

INSTRUCTIONS FOR USE

Fusion, Flex and Classic Devices

SomnoDent[®]
SLEEP APNEA DEVICE

RxOnly


SomnoMed[®]
The Leader In COAT[™]
(Continuous Open Airway Therapy)

Your information	4	SomnoDent Fusion Device	10
Introduction	5	Get to Know Your Fusion Device	10
What is sleep apnea?	6	Adjust Your Fusion — Using the Wings	11
Instructions for daily use of your SomnoDent	6	Wing Removal	12
Contraindications	7	Wing Installation	12
Warnings	7	Adjust Your Fusion — Using the Screw	13
Precautions	7	Forward Adjustment	14
Cleaning	7	Backward Adjustment	14
Advice on cleaning	8	Accessories	15
Storage instructions	8	SomnoDent Fusion Calibration Log	16
Regular inspection of your SomnoDent	9		
Repair of damaged devices	9		
Warranty	9		

CONTENTS

CONTENTS

SomnoDent Flex & Classic Devices	17
Get to Know Your Flex & Classic Device	17
Adjust Your Flex & Classic	18
Forward Adjustment	19
Backward Adjustment	20
Accessories	20
SomnoDent Flex & Classic Calibration Log	21
Sleep and Comfort Diary	22



Name

Physician

Dentist

Model

Serial No.

Date of Purchase

My SomnoDent
SLEEP APNEA DEVICE

Dear SomnoDent User

Thank you for selecting Continuous Open Airway Therapy (COAT).

Your SomnoDent is manufactured to the highest medical device standards, and with supporting independent clinical evidence published since 2001, SomnoDent is recognized as a leading medical oral device for the treatment of Obstructive Sleep Apnea (OSA).

These instructions will provide you with useful information on the correct use and care of your SomnoDent device.

Please be sure to read this information carefully and should you have any questions, contact your qualified SomnoMed Sleep Dentist.

SomnoMed®

**Restful Nights. Refreshing Sleep.
Energetic Days!**

Introduction

The SomnoDent® is a medical oral device worn during sleep to increase the patient's pharyngeal space, which improves their ability to exchange air during sleep. SomnoDent comprises of upper and lower dental trays with a unique patented wing coupling component, allowing normal mouth opening and closing.

These User and Care Instructions apply to the types of SomnoDent devices below:

SomnoDent Fusion Classic
SomnoDent Fusion Flex
SomnoDent Flex
SomnoDent Classic

Adjusting SomnoDent

If your SomnoDent is effective and reduces your Snoring & Sleep Apnea symptoms there is no need to adjust your device.

Should you find the device is not controlling your symptoms as well as you would like you can adjust the device and bring your jaw further forward.

There is a calibration tool located in the base compartment of your storage container. Use this device and follow the instructions in the

booklet to adjust your device a 0.5-1.0 mm at a time. Make sure you adjust both sides of the device evenly.

Note: Check with you SomnoMed Dentist prior to making adjustments to your device. As they may wish to make any adjustments for you in order to make sure it is done correctly and you are happy with your treatment.

DentiTrac Micro-Recorder

With your permission your clinician may have decided to embed a DentiTrac® micro-recorder into your SomnoDent to record compliance with oral device therapy in combination with the DentiTrac System. The embedded DentiTrac micro-recorder does not impact the efficacy or safety of the SomnoDent. DentiTrac monitors the wear time of SomnoDent by measuring oral temperature, as well as tracking head position. The micro-recorder's function is the capture and store clinical usage data.

During scheduled visits with your clinician, the data within the DentiTrac is uploaded to a web application for cloud-based reporting using a DentiTrac Base Station at the clinician's office.

Caution:

Take care to follow care instructions for the oral device (p8). Ensure the device is not exposed to hot water as this may damage the micro-recorder.

What is sleep apnea?



Normal

During normal sleep the muscles that control the tongue and soft palate hold the airway open.

Snoring

When these muscles relax, the tissues of the upper airway vibrate as air passes over them, creating a snoring noise.



