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 antibacterial liquid soap.  
  Hot water should not be used.
• 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.
• The patient may reinsert the dreamTAP™ every 2 weeks in a solution of diluted hydrogen peroxide (use equal parts hydrogen peroxide solution and water) for no more than 5 minutes.  Afterwards, the appliance must be rinsed thoroughly with cool water and air-dry to try.

Note: The latest way to keep the dreamTAP™ clean is to brush it each morning after use.  The patient should sparingly soak the appliance if further measures need to be used in order to clean the appliance.

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.

AM Aligner

Refer to separate AM Aligner instructions.

Product Disposal

The dreamTAP™ may be placed in the general household waste receptacle.

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 a soreness or discomfort in your jaw or teeth.  If discomfort persists, you should consult the prescriber.
• Federal Law restricts this device to sale by prescription only.
• Do NOT use if you have any temporary crowns, removable dentures, or bridges.
• 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 120°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 if you have not seen a dentist in the last 12 months or are under active treatment.
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Possible side effects:
These possible side effects are 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 breath or gagging discomfort due to pressure of the appliance.
• Slight jaw or gum soreness.  This will improve as you become accustomed to wearing the dreamTAP™.
• Slight jaw soreness or tightness, initially and with adjustments.
• Temporary bite change.  This will resolve approximately 20 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 their mouth at night.
• Movement of the teeth.
• Pain in the jaw joint.
• Permanent bite change.

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 re-train the hardware.

Short Hook PART96ASM

Medium Hook PART97ASM

Long Hook PART97ASM

Airway Management Contacts

Manufacturer
3418 Midcruft Dr, Suite 114
Carrollton, TX 75006
Tel: (866) 264-7667
Fax: (214) 691-3151
Email: contactam@amisleep.com
Website: www.amisleep.com

United States and Canada
Airway Management
866-264-7667

EU Authorized Representative
Cyton Bioscience Ltd
Eden Office Park
Green
Bristol
BS200 00D
United Kingdom
The dreamTAP™ is a unitary device intended to reduce or eliminate nighttime snoring and its associated noise. The dreamTAP™ is designed to help patients sleep better by attaching to the soft tissue of the throat from collapsing and obstructing the airway. The Adjustment Key is intended to decelerate the lateral mobility. Place the appliance in the pressure pot or warm water bath to cure the acrylic.

Fitting the dreamTAP™ TL Trays

Note: the living of the dreamTAP™ TL is a significantly different material than the ThermAcryl™. It is essential to make certain that both trays fit over the patient's teeth. If the trays are too loose or too tight, the laboratory may need to modify the trays. Before you fit the patient with the dreamTAP™, inspect it to make sure the piece and design are not damaged, chipped or defective. If there is any evidence that the device may be damaged or defective, do not use it. Also check the dreamTAP™™-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, the laboratory may need to modify the trays.

1. Start with the Lower Tray. Position the tray over the teeth. Using your thumbs, push the tray forward. This will extend the space between the trays. If the trays are too tight, see the Tray Adjustment section.
2. Take the Upper Tray and approach it to the patient's teeth at the patient's treatment position. The maxilla (upper jaw) is the starting position. With the trays coupled in the mouth, have the patient bite down.
3. If the trays are too tight, see the Adjustment Key section.
4. With both trays hooked together in the patient's mouth, instruct the patient to turn the Adjustment Key a half turn clockwise (towards the left every 45°) until the patient's teeth are end to end. This may cause the tray to lose retention and will ruin the trays because the TL lining cannot be added back to the tray. If this occurs, the laboratory may need to remove the trays.

Adjustments

Adjustments can be made to the dreamTAP™ TL Trays unless the bite is too heavy or the patient is unable to adjust. Instruct the patient to consult the laboratory that you contacted the laboratory that made the dreamTAP™ TL to discuss the case.

WARNING: dreamTAP™ is intended to be used as a sleep appliance to decrease the lateral movement of the hook on the bar of the appliance. The appliance should be removed per night until all the symptoms of sleep-related breathing disorders have cleared.

The patient should gently relax once the dreamTAP™ is not damaged and is 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 practitioner looking at the device.

1. Instruct the patient to turn the Adjustment Key clockwise or counter clockwise (towards the left every 45°) until the patient's teeth are end to end. This may cause the tray to lose retention and will ruin the trays because the TL lining cannot be added back to the tray. If this occurs, the laboratory may need to remove the trays.
2. Instruct the patient to inspect the device prior to each use. If there is any material missing or excessive wear, the patient should contact you, the prescriber.