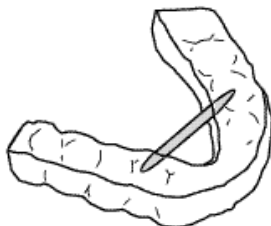
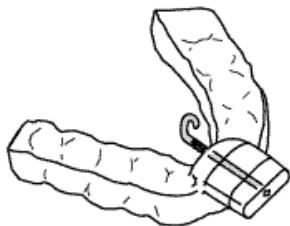


# Clinician Instruction Booklet

TAP

TAP TL



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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 (TAP®) is intended to reduce or alleviate nighttime snoring and obstructive sleep apnea (OSA). The appliance is for adult patients to be used 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, or dentures.

## Introduction

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

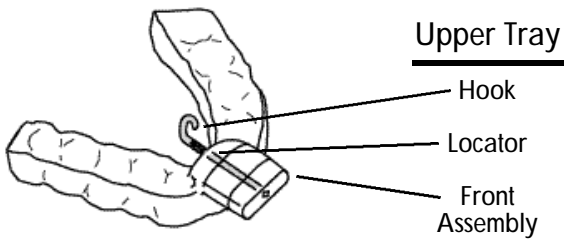
The TAP device consists of an upper tray that fits over the upper teeth and a lower tray that fits over the lower teeth. A hook mechanism attached to the upper tray fastens to a lingual bar attached to the lower tray and positions the lower jaw forward, preventing the soft tissue of the throat from collapsing and obstructing the airway. The front piece on the TAP permits the patient to adjust the protrusion of his/her lower jaw to the most effective and comfortable position. The device is constructed from a durable acrylic mixture with a choice of two different unique linings that allow maximum comfort and ease of fitting.

Each TAP package contains:

1. An upper and lower tray
2. Instructions for use
3. Storage case

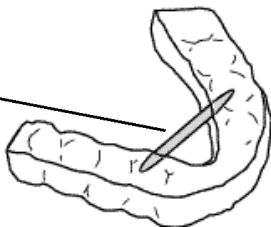
**Note:** Read all instructions before fitting the TAP.

**Caution:** Federal (U.S.A.) law restricts this device to sale by or on the order of a physician, dentist, or a professional trained in sleep disorders.



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, the patient should contact the prescriber immediately.
- The user may experience soreness or discomfort in the temporomandibular joint (TMJ), jaw, or teeth. If discomfort persists, the patient should contact the prescriber.
- In the morning, some patients may sense a change in their bite. This sensation should disappear within one hour. If it continues for more than four hours, the patient should contact the prescriber.
- The patient should return to the prescriber at least yearly for reevaluation. The Thermacryl™ lining usually lasts only one year and will need to be replaced if the lining material becomes loose or damaged. If the appliance becomes loose, the patient should contact the prescriber.

There are possible side effects associated with using the TAP appliance. These side effects are not common for all patients. If the patient experiences any of the following side effects, instruct him/her to contact you, the prescriber.

- Slight tooth discomfort due to pressure of the appliance.
- Excess salivation initially. This will improve as the patient becomes accustomed to wearing the TAP.
- Slight jaw soreness or tightness initially and with adjustments.
- Temporary bite change. This will subside approximately 30 minutes after the TAP is taken out of the mouth in the morning.
- Unconsciously taking the TAP out of his/her mouth at night.

## Fitting the TAP® ThermAcryl Trays

**Note:** The following instructions only pertain to the ThermAcryl™-lined TAPtrays. For TAP TL instructions, see page 12.

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

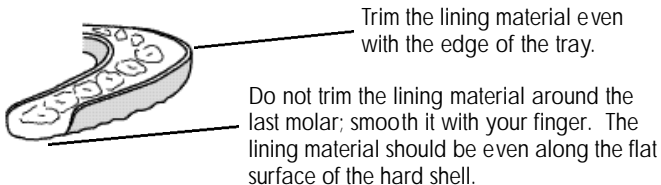
1. Before you fit the patient with the TAP, inspect it to make sure the pieces are not damaged. If there is the slightest indication that the device may be damaged, do not fit it.
2. Place the lower TAP tray in a water bath that is heated to 160° until the ThermAcryl lining softens (turns clear). Wet your hands before fitting the tray.

**Warning:** Do not leave the trays in the water bath too long. The hard plastic shell may warp! The trays should be removed from the water bath and fitted as soon as the lining material turns clear.

3. Position the lower tray over the teeth. Using your thumbs, push the appliance over the teeth starting from the back and working your way forward. Some ThermAcryl will express out of the tray.
4. Remove the lower unit from the mouth by the hard material.