Sleep apnea

If the muscles are too weak to hold the tongue and pharyngeal muscle in position, the airway may become obstructed and short respiratory arrests may occur.



SomnoDent COAT

With SomnoDent your tongue base is held forward to open the airway and allow you to breathe normally.

How to wear your SomnoDent

Always insert the upper plate first!

Place the upper plate in your mouth as indicated in Fig. 1. Press up on the plate with both thumbs to ensure that it fits securely and comfortably.



Fig. 1: Inserting the upper plate

Inserting the lower plate

Place the lower plate in your mouth. Press down on both sides of the plate using your index fingers to ensure it fits comfortably.

Engaging the wings

Once the upper and lower plates are securely in position, bring your lower jaw slightly forward to allow the 'wings' to engage. Slowly close your mouth until your lips lightly touch each other.

Removal

Always remove the lower plate first. Using your thumbs on both sides, gently pull the lower plate in an upwards motion to remove. Using both your index fingers and thumbs, gently pull the upper plate down and forwards to remove.



Fig. 2: Removing the lower plate

Tip: Use lip balm during the first few nights of wearing your SomnoDent to help keep lips moist.

Always clean your SomnoDent after each use

You may initially experience a mild plastic taste & smell. This will disappear with storage and use.

Tip: Storing the device in fresh water when not in use and changing the water regularly will help this disappear.

Indications for Use

The SomnoDent® oral devices are intended for the treatment of night time snoring and obstructive sleep apnea in patients 18 years of age or older.

If your clinician has requested a DentiTrac micro-recorder to be embedded into your SomnoDent® device, this micro-recorder is intended to measure the use of your SomnoDent. The embedded micro-recorder will not impact the efficacy or safety of the SomnoDent.

Contraindications

These devices are contraindicated for patients who:

- have central sleep apnea
- have severe respiratory disorders
- have loose teeth
- have advanced periodontal disease
- are under 18 years of age

Warnings

Use of these devices 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

The SomnoDent with DentiTrac Micro-Recorder will only capture and store patient compliance data. In order to view and use the data, a DentiTrac Base Station is required to extract the data and upload this information onto a cloud-based system.

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 these devices.

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 tissues in the mouth and/or a slight change in your bite. These possible side effects should diminish within an hour of removing the device. If any of these side effects continue, contact your sleep dentist and maintain regular sleep dental check-ups.

Tool Kit

Your calibration tool and cleaning brush are located in the handy maintenance kit underneath the storage case.

Important

Keep your device away from sunlight.
Keep away from pets and small children.

Cleaning

Always clean your device in the morning immediately after having removed it from your mouth.

After each use, rinse in cold or lukewarm water and clean with the brush provided or a soft toothbrush and liquid soap. Then rinse well. Avoid hot or boiling water as it will damage the device. Water temperature for cleaning should be <45°C/113°F to avoid damage.

SomTabs have been specially formulated to clean your SomnoDent device and will not harm, Scratch or damage your device.

Visit www.somnomed.com.au to order SomTabs or learn more about cleaning your device.

Caution:

Do not use toothpaste, as it contains abrasives, and may damage the device. Do not use mouthwash to clean device. Doing so will cause the material in the SomnoDent to deteriorate. Do not use ultrasonic cleaning. Avoid organic solvents like ethanol, acetone etc. for cleaning.

Never use hot or boiling water!

Hot or boiling water damages your SomnoDent and/or micro-recorder. This will invalidate the warranty.

Advice on cleaning

Patients with amalgam fillings or ulcers who use Pyralvex (a solution for mouth ulcers and denture irritation) may over time notice discolouration in the Flex lining of their SomnoDent.

Discolouration of the material will not adversely affect the performance or longevity of the device. Please note: To reduce the possibility of discolouration do not drink coffee, tea or cola

with the device in place. Always brush teeth thoroughly before use.

FUSION: Unclip and remove your Fusion wings for easier access to all surfaces and prevent the build-up of plaque.

Storage instructions

Always store your SomnoDent in a container of clean water with the lid off when not in use. A storage container is included for your convenience.

