

# Instructions for Use — SomnoDent® Signature and Standard Line

Fusion®, Flex®, Classic®, Herbst Advance®, Herbst® Telescopic, Herbst® Shim, AIR & AIR+ Devices

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



**Fusion®**



**Classic®**



**Flex®**



**Herbst Advance®**



**Herbst® Shim**



**Herbst Telescopic®**



**AIR / AIR+**

 Rx Only

[www.somnomed.com](http://www.somnomed.com)

## 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 is comprised of upper and lower dental splints with a unique patented wing coupling component, allowing normal mouth opening and closing.

The calibration tool is located in your storage case. Your clinician may have decided to incorporate a DentiTrac® micro-recorder embedded into your SomnoDent to record compliance with oral device therapy in combination with the DentiTrac System. During scheduled visits, the data within the DentiTrac uploads to a web application for cloud-based reporting using a DentiTrac Base Station at the clinician's office. The DentiTrac micro-recorder monitors the wear time through oral temperature, as well as tracks movements and head position. The inclusion of the embedded DentiTrac micro-recorder provides additional information when used in combination with the DentiTrac System, but does not impact the operating principles or safety of the SomnoDent.

*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.*

The DentiTrac Micro-Recorder captures and stores clinical usage data. To view and analyze this data, additional components of the DentiTrac system are required. A DentiTrac Base Station is used to extract the compliance data from the DentiTrac Micro-Recorder; this data is uploaded to a secure cloud-based system. Additionally, the clinician can view and create patient compliance reports from the cloud-based system via an internet account. The DentiTrac Base Station must be purchased separately. DentiTrac is not available in Herbst Telescopic or Herbst Shim.

### Caution

Take care to follow care instructions for the oral device (pg.4). Ensure the device is not exposed to extreme temperatures in excess of **45°C / 113°F** as this may damage the micro-recorder.

## Indications for Use

The SomnoDent devices are intended for the treatment of nighttime snoring and mild to moderate Obstructive Sleep Apnea in patients 18 years of age or older.

Optionally, if the DentiTrac micro-recorder is completely embedded into the SomnoDent device, the micro-recorder is intended to measure patient compliance to oral device/appliance therapy in combination with the DentiTrac System.

## 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.

## 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.

## **Regular inspection of your SomnoDent with or without the DentiTrac micro-recorder**

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, including those under warranty, should be taken to your SomnoMed dental sleep provider, not sent directly to SomnoMed.*

### **Warranty**

SomnoMed warrants all SomnoDents supplied to be free from defects in materials and workmanship for a period of 36 months for Fusion, Flex, Classic SUAD, and SUAD Ultra, 12 months for AIR+, 24 months for Herbst and Herbst Advance, and 36 months for Medicare Patients, from the date of delivery.

*SomnoMed gives no warranty that the SomnoDent will be efficacious in the treatment of snoring or Obstructive Sleep Apnea.*

1. The SomnoDent warranty is invalidated if the patient has subsequent substantial restorative work.
2. Additionally, the SomnoDent warranty is covered only for in-mouth breakage.
3. The warranty covers only repair of the device. If new casts or impressions are required, the warranty is void.
4. Warranty repair work may only be completed by the authorized SomnoMed facility at which the SomnoDent was originally manufactured.
5. 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 authorized technicians are not covered under warranty.

## 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 mild detergent. Then rinse well. Avoid hot or boiling water as it will damage the device and/or micro-recorder. Water temperature for cleaning should be  $<45^{\circ}\text{C}/113^{\circ}\text{F}$  to avoid damage. 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.

### Caution:

Do not use toothpaste, as it contains abrasives, and may damage the device. **Never use hot or boiling water!** Hot or boiling water damages your SomnoDent and/or micro-recorder. This will invalidate the warranty.

### Important

Keep your device away from sunlight.

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

Some patients with amalgam fillings or users of Pyralvex (a solution for mouth ulcers and denture irritation) may over time notice discoloration in the lining of their SomnoDent. Discoloration of the material will not adversely affect the performance or longevity of the device.

**Please note:** *To reduce the possibility of discoloration do not drink coffee, tea or cola with the device in place. Always brush teeth thoroughly before use.*

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

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

Visit [www.somnomed.com](http://www.somnomed.com) to learn more about cleaning your device.

## ***Instructions for daily use of your SomnoDent***

### **Inserting the upper splint**

Place the upper splint in your mouth as indicated in Fig. 1. Press up on both sides of the splint using your thumbs to ensure it fits securely and comfortably.



**Fig. 1:** Inserting the upper splint.

### **Inserting the lower splint**

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

### **Engaging the wings**

Once the upper and lower splints 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.



**Fig. 2:** Removing the lower splint

### **Removal**

Always remove the lower splint first. Using your thumbs on both sides, gently pull the lower splint in an upwards motion to remove as indicated in Fig. 2. Using both your index fingers and thumbs, gently pull the upper splint down and forwards to remove.

## Storage Instructions

Always store your SomnoDent Fusion, Flex, Classic, Herbst Advance, Herbst and AIR (with ball clasps) devices in a container of clean water 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 crack corrosion and possible discoloration of the metal components (caused by build up of salts and saliva). The device should be fully submerged.

For the AIR + (with PolyPlus), we recommend gently cleaning, rinsing with water and storing in the retainer case **dry**.

When traveling, protect your device by placing it inside the SomnoDent storage container. The SomnoDent storage container is not air tight.

