

INTRODUCTION

Due to airflow through the mouth, some patients experience dry mouth leading to mild discomfort when using an oral appliance. The Mouth Shield has been designed for use with the custom TAP* appliances to reduce oral breathing therefore lessening the drying effect that oral breathing can have.

The Mouth Shield is attached to the custom TAP hardware and sits inside the lips, reducing flow through the mouth and promoting nasal breathing.

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.

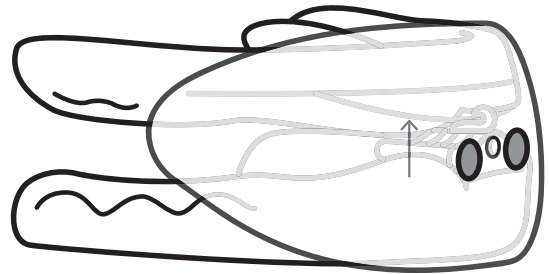
*custom TAP includes TAP 3, TAP 3 Elite, and dreamTAP custom oral appliances

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 -4oF to 122oF (-20oC to 50oC)
- Operating temperature range of the Mouth Shield is 40oF to 105oF (5oC to 40oC)
- 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.

INSTRUCTIONS

CUSTOM MOUTH SHIELD



AM AIRWAY
MANAGEMENT

TAP SYSTEM™
myTAP™



TAP CUSTOM



myTAP PAP



TAP PAP™ CS



Airway Management Contacts

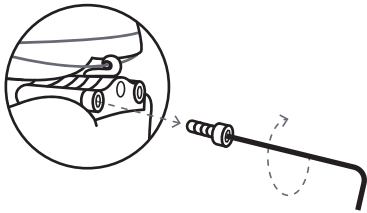
Manufacturer	4300 Alpha Rd, Suite 115 Farmers Branch, TX 75244 Tel: (866) 264-7667 Fax: (214) 691-3151 Email: contactami@amisleep.com Website: www.tapintosleep.com
United States and Canada	Airway Management (866) 264-7667 (214) 691-3151 contactami@amisleep.com
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Australian Sponsor	Emergo Australia Level 20 Tower II, Darling Park 201 Sussex Street Sydney, NSW 2000 Australia

INTENDED USE

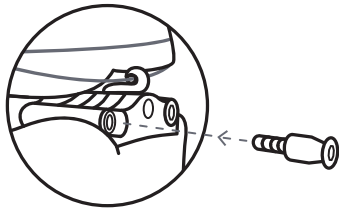
The Mouth Shield is an optional comfort accessory to be used with the custom TAP oral appliance to prevent drying of the mouth while wearing a custom TAP. It is intended for single patient adult use.

OPERATING INSTRUCTIONS

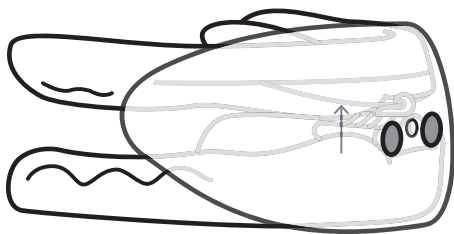
1. Remove the front plate screws from the custom TAP.



2. Replace the screws with the Mouth Shield screws.

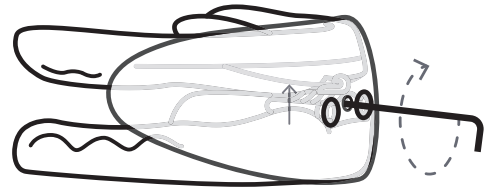


3. The Mouth Shield should be placed over the new screws with the arrows facing up. The Mouth Shield should be pushed firmly over the screws so it “clips” into place and rests against the custom TAP trays.



4. 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 custom TAP in the correct position.

5. Adjustment of the custom TAP can be made while the Mouth Shield is attached through the small opening over the adjustment mechanism.



6. 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 shield should be replaced yearly.

DISPOSAL

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

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.