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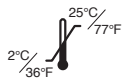
DENTAL LIGHT-CURED RESTORATIVE COMPOSITE

CLEARFIL MAJESTY™ ES Flow Universal



ENGLISH INSTRUCTIONS FOR USE

I. INTRODUCTION

CLEARFIL MAJESTY ES Flow Universal is an intra-oral, light-cure, flowable, radiopaque restorative material which provides accurate color matching, high polishability and excellent physical properties, making it ideal for both anterior and posterior restorations (including the occlusal surface). It shows colour stability and has radiopacity equal to or greater than 1 mm aluminum, and is classified as a Type 1 and Class 2 (Group 1) material by ISO 4049. In addition, it is classified as a Type 2 and Class 2 (Group 1) material by ISO 4049 when using for cementation. The general clinical benefit of this product is to restore tooth function for the following INDICATIONS FOR USE.

II. INDICATIONS FOR USE

CLEARFIL MAJESTY ES Flow Universal is indicated for the following restorative applications:

[1] Direct restorations for all cavity classes, cervical lesions (e.g. root surface caries, v-shape defects), tooth wear, and tooth erosion
[2] Cavity base / liner
[3] Correction of tooth position and tooth shape (e.g. diastema closure, tooth malformation)
[4] Intraoral repair of fractured restorations
[5] Cementation of ceramic and composite inlays, onlays and veneers with less than 2 mm thickness

III. CONTRAINDICATIONS

Patients with a history of hypersensitivity to methacrylate monomers

IV. INCOMPATIBILITIES

Do not use eugenol-containing materials for pulp protection or temporary sealing, since the eugenol can retard the curing process.

V. PRECAUTIONS

1. Safety precautions

1. This product contains substances that may cause allergic reactions. Avoid use of the product in patients with known allergies to methacrylate monomers or any other components.
2. If the patient demonstrates a hypersensitivity reaction, such as rash, eczema, features of inflammation, ulcer, swelling, itching or numbness, discontinue use of the product and seek medical attention.
3. Wear gloves or take other appropriate protective measures to prevent the occurrence of hypersensitivity that may result from contact with methacrylate monomers or any other components.
4. Exercise 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 them in the event of splashing material.
5. If the product comes in contact with human body tissues, take the following actions:
   <If the product gets in the eye>
   Immediately wash the eye with copious amounts of water and consult a physician.
   <If the product comes in contact with the skin or the oral mucosa>
   Immediately wipe the area with a cotton pellet or a gauze pad moistened with alcohol, and rinse with copious amounts of water.
6. Exercise caution to prevent the patient from accidentally swallowing the product.
7. The needle tip is single use only. Do not reuse the needle tip to prevent cross-contamination. Discard it after use.
8. If the instruments associated with this product are damaged, use caution and protect yourself; immediately discontinue use.
9. Dispose of this product as a medical waste to prevent infection. The needle tip must be disposed of after covering the tip of the needle to prevent injury.

2. Handling and manipulation precautions

【CLEARFIL MAJESTY ES Flow Universal】

1. The product must not be used for any purposes other than specified in [II.INDICATIONS FOR USE].
2. The use of this product is restricted to dental professionals.
3. Amalgam or other lining materials remaining in the cavity will prevent the passage of light and the polymerization of the product. Completely remove any lining material when preparing the cavity.
4. When light-curing the product, note the depth of cure in this Instructions for Use.
5. Use a pulp capping agent in a cavity close to the pulp or in the event of accidental pulp exposure.
6. Use a rubber dam to prevent contamination and to control moisture.
7. Do not mix the product with other materials. The mixed materials may cause a change in physical properties, including a possible decrease in the expected results.
8. Before wiping the residual paste adhering to the needle tip or the junction of the syringe with an alcohol gauze pad, squeeze the pad to remove excess alcohol. Use of excessive alcohol in the gauze pad can cause penetration of alcohol into the tip and dilute the paste. In such cases, it may cause decrease in physical properties from the expected results.
9. When attaching the needle tip, turn the needle tip clockwise and attach it securely, thereby preventing paste from leaking at the junction of the needle tip and the syringe.
10. When attaching the needle tip, make sure there is no residual paste at the junction of the syringe, which could cause the needle tip to fall off.
11. The paste contains a light-cure catalyst that is highly photo-reactive. During use, adjust the angle and/or distance of the dental light or loupe light to reduce the intensity of light entering the oral cavity, in order to prevent premature polymerization of the paste. Ambient light may also affect the setting of the paste. LED light sources may especially result in faster setting times than that of traditional lights.
12. After the paste has been dispensed, the syringe should be capped securely as soon as possible to prevent the paste from hardening by ambient light, and to prevent foreign matters from entering the syringe.
13. Do not use the product as a provisional cement.
14. Excess paste can be removed after tack light-curing it for 1 second. When removing the excess paste, hold the restorationin place to avoid the possibility of lifting the restoration, since there could be some insufficiently cured resin paste.
15. When using for cementation, only use the product for restorations that are sufficiently translucent and have an adequate thickness (2 mm or less).
16. To expel air from the Needle tip nozzle and prevent to mix air bubbles to the paste, set the nozzle upward and push the plunger slowly (outside of the patient's mouth) until the paste reaches the nozzle.

