

5. Place the device back in the patient's mouth.
6. Dial the hook counterclockwise until the patient's teeth are end-to-end. This may be the patient's starting position.
7. Again, mark the base plate even with the anterior side of the hook. This indicates the patient's starting position.

NOTE: On the protrusion gauge on the base plate, each mark and each space between the marks is 1mm wide. The protrusion gauge is 7mm long - from the front of the plate to the most posterior mark. Have the patient wear the appliance in this end-to-end position for 3-4 nights before starting the adjustments.

8. From the starting position, instruct the patient to turn the Adjustment Key a half turn (180 degrees) clockwise per night until all the symptoms are alleviated. The patient should leave the hook in the adjusted position – not dialed back to remove the appliance. The appliance should be detached from teeth before unhooking.
9. If any position becomes uncomfortable, the patient should dial the hook back until pain subsides. Caution the patient against starting to dial forward again until the jaw is comfortable. If the patient's pain does not subside, you may want to schedule a consultation for evaluation.

NOTE: Have the patient return to your office for examination and assessment to ensure the Tap® 3 is not damaged and is still effectively treating the patient's sleep disordered breathing. If the patient loses count of how far forward the hook is dialed, have him/her dial the Adjustment Key counterclockwise until the teeth are end to end (or in the starting position). Then have the patient dial the hook as many turns clockwise (or forward) as the previous nights hook position.

MULTIPLE HOOK SIZES

There are three different hooks available for use with the Tap 3®: Standard, Class I Hook, and Class II Hook. The appropriate hook will be selected by the fabricator, depending on bite registration. The hooks allow the fabricator and the dentist the greatest range of adjustment - without having to reset the hardware.

DIRECTIONS FOR DAILY USE

Instruct your patient in the daily use of the TAP® 3 appliance.

1. Before inserting the TAP® 3, the patient should brush his/her teeth and floss well.
2. Instruct patient to inspect the device prior to each use.

NOTE: If there is evidence of material separation, degradation or damage, the patient should discontinue use and contact you, the prescriber.

3. Tell patient to engage the hook of the upper tray with the socket in the lower tray before inserting in mouth. Patient should make sure that the hook is not dialed too far forward. The trays should snap comfortably over teeth while engaged.

NOTE: It is difficult for patient to engage the hook and socket if the trays are already in the mouth -- hook receptacle is small and may pinch the tongue.

4. Once the TAP is in place, encourage the patient to relax.
5. After use, the patient can remove either the upper or lower tray by gently opening the mouth while the hook is still engaged. At the

same time, the patient can lift up on the lower tray or pull down on the upper tray to loosen either tray and remove.

WARNING: If trays disengage while in the mouth, patient should take the trays out, re-engage the hook and socket and re-insert in mouth. Attempting to re-engage the trays while still in mouth may damage the hook or socket.

WARNING: TAP® 3 trays should never be worn separately.

OPERATING THE ADJUSTMENT KEY

1. To pull the lower jaw forward, instruct the patient to turn the Adjustment Key clockwise.
2. To return the lower jaw to the starting position, have the patient turn the Adjustment Key counterclockwise.

HOME CARE INSTRUCTIONS

WARNING: Instruct the patient that it is imperative to use the Good Morning Positioner each day to reduce the risk of permanent bite change.

**GOOD MORNING POSITIONER -
REFER TO INSTRUCTIONS INCLUDED**

- Each morning after use, instruct the patient to thoroughly clean the TAP® 3 appliance using a regular soft toothbrush, cool water and antibacterial liquid soap.
DO NOT USE HOT WATER
- Instruct the patient to dry the appliance completely before storing in the container.
- The patient may freshen the Tap® 3 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 allowed to dry.

NOTE: The best way to keep the TAP® 3 clean is to brush it each morning after use.

WARNING: The Tap® 3 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. In addition, instruct the patient not to clean the appliance in hot or boiling water, or soak it in bleach or hydrogen peroxide. This will cause the trays to distort or the lining to become brittle and delaminate. Instruct the patient not to tamper with any of the Tap® 3 hardware.



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DENTIST INSTRUCTIONS:

TAP® 3

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

It consists of an upper tray that fits over the upper teeth and a lower tray that fits over the lower teeth. It 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 the patient to adjust the protrusion of his/her lower jaw to the most effective and comfortable position.

The Tap® 3 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.

The device is fabricated from the dental casts of each individual patient. The outer layer of the Tap® 3 trays is a durable polymer (polycarbonate) and there is a choice of two unique linings: Triple Laminate (TL) and ThermAcryl®. The TAP® 3 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 pressure-formed over the dental cast with the polyurethane covering the teeth. The hard outer layer is then 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.



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Each Tap® 3 package contains:

- | | |
|----------------------------|-------------------------------|
| 1. An upper and lower tray | 4. Instructions |
| 2. Storage case | 5. Good Morning Positioner |
| 3. Adjustment Key | 6. Class I and Class II Hooks |

CONTRAINDICATIONS: This device is contraindicated for patients with loose teeth, loose dental work, dentures, or other oral conditions which would be adversely affect by wearing dental appliances. In addition, the appliance is contraindicated for patients who have central sleep apnea, severe respiratory disorders or who are under 18 years of age.

Read all instructions before using the TAP® 3

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 patient may experience soreness or discomfort in jaw or teeth. If discomfort persists, contact the prescriber.
- In the morning, some patients may sense a change in their bite. This change should disappear as the day progressed. If it continues with no change, contact the prescriber.
- Patient may experience obstruction of oral breathing with any oral appliance.
- Patient should return to the prescriber at least yearly (or as often as necessary) for re-evaluation. If the 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.
- Allergic reactions may be encountered in patients who are sensitive to nickel or self-curing acrylic.

