

Resin-based Dental Restorative Material
PALFIQUE
OMNICHROMA Flow

ENGLISH

Carefully read all information, precautions, notes and materials before using.

PRODUCT DESCRIPTION AND GENERAL INFORMATION

1) PALFIQUE OMNICHROMA FLOW is a low viscosity, light-cured, radiopaque composite resin for use in anterior and posterior restorations and is indicated for all carious classes. PALFIQUE OMNICHROMA FLOW is a single shade material. Direct placement of PALFIQUE OMNICHROMA FLOW into a prepared cavity allows for easy handling.

2) PALFIQUE OMNICHROMA FLOW contains 71% by weight (57% by volume) of spherical silica-zirconia filler (mean particle size: 0.3µm, particle size range: 0.2 to 0.4µm) and composite filler. PALFIQUE OMNICHROMA FLOW contains 1,6-bis(methylacryl-ethoxybenzylaminoo)trimethyl hexane (UDMA), 1,9-nonamethylene glycol dimethacrylate, Mequinol, Dimethyl hydroxyl tolune and UV absorber.

3) PALFIQUE OMNICHROMA FLOW is available in SYRINGE.

INDICATIONS

- Direct anterior and posterior restorations
- Cavity base or liner
- Repair of porcelain/composite

CONTRAINDICATIONS

PALFIQUE OMNICHROMA FLOW contains methacrylic monomers and UV absorber. DO NOT use PALFIQUE OMNICHROMA FLOW for patients allergic to or hypersensitive to methacrylic and related monomers, UV absorber or any of the other ingredients.

PRECAUTIONS

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

2) PALFIQUE OMNICHROMA FLOW is designed for sale and use by licensed dental care professionals only. It is not designed for sale nor use by non-dental care professionals.

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

4) If PALFIQUE OMNICHROMA FLOW causes an allergic reaction or hypersensitivity, discontinue its use immediately.

5) Use examination gloves (plastic, vinyl or latex) at all times when handling PALFIQUE OMNICHROMA FLOW to avoid the possibility of allergic reaction from methacrylic monomers or UV absorber.

Note: Certain substances/materials may penetrate through examination gloves. If PALFIQUE OMNICHROMA FLOW 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 OMNICHROMA FLOW with eyes, mucosal membrane, skin and clothing.

- If PALFIQUE OMNICHROMA FLOW comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.

- If PALFIQUE OMNICHROMA FLOW comes in contact with the mucosal membrane, wipe the affected area immediately, and thoroughly flush with water after the restoration is completed.

- If PALFIQUE OMNICHROMA FLOW comes into contact with the skin or clothing, immediately saturate the area with an alcohol soaked cotton swab or gauze.

- Instruct the patient to rinse his mouth immediately after treatment.

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

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

9) Clean the placement instruments and brushes with alcohol after use.

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

11) This product is designed to be used at room temperature (18 - 30°C / 62 - 84°F). Allow product to reach room temperature prior to use. Cold material may be difficult to extrude. After removing from the refrigerator, allow the product to sit 15 minutes or until it reaches room temperature.

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

INDICATIONS FOR FILLING AND CURING

PALFIQUE OMNICHROMA FLOW is designed to be cured by either a halogen or LED curing-light with a wavelength of 400-500 nm. Be sure to light-cure PALFIQUE OMNICHROMA FLOW extra-orally and check the time needed for complete hardening of PALFIQUE OMNICHROMA FLOW with your light-curing unit before performing the bonding procedure. The following table summarizes the relationship between curing time and increment depth:

Light type	Intensity (mW/cm²)	Curing time (seconds)	Increment depth (mm) ¹⁾
Halogen	400	20	2.7
	400	40	3.8
	600	20	3.0
	800	10	2.9
LED	800	20	3.5
	400	20	2.7
	400	40	3.7
	600	20	2.9
	800	10	2.8
	1200	10	3.4
	2300	6	3.0

1) Increment depth was determined on the basis of test results performed in accordance with "depth of cure" of ISO 4049

STORAGE

1) Store PALFIQUE OMNICHROMA FLOW at temperatures between 0 - 25°C (32 - 77°F).

2) AVOID direct exposure to light and heat.

3) DO NOT use PALFIQUE OMNICHROMA FLOW after the indicated date of expiration on the syringe package.

DISPOSAL

To safely dispose of excess PALFIQUE OMNICHROMA FLOW, extrude unused portion from SYRINGE and light-cure before disposal.

CLINICAL PROCEDURE

Determine if this product is suitable for application to the case before use. The desirable esthetic outcome may not be obtained depending on the case (e.g. a case where very little tooth structure remains, the underlying tooth is extremely discolored, or the color of the underlying tooth is to be changed to another color, etc.).

1. Cleaning

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

2. Isolation

A rubber dam is the preferred method of isolation.

3. Cavity Preparation

Prepare the cavity. In case where no cavity preparation has been made (caries-free cervical defects), clean the tooth surface with a rubber cup and a fluoride-free cleaning paste. Rinse thoroughly 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 restoration, thereby enhancing both esthetics and retention.

