The Klearway® Oral Appliance

Today's most thoroughly researched oral appliance for the treatment of snoring and mild obstructive sleep apnea (OSA)
A clinically proven oral appliance with the following special features:

- Extensively researched and tested
- Multiposition, patient adjustable advancement
- Comfortable and well-tolerated by patients
- Excellent retention
- Developed by a recognized academic in the field of OSA
Indications for use of the Klearway® Oral Appliance:

OSA is a disorder of the upper respiratory tract in which the tongue is sucked back against the posterior wall of the pharynx by the negative pressure of inhalation. If the obstruction remains in place for more than 10 seconds, and occurs more than five times per hour, the patient will usually suffer the symptoms of sleep deprivation the following day. This is known as obstructive sleep apnea (OSA). In severe cases this condition can be life-threatening.

Snoring occurs when the tongue is posteriorly displaced, but does not contact the posterior pharyngeal wall. This narrows the airway and causes air to move more rapidly through the passages, causing the vibrations of snoring. All OSA patients are snorers, but not all snorers have OSA. Because OSA can be a serious disorder, all snorers should be screened for the condition. It is also recommended that patients not be treated without a referral from a medical doctor who is competent in the field of sleep disorders.

Oral appliances have been found to be effective in treating snoring and mild OSA, and in moderate to severe OSA patients when CPAP or uvula surgery have proven unsuccessful.

Klearway® is the most thoroughly researched oral appliance for the treatment of snoring and OSA.
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Proven superior to other oral appliances for the treatment of snoring and OSA, Klearway’s comfortable, thermal sensitive material enables a better fit, and therefore, better retention.

The advantages of the Klearway® appliance:

- Facilitates slow and gradual movement of jaw position by permitting the patient to adjust the appliance according to his or her own comfort level with the guidance of the attending dentist.
- Can be adjusted to over 44 positions, in increments of 0.25mm.
- Fabricated of thermoactive acrylic, which significantly decreases soft tissue and tooth discomfort.
- Permits lateral and vertical jaw movement, enabling patients to yawn, swallow and drink water without dislodging the appliance.
- Provides full occlusal coverage of both arches.
- Does not encroach on tongue space.
**Clinical Use:**
Prior to treatment with an oral appliance, the patient must be assessed by the attending physician and/or a sleep disorder specialist. In most cases, the physician may require an overnight polysomnogram to diagnose the sleep disorder and to provide the dentist with a written referral or prescription and diagnostic report.

The dental examination should include the following: a medical/dental history; soft tissue/intraoral assessment; periodontal evaluation; temporomandibular joint (TMJ)/occlusal examination; intraoral habit assessment; examination of teeth and restorations; dental radiographs no older than six months (panoramic or full mouth survey, cephalometric radiograph); and diagnostic models. The Apnea Link or the Epworth Sleepiness Scale may also be used as a screening tool at the initial exam and during duration of the oral appliance therapy.
Records – The technician at Great Lakes Orthodontics will require a stone model of both arches from impressions. Make sure the impressions extend into the vestibules for utmost retention. In addition to the models, we also require a bite registration, two-thirds the distance from centric occlusion to full protrusion, with a 5mm incisal vertical opening. A George gauge should be utilized with the White 5mm fork for utmost accuracy.

The clasping is standard, however, the dentist may indicate where he or she would like the clasps. An accurate bite registration is critical in fabricating an appliance which will not impair the teeth, soft tissues, or TMJ/occlusion. Since added retention for the Klearway appliance may depend on four Ball clasps, the patient should have at least one clinically sound tooth in each quadrant.
Insertion and activation – When the appliance is returned from Great Lakes, first verify the location of the clasps on the appliance, and record the opening of the expansion screw with a Boley gauge. Have the patient prepare the appliance for insertion by holding it under running hot tap water. The water should be no warmer than can be tolerated by the patient’s fingers, and the appliance should not be heated in any other manner.

The Klearway is then inserted into the mouth, pressing the upper rim onto the upper back teeth first. Once seated on the upper teeth, the patient should close the lower teeth forward into the lower portion of the appliance and bite firmly. To secure the appliance, have the patient use fingers to press along the buccal segments and use the tongue to address the lingual area.