POSSIBLE SIDE EFFECTS:

These side effects are not uncommon. If the patient experiences any of the following side effects, they should contact the prescriber immediately.

- Slight tooth or gingival discomfort due to pressure of the appliance
- Excess salivation – will improve as the patient becomes accustomed to wearing the TAP® 3.
- Slight jaw soreness or tightness – initially and with adjustments
- Temporary bite change - will subside approximately 30 minutes after TAP® 3 is taken out of the mouth in the morning and the Good Morning Positioner is used
- Unconsciously taking the TAP® 3 out of his/her mouth at night
- Movement of the teeth
- Pain in the jaw joint
- Permanent bite change

FITTING THE TAP® 3 TRAYS

NOTE: The lining of the Tap® 3 is a significantly different material than the ThermAcryl® lined TAP® 3. Make absolutely certain that both trays

fit over the patient's teeth. If the trays are too loose or too tight, call SML to discuss. As the patient adapts to the TAP® 3, 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® 3, inspect it carefully. If there is the slightest indication of damage or defects, do not fit it. Also, clean the TAP® 3 by gently scrubbing it with antibacterial soap and rinsing thoroughly.
2. Position the lower tray over the teeth. Using your thumbs, push the appliance on the teeth - starting from the back and working your way forward.
3. If the trays are too tight consult "Tray Adjustments."
4. Repeat the process with the upper tray.
5. Have the patient place both trays in their mouth. Trays should "snap" over the teeth. Instruct the patient to hook the trays together OUTSIDE of the mouth before putting the appliance in the mouth.
6. Ask the patient if trays:
 - a. are tight (but not uncomfortable)
 - b. fit equally in all areas
 - c. are comfortable to tongue
 - d. can be removed

If the patient answers "no" to any of the above questions, adjust the TAP® 3 appliance (slightly) until it is comfortable

7. With both trays hooked together in the patient's mouth, adjust the patient's jaw to a normal bite position (lips together, teeth apart and lower jaw not pulled forward) by dialing the Adjustment Key.
NOTE: This position does not have to be exact, it is just a position that is easy to find as a starting point.
8. Observe the lower unit in relation to the upper unit. There must be a minimum of 1mm space bilaterally in the posterior areas at all times (in all positions.) This allows you to add posterior stops once the patient has found a treatment position. If the practitioner desires posterior support, it can be added once the patient reaches the final treatment position.

WARNING: If any damage occurs, tell the patient not to use the appliance and return to your office for repair.

TRAY ADJUSTMENTS

Adjustments can be made to the TAP® 3 trays and/or the lining if they are too tight. Should adjustments be required, contact SML to discuss. Do not remove too much of the lining at once. This may cause the tray to lose retention and will ruin the trays, because the TL lining cannot be added back to the trays. If the trays are over adjusted, the laboratory may charge you to remake them. Be conservative with your adjustments.

If the trays are too loose, return them to the laboratory with new, accurate models.. If the trays are too tight, follow the instructions below.

1. Reduce the height of the flanges covering the teeth.
2. If the patient still complains of tightness or discomfort of the anterior teeth, carefully remove a small amount of the dual laminate lining from the areas of the tray with too much retention.

Use a thin straight acrylic burr and then a sharp knife to remove the tags.

3. Fit the tray in the patient's mouth with each adjustment.

POSTERIOR STOPS

Make sure there is a space - bilaterally - between the trays prior to adding acrylic posterior stops. The objective is to create bilateral (even posterior) stops at the patient's treatment position. Since the relationship of the maxilla to the mandible changes with the changes in protrusion, this procedure must be repeated if the treatment position changes.

1. Roughen the hard plastic in the occlusal area of the 1st and 2nd molar on the lower tray.
2. Lubricate the upper tray with Vaseline (keeps the trays from sticking together)
3. Then mix a small amount of autoseal orthodontic acrylic, and once it is in the doughy stage place it over the second molars on the lower tray only. Then, place the lower tray in the patient's mouth.
4. Couple the upper Tap® 3 tray with the lower tray – being careful not press the two together. Have the patient gently snap the upper tray over his/her teeth by pushing it up with his/her thumbs. Be sure the patient doesn't bite down on the stops. The hook should be set in the patient's treatment position.
5. With the trays coupled in the mouth, have the patient bite down.
6. Once the posterior stops are set, smooth and polish the stops. This will ensure there aren't any rough spots that may irritate the patient.

DECREASING LATERAL MOVEMENT

To decrease the lateral movement of the hook on the bar of the lower appliance, apply orthodontic acrylic under the bar. Remove acrylic in the midline to allow space for the hook and the desired lateral mobility. Place the appliance in the pressure pot or warm water bath to cure the acrylic.

HOOK AND SETTING ADJUSTMENTS

The hook moves forward and back ,using the Adjustment Key to dial the adjustment screw clockwise or counterclockwise. Each 180 degree turn is .25mm adjustment.

1. Instruct the patient to couple the trays together by placing the hook behind the bar on the lower tray. Have the patient place the device in his/her mouth.
2. Dial the Adjustment Key clockwise to the patients maximum mechanical protrusion(MMP). The patient will feel a slight stretch in temporomandibular joints at this point.
3. Remove the trays by pulling on the posterior.
4. Mark the Base Plate even with the anterior side of the hook to indicate the MMP point. The MMP mark is a permanent record of the patient's maximum range of motion at the initiation of treatment.