

Aligners

Instructions for Use

Product Description:

Aligners are a series of clear plastic aligners that are used to replace the traditional orthodontic wires and brackets for aligning misaligned or maloccluded teeth. This series of aligners is transparent medical-grade thermoplastic copolyester material moulded for the use in orthodontic alignment of teeth from one position to another. The Aligners are used in correcting various malocclusions. Hence, it requires precise treatment planning before fabrication. A thorough understanding of the process and steps is required before proceeding to provide a successful aligner treatment.

Reference: AJO

Intended Use and Indications:

Intended Use:

Aligners are intended to be used in the alignment of teeth through orthodontic treatment of misalignment and malocclusion. The aligners guide the teeth to their final position by applying continuous gentle forces.

Indications:

Aligners are indicated for the alignment of teeth during orthodontic treatment of malocclusion.

Contraindications:

Aligners are contraindicated for use in patients with the following condition:

- Active periodontal disease

Precautions:

- 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.
- Certain medical conditions and the use of certain medications may affect orthodontic treatment outcomes.
- Treatment of severe open bite, severe overjet, mixed dentition, and/or skeletally narrow jaw may require supplemental treatment in addition to aligner treatment.
- Skeletal expanders, 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 anaesthesia and proper healing must be taken into account before 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 (e.g., crowns, bridges) may become dislodged and require re-cementation or, in some instances, replacement.
- Aligners are not effective in the movement of dental implants.

Warnings for use

- This product is to be used by a Dental Practitioner only.
- In rare instances, some patients may be allergic to the aligner material. In such cases, discontinue use and consult a healthcare professional immediately.
- This product is not designed, sold, or intended for use except as indicated.
- Orthodontic appliances, or parts thereof, may be accidentally swallowed or aspirated and may be harmful.

Potential Complications:

The complications that may occur, related to the use of the Aligners, will not expose the patient to risk other than those posed by conventional orthodontic treatment. The following risks are well-known and well-documented in the literature:

- Dental tenderness may be experienced following initial aligner placement and after switching to each new aligner in the series.
- The product may temporarily affect speech and may result in a lisp, although any speech impediment 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.
- Attachments may be temporarily bonded to one or more teeth during the course of treatment to facilitate aligner retention and/or tooth movement.
- All attachments should be removed upon completion of treatment.
- 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.
- At the end of treatment, the bite may require adjustment by the doctor.
- Teeth may shift position after treatment. Consistent wearing of retainers at the end of treatment should reduce this tendency.
- All teeth should be at least partially covered to help prevent supra-eruption.
- A temporary increase in salivation or dryness of the 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, and the tooth may require additional dental treatment such as endodontic and/or additional restorative work/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 temporomandibular joint (jaw joint) may result in joint pain, headaches, or ear problems.

These would be managed and addressed by the treating Dental Practitioner.

Clinical Applications:

This is a single-use medical device only to be used by a dental professional in a location deemed fit to conduct the procedure. This is to be determined by the dental professional. It is the responsibility of the dentist to ensure that regular maintenance (if required) is being conducted.

How Supplied:

This device is to be provided to the end user according to the Aligner Design specification. The product should be processed using the health facility practices. This service is provided by AstraDent Digital Dental Solutions to ensure that the dental professional's needs and the patient's needs are met.

Directions for Use:

