Please Read All Instructions Carefully

Indication for Use: The Brava Plus System by Brius Technologies 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 limits the sale of this appliance to licensed dental professionals.

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 the patient shows any signs of hypersensitivity, discontinue use immediately.

Caution: This system is customized for each individual patient and cannot be reused or transferred. It should only be used for the patient for which the system is designed and constructed.

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

Caution: Make sure you are using the correct Brava Plus 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
3. Patients with severe mandibular tori
4. Patients with clinical crown height less than 2.5mm*

***Note:** Brava Plus brackets are customized to fit the shape of each tooth's lingual crown. There is a minimum crown width and height requirement for Standard Brava Plus custom brackets:

- Standard bracket minimum width: 2.9mm
- Standard bracket minimum height: 2.5mm

Narrow Brava Plus brackets are typically used on lower anterior teeth. When the lingual crown width is less than 2.9mm the BRIUS design team selects a narrow bracket for that tooth. Narrow brackets are custom-fit to each tooth and have a similar bonding surface area to standard Brava Plus brackets. There is a minimum width and height requirement for narrow brackets:

- Narrow bracket minimum width : 2.4 mm
- Narrow bracket minimum height 3.0 mm

Precautions:

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

Complications: Brava can cause serious side effects; however, these side effects only occur in a small number of patients. These side effects often immediately go away if Brava Plus is removed. These side effects include:

- Discomfort
- Tissue damage
- Decalcification and Dental Caries
- Root Resorption
- Periodontal disease and bone loss
- Injury from Orthodontic Appliances
- Complications due to Temporary Anchorage Device
- Temporomandibular (Jaw) Joint Dysfunction
- Non-Ideal Results
- Allergic Reaction
- Severe tooth mobility
- Dehiscence or fenestration
- Complications due to the Use of Tobacco Products

If any of the complications mentioned above do occur, inform your treating doctor immediately.

Storage:

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

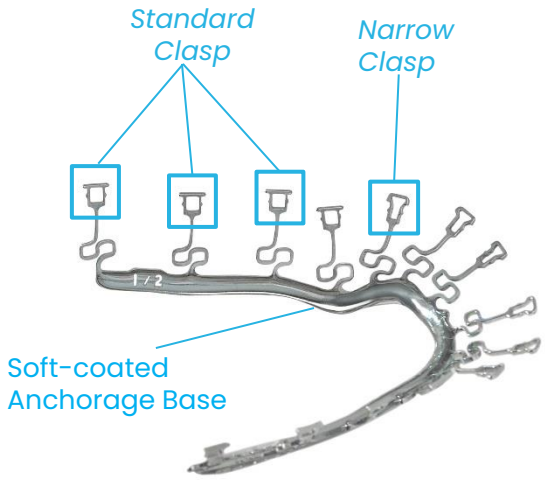
Device Description: The Brava Plus system is an orthodontic device that consists of three main components: the Independent Movers appliance, the brackets, and indirect bonding trays.

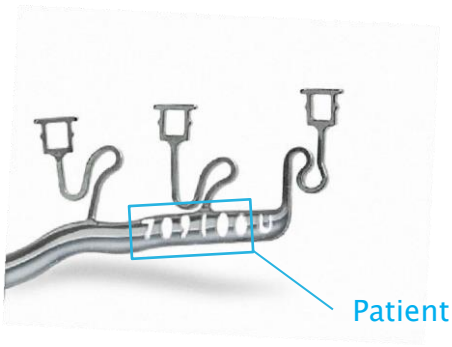
Independent Movers:

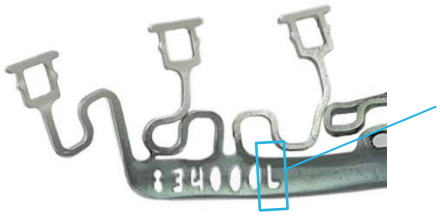
Anchorage Base: provides the anchorage platform for all Brava Plus Independent Movers, ensures predictable tooth movement, and prevents unwanted side effects from loss of anchorage during tooth movement. The Anchorage Base, made from nickel titanium (NiTi), features a solid bar that extends around the arch, distributing forces equally and providing anchorage for arms that are preprogrammed with shape memory. The Anchorage Base is coated for patient comfort. The Base is marked for identification by the user: patient ID number, upper and lower arch identification, and staged case identification (if the treatment plan indicates staging).

