

## Oral Appliance Treatment Consent Form

Snoring and Obstructive Sleep Apnea (OSA) are breathing disorders, which occur during sleep, due to the narrowing or total closure of the airway. Snoring is a noise created by the partial closure of the airway and is often no greater problem than noise itself. However, consistent loud snoring with OSA symptoms has been linked to medical disorders such as hypertension (high blood pressure) and stroke. OSA occurs when the airway completely closes many times during the night. It can significantly reduce the oxygen levels in the body and disrupt sleep. To varying degrees, this can result in excessive daytime sleepiness, irregular heartbeat, hypertension, and occasionally heart attack and stroke. If you suspect that you have symptomatic snoring or OSA you should consult your general medical practitioner.

The oral appliance (OAT) is effective in the treatment of snoring and OSA. **It assists breathing by keeping the lower jaw and tongue forward during sleep, which opens the airway space in the throat.** The OAT has substantially reduced snoring and OSA for many people but there is no guarantee that the therapy will be successful for every individual. Several factors contribute to snoring and OSA including nasal obstruction, narrow airway space in the throat and excess weight. Other accepted treatment for snoring and OSA that should be considered by sufferers included lifestyle changes (weight loss), behavioral modification, continuous positive airway pressure (CPAP) and surgical procedures.

### **Possible Complications**

The OAT is a custom made mandibular advancement appliance that is only worn at night. Some patients may not be able to tolerate the OAT or any other device in their mouth. Some patient may develop temporary side effects such as sore jaw joints, difficulty biting down or chewing, excessive salivation, dry mouth, sore teeth, irritation of the soft tissues in the mouth and or a slight change in their bite. In some cases a permanent “bite” change may occur. If any unusual symptoms or side effects occur **you must contact your dentist immediately.**

### **Length of Treatment**

The OAT is a mechanical device to keep the airway open during sleep. It does not cure snoring or OSA. It must be worn each night to be effective. Snoring may develop into OSA and it is possible that the appliance may not maintain its effectiveness over time and needs to be checked at least twice a year by your dentist to ensure a proper fit and effectiveness. Follow-up sleep studies are also needed to ensure that your oral appliance is treating your OSA effectively.

### **Unusual Occurrences**

As with any form of medical or dental treatment unusual occurrences can and do occur. Broken or loosened teeth, dislodged dental restorations, sore mouths, gum disease, deterioration of tooth structure, non-vital teeth (dead teeth), muscle spasms, and ear problems are examples of possible unusual occurrences. These complications are unusual and infrequent. Additional medical and dental risks that have been mentioned may occur but are unlikely to. If any unusual symptoms occur you should cease using the appliance immediately until you see your dentist or doctor. Please call your doctor or our office if you have any questions or problems regarding the treatment.

### **Changes in your dentition (teeth)**

Your OAT is designed and custom built for your mouth and your teeth as they are today. If you need dental work in the future such as implants, crowns, bridges, fillings, etc. you may need to have your OAT appliance modified to fit the new shape of your teeth. Future modifications to your OAT appliance due to changes in dentition are not part of your initial fee and are not considered warranty items; additional fees will apply.

### **Warranty**

Your OAT appliance has a warranty from the date of delivery that covers manufacturing defects. This warranty does not cover appliances that are lost, broken from miss-use, improperly adjusted, adjusted past the stops, soaked in incorrect materials, cleaned improperly, etc. Please see warranty card and user manual included with your appliance for more details.

## Adjustments

Your SomnoDent appliance is a medical device. It should only be adjusted by a trained medical professional. If your physician or dentist has properly trained you and instructed you to adjust it please keep close track of the position of each side of your appliance. If this relationship is altered your appliance will need to be sent back to the lab for calibration (additional charges apply). If your appliance is causing TMJ pain or other discomfort please call your dentist as soon as possible.

## Adjustment Fees

Your SomnoDent appliance comes with no-charge adjustments for SIX months. After six months current oral appliance adjustment fees will apply.

## Adjustment Phase

After receiving your SomnoDent appliance you will be instructed to return to our office for a series of adjustments. During this adjustment phase we will index the appliance forward in effort to better treat your snoring and or sleep apnea. This may involve many visits to our office or you may be trained on how to adjust the appliance. Please be prepared to come in to our office or adjust your appliance at home frequently during this phase.

## Jaw Joint Stiffness / Discomfort

This appliance works by holding your bottom jaw open and forward while you sleep. This new position can cause jaw joint stiffness and or discomfort in some patients. If this happens to you please cease wearing your appliance and call our office for us to make adjustments.

## Success Rate & Clinical Guarantee

While the SomnoDent appliance is very effective at treating snoring and OSA we cannot guarantee the success of the product in any way due to the inherent differences between patients. We guarantee that we will provide you a properly fitted oral appliance and we will work with you for up to six months to adjust your appliance for you. Clinical effectiveness will be determined by a sleep test interpreted by a licensed MD.

- **I have been assessed for snoring and or OSA and understand that I should be examined by my medical GP and that I may also need to have a sleep study performed.**
- **I have read and understand the conditions and information in this consent form.**
- **I have discussed the information contained in this consent form with my dentist.**
- **I have had explained to me the cost of the treatment and I accept responsibility for that cost. Including any cost not covered or denied by my medical/dental insurance.**
- **I authorize my dentist to provide me with treatment using SomnoDent MAS**

Patient Signed: \_\_\_\_\_

Dentist Signature: \_\_\_\_\_

Dated: \_\_\_\_\_

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