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INSTRUCTIONS FOR USE

MultiMatch™

Universal Chameleon Restorative Composite

**Indications For Use:**

Premier's MultiMatch Universal Chameleon Restorative Composite is a nano-hybrid dental restorative intended for direct placement in all cavity classes in anterior and posterior teeth. Additional indications include repair of enamel defects, repair of provisionals, and repair of porcelain restorations, minor occlusal build-ups, core build-ups, and incisal abrasions.

Description of Device:

Premier MultiMatch Universal Chameleon Restorative is a light-cured, radiopaque, resin-based nano-hybrid restorative composite. It is formulated for direct placement in any type of anterior and posterior cavity form. It is intended to be used with a dental bonding agent and can be sculpted prior to curing. Once light cured, the composite can be easily finished and polished to achieve a highly esthetic and durable restoration. Available in three chameleon shades, MultiMatch Universal Chameleon Restorative can be dispensed via a unit-dose capsule or syringe to provide a restoration with an excellent visual color match to the surrounding dentition.

Contents:

The system is delivered using either a syringe or Unit Dose capsule for single patient use.

SKU	Contents
3005200	One 4gm Syringe Light Shade
3005201	One 4gm Syringe Medium Shade
3005202	One 4gm Syringe Dark Shade
3005210	20 pack of Unit Dose capsules for Light Shade
3005211	20 Pack of Unit Dose capsules for Medium Shade
3005212	10 Pack of Unit Dose capsules for Dark Shade

Contraindications:

Do not use MultiMatch Composite on patients with known allergies to the materials of this product.

Ensure that all existing restorative materials are removed from the operative site if replacing a restoration.

Do not place or restore tooth with MultiMatch composite if you cannot achieve isolation and / or apply the bonding agent correctly.

PRECAUTIONS:

- Avoid contamination of product. Do not mix components with those of other materials. Do not return dispensed components to their original container. Dispose of leftover material properly.
- Do not apply MultiMatch onto tooth unless a bonding agent is first applied.
- Wear personal protective equipment when using and handling this product.

- Ensure that the tooth is free of debris, materials, or stains that may interfere with shade selection or application process.
- A rubber dam is recommended to be used to isolate the oral cavity.
- Unit Dose Capsules: are single patient use. The reuse of a single use device can expose patients and staff to cross contamination.
- Composite Syringes:
 - Use a protective plastic sheath barrier on the syringe in order to mitigate potential cross-contamination between patients.
 - When using syringe after dispensing on the pad cover before use to prevent unintended polymerization.
- To achieve the best results when using MultiMatch Chameleon Restorative Composite for restoring deep Class 3 or 4 cavity preparations, covering darkly stained tooth structure (such as amalgam staining), or opaque teeth, it is suggested to utilize a color blocker.

WARNINGS:

- Do not light-cure MultiMatch less than the recommended curing time.
- Do not apply MultiMatch onto tooth unless a bonding agent is first applied.
- Do not apply MultiMatch in greater than 2mm increments.
- For use by a trained dental professional only.
- Avoid contact skin, eyes, and soft tissues.
- Do not use after the shelf life period indicated on product labeling/packaging.
- Unit Dose Capsules: Capsules are single patient use. Do not re-use Unit Dose Capsules.
- Composite Syringes: To prevent syringes from getting contaminated, do not directly dispense intraorally. Use a protective plastic sheath barrier on the syringe. Do not reuse and dispose if it becomes contaminated.

Adverse Reactions:

- If an allergic reaction to MultiMatch Composite material occurs, discontinue its use immediately and consult a physician.
- If a serious incident has occurred in relation to the device, please report the incident to the manufacturer and/or competent authority of the Member State where the device was used.
- Restoration may fail if bonding agent is not applied, or curing times are not met, or if MultiMatch is applied in greater than 2mm increments.

Materials:

Premier's composite is available in 3 shades of light, medium, and dark for optimal restorative color match. MultiMatch Composite has a radiopacity value above 250% Aluminum.

