Anti-Snoring and Sleep Apnea Devices

Patient Instructions & Information

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1. Device Description:

DynaFlex® Anti-Snoring & Sleep Apnea Devices are intraoral devices used for treating snoring and sleep apnea, and consist of two custom fitted trays which fit over the upper and lower teeth and engage by means of adjustable lugs, or by the Herbst® mechanism which is a rod and tube assembly that orientates the jaws in a predetermined relationship. These devices function as a mandibular re-positioner, which acts to increase the patient's pharyngeal space, improving their ability to exchange air during sleep. The devices are custom made for each patient and have the ability of the adjustment mechanism, which enables the amount of mandibular advancement, to be set by the patient's dentist or physician at the time of fitting the device. The devices are sold by prescription only.

The functional relationship built into the devices acts to position the lower jaw forward and open vertically from its normal location which causes a protrusion of the mandible in relation to the maxilla. This forward repositioning, which is temporary while the appliance is being used, increases the pharyngeal space which assists the patient with improved air exchange. The prescribing dentist or physician determines the exact repositioning of the lower bite via a wax construction bite obtained from the patient in the clinic. The dentist or physician is also able to fine tune the jaw positioning clinically as needed by altering the Herbst® mechanism and/or adjusting the acrylic portions of the appliance.

2. Appliance Selection, Sleep Study, Device Exam & Prescribing:

The selection of the appropriate snoring/sleep apnea appliance will depend on patient and/or doctor preference. While the appliances may look different the basic function of the appliance remains the same and therefore, most appliances will achieve very similar results.

It is imperative that each patient have a sleep study completed prior to prescribing an intraoral appliance for use. The sleep study will determine the level or severity that the patient is currently experiencing and this information should be used by the prescribing dentist to determine the needed device.

Each patient should be subject to a complete and comprehensive dental exam prior to prescribing a snoring or sleep apnea device. Once the patient has undergone a comprehensive dental exam complete with full records and a sleep study than the dentist can accurately prescribe a snoring or sleep apnea device.

3. Indications for Use:

DynaFlex® Anti-Snoring & Sleep Apnea Devices are intended to reduce night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults. The devices are worn while sleeping to support the lower jaw in a forward position prescribed by the dentist, and is removable by the patient.

4. Contraindications:

- Have central sleep apnea.
- Have loose teeth or advanced periodontal disease.
- Are under 18 years of age.

5. Warnings:

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

6. Precautions:

Patients with a history of asthma, breathing, respiratory disorders, or other relevant health problems, should discuss the use of these devices with their healthcare provider before using them.

7. Operating Instructions

The appliance should be placed in mouth prior to sleeping. The appliance should remain in for the entire sleep period.

A. Cleaning – Brush with toothbrush and toothpaste before each use

B. Storage – Store dry in provided case when not in use.

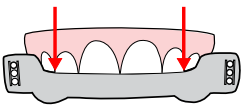
C. Fit Adjustment – All adjustments should be done by the prescribing dentist or physician.

D. Product Life & Replacement – Expect a 2-3 year product life with the appliance. Appliance replacement signs are; cracks in the acrylic and failure of the device to maintain retention in the patient's mouth. If one of these problems occurs please return the appliance to your doctor/dentist for evaluation and potential replacement.

⚠ WARNING

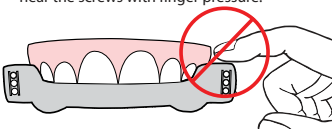
TO PROPERLY REMOVE

Using both index fingers, pull down in the front area of the upper appliance.



TO AVOID BREAKAGE

DO NOT pull down the back of the appliance near the screws with finger pressure.



DynaFlex®

NADL National Association of Dental Laboratories

ISO 13485 MEDICAL

AAOF CORPORATE PARTNER

IFU (C) rev. D (04/2019)