

Self-Cured Dental Universal Adhesive

PALFIQUE UNIVERSAL BOND

Palfique Universal Bond

English

Read all information, precautions and notes before using.

■PRODUCT DESCRIPTION AND GENERAL INFORMATION

1. PALFIQUE UNIVERSAL BOND is a two-component self-cured dental adhesive system for both direct and indirect restorations that can be used with Self-etch, Selective-enamel-etch and Total-etch techniques. As a universal adhesive, PALFIQUE UNIVERSAL BOND is designed to be fully compatible with light-cured, self-cured composite materials.

2. PALFIQUE UNIVERSAL BOND improves the bond strength of polymerizable resin material (adhesive resin cement, acrylic resin and composite resin) to indirect restorative materials such as glass-ceramics (porcelain), oxide-ceramics (zirconia and alumina), metals (precious and non-precious) and resin materials including inorganic filler.

3. PALFIQUE UNIVERSAL BOND contains Phosphoric acid monomer, Bisphenol A (di(2-hydroxy propyl) dimethacrylate (Bis-GMA), Triethylene glycol dimethacrylate (TEGDMA), 2-Hydroxyethyl methacrylate (HEMA), MTU-6 (thiouacil monomer), Silane coupling agent, Peroxide, Borate catalyst, Acetone, Isopropanol and Purified water.

INDICATIONS

- Direct anterior and posterior restorations with light-curing, dual-curing, and self-curing composite materials
- Intraoral repair of composite restorations, porcelain fused to metal, metal, and all-ceramic restorations without an additional primer
- Cementation of indirect restorations and veneers when combined with light-cure, dual-cure, and self-curing resin cements
- Bonding of core build-ups made of core build-up materials
- Bonding of denture resin to metal base, clasp or attachment
- Repair of denture with metal base, clasp or attachment
- Bonding of opaque resin to a metal base in the fabrication of resin-faced crowns

■CONTRAINDICATIONS

PALFIQUE UNIVERSAL BOND contains methacrylic monomers, organic solvents and acids. DO NOT use PALFIQUE UNIVERSAL BOND for patients allergic to or hypersensitive to methacrylic monomers, related monomers, organic solvents and acids.

■PRECAUTIONS

- DO NOT use PALFIQUE UNIVERSAL BOND for any purpose other than those listed in these instructions. Use PALFIQUE UNIVERSAL BOND only as directed herein.
- PALFIQUE UNIVERSAL BOND is designed for sale and use by licensed dental care professionals only. It is not designed for sale nor is it suitable for use by non-dental care professionals.
- DO NOT use PALFIQUE UNIVERSAL BOND if the safety seals are broken or appear to have been tampered with.
- IF PALFIQUE UNIVERSAL BOND causes an allergic reaction or oversensitivity, discontinue its use immediately.
- Use examination gloves (plastic, vinyl or latex) at all times when handling PALFIQUE UNIVERSAL BOND to avoid the possibility of allergic reactions caused by methacrylic monomers. Note: Certain substances/materials may penetrate through examination gloves. If PALFIQUE UNIVERSAL BOND comes in contact with the examination gloves, remove and dispose of the gloves, and wash hands thoroughly with water as soon as possible.
- Avoid contact of PALFIQUE UNIVERSAL BOND with eyes, mucosal membrane, skin and clothing.
 - If PALFIQUE UNIVERSAL BOND comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.
 - If PALFIQUE UNIVERSAL BOND comes in contact with the mucosal membrane, wipe the affected area immediately, and thoroughly flush with water after the completing the restoration. Affected areas may whiten from protein coagulation; however, whitening should disappear within 24 hours. If whitening does not disappear within 24 hours, immediately contact a physician, and the patient should be so advised.
 - If PALFIQUE UNIVERSAL BOND comes into contact with skin and clothing, immediately saturate the area with an alcohol-soaked cotton swab or gauze and flush with water.
- Instruct the patient to rinse his mouth immediately after treatment.
- DO NOT use PALFIQUE UNIVERSAL BOND directly to the cavity being in close proximity to the pulp. Pulp protection with glass ionomer lining or calcium hydroxide is recommended. DO NOT use EUGENOL BASED MATERIALS to protect the pulp as these materials will inhibit curing of PALFIQUE UNIVERSAL BOND.
- Be aware that when a restoration is chipped from misaligned occlusion or bruxism (clenching, grinding or tapping), the repaired restoration may chip again.
- DO NOT use mixing wells supplied by other manufacturers.
- Use the mixing well or disposable mixing well provided when dispensing and mixing of PALFIQUE UNIVERSAL BOND. If PALFIQUE UNIVERSAL BOND is not dispensed into the rubbery it may be difficult to remove the cured PALFIQUE UNIVERSAL BOND from mixing well. The cured PALFIQUE UNIVERSAL BOND can be removed by inverting the rubber.
- DO NOT mix PALFIQUE UNIVERSAL BOND with other brands of primers or adhesives.
- To avoid splashing the liquid, the bottle of PALFIQUE UNIVERSAL BOND should not be opened immediately after taking out of the refrigerator. PALFIQUE UNIVERSAL BOND should be brought to room temperature before using. After removing from the refrigerator, allow the product to sit for 20 minutes or until it reaches room temperature.

