

INSTRUCTIONS FOR USE

Herbst® Advance, Telescopic & Shim Devices

SomnoDent[®]
SLEEP APNEA DEVICE

RxOnly


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

Your information	4	SomnoDent Herbst Advance Hardware	10
Introduction	5	Get to Know Your Herbst Advance	10
What is Obstructive Sleep Apnea?	5	Adjust Your Herbst Advance	11
Instructions for Daily Use of Your SomnoDent	6	Adjustment — Right Side	12
Contraindications	6	Adjustment — Left Side	13
Warnings	6	Accessories	14
Precautions	7	Herbst Advance Calibration Log	15
Cleaning	7		
SomTabs Instructions	7		
Advice on cleaning	8		
Storage instructions	8		
Regular Inspection of Your SomnoDent	9		
Repair of Damaged Devices	9		
Warranty	9		

SomnoDent Herbst Telescopic Hardware	16
Get to Know Your Herbst Telescopic	16
Adjust Your Herbst Telescopic	17
Forward Adjustment	18
Backward Adjustment	19
Herbst Telescopic Calibration Log	20

SomnoDent Herbst Shim Hardware	21
Get to Know Your Herbst Shim	21
Adjust Your Herbst Shim	22
Forward Adjustment	23
Backward Adjustment	23
Herbst Shim Calibration Log	24

Sleep and Comfort Diary	25
-------------------------------	----



Name

Physician

Dentist

Model

Serial No.

Date of Purchase

My SomnoDent
SLEEP-APNEA DEVICE

Dear SomnoDent User

Thank you for selecting SomnoDent therapy.

Your SomnoDent is manufactured to the highest medical device standards, and with supporting independent clinical evidence published since 2001, SomnoDent is recognized as the 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 Professional.

SomnoMed®

Restful Nights. Refreshing Days!

Introduction

Worn during sleep, SomnoDent devices fit over the upper and lower teeth. The device slightly moves the lower jaw forward, helping to keep the airway open and allowing the patient to breathe normally.

The SomnoDent line of devices are customized to each patient and offer superior comfort and quality. They are uniquely compliant and highly effective.

These User and Care Instructions apply to all 3 types of SomnoDent Herbst devices:

- **SomnoDent Herbst Advance**
- **SomnoDent Herbst Telescopic**
- **SomnoDent Herbst Shim**

What is obstructive 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.

Caution:

Federal law restricts these devices to sale by or on the order of a dentist or licensed healthcare practitioner.

Inserting the upper plate

Hold the upper and lower plates together and gently mount the upper plate to your teeth. Press up on the plate with both thumbs to ensure that it fits securely and comfortably.

Inserting the lower plate

Once the upper plate is securely in place, insert the lower plate onto your teeth. Press down on both sides of the plate using your index fingers to ensure it fits comfortably.

Removal

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

Indications for use

The SomnoDent Herbst devices are intended for the treatment of mild to moderate obstructive sleep apnea in patients 18 years of age or older.

Contraindications

The devices are contraindicated for patients who:

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

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
- dry mouth
- pressure sensitive teeth

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.

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

Cleaning

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

Always clean your device in the morning immediately after having removed it from your mouth. Use the brush provided or a soft tooth brush but do not use toothpaste as it contains abrasives.

In addition to cleaning your device every morning we recommend that you use SomTabs to thoroughly clean your device once a week or as required.

SomTabs will thoroughly clean and disinfect the hard to reach areas of your device.

SomTabs Instructions

SomTabs is recommended by SomnoMed for the gentle and thorough cleaning of SomnoMed devices. SomTabs thoroughly clean the hard-to-reach areas of your device.

1. Dissolve a SomTabs tablet in sufficient amounts of warm water in the storage case. (approx. 35°C/ 95 °F).
Never use hot water as hot water damages your device and will invalidate the warranty.

2. Carefully place your SomnoDent device in the storage case. All parts must be completely immersed in the cleaning solution.

3. After about 15 minutes, remove the device and small parts from the storage case. Make sure not to lose any small parts! Empty the solution from the storage case.

4. After having removed the device from the the storage case, thoroughly brush it with a tooth brush and rinse it under cool running water.

5. Clean the metal components of the SomnoDent Flex, Edent, Classic or Herbst devices with a cleaning brush or tooth brush.

6. Dry all parts of the device and storage case carefully and thoroughly using a clean towel.

7. When not in use, the device should be stored as per your SomnoMed device instructions for use.

Important

Keep your device away from sunlight.

Caution:

Do not use toothpaste, as it contains abrasives, and may damage the device.

Do not put SomTabs tablets into the mouth.

Do not swallow the cleaning solution and do not use it as a mouthrinse.

Contents

Sodium Bicarbonate, Potassium Caroate, Citric Acid, Sodium Citrate, Sorbitol, Sodium Lauryl Sulfate, Sodium Percarbonate, CI73015.

Ordering SomTabs refills

Make sure you never run out of SomTabs to clean your device. Order your SomTabs refills in advance.

Place your order online by logging on to the SomnoMed website at www.somnomed.com or call 1.888.447.6673.

