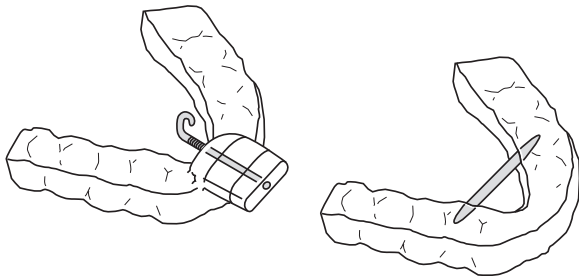




Patient Instruction Booklet

TAP[®] I



PRTD13
Revision D, 2012



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Caution: Federal (U.S.) law restricts this device to sale by or on the order of a dentist or physician.

 This device complies with the requirements of directive 93/42/EEC concerning medical devices.





Important Safeguards

SAVE THESE INSTRUCTIONS

The following words in this manual have special significance:

Warning: Means there is a possibility of injury to yourself.

Note: Indicates points of particular interest for more efficient and convenient operation.

Indications

The Thornton Adjustable Positioner® I (TAP® I) is 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. Read all instructions before using the TAP® I appliance.


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, severe respiratory disorders or are under 18 years of age.




Introduction

The Thornton Adjustable Positioner® I (TAP® I) is an oral device intended to reduce or alleviate nighttime snoring and obstructive sleep apnea (OSA).



The TAP® I device consists of an Upper Tray that fits over the upper teeth and a Lower Tray that fits over the lower teeth. A hook mechanism attached to the Upper Tray hooks around a bar 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 front piece of the TAP® I permits you to adjust the protrusion of the lower jaw to the most effective and comfortable position.



The device is fabricated on the dental casts of individual patients. The outer layer of the TAP® I trays is a durable plastic and there is a choice of two unique linings. The first lining, TAP® I ThermAcryl®, is a thermoplastic material which softens when heated. Once the outer trays are vacuum formed over the dental casts, the ThermAcryl® is molded into the trays. At the time of delivery, the trays are placed in hot water, which softens the ThermAcryl® and are then fitted to the patient.



The second lining, TAP[®] I Triple Laminate (TL), consists of a dual laminate polymer plus an outer hard plastic shell. 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 vacuum formed over the dental casts with the polyurethane side covering the teeth. Then the hard outer layer is vacuum formed over the dual laminate 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 trays usually does not take as long as the TAP[®] I ThermAcryl[®] and the lining is much more comfortable in the mouth.

Each TAP[®] I package contains:

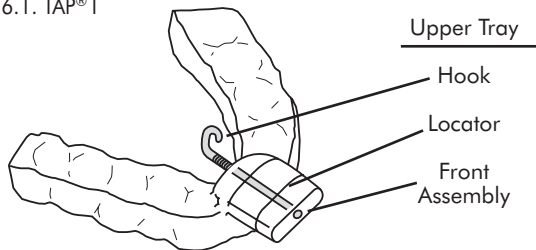
1. An Upper and Lower Tray
2. Instructions for Use
3. Storage Case
4. AM Aligner

Note: Read all instructions before using the TAP[®] I.



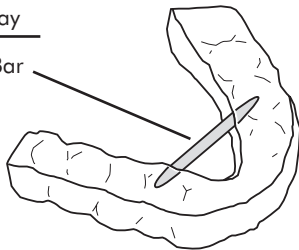


Fig. 6.1. TAP® I



Lower Tray

Lingual Bar





Warnings

- This device is intended to reduce or alleviate nighttime snoring and obstructive sleep apnea (OSA). If symptoms of breathing difficulties or other respiratory disorders exist or persist, with or without the use of the device, you should contact the prescriber immediately.
- 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 sensation should disappear within one hour. If it continues for more than four hours, you should contact the prescriber.
- You may experience obstruction of oral breathing with any oral appliance in the mouth.
- You should return to the prescriber at least yearly, or as often as necessary for re-evaluation. If your TAP® I 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.
- Allergic reaction may be encountered in people who are sensitive to nickel or self-curing acrylic.





Possible Side Effects

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

- 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® I.
- Slight jaw soreness or tightness, initially and with adjustments.
- Temporary bite change. This will subside approximately 30 minutes after the TAP® I is taken out of the mouth in the morning and the AM Aligner is used.
- Unconsciously taking the TAP® I out of your mouth at night.
 - Movement of teeth.
 - Pain in the jaw joint.
 - Permanent bite change.
- Allergic reaction to the stainless steel parts, which contain a trace of nickel.