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■PRECAUTIONS FOR MEDICATIONS AND MATERIALS

- Some materials and medications (hemostatic material) inhibit setting/adhesion of PALFIQUE UNIVERSAL BOND.
- DO NOT USE products that contain:
 - eugenol,
 - aluminum chloride,
 - ferrie sulfate,
 - calcium sulfate,
 - aluminum sulfate,
 - diammine silver fluoride [molecular formula: Ag(NH₃)₂F]
- PALFIQUE UNIVERSAL BOND does not adhere to tooth structure immediately after application of materials that contain:
 - hydroxygenous rine and oil of the surface,
 - sodium hypochlorite.
- To avoid splashing the liquid, the bottle of PALFIQUE UNIVERSAL BOND should not be opened immediately after taking out of the refrigerator. PALFIQUE UNIVERSAL BOND should be brought to room temperature before using. After removing from the refrigerator, allow the product to sit for 20 minutes or until it reaches room temperature.

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■DISPOSAL

Unused PALFIQUE UNIVERSAL BOND is to be absorbed into an inert absorbent material such as gauze or cotton, and disposed of in accordance with local regulations.

■CLINICAL APPLICATION FOR DIRECT RESTORATIONS AND INTRAORAL REPAIR OF RESTORATIONS WITH COMPOSITE RESIN

1. Cleaning

Thoroughly clean the tooth surface with a rubber cup and a fluoride-free paste then rinse with water.

2. Isolaton

The rubber dam is the preferred method of isolation.

3. Cavity preparation

Prepare the cavity and rinse with water. Add levels to the enamel margins of anterior preparations (class III, IV, V), as well as chamfers to the margins of posterior preparations (class I, II) because bevles and chamfers assist in erasing demarcations between the cavity margins and the restoration, thereby enhancing both esthetics and retention.

- If the adherent surface involves uncut enamel, apply etching agent to the uncut enamel. See section "Selective-enamel-etch technique".

4. Drying

- Dry the cavity by using a blotting technique or an air syringe technique.
- DO NOT desicate the vital tooth. Desiccation can lead to post-operative sensitivity.
- The substances listed below, which inhibit curing of PALFIQUE UNIVERSAL BOND, should be removed from the tooth surface by thoroughly cleaning the tooth surface with alcohol, citric acid, or the application of phosphoric acid to 2 to 3 seconds before application:
 - Oil mist from handpiece,
 - Saliva, blood and exudates.

5. Etching of the tooth structure (optional)

Clinically adequate adhesive bonds are achieved by the application of the adhesive. Selectively etching the enamel or using the "total etching procedure" can achieve higher adhesive values.

(a). Selective-enamel-etch technique

Apply phosphoric acid gel only to the enamel surrounding the margin of prepared cavity and leave phosphoric acid gel in place for 10-15 seconds. Rinse the etched surface thoroughly (at least 15 seconds) with water, and then dry with mild air.

(b). Total etch technique

Apply phosphoric acid gel onto the prepared enamel first, and then the dentin. The etchant should be left to react on the enamel and dentin for 10-15 seconds. Rinse thoroughly (at least 15 seconds) with water and dry with mild air or with cotton pellets; do not overdry.

6. Preparing the adhesive surface during repair

- 6.1 Ceramics other than Porcelain, and Composite materials
Beverl the margin if necessary. Roughen the area using air abrasion or grinding with a diamond bur using a slow speed to prepare the surface for adhesion. Thoroughly rinse and dry the surface.
- 6.2 Metal restorations

Roughen the area using air abrasion or grinding with a diamond bur using a slow speed to prepare the surface for adhesion. Thoroughly rinse and dry the surface.