By storing in water, the material will not dry out and will help prevent cracks, corrosion and possible discolouration of the components caused by build up of salts and saliva. The device should be fully submerged with the lid off for air circulation.

When traveling, clean and dry your device and protect it by placing it inside storage container. Please note the SomnoDent storage container is not air or water tight.

Regular inspection of your SomnoDent

Regularly inspect the device for signs of damage, such as fractures and cracks. If the device is damaged or broken, the device must NOT be used any longer in order to avoid injuries, such as choking or laceration. If the device is damaged, immediately take it to your SomnoMed dental sleep provider who will arrange for it to be repaired by a SomnoMed laboratory.

Repairs

All repairs, including those under warranty, should be taken to your SomnoMed Dentist and not sent directly to SomnoMed.

Note: Please keep the models of your teeth that were taken by your dentist at the time your SomnoDent was made. In the unlikely event of a break you will need to return these models with your device for repair.

Should you not have these models you may incur additional costs out side of warranty.

Warranty

SomnoMed warrants all SomnoDents supplied to be free from defects in materials and workmanship for a period of 36 months from the date of delivery to the Providing Dentist. [SomnoMed gives no warranty that the SomnoDent will be efficacious in the treatment of snoring or Obstructive Sleep Apnea]

a. The SomnoDent warranty is invalidated if the patient has subsequent substantial restorative work.

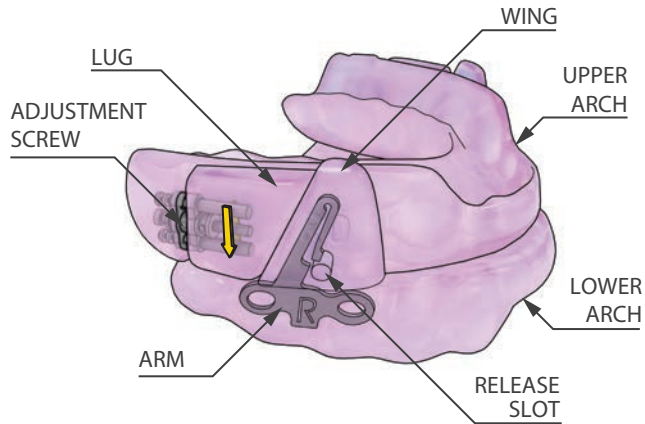
b. Additionally, the SomnoDent warranty is covered only for in-mouth breakage.

c. The warranty covers only repair of the device. If new models or impressions are required, the warranty is void. In such cases SomnoMed offers to remake the device at a reduced cost.

d. Warranty repair work may only be completed by the authorised SomnoMed facility at which the SomnoDent was originally manufactured.

e. Repairs not covered under warranty include, but are not limited to: reset bites, acrylic fracture; clasp repair; wing repair; and other damage not caused by manufacturing defects.

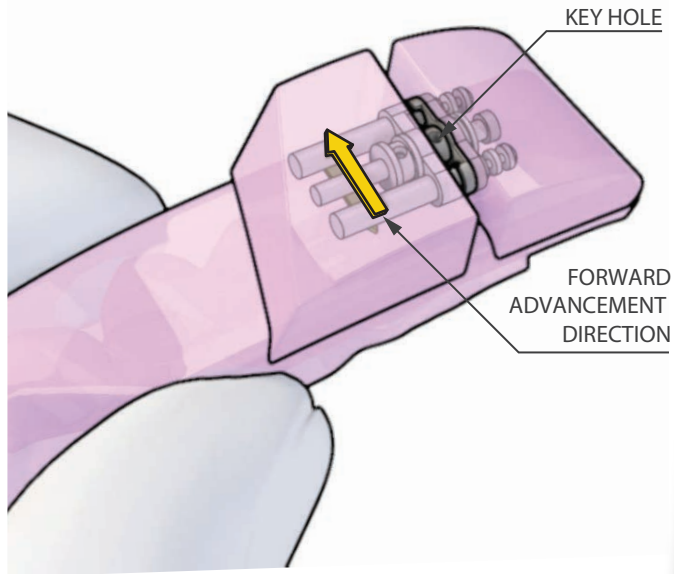
For example, repairs caused by defective or distorted models, defective or distorted bite records, calculus deposits and device modifications made by non SomnoMed authorised technicians.