- Always wash your hands before putting on and after removing aligners.
- Initially you might feel a little different while talking and might salivate more than usual. Please be aware that this is normal and settles in a week to 10 days of regular wear.
- Please note that it will take almost 1 week to 10 days of wear for you to get adjusted to the aligners. Until then you might feel a slight obstruction in your mouth. This is normal.
- In case the aligners cause discomfort, contact your dentist immediately.
- Aligners must be worn at all times except during eating and brushing. They must be worn for a minimum of 20–22 hours a day for adequate tooth movement.
- Each aligner must be worn for 2 weeks or as instructed by your Orthodontist. In the case of any unavoidable reason, where you are unable to wear an aligner for the prescribed duration, wear it for a day or two extra before moving on to the next aligner. Make sure you discuss with your Orthodontist before you go onto the next aligner.
- Always seat aligners on the back teeth with both your thumbs and then the front. Make sure it's seated well covering all teeth. While wearing the aligner if you feel the aligner is not seated fully, use the provided chewies as instructed, to help you seat the aligner better.
- While removing the aligners, engage from the inner aspect using an aligner remover provided to you.
- Your dentist might place some attachments on your teeth for faster and more precise tooth movement, and inform your Orthodontist in the event of attachment breakage.

Instructions for Aligner Maintenance:

- Never clean aligners using hot water or soap, or cleansing solutions. Use a cleansing tablet as prescribed by your Orthodontist.
- Rinse with room temperature water every time you remove it and put it back. If you are a pet owner, keep the case and aligners away from your pet's reach.
- Please note that the success and timely completion of your treatment solely depend on regular wear, switching of trays, and visits to your orthodontist at the recommended intervals.

Storage and Handling:

- There are no special storage conditions required. Store at room temperature.
- Each set of aligners should not be used after the **Use-by date**, which is **180 days from the date of manufacture**, to ensure optimal material integrity, precise fit, and consistent performance.
- Each set of aligners will be stored in a separate pouch. After using the particular set for the instructed duration, put the aligners back in the same pouch corresponding to its number. Do not discard the aligners when you go to the next set.
- Whenever you remove aligners, always store them in the box provided and not in tissue as you might misplace it or damage it. In the event of which, you may incur additional charges for the fabrication of the replacement aligner.

Duration of Use:

Each aligner is worn for 20-22 hours per day for a two-week period, after which it is replaced by the next stage aligner. This is repeated for the duration as prescribed by the Dental Practitioner.

Disposal Instruction:

Used Aligners are considered non-hazardous but biologically contaminated medical waste and should be disposed of in accordance with standard clinical and local regulations for dental appliances.

Symbols Used in Labeling

#	Symbol	Title	Description
1		Manufacturer	Indicates the medical device manufacturer and address.
2		Country of manufacture and Date of manufacture	- Indicates the date when the medical device was manufactured. - IN - identify the country 'India' where the product was manufactured as defined in ISO 3166-1.
3		Health Care Centre or Doctor	To indicate the address of the health care centre or doctor where medical information about the patient may be found.
4		Patient Name	Indicates the name of the patient.
5		Importer	Indicates the entity importing the medical device into the locale.
6		Distributor	Indicates the entity distributing the medical device into the locale.
7		Consult instructions for use or consult electronic instructions for use	Indicates the need for the user to consult the instructions for use.
8		Fragile, handle with care	Indicates a medical device that can be broken or damaged if not handled carefully.
9		Keep dry	Indicates a medical device that needs to be protected from moisture.
10		Medical device	Indicates the item is a medical device.
11		Do not use if the package is damaged, and consult instructions for use	Indicates a medical device that should not be used if the package has been damaged or opened, and that the user should consult the instructions for use for additional information.
12	Rx only	Prescription device	United States Federal Law restricts this device to sale by or on the order of a dentist.
13	Mfg. Lic. No	Manufacturing Licence Number	Manufacturing licence granted by the State Licensing Authority or the Central Licensing Authority of India.
14	"Custom-made device"	Custom-made devices	"custom-made medical device" means a medical device made specifically in accordance with a written prescription of a registered medical practitioner, specialised in the relevant area, under his responsibility for the sole use of a particular

#	Symbol	Title	Description
			patient, but does not include a mass production of such a device.
15		Catalogue number	Indicates the manufacturer's catalogue number so that the medical device can be identified.
16		Use-by date	Indicates the date after which the medical device is not to be used.

Contact Information:

For any questions regarding this product, please contact the manufacturer:

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