DOCTOR INSTRUCTIONS FOR USE
TABLE OF CONTENTS

Introduction ........................................ 3
Technical Components........................... 5-8
Material Content................................................ 9
Prescribing ProSomnus Sleep Devices ..... 9-12
Daily Use and Maintenance ................. 12-13
Homecare Instructions......................... 13-14
Package Contents ................................. 14-15
Manufacturing Requirements .............. 15
Warnings ................................................... 15-17
Warranty and Repair............................... 18

ProSomnus Sleep and Snore Devices include the ProSomnus® MicrO2® Sleep and Snore Device, the ProSomnus® [IA] Sleep and Snore Device with Monogram™ Customization Options, the ProSomnus® [CA] Sleep and Snore Device and the ProSomnus [PH] Sleep and Snore Device. These devices will also be referred to as the ProSomnus Sleep Devices.

“These FDA accepted devices comply with the requirements of directive 93/42/ EEC concerning medical devices. Caution: Federal (U.S.) law restricts this device to sale by, or on the order of, a dentist’s prescription only.”
PROSOMNUS SLEEP AND SNORE DEVICES INTRODUCTION

The ProSomnus Sleep Devices are intended to reduce night time snoring and mild to moderate Obstructive Sleep Apnea (OSA) in adults by holding the lower jaw forward during sleep which prevents the tongue and throat tissues from collapsing into the airway. The ProSomnus Sleep Devices are patient specific to maximize tongue space and the ability to open and close during wear.

There may be a fully embedded Compliance Sensor in the lower arch device. This Sensor does not affect the intended use for the treatment of mild to moderate OSA. The Sensor does not affect the care of the device. To learn more about the Sensor and how it works, please visit ProSomnus.com. The ProSomnus Sleep Device series of arch forms are designed to match the advancement positions the dentist has prescribed. Jaw advancements are easily achieved by simply removing the current Upper or Lower Arches and inserting the next Upper or Lower Arch in the ProSomnus Sleep Device series. If the patient has a ProSomnus [CA] or [PH] Sleep and Snore Device, it can easily be adjusted to the advancement positions the dentist has prescribed, by simply adjusting the expansion screws on the Upper [CA] Arch or the Herbst Nut on the [PH] per the dentist’s instructions. See pages 11-13 for details.

The dentist prescribes the amount of advancement increments according to the treatment plan. The ProSomnus Sleep Devices are simple to use, comfortable to wear, and easy to keep clean. These devices are patient-specific for single-patient use. ProSomnus Sleep Devices are intended to be worn during sleep by adults 18 years or older.

Digital Simplicity. The first CAD/CAM milled OSA device, the ProSomnus Sleep Devices are precise, predictable, and easy to use.

Comfortable Profile for Patients. The only OSA devices made from control-cured PMMA, compact without compromising durability or retention. Easy to wear providing maximum tongue space and comfort. Dual 90° Posts and precision placed Herbst Arms for freedom of movement to open and close during wear.
Easy Adjustment. The ProSomnus MicrO₂ and [IA] Sleep and Snore Devices offer an Iterative Advancement method similar to changing aligners. The ProSomnus [CA] and [PH] Sleep and Snore Devices offer a Continuous Advancement capability that allows for small advancements. The ProSomnus Sleep Device design is based on the clinical expertise of leaders in the field of Dental Sleep Medicine.

ProSomnus® MicrO₂ Sleep and Snore Device

ProSomnus® [IA] Sleep and Snore Device with Monogram™ Customization

ProSomnus® [CA] Sleep and Snore Device

ProSomnus® [PH] Sleep and Snore Device
TECHNICAL COMPONENTS
The ProSomnus Sleep Devices are intended to reduce night
time snoring and mild to moderate Obstructive Sleep Apnea
(OSA) in adults.

There may be a fully embedded Compliance Sensor in the
lower arch device. This Sensor does not affect the intended
use for the treatment of mild to moderate OSA. The Sensor
does not affect the care of the device. To learn more about
the Sensor and how it works, please visit ProSomnus.com.