【Dental light-curing unit】

1. Do not look directly at the light source. Protective glasses are recommended.
2. Low light intensity causes poor adhesion. Check the lamp for service life and the dental curing light guide tip to ensure it is not contaminated. It is advisable to check the dental curing light intensity using an appropriate light evaluating device at appropriate intervals.
3. 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 has to be light-cured, it is advisable to divide the area into several sections and light-cure each section separately.
4. Check the conditions required to cure the paste by referring to the light-curing times listed in this instructions for use before using the product.

3. Storage precautions

1. The product must be used by the expiration date indicated on the package.
2. The product must be stored at 2-25°C/ 36-77°F when not in use.
3. When the product is stored in the refrigerator, it should be left at room temperature for more than 15 minutes before each use.
4. The product must be kept away from extreme heat or direct sunlight.
5. The product must be stored in a proper place where only dental practitioners can access.

VI. SHADE SYSTEM AND COMPONENTS

1. Shades

CLEARFIL MAJESTY ES Flow Universal is available the following shades. These shades are designed to cover all cavity classes with shades as shown in Table 1.

Low：U, UD
Super Low：U, UD
High：U, UD

2. Components

Main contents

1) CLEARFIL MAJESTY ES Flow Universal
2) Accessories
   • CLEARFIL MAJESTY ES Flow　Needle tip (N)

Please see the outside of the package for detailed contents and quantity of each component.

3. Ingredients

Ingredients ≥ 1% by mass according to ISO 4049, and other ingredients:

Silanated barium glass filler/
Hydrophobic aromatic dimethacrylate/
Triethyleneglycol dimethacrylate (TEGDMA)/Silanated silica filler/
dl-Camphorquinone/Initiators/Accelerators

[NOTE]
The total amount of inorganic filler is from 51 vol% to 64 vol%. The particle size of inorganic fillers ranges from 0.18 μm to 3.5 μm.

VII. CLINICAL PROCEDURES

A. Standard procedure I (INDICATIONS FOR USE [1] to [3])

[1] Direct restorations for all cavity classes, cervical lesions (e.g. root surface caries, v-shape defects), tooth wear, and tooth erosion
[2] Cavity base / liner
[3] Correction of tooth position and tooth shape (e.g. diastema closure, tooth malformation)

A-1. Shade selection

Clean the tooth with pumice and water to remove surface stains,then select the appropriate shade using the CLEARFIL MAJESTYES-2 shade guide or VITA Classical A1-D4 shade guide. Select the shade depending on cavity class as shown in Table 1.
For example, if the cavity class is "II" and the shade is "C2", then select “U” shade.

Table 1

Shade / Cavity Class	A1 (B1, B2)	A2 (D2, C1)	A3 (C2, D4, D3)	A3.5 (B3, B4)	A4 (C3, C4)
I	U				
II					
III	U			UD	
IV					
V					

A-2. Syringe preparation

Remove the cap from the selected syringe and attach a needle tip securely.
Cover the entire syringe with a disposable barrier (e.g. a poly bag) to prevent saliva and blood contamination.
Disinfect the syringe by wiping with an absorbent gauze pad with alcohol both before and after use.

A-3. Isolation and 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.

A-4. Cavity preparations

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

A-5. Pulp protection

Any actual or near pulp exposure can be covered with a hard setting calcium hydroxide material or other indicated material. Do not use eugenol material for pulp protection.

A-6. Tooth surface treatment and bonding

Tooth surface treatment and bonding should be performed according to the Instructions for Use of the bonding system (e.g. CLEARFIL SE BOND, CLEARFIL SE BOND 2 or universal bond manufactured by Kuraray Noritake Dental Inc. (Kuraray's universal bond, e.g. CLEARFIL Universal Bond Quick or CLEARFIL TRI-S BOND Universal Quick)).

A-7. Placement and light-curing of CLEARFIL MAJESTY ES Flow Universal

Place the chosen shade of the paste into the cavity and light-cure with a dental curing unit. Depending on the depth of cure, incremental curing may be required. Refer to Table 2 for the relationship between curing time and depth of cure with a visible light source. When using the product for a base or liner, the paste can be placed and light-cured, then followed by the placing of a light-cure composite resin(e.g. CLEARFIL AP-X, CLEARFIL MAJESTY ES-2, CLEARFIL AP-X ES-2 or CLEARFIL MAJESTY Posterior).

