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.

Daily - After Each Wear

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

- Immerse the appliance in lukewarm water.
- Clean the Nylon flexTAP with a denture brush. Use the smaller end of the brush to clean the inner surface for at least one minute. Then, switch to the larger brush and clean the outer surface for an additional minute.
- Rinse well with clean, lukewarm water.
- Inspect the appliance to confirm it is visibly clean. If necessary, repeat the cleaning process.
- Once clean, dry the appliance with a clean tissue or towel, and place it back in its container.

Caution:

- Do not put your Nylon flexTAP in water exceeding 45ºC.
- Do not use toothpaste on your appliance as it may be too abrasive.
- Do not use chlorine-based products, bleach, acetic acid, household cleaning products, or alcoholic solutions on your nylon appliance.

Warning: The Nylon flexTAP should be stored in a cool dry place. The appliance is made from sensitive materials and should not be stored where temperatures exceed -4ºF to 122ºF (-20ºC to 50ºC), such as in the glove compartment of a car or the cargo hold of an airplane.

Warning: Instruct the patient not to disassemble any of the Nylon flexTAP hardware. The Nylon 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 Nylon flexTAP appliance. Also give your patient a copy of the Patient Instruction Booklet.

1. The patient should brush their teeth and floss well before inserting the Nylon 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 their mouth. The patient should make sure the dial is not dialed too far back so that he/she cannot comfortably snap the trays over their teeth while engaged. The patient should use their 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 Nylon flexTAP is in their mouth.
5. After use, the patient can remove either the Upper or Lower tray by gently opening the mouth while the 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 remove.

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

Continued Adjustments with Adjustment Dial

Note: Operating the Adjustment Dial is written from the perspective of the patient with the appliance in their 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 Adjustment 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 Adjustment Dial clockwise (towards the right ear).

AM Aligner® and Mouth Shield

Note: The AM Aligner should be used daily after use of your Nylon 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 Mouth Shield instructions for more information.

Product Disposal

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

Warnings and Possible Side Effects

Note: Read all instructions before using the Nylon flexTAP.

Warnings:

- The medical history of the patients, including history of asthma, breathing, or respiratory disorders, or other relevant health problems, should be considered before prescribing the device.
- 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 Nylon 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 Nylon flexTAP outside the temperature range of -4ºF to 122ºF (-20ºC to 50ºC)
- 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 Nylon flexTAP if vomiting or feeling nauseous.

Instruction for Use

Patient | **Clinician**

NYLON flexTAP®

More Information

TAP | TAP SLEEP CARE
tapintosleep.com

Airway Management Contacts

Manufacturer

Airway Management, Inc.
4300 Alpha Rd, Suite 115
Farmers Branch, TX 75244
Tel: (866) 264-7667
Fax: (214) 691-3151
Email: contactami@amisleep.com
Website: www.tapintosleep.com

NON STERILE | MD

AM AIRWAY MANAGEMENT

Patents: www.tapintosleep.com/patents

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Warnings and Possible Side Effects [cont]

- 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 Nylon flexTAP in the dishwasher or use dishwashing liquid to wash the Nylon flexTAP.
- Do NOT clean the Nylon flexTAP with products that contain chlorine, bleach, moisturizer, antiseptic, anti-bacterial agents or alcohol.
- Do NOT store the Nylon flexTAP in direct sunlight.
- The operating temperature range of the Nylon flexTAP is 40ºF to 104ºF (5ºC to 40ºC)
- For use by adults only.
- Discontinue use if the Nylon 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 Nylon flexTAP appliance. Common side effects include:

- Slight tooth or gingival discomfort due to pressure of the appliance.
- Excess salivation initially. This will improve as you become accustomed to wearing the Nylon flexTAP.
- Slight jaw soreness or tightness, initially and with adjustments.
- Temporary bite change. This should subside approximately 30 minutes after the Nylon flexTAP is taken out of the mouth in the morning and the AM Aligner is used.
- Unconsciously taking the Nylon flexTAP out of their mouth at night.
- Orthodontic movement of the teeth.
- Pain or dysfunction of the temporomandibular joint and associated muscles.
- Permanent bite change.

Contact your prescriber immediately if any occur or persist.

Any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority of the Member State in which the user and/or patient is established.

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 for Use:

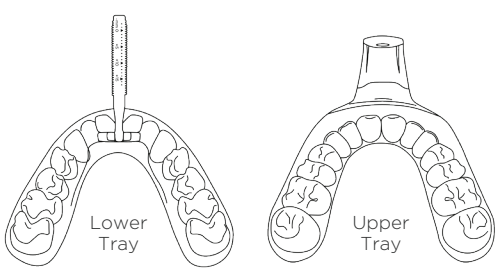
- The Nylon flex Thornton Adjustable Positioner® (Nylon flexTAP®) is intended to reduce or alleviate nighttime snoring and mild to moderate obstructive sleep apnea (OSA) for adults, 18 years or older.