Advice on cleaning

Some patients with amalgam fillings or users of Pyralvex (a solution for mouth ulcers and denture irritation) may over time notice discoloration 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 discoloration do not drink coffee, tea or colas with the device in place. always brush teeth thoroughly before use.

Denture cleaning tablets dissolve to form active oxygen, an oxidizing agent, which may damage the metal components of your SomnoDent. Ensure that you use a "partial denture cleaner" and rinse in cold water after soaking for a maximum period of 15 minutes.

If you are using a partial denture cleaner, soak your Somnodent for 5 minutes only and then thoroughly rinse and store over night.

Never use hot or boiling water!

Hot or boiling water damages your SomnoDent and this will invalidate the warranty.

Storage instructions

Always store your SomnoDent in the storage container when not in use. A storage container is included for your convenience.

When travelling, protect your device by placing it inside the SomnoDent storage container.

Regular inspection of your SomnoDent Herbst Device

Regularly inspect the device for signs of damage and cracks. 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.

Take your SomnoDent with you to your regular dental checkups.

Repair of damaged devices

Damaged or broken devices must not be used any longer in order to avoid injury. Immediately contact your SomnoMed dental sleep provider, who will arrange for the device to be repaired by an expert.

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 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 casts or impressions are required, the warranty is void. In such cases SomnoMed offers to remake the device at a reduced cost.

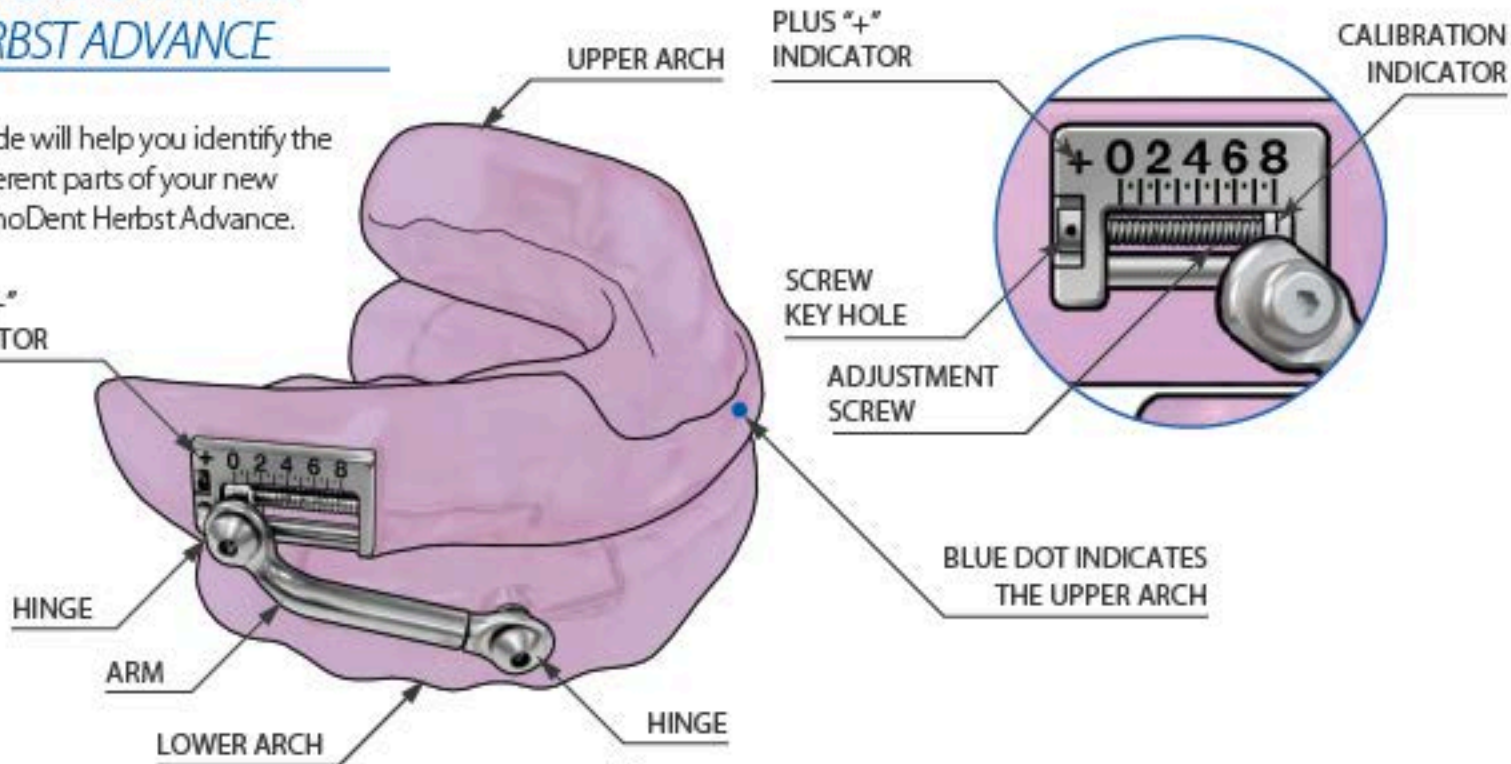
d. Warranty repair work may only be completed by the authorized SomnoMed facility at which the SomnoDent was originally manufactured.