## ADJUST YOUR FUSION

Wing 0  
Starting Position 0.0mm

Wing 1  
+1.0mm adjustment

Wing 1 + 5 Screw Turns  
+1.5mm adjustment

Reverse ←      → Forward

<b>90° Turns</b>	-5	1	5	10	20	25	30	35	40	45	50	55
<b>Adjustment (mm)</b>	-0.5	0.1	0.5	1.0	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5

<b>WINGS</b>	0	1	2	3
<b>Adjustment (mm)</b>	0.0	1.0	2.0	3.0

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 fit. Combine the use of the screw and wings to achieve a precise adjustment with 9.0mm (- 0.5 / + 8.5mm) of range.

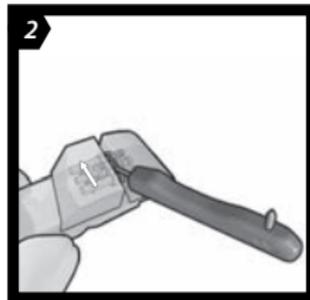
### Calibration Recommendations

When your sleep dentist decides it's time to calibrate 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 L0 and R0 wings with larger adjustment wings before calibrating with the screws.

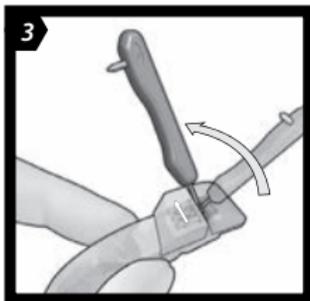
## FORWARD ADJUSTMENT



Hold upper tray with calibration screw facing toward you.



Fit the calibration tool into the adjustment keyhole.

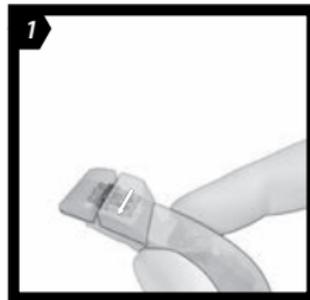


Rotate the calibration tool 90° in the direction of the yellow arrow.

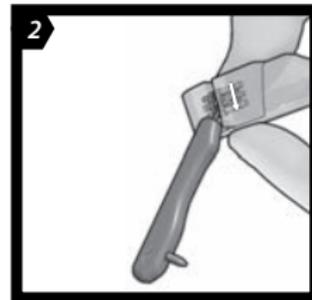


**IMPORTANT**  
COUNT YOUR  
TURNS, AND REPEAT  
ADJUSTMENT ON  
BOTH SIDES

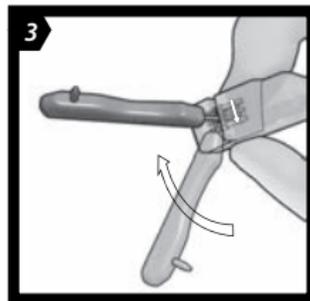
## BACKWARD ADJUSTMENT



Hold upper tray with calibration screw facing toward you.



Fit the calibration tool into the adjustment keyhole.

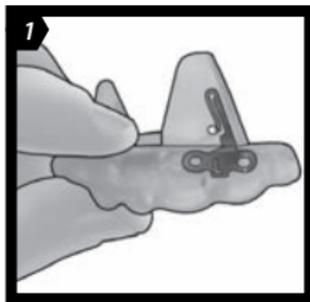


Rotate the calibration tool 90° in the direction of the yellow arrow.

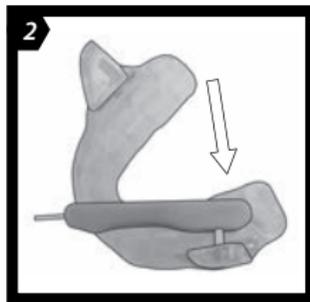


**IMPORTANT**  
COUNT YOUR  
TURNS, AND REPEAT  
ADJUSTMENT ON  
BOTH SIDES

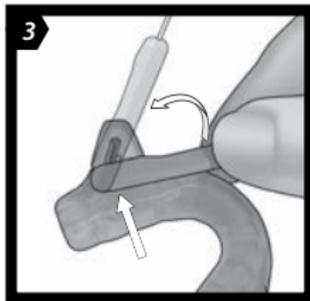
## WING REMOVAL



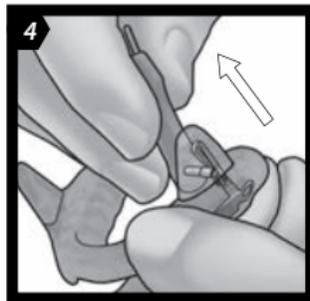
Grip lower tray for controlled removal.



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

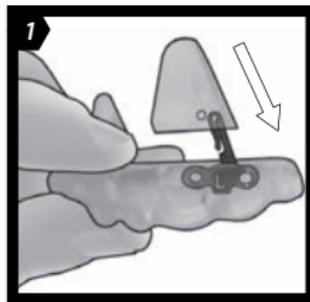


Rotate tool 90° to begin releasing Wing. **Note:** Firmly press the tool against the inside surface of the Wing.



Lift Wing in direction of the metal arm.

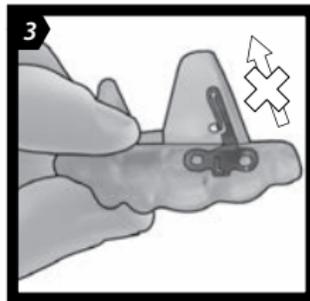
## WING INSTALLATION



Grip tray and gently push Wing onto arm.