**Note:** Do not touch the soft lining material. It may distort.

5. While the ThermAcryl is soft, trim away all material beyond the edge of the hard shell with curved scissors. Use the edge of the tray as a guide. Make certain there is no material on the gingival. Smooth the edge of the tray with a wet finger.



6. Place the lower tray back in the patient's mouth to allow the lining material to form. Let it sit for approximately 1-2 minutes (until the material is almost white). As the material is hardening, take the tray in and out of the patient's mouth several times to ensure that it does not lock on the patient's teeth.

**Note:** Do not leave it in the patient's mouth too long because ThermAcryl has a 1% shrinkage rate.

7. Repeat the same process for the upper tray. Press down (especially in posterior) with even pressure, trying not to rock the appliance.

**Note:** If more material extrudes onto the soft tissue, trim as before, reheat and then refit. When all trimming is completed, smooth the edge of the tray with a wet finger.

8. Have the patient take each unit in and out a few times before the lining material completely hardens. This will prevent the tray from becoming too tight on the teeth.

9. Once both trays are properly fitted and trimmed, allow them to bench cure or place them in a cup of cool water for a few minutes until the ThermAcryl lining hardens (turns white).

10. Have the patient place both trays in his/her mouth (they should "snap" over the teeth, but not uncomfortably). It is suggested that the patient hook the trays together outside of the mouth before putting the appliance in the mouth.

Ask the patient if:

- a. the units are tight, but not uncomfortable
- b. equal in all areas
- c. comfortable to the tongue
- d. he/she is able to remove the units

If the patient answers "no" to any of the above questions, reheat, refit, cool and seat the TAP appliance in the mouth until it is comfortable for the patient.

11. With both units in his/her mouth, have the patient close the mouth to a normal breathing position (lips together, teeth apart).

**Note:** This does not have to be exact, it is just a position that is easy to find as a starting point.

12. With the patient in this position, look at the lower unit in relation to the upper unit in the anterior area. It is extremely important that there is a minimum of 1mm space bilaterally in the posterior areas at all times, in all positions. This will lessen the likelihood of TMJ symptoms. The only contact should be in the anterior area.

**Warning:** Instruct the patient not to bite down on the hook because it may break. It is suggested that the patient hook the trays together outside of the mouth before putting the appliance in the mouth. If the hook is bent, do not use it at all.

**Note:** The ThermAcryl lining may have to be relined within 12-14 months. If the appliance needs to be relined before this time, ask the patient how he/she is caring for the appliance. A solution of half hydrogen peroxide and half water is a gentle agent in which to clean the appliance. Do not use bleach. It will cause the lining to become brittle, and crumble.

## Fitting the TAP® TL Trays

**Note:** The following instructions pertain to the TAP Triple Laminate (TAPTL) trays. For TAP instructions, see page 8.

The lining of the TAP TL is a significantly different material than the ThermAcryl-lined TAP. Although the TAP TL is returned with the patient's impression seated in the tray, it is essential to make certain that both trays fit over the patient's teeth.

1. Before you fit the patient with the TAP TL, inspect it to make sure that the pieces are not damaged. If there is the slightest indication that the device may be damaged, do not fit it.
2. Start with the lower tray (the appliance with the lingual bar). Position it over the teeth, and using your thumbs, push the appliance on the teeth starting from the back and working your way forward.
3. Repeat the same process with the upper tray.

**Tray Adjustments:** There are two options in adjusting the lining of the TAP TL trays if it is too tight or too loose. The first is a heating adjustment, which allows for adjusting tight and loose retention. The second involves a burr to adjust the lining; however, a burr can only be used if the trays are too tight.

**Note:** Contact your laboratory to discuss which option is best for your case.

## Heating Adjustment

1. If the trays are **too tight**, heat them in hot water (200<sup>o</sup>+) for 30 seconds. Then place the trays in the patient's mouth and remove several times while cooling.
  2. If the trays are still too tight, repeat the process, and if necessary, trim the length of the flanges.
  3. As a last step to relieve tension, reduce retension by slightly adjusting the lining with a burr (Airway Management Inc. suggests that you use a Brassler burr from the Soft Reline Removal and Trimming Kit).
- Note:** Do not over-adjust, or you may lose the retention necessary.
4. If the TAP TL is **not tight enough**, heat the posterior area on one side in 200<sup>o</sup> water. Leave for 30 seconds.
  5. Remove and press the flanges together slightly with your fingers.
  6. Hold the device while it cools down.
  7. The appliance should now be tighter on that side. Repeat the procedure as necessary.

