

## **INFORMATION FOR DENTISTS**

### **INDICATIONS FOR USE**

The Express 4 Sleep appliance is intended for use on adult patients 18 years of age and older for the temporary or trial treatment of snoring and mild to moderate obstructive sleep apnea. For prescription use only (RX only), **to be used for a maximum of 30 consecutive days.**

### **IMPORTANT SAFEGUARDS –SAVE THESE INSTRUCTIONS**

*The following words in this manual have special significance:*

**WARNING:** means there is a possibility of injury to your self

**NOTE:** indicates points of particular interest for more efficient and convenient operation

**CONTRINDICATIONS:** This device is contraindicated for patients with loose teeth, loose dental work, numerous missing teeth, dentures or other oral conditions that would be adversely affected by wearing an intraoral dental device which maintains the jaws in a protrusive jaw position. The Express 4 Sleep appliance is also contraindicated for patients who have central apnea, severe respiratory disorders, or are under eighteen years of age.

### **PRODUCT DESCRIPTION**

The Express 4aSleep appliance is a dental device in the category of mandibular advancement device. The Express 4 Sleep is a dual-layer oral mouthpiece. The inner layer softens in hot water, between 180-185°Fahrenheit and takes the shape of the posterior teeth for a snug comfortable fit. The outer layer remains stable in the simmering water and maintains the Express 4 Sleep's shape. It is customized to the patient's mouth based on the predetermined maxillo-mandibular relationship and is fit over maxillary and mandibular teeth. It is fit to the patient by a trained dentist.

The device characteristics of the Express 4 Sleep appliance are as follows:

- An interarch component, customizable to fit over the maxillary and mandibular teeth
- The prescribed protrusive jaw position is maintained by the labial flanges and by impressions of the maxillary and mandibular arches covered by retainers and processed into the interarch component
- By supporting the mandible in a protrusive jaw position, the Express 4 Sleep appliance passively advances the tongue
- There is an open area between the upper and lower anterior teeth
- This open area is to facilitate a forward tongue position against the lips. If the mouth is closed, the patient is nasally competent and nose breathing during sleep
- This open area facilitates mouth breathing if the patient is nasally incompetent and sleeps with their mouth open
- Opening and closing movements are permitted with the appliance in place
- By deterring collapse of the tongue on the airway when the patient is asleep the Express 4 Sleep appliance treats mild to moderate obstructive sleep apnea
- Maximum protrusion allowed by the Express 4 Sleep is 3 mm beyond "edge to edge"

### **Material Composition**

Body of the Express 4 Sleep appliance:

Ethylene-1-octene copolymer, Thermoplastic Elastomer, Lubricating Oil, Polypropylene Homopolymer, – Ethyl-vinyl acetate copolymer, Sodium aluminosulphosilicate

All materials are FDA and CAS approved as safe and biocompatible.

**NOTE: Read all instructions before using the Express 4 Sleep appliance.**

### **WARNINGS**

This device is intended for use on adult patients 18 years of age and older for the temporary or trial treatment of snoring and mild to moderate obstructive sleep apnea. For prescription use only (RX only), **to be used for a maximum of 30 consecutive days.**

- If symptoms of breathing difficulty or other respiratory disorders exist or persist with or without use of the Express 4 Sleep appliance patient should contact you immediately.
- Patient may experience soreness or discomfort in their jaw or teeth. If the discomfort persists, the patient should contact you.

- First thing in the morning the patient may sense a change in their bite. This sensation should disappear within one hour. If it continues for more than two hours, instruct patient to chew a piece of sugarless gum for 15-30 minutes or until their back teeth are meeting. If they cannot get back to their old bite and experience pain or discomfort trying, they should contact you.
- Under normal circumstances the patient should *not* experience obstruction of oral breathing with the Express 4 Sleep appliance in their mouth. If the patient experiences breathing difficulty with the Express 4 Sleep appliance in place, the patient should contact you.
- The patient should return to you, the dentist who fit the Express 4 Sleep appliance every six months for a re-evaluation. If the appliance becomes loose, damaged or does not fit properly at any time, the patient should contact you.

**POSSIBLE SIDE EFFECTS** - There are possible side effects associated with use of the Express 4 Sleep appliance. These side effects are not common. If the patient experiences any of the following side effects they should contact you, the dentist who prescribed and customized the Express 4 Sleep appliance.

