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Medi-Galaxy Flow

Dental Light-Cured restorative Composite

Evaluated according to ISO7405 & ISO4049.

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

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.



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Instruction For Use

I. INTRODUCTION

Medi Galaxy Flow is a flowable, radiopaque restorative composite resin which provides desirable color matching, high polish ability and excellent physical properties, ideal for both anterior and posterior restorations. Medi galaxy Flow can be used on its own or together with Medi Jupite,Medi Opaque Posterior.

II. INDICATIONS

Medi Galaxy Flow is indicated for the following restorative applications:

- Direct restorations for anterior and posterior teeth (Class I - III, V cavities, cervical caries, root erosion)
- Cavity base / liner
- Intraoral repairs of fractured crowns/bridges/composite resin

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.
- 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 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.
- 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.
- 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 4 - 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 Galaxy Flow is available in 13 shades;
BODY : A1, A2, A3, A3.5, A4,A6,B1, B2, B3,C3, D3,
ENAMEL : C2,D2

3. Ingredients

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

The total amount of inorganic filler is approx. 63vol%. Theinorganic(filler) particle size is 0.30-4.0 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 Galaxy Flow**:Place the selected shade of the product into the cavity.

| Light power | 500mW/ cm2 | 800mW /cm2 |
|------------------|------------|------------|
| Medi Galaxy Flow | 40 sec. | 20 sec. |

Curing time and depth of cure for each dental curing unit