

Patient Instructions for Appliance Use

SleepAPP[®]dotMAD Mandibular Advancement Device for Snoring and Mild to Moderate Obstructive Sleep Apnea

Caution: Federal law restricts this device to sale by or on the order of a licensed dentist

Prior to Placement - Warm the appliance under tap water for 5-10 seconds. If warm water is not available, hold the device in the mouth for ten seconds, or until the appliance slides properly onto the teeth.

Night one: Consider wearing the device for at least one hour prior to bed. If there are any discomforts or concerns, do not wear the device to sleep and contact your provider at the next opportunity. If the device is comfortable, wear the device to sleep for a two-hour period, remove the device for the rest of the night.

Subsequent nights: Add 2 hour increments of time each night that the previous morning resulted in an expeditious return to normal muscle comfort, range of motion and accurate dental bite. Continue this process until the device is worn all night, typically by night 3 or 4. If the bite is not restored fully each day, discontinue use and contact your dental provider.

In the Morning: It is normal to feel a change in your bite. It will feel as if your front teeth hit prematurely preventing your back teeth from hitting properly. Tooth movement is not likely to cause this. The jaw simply remains slightly forward until a gentle stretch of the muscles is accomplished. When the repositioning has occurred, your bite will normalize. This typically takes only minutes. The proper use of stretching exercises, demonstrated by your provider, will help limit the risk of any permanent change to your bite.

- Remove the device and plan for 5-15 minutes to relax on your back as you are waking up.
- Gently stretch your jaw through its entire range of motion.
- Curl the tip of your tongue to the back of your throat. You will feel a tightening of the muscles and a pulling back of the jaw. Hold this position for repetitions of a ten count.
- Your goal is to restore the bite and have jaw comfort within 30 minutes.
- Contact your provider if you are unable to meet these goals. Failure to do so could result in a permanent change in your bite. It is possible that the initial positioning of the jaw could be too aggressive and will need to be adjusted.
- Use the morning repositioning device provided by your dentist to assure no bite change has occurred.

Appliance adjustment procedure:

The goal of the adaptation period is to incrementally advance the mandible at a rate that does not cause discomfort or difficulty restoring the bite easily with the morning stretch exercises / am positioning device prescribed and demonstrated by your dental provider.

- Your provider will suggest a rate at which he/she will serially replace the advancement straps in order to determine the optimal subjective repositioning of the jaw in sleep to improve the observed / experienced symptoms. Your dentist may wish to replace the straps only during a follow up visit so a full assessment of your adaptation is made. These few follow up visits will allow for monitoring of your bite management and to ultimately recommend an objective sleep test or monitoring to assure an optimal response to treatment..
- Adjust the tightness of the screws to control the amount of freedom of movement of the mandibular element in use. This can vary with small screw adjustments from essentially immobile to fully mobile jaw movement.
- **Caution!** Patients with a known allergy to methyl-methacrylate should notify their provider if this has not been discussed to consider the appropriateness of the use of this device.
- **Caution!** Avoid damage to screws or the appliance from over-tightening.
- **Caution!** Use the screwdriver provided or a screwdriver that fits the screw appropriately. Use pressure on the screwdriver into the screw with deliberately slow movements to prevent screw damage.
- **Caution!** Make it a habit when placing the device at night to confirm visually that the screws are fully in place. If in the unlikely event of a loosening of the screw, be sure the head of the screw remains within the funnel that confines it. No loosening of the screws should be expected, but should be reported to your dental provider.
- Your dentist may allow you to replace the straps at a prescribed interval. Follow the instructions precisely. The advancement process should be determined by patient response to therapy. When the patient and bed partner determine that the treatment goals have been subjectively met, the advancement process should cease until follow up visit with the dental provider and the need for follow up sleep testing with the appliance in use is determined.
- Always take your oral appliance with you to all your dental visits for examination and potential maintenance procedures.

Appliance Care Instructions:

- Brush and floss your teeth, brush your tongue, and rinse your mouth thoroughly before bed.

In The Morning:

- Remove all the saliva from the appliance with cool water and/or a small dollop of liquid hand soap and soft toothbrush as needed. Rinse thoroughly. You may notice excessive salivation initially.
- As frequently as needed to maintain a clean appliance, soak the appliance in water with a denture cleaner effervescent tablet. "Retainer Brite" or suitable alternative is recommended. Follow printed instructions for the cleaner use. Do not soak for more than 20 minutes. Allow the device to air dry in the day. store in a dark cabinet.
- Do not clean the appliance in the dishwasher. Avoid exposure of the appliance to heat.
- Prevent ANY exposure of the appliance to pets.

Appliance Storage instructions:

Store the device to air dry inside a dark cabinet or drawer. When traveling, be sure the device has air-dried before sealing it in its case.

Avoid exposure to temperatures above body temperature.

Protect the device from pets!

Contraindications: This device is contraindicated for those patients who:

- have central sleep apnea
- have severe respiratory disorders
- have loose teeth or severe periodontal disease
- are under 18 years of age

Warnings: The use of this device may cause:

- tooth movement or permanent changes in the dental occlusion (bite)
- gingival or dental soreness
- pain or soreness in the jaw joints
- obstruction of oral breathing
- For questions or concerns, contact the dentist who provided you with this appliance.