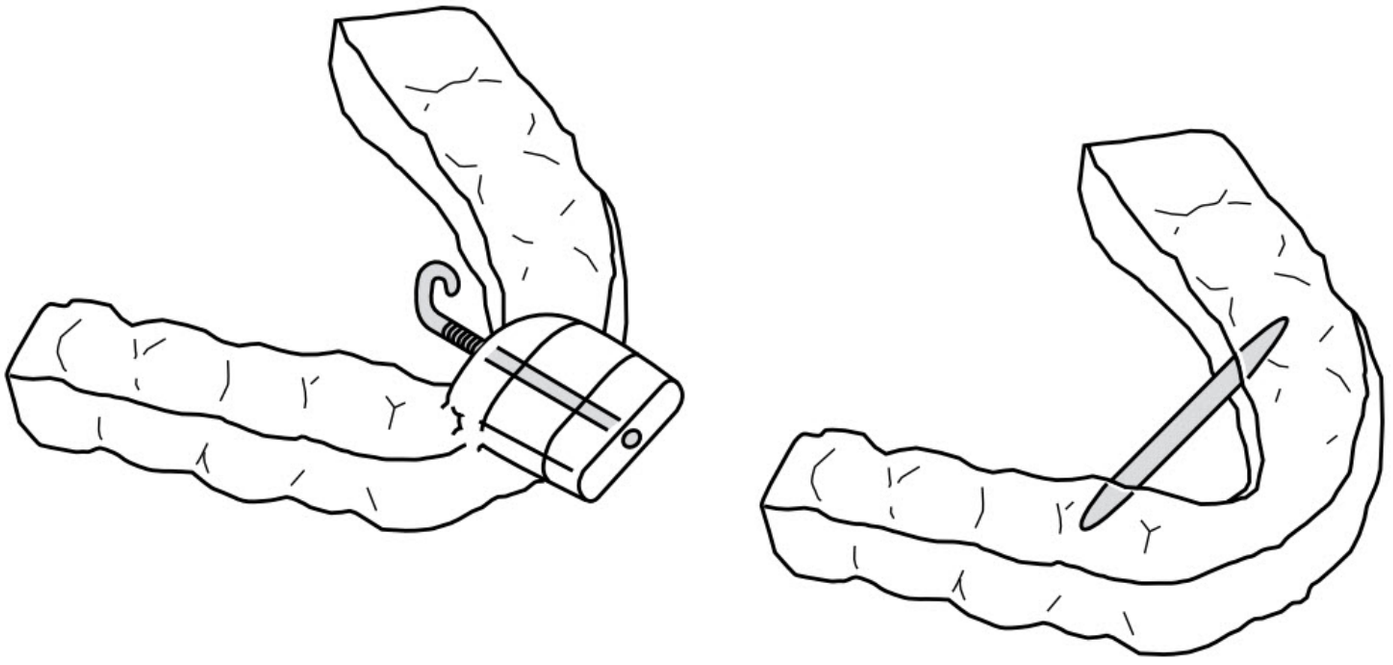
Clinician Fitting Instructions

☐ TAP® I ThermAcryl® ☐ TAP® I TL

TAP® I



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

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 when sleeping at home or in sleep laboratories and is for single patient use.

Contraindications

This device is contraindicated for patients with advanced periodental disease, 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.

Note: Dentist should consider the medical history of the patients, history of asthma, breathing, or respiratory disorders, or other relevant heath problems, and refer the patient to the appropriate healthcare provider before prescribing the device.

Introduction

The Thornton Adjustable Positioner (TAP®) 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 assembly on the TAP® I permits the patient to adjust the protrustion of his/her lower jaw to the most effective and comfortable positions.

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 a 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.

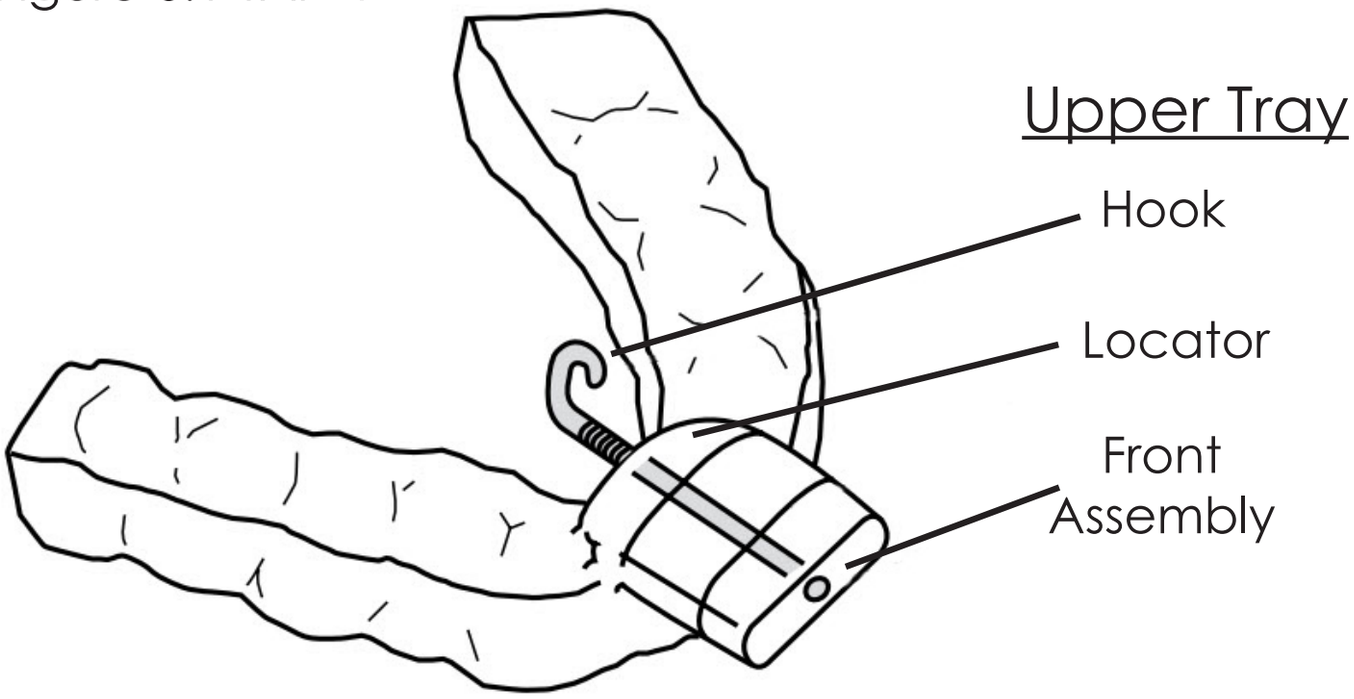
The lining is unique because the trays are returned to the dentist with the patient's dentition already impressed into the tray. Delivering the trays usually does not take as long as the TAP®I ThermAcryl® and the lining is much more comfortable in the mouth.

