INFORMED CONSENT FOR ORAL APPLIANCE THERAPY TO TREAT OSA
ORAL APPLIANCE THERAPY IS A TREATMENT, IT IS NOT A CURE!

Patient Name:_____Date:_____

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, occasionally heart attack and stroke.

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

Oral appliances may be helpful in the treatment of snoring, upper airway resistance (UARS), and sleep apnea. Oral appliances are designed to assist breathing by keeping the tongue and jaw 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 excessive weight. Because each person is different and presents with unique circumstances, oral appliances will not reduce snoring and/or sleep apnea for everyone. Post testing for appliance efficacy is required by your MD/Pulmonary Group as part of the therapy process.

POSSIBLE COMPLICTIONS: Some people may not be able to tolerate the appliance in their mouth. Also, some individuals will develop temporary adverse side effects such as excessive salivation, sore jaw joints, sore teeth, tooth movement and a change in their "bite". However there usually diminish within an hour or so after appliance removal in the morning. On rare occasion, a permanent "bite" change may occur due to joint changes and/or tooth movement. Generally this can be mitigated by daily use of the fabricated AM deprogrammer dispensed with your appliance. Parafunctional exercises are to be performed as demonstrated daily after removal of appliance. These complications may not be fully reversible once appliance therapy is discontinued. If not, restorative, orthodontic, and or surgical treatment may be required for which you are responsible. Should you elect to discontinue appliance therapy, you will be directed immediately back to your referring MD to initiate PAP or other therapeutic modality. To repeat, any number of temporary or permanent dental issues can develop as a result of long term treatment of OSA with a mandibular advancement device (MAD), including but not limited to: jaw joint pain, TMJ dysfunction, morning headaches, popping and noise in the jaw, sore teeth, dental decay, gum (periodontal) disease, gingivitis, worsening of periodontal pockets, tooth loss, loosening of teeth, dry mouth or excess saliva, fracturing or loosening of dental fillings, crowns or bridges, short term or long term bite changes, spacing or shifting of teeth, tilting of teeth, profile changes, lessening of overbite or overjet, dental infection, infection of the gums, difficulty chewing, oral cysts, oral tumors, oral cancer, and death.
You should be aware that complications as a result of oral appliance therapy have been minor, mostly short -term muscle soreness and excessive saliva. Jaw shifts that create bite problems are the most common complication but are mostly prevented by using the morning repositioning appliance that is provided with your MAD. It is the patient's responsibility to immediately inform Dr. Selleck of any issues which may develop to minimize the chances of a permanent condition or complication complicating the therapy.

Oral appliances can and will break. The possibility that these parts may be swallowed or aspirated does exist. For patients with sleep apnea, the device must be worn every night. Discontinuation of use is a hazard to your health and can lead to heart attack, stroke, or even death. You must advise or consult with your prescribing MD before discontinuing use and for recommendations of alternative therapy such as PAP 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 appliance must be worn nightly for a life time to be effective. Over time, simple snoring may develop into sleep apnea. Sleep apnea also may become worse. Therefore, the appliance may not maintain its effectiveness. The oral appliance needs to be checked at least twice a year to insure 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 who have been diagnosed as having 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 levels sufficiently high to prevent abnormal heart rhythms and other problems is to be retested as noted above.

FINAL SLEEP STUDY AND EVALUATION: After your appliance is delivered, it will be adjusted to achieve the best improvements in symptoms such as snoring and daytime sleepiness. When your symptoms have improved and you and Dr. Selleck are satisfied with the results of the adjustments, you will be referred back to your physician for post-treatment evaluation. This evaluation is to assess the effectiveness of MAD in maintaining an open airway during sleep and often includes a repeat sleep study. This is a mandatory step in clinical therapy. Failure to agree to obtain follow up testing as prescribed by your physician may mean your appliance will not be delivered to you.

Initial_____

DIAGNOSIS:

I understand that I have been diagnosed with obstructive sleep apnea (OSA) by a sleep physician and have been prescribed treatment for oral appliance therapy (OAT). I have been informed that OSA may result in excessive daytime sleepiness, irregular heartbeat, high blood pressure, strokes, diabetes, gastric reflux, depression, heart attacks, and increased risk for driving accidents.

UNUSUAL OCCURANCES:

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 consequences.

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 of come to the office if you have any questions or problems regarding treatment.

FOLLOW-UP APPOINTMENTS are required with Dr. Selleck on a 6 month or yearly basis to check the effectiveness of your appliance and monitor appliance condition and evaluate any dental complications that may occur. Failure to maintain these follow-up appointments will constitute a lack of compliance with Dr. Selleck's treatment plan. Any decision on your part to forego follow-up appointments places your health at risk and increases the probability of complications and treatment failure.

Additionally, recall appointments should be kept with your general dentist on a three month schedule for the first year that you wear a MAD to evaluate your dental hygiene, gums and check for decay. By signing this agreement you agree that you have heard this recommendation; avoiding this preventive oversight might result in excessive dental disease.

PROGNOSIS:

I understand that oral appliances have been shown to be an effective treatment of OSA and snoring in most individuals. OAT is a method of managing my OSA only when it is being used. The oral appliance's effectiveness is monitored by follow-up, overnight sleep testing by a sleep physician. My dentist or physician has discussed with me that my prognosis for successful OAT is ☐ Poor < 50%, ☐ Guarded 50-80%, or ☐ Good > 80%. I understand that OAT may not be effective.

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Patient Initial

I understand that the quality of treatment can be negatively affected by alcohol consumption, smoking, weight gain, medications and other medical conditions.

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Patient Initial

CONTINUOUS WEAR:

I understand that OSA is a chronic condition and OAT must be continually managed. I agree to contact my physician or dentist if my symptoms worsen. I agree to have my treatment monitored semi-annually by my physician and my dentist. I realize that OSA can only be objectively measured by overnight home sleep test or in lab sleep test and that my condition must be monitored periodically by my physician and dentist.

WHEREFORE: I give my consent for the treatment of my OSA using a mandibular advancement device (MAD). I agree and consent to allow Dr. _____ and his staff to examine my mouth, teeth, jaws, gums, and associated structures. I give consent for the taking of x-rays, photos, impressions and any other procedures necessary for the treatment of my OSA. I give consent for a home sleep study, if necessary, for the adjustment of my appliance. I consent for the contents of my record to be shared with my medical providers whose names I have provided and insurance company(s) for the purpose of obtaining medical coverage.

I affirm that I have read this document and have been given adequate information regarding the treatment of my condition to give my informed consent. I understand the proposed treatment of my OSA using MAD therapy and I have been given the opportunity to ask questions. All my questions have been answered and I am ready to proceed with treatment.

_____
Patient Signature

Name of your Primary Care Dentist:_____,
CITY_____

Primary Care Dentist Telephone number:_____