

Device Description:

The SML Clear Moves are a series of clear, lightweight thermoformed plastic aligners designed to be worn in sequence to facilitate the movement of the teeth to the final desired position. The sequential aligners introduce incremental movements that move teeth by way of gentle continuous force. The aligners are to be worn 20 to 22 hours a day and are to be removed only for eating and for cleaning. The typical wear time for each aligner is determined by the dental practitioner, generally a two week minimum duration prior to being replaced by the next aligner in sequence.

Caution:

Federal law restricts this device for sale by or on the order of a dentist.

Contraindication:

The SML Clear Moves are contraindicated for use in patients with the following condition:

- Active periodontal disease.

Warnings:

- Rarely, patients may be allergic to plastic. Patients with a history of plastic allergies should not use this product.
- Damaged or broken aligners should not be used as small pieces of plastic can be swallowed or aspirated.

Precautions:

- Aligners are intended to only be removed for eating, drinking, and for oral care. Unnecessary and excessive removal and insertion of aligners may prematurely damage and/or break the aligners.
- Keep aligners away from hot water and harsh chemicals. Keep aligners out of reach of young children and pets. Always store aligners in a cool, dry place.
- Bonded auxiliaries, elastics, and other fixed and/or removable orthodontic appliances, may be needed for more complicated treatment plans where aligners alone may not be adequate to achieve the desired outcome.
- Oral surgery may be necessary to correct severe crowding or jaw imbalances. If oral surgery is required. Risks associated with anesthesia and proper healing must be taken into account prior to treatment.
- Atypically-shaped, erupting, and/or missing teeth may affect aligner adaptation and may affect the ability to achieve the desired results.

- Existing dental restorations (ex: crowns, bridges) may become dislodged and require re-cementation or, in some instances, replacement.
- Aligners are not effective in the movement of dental implants.
- Certain medical conditions and use of certain medications may affect orthodontic treatment outcomes.
- The product may temporarily affect speech and may result in a lisp, although any speech impediment associated with the product usually disappears within one or two weeks.
- Failure to wear the appliances for the prescribed number of hours per day and/or not using the product as directed by your doctor can lengthen the treatment time and affect the ability to achieve the desired results.
- Gums, cheeks, or lips may be scratched or irritated by the product.
- Risks associated with interproximal reduction, which may be prescribed to create space for tooth movement as part of treatment must be taken into account.
- Tooth decay, periodontal disease, and permanent markings from stains and decalcification may occur if patients do not brush and floss their teeth properly during treatment or if they consume foods or beverages containing sugar while wearing aligners.
- The bite may change throughout the course of treatment and may result in temporary patient discomfort.
- Teeth may shift position after treatment. Consistent wearing of retainers at the end of treatment should reduce this tendency.
- It is recommended that all teeth should be at least partially covered to help prevent supra-eruption.
- Temporary increase in salivation or dryness of mouth may occur.
- A tooth that has been previously traumatized or significantly restored may be aggravated.
 - In rare instances, the useful life of the tooth may be reduced. The tooth may require additional dental treatment such as endodontic and/or additional restorative work, and/or the tooth may be lost.
- The health of the bone and gums which support the teeth may be impaired or aggravated.
- The length of the roots of the teeth may be shortened during orthodontic treatment, which may become a threat to the longevity of the teeth.

- In rare instances, problems in the temporo-mandibular joint (jaw joint) may result in joint pain, headaches, or ear problems.
- At the end of treatment, the bite may require adjustment by your doctor.

Directions for Use:

- Upon receipt of aligners, open the bag and rinse well with cool water before putting it into the mouth.
- Remove your aligners to eat, brush, cigarette smoking and drink hot beverages.
- Drinking hot liquids can cause defects in the aligners since they are heat activated.
- Do not chew gum while wearing aligners. Hard candy mints are ok to have while wearing aligners.
- Do not smoke with aligners as this will cause aligners and teeth to stain and may deform the aligner.
- Wear aligners for at least 22 hours every day & night during treatment.
- It is normal for new aligners to fit tightly and apply pressure to your teeth. This pressure should lessen the longer you wear each step.
- Contact your doctor or office who supplied treatment if you experience any fitting issues or severe pain.
- Remove the aligners to eat. Brush and floss after every meal to prevent food and drink from getting trapped under the aligner. Do not chew gum while wearing your aligners.
- While wearing your aligners you may experience dry mouth. Drink plenty of water.
- Use care when cleaning your Aligners. Do not pinch the ends of the horseshoe, as this can cause them to break. Do not twist the horseshoe shape, as this can also cause them to break.
- When directed by your doctor, advance to the next step.
- Make sure to bring your current and previous set of aligners with you to any checkups.
- If an aligner is lost or does not fit, contact your dentist immediately.
- Do not dispose of your used aligners until your treatment is complete as you may have to back track into a previous stage. Once completed, dispose of aligners in a household garbage can.
- When removed, store your aligners in the provided carrying case.



Placement and Removal Instruction:

Place the aligners onto your teeth, making sure to put the upper arch aligner on your upper teeth, and lower arch aligner on your lower teeth. Use equal pressure to insert the aligners and do not bite them in as they may distort.

- Orient the aligner so that it is aligned with your front teeth then push towards the gums and back to fully seat the aligner.

To remove your aligners, use your fingers to grasp the aligner's edge and gently pull away from your teeth.

- Start at the back molars
- Gently remove from the back going forward then slide them off the front teeth.
- This will help avoid damaging the Aligners.
- If resistance is felt, it may be necessary to repeat the previous step in several locations.
- Do not bend, twist, or use excessive force when removing aligners or they may distort or be damaged.
- Do not use sharp objects to remove your aligners.

Cleaning Instruction:

To clean your aligners, you can use a normal toothbrush and toothpaste.

- Our Aligners will not scratch with toothpaste.
- Rinse under running cool water or use an approved dental appliance cleaner.
- You may also choose to soak them in a 3% peroxide solution if you want to disinfect them.

Storage Condition:

Store your upcoming aligners in their original packaging, in a cool, dry place.

RX Only

If you suspect an adverse reaction, discontinue use immediately and consult your doctor. Your doctor, not SML Co., is responsible for managing your orthodontic treatment.

Symbols Glossary

ANSI/AAMI/ ISO 15223-1:2012 Medical devices – Symbols to be used with medical device labels, labeling and information to be supplied – Part 1: General requirements.

Symbols	Title of Symbols (Reference Number)
	Consult Instructions for Use (5.4.3)
	Caution: Consult accompanying documents (5.4.4)
	Non-sterile device.
	Single-use only.
	For USA Only (Federal law (USA) restricts this device to sale by or the order of a licensed dentist.) Manufacturer (5.1.1)

FABRICATED BY:



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Indications for Use:

The SML Clear Moves are indicated for the treatment of tooth malocclusion in patients with permanent dentition (i.e. all second molars). The SML Clear Moves position teeth by way of continuous gentle force.

CAUTION: Federal law requires a written prescription, signed by a licensed medical professional.

