



LB-002 Brava by Brius™ Instructions for Use

Please Read all Instructions Carefully

Device Description: Brava is a set of custom metal orthodontic devices.

Indication for Use: Brava is designed for use as an orthodontic appliance which exerts gentle force on tooth surfaces to gradually move teeth in a predefined manner.

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

Caution: This product may contain nickel, titanium, copper, chromium, molybdenum, zirconium, tin, gold, platinum, silver, iridium, zinc, palladium and nitride and should not be used with known allergic sensitivity to those materials. In the event patient shows any signs of hypersensitivity, discontinue use immediately.

Caution: This system is customized for each individual patient and cannot be reused. Only the patient that the system is designed and constructed for should use this system.

Caution: The digital bonding tray (DBT) must be used to place the brackets on the teeth. Do not place the brackets manually.

Caution: Make sure you are using the correct appliance for each jaw. The letter U indicates the upper jaw and L indicates the lower jaw.

Contraindications:

1. Patients with poor oral hygiene
2. Patients with active periodontal disease

Precautions:

1. Brava is non-sterile.
2. Accidental swallowing of Brava may be harmful.
3. Clean around the Brava as instructed by the Brava Patient Guidelines.

Complications: Brava 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 Brava is removed. These side effects include:

- Discomfort
- Tissue damage
- Relapse (tooth movement post treatment)
- Decalcification and Dental Caries
- Root Resorption
- Nerve Damage
- Periodontal Disease
- Injury from Orthodontic Appliances
- Temporomandibular (Jaw) Joint Dysfunction
- Ankylosed,
- Occlusal Adjustment
- Non-Ideal Results
- Allergic Reaction
- Complications due to Third Molars
- Complications due to the Use of Tobacco Products
- Complications due to Temporary Anchorage Device

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

Storage:

The Brava device should be stored at room temperature in its original packaging until placement on the patient.

Recommended Procedure:

1. Prepare the teeth for bracket bonding.
 - a. Isolate, Prophyl, Rinse, Dry
 - b. Micro-Etch
 - c. Rinse & Dry
 - d. Etch
 - e. Rinse & Dry
 - f. Apply, Dissipate and Light Cure Bonding Resin
2. Install the brackets using the provided DBT tray with brackets.
 - a. Apply Composite
 - b. Clear Excess with Microbrush
 - c. Press DBT firmly over dentition



- d. Light Cure for 10 seconds on each tooth
 - e. Remove the Tray
3. Engage Brava into the brackets bonded with the DBT tray.
4. Apply SoftFlow for Patient Comfort

Period of Use:

1. Brava should remain installed until the teeth reach the position of the treatment plan.

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