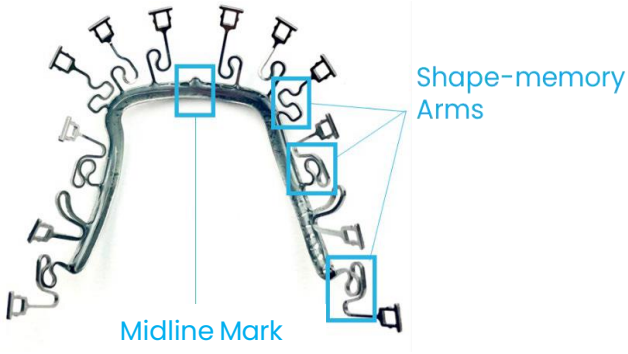
Shape-memory Arms connect to the Anchorage Base to the teeth, delivering gentle continuous forces that move teeth predictably over long distances during treatment. Each pre-programmed arm is designed to produce an optimal force vector for each tooth until it aligns nears its projected position at which time the arm becomes passive and tooth movement ends. Arms are activated when engaged in Brava Plus brackets and remain active until the arm is no longer active.

Clasps are positioned at the end of each arm and are designed to engage all Independent Movers into Brava Plus brackets. From the moment the clasp is first engaged, it moves teeth in all six degrees of freedom all at once. A spring-lock feature on the clasp ensures that it remains securely engaged in the bracket slot. A “Narrow” clasp is designed for slender teeth such as lower incisors.





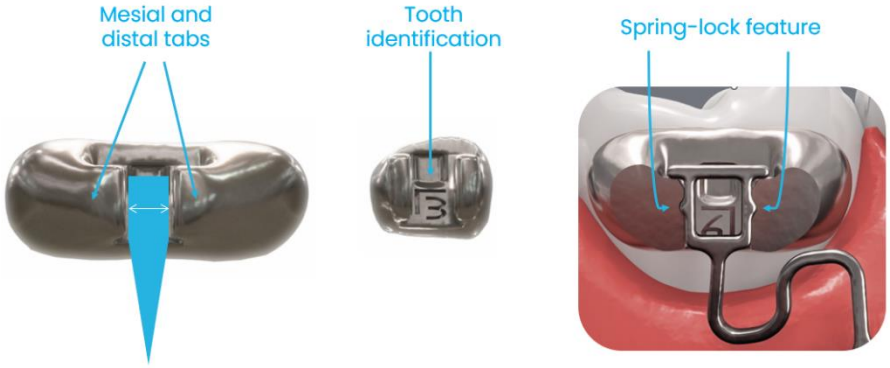


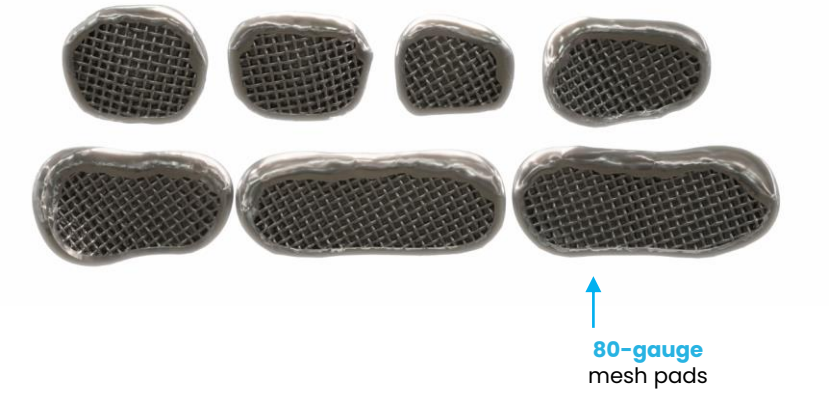


Brava Plus Brackets:

The Brava Plus System features self-engaging brackets that have no moving parts and are custom-made to fit each tooth. These brackets have smooth and rounded edges that minimize patient discomfort. Though all brackets share the same key components, they vary in size and shape to accommodate different teeth. Indirect Bond (IDB) trays are pre-loaded with standard and narrow brackets. Universal Brackets are not included in IDB trays and are designed to fit any tooth in treatment. Universal brackets replace custom brackets when they are damaged or lost. An individual tooth segment from the original IDB tray can be used to bond a Universal bracket in its correct position on the tooth, but a custom adhesive base will be created. Universal bracket should only be used as a temporary solution until a replacement custom bracket can be ordered and bonded.