Each TAP®I package contains:

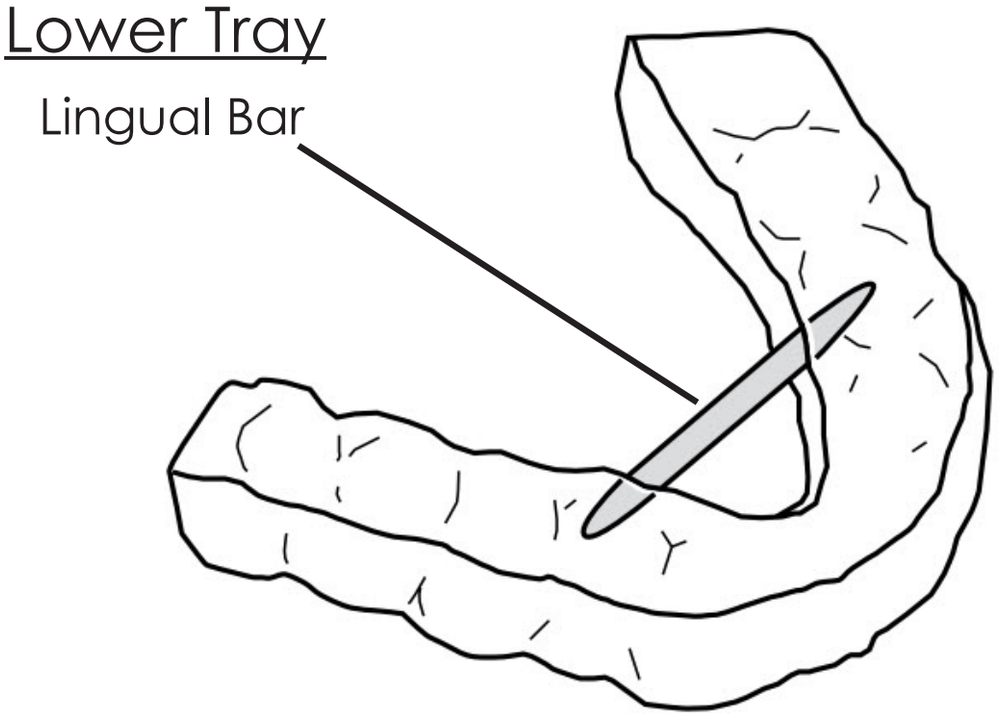
1. An Upper and Lower Tray
2. Instructions for Use
3. Storage Case
4. AM Aligner

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

Figure 6.1 TAP®I



Note: The metal parts are made of medical grade stainless steel. If the patient experiences any reaction, have him/her contact the prescriber immediately.



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 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 may experience obstruction of oral breathing with any oral appliance in the mouth.

- The patient should return to the prescriber at least yearly, or as often as necessary, for re-evaluation. If the TAP® I is lined with ThermAcryl®, the lining will need to be replaced yearly. If the appliance becomes loose, damaged, or does not fit properly, the patient should 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® I appliance. These side effects are not common, If the patient experiences any of the following side effects, instruct him/her to contact you, the prescriber.

- Slight tooth or gingival discomfort due to pressure of the appliance.
- Excess salivation initially. This will improve as the patient becomes 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 Aligners is used.
- Unconsciously taking the TAP® I out of his/her mouth at night.
- Orthodontic movement of the teeth.
- Pain or dysfunction of the temporomandibular joint and associated muscles.
- Permanent bite change.
- Allergic reaction to the stainless steel parts, which contains nickel.

Fitting the TAP® I ThermAcryl® Trays

Note: The following instructions only pertain to the ThermAcryl®-lined TAP®I trays. For TAP®I TL instructions, see page 15.

As the patient adapts to the TAP®I, 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®I, inspect it to make sure the pieces are not damaged and free from any physical or cosmetic defects. If there is the slightest indication that the device may be damaged or defective, do not fit it. Also, clean the TAP® I by gently scrubbing it with antibacterial soap and thoroughly rinsing it.

2. Place the lower TAP® I tray in a water bath that is heated to 160°F 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 completely 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. Press down with even pressure, especially in the posterior: do not rock the appliance over the teeth. Some ThermAcryl® will express out of the tray.

4. Remove the lower tray from the mouth by the hard outer shell.

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.

Figure 10.1 Trimming the lining material

Trim the lining material even with the edge of the tray

Do not trim the lining material around the last molar; smooth it with your finger. The lining material should be even along the flat surface of the hard shell.

6. Place the lower tray back in the patient's mouth. Let it sit for approximately 1-2 minutes (until the material is almost white)

7. 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 in the patients' mouth too long. If left in too long, the ThermAcryl® will lock onto the teeth and will be difficult to remove.

8. Repeat the same process for the upper tray.

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

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 no uncomfortably). Instruct the patient to hook the trays together outside of the mouth before putting the appliance in the mouth. This will prevent the Hook from damage.