Note: The ProSomnus Sleep Devices are customized patient
specific dental devices. The patient’s device may vary in
features selected as part of the Monogram Customization
Options available on the ProSomnus [IA] Device. For example,
add Anterior Discluders, Airway Openings, Different Dual
Post Angles, Splint Coverage Options, Compliance Sensor
Capability, Unlimited Advancement Arches, and more, all
with the intent of optimizing treatment outcomes, patient
experiences, and clinical efficiency.

PROSOMNUS MICRO₂ AND [IA]
SLEEP AND SNORE DEVICE

Product Components: Lateral View

ARCH IDENTIFIER
Easy to identify
Upper or
Lower and the
adjustment
increment

DUAL 90 DEGREE
POSTS
Keeps jaw forward at
night without metal
screw mechanisms

CONTOURED LIP
BORDERS
Designed to enhance
comfort and lip closure

CONTOURED CHEEK BORDERS
Maximizes comfort
and fit
Product Components: Occlusal View

LINGUALESS DESIGN
Provides more room and comfort for the tongue

LOW PROFILE DESIGN
Promotes comfort and simplicity

PATIENT–SPECIFIC DESIGN
Designed to specifically fit the shape of each patient’s teeth

PROSOMNUS [IA] MONOGRAM CUSTOMIZATION OPTIONS

DIFFERENT POST ANGLES
AIRWAY OPENING

ANTERIOR DISCLUDER
METAL-FREE HOOKS
AND MORE!
PROSOMNUS [CA] SLEEP AND SNORE DEVICE

Product Components: Lateral View

ADVANCEMENT MARKINGS
Raised bumps on device provide reference for advancement location

LINEAR GUIDE
Ensures consistent strength with precision advancement throughout advancement range

FLAT PLANE SPLINT
Consistent vertical throughout protrusion range

LOWER UNIQUE DEVICE IDENTIFIER (UDI)
Precisely positioned at the provided bite registration

SPLIT UPPER 90° POST WITH EXPANSION SCREW
Allows advancement in small increments

Product Components: Occlusal View

LINGUALESS DESIGN
Provides more room and comfort for the tongue

LOW PROFILE DESIGN
Promotes comfort and simplicity

PATIENT–SPECIFIC DESIGN
Designed to specifically fit the shape of each patient’s teeth
PROSOMNUS [PH] SLEEP AND SNORE DEVICE

Product Components: Lateral View

- **WRENCH RULER**
  Using the wrench ruler for advancement measurement

- **UPPER GOLD SCREW**
  Provides orientation

- **HERBST ARM WITH ADJUSTMENT NUT**
  Allow advancement in small increments

- **LOWER UNIQUE DEVICE IDENTIFIER (UDI)**
  Precisely positioned at the provided bite registration

- **FLAT PLANE SPLINT**
  Consistent vertical throughout protrusion range

Product Components: Occlusal View

- **LINGUALESS DESIGN**
  Provides more room and comfort for the tongue

- **ANTERIOR & POSTERIOR COMFORT BUMPS**
  Designed for patient comfort

- **LOW PROFILE DESIGN**
  Promotes comfort and simplicity

- **CAPPED SCREW**
  Designed for patient comfort

- **PATIENT–SPECIFIC DESIGN**
  Designed to specifically fit the shape of each patient’s teeth
MATERIAL CONTENT
ProSomnus MicrO₂ Sleep and Snore Devices
Material Content: Polymethylmethacrylate (PMMA) with high molecular weight Methylmethacrylate.
Ball Clasps: Medical Grade Stainless Steel.

ProSomnus [CA] and [PH] Sleep and Snore Devices
Material Content: Polymethylmethacrylate (PMMA) with high molecular weight Methylmethacrylate.
Ball Clasps: Medical Grade Stainless Steel.
Expansion Screws and Herbst Arm: Medical Grade Stainless Steel.

Note: These devices are entirely made of Medical Grade material. Stainless Steel contains Nickel and Chromium. Hazardous Substances at or below NIOSH Recommended Exposure Limits.
If your patient experiences any reaction, contact prescriber immediately.

