

flexTAP[®] with ThermAcryl[®]

Clinician Instruction for Use

 **AIRWAY**
MANAGEMENT

TAP SLEEP CARE
tapintosleep.com

Important Safeguards

SAVE THESE INSTRUCTIONS

The following words in this manual have special significance.

Warning: Means there is a possibility of injury.

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

Indications:

- The flex Thornton Adjustable Positioner® (flexTAP®) is intended to reduce or alleviate nighttime snoring and sleep related breathing disorders including 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 a dental appliance.
- In addition, the appliance is contraindicated for patients who have central sleep apnea, have severe respiratory disorders or who are under 18 years of age.
- Severe Class 2 or severe Class 3 malocclusion may require a different custom splint or TAP® hardware.

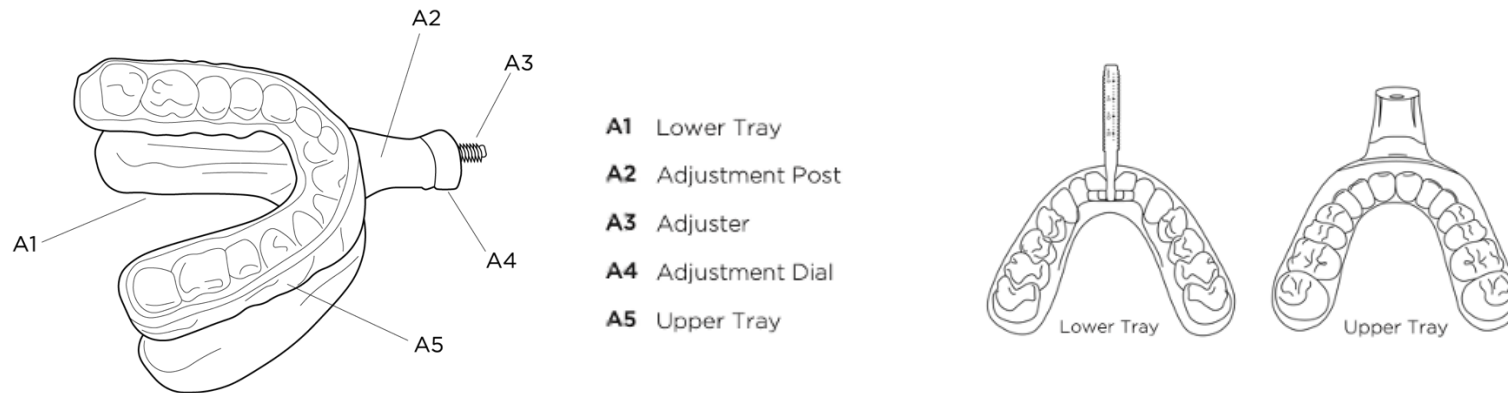
Introduction

The flexTAP is a custom-made oral device intended to reduce or alleviate nighttime snoring and obstructive sleep apnea (OSA). Our proprietary Vertex Technology® is the design of the post angulation in the flexTAP hardware. The post is angled at a 45-degree angle, allowing the patient to advance their lower jaw both vertically and horizontally at the same time.

The flexTAP device consists of an Upper Tray that fits over the upper teeth and Lower Tray that fits over the lower teeth. The flexTAP Adjuster (a threaded, numbered mechanism shown in Figure 1, A3) attached to the Lower Tray fits into an Adjustment Post (Figure 1, A2) on the Upper Tray. These components are tethered and adjusted by the flexTAP Adjustment Dial (Figure 1, A4). The device holds the lower jaw forward, preventing the soft tissue of the throat from collapsing and obstructing the airway.

Upper Tray and Lower Tray image

Figure 1 (image of parts)



The flexTAP Adjustment Dial (Figure 1, A4) allows the patient to adjust the amount of protrusion of the lower jaw to the most effective and comfortable position. Each half turn (counterclockwise “from user’s perspective”) of the flexTAP Adjustment Dial will advance in 1/3 mm increments.

Linings: The device is fabricated on the dental casts (traditional plaster or digitally printed) of individual patients. The outer layer of both flexTAP trays is patented over molded ThermAcryl® and Polycarbonate hardware frames, bonded to an initial inner ThermAcryl vacuumformed plastic. These liners soften when heated and molded to the patient's teeth at the time of fabrication and delivery. The lining is unique because it can be slightly reheated and remolded if the patient has had any dental work, such as a crown or to achieve the most comfortable fit while maintaining retention.

