

Resin-based Dental Restorative Material

PALFIQUE OMNICHROMA BLOCKER Flow**ENGLISH**

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

■ PRODUCT DESCRIPTION AND GENERAL INFORMATION

- 1) PALFIQUE OMNICHROMA BLOCKER FLOW is a low viscosity, light-cured, radiopaque composite resin for use in anterior and posterior restorations. Direct placement of PALFIQUE OMNICHROMA BLOCKER FLOW into a prepared cavity allows for easy handling.
- 2) PALFIQUE OMNICHROMA BLOCKER FLOW contains 71% by weight (57% by volume) of spherical silica-zirconia filler and composite filler. The spherical filler contained in PALFIQUE OMNICHROMA BLOCKER FLOW (mean particle size: 200 nm; particle size range: 100 to 300 nm) facilitates excellent gloss retention and wear resistance.
- 3) PALFIQUE OMNICHROMA BLOCKER FLOW contains Bisphenol A di(2-hydroxy propoxy) dimethacrylate (Bis-GMA), Bisphenol A polyethoxy methacrylate (Bis-MPEPP), Triethylene glycol dimethacrylate (TEGDMA), 1,6-bis(methacryloyloxy)carbonylaminotrimethyl hexane (UDMA), Mequinol, Dibutyl hydroxyl toluene and UV absorber.
- 4) PALFIQUE OMNICHROMA BLOCKER FLOW is available in SYRINGE.
- 5) PALFIQUE OMNICHROMA BLOCKER FLOW is designed for masking slight stain and discoloration. PALFIQUE OMNICHROMA BLOCKER FLOW can be used as a thin layer at the lingual cavity wall of extensive class III and IV restorations or reconstruct a highly opaque tooth.

■ INDICATIONS

For use as a tooth shade resin in dental procedures, such as:

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

■ CONTRAINDICATIONS

PALFIQUE OMNICHROMA BLOCKER FLOW contains methacrylic monomers and UV absorber. DO NOT use PALFIQUE OMNICHROMA BLOCKER 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 BLOCKER FLOW for any purpose other than those listed in these instructions. Use PALFIQUE OMNICHROMA BLOCKER FLOW only as directed herein.
- 2) PALFIQUE OMNICHROMA BLOCKER 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 BLOCKER FLOW if the safety seals are broken or appear to have been tampered with.
- 4) If PALFIQUE OMNICHROMA BLOCKER 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 BLOCKER FLOW to avoid the possibility of allergic reactions from methacrylic monomers or UV absorber.

Note: Certain substance/materials may penetrate through examination gloves. If PALFIQUE OMNICHROMA BLOCKER 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 BLOCKER FLOW with eyes, mucosal membrane, skin and clothing.
- If PALFIQUE OMNICHROMA BLOCKER FLOW comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.
- If PALFIQUE OMNICHROMA BLOCKER 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 BLOCKER 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 BLOCKER FLOW should not be ingested or aspirated. Ingestion or aspiration may cause serious injury.

8) To avoid the unintentional ingestion of PALFIQUE OMNICHROMA BLOCKER 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 BLOCKER 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 BLOCKER FLOW extra-long and check the time needed for complete hardening of PALFIQUE OMNICHROMA BLOCKER FLOW with your light-curing unit before performing the bonding procedure. The following table summarizes the relationship between curing time and increment depth.

Relationship between curing time and increment depth:

Light type	Intensity(mW/cm ²)	Curing time(seconds)	Increment depth (mm) ¹⁾
Halogen	400	20	1.5
		40	2.0
	600	20	1.6
	800	10	1.5
LED	400	20	1.7
		40	1.9
	600	20	1.4
	800	10	1.3
	1200	10	1.6
	2300	6	1.9

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 BLOCKER FLOW at temperatures between 0 - 25°C (32 - 77°F).
- 2) AVOID direct exposure to light and heat.
- 3) DO NOT use PALFIQUE OMNICHROMA BLOCKER FLOW after the indicated date of expiration on the syringe package.

■ DISPOSAL

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

■ CLINICAL PROCEDURE**1. Cleaning**

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

2. Shade Selection

Select PALFIQUE OMNICHROMA BLOCKER FLOW as the initial layer under PALFIQUE OMNICHROMA or PALFIQUE OMNICHROMA FLOW, when masking slight stain or extensive Class III or IV direct cavity restorations.

3. Isolation

A rubber dam is the preferred method of isolation.

4. 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.

- 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.

5. 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 BLOCKER FLOW. PALFIQUE OMNICHROMA BLOCKER FLOW is not indicated for direct pulp capping.

