

## **TERMS & CONDITIONS FOR PRESCRIBERS OF ORTHOAPNEA**

**The following information must be fully discussed with all patients before prescribing the ORTHOAPNEA appliance. By sending a prescription to Ashford Orthodontics Ltd for such a device, you will be confirming that you have adhered to these terms & conditions, and that the patient has given their consent to this treatment and will be bound by the information set out below.**

Dental Society for Sleep medicine – SEMODS [www.semods.es](http://www.semods.es)

### **Informed consent for the use of the ORTHOAPNEA device for the treatment of Snoring and Sleep Apnoea.**

The custom-made intra-oral mandibular repositioner from Orthoapnea is an alternative for the treatment of snoring, the syndrome of the increased resistance of the upper airway, and sleep apnoea, and respectively hypopnea.

There is enormous scientific evidence for the efficiency of the Orthoapnea device, and all international societies of sleep medicine recommend its use in certain cases.

The alternatives for the treatment of respiratory sleep disorders are the following:

1. The use of the continuous positive airway pressure (CPAP) by the CPAP-mask.
2. Intra-oral mandibular advancement devices
3. Surgical operations to the pharynx and the upper airways

### **Information about the ORTHOAPNEA mandibular repositioner device:**

The intraoral mandibular repositioner splint moves the mandible forward and arranges for its retention in this position during sleep, in order to extend the area of the upper airways. A restriction, or the total collapse of the upper airways, which could be the cause of snoring and possible Apnoea, is hereby avoided. Finally this allows an increase to the passage of airflow.

**The efficiency of the Orthoapnea device is very high**, both in relation to the decline/elimination of snoring and to the SAOS (obstructive sleep apnoea syndrome) has been proven in a huge number of studies. Nevertheless these studies declare that not all patients achieve a clear improvement. The examination of the upper airways helps to distinguish patients to whom a device treatment would be useful or to the contrary, where a surgical intervention is more appropriate. Surgical intervention however is not always reliable. Orthoapnea is a reversible treatment, which means its termination is possible at all times (compared with the surgical operation).

The therapeutic effect of Orthoapnea is only noted by wearing the device, which means if we cease to use the splint during the night, then all the typical symptoms of SAOS or snoring will appear again.

The Orthoapnea device is used directly onto teeth and as such should only be prescribed by a dentist, who has is competent in the area of sleep medicine. ([www.semods.es](http://www.semods.es)), Before beginning any treatment, a full dental examination is necessary, including a radiograph, so that

good dental health is confirmed. Furthermore the ORTHOAPNEA-user should visit their dentist regularly.

### **Possible side effects of ORTHOAPNEA.**

#### **1. Toothaches and pain at the temporomandibular joint (TMJ).**

In the first couple days of usage, pressure and slight pain on the teeth may be noticed, whilst removing the splint in the mornings. Also, slight modifications to the occlusion may be experienced, but this usually disappears within an hour or so, if the patient regularly performs masticatory movements. Because of the mandibular advancement, it is possible that the temporomandibular joint can initially become temporarily disturbed. All of these changes are usually very minor for most patients and only exist for a short space of time, but they can be the reasons why some patients choose to exclude such treatments. In exceptional cases these changes could become permanent (joint roaring or joint lesions with articular cartilage loss). This side effect is very seldom experienced, but not impossible to dismiss entirely.

#### **2. Excessive salivation.**

Possible excessive salivation disappears through regular and extended use.

#### **3. Movement of the dentition and changes in occlusion.**

In the midterm, it is possible that slight movements of the teeth may be noticed, which may lead to changes in the occlusion and the jaw profile, and in exceptional cases this can result in the termination of the use of ORTHOAPNEA or the beginning of an orthodontic reparation treatment (orthodontic or dental restorative etc.).

#### **4. Accidents.**

The possibility of swallowing the splint or its parts is extremely slight, but not impossible. Circumstances in which this could occur are: the patient being in a state of intoxication or their involvement in an aggressive act etc. The same is true in cases of loss or lesion of teeth caused by traumas while wearing the splint.

#### **5. Orthoapnea is a custom made device.**

Any change to the patients dentition, for example the insertion of crowns, bridges, implants or space restorations, will lead to the device no longer fitting correctly, and as such a new device would be needed at the patients expense.

### **Additional information:**

Some patients don't tolerate the extended use of ORTHOAPNEA: they may experience uncontrolled nausea, or have difficulties in falling asleep, or may experience psychological issues etc, but these non tolerance issues mentioned would not constitute a failure of the device and as such there would be no refund of treatment costs.

The relationship between these nominal treatment risks and the advantages which may be achieved should be kept in context. In cases of normal snoring, the possibility of the reduction or total elimination of the nocturnal roar should be remembered. For those patients who suffer from SAOS, the chance of a significant improvement or total elimination of all symptoms and related problems, must also be kept in context.

**Follow-up examinations:**

The best way to avoid these little-known side effects is to visit your Dentist regularly, so that any such irregularities are detected early. Every patient who wants to undergo this treatment, is obliged to seek special Odontological check-ups, whilst using the splint. These examinations should be carried out at regular intervals, as instructed by the clinician, and should become less frequent after the first year of treatment to longer intervals. Every patient should be assessed individually, although in general 1 or 2 check-ups should be carried out annually.

**IT IS ADVISABLE TO GET THE PATIENT TO SIGN THAT THEY HAVE HAD ALL OF THIS INFORMATION EXPLAINED TO THEM PRIOR TO COMMENCING TREATMENT. THIS FORM SHOULD BE PRINTED OFF, SIGNED BY THE PATIENT AND CLINICIAN, AND RETAINED WITH THE PATIENTS NOTES.**

**BY PRESCRIBING TO ASHFORD ORTHODONTICS, YOU WILL BE CONFIRMING THAT THIS HAS BEEN DONE AND THAT THE CLINICIAN AND PATIENT ARE HAPPY TO COMMENCE TREATMENT IN ACCORDANCE WITH ASHFORD ORTHODONTICS LTD TERMS & CONDITIONS.**

NAME OF CLINICIAN: .....

REGISTRATION No. OF CLINICIAN : .....

SIGNATURE OF CLINICIAN: .....

PRACTICE ADDRESS: .....

DATE: .....

I have read the terms & conditions and all other information about the use of this mandibular advancement device. The patient and I are happy to proceed, and that all elements of this treatment has been fully explained.

PATIENTS NAME.....

PATIENTS SIGNATURE: .....

DATE: .....