11. Ask the patient if:
    a. the units are tight, but not uncomfortable
    b. equal fit 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® I appliance in the mouth until it is comfortable for the patient.

12. With both trays in his/her mouth and hooked together, have the patient close his/her jaw to a normal bite position (lips together, teeth apart, and lower jaw not pulled forward.)

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

13. 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 1 mm space bilaterally in the posterior areas at all times, in all positions.

If the practitioner desires posterior support, which AMI recommends, he/she can add it once the patient reaches the final treatment position. See Posterior Stops section.

Warning: Instruct the patient not to bite down on the Hook. The patient should hook the trays together outside of the mouth before putting the appliance in the mouth. If the Hook is damaged, tell the patient not to use the appliance and replace the Hook with a Closed Hook.

Note: The ThermAcryl® lining will 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. See Homecare Instructions.

Reline Instructions for ThermAcryl® Trays

1. Heat the trays in a hot water bath (approx. 160° F) until the ThermAcryl® turns clear. Do not leave the trays in the water bath too long. The trays will warp.

2. Remove the ThermAcryl® with a spatula. Let trays cool.

3. Place the ThermAcryl® beads in a hot water bath and heat until the beads coagulate and become clear.

4. Coat the inner liner tray with a liquid monomer that will adhere the ThermAcryl® to the inner liner tray.

5. Trim the trays completely to the top with the heated ThermAcryl®.

6. Refit the trays to patient. See steps 3-13 in section Fitting the TAP®I ThermAcryl Trays.

Fitting the TAP® I TL Trays

Note: The following instructions pertain to the TAP Triple Laminate (TAP® I TL) trays.

The lining of the TAP® I TL is a significantly different material than the ThermAcryl®-lined TAP® I . Although the TAP® I 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.

Note: If the trays are too tight, call the laboratory that made the device to discuss the case.

1. Before you fit the patient with the TAP® I TL, inspect it to make sure that the pieces are not damaged and free from physical or cosmetic defects. If there is the slightest indication that the device may be damaged or defective, do not fit it. Also, clean the TAP® I by gently scrubbing it with antibacterial soap and thoroughly rinsing it.

2. Start with the lower tray (*the tray 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. If the trays are too tight, see section Tray Adjustments.

4. Repeat the same process with the upper tray.

5. Have the patient place both trays in his/her mouth (they should "snap" over the teeth, but not uncomfortably). Instruct the patient to hook the trays together outside of the mouth before putting the appliance in the mouth. This will prevent the Hook from damage.

Ask the patient if:

a. the units are tight, but not uncomfortable
b. equal fit 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, slightly adjust the TAP® I appliance until it is comfortable for the patient. See section Tray Adjustments.

6. With both trays in his/her mouth and hooked together, have the patient close his/her jaw to a normal bite position (lips together, teeth apart, and lower jaw not pulled forward).

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

7. 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 1 mm space bilaterally in the posterior areas at all times, in all positions. If the practitioner desires posterior support, which AMI recommends, he/she can add it once the patient reaches the final treatment position. See Posterior Stops Section.

Warning: Instruct the patient not to bite down on the Hook because it may break. The patient should hook the trays together outside of the mouth before putting the appliance in the mouth. If the Hook is bent do not use the appliance and replace the hook with a Closed Hook.

Tray Adjustments

Adjustments can be made to the trays and/or the lining if they are too tight. If adjustment need to be made, it is suggested that you contact the laboratory that made the TAP® I to discuss the case.

Do not remove too much of the TL lining at once. This may cause the tray to lose retension and will ruin the trays because TL lining cannot be added back to the trays. If the trays are over-adjusted, the laboratory may charge you for a re-make of the trays.
Be conservative with your adjustments.

If the trays are too loose, return them to the laboratory. If the trays are too tight follow the instructions below:

1. First, reduce the height of the flanges covering the teeth.
Do not relieve the lining.

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 retension. Use a thin straight acrylic burr and then a sharp knife to remove the tags. See the Burr Suggestions below.

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

Burr Suggestions
The TAP® I TL can be modified with straight burrs from Brassler USA Soft Reline Removal and Trimming Kit. The toll-free number is 1-800-841-4522.

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

261GSQ-023 - small
251GSQ-060 - medium
79GSQ-070 - large

It is extremely important that there is space bilaterally between the trays prior to adding the 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.

To add Posterior Stops:

1. Roughen the hard plastic in the occlusal area of the 1st and 2nd molar on lower tray.

2. Lubricate the upper tray with Vaseline and place in the patient's mouth. The Vaseline will keep the trays from sticking together when adding the Posterior Stops.

3. Place the lower tray in the patient's mouth while the acrylic is in the doughly stage.

4. Help the patient to couple the upper TAP® I tray with the lower while the lower is in the patient's mouth. 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. See Hook Setting and Adjustments Section.

5. With the trays coupled in the mouth, have the patient bite down.

6. Once the Stops are set, first smooth the area with your finger. This will ensure there isn't any rough spots that may irritate the patient.

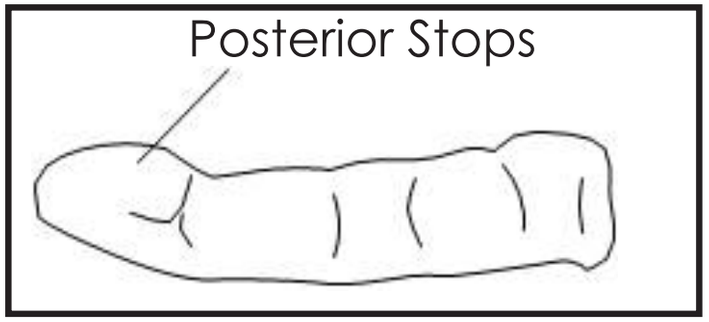


Figure 20.1 Side view of lower tray with Posterior Stop.

