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DENTAL LIGHT-CURED RESTORATIVE COMPOSITE

CLEARFIL™ AP-X Esthetics Flow

ENGLISH INSTRUCTIONS FOR USE

I. INTRODUCTION

CLEARFIL AP-X Esthetics Flow is a 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. CLEARFIL AP-X Esthetics Flow can be used alone or together with CLEARFIL AP-X or CLEARFIL AP-X Esthetics.

II. INDICATIONS

CLEARFIL AP-X Esthetics Flow 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

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. 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 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. Use caution to prevent the patient from accidentally swallowing the product.
7. 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.

2. Handling and manipulation precautions

[CLEARFIL AP-X Esthetics Flow]

1. The product must not be used for any purposes other than specified in [II.INDICATIONS].
2. The use of this product is restricted to licensed 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 composite materials. The mixed materials may cause decrease in physical properties from 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 it 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 with 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 the restoration, adjust the angle and/or distance of the dental light or loupe light to reduce the intensity of light entering the oral cavity to prevent premature polymerization of the paste.
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.

[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 be free from contamination. 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 AP-X Esthetics Flow is available in the following 12 shades:

A1, A2, A3, A3.5, A4, KA6, B1, B2, XW, W, A2D, A3D

2. Components

Main contents

- 1) CLEARFIL AP-X Esthetics Flow
- 2) Accessories
 - Needle tip (N)

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

3. Ingredients

Principal ingredients:

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

[NOTE]

The total amount of inorganic filler is from 48 vol% to 62 vol%. The particle size of inorganic fillers ranges from 0.18 µm to 3.5 µm.

VII. CLINICAL PROCEDURES

A. Standard procedure I (Indications [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 taking

Clean the tooth with pumice and water to remove surface stains, then select the appropriate shade using the CLEARFIL AP-X ES-2 shade guide. VITA Classical shade guide can also be used for A1, A2, A3, A3.5, A4, B1 and B2. If indicated, two or more shades of this product can be used for restoring the tooth.

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 materials. Do not use eugenol materials 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 used (e.g. CLEARFIL TRI-S BOND or CLEARFIL SE BOND).

A-7. Placement and light-curing of CLEARFIL AP-X Esthetics Flow

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 the following table 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 and then followed by the placing of a light-cure composite resin(e.g. CLEARFIL AP-X or CLEARFIL AP-X Esthetics).

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

Type of light source (Light intensity)	Curing time	Shade and depth of cure	
		A1, A2, A3, A3.5, A4, B1, B2, XW, W	KA6, A2D, A3D
High-intensity BLUE LED* (More than1500 mW/cm ²)	Twice for 3 or 5 sec.	2.0 mm	1.5 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 [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 AP-X Esthetics Flow

- 3-1. The application of an opaque resin 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 the Table “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”.

[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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