GET TO KNOW YOUR FUSION DEVICE

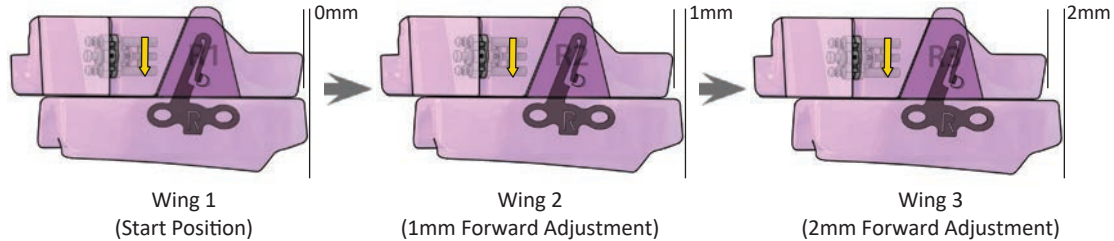
This guide will help you identify the different parts of your new SomnoDent Fusion.

10



SomnoDent[®] FUSION

ADJUST YOUR FUSION — USING THE WINGS

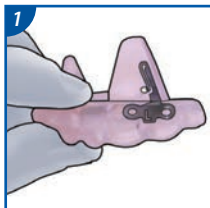


WING	1	2	3
Adjustment Forward	0	1mm	2mm

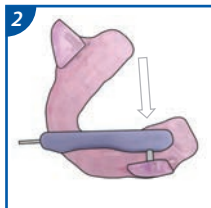
Your SomnoDent Fusion can be advanced in easy 1.0mm increments by changing over the wings. The two additional wings provide a total of 2.0mm range when progressing from wings R1 & L1 (the start position).

See page 12 for wing installation and removal instructions.

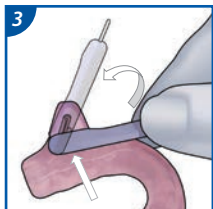
WING REMOVAL



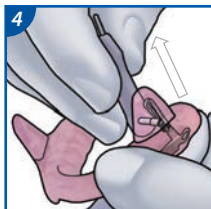
Grip lower arch for controlled removal.



Align the pin to release slot and gently press pin in place.

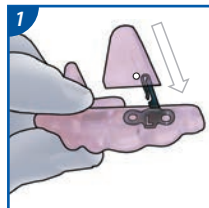


Rotate Tool 90° to begin releasing Wing. Note: Firmly press the Tool against the inside surface of the Wing.

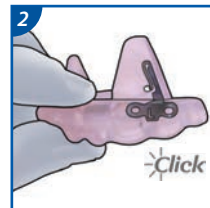


Lift Wing in direction of the metal arm.

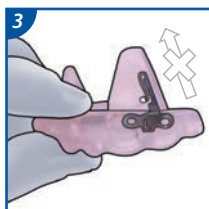
WING INSTALLATION



Grip arch and gently push Wing onto arm.

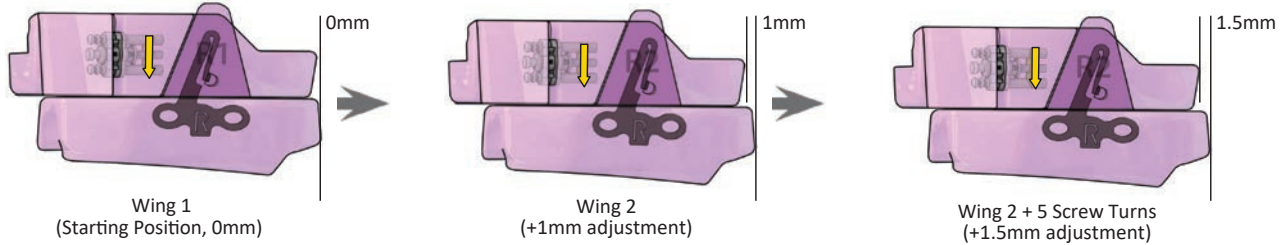


You will hear an audible 'Click' when Wing is installed correctly.