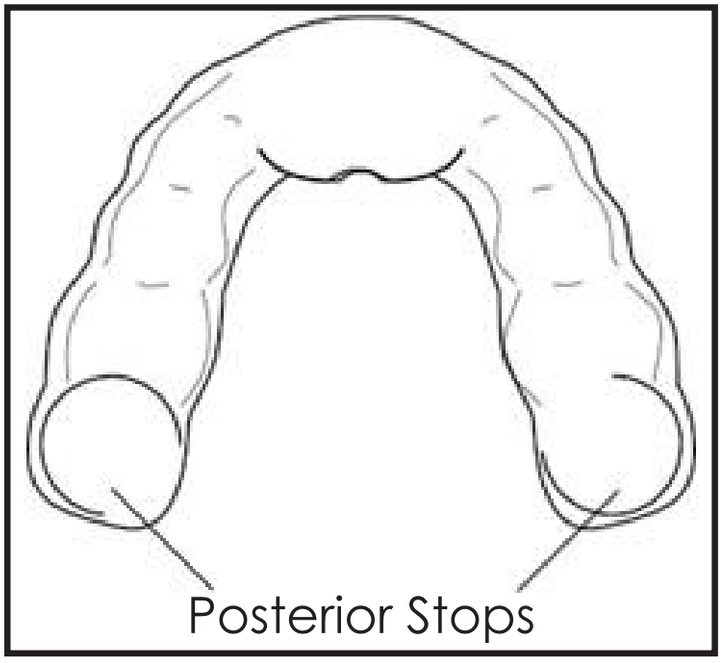


Figure 20.2 Top view of lower tray with Posterior Stop.

Note: The setting adjustments are written from the perspective of the practitioner looking at the patient.

The initial treatment position of the Hook should be set by the prescriber according to the following instruction. The Hook moves forward and back by turning the knob of the Front Assembly clockwise or counter clockwise. Each 120° turn is a .25mm adjustment.

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 a slight stretch in his/her temporalmandibular joints at this point (see figure 23.1).

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 trays by pulling on posterior of the trays.

4. Cut the protruded threads of the Hook flush with the front of the Front Assembly (see figure 24.1)

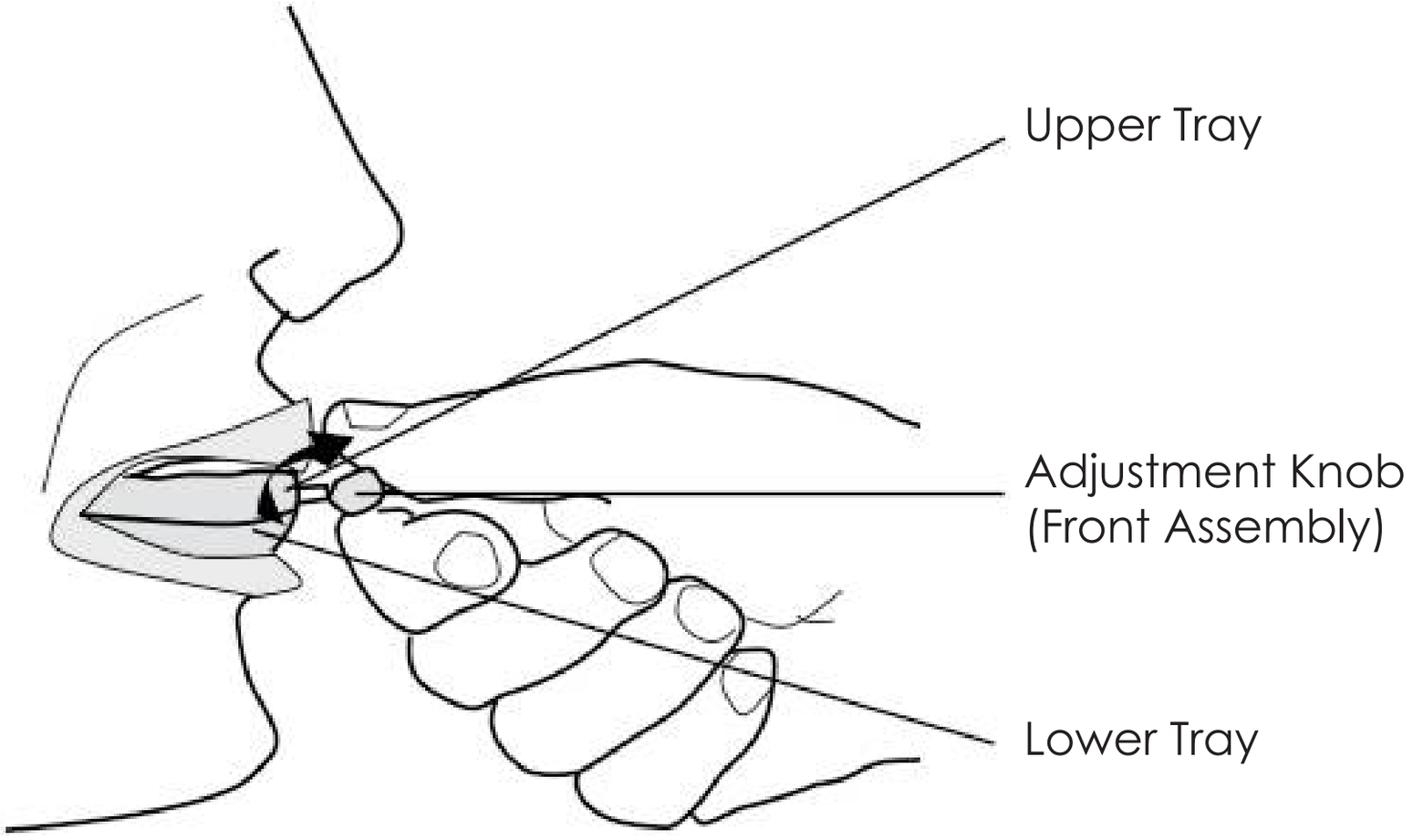


Figure 22.1 Clinician advancing the lower jaw forward.