6. Bonding System

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

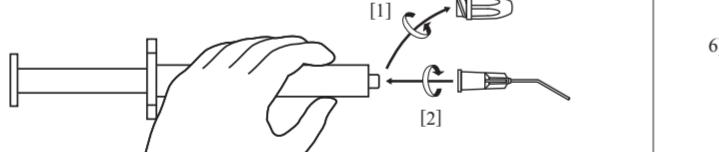
- If using self-cured or dual-cured bonding systems, please confirm that such bonding systems are compatible with the light-cured composite resins being used.

- 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.

7. 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 BLOCKER 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.

8. Filling and contouring

Fill the cavity with PALFIQUE OMNICHROMA BLOCKER FLOW as an initial layer. 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 BLOCKER 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.

9. Curing

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

- Follow the filling and curing instructions of PALFIQUE OMNICHROMA FLOW/ PALFIQUE OMNICHROMA to be layered over the cured PALFIQUE OMNICHROMA BLOCKER FLOW.

10. Finishing

Shape and polish the restoration according to instructions for PALFIQUE OMNICHROMA/ PALFIQUE OMNICHROMA FLOW used as the surface layer of the restoration.

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 BLOCKER FLOW es una resina compuesta fotopolimerizable y radiopaca de baja viscosidad para usar en restauraciones anteriores y posteriores. La colocación directa de PALFIQUE OMNICHROMA BLOCKER FLOW en una cavidad preparada permite una sencilla manipulación.

2) PALFIQUE OMNICHROMA BLOCKER FLOW contiene el 71% en peso (57% en volumen) de relleno esférico de sílice-zirconio y relleno de composite. El relleno esférico contenido en PALFIQUE OMNICHROMA BLOCKER FLOW (tamaño medio de las partículas: 200 nm, rango de tamaño de las partículas: 100 a 300 nm) facilita una excelente conservación del brillo y resistencia al desgaste.

3) PALFIQUE OMNICHROMA BLOCKER FLOW contiene bisfenol A di(2-hidroxipropoxi) dimetacrilato (Bis-GMA), bisfenol A polietoxi metacrilato (Bis-MPEPP), trietilenoglicol dimetacrilato (TEGMDA), 1,6-bis(metacrilatoetiloxy)carbonylaminotrimetil hexano (UDMA), mequinol, dibutil hidroxil tolueno y absorvente de rayos UV.

4) PALFIQUE OMNICHROMA BLOCKER FLOW está disponible en JERINGA.

5) PALFIQUE OMNICHROMA BLOCKER FLOW está diseñado para ocultar ligeras manchas y decoloración. PALFIQUE OMNICHROMA BLOCKER FLOW puede utilizarse como una fina capa en la pared lingual de la cavidad para grandes restauraciones de clase III o IV o reconstrucciones de un diente altamente opaco.

■ INDICACIONES

Para usar como resina de tonalidad dental en procedimientos dentales, tales como:

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

■ CONTRAINDICACIONES

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

■ PRECAUCIONES

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

2) PALFIQUE OMNICHROMA BLOCKER 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.

3) NO use PALFIQUE OMNICHROMA BLOCKER FLOW si los sellos de seguridad están rotos o parecen haber sido manipulados.

- 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.

5. Pulp Protection

El método preferido para aislar es un dique de goma.

4. Preparación de la cavidad

Prepare la cavidad. En el caso de que no se haya preparado la cavidad (defectos cervicales exentas de caries), limpie la superficie del diente con una copa de goma y una pasta sin flúor. Despues, enjuáguela con agua.

2. Selección de la tonalidad

Elija PALFIQUE OMNICHROMA BLOCKER FLOW como capa inicial bajo PALFIQUE OMNICHROMA o PALFIQUE OMNICHROMA FLOW para ocultar ligeras manchas o con restauraciones directas de grandes cavidades clase III o IV.

3. Aislamiento

El método preferido para aislar es un dique de goma.

4. Preparación de la cavidad

Prepare la cavidad. En el caso de que no se haya preparado la cavidad (defectos cervicales exentas de caries), limpie la superficie del diente con una copa de goma y una pasta sin flúor. Despues, enjuáguela con agua.

5. Protección de la pulpa

Debe aplicarse hidróxido cálcico si la cavidad está muy cerca de la pulpa. NO UTILICE MATERIALES BASADOS EN EUGENOL para proteger la pulpa, ya que inhibirían la polimerización de PALFIQUE OMNICHROMA BLOCKER FLOW em pacientes alérgicos o hipersensivos aos monómeros metacrílicos e monómeros relacionados, absorbente de UV ou quaisquer outros ingredientes.

6. Sistema adhesivo

Aplique un sistema adhesivo según las instrucciones del fabricante.

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

- En caso de reparaciones de porcelana/compósito, asegúrese de acondicionar la superficie de la porcelana/compósito con un silano ANTES de proceder con la adhesión.

7. Dispensación