Installation is complete if the Wing cannot be removed by hand.

ADJUST YOUR FUSION — USING THE SCREW



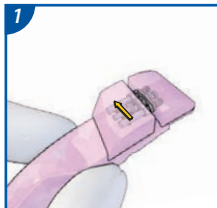
		REVERSE ← → FORWARD														
90° TURNS	-5	1	5	10	20	25	30	35	40	45	50	55	WING	1	2	3
Adjustment (mm)	-0.5	0.1	0.5	1.0	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5	Adjustment Forward	0	2mm	3mm

Your SomnoDent Fusion can be advanced easily by changing the wings in 1.0mm increments, or more precisely by adjusting the screw in 0.1mm increments, giving you control of your treatment and the best possible jaw position to control your symptoms. Combine the use of the screw and wings to achieve a precise adjustment with 8.0mm range of lower jaw extension; backwards - 0.5 and forwards + 7.5mm from the start position.

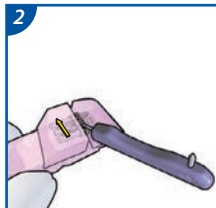
Calibration Recommendations

When your sleep dentist decides it's time to adjust your device — they will place the upper and lower SomnoDent in your mouth and ask you to extend your lower jaw forward. If you can extend your lower jaw 1.5mm or more — your sleep dentist may recommend to begin to advance your device by exchanging the L1 and R1 wings with larger adjustment wings before calibrating with the screws.

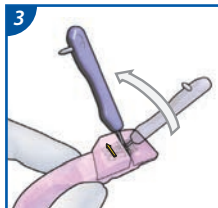
FORWARD ADJUSTMENT




Hold upper splint with calibration screw facing towards you.



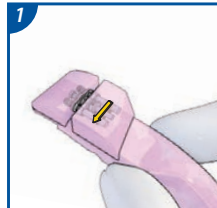
Fit the calibration tool into the adjustment keyhole.



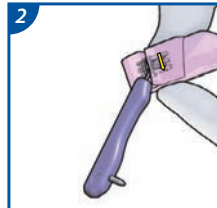
Rotate the calibration tool 90° in the direction of the yellow arrow.


IMPORTANT
COUNT YOUR
TURNS,
AND REPEAT
ADJUSTMENT
ON BOTH SIDES.

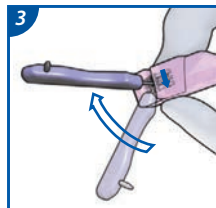
BACKWARD ADJUSTMENT




Hold upper splint with calibration screw facing towards you.



Fit the calibration tool into the adjustment keyhole.



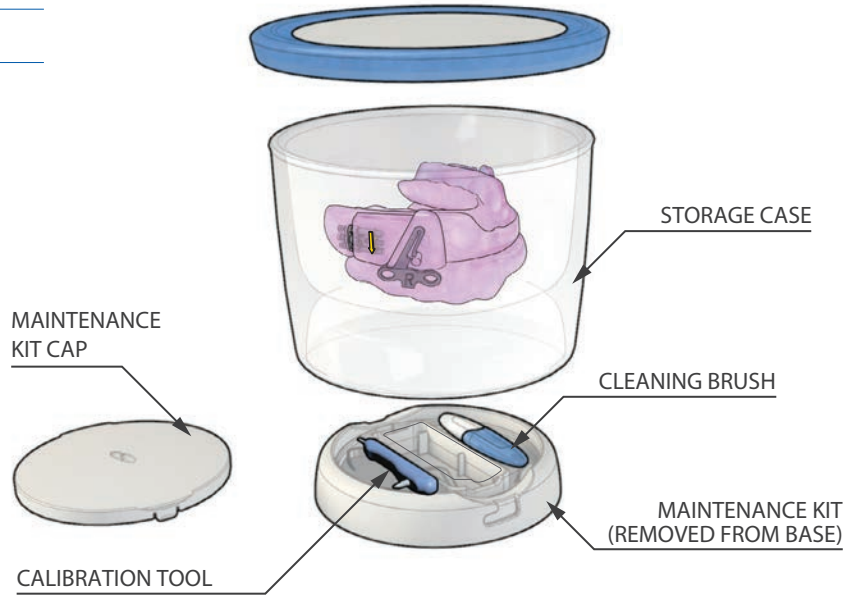
Rotate the calibration tool 90° opposite to the yellow arrow.