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

6. Dial the Hook counter clockwise until the patient's teeth are end to end. This is the patient's **starting position** (see figure 24.2)

7. From the starting position, instruct the patient to turn the knob a half turn (180 degrees) counter-clockwise per night until all symptoms are alleviated. The patient should count each turn so that he/she knows how far forward to dial the Hook each night.

8. If any position becomes uncomfortable, dial the Hook back until the pain subsides. Instruct the patient not to start dialing forward again until the jaw is comfortable.

Have the patient return to your office at least yearly for examination and assessment to ensure the TAP® is not damaged and is still effectively treating the patient's sleep disordered breathing.

Note: If the patient loses count of how far forward (or back) the Hook is dialed, instruct him/her to dial the Hook clockwise until the teeth are end to end (or in the starting position). Then have the patient dial the Hook as many turns counter-clockwise (or forward as the previous night's Hook position.

Fig 24.1
Maximum Mechanical Protrusion (MMP)

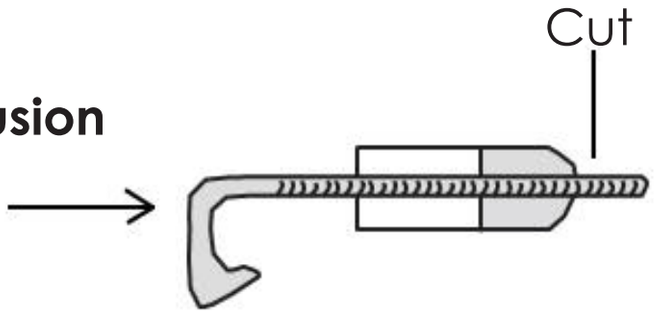


Fig 24.2
Starting Position (SP - 25 Turns Back)

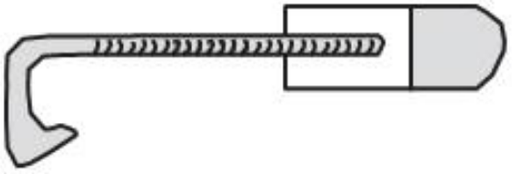
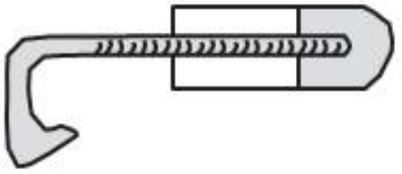


Fig 24.3
Initial Treatment Position (7 Turns Forward)



Replacement Place Set

The Replacement Plate Set can be used as a substitute for the Front Assembly. Once the Replacement Plate is used, the patient will achieve greater lip competence but will not be able to dial his/her lower jaw forward and back. However, the hook can still be adjusted by unscrewing the two button-head screws on the plate and rotating it 180 degrees. The screws should then be screwed back into place.

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 so the knob is perpendicular to the ground, exposing screws. Unscrew the screws that attach the Front Assembly to the TAP® I appliance.

3. Once the screws are removed, twist the Front Assembly counter clockwise until it is unattached from the Hook.

4. Screw on the Replacement Plate Locator Nut 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 Locator Nut Replacement Plate.

5. Using a .050 Allen Wrench (small Allen wrench), screw in the two button head socket screws through the Locator Nut 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.

Note: If the patient wants/needs the Front Assembly to be added back to his/her appliance you will need to replace the old Hook with a new uncut Hook, as well as order a new Front Assembly.

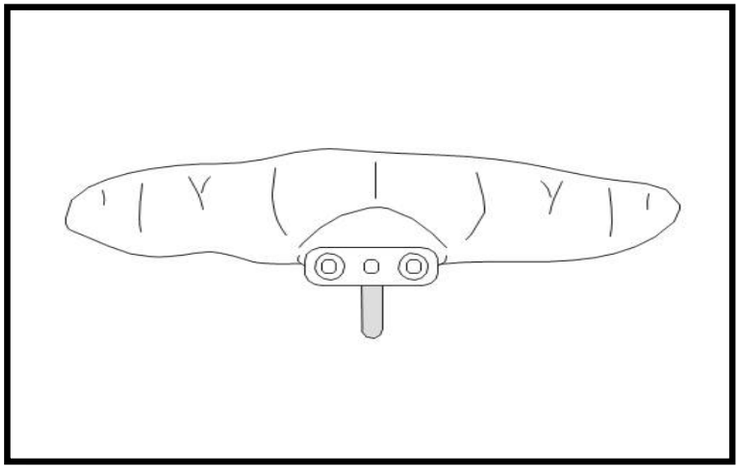


Fig 26.1 Replacement Plate (Front View)

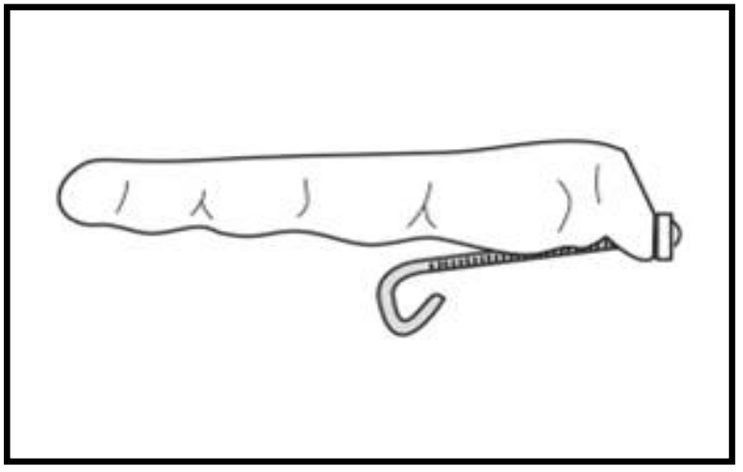


Fig 26.2 Replacement Plate (Side View)

Directions for Daily Use

Instruct your patient in the daily use of the TAP® I appliance. Also give your patient a copy of the Patient Instruction Booklet.

