

INSTRUCTIONS FOR USE

SomnoDent FUSION[®]

RxOnly



English

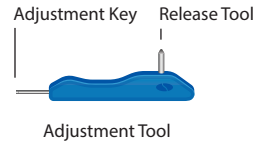
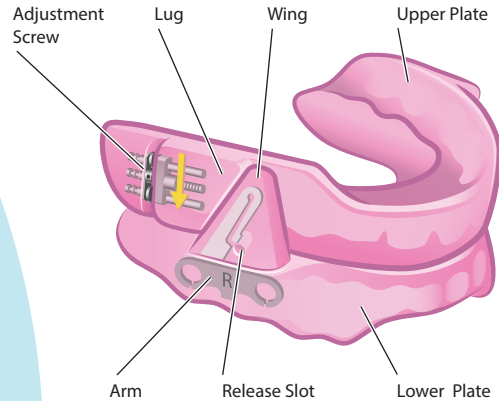


Thank you for selecting SomnoDent Fusion

These instructions provide you with important information on the correct use and care of your SomnoDent Fusion (hereafter referred to as “device”).



Important: Please read this entire guide carefully before using your device. Contact your dental sleep professional should you have any questions.



Additional Wings (3 sizes)

Indications for use

SomnoDent Fusion is a patient-matched mandibular advancement device (MAD), available under medical prescription and intended for the treatment of patients 18 years of age or older with:

- » Mild to moderate obstructive sleep apnea (OSA)
- » Severe obstructive sleep apnea in the case of continuous positive airway pressure (CPAP) failure, non-compliance or refusal
- » Snoring

Contraindications

These devices are contraindicated for patients who:

- » Have central sleep apnea
- » Have severe respiratory disorders
- » Have temporomandibular joint dysfunction (TMJ)
- » Have loose teeth
- » Have advanced periodontal disease
- » Are under 18 years of age

Precautions

Dentists should consider the medical history of the patient, 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.

Warnings

Use of these devices may cause:

- » Tooth movement and changes in occlusion
- » TMJ pain or tenderness
- » Obstruction of oral breathing
- » Excessive salivation
- » Gingival or dental soreness

Before first use

Before first use, thoroughly clean your device by following the cleaning instructions in this manual.

Possible side effects

You may experience some temporary side effects such as sore jaw joints, increased salivation, dry mouth, sore teeth, irritation of the soft tissue in the mouth and/or a slight change in bite.

These possible side effects should diminish within an hour of removing your device. If any of these side effects continue, contact your dental sleep professional and maintain regular sleep dental check-ups.

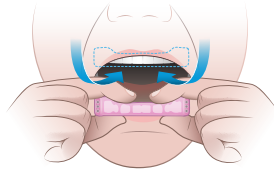
Changes in bite or jaw stiffness and pain upon removal of your device may be alleviated with clenching exercises. To assist with these exercises, use a SomnoMed Morning Repositioner or chew gum upon removal of your device. The Morning Repositioner is supplied separately. Please contact your dental sleep professional for more information.

Using your device

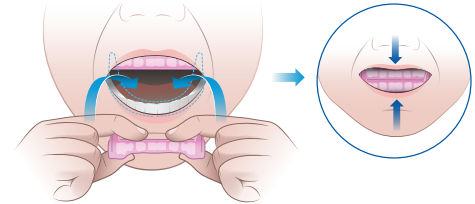
Important

- » Keep your device away from pets and small children
- » Always follow maintenance instructions for cleaning and care of your device
- » You may initially experience a mild plastic smell or taste. This will disappear with use
- » If any device components are damaged or broken, discontinue use to avoid injuries such as choking or laceration

Fitting your device

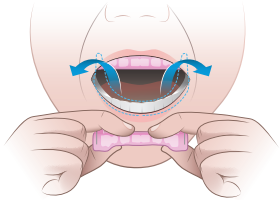


- 1** Mount the upper plate to your top row of teeth first. Press upwards on the plate with both thumbs to ensure that it fits securely and comfortably.