Note: ThermAcryl is a heat sensitive lining and may deform if subjected to temperatures greater than 160°F. If it is heated for too long or above 160°F the trays impressions of your teeth will deform and your flexTAP will no longer fit.

Each flexTAP package contains:

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

Fitting the flexTAP ThermAcryl Trays

Note: The following instructions only pertain to the ThermAcryl lined flexTAP trays.

Before you fit the patient with the flexTAP, inspect it to make sure the pieces are not damaged and are 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.

1. Clean the flexTAP by gently scrubbing and rinsing it thoroughly.
2. Place the Lower Tray of the flexTAP in the patient's mouth. If it does not fit immediately, easily, or comfortably, place the lower tray in a water bath that is heated to 160°F until the ThermAcryl lining softens (turns malleable).

Warning: Do not leave the trays in the water bath too long. The outer trays may warp! The trays should be removed from the water bath and fitted as soon as the lining material becomes malleable.

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 appliance over the teeth.
4. Remove the Lower Tray from the mouth by placing your fingers on the underside / edges of the tray.
5. Once the ThermAcryl has hardened, place into or under cool water to speed the cooling process.
6. Place the Lower Tray back in the patient's mouth to check the fit.

Note: Repeat the same process (steps 2-6) for the Upper Tray.

7. Once both trays are properly fitted, have the patient place both trays in his/her mouth. They should “snap” over the teeth, but not uncomfortably. Instruct the patient to tether the trays together outside of the mouth before putting the appliance in the mouth.

Ask the patient if:

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

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

Tray Adjustments

Warning: If any damage occurs, tell the patient not to use the appliance and return to you for repair.

Adjustments can be made to the flexTAP ThermAcryl trays if they are too tight, loose or uncomfortable. It is also recommended to contact your TAP fabrication lab for additional tips. You should also try to re-fit after each incremental tray adjustment to prevent over adjustment.

Be conservative with your adjustments. ThermAcryl is a heat sensitive lining and may deform if subjected to temperatures greater than 160°F. If it is heated for too long or above 160°F, the tray impressions of your teeth will deform and your flexTAP will no longer fit.

If the tray is:

- Too loose: reheat, reseat, and press the trays firmly onto the dentition. Then, place the trays into or under cool water to speed the cooling process.
- Too tight: reheat and reseat. Then, lift the appliance up and down several times to loosen the fit. Place the trays into or under cool water to speed the cooling process.
- If the trays are too tight because they are tall, you can shorten them using a Brasseler Bristle Brush #209-0616-411-144 #12 Standard Stiff.
- If the trays are too tight due to excess material in the interproximal spaces / occlusal contact, use the Brasseler Bristle Brush #209-0616-411-144 #12 Standard Stiff to relieve these areas.

Initial Setting of the Adjustment Dial

Note: The setting adjustments are written from the perspective of the practitioner looking at the patient. The initial treatment setting should be set by the prescriber.

Figure 2 (Adjuster with mm markings)

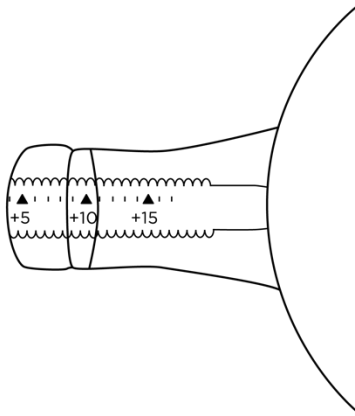


Figure 3 (image of cutting the extra threaded adjuster)

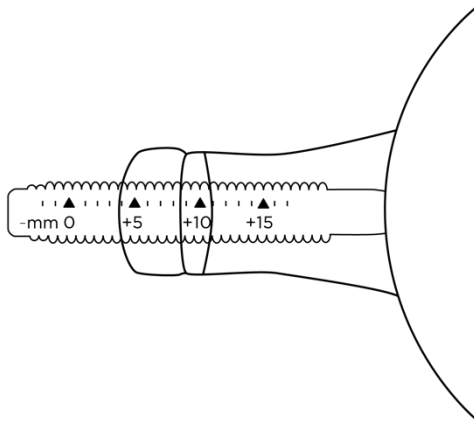


Figure 4 (Adustment Dial)



1. Many practitioners prefer an initial setting at the edge to edge (lower in line with the upper) position.
2. Once this is achieved, you can cut the extra threaded Adjuster off from where it sticks out past the Adjustment Dial (See Figure 3).
3. Advise the patient to wear it in their starting position for the first 3 to 4 days to acclimate to the device.
4. Upon acclimation, advise the patient to gradually advance ($\frac{1}{2}$ turn or = .3 mm) the dial. If at any point the advancement becomes uncomfortable, tell them to stop advancement.
5. To pull the lower jaw forward with the appliance in the mouth, turn the Adjustment Dial clockwise (towards the patient's right ear).
6. To return the patient's lower jaw to the starting position with the appliance in the mouth, turn the Adjustment Dial (See Figure 4) counterclockwise (towards their left ear).
7. The upper side of the flexTAP Adjuster has mm markings (See Figure 2) to track positional change. The patient can track this change by notating the mm number at the end of the Adjustment Dial in their notes upon beginning of treatment.

