

1. Company Identification

J&J Orthodontics
6737 Palo Verde Pl
Rancho Cucamonga CA 91739 USA

2. Product Identification

Product Name: Orthodontic BiteForce™ NC3 Device
Product Part Number: Various part numbers

3. Intended Use

The BiteForce™ NC3 Device is designed for seamless chairside installation without necessitating the removal of brackets or archwires. For optimal outcomes, the device must be installed at the appropriate phase of orthodontic treatment. The following preparatory steps must be completed prior to installation:

- Ensure the mandibular arch is sufficiently aligned to allow the placement of a rectangular archwire.
- Confirm that the maxillary arch exhibits adequate transverse width to accommodate an advanced mandibular position. In cases of relative maxillary transverse deficiency, coordinate the transverse dimensions of both arches accordingly.

4. Push Rod Positioning Options

The push rod may be placed in one of the following three positions:

a. Bicuspid Position (Recommended Option)

- Positioning the push rod distal to the bicuspid is a newer and preferred method.

- Advantages: Enhanced patient comfort, improved aesthetics, and minimized interference.

Clinical Note: A steeper vertical angle at the first bicuspid may result in upper first molar intrusion; monitor accordingly.

b. Cuspid Position (Traditional Option)

- Placement distal to the cuspid remains a viable alternative, particularly when bicuspid placement is unsuitable, such as:

- Over-activation with a 22 mm push rod at first bicuspids.
- Excessive vertical placement.
- Severe Class II malocclusions with significant mandibular retrusion.

c. Omega Loop

- This option provides flexibility in angulation and prevents the push rod from contacting the bracket.

Clinical Note: Similar to bicuspid placement, Omega loop positioning may result in increased upper first molar intrusion.

5. Arch Preparation Guidelines

Step 1: Rectangular Archwire Placement

- Use a minimum of:
 - 0.017" × 0.025" stainless steel for 0.018" slot brackets.
 - 0.019" × 0.025" stainless steel for 0.022" slot brackets.

Step 2: Mandibular Arch Stabilization

- Implement strategies to prevent lower anterior flaring:
 - Ensure negative torque on lower anterior brackets
 - Cinch back the mandibular archwire distal to the terminal molar.
 - Lace the entire mandibular arch from first molar to first molar beneath the archwire to minimize ligature breakage.

Step 3: Preventing Rotation and Debonding

- Steel ligate the bracket mesial to the push rod.
- Use elastomeric ligatures with guards beneath the archwire to prevent bracket contact and enhance activation by 1.5–2 mm.
- Install a distal stop (e.g., Screwable lock SKU. 510-504) to avoid contact between the push rod and bracket.

6. Push Rod Selection and Measurement

- Utilize the Measurement Guide:
 - Measure from the distal end of the maxillary molar tube to the distal side of the mandibular stop on each side while the patient is in centric occlusion.
 - When uncertain, opt for the shorter push rod length.
 - Select left and right push rods as required. Measure both sides independently.

7. L-Pin Installation Procedure

- 1) Ensure the headgear tube is free of debris.
- 2) Insert the L-pin into the spring module, with the ball facing buccally.
- 3) Insert from distal to mesial into the headgear tube, maintaining 1–2 mm clearance between the buccal tube end and spring eyelet.
- 4) Bend the L-pin:
 - Occlusally: Flip the spring gingivally, bend occlusally, and allow it to fall into place. The tip can be tucked behind the tube.
 - Gingivally: Bend over the gingival tube or secure behind the elastic hook.

Clinical Notes:

- The L-pin may be trimmed if excessively long.
- Orienting the L-pin over the headgear tube prevents occlusal or buccal interference.

