premier

US

INSTRUCTIONS FOR USE

Bond-PR®

Universal Adhesive

Indications For Use:

- Bonding of methacrylate-based light-, dual-, and self-cure composites, compomers, core build-up materials, sealants, and cements.
- Intraoral repair of composite and compomer restorations.
- Root surface desensitization.
- Cavity sealing prior to amalgam or temporary restorations.
- Cementation of indirect restorations, including veneers, with resin cement.
- Intraoral repair of composite, ceramic, porcelain-fused-to-metal, zirconia and other all-ceramic restorations.

Description of Device:

Premier's Bond-PR® Universal Adhesive is a universal light-cure self-etch one component bonding agent with combines Etch, Primer and Adhesive into a single component for ease of application. Bond-PR® is suitable for all direct and indirect bonding procedures and all etching techniques. It can also serve as a universal primer for all restoration materials. Bond-PR® forms an excellent bond with dentin, enamel and any light-cure, self- or dual-cure composites, compomers, core build-up materials, sealants, and cements. Bond-PR® is available in bottles for multiple usages.

Depending on the indication, Bond-PR® is used:

- In a self-etching procedure to enable quick treatment time and to reduce post-operative sensitivities.
- With selective etch; etching solution is used to maximize the adhesion to the tooth enamel.
- In a total etch procedure with a prior phosphoric acid etching step of enamel and dentin.

Bond-PR® is free of bisphenol A (BPA) and BIS-GMA.

Contraindications:

Do not use Bond-PR® on patients with known allergies to acrylate-based materials or contained allergens.

Not to be used for direct pulp capping.

Interactions:

- Seat temporary restorations with a eugenol-free cement (e.g., NexTemp® Temporary Cement). Avoid eugenol-containing cements, as they can inhibit the polymerization of Bond-PR® during final cementation.
- Do not clean Zirconia, aluminum oxide, or metal restorations with phosphoric acid. After try-in, use a universal cleaner (e.g., UniClean™ Universal Cleaner).
- Do not use disinfectants (except chlorhexidine solutions), astringents, dentin sealants, or rinsing solutions containing EDTA or hydrogen peroxide prior to applying Bond-PR®. Residues can impair bond strength and curing, especially with dual- and self-cure materials.

PRECAUTIONS:

- Avoid contamination of the product. Do not mix components with those of other materials. Do not return dispensed components to their original container. Dispose of leftover material properly.
- Wear personal protective equipment, including protective eyewear and gloves, when using and handling this product.
- Ensure that the tooth is free of debris, materials, or stains that may interfere with application process.
- Close the flip cap immediately after dispense the product to avoid evaporation or contamination.
- Not recommended to be used with precious alloys as it may cause reduced bond integrity.

WARNINGS:

- Do not light-cure Bond-PR® less than the recommended curing time.
- For use by a trained dental professional only.
- Avoid contact skin, eyes, and soft tissues.
- Do not use after the shelf-life period indicated on product labeling/packaging.

Adverse Reactions:

- If an allergic reaction to Bond-PR® material occurs, wash thoroughly with soap and water after contact; discontinue its use immediately and consult a physician.
- In case of contact with eyes, rinse immediately with plenty of water and seek medical advice.
- If an incident or serious incident has occurred in relation to the device, please report the incident to the manufacturer.

Contents and Setup:

SKU	Description	Contents
3005250	Standard pack - 1 x 5 ml flip top bottle	5 ml
3005255	Value Pack - 3 x 5 ml flip top bottles	15ml

Materials:

Product Composition, % WT: Urethane Dimethacrylate < 50%; HEMA <30%, 10-MDP <10%; Photoinitiators < 3%; Water < 3%; Ethanol < 20%; Adhesion Promoter < 10%; Inhibitor <3%. None of the ingredients in the product contain pharmacologically active components.

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Directions for Use:

1. Wear personal protection equipment when handling Bond-PR®.

2. Preparation

   2a. Direct Restoration Prep – Prepare tooth according to clinical requirements. Rinse with water and air dry.

   2b. Indirect Restoration Prep – Prepare the surface of the ceramic restoration:

   - Etch porcelain ceramic surfaces with hydrofluoric acid in accordance with manufacturer's instructions. Treat using material with silane coupling agent.
   - Prepare the surface of the Zirconia ceramic, aluminum oxide ceramic, composite, and metal surfaces restorations:

     i. Roughen restoration surface preferably by sandblasting.

     ii. For the best possible bond, do not clean the surface of Zirconia, aluminum oxide, or metal restorations with phosphoric acid.

   Note: If using Bond-PR® as a primer, do not light cure the adhesive on the restoration.

3. Shake – Shake the bottle briefly prior to dispensing.

4. Etching (selective or total) – Apply a commonly used phosphoric acid etching solution (e.g. Spot-On™ Etch or Premier® Etch) to the prepared or unprepared tooth (dentin and/or enamel) following the manufacturer's Instruction. Etch time for dentin is 15 seconds, for enamel is 30 seconds. Rinse thoroughly with water and dry with water-free and oil-free air or with cotton pellets. Do not overdry.

5. Dispensing – The bottle contains a flip cap, which can be easily opened and closed with one hand. Bond-PR® can be dispensed into a small well and directly applied by using a brush or a micro-applicator. Protect from light.

6. Application – Apply one layer of Bond-PR® with a brush or a micro-applicator. Ensure the entire surface of desired bonding structure is covered. Avoid contact with the oral mucosa. When bonding to dentin, leave undisturbed for 10 seconds. When bonding to all other surfaces, leave undisturbed for 20 seconds.

   Air dry with a gentle stream of air to volatile solvent, until no movement of the Bond-PR® film is noticed, at least 5 seconds.

7. Curing – Cure the adhesive layer with a dental curing light with an irradiance of at least 1000 mW/cm^{2}such as Premier's Lumira™ Curing light or similar for 10 seconds.

8. For indirect restorations – Follow the manufacturer's instructions for use to apply the cement.

Handling:

To prevent contamination, the bottle should be handled outside the treatment area with new, unused disposable gloves. The bottles cannot be reprocessed. Dispose the bottles if contaminated. Do not put the Bond-PR® bottle into a disinfection bath or a washer-disinfector (thermal disinfector).

Storage:

- Keep product in original packaging.
- Do not store at temperatures over: 24°C (75°F).
- If stored in refrigerator, allow product to reach room temperature prior to use. Shelf life at room temperature is 24 months.
- Avoid direct exposure to light and heat.

Shelf Life:

- Bond-PR® has an expiration date of 2 years (24 months) from the date of manufacturing.
- Do not use after product has expired. See expiry date on the product label.

Disposal:

For disposal, always follow Federal or local laws applicable to the jurisdiction

Discard used bottles, brushes in appropriate waste stream. Do not reuse and dispose if brush becomes contaminated.

For Further Information:

To obtain SDS or IFU, visit premierdentalco.com or call Premier at 610-239-6000.

Symbols:

A full explanation of symbols used on Premier® Dental packaging and literature is located at premierdentalco.com/symbol-glossary

Symbols	Symbol Meaning
	Part Number
	Expiry Date
	Date and Country of Manufacture
	Manufacturer
	Batch number
	Caution: See instructions for use
	Indicates the upper limit of temperature to which the device can be safely exposed.
	Irritant: An immediate skin, eye or respiratory tract irritant
	Warning. Flammable liquid and vapor
	Medical Device
	Non-Sterile
Rx ONLY	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician
	See Instructions For Use on premierdentalco.com
	Keep away from sunlight