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 authorized technicians.

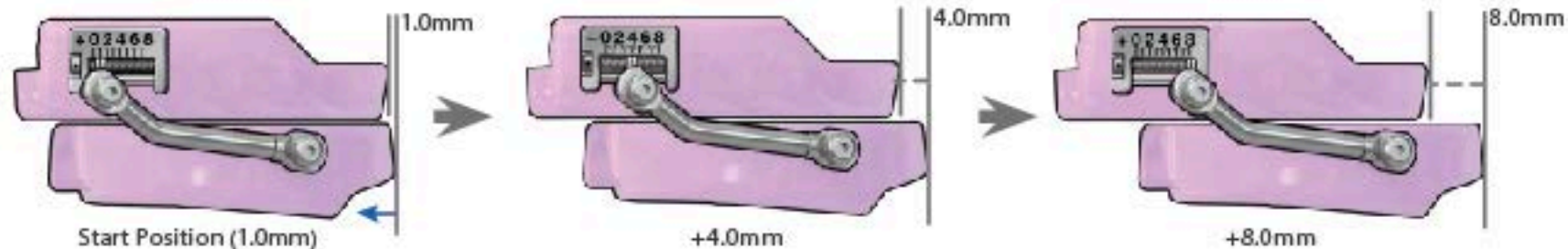
GET TO KNOW YOUR HERBST ADVANCE

This Guide will help you identify the different parts of your new SomnoDent Herbst Advance.

PLUS "+"
INDICATOR



ADJUST YOUR HERBST ADVANCE



REVERSE ← 1.0 → FORWARD

90° TURNS	-10	-5	+5	+10	+15	+20	+25	+30	+35	+40	+45	+50	+55	+60	+65	+70
Adjustment (mm)	-10.0	-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

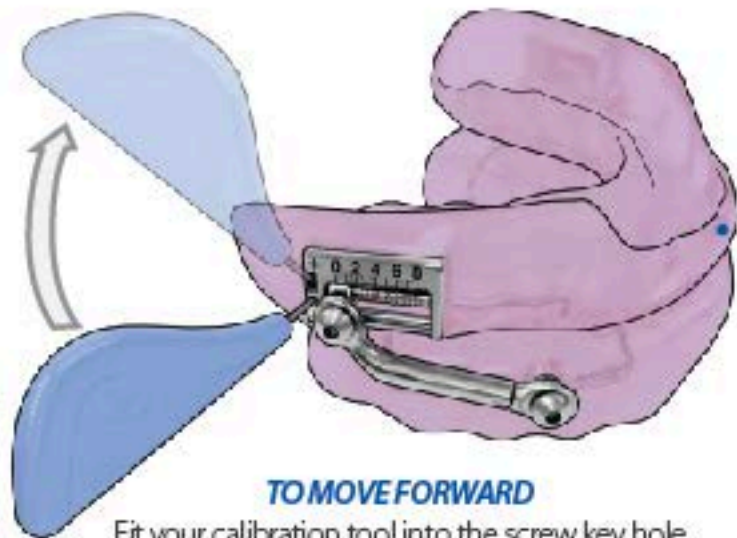
Your SomnoDent Herbst Advance can be adjusted within an 8.0mm range, in 0.1 mm steps, giving you total control of your treatment and the best possible fit.

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.

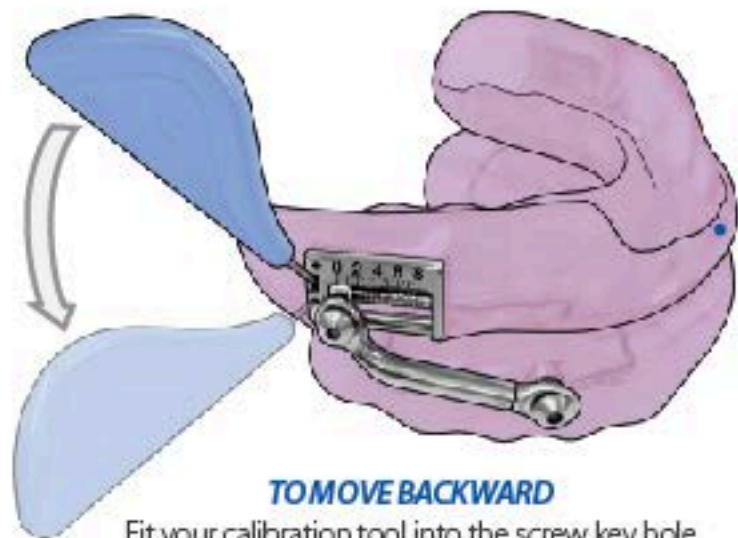
ADJUSTMENT — RIGHT SIDE

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.