Note: The total adjustment range of the flexTAP is 17mm. The protrusion range will vary patient to patient based on their natural bite, protrusion abilities, comfort, and treatment needs.

Note: Measurements are accurate to within +/- 0.5 mm and are intended to indicate changes in position for a given user. Round off readings to the nearest 0.5 mm.

Note: This should not be used independently as a measurement device as the absolute position may change relative to the fit of the tray.

Note: Have the patient contact or return to your office for examination and assessment annually (more frequently if desired) to ensure the flexTAP is still effectively treating the patient's sleep related breathing disorder and to ensure the flexTAP is not damaged.

Optional Product Enhancements

Note: Although the below are optional, they are designed to allow for better treatment outcomes while using flexTAP.

Figure 5 (AM Aligner)

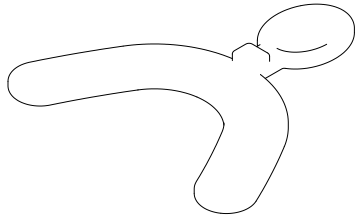
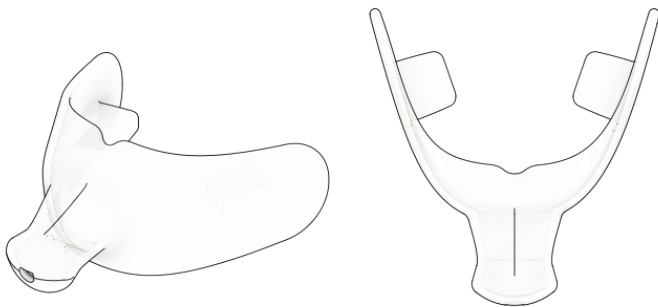


Figure 6 (Mouth Shield)



AM Aligner[®]

The AM Aligner (See Figure 5) is a morning repositioner that is included with every flexTAP appliance. The purpose of the AM Aligner is to reposition the patient's jaw after each use of the flexTAP. It is made of a unique thermoplastic material and is used to take a registration of the patient's normal, comfortable bite before the patient begins to use the flexTAP. Please see the AM Aligner instructions for more information.

Mouth Shield

The flexTAP Mouth Shield (See Figure 6) is included with every flexTAP and is designed to alleviate certain side effects like dry mouth or excess saliva by sealing the mouth, providing greater comfort.

Another benefit to sealing the mouth is the promotion of nasal breathing. Research shows this is the best way to breathe. Please see the flexTAP Mouth Shield instructions for more information.

Posterior Stops

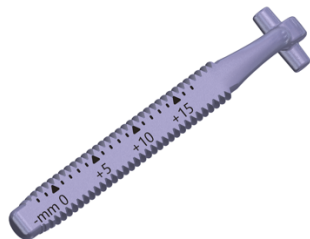
Posterior stops can be utilized by incorporating the flexTAP Mouth Shield which includes built in pads on the sides. Please see the flexTAP Mouth Shield instructions for further information.

Adjuster

The flexTAP Adjuster (See Figure 7) is designed to be interchangeable. It is made to clip out of the lower tray. When the user is wearing their flexTAP, forces pull the adjuster forward, keeping it in place.

Note: If you wish to lock the adjuster in place, you can use additional ThermAcryl bonded over the adjuster on the lower tray.

Figure 7



Homecare Instructions

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

- Each morning after use, instruct the patient to thoroughly clean the flexTAP appliance using a regular soft toothbrush, cool water, and toothpaste. Hot water should not be used. Rinse thoroughly after cleaning.
- Instruct the patient to dry the appliance completely before storing in the container. It may help to leave the container open to ensure that the flexTAP dries thoroughly.

Note: The best way to keep the flexTAP clean is to brush it each morning after use.

Note: For cleaning difficult stains, use OrthoFresh as needed. If there is remaining stain after use of OrthoFresh, use a soft toothbrush and rinse with cold water. To order visit your doctor or visit www.orthofresh.com.