IMPORTANT
COUNT YOUR
TURNS,
AND REPEAT
ADJUSTMENT
ON BOTH SIDES.

ACCESSORIES

During the day or when not in use immerse the device in fresh water inside the storage container with the lid off.

The maintenance kit in the base holds everything you need to use and maintain your SomnoDent. Always follow the cleaning instructions to be sure your SomnoDent is kept in top condition.

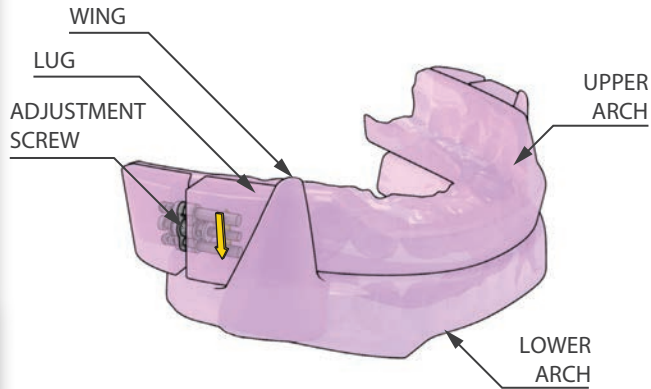


Keep a log of your Fusion Calibration settings.*

Date	Wing #	Number of 90° Rotations

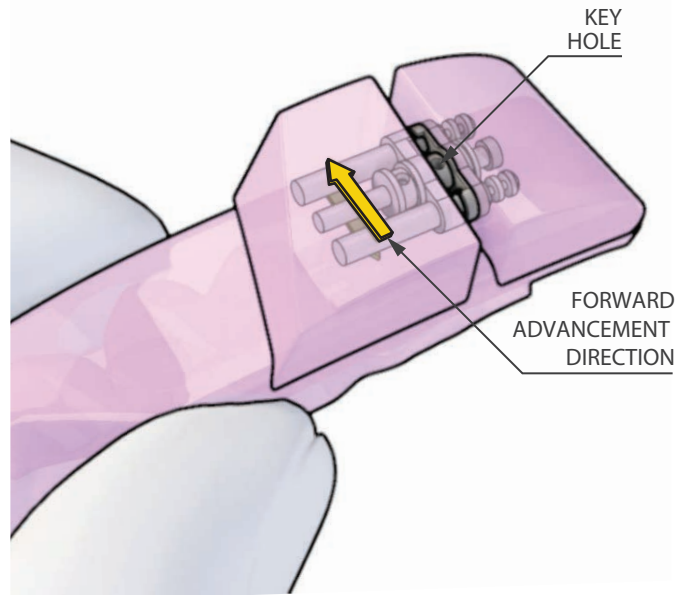
Date	Wing #	Number of 90° Rotations

*Make sure you keep a Sleep Diary for the first 30 nights (located at the back of this User Guide).