8. Push Rod Placement Procedure

- 1) Identify the correct side (right/left) push rod.
- 2) Position the push rod loop over the archwire distal to the desired tooth (bicuspid or cuspid).
- 3) Instruct the patient to open their mouth, compress the spring, and insert the push rod.
- 4) Verify activation:
 - Approx. 200 grams of force should be generated.
 - Maintain a gap of 1–2 mm between the spring and the push rod stop in centric occlusion.
- 5) Secure the mesial end of the push rod by crimping with Weingart pliers.
- 6) Check for any interference:
 - Confirm normal mandibular movement and ensure no impingement.

Clinical Notes:

- If the patient occludes on the spring assembly, adjust the L-pin or shift the assembly buccally using Weingart pliers (SKU. JDP-3).
- Additional clearance may be created by repositioning the push rod mesial to the stop, while keeping the distal portion straight.

9. Removal of the BiteForce™ NC3 Device

The BiteForce™ NC3 Device should be removed when the following clinical criteria are met:

- The buccal segments and molar relationships exhibit a Class I occlusal relationship.
- The maxillary incisors demonstrate ideal torque and alignment.
- Overjet has been effectively eliminated.

Note: Clinical studies indicate that correction of Class II malocclusion using the NC3 device typically occurs within a 4–6 months period.

Clinical Notes:

- Mandibular incisors may exhibit a rebound of approximately 2–3 degrees post-removal of the spring, particularly when negative torque is applied to the incisor brackets.
- A slight overcorrection of 1–2 mm is advisable to compensate for potential relapse.
- After achieving the intended correction, it is recommended to maintain the deactivated appliance in situ for a minimum of one follow-up appointment interval to ensure stability.

10. Procedure of Removal

Once Class II correction is confirmed, proceed with device removal as follows:

- 1). Ensure the push rod and spring module remain engaged. Instruct the patient to maintain occlusal contact (bite together).
- 2). Utilize Weingart pliers (SKU. JDP-3) to unbend the L-pin. Thread the pin through the buccal tube; the active spring will facilitate distal pin extrusion.

11. Push Rod Removal Procedure

Following removal of the spring module, proceed to remove the push rod:

- Initially, rotate the push rod so that the bend is oriented occlusally.

There are three recommended techniques for push rod removal:

Option 1: Use a pin and ligature cutter to place the tips at the cinched end of the push rod. Apply pressure to sever and remove.

Option 2: With fingers, grasp the distal end of the push rod while securing the mesial loop using Weingart pliers(SKU. JDP-3). Twist the loop away from the straight rod and rotate the rod to disengage from the archwire.

Option 3: If an archwire replacement is scheduled at this stage of treatment, the push rod may be removed concurrently with the existing archwire.

12. Post-Removal Monitoring and Management

After removal of the BiteForce™ NC3 Device, continued evaluation and management are essential. Consider the following clinical measures:

- If residual space exists post-removal, apply power chain from molar to molar to facilitate space closure.
- In cases of excessive proclination of the mandibular incisors, replace the existing archwire with a more flexible alternative (e.g., Nickel Titanium) and utilize power chain to assist with uprighting.
- To enhance occlusal settling post-device removal, consider switching to a more flexible mandibular archwire (e.g., Nickel Titanium) and prescribe nighttime use of box elastics.
- To minimize the risk of relapse, Class II elastics may be prescribed based on clinical assessment.

13. Storage

- Store in a dry, dust-free environment post-sterilization.
- Sterility is maintained only if the packaging remains intact and validated per packaging manufacturer's guidelines.

14. Disposal

Dispose of used or damaged devices in accordance with local, state, and federal regulations.

15. REGULATORY INFORMATION

The following symbols might appear on the label:

PICTOGRAMS

	MANUFACTURER		AUTHORIZED REPRESENTATIVE
	DATE OF MANUFACTURE		KEEP AWAY FROM SUNLIGHT
	DO NOT REUSE		CONSULT INSTRUCTIONS
	LOT NUMBER		CATALOG NUMBER
	NON STERILE		CAUTION
	SHELF LIFE		CE MARKING

INSTRUCTIONS FOR USE

BiteForce™ NC3 Device

