DIRECTIONS FOR USE - ENGLISH

For dental use only.
USA: Rx only.

1. PRODUCT DESCRIPTION
ProBOND® All Purpose Bonding Agent is comprised of a separate dentin primer and light cured, dentin/enamel adhesive. It is designed as an all purpose adhesive system for bonding resin based materials to enamel and dentin, as well as to metals, amalgam, porcelain, and composite. The ProBOND® Primer enables bonding to either etched or unetched, hydrated (“moist”) dentin. For most clinical applications, conditioning with separately available 34% phosphoric acid is recommended prior to ProBOND® Primer and/or Adhesive application.

ProBOND® Adhesive, when used without ProBOND® Primer, is an effective etched-enamel-only bonding agent.

When cementing indirect restorations, the film thickness of the ProBOND® Adhesive can be controlled by the operator to permit marginal resin cement gaps of 30 microns or less (on average) to insure complete seating of restorations, with pre-curing of the ProBOND® Adhesive.

1.1 Delivery forms
ProBOND® All Purpose Bonding Agent Primer and Adhesive are available in:
• 4.5mL tri-laminated bottles

1.2 Composition
Primer: PENTA (Dipentaerythritol pentacrylate phosphoric acid ester), Acetone, Ethanol, Stabilizers
Adhesive: UDMA resin, Polymerizable methacrylate monomers, PENTA, Camphorquinone (CQ) Photoinitiator, Glutaraldehyde, Stabilizers

1.3 Indications
• Direct composite and compomer restorative
• Direct, dual cure or self cure composite restorations and core build-ups
• Indirect Restorations; light cured, resin cemented veneers
• Indirect restorations; dual cured and self cured resin cemented inlays, onlays, crown and bridge retainers
• Composite, ceramic and amalgam repairs

1.4 Contraindications
• ProBOND® Bonding Agent components are contraindicated for use with patients who have a known hypersensitivity to methacrylate resins or any of the components.
• ProBOND® Bonding Agent components are contraindicated for direct application to dental pulp tissue (direct pulp capping).

1.5 Compatible restoratives/cements
• ProBOND® 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.
• ProBOND® Adhesive 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
ProBOND® All Purpose Bonding Agent components contain polymerizable methacrylates which may be irritating to skin, eyes and oral mucosa and may cause allergic contact dermatitis in susceptible persons.
• 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
1. This product is intended to be used only as specifically outlined in the Directions for Use. Any use of this product inconsistent with the Directions for Use is at the discretion and sole responsibility of the practitioner.
2. 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.
3. Wear suitable protective eyewear, clothing and gloves. Protective eyewear is recommended for patients.
4. Contact with saliva and blood during placement may cause failure of the restoration. Use of rubber dam or adequate isolation is recommended.
5. The ProBOND® All Purpose Bonding Agent bottles should be tightly closed immediately after use.
6. ProBOND® All Purpose Bonding Agent is not recommended for use where light transmission may be compromised, e.g. endodontic post space/post cementation.
7. When used in conjunction with cementation of indirect restorations, the adhesive must be thinned prior to curing to prevent incomplete restoration seating. (See Step-By-Step Instructions, “Simplified Dry Brush Technique”)
8. Use only in well ventilated areas. Avoid inhaling vapor.
10. 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.
   - ProBOND® 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.

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 10-24°C/50-75°F.
- Protect from moisture. Do not freeze. Do not use after expiration date.

3. STEP-BY-STEP INSTRUCTIONS
1. Direct restoration
   - Light cured composite resin and composites, dual cured or self cured composite/core build-up
   1.1 Cleaning
      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® Prophyaxis Paste. Wash thoroughly with water spray and blot or lightly air dry. Do not desiccate dentin.
   1.2 Pulp Protection
      For direct and indirect pulp capping, cover the dentin close to the pulp (less than 1 mm) with a hard setting calcium hydroxide liner (Dycal® Liner) leaving the rest of the cavity surface free for bonding with ProBOND® All Purpose Bonding Agent.
   1.3 Tooth Conditioning/Dentin Pretreatment
      When used as a bonding agent for composite materials, it is recommended to follow the total-etch technique (see complete Directions for Use, Caulk® 34% Tooth Conditioner Gel). When used as a bonding agent for compomer materials in non-stress bearing situations, acid etching of dentin is optional. NOTE: When used as an enamel-only bonding agent, i.e., entire preparation is within enamel, following acid etching, rinsing and drying of enamel, only application of ProBOND® Adhesive is necessary (proceed to Section 1.5).
      Important Technique Note: Once the surfaces have been properly treated, they must be kept uncontaminated. If salivary contamination occurs, repeat procedure beginning at Step 1.1.
   1.4 Application of ProBOND® Primer
      - Dispense 2-3 drops of ProBOND® Primer into a clean dispensing well, and REPLACE CAP IMMEDIATELY.
      - Using a clean disposable brush, generously apply ProBOND® Primer to thoroughly wet the exposed dentin without scrubbing the surface. Be sure to keep the tooth surface wet with primer for 30 seconds. If necessary reapply ProBOND® Primer in order to maintain a wet surface. Do not rinse the dentin primer from the surface of the dentin.
      - Remove excess solvent by gently drying with clean, dry air from a dental syringe for at least 5 seconds. Surface should have a uniform glossy appearance. If not, repeat application and air dry.

