

Patient Instruction Booklet

TAP® 3 ThermAcryl

TAP® 3 TL

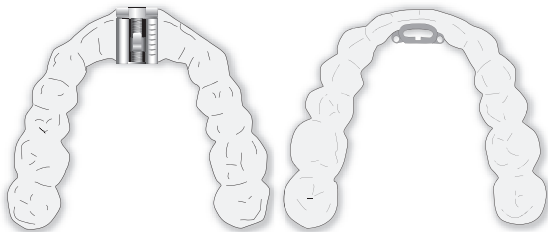



Table of Contents

| | |
|-----------------------------------|----|
| Important Safeguards..... | 3 |
| Introduction..... | 4 |
| Warnings..... | 7 |
| Possible Side Effects..... | 8 |
| Directions for Daily Use..... | 9 |
| Operating the Adjustment Key..... | 10 |
| Exercise Bite Tab..... | 11 |
| Homecare Instructions..... | 13 |
| Notes..... | 15 |

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.

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® 3 (TAP® 3) 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® 3 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.

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

The TAP® 3 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 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® 3 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 outer layer of the TAP® 3 trays is a durable polymer (polycarbonate) and there is a choice of two unique linings. The first lining, TAP® 3 ThermAcryl®, is a thermoplastic material which softens when heated. Once the outer trays are pressure 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.

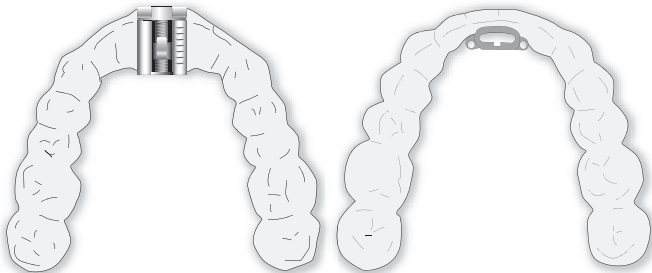
Note: ThermAcryl® is a heat sensitive lining and may deform if subjected to temperatures greater than 160°F. If it is heated above 160°F the impressions of your teeth in the tray will deform and your TAP® 3 will no longer fit.

The second lining, TAP® 3 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 a hard polymer. In the fabrication process, the dual laminate is pressure formed over the dental casts with the polyurethane side covering the teeth. Then the hard outer layer is pressure 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® 3 ThermAcryl® and the lining is much more comfortable in the mouth.

Each TAP® 3 package contains:

1. An Upper and Lower Tray
2. Instructions for Use
3. Storage Case
4. Two Exercise Bite Tabs
5. Adjustment Key

Fig. 6.1 TAP[®] 3



Note: The metal parts are made of medical grade stainless steel.
If you experience any reaction, contact your prescriber immediately.

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

- 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[®] 3 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.

Possible Side Effects

There are possible side effects associated with using the TAP® 3 appliance. These side effects are not common. 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.
- Slight jaw soreness or tightness, initially and with adjustments.
- Temporary bite change. This will subside approximately 30 minutes after the TAP® 3 is taken out of the mouth in the morning and the Exercise Bite Tabs are used.
- Unconsciously taking the TAP® 3 out of your mouth at night.
- Movement of 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 cracks.
2. Engage the Hook of the Upper Tray with the Socket of the Lower Tray before placing the trays in your mouth. Make sure the Hook is not dialed too far forward that you can not comfortably snap the trays over your teeth while engaged. Use your thumbs to push the tray from the bottom to snap it over your teeth. Repeat the same process for the lower tray.

Note: It is difficult to engage the Hook and Socket if the trays are already in the mouth because the Hook receptical in the Socket is too small and you may pinch your tongue.

3. Gently relax your jaw once the TAP[®] 3 is in your mouth.
4. 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: If the trays disengaged while in the mouth, take the trays out, reengage the Hook and Socket 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 Socket.

Warning: The TAP[®] 3 trays should never be worn separately. 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 with the TAP® 3 in his/her mouth.

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 10.1.
2. To return your lower jaw to the starting position with the appliance in the mouth, turn the Adjustment Key clockwise (towards your right ear).

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

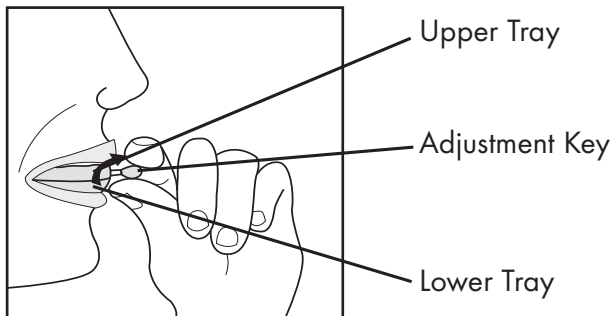


Fig. 10.1 Patient advancing the lower jaw forward.

When the lower jaw is pulled forward during the night, it may make the jaw muscles sore and temporarily change the bite. The Exercise Bite Tabs are intended to be used as an exercise tool to put your jaw back into a normal bite position.

1. Take both Exercise Bite Tabs.
2. Place one Exercise Bite Tab between the teeth on each side of the mouth. See figure 12.1 on page 12.
3. Pull your lower jaw back.
4. Once your lower jaw is in the back position, squeeze as if to put your back teeth together. See figure 12.2 on page 12.
5. Remove the Exercise Bite Tabs to see if your teeth come together.
6. Repeat the process until the jaw is back in normal bite position.

Warning: It is imperative to use the Exercise Bite Tabs each morning to reduce the risk of permanent bite change.

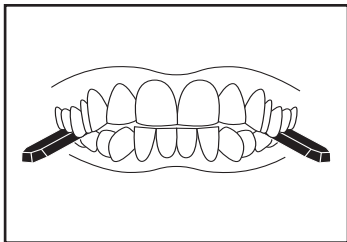


Fig. 12.1 Exercise Bite Tabs positioned between teeth.

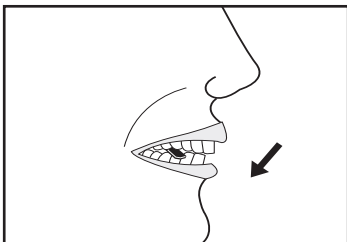


Fig. 12.2 Squeeze the back teeth together.

Each morning after use, thoroughly clean your TAP® 3 appliance using a regular soft toothbrush, cool water and antibacterial liquid soap. 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 dries thoroughly.

You may disinfect your TAP® 3 appliance once every two weeks in a solution of mouthwash and water (half mouthwash and half water) or you may substitute a denture cleanser, like Efferdent, for mouthwash. Your TAP® 3 should be soaked in this solution for no more than 10-15 minutes. A small, ultrasonic device can be used with the denture cleanser daily for 5 minutes. Rinse with water before use. Always brush your teeth and floss well before inserting the TAP® 3 in your mouth.

Note: Using mouthwash 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® 3 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 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 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 hardware. The TAP[®] 3 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 the TAP[®] 3 is not damaged and is still effectively treating your sleep disordered breathing.

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

The Thornton Adjustable Positioner® 3 (TAP® 3)
is manufactured by:
Airway Management, Inc.
Post Office Box 12557
Dallas, Texas 75225-0557

866.AMI.SNOR www.tapintosleep.com

© Airway Management, Inc.