

Doctor / Dentist

Instructions For Use

Anti-Snoring
& Sleep Apnea
Devices



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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

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. 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. The separate two piece construction is desirable for patients that want greater range of motion and lateral excursion.

Herbst® Appliance

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. The adjustment mechanisms are designed for the doctor to incrementally advance the mandible to the desired position. 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.

- 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 3-5 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.

ACCU-FIT™

Instructions And Warranty Information

Instructions For Doctor Only

Use the processes below only as needed; the patient should
NEVER heat the device on their own.

Accu-Fit™ Material Instructions

For Milled DynaFlex Dorsal®, Adj. Herbst®, DreamTAP®, and TAP3®

Standard Delivery:

Following this procedure ensures a perfect fit in a matter of minutes each and every time.

1. Place in 160 degree water for approximately 3-5 seconds
2. Immediately place heated device in the mouth.
3. Allow device to cool in mouth for 10 seconds
4. Remove device and finish cooling liner with cold water until white.

New Crown/Bridge Delivery:

Always have opposing device in mouth when reforming to new dentition to maintain current dimensions.

1. Place device in 160° water until liner turns clear (10-15 seconds).
Caution: If water is too hot device will warp.
2. Once the liner is clear, quickly remove the device and allow cooling for approximately 10 seconds.
Caution: If white spots start to show, re-heat until clear again.
3. Fit heated device to new dentition, be sure opposing device is in place.
4. Once seated, cool the Accu-Fit with short bursts of air (an air/water syringe).
Cool in mouth for 30-60 seconds.
Caution: DO NOT leave device unattended, device will permanently lock onto teeth if fully cooled in mouth and will have to be cut out.
5. Once removed from mouth, trim (do not pull) away the flashed excess material from the device with curved scissors.
6. Finish cooling the liner with cold water or freeze spray, until fully white again.
7. Using a polishing brush, remove the reaming edges of the liner and smooth.

Medical Device Warranty

DynaFlex® Sleep Devices

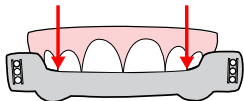
DynaFlex® warrants all DynaFlex® Oral Sleep Apnea Devices supplied to be free from defects in materials and in fabrication for a period of 36 months from the date of delivery to the providing medical practitioner. This device is meant for treating snoring and Obstructive Sleep Apnea at the source; however DynaFlex® does not make any guarantees regarding the outcome treatment for Obstructive Sleep Apnea.

- The DynaFlex® Warranty is invalidated if the Medical Device needs to be re-made due to change in the patient's oral anatomy.
- The longevity of the Medical Device is left up to the patient once received from the providing Dentist. The DynaFlex® Warranty is invalidated if the patient breaks a particular area on the Medical Device that cannot be repaired and therefore the Medical Device needs to be remade.
- Repairs not covered under warranty include, but are not limited to: clasp repair, bite resets, new device mechanisms (i.e. Dorsal® screw or Herbst® arm), relines, and other damages not caused by fabrication defects, i.e. distorted models, bad bite registration from office, calculus deposits, and device modifications made by non DynaFlex® authorized technicians.

WARNING

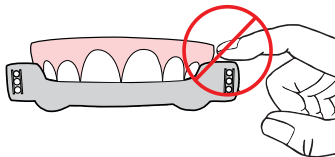
TO PROPERLY REMOVE

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.





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