Warning: The flexTAP 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 flexTAP hardware. The flexTAP is a medical device and the patient must not tamper with it other than following specific instructions in the patient instruction booklet.

Directions for Daily Use

Instruct your patient in the daily use of the flexTAP appliance. Also give your patient a copy of the Instruction Booklet.

1. The patient should brush his/her teeth and floss well before inserting the flexTAP.
2. Instruct the 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 insert the Lower Tray and Upper Tray tethered together before placing the trays in his/her mouth. The patient should make sure the flexTAP dial is not dialed too far back that he/she cannot comfortably snap the trays over his/her teeth while engaged. The patient should use his/her thumbs to push the tray from the bottom to snap it over the upper teeth. Repeat the same process on the lower tray.
4. The patient should gently relax once the flexTAP is in his/her mouth.
5. After use, the patient can remove either the Upper or Lower tray by gently opening the mouth while the flexTAP Adjuster is 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 to remove the full unit.

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

Continued Adjustments with the flexTAP Dial

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

Note: Continued adjustments should be done under the advice of your prescriber.

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

AM Aligner & Mouth Shield

Note: The AM Aligner should be used daily after use of your flexTAP.

Cleaning:

Clean the AM Aligner with a soft toothbrush and warm water once a week.

Clean your Mouth Shield daily by running it under hot water and leaving it to air dry out of direct sunlight. It can also be cleaned using mild soap and warm water solution.

Refer to separate AM Aligner and flexTAP Mouth Shield instructions for more information.

Product Disposal

The flexTAP may be placed in the general household waste receptable.

Warnings and Possible Side Effects

Note: Read all instructions before using the flexTAP.

Warnings:

- This device is intended to reduce or alleviate nighttime snoring and obstructive Sleep apnea (OSA). If symptoms, breathing difficulties or other respiratory disorders exist or persist, with or without the device, the patient should contact the prescriber immediately.
- The flexTAP should only be used as directed. Do NOT misuse the product.
- 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.
- US Federal Law restricts this device to sale by prescription only.
- Do NOT use if you have braces.
- Do NOT use if you have not seen a dentist in the last 12 months or are under active treatment.
- Do NOT use if you have loose teeth, loose crowns, or loose fillings.
- Do NOT use if you have temporary crowns, removable dentures, or bridges.
- You may experience obstruction of oral breathing with any oral appliance in the mouth.
- Do not store or transport the flexTAP outside the temperature range of -4°F to 122°F (-20°C to 50°C)
- You must have at least 8 natural, healthy teeth in each arch.
- In the event of muscle or jaw joint pain, discontinue use for a minimum of two days or until pain subsides and consult the prescriber.
- Discontinue use if experience discomfort and consult the prescriber.
- Do NOT use the flexTAP if vomiting or feeling nauseous.
- Do NOT use if the patient cannot remove the product themselves.
- You should return to the prescriber at least yearly, or as often as necessary, for re-evaluation.
- If the appliance becomes loose, damaged, or does not fit properly, contact the prescriber.
- Do NOT wash the flexTAP in the dishwasher or use dishwashing liquid to wash the flexTAP.

- Do NOT clean the flexTAP with products that contain chlorine, bleach, moisturizer, antiseptic, anti-bacterial agents or alcohol.
- Do NOT store the flexTAP in direct sunlight.
- The operating temperature range of the flexTAP is 40°F to 104°F (5°C to 40°C)
- For use by adults only.
- Discontinue use if the flexTAP is damaged or cracked.
- Discontinue use if reaction occurs and consult prescriber.

Possible Side Effects:

There are possible side effects associated with using the flexTAP 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 flexTAP.
- Slight jaw soreness or tightness, initially and with adjustments.
- Temporary bite change. This should subside approximately 30 minutes after the flexTAP is taken out of the mouth in the morning and the AM Aligner is used.
- Unconsciously taking the flexTAP 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.

If the patient experiences any reaction, have him/her contact the prescriber immediately.

Airway Management Contacts



Manufacturer

Airway Management, Inc.
4300 Alpha Road, Suite 115
Dallas, TX 75244, USA

Tel: (866) 264-7667

Fax: (214) 691-3151

Email: contactami@amisleep.com

Website: www.tapintosleep.com

EU REP

EU Authorized Representative

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

AU REP

Australian Authorized Representative

Emergo Australia
Level 20
Tower II, Darling Park
201 Sussex Street
Sydney, NSW 2000
Australia



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