

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 TAP 1 may be placed in the general household waste receptacle.

Warnings, Contraindications and Possible Side Effects

Note: Read all instructions before using the TAP 1

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 TAP 1 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 TAP 1 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 TAP 1 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 appliance becomes loose, damaged, or does not fit properly, contact the prescriber.
- Do NOT wash the TAP 1 in the dishwasher or use dishwashing liquid to wash the TAP 1.
- Do NOT clean the TAP 1 with products that contain chlorine, bleach, moisturizer, antiseptic, anti-bacterial agents or alcohol.
- Do NOT store the TAP 1 in direct sunlight.
- The operating temperature range of the TAP 1 is 40°F to 104°F (5°C to 40°C)
- For use by adults only.
- Discontinue use if the TAP 1 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.

Contraindications for the TAP 1:

- 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.

Possible side effects:

There are possible side effects associated with using the TAP 1 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 TAP 1.
- Slight jaw soreness or tightness, initially and with adjustments.
- Temporary bite change. This should subside approximately 30 minutes after the TAP 1 is taken out of the mouth in the morning and the AM Aligner is used.
- Unconsciously taking the TAP 1 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.

Patient Instruction for Use

TAP™ 1



AM AIRWAY
MANAGEMENT

TAP SYSTEM™

PRTD13 Rev. D, 2019

myTAP



TAP Custom



myTAP PAP



TAP PAP CS



Airway Management Contacts

Manufacturer



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This product is protected by U.S. and foreign patents. For a list of patents related to this product please go to <http://amisleep.com/patents>

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 Thornton Adjustable Positioner™ 1 (TAP™ 1) 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 laboratories and is for single patient use.

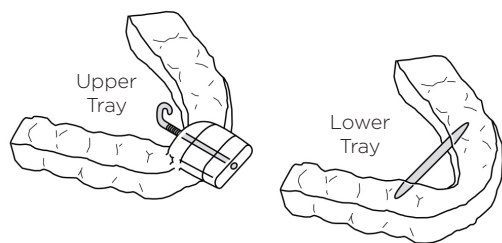
Contraindications: This device is contraindicated for patients with loose teeth, loose dental work, dentures, or other oral conditions which would be adversely affected by wearing dental appliances. In addition, the appliance is contraindicated for patients who have central sleep apnea, have severe respiratory disorders or who are under 18 years of age.

Intended Use

The TAP™ 1 is a custom made oral device intended to reduce or alleviate nighttime snoring and obstructive sleep apnea (OSA). The appliance is for adult patients to be used when sleeping at home or in sleep laboratories and is for single patient use.

Introduction

The TAP® 1 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 Upper Tray fits into a Socket attached to the Lower Tray and positions the lower jaw forward, preventing the soft tissue of the throat from collapsing and obstructing the airway. The Adjustment Key of the TAP® 1 permits you to adjust the protrusion of the lower jaw to the most effective and comfortable position.



Linings: The device is fabricated on the dental casts of individual patients. The TAP 1 comes with 1 different liner options. The first two liner options are ThermAcryl or AccuTherm. With these options, the outer layer of the TAP 1 trays is a durable PET-G plastic and the inner layer is a thermoplastic material (ThermAcryl or AccuTherm). Both ThermAcryl and AccuTherm soften 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 a heat sensitive lining 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 TAP 1 will no longer fit.

The third lining option, TAP 1 Triple Laminate (TL), consists of a rubbery inner layer that is molded to the patient's dental casts during fabrication. This lining cannot be remolded or relined so it is not recommended for patients who are expecting to have dental work done, like a crown.

Each TAP™ 1 package contains:

- | | |
|----------------------------|-----------------|
| 1. An Upper and Lower Tray | 3. Storage Case |
| 2. Instructions for Use | 4. AM Aligner |

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 TAP 1 appliance clean is to brush it each morning after use.

Warning: The TAP™ 1 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 TAP™ 1 hardware. The TAP™ 1 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 TAP™ 1 is not damaged and is still treating your snoring or sleep apnea.

Directions for Daily Use

1. Inspect the device prior to each use. Contact your prescriber if you observe any material separation, material degradation, or damaged parts.
2. Place the TAP 1 in your mouth with the Hook already engaged with the Lingual Bar. Before placing the engaged TAP 1 into your mouth, make sure that the Hook is in its initial starting point (the lower tray is not pulled forward). Gently relax your jaw once the TAP® 1 is in your mouth.
3. To remove either the upper or lower trays, gently open your mouth while the Hook is still engaged. At the same time, lift up on the lower tray or pull down on the upper tray to loosen either tray and remove.

Warning: TAP® 1 trays should never be worn separately. The patient should always wear both trays when using the appliance.

Warning: If the trays disengage while in the mouth, take the trays out, reengage the Hook and Lingual Bar and place back in your mouth. If you try to reengage the trays while still in the mouth and you bite down on the Hook, it might damage the Hook or Bar.

Operating the Adjustment Key

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

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

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