SomnoGuard® AP2 **Mandibular Advancement Device** - Fitting Procedure Notes

Patient: _____ DOB:_____

Performed by: _____ Date: _____

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)

An examination of the Oral Cavity, teeth and gums was conducted. No loose teeth or periodontal disease or dentures were noted or reported by the patient. Any identified removable bridges were removed for the fitting.

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 is that the patient must have at least 7mm of mobility to be an appropriate candidate for Oral Appliance therapy. An assessment of the patients normal occlusion was conducted by exercising the patient's bite by opening and closing several times and taking note of the relation and distance of the upper and lower teeth at the normal closed position.

The two halves of the appliance were removed from the packaging and using the provided allen key, the titration screw was turned approximately 15 times counterclockwise to remove most of the screw from the Post of the Mandibular tray. The titration screw of the lower tray was slid into the C-Channel of the maxillary tray to connect the two halves and the assembled appliance was positioned on the shaft of the strainer mechanism for stabilizing during its immersion in the boiling water.

The SomnoGuard AP2 was placed in a bath of boiling water for a period of at least 3 ½ minutes to soften the thermodynamic copolymer material. Upon removal from the bath, the two halves were seperated and the lower tray placed back on the strainer, hard acrylic side down, and returned to the warm bath. Ample time was afforded to allow the upper tray copolymer material to cool to a temperature that was tolerable for the patient to avoid potential scalding as deduced by the practicioner before placing in the patient's mouth. Aligning the Upper tray on the midline with the teeth positioned within approximately 1mm from the front of the tray, the Appliance was pressed upwards, approximately half the depth of the copolymer, in a uniform fashion to obtain a partial impression of the upper teeth. The upper tray was left in place for at least 45 seconds to permit the material to mold to the patient's teeth and cool to maintain the precise impression.

The lower tray was removed from the bath of water to allow it to become temperate enough to handle and the titration screw removed completely. Leaving the upper, partially fit tray in place, the lower Mandibular tray was tested to assess being temperate enough not to potentially scald the patient, and positioned intra-orally onto the lower arch taking care to orient on the midline, and positioning the anterior edge of the tray the appropriate distance forward of the front of the teeth to duplicate the position of normal occlusion previously described.), pressing down slightly to affix the tray in place, the patient was instructed to bite down firmly to facilitate the complete impression of the lower tray. Observing that the lower teeth penetrate completely into the lower tray and impacting the hard acrylic, the patient was instructed to hold the appliance securely in their bite, while palpating any displaced copolymer on the lingual surface with their tongue to press any such material back into the tray and to conform to the lingual surface of the teeth. Any material displaced on the outer surface of the teeth/gums was palpated likewise by the clinician. The

appliance was left in place for at least 1 minute to allow the copolymer to solidify to maintain the obtained impression.

The patient was instructed to open their mouth and remove both halves of the appliance. The two halves were separated and the upper tray (C-Channel) placed hard side down on the strainer and returned to the hot water bath (cycling the kettle to a boil on occasion and then turning off). The lower tray was cooled in a cool water bath or under a cool faucet and inspected/trimmed if any material protruded above the plane of the tray that would prohibit smooth unrestricted of movement of the finished appliance.

The Upper Tray was reheated for approximately 30-45 seconds to re-soften the material. The lower tray was position on the lower teeth and the reheated upper tray placed carefully on the upper teeth to return it to the original partial impression placement. Upon confirming location, the patient was instructed to bite completely into the Appliance to facilitate the full impression of the Upper (Maxillary) Tray. Confirmation of full penetration of the upper teeth at some point against the hard housing of the upper tray, the patient was again instructed to hold the appliance securely in their bite and to use their tongue to manipulate any displaced copolymer material on the lingual side, back against their teeth, particularly in the region of the molars, to optimize retention. Any externally displaced copolymer was likewise manipulated back into the tray. The appliance was left in place for at least one minute to permit copolymer on upper tray to solidify.

The Appliance was removed and the upper 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.

The Locking Nut was threaded onto the shorter (original) screw and the Screw/Nut reinstalled into the post on the lower tray from the lingual side of the post. Using the Allen Key, the screw/nut was turned clockwise completely into the post until the threads of the screw were just flush with the front surface of the lower tray. The nut was tightened against the lingual surface of the post and assembly of the two halves of the appliance attempted. If the remaining space between the head of the screw and the lock nut was insufficient to permit free lateral movement, the lock nut was released from the surface of the post and the allen key used to turn the screw counter-clockwise, just enough (1/2 turn) to accommodate the C-Channel. Once attained, the locking nut is secured with gentle pressure against the face of the post with the provided wrench.

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.

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