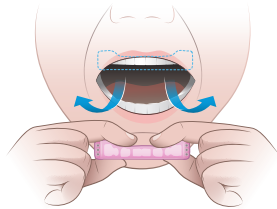


- 2** Mount the lower plate to your bottom row of teeth. Press down on both sides of the plate using your index fingers to ensure that it fits securely.
- 3** Once the upper and lower plates are securely in position, bring your lower jaw slightly forwards to allow the wings on the upper and lower plates to engage. Slowly close your mouth until your lips lightly touch each other.

Removing your device



- 1 Remove the lower plate from the teeth first. Use your thumbs on both sides to push the plate upwards and remove it from your mouth.



- 2 Gently pull the upper plate down using both index fingers and thumbs. Remove the upper plate from your mouth.

Adjusting your device

The mandibular advancement setting on the device can be adjusted using the following methods:

METHOD 1

Wing Adjustment

Change the wings to make 1.0 mm adjustments to the device's mandibular advancement. Refer to section "Wing Adjustment"

METHOD 2

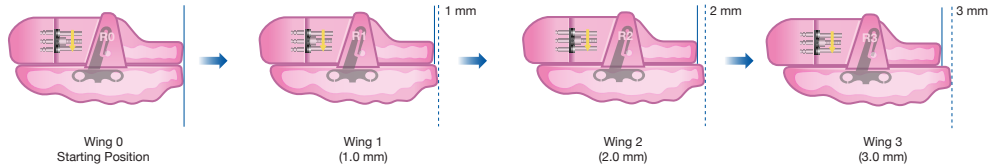
Screw Adjustment

The adjustment screw enables precise 0.1 mm changes to the device's mandibular advancement. Refer to section "Screw Adjustment"

Important: Your dental sleep professional will advise the amount of adjustment for your therapy.

Wing Adjustment

The device's mandibular advancement can be adjusted up to 3.0 mm from the starting position by changing the wings. Each change in wing size adjusts the device's mandibular advancement by 1.0 mm. Please refer to the section "Replacing the wings" to learn how to correctly remove and attach the wings.

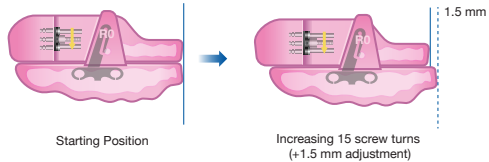


Wing	0	1	2	3
Adjustment (mm)	Starting Position	1.0	2.0	3.0

Screw Adjustment

Use the adjustment screw to change the device's mandibular advancement between -1.0 mm to +5.0 mm from the starting position determined by your dental sleep professional. Each 90° turn of the adjustment screw precisely changes the mandibular advancement in 0.1 mm steps.

Please refer to the section “Using the adjustment screw” to learn how to adjust using the screw.

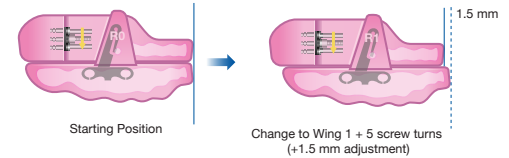


90° Turns	-10	1	5	10	15	20	25	30	35	40	45	50
Adjustment (mm)	-1.0	0.1	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0

Decreasing ← Starting Position → Increasing

Combining wing and screw adjustment

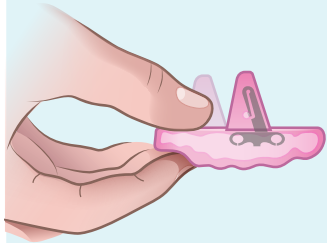
Achieve the desired mandibular advancement using a combination of wing and screw adjustments. The device has a total adjustment range of 9.0 mm (-1 / +8 mm from the starting position).



TIP! Use the wing adjustment first. Use the screw adjustment if the maximum wing adjustment is reached or an adjustment smaller than 1.0 mm is required.

