

# Prime & Bond Elect™

## Universal Dental Adhesive

DENTSPLY

### DIRECTIONS FOR USE – ENGLISH

For dental use only. USA: Rx only.

#### 1. PRODUCT DESCRIPTION

Prime&Bond Elect™ Universal Dental Adhesive is a universal self-priming dental adhesive system designed to bond resin based materials to enamel and dentin as well as to metals and ceramic. Prime&Bond Elect™ Universal Dental Adhesive combines etchant, primer and adhesive in a one-bottle material. This robust formulation allows the operator to utilize selective phosphoric acid etching of enamel, phosphoric acid etching of both enamel and dentin, or no phosphoric acid etching prior to application, ensuring high bond strength and protection against microleakage.

When mixed with Self Cure Activator, Prime&Bond Elect™ Universal Dental Adhesive is designed to be used with DENTSPLY manufactured dual cure/self cure resin cements to bond all indirect restorations and DENTSPLY manufactured dual cured composite restoratives. When used with the Amalgam Bonding Accessory Kit, available separately, Prime&Bond Elect™ Universal Dental Adhesive also adhesively bonds fresh amalgam to enamel and dentin.

##### 1.1 Delivery forms

Prime&Bond Elect™ Universal Dental Adhesive is available in:

- 5.0mL tri-laminated bottle
- 0.125mL disposable containers for single patient use

Self Cure Activator is available in:

- 4.5mL tri-laminated bottle

##### 1.2 Composition

*Prime&Bond Elect™ Adhesive:* Mono-, di- and trimethacrylate resins; PENTA (dipentaerythritol penta acrylate monophosphate); Diketone; Organic phosphine oxide; Stabilizers; Cetylamine hydrofluoride; Acetone; Water

*Self Cure Activator:* Mono- and Di-methacrylate Resins; Catalyst; Photoinitiators; Stabilizers; Acetone; Water

*Amalgam Bonding Base and Amalgam Bonding Catalyst:* Dimethacrylate resins; Initiators; Stabilizers

##### 1.3 Indications

*Prime&Bond Elect™ Adhesive (visible light cured):*

- Direct, light cured composite and compomer restorative
- Indirect restorations; light cured, resin cemented veneers
- Composite, ceramic and amalgam repairs
- Cavity varnish for use with fresh amalgam

*Prime&Bond Elect™ Adhesive with Self Cure Activator (dual cure or self cure):*

- Direct, dual cure or self cure composite restorations and core build-ups
- Indirect restorations; dual cured and self cured resin cemented inlays, onlays, crown and bridge retainers
- Dual cured and self cured resin cemented endodontic post cementation

*Prime&Bond Elect™ Adhesive with Self Cure Activator and Amalgam Bonding Base & Catalyst (dual cure or self cure):*

- Adhesive bonding of direct amalgam restoration

##### 1.4 Contraindications

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

##### 1.5 Compatible restoratives/cements

- Prime&Bond Elect™ Adhesive is chemically compatible with conventional methacrylate-based visible light cured composite restorative and cement materials including DENTSPLY visible light cured composite and compomer restorative and cement materials.
- Prime&Bond Elect™ Adhesive mixed with Self Cure Activator is chemically compatible with conventional methacrylate-based dual and self cured composite restorative materials including DENTSPLY dual and self cured composite restorative and cement materials. (see complete directions for use of selected restorative/cement material).

## 2. GENERAL SAFETY NOTES

Be aware of the following general safety notes and the special safety notes in other chapters of these directions for use.



#### Safety alert symbol

This is the safety alert symbol. It is used to alert you to potential personal injury hazards. Obey all safety messages that follow this symbol to avoid possible injury.

##### 2.1 Warnings

Prime&Bond Elect™ Adhesive contains polymerizable methacrylates which may be irritating to skin, eyes and oral mucosa and may cause allergic contact dermatitis in susceptible persons. Prime&Bond Elect™ Adhesive is acidic and may cause burns.

- **Avoid eye contact** to prevent irritation and possible corneal damage. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.
- **Avoid skin contact** to prevent irritation and possible allergic response. If contact with skin occurs, immediately remove material with cotton and wash thoroughly with water and soap. In case of skin sensitization or rash, discontinue use and seek medical attention.
- **Avoid contact with oral Soft Tissues/mucosa** to prevent inflammation. If accidental contact occurs, immediately remove material from the tissues. Flush mucosa with plenty of water after the restoration is completed and expectorate/evacuate the water. If inflammation of mucosa persists, seek medical attention.