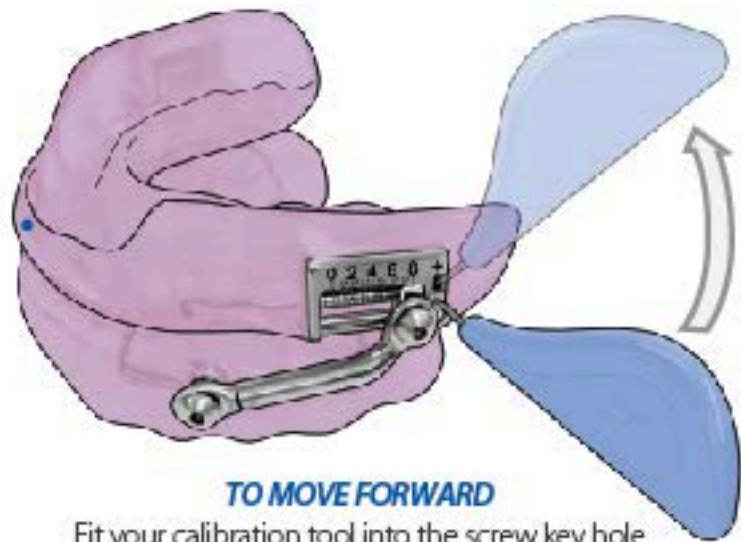


TO MOVE BACKWARD

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

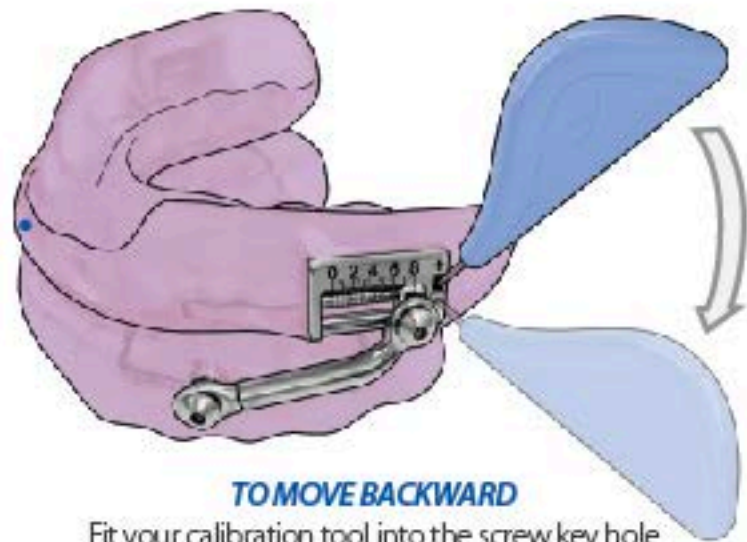
ADJUSTMENT — LEFT SIDE

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.



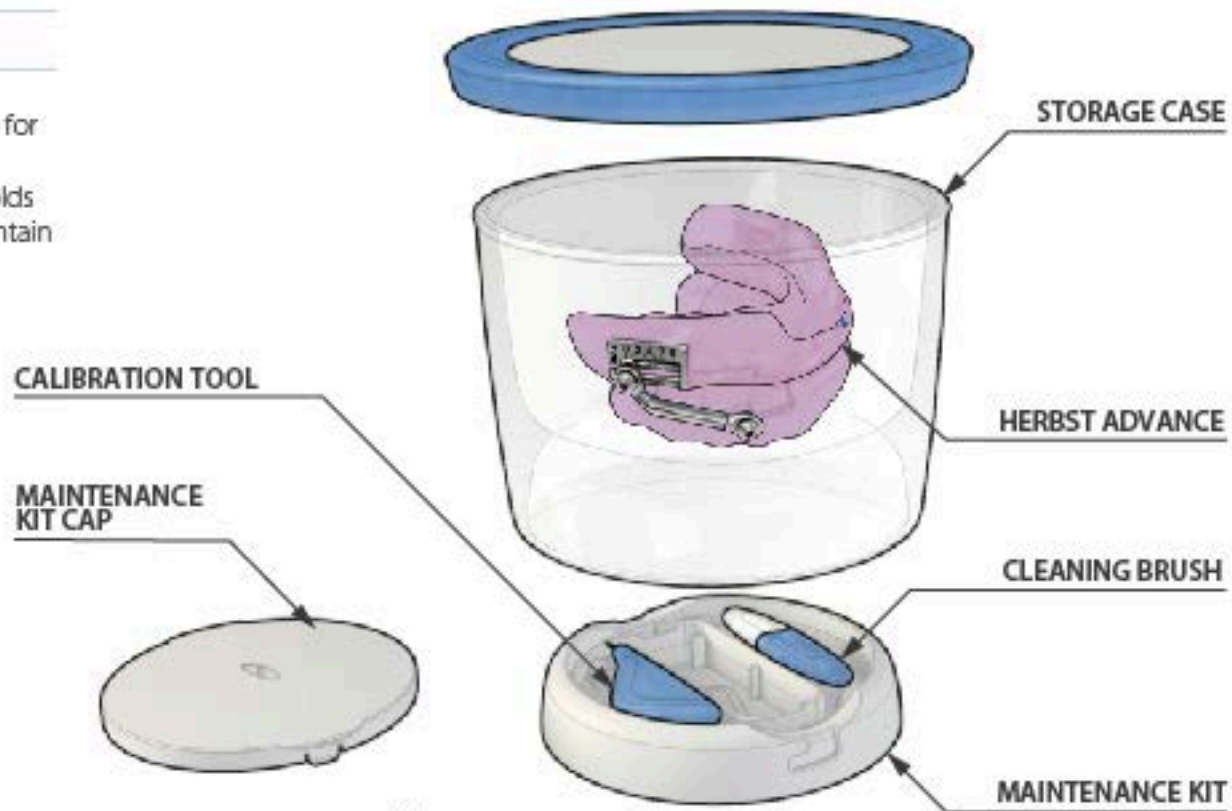
TO MOVE BACKWARD

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

ACCESSORIES

Place the device in the storage case for storage overnight.

