

Sleep – Anti-Snoring Devices

Instructions for Use

Description:

A dental device chosen for a certain patient, that is designed with various configurations, fitting over the standing teeth, and holding the lower jaw in a protruded position. This holds the tongue and associated tissues in a forward position and thereby maintains an open airway. The device is worn at night, with the open airway minimizing/eliminating snoring.

Indications:

The most appropriate device that will hold the lower jaw in a protruded position when sleeping, thereby maintaining a more open airway will be determined. The decision will indicate the form of the device, the most appropriate materials from which it should be manufactured, and the specifications to ensure it meets the functional needs of the patient. This information is communicated to the manufacturing laboratory by way of a laboratory work sheet

Contraindications:

From the manufacturing laboratory perspective, there are no contraindications to this device, as long as the laboratory follows the specified prescription and the recommended instruction for use is followed. Any contraindications must be outlined to the manufacturer

Warning and Precautions

This product is to be used by a user or patient who is aware and has an expected level of knowledge in the use of this device.

If required, the treating dental professional is expected to prepare the patient's mouth following an accepted protocol to ensure the capability to manufacture a device that meets the required specifications and limitations of the chosen design and materials parameters.

Adverse Reactions:

- Salivary fluctuations.
- Tooth pain.
- Headaches and Temporomandibular joint discomfort.
- Occlusal changes.

Clinical Applications:

This is a single-use medical device that can be used the end-user in a location deemed fit to install the product. It is the responsibility of the end-user to ensure that regular maintenance (if required) is being conducted.

How Supplied:

This device is to be provided to the end user according to the laboratory work sheet details. It is required that this product is cleaned and sterilized prior to use. This service is provided by the Modern Dental Group to ensure that all applicable requirements are addressed. Note, that there are no special storage conditions that is required, since the product is intended to be used immediately.

Instructions for Use

1. Mouth Preparation
 - a. All teeth are of sound structure and are caries-free
 - b. All soft tissues are sound and able to bear the functional pressure of the device
 - c. Temporomandibular joints are sound
2. Product Type
 - a. Mandibular Advancement Device
3. Finishing and Polishing
4. Fitting









Contact Information:

For any questions regarding this product, please contact the manufacturer:



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Symbols Used in Labeling

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|---|--|--|--|
|  | Manufacturer's Address |  | Single-Use Only |
|  | Date of Manufacture (Year and Month) |  | Non-sterile |
|  | Consult Instructions for Use |  | Batch Code (Lot Number) |
|  | Do Not Use if Package is Damaged or Opened |  | Use by Date: Year-Month (YYYY-MM) (if applicable) |