Note: These devices may also include Medical Grade Stainless Steel clasps or other wire components to aid in a secure fit, not shown. If the patient experiences any reaction, contact the prescriber immediately. There may be a fully embedded Compliance Sensor in the lower arch device. This Sensor does not affect the intended use for the treatment of mild to moderate OSA. The Sensor does not affect the care of the device. To learn more about the Sensor and how it works, please visit ProSomnus.com.

PRESCRIBING THE MICR0₂ SLEEP AND SNORE DEVICE
The ProSomnus MicrO₂ Sleep and Snore Device may be purchased as a series of four or six devices, or may be purchased separately. The Series A, Series B, Series C, and Series D are considered ‘starter sets.’ One of these series is usually selected if your patient is not already wearing the ProSomnus MicrO₂ Sleep and Snore Device.

ProSomnus MicrO₂ Sleep and Snore Device Series A and B includes four arches:
1 set of Upper and Lower Initial Arches milled at the bite registration position. Initial Arches are identified as being in the Zero (0) position. Series A includes two more Advancement Arches. The additional Upper Advancement Arch is milled at 2.0mm. The additional Lower Advancement Arch is milled at 1.0mm. Advancements are measured and milled from the Zero (0) position. Series B includes two more Advancement Arches. The additional Upper Advancement Arch is milled at 2.5mm. The additional Lower Advancement
Arch is milled at 1.5mm. Advancements are measured and milled from the Zero (0) position.

ProSomnus MicrO₂ Sleep and Snore Device Series C and D includes six arches:
1 set of Upper and Lower Initial Arches milled at the bite registration position. Initial Arches are identified as being in the Zero (0) position. Series C includes four more Advancement Arches. The additional Upper Advancement Arches are milled at 1.5mm and 3.0mm. The additional Lower Advancement Arches are milled at 0.5mm and 1.0mm. Advancements are measured and milled from the Zero (0) position. Series D includes four more Advancement Arches. The additional Upper Advancement Arches are milled at 2.0mm and 4.0mm. The additional Lower Advancement Arches are milled at 1.0mm and 2.0mm. Advancements are measured and milled from the Zero (0) position.

ProSomnus MicrO₂ Sleep and Snore Device Custom Series also includes four or six arch devices: 1 set of Upper and Lower Initial Arches milled at the bite registration position. Initial Arches are identified as being in the Zero (0) position. The Custom Series with 4 arches includes 2 Advancement Arches of your choosing; each one milled at the advancement amounts you select. The Custom Series with 6 Arches includes 4 Advancement Arches of your choosing; each one milled at the advancement positions you select. Advancements are measured and milled from the Zero (0) position.

ProSomnus MicrO₂ Sleep and Snore Device Upper Initial Arch or Lower Initial Device may be ordered singly, to be used for a replacement, or as a spare.

ProSomnus MicrO₂ Sleep and Snore Device Advancement Arches may be ordered singly, in any arch, advancement scheme, or quantity you select.

ProSomnus MicrO₂, Series A (Example Only)
(0) = Initial Device Position per Bite Registration
(+1) = Advanced 1mm from (0) position
(+2) = Advanced 2mm from (0) position
(+3) = Advanced 3mm from (0) position
(combined U2 + L1)
This is an example only. You select the advancements and U/L combinations you require.
Advancement Arches may be ordered in any amount you require. Standard advancements are set at 0.5mm and 1.0mm increments.

Each Upper and Lower Arch will have the advancement measurement embossed on the side post, along with the Arch Identifier (U) or (L).

Each Upper and Lower Arch also has a Unique Device Identifier embossed for identification and traceability.

**PREScribing the [IA] Sleep and Snore Device**

The ProSomnus [IA] Sleep and Snore Device follows the same Iterative Advancement protocol as described in the ProSomnus MicrO2 Sleep and Snore Device section, with the exception that there is no 6 Arch Series and only a 4 Arch Series with the ProSomnus [UA] Unlimited Advancement offering included.

ProSomnus [UA], Unlimited Advancement Arches starts with ordering ProSomnus [IA] Series A or B. When the advancement is completed using that series and you find you will need another arch at a 1.0mm or 0.5mm position that differs from the initial series, simply order the extra desired advancement arch. If you find you need another arch after that, again order another 1.0mm or 0.5mm position that differs from the previous series and additional arch(es). Repeat until satisfied that your patient is in the treatment position you desired.