Brackets Custom Fit to Each Tooth





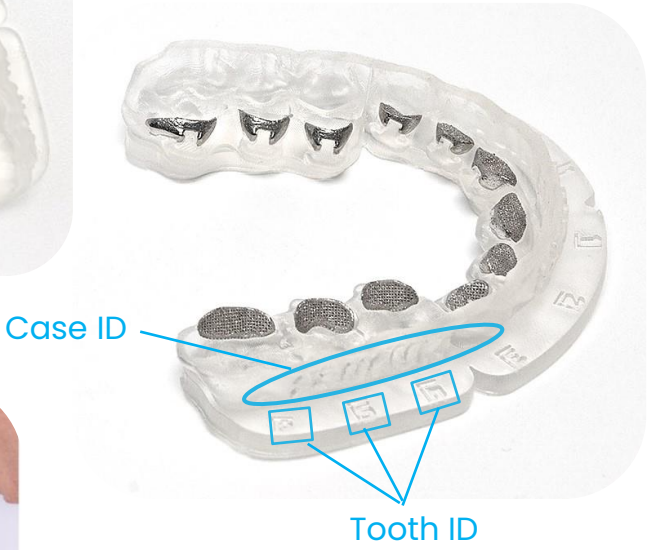
Bracket Features

- Vertical Slot simplifies insertion and engagement of the clasp.
- Mesial and Distal Tabs are rounded for comfort and house the clasp during treatment.
- Tooth Identification appears in the vertical slot of the bracket to easily match brackets to teeth.
- Spring-lock feature secures the clasp in place during treatment and gives control in all six degrees of freedom.
- Bonding Pad with 80-gauge mesh follows the anatomical contours of each tooth and delivers optimal bond strength.

Brava Plus Indirect Bonding (IDB) trays

The Brava Plus indirect bonding trays are designed to provide optimal comfort and precision when bonding brackets on all teeth in treatment. Each IDB tray fits snugly around the arches, ensuring that brackets are delivered accurately to their intended locations. The IDB tray is uniquely designed to control moisture and prevent contamination , yet when removed the tray releases from the brackets minimizing clean-up of tray materials and excess adhesive flash.

The lower IDB tray comes in three segments: one anterior segment and two posterior segments. Typically, all three segments will fit in the mouth at the same time during the bonding appointment. The upper IDB tray comes in one full-arch unit but can be easily separated into three separate segments like the lower arch. The extended occlusal ledge improves handling and stability during delivery to the mouth. The flat occlusal ledge also provides visual confirmation that the tray is fully seated.. All tray segments are labelled with the Case ID number , tooth identification, and anterior segments contain a midline mark.



Staging Treatment with Brava Plus

Most cases are treated with one Brava Plus appliance. However, some cases benefit from progressively activated, or staged Brava Plus appliances. When a case is staged, only a portion of planned tooth movement is activated with the first Brava Plus appliance.

The BRIUS clinical team recommends staging to the provider when the following treatment goals are planned:

- Close extraction spaces (more than 4 mm)
- Expand an arch (more than 4 mm)
- Align severely rotated teeth (more than 30°)

To avoid confusion, identification marks are placed on every staged Brava Plus appliance. Visual inspection of the Anchorage Base determines both the stage and how many stages are planned during treatment.

To prevent any mix-ups, each stage of the Brava appliance is marked for identification. By visually inspecting the Anchorage Base, one can determine the current stage of treatment and the total number of stages planned.

The first number before the dash in the identification marks denotes the stage. The second number after the dash denotes how many stages are planned for the case. While a staged case typically features two stages of Brava Plus appliances to complete treatment, more complex cases may benefit from three stages.

To ensure optimal treatment efficiency with staged cases, only request a replacement if the Brava appliance becomes damaged within two months of its insertion date. After two months from its insertion, a damaged appliance can be replaced by simply inserting the next stage. If breakage occurs during the final stage, and it's too early to finish with finishing aligners, then request a replacement for the last stage using the BRIUS Case Planner.

