GERGEN'S
ORTHODONTIC LAB

Caution: Federal law restricts this device to sale by or on the order of a dentist

Indications for Use

The Acrylic Herbst Appliance is intended for the reduction of night time snoring and mild to moderate obstructive sleep apnea (OSA) in adults 18 years of age or older.

Device description

The Acrylic Herbst Appliance is a removable, intraoral device which is customized for each patient. The device is designed to reposition the patient's mandible into a forward position. This increases the pharyngeal space and therefore improves the patient's ability to exchange air during sleep.

Package contents:

- Herbst appliance
- Titration Key
- Protective case
- Allen wrench for attachment screws

Directions for Use

The device is comprised of customized acrylic splints which are bilaterally connected via a telescoping Herbst mechanism. The post and sleeve mechanism advances the jaw into a forward position. If the desired relief is not immediately achieved, this design allows for additional forward movement of the mandible. The telescopic arms allow the clinician to advance the mandible more precisely. The threaded system provides advancement in 1/16 millimeter (mm) increments. For example, a 90 degree turn of the advancement collar until the next hole appears results in 1/16mm of jaw translation. Therefore a 180 degree turn is 1/8mm of translation. The mechanism will gradually allow up to 5mm of movement. Please be aware that the (+) and (-) symbols on the advancement sleeve indicates the direction of advancement: (+) advances and (-) retracts. NOTE: This device should only be fitted and titrated by the prescribing clinician.

It is recommended for the patient to have a follow-up visit after 7-10 days of initial use, then again at 30 days, and then every 6 months to ensure fit and effectiveness of the device.

Warning

Use of the device may cause any of the following conditions listed below. If any of these complications occur, the patient should immediately discontinue use of the device.

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

Material information

The Acrylic Herbst Appliance components are manufactured from methylmethacrylate and stainless steel. These materials are biocompatible, corrosion-resistant and non-toxic under biological conditions.

Contraindications

The device is contraindicated for patients who:

- are under 18 years of age
- have with central sleep apnea
- have severe respiratory disorders
- have loose teeth or advanced periodontal disease
- are not able or capable of adhering to the aftercare instructions due to their mental state

Precautions

- The prescribing dentist 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 a physician before prescribing the device.
- This product should only be used by a dentist experienced in the field of sleep disorders.
- The prescribing dentist should consider performing a temporomandibular joint (TMJ) examination prior to using the Acrylic Herbst Appliance to insure that the patient is not predisposed to TMJ risks that use of the appliance could aggravate further.
- The patient must be given detailed information on the risks involved with the appliance use.
- The prescribing dentist should discuss with the patient the result expected from the use of this product. The patient must therefore be instructed about risks in daily usage, the possible complications (as listed under “Warnings”) and any special behavior that may be necessary for the safe use of the device. Compliance with the dentist’s instructions is required. Special attention should be paid to the necessity of regular follow-up examinations.
- The prescribing dentist must provide a copy of the patient “Instructions for Use” to the patient at the time of device fitment and delivery.
- The product must be handled and stored with care. Damage or scratches on the appliance can considerably impair the strength of the product and its resistance to fatigue.
- The patient should be instructed to inform their dentist immediately regarding any unusual changes in the appliance. The patient should be monitored in case any changes appear in the regions adjacent to the device. The dentist must then evaluate whether clinical failure of the device has occurred and discuss with the patient any necessary measures which must be taken.

Product Complaints:

Any dissatisfaction with the product quality, labeling or performance should be reported to Gergen’s Orthodontic Lab immediately. Furthermore, if the device "malfunctions," (i.e., does not meet any of the performance specifications or does not perform as intended) and may have caused or contributed to the death or serious injury of the patient, Gergen’s Orthodontic Lab should be notified immediately by telephone, fax, or written correspondence. When filing a complaint, the product name and the prescribing dentist name should be provided along with the name and address of the person filing the complaint.

For additional information, please contact:

Manufactured by:

Gergen’s Orthodontic Lab, Inc.
Sleep Appliance Division
1745 West Deer Valley Rd, Ste. 112
Phoenix, AZ 85027

Phone: 623-533-3202
Fax: 623-879-6166