

flexTAP[®] with ThermAcryl[®]

Patient 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

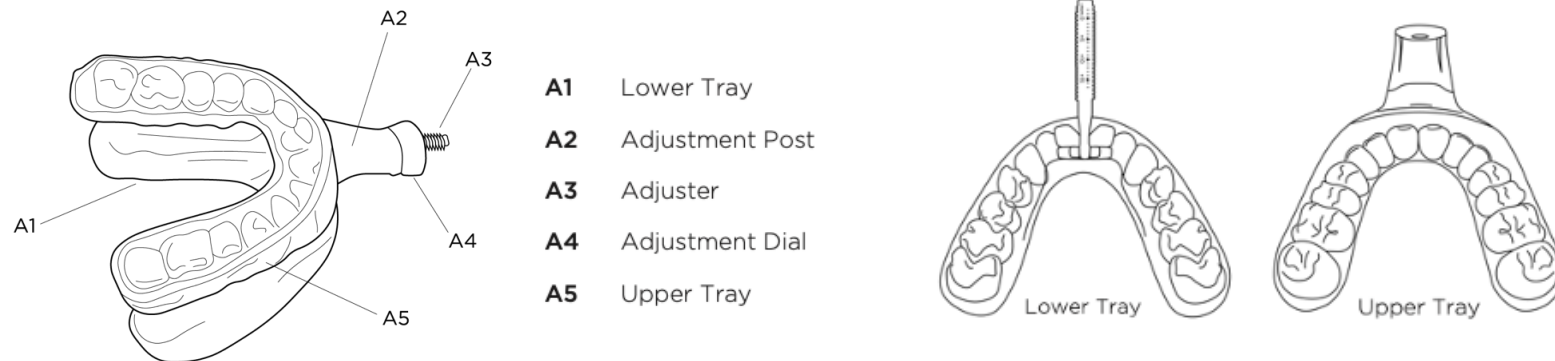
Introduction

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

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 (Figure 5) 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 (Figure 6) instructions for more information.

Figure 5 (AM Aligner)

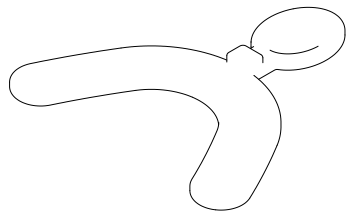
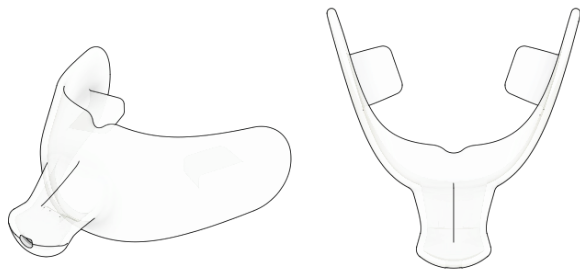


Figure 6 (Mouth Shield)



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



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Patents: <http://tapintosleep.com/patents>



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