**PREScribing the ProSomnus [CA] Sleep and Snore Device**

The ProSomnus [CA] Sleep and Snore Device uses a Continuous Advancement protocol. The Upper Arch has a split 90° Post that contains an adjustable expansion screw allowing for small incremental adjustments in a range from -1.0mm to 5.0mm.

The ProSomnus [CA] Sleep and Snore Device provides an Upper Arch with Continuous Advancement titration capability and a Lower Arch (L0). When the advancement is completed using that Upper Advancement range and you find you will need more advancement, simply order an additional Lower Advancement Arch (L5), which adds another 5.0mm or total advancement up to 11.0mm.
PRESCRIBING THE [PH] SLEEP AND SNORE DEVICE

The ProSomnus [PH] Sleep and Snore Device also uses a continuous advancement protocol. The Upper Arch is connected by a Herbst Arm to the Lower Arch with an adjustment nut allowing for small incremental adjustments in a range from -1.0mm to 6.0mm.

The ProSomnus [PH] Sleep and Snore Device provides continuous advancement titration capacity and is Medicare E0486 verified.

DAILY USE AND MAINTENANCE

Directions for Daily Use

1. Patients should not insert until just prior to sleep.
2. Patients should inspect the device prior to each use. Patients should contact their prescriber if they observe any material degradation or cracks.
3. Patients should rinse with water before use. Patients should always brush their teeth and floss well before inserting the ProSomnus Sleep Device in their mouth.
4. Select the correct arches:

   For the ProSomnus MicrO₂ and [IA] Sleep and Snore Devices
   1. Lower Arch (L)
   2. Upper Arch (U)
   3. Upper and Lower Arches will have the advancement label on the left posts.
   4. The initial Upper and Lower Arches will each be marked with a Zero (0), reflecting the initial position of prescribed repositioning bite.

   For the ProSomnus [CA] Sleep and Snore Device
   1. Lower Arch (L)
   2. Upper Arch with Expansion Screws
   3. Lower arches will have the advancement label on the left posts.
      a. The initial Lower Arches will be marked with a Zero (0), reflecting the initial position of prescribed repositioning bite.
      b. The Upper Expansion Screw is set at 0.0mm which represents the patient’s initial bite position.

4. Place the Upper and Lower Arches together as one device. Ensure the lower posts are in front of the upper posts. Place into the mouth and seat the device on to the teeth.
5. Alternatively insert the arches separately. First, insert the Upper Arch:
   a. Patient uses thumbs and forefingers to push the Upper Arch with Expansion Screws securely onto upper teeth.
6. Second, insert Lower Arch:
   a. Patient should open wide and repeat the same process to push the Lower Arch (L) onto lower teeth. DO NOT CLOSE without moving lower jaw forward. Move lower jaw forward, then close slowly. The Lower Arch posts pointing upward belong in front of the Upper Arch posts that are pointing downward.

For the ProSomnus [PH] Sleep and Snore Device
1. Lower Arch and Upper Arch connected with Herbst Arm.
   a. The Herbst adjustment nut is set at Zero (0), reflecting the initial position of prescribed repositioning bite.
2. Place the Upper and Lower Arches together as one device. Ensure the Herbst Arms are evenly positioned. Place into the mouth and seat the device on to your teeth.
3. Gently relax your jaw and settle down for a restful night.
4. To remove the device, first loosen the Lower Arch. Gently open your mouth and place your thumbs into your cheek areas below the fin on both sides of the device.
5. Apply even, upward pressure at the side edges of the device to lift off of your teeth.
6. Repeat the same process for the Upper Arch by applying downward pressure, using your index fingers.
7. Once the upper and lower arches are freed from your teeth, remove the device all together.

Note: Do not remove one-handed, this will place unnecessary torque on the device frame and can cause breakage.

⚠️ Warning: The individual arches of the ProSomnus Device should never be worn separately. Always wear both Upper and Lower devices together.

⚠️ Warning: Store out of reach of small children.