**Note:** If you cannot make the trays fit, contact the lab that made the appliance.

## Burr Adjustments

1. Use one of the burs from the suggestion below to carefully remove a small amount of the (Durasoft) lining from the areas of the tray with too much retention.
2. Fit the tray in the patient's mouth with each adjustment.

**Warning:** Do not remove too much of the TAP TL lining at once. This may cause the tray to lose retention and will ruin the tray.

The TAP TL can be modified with straight burs from Brassler USA Soft Reline Removal & Trimming Kit. The toll-free number is 1-800-841-4522.

It is suggested that you order only three burs out of the kit. Those include numbers:

H251GSQ-060 or H351 FSQ-060 - medium

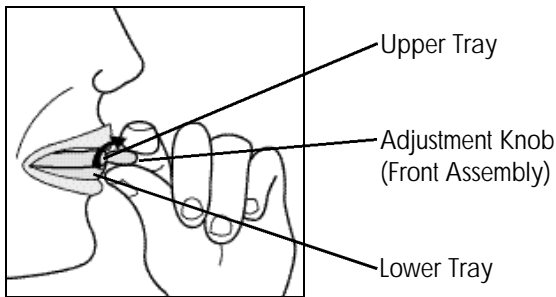
H79GSQ-070 - large

H219S-023 - burr to cut out plastic around lingual bar

## Hook Setting & Adjustments

The initial position of the hook should be set by the prescriber or according to the following instruction. The hook moves forward and back by turning the knob of the Front Assembly clockwise or counter clockwise.

1. Place the device in the patient's mouth. Instruct the patient to move his/her lower jaw forward enough to engage the hook and lingual bar.
2. Dial the adjustment knob (Front Assembly) clockwise to the patient's **maximum mechanical protrusion (MMP)**. The patient will feel some discomfort at this point.



**Note:** When the hook is dialed forward, part of the threads will begin to protrude from the front of the Front Assembly.

3. Remove the appliance.

4. Cut the protruded threads of the hook flush with the front of the Front Assembly (see figure 16.1).

5. Place the device back in the patient's mouth.

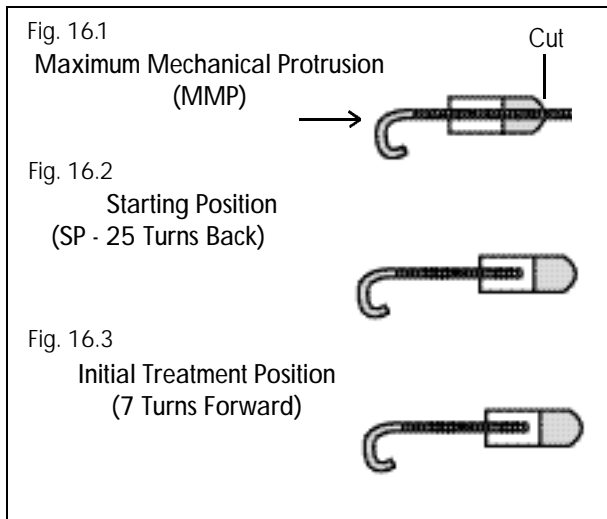
6. Dial the hook back in increments of five until the patient can hook and unhook the device. Count the turns. This is the patient's **starting position** (see figure 16.2).

**Note:** The starting position should be approximately 25 turns back from maximum mechanical protrusion.

7. From the starting position, turn the knob clockwise while the patient is sitting upright. Count the turns.

8. When the patient's jaw is dialed as far forward as is comfortable, he/she has reached the **maximum comfortable position (MCP)**, also called the **initial treatment position** (see figure 16.3).

For example, the **starting position**, where the patient can engage the hook and the bar, is determined to be 25 turns back from MMP. The maximum that the patient can then dial the hook forward with comfort is seven turns. This is the patient's **maximum comfortable position (MCP)**.



9. Continue to dial the hook forward one turn ( $180^{\circ}$ ) per night until all the symptoms are alleviated.

10. If any position becomes uncomfortable, dial the hook back until the pain subsides. Do not start dialing forward again until the jaw is comfortable.

**Note:** If the patient loses count of his/her maximum comfortable position, instruct him/her to dial the hook out until flush with the Front Assembly and then turn the dial knob back the same number of turns as his/her starting position (20–25 turns). Finally, have the patient dial the hook forward to his/her maximum comfortable position.