Inadequate polymerization due to insufficient solvent evaporation
- Follow evaporation instructions above
  - Proceed immediately to application of ProBOND® Adhesive (Section 1.5).
  NOTE: Any ProBOND® Primer in contact with enamel will not adversely affect adhesive bond.
1.5 Placement of ProBOND® Adhesive
   - Dispense one drop of ProBOND® Adhesive into a clean dappen dish or dispensing well. Replace cap immediately.
• With a small, clean brush, apply a thin uniform layer of adhesive to the etched and primed tooth structure. Remove excess by gentle air stream with clean, dry air from a dental syringe.
• Cure 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

CAUTION

2. Indirect restorations
• Light cured cementation procedure – Porcelain Veneers
• Dual or self cured cementation procedures – Porcelain, Ceramic, Composite, Metal: Inlays and Onlays; Full Coverage Crowns and Bridge Retainers; Resin-Bonded-to-Etched Enamel Metal Bridges (Maryland Bridges)

2.1 Remove temporary restoration if present and remove residual temporary cement with an explorer, rubber cup and prophylactic paste such as NUPRO® Prophylaxis Paste or water/flour of pumice. Rinse thoroughly and carefully dry preparation without desiccating dentin.
2.2 Check the fit and esthetics of the restoration. Technique Tip: Occlusal adjustment of veneers, inlays and onlays is best accomplished after final cementation.
2.3 Preparation of restoration.
• Treat surface of restoration according to manufacturer’s or dental laboratory 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.
• For light cured veneer cementation only: Apply a single coat of ProBOND® Adhesive to the internal bonding surface of the veneer. To assure minimal film thickness, follow the Simplified Dry Brush Technique outlined below. DO NOT LIGHT CURE. Protect treated veneer from exposure to ambient light while tooth preparation is being treated.

2.4 Tooth Conditioning/Dentin Pretreatment
When used as a bonding agent for veneer, inlay or onlay luting composite cements, it is recommended to follow the total etch technique. For full coverage crowns on vital teeth it is recommended not to etch dentin to minimize the possibility of post-operative sensitivity. Condition available enamel only (see complete Directions for Use, Caulk® 34% Tooth Conditioner Gel).

2.5 Application of ProBOND® All Purpose Bonding Agent
• If the preparation contains any exposed dentin, follow the steps for ProBOND® Primer application outlined in Section 1.4. Follow by application of ProBOND® Adhesive Simplified Dry Brush Technique, below.
• If the entire preparation is within enamel, following acid etching, rinsing and drying of enamel proceed directly to application of ProBOND® Adhesive, Simplified Dry Brush Technique, below.

Simplified Dry Brush Technique/ProBOND® Adhesive Application
• Using a clean natural or synthetic brush apply a thin layer of ProBOND® Adhesive over the entire surface of the preparation. Avoid over-saturating the brush with bonding agent.
• Thin the bonding agent on the preparation using with clean, dry air from a dental syringe for 10-15 seconds. Reapply compressed air to any areas of pooling of the bonding agent.
• Using a second clean unused synthetic or natural brush tip, remove excess adhesive on any areas prone to pooling, e.g., the gingival marginal areas, incisal areas and internal line angles. If necessary during this “dry brush” adhesive thinning procedure, remove any brush excess on a clean paper pad.

2.6 Light cured veneer cementation
Do not cure thinned adhesive applied to tooth preparation. Apply light cured esthetic resin cement of choice as per manufacturer’s instructions.

Dual or self cured restoration cementation
Light cure the Adhesive covered preparation for 10 seconds using a visible light curing unit. Apply dual or self cured resin-based cement of choice as per manufacturer’s instructions.

2.7 Seat restoration, remove excess, light cure, finish and polish as per cement manufacturer’s instructions.

3. Composite, ceramic and amalgam repairs
1. 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.

2. Tooth Conditioning/Dentin Pretreatment
Etch tooth (but not the surface of the microetched amalgam) (see complete Directions for Use, Caulk® 34% Tooth Conditioner Gel). Etch ceramic restoration repair area with hydrofluoric acid according to manufacturer’s instructions.

3. 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.
4. Application of ProBOND® All Purpose Bonding Agent
   Apply ProBOND® Primer and Adhesive as described for direct restorations, as outlined in sections 1.4 through 1.5.

5. Completion
   Complete repair with placement and curing of desired shade(s) of light cured composite restorative following manufacturer’s directions.

4. HYGIENE

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

Cleaning and disinfection
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.

Re-usable brush handle
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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