##### 2.2 Precautions

- This product is intended to be used only as specifically outlined in these Directions for Use. Any use of this product inconsistent with the Directions for Use is at the discretion and is the sole responsibility of the practitioner.
- Devices marked "single use" on the labeling are intended for single use only. Discard after use. Do not reuse in other patients in order to prevent cross-contamination.
- Contact with saliva and blood during placement may cause failure of the restoration. Use of rubber dam or adequate isolation is recommended.
- Wear suitable protective eyewear, mask, clothing and gloves. Protective eyewear is recommended for patients.
- The Prime&Bond Elect™ Adhesive bottles should be tightly closed immediately after use.
- Once Prime&Bond Elect™ Adhesive is mixed with Self Cure Activator, apply immediately onto prepared surfaces.
- Use only in well ventilated areas. Avoid inhaling vapor.
- Flammable: Prime&Bond Elect™ Adhesive contains acetone. Keep away from sources of ignition.
- Compared to selectively applying phosphoric acid (selective etching) to enamel, Prime&Bond Elect™ Adhesive is less effective on unetched, unground, unprepared, or uncut enamel. For optimal bonding results, the enamel should be beveled and/or phosphoric acid conditioned before treatment with Prime&Bond Elect™ Adhesive.

##### Interactions:

- Eugenol- and hydrogen peroxide containing materials should not be used in conjunction with this product because they may interfere with hardening and cause softening of the polymeric components of the material.
- Prime&Bond Elect™ Adhesive is light cured material. Protect from ambient light.
- If mineral-impregnated (e.g., ferric compounds) retraction cords and/or hemostatic solutions are used in conjunction with adhesive procedures, marginal seal may be adversely affected, allowing microleakage, subsurface staining and/or restoration failure. If gingival retraction is necessary, use of plain, non-impregnated cord is recommended.
- The use of a dual cure adhesive system such as Prime&Bond Elect™ Dual Cured Adhesive can shorten working time of a dual cure resin cement system. This effect should be investigated in the laboratory prior to clinical use.
- Variable in vitro data exist regarding use of light-cured-only adhesives such as Prime&Bond Elect™ Adhesive without Self Cure Activator in conjunction with dual cured or self cured resin restoratives or cements. Chemical/Product incompatibility may adversely affect product efficacy, leading to premature restoration failure.

##### 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.

##### 2.4 Storage

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°-8°C/35°-46°F. Allow material to reach room temperature prior to use. Protect from moisture. Do not freeze. Do not use after expiration date.

## 3. STEP-BY-STEP INSTRUCTIONS

Prime&Bond Elect™ Universal Dental Adhesive offers the operator total flexibility to utilize:

- selective phosphoric acid etching of just enamel,
- phosphoric acid etching of both enamel and dentin,
- or no phosphoric acid etching prior to application

##### 3.1 General procedures

###### 1. Cleaning: 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 NUPRO® Prophylaxis Paste. Wash thoroughly with water spray and blot or lightly air dry. Do not desiccate dentin.

###### • Indirect restoration

- Treat surface of restoration according to manufacturers or dental laboratory's instructions, i.e., etching or mechanical roughening.
- Apply Calibra® Silane Coupling Agent (available separately) to ceramic restorations designed to be silanated following manufacturer's instructions.
- A. Light cured cement e.g., veneer cementation
  - Apply a single coat of Prime&Bond Elect™ Adhesive to the internal bonding surface of the restoration. Immediately air dry for 5 seconds.
- B. Dual/Self cured cement e.g., full coverage crown
  - Apply a single coat of Prime&Bond Elect™ Adhesive and Self Cure Activator mixture to the internal bonding surface of the restoration. Immediately air dry for 5 seconds.
  - Cure mixed adhesive/activator for 10 seconds.

###### • Composite, ceramic and amalgam repairs (light cured composite resin and compomers)

- Preparation, Cleaning: Roughen the fractured surface as much as possible with a diamond bur. Create mechanical retention where possible. For best results, sandblast the area to be repaired with an intraoral microetcher (50µ alumina). Rubber dam is recommended with high speed evacuation. Rinse microetched areas for 15-20 seconds with water. Air dry. **NOTE:** Bevel porcelain margins before etching.
- Etch ceramic restoration repair area with hydrofluoric acid according to manufacturer's instructions.

