

- Use the white case to store your “backup” aligners. These are the previous set of aligners that you just finished wearing. If your “current stage” aligner is lost or broken, your doctor may recommend that you temporarily use your “backup” aligners while a replacement for the “current stage” is made.

- When it is time for your next aligner stage, shift the aligners in the cases. Throw away the old “backup” aligners. Clean and place the aligners that you just finished wearing into the white case. Use the empty blue case to store your new “current stage” aligner.




- Do not store aligners near a heat source. This may cause them to distort, resulting in improper fit in your mouth.

Oral Hygiene

During treatment it is important to maintain good oral hygiene. Trapping food in your aligners during treatment can lead to decay.

- You should remove your aligners when eating or drinking any beverage other than cool water.
- You should brush and floss your teeth before inserting your aligners.
- We recommend regular dental checkups and cleaning for the continued health of your teeth and gums.

If you have additional questions after reading these directions, please consult your doctor.

Symbol Glossary		
Symbol and Standard* Reference No.	Title of Symbol	Description of Symbol
 5.4.4	Caution	Indicates the need for the user to consult the instructions for use for important cautionary information such as warnings and precautions that cannot, for a variety of reasons, be presented on the medical device itself
 5.4.3	Consult Instructions for Use	Indicates the need for the user to consult the instructions for use.
*Source: ISO 15223-1:2016, Medical devices — Symbols to be used with medical device labels, labelling and information to be supplied — Part 1: General requirements		
	Prescription Use	Caution - Federal law restricts this device to sale by or on an order of a dentist.
**81 FR 38911 Use of Symbols in Labeling, Final Rule		



SureSmile® Aligner

Patient Directions For Use

Your SureSmile® Aligners were custom made for you based on your doctor’s prescription. Please read these directions carefully before use.

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EC	REP
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Rx only

suresmilealigner.com

For Professional Use Only – Rx Only

Device Description

SureSmile® Aligners are fabricated from clear thin thermoformed plastic in a sequential series to reposition the teeth progressively. Minor, incremental changes in tooth positions in each subsequent aligner deliver corrective forces to straighten the teeth.

Indications for Use

SureSmile® Aligners are indicated for the treatment of tooth malocclusion in patients with permanent dentition.

Contraindications

SureSmile® Aligners are contraindicated for use in patients with active periodontal disease.

⚠ Warnings

- In rare instances, some patients may be allergic to plastic. Patients with a history of allergic reactions to plastics should not use this product.
- Do not use damaged or broken aligners, as their parts can be accidentally swallowed or aspirated, and may be harmful.

Precautions

- The patient may experience tenderness or temporary discomfort at initial aligner placement and after switching to each new aligner.
- The aligner may initially affect speech and may result in a lisp, usually disappearing within two weeks.
- The patient may experience a temporary increase in salivation or dryness of mouth.
- The aligners may scratch or irritate the patient's lips, cheeks or gums.
- The patient should not wear aligners when drinking hot, sweet, or colored liquids.
- If patient does not brush and floss correctly during treatment, or if they consume sugary foods or beverages while wearing aligners, they may be subject to tooth decay, periodontal disease and permanent markings from decalcification and staining.
- Lack of compliance in wearing the aligners for the prescribed number of hours per day or not using the aligners as directed can increase treatment time and affect desired results.
- The patient's teeth may shift position after treatment. To help prevent this, the patient should wear retainers.

Adverse Reactions

Allergic reactions, to plastics.

Step-by-Step Instructions

- Wear your aligners per your doctor's instructions, usually 20-22 hours daily (includes sleeping).
- Remove your aligners when eating all snacks and meals, and when drinking all liquids except for cool water. Do not chew gum while wearing your aligners.
- Handle your aligners with care. Handle ONE aligner at a time when inserting, removing or cleaning.
- If an allergic reaction occurs while wearing your aligners, discontinue use and consult a health care professional immediately.
- If your aligner or an attachment is lost or broken, do not use it, and immediately contact your doctor.

Cleaning Your Aligners

Retainer Brite® products are recommended to clean your SureSmile® aligners safely and effectively. Retainer Brite® product samples were provided with your aligners to assist you with cleaning and hygiene.

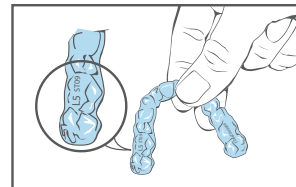
- You should NOT use toothpaste or soak your aligners in mouthwash, as this can scratch or dull the plastic, adversely affecting the clarity.
- You should follow the specific directions for use provided with each Retainer Brite® product.
- Never put Retainer Brite® Cleaning Tablets or tablet solution in your mouth.

Inserting Your Aligners

A Chewies™ Aligner Tray Seater is recommended to seat your SureSmile® aligners safely and effectively. Follow the instructions provided in your patient kit.

- Wash your hands thoroughly with soap and water before handling your aligners.
- Clean your aligners before you insert them.

- Make sure you have the correct aligner. Each aligner is engraved with the first four letters of your name, a "U" for upper teeth or an "L" for lower teeth, followed by the stage number.



- Insert only one aligner at a time. Trying to seat two at once, or using excessive pressure, may damage your aligners.
- Place your aligner over your teeth by hand and apply slight pressure until it is seated most of the way.
- Insert the Chewies™ Aligner Tray Seater into your mouth and position it between your upper and lower arches.
- Gently bite down on the Chewies™ Aligner Tray Seater and work your aligner into place until fully seated.
- Minor discrepancies between the new aligner and the current tooth position are normal since the teeth need time to conform to the new aligner position. If you experience sharp pain or significant discomfort, remove the aligners and inform your doctor immediately.

Removing Your Aligners

The Retainer Retriever tool is recommended to remove your SureSmile® aligners safely and effectively. Follow the instructions provided in your patient kit.

- Grasp Retainer Retriever by the end with the hole in it.
- Insert hooked end of Retainer Retriever into your mouth.
- Using the hook, gently grasp an edge of your aligner near front of mouth and pull away from the arch.
- If resistance is felt, it may be necessary to repeat the previous step in several locations along your arch. Do not use excessive force to try to remove your aligner.
- Be careful when removing your aligners, especially if there are multiple attachments.
- Do not bend, twist or use excessive force to remove your aligner as this may damage it.
- DO NOT use sharp objects to remove your aligners.
- Consult with your doctor if your aligners are extremely difficult to remove.
- To help prevent damage to your aligners, avoid unnecessary removal.

Storing and Changing Your Aligners

To help protect your aligners from loss or damage, store them in a case when they are not in your mouth. Two cases (one blue, one white) were included in your kit.

- Use the blue case to store your "current stage" of aligners when you take them out of your mouth (i.e. while eating).