

# FUSION SELF LUTE

## SELF CURING / CHEMICAL CURING RESIN BASED LUTING CEMENT

### Product Description :

Fusion Self Lute is a Self Curing/Chemical Curing polymer resin based luting cement for permanent cementation of crowns & bridges.

### Composition :

**Base Paste :** Bisphenol A Glycidyl Methacrylate, Ethoxlated Bisphenol A Dimethacrylate, Triethylene Glycol Dimethacrylate, Silanated Barium Glass Powder, Amorphous Silica, Curing Agents and Stabilizer.

**Catalyst Paste :** Bisphenol A Glycidyl Methacrylate, Ethoxlated Bisphenol A Dimethacrylate, Triethylene Glycol Dimethacrylate, Silanated Barium Glass Powder, Amorphous Silica, Curing Agent and Stabilizer, Pigment

**Intended purpose/Intended use :** It is used for permanent cementation of indirect restorations.

**Indications for use :** Cementation of indirect restoration (Inlays, crowns bridges, posts) made of :

- ◆ Metal and metal ceramics, reinforced composite.
- ◆ All ceramics
- ◆ Composites.

**Instructions for use :** Dispense the material from the syringe through auto mix tip. The initial set will occur in 2:00-2:30(min:sec) with a final set at 3-4 minutes.

**1. Metal to Enamel / Dentin :** Metal restorations to tooth structure-crowns, inlays, bridges, and posts including Maryland bridges. After try-in, sandblast each side of the restoration. Using a metal primer of your choice, treat the metal exposed to the paste. Clean tooth with non-fluoridated prophyl paste or pumice. To prepare tooth for bonding, use a universal dentin / enamel bonding system. Mix equal amounts of catalyst and base pastes and use a plastic instrument or injection system to place in restoration. Avoid trapping air bubbles. Seat Restoration on tooth and hold in place until paste reaches initial set (about 2:00-2:30 minutes). Use a scaler or explorer to remove excess cement immediately upon initial set. It is important to wait until the final set to remove excess cement.

**2. Metal to Metal :** Implant prosthesis or crown on post. Sandblast all external metal surfaces to be exposed to paste. Rough intra-oral metal with a micro-etcher or bur. Using a metal primer of your choice, treat the metal exposed to the paste. Clean posts or Abutments with non-fluoridated prophyl paste or pumice. Mix equal amounts of catalyst and base pastes and use a plastic instrument or injection system to place in restoration. Avoid trapping air bubbles. Seat restoration on tooth and hold in place until paste reaches initial set (about 2:00-2:30 minutes). Use scaler or explorer to remove excess cement immediately upon initial set. It is important to wait until final set to remove excess cement.

**3. Ceramic Restorations to Teeth (Porcelain Veneers, In-lays, On-lays)** After try-in, etch ceramic restoration and place in acetone or ethanol in ultrasonic cleaner for 1-2 minutes. Place silanating agent on internal or porcelain restoration. Clean tooth with non-fluoridated prophyl paste or pumice. To prepare tooth for bonding, use a universal dentin / enamel bonding system. Mix equal amounts of catalyst and base pastes and use a plastic instrument or injection system to place in Restoration. Avoid trapping air bubbles. Seat restoration on tooth and hold in place until paste reaches initial set (about 2:00-2:30 minutes) use scaler or explorer to remove excess cement immediately upon initial set. It is not important to wait until final set to remove excess cement. 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 it. ◆ 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 the use of 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 :

1. Do not use eugenol containing material and hydrogen peroxide since they might alter the curing process.
2. Allow the product to reach the room temperature before use.
3. Tightly close the cap after each use and store as recommended. (Refer to storage conditions in IFU).
4. Do not use this product for any purposes other than specifically outlined in the indications for use.
5. Paste must be applied only on the treated restoration surface (Do not apply on the tooth directly).

**Contraindications :** Do not use in patients, if allergic to any of its components.

### 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 date of manufacturing.

### Presentation :

Ref : 30008

**Intro Pack :** 1 x 9g Automix Syringe, 10 x Automix 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"

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

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

**EC REP** Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION"

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

**TEMPERATURE LIMIT** Symbol for "TEMPERATURE LIMIT" **KEEP AWAY FROM SUNLIGHT** Symbol for "KEEP AWAY FROM SUNLIGHT" **MD** 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.