

The OASYS® system Technical Information

The OASYS Oral Airway System is custom made for the individual patient on prescription by a qualified health professional. This device is intended for use for treating snoring and/or sleep apnea. This device is a removable medical device to be fitted in the patient's mouth as a mandibular repositioner and as a nasal dilator. This device is intended for use during sleep to aid in the treatment of snoring and sleep apnea by means of mandibular and tongue repositioning and by acting as a nasal dilator. Simple snoring is a form of sleep disorder breathing in which there is narrowing of the upper airway, which leads to end inspiratory noise produced by the vibration of the pharyngeal soft tissues. This device is not indicated for the treatment of central apnea.

The OASYS Oral/Nasal Airway System™ is designed to open the entire upper airway with one system through synergistic dual action that reduces upper airway resistance from nose to throat, and prevent airway collapse.

The OASYS Oral/Nasal Airway System™ functions to:

- Act as a mandibular repositioner
- Act as a nasal dilator

The OASYS Oral/Nasal Airway System™ is the first dental device to be reviewed by both the Dental and ENT divisions of the FDA and to be approved as a dental device for treatment of snoring and sleep apnea through mandibular repositioning as well as a nasal dilator for reduction of nasal resistance and improved nasal breathing.

The OASYS Oral/Nasal Airway System™ is designed to achieve these functions with the following goals:

- Maintain maximum intraoral volume.
- Minimize the force on the teeth.
- Have no components that extend extra orally through the lips.
- Reduces upper airway resistance.
- Allows mouth breathing to occur, if required.

MAXIMAL INTRAORAL VOLUME

The OASYS Oral/Nasal Airway System™ maintains maximal tongue space by positioning the connectors and adjustment components outside of the dental arch leaving the palate and anterior oral space completely free for the tongue to position itself up and forward. There is an open space for the tongue to go between the incisor teeth.

THE OASYS ORAL/NASAL AIRWAY SYSTEM™ REDUCES THE FORCES ON THE TEETH BY DESIGN.

The OASYS Oral/Nasal Airway System™ fits securely onto the lower arch only. The upper flange extends in front of the upper arch and under the upper lip. This maintains a slippage during mandibular movements during usage. There is a natural give to the wires that creates a yielding give when the mandible pulls back on the device. Provided is an upper splint that distributes the forces through the entire arch. Together these act to reduce the forces on the teeth.

INSTRUCTION FOR IMPRESSION AND BITE REGISTRATION

Alginate impressions of the upper and lower dental arches are taken with careful attention to extend the impression up to capture the vestibule of the maxillary arch. The impressions are poured in dental stone.

A bite registration is taken in wax or a fast set dental impression/bite registration material (such as Blu-Mousse (thixotropic vinyl polysiloxane). with the mandible brought forward so that the incisor teeth are aligned edge to edge and the bite is open 3-4 mm. This will be the starting point for the mandibular repositioning.

INSTRUCTIONS FOR FITTING THE OASYS ORAL NASAL/AIRWAY SYSTEM™

Step 1. Upper Splint Fitting

Remove the device from the container. (There are two parts the device itself and the upper splint.)

Begin by fitting the upper splint over the upper dental arch as you would for a periodontal splint or an orthodontic retainer. If the splint is too tight use crown cutting scissors and shorten the length of the material in the area that feels tight. The most common area is the area labial region in the canine and incisor teeth region.

Step 2. OASYS Oral/Nasal Airway System™ Fitting

The device is oriented for insertion. Have the patient open their mouth and seat the lower segment over the lower arch. With your index fingers over the occlusal surface of the lower portion of the device, seat the device onto the teeth as one would seat a lower splint. If there are undercuts preventing this

seating remove them with an acrylic bur on a slow speed hand piece or a lab motor. Continue to adjust the fit until the device fits firmly in place. It should fit securely without too much pressure on any individual area.

Step 3. Seating the OASYS in the Mouth.

Give the patient a hand mirror to begin their training for the insertion of the device.

The upper segment should be introduced into the oral cavity by bringing the mandible into the forward position and closing down as best as one can. With the index finger into the corner of the lip, bring the lip over the nasal labial button on one side and then repeat on the other side.

