SomnoGuard® SPX 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 fitting handle, one of the identical trays was secured to the fitting handle by snapping the front titration posts into the retaining snaps in the handle.

The SomnoGuard SPX was placed in a bath of boiling water for a period of 60 seconds to soften the thermodynamic copolymer material. Upon removal from the bath, the tray/handle assembly was set aside for 60 seconds to permit the softened copolymer to set up for stable handling. Aligning the tray on the upper dental arch, care was taken to place the centering mark on the midline of the teeth, positioned within approximately 1mm from the front of the tray, the appliance was pressed upwards to set the teeth in the copolymer. Care was then taken to match the curvature of the upper arch with the width of the back sections of the tray. Once in place following the dimensions of the upper arch, the copolymer on the lingual side of the teeth was pressed upward and against the inside of the dental arch to conform to the lingual side of the teeth. The upper tray was left in place for at least 60 seconds to permit the material to mold to the patient's teeth and cool to maintain the precise impression. Removing the tray gently from the teeth permitted an initial assessment of retention achieved. With minimal, but adequate retention demonstrated, the tray was cooled in a bath of cold water for 10 seconds and repositioned on the upper arch to assess placement and retention. The upper tray stayed securely in place on its own and was placed and removed by the patient without undue effort.

With the now custom fit upper tray in place, the same process was repeated with the lower tray to achieve demonstrated retention. Implicit care was taken to align the centering marks on both appliance halves when positioning the lower tray. The patient was instructed to raise their tongue to the roof of their mouth for the placement of the tray and matching of the curvature of the lower arch. The copolymer was then pressed down and outward upon the surface of the lower molar teeth. The patient was then instructed to lower their tongue and close their bite to told the appliance in place while the material cooled for 60 seconds.

The patient was instructed to open their mouth and remove both halves of the appliance and confirmation of ample retention recorded. Any excess material protruding below the underside surface of the trays was trimmed with flush cut snips.

Assessment of the patient's bite was performed to set the positioning of the trays with the provided Titration Straps or turnbuckles, at or very close to their normal occlusion. The appropriate length of fixed-length straps, or adjustable length of the turnbuckle, was derived by referencing the patient's distance of over/under jet assessed at the normal close position. The appropriate straps were selected and removed from the 10mm set of straps with the snips, or if using the turn-buckles, the length was set by turning the two post-mount ends of the turnbuckle equally and precisely adjusting with the provided open-end wrench. The precise length of the turnbuckles was confirmed and adjusted with the provided SomnoGuard Turnbuckle Length measuring tool.

The slightly curved end of the strap was mounted on the FRONT POST of the UPPER tray. Orienting the lower tray with the flat surfaces proximate to each other, the other end of the strap was mounted on the BACK POST of the LOWER tray, thus "pulling" the lower tray and jaw forward and prevent reward travel of the jaw and associated musculature. The unused back posts on the Upper tray and the front posts on the Lower tray were removed with the flush cut snips, taking care to ensure there was no rough/sharp edges created with the removal.

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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