The maintenance kit in the base holds everything you need to use and maintain your SomnoDent.



Keep a log of your Herbst Advance Calibration settings.*

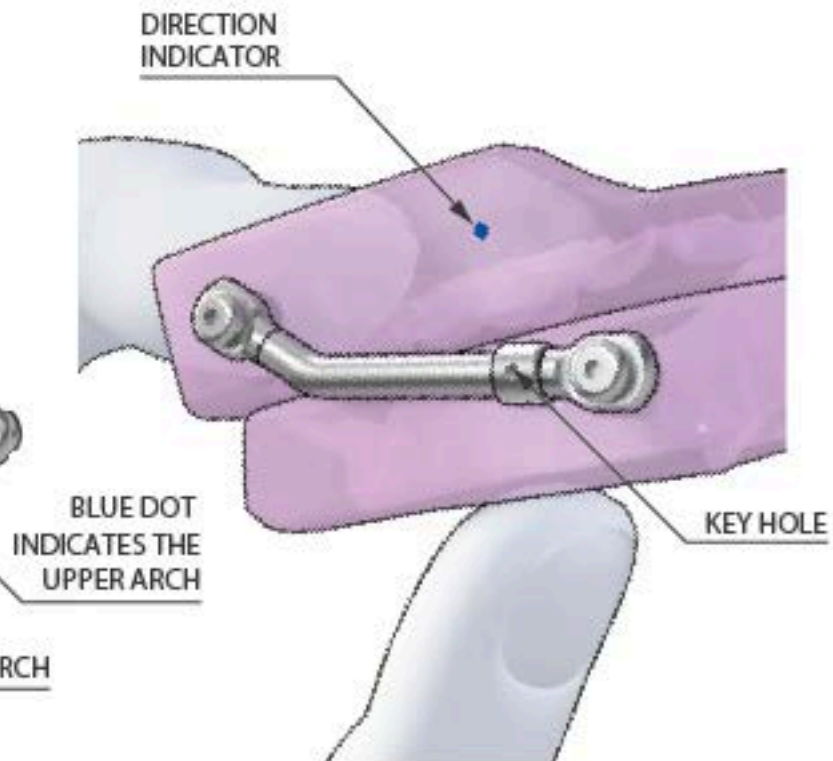
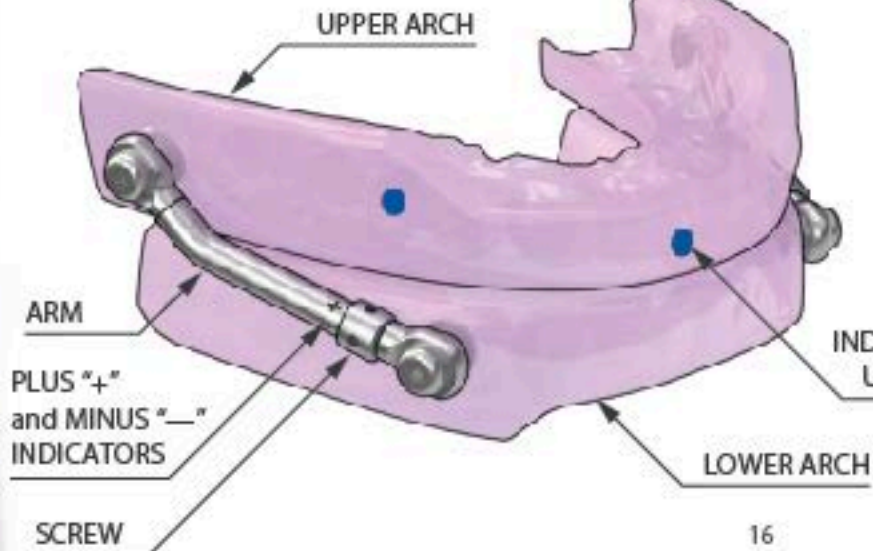
Date	Number of Millimeters

