

dreamTAP[®] with Triple Laminate[®] (TL)

Clinician Instruction for Use



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.

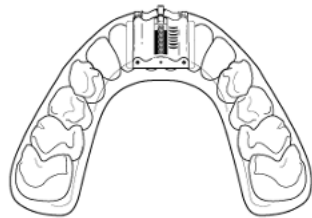
Indications: The dream Thornton Adjustable Positioner (dreamTAP®) is intended to reduce or alleviate nighttime snoring and sleep related breathing disorders including obstructive sleep apnea (OSA). The appliance is for adult patients to be used when sleeping at home or in a sleep laboratory and is for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

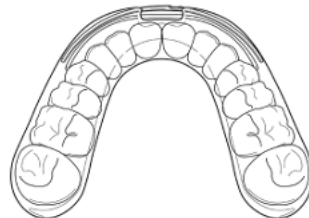
Introduction

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.



Upper Tray



Lower Tray

The dreamTAP is supplied with a bar that is larger in diameter than the opening of the hook, preventing the appliances from disengaging. The bar contains a small, flat area that will allow engagement of the hook.

Linings: The device is fabricated on the dental casts of individual patients. The outer layer of the dreamTAP TL trays consists of a dual laminate. The dual laminate is a sheet of plastic with a layer of soft polyurethane that is bonded to a layer of hard polymer. In the fabrication process, the dual laminate is pressure formed over the dental casts with the polyurethane covering the teeth. Then the hard outer layer is covered in orthodontic acrylic, creating a triple laminated tray. The lining is unique because the trays are returned to the dentist with the patient's dentition already impressed into the tray. Delivering the TL trays usually does not take as long as the dreamTAP ThermAcryl and the lining is much more comfortable in the mouth.

Each dreamTAP package contains:

1. An Upper and Lower Tray
2. Instructions for Use
3. Storage Case
4. AM Aligner
5. Adjustment Key
6. 2 Additional Hooks

Fitting the dreamTAP TL Trays

Note: The lining of the dreamTAP TL is a significantly different material than the ThermAcryl-lined dreamTAP. It is essential to make certain that both trays fit over the patient's teeth. If the trays are too loose or too tight, call the laboratory that made the device to discuss the case.

1. Before you fit the patient with the dreamTAP TL, inspect it to make sure the pieces are not damaged and free from any physical or cosmetic defects. If there is the slightest indication that the device may be damaged or defective, do not fit it. Also, clean the dreamTAP by gently scrubbing it with antibacterial soap and rinsing it thoroughly.
2. Start with the Lower Tray. Position it over the teeth. Using your thumbs, push the appliance on the teeth starting from the back and working your way forward.
3. If the trays are too tight, see the Tray Adjustment section.
4. Repeat the same process with the Upper Tray.
5. Have the patient place both trays in their mouth (they should “snap” over the teeth, but not uncomfortably). Instruct the patient to engage the trays together outside of the mouth before putting the appliance in the mouth.
6. Ask the patient if:
 - a. the trays are tight, but not uncomfortable
 - b. equal fit in all areas
 - c. comfortable to the tongue
 - d. he/she is able to remove the trays

If the patient answers “no” to any of the above questions, slightly adjust the dreamTAP TL appliance until it is comfortable for the patient. See the Tray Adjustments section.

7. With both trays hooked together in the patient's mouth, adjust the patient's jaw to a normal bite position (lips together, teeth apart and lower jaw not pulled forward) by dialing the Adjustment Key.

Note: This position does not have to be exact, it is just a position that is easy to find as a starting point.

8. With the patient in this position, look at the lower unit in relation to the upper unit. It is extremely important that there is a minimum of 1mm space bilaterally in the posterior areas at all times, in all positions. This will allow you to add posterior stops once the patient has found a treatment position. If the practitioner desires posterior support, which Airway Management recommends, he/she can add it once the patient reaches the final treatment position.

Warning: If any damage occurs, tell the patient not to use the appliance and return to your office for repair.

Tray Adjustments

Adjustments can be made to the dreamTAP TL trays and/or the lining if they are too tight. If adjustments need to be made, it is suggested that you contact the laboratory that made the dreamTAP TL to discuss the case.

Do not remove too much of the TL lining at once. This may cause the tray to lose retention and will ruin the trays because the TL lining cannot be added back to the trays. If the trays are over-adjusted, the laboratory may charge you for a remake of the trays.

Be conservative with your adjustments.

If the trays are too loose, return them to the laboratory. If the trays are too tight, follow the instructions below.

1. First, reduce the height of the flanges covering the teeth. Do not relieve the lining.
2. If the patient still complains of the tightness or discomfort of the anterior teeth, carefully remove a small amount of the dual laminate lining from the areas of the tray with too much retention. Use a thin straight acrylic burr and then a sharp knife to remove the tags. See burr suggestions below.
3. Fit the tray in the patient's mouth with each adjustment.

Burr Suggestions

The dreamTAP TL can be modified with straight burrs from Brassler USA Soft Reline Removal & Trimming Kit. Toll Free: (800) 841-4522. It is suggested that you only order three burrs out of the kit.

