

INFORMED CONSENT FOR THE TREATMENT OF SLEEP DISORDERED BREATHING WITH ORAL APPLIANCE THERAPY

Name: _____ Date: _____

You have been diagnosed by your physician as requiring **treatment for sleep-disordered breathing** (snoring, upper airway resistance syndrome and/or obstructive sleep apnea). This condition may pose serious health risks since it disrupts normal sleep patterns and can reduce blood oxygen levels, which, in turn, may result in the following: Excessive daytime sleepiness, irregular heartbeat, high blood pressure, heart attack, stroke, morning headaches, motor vehicle accidents, depression or anxiety, memory loss, and/ or mental impairment. Sleep apnea is a medical condition with serious health consequences. For that reason, all patients are advised to see their physician to aid in diagnosis and treatment, as well as management of other health conditions as necessary. Initials: _____

There are many factors that contribute to sleep disordered breathing. These include, but are not limited to, weight gain, increasing age, hypertension, hormonal imbalances such as hypothyroidism or menopause, enlarged tonsils or adenoids, malocclusion (incorrect bite or tooth positioning), problems such as Temporomandibular Joint Disorder or orthodontic problems, as well as loss of posterior teeth or all teeth. Initials: _____

FDA-approved **oral appliances** used in the treatment of snoring/sleep apnea are designed to assist the patient in breathing by changing the space between the upper and lower jaw and maintaining the tongue in a more forward position during sleep. This opens the airway and creates the optimal breathing position which is different for each patient. The optimal breathing position allows air to flow through the airway and thus reduces the snoring and apenic events. There are numerous studies showing the effectiveness of oral appliances for the reduction of snoring and sleep apnea. However, there are no guarantees that a dental appliance will be successful or safe for every individual. 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 the symptoms related to your sleep disordered breathing. Dental appliances do not reduce snoring in all individuals. Initials: _____

Published studies show that short-term **side effects** of oral appliance use may include: excessive salivation, difficulty swallowing (with appliance in place), sore teeth, jaw joint (TMJ) pain, dry mouth, tooth movement, and short-term bite changes. Some people may not be able to tolerate the appliance in their mouth. Oral appliances can wear and break. The possibility that these or broken parts from them may be swallowed or aspirated exists. Long-term and more serious complications may 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 appliance therapy is discontinued. If you desire correction of this, you will be informed of your choices and financial responsibility, including but not limited to: TMJ therapy, restorative dentistry, and/or orthodontic treatment. 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 for recommendations of alternative therapy. The following conditions exist and are present prior to oral appliance therapy:

Initials: _____

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, devitalization of teeth, muscle spasms, and ear problems are a few infrequent complications. Additional medical and dental risks that have not been mentioned may occur.

Initials: _____

Follow-up visits with our office are mandatory to ensure proper fit and allow an examination of your mouth to assure a healthy condition. The oral appliance is strictly a mechanical device to maintain an open airway during sleep. It does not cure snoring or sleep apnea. Therefore, the device must be worn nightly for a lifetime to be effective. 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 or discomfort would occur, it is recommended that you schedule an office visit to evaluate the situation. When your appliance places your airway in the optimal position, a follow-up sleep study will be recommended - either home-based (the Watch PAT-100 or simple oximetry) or lab-based (a polyomnograph (PSG)). This is very important to check the effectiveness of the appliance. In some cases it may be necessary to repeat the sleep study on a yearly basis.

Initials: _____

Alternative Treatments for sleep disordered breathing include: lifestyle changes and behavioral modifications, positive airway pressure, and various surgeries. You have chosen to use oral appliance therapy to treat your sleep disordered breathing. It is your responsibility to report any side effects and to direct any questions regarding your therapy to our office. Failure to treat sleep disordered breathing and failure to follow our instructions regarding use of the appliance may increase the likelihood of significant medical complications.

Initials: _____

By signing this consent form, you are indicating that you have read and understood the above paragraphs, have asked this provider any questions you may have about this form and treatment, and are willing to accept any and all risks known and unknown involving the wearing of an oral appliance.

By signing this form you also understand that if you are not under the care of our office or another sleep physician's care, you should cease wearing your appliance.

You are also consenting to the taking of photographs and x-rays before, during, and after treatment, and their use in scientific papers and demonstrations.

Signed: _____ Date: _____

Witness: _____ Date: _____