Date	Number of Millimeters

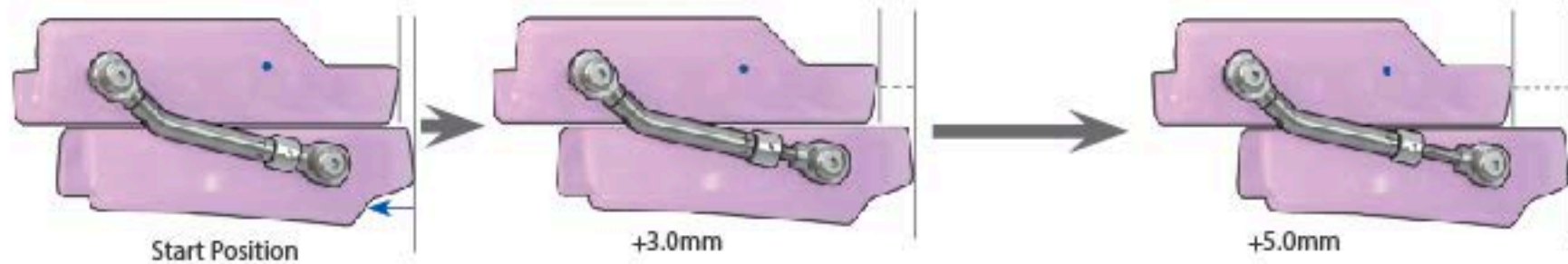
*Make sure you keep a Sleep Diary for the first 30 nights (located at the back of this User Guide).

GET TO KNOW YOUR HERBST TELESCOPIC

This Guide will help you identify the different parts of your new SomnoDent Herbst Telescopic.



ADJUST YOUR HERBST TELESCOPIC

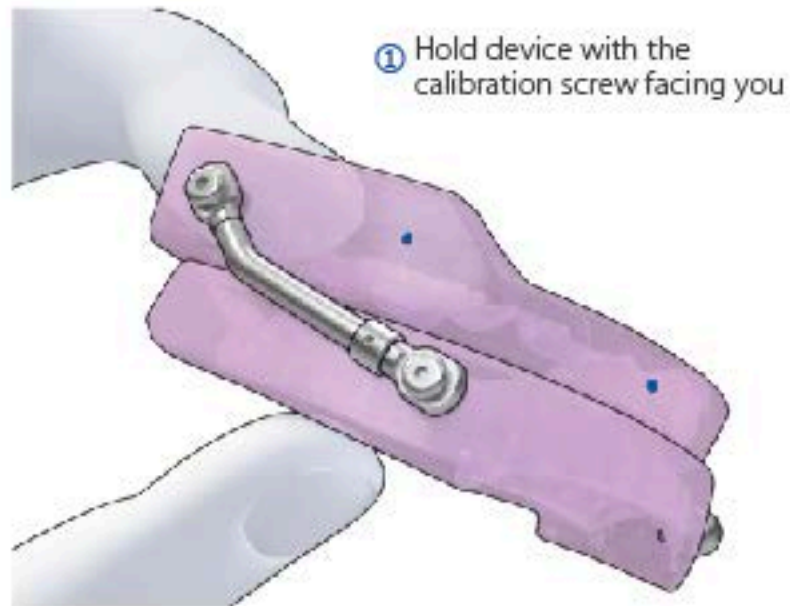


90° Turns (n)	1	4	8	16	24	32	40	48	56	64	72	80
Adjustment (mm)	0.0625	0.25	0.5	1.0	1.5	2.0	2.5	3.0	3.5	4.0	4.5	5.0

Your SomnoDent Herbst 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.