- Treatment of the Restoration: Rinse with water for 10 seconds. Air dry. **NOTE:** Apply Calibra® Silane Coupling Agent to porcelain surfaces to be repaired following manufacturer's instructions.

## 2. Pulp protection

For direct and indirect pulp capping, cover the dentin close to the pulp (less than 1mm) with a hard setting calcium hydroxide liner (Dycal® Liner) leaving the rest of the cavity surface free for bonding with Prime&Bond Elect™ Adhesive.

## 3. Enamel and dentin pre-treatment

Prime&Bond Elect™ Adhesive offers operators the choice of enamel and dentin pre-treatment prior to adhesive application: Total-Etch (34% phosphoric acid application to enamel and dentin), Selective-Etch (34% phosphoric acid application to enamel only), or Self-Etch (no pre-treatment with phosphoric acid).

Table 3

| Preparation  | Clinical Examples   | Recommended Enamel & Dentin Pre-treatment   |
|--|---|---|
| Mostly enamel – may have small areas of exposed dentin           | <ul style="list-style-type: none"> <li>• Indirect Veneer Cementation</li> <li>• Small/shallow Direct Restorations</li> </ul>  | • Total-Etch – 34% phosphoric acid application to enamel and dentin                     |
| Mostly dentin – with available enamel, especially enamel margins | <ul style="list-style-type: none"> <li>• Direct restorations (all cavity classes),</li> <li>• Uninstrumented enamel,</li> <li>• Indirect Inlay/Onlay cementation</li> </ul> | • Selective-Etch – 34% phosphoric acid application to enamel, incidental dentin contact |
| Mostly dentin – little or no enamel                              | • Indirect full-coverage crown, endodontic post cementation   | • Self-Etch – No application of phosphoric acid   |

### 3.1 Total-Etch option

- After application of rubber dam or other suitable isolation technique, apply Caulk® 34% Tooth Conditioner Gel. Attach disposable needle to end of syringe, needle tip may be bent for easy access. Gently extrude conditioner gel to the cavity surfaces starting at the enamel margins. For best results, condition enamel for at least 15 seconds and dentin for 15 seconds or less.
- Rinsing and Drying: Remove gel with aspirator tube and/or vigorous water spray and rinse conditioned areas thoroughly for at least 15 seconds. Remove rinsing water completely by blowing gently with an air syringe or by blot drying with a cotton pellet. Do not desiccate dentin. Proceed immediately to application of Prime&Bond Elect™ Adhesive.
- Once the surfaces have been properly treated, they must be kept uncontaminated. If salivary contamination occurs, thoroughly clean with vigorous water spray, dry, and repeat conditioning procedure of enamel for 5 seconds only. Rinse and dry as described above.

### 3.2 Selective-Etch option

- Apply Caulk® 34% Tooth Conditioner Gel as above, gently extruding to the enamel (margins) only. For best results, condition enamel for 15 seconds. Any incidental contact of conditioner gel to dentin should be limited to 15 seconds or less.
- Rinse and dry as outlined above.

### 3.3 Self-Etch option

- No application of Caulk® 34% Tooth Conditioner Gel. Following cleaning Section 1 of 3.1 *General procedures* and pulp protection Section 2 of 3.1 *General procedures*, proceed directly to adhesive application below.

## 3.2. Prime&Bond Elect™ Universal Dental Adhesive Application

**Light Cured Procedures:** Prime&Bond Elect™ Adhesive

- Direct, light cured composite and compomer restorative
- Indirect restorations; light cured, resin cemented veneers
- Composite, ceramic and amalgam repairs
- Cavity varnish for use with fresh amalgam
  - Application of Prime&Bond Elect™ Adhesive following selected enamel and dentin pre-treatment option
    - Unit Dose Container: Grasp container at each end, or insert into holder, placing thumb along center score. Firmly apply pressure until container separates. Holder may be placed on the tabletop or held between fingers for convenience. Insert disposable applicator into opening to saturate applicator tip.
    - Conventional Bottle: Place 2-3 drops of Prime&Bond Elect™ Adhesive into a clean well. Replace cap promptly.
- Using the disposable microbrush applicator tip supplied, immediately apply generous amounts of Prime&Bond Elect™ Adhesive to thoroughly wet all the tooth surfaces. Agitate the applied adhesive for 20 seconds. Re-wetting of the microbrush may be required in order to coat the preparation for the full 20seconds.
- Remove excess solvent by gently drying with clean, dry air from a dental syringe for at least 5 seconds. Recommended technique is to begin drying/evaporation with the syringe approximately 4-6 inches (10-15cm) 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 not show areas of excessive adhesive thickness or pooling. Repeat air drying/evaporation outlined above if necessary.



