



GTIN: 7640178010604

#SMT3042

Medi-Opaque Posterior

LIGHT-CURED RESTORATIVE COMPOSITE

INSTRUCTIONS FOR USE

I. INTRODUCTION

Medi Opaque Posterior Light curing restorative composite resin with outstanding esthetic and physical properties.

II. INDICATION

- Direct restorations for anterior and posterior teeth (Class I - V cavities)
- Correction of tooth position and tooth shape (e.g. diastema closure, dwarfed tooth, etc.)
- Intraoral repairs of fractured crowns / bridges

III. CONTRAINDICATION

Patients with a history of hyper-sensitivity to methacrylate monomers

IV. INCOMPATIBILITY

Do not use eugenol containing materials for pulp protection or temporary sealing, since the eugenol could retard the bonding system curing process.

V. PRECAUTIONS

1. Safety precautions

1. Avoid use of the product for patients with a history of hyper-sensitivity to methacrylate monomers.
2. If any hypersensitivity occurs, such as dermatitis, discontinue use of the product and consult a physician.
3. Wear gloves or take other appropriate protective measures to prevent the occurrence of hyper-sensitivity that may result from contact with methacrylate monomers.
4. Use caution to prevent the product from coming in contact with the skin or getting into the eye. Before using the product, cover the patient's eyes with a towel to protect the patient's eyes from splashing material.
5. If the product comes in contact with human body tissues, take the following actions;

Contact with eye:

Immediately wash the eye with copious amounts of water and consult a physician.

Contact with skin:

Immediately wipe it off with a cotton pledget moistened with alcohol or gauze and wash with copious amounts of water.

6. Use caution to prevent the patient from accidentally swallowing the product.
7. Avoid looking directly at the dental curing unit when curing the product.

2. Handling and manipulation precautions

1. Do not use the product in conjunction with the other composite resins. Mixing materials may cause a change in physical properties, possibly a decrease, from the properties expected.
 2. When light curing the product, note the depth of cure in this instructions for use.
 3. The product polymerize under an operating light or natural light (sunlight from windows). Avoid operating light or natural light, and use within 5 minutes from dispensing.
 4. The emitting tip of the dental curing unit should be held as near and vertical to the resin surface as possible. If a large resin surface is to be light cured, it is advisable to divide the area into several sections and light-cure each section separately.
 5. Low intensity of light causes poor adhesion. Check the lamp for service life and the dental curing unit guide tip for contamination. It is advisable to check the dental curing light intensity using an appropriate light evaluating device at appropriate intervals.
 6. The use of the product is restricted to a licensed dental professional.
- #### 3. Storage precautions
1. Do not use after the expiration date. Note the expiration date on the outside of package.
 2. Keep away from extreme heat or direct sunlight.
 3. The product must be stored at 15-24°C when not in use.
 4. Replace the cap as soon as possible after the composite has been dispensed from the syringe.
 5. The product must be stored in proper places where only dental practitioners can access it.

VI. COMPONENTS

- 1) Components Please see the outside of the package for contents and quantity.
- 2) Ingredients Principal ingredients:
 - Silanated silica glass filler
 - Silanated barium glass filler
 - (Bis-GMA)
 - (TEGDMA)
 - dl-Camphorquinone

The total amount of inorganic filler is approx. 67 vol%.

1. Shades

Medi Opaque Posterior is available in 6 shades; A1, A2, A3, B2, E2, E3

VII. CLINICAL PROCEDURES

1. Cleaning tooth structure

Be sure the cavity is adequately cleaned. An adequately cleaned cavity assures maximum adhesive performance.

2. Moisture control

Avoid contamination of the treatment area from saliva or blood to produce optimal results. A rubber dam is recommended to keep the tooth clean and dry.

3. Cavity preparations

Remove any infected dentin and prepare the cavity in the usual manner.

4. Shade selection

Select an appropriate shade using the shade guide.

5. Pulp protection

Any actual or near pulp exposure should be covered with a hard setting calcium hydroxide material. However, usually a cement lining or basing is not necessary. Do not use eugenol materials for pulp protection.

6. Acid etching uncut enamel

If the resin restorative material will extend to uncut enamel, apply etching agent (e.g. **Medi Etch GEL**) to the enamel, let it stay for 10 seconds, wash with water, and then dry.

7. Application of bonding agent

Tooth surface treatment and bonding should be performed according to Instructions for Use of the bonding system used (e.g. **Medi Etch Bond** or **Medi Etch Bond PLUS**).

8. Placement and light curing .

1. Dispensing

Dispense the necessary amount of **Medi Opaque Posterior**. After dispensing the resin, turn the plunger counter-clockwise a half turn to prevent excess resin from escaping. Replace the syringe cap immediately to prevent premature setting of the resin. Use the resin within 5 minutes of dispensing. Extended exposure to the operating light will allow the resin to cure.

- Apply **Medi Oxy** solution and securely attach the disposable tip onto the syringe.

- Apply **Medi Oxy** solution, Cover all exposed resin. In the case of an indirect restoration or full composite direct resin restoration, be sure to cover the margins. Take care to fill all embrasures (i.e., gingival, buccal, and lingual).

- Allow light-cure the composite with a dental curing unit* following the times in the table below.

Light power	500mW/ cm2	800mW /cm2
MediOpaquePosterior	40 sec.	20 sec.

- Remove excess **Medi Oxy** solution with air/water spray.

Exposure time for increments of 2 mm

2. Placement

Incremental placement and light-curing each increment is strongly recommended especially in deep cavities and in Class II cavities.

3. Curing

Light-cure the resin with a dental visible light curing unit* following the table. Hold the light tip as close to the resin as possible.

Evaluated according to ISO 10650-1 & ISO 10650-2.

Physical Properties

Compressive strength 352(±0.08) MPa
Elasticity modulus 12.1(±0.08) GPa
Fracture Toughness: 1.57 (±0.04) MPa.m^{1/2}
Surface Hardness (KHN): 76.03(± 2.24)
Flexural Strength: 138 (11) MPa
Flexural Modulus: 9.6 (0.6) MPa

[Caution]

Federal(U.S.A.)law restricts this device to sale by or on the order of a licence dentist.

[WARRANTY]

SwissMediTec GmbH. will replace any product that is proven to be defective. SwissMediTec GmbH. does not accept liability for any loss or damage, direct, consequential or special, arising out of the application or use of or the inability to use these products. Before using, the user shall determine the suitability of the products for the intended use and the user assumes all risk and liability whatsoever in connection therewith.



SwissMediTec GmbH

Businesspark
Bahnhofstrasse 42
6162 Entlebuch
Switzerland

Tel.: +41 41 481 00 86
+41 79 482 32 98

www.swiss-meditec.ch

email: info@swiss-meditec.ch