

SomnoDent®

ALPHA

Mandible Repositioning Antisnoring Orthosis



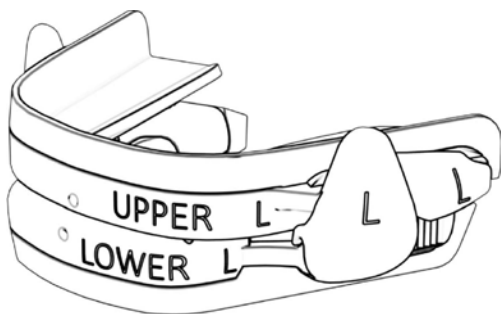
Instructions for Use

Rx Only




SomnoMed®
The Leader In COAT
(Continuous Open Airway Therapy)*

The New SomnoDent **ALPHA**



The SomnoDent **ALPHA** is a device that functions as a mandibular repositioner, which acts to increase the patient's pharyngeal space during sleep. The increase in the patient's pharyngeal space improves their ability to exchange air during sleep. The device consists of two generic trays, which cover the upper and lower teeth. The lower tray is held in a protrusive position by an advancement mechanism. The device advances the mandible in the sagittal plane to increase the patient's pharyngeal space during sleep and reduce the apnea symptoms.

SomnoDent **ALPHA** can only be prescribed and fitted by a licensed, trained healthcare provider.

Intended Use

The SomnoDent **ALPHA** is temporarily intended as an aid in the reduction of simple night time snoring and mild to moderate obstructive sleep apnea (OSA) in patients 18 years and older.

Contraindications

The device is contraindicated for patients who:

- Have Central Sleep Apnea (CSA).
- Have severe respiratory disorders.
- Have loose teeth, loose crowns, loose fillings or advanced periodontal disease.
- Are under 18 years of age.

Warnings

Use of the device may cause:

- Tooth movement or changes in dental occlusion.
- Gingival or dental soreness.
- Pain or soreness to the temporomandibular joint.
- Obstruction of oral breathing.
- Excessive salivation.

Precautions

Dentists should consider the medical history of the patients, including history of asthma, breathing, or respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing the device.

The SomnoDent **ALPHA** can be safely used for 90 days of treatment.

The SomnoDent **ALPHA** is only to be worn by the prescribed patient to avoid cross contamination.

The SomnoDent **ALPHA** is not recommended when the patient has the following:

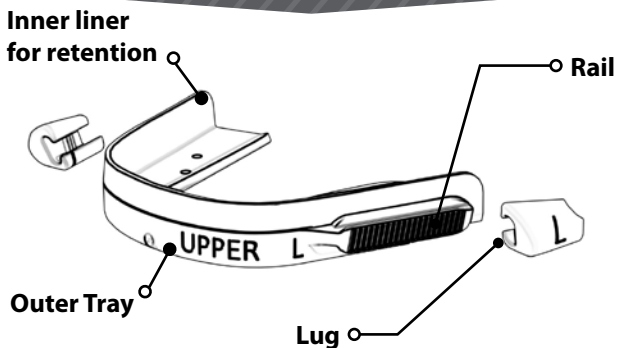
- Removable dentures, bridges, temporary crowns, braces or active orthodontic treatment.
- Fewer than 8 original upper teeth.
- Short teeth or insufficient undercuts to retain the device.
- Large crossbite.
- Has not seen a dentist within the last 12 months.

Discontinue use and contact Provider/Dentist when:

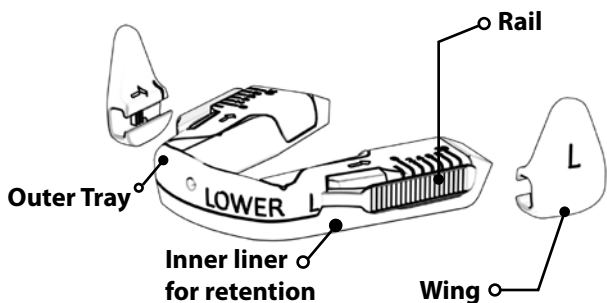
- The SomnoDent **ALPHA** has any visible damage or deterioration.
- The device has been modified.
- Pain or soreness occurs to the temporomandibular joint or excessive pain occurs.
- An allergic reaction is experienced.

