Prim & Bond Elect

Universal Dental Adhesive

1. PRODUCT DESCRIPTION

Prim & Bond Elect Universal Dental Adhesive is a universal self-priming dental adhesive system designed to bond resin-based restorative materials to enamel and metal. It is contraindicated for direct application to dental pulp tissue (direct pulp capping).

2. DIRECTIONS FOR USE – ENGLISH

Universal Dental Adhesive

1.1 Indications

- Adhesive bonding of direct amalgam restoration
- Indirect restoration
- Dual cured and self cured resin cemented endodontic post cementation
- Amalgam Bonding Base and Amalgam Bonding Catalyst

1.2 Contraindications

- 5.0 mL tri-laminated bottle
- 4.5 mL tri-laminated bottle

1.3 Adverse reactions

- May irritate the eyes and skin. Eye contact: irritation and possible corneal damage. Skin contact: irritation or possible allergic response. If contact with skin occurs, immediately remove material with soap and water and seek medical attention. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.

1.4 Warnings

- eyes and oral mucosa and may cause allergic contact dermatitis in susceptible persons. Prim & Bond Elect Adhesive is acids and may cause burns.
- Avoid eye contact to prevent cross-contamination.
- redness or irritation of the mucous membranes: inflammation, edema, sloughing. See Warnings.
- Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product. Keep out of direct sunlight and store in a well ventilated place at temperatures between 2 º-8 ºC/35 º-46 ºF. Allow material to reach room temperature prior to use. Protect from moisture. Do not freeze. Do not use after expiration date.

2.1 Interactions

- Amalgam Bonding Base and Amalgam Bonding Catalyst: interactions with materials containing anti-fungal agents or rubber dam materials. (see complete directions for use of selected restorative/cement material).

2.2 Ideal interactions

- 2.3. Adverse reactions

- Product may irritate the eyes and skin. Eye contact: irritation and possible corneal damage. Skin contact: irritation or possible allergic response. Reddish rashes may be seen on the skin. Mucous membranes: inflammation, edema, sloughing. See Warnings.

3. STEP-BY-STEP INSTRUCTIONS

Cleansing: Preparation for all adhesive procedures

- Clean freshly instrumented enamel and dentin with water spray and then air dry. Clean uninstrumented enamel and dentin with a rubber cup and pumice or a cleaning paste such as NU PRO Prophylaxis Paste. Wash thoroughly with water spray and blot or air dry for 5 seconds.

4. Storage

Prim & Bond Elect Adhesive is contraindicated for use with patients who have a known hypersensitivity to methacrylate resins. Prim & Bond Elect Adhesive is contraindicated for direct application to dental pulp tissue (direct pulp capping).

5.0 mL tri-laminated bottle
- 4.5 mL tri-laminated bottle

4.5 mL tri-laminated bottle

6.0 mL tri-laminated bottle

8.0 mL tri-laminated bottle


1. Do not use after expiration date. ISO standard uses: "YYYY/MM"

4. HYGIENE

3. Indirect restorations; dual cured and self cured resin cemented inlays, onlays, crowns and bridge retainers.

3.2. Prime&Bond Elect™ Universal Dental Adhesive Application

- Composite, ceramic and amalgam repairs
- Dual cured and self cured direct composite restorative/core build-up material
- Dual cured resin cement for indirect restoration cementation
- Adhesive bonding of direct amalgam restoration.

4.1 Cleaning and disinfection

Bottles:
- A protective barrier is recommended to avoid package contamination. Disinfect contaminated bottles with a water-based hospital-level disinfection solution. Wipe bottles gently.

Unit Dose Holder and Mixing Well:
- Water-based hospital-level disinfection solution according to national/local regulations.

Preparation

areas of exposed dentin

enamel, especially enamel

Mostly dentin – little or no enamel

Pulp protection

Total-Etch (34% phosphoric acid application to enamel and dentin), Selective-Etch (34% phosphoric acid to enamel, incisal dentin contact)

• tooth isolation (rubber dam or other suitable isolation technique) and
• application of Prime&Bond Elect™ Adhesive as per restorative material manufacturer's directions.

NOTE: When used as tooth cement, Prime&Bond Elect™ Adhesive is not an amalgam adhesive.

3.2 Prime&Bond Elect™ Dual Cured Adhesive Application

Dual cure or self cure composite restorative/composite restorative

• Conventional Bottle: Place 2-3 drops of Prime&Bond Elect™ Adhesive into a clean well. Replace cap promptly.

• Disposable applicator into opening to saturate applicator tip. For endodontic post cementation, a paper point pre-wet with the adhesive mixture may aid in bringing the adhesive into place. Dampen needle with water and, if necessary, select needle(s) for endodontic post cementation. Disposable needle comes with a disposable needle and needle tip. Needle tip is cut off at a 45° angle and points are bent for easy access. Gently extrude conditioner gel to the cavity for selected technique.

• Rinse and dry as described above.

• Conventional Bottle: Place 2-3 drops of Prime&Bond Elect™ Adhesive into a clean well. Air dry.

• Prime& Bond Elect™ Adhesive to thoroughly wet all the tooth surfaces. Agitate the applied adhesive/activator mixture for 20 seconds. Saturate all tooth surfaces with the mixed adhesive/activator.

• Rinse and dry as described above.

• Remoove excess solvent by gifting with dry rolls, dry air or dental spray for up to 5 seconds. Recommended technique is to begin drying/evaporation with the syringe approximately 4-6 inches (10-15 cm) away from the surface, gradually bringing the source to within 0.5 inches (10mm) of the surface. Surface should have a uniform glossy appearance. If not, repeat application and air dry. Surface should show areas of excessive adhesive-thickness or pooling. Repeat air drying/evaporation cut-off above as necessary.

Inadequate polymerization due to insufficient solvent evaporation

• Follow evaporation instructions above

Inadequate polymerization due to insufficient curing

• Inadequate polymerization due to insufficient cleaning/drying

Inadequate polymerization due to insufficient evaporation

• Follow evaporation instructions above

4. HYDROGEN

Chemo-contamination

• Do not reuse single use products. Dispose in accordance with local regulations.

• Replace empty bottles with manufacturer's replacement products as described below.

Cleaning and disinfection

To prevent bottle exposure to spatter or spray of body fluids or contaminated hands, or oral tissues, use of a protective barrier is recommended to avoid package contamination. Disinfect contaminated bottles with a water-based hospital-level disinfection solution according to national/local regulations. Replicated disinfection may damage label. NOTE: Vigorous wiping can damage the label. Wipe dry with a paper towel.

Unit Dose Holder and mixing well:
- Remove residual adhesive with tissue. Clean by scrubbing with water and soap. Disinfect with a water-based hospital-level disinfection solution according to national/local regulations.

5. LOT NUMBER AND EXPIRATION DATE

1. The Lot Number and Expiration Date are located at the bottom of the bottle.

The following numbers should be quoted in all communications:
- Lot Number
- Expiration Date

Manufactured by:
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