



Instructions for Use for SomnoDent SUAD™ Devices

A custom-fitted oral device intended to reduce or alleviate nighttime snoring and obstructive sleep apnea.

CONTRAINDICATIONS

The device is contraindicated for patients who:

1. Have central sleep apnea
 2. Have severe respiratory disorders
 3. Have an edentulous mandibular arch
 4. Have loose teeth or advanced periodontal disease
 5. Are under 18 years of age
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1. Assemble the device by placing the lower rods into the upper tubes keeping both halves in the same horseshoe shape. Note that the smooth flat surfaces must be facing each other when the device is assembled. Place the elastics onto the elastic holders as shown in the picture unless directed differently by your Dental Practitioner.
 2. The device should be soaked in warm water for approximately 1 – 2 minutes prior to insertion. The material that fits against your teeth is a thermo-molecular material that softens when heated allowing for easier placement of the device. Do not heat the water with any device such as a kettle or cook top as this will cause distortion or destroy the thermo-molecular material.
 3. While the device is soaking in the warm water, thoroughly brush and floss your teeth. If you have had any coffee, tea, or cigarettes during the day they will leave a fine film on your teeth and due to the nature of the acrylic material, failure to brush your teeth may result in staining of the device. Please note that older amalgam (metal) fillings may cause a discoloration to the inner portion of the device. This discoloration will not affect the function or longevity of the device.
 4. Each arch must be gently fitted onto the teeth by hand. Holding onto the lower arch of the assembled device, place the device into your mouth and push the whole device upwards onto your upper teeth. Now using your index finger on both hands, separate the two halves of the device and gently push the lower arch onto your lower teeth. Close your jaw to further seat the device into place.

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5. Clean your device in the morning immediately after having removed it from your mouth. After each use, rinse in cold or lukewarm water and clean with the brush provided or a soft toothbrush and mild detergent. Then rinse well. Avoid hot or boiling water as it will damage the device. Do not use mouthwash to clean device. Doing so will cause the material in the SomnoDent SUAD devices to deteriorate. Do not use ultrasonic cleaning. Avoid organic solvents like ethanol, acetone etc. for cleaning.
6. If using orthodontic elastics; do not replace them daily; replace them approximately every 2-3 weeks.

WARNINGS

Use of the device may cause:

1. Changes in dental occlusion
2. Gingival or dental soreness
3. Pain or soreness to the temporomandibular joint
4. Obstruction of oral breathing
5. Excessive salivation

PRECAUTIONS

Dentists should consider the medical history of the patient, including history of asthma, breathing, or respiratory disorders, or other relevant health problems, and refer the patient to the appropriate healthcare provider before prescribing the device.

Manufactured for



SomnoMed US

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REVISION HISTORY

Revision	Brief Description of Change	Effective Date	CO#
A	New Document	3/2/16	CO16-012
B	Change of address	10/14/2016	CO16-053

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