1. The patient should brush his/her teeth and floss well before inserting the TAP® I.

2. Instruct your patient to inspect the device prior to each use. If there is any material separation, material degradation or damaged parts, the patient should discontinue use and contact you, the prescriber.

3. Tell the patient to place the TAP® I in his/her mouth with the Hook and Lingual Bar already engaged. Before the patient places the engaged TAP® I into his/her mouth, remind him/her to make sure that the Hook is in its initial starting point (the lower tray is not pulled forward).

Warning: Warn 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®1 and to return it to you for a replacement Hook. The replacement Hook should be a Closed Hook, which requires that the hook is engaged before the trays are placed in the mouth.

4. 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 remove either tray more easily.

Warning: The TAP® I trays should never be worn separately. The patient should always wear both trays when using the appliance.

Operating the Dial

Note: Operating the Front Assembly is written from the perspective of the patient with the appliance in his/her mouth.

1. To pull the lower jaw forward with the appliance in the mouth, instruct the patient to turn the knob counter clockwise (towards the left ear). See Figure 28.1.

2. To return the lower jaw to the starting position with the appliance in the mouth, have the patient turn the knob clockwise (toward the right ear).

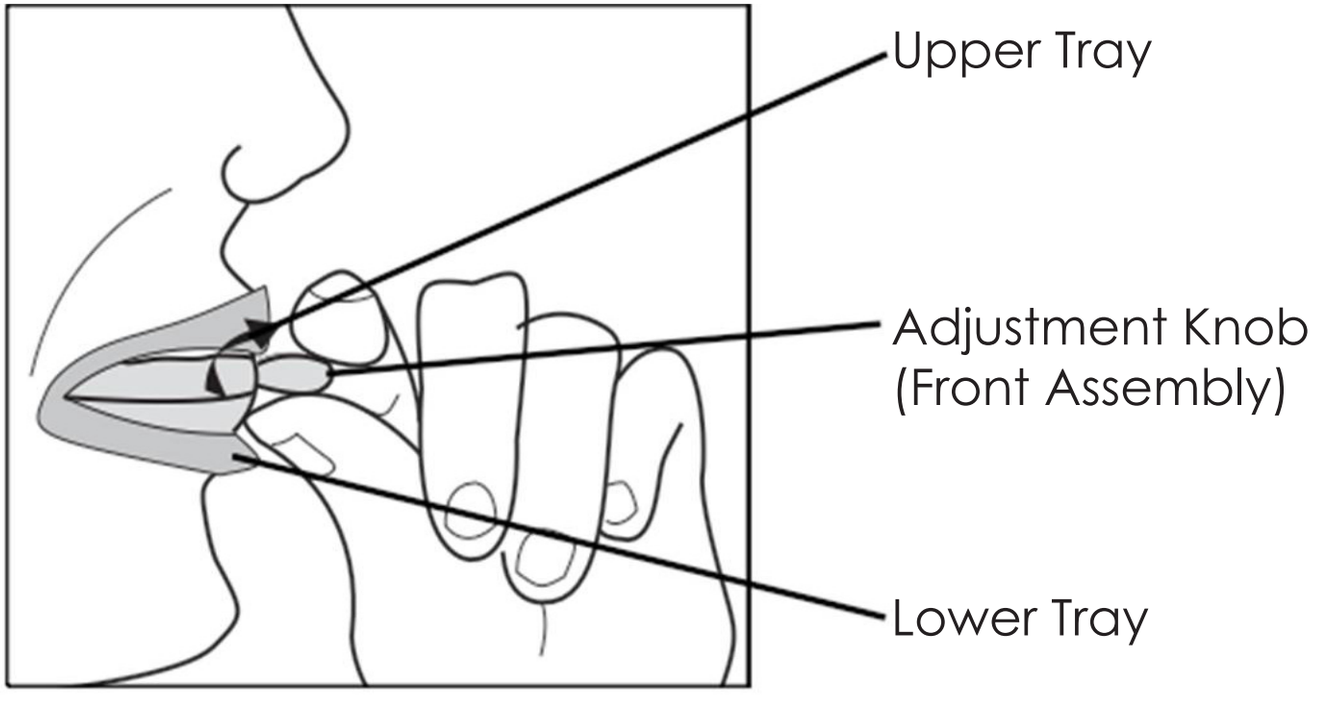


Fig. 28.1 Patient advancing the lower jaw forward.

AM Aligner

The purpose of the AM Aligner is to counteract the forces that represent the most significant side effect of a mandibular advancement device used for the treatment of obstructive sleep apnea and other sleep disordered breathing. Repositioning the mandible forward at night creates a transient malocclusion in the morning with anterior tooth contact and posterior open bite.

The AM Aligner is designed to reestablish the proper intercuspation of the teeth. The forces that are inherent in repositioning the mandible forward can also incline the maxillary anterior teeth lingually and the mandibular anterior teeth facially. The AM Aligner counteracts this movement by creating a centric occlusion splint that is fabricated before the MAD is delivered.

The AM Aligner is constructed of a unique thermoplastic material that can be made in the office. It is used every day by the patient to return the mandible the original relationship to the maxilla.

1. Place Aligner in water heated above 160°F.

2. While the Aligner is in the water, have the patient practice closing in their usual bite position. Every morning it is important that the patient return to this position so that their occlusion doesn't change.