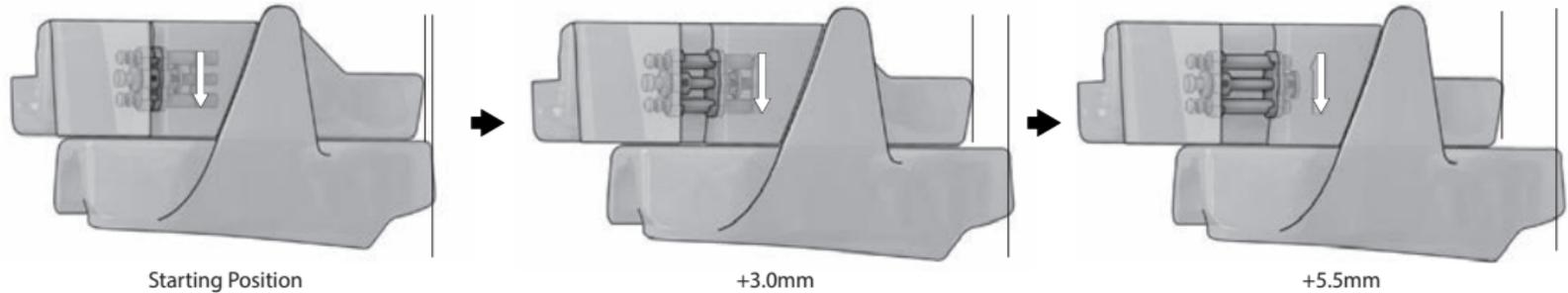


You will hear an audible 'CLICK' when Wing is installed correctly.



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

# ADJUST YOUR FLEX & CLASSIC



Reverse ←      → Forward

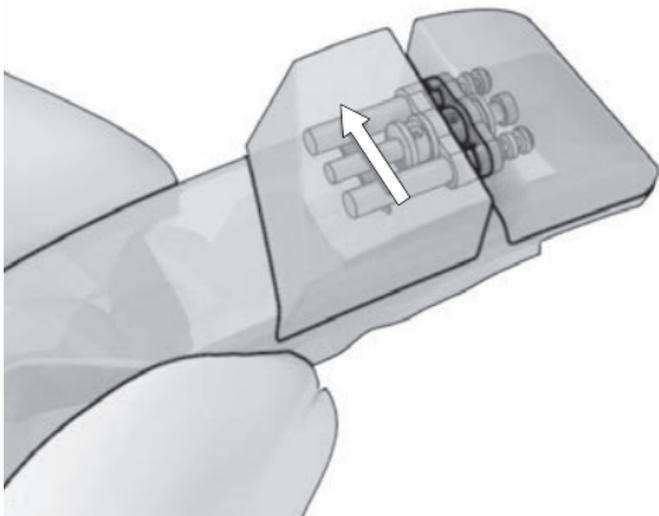
<b>90° Turns</b>	-5	1	5	10	20	25	30	35	40	45	50	55
<b>Adjustment (mm)</b>	-0.5	0.1	0.5	1.0	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5

Your SomnoDent Flex & Classic can be adjusted within a 6.0mm range, giving you control of your treatment and best possible fit.

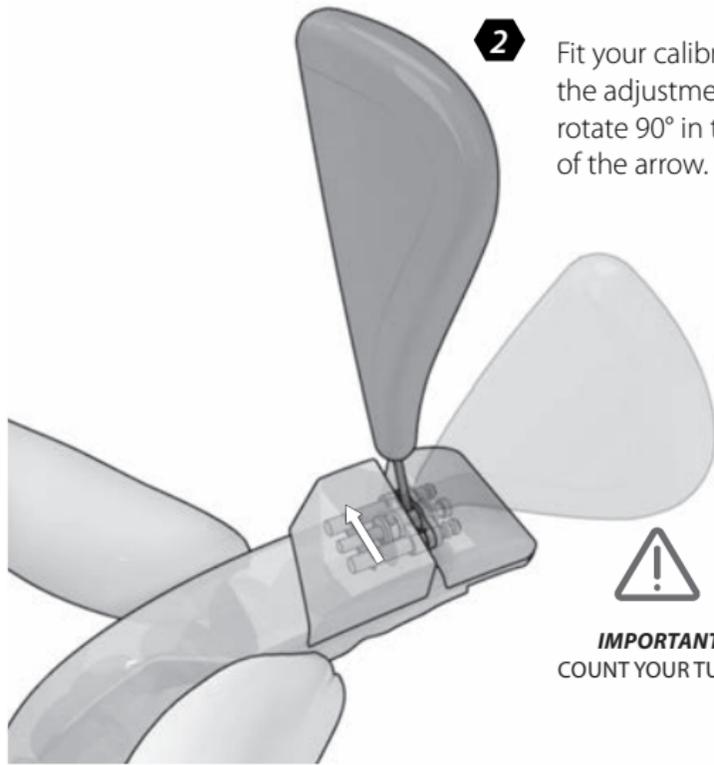
Simply fit the calibration tool into the Keyhole and rotate 90° for a precise 0.1mm adjustment.

## FORWARD ADJUSTMENT

- 1** Hold Upper Tray with calibration screw facing toward you.

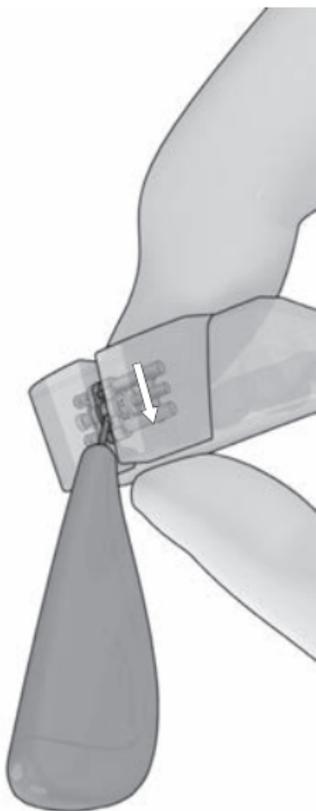


- 2** Fit your calibration tool into the adjustment keyhole and rotate 90° in the direction of the arrow.