Those include numbers:

- 261GSQ-023 Small
- 251GSQ-060 Medium
- 79GSQ-070 Large

Posterior Stops

It is extremely important that there is a space bilaterally between the trays prior to adding acrylic posterior stops. The objective is to create bilateral, even posterior stops at the patient's treatment position. Since the relationship of the maxilla to the mandible changes with the changes in protrusion, this procedure must be repeated if the treatment position changes.

1. Roughen the hard plastic in the occlusal area of the 1st and 2nd molar on the Lower Tray. Add auto cure acrylic to rough area.
2. Lubricate the Upper Tray with Vaseline and place in the patient's mouth. The Vaseline will keep the trays from sticking together when adding the Posterior Stops.
3. Place the lower tray in the patient's mouth while the acrylic is in the doughy stage.
4. Help the patient to couple the upper dreamTAP tray with the lower while the lower is in the patient's mouth. Have the patient gently snap the upper tray over his/her teeth by pushing it up with his/her thumbs. Be sure the patient doesn't bite down on the stops. The Hook should be set in the patient's treatment position. See Hook Settings and Adjustments section.
5. With the trays coupled in the mouth, have the patient bite down.
6. Once the Posterior Stops are set, first smooth the area with your finger. This will ensure there isn't any rough spots that may irritate the patient.

Decreasing Lateral Movement

To decrease the lateral movement of the hook on the bar of the upper appliance, apply orthodontic acrylic around the bar. Apply the acrylic towards the midline to the desired lateral mobility. Place the appliance in the pressure pot or warm water bath to cure the acrylic.

Hook Setting and Adjustments

Note: The setting adjustments are written from the perspective of the practitioner looking at the patient.

The initial treatment position of the Hook should be set by the prescriber according to the following instructions. The Hook moves forward and back using the Adjustment Key to dial the Adjustment Screw clockwise or counterclockwise. Each 180-degree turn is .25 mm adjustment.

1. Instruct the patient to couple the trays together by inserting the hook over the flat area in the bar. Have the patient place the device in his/her mouth.
2. Dial the Adjustment Key counterclockwise to the patient's maximum mechanical protrusion (MMP). The patient will feel a slight stretch in his/ her temporalmandibular joints at this point. If the patient doesn't reach his maximum passive protrusion when engaged, continue to dial the Adjustment Key until he/she reaches this point.
3. Remove the trays by pulling on the posterior of the trays.
4. Place the device back in the patient's mouth.
5. Dial the Hook clockwise until the patient's teeth are end to end. This may be the patient's starting position.
6. Again, mark the Base Plate even with the anterior side of the Hook. This indicates the patient's starting position.

Note: On the protrusion gauge on the Base Plate, each mark and each space between the marks are 1mm wide. The protrusion gauge is 7mm long from the front of the plate to the most posterior mark. Have the patient wear the appliance in this end-to-end position for 3-4 nights before starting the adjustments.

7. From the starting position, instruct the patient to turn the Adjustment Key a half turn (180 degrees) clockwise (towards their right ear) per night until all the symptoms are alleviated. The patient should leave the Hook in the adjusted position to remove the appliance. The appliance should be detached from the teeth before unhooking.
8. If any position becomes uncomfortable, the patient should dial the Hook counterclockwise until pain subsides. Instruct the patient not to start dialing the hook again until the jaw is comfortable. If the patient's pain does not subside, you may want to schedule a consultation for evaluation.

Note: If the patient's mandible needs to be moved further forward, there are different sizes of hooks to increase the amount of protrusion. See section on Multiple Hook Sizes.

Note: Have the patient return to your office for examination and assessment to ensure the dreamTAP is not damaged and is still effectively treating the patient's sleep related breathing disorder.

Operating the Adjustment Key

Note: Operating the Adjustment Key is written from the perspective of the patient with the appliance in his/her mouth.

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

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.

Homecare Instructions

Warning: Instruct the patient that it is imperative to use the AM Aligner each day to reduce the risk of permanent bite change.

- Each morning after use, instruct the patient to thoroughly clean the dreamTAP appliance using a regular soft toothbrush, cool water and toothpaste. Hot water should not be used. Rinse thoroughly after cleaning.
- Instruct the patient to dry the appliance completely before storing in the container. It may help to leave the container open to ensure that the dreamTAP dries thoroughly.

Note: The best way to keep the dreamTAP 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. In addition, explain to the patient not to 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: Instruct the patient not to 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.

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.

Multiple Hook Sizes

There are three different hooks available for use with the dreamTAP; Short, Medium, and Long. The appropriate hook will be selected by the fabricator depending on the bite registration of the patient. The different hooks allow the fabricator and the dentist the greatest range of adjustment without having to reset the hardware.

Short Hook

PART 95ASM



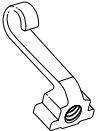
Medium Hook

PART96ASM



Long Hook

PART97ASM



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.

Airway Management Contacts



Manufacturer

Airway Management, Inc.

4300 Alpha Road, Suite 115

Dallas, TX 75244, USA

Tel: (866) 264-7667

Fax: (214) 691-3151

Email: contactami@amisleep.com

Website: www.tapintosleep.com

EU REP

EU Authorized Representative

MDSS GmbH

Schiffgraben 41

30175 Hannover

Germany

AU REP

Australian Authorized Representative

Emergo Australia

Level 20

Tower II, Darling Park

201 Sussex Street

Sydney, NSW 2000

Australia



Patents: <http://tapintosleep.com/patents>



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