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## **Informed Consent for the Treatment of Sleep-Related Breathing Disorders with Oral Appliance Therapy**

### **Diagnosis**

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 a person's 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) for snoring and/or OSA attempts to assist breathing by keeping the tongue and jaw in a forward position during sleeping hours. 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.

*A post-adjustment polysomnogram (sleep study) is necessary to objectively assure effective treatment. This must be obtained from your physician.*

### **Side-Effects and Complications of Oral Appliance Therapy**

Published studies show that short-term side effects of oral appliance therapy may include excessive salivation, 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. There are also reports of dislodgement of ill-fitting dental restorations. 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 oral appliance therapy is discontinued. If not reversible, restorative treatment or orthodontic intervention may be required for which you will be responsible.

Follow-up visits with the provider of your oral appliance are mandatory to ensure proper fit and a healthy condition. If unusual symptoms or discomfort occur that fall outside the scope of this consent, or if pain medication is required to control discomfort, it is recommended that you cease using the appliance until you are evaluated further.

**Length of Treatment**

The oral appliance is strictly a mechanical device to maintain an open airway during sleep. It does not cure snoring or sleep apnea. Therefore, over time, the device must be worn nightly for a lifetime of effectiveness. The oral appliance needs to be checked at least once a year to ensure proper fit and the mouth examined at the time to assure a healthy condition. If any unusual symptoms occur, you are advised to schedule an office visit to evaluate the situation.

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

Other accepted treatments for sleep-related breathing disorders include behavioral modification, continuous positive airway pressure (CPAP) and various surgeries. The risks and benefits of these alternative treatments should be discussed with your healthcare provider.

It is your decision to choose oral appliance therapy to treat your sleep-related breathing disorder and you are aware that it may not be completely effective for you. It is your responsibility to report the occurrence of side effects and to address any questions to this provider’s office. Failure to treat sleep-related breathing disorders may increase the likelihood of significant medical complications.

**Snoring Treatment Only:**

If you will be getting an Oral Appliance solely for snoring treatment, it is still recommended that a polysomnograph (overnight sleep test) or an at home sleep test be done. Without a sleep test, there is no way of knowing if you have Sleep Apnea or another condition contributing to your snoring. An oral appliance may treat your snoring, but will not treat any other contributing factors that can continue to pose health risks.

I understand that what my risk for sleep apnea is and have chosen to not be tested by either a home monitoring or polysomnography (overnight sleep study) and that I may or may not have sleep apnea.

**Disclaimer** – This appliance is made custom-made for you and cannot be used for anyone else. Oral appliance therapy affects each person differently and there is no way to determine what affect it will have in your case.

***This appliance cannot be refunded.***

I certify that I have read, or had read to me, the contents of this form. I realize and accept the risks and limitations involved. I have asked any all questions that I have about this form and the treatment, and I consent to the performance of oral appliance therapy.

Please sign and date this form below in the presence of the doctor. You will receive a copy.

Patients Signature: \_\_\_\_\_ Print Name: \_\_\_\_\_

Date: \_\_\_\_\_

Doctors Signature: \_\_\_\_\_ Print Name: \_\_\_\_\_

Date: \_\_\_\_\_

Witness: \_\_\_\_\_



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Patient Name: \_\_\_\_\_ DOB: \_\_\_\_/\_\_\_\_/\_\_\_\_ Date: \_\_\_\_\_

**DAYTIME SLEEPINESS SURVEY**

- Circle one
- What is the chance of falling asleep when sitting and reading? -----0 1 2 3
  - What is the chance of falling asleep when watching TV? -----0 1 2 3
  - What is the chance of falling asleep when sitting inactive in a public place (e.g. a theater or a meeting?) -----0 1 2 3
  - What is the chance of falling asleep as a passenger in a car for an hour? -----0 1 2 3
  - What is the chance of falling asleep when lying down to rest in the afternoon when circumstances permit? -----0 1 2 3
  - What is the chance of falling asleep when sitting and talking to someone? -----0 1 2 3
  - What is the chance of falling asleep when sitting quietly after a lunch without alcohol? -----0 1 2 3
  - What is the chance of falling asleep when in a car, while stopped for a few minutes in traffic? -----0 1 2 3

**Total Score:** \_\_\_\_\_

Circle 0 to 3 based on:

- 0 – No chance of dozing
- 1 – Slight chance of dozing
- 2 – Moderate chance of dozing
- 3 – High chance of dozing

If total score is:

- 0 - 5 Lower than normal sleepiness
- 6 – 10 Higher than normal sleepiness
- 11 – 15 Excessive daytime sleepiness
- 16 + Severely excessive daytime sleepiness

**Please circle Yes or No**

- Do you SNORE loudly? ..... Yes or No
- Do you often feel tired, fatigued, or sleepy during the daytime?..... Yes or No
- Has anyone observed you stop breathing during your sleep?..... Yes or No
- Do you have or are you being treated for high blood pressure?.....Yes or No
- Are you obese/ very overweight – BMI more than 35 kg/m2?..... Yes or No
- Age over 50 years old?..... Yes or No
- Are you male?..... Yes or No
- Is your neck circumference over 17 inches(male) or 15 inches(female)? ... Yes or No

**SCORE:** \_\_\_\_\_

If YES to 0 – 2 then low risk of sleep apnea

If YES to 3 – 4 of the above, then you are at intermediate risk of having sleep apnea

If YES to 5 – 8 of the above, then you are at high risk of having sleep apnea