

## **INFORMED CONSENT FOR THE TREATMENT OF SLEEP-RELATED BREATHING DISORDERS WITH ORAL APPLIANCE THERAPY**

You have been diagnosed by your Physician as requiring treatment for a sleep-related breathing disorder, such as snoring and/or obstructive sleep apnea (OSA). OSA may pose serious health risks since it disrupts normal sleep patterns and can reduce normal blood oxygen levels. This condition can increase your risk for excessive daytime sleepiness, driving and work-related accidents, high blood pressure, heart disease, stroke, diabetes, obesity, memory and learning problems, and depression.

### **What is Oral Appliance Therapy?**

Oral appliance therapy (OAT) utilizes a custom-made, adjustable FDA cleared appliance specifically made to assist breathing by keeping the tongue and jaw in a forward position during sleeping hours. In order to derive the benefits of OAT, the oral appliance must always be worn when you sleep.

### **Benefits of Oral Appliance Therapy**

OAT has effectively treated many patients. However, there are no guarantees that it will be effective for you. Every patient's case is different, and there are many factors that influence the upper airway during sleep. It is important to recognize that even when the therapy is effective, there may be a period of time before the appliance functions maximally. During this time, you may still experience symptoms related to your sleep-related breathing disorder. Additionally, durable medical equipment such as your oral appliance requires specific homecare, maintenance and periodic replacement.

### **Possible Risks, Side-Effects and Complications of Oral Appliance Therapy**

With an oral appliance, some patients experience excessive drooling, difficulty swallowing (with appliance in place), sore jaws or teeth, jaw joint pain, dry mouth, gum pain, loosening of teeth, and short-term bite changes. It is possible to experience dislodgement of dental restorations, such as fillings, crowns and dentures. Most of these side effects are minor and resolve quickly on their own or with minor adjustment of the appliance.

Long-term complications include bite changes that may be permanent resulting from tooth movement or jaw joint repositioning. These complications may or may not be fully reversible once OAT is discontinued. These changes are likely to continue to worsen with continued use of the device.

It is mandatory for you to complete follow-up visits with the Dentist who provided your oral appliance to ensure proper fit and optimal positioning. If unusual symptoms or discomfort occur or if pain medication is required to control discomfort, it is recommended that you cease using the appliance until you are evaluated further. Follow-up assessments are necessary to assess your health and monitor your progress.

Once your oral appliance is in an optimal position, a post-adjustment assessment by your Physician is necessary to verify that the oral appliance is providing effective treatment.

### **Alternative Treatments for Sleep-Related Breathing Disorders**

Other accepted treatments for sleep-related breathing disorders include positive airway pressure (PAP) therapy, various surgical and implant procedures, and positional therapy (which prevents patients from sleeping on their back instead on their side). The risks and benefits of these alternative treatments should be discussed with your Physician who diagnosed your condition and prescribed treatment.

It is your decision to choose OAT alone or in combination with other treatments to treat your sleep-related breathing disorder. However, none of these may be completely effective for you. It is your responsibility to report the occurrence of side effects and to address any questions to this office



(address below), or to your Physician. Failure to treat sleep-related breathing disorders may increase the likelihood of significant medical complications and/or accidental injury.

**Patient's Privacy and Confidentiality**

I acknowledge receipt of the office's privacy policies. This includes a summary of the HIPAA federal law and the applicable state laws.

**Patient Obligations and Acknowledgements**

1. I understand the explanation of the proposed treatment. Further additional communication tools such as videos, pamphlets or articles may be available at my request.
2. I have read this document in its entirety and have had an opportunity to ask questions. Each of my questions has been answered to my satisfaction. If I do not understand this document, I have been offered this document in a different language or have been offered a language interpreter. My family alone is not acceptable to be my interpreter.
3. I agree that regularly scheduled follow-up appointments with my Dentist (oral appliance provider) are essential. These visits will attempt to minimize potential side effects and to maximize the likelihood of management of my OSA.
4. I understand that I must schedule a post-adjustment assessment with my Physician to verify that the oral appliance is providing effective treatment.
5. I will notify this office of any changes to the OAT, my teeth and my medical condition(s).
6. I understand that I must maintain my oral appliance through regularly scheduled follow-up appointments with my general dentist and my oral appliance provider dentist, if not the same.
7. I understand that if I discontinue OAT, I agree to inform and follow up with my Physician and Dentist (oral appliance provider).
8. I understand that refusing to participate and cooperate as stated herein will put my health at risk.
9. I consent to treatment with a custom-made, adjustable, FDA cleared oral appliance to be delivered and adjusted by my Dentist (oral appliance provider). I agree to follow all post-delivery and homecare instructions

Please sign and date this form below to confirm your agreement with the above statements. You will receive a copy of this document for your records, and it will be included in your patient records.

Patient Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

If patient is a minor, please sign as Parent or Legal Guardian

Signature: \_\_\_\_\_ Date: \_\_\_\_\_  
Parent or Legal Guardian

Print Name: \_\_\_\_\_

Witness Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

Dentist Acknowledgement  
Signature: \_\_\_\_\_ Date: \_\_\_\_\_

Print Name: \_\_\_\_\_

Office Name and Address and Contact Information:

Orthodontic Associates of Collegeville  
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