6.3 Porcelain

- Beverl the margin if necessary. DO NOT roughen the surface; Polish the area to prepare a clean and fresh surface for adhesion. Thoroughly rinse and dry the surface.
- When using air abrasion, use at least 30 to 50 micron grid of alumina powder.
- The substances listed below inhibit adhesion and must be removed from the adhesive surface by mechanical cleaning or alcohol soaking.
 - Oil mist from handpiece
 - Plaque, tartar, saliva, blood and exudate fluids
- If necessary, protect the surface not being bonded with metal separator, paraffin film, Vaseline, etc.

7. Dispensing of PALFIQUE UNIVERSAL BOND

Allow PALFIQUE UNIVERSAL BOND to reach room temperature prior to use. Open the bottle by removing the cap and dispense one drop each of PALFIQUE UNIVERSAL BOND A and B into the mixing well or disposable mixing well. Mix thoroughly with a disposable applicator.

- Complete the application within 1 minute of dispensing when using the mixing well since PALFIQUE UNIVERSAL BOND contains volatile solvents. After mixing, the color of PALFIQUE UNIVERSAL BOND changes gradually based on the reaction of the catalyst of PALFIQUE UNIVERSAL BOND, this is normal and does not indicate a problem with PALFIQUE UNIVERSAL BOND.
- Complete the application within 3 minutes of dispensing when using disposable mixing well.
- Be sure to hold the bottles of PALFIQUE UNIVERSAL BOND A and B vertically when dispensing. DO not hold the bottles diagonally or horizontally while dispensing; this could cause the PALFIQUE UNIVERSAL BOND flow back into the nozzle and become contaminated.
- Wipe off excess PALFIQUE UNIVERSAL BOND from the tip of the nozzle prior to closing.
- Immediately after dispensing, tightly replace the bottle caps of PALFIQUE UNIVERSAL BOND A and B.

8. Application of PALFIQUE UNIVERSAL BOND

- Using the disposable applicator, apply PALFIQUE UNIVERSAL BOND to the entire adherent surface(s). Take care not to omit any surfaces where PALFIQUE UNIVERSAL BOND should be applied.
- In the case of intraoral repair of restorations, if the adherent surface includes tooth structure and restorations (ceramics, porcelain, metals or composite materials), apply PALFIQUE UNIVERSAL BOND to the entire adherent surface at once. No extra primers are needed.
- If PALFIQUE UNIVERSAL BOND pools on the cavity floor or a cavosurface angle and is too thick to air thin, remove the excess with a paper point or a new disposable applicator.
- Be careful not to allow excess PALFIQUE UNIVERSAL BOND to flow into the subgingival, thoroughly rinse and dry the area.
- If saliva, blood, or other fluids contaminate the applied PALFIQUE UNIVERSAL BOND, thoroughly rinse the cavity with water, dry and re-apply PALFIQUE UNIVERSAL BOND.
- DO NOT rinse the applied PALFIQUE UNIVERSAL BOND with water except in unintentional contamination.
- DO NOT wait too long after the application of PALFIQUE UNIVERSAL BOND. Air dry within 30 seconds after application, to ensure the appropriate film thickness.

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- 2. **Dispensing of PALFIQUE UNIVERSAL BOND**
Allow PALFIQUE UNIVERSAL BOND to reach room temperature prior to use. Open the bottle by removing the cap and dispense one drop each of PALFIQUE UNIVERSAL BOND A and B into the mixing well or disposable mixing well. Mix thoroughly with a disposable applicator.
- Complete the application within 1 minute of dispensing when using the mixing well since PALFIQUE UNIVERSAL BOND contains volatile solvents. After mixing, the color of PALFIQUE UNIVERSAL BOND changes gradually based on the reaction of the catalyst of PALFIQUE UNIVERSAL BOND, this is normal and does not indicate a problem with PALFIQUE UNIVERSAL BOND.
- Complete the application within 3 minutes of dispensing when using the disposable mixing well.
- Be sure to hold the bottles of PALFIQUE UNIVERSAL BOND A and B vertically when dispensing. DO not hold the bottle diagonally or horizontally while dispensing; this could cause PALFIQUE UNIVERSAL BOND flow back into the nozzle and become contaminated.
- Wipe off excess PALFIQUE UNIVERSAL BOND from the tip of the nozzle prior to closing.
- Immediately after dispensing, tightly replace the bottle caps of PALFIQUE UNIVERSAL BOND A and B.

