









Metal Brackets and Molar Tubes

The products covered by this instruction include:

- Advant-Edge® Stainless Steel Brackets
- Nu-Edge® Cobalt Chromium Brackets
- Nu-Edge SL Cobalt Chromium Brackets
- Straight-Edge® Stainless Steel Brackets
- Tip-Edge® PLUS Stainless Steel Brackets
- Tip-Edge Rx-I
- Molar Tubes

Symbols Used on Labeling

	Manufacturer.
	Date of manufacture.
	Batch code.
	Caution! See warnings and precautions.
	Consult instructions for use.
	Do not re-use.
	Do not use if package is damaged.
	Product is not sterilized.

Indications for Use

Intended for use in orthodontic treatment.

Warnings

- This product is intended for single use (its reuse may cause cross contamination, loss of material integrity, and compromise overall product safety and performance).
- Don't reuse the bracket in the event of a premature debond as the bracket may have been deformed. Bond a new bracket (with the same part number).
- This product contains nickel and/or chromium, and a small percentage of the population is known to be allergic to these metals. In case of an allergic reaction, refer the patient to consult a physician.
- The color mark provides orientation reference for the positioning of the bracket.

Precautions

- Advise patients not to bite hard materials, such as ice chips, pen caps, whole apples, etc. to prevent damages to the brackets and/or teeth.

Contraindications

- Bonding brackets and tubes to patients with compromised oral health, such as poor oral hygiene, periodontal disease, or preexisting dental conditions (i.e. decalcification, carious lesions, large restorations) can increase the risk of tooth damage.
- Bonding brackets and tubes to uncooperative patients can increase the risk of tooth damage.

Instructions for Use

This product must be used by qualified orthodontists or dentists trained in orthodontics.

Bracket Bonding

Prepare tooth surface before bonding the bracket following the adhesive manufacturer's instructions.

Remove any adhesive flash to minimize adhesive staining, plaque retention, and to facilitate debonding.

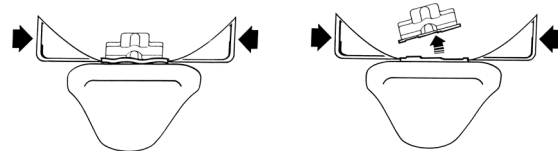
After the bracket is bonded, remove the position jig (for brackets that have a jig).

Bracket Debonding

Ensure there is no adhesive flash over the bracket base. Remove any flash prior to debond.

No special debonding technique is required. Remove the bracket using a debonding plier or instrument of doctor's preference. Apply gentle pressure until the bracket debonds.

Care should be taken to contain small parts so they are not accidentally inhaled or ingested by the patient. As an added safety measure, it is recommended to leave brackets ligated to the archwire when debonding.



Storage Condition

Product should be kept in a clean location.

Product Performance Structure and Composition

For Nu-Edge® SL Cobalt Chromium Brackets, the body and base are molded using cobalt-chromium.

For Nu-Edge Cobalt Chromium Brackets, the body is molded using cobalt-chromium alloy and the base is molded using AISI316L stainless steel.

For Straight-Edge® Stainless Steel Brackets, Tip-Edge® PLUS Stainless Steel Brackets and Molar Tubes, the body and base are molded using AISI316L stainless steel.

NOTICE:

TP Orthodontics, Inc. warrants that its products are free from defects in materials and workmanship. TPO's liability and the customer's sole remedy in the event of any claimed defect shall be limited to replacement of the product, or at TPO's discretion, refund of the purchase price. This warranty is in lieu of any other warranties, express or implied, including any implied warranty of merchantability, fitness for a particular purpose, or otherwise, and of any other obligations or liability on TPO's part. Other than the warranties listed above, under no circumstances will TPO be liable for any loss, damages arising in connection with use, or inability to use, TPO's products.