An alternative to this is to position the upper segment first. Angle one nasal labial button under the corner of the lip into position and then rotate the device into position on the other side to get the nasal button under the other lip and the upper segment into position against the upper teeth. Instruct the patient to bring the mandible into position with the path of insertion of the lower segment and snap the lower segment into place over the lower teeth with your index finger. Remove the device by having the patient open with the mandible protruding and lifting the OASYS up at the lower front corners.

Step 4. Adjusting the Mandibular Position

Instruct the patient to bring their mandible forward near the maximal position. Push the upper section against the upper anterior teeth. With the patient maintaining the forward position remove the OASYS from the lower arch. While maintaining the relationship between the upper and lower segments, loosen one of the locks just enough to slide the locking collar along the wire up against the tube and tighten the screw to lock the collar securely. Repeat this for the other side.

Reinsert the OASYS into the patient's mouth and check the position making adjustments in the position until desired repositioning is achieved.

Step 5. Adjusting the Nasiolabial Buttons

To adjust the position the initial adjustment can be made with the OASYS before inserting it in the patient's mouth. Further adjustments can be made by having the patient keep their mouth closed while opening their lips enough to introduce your index finger through the lips and bend the button in the desired direction. Next check the amount of stretch on the tissue and adjust to get a moderate stretch without discomfort.

Have the patient breath through the nose for a few minutes. This should become easier after a brief period of use. If you have instrumentation to measure the nasal volume such as Acoustic Rhinometry the initial readings should be made prior to fitting with the after treatment readings made after a few minutes of usage to appreciate the effect.

Patient education is an important part of the treatment. All dental devices are foreign objects that the patient has to get used to. Ideally a person would breathe easily all night long without any type of aid. Dental devices are the gentlest and kindest treatment for this serious disorder that has great potential to lead to many life-threatening diseases. Patients will usually be very happy to use the OASYS Oral/Nasal Airway System™ and see its advantages when they appreciate that this device is opening the nose and throat at the same time. Showing them the effect though instrumentation or on the grafts provided are great educational tools for you to use.

Very few patients have trouble adapting to the nasal dilators and they may be removed and OASYS Oral/Nasal Airway System™ makes an excellent mandibular repositioner that maintains its advantages of full oral volume and gentleness on the teeth.

Instructions for the professional to provide the patient.

Trouble shooting.

Problem: Can't position the device over the teeth without inserting the upper portion fully in place.

In this case it is necessary to guide the upper portion in front of the upper teeth and under the upper lip and then snap the lower section into place over the lower dental arch. It may be necessary to loosen the locking collar and pull the upper segment forward.

Problem: The fit is too loose.

If the device fits over the teeth but is not secure on the teeth it may be necessary to add a layer of acrylic to the inner surface of the lower segment.

Mix clear orthodontic acrylic to a loose creamy consistency and load the inside of the lower portion with just enough material to spread and provide a thin coat of acrylic (usually about 1/3 of the volume). Allow the vapors to dissipate for about 10 seconds. Place the device into the mouth and seat firmly onto the teeth. Hold it in place for one minute. It is very important not to leave it in too long and allow the acrylic to completely set up. Remove and check for proper impression of the teeth without any pull away of material or tearing from an undercut.

Place in warm water or preferred a pressurized pot for about 5 minutes.

Reduce any obvious undercuts and repeat fitting.

Instructions for cleaning and maintenance should be given to the patient:

- Clean daily by brushing with any standard toothpaste or liquid soap.
- The OASYS Oral Airway System can be stored dry in its case
- If you have a dog be careful to keep device in a closed drawer so that the dog doesn't destroy the device

Side effects that might occur while wearing dental devices for sleep apnea. These side effects should be reviewed verbally and in writing with the patient

Side effects:

- Tooth movement or changes in dental occlusion
- Gingival or dental soreness
- Pain or soreness to the temporomandibular joint
- Obstruction of oral breathing
- Excessive salivation

In almost all cases, these conditions are easily addressed and resolved, most never occur and if they do, they do not last beyond the initial period of using the device. The doctor should review with the patient the side effects and instruct the patient to contact the doctor and discuss the situation or schedule a visit if there are any concerns. The patient should be seen for follow up visit 7-10 days following delivery of the device and again after 30 days. The patient should be seen every 6 months in order to be re-examined to review status and check for TMJ and dental condition.

Prescription Device

Caution: Federal law restricts this device for sale by or on the order of a physician.

Contraindications

The device is 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

Precautions

Dentists should consider the medical history of the patients, 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.

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