Contraindications:

- This device is contraindicated for patients with loose teeth, loose dental work, dentures, advanced periodontal disease 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.

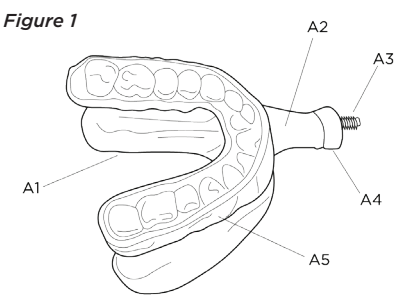
Introduction

The Nylon 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 Nylon flexTAP hardware. The post is angled, allowing the patient to advance their lower jaw both vertically and horizontally at the same time.



The Nylon flexTAP device consists of an Upper Tray that fits over the upper teeth and Lower Tray that fits over the lower teeth. The 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 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.

Figure 1



A1 **Lower Tray**
A2 **Adjustment Post**
A3 **Adjuster**
A4 **Adjustment Dial**
A5 **Upper Tray**

The 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 Adjustment Dial will advance in 1/3 mm increments.

Linings: The device is fabricated digitally using digital scans of individual patients. The trays are digitally printed medical-grade nylon material.

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

Fitting the Nylon flexTAP Trays

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

Before you fit the patient with the Nylon 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 Nylon flexTAP by gently scrubbing and rinsing it thoroughly.
2. Place the Lower Tray of the Nylon flexTAP in the patient's mouth. If it does not fit immediately, easily, or comfortably, place the lower tray in a warm water bath (do not exceed 45ºC).
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. Place the Lower Tray back in the patient's mouth to check the fit.
   A. **Note: Repeat the same process (steps 2-5) for the Upper Tray.**
6. Once both trays are properly fitted, have the patient place both trays in their 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.
7. **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: Adjustments are possible.

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 Nylon flexTAP 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.

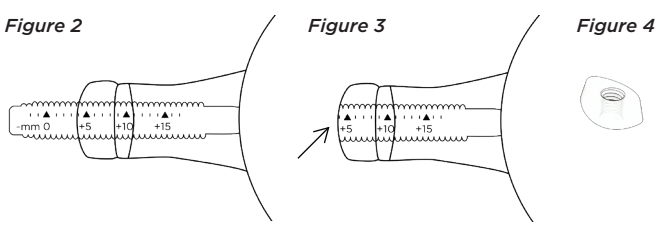
If the tray is:

- **Too loose:** You can add Acrylic into the loose tray area. Contact your TAP fabrication lab for instructions.
- **Too tight:**
  - If the trays are too tight because they are tall, you can shorten them using a Brasseler carbide burr # H79 GSQ size 040.
  - If the trays are too tight due to excess material in the interproximal spaces / occlusal contact, use the Brasseler carbide burr #H79 GSQ size 040 to relieve these areas.

Adjustment Dial Instructions

Note: The initial treatment setting should be set by the prescriber.

Figure 2 ***Figure 3*** ***Figure 4***



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 3-4 days to acclimate to the device.
4. Upon acclimation, advise the patient to gradually advance (½ turn = 0.3 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 (See Figure 4) towards the patient's left ear.
6. To return the lower jaw to the starting position with the appliance in the mouth, turn the Adjustment Dial (See Figure 4) towards the patient's right ear.
7. The upper side of the 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 Nylon 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.

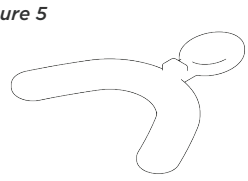
Note: This should not be used independently as a measurement device as the absolute position may change relative to the fit of the tray.

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

Optional Product Enhancements

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

Figure 5 ***Figure 6***



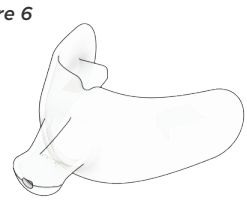


Figure 7

AM Aligner®

The included AM Aligner *(See Figure 5)* counteracts jaw discomfort 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 Nylon flexTAP. Please see the AM Aligner instructions for more information.

Mouth Shield

The Mouth Shield *(See Figure 6)* is included with every Nylon 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 Mouth Shield instructions for more information.

Posterior Stops

Posterior stops (see Figure 7) can be utilized in the printed trays as shown, or by incorporating the mouth shield that has built in posterior pads. If the patient presents the need for posterior stops after the device is printed, you can add acrylic posterior stops. Please contact your TAP fabrication lab for further instructions.

Adjuster Note

Figure 7

The 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 Nylon flexTAP, forces pull the adjuster forward, keeping it in place.

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