- Scalloped bevel could be desirable depending on the esthetics and retention.
- In the case of porcelain/composite repairs, roughen the surface with a bur or a diamond point to prepare the area for adhesion; apply phosphoric acid etch for cleaning; rinse thoroughly with water; air dry thoroughly and treat with a silane coupling agent, followed by a metal primer if metal is exposed on the fractured surfaces according to manufacturer's instructions.

4. Pulp Protection

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 curing of PALFIQUE OMNICHROMA FLOW. PALFIQUE OMNICHROMA FLOW is not indicated for direct pulp capping.

5. Bonding System

Apply a bonding system according to its manufacturer's instructions.

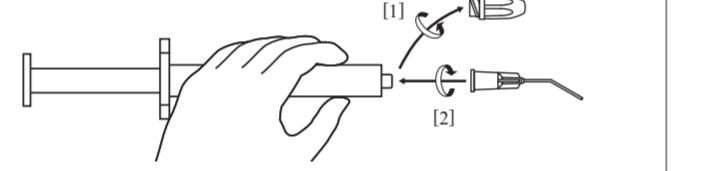
- If using self-cured or dual-cured bonding systems, please confirm that such bonding systems are compatible with the light-cured composite resins being used.

- In case of porcelain/composite repairs, be sure to condition the surface of porcelain/composite with a silane coupling agent BEFORE performing the bonding procedure.

6. Dispensing

- Hold the nozzle and turn the cap counterclockwise for removal. [1]

- Hold the nozzle and place the Dispensing Tip (metal tip) onto it. Turn the Dispensing Tip clockwise until it is securely locked. [2]



- Accessories and Dispensing Tips are exclusively designed for the SYRINGE of PALFIQUE OMNICHROMA FLOW. Use the attached Dispensing Tips (metal tips).

- Dispensing Tips (TOKUYAMA Dispensing Tip) are also sold separately.
- Use uncontaminated gloves when handling the syringe and attaching the Dispensing Tip.

7. Filling and contouring

Cavities can be directly filled from the Dispensing Tip, or indirectly filled with an instrument after extruding the paste on the mixing pad. Increments should not exceed the indicated curing depth at a time (please refer to the aforementioned table).

- DO NOT apply excessive force to extrude the material from the syringe immediately after removal from the refrigerator.

- DO NOT mix PALFIQUE OMNICHROMA FLOW with other brands of resin composite to avoid incomplete cure, entrapment of air bubbles or losing its color adjustment.

- After extruding the paste, remove and discard the Dispensing Tip, wipe the nozzle with gauze and replace the cap immediately.

- This product is provided non-sterile and is not intended to be sterilized by the user.

- Use PALFIQUE OMNICHROMA BLOCKER or PALFIQUE OMNICHROMA BLOCKER FLOW under PALFIQUE OMNICHROMA FLOW for the direct restoration of extensive Class III or IV cavity. PALFIQUE OMNICHROMA FLOW can appear semi-translucent when PALFIQUE OMNICHROMA FLOW is not adequately surrounded by a cavity wall. If applied in direct restorations of extensive Class III or IV cavity, the cured PALFIQUE OMNICHROMA FLOW may appear dark.

- In the case of repair of porcelain / composite, the application of an opacifier to the fractured surfaces as an initial layer is needed to hide a metal portion if it exists. Then, place PALFIQUE OMNICHROMA FLOW onto the fractured surfaces.

- In the case of masking tooth discoloration, apply PALFIQUE OMNICHROMA BLOCKER, PALFIQUE OMNICHROMA BLOCKER FLOW or a dental color masking material such as an opacifier on the discolored surface to mask the discoloration, followed by the placement of PALFIQUE OMNICHROMA FLOW.

8. Curing

Light-cure each increment for at least the indicated time (see aforementioned table).

- If other brands of composite resins are layered over the cured composite, follow their instructions.

9. Finishing

Shape and polish the restoration. For finishing, use finishing discs and/or fine finishing diamond points. Use metal finishing strips or vinyl polishing strips for proximal surfaces. For polishing, polish with rubber points or any suitable polishing tools. For final polishing, use felt discs or cotton wheels with polishing paste, or suitable polishing tools.

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.

Specifications are subject to change without notice. When the product specification changes, the instructions and precautions may change also.

ESPAÑOL

Lea detenidamente toda la información, las precauciones, las notas y los materiales antes de usar el producto.

DESCRIPCIÓN DEL PRODUCTO E INFORMACIÓN GENERAL

1) PALFIQUE OMNICHROMA FLOW es una resina compuesta fotopolimerizable y radiopaca de baja viscosidad para usar en restauraciones anteriores y posteriores, indicada para toda clase de caries. PALFIQUE OMNICHROMA FLOW es un material de un solo tono. La colocación directa de PALFIQUE OMNICHROMA FLOW en una cavidad preparada permite una sencilla manipulación.