## Replacement Plate Set

**Important:** Only remove the front assembly if the patient is getting good results and does not need more adjustments.

1. Before starting, mark where the hook is positioned in the locator with a black marker.
2. Using a 5/64" allen wrench, remove the plastic front piece by twisting the knob to one side and exposing screws. Unscrew the screws that attach the front assembly to the TAP appliance.
3. Once the screws are removed, twist the plastic front assembly counter clockwise until it is unattached from the hook.
4. Screw on the replacement plate until it is lined up with the locator and the hook is at the position marked. Cut off excess threaded wire. Use a burr or cutting tool to grind the cut end of the hook flush with the replacement plate.
5. Using a .050 allen wrench, screw in the two button head socket screws through the replacement plate and into the locator. The screws should be smooth enough for the patient's mouth, but may be smoothed slightly with a burr or covered with acrylic. The hook may also be held in place with acrylic.

## Directions for Daily Use

Instruct the patient in the daily use of the TAP appliance.

1. Inspect the device prior to each use. Discontinue use if there is any material separation, material degradation or cracks.
2. Place the upper and lower trays over the teeth.
3. Move the lower jaw forward so that the bar on the lower tray engages with the hook attached to the upper tray.

**Note:** You can also place the TAP in the patient's mouth with the hook already engaged. Before placing the engaged TAP into the patient's mouth, make sure that the hook is in its initial starting point (the lower tray is not pulled forward).

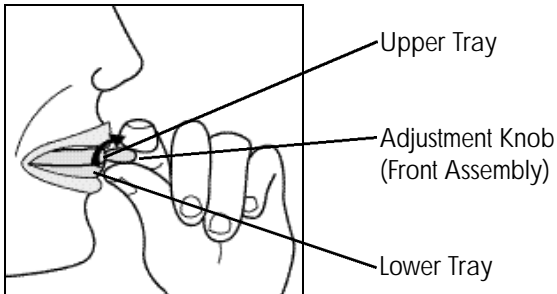
4. After use, disconnect the hook from the lower tray by slowly moving the lower jaw forward. Once the trays are separated they may be removed.

**Note:** The patient can also remove the device by gently opening the mouth while the hook is still engaged to "pop" the lower or upper tray off the teeth.

**Warning:** Instruct the patient not to bite down on the hook because it may bend or break. If the hook is bent, instruct your patient not to use the TAP and to return it to you for a replacement hook. The replacement hook should be a Closed Hook.

## Operating the Dial

1. To pull the lower jaw forward with the appliance in the mouth, turn the dial counter clockwise (towards the left ear).
2. To return the lower jaw to the starting position with the appliance in the mouth, turn the dial clockwise (toward the right ear).



## Exercise Leaf Gauge

When the jaw is pulled forward during the night, it may make the jaw muscles sore and temporarily change the bite. The Leaf Gauge is intended for the patient to use as an exercise tool to put the jaw back into normal bite position.

1. Place several sheets of the leaf gauge between the patient's front teeth (make sure the back teeth are not touching).
2. Slide the lower jaw forward and then back holding the plastic between the teeth.
3. Once the jaw is back, squeeze to put the back teeth together.
4. Repeat the several times.
5. Finally, remove the Exercise Leaf Gauge to see if teeth come together.

Each morning after use, thoroughly clean the TAP oral appliance using a regular toothbrush, cool water and toothpaste.

**Warning:** Instruct the patient not use hot water, and to dry the appliance completely before storing in the container. It may help to leave the container open to ensure that the TAP dries thoroughly.

The patient may disinfect the TAP appliance every three days in a solution of hydrogen peroxide and water (half hydrogen peroxide and half water). The TAP should be soaked in this solution for 10-15 minutes. Rinse with water before use. If an odor or bad taste develops, the patient may also soak the TAP in mouthwash for 5 minutes. Instruct the patient to brush his/her teeth and floss well before inserting the TAP in his/her mouth.

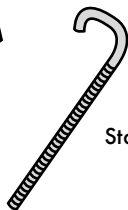
**Note:** The lining of the TAP is a heat-sensitive material. Instruct the patient to be very careful and to store it in a cool, dry place, and do not leave the appliance where the temperature may reach or exceed 120<sup>o</sup>-140<sup>o</sup>. This may cause distortion of the lining material and alter the fit of the TAP.

**Warning:** Instruct the patient not to put the TAP in the glove compartment of a car or the cargo hold of an airplane.

## Parts & Tools



U-Hook (Closed Hook)

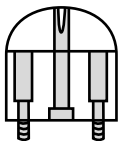


Standard Hook

Lingual Bar



Front Assembly

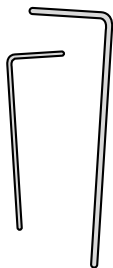


Replacement Plate Set



Locator

Allen Wrenches

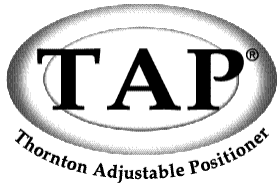








We are proud to offer  
our patients the TAP<sup>®</sup>.



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