**IMPORTANT**  
COUNT YOUR TURNS

## ***BACKWARD ADJUSTMENT***



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

SUAD™



SUAD™ Ultra



### ***Instructions for daily use of your SomnoDent SUAD and SUAD Ultra***

#### **Assembly Instructions**

Assemble the device by placing the lower rods into the upper tubes keeping both halves in the same horseshoe shape. Note that the smooth flat surfaces must be facing each other when the device is assembled. Place the elastics onto the elastic holders as shown in the picture unless directed differently by your Dental Practitioner.

#### **Storage Instructions**

The device should be soaked in warm water for approximately 1-2 minutes prior to insertion. The material that fits against your teeth is a thermo-molecular material that softens when heated allowing for easier placement of the device.

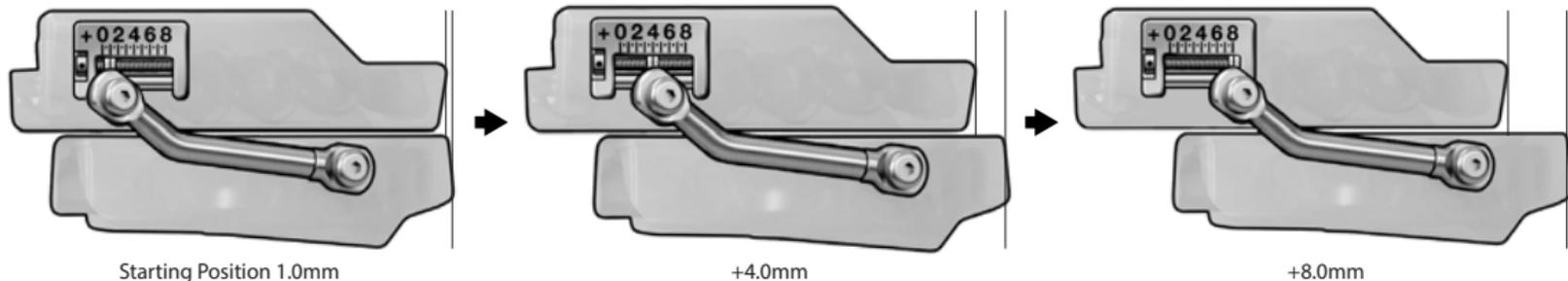
*Each arch must be gently fitted onto teeth by hand; **DO NOT BITE INTO PLACE** as this may cause the inner material to separate from the outer shell (delaminating).*

Holding onto the lower arch of the assembled device, place the device into your mouth and push the whole device upwards onto your upper teeth. Now using your index finger on both hands, separate the two halves of the device and gently push the lower arch onto your lower teeth. Close your jaw to further seat the device into place.

If using orthodontic elastics; do not replace them daily; replace them approximately every 2-3 weeks.

# ADJUST YOUR HERBST ADVANCE

**Precaution:** Do not advance beyond 8.0mm as this may damage the device. Contact your dentist for advice.



Reverse ←      → Forward

<b>90° Turns</b>	-10	-5	+5	+10	+15	+20	+25	+30	+35	+40	+45	+50	+55	+60	+65	+70
<b>Adjustment (mm)</b>	-1.0	-0.5	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5	6.0	6.5	7.0

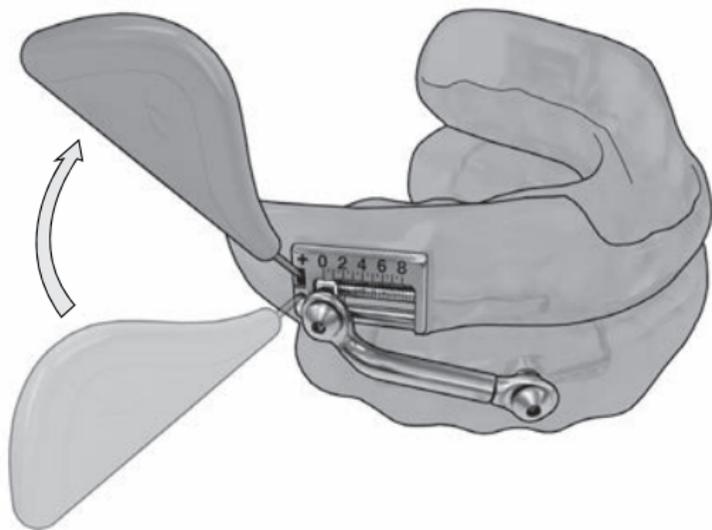
Your SomnoDent Herbst Advance can be adjusted within an 8.0mm range, in 0.1mm steps, giving you total control of your treatment and the best possible fit.

Use the calibration tool (shown on the following page) to visually calibrate your Herbst Advance device, using the measurements indicated on the side.

**Always make sure you repeat the same calibration on both sides of the device.**

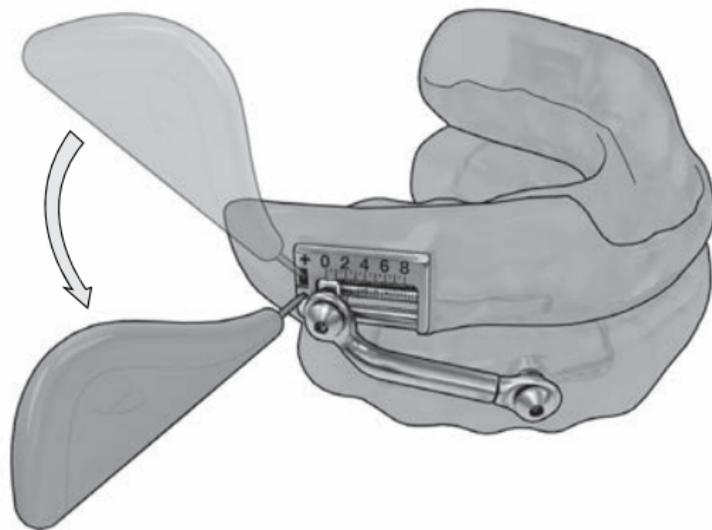
## **ADJUSTMENT – RIGHT SIDE**

Always repeat the same calibration on both sides of your device



### **TO MOVE FORWARD**

Fit your calibration tool into the screw key hole and rotate upward, toward the plus indicator.

