

Self-Cured Dental Universal Adhesive

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-etch-and-etch Total-etch techniques. As a universal adhesive, PALFIQUE UNIVERSAL BOND has been designed to be fully compatible with light-cured, self-cured and dual-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 propoxy) dimethacrylate (Bis-GMA), Triethylene glycol dimethacrylate (TEGDMA), 2-Hydroxyethyl methacrylate (HEMA), MTU-6 (monómtero tioarilico), 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

1) DO NOT use PALFIQUE UNIVERSAL BOND for any purpose other than those listed in these instructions. Use PALFIQUE UNIVERSAL BOND only as directed herein.

2) 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.

3) DO NOT use PALFIQUE UNIVERSAL BOND if the safety seals are broken or appear to have been tampered with.

4) If PALFIQUE UNIVERSAL BOND causes an allergic reaction or oversensitivity, discontinue its use immediately.

5) Use examination gloves (plastic, vinyl) or latexes) at all times when handling PALFIQUE UNIVERSAL BOND to avoid the possibility of allergic reactions from methacrylic monomers. Note: Certain substances/materials may penetrate through examination gloves. If PALFIQUE UNIVERSAL BOND come 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 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 the skin or 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.

7) PALFIQUE UNIVERSAL BOND should not be ingested or aspirated. Ingestion or aspiration may cause serious injury.

8) To avoid the unintentional ingestion of PALFIQUE UNIVERSAL BOND, do not leave it unsupervised within the reach of patients and children.

9) DO NOT expose PALFIQUE UNIVERSAL BOND or its vapor to open flame because PALFIQUE UNIVERSAL BOND is flammable.

10) To avoid cross infection or lowering bond strength, DO NOT reuse the disposable applicator and disposable mixing well. Clean the mixing well thoroughly with alcohol after each use.

11) 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.

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

13) DO NOT use mixing wells supplied by other manufacturers.

14) 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 rubber 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.

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

16) 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 must 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.

■PRECAUTIONS FOR MEDICATIONS AND MATERIALS

1) Some materials and medicaments (hemostatic material) inhibit setting/adhesion of PALFIQUE UNIVERSAL BOND.

DO NOT USE products that contain:

- eugenol,

- aluminum chloride,

- ferric sulfate,

- calcium sulfate,

- aluminum sulfate,

- diamine silver fluoride [molecular formula: Ag(NH₃)₂F]

2) PALFIQUE UNIVERSAL BOND does not adhere to tooth structure immediately after applications of materials that 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.

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

1. Restoring with a light-cured, self-cured or dual-cured composite resin according to its manufacturer's instructions. The overfilled composite resin should be thoroughly finished and polished.

■CLINICAL APPLICATION FOR CEMENTATION OF INDIRECT RESTORATIONS

1. Preparing the adhesive surface of the restoration

1.1 Ceramics other than Porcelain, and Composite materials

Roughen the interior of the restoration by sandblasting (0.1 to 0.2 MPa), air abrasion or grinding with a diamond bur using a slow speed to prepare the surface for adhesion.

Thoroughly rinse and dry the surface.

1.2 Metal restorations

Roughen the area by sandblasting (0.3 to 0.5 MPa), air abrasion or grinding with a diamond bur using a slow speed to prepare the surface for adhesion. Thoroughly rinse and dry the surface.

1.3 Porcelain

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 the sandblaster or air abrasion, use at least 30 to 50 micron grid of alumina powder.

- If unable to roughen or polish the adhesive surface, etch the area for adhesion with phosphoric acid then thoroughly rinse and dry.

- The substances listed below inhibit adhesion and must be removed from the adhesive surface by mechanical cleaning or alcohol soaking. Clean the restoration after adjustment is complete.

1) Gypsum and investment

2) Silicone oil from fit check material

3) Oil mist from headpiece

4) Plaque, tartar, saliva, blood and exudate fluids

5) Temporary restoration and temporary cement

If necessary, protect the surface not being bonded with metal separator, paraffin film, Vaseline, etc.

1. Cleaning

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

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.

- Wipe off excess PALFIQUE UNIVERSAL BOND from the tip of the nozzle 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.

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- 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.

■CLINICAL APPLICATION FOR BONDING OF ACRYLIC RESIN TO METAL BASE, CLASP OR ATTACHMENT

1. Preparing the adhesive surface

Roughen the area by sandblasting (0.1 to 0.2 MPa), or by grinding with a diamond bur using a slow speed to prepare the surface for adhesion. Thoroughly rinse and dry the surface.

- The substances listed below inhibit adhesion and must be removed from the adhesive surface by mechanical cleaning or alcohol soaking.

1) Oil mist from headpiece

2) 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.

- 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), use 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. If PALFIQUE UNIVERSAL BOND flows 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.

9. Air Dry

Using an oil-free air/water syringe, apply weak air continuously to PALFIQUE UNIVERSAL BOND surface until the PALFIQUE UNIVERSAL BOND stays in the same position without any movement. Finish by using mild air to the surface. Use a vacuum aspirator to prevent spatter of PALFIQUE UNIVERSAL BOND.

- If saliva, blood, or other fluids contaminate the applied PALFIQUE UNIVERSAL BOND, thoroughly rinse with water, dry and re-apply fresh PALFIQUE UNIVERSAL BOND.

- Do not rinse the applied PALFIQUE UNIVERSAL BOND with water except in unintentional contamination.

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

10. Composite resin

Restoring with a light-cured, self-cured or dual-cured composite resin according to its manufacturer's instructions. The overfilled composite resin should be thoroughly finished and polished.

■CLINICAL APPLICATION FOR CEMENTATION OF INDIRECT RESTORATIONS

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encuentre may cerca de la pulpa. Se recomienda proteger la pulpa con revestimiento de ionómero de vidrio o hidróxido de calcio. NO use MATERIALES A BASE DE EUGENOL para proteger la pulpa, ya que estos inhiben la polimerización de PALFIQUE UNIVERSAL BOND.

12) Tenga precaución que cuando una restauración se asilla por oclusión desalineada o bruxismo (apretar, rechinar o repiquetear los dientes), la restauración reparada podría volver a astillarse.

13) NO use pocillos de mezcla suministrados por otros fabricantes.

14) Use el pocillo de mezcla o el pocillo de mezcla desechable suministrado cuando dispensa o mezcla PALFIQUE UNIVERSAL BOND. Si PALFIQUE UNIVERSAL BOND no se dispensa en el mezclador de goma, podría ser difícil retirar del pocillo de mezcla cuando esté polimerizado. PALFIQUE UNIVERSAL BOND se puede retirar invirtiendo la goma.

15) No mezcle PALFIQUE UNIVERSAL BOND con acondicionadores o adhesivos de otras marcas.

16) Para evitar salpicaduras de líquido, la botella de PALFIQUE UNIVERSAL BOND no se debe abrir inmediatamente después de sacarla del refrigerador. PALFIQUE UNIVERSAL BOND debe alcanzar la temperatura ambiente antes del uso. Después de sacar el producto del refrigerador, deje que se asiente durante 20 minutos o hasta que alcance la temperatura ambiente.

■PRECAUCIONES CON MEDICAMENTOS Y MATERIALES

1) Algunos materiales y medicamentos (material hemostático) inhiben el endurecimiento/adhesión de PALFIQUE UNIVERSAL BOND.

NO USE productos que contengan:

- eugenol,

- cloruro de aluminio,

- sulfato de hierro,

- sulfato de calcio,

- sulfato de aluminio,

- fluoruro diamino de plata [fórmula molecular: Ag(NH₃)₂F]

2) PALFIQUE UNIVERSAL BOND no se adhiere inmediatamente a la estructura del diente tras la aplicación de materiales que contienen:

- peróxido de hidrógeno (oxidol),

- hipoclorito de sodio

Recomendamos evitar el uso de estos materiales el día de la cementación, sin embargo, estos se pueden utilizar para el tratamiento del conducto radicular, ya que la inhibición que causan normalmente se evapora en un periodo de cinco días.

■CONSERVACIÓN

1) Conserve refrigerado a temperaturas entre 0 y 10 °C (32 y 50 °F).

2) Manténgase alejado del calor, la luz solar directa, las chispas y las llamas.

3) NO debe utilizarse después de la fecha de caducidad indicada en el frasco o envase exterior.

■ELIMINACIÓN DE RESIDUOS

El producto PALFIQUE UNIVERSAL BOND no utilizado debe absorberse con un material absorbente inerte como gasa o desecharse de acuerdo con la normativa local.

■APLICACIÓN CLÍNICA PARA RESTAURACIONES DIRECTAS Y REPARACIÓN INTRAORAL DE RESTAURACIONES CON RESINA DE COMPOSITE

1. Limpieza

Limpie a fondo la superficie del diente con una copa de goma y una pasta sin fluoruros, y a continuación enjuague con agua.

2. Aislamiento

El diseño de goma es el método de aislamiento preferible.

3. Preparación de la cavidad

Prepare la cavita y enjuáguela con agua. Añada bisles a los márgenes de esmalte de las preparaciones anteriores (clase III, IV, V), así como chafalanes a los márgenes de las preparaciones posteriores (clase I), porque los bisles y los chafalanes ayudan a borrar las demarcaciones entre los márgenes de la cavita y la restauración, mejorando así la superficie adherente inclusive esmalte sin cortar, aplique agente de grabado al esmalte sin cortar. Consulte la sección "Técnica de grabado selectivo del esmalte".

4. Secado

Seque la cavidad con una torunda o una jeringa de aire.

- NO desecue el diente vital. La desecación puede provocar sensibilidad postoperatoria.

- Las sustancias que se listan a continuación, las cuales inhiben la polimerización de PALFIQUE UNIVERSAL BOND, se deben eliminar de la superficie del diente limpiando esta última minuciosamente con alcohol o ácido cítrico, o aplicando ácido fosfórico durante 2 o