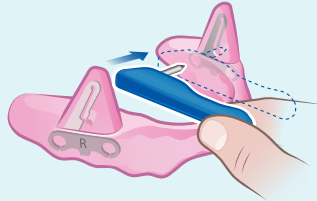
Replacing the wings / Removing the wings

STEP 1



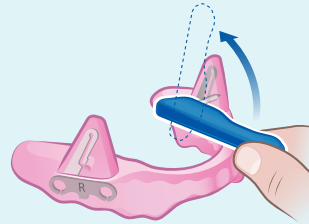
Hold the lower plate with a firm grip.

STEP 2



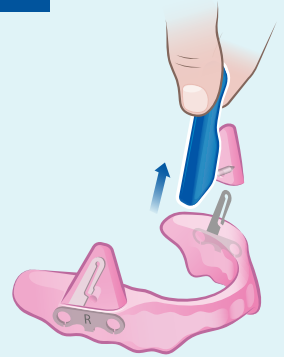
Insert the release tool into the release slot located on the inside of the wing.

STEP 3



Rotate the release tool upwards to align with the metal arm. Keep the tool pressed firmly against the wing while turning.

STEP 4



Lift the wing off the lower plate in the direction of the metal arm.

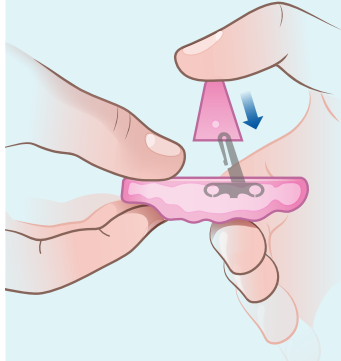
Replacing the wings / Attaching the wings

STEP 1



Select a pair of wings the same size. Check the number and the left/right markings.

STEP 2



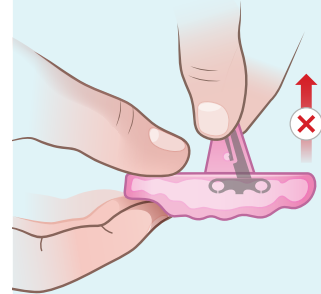
Hold the lower plate with a firm grip and gently push the left wing onto the arm marked "L".

STEP 3



Push the wing until you hear an audible 'Click'.

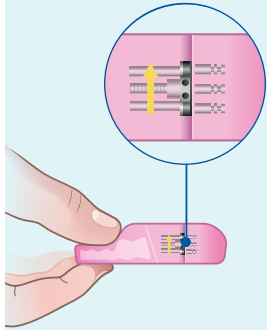
STEP 4



Check the wing cannot be removed by hand. Repeat steps to attach the right wing. Always attach both wings.

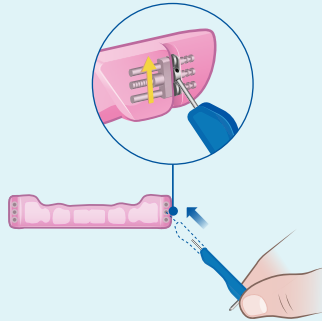
Using the adjustment screw / Increasing mandibular advancement

STEP 1



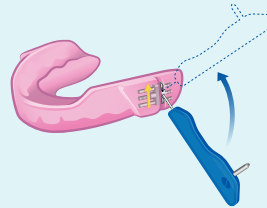
Hold the upper plate with the adjustment arrow pointing up and locate the two keyholes.

STEP 2



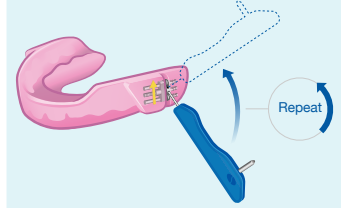
Insert the adjustment key into the bottom keyhole.

STEP 3



Rotate the adjustment tool 90° upwards in the direction of the yellow arrow. Counting the number of turns, repeat until desired adjustment is achieved.

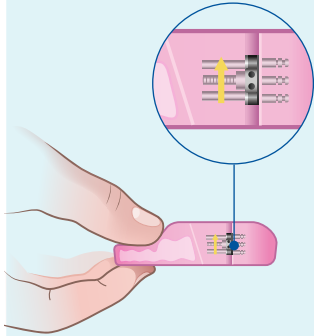
STEP 4



Important
Repeat on the other side, completing the same number of turns.

