

Instructions and Care for Your Klearway™ Appliance



Great Lakes®

DENTAL TECHNOLOGIES

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Great People. Great Products. **Great Lakes.**

General Information

Oral appliances have a definite role in the management of selected patients with Obstructive Sleep Apnea and/or snoring. The appliance will not cure the apnea and/or snoring but works non-surgically to realign the jaw and/or tongue in relation to the airway. Its intention is to prevent the apnea and/or snoring from occurring during sleep and it must be worn each night to produce the desired effect. Regardless of how long it is worn, the symptoms of obstructive sleep apnea and/or snoring will return when the appliance is discontinued.

There are no guarantees that an appliance will be successful in every patient due to physiologic, anatomic variations and patient tolerance of the appliance. After wearing the appliance over a period of time, some patients will need to repeat an overnight sleep study to determine the effect of the appliance.

This device is contraindicated for patients who; have central sleep apnea, have loose or advanced periodontal disease, or are under the age of 18.

WARNINGS: Tooth Movement, Gingival or Dental soreness.

Cooperation in caring for and wearing the appliance as instructed and in maintaining the highest standard of oral hygiene is absolutely essential. In fact, the ultimate success of treatment is directly related to the degree of patient cooperation.

Insertion/Removal

The appliance is made with a temperature sensitive acrylic material which is rigid when cool but soft and flexible when heated under hot water.

To insert the appliance, first submerge it in a container of hot tap water, or hold the appliance under running hot water only as hot as your fingers can tolerate for at least one minute. Do not heat the appliance by any other means as you may irreversibly damage it. Insert the appliance into your mouth and press the upper rim up onto the upper back teeth using both thumbs. Once seated on the upper teeth, close your lower teeth forward into the lower portion of the appliance and bite firmly. To secure the appliance, use fingers to press along the (buccal), cheek side segments and use the tongue to address the (lingual), tongue side area.

To remove the appliance, swish with warm water, then push up on the edges of the lower rim with both thumbs while at the same time opening your mouth. Once the lower rim is off your teeth, grasp the edges of the upper back portion and pull downward which will dislodge the appliance from your mouth. Do not remove the appliance by simply opening your mouth. Each arch must be dislodged separately or the wire work may be distorted and the appliance subsequently ruined. Doctors have reported that patients will remove the appliance while in the shower.

Activation

After approximately one month of regular wear, the doctor may give you a special key and request that you activate the appliance weekly until the next appointment. Each turn or activation will move your lower jaw gradually forward in 0.25mm increments which has a direct effect on the three dimensional size of your airway.

There is an arrow marked on the metal expansion screw to show the correct direction for advancement. Insert the tip of the key into the hole where the arrow begins. Turn or push the key in the direction of the arrow. After the key is turned once from one side to the other, remove the key. A new hole will appear where the arrow begins and will be used for your next turn. If the key is removed before the new hole appears, you will be unable to place the key into the next advancement hole. Pushing the key in the opposite direction of the arrow will close or retract the expansion screw rather than open or advance it. Never advance the screw more than two turns per week unless instructed to do so by the doctor.

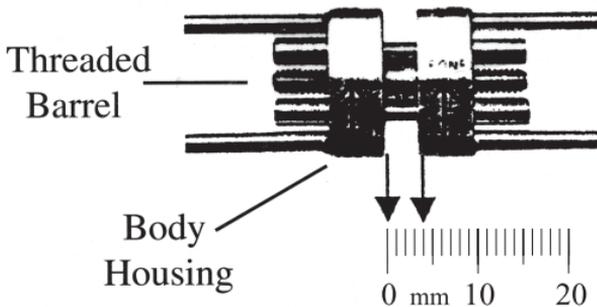
Klearway™ Advancement Screw Record

Measure the amount of screw opening every day to confirm that the screw is not self-closing*.

Amount of Opening

_____ mm
_____ mm
_____ mm
_____ mm
_____ mm

Snore Score
(10=Untreated 0=Silence)



*Notify your doctor if the threaded barrel is flush with the body housing of the screw. At this point you have approximately 3mm of expansion left before the screw has reached maximum advancement and disengages.

Cleaning

It is important to never soak your appliance for longer than the times noted below. Store it dry in the case provided after following these simple cleaning instructions.

- **Only use COOL water when cleaning**

Regularly clean the appliance the same way you clean your teeth - with a toothbrush, toothpaste (NO whitening, peroxide, baking soda, tartar control or abrasives) and COOL water. Hot water while cleaning may dull the finish or warp the appliance.

- **Do not use effervescent denture cleansers or mouthwash containing alcohol or colored mouthwash**

Over-the-counter effervescent denture cleansers or alcohol can alter the color and damage or weaken the appliance. Using these products may void the warranty. Colored mouthwash can permanently stain the appliance.

- **We recommend DentaSOAK® for cleaning your appliance**

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 convenient three month, six month, or one year supply.

To order DentaSOAK, ask your dentist or order on-line at dentasoak.com.

Your order will arrive in about 10 days.

DentaSOAK is not available in Canada.

Side Effects

A sense of the teeth not touching properly may be experienced by some patients in the morning. This usually self-corrects within an hour or so. In addition, you may experience an excessive amount of saliva for the first month. If significant jaw or joint discomfort occurs, stop turning the screw until your next visit. If the discomfort has not subsided in one or two days, call the office immediately for further instructions.

If you have any other concerns not listed on this brochure, it should be discussed with your doctor or dentist promptly.