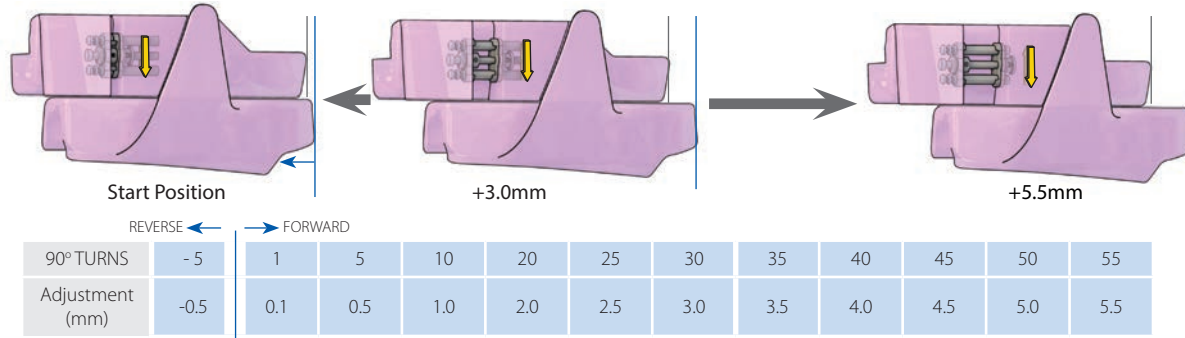


GET TO KNOW YOUR FLEX & CLASSIC DEVICE

This guide will help you identify the different parts of your new SomnoDent Flex & Classic.



ADJUST YOUR FLEX & CLASSIC

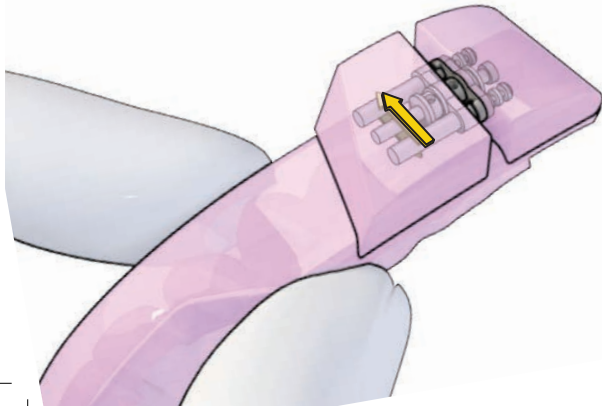


Your SomnoDent can be adjusted within a 6.0mm range, giving you control of your treatment to find the best possible jaw position to control your symptoms.

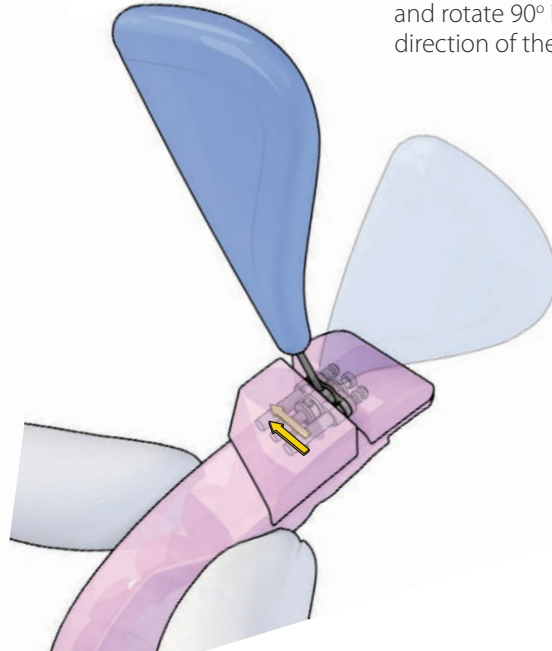
Simply fit the calibration tool into the keyhole and rotate 90° for a precise 0.1mm adjustment. Make sure you adjust both sides evenly.

FORWARD ADJUSTMENT

- 1 Hold Upper with calibration screw facing toward you.