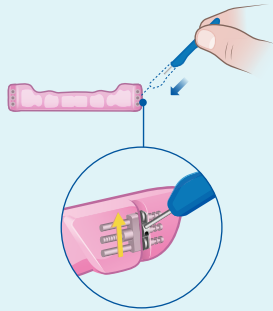
Using the adjustment screw / Decreasing mandibular advancement

STEP 1



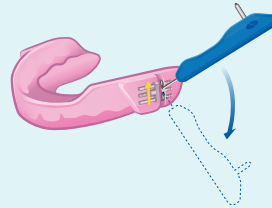
Hold the upper plate with the adjustment arrow pointing up and locate the two keyholes.

STEP 2



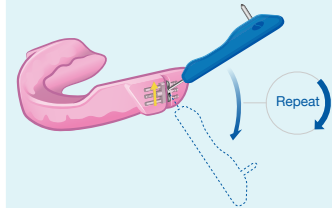
Insert the adjustment key into the top keyhole.

STEP 3



Rotate the adjustment tool 90° downwards in the opposite direction of the yellow arrow. Counting the number of turns, repeat until desired adjustment is achieved.

STEP 4

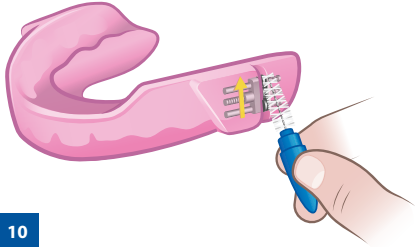


Important
Repeat on the other side, completing the same number of turns.

Cleaning

Clean your device immediately after each use.

- 1 Rinse in cold or lukewarm water with a temperature no greater than 45°C/113°F.
- 2 Clean with a soft toothbrush and mild liquid soap.
- 3 Use the supplied cleaning brush to clean the area around the adjustment screws.
- 4 Rinse well in cold or lukewarm water.



SomnoMed recommends using SomTabs, cleaning tablets specially formulated to clean oral devices. SomTabs clean hard to reach areas to effectively eliminate odours.

TIP! For easier access to all surfaces while cleaning, you may need to remove the wings on the device.

Caution

- » Never use hot or boiling water on your device
- » Do not use toothpaste as it contains abrasives that may damage your device
- » Do not use mouthwash to clean your device
- » Do not use ultrasonic cleaning
- » Do not use organic solvents like ethanol, acetone, etc

Storage

Use the storage container supplied with the lid off to store your device. Ensure the storage container is clean and dry. Store your device out of direct sunlight.



Travelling

Protect your device when travelling by using the supplied storage container. Ensure your device is thoroughly clean and dry before storing.

Important: Do not travel with your device stored in water or any other liquid.

Maintaining the appearance of your device

To reduce the possibility of discolouration, always brush your teeth thoroughly before use. Do not smoke or drink coffee, tea, colas or wine with your device in place.

Amalgam fillings or the use of Pyralvex® (a solution for mouth ulcers and denture irritation) may cause discolouration of your device over time.

Discolouration of the material will not adversely affect the performance or life of your device.

*Pyralvex is a trademark and brand of Meda AB, Sweden.

Regular Inspection

Regularly inspect your device for signs of damage, including cracking. If your device is damaged or broken, it must no longer be used. This will avoid injuries, such as choking or laceration.

If your device is damaged, immediately contact your dental sleep professional. They will arrange for your device to be repaired by an authorised SomnoMed facility.

Warranty

During the warranty period for material defects applicable in the end consumer's country, SomnoMed shall assume responsibility for the warranty for material defects (but not for damage to the contractual merchandise by the end consumer).

Refer to www.somnomed.com for the latest information on SomnoMed's warranty policy.

The warranty does not cover damage from improper use, abuse, pet chewing, exposure to excessive heat, exposure to caustic cleaners, or where dental work is completed post order placement.

Returning your device

Warranty repair work can only be completed by an authorised SomnoMed facility. You must return your device through your dental sleep professional. Do not return your device directly to SomnoMed.

Do not include any accessories with your return. New accessories will not be issued with device repairs.



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