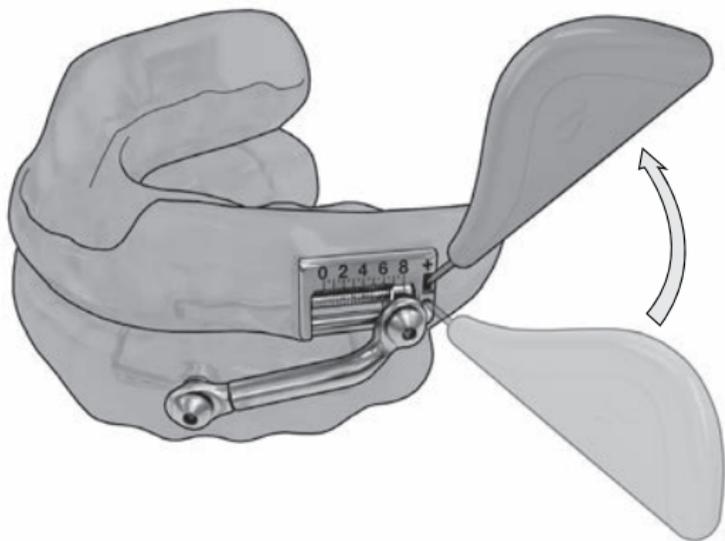


### **TO MOVE BACKWARD**

Fit your calibration tool into the screw key hole and rotate downward, away from the plus indicator.

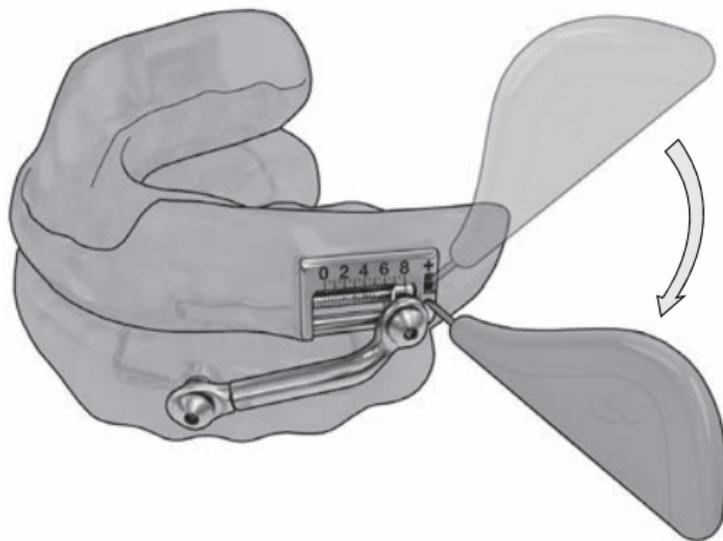
## ***ADJUSTMENT – LEFT SIDE***

Always repeat the same calibration on both sides of your device



### **TO MOVE FORWARD**

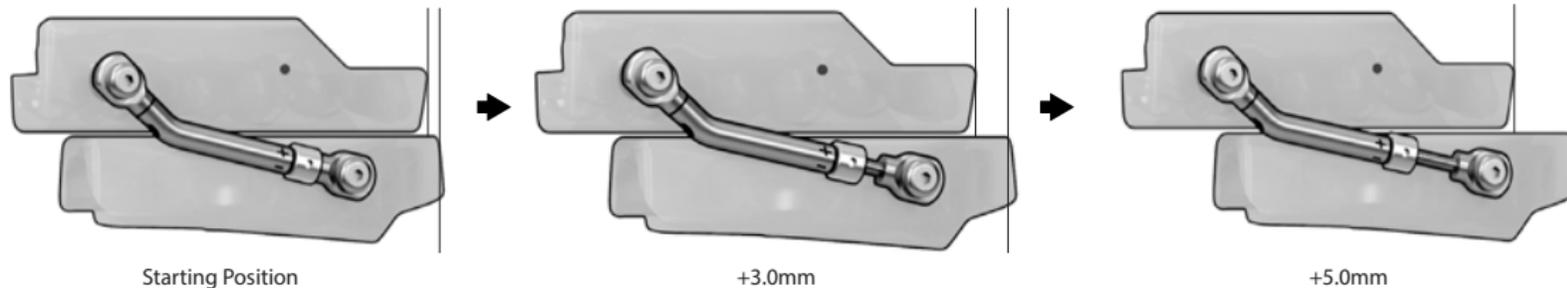
Fit your calibration tool into the screw key hole and rotate upward, toward the plus indicator.



### **TO MOVE BACKWARD**

Fit your calibration tool into the screw key hole and rotate downward, away from the plus indicator.