Period of Use:

Brava Plus should remain installed until the teeth reach the position of the treatment plan or until the teeth stop moving, whichever happens first. If the case is staged, each Brava Plus appliance should remain installed for at least four months before transitioning to the next progressively activated Brava Plus appliance.

Staged Case identification

Initial Bonding Phase I: Tray Preparation

Gather required materials for IDB tray preparation

1. Upper and lower Brava IDB trays from the Brava Plus Patient Kit
2. Assure Plus™ primer
3. Bracket adhesive: (A) AO Brace Paste™ (B) Reliance GoTo™ or (C) Transbond Plus™
4. Microbrushes (fine tip preferred)
5. Mixing well
6. Light-proof container
7. LED curing light

Step 1: Select an area with low light to pre-paste the IDB trays. Do not pre-paste the IDB trays in direct light because the adhesive will precure, which can lead to debonded brackets. Prepare one tray segment at a time to minimize light exposure.

Step 2: Dispense Assure Plus primer into a mixing well. Using a Microbrush, apply a very thin layer of primer onto every bracket pad in the IDB tray segment. Avoid touching the tray with primer because it can adhere to the tray material and increase clean-up time. Use a dry Microbrush to remove any excess primer.

Step 3: Light cure Assure Plus primer 5 seconds each bracket.

Step 4: Dispense one of the required adhesives directly onto the bracket pads in the tray segment. Avoid creating unwanted flash by using a minimal amount of adhesive.

Step 5: Use a dry Microbrush to spread out the adhesive until a thin layer covers the entire bracket pad. Add more adhesive if needed to cover the entire bonding pad but remember to aim for minimal flash.

Step 6: Immediately store the pre-pasted IDB tray segment in a light-proof container. Select another tray segment and follow the same procedure until all tray segments are pre-pasted and stored in a dark container.

IMPORTANT: *make sure the container(s) with pre-pasted trays are removed from direct light until the patient is ready for bonding.*

Initial Bonding Phase 2: Teeth Preparation

Gather required materials for teeth preparation, bonding, and post bonding.

1. Microetcher and large pod of 50-micron aluminum oxide
2. Phosphoric acid etch
3. Assure Plus® primer
4. Bracket adhesive: (A) AO Brace Paste™ (B) Reliance GoTo™ or (C) Transbond Plus™
5. LED curing light (+1600 mW/cm^2)
6. Lingual Weingart pliers (fine-tip)
7. Scaler & mouth mirror
8. Microbrushes and mixing wells
9. NOLA™ Dry Field System
10. Pre-pasted IDB trays
11. Cotton pliers & cotton rolls
12. Bite turbo material
13. Dental floss & interproximal strip
14. IPR disc or strips, if IPR indicated
15. Preferred primer/etch for porcelain and metal restorations if present.

Step 1: Using a mouth mirror, ensure teeth are clean with no plaque, stains, or calculus. If a tooth cleaning was not done recently, then use a scaler to remove plaque or calculus, and prophy the lingual surface of each tooth in treatment. If unable to resolve, then reschedule bonding appointment and refer patient to their dentist for a cleaning.

Step 2: Check for any dental restorations (e.g., porcelain crowns) because they may require a different primer/etch.

Step 3: Microetch the lingual surface of all teeth to be bonded with 50-micron aluminum oxide for 1-2 seconds. SKIPPING THIS STEP REDUCES BOND STRENGTH.

Step 4: Rinse each tooth with air and water.

Step 5: Insert the NOLA Dry Field System to isolate and prevent moisture contamination.

*NOTE**:** When bonding both arches, the best practice is to bond the lower arch first. The lower arch IDB tray comes in three segments, which helps to eliminate moisture contamination. The upper arch IDB tray is one full-arch unit, but it can be easily sectioned into three individual segments when needed (e.g., lingually tipped-in teeth).*

Initial Bonding Phase 3: Bonding IDB Tray Segments

NOTE: Brius recommends bonding the lower arch first to minimize the potential for contamination. When bonding sectioned IDB trays, always deliver the posterior tray segments first. Bond each tray segment one at a time and leave in place until the anterior tray is inserted. Visually confirm the flat occlusal surface of the anterior tray aligns with both posterior trays, ensuring all three trays are fully seated. Remove all three tray segments at the same time.