Table 2: Relationship between curing time and depth of cure for type of light source.

Type of light source (Light intensity)	Curing time	Depth of cure
High-intensity BLUE LED* (More than 1500 mW/cm^2)	Twice for 3 or 5 sec.	2.0 mm
Middle-intensity BLUE LED* (1100-1400 mW/cm^2)	10 sec.	
Low-intensity BLUE LED* (800-1000 mW/cm^2)	20 sec.	
High-intensity Halogen lamp (More than 800 mW/cm^2)	10 sec.	
Low-intensity Halogen lamp (400-700 mW/cm^2)	20 sec.	

The effective wavelength range of each dental curing unit must be 400 - 515 nm.
*Peak of emission spectrum: 450 - 480 nm

A-8. Finishing

Contour the restoration and adjust the occlusion using a fine diamond point. Polish with silicon rubber points or polishing discs in the usual manner.

B. Standard procedure II (INDICATIONS FOR USE [4])

[4] Intraoral repair of fractured restorations

B-1. Shade taking and syringe preparation

Follow the same procedure described in "A-1" and "A-2".

B-2. Preparation of fractured surfaces

If necessary, bevel the margin with a fine diamond bur. Then follow the surface treatment procedures of the fractured area depending on the surface material according to the instructions for use of the bonding agent, silane coupling agent or metal adhesive primer.

B-3. Placement and light-curing of CLEARFIL MAJESTY ES Flow Universal

3-1. The application of an opaque resin (e.g. CLEARFIL ST OPAQUER) at the fractured surfaces as an initial layer is optional. Before application, refer to its instructions for use.

3-2. Place the chosen shade of the paste onto the fractured surfaces and light-cure with a dental curing unit. Depending on the depth of cure, incremental curing may be required. Refer to Table 2 "Relationship between curing time and depth of cure for type of light source" in section "A-7".

B-4. Finishing

Follow the same procedure described in "A-8".

C. Standard procedure III (INDICATIONS FOR USE [5])

[5] Cementation of ceramic and composite inlays, onlays and veneers with less than 2 mm thickness

C-1. Cleaning the prepared tooth

When cementing to the prepared tooth, remove the temporary sealing material and temporary cement in the usual manner; clean the cavity using moisture control. Trial fit the prosthetic restoration to check its fit on the prepared tooth, as necessary.

C-2. Treatment of the sufficiently translucent restoration

Follow the Instructions for Use of CLEARFIL CERAMIC PRIMER PLUS.

C-3. Treatment of tooth preparation

Tooth surface treatment and bonding should be performed according to the Instructions for Use of the bonding system used (e.g.Kuraray's universal bond).
[NOTE]
It is necessary to light-cure the bonding agent before cementing. Refer to the light-curing time in the Instructions for Use.

C-4. Syringe preparation

Select the suitable shade and follow the same procedure described in "A-2".

C-5. Cementing the prosthetic restoration

(1) Apply the paste over the entire adherent surface of the prosthetic restoration or the entire prepared tooth.
(2) Place the prosthetic restoration on the prepared tooth.

C-6. Removing the excess paste

Remove any excess paste using either of the following two methods:
Removing method for tack-cured excess paste:
Light-cure any excess paste in several spots for 1 second. Holding the prosthetic restoration in position, remove the tack-cured excess paste using a dental explorer. It is advisable to determine in advance the light-curing time of the excess paste by light-curing some paste on a mixing pad.
Removing method using a small brush:
Any excess paste remaining at the margins can be removed with a small brush. Light-cure the margins of the prosthetic restoration using the dental curing unit. Confirm the curing time by referencing Table 3.
[It is possible to cover the margins with a protective gel (e.g. PANAVIA F 2.0 OXYGUARD II) according to the Instructions for Use.]

C-7. Final curing

Light-cure the entire surface of the prosthetic restoration using the dental curing unit. It is advisable to light-cure the margins well for a strong bond. Please confirm the curing time by referencing the following Table 3:

Table 3: Light-curing time for cementation procedure

Type of light source (Light intensity)	Curing time
High-intensity BLUE LED* (More than 1500 mW/cm^2)	Twice for 3 or 5 sec.
BLUE LED* (800-1400 mW/cm^2)	10 sec.
High-intensity Halogen lamp (More than 800 mW/cm^2)	10 sec.
Low-intensity Halogen lamp (400-700 mW/cm^2)	20 sec.

The effective wavelength range of each dental curing unit must be 400 - 515 nm.
*Peak of emission spectrum: 450 - 480 nm

C-8. Polishing the margins

Polish the margins using appropriate instruments for the polishing of composite resins.

[WARRANTY]

Kuraray Noritake Dental Inc. will replace any product that is proven to be defective. Kuraray Noritake Dental Inc. 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.

[NOTE]

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