

# Fusion Ultra D/C Universal

Dual Cure Self Adhesive Universal Resin Cement



**Product Description :** Fusion Ultra D/C Universal Automix is a dual-cure (light- and/or self-cure), radiopaque self-adhesive resin cement designed for cementation of crowns, bridges, inlays, onlays and posts. It is supplied in an automix delivery system which can mix equal amounts of two components.

**Composition :**

**Base :** Bis-phenol A Diglycidylmethacrylate (Bis-GMA), Triethylene Glycol Dimethacrylate (TEGDMA), Silanated Barium Glass Filler, Silanated Amorphous Silica, BHT, Curing Agents and Stabilizers.

**Catalyst :** Bis-phenol A Diglycidylmethacrylate (Bis-GMA), Triethylene Glycol Dimethacrylate (TEGDMA), Pigments, Silanated Barium glass filler, Silanated Amorphous Silica, Curing Agents and Stabilizers.

**Intended purpose/Intended use:** It is intended to be used for cementation of indirect restorations.

**Indications for use :**

1. Cementation of crowns, bridges, inlays and onlays.
2. Cementation of prosthetic restorations on implant abutments and frames.
3. Cementation of adhesion bridges and splints.
4. Cementation of posts and cores.

**POSSIBLE SIDE EFFECTS :**

The oral mucosal membrane may turn whitish when contacted by the product due to the coagulation of protein. This is usually a temporary phenomenon that will disappear in a few days. Instruct patients to avoid irritating the affected area while brushing.

**Handling and manipulation precautions :**

- a. Use a rubber dam to prevent contamination and to control moisture.
- b. Use a pulp capping agent in a cavity close to the pulp or in the event of accidental pulp exposure.
- c. Placing the prosthetic restoration should be completed within 40 seconds after the insertion of the paste into the cavity. Failure to do so will cause premature polymerization of the paste, due to the effects of temperature and/ or water in the oral cavity.
- d. Make sure to dispense an equal amount of Base & Catalyst Paste for mixing.
- e. Do not immerse the syringe into a disinfecting solution.
- f. Replace the syringe cap in the proper direction as soon as possible after the paste has been dispensed from the syringe.

**Instructions for use:**

**Mixing :** The syringe dispenses both Base & Catalyst Paste to a ratio of 1:1. Dispense of required volume on to a mixing pad and using the provided spatula mix the paste for 15-20 seconds or until a homogeneous consistency is obtained.

**Using the intraoral delivery tip :**

For intraoral delivery as in the case of post cementation, use the intraoral delivery tip.

**Pretreatment of restoratives : table 1**

S. No.	Restoration Materials	Pretreatment
1.	Metal Metal oxide ceramics Hybrid ceramics Indirect composites Composites	Sandblast with 30 - 50 µm alumina powder at an air pressure of 0.4MPa
2.	Glass fibre post	Do not pretreat
3.	Conventional ceramics	Etch using 37% phosphoric acid (Actino Gel/Microgel) and pretreat using silane (Silane X)
4.	Tooth	Isolate and clean

**Applications:**

For Cementation of crowns, bridges and onlays made of ceramics, hybrid ceramics composite resin or metal:

- a. Pretreat the surface as per table 1.
- b. Apply the mixed cement to the restoration.
- c. Within 40 seconds, Place the restoration in place.
- d. Light cure for 10 seconds or chemical cure for 3-5 minutes, before removing the excess cement.
- e. Maintain isolation for 10 minutes.

For Cementation of metal cores, Resin cores, metal posts or glass fiber posts:

- a. Place the mixed resin cement into the endodontic space using the intraoral delivery tip
- b. Quickly place the post into position and vibrate slightly to avoid air bubbles
- c. Light cure for 10 seconds or chemically cure for 3-5 minutes
- d. Apply bonding agent and proceed with core build up

The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

**Warnings :**

This product will adhere to metal instruments. Remove excess material from the instrument immediately after using. The cement contains certain methacrylates and other ingredients which may cause irritation or sensitivity in some individuals. If contact occurs with skin, immediately wash with soap and water. Improper use may result in allergic reaction or skin and tissue irritation. If this occurs, discontinue use of this product. Protective gloves and eye wear should be worn while handling this product. If contact occurs with eye. Flush immediately with large volumes of water and seek medical attention immediately. Do not expose materials to elevated temperatures or intense light. Do not store in the vicinity of alcohol based materials. Do not remove or reverse the syringe caps as this may promote polymerization.

**Precautions:** Use of zinc oxide, eugenol containing materials must be avoided. Do not use a lentulo spiral to insert the paste into the root canal; this can accelerate the polymerization of the paste beyond the desirable limits. Avoid direct sunlight or surgery operating lights, otherwise the paste inside the tip may harden, leading to a shortened working time.

**Contraindications :**

1. Patients with a history of hypersensitivity to methacrylate monomers.
2. Do not use eugenol-containing materials prior to the use of Fusion Ultra D/C Universal, since the eugenol can retard the curing process.
3. Do not use hemostatic agents containing ferric compounds since these materials may impair adhesion and may cause discoloration of the tooth margin.
4. Do not use a hydrogen peroxide solution for cleaning cavities as it might weaken bonding.

**Storage Conditions :** Store at temperature between 10°C(50°F) to 24°C(75°F). Close the cap carefully after use. Keep away from moisture. Shelf life not affected after opening if stored in a cool dry place.

**Shelf Life :**

2 years from the date of manufacturing.

**Presentation :**

Ref: 30007

1 x 9 g Automix Syringe, 10 x Mixing Tips, 10 x Intraoral Delivery Tips.

**Disposal Conditions :** To be disposed off based on the prevailing rules of the country in which it is used.

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UDI Symbol for "UNIQUE DEVICE IDENTIFIER" Symbol for "CORROSIVE"

LOT Symbol for "BATCH CODE" Symbol for "USE-BY DATE" Symbol for "NON STERILE" Symbol for "KEEP DRY"

Symbol for "CAUTION" Symbol for "CONSULT INSTRUCTION FOR USE" Symbol for "CATALOGUE NUMBER"

Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION"

Symbol for "DO NOT USE IF PACKAGE IS DAMAGE" Symbol for "KEEP OUT OF THE REACH OF CHILDREN" Symbol for "MANUFACTURER"

Symbol for "TEMPERATURE LIMIT" Symbol for "KEEP AWAY FROM SUNLIGHT" Symbol for "MEDICAL DEVICE"

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding. For feedback, complaints and reporting of unexpected events contact customer care.