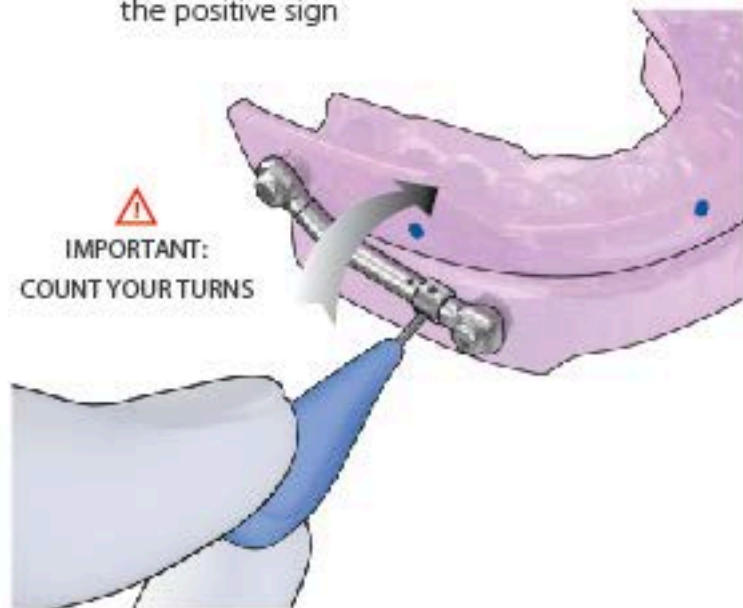
FORWARD ADJUSTMENT



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

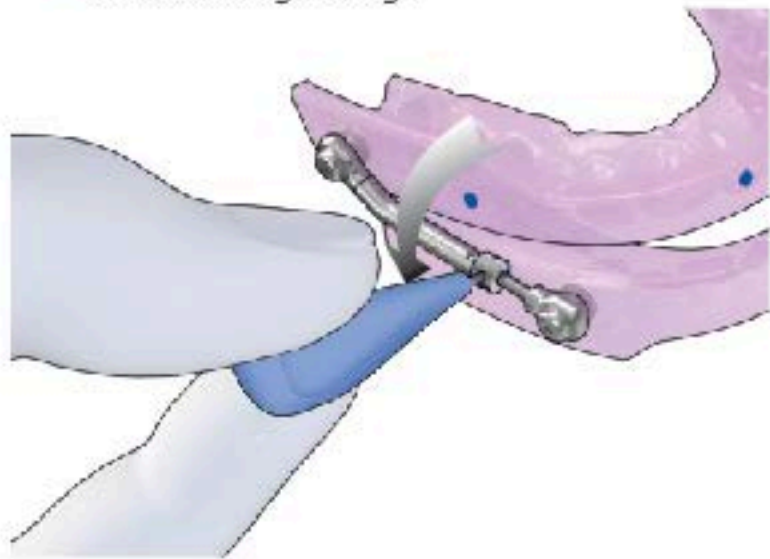
- ② Fit your calibration tool into the adjustment keyhole and rotate 90° in the direction of the positive sign

 **IMPORTANT:**
COUNT YOUR TURNS

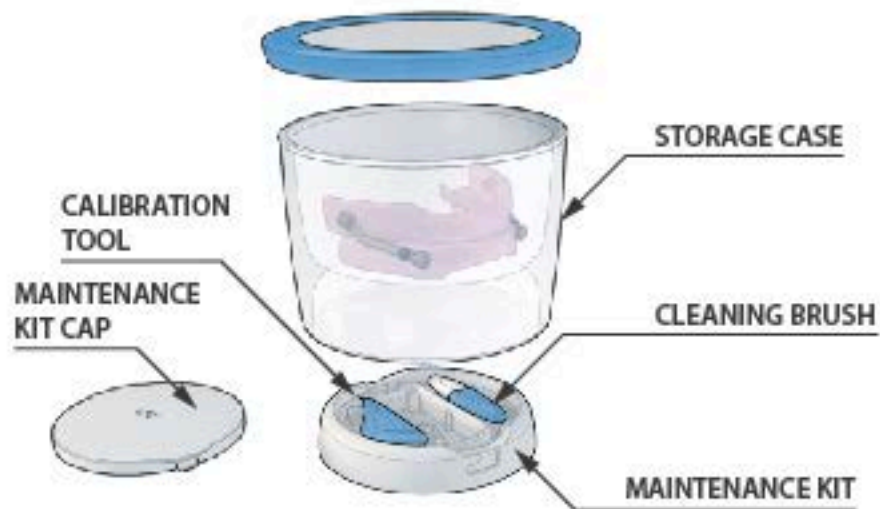


BACKWARD ADJUSTMENT

- ③ Rotate your allen key in the direction toward the negative sign



ACCESSORIES



Place the device in the storage case for storage overnight. The maintenance kit in the base holds everything you need to use and maintain your SomnoDent.

Keep a log of your Herbst Telescopic Calibration settings.*

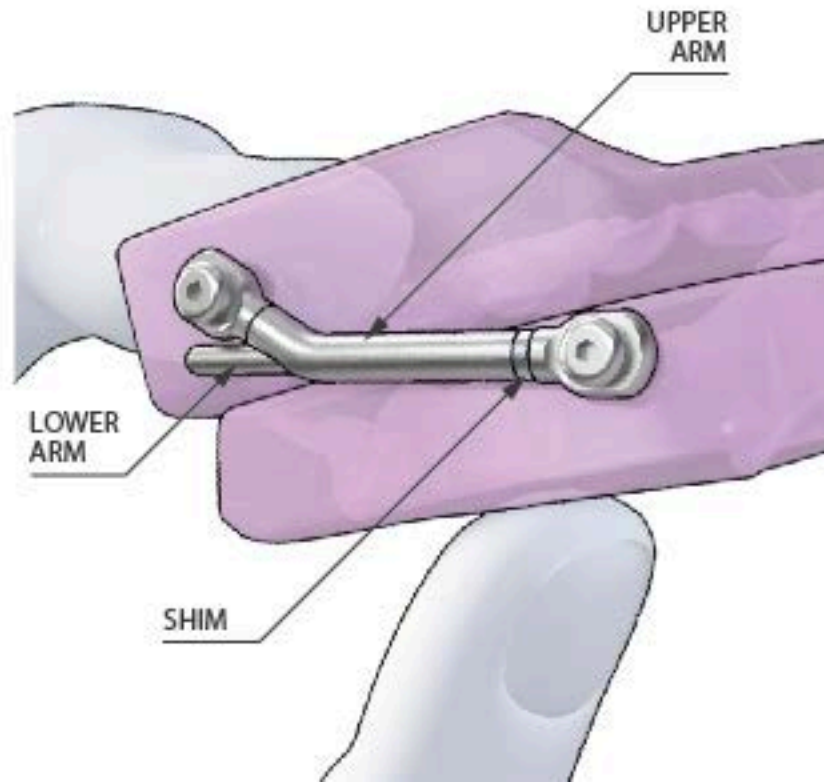
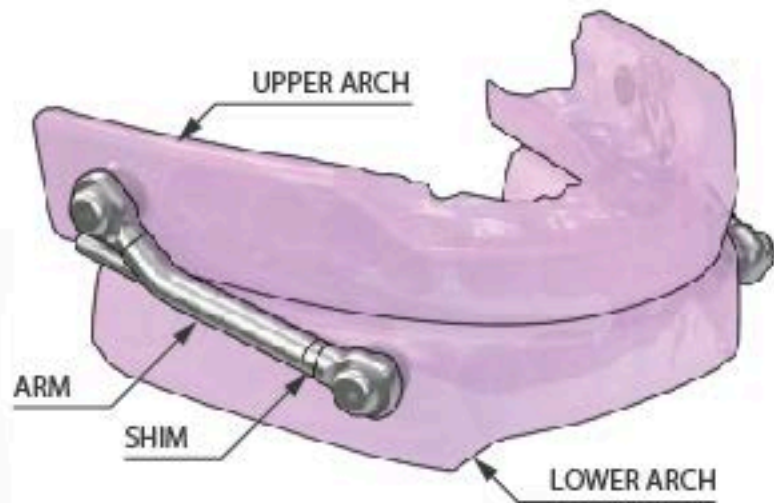
Date	Number of 90° Rotations

