OBSERVATION/ADJUSTMENT VISITS:

Schedule observation visits (as summarized below) to ensure that the appliance is comfortable and effective and that no dental problems have developed.

Week 1-4: Inital Seating & Follow-Up

Make any necessary adjustments for the fit and positioning over aligners. If more lower protrusion is desired, adjust upper buccal (sagittal) screws:

10 turns = 1mm. Midline screw adjustment may not be necessary. Fit the SML™ Good Morning Positioner. Follow the included fitting instructions, and instruct the patient in its use.

Month 1: Teeth/Appliance Evaluation

Check ASA comfort and fit. Make any necessary adjustments in jaw position. Consider evaluating mid-palatal and lower traverse adjustment screws to ensure posterior fit. Once the patient tells you he/she is feeling rested and greatly improved, refer back to Home/Lab Sleep Test in evaluating appliance efficacy.

Month 6: Progress Check

Assess progress with the appliance and address any patient concerns. Consider additional follow-up sleep test to evaluate efficacy and address potential need for further titration.

Year 1: Teeth/Appliance Inspection

Assess progress with appliance and address any patient concerns. Address need for any appliance repairs. Consider additional follow-up sleep test to evaluate efficacy and need for further titration.

IMPORTANT: The importance of adhering to this regimen cannot be overemphasized. The follow-up visits listed above are the minimum amount of visits necessary to assure the best possible experience for your patient.
We recommend that every doctor repeat Week 1 – Year 1 visit scheduling as needed throughout course of patient's lifetime treatment.

FABRICATED BY:

SML® - Space Maintainers Laboratories
9129 Lurline Ave, Chatsworth, CA
1-800-423-3270
www.SMLglobal.com

THE ALIGNER SLEEP APPLIANCE (ASA)™ IS MANUFACTURED EXCLUSIVELY BY SML®

NADSMSM CERTIFIED APPLIANCE

SPACE MAINTAINERS LABORATORIES



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

CLINICAL INSTRUCTIONS FOR USE:
ALIGNER SLEEP APPLIANCE (ASA)™

The **Aligner Sleep Appliance (ASA)™** is used for reducing nighttime snoring and mild-to-moderate Obstructive Sleep Apnea in adults. Dentist prescribed for aligner/Invisalign® therapy, the appliance is worn while sleeping to support the lower jaw in a mild forward position. Two-piece construction allows for patient comfort, while expansion screws on both sides of the upper portion are activated to gradually move the jaw forward. Each appliance is custom made for the patient and is fully adjustable.

REV.B. AUG. 2016

CONTRAINDICATIONS

This appliance is contraindicated in the following instances:

- Central Sleep Apnea
- Severe respiratory disorders
- Loose teeth or advanced periodontal disease
- Patients under 18 years of age
- Edentulous or insufficient number of teeth to retain the device
- Inadequate mandibular range of motion
- Myofacial dysfunction
- Anthropathy of the TMJ
- If the patient is undergoing dental work that requires temporary crowns

RISKS

Use of the device may cause:

- Gingival irritation or dental soreness
- Pain or soreness of the TMJ or facial muscles
- Obstruction of oral breathing
- Increased salivation

OFFICE PROTOCOL

Oral Health and Medical Health History Assessment:

The dentist *must* perform a complete oral health assessment as well as a medical health history assessment including:

- Full medical and dental health history
- Dental radiographs
- Clinical oral evaluation
- General patient interview

NOTE: Dentists should evaluate the medical health history of the patient – including history of asthma, breathing or respiratory disorders, other relevant health problems – and refer the patient to the appropriate healthcare provider *before prescribing the device.*

IT IS ESSENTIAL THAT THE PATIENT BE TESTED WITH A HOME SLEEP TESTING DEVICE OR AN OVERNIGHT-ATTENDED PSG TO VALIDATE – WITH OBJECTIVE DATA – TREATMENT POSITION EFFICACY.

ALWAYS follow-up with your patient's sleep physician (and any other treating physicians) with regard to status of your mutual patient.

DELIVERY DAY INSTRUCTIONS

1. Insert upper and lower aligner.
2. Position dental chair – back 30 degrees.
3. Insert Upper ASA in patient's mouth (over the aligner).
4. Insert Lower ASA in patient's mouth (over the aligner).
5. Instruct patient to bring their mandible forward to engage appliance (lower fins to upper stops).
6. Upright patient. Check interocclusal space to ensure proper fit for fins and stops.
7. Using articulating paper, confirm interactive flat surface between upper and lower. Remove any interfacing that prevents full contact between the upper and lower member.
8. Make further adjustments as needed.

WARNINGS

Performance may be adversely affected by: weight gain, obesity, alcohol consumption, sedative use, allergies, smoking, any cold or sickness that compromises nasal breathing, very high altitudes, increased age, and hormonal changes in women such as menopause. Patient should be instructed as follows:

DO NOT wear the appliance if broken.
DO NOT run or exercise with the appliance in your mouth.
DO NOT attempt to modify the appliance.
DO NOT share the appliance.
DO NOT expose appliance to extreme heat or leave in car for prolonged periods.
DO NOT attempt to pop the appliance in and out of your mouth with your tongue. This may damage or alter the adjustment.

IMPORTANT NOTE: Patient Instructions (including risks and benefits, care, maintenance, and warnings) should be dispensed and reviewed with the patient upon delivery of appliance.

CARE AND CLEANING

Each morning after use, patient should rinse appliance in cold water and gently brush all surfaces clean. DO NOT USE TOOTHPASTE. After cleaning, rinse appliance under cool water. Air dry before storing.

We recommend that patient clean appliance every morning with an appropriate appliance cleaner, e.g. OAP Appliance Foam Cleaner – available from SML (1-800-423-3270) or www.SMLglobal.com. Follow manufacturer instructions for use

Patient should be instructed to keep the expansion screws clean and examine them often for signs of wear and tear. If there is a suspicion or indication that damage has occurred, patient should not wear appliance until contacting dentist for proper appliance inspection.

CAUTION: DO NOT bleach the appliance or soak in mouthwash or alcohol. Doing so may weaken appliance.

DO NOT place appliance in hot or boiling water or expose to excessive heat. This may distort the appliance and render it unusable.

STORAGE: Dry the appliance before storing. Place in a dry plastic case whenever it is not in use. Keep appliance out of reach of family and pets.

IMPORTANT

The titration screw used on this appliance requires ten ¼ turns to achieve 1mm of expansion. Each ¼ turn (90-degree rotation) of the turnbuckle equals one-tenth of a millimeter.

If palatal expansion is necessary, the midline screw is there to follow the clear tray treatment protocol. The midline screw requires 4 turns to achieve 1mm of expansion.

Maximum Expansion: 5mm

NOTE: 60% to 70% PROTRUSIVE CONSTRUCTION BITE REQUIRED (as per standard OSA repositioning guidelines).

