

Patient Instruction Booklet

□ TAP® Elite ThermAcryl®

□ TAP® Elite TL

TAP® 3 Elite

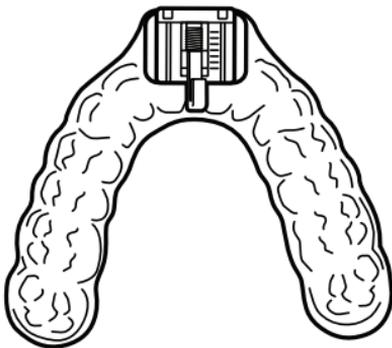


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Caution: Federal (U.S.) law restricts this device to sale by or on the order of a dentist or physician.

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

SAVE THESE INSTRUCTIONS

The following words in this manual have special significance.

Warning: Means there is a possibility of injury.

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

Indications

The Thornton Adjustable Positioner® 3 Elite (TAP® 3 Elite) 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.

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.

The Thornton Adjustable Positioner® 3 Elite (TAP® 3 Elite) is an oral device intended to reduce or alleviate nighttime snoring and obstructive sleep apnea (OSA).

The TAP® 3 Elite 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 onto a lingual shelf 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®3 Elite permits the patient to adjust the protrusion of his/her lower jaw to the most effective and comfortable position.

The TAP® 3 Elite is supplied with the double bar design to prevent the hook from disengaging. Any adverse events that might occur due to the removal of one of the bars are the responsibility of the person performing the alteration.

Linings: The device is fabricated on the dental casts of individual patients. The outer layer of the TAP® 3 Elite trays is a durable polymer (polycarbonate) and there is a choice of two unique linings. The first lining, TAP® 3 Elite ThermAcryl® is a thermoplastic material which softens when heated and molded to the patient's teeth at the time of delivery. The lining is unique because it can be rehaed and remolded to the patient if the patient has had any dental work, like a crown.

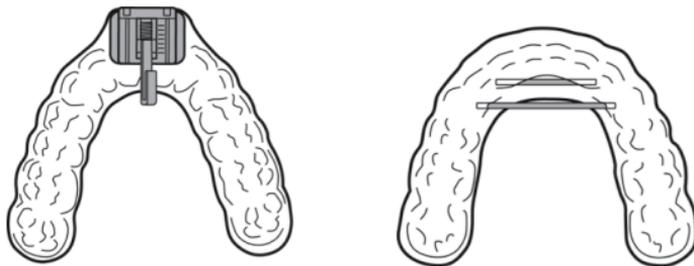
Note: ThermAcryl® is a heat sensitive lining and may deform if subjected to temperatures greater than 160° F. If it is heated above the 160° F the impressions of your teeth in the tray will deform and your TAP® 3 Elite will no longer fit.

The second lining, TAP® 3 Elite Triple Laminate (TL), consists of a rubbery inner layer that is molded to the patient's dental casts during fabrication. This lining is more comfortable than the ThermAcryl, but it cannot be remolded or relined so it is not recommended for patients who are expecting to have dental work.

Each TAP® 3 Elite package contains:

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

Fig. 6.2 TAP® 3 Elite Double Lingual Bar



Note: The Double Lingual Bar Design is required for Medicare billed devices. The modified design was created to meet Medicare’s requirements to “lock” or “hinge” the devices together.

Note: Read all instructions before using the TAP® 3 Elite.

- This device is intended to reduce or alleviate nighttime snoring and obstructive sleep apnea (OSA). If symptoms or breathing difficulties or other respiratory disorders exist or persist, with or without use of the device, the patient 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 change should disappear as the day progresses. If it continues with no change, 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 the TAP® 3 Elite 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 reactions 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® 3 Elite 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® 3 Elite.
- Slight jaw soreness or tightness, initially and with adjustments.
- Temporary bite change. This will subside approximately 30 minutes after the TAP® 3 Elite is taken out of the mouth in the morning and the AM Aligner is used.
- Unconsciously taking the TAP® 3 Elite out of his/her mouth at night.
- Movement of the teeth.
- Pain in the jaw joint.
- Permanent bite change.

1. Inspect the device prior to each use. Contact your prescriber if you observe any material separation, material degradation or damaged parts.
2. **Engage the Hook of the Upper Tray into the Lingual Shelf before placing the trays in your mouth. Make sure the Hook is not dialed too far forward that you cannot comfortably snap the trays over your teeth while engaged.**

Note: It is difficult to engage the Hook and Lingual Shelf if the trays are already in the mouth. The Hook receptacle may pinch your tongue when trying to engage.

3. Gently relax your jaw once the TAP® 3 Elite is in your mouth.
4. To remove either the upper or lower trays, gently open your mouth while the Hook is still engaged. Lift up on either the upper or lower tray on one side from the back of the mouth, next to the last tooth.

Warning: If the trays disengage while in the mouth, take the trays out, reengage the Hook and Lingual Shelf 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 Lingual Shelf.

Warning: The TAP® 3 Elite trays should never be worn separately. Always wear both trays when using the appliance.

Warning: The Hook should never be engaged by hooking it onto the second (posterior) bar.

Note: Operating the Adjustment Key is written from the perspective of the patient with the TAP® 3 Elite in his/her mouth. Always adjust your appliance when looking in the mirror.

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

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

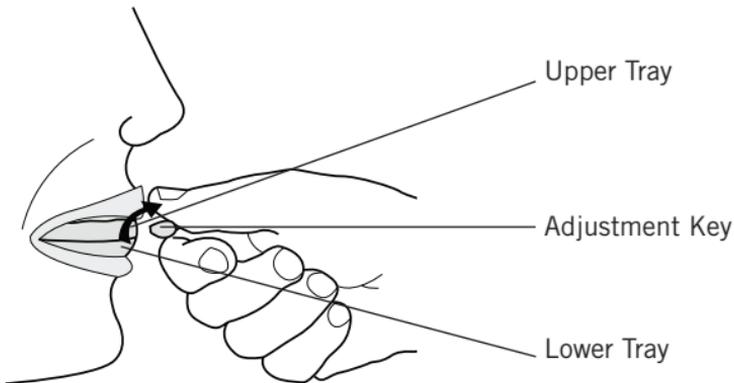


Fig. 11.1 Patient advancing the lower jaw forward.

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 a hot car or hot water). This would cause distortion of the appliance.

Instructions

1. After removing the TAP® 3 Elite 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. See Figure 12.1.

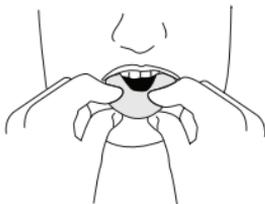


Fig. 12.1 Insert the AM Aligner over upper teeth.

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 teeth back together. See Fig. 13.1.
5. Repeat the process of squeezing the jaw together into the AM Aligner until usual bite position is achieved.
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.



Fig. 13.1 Squeeze or bite on tray.

- 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.

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 TAP® 3 Elite appliance using a regular soft toothbrush, cool water and an 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® 3 Elite dries thoroughly. Please store your appliance out of reach of pets and small children.

You may freshen the TAP® 3 Elite every two 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 allow to dry. Always brush your teeth and floss well before inserting the TAP® 3 Elite in the mouth.

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® 3 Elite 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® 3 Elite 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, 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® 3 Elite hardware. The TAP® 3 Elite is a medical device and you must not tamper with it other than following specific instructions in this booklet.

Return to your prescriber at least yearly for examination and assessment to ensure that the TAP® 3 Elite is not damaged and is still treating your sleep disordered breathing.

We are proud to offer our patients the TAP® 3 Elite.



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