2) PALFIQUE OMNICHROMA FLOW contiene el 71% en peso (57% en volumen) de relleno esférico de silice-zirconio (tamaño medio de las partículas: 0.3 µm, rango de tamaño de las partículas: 0.2 a 0.4 µm) y relleno de composite.

PALFIQUE OMNICHROMA FLOW contiene 1,6-bis(metacrilato-etiloxcarbonilamino)trimetil hexano (UDMA), 1,9-nonametileno glicol dimetacrilato, Mequinol, Dimetyl hidroxil tolune y absorbente de rayos UV.

3) PALFIQUE OMNICHROMA FLOW está disponible en JERINGA.

INDICACIONES

- Restauraciones anteriores y posteriores directas
- Revestimiento a base de cavidad
- Reparación de porcelana/compósito

CONTRAINDICACIONES

PALFIQUE OMNICHROMA FLOW contiene monómeros de metacrilato y absorbente de rayos UV. NO use PALFIQUE OMNICHROMA FLOW para pacientes alérgicos o hipersensibles al metacrilato y monómeros relacionados, absorbente de rayos UV o cualquier otro de los demás ingredientes.

PRECAUCIONES

1) NO use PALFIQUE OMNICHROMA FLOW para ninguna otra finalidad que las indicadas en estas instrucciones. Use PALFIQUE OMNICHROMA FLOW solamente como se instruye en este documento.

2) PALFIQUE OMNICHROMA FLOW está diseñado solamente para venta y uso por parte de profesionales acreditados para el tratamiento dental. No está diseñado para su venta ni uso por parte de personal distinto a los profesionales del tratamiento dental.

5. Sistema adhesivo

Aplique un sistema adhesivo según las instrucciones del fabricante.

- Si deseas utilizar un adhesivo autopolimerizable o de polimerización dual, debe asegurarse de que sea compatible con las resinas compuestas fotopolimerizadas que está empleando.

5) Use guantes de exploración (de plástico, vinilo o látex) siempre al manipular PALFIQUE OMNICHROMA FLOW a fin de evitar posibles reacciones alérgicas a los monómeros metacrílicos o al absorbente de rayos UV.

Nota: Ciertas sustancias/materiales pueden penetrar a través de los guantes de exploración. En caso de contacto de PALFIQUE OMNICHROMA FLOW con los guantes de exploración, quiteles y lávese las manos abundantemente con agua lo antes posible.

6) Evite el contacto de PALFIQUE OMNICHROMA FLOW con los ojos, las mucosas, la piel y la ropa.

- En caso de contacto de PALFIQUE OMNICHROMA FLOW con los ojos, enjuáguelos bien con agua y acuda inmediatamente al oftalmólogo.

- En caso de contacto de PALFIQUE OMNICHROMA FLOW con la membrana mucosa, límpie inmediatamente el área afectada y enjuague cuidadosamente con agua luego de completada la restauración.

- En caso de contacto de PALFIQUE OMNICHROMA FLOW con la piel o la ropa, láve abundantemente inmediatamente la zona con una gasa o hisopo de algodón impregnado de alcohol.

- Indique al paciente que se enjuague la boca inmediatamente después del tratamiento.

7) Relleno y contorno

Las cavidades se pueden obturar directamente con la punta de dispensación o indirectamente con un instrumento después de extruir la pasta en el bloque de mezcla. En cada incremento individual no se debe superar la profundidad de polimerización indicada (consulte la tabla antes mencionada).

- NO aplique una fuerza excesiva para extruir el material de la jeringa inmediatamente después de sacarlo del refrigerador.

- Para evitar una polimerización incompleta, el atrapamiento de burbujas de aire o la pérdida de ajuste de su color, NO mezcle PALFIQUE OMNICHROMA FLOW con otras marcas de resina compuesta.

- Después de extruir la pasta, retire y deseche la punta de dispensación, límpie la boquilla con una gasa y vuelva a colocar inmediatamente la tapa.

- Este producto se proporciona no estéril y no está previsto para ser esterilizado por el usuario.

- Use PALFIQUE OMNICHROMA BLOCKER o PALFIQUE OMNICHROMA BLOCKER FLOW bajo PALFIQUE OMNICHROMA FLOW para la restauración directa de grandes cavidades de clase III o IV. PALFIQUE OMNICHROMA FLOW puede parecer semitranslúcido cuando PALFIQUE OMNICHROMA FLOW no esté rodeado adecuadamente por la pared de una cavidad. Si se aplica en restauraciones directas de grandes cavidades de clase III o IV, el PALFIQUE OMNICHROMA FLOW fotopolimerizado puede parecer oscuro.

- En caso de una reparación de porcelana/compósito, la aplicación de un opacificador a las superficies fracturadas como capa inicial es necesario para ocultar una porción metálica, en caso de existir. Entonces, ponga PALFIQUE OMNICHROMA FLOW en las superficies fracturadas.

- En caso de enmascarar una decoloración del diente, aplique PALFIQUE OMNICHROMA BLOCKER, PALFIQUE OMNICHROMA BLOCKER FLOW o un material de enm