## ADJUST YOUR HERBST TELESCOPIC

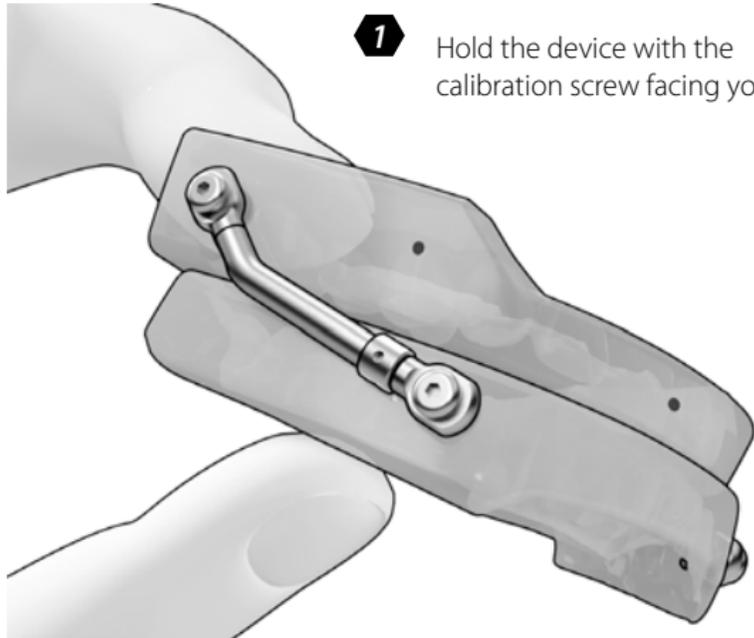


<b>90° Turns</b>	1	4	8	16	24	32	40	48	56	64	72	80
<b>Adjustment (mm)</b>	0.0625	0.25	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0

Your SomnoDent Herbst Telescopic can be adjusted within a 5.0mm range, giving you control of your treatment and the best possible fit.

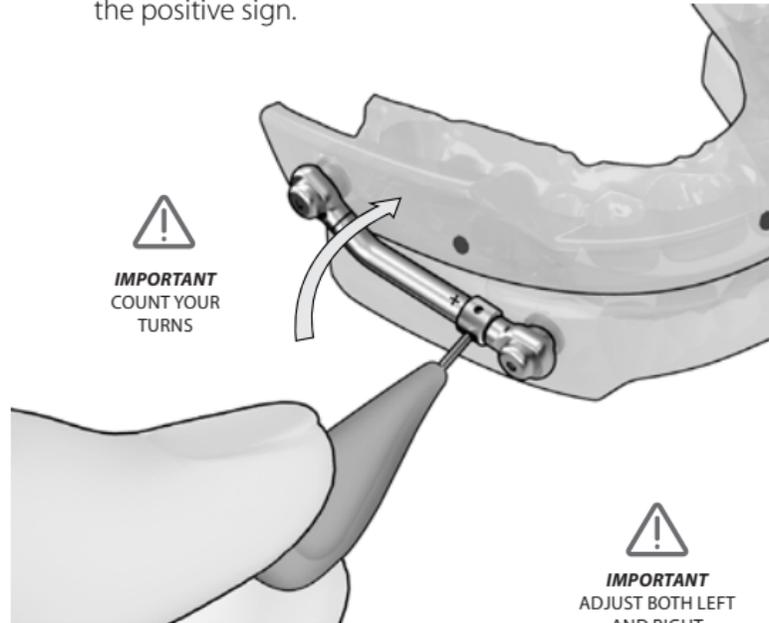
Simply fit the calibration tool into the keyhole and rotate 90° in the direction required.

# FORWARD ADJUSTMENT



- 1** Hold the device with the calibration screw facing you.

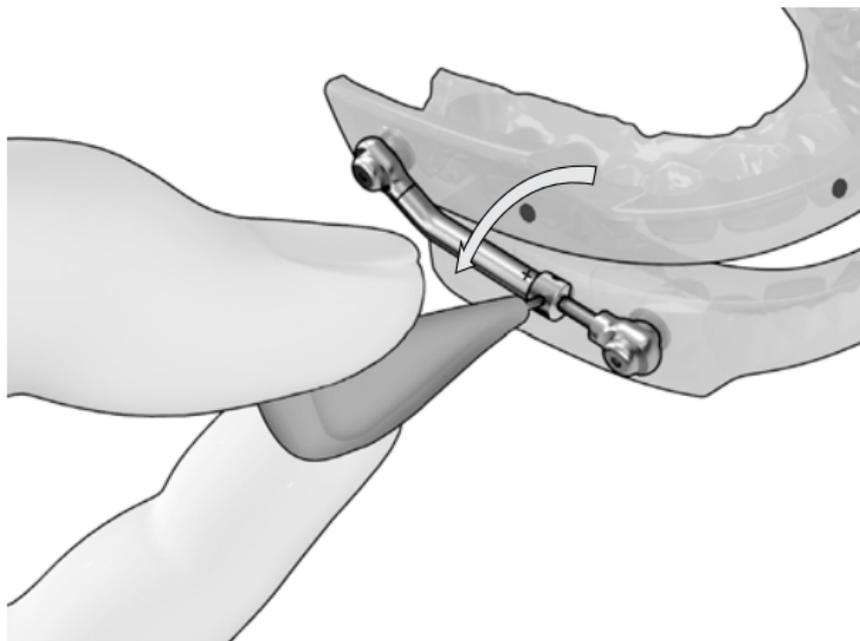
- 2** Fit your calibration tool into the adjustment keyhole and rotate 90° in the direction of the positive sign.