Date	Number of 90° Rotations

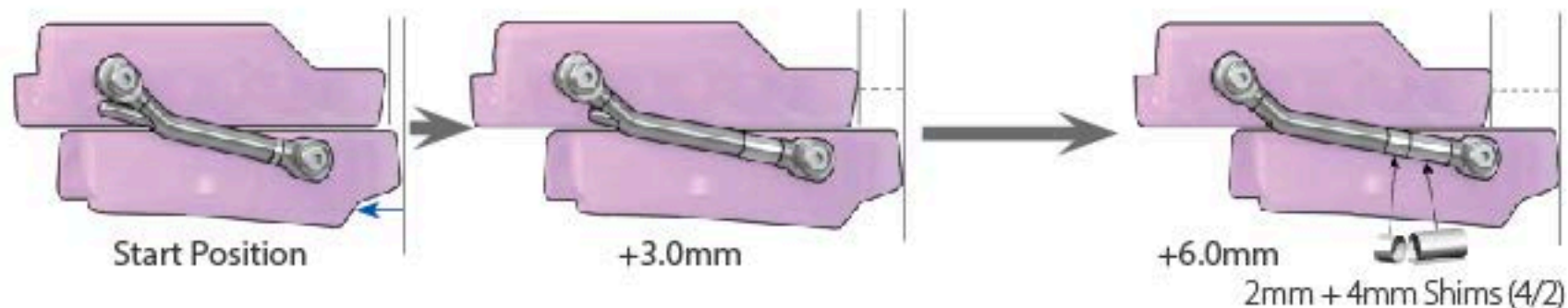
*Make sure you keep a Sleep Diary for the first 30 nights (located at the back of this User Guide).

GET TO KNOW YOUR HERBST SHIM

This Guide will help you identify the different parts of your new SomnoDent Herbst Shim.



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.

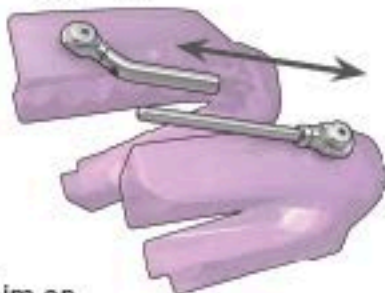
1 set of (1, 2, 3, 4 and 5 mm shims) are provided. Simply add or remove shims to the lower arm to facilitate precise adjustment.

FORWARD ADJUSTMENT

- ① Hold device with the Calibration Arm facing you.



- ② Disengage Upper and Lower Arms.



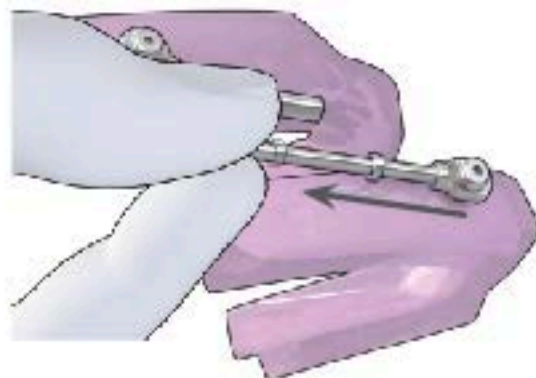
- ③ Place Shim on Lower Arm and push to base of the Lower Arm.




IMPORTANT:
ADJUST BOTH LEFT
AND RIGHT SIDES
EQUALLY

BACKWARD ADJUSTMENT

- ④ Remove Shim from Lower Arm using finger.



Keep a log of your Herbst Shim Calibration settings.*

Date	Number of Millimeters

Date	Number of Millimeters

*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.

SomnoDent 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	
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	

Night	Date	Sleep and Wearing Notes	Hours Worn	Comfort Level	Doctor Setting Instructions
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	
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	



PCI.US.S.5022A

Copyright © 2013 SomnoMed, All rights reserved.
SomnoMed® and SomnoDent® are registered trademarks of SomnoMed, Inc.

SD HERBST INSTRUCTIONS FOR USE COMBO BOOKLET 03.01



7460 Warren Parkway, Suite 190, Frisco, TX 75034 — p 1.888.447.6673 — f 972.377.3404 — www.somnomed.com