Step 1: Apply phosphoric acid etch to the lingual surface of the teeth to be bonded in one tray segment. If bonding a buccal segment, apply etch to the appropriate buccal surfaces too. AVOID ETCHING THE ENTIRE ARCH. Etch for 30-60 seconds, following the manufacturer's instructions. If porcelain or metal crowns are present, use a preferred primer/etch product instead of phosphoric acid etch.

Step 2: Rinse all etched teeth thoroughly using air and water. (10 seconds per tooth for gel etch and 5 seconds for liquid etch)

Step 3: Air dry the teeth until the surfaces are chalky white. Visually inspect the bonding surfaces. If all teeth are not chalky white, repeat the etch procedure again.

Step 4: Apply a very thin layer of Assure Plus primer to the etched teeth in anticipation of receiving one of the three tray segments.

Step 5: Light cure Assure Plus primer for 5 seconds per tooth.

Step 6: Select one of the pre-pasted posterior IDB tray segments from its container. Use your fingers or Lingual Weingart pliers to pick up the tray segment and then seat the tray in a rolling motion starting from the lingual towards the labial/buccal.

Step 7: Apply light occlusal pressure and light lingual pressure using your fingers. Ensure the tray is fully seated, snug, and not moving. The surface of the tray should appear completely flat, which confirms it's fully seated.

Step 8: Light cure each bracket through the tray for 5 seconds. Then light cure each bracket a second time for 5 seconds. If LED curing light intensity measures less than 1600 mW/cm^2 then light cure again.

Step 9: Leave the first tray segment in place. Repeat steps 1-8 for the second posterior tray segment, and then again for the anterior tray segment. Confirm the flat occlusal surface of the anterior tray aligns at the cuspids with both posterior trays.

Step 10: Carefully remove both posterior trays by peeling the tray from the buccal side while rolling towards the lingual. Use a thick scaler or Weingart to help release the brackets on the lingual side. Then remove the anterior tray by peeling the tray from the labial side while rolling towards the lingual.

Step 11: When all tray segments are removed, light cure each bracket for a third time for 5 seconds per bracket.

Initial Bonding Phase 4: Bonding Full- Arch IDB Trays

NOTE: When bonding the upper arch, the best practice is to deliver the upper IDB tray in one unit. If you choose to segment the upper tray for the initial bonding, then follow the bonding procedures as described in Phase 3.

Step 1: Apply phosphoric acid etch to the lingual surface of all teeth to be bonded. If bonding a buccal segment, apply etch to the appropriate buccal surfaces too. Etch each tooth for 30-60 seconds, but no more than 90 seconds. Consider etching one half of the arch at a time to avoid over-etching and weakening bond strength. Follow the etch manufacturer's instructions. If porcelain or metal crowns are present, use a preferred primer/etch product instead of phosphoric acid etch.

Step 2: Rinse all etched teeth thoroughly using air and water. (10 seconds per tooth for gel etch and 5 seconds for liquid etch)

Step 3: Air dry the teeth until the surfaces are chalky white. Visually inspect the bonding surfaces. If all teeth are not chalky white, repeat the etch procedure again.

Step 4: Apply a very thin layer of Assure Plus primer to each etched tooth.

Step 5: Light cure Assure Plus primer for 5 seconds per tooth.

Step 6: Select the pre-pasted upper arch tray from its container. Use your fingers to fully seat the tray starting from the posterior.

Step 7: Apply light occlusal pressure and light lingual pressure using your fingers to ensure the tray is snug and not moving during light cure. The surface of the tray should appear completely flat, which confirms it's fully seated.

Step 8: Light cure each bracket for 5 seconds. Then light cure each bracket a second time for 5 seconds. If LED curing light intensity measures less than 1600 mW/cm2 then light cure again.

Step 9: Remove the upper IDB tray by peeling the tray from the buccal side while rolling towards the lingual. Use a thick scaler to help release the brackets on the lingual side.

Step 10: When the upper tray is removed, light cure all upper brackets for a third time for 5 seconds per bracket.

Initial Bonding Phase 5: Post-Bonding Instructions

NOTE: if any brackets remain in the IDB tray or if any brackets debond while engaging the Brava appliance, follow the rebonding instructions.

Step 1: Check for and remove any residual IDB tray material if present using a large scaler or explorer.

