



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. It is packaged in traditional syringes or Pre-loaded tips (PLTs).

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 hypersensitivity 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

Immediately wipe it off with a gauze or cotton soaked with alcohol or and rinse with Plenty of water.

- 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 Instructions for Use.
- 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 2 - 8°C / 36 - 47°F 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**
- Needle tips :20 pcs
- Shade guide

3. Ingredients

Principal ingredients;

- Silanated barium glass filler
- Silanated colloidal silica
- Triethylenglycol dimethacrylate (TEGDMA)
- Hydrophobic aromatic dimethacrylate
- dl-Camphorquinone

The total amount of inorganic filler is approx. 62vol%. The inorganic (filler) 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 and attach a needle tip securely.

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, and light-cure the paste with a dental curing unit* following the times in the table below.

Curing time and depth of cure for each dental curing unit

Light source	Curing time/Sec	Depth of Cure(mm)	
		A1, A2, A3, A3.5, A4, B1, B2, B3, C3, D3, C2, D2	A4, C4,
Conventional halogen	20	2.0	1.5
Fast halogen	10		
Plasma arc	5		
Blue LED	20		

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

Curing time: 40 s/2mm

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.



Reference Number



Keep away from sunlight



Refer to instruction manual



Keep Dry



Storage temperature range



Expiry date



Date of Manufacture



Manufactures address



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