3. Place softened wafer over upper teeth with 4mm of wafer facial and buccal to the teeth.

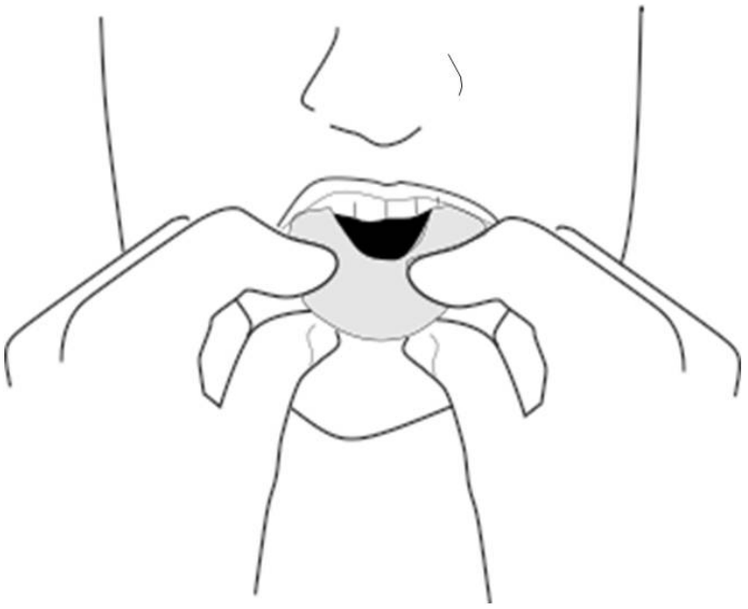


Fig. 30.1 place softened wafer over upper teeth

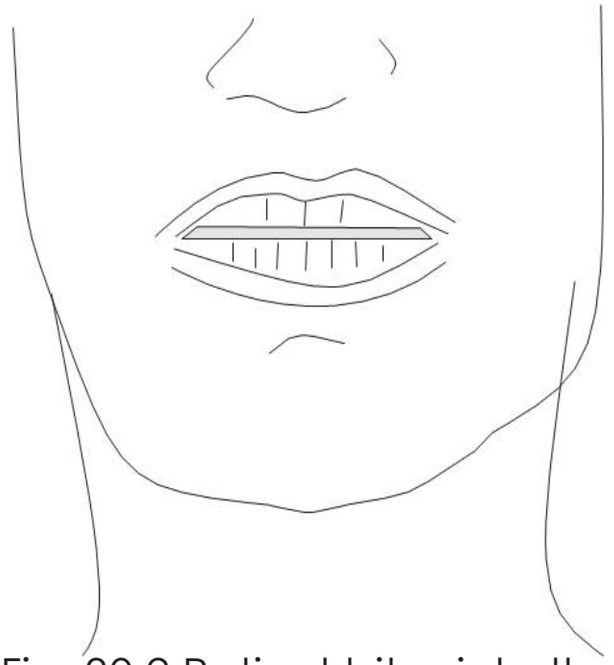


Fig. 30.2 Patient bites into their most retruded position

4. Have patient bite hard into their usual bite position. The patient should try to bite all the way through the Aligner. (When held to the light, the plastic should be very thin almost translucent where the tooth indentations are).

5. Mold the excess plastic over the upper teeth.

Fig. 31.1 Mold the excess plastic over the upper teeth beginning in the middle and working your way backwards.

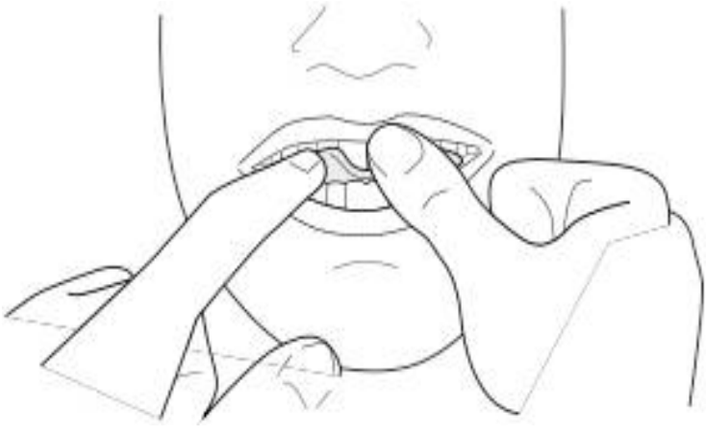


Fig. 31.2 Using your thumb, create a slight dip in the middle so that the aligner dips down over the bottom front teeth.

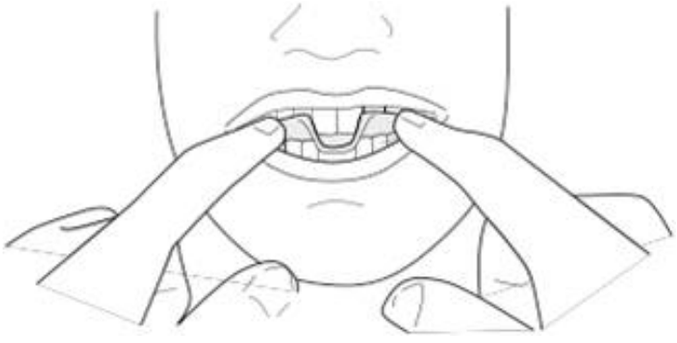


Fig. 31.3 Continue molding to the sides.

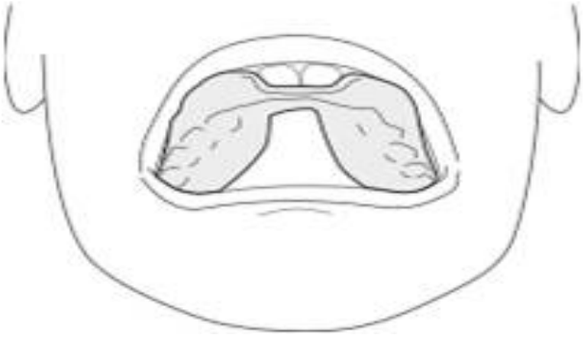


Fig. 31.4 View from underneath with patient's mouth open.

6. Have patient mold lingual plastic with tongue against palate.

Fig 32.1 Patient uses tongue to mold against palate.