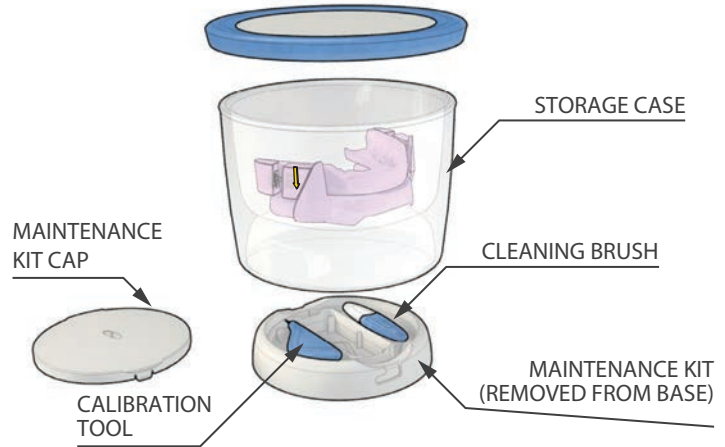
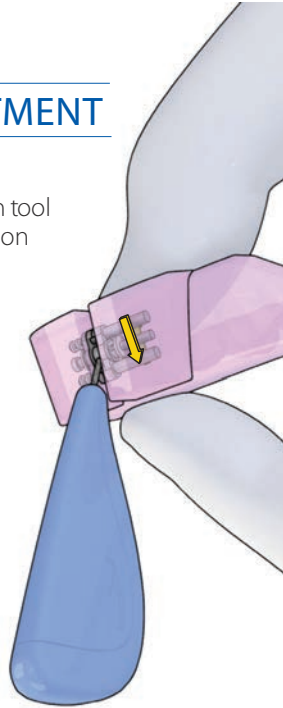
- 2 Fit your calibration tool into the adjustment keyhole and rotate 90° in the direction of the arrow.




IMPORTANT
NOTE TO COUNT
YOUR TURNS

BACKWARD ADJUSTMENT

- 3 Rotate your calibration tool in the opposite direction of the arrow.



ACCESSORIES

During the day or when not in use immerse the device in fresh water inside the storage container with the lid off.

The maintenance kit in the base holds everything you need to use and maintain your SomnoDent. Always follow the cleaning instructions to be sure your SomnoDent is kept in top condition.

*Keep a log of your Flex & Classic Calibration settings.**

Date	Number of 90° Rotations

Date	Number of 90° Rotations

*Make sure you keep a Sleep Diary for the first 30 nights (located at the back of this User Guide).



Sleep and Comfort Diary

Log your Sleep and SomnoDent Comfort Rating in the diary provided on the following pages for the first 30 nights and discuss any issues with your sleep dentist.

SomnoDent works best when fitted correctly and should be snug yet comfortable in your mouth.

Continuous Open Airway Therapy is clinically validated as an effective treatment for mild to moderate obstructive sleep apnea, so make sure you start your treatment tonight, so you can experience Restful Nights and Refreshing Days!

Comfort Ratings

- 5 Excellent Comfort — able to sleep entire night without a problem
- 4 Good Comfort — able to sleep most of the night without discomfort
- 3 Fair Comfort — able to wear it and sleep a little, but prefer to take device out
- 2 Poor Comfort — wore my device but unable to sleep with it
- 1 Need Assistance — unable to wear my device, even while awake

Night	Date	Sleep and Wearing Notes	Hours Worn	Comfort Level	Doctor Setting Instructions
1				5 4 3 2 1	
2				5 4 3 2 1	
3				5 4 3 2 1	
4				5 4 3 2 1	
5				5 4 3 2 1	
6				5 4 3 2 1	
7				5 4 3 2 1	
8				5 4 3 2 1	
9				5 4 3 2 1	
10				5 4 3 2 1	

Night	Date	Sleep and Wearing Notes	Hours Worn	Comfort Level	Doctor Setting Instructions
11				5 4 3 2 1	
12				5 4 3 2 1	
13				5 4 3 2 1	
14				5 4 3 2 1	
15				5 4 3 2 1	
16				5 4 3 2 1	
17				5 4 3 2 1	
18				5 4 3 2 1	
19				5 4 3 2 1	
20				5 4 3 2 1	

Night	Date	Sleep and Wearing Notes	Hours Worn	Comfort Level	Doctor Setting Instructions
21				5 4 3 2 1	
22				5 4 3 2 1	
23				5 4 3 2 1	
24				5 4 3 2 1	
25				5 4 3 2 1	
26				5 4 3 2 1	
27				5 4 3 2 1	
28				5 4 3 2 1	
29				5 4 3 2 1	
30				5 4 3 2 1	



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