

FOLLOW-UP/MAINTENANCE VISITS:

Schedule transition visits (every 3-4 weeks) and observational visits (as needed) to make sure the appliance is comfortable and effective and that no dental problems have developed

Visit 1: Comfort Check

Make any necessary adjustments for the fit, comfort and positioning of the first set of aligner trays.

Follow-Up Visits (Scheduled By Dentist)

Schedule appointments for aligner tray transition to each subsequent stage. At each scheduled visit, assess progress, address any concerns and prescribe the next set of trays when warranted.

NOTE: Instruct patient to keep most recently used aligner trays in a separate case after transitioning to the next wear stage. In the event of loss or breakage to the current tray (s), you may recommend a temporarily return to wearing aligner tray (s) from the previous stage while a replacement is being fabricated.

IMPORTANT: The need to adhere to this care regimen and schedule cannot be overstated. The follow-up visits listed above are the minimum amount of visits necessary to assure the best possible experience for you. You should call your dentist for additional visits whenever you feel they may be necessary. To ensure the best possible outcome with the appliance, it is essential to have a proper fit and to have your mouth evaluated regularly throughout treatment.

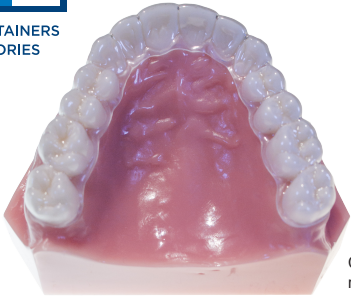
WARRANTY:

The SML® ClearAlign is custom made to ensure comfort and durability. Your device is warranted by the certified laboratory employed by your dentist. This is a manufacturers warranty. Your doctor, not SML®, is responsible for managing your orthodontic treatment. If you expect an adverse reaction, discontinue use and consult your doctor. If your SML® ClearAlign is broken or damaged in any way, it is very important that you cease using the device and contact your dentist to have it repaired immediately.

FABRICATED BY:



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



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

CLINICAL INSTRUCTIONS FOR USE:
SML® ClearAlign
Invisible 5-Tray System

Designed exclusively for correcting minor to intermediate crowding, spacing or orthodontic relapse, SML® ClearAlign employs a series of up to 5 flexible alignment trays – constructed of thermoplastic polyurethane and custom made for the individual patient via cad-cam process.

Patients must have adequate natural undercuts for retention of the vacuum form material. Each tray is worn – one at a time -- over the teeth for a period of 3-4 weeks until treatment is complete.

Retention cannot be increased during treatment and the appliance cannot be modified to accommodate new tooth restorations or the loss of posterior teeth.

The SML® ClearAlign system is indicated for the treatment of malocclusion in patients with permanent dentition. Trays are worn for a period of 20-22 hours each day and are inserted and removed by the patient and adjusted by the prescribing dentist.



CONTRAINDICATIONS

This appliance is contraindicated in the following instances:

- 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
- Ankylosis of the TMJ
- Patient is undergoing any type of orthodontic treatment
- Patient is undergoing dental work that requires temporary crowns

WARNINGS

Use of the appliance may cause:

- Gingival irritation or dental soreness
- Pain or soreness of the TMJ or facial muscles
- Increased salivation or dry mouth

NOTE: Remind your patient that if they experience any of the above problems to discontinue use and call your office for a follow up appointment

PRECAUTIONS:

Patient should be instructed as follows:

- DO NOT wear the appliance while eating.
- DO NOT "bite" appliance trays into position. Damage may result.
- DO NOT wear the appliance while drinking hot, sweet or colored liquids.
- DO NOT wear the appliance if broken
- DO NOT use toothpaste or denture cleaner to clean the appliance.
- DO NOT soak appliance in mouthwash.
- 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 attempt to pop the appliance in and out of your mouth with your tongue. This may damage or alter the adjustment.
- DO NOT use excessive force – via sharp object or otherwise – to remove appliance.
- DO NOT place appliance in hot or boiling water or expose to excessive heat.

OFFICE PROTOCOL:

Oral Health and Medical Health History Assessment:

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: Evaluate the medical health history of the patient, including asthma, breathing, respiratory disorders, or other relevant health problems. Refer the patient to the appropriate healthcare provider for treatment of health problems before prescribing the appliance.

IMPRESSIONS:

Using a high-quality alginate take dental impressions of the upper and lower arch of teeth and palate. Please create the model in your office, evaluate for defects, trim and dry before shipping to the lab.

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:

Patient should clean each aligner tray in cold water prior to insertion and gently brush all surfaces clean. DO NOT USE TOOTHPASTE. Doing so may abrade your appliance. DO NOT bleach the appliance or soak in mouthwash or alcohol. Doing so may weaken the appliance. After cleaning, rinse appliance under cool water. Air dry before storing.

We recommend that patient clean appliance 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 examine appliance often for signs of wear and tear. If there is a suspicion or indication that damage has occurred, patient

STORAGE: Patient should place appliance in a dry plastic case (provided) whenever it is not in mouth. Keep appliance out of reach of family and pets.

BEFORE



AFTER