Note: Dogs are attracted to the smell of oral devices. Keep out of reach of dogs.

**HOMECARE INSTRUCTIONS**

Note: Sterilization is not required for this device.

**Daily**
1. Each morning after use, thoroughly clean the ProSomnus Sleep Device using a regular soft toothbrush, cool or warm water and mild detergent, such as orthodontic device cleaners, or antibacterial liquid soaps. Do not use denture cleaners, as they may be too harsh.
**Warning:** Do not clean the appliance in hot or boiling water. This can cause the PMMA material to warp.

2. Rinse thoroughly and dry the appliance completely before storing in the container. It may help to leave the container open to ensure that the devices dry thoroughly.

3. Daily soaking of the devices is not necessary, nor recommended.

**Note:** Water can etch the surface of the PMMA and leave mineral deposits. Mouthwash or concentrated bleach solutions can permeate the PMMA material.

**Storage**
ALWAYS keep out of reach of small children and pets.

**Warning:** The ProSomnus Sleep Device should be stored in a cool, dry place. The device is made from materials that should not be stored where temperatures exceed 104°F, such as in cars, direct sunlight, etc.

**Warning:** The ProSomnus Sleep and Snore Devices are FDA cleared medical devices. You must not tamper with it other than following the specific instructions in this booklet.

**PACKING CONTENTS**
Each ProSomnus MicrO₂ and [IA] Sleep and Snore Device Package Contains:
1 or more Lower Arches
- Identified by inscribed (L)
1 or more Upper Arches
- Identified by inscribed (U)
Upper and Lower Arches will have the advancement measurement labeled on the sides
- The initial Upper and Lower devices will be marked with a Zero (0), reflecting the initial position of the prescribed lower jaw repositioning bite.
- Additional series devices will be included per dentist prescription. These will be marked with a number that reflects the prescribed advancement positions in (mm) increments and in relation to the initial bite position.

Instructions for use
Storage case(s)

Each ProSomnus [CA] Sleep and Snore Device Package Contains:
1 Upper [CA] Arch with Expansion Screws
1 Lower Arch
- Identified by inscribed (L)
- Lower Arch will also have an inscribed number (e.g. L0)
Patient Instructions for use
Storage case(s)

Each ProSomnus [PH] Sleep and Snore Device
Package Contains:
1 Upper [PH] Arch and 1 Lower [PH] Arch connected by the Herbst Arm
Adjustment wrench
Instructions for use
Storage case(s)

MANUFACTURING REQUIREMENTS
Repositioning Bite Registration
A Repositioning open bite at a protrusive position.
Bite registration material must extend to cover the full length of the arch.
Needs to represent the correct midline position, as determined by the prescribing dentist.
Needs a minimum of 3.0mm occlusal table clearance to allow for upper and lower flat plane coverage.

ProSomnus Sleep Device Prescription
Please identify the advancement iterations you require.
Please sign your prescription.

Accurate U/L Full Arch Models or Impressions
Must capture distal surfaces of terminal molars.
Recommend PVS impression material.
Digital Impression Policy: ProSomnus receives digital impressions. For quality assurance purposes, sleep devices made from digital impressions are fit against a 3D printed model of the digital impression.
Device is designed to fit stone models from impressions, always test fit on models.

Note: ProSomnus [CA] Sleep Devices require 8.0mm of dentition height on the upper arch to accommodate the expansion screw. If minimum is not met, options are to increase vertical or select an alternate ProSomnus Sleep and Snore Device.

IMPORTANT SAFEGUARDS
(SAVE THESE INSTRUCTIONS)
The following words in this manual have special significance:

⚠️ Warning: Means there is a possibility of injury to yourself or the device.

Note: Indicates points of particular interest for more efficient use and convenient operation.
Indications
The ProSomnus Sleep Devices are intended to reduce night time snoring and mild to moderate Obstructive Sleep Apnea (OSA) in adults. There may be a fully embedded Compliance Sensor in the lower arch device. This Sensor does not affect the intended use for the treatment of mild to moderate OSA. The Sensor does not affect the care of the device. To learn more about the Sensor and how it works, please visit ProSomnus.com.

