

BioSmart™ Aligners (T/SM)

Orthodontic appliance – Clear Aligner

Instructions for Use

General Information

BioSmart™ system is an orthodontist-prescribed treatment that uses a series of thin, clear, and removable trays. These aligners are manufactured using precision 3D printing technology that is either directly printed or fabricated using thermoformed sheets. They gradually move the patient's teeth in small increments—from their original position to a more ideal alignment—as guided by your orthodontist.

Indications for Use:

This system is designed for the orthodontic correction of misaligned teeth and malocclusions.

Contraindications for Use:

This System is contraindicated for use in patients with the following conditions:

- Active/severe periodontal disease
- Untreatable TMJ disorders
- Moderate-Severe skeletal discrepancies

Precautionary Information for Patients

- Aligners should only be removed for eating, drinking (other than normal temperature water), and performing oral hygiene. Frequent or unnecessary removal and reinsertion—can lead to premature damage or breakage.
- Avoid foods and beverages like turmeric, coffee and tea, as they can stain or damage your aligners.
- **Instructions regarding proper techniques for inserting and removing** aligners should be given to prevent damage (kindly refer to the pictorial inserts in the aligner pouch).
- **Some discomfort and tenderness/pain might be there** when they first start wearing aligners and each time they switch to a new one.
- Temporary increase in saliva or a feeling of dry mouth may be observed.
- To help prevent teeth in unusual positions from over-erupting (or in simpler terms, teeth coming out), it's best to keep them partially covered with an aligner and not fully covered.
- Teeth that have had previous trauma or large restorations (like fillings or crowns) may become sensitive or require additional treatment.
- The aligners might **temporarily affect speech** and cause a **slight lisp**, but this typically goes away within a week or two.
- The aligners may cause **irritation to gums, cheeks, or lips (recommended to use gels or ointment as prescribed by the treating Orthodontist to resolve this)**.
- Brushing and flossing is mandatory. Eating or drinking sugary foods and wine etc. while wearing aligners, there is a risk of tooth decay, gum disease, or permanent staining of aligners.
- The bite may shift during treatment, which can occasionally cause mild, temporary discomfort. This does not impact the treatment outcome.
- At the end of treatment, Orthodontists may need to make minor bite adjustments to ensure proper alignment.
- Pre-existing temporomandibular joint related issues may cause headache, joint or ear pain.
- **Do not expose aligners to very hot water or harsh cleaning agents (such as toothpaste which has a high abrasive content)**, as these can cause warping or damage.
- Store aligners out of reach of young children and pets.
- Always keep aligners in a cool, dry place when not in use – recommended to use the jewel box provided with the aligners.

- Unusually shaped, or missing teeth can impact how well the aligners fit and may limit the ability to achieve optimal treatment outcomes. Reshaping or replacement of those teeth can be done for better aesthetics post a aligner treatment.
- Pre-existing dental restorations such as crowns or bridges may become dislodged during treatment, potentially requiring re-cementation or replacement.
- After treatment, teeth can naturally shift over time. Wearing retainers as instructed by the treating Orthodontist helps maintain results as expected.
- Maintaining oral hygiene protocols as recommended by the Orthodontist can help preserve the health of the gums and bones as they may be affected during a aligner treatment.
- Excessive pressure can sometimes lead to undesirable shortening of the tooth roots, which may affect the long-term health of the teeth.

Note: - Not wearing aligners for the recommended number of hours each day or not following the Orthodontist's instructions can extend the patient's treatment time and impact the results.

Precautionary Information for Dental Personnel

- Kindly ensure that the usage guide for patients is thoroughly discussed with the patients before handling the aligners.
- Rinse each new set of aligners with cold water before placing them in the mouth
- Each aligner is intended to be worn for 20–22 hours per day and replaced every 1–2 weeks (or as per the timelines prescribed by the treating Orthodontist).
- When placing the first aligner, check for any contact with soft tissue that could cause irritation. If needed, carefully trim the aligners and polish the edges.
- Complete the placement of attachments as needed and carry out any required interproximal reduction (IPR) as per the advised treatment plan.
- If applicable, add pontics to the aligners using the Pontic System or a similar product.
- Provide the patient with storage cases for their aligners. Instruct them to always store aligners in the case when not in use to prevent loss or damage.
- Dispense the appropriate number of aligners to cover the time until the patient's next scheduled visit.
- If additional aligners are necessary, new impressions or scans may be required.
- Small attachments may be temporarily placed on patients' teeth to help with aligner fit and tooth movement. These can sometimes come off and need to be replaced.
- All attachments should be removed when treatment is finished (as per advised treatment plan).
- As per the advised treatment planning, InterProximal Reduction to create space for proper alignment might be recommended in certain cases.
- Cases with severe misalignment may require additional attachments or alternatives or auxiliaries along with aligner therapy.
- In cases where aligners alone are insufficient to achieve the desired results, additional appliances such as skeletal expanders, bonded auxiliaries, elastics, or other fixed and/or removable orthodontic devices may be necessary for more complex treatment plans.
 - ✓ In cases, with severe jaw discrepancies or TMJ disorder a aligner treatment should be started after resolving the above-mentioned issues.