- Slight tooth or gingival discomfort, due to pressure from the appliance
- Excessive salivation initially. This will improve as the patient becomes accustomed to wearing the Express 4 Sleep appliance
- Slight jaw soreness or tightness initially that will ease with wearing the appliance
- Morning sensation of bite change. This will subside between 30 minutes and 2 hours after the Express 4 Sleep appliance is removed. If this perceived bite change persists longer, chewing a piece of sugarless gum will usually correct this problem. If it does not, the patient should contact you, the dentist who prescribed and customized the Express 4 Sleep appliance
- Removing the Express 4 sleep appliance while the patient is asleep. This usually stops after an adjustment period
- Movement of teeth. Both the upper and lower are retainers. This would be a most improbable response. Should it occur, the patient should contact you, the prescribing dentist
- Permanent bite change. This should not occur with a timely call to you, the prescribing dentist when the patient first notices this symptom
- Allergic or toxic reaction to the materials in the appliance. If this occurs, the patient should discontinue use and call you, the prescribing dentist immediately

**Prior to prescribing and customizing the Express 4 Sleep appliance for a patient**, the dentist should consider the medical history of the patient including history of asthma, breathing or respiratory disorders or other relevant health problems. If a concern exists, the patient should be referred to the appropriate healthcare provider before prescribing and customizing the device.

#### **ORAL APPLIANCE PROTOCOL**

##### I) Medical Assessment

A) The patient sleeps with an FDA Class III HST and the report is analyzed and signed by a Board Certified Sleep specialist.

B) If the patient has obstructive sleep apnea, a sleep specialist or the primary care physician is consulted relative to the best treatment modality. If an oral appliance is indicated in the opinion of the patient's physician, a work order for one is signed.

C) A dentist with a written prescription for an oral appliance or written referral letter to the dentist with diagnosis expressed as part of a treatment plan, plus interpretation and summary report of sleep study, treats the patient with the oral appliance.

##### II) Dental Assessment

A) History – medical and dental

B) Examination by dentist

C) Consultation and treatment plan

D) Possible referral to original referrer or other medical specialist

E) Written report

##### III) Clinical Standards

The American Academy of Sleep Medicine has established as criteria for oral appliances to define successful treatment of obstructive sleep apnea syndrome:

- A) post-treatment Apnea-Hypopnea Index (AHI) 10 or below
- B) post-treatment AHI reduced by at least 50% from baseline AHI
- C) both criteria are met

IV) Clinical procedure

- A) Baseline objective testing - polysomnogram
- B) Maxillary and mandibular vacuum formed retainers, appliance customization of the Express 4 Sleep appliance, delivery of the Express 4 Sleep appliance
- C) Patient signs informed consent, given appliance instructions and patient exercise regimen
- D) Appliance adjustments
- E) Completion of treatment, written letter to sleep specialist explaining results, and recommendation for follow-up polysomnogram

V) Periodic Evaluation

- A) Six month recalls for two years following appliance fabrication to check effectiveness, fit, TMJ status and to check for possible tooth shifting or bite change
- B) Annual recall after initial one year period
- C) A caries screening is recommended at all recalls

If neither clinical standard for success as described in (III) above is met, the patient protocol is as follows:

- A) If greater protrusion is possible or greater vertical dimension is required, a new position is used to refit the body of the Express 4 Sleep appliance over the existing maxillary and mandibular vacuum formed retainers.

#### **CLINICIAN ADJUSTMENT OF THE EXPRESS 4 SLEEP APPLIANCE**

It is very important that patients be able to easily and smoothly insert and remove the Express 4 Sleep by themselves. Patients should be carefully queried to make sure the appliance is not irritating their soft tissue before they leave and instructed to come in immediately for adjustment if they develop a sore spot.

The Express 4 Sleep appliance is adjustable by the dentist for anterior mandibular movement. If greater protrusion is possible or greater vertical dimension is required, a new position is used to refit the body of the Express 4 Sleep over the maxillary and mandibular teeth.

The starting bite position for the Express 4 Sleep appliance should be a comfortable protrusive jaw position for the patient. It is recommended that patient comfort be a consideration in further anterior adjustment. The appliance should never be recustomized to a position in which the patient is uncomfortable either wearing it or in the morning after awakening. Efficacy should be monitored by objective measurement – a full polysomnographic study at a sleep lab.