1. Company Identification

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

2. Product Identification

Product Name: BiteForce Distalizing Appliance
Product Description: Orthodontic appliance designed for distalization purposes.

3. Indications for Use

The BiteForce Distalizing Appliance is intended to establish an ideal Class I occlusal relationship at the initiation of orthodontic treatment, prior to the placement of brackets or aligners. It is particularly effective during the early phase of treatment, when there are no competing forces and patient compliance is typically optimal.

- The appliance is bonded from the first molar to the canine (cuspid) or first premolar.
- A molar buccal tube hook is bonded to the mandibular first or second molar.
- Elastics are used to connect the appliance to the molar buccal tube.

4. Arch Preparation (Maxillary/Mandibular)

The appliance is placed on either the maxillary or mandibular arch. A stable and consistent anchorage source must be selected to prevent unwanted anterior tooth movement. Recommended anchorage includes directly bonded molar tubes, although the final choice should be made at the discretion of the orthodontist.

5. Measurement and Appliance Selection

• Measuring the Maxillary Segment:

Using a BOLEY Caliper (J-52-29), measure the distance from the midpoint of the buccal groove on the facial surface of the maxillary first molar (U6) to the mesial third of the facial surface of the maxillary cuspid (U3) or first premolar.

Measure both sides individually, as asymmetry may necessitate different appliance sizes.

• Selecting the Appliance Size:

Based on the measurement obtained:
If the measurement is between two standard sizes (e.g., 18 mm and 20 mm), select the appliance based on the desired degree of molar rotation:
For increased molar rotation, select the smaller size.
For reduced molar rotation, select the larger size.

6. Preparation, Placement, and Alignment

• Tooth Preparation for Bonding:

1). Cleaning: Clean the first molar and cuspid (or premolar) using non-fluoride prophy paste.
2). Rinsing and Drying: Thoroughly rinse with water and air-dry.
3). Etching: Etch the designated bonding surfaces according to the adhesive manufacturer's instructions.
4). Final Rinse and Drying: Rinse again and air-dry the etched surfaces completely.
5). Adhesive Application: Apply light-cure adhesive generously to both bonding pads.

• Placement and Alignment:

1). Placement:
Using forceps or tweezers, hold the appliance arm and position it onto the dentition.
Begin by positioning the molar pad, followed by aligning the cuspid/premolar pad.
Ensure the vertical groove on the posterior appliance pad aligns with the center of the buccal surface of the molar.
The occlusal edge of the molar pad should be parallel with the cusp tips.
2). Alignment:
Position both bonding pads optimally.
Ensure that the cuspid pads are placed symmetrically on both sides to prevent occlusal canting.

7. Bonding Procedure

1). Carefully remove excess adhesive from the tooth surface while maintaining appliance alignment.
2). Light-cure the molar pad completely.
3). Light-cure the cuspid or premolar pad completely.

8. Molar Buccal Tube Placement and Activation

• Placement:

Bond molar buccal tubes to the first or second molars, preferably the second molar when sufficient crown structure is available, to achieve more favorable force vectors. The buccal tube should be bonded to the mesial cusp, with the hook aligned in the same plane as the elastic when stretched to the appliance button hook. This ensures effective elastic engagement and performance. The bonding procedure is consistent with standard protocols for metal brackets and auxiliaries.

• Activation:

1). Attach an elastic to the hook on the mandibular first or second molar, then stretch and connect it to the hook on the maxillary cuspid pad.
2). Schedule follow-up appointments 4 to 6 weeks post-placement, and subsequently at 6-week intervals, to monitor progress. During each appointment:
Assess treatment progress
Communicate findings with the patient
Reinforce and encourage compliance

9. Monitoring Compliance

As this appliance is used early in treatment, it relies heavily on patient compliance. At each follow-up, assess for:

- Cuspid mobility and extrusion
- Extrusion and possible mobility of lower molars
- Development of interproximal spaces

• Changes in occlusal bite (bite opening)
• Patient ability to manage elastic placement independently

10. Debonding Procedure

1). Remove residual adhesive around the cuspid/premolar pad using a tapered flame burr to create a shallow concave channel.
2). Instruct the patient to bite on a cotton roll perpendicular to the involved tooth for stabilization.
3). Use one of the following instruments for removal:
a. Debonding Pliers (45-Degree) – JDP-78
b. Debonding Pliers TC (90-Degree) – JDP-78TC
c. Adhesive Remover – XJDP-36T
d. Posterior Band Remover – JDP-36T
4). Position the instrument at the adhesive interface and gently apply sustained pressure in the occlusal-gingival direction until bond failure occurs.
5). Once the cuspid/premolar pad is removed, repeat the process to debond the molar pad.
6). Remove any residual adhesive with an adhesive remover or burr.
7). Polish the tooth surfaces to restore a smooth finish.

11. Warnings and Precautions

• Exercise caution to avoid accidental impact or forceful manipulation of the appliance during wear.
• This product contains trace amounts of Nickel, Chromium, and Styrene—substances identified by the State of California as potential carcinogens.
• Potential risks may include soft tissue discomfort, root resorption, and unintended tooth movement following treatment.

12. Disposal Instructions

• Dispose of any damaged or defective appliances responsibly.
• Handle all components with care during use.
• Follow local regulations for the environmentally safe disposal of used devices and packaging materials.

13. Serious Incident Reporting

In the event of a serious incident related to this device, or any observed malfunction or performance issue, report the occurrence promptly to the manufacturer, authorized representative, or local distributor. Additionally, notify the relevant national health authority in accordance with applicable regulations.

14. REGULATORY INFORMATION

The following symbols might appear on the label:

PICTOGRAMS

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

INSTRUCTIONS FOR USE

BiteForce™

DISTALIZING APPLIANCE

J&J® ORTHODONTICS