

## **INFORMED CONSENT FOR THE TREATMENT OF SNORING AND/OR OBSTRUCTIVE SLEEP APNEA WITH ORAL APPLIANCES**

Snoring and Obstructive Sleep Apnea are both breathing disorders that 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 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 where the airway totally collapses 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 and increased risk of high blood pressure and occasionally heart attack and stroke.

Oral appliances may be helpful in the treatment of snoring and sleep apnea. Those diagnosed with mild or moderate sleep apnea are better candidates for improvement with this therapy than those severely affected. Oral appliances are designed to assist breathing by 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. **Since each person is different and presents with unique circumstances, oral appliances will not reduce snoring and/or sleep apnea for everyone.** Furthermore, some people may not be able to tolerate the appliance in their mouth. Other treatments include weight loss, positional therapy, continuous positive airway pressure (CPAP) and surgery. Polysomnography and other objective tests following treatment will be necessary to document effectiveness of the appliance therapy.

### Side Effects

Some individuals will notice temporary side effects such as excessive salivation, sore joints and muscles, dry mouth, sore teeth and a slight change in "bite". However, these are generally minor and usually diminish shortly after appliance removal each morning.

### Complications

**A permanent bite change can occur due to the permanent movement of teeth or from permanent jaw joint repositioning due to the stresses of the appliance each night. A permanent bite change of this nature can have damaging long-term effects on the teeth, musculature and jaw joint and should be managed by an experienced dentist. Treatment options include discontinuing use of the appliance, bite adjustment (slight reshaping of certain teeth), restorations with crowns and orthodontic intervention (braces). Use of a morning bite splint each day will minimize the possibility of permanent bite changes occurring.**

Occasionally, people are unable to tolerate the appliance in their mouths and may need to discontinue use of the appliance. Over time, the components of the appliance may become worn out or broken. If pieces separate from the appliance, there is a chance they may be swallowed or aspirated into the lungs. Broken or loosened teeth, dislodged dental restorations, mouth sores and inflamed gums may occur.

#### How Long Should the Appliance Last?

Longevity depends on care, maintenance and oral conditions, but in general, between 2-5 years is a reasonable expectation. The oral environment can be a very demanding one. Third party payers have different guidelines for when they will provide benefit for a new appliance and for coverage of repairs. Some have no benefit for repairs. Some will provide benefits after a 3 year time period and for others such as Medicare, there is a 5 year time period. This means the device may need to be serviced, repaired, or replaced without having the benefit of third party assistance and in this case the patient will be responsible for those costs.

#### Periodic Examinations

It is advised that the oral appliance and oral structures be checked by Dr. Kenworthy six months after delivery and then once a year after that to ensure that the appliance is in good condition and that the oral structures are healthy. If any unusual symptoms occur, it is recommended that the appliance not be used until an office visit is scheduled to evaluate the situation. If periodic examinations with Dr. Kenworthy are not attended as prescribed, potential complications are more likely to become detrimental. It is your responsibility to comply with these regular examinations.

The oral appliance is strictly a mechanical device to maintain an open airway during sleep. It does not cure your snoring or sleep apnea. Therefore, the device must be used nightly for a lifetime to be effective. Untreated sleep apnea can result in an increased risk of heart attack, stroke, high blood pressure and accidents. See your prescriber prior to discontinuing use and for options of treatment.

#### Follow-Up Sleep Test

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 level sufficient and breathing normal is to have a consultation with a sleep specialist for a follow-up sleep test while utilizing the appliance. This is a must for apnea patients.

#### Financial Considerations

To minimize the financial impact on our patients we will estimate the insurance benefit and the copayment amount. The copayment is due at the initial visit.

I understand my following responsibilities :

- Have regular, periodic evaluations as determined by Dr. Kenworthy for the length of treatment. (Six months after delivery and annually thereafter). A fee is charged for follow up visits after the 90 day adjustment period. To receive information about benefits for this appointment contact your insurance carrier prior to the appointment. The procedure code is 99213 and the fee is \$140.
- I understand that although Dr Kenworthy’s office will attempt to assist when possible with arranging follow up visits, it is ultimately my responsibility to make sure that these appointments are scheduled and attended.
- Comply with use of the morning bite splint as instructed and if the teeth don’t fit into the splint I will immediately notify Dr. Kenworthy.
- I understand that bite changes may occur and will notify Dr. Kenworthy IMMEDIATELY if I notice any changes in my bite.
- I will notify Dr. Kenworthy IMMEDIATELY of discomfort or change in my mouth, jaw joint or teeth.
- Until appropriate therapy is initiated and symptoms have resolved driving precautions should be exercised at all times.
- Submit to a follow-up sleep test utilizing the oral appliance when requested to do so.

I give consent to have allow Paul Kenworthy, DMD’s office to communicate with spouse, partner, or other household members regarding appointments, costs, etc. related to treatment.

\_\_\_\_\_

Signature

I understand that payments sent to me from my insurance carrier are intended as payment to the provider of treatment (Paul Kenworthy, DMD). In the event a check is sent to me, I agree to endorse this check and forward it to Paul Kenworthy, DMD in a timely fashion (within 7 days). I understand that if this is not done, that all legal recourse will be undertaken by Paul Kenworthy, DMD to recover these funds.

\_\_\_\_\_

Signature

The warranty period for your appliance is \_\_\_\_ years. The warranty covers wear and tear from normal use and **does not** extend to appliance damage from dog chewing, appliance loss, abuse and/or neglect of the appliance and any dental treatment (crowns, bridges, extractions, etc.) that causes the appliance to no longer fit. If the appliance needs replacement for reasons of dog (or other pet chewing), appliance loss, or abuse and/or neglect, the cost for replacement could range from \$1,500 to \$2,500 depending time lapse since delivery and the need for new impressions and bite.

\_\_\_\_\_

Signature

I understand that if I elect not to have the appliance inserted that I am responsible for an out-of-pocket cost of \$1,000 to cover the administrative costs and lab costs involved with appliance fabrication (**Not applicable for patients with Medicare or Medicaid coverage**).

\_\_\_\_\_

Signature

I understand that it is my responsibility to coordinate with my employer and physician about specifics with my employment regarding oral appliance treatment of my obstructive sleep apnea and meeting of DOT or FAA regulations.

\_\_\_\_\_

Signature

I consent to the taking of photographs and x-rays before, during and after treatment and their use in scientific papers and presentations. My signature below indicates I have read and understand this information concerning oral appliances for the treatment of snoring and/or sleep apnea and that my questions have been answered and I have been shown a demonstration appliance. I am willing to accept any and all risks known and unknown involved. I understand I will receive a copy of this disclaimer if I request one. I give consent to Dr. Kenworthy to consult with my healthcare providers regarding this disorder and to exchange medical records to assist in the management of my disorder.

Patient Name (Printed) \_\_\_\_\_

Patient signature \_\_\_\_\_ Date \_\_\_\_\_

Witness \_\_\_\_\_ at Paul Kenworthy, DMD, PC