### Inadequate polymerization due to insufficient solvent evaporation

- Follow evaporation instructions above

- Cure Prime&Bond Elect™ Adhesive for 10 seconds using a curing light, spectral output containing 470nm, minimum light output at least 550mW/cm². Proceed immediately to completion/restorative material placement.



### Inadequate polymerization due to insufficient curing

- Check compatibility of curing light
- Check curing cycle
- Check curing output before each procedure

- Completion: Place light cured restorative material, light cured resin cement or fresh amalgam over the cured Prime&Bond Elect™ Adhesive as per restorative material manufacturer's directions.

**NOTE:** When used as a cavity varnish, Prime&Bond Elect™ Adhesive is not an amalgam adhesive.

## 3.3 Prime&Bond Elect™ Dual Cured Adhesive Application

**Dual Cured or Self Cured Procedures:** Prime&Bond Elect™ Adhesive with Self Cure Activator mixture

- Direct, dual cure or self cure composite restorations and core build-ups.
- Indirect restorations; dual cured and self cure resin cemented inlays, onlays, crown and bridge retainers.
- Dual cured and self cured resin cemented endodontic post cementation.
- Adhesive bonding of direct amalgam restoration.
  - Clean preparation and treat restoration following Section 1 of 3.1 *General procedures*. Place Dycal® Liner if needed following Section 2 of 3.1 *General Procedures*.
  - For direct core build-up, place pin, post or matrix as needed.
  - Tooth Conditioning/Dentin pretreatment: See Table 3 for clinical recommendations. Follow Section 3.1 *Total-Etch option*, 3.2 *Selective-Etch option*, or 3.3 *Self-Etch option* for selected technique.
  - Application of Prime&Bond Elect™ Dual Cure Adhesive System following selected enamel and dentin pre-treatment option
    - Place 1-2 drops of Prime&Bond Elect™ Adhesive into a clean plastic mixing well. Replace cap promptly.
    - Place an equal number of drops of Self Cure Activator into the same mixing well. Replace cap promptly. Mix contents for 1-2 seconds with a clean, unused brush tip.
    - Using the disposable microbrush applicator tip supplied, immediately apply generous amounts of mixed Adhesive/Activator to thoroughly wet all the tooth surfaces. Agitate the applied adhesive/activator mixture for 20 seconds. **NOTE:** For endodontic post cementation, a paper point pre-wet with the adhesive mixture may aid in bringing the adhesive mixture down to the deepest portion of the preparation.
    - Remove excess solvent by gently drying with clean, dry air from a dental syringe for at least 5 seconds. Recommended technique is to begin drying/evaporation with the syringe approximately 4-6 inches (10-15cm) 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 not show areas of excessive adhesive thickness or pooling. Repeat air drying/evaporation outlined above if necessary. **NOTE:** For endodontic post cementation, use of clean, dry paper points may aid in thorough removal of solvent/excess adhesive in post space.



### Inadequate polymerization due to insufficient solvent evaporation

- Follow evaporation instructions above

- Cure mixed Adhesive/Activator for 10 seconds.

- Completion – dispense, mix and apply per manufacturer's directions:
  - Dual cure or self cure direct composite restorative/core build-up material
  - Dual cured resin cement for indirect restoration cementation
  - Amalgam Bonding Base and Amalgam Bonding Catalyst for amalgam bonding

## 4. HYGIENE



### Cross-contamination

- Do not reuse single use products. Dispose in accordance with local regulations.
- Reprocess reusable products as described below.

### 4.1 Cleaning and disinfection

**Bottles:** To prevent bottles from 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. Repeated disinfection may damage label. **NOTE:** Vigorous wiping can destroy the label. Wipe bottles gently.

**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. Do not use after expiration date. ISO standard uses: "YYYY/MM"
2. The following numbers should be quoted in all correspondence:
  - Reorder Number
  - Lot number
  - Expiration date

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