

## Brava Aligners Instructions

**Device Description:** Brava aligners are custom thermoplastic orthodontic devices.

**Indication for Use:** Brava aligners are intended for use in the alignment of permanent teeth (i.e. all second molars) through orthodontic treatment of misalignment and malocclusion. Brava aligners sequentially position teeth by way of applying force using a series of incremental minor tooth movements.

**Caution:** Rx only. Federal law restricts this device to sale by or on the order of a physician.

### Indications:

- Moderate/mild crowding 5-to-5 that requires:
  - up to 1.5 mm buccal/lingual tooth movements
  - up to 15 degrees of angulation, and rotation corrections
  - up to 10 degrees of torque
  - up to 1 mm intrusion, and
  - up to 0.5 mm extrusion
- Limited space closure, up to 1.5 mm across the arch.
- No posterior expansion/constriction, no bodily or angular molar inter-arch corrections.
- Only moderate remaining bite corrections.

### Contraindications:

1. Patients whose permanent teeth or second molars have not yet erupted
2. Patients with poor oral hygiene
3. Patients with active periodontal disease
4. Patients with dental prosthetics or implants

### Warnings:

1. If you have an allergic reaction, please discontinue use and contact your doctor and Brius Customer Service.

### Precautions:

1. Aligners are non-sterile, rinse before use.
2. Accidental swallowing of aligners may be harmful.
3. Keep your aligners away from children and pets
4. Keep your aligners away from hot, acidic, sweet or colored liquids.
5. Keep your aligners out of excessive heat.
6. Do not wear Brava aligners while eating, drinking, chewing gum or using tobacco products. Brush and floss after eating to prevent food from getting stuck in teeth and under aligners.
7. Clean your aligners after brushing your teeth by gently brushing your aligners using a toothbrush and toothpaste and rinsing with cool water.

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**Complications:** Brava aligners can cause serious side effects; however, these side effects only occur in a small number of people. Your doctor can monitor you for them. These side effects often go away if you stop wearing the aligners. These side effects include:

- Discomfort
- Tissue damage
- Relapse (tooth movement post-treatment)
- Extractions (tooth removal)
- Orthognathic Surgery
- Decalcification and Dental Caries
- Root Resorption
- Nerve Damage
- Periodontal Disease
- Injury from Orthodontic Appliances
- Headgear injuries
- Temporomandibular (Jaw) Joint Dysfunction
- Impacted, Ankylosed, Unerupted Teeth
- Occlusal Adjustment
- Non-Ideal Results
- Allergies
- General Health Problems
- Complications due to Third Molars
- Complications due to the Use of Tobacco Products
- Complications due to Temporary Anchorage Device

If any of the complications mentioned above do occur, a referral may be necessary to your family dentist or another dental or medical specialist for further treatment.

### Recommended Wear Procedures:

1. Carefully remove Brava aligners from the packaging and ensure that they are free of defects or damage and are contained in sealed bags with your name. Keep the sealed bags for future use as storage for previously worn aligners. Do not use defective products or products labeled with someone else's name.
2. Rinse the Brava aligners thoroughly with cool water. DO NOT use hot water!
3. Place the Stage 1 Brava aligner(s) on your teeth and push down. Wear the Stage 1 aligner(s) for 22 hours per day for two weeks. Brava aligners fit snugly and apply pressure to your teeth, but this pressure will decrease over time as you wear your aligners as prescribed.
4. After wearing each stage of aligner for two weeks, advance to the next stage.
5. Your aligner packages are sequentially numbered for easy identification. Once you have worn the aligner for two weeks, return it to its original package and move to the next stage. Before storing the aligner, rinse thoroughly with cool water and dry completely.
6. During treatment, if an aligner becomes damaged or will not fit properly, return to the last stage and wear the previously worn aligner until you can move to the next stage.
7. After treatment is complete, dispose of all aligners in accordance with local government policy.

### Using and Storing Brava Aligners:

1. Brava aligners should be worn 22 hours per day.
2. When not in use, place the aligners inside the provided storage case to protect them from damage or loss.
3. Store your aligners in a cool dry place when not wearing them.
4. Do not wear aligners after the expiration date that appears on the bag.
5. Maintain good oral hygiene during treatment and clean aligners regularly.

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### Cleaning Brava Aligners:

1. Clean aligners daily, preferably every time you brush your teeth.
2. Remove the aligners from your mouth and rinse them with lukewarm water to remove any saliva or debris.
3. Use a soft-bristle toothbrush and a mild, non-abrasive toothpaste to gently brush the aligners. Avoid using toothpaste that contains whitening agents, as they can potentially discolor or damage the aligners.
4. Soak the aligners in a denture cleaner or a specialized aligner cleaning solution. Follow the instructions provided by the manufacturer or your orthodontist regarding the soaking duration. Typically, 15 to 30 minutes is sufficient.
5. Avoid hot water. Do not use hot water to clean the aligners because it can distort or warp the plastic material.
6. Avoid using harsh chemicals such as bleach, alcohol-based solutions, or mouthwash because they can damage the aligners.
7. After cleaning, make sure the aligners are completely dry before placing them back in your mouth. Moisture can promote the growth of bacteria and affect oral health.

**Helpful hint:** You may notice a slight lisp when you initially start wearing Brava aligners. This typically goes away after a few days. You may also experience dry mouth during aligner treatment, so drink plenty of water to keep your mouth lubricated and clean aligners after every meal.