Product Composition, % WT Bis-GMA < 10%; Comonomer diluents < 10%; Photoinitiators < 2%; Pigments < 0.2%; Dental

Technology in partnership
with BJM Laboratories, Ltd.

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glass filler < 90%; Fumed silica < 5%; FILLER CONTENT The filler system comprises glass fillers and modified silica: 80-85 weight-% or 60-70 volume-%. The particle size of the fillers range: < 6 µm. None of the ingredients in the product contain pharmacologically active components.

Directions for Use:

1. Wear personal protection equipment when handling MultiMatch Composite.
2. Select the shade desired based on the chart below.

Composite Shade	VITA® Shade Guide Equivalent
Light	A1, A2, B1, B2, C1, C2, D2
Medium	A3, A3.5, B3, B4, D3, D4
Dark	A4, C3, C4

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Note: To determine the color of the tooth to be restored, a VITA-matched shade guide may be used to check the color of any adjacent teeth. A single shade of MultiMatch Composite will be sufficient to restore the tooth.

3. After shade selection, isolate the tooth with preferred isolation method and prepare the tooth.
4. Bonding treatment: For bonding to enamel and/or dentin, use a light-cured bonding system. Follow manufacturer’s instructions regarding etching, priming, adhesive application and curing.
5. There are two methods of delivering the MultiMatch Composite system:
 - a. Unit Dose capsule delivery: Firmly seat the Unit Dose capsule into a composite dispenser. Remove the sealing cap from the capsule tip and discard. Inject the composite material directly into the cavity starting with the deepest portion.
 - b. Syringe Delivery: Slowly extrude material onto a pad. Use your instrument(s) of choice to apply to the restorative area. Turn syringe back two full turns after use for optimal performance the next time.
6. Apply composite layers up to 2mm in thickness and ensure the material is packed tightly within the cavity.
7. Cure each layer for a minimum of 20 seconds. MultiMatch

Composite is designed to be used with either a halogen or LED curing-light with a wavelength of 400-500 nm. See below for recommended curing times.

8. Adjust occlusion as needed. Complete the finishing and polishing using Premier’s Solo Diamond® and Poli-Pro Disk™ composite polishing system or your preferred system.

Recommended curing times:			
Light Type	Intensity (mW/cm2)	Curing Time (sec)	Light, Medium, Dark* (Incremental depth, mm)
Halogen (Ellipse 2 or similar)	650-1000 or Below 1000	20	2.0
LED (Demi Ultra or similar)	1100 – 1300 or above 1000	20	2.0

* Consider additional curing time for dark shade

Cleaning:

Unit Dose Capsules: Capsules are single patient use. Do not reuse Unit Dose Capsules.

Composite Syringes: To prevent syringes from getting contaminated, do not directly dispense intraorally. Use a protective plastic sheath barrier on the syringe. Do not reuse and dispose if it becomes contaminated.

Storage:

Replace the syringe cap after each use to prevent material from hardening within the syringe.

Product shall be stored at temperatures between: 10 - 24°C (50 - 75°F).

Avoid direct exposure to light and heat.

Shelf Life:

MultiMatch Composite has an expiration date of 2 years (24 months) from the date of manufacturing.

Do not use after product has expired. See expiry date on the product label.

Disposal:












For disposal, always follow Federal or laws applicable to the jurisdiction.

For Further Information:

To obtain SDS or IFU, visit premierdentalco.com or call Premier at 610-239-6000.

Symbol Meaning

A full explanation of symbols used on Premier® Dental packaging and literature is located at premierdentalco.com/symbol-glossary

Symbols	Symbol Meaning
	Part Number
	Expiry Date
	Date and Country of Manufacture
	Manufacturer
	Batch number
	Caution: See instructions for use
	The upper and lower limits of temperature of use, storage and transportation
	Irritant: An immediate skin, eye or respiratory tract irritant
Rx ONLY	CAUTION: U.S. Federal law restricts this device to sale by or on the order of a physician
	Consult instructions for use
	Keep away from sunlight
	Single Use