

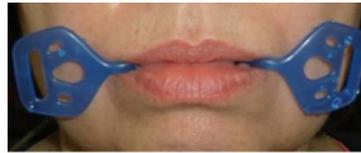
THE APINATOR™ INFORMATION AND INSTRUCTIONS FOR THE DENTIST



The Apinator™ is an innovative, dual-layer oral mouthpiece for the treatment of mild to moderate sleep apnea and snoring. The inner layer softens in hot water between 170 - 180° Fahrenheit and takes the shape of the front teeth for a snug, comfortable fit. The outer layer remains stable in the hot water and maintains the Apinator's shape. It is formed over maxillary and mandibular vacuum formed full arch trays. This is a 3 piece system.

Indication for Use: The Apinator™ is intended for use on adult patients 18 years of age and older as an aid for the reduction and/or alleviation of snoring and mild to moderate obstructive sleep apnea. The Apinator™ can be used as a temporary or trial device to determine efficacy and patient tolerance to oral appliance therapy or as a permanent device.

Contraindications: Not recommended for patients with loose teeth or dental work, numerous missing teeth, dentures or other oral conditions that would be adversely affected by wearing an intraoral dental device which maintains the jaws in a protrusive jaw position. The Apinator™ is also contraindicated for patients who have central apnea, severe respiratory disorders, or are under eighteen years of age.



INSTRUCTIONS FOR FITTING THE APINATOR™



Supplies:

- Pot for heating water, 6 inches deep preferred
- A thermometer that measures at least to 212°F
- Timer, watch or a clock with a second hand

1. Fabricate and seat vacuum formed full arch trays over the teeth
2. Simmer water to 170-180° F.
3. Hold the Apinator™ by the right wing and immerse the intraoral portion for 45 seconds
4. Insert in patient's mouth centered over teeth with the word APINATOR right side up
5. Patient bites into upper and lower grooves in the Apinator™ until firm resistance is felt
6. Close lips, push with tongue, suck in with lips – this will draw out air and water
7. After 60 seconds run under cold water
8. Retry the Apinator™ to confirm snug fit
9. If the fit is not snug, repeat above steps
10. Fit Velcro strap for security

Scientific Concepts/Device Design

The more room created for the tongue in the mouth, the less likely the tongue is to collapse on the airway during sleep. Tongue space in the mouth can be increased in two ways: 1) advance mandible forward; 2) increase interarch vertical dimension. The Apinator™ further maximizes the gain by taking up the least intraoral space. The Apinator™, by virtue of its innovative extraoral wings, reduces appliance bulk in the mouth and creates more intraoral tongue space than other appliances.

The Apinator™ has three component parts; an upper vacuum-formed retainer, a lower vacuum-formed retainer and a soft, flexible anterior repositioning jig with external retention wings. The Apinator™ will support the mandible during sleep in a position in which the dental arches are more vertically open and more protrusive than they would normally be. This is the basic formula of most sleep appliances. The unique premise on which the Apinator™ is based is that adequate space for the tongue in the mouth is more important than specific determination of vertical and protrusive measurements that in other devices, take up tongue space in the palate or interarch area with material or adjustment mechanisms. The vacuum formed retainers are a second stage procedure to prevent movement of teeth from a treatment-altered position of muscle and tongue activity.

The Apinator™ has a unique extraoral elastic/Velcro strap to assist retention, prevent accidental dislodging, swallowing, and allow reduction of the intraoral size of the device. During sleep the intraoral component can be held in place by biting into it and keeping the lips together, frictional fit of the moldable material of the inner channel or by an elastic/Velcro band attached to the extraoral wings and wrapped around the back of the head.

Homecare Instructions for Your Patient:

Please inspect your Apinator™ and custom full arch trays each day prior to use. If you notice any cracks or tears, please contact your prescribing dentist.

1. Position the maxillary custom full arch tray over the maxillary teeth and use your thumbs to firmly snap it on to your teeth. Repeat this process for the mandibular arch.
2. Insert the Apinator™ over your lower front teeth into the custom grooves. Gently slide your lower jaw forward and close your upper front teeth into the upper custom grooves and both arches are engaged in the Apinator™. Attach the elastic/Velcro strap from one extraoral wing around the back of your neck and into the extraoral wing on the opposite side. The strap should be snug without pulling the extraoral wings.
3. When you remove the Apinator™ in the morning, remove front blue component and then remove the custom full arch trays.

Clean the Apinator™ and full arch trays daily with a soft toothbrush/ toothpaste. Rinse well and store dry in a container away from children and pets. Semi-annual visits to your prescribing dentist/doctor is recommended, for evaluation of your teeth, bite and the Apinator™.

Warning: Eating/drinking high sugar foods before inserting the Apinator™ could cause tooth decay and periodontal issues. Brush, floss and rinse before inserting the Apinator™ each night. When the appliance is not in the mouth please store dry in a container in a safe place. *It is a near certainty that dogs or cats will chew up the Apinator™ appliance if it is not stored properly.*

Possible Risks/Side Effects

1. Soreness of teeth, gums, face or jaws can occur. CALL YOUR DENTIST/DOCTOR IF THIS OCCURS.
2. Breathing difficulties with the Apinator™ in the mouth. IF YOU EXPERIENCE BREATHING DIFFICULTY, REMOVE THE APINATOR FROM YOUR MOUTH AND CONTACT YOUR DENTIST/DOCTOR.
3. The risk of swallowing, aspirating or gagging on the Apinator™ is negated by the presence of the extraoral wings. NEVER REMOVE THE EXTRAORAL WINGS.
4. Loosening, flaring or general tooth movement - the Apinator™ is used in conjunction with vacuum-formed retainers which prevent tooth movement. IF YOU EXPERIENCE LOOSENING, FLARING OR GENERAL TOOTH MOVEMENT, CONTACT YOUR PRESCRIBING DENTIST/DOCTOR.
5. Materials are very non-allergic, however, DISCONTINUE USE IF SWELLING OR SKIN IRRITATION OCCURS, CALL TREATING HEALTHCARE SPECIALIST.
6. Increased salivation may occur upon initial use. This is a temporary condition that will usually stop within one week of use.
7. Heating in water above 180° F risks destroying Apinator™. DO NOT DO THIS. USE OF A THERMOMETER TO MEASURE WATER TEMPERATURE IS RECOMMENDED.
8. To reduce the risk of bacterial contamination, dental decay or periodontal issues, METICULOUS HYGIENE IS RECOMMENDED PRIOR TO DAILY USE.
9. Difficulty closing on posterior teeth in morning can occur. If this happens, CONSULT YOUR DENTIST/DOCTOR.
10. Avoid extreme temperatures. Excessive heat causes softening and distortion; excessive cold causes hardening and brittleness.