

Patient Instruction Booklet

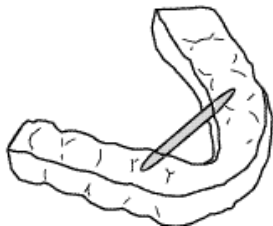
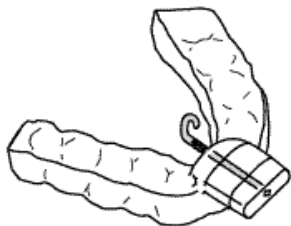


Table of Contents

Important Safeguards.....	3
Introduction.....	4
Warnings.....	6
Possible Side Effects.....	7
Directions for Daily Use.....	8
Operating the Dial.....	9
Exercise Leaf Gauge.....	10
Homecare Instructions.....	11



This device complies with the requirements of directive 93/42/EEC concerning medical devices.

SAVE THESE INSTRUCTIONS

The following words in this manual have special significance:

Warning: Means there is a possibility of injury to yourself.

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 at home or in sleep laboratories and is for single-patient use. Read all instructions before using the TAP appliance.

Contraindications

This device is contraindicated for patients with loose teeth, loose dental work, or dentures.

Introduction

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

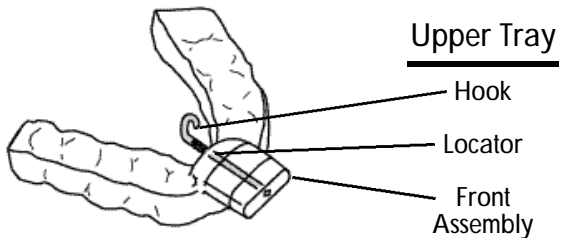
The TAP device consists of an upper tray that fits over the upper teeth and a lower tray that fits over the lower teeth. A hook mechanism attached to the upper tray fastens to a lingual bar attached to the lower tray and positions the lower jaw forward preventing the soft tissue of the throat from collapsing and obstructing the airway. The front piece on the TAP permits you to adjust the protrusion of your lower jaw to the most effective and comfortable position. The device is constructed from a durable acrylic mixture with a choice of two different unique linings that allow maximum comfort and ease of fitting.

Each TAP package contains:

1. An upper and lower tray
2. Instructions for use
3. Storage case

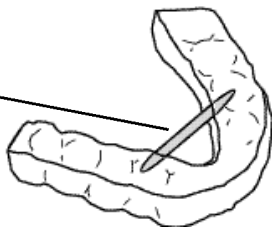
Note: Read all instructions before using the TAP.

Caution: Federal (U.S.A.) law restricts this device to sale by or on the order of a physician, dentist, or a professional trained in sleep disorders.



Lower Tray

Lingual Bar



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, you should contact your prescriber immediately.
- You may experience soreness or discomfort in your jaw or teeth. If discomfort persists, you should contact your prescriber.
- In the morning, you may sense a change in your bite. This sensation should disappear within one hour. If it continues for more than four hours, you should contact your prescriber.
- You should return to the prescriber at least yearly for reevaluation. The Thermacryl™ lining will need to be replaced if the lining material becomes loose or damaged. If the appliance becomes loose, you should contact your prescriber.

There are possible side effects associated with using the TAP appliance. If you experience any of the following side effects, you should contact your prescriber.

- Slight tooth discomfort due to pressure of the appliance.
- Excess salivation initially. This will improve as you become accustomed to wearing the TAP.
- Slight jaw soreness or tightness, initially and with adjustments.
- Temporary bite change. This will subside approximately 30 minutes after the TAP is taken out of the mouth in the morning.
- Unconsciously taking the TAP out of your mouth at night.

Directions for Daily Use

1. Inspect the device prior to each use. Discontinue use if you observe any material separation, material degradation or cracks.
2. Place the upper and lower trays over your teeth.
3. Move your lower jaw forward so that the lower tray engages with the hook attached to the upper tray.

Note: You can also place the TAP in your mouth with the hook already engaged. Before placing the engaged TAP into your mouth, make sure that the hook is in its initial starting point (the lower tray is not pulled forward).

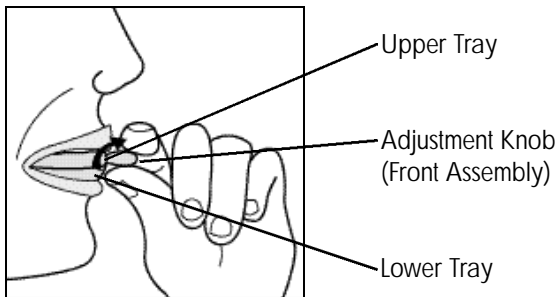
4. After use, disconnect the hook from the lower tray by slowly moving your lower jaw forward. Once the trays are separated they may be removed.

Note: You can also remove the device by gently opening your mouth while the hook is still engaged to "pop" the lower or upper tray off the teeth.

Warning: Do not bite down on the hook because it may bend or break. If the hook is bent, do not use the TAP and return it for a replacement hook. The replacement hook should be a Closed Hook.

Operating the Dial

1. To pull your lower jaw forward with the appliance in the mouth, turn the dial counter clockwise (towards your left ear).
2. To return your lower jaw to the starting position with the appliance in the mouth, turn the dial clockwise (toward your right ear).



Exercise Leaf Gauge

When your jaw is pulled forward during the night, it may make the jaw muscles sore and temporarily change the bite. The Leaf Gauge is intended for you to use as an exercise tool to put your jaw back into normal bite position.

1. Place several sheets of the leaf gauge between your front teeth (make sure your back teeth are not touching.)
2. Slide your lower jaw forward and then back holding the plastic between your teeth.
3. Once your jaw is back, squeeze to put your back teeth together.
4. Repeat this several times.
5. Finally, remove the Exercise Leaf Gauge to see if your teeth come together.

Each morning after use, thoroughly clean your TAP oral appliance using a regular toothbrush, cool water and toothpaste.

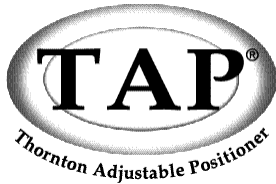
Warning: Do not use hot water! Dry your appliance completely before storing in the container. It may help to leave the container open to ensure that your TAP dries thoroughly.

You may disinfect your TAP appliance every three days in a solution of hydrogen peroxide and water (half hydrogen peroxide and half water). Your TAP should be soaked in this solution for 10-15 minutes. Rinse with water before use. If an odor or bad taste develops, you may also soak your TAP in mouthwash for 5 minutes. Always brush your teeth and floss well before inserting the TAP in your mouth.

Note: The lining of your TAP is a heat-sensitive material. Be very careful to store it in a cool, dry place. Do not leave the appliance where the temperature may reach or exceed 120^o-140^o. This may cause distortion of the lining material and alter the fit of your TAP.

Warning: Do not put your TAP in the glove compartment of your car or the cargo hold of an airplane.

We are proud to offer
our patients the TAP[®].



The Thornton Adjustable positioner (TAP[®])
is a product of:
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