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## AFFIDAVIT FOR INTOLERANCE TO CPAP

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I have attempted to use the nasal CPAP to manage my sleep-related breathing disorder (apnea) and find it intolerable to use on a regular basis for the following reason(s):

- Mask leaks
- An inability to get the mask to fit properly
- Discomfort caused by the straps and headgear
- Disturbed or interrupted sleep caused by the presence of the device
- Noise from the device disturbing sleep or bed partner's sleep
- CPAP restricted movements during sleep
- CPAP does not seem to be effective
- Pressure on the upper lip causes tooth-related problems
- Latex allergy
- Claustrophobic associations
- An unconscious need to remove the CPAP apparatus at night
- Other: \_\_\_\_\_

Because of my intolerance or inability to use the CPAP, I wish to have an alternative method of treatment. That form of therapy is **oral appliance therapy (OAT)**.

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PATIENT SIGNATURE

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DATE



# INFORMED CONSENT

For the Treatment of Sleep-Disordered Breathing with Oral Appliances

Snoring and obstructive sleep apnea are both breathing disorders that occur during sleep due to narrowing or total closure of the airway. Snoring is a noise created by the partial closure of the airway and may often be no more problematic than the noise itself. However, consistent, loud, heavy snoring has been linked to medical disorders such as high blood pressure. Obstructive sleep apnea is a serious condition; the airway totally closes many times during the night and can significantly reduce oxygen levels in the body and disrupt sleep. In varying degrees, this can result in excessive daytime sleepiness, irregular heartbeat, high blood pressure, reflux, depression, and occasionally heart attack and stroke.

Because any sleep-disordered breathing may potentially represent a health risk, all individuals will be tested by an overnight sleep recorder in their home or by a polysomnogram in a sleep laboratory.

Oral appliances may be helpful in the treatment of snoring, upper airway resistance syndrome (UARS), and sleep apnea. Oral appliances are designed to assist breathing by keeping the jaw and tongue forward, thereby opening the airway space in the throat. While documented evidence exists that oral appliances have substantially reduced snoring and sleep apnea for many people, there are no guarantees this therapy will be successful for every individual. Several factors contribute to the snoring/apnea condition, including nasal obstruction, narrow airway space in the throat, and excess weight. Because each person is different and presents with unique circumstances, oral appliances will not reduce snoring and/or apnea for everyone. Post-testing will be done to assure effective treatment.

## POSSIBLE COMPLICATIONS

Some people may not be able to tolerate the appliances in their mouths. Also, some individuals will develop temporary adverse side effects such as excessive salivation, sore jaw joints, sore teeth, and a slight change in their "bite." However, these usually diminish within an hour after appliance removal in the morning. On rare occasions, a permanent bite change may occur due to jaw joint changes and/or tooth movement. Generally, this can be prevented with modifications to the appliance. If not, restorative, orthodontic, and/or surgical treatment may be required, for which you are responsible. Oral appliances can wear and break. The rare possibility that these, or broken parts from them, may be swallowed or aspirated exists. For patients with sleep apnea, the device must be worn nightly. Discontinuation of use is a hazard to your health and can lead to a heart attack, stroke, or even death. See your prescriber before discontinuing use and for recommendations of alternative therapy such as CPAP and/or surgery.

## 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 to remain effective. Over time, simple snoring may develop into sleep apnea, and sleep apnea may become worse; therefore, the appliance may not maintain its effectiveness. The oral appliance needs to be checked at least twice a year to ensure proper fit, and the mouth examined at that time to assure a healthy condition. If any unusual symptoms occur, you are advised to schedule an office visit to evaluate the situation. Individuals diagnosed with sleep apnea may notice that after sleeping with an oral appliance they feel more refreshed and alert during the day. This is only subjective evidence of

improvement and may be misleading. The only way to accurately measure whether the appliance is keeping the oxygen level sufficiently high to prevent abnormal heart rhythms and other problems is to be retested with a sleep recorder or polysomnogram.

#### ALTERNATIVE TREATMENTS

Other accepted treatments for sleep-disordered breathing include behavior modification, weight loss, continuous positive airway pressure (CPAP), and surgery. You have chosen oral appliance therapy to treat your particular problem and are aware that it may not be completely effective for you.

#### UNUSUAL OCCURRENCES

As with any form of medical or dental treatment, unusual occurrences can and do happen. Broken or loosened teeth, dislodged dental restorations, mouth sores, periodontal problems, root resorption, non-vital teeth, muscle spasms, and ear problems are all possible occurrences. Most of these complications and unusual occurrences are infrequent. Additional medical and dental risks that have not been mentioned may occur. Good communication is essential for the best treatment results. Please call or come to the office if you have any questions or problems regarding treatment. I consent to the taking of photographs and x-rays before, during, and after treatment, and their use in scientific papers and demonstrations.

#### FOLLOW-UP VISITS

Patients will be seen twice a year for the lifetime of the appliance. There will be no charge for the first two months of evaluation. A standard charge will then be applied for subsequent follow-up visits.

I authorize the release of a full report of examination findings, diagnosis, treatment programs, etc., to any referring or treating dentist or physician. I additionally authorize the release of any medical information to insurance companies or for legal documentation to process claims. I understand that I am responsible for all fees for treatment regardless of insurance coverage.

**I certify that I have read, or had read to me, the contents of this form. I realize and accept any risks and limitations involved, and do consent to treatment. I understand that the only way to measure the efficacy of an intraoral sleep apnea appliance is via follow-up polysomnography, which I agree to do following fitting and adjustments.**

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PATIENT SIGNATURE

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DATE

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WITNESS SIGNATURE

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DATE