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Resin-based Dental Restorative Material

# OMNICHROMA

## ENGLISH

**Read all information, precautions and notes before using.**

### ■ PRODUCT DESCRIPTION AND GENERAL INFORMATION

- 1) OMNICHROMA is a light-cured, radiopaque composite resin for use in anterior and posterior restorations and is indicated for all carious classes. OMNICHROMA is a single shade material.
- 2) OMNICHROMA contains 79% by weight (68% by volume) of spherical silica-zirconia filler (mean particle size: 0.3 µm, particle size range: 0.2 to 0.6 µm) and composite filler. OMNICHROMA contains 1,6-bis(methacryl-ethyloxycarbonylamino) trimethyl hexane (UDMA), Triethylene glycol dimethacrylate (TEGDMA), Mequinol, Dibutyl hydroxyl toluene and UV absorber.
- 3) OMNICHROMA is available in either SYRINGE or Pre Loaded Tip (PLT).

### ■ INDICATIONS

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

- Direct anterior and posterior restorations
- Direct bonded composite veneer
- Diastema closure
- Repair of porcelain/composite

### ■ CONTRAINDICATIONS

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

### ■ PRECAUTIONS

- 1) DO NOT use OMNICHROMA for any purpose other than those listed in these instructions. Use OMNICHROMA only as directed herein.
- 2) OMNICHROMA 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 OMNICHROMA if the safety seals are broken or appear to have been tampered with.
- 4) If OMNICHROMA causes an allergic reaction or hypersensitivity, discontinue its use

immediately.

- 5) Use examination gloves (plastic, vinyl or latex) at all times when handling OMNICHROMA to avoid the possibility of allergic reactions from methacrylic monomers. Notes: Certain substance/materials may penetrate through examination gloves. If OMNICHROMA 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 with eyes, mucosal membrane, skin and clothing.
  - If OMNICHROMA comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.
  - If OMNICHROMA comes in contact with the mucosal membrane, wipe the affected area immediately, and thoroughly flush with water after the restoration is completed.
  - If OMNICHROMA 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) OMNICHROMA should not be ingested or aspirated. Ingestion or aspiration may cause serious injury.
- 8) To avoid the unintentional ingestion of OMNICHROMA, 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.
- 12) Be aware that when a restoration is chipped from misaligned occlusion or bruxism (clenching, grinding or tapping), the repaired restoration may chip again.
- 13) DO NOT mix OMNICHROMA with other brands of resin composite to avoid losing its color adjustment.

## ■ INDICATIONS FOR FILLING AND CURING

OMNICHROMA 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 extra-orally and check the time needed for complete hardening of OMNICHROMA 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	2.7
		40	3.3
	600	20	3.1
	800	10	2.7
		20	3.3
LED	400	20	2.5
		40	3.6
	600	20	2.9
	800	10	2.6
		20	3.1
	1200	10	3.0
	2300	6	2.9

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. Use a dispenser that fits the PLT of OMNICHROMA. For proper use and proper disinfection, see manufacturer’s instructions.
- 3) Use light, controlled pressure to prevent any continued extrusion of material following pressure release.

#### ■ STORAGE

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

#### ■ DISPOSAL

To safely dispose of excess OMNICHROMA, 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. Isolation**

A 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 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**

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 OMNICHROMA. OMNICHROMA is not indicated for direct pulp capping.

## **5. Bonding System**

Apply a bonding system according to its 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.

## **6. Dispensing**

### **6-1. 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 the cavity or indirectly on the mixing pad.

### **6-2. 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.

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

## 7. Filling and Contouring

Fill the cavity incrementally. Increments should not exceed the indicated curing depth (please refer to the aforementioned table).

- Use OMNICHROMA BLOCKER under OMNICHROMA for the direct restoration of extensive Class III or IV cavity. OMNICHROMA can appear semi-translucent when OMNICHROMA is not adequately surrounded by a cavity wall. If applied in direct restorations of extensive Class III or IV cavity, the cured OMNICHROMA may appear dark.
- In the case of repair of porcelain / composite, the application of an opaquer to the fractured surfaces as an initial layer is needed to hide a metal portion if it exists. Then, place OMNICHROMA into the fractured surfaces.
- In the case of masking tooth discoloration, apply OMNICHROMA BLOCKER or a dental color masking material such as an opaquer on the discolored surface to mask the discoloration, then place OMNICHROMA.

## 8. 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.

## 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.

**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 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.

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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)