

SomnoGuard® AP Mandibular Advancement Device

Fitting Procedure Detailed Notes

Patient: _____

Date: _____

Performed by: _____

Procedure notes:

The patient presented for the fitting of an Oral Appliance for the treatment of (Obstructive Sleep Apnea/Snoring) as diagnosed by (HST/PSG) on _____.
(Date)

Notes: _____

An examination of the Oral Cavity, teeth and gums was conducted. No loose teeth or removable implants or dentures were note or reported by the patient.

An assessment of the patient's Mandibular mobility was conducted by having the patient retract their Mandible as much as possible and noting the distance between the upper and lower teeth at maximum retraction and then having the patient thrust their Mandible forward as much as possible and assessing the distance again from the upper to lower teeth. The two distances combined comprising the maximum range of motion and the recommendation of the manufacturer to limit the advancement to no more than 1/3 of the overall range of mobility from the most posterior perspective being considered the baseline for initiation of therapy.

The Maxillary (Top) Tray of the SomnoGuard AP was placed in a bath of boiling water for a period of at least 3 ½ minutes to soften the thermodynamic material. Upon removal from the bath, time was afforded to allow the material to cool to a temperature that was tolerable for the patient without scalding as deduced by the practitioner before placing in the patient's mouth. Aligning the Appliance on the midline with the teeth at the foremost position on the tray, the Appliance was thrust upwards in a uniform fashion to facilitate an impression of the teeth. Upon obtaining as much of an impression as possible in the first impression the appliance was left in place for 10-15 seconds to permit the material to mold to the patient's teeth and cool to maintain the precise impression. The Appliance was removed by exerting uniform downward pressure.

The Mandibular tray meanwhile was immersed in the boiling water bath for a period of 3 ½ minutes. Upon removal from the bath the two halves of the Appliance were assembled with the Adjustment Screw mechanism of the Mandibular Tray engaging the C-Channel Mechanism of the Maxillary Tray. The Mandibular tray was positioned intra-orally into the previously achieved impression (whether full or partial) and the patient instructed to thrust their Mandible forward until the lower teeth were proximate to the front of the lower tray. The patient was then instructed to bite down firmly to facilitate the complete impression of the lower tray.

Communication was consistent throughout the fitting process to ensure the temperature of the molding material was tolerable to the patient and they were able to be compliant with the duration necessary to establish proper fitting of the Appliance.

The patient was instructed to release their bite at which point the complete Appliance was removed. The two halves were separated and the Mandibular portion cooled in a cool water bath.

As indicated, when only a partial impression was obtained with the initial Maxillary Tray impression, the Maxillary Tray was reheated for approximately 30 seconds to soften the material. The two halves were then reassembled and placed intra-orally onto the Mandibular Teeth and the patient guided to insert the Maxillary (upper) teeth into the partial impression previously obtained. Upon confirming appropriate location, the patient was instructed to bite completely into the Appliance to facilitate the full impression of the Upper (Maxillary) Tray.

The Appliance was removed and the Maxillary Tray cooled to lock the impression. Any excess material presenting laterally of the margins of the tray was removed with scissors. Material presenting above the surface of both trays that would impact the free movement of the trays relative to each other was also removed.

A trial fit of the device was performed. Modifications of excess material or irregular surfaces was performed by softening and molding the material or excising any excess material until the fit was deemed complete and reported as comfortable by the patient.

The patient was provided with Instructions for Use and instructed on the post-fitting Titration process to schedule a follow up consult for assessment of efficacy and potential adjustment in the timeframe specified by the physician.

The patient was provided with the Custom Fitted SomnoGuard Appliance, Instructions for Use, Storage Container and post-fitting instructions and encouraged to begin their therapy that evening.

Notes: _____

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