

3M ESPE

Vitremer™

Core Buildup/Restorative

ENGLISH

General Information

The Vitremer™ core buildup/restorative system, manufactured by 3M ESPE, is comprised of shaded glass ionomer powders, the glass ionomer liquid, the primer and a finishing gloss. Vitremer core buildup/restorative is a two part, powder/liquid composition. The powder is a radiopaque, fluoroaluminosilicate glass. The liquid is a light sensitive, aqueous solution of a modified polyalkenoic acid. Vitremer core buildup/restorative provides the major benefits of glass ionomer cements -adhesion to tooth structure, fluoride release and biocompatibility.

Vitremer core buildup/restorative will set by exposure to visible light. It also has two self-curing mechanisms to provide a relatively rapid set where light does not penetrate and thus allows for bulk placement.

Vitremer core buildup/restorative is recommended for use with Vitremer primer, a one part, visible light cure cavity primer. Its function is to adequately wet the bonding surfaces to facilitate adhesion of the glass ionomer. In use, the primer is dispensed, applied, air dried and light cured. Adequately air drying and then light curing the primer separately before placement of the glass ionomer maximizes adhesion of the glass ionomer to tooth structure particularly when the glass ionomer is placed in bulk.

To maximize the final esthetics of a Vitremer restoration, application of the Vitremer finishing gloss is recommended. The finishing gloss is a single component, light cure, unfilled dental resin.

Indications

The Vitremer core buildup/restorative system is indicated for:

- Class III and Class V restorations
- Restoration of cervical erosion/abrasion lesions.
- Restoration of root caries lesions.
- Class I and Class II restorations in primary teeth.
- Temporary repair of fractured teeth.
- Filling defects and undercut areas in crown preparations.
- As a core buildup where at least half the coronal tooth structure is remaining to provide structural support for the crown.
- Laminate/Sandwich Restorations.
- Interim Restoration.

Precautionary Information for Patients:

These products contain substances that may cause an allergic reaction by skin contact in certain individuals. Avoid use of this product in patients with known acrylate allergies. If prolonged contact with oral soft tissue occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed, remove the product if necessary and discontinue future use of the product.

Precautionary Information for Dental Personnel:

These products contain substances that may cause an allergic reaction by skin contact in certain individuals. To reduce the risk of allergic response, minimize exposure to these materials. In particular, avoid exposure to uncured product. If skin contact occurs, wash skin with soap and water. Use of protective gloves and a no-touch technique is recommended. Acrylates may penetrate commonly used gloves. If product contacts glove remove and discard glove, wash hands immediately with soap and water and then re-glove. If allergic reaction occurs, seek medical attention as needed.

3M ESPE MSDSs can be obtained from www.3MESPE.com or contact your local subsidiary.

Hazardous Information: Vitremer Primer is a flammable material.

Instructions for Use

I. As an Esthetic Restorative and as a Core Buildup

- 1. Shade selection.** For esthetic restorations, select the desired powder shade using the Vitremer shade guide. For core buildups, the blue shaded powder will provide contrasting color to tooth structure and is recommended for this application. The other Vitremer powder shades may also be used for core buildups if desired.
- 2. Isolation.** Rubber dam is the preferred method of isolation. Gingival retraction and cotton rolls may also be used.
- 3. Cavity preparation.** Remove caries. Prepare cavity with minimal tooth reduction and with rounded internal line angles. Finish cavosurface margin to a butt joint. If no preparation is required, clean surfaces to be restored with a plain pumice/water slurry. Rinse and dry cavity.

- 4. Retention.** For core buildups, multiple missing cusps may require placement of pins for retention.
- 5. Pulp protection.** If there is no exposure or near exposure of the pulp, no liner is required. The Vitremer core buildup/restorative system is **not recommended for direct pulp capping.**
- 6. Matrix placement.** Place a matrix appropriate for the restoration if desired.
- 7. Priming.** Dispense a few drops of the Vitremer primer into a well. Using a brush, apply primer for about 30 seconds to enamel and dentin surfaces to be bonded. Replenish primer as needed to assure that the surfaces are kept wet with the primer for the recommended application time. For core buildups with pins, apply primer to pins as well.
- 8. Dry the primer** using an air syringe for about 15 seconds. **Do not rinse.** After drying, the primed surfaces will remain shiny in appearance. **Light cure the dried primed surfaces for 20 seconds** using a 3M ESPE curing unit or other dental visible light curing unit of comparable intensity. The light cured surfaces will appear glossy.

Notes:

- By adequately drying and separately light curing the primer, maximum adhesion of the glass ionomer to tooth structure can be obtained.
- The primer is light sensitive and contains alcohol. Minimize ambient light exposure and evaporation by dispensing just prior to use and replacing vial cap immediately after dispensing.
- 9. Dispensing powder and liquid.** The Vitremer powder jars contain protective seals. Remove seal completely before use. Unscrew cap, peel off seal and discard. Replace cap. The standard powder/liquid ratio of 2.5/1 by weight can be obtained with an equal number of level powder scoops and liquid drops. Additional powder may be incorporated to obtain a thicker consistency mix. Two scoops of powder and 2 drops of liquid will provide an adequate amount of material for most esthetic restorations. Four scoops of powder and 4 drops of liquid will provide an adequate amount of material for most core buildups. Using a separate mix for each restoration to be placed is recommended. Shake the jar to fluff the powder before dispensing. Insert the scoop into the jar, overfill it with loosely packed powder and withdraw it against the plastic leveler to remove excess powder and obtain a level scoop. Dispense the desired number of powder scoops onto the mixing pad. To best obtain a proper liquid drop size, hold the Vitremer liquid vial vertically with the dropper tip down and without the tip contacting the mixing pad. Squeeze the vial to dispense the desired number of liquid drops onto the mixing pad.

Notes:

- The glass ionomer powders are sensitive to high humidity. Store with jar caps securely tightened and away from high humidity.
- The glass ionomer liquid is light sensitive. Protect it from ambient light by dispensing just prior to use and replacing vial cap immediately after dispensing.
- 10. Mixing.** Using a cement spatula, mix the powder into the liquid. All of the powder should be incorporated into the liquid within 45 seconds. **Working time of the standard powder/liquid ratio is 3 minutes from the start of mix at a room temperature.** Higher temperatures will shorten working time. Lower temperatures will lengthen working time. Back load a delivery tip by pressing it over the mixed glass ionomer, insert piston flush with the back of the tip and place tip into a 3M ESPE dispenser.
- 11. Placement.** Placement of the material in a dry field is recommended. Syringe the mixed glass ionomer into the cavity keeping the syringe tip immersed in the material to minimize air entrapment. Contour the restoