

ENGLISH • • • • •
Read all information, precautions and notes before using.**■ PRODUCT DESCRIPTION AND GENERAL INFORMATION**

1. PALFIQUE BOND is a one-component, one-coat application, self-etching, light-cured, dental adhesive system with excellent handling and adhesive properties and exceptional marginal integrity toward cut/uncut enamel and dentin when used in combination with light- or dual-cured composite materials.
 2. A light-curing unit having the camphorquinone (CQ) wavelength range (peak: 470nm, spectrum: 400 to 500nm) can be used for curing PALFIQUE BOND.
 3. PALFIQUE BOND contains Phosphoric acid monomer, Bisphenol A di(2-hydroxy propoxyl) dimethylacrylate (Bis-GMA), Triethylene glycol dimethacrylate, 2-Hydroxyethyl methacrylate (HEMA), Camphorquinone, alcohol and purified water. The pH level immediately after dispensing is approximately 2.8.
 4. PALFIQUE BOND is dispensed in a Bottle.

■ INDICATIONS

Bonding of light- or dual-cured composite material to:

- cut/uncut enamel.
- cut/uncut dentin.
- fractured porcelain/composite repair.

■ CONTRAINDICATIONS

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

■ PRECAUTIONS

- 1) DO NOT use PALFIQUE BOND for any purpose other than those listed in these instructions. Use PALFIQUE BOND only as directed herein.
- 2) PALFIQUE 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.
- 3) DO NOT use PALFIQUE BOND if the safety seals are broken or appear to have been tampered with.
- 4) If PALFIQUE BOND causes an allergic reaction or oversensitivity, discontinue its use immediately.
- 5) Use examination gloves (plastic, vinyl or latex) at all times when handling PALFIQUE BOND to avoid the possibility of allergic reactions from methacrylic monomers. Note: Certain substances/materials may penetrate through examination gloves. If PALFIQUE BOND comes in contact with the examination gloves, remove and dispose of the gloves, and wash hands thoroughly with water as soon as possible.
- 6) Avoid contact of PALFIQUE BOND with eyes, mucosal membrane, skin and clothing.
- If PALFIQUE BOND comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.
- If PALFIQUE BOND comes in contact with the mucosal membrane, wipe the affected area immediately, and thoroughly flush with water after the restoration is completed. Affected areas may whiten from protein coagulation, but such whitening should disappear within 24 hours. If such whitening does not disappear within 24 hours, immediately contact a physician, and the patient should be so advised.
- If PALFIQUE BOND comes into contact with the skin or clothing, immediately saturate the area with alcohol-soaked cotton swab or gauze.
- Instruct the patient to rinse his mouth immediately after treatment.
- 7) PALFIQUE BOND should not be ingested or aspirated. Ingestion or aspiration may cause serious injury.
- 8) To avoid the unintentional ingestion of PALFIQUE BOND, do not leave it unsupervised within the reach of patients and children.
- 9) DO NOT expose PALFIQUE BOND or the vapor to open flame because PALFIQUE BOND is flammable.
- 10) To avoid cross infection or lowering bond strength, DO NOT reuse the disposable applicator. Clean the dispensing well thoroughly with alcohol after each use.
- 11) DO NOT use PALFIQUE BOND directly to the cavity being in close proximity to the pulp. Pulp protection with glass ionomer lining or calcium hydroxide is recommended.
- 12) When using a light-curing unit, protective eye shields, glasses or goggles should be worn at all times.
- 13) Be aware that when a restoration is chipped from misaligned occlusion or bruxism (clenching, grinding or tapping), the repaired restoration may chip again.
- 14) DO NOT mix PALFIQUE BOND with other brands of primers or adhesives.
- 15) PALFIQUE BOND should be brought to room temperature before using if it is stored under refrigeration.

■ PRECAUCIONES PARA MEDICAMENTOS Y MATERIALES

- 1) Some materials and medicaments (hemostatic material) inhibit the adhesion of PALFIQUE BOND for an extended period even after careful meticulous cleansing with water. DO NOT USE products which contain:
 - eugenol,
 - diammin silver fluoride [molecular formula: Ag(NH₃)₂F],
 - phenols such as paraclorophenol, guaiacol, phenol,
 - aluminum chloride,
 - ferric sulfate,
 - aluminum sulfate,
 - epinephrine.
- 2) PALFIQUE BOND does not adhere to tooth structure immediately after applications of materials which contain:
 - hydrogen peroxide (oxydol),
 - sodium hypochlorite

We advise avoiding the use of these materials on the day of cementation, however these materials can be used for root canal treatment as the inhibition caused by these materials usually evaporates within five days.

■ STORAGE

- 1) Store PALFIQUE BOND at a temperature between 0 to 25°C (32 to 77°F). Storage under inappropriate condition will accelerate the degradation of PALFIQUE BOND.
- 2) If not in use for a prolonged period of time, store in a cool dark place.
- 3) Keep away from heat, direct sunlight, sparks and open flames.
- 4) DO NOT use after the indicated expiration date on the bottle/package.

■ DISPOSAL

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

■ CLINICAL PROCEDURES

1. **Cleaning**
Thoroughly clean the tooth surface with a rubber cup and a fluoride-free paste then rinse with water.
2. **Isolation**
The rubber dam is the preferred method of isolation.
3. **Cavity preparation**
Prepare the cavity and rinse with water. Add bevels to the enamel margins of anterior preparations (class III, IV, V), as well as chamfers to the margins of posterior preparations (class I, II). Bevels and chamfers assist in erasing demarcations between the cavity margins and the restoration, enhancing both esthetics and retention.
 - If there is an adherent surface including uncut enamel, apply etching agent to the uncut enamel.
 - In case of porcelain/composite repairs, roughen the surface with a bur or a diamond

point to prepare the area for adhesion; apply phosphoric acid for cleaning; rinse thoroughly with water; air dry thoroughly and treat with a silane coupling reagent according to its manufacturer's instructions.

4. Drying

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

5. Pulp Protection

Glass ionomer lining or calcium hydroxide should be applied if the cavity is in close proximity to the pulp. DO NOT USE EUGENOL BASED MATERIALS to protect the pulp as these materials will inhibit the curing of PALFIQUE BOND.

6. Dispensing

Open the Bottle by removing the cap and dispense one or two drops of adhesive into the dispensing well. Immediately after dispensing, tightly replace the Bottle cap.
 - Be sure to hold the Bottle of PALFIQUE BOND vertically when dispensing. Do not hold the Bottle diagonally or horizontally while dispensing; this could cause the adhesive to flow back into the nozzle and become contaminated.
 - Wipe off excess adhesive from the tip of the nozzle prior to closing.

7. Application

Using the disposable applicator, apply PALFIQUE BOND on the surface to be bonded and wait 10 seconds or more:
 - Ensure PALFIQUE BOND covers all surfaces where the composite resin will be applied.
 - Protect the dispensed adhesive and the inserted applicator from ambient light before the application using a light blocking plate.
 - Complete the application within 5 minutes after dispensing because PALFIQUE BOND contains a volatile alcohol.
 - Be careful not to allow excess PALFIQUE BOND to flow into the subgingival. If PALFIQUE BOND flows into the subgingival, thoroughly rinses and dry the area.
 - If the adherent surface include ceramics, porcelain or composite, prepare the surface according to the appropriate procedures prior to the application of PALFIQUE BOND.

8. Air Dry

Using an oil-free air/water syringe, apply mild air continuously to the PALFIQUE BOND surface until the runny PALFIQUE BOND stays in the same position without any movement (usually for 5 seconds). Use a vacuum aspirator to prevent spatter of the adhesive.

- If accidental spattering occurs, it may cause the tissue to whiten or possible allergic reaction.

- If the adhesive pools on the cavity floor or the cavosurface angle and is too thick to air thin, blot the excess with a new disposable applicator before mild air application.

- If saliva, blood, or other fluids contaminate the applied adhesive, thoroughly rinse the cavity with water, dry and re-apply new adhesive.

- Do not rinse the applied adhesive with water except in unintentional contamination.

9. Light-cure

Light-cure the surface for 10 seconds or more, keeping the curing light tip within a distance of 2 mm from the surface. If the cavity is too large or the light tip is too distant (e.g. MOD), divide the area into segments and light-cure each segment individually.

- Confirm that the light-curing unit has sufficient intensity (>300mW/cm²) before using. Note that using a cracked light guide will lower the intensity.

10. Light-cured Composite

Restore with light-cured composite resin according to its manufacturer's instructions. The composite resin must be finished and polished.

- When dual-cured composite resins are placed into a cavity, the first increment must be light-cured using a layering technique.
 - Do not use self-cured composite resins here because the Phosphoric acid monomer contained in PALFIQUE BOND may interfere with the curing of the self-cured resins, leading to their premature detachment.

IMPORTANT NOTE: The manufacturer is not responsible for damage or injury caused by improper use of this product. It is the personal responsibility of the dental professional to ensure the product is suitable for application before use.

11) DO NOT use PALFIQUE BOND directly to the cavity being in close proximity to the pulp. Pulp protection with glass ionomer lining or calcium hydroxide is recommended.

12) When using a light-curing unit, protective eye shields, glasses or goggles should be worn at all times.

13) Be aware that when a restoration is chipped from misaligned occlusion or bruxism (clenching, grinding or tapping), the repaired restoration may chip again.

14) DO NOT mix PALFIQUE BOND with other brands of primers or adhesives.

15) PALFIQUE BOND should be brought to room temperature before using if it is stored under refrigeration.

■ PRECAUCIONES PARA MEDICAMENTOS Y MATERIALES

- 1) Some materials and medicaments (hemostatic material) inhibit the adhesion of PALFIQUE BOND for an extended period even after careful meticulous cleansing with water. DO NOT USE products which contain:
 - eugenol,
 - diammin silver fluoride [molecular formula: Ag(NH₃)₂F],
 - phenols such as paraclorophenol, guaiacol, phenol,
 - aluminum chloride,
 - ferric sulfate,
 - aluminum sulfate,
 - epinephrine.

■ DESCRIPCIÓN DEL PRODUCTO E INFORMACIÓN GENERAL

1. PALFIQUE BOND es un adhesivo dental monocomponente, de una sola aplicación, autograbante, fotopolimerizable con un excelente manejo y propiedades adhesivas y una excepcional integridad marginal hacia el esmalte (biselado/no biselado) y en dentina cuando se usa en combinación con materiales de composite fotopolimerizables o duales.

2. Para la polimerización de PALFIQUE BOND puede emplearse una lámpara de polimerización con el intervalo de longitudes de onda propio de la camphorquinona (pico: 470 nm, espectro: 400 a 500 nm).

3. PALFIQUE BOND contiene monómeros de ácido fosfórico, di(2-hidroxí propoxi) dimetacrilato de bisfenol A (Bis-GMA), triétileno-glicol dimetacrilato, HEMA (2-hidroxíetil metacrilato) (HEMA), camphorquinona, alcohol y agua purificada. El pH inmediatamente después del dispensado es de aproximadamente 2.8.

4. PALFIQUE BOND se presenta en un frasco (Bottle).

■ INDICACIONES

Adhesión de composite fotopolimerizable o de polimerización dual a:

- esmalte tallado o sin tallar
- dentina tallada o sin tallar
- Reparaciones de fracturas de porcelanas/composites.

■ CONTRAINDICACIONES

PALFIQUE BOND contiene monómeros metacrílicos, disolventes orgánicos y ácidos.

NO utilice PALFIQUE BOND en pacientes alérgicos o hipersensibles a los monómeros metacrílicos, monómeros relacionados, disolventes orgánicos o ácidos.

■ PRECAUCIONES

- 1) NO utilice PALFIQUE BOND para ninguna finalidad distinta de las que figuran en estas instrucciones. Utilice PALFIQUE BOND únicamente del modo aquí indicado.

2) PALFIQUE BOND está previsto para su venta y utilización exclusivas por profesionales odontológicos debidamente autorizados. No está prevista su venta ni reseda a su uso por personas que no sean profesionales de la odontología.

3) NO utilice PALFIQUE BOND si los precintos de seguridad están rotos o parecen haber sido manipulados.

4) SI PALFIQUE BOND provoca una reacción alérgica o de hipersensibilidad, suspenda inmediatamente su uso.

5) Emplee en todo momento guantes de exploración (de plástico, vinilo o látex) al manipular PALFIQUE BOND a fin de evitar la posibilidad de reacciones alérgicas a los monómeros acrílicos. Nota: determinadas sustancias o materiales pueden atravesar los guantes de exploración. Si PALFIQUE BOND entra en contacto con la zona a fondo.

- Si la superficie adherente incluye cerámica, porcelana o composite, prepare la superficie de acuerdo con los procedimientos pertinentes antes de utilizar PALFIQUE BOND.

6) Evite el contacto de PALFIQUE BOND con los ojos, las mucosas, la piel o la ropa.

- En caso de que PALFIQUE BOND entre en contacto con los ojos, lávelo abundantemente con agua y consulte inmediatamente a un oftalmólogo.

- En caso de que PALFIQUE BOND entre en contacto con mucosas o tejidos blandos, límpie inmediatamente el área afectada y lávelo abundantemente con agua una vez finalizada la restauración. Las zonas afectadas pueden adoptar un color blanquecino por la coagulación de las proteínas, pero dicho color debería

desaparecer en un plazo de 24 horas. Si no es así, debe ponerse en contacto inmediatamente con un médico. También debe advertirse al paciente en ese sentido.

- En caso de que PALFIQUE BOND entre en contacto con la piel o la ropa, sature inmediatamente la zona con un algodón o una gasa empapados en alcohol.
- De instrucciones al paciente para que se enjuague inmediatamente después del tratamiento.

7) PALFIQUE BOND no debe ingerir ni inhalar. Su ingestión o inhalación pueden provocar lesiones graves.

- 8) Para evitar la ingestión accidental de PALFIQUE BOND, no debe dejarse sin supervisión al alcance de pacientes o niños.
- 9) NO exponga PALFIQUE BOND ni sus vapores a una llama, ya que PALFIQUE BOND es inflamable.

10) Para evitar infecciones cruzadas o una disminución de las fuerzas adhesivas NO reutilice el aplicador desecharable. Limpie el recipiente de dispensación inmediatamente con alcohol.

11) NO utilice PALFIQUE BOND directamente sobre una cavidad que esté muy próxima a la pulpa. Se recomienda el uso de una base cavitaria a base de ionómero de vidrio o de hidróxido de calcio.

12) Cuando utilice una lámpara de polimerización deberá emplear en todo momento protectores oculares, gafas de seguridad o similares.

13) Tenga en cuenta que si una restauración se ha fracturado por maloclusión o bruxismo (rechinar, apretar o golpear los dientes), la restauración reparada puede fracturarse de nuevo.

14) NO mezcle PALFIQUE BOND con acondicionadores o adhesivos de otras marcas.

15) PALFIQUE BOND debe alcanzar la temperatura ambiente antes de su uso si se conserva bajo refrigeración.

El fabricante de PALFIQUE BOND no se hace responsable de los daños materiales o lesiones provocados por el uso inadecuado de este producto. Es responsabilidad del usuario asegurarse de que el producto es adecuado para una aplicación determinada antes de su empleo.

Las especificaciones del producto de PALFIQUE BOND están sujetas a modificación previo aviso. Cuando se produzcan modificaciones en las especificaciones del producto, es posible que las instrucciones e indicaciones de precaución también se modifiquen.

■ PRECAUCIONES RELATIVAS A MEDICAMENTOS Y MATERIALES

- 1) Ciertos materiales y medicamentos (hemostáticos) inhiben la adhesión de PALFIQUE BOND durante un período prolongado incluso después de una limpieza meticulosa con agua. NO UTILICE productos que contengan:

- eugenol
- fluoruro diaminio de plata [fórmula molecular: Ag(NH₃)₂F]
- fenoles, como p.ej. paraclorofenol, guaiacol, fenol
- cloruro de aluminio
- sulfato férreo
- sulfato de aluminio
- epinefrina

2) PALFIQUE BOND no se adhiere a las estructuras dentarias inmediatamente tras la aplicación de materiales que contienen:

- peróxido de hidrógeno
- hipoclorito sódico

Se recomienda no

