the mouth.
- Do not store or transport the dreamTAP outside the temperature range of -4°F to 122°F (-20°C to 50°C)
- You must have at least 8 natural, healthy teeth in each arch.
- In the event of muscle or jaw joint pain, discontinue use for a minimum of two days or until pain subsides and consult the prescriber.
- Discontinue use if experience discomfort and consult the prescriber.
- Do NOT use the dreamTAP if vomiting or feeling nauseous.

- Do NOT use if the patient cannot remove the product themselves.
- You should return to the prescriber at least yearly, or as often as necessary, for re-evaluation. If the dreamTAP is lined with ThermAcryl, the lining will need to be replaced at least yearly.
- If the appliance becomes loose, damaged, or does not fit properly, contact the prescriber.
- Do NOT wash the dreamTAP in the dishwasher or use dishwashing liquid to wash the dreamTAP.
- Do NOT clean the dreamTAP with products that contain chlorine, bleach, moisturizer, antiseptic, anti-bacterial agents or alcohol.
- Do NOT store the dreamTAP in direct sunlight.
- The operating temperature range of the dreamTAP is 40°F to 104°F (5°C to 40°C)
- For use by adults only.
- Discontinue use if the dreamTAP is damaged or cracked.
- Patients who are sensitive to nickel or self-curing acrylic may experience allergic reactions. Discontinue use if reaction occurs and consult prescriber.

Possible Side Effects:

There are possible side effects associated with using the dreamTAP appliance. These side effects are not uncommon. If you experience any of the following side effects, you should contact your prescriber immediately.

- Slight tooth or gingival discomfort due to pressure of the appliance.
- Excess salivation initially. This will improve as you become accustomed to wearing the dreamTAP.
- Slight jaw soreness or tightness, initially and with adjustments.
- Temporary bite change. This should subside approximately 30 minutes after the dreamTAP is taken out of the mouth in the morning and the AM Aligner is used.
- Unconsciously taking the dreamTAP out of his/her mouth at night.
- Orthodontic movement of the teeth.
- Pain or dysfunction of the temporomandibular joint and associated muscles.
- Permanent bite change.
- The metal parts are made of medical grade stainless steel or Cobalt Chromium.
- If the patient experiences any reaction, have him/her contact the prescriber immediately.

AM Aligner® & Mouth Shield

The AM Aligner should be cleaned with a soft toothbrush and warm water once a week. Refer to separate AM Aligner or Mouth Shield instructions for more information.

Product Disposal

The dreamTAP may be placed in the general household waste receptable.

Parts

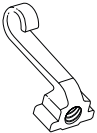
Short Hook
PART 95ASM



Medium Hook
PART96ASM



Long Hook
PART97ASM



Airway Management Contacts



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PRTD41 (Digital English, 2 of 7) REV I, 2023

