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Medi-Classic

Dental Light-Cured restorative Composite

Instruction For Use

I. INTRODUCTION

Medi Classic is a light-cure, radiopaque restorative material which provides accurate color matching, high polishability and excellent physical properties, making it ideal for both anterior and posterior restorations. It is formulated with optimal viscosity, assuring easy handling and placement.

II. INDICATIONS

Medi Classic is indicated for the following restorative applications:

- 1-Direct anterior and posterior restorations teeth (including occlusal surfaces)
- 2-Direct veneers
- 3-Correction of tooth position and tooth shape.
- 4-Indirect restorations including inlays, onlays and veneers
- 5-Intraoral repairs of fractured restorations
- 6-Core build-ups
- 7-Splitting

III. CONTRAINDICATION

- Patients with a history of hyper-sensitivity to methacrylate monomers

IV. INCOMPATIBILITIES

Eugenol could retard the bonding system curing process and should not be used.

V. PRECAUTIONS

1. Safety precautions

- Avoid use of the product for patients with a history of hypersensitivity to methacrylate monomers.
- If any hypersensitivity occurs, such as dermatitis, discontinue use of the product and consult a physician.
- Wear gloves or take other appropriate protective measures to prevent the occurrence of hypersensitivity that may result from contact with methacrylate monomer.
- 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.
- If the product comes in contact with body tissues, take the following actions:

If the product gets in the eye

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

If the product comes in contact with the skin

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

2. Handling and manipulation precautions

- Do not use the product together with the other composite resin. Mixing materials may result in a physical property change, possibly a decrease, from the properties expected.
 - Remove any lining material such as Amalgam when preparing the cavity which may prevent the passage of light and the polymerization of the product
 - When light curing the product, note the light curing depth in this IFU.
 - 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.
 - Low light intensity 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 unit intensity using an appropriate light-evaluating device at appropriate intervals.
 - The product should be returned to room temperature before dispensing when it has been taken out of a refrigerator. Failure to do this could cause difficulty using the plunger.
 - Use caution not to get your fingers injured by any sharp edge that might occur due to damage.
 - The use of this product is restricted to licensed dentist.
- ##### 3. Storage precautions
- Do not use the product after the expiry date. Note the expiry date on the outside of the package.
 - The product must be stored at 15-24 °C when not in use.
 - Keep away from extreme heat, direct sunlight.
 - After the paste has been dispensed, the syringe should be capped securely as soon as possible to prevent the paste inside the syringe from being hardened by ambient light and to keep foreign matter from entering the syringe.
 - The product must be stored in proper places where only dental practitioners can access it.

VI. SHADES SYSTEM AND COMPONENTS

1. Shades

Medi Classic is available in 13 shades;

1: A1, A2, A3, A3.5, A4, A6, B1, B2, B3, C3, D3, C4, B4

ENAMEL : C2, D2

2. Components

- **Medi Classic 1x 2ml(4.5g)**

3. Ingredients

Principal ingredients;

- Silanated barium glass filler, Silanated colloidal silica, (TEGDMA), dl-Camphor-quinone, The total amount of inorganic filler is approx, 62vol% particle size is 0.20-4.0 µm.

VII. CLINICAL PROCEDURES

- Direct restorations for anterior and posterior teeth (Class I - III, V cavities, cervical caries, root erosion)

1. Shade selection

Select an appropriate product shade corresponding with the shade of the tooth to be treated using Shade guide. Two or more shades may be combined to achieve a better overall match.

2. Syringe preparation

Selected syringe.

3. Cavity preparation

Ensure the cavity is clean.

4. Moisture control and pulp protection

Avoid contamination of the treatment area from saliva or blood to assure optimal results.

Do not use eugenol materials for pulp protection.

5. Tooth surface treatment and bonding

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

6. Placement and light curing of Medi Classic

- Place the selected shade of the product into the cavity,
- 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

Light power	500mW/cm2	800mW /cm2
Medi Classic	40 sec.	20 sec.

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

- Remove excess Medi Oxy solution with air/water spray.
- Exposure time for increments of 2 mm

7. Finishing

Using a fine diamond point contour the restoration and adjust the occlusion. Polish with silicon rubber points or polishing discs in the classical manner.

Physical and Performance Properties

Radiopacity: 2.10 (±0.04) mmAl

Compressive strength: 338-352 (±0.08) MPa

Elasticity modulus: 15.1 (±0.07) GPa

Fracture Toughness: 1.71 (±0.09) MPa.m^{1/2}

Surface Hardness (KHN): 75.03 ± 2.10

Flexural Strength: 131 (±14) MPa

Flexural Modulus: 10.6 (±0.6) MPa

Water Sorption: 23.1 (±2.1) µg/mm³

Water Solubility: 1.0 (±0.7) µg/mm³

Intensity for curing (for photo-initiated resins): 1200-2000 mW/cm wavelength for curing (for photoinitiated resins): 400-520 nm. Maximum absorbance 450-480

(468)nm. Depth of Cure: 2.22 (±0.03) mm

ISO7405 and ISO4049 compliant

CAUTION

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