Contraindications
As with all jaw repositioning devices, these devices are contraindicated for patients who have loose teeth, advanced periodontal disease, or lessened tooth stability due to orthodontic treatment. Further, these devices are contraindicated for patients having Central Sleep Apnea, or severe respiratory disorders.

⚠️ WARNINGS

Device Warnings
Note: Read all warnings and be sure to advise your patients of warnings, side effects, and safety measures before inserting the ProSomnus Sleep Device.

1. The ProSomnus Sleep Devices are intended to reduce night time snoring and mild to moderate Obstructive Sleep Apnea (OSA) in adults. There may be a fully embedded Compliance Sensor in the lower arch device. This Sensor does not affect the intended use for the treatment of mild to moderate OSA. The Sensor does not affect the care of the device. To learn more about the Sensor and how it works, please visit ProSomnus.com. If symptoms of breathing difficulties or other respiratory disorders occur, exist or persist, with or without the use of the device, the patient should contact their prescribing dentist or medical physician immediately. If wearing the device during this occurrence, it is recommended to remove the device until they communicate with their prescriber.

2. Patients may experience excessive salivation. This is normal for the first few weeks, but if it persists, you should contact your prescriber.

3. Patients may experience soreness or discomfort in their jaw, inside cheeks or teeth. If discomfort persists, they should discontinue wearing the device and contact their prescriber.

4. Patients may feel a change in their bite in the morning. It is recommended to gently squeeze their back teeth together until their bite feels correct. This sensation should disappear within one hour, each day. If it continues for more than four hours, they should contact...
5. The ProSomnus Sleep Devices allow your patients to open their mouth and breathe during sleep. However, if they experience obstruction of oral breathing, they should remove the device and contact their prescriber.

Note: Patients should return to their prescriber at least yearly, or as often as necessary for evaluation of effective positioning, dental and bite evaluation, device fit, and material evaluation. If they experience any problems with their ProSomnus Sleep Device; becoming loose, damaged, or improper fit, they should contact their prescriber.

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

POSSIBLE SIDE EFFECTS
As with all jaw repositioning devices, there are possible side effects associated with using the ProSomnus Sleep Device. These side effects are not common and can usually be remedied or managed together with the assistance of the prescriber. However, if left unattended or untreated, some side effects can become difficult to reverse or become permanent. If your patients experience any of the following side effects, they should contact their prescriber immediately.

- Slight tooth or gingival discomfort due to pressure of the appliance. This can usually be adjusted by their prescribing dentist.
- Slight jaw soreness or tightness, both in the beginning and with each initial seating of the Upper Series’ Advancement Devices. This is usually temporary, but if it persists, they should contact their prescriber.
- Newly discovered bite change. Each morning your patients’ muscles need to resettle their jaw into their original closed bite position. It is recommended that they gently squeeze their back teeth together until their bite feels correct. This sensation should disappear within one hour, each day. If it continues for more than four hours, they should contact their prescriber.
  - Left unattended, this could lead to permanent bite change.
- Device falling out, or they may unconsciously take the device out of their mouth during the night.
- Movement of teeth.
- Pain in the jaw joint.
• Permanent bite change.
• Possibility of loosening crowns.

**WARRANTY AND REPAIR**
Terms and Conditions
ProSomnus Sleep Devices carry a service warranty of 3 years* from date of manufacture for a one-time repair, reline, or replacement per arch. Non-standard designs are not warranted. Upon repair or reline, the service warranty is retired. Upon one-time replacement, the remainder of the original warranty period, from original date of manufacture, remains intact.

**ProSomnus [PH] Herbst-style Sleep Devices**
After structural review of the case, all Herbst-style parts should be replaced by the prescribing dentist. ProSomnus offers a ProKit for purchase which includes all Herbst-style replacement parts. Please return any defective parts to ProSomnus for investigation.

*ProSomnus [PH] carries a best in class service warranty of 3 + 2 years for Medicare patients. Please contact ProSomnus to arrange verification of patient’s Medicare coverage.*

ProSomnus.com (Terms and Conditions Section)
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U.S. Patent No. 9,808,327
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