

PRODUCT PROFILE

NAME OF PRODUCT: OASYS® Oral / Nasal Airway System

MANUFACTURER: Dream Systems, LLC

BRIEF DESCRIPTION: The first dental device for snoring and obstructive sleep apnea that treats the two major causes of sleep disordered breathing by addressing upper airway resistance in the nasal region and blockage in the throat region.

BENEFITS FOR DOCTOR'S OFFICE: The OASYS® Oral/Nasal System strengthens the throat area by pulling the lower jaw and tongue forward to prevent the tongue from blocking the airflow and strengthening the throat against collapse. The OASYS also has the dual function of opening the path of air through the nose. The nasal button creates a gentle stretch of the upper lip region putting a traction on the inner nasal tissue to dilate the nose increasing the nasal volume up to 300% and reducing the resistance up to 80%.

BENEFITS FOR PATIENT: A good nights sleep!

WHAT TO SEND LABORATORY: Lower alginate full arch impression
PVS putty border molding of posterior ventral surface of tongue and mylohyoid region
Upper alginate full arch impression including complete anterior labial vestibule for the nasal button placement
Bite registration at 80% protrusive

INDICATIONS: Snoring
Mild to Moderate Obstructive Sleep Apnea, validated by PSG (AHI 10-30)
Non-compliant Mild to Moderate OSA
Severe OSA with failed CPAP

CONTRA-INDICATIONS Central Sleep Apnea
Severe respiratory disorders
Advanced periodontal disease/loose teeth
Under the age of 18



PREPARATION INSTRUCTIONS: Lower alginate full arch impression
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DAYS IN LAB: 5

SEATING INSTRUCTIONS: Insert and adjust upper splint with scissors.
Insert lower appliance and adjust undercuts with acrylic bur.
Evaluate mandibular protrusion - accepted range is 60-80%. Adjust by pulling the connecting wire through the tube which moves the upper flange in a posterior direction and locking it in place with the locking screw/adjustment collar.
Adjust nasal-labial buttons by bending the attachment arms with orthodontic pliers.

AFTER CARE: Clean daily by brushing with any standard toothpaste.
Appliance may be stored dry in its case.
If you have a dog, keep appliance stored in a drawer.

INSURANCE CODE: Medical insurance codes may need to be used

CHAIRSIDE INSTRUCTIONS: Possible side effects include:
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 past the initial period of using the device. Patient should be advised to contact their dentist if there are any concerns. Patients should be routinely seen for a follow up visit 7-10 days post insertion.

TESTIMONIALS & QUOTES:

See website / testimonials - www.oasysleep.com

CLINICAL TESTING:

Passed all clinical trials for FDA approval.
OASYS is the only oral appliance FDA approved for both
functions of mandibular repositioning as well as nasal dilation.

UNIVERSITY REPORTS

12 page bibliography of references available upon request.