SomnoDent **ALPHA**

Upper Tray & Lugs



Lower Tray & Wings



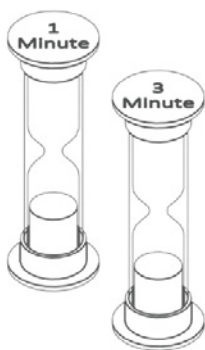
Included Accessories

(located beneath the top tray)

**Device
Preparation
Handle**



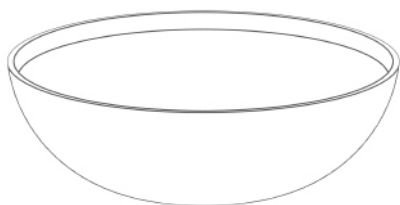
Storage Container



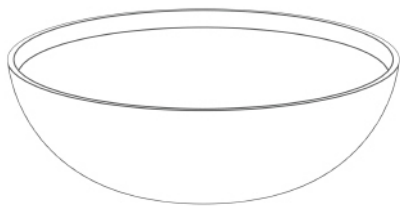
**White 1 Minute Timer
& Blue 3 Minute Timer**

Additional Accessories

(not included)



Cold water bowl



Hot water bowl

Adjustment Guide

The adjustment range of SomnoDent **ALPHA** is 0-20 mm. An example setting is illustrated below.



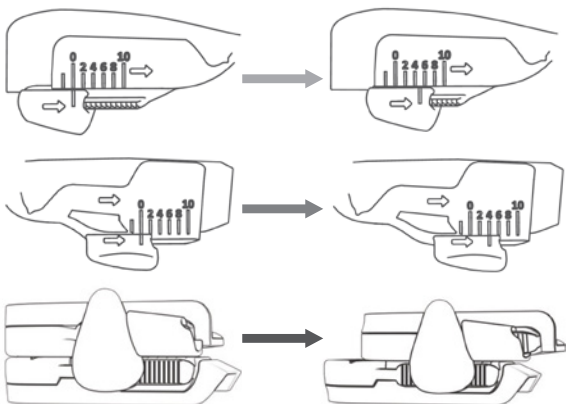
At the beginning of treatment, the wings and lugs must be adjusted so that they come in contact when worn to support the lower mandible.



Always adjust Left and Right sides at the same time



Lugs and wings move in one direction only. If adjusted too far, see Pages 14-15 for instructions on removing and re-attaching the lug or wing.



Factory Setting

Lug: 0mm

Wing: 0mm

+9mm Setting

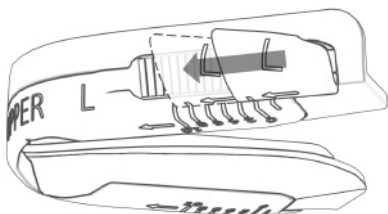
Lug: 5mm

Wing: 4mm

Lug Setting	0	1	1	2	2	...	10
Wing Setting	0	0	1	1	2	...	10
Total Setting	0	1	2	3	4	...	20

Lug Adjustment

On the UPPER tray, gently push the left lug in direction of arrow to setting specified by the prescriber.

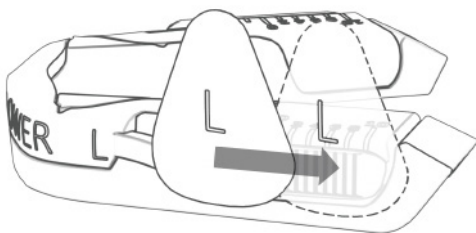


Repeat for the Right Lug



Wing Adjustment

On the LOWER tray, gently push the left wing in direction of arrow to setting specified by the prescriber.



Repeat for the Right Wing

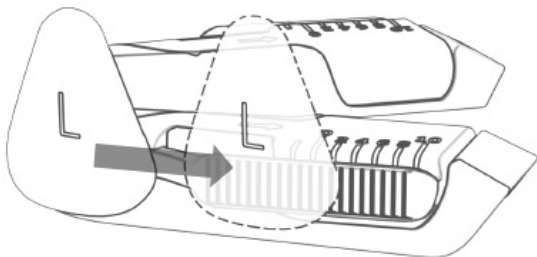
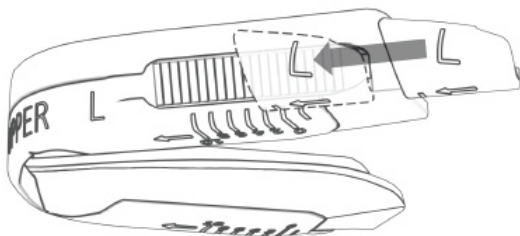
Step 1

Attach Lugs and Wings

Place the lugs at start of UPPER rail so arrows point in the same direction.

Place the wings at start of the LOWER rail so that the arrows point in the same direction.

Gently push the wings and lugs in direction of arrow to factory setting of 0mm.



Step 2

Boiling Water

Gently screw the handle into the hole at the front of the UPPER tray.



Pour near boiling water (minimum **95° C / 203°F**) into a large bowl.

Use a microwave safe bowl if heating water in a microwave. Never heat SomnoDent **ALPHA** in a microwave.

While holding the handle, completely submerge the UPPER tray.



Do not touch boiling water as it may scald.



Start timer for **1 Minute**. By the end of 1 Minute, the inner liner material should turn clear.

Step 3

Insert Upper Tray

At the end of **1 Minute**, remove UPPER tray from boiling water.

Wait **10 seconds** before handling device to avoid scalding.