- 3. **Application of PALFIQUE UNIVERSAL BOND**
Using the disposable applicator, apply the mixed PALFIQUE UNIVERSAL BOND on the surface to be bonded.
- Ensure PALFIQUE UNIVERSAL BOND covers all surfaces where the cement will be applied.
- DO NOT over apply. One application of PALFIQUE UNIVERSAL BOND is sufficient. Too thick of a layer may compromise the fit of the restoration.
- DO NOT allow saliva, blood, oil, water etc. to come in contact with the surface to be bonded. If the treated surface is contaminated, thoroughly rinse with water, dry and re-apply fresh PALFIQUE UNIVERSAL BOND.
- DO NOT wait too long after the application of PALFIQUE UNIVERSAL BOND. Air dry within 30 seconds after application, to ensure the appropriate film thickness.

- 4. **Air dry**
Using an oil-free air/water syringe, apply mild air to the surface. Use a vacuum aspirator to prevent spatter of PALFIQUE UNIVERSAL BOND
- Be sure to dry the surface after PALFIQUE UNIVERSAL BOND is applied.

- 5. **Cementing**
Cement with a composite resin cement according to its manufacturer's instructions.

- 6. **Preparation of the adhesive surface during repair**
 - 6.1 Ceramics other than Porcelain, and Composite materials
Beverl the margin if necessary. Roughen the area using air abrasion or grinding with a diamond bur using a slow speed to prepare the surface for adhesion. Thoroughly rinse and dry the surface.
 - 6.2 Metal restorations
- Roughen the area using air abrasion or grinding with a diamond bur using a slow speed to prepare the surface for adhesion. Thoroughly rinse and dry the surface.
- 6.3 Porcelain
 - Beverl the margin if necessary. DO NOT roughen the surface; Polish the area to prepare a clean and fresh surface for adhesion. Thoroughly rinse and dry the surface.
 - When using air abrasion, use at least 30 to 50 micron grid of alumina powder.
 - The substances listed below inhibit adhesion and must be removed from the adhesive surface by mechanical cleaning or alcohol soaking.
 - Oil mist from handpiece
 - Plaque, tartar, saliva, blood and exudate fluids
 - If necessary, protect the surface not being bonded with metal separator, paraffin film, Vaseline, etc.

- 7. **Dispensing of PALFIQUE UNIVERSAL BOND**
Allow PALFIQUE UNIVERSAL BOND to reach room temperature prior to use. Open the bottle by removing the cap and dispense one drop each of PALFIQUE UNIVERSAL BOND A and B into the mixing well or disposable mixing well. Mix thoroughly with a disposable applicator.
- Complete the application within 1 minute of dispensing when using the mixing well since PALFIQUE UNIVERSAL BOND contains volatile solvents. After mixing, the color of PALFIQUE UNIVERSAL BOND changes gradually based on the reaction of the catalyst of PALFIQUE UNIVERSAL BOND, this is normal and does not indicate a problem with PALFIQUE UNIVERSAL BOND.
- Complete the application within 3 minutes of dispensing when using disposable mixing well.
- Be sure to hold the bottles of PALFIQUE UNIVERSAL BOND A and B vertically when dispensing. DO not hold the bottles diagonally or horizontally while dispensing; this could cause the PALFIQUE UNIVERSAL BOND flow back into the nozzle and become contaminated.
- Wipe off excess PALFIQUE UNIVERSAL BOND from the tip of the nozzle prior to closing.
- Immediately after dispensing, tightly replace the bottle caps of PALFIQUE UNIVERSAL BOND A and B.

- 8. **Application of PALFIQUE UNIVERSAL BOND**
Using the disposable applicator, apply PALFIQUE UNIVERSAL BOND to the entire adherent surface(s). Take care not to omit any surfaces where PALFIQUE UNIVERSAL BOND should be applied.
- In the case of intraoral repair of restorations, if the adherent surface includes tooth structure and restorations (ceramics, porcelain, metals or composite materials), apply PALFIQUE UNIVERSAL BOND to the entire adherent surface at once. No extra primers are needed.
- If PALFIQUE UNIVERSAL BOND pools on the cavity floor or a cavosurface angle and is too thick to air thin, remove the excess with a paper point or a new disposable applicator.
- Be careful not to allow excess PALFIQUE UNIVERSAL BOND to flow into the subgingival, thoroughly rinse and dry the area.
- If saliva, blood, or other fluids contaminate the applied PALFIQUE UNIVERSAL BOND, thoroughly rinse the cavity with water, dry and re-apply PALFIQUE UNIVERSAL BOND.
- DO NOT rinse the applied PALFIQUE UNIVERSAL BOND with water except in unintentional contamination.
- DO NOT wait too long after the application of PALFIQUE UNIVERSAL BOND. Air dry within 30 seconds after application, to ensure the appropriate film thickness.

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