3M ESPE RelyX[™] Luting Plus Luting Cement

ENGLISH

Description of Product

RelyX Luting Plus, manufactured by 3M ESPE, is a self-curing, radiopaque, fluoride-releasing, resin-modified glass ionomer luting cement. The cement consists of a base and catalyst paste packaged in the 3M ESPE Clicker[™] Dispensing System. The paste/paste formulation offers greater convenience over the traditional powder/liquid cement systems. The cement is available in a white shade.

Indications For Use

Cementation of porcelain-fused-to-metal (PFM) crowns and bridges Cementation of metal crowns, bridges, inlays and onlays (including prefabricated provisional metal crowns)

Cementation of all-alumina or all-zirconia strengthened restorations (i.e. 3M ESPE Lava[™] All-Ceramic System or Procera[™] AllCeram restorations)

Cementation of prefabricated or cast posts

Cementation of orthodontic appliances

Precautions

RelyX Luting Plus cement contains acrylate resins including HEMA (2-hydroxyethylmethacrylate). Avoid use of this product on patients with known acrylate allergies. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured resins. Use of protective gloves and a no-touch technique is recommended. If skin contact occurs, wash skin with soap and water. Acrylates may penetrate commonly used gloves. If cement contacts glove, remove and discard glove, wash hands immediately with soap and water and then re glove. If accidental contact with eyes or prolonged contact with oral soft tissue occurs, flush with large amounts of water. If irritation persists, consult a physician.

Pulp Protection

Cover areas in close proximity to the pulp by applying small amounts of hard-setting calcium

hydroxide material (e.g., Alkaliner[™] MiniTip[™] Calcium Hydroxide Liner, manufactured by 3M ESPE) or resin-modified glass ionomer liner (e.g., Vitrebond[™] Light Cure Glass Ionomer Liner/Base, manufactured by 3M ESPE) prior to taking an impression for the final restoration.

Preparation

• Remove the temporary restoration and thoroughly clean the preparation of any temporary cement residue using an oil-free pumice paste.

• Rinse the prepared tooth or cavity with a water spray, and dry with air, cotton, or a paper tip. Leave tooth surface moist. **Do not overdry**.

• Try in final restoration and check for fit. Adjust if necessary.

• Thoroughly clean the bonding surface of the restoration.

• Keep area isolated from blood and saliva contamination during cementation process.

Dispensing and Application

• For first time use, remove the Clicker dispenser from the foil package. Discard foil.

• Remove cap from the Clicker dispenser by holding down the cap lever and sliding the cap off of the dispenser.

• For first time use from a new cartridge, dispense a small amount of material to ensure even dispensing. Discard this material.

• Fully depress clicker lever to dispense "1 Click" of cement onto mix pad. Allow paste to fully extrude, then release lever. Repeat dispensing process for additional material. The paste is automatically dispensed in equal volumes. (The actual weight ratio dispensed is 1.3:1)

• Note: Dispense and mix cement immediately prior to use to avoid water evaporation and drying out of the cement pastes.

• Wipe the dispenser tips clean with gauze to prevent cross contamination of the two pastes.

• Replace cap by sliding onto dispenser until securely latched and an audible click is heard.

• Using a plastic or metal cement spatula, mix the pastes together for 20 seconds until a uniform color is achieved. Avoid the incorporation of air bubbles.

• The working time of the mixed cement is 2.5 minutes at 23°C/73°F. Higher temperatures

and longer mix times may shorten the working time. Lower temperatures will lengthen the working time.

• Apply a thin layer of cement to the inside surface of the restoration. The cement may also be applied directly to the tooth surface for inlay/onlay restorations.

• Seat the restoration with light pressure. Maintain light pressure on the restoration to hold proper positioning during setting process.

Clean Up and Finishing

• Remove excess cement when it has reached a waxy stage after 2 minutes from placement in the mouth. Use a suitable instrument (e.g. scaler, explorer) for this process.

• Finish restoration and check occlusion when material has completely set after 5 minutes from placement in the mouth.

Storage and Use

• Shelf life at room temperature of an unopened foil package is 24 months. Expiration date is noted on package.

• Keep dispenser in foil package until time for initial use. Once the foil pouch is opened, the shelf life of the cement in the Clicker dispenser is 6 months. Refrigeration of material can extend shelf life. Allow material to come to room temperature prior to use.

• RelyX Luting Plus cement is designed to be used at room temperature of 21-24°C or 70-75°F.

• Store Clicker paste dispensers in a cool environment. Do not expose the cement to elevated temperatures. Do not allow the pastes to dry out. Store with cap securely attached to the dispenser.

• The Clicker dispenser can be cleaned and disinfected by following standard infection control practices for surfaces that have been touched.

No person is authorized to provide any information which deviates from the information provided in this instruction sheet.

Warranty

3M ESPE warrants this product will be free from defects in material and manufacture. 3M ESPE MAKES NO OTHER WARRANTIES INCLUDING ANY IMPLIED WARRANTY OF MERCHANTABILITY OR FITNESS FOR A PARTICULAR PURPOSE. User is responsible for determining the suitability of the product for user's application. If this product is defective within the warranty period, your exclusive remedy and 3M ESPE's sole obligation shall be repair or replacement of the 3M ESPE product.

Limitation of Liability

Except where prohibited by law, 3M ESPE will not be liable for any loss or damage arising from this product, whether direct, indirect, special, incidental or consequential, regardless of the theory asserted, including warranty, contract, negligence or strict liability.

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