



# **Anti-Snoring and Sleep Apnea Devices**

Doctor/Dentist Instructions For Use

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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 industry standard Herbst mechanism which is a rod and tube type 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 to be 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 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.

DynaFlex® Anti-Snoring & Sleep Apnea Devices are offered in different models called the Dorsal Appliance and the Herbst Appliance. The fundamental difference in these devices is explained below.

### Dorsal Appliance

1. The Dorsal is a two-piece design with separate upper and lower acrylic portions that when engaged posture the mandible into protrusive position via acrylic fins built in the lower acrylic portion.
2. The Dorsal is an adjustable design utilizing advancement screws on the upper acrylic portion. The screws allow the doctor the ability to adjust the mandible to the most desirable position.
3. The separate two piece construction is desirable for patients that want greater range of motion and lateral excursion.

### Herbst Appliance

1. The adjustable Herbst is a one piece construction held together by two adjustment mechanism on the buccal or outer are of the upper and lower appliance.

2. The adjustment mechanisms are designed for the doctor to incrementally advance the mandible to the desired position.
3. This appliance is desirable for the patient that wants a minimal amount of acrylic to preserve as much tongue space and would like the adjustment capability.

## **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:**

Dentists should consider the medical history of their 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. Patients should be evaluated for severe obstructive sleep apnea as well as central sleep apnea which are important contraindications for use of this device.

## **7. Appliance Fit & Adjustments**

The dental staff or dentist should remove appliance from the packaging and rinse under water. Then place the device in patient's mouth, checking for proper fit and function of the appliance. The appliance adjustments should always be performed by the prescribing dentist. Any adjustments in the fit of the device should easily be made chair-side to ensure that their patient is pleased with the fit and function of their new appliance.

## 8. Guidance on mandibular opening:

Standard mandibular opening for a snoring/sleep apnea device is 3-4mm between the maxillary and mandibular teeth. This allows for increased air volume and facilitates airway opening.

## 9. Guidance on mandibular advancement:

Standard mandibular advancement for a snoring/sleep apnea device is situation dependent. Generally, the mandible is advanced between 5-7mm from the patient's centric occlusion for proper appliance construction. Typically, the forward mandibular position will cause increased air volume in the patient's pharyngeal space.

## 10. Operating Instructions:

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

- Storage – Store in provided case when not in use
- Fit Adjustment – All adjustments should be done by the prescribing dentist or physician
- 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. Once you have determined the need for a new appliance, please send a new prescription with a new set of models and bite.

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 **DynaFlex®**

online: [www.dynaflex.com](http://www.dynaflex.com) toll free: **800-489-4020**

