

# OMNICHROMA BLOCKER

Read all information, precautions and notes before using.

## ■ PRODUCT DESCRIPTION AND GENERAL INFORMATION

- 1) OMNICHROMA BLOCKER is a light-cured, radiopaque, composite resin. OMNICHROMA BLOCKER contains 82% by weight (71% by volume) of silica-zirconia filler and composite filler. A high filler load offers decreased polymerization shrinkage. All inorganic filler contained in OMNICHROMA BLOCKER is a spherical filler (mean particle size: 0.2  $\mu\text{m}$ , particle size range: 0.1 to 0.3  $\mu\text{m}$ ). The monomer matrix contains Bis-GMA and Triethylene glycol dimethacrylate.
- 2) OMNICHROMA BLOCKER is provided either in SYRINGE or Pre Loaded Tip (PLT).
- 3) OMNICHROMA BLOCKER is designed for use as a thin layer at the lingual cavity wall of extensive class III and IV restorations. OMNICHROMA BLOCKER can mask slight discoloration or reconstruct a highly opaque tooth

## ■ INDICATIONS

For use as a tooth shade resin in dental procedures.

## ■ CONTRAINDICATIONS

OMNICHROMA BLOCKER contains methacrylic monomers. DO not use OMNICHROMA BLOCKER for patients allergic to or hypersensitive to methacrylic and related monomers.

## ■ PRECAUTIONS

- 1) DO NOT use OMNICHROMA BLOCKER for any purpose other than those listed in these instructions. Use OMNICHROMA BLOCKER only as directed herein.
- 2) OMNICHROMA BLOCKER 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 OMNICHROMA BLOCKER if the safety seals are broken or appear to have been tampered with.
- 4) If OMNICHROMA BLOCKER causes an allergic reaction or oversensitivity, discontinue its use immediately.
- 5) Use examination gloves (plastic, vinyl, or latex) at all times when handling OMNICHROMA BLOCKER to avoid the possibility of allergic reactions from methacrylic monomers.  
Note: Certain substances/materials may penetrate through examination gloves. If OMNICHROMA BLOCKER 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 OMNICHROMA BLOCKER with eyes, mucosal membrane, skin and clothing.
  - If OMNICHROMA BLOCKER comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.
  - If OMNICHROMA BLOCKER comes in contact with the mucosal membrane, wipe the affected area immediately, and thoroughly flush with water after the restoration is completed.
  - If OMNICHROMA BLOCKER 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) OMNICHROMA BLOCKER should not be ingested or aspirated. Ingestion or aspiration may cause serious injury.
- 8) To avoid the unintentional ingestion of OMNICHROMA BLOCKER, do not leave it unsupervised within the reach of patients and children.
- 9) Clean the placement instruments with alcohol after use.

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

### ■ INDICATIONS FOR FILLING AND CURING

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

Relationship between curing time and increment depth:

Light type	Intensity (mW/cm <sup>2</sup> )	Curing time (seconds)	Increment depth (mm) <sup>1)</sup>
Halogen	400	20	1.8
	600	20	1.9
	800	10	1.7
		20	2.0
LED	400	20	1.6
	600	20	1.7
	800	10	1.7
		20	1.9
	1200	10	1.8
	2300	6	1.9

1) Increment depth was determined on the basis of test results performed in accordance with section 7.10 “depth of cure” of ISO 4049: 2009.

### ■ SPECIAL NOTES FOR THE USE OF PLT

- 1) PLTs are designed for single patient use only. Do not re-cap and/or re-use the PLT tip once material has been dispensed for that patient.
- 2) Dispensers are not provided for OMNICHROMA BLOCKER. Use a dispenser that fits the PLT of OMNICHROMA BLOCKER. For proper use and proper disinfection, see manufacturer’s instructions.
- 4) Use light, controlled pressure to prevent any continued extrusion of material following pressure release.

### ■ STORAGE

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

### ■ DISPOSAL

To safely dispose of excess OMNICHROMA BLOCKER, extrude unused portion from SYRINGE or PLT 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 OMNICHROMA BLOCKER as the initial layer under OMNICHROMA, with direct restorations of extensive Class III or IV cavity using OMNICHROMA.

### **3. Isolation**

A rubber dam is the preferred method of isolation.

### **4. 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 restoration, thereby enhancing both esthetics and retention.

- Scalloped bevel could be desirable depending on the esthetics and retention.
- 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 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**

Glass ionomer or a calcium hydroxide lining 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 bonding agent and/or OMNICHROMA BLOCKER. OMNICHROMA BLOCKER is not indicated for direct pulp capping.

### **6. Bonding System**

Apply a bonding system according to manufacturer's instructions.

- Do not use self-cured bonding systems other than TOKUYAMA UNIVERSAL BOND. Self-cured or dual-cured bonding systems may not provide effective adhesion when used with light-cured composite resins. If you want to use self-cured or dual-cured bonding systems, please confirm that such bonding systems are compatible with the light-cured composite resins being used.

### **7. Dispensing**

#### **7-1. PLT**

Please read ■SPECIAL NOTES FOR THE USE OF PLT before use.

- Load the PLT into a dispenser that fits the PLT.
- Remove the PLT cap.
- Extrude the paste directly into cavity or indirectly on the mixing pad.

#### **7-2. SYRINGE**

Remove the syringe cap. Extrude the paste onto a mixing pad by turning the handle clockwise. After dispensing, turn the handle counterclockwise by a half to full turn to release residual pressure inside the syringe and re-cap the syringe immediately after dispensing.

- DO NOT apply unnecessary force to the syringe immediately after removing from the refrigerator.

### **8. Filling**

Fill the cavity with OMNICHROMA BLOCKER as an initial layer. Increments should not exceed the indicated depth (please refer to the aforementioned table).

- DO NOT mix OMNICHROMA BLOCKER with other brands of resin composite to avoid incomplete cure or voids.

### **9. Curing**

Light-cure each increment for at least the indicated time (please see aforementioned table), keeping the curing-light tip within a distance of 2 mm from the increment.

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

## 10. Finishing

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

CAUTION: Federal law restricts this device to sale by or on the order of a dental professional.

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 user to ensure that this product is suitable for an appropriate application before use.

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

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Manufacturer

**Tokuyama Dental Corporation**

38-9, Taitou 1-chome, Taitou-ku, Tokyo 110-0016, Japan

Tel: +81-3-3835-7201

URL: <http://www.tokuyama-dental.com/>

North America

**Tokuyama Dental America Inc.**

Tel: (877) 378-3548 (Toll-Free)