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[®] I in your mouth with the Hook already engaged with the Lingual Bar. Before placing the engaged TAP[®] I into your mouth, make sure that the Hook is in its initial starting point (the lower tray is not pulled forward).**
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: Do not bite down on the Hook because it may bend or break. If the Hook is bent, do not use the TAP[®] I and return it to your provider for a replacement Hook.

Warning: The TAP[®] I trays should never be worn separately. Always wear both trays when using the appliance.



Operating the Dial

Note: Operating the Front Assembly (Knob) is written from the perspective of the patient with the TAP® I in his/her mouth.

1. To pull your lower jaw forward with the appliance in the mouth, turn the Knob counter clockwise (towards your left ear). See figure 11.1.
2. To return your lower jaw to the starting position with the appliance in the mouth, turn the Knob clockwise (towards your right ear).

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

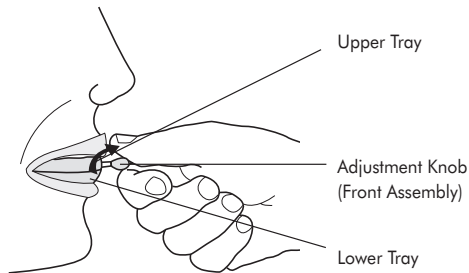


Fig. 11.1 Patient advancing the lower jaw forward.

Use of the AM Aligner

Purpose

The purpose of the AM Aligner is to counteract the forces that represent the most significant side effect of a dental device used for the treatment of obstructive sleep apnea, snoring, and other sleep disordered breathing. The AM Aligner is constructed of a unique thermoplastic material to be used every morning to return the teeth to their original position.

Contraindications

Allergic response may occur to the thermoplastic material. Do not store or soak at high temperatures (such as hot car or hot water). This would cause distortion of the appliance.

Instructions

1. After removing the TAP® I in the morning, wait thirty minutes to use the AM Aligner.
2. When you are ready to use the AM Aligner, insert the Aligner over your upper teeth.

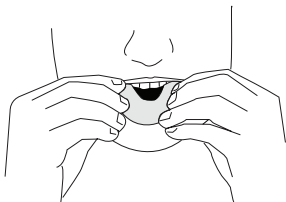


Fig. 12.1 Insert Aligner over upper teeth.



3. Pull your lower jaw back to engage your lower teeth into the indentations on the bottom of the tray.

4. Once your lower jaw is in the correct position, squeeze or bite on the tray as if to put your back teeth together.

5. Repeat the process of squeezing the jaw together into the AM Aligner until usual bite position is achieved.



Fig. 13.1 Squeeze or bite on tray.

6. This may take anywhere from 5 to 10 minutes.

7. If it takes longer than 10 minutes, take a hot shower or place a warm pack on the joints to warm up the jaw joints and accomplish this process faster.

Contact your dentist if these methods are not successful.

8. To remove the AM Aligner, take the tray off your back teeth first and then remove it from your mouth.







Homecare Instructions

Each morning after use, thoroughly clean your TAP[®] I appliance using a regular soft toothbrush, cool water and antibacterial liquid soap, or ADA approved toothpaste.. 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 TAP[®] I dries thoroughly. Please store your appliance out of reach of pets and small children.



You may disinfect your TAP[®] I appliance once every two weeks in a solution of hydrogen peroxide and water (half hydrogen peroxide and half water) or you may substitute mouthwash or a denture cleanser, like Efferdent, for hydrogen peroxide. Your TAP[®] I should be soaked in this solution for no more than 10-15 minutes. Rinse with water before use. Always brush your teeth and floss well before inserting the TAP[®] I in your mouth.



Note: Using hydrogen peroxide, or a denture cleanser will cause the plastic materials of the appliance to deteriorate more rapidly or delaminate more easily. The best way to keep the TAP[®] I appliance clean is to brush it each morning after use. Sparingly soak the appliance if further measures need to be used in order to clean the appliance.



Warning: The TAP[®] I should be stored in a cool, dry place. The appliance is made from heat 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, do not clean the appliance in hot or boiling water, nor soak it in bleach or excessive soaking with 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[®] I hardware. The TAP[®] I is a medical device and you must not tamper with it other than following the specific instructions in this booklet.

Return to your prescriber at least yearly for examination and assessment to ensure that the TAP[®] I is not damaged and is still treating your sleep disordered breathing.



We are proud to offer our patients the TAP[®] I.



The Thornton Adjustable Positioner[®] I (TAP[®] I)
is manufactured by:
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