To remove the appliance, the patient should rinse with warm tap water, prior to removal. This will enable the patient to remove the appliance while it is soft and pliable. (Tip: Some patients find it easier to remove the appliance during their morning shower when they can expose the acrylic longer to warm water.) When you are sure the patient can insert and remove the appliance easily, and he or she is comfortable with the appliance inserted, schedule a follow-up appointment in one-week’s time. After the patient has demonstrated regular consistent wear, the appliance is activated or turned twice per week on average by inserting the
tip of the key into the hole on the right side of the expansion screw. Turn or push the key towards the left. There is an arrow marked on the metal expansion screw to show the correct direction. Always have the patient remove the key after turning. A new hole will appear on the right side of the appliance to be used for the next turn later in the week.

The patient can be instructed to turn the expansion screw one increment at a time twice a week as long as the appliance remains comfortable. Turning the key back to the right side will close or retract the expansion screw, if this is desired. Each turn or activation will gradually move the jaw forward, thus increasing the three-dimensional size of the airway and improving the patient’s ability to breathe comfortably.

Follow-up — For the first week follow-up, measure the amount of opening of the expansion screw with a Boley gauge. Check the patient for jaw muscle discomfort and any sore teeth or soft tissue spots. If the patient is experiencing significant jaw discomfort, turn the screw in the reverse direction of the arrow to decrease the amount of mandibular protrusion until the patient is comfortable. Relieve the acrylic around any sore spots or uncomfortable teeth. The patient can be scheduled for follow-up in a month.
One-month follow-up – Again, measure and record the opening of the expansion screw with a Boley gauge. If the patient remains comfortable, have him or her continue to activate the appliance two times per week until the next appointment.

Verify that the appliance has not been distorted or opened vertically by making sure the anterior shelves are in contact. This is necessary to prevent mandibular rotation during sleep. A headgear plier can be used to vertically close the posterior arms of the expansion screw to ensure contact of the sliding shelves.

Titration appointment – When the patient reports a cessation of snoring and/or resolution of the symptoms, it may be unnecessary to move the mandible further forward. The expansion screw can be tied off with stainless steel ligature wire or filled in with cold cure acrylic to prevent any further movement of the mandible. At this time the patient should be referred back to his or her physician and/or sleep specialist for a reevaluation.

Six-month follow-up – As long as the appliance has shown to be effective and the patient is comfortable, six-month recall appointments will be sufficient to check the occlusion and verify that the appliance has not been distorted.
The developer of the Klearway® appliance

Alan A. Lowe, DMD, PhD., FRDC(C), is Professor and Head of the Department of Clinical Sciences at the University of British Columbia in Vancouver, British Columbia, Canada. Dr. Lowe has been involved in the research of oral appliances for use in treating snoring and OSA disorders since 1987. He is known in his field as the prominent investigator who compares the usefulness of oral appliances and other treatment modalities. Dr. Lowe has given a number of lectures and has authored and coauthored several articles on the use of oral appliances for the treatment of sleep disorders.
The patient should not remove the appliance by simply opening his or her mouth. This can permanently distort the wire work and render the appliance useless. Some patients will experience a sense of the teeth not touching in the morning. This will disappear within an hour or so. For the first month or more, some will have an excessive amount of saliva, a symptom which will also go away on its own. If the patient experiences significant jaw or joint discomfort, have him or her stop turning the screw until the next visit. Ask that the patient call the office if the discomfort doesn’t subside within one or two days.

To clean the appliance, the patient can use a stiff toothbrush and any toothpaste. The appliance should be thoroughly brushed, inside and outside, as well as the expansion screw. Because this product is made from thermoacrylic material, it does not have to be kept in mouthwash or water when it is not in the mouth. We recommend DentaSOAK™ for your patients. Gentle, effective, and easy to use, DentaSOAK cleans and destroys infection-causing bacteria - in just 15 minutes. DentaSOAK is non-toxic, alcohol free, and persulfate free. DentaSOAK is available in a three month, six month, or one year supply. FREE patient brochures are available. To order DentaSOAK, call Great Lakes Products Customer Service toll-free at 800-828-7626, direct at 716-871-1161, or fax your order to 716-871-0550. Your DentaSOAK order will arrive in about 10 days. ■