Additional information: If an extraction is part of the treatment plan, maintain the space during healing. Attachments should only be placed after the extraction site has fully healed.

Instructions for Use for patients: -

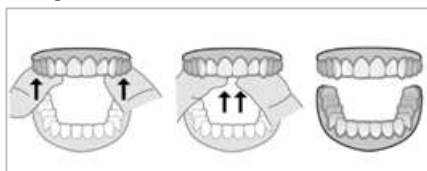
To ensure effective treatment and prevent damage to your aligners, kindly check if the treating Orthodontist has prescribed a thermoformed or a direct print aligner for that specific phase and please follow these guidelines carefully.

Kindly ensure that the usage guide for patients is thoroughly discussed with your treating Orthodontist before receiving the aligners.

- **Wear your aligners** according to your Orthodontist's instructions—typically **20 to 22 hours per day**.
 - Aligners are usually changed every **1 to 2 weeks**, or as directed by your Orthodontist.
- **Wash your hands** thoroughly with soap and water before handling your aligners.
- **Remove** your aligner while having your food.
- Avoid foods and beverages like turmeric, coffee and tea, as they can stain or damage your aligners.
- **Only water and colourless liquids can be taken while wearing aligners.**
- Always **handle one aligner at a time** to prevent mix-ups or damage.
- **Rinse your aligners** with water after removing them from the packaging before first use.
- **Do not use excessive force** to bend or twist the aligners during removal.
- **Avoid using sharp objects (e.g. scissors)** to take out your aligners. If needed, always use the aligner removal tool that has been provided with the aligner kit.
- When storing the aligner after each use, avoid direct sunlight and store in the jewel box provided.

Aligner Insertion Instructions (for thermoform aligners):

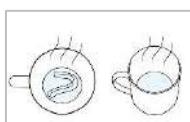
- **Confirm you are using the correct aligner:**
- The **upper (U)** aligner is for your top teeth.
- The **lower (L)** aligner is for your bottom teeth.
- Each aligner is **printed** with your unique number, along with a "U" or "L" and the corresponding **stage number** to help you identify it easily.
- You may start by inserting either the upper or lower aligner.
- **First**, gently place the aligner over your front teeth.
- Then, using your fingertips, **apply equal pressure** on the tops of your left and right back molars until the aligner **snaps into place**.



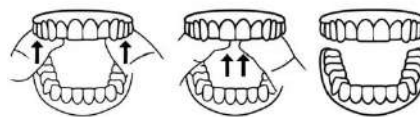
- **Do not bite your aligners into place**, as this may damage them.
- Use Chewie that has been provided with your aligner kit in case of any difficulty while wearing your aligners.

Aligner Insertion Instructions (for DPA):

- **Submerge the aligners completely in hot water above 60°C for less than a minute.**
- Insert the aligners by gently pressing it in front region followed by back region (make sure the aligner not hot enough to damage the oral tissues)



but is also worn **before it cools down**).



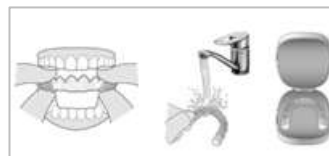
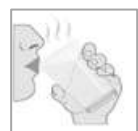
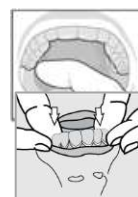
- Use Chewie that has been provided with your aligner kit in case of any difficulty while wearing your aligners.

Note: Proper insertion and removal techniques are important to prevent cracking or warping.

If you experience sharp pain or significant discomfort while wearing your aligners, discontinue use immediately and contact your Orthodontist.

Aligner Removal Instructions:

- Begin on one side of your mouth. **Use your fingertip on the inside of the back molar** to gently release the aligner from your tooth.
- Repeat this step on the other side of your mouth before attempting full removal.
- Once both back sides are disengaged, **gently work your way forward**, slowly prying the aligner away from your teeth using your fingertips.
- For Direct print aligners, if it is **difficult to remove** the aligners it is advised to **have some warm water** and then remove it.
- After the aligners are removed, wash it in running water and keep it in the box provided, **out of light**.



Note: Always retain your most recently used aligners (or additional previous sets as advised by your Orthodontist). In the event that your current aligner is lost or damaged, your Orthodontist may instruct you to temporarily revert to the previous stage while a replacement is prepared.

Once your treatment is complete and confirmed by your Orthodontist, all used aligners should be returned to your Orthodontist.

Customer Information

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Limitation of Liability

Except where prohibited by law, Synapse HealthTech Pvt. Ltd. will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.