Step 2: Check for and remove any flash using a sharp scaler or a finishing bur.

Step 3: Remove the NOLA Dry Field System and thoroughly rinse. Use dental floss to inspect for interproximal flash, to ensure the contacts have not been bonded together. If flash is detected use a scaler, serrated strip, or dental floss to remove any bonding material present.

Step 4: Perform any IPR indicated on the Treatment Plan Summary unless it is not accessible. Document the amount of IPR in the patient chart and on the Treatment Plan Summary sheet provided inside the Brava Plus New Patient Kit. Typically, all IPR should be completed within the first 3 months.

Step 5: Insert the Brava Plus appliance on both arches using the standard engagement order.

Using Lingual Weingart pliers grasp the handle of the clasp and insert it behind the tabs of the Brava Plus bracket in the vertical slot.

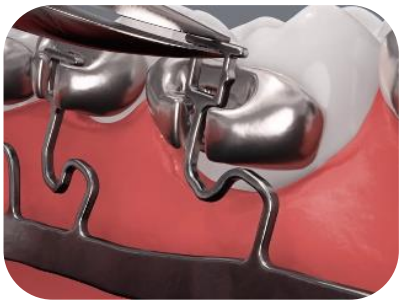
Position one tip of the Lingual Weingart pliers under the base of the bracket and the other tip on top of the clasp.

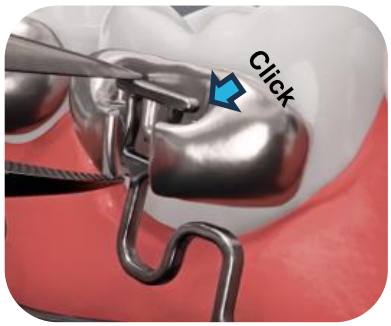
Gently squeeze the mesial and distal sides of the clasp until the clasp fully seats in the vertical slot. An audible click confirms the clasp is fully engaged.

Repeat the process for every clasp following the engagement order of:
- 1st - First molars
- 2nd - First bicuspids
- 3rd – Incisors

Then engage all remaining teeth.

Fine-Tipped Lingual Weingart Pliers





Initial Bonding Phase 5: Post-Bonding Instructions (continued)

Step 6: Check to ensure each clasp is fully engaged by tugging occlusally with a scaler. If a clasp becomes dislodged, use Lingual Weingart pliers to re-engage.

Step 7: Check for occlusal interferences. Place bite turbos to prevent collisions, which can cause damage to the appliance.

Step 8: Place SoftFlow™ or a comfort product over any areas of discomfort

Bracket Rebonding Instructions:

NOTE: if any brackets remain in the IDB tray or if any brackets debond while engaging the Brava Plus appliance, follow these instructions.

Step 1: Remove the custom Brava Plus bracket(s) from the IDB tray.

Step 2: Clean the bracket pad using a microetcher so that it can be reused. If the bracket is not reusable, then select one of the universal brackets, which are available from BRIUS in 5pks. Universal brackets can be bonded to any tooth.

Step 3: Re-insert the bracket into the same bracket well in the IDB tray using Lingual Weingart pliers.

Step 4: Using scissors, cleanly cut the IDB tray on each side of the inserted bracket to create an individual tooth IDB tray. If more than one bracket debonded, then create one segment per tooth. Do not use multi-tooth tray segments when rebonding Brava Plus brackets.

Step 5: Apply Assure Plus primer to the bonding pad of each bracket to be rebonded.

Step 6: Light cure each bracket pad for 5 seconds.

Step 7: Apply bracket adhesive to the bonding pad, ensuring full coverage using a Microbrush and one of the following adhesives:
(A) AO Brace Paste™ (B) Reliance GoTo™ (C) Transbond Plus™

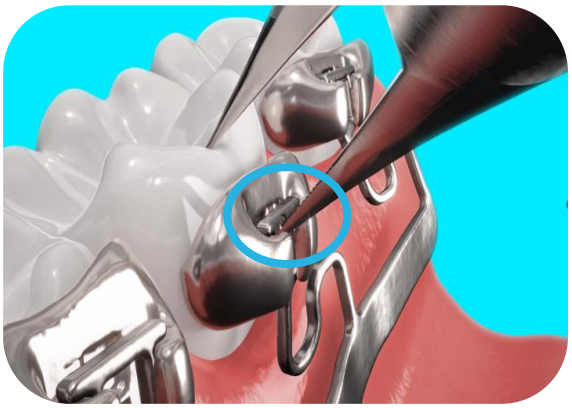
Step 8: Store individual tooth IDB tray segment(s) in a light-proof container until ready for bonding.