Insert and align UPPER tray to the patient's upper teeth, placing from front teeth to back teeth. Remove handle from the tray and place to the side.



If the device needs to be re-fitted, due to loss of retention or deformed lining, simply place in boiling water to return to original shape, and re-mold to teeth to provide an ideal fit. Please note all fittings and adjustments of the device must be performed by a dentist, physician, or health care provider to avoid complications.

Step 4

Shape to Teeth

Bite firmly on UPPER tray.

Start timer for **3 Minutes**.

Firmly rub cheeks around device to shape the UPPER tray around teeth.

Use your finger to rub the material around the inside surface of the teeth to ensure a good fit.



Fitting may be assisted by running fingers along lining to push into undercuts.

Step 5

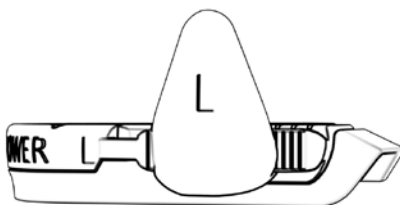
Cold Water

Gently remove the UPPER tray with your hands. Start timer for **1 Minute** and submerge the device in cold water.



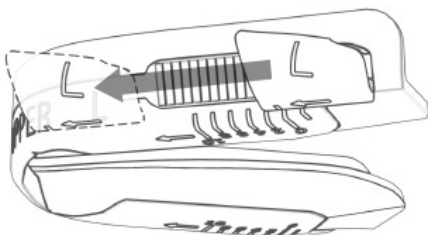
At the end of **1 Minute**, remove the UPPER tray from the water and place the UPPER tray back in the patient's mouth before inserting and fitting the LOWER tray.

Repeat Steps 2-5 for LOWER Tray



Lug Removal

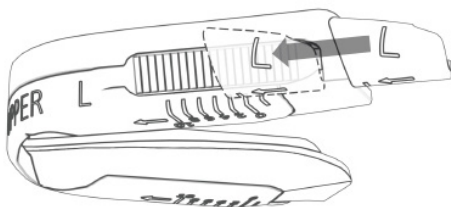
On UPPER tray, gently push the lug in direction of arrow until removed from end of rail.



Reattach Lug

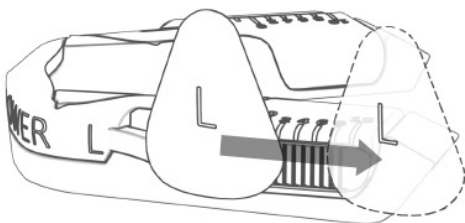
Place the lug at start of UPPER rail so arrows point in the same direction.

Gently push the lug in direction of arrow to setting specified by the prescriber.



Wing Removal

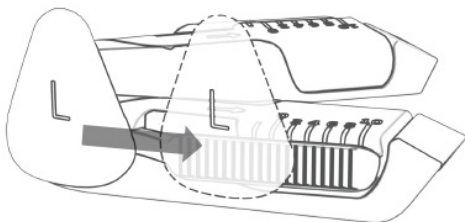
On LOWER tray, gently push the wing in direction of arrow until removed from end of rail.



Reattach Wing

Place the wing at start of the LOWER rail so that the arrows point in the same direction.

Gently push the wing in direction of the arrow to the setting specified by the prescriber.



Cleaning and Maintenance

Before each use, inspect the device for damage or deterioration. Do not use if damaged or deteriorated.

Do not modify device except as specified in these instructions.

After each use, clean device under warm water (***below 40°C / 104°F***) with a soft toothbrush. Once a week, clean device using a mild soap and a soft toothbrush. Contact Provider / Dentist if the device is too tight, too loose or does not fit on your teeth.

Do not use toothpaste, as this may damage the device.

Keep device away from alcohols and alcohol-based cleaners, as they can damage the device.

Storage

Dry device thoroughly before storing in the Storage Container with the lid open.

The materials are heat sensitive and may deform if exposed to temperatures above **50°C / 122° F** and no longer fit to your teeth.

Store out of reach of children and pets.

Troubleshooting

Problem

Solution

The tray is too tight

Steps 2-5 can be repeated to obtain the proper fit.

The tray is too loose

Steps 2-5 can be repeated to obtain the proper fit.

Remove wings and lugs from upper and lower tray to allow for easier shaping of the inner liner material to the patient's teeth.

The material does not turn clear

Ensure the water is **95°C / 203°F** (no more than **1 minute** after boiling).

There is a gap between front teeth and lining

During fitting, position the tray as far back in mouth as possible.
Mold lining towards teeth while pressing down on tray.

The second tray does not fit in mouth

Insert the trays into mouth one at a time.
Insert the UPPER tray before the LOWER tray.
Ensure the wings and lugs are set to zero.



NOTES



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Patent pending.
SPC-0555-D



Initial Setting: _____

Patient Initials: _____