Ortho-Choice[™] OBA Orthodontic Bracket Adhesive

- Light Cure
- •Fluoride Releasing

Pulpdent Ortho-Choice OBA provides the security of firmly bonded orthodontic brackets along with all the advantages of long-term fluoride release. Saving valuable chairside time, visible light curing provides rapid curing on-demand and assures proper placement for each bracket. Pulpdent OBA works equally well with metal, ceramic and clear sapphire brackets.

The thick consistency of Ortho-Choice OBA permits unlimited time for placement and positioning of the bracket and prevents bracket drift. Complete cure and optimum bond strength are achieved after light curing each bracket for 30-40 seconds (10 seconds for each bracket side).

PRODUCT DESCRIPTION

Light cure, fluoride-releasing orthodontic bracket adhesive.

INDICATIONS

Indicated for use as an adhesive for metal, ceramic, and clear sapphire orthodontic brackets.

CONTRAINDICTAIONS

Not indicated for use on acrylic surfaces.

INSTRUCTIONS FOR USE

1. Clean: Clean the enamel surfaces to be bracketed with an oil-free prophy paste. Rinse and dry thoroughly.

2. Isolate: Keep teeth to be bracketed free of moisture contamination throughout the bracketing procedure. Maintain a dry field using standard isolation procedures.

3. Etch: Apply Etch-Rite[™] etching gel or Pulpdent Semi-Gel etchant to the tooth surface to be bracketed for 20 seconds (40 seconds for primary teeth). Rinse with copious amounts of water and dry with clean, oil-free, and moisture-free air. DO NOT DISTURB THIS SURFACE. This surface should appear chalky white. If not, repeat the above etching procedure.

4. Apply Bonding Resin: Dispense a small amount of Ortho-Choice Bonding Resin into a mixing well and apply a very thin coat to the etched enamel surface with a clean brush applicator. Too much Bonding Resin can cause brackets to drift. It is not necessary to cure the Bonding Resin.

5. Apply Bracket Adhesive: Dispense bracket adhesive from the syringe and apply ½mm onto the entire tooth contacting the surface of the bracket base.

Note: Ortho-Choice OBA is light-activated. Keep syringe tip clean and replace syringe cap immediately after use.

6. Place Bracket: Place the bracket on the tooth with firm pressure so that excess adhesive is expressed from the perimeter of the bracket. Remove excess with an explorer or plastic instrument. Position the bracket. The high viscosity of the adhesive is designed to prevent bracket drift after positioning.

7. Light Cure: OBA light cures in 10 seconds. It is recommended to light cure 10 seconds on each bracket side.

8. Place Archwires: Archwires can be inserted and secured immediately after light curing.

9. Bracket Removal: After treatment is completed, the brackets are removed in the usual manner.

Note: When bonding to porcelain, first etch porcelain surfaces with Pulpdent Porcelain Etch Gel and apply Silane following manufacturer's instructions for use. The Pulpdent Porcelain Prep Kit is ideal for this application.

Note: When debonding from porcelain restorations, special care must be taken. Debonding can cause porcelain to chip, fracture, or delaminate.

STORAGE AND HANDLING

• Store tightly sealed in original container at cool room temperature. Avoid direct light, extremes of temperature, contamination, and sources of ignition.

• Shelf life of unopened product: 2 years from date of manufacture.

• Re-cap immediately after use.

Note: If Ortho-Choice OBA has been refrigerated, return to room temperature before use for optimal viscosity.

CAUTION

Uncured material may cause eye or skin irritation on contact. Dental professionals should wear safety glasses and surgical gloves. Do not exceed the manufacturer's recommended curing time for the light you are using.

REPORTING OF SERIOUS INCIDENTS

Any serious incidents involving the device should be reported to the manufacturer and the Competent Authority of the Member State in which the incident occurred, or other appropriate regulatory body. Reports of serious incidents should be sent to: Pulpdent Corporation

80 Oakland Street, Watertown, MA 02472 USA Tel: 617-926-6666 / Fax: 617-926-6262 email: pulpdent@pulpdent.com

Note: Apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient. For additional information, refer to: https://www.fda.gov/medi-cal-devices/dental-devices/multiple-use-dental-dispenser-devices

Note: Refer to the Safety Data Sheet for a list of materials present in this product.



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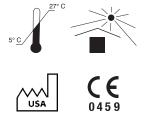
SAFETY DATA SHEET





PULPDENT®

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