Step 9: Follow the recommended bonding procedures in Phase 2, Phase 3 and Phase 4.

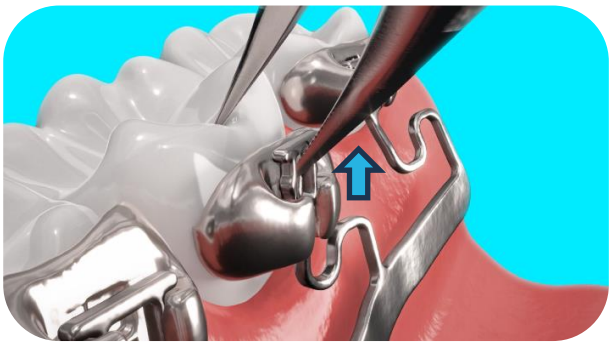
Disengaging Independent Movers from Brava Plus Brackets:

NOTE: To enhance patient comfort during disengagement, consider placing a cotton roll on the occlusal surface of the tooth.

Step 1: Use the tips of Lingual Weingart pliers to disengage each Brava Plus clasp from its self-engaging bracket by placing one tip of the plier inside the window of the clasp and the other tip on the tooths occlusal surface.

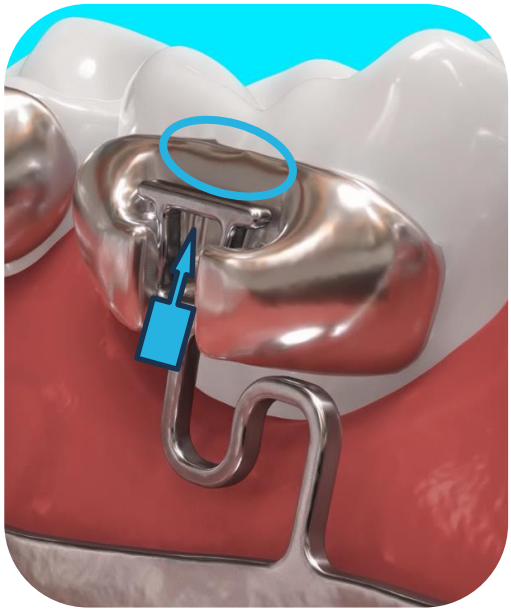


Step 2: Squeeze the pliers until the clasp lifts out of the vertical slot.



Alternative Method:

- Place one tip inside the window of clasp
- Place one tip on the occlusal side of the bracket
- Squeeze the pliers until the clasp lifts out of the vertical slot



Bracket Debonding Instructions:

Step 1: Remove the Brava Plus Independent Movers appliance.

Step 2: Select a debonding instrument like the Hu-Friedy Lingual Bracket Removing Pliers (678-703).

Step 3: Place the tips of the pliers on the occlusal and gingival side of the brackets and then gently squeeze to remove the brackets.

Step 4: Polish the lingual surface of each tooth to remove any remaining adhesive using a high-flute non-cutting bur or a round white stone.

Step 5: Begin finishing aligner protocol.

Debonding Instrument

The tips of the Angled Bracket Removing Pliers are placed at the bracket/enamel interface

Brava Finishing Aligners

If there are minor discrepancies such as small rotations, gaps, and slight misalignments, up to 5 finishing aligners are provided with Brava Plus Patient kits to address these issues.

To determine when to remove brackets and scan for finishing aligners, please follow the guidelines provided by BRIUS. After removing the brackets, put an Essix-type retainer on the patient's dentition until the aligners are delivered to prevent teeth from drifting.

Device Description: Brava aligners are custom thermoplastic orthodontic devices.

Indication for Use: Brava aligners are intended for use in the alignment of permanent teeth 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.

Guidelines for When to Start Brava Finishing Aligners:

- 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

Brava Finishing Aligners (continued)

Warnings:

1. If patient experiences an allergic reaction, then discontinue use.

Precautions:

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