7. Have patient close their lips and suck on the material to create a good fit around the teeth.

8. Let set in the mouth for two minutes.

9. Carefully loosen the plastic from the back teeth first, then remove the Aligner from the mouth. The Aligner should have a good shape of the upper arch with deep indentations of the lower arch on the bottom of the tray.

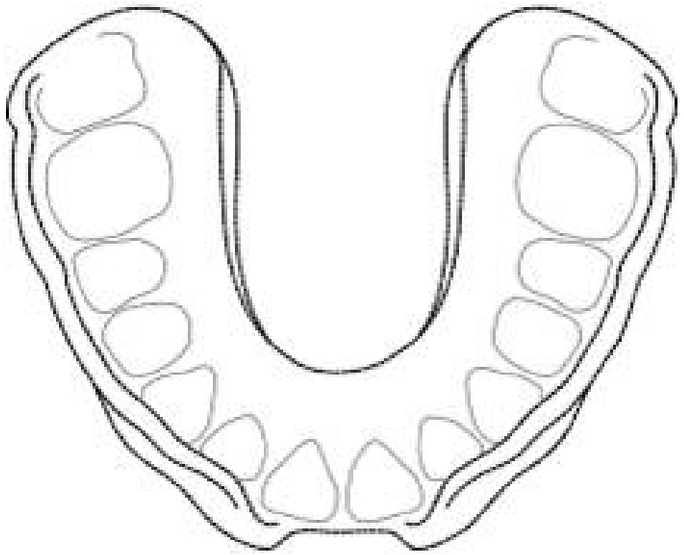


Fig. 33.1 Top view arch

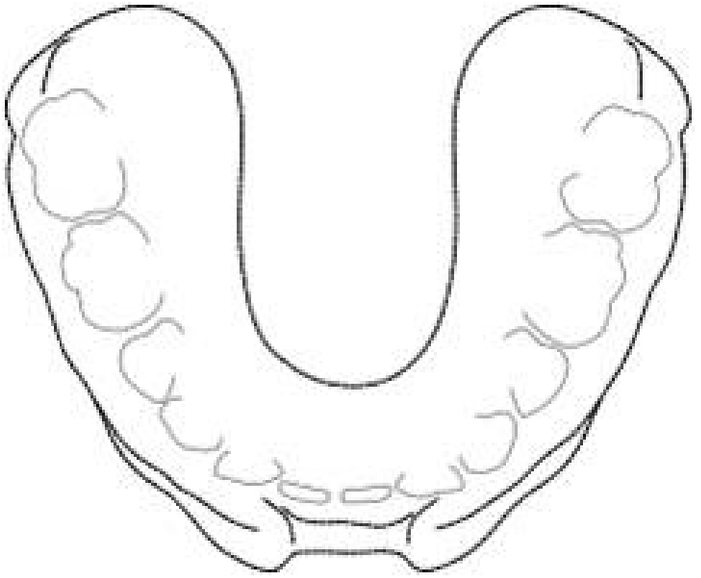


Fig. 33.2 Bottom view arch

10. Place the plastic wafer under cool water for 1 minute to fully set the plastic in position.

11. Put Aligner back in the mouth and check for fit.

12. Repeat if it doesn't fit precisely.

13. Place the plastic wafer inside the TAP storage box along with the TAP®I device.

Contraindications
Allergic response may occur to the thermoplastic material.

Severe Class 2 or severe Class 3 malocclusions may require a custom splint.

Do not store or soak at high temperatures (such as hot car or hot water). This would cause distortion of the appliance.

Warning: Instruct the patient that it is imperative to use the AM Aligner each day to reduce the risk of permanent bit change.

Each morning after use, instruct the patient to thoroughly clean the TAP® I appliance using a regular soft toothbrush, cool water and an antibacterial liquid soap. Hot water should not be used.

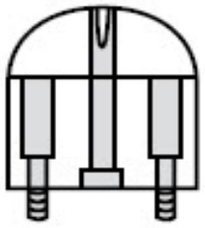
Instruct the patient to dry the appliance completely before storing in the container. It may help to leave the container open to ensure the TAP® I dries thoroughly.

The patient may disinfect the TAP® I appliance every two weeks in a solution of mouthwash and water (half mouthwash and half water), or the patient can substitute a denture cleanser, like Efferdent, for mouthwash. The TAP® I should be soaked in this solution for only 10-15 minutes and rinsed thoroughly with water before use or storage. Instruct the patient to brush his/her teeth and floss well before inserting the TAP® I in mouth.

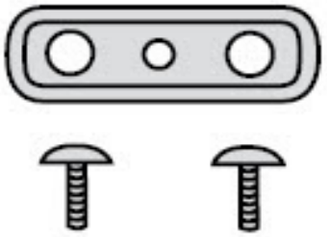
Note: Using mouthwash or a denture cleanser will cause the plastic materials of the appliance to deteriorate more rapidly. The best way to keep the TAP® I clean is to brush each morning after use. The patient should sparingly soak the appliance if further measures need to be used in order to clean the appliance.

Warning: The TAP® I should be stored in a cool, dry place. The appliance is made from 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, explain to the patient not to 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.

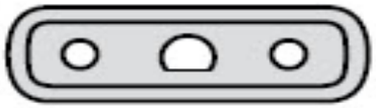
Warning: Instruct the patient not to disassemble any of the TAP® I hardware. The TAP® I is a medical device and the patient must not tamper with it other than following specific instructions in this booklet.



Front Assembly



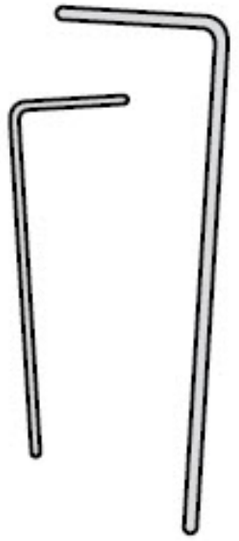
Replacement
Plate Set



Locator

U-Hook
(Closed Hook)

Lingual Bar



Allen Wrenches

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