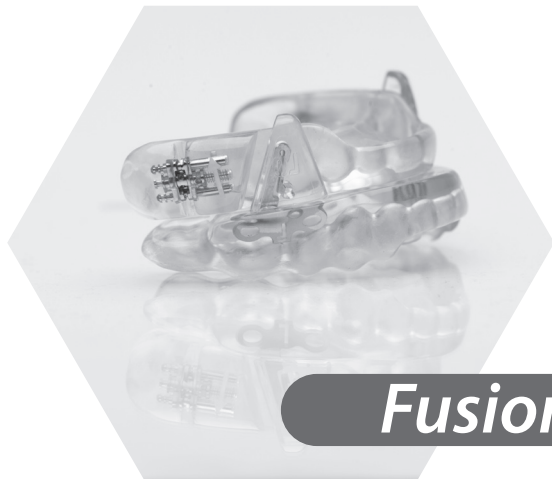


Instructions for Use

Fusion Devices



Fusion[®]



Rx Only

www.somnomed.com

Introduction

The SomnoDent® is a medical device worn orally during sleep. The SomnoDent® device is comprised of an upper and lower dental splint that brings the lower jaw forward and improves the wearers' ability to breathe during sleep.

SomnoDent® devices may come with a Denti-Trac® micro-recorder embedded in the lower splint to record compliance with oral device therapy. The clinician may have decided to incorporate a Denti-Trac® micro-recorder into the SomnoDent® device to record compliance with oral device therapy in combination with the Denti-Trac® system. During scheduled visits, the data within the Denti-Trac® uploads to a web application for cloud-based reporting using a Denti-Trac® Base Station at the clinician's office. The Denti-Trac® micro-recorder monitors the wear time through oral temperature, as well as tracks movements and head position. The inclusion of the embedded Denti-Trac® micro-recorder provides additional information when used in combination with the Denti-Trac® System, but does not impact the operating principles or safety of the SomnoDent®.

The SomnoDent® with Denti-Trac® Micro-Recorder will only capture and store patient compliance data. In order to view and use the data, a Denti-Trac® Base Station is required to extract the data and upload this information onto a cloud-based system.

The Denti-Trac® Micro-Recorder captures and stores clinical usage data. To view and analyze this data, additional components of the Denti-Trac® system are required. A Denti-Trac® Base Station is used to extract the compliance data from the Denti-Trac® Micro-Recorder; this data is uploaded to a secure cloud-based system. Additionally, the clinician can view and create patient compliance reports from the cloud-based system via an internet account. The Denti-Trac® Base Station must be purchased separately.

Caution

Take care to follow care instructions for the oral device (pg.4). Ensure the device is not exposed to extreme temperatures in excess of **45°C / 113°F** as this may damage the micro-recorder.

Indications for Use

SomnoDent® devices are intended for the treatment of nighttime snoring and mild to moderate Obstructive Sleep Apnea in patients 18 years of age or older.

Optionally, if the Denti-Trac® micro-recorder is completely embedded into the SomnoDent® device, the micro-recorder is intended to measure patient compliance to oral device/appliance therapy in combination with the Denti-Trac® System.

Contraindications

These devices are contraindicated for patients who:

- Have central sleep apnea.
- Have severe respiratory disorders.
- Have loose teeth.
- Have advanced periodontal disease.
- Are under 18 years of age.

Warnings

Use of these devices may cause:

- Tooth movement or changes in dental occlusion.
- Gingival or dental soreness.
- Pain or soreness to the temporomandibular joint.
- Obstruction of oral breathing.
- 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 these devices.

Possible Side Effects

You may experience some temporary side effects, such as sore jaw joints, increased salivation, dry mouth, sore teeth, irritation of the soft tissues in the mouth and/or a slight change in your bite. These possible side effects should diminish within an hour of removing the device. If any of these side effects continue, contact your sleep dentist and maintain regular sleep dental check-ups.

Regular inspection of your SomnoDent® devices with or without the Denti-Trac® micro-recorder

Regularly inspect the device for signs of damage, such as fractures and cracks. If the device is damaged or broken, the device must NOT be used any longer in order to avoid injuries, such as choking or laceration. If the device is damaged, immediately take it to a SomnoMed dental sleep provider who will arrange for it to be repaired by a SomnoMed laboratory. ***Repairs, including those under warranty, should be taken to a SomnoMed dental sleep provider, not sent directly to SomnoMed.***

Cleaning & Storage

Always 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 and/or micro-recorder. Water temperature for cleaning should be <45°C/113°F to avoid damage. Do not use mouthwash to clean device. Doing so will cause the material in the SomnoDent® to deteriorate. Do not use ultrasonic cleaning. Avoid organic solvents like ethanol, acetone etc. for cleaning.

Caution:

Do not use toothpaste, as it contains abrasives, and may damage the device. ***Never use hot or boiling water! Hot or boiling water damages your SomnoDent® and/or micro-recorder. This will invalidate the warranty.***

Important

Keep your device away from sunlight. Patients may initially experience a mild plastic taste. This will disappear with storage and use. Some patients with amalgam fillings or users of Pyralvex (a solution for mouth ulcers and denture irritation) may over time notice discoloration in the lining of their SomnoDent®. Discoloration of the material will not adversely affect the performance or longevity of the device.

Please note: *To reduce the possibility of discoloration do not drink coffee, tea or cola with the device in place. Always brush teeth thoroughly before use.*