

LB-004 Brava by Brius™ Refiner DFU

Device Description: Brava refiners are custom thermoplastic orthodontic devices.

Indication for Use: The Brava Refiners are intended for use in the alignment of permanent teeth (i.e. all second molars) through orthodontic treatment of misalignment and malocclusion. Brava refiners 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.

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

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



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Recommended Procedure:

1. Carefully remove the Brava refiners from the packaging and ensure that they are free of defects or damage and are contained in sealed bags with your name. Do not use defective products or products labeled with someone else's name.
2. Rinse the Brava refiners thoroughly with cool water.
3. Place the Brava stage 1 refiners on your teeth and push down. Wear these stage 1 refiners for 22 hours a day for two weeks. Brava refiners will fit snugly and apply pressure to your teeth, but this pressure will lessen over time as you wear your refiners.

Note: You may notice a slight lisp when you initially start wearing your refiners. This typically goes away after a few days. You may experience dry mouth during refiner treatment, drink water.

4. Wear each stage of refiners for two weeks before advancing to the next stage.
5. Your refiner packages are sequentially numbered for easy identification. Once you have worn the refiners for two weeks, move to your next refiner.
6. Once you have moved onto the next refiner in your treatment, keep your previously worn refiner in the package it came in, just in case you lose or break your current one. Before storing the refiner rinse thoroughly with cool water.
7. After treatment is complete, dispose of all refiners in accordance with local government policy.

Period of Use/Storage:

1. The refiners should be worn 22 hours per day.
2. Do not wear refiners after expiration date printed on the bag it came in.
3. Store your refiners in a cool dry place when not wearing them.