**!**  
**IMPORTANT**  
COUNT YOUR  
TURNS

**!**  
**IMPORTANT**  
ADJUST BOTH LEFT  
AND RIGHT  
CALIBRATION SCREWS

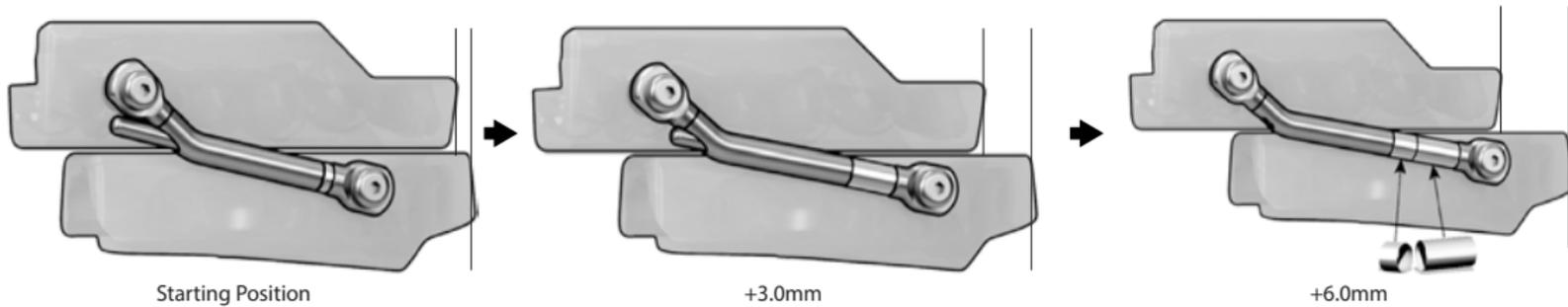
## ***BACKWARD ADJUSTMENT***



**3**

Rotate the calibration tool in the direction toward the negative sign.

## ADJUST YOUR HERBST SHIM



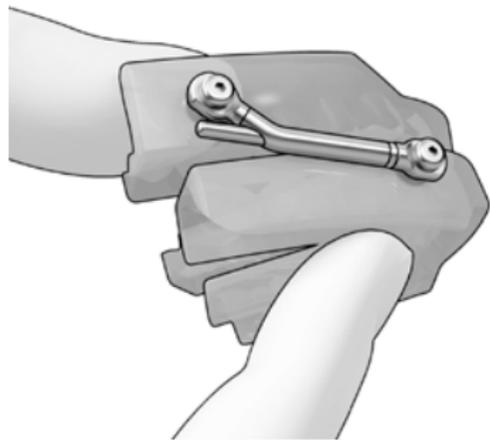
Adjustment (mm)	0	1	2	3	4	5	6	7	8	9	10
Combination of Shims	0	1	2	3	4	5	4/2	4/3	5/3	5/4	5/3/2

Your SomnoDent Herbst Shim can be adjusted within a 10mm range, giving you control of your treatment and the best possible fit.

1 set of (1, 2, 3, 4 and 5 mm) shims are provided. Simply add or remove shims to the lower arm to facilitate precise adjustment.

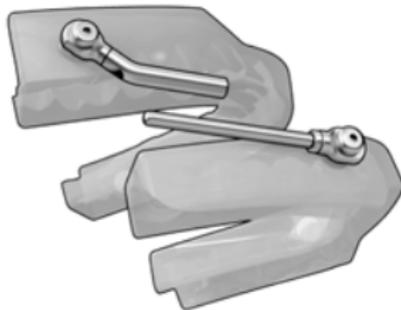
## FORWARD ADJUSTMENT

- 1** Hold the device with the calibration arm facing you.

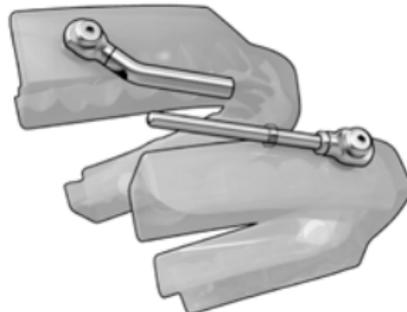


**IMPORTANT**  
ADJUST BOTH LEFT  
AND RIGHT  
CALIBRATION  
SCREWS

- 2** Disengage Upper and Lower Arms.

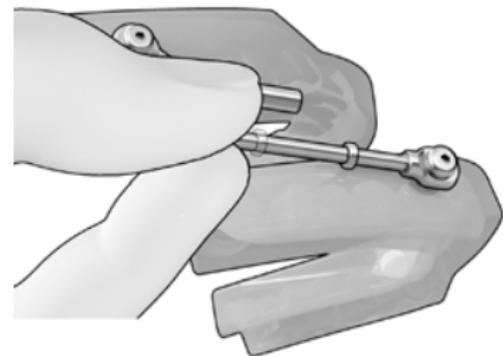


- 3** Place Shim on Lower Arm and push to base of the Lower Arm.

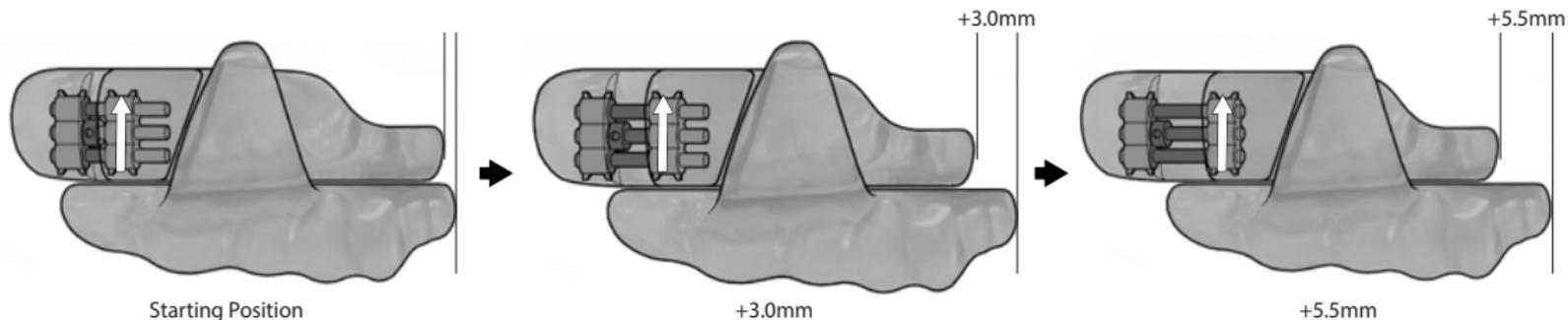


## BACKWARD ADJUSTMENT

- 4** Remove Shim from Lower Arm using finger.



