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 delaminates.

Warning: instruct the patient not to dissemble 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.

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 size hooks allow the fabricator and the dentist the greatest range of adjustment without having to reset the hardware.

ASD: If symptoms, breathing difficulties or other respiratory disorders exist or persist, or 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.

Possible side effects

• Slight tooth or gingival discomfort due to pressure of the appliance.
• Excess salivation initially. This will improve as you become accustomed to wearing dental appliances.
• Severe Class 2 or severe Class 3 malocclusion may require a custom splint.
• 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 dreamTAP™

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

Possible side effects:

• 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 AP Aligner is used.

Warnings:

• 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

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Fitting the dreamTAP AccuTherm Trays

Note: The following instructions only pertain to the AccuTherm™-lined dreamTAP™ trays.

As the patient adapts to the dreamTAP™, he/she should be able to sleep with it through the night. This typically takes a week.

Before you fit the patient with the dreamTAP™, inspect it to make sure the pieces are not damaged and the tray housing is not fragile. Inspect the housing to make sure the device is not damaged and that the inner layer is not discolored.

Close the dreamTAP™ gently, ontaving and moistening it slightly.

Place the Lower Tray of the dreamTAP™ in the patient’s mouth. If it does not fit adequately, the patient should feel a slight stretch in the lining material. If the lining is heated to 80°C 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 bath, and the Hook not turned more than 180°. If any position becomes uncomfortable, the patient should dial the Hook counter-clockwise to loosen the fit. Then remove the Hook by the hard outer shell.

Place the lower tray back in the patient’s mouth.

Note: This does not have to be exact. It is just that position is easy to find as a reference point. It is recommended that the patient turn the Adjustment Key until he/she reaches this point.

If the patient asks to turn the Adjustment Key clockwise, instruct the patient to dial the Adjustment Key to the desired lateral mobility. Place the appliance in the pressure pot or warm water bath to cure the acrylic.

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. First, the patient should brush his/her teeth and floss before inserting the appliance.

2. Instruct your patient to instruct the device prior to each use. If there is any material separation or dirt to the appliance, the patient should discontinue use and contact you, the prescriber.

3. The patient should engage the Keep of the Lower Tray with the bar of the Upper Tray and the bar of the Upper Tray with the bar of the Lower Tray. The teeth should be placed in the mouth with the upper teeth facing forward. The patient should use he/she’s thumbs to push the tray from the bottom up to the upper teeth. Repeat the same process on the lower tray.

4. After use, the patient should remove both the Upper and Lower trays to prevent material from building up. 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 looking at the patient.

1. To loosen rearward, instruct the patient to turn the Adjustment Key clockwise (towards their right ear) until the plastic hook engages.”

2. With the trays coupled in the mouth, have the patient turn the Adjustment Key counter-clockwise (towards their left ear).