

Warnings

- Use of the Mouth Shield should be discontinued if nausea, nasal congestion, or any condition that would decrease or prevent breathing through the nose occurs.
- Discontinue use if reaction occurs and consult prescriber.
- Discontinue use if experiencing discomfort and consult prescriber.
- Mouth Shield is single patient use.
- Discontinue use if damaged or deteriorated and seek replacement.
- Do not use if vomiting or feeling nauseous.
- Do not use if patient is unable to remove by themselves.
- Use on adults only (>66lb/30kg).
- Do not misuse the Mouth Shield.
- Do not store or transport the Mouth Shield outside temperature range -4°F to 122°F (-20°C to 50°C)
- Operating temperature range of the Mouth Shield is 40°F to 105°F (5°C to 40°C)
- Do not store in direct sunlight.
- Do not wash in dishwasher.
- Do not clean in products that contain chlorine, bleach, moisturizer, antiseptic, anti-bacterial agents, or alcohol.

Airway Management Contacts

Manufacturer



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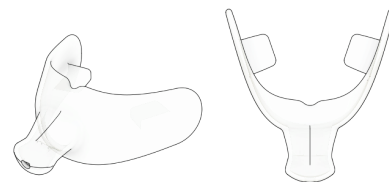
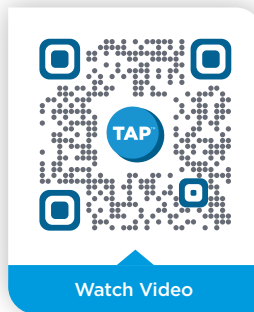


Patents:
<http://tapintosleep.com/patents>

PRTD170 REV A, 2022

Instruction for Use

flexTAP[®] MOUTH SHIELD



Scan QR code for videos and more information on Mouth Shield.

Introduction

Due to airflow through the mouth, some patients experience dry mouth and or excessive saliva leading to mild discomfort when using an oral appliance. Furthermore, the flexTAP™ post may pose some discomfort. The flexTAP™ Mouth Shield has been designed to reduce oral breathing therefore lessening the drying effect and/or excessive saliva that oral breathing can have. It can also act as comfort sleeve for the flexTAP™ post.

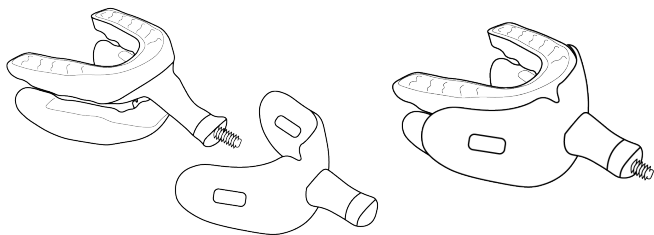
The flexTAP™ post is inserted into the Mouth Shield and sits inside the lips.

Use of the Mouth Shield should be discontinued if nausea, nasal congestion, or any condition that would decrease or prevent breathing through the nose occurs.

Intended Use

The flexTAP™ Mouth Shield is an optional comfort accessory to be used with the flexTAP custom oral appliance to prevent drying and/or excess saliva of the mouth while wearing the flexTAP. It is intended for single patient adult use.

Operating Instructions



The flexTAP Mouth Shield should be placed over the post with the center pivot facing up or towards the upper tray. As the Mouth Shield is designed to allow for the lower tray to be more advanced, it is important to position it correctly on your flexTAP.

The Mouth Shield should be pushed firmly over the dial and post so it “clips” into place and rests against the flexTAP trays.

The Mouth Shield should rest comfortably in your mouth, between your teeth and the inside of your lips/cheeks. If it feels bulky, you may want to check that it is fully inserted on the flexTAP in the correct position.

The Mouth Shield can be trimmed to maximize comfort and fit.

The Mouth Shield may include side bite tabs/ posterior pads. These tabs can assist with maintaining tray retention and increasing the vertical position of the flexTAP. The tabs can be removed if preferred.

Operating Instructions [Continued]

Adjustment of the flexTAP must be made before applying the flexTAP Mouth Shield. The Mouth Shield can also be removed if further adjustments need to be made.

Use of the Mouth Shield should be discontinued if nausea, nasal congestion, or any condition that would decrease or prevent breathing through the nose occurs. The Mouth Shield should be replaced if it shows signs of tearing or deterioration. The Mouth Shield should be replaced at least yearly.

Cleaning

The Mouth Shield should be removed from the appliance and cleaned daily by running it under hot water and leaving it to air dry out of direct sunlight. It can also be cleaned using a mild soap and warm water solution. Inspect for signs of damage daily and replace immediately if showing signs of wear.

- Do not store in direct sunlight.
- Do not wash in dishwasher.
- Do not clean in products that contain chlorine, bleach, moisturizer, antiseptic, anti-bacterial agents or alcohol.
- Do not soak the Mouth Shield in cleaning solutions for more than 10 minutes per day.

Note: Failure to follow instructions may compromise the performance of the Mouth Shield.

Disposal

The flexTAP Mouth Shield may be placed in the general household receptacle.