# ADJUST YOUR SOMNODENT AIR / AIR+



Starting Position

+3.0mm

+5.5mm

Reverse ←      → Forward

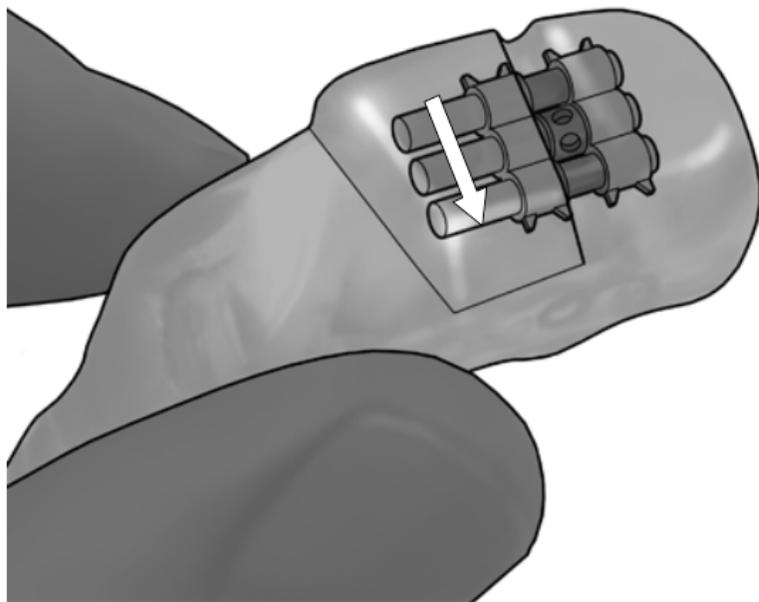
<b>90° Turns</b>	-5	1	5	10	20	25	30	35	40	45	50	55
<b>Adjustment (mm)</b>	-0.5	0.1	0.5	1.0	2.0	2.5	3.0	3.5	4.0	4.5	5.0	5.5

Your SomnoDent Air or Air+ can be adjusted within a 6.0mm range, giving you control of your treatment and the best possible fit.

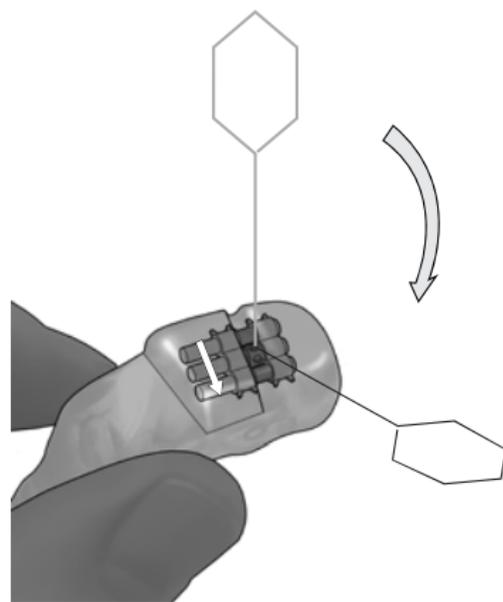
Simply fit the calibration tool into the keyhole and rotate 90° in the direction required for a precise 0.1mm adjustment.

## FORWARD ADJUSTMENT

- 1** Hold the device with the calibration screw facing you.

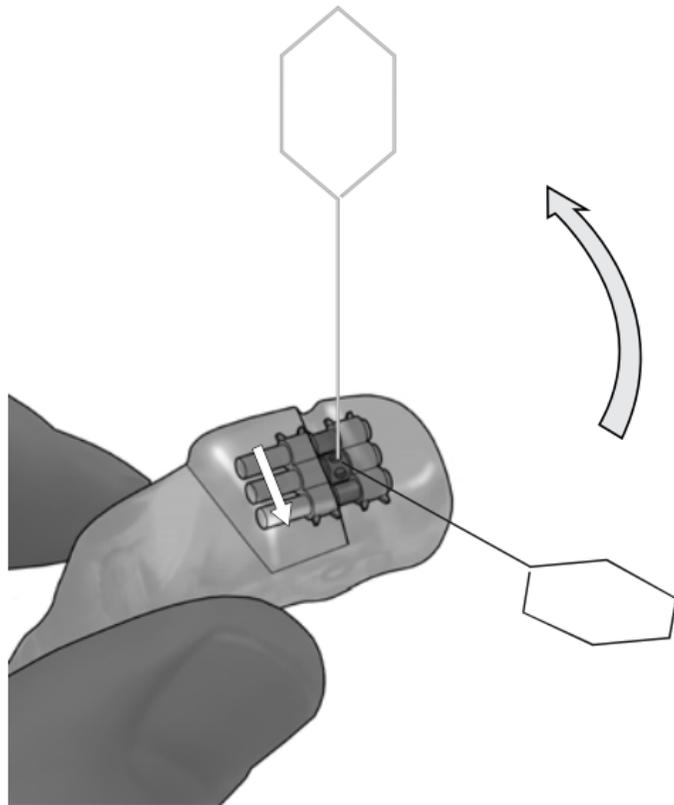


- 2** Fit your calibration tool into the adjustment keyhole and rotate 90° in the direction of the arrow.



**IMPORTANT**  
COUNT  
YOUR TURNS

## ***BACKWARD ADJUSTMENT***



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



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6513 Windcrest Drive, Suite #100, Plano, Texas 75024  
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SD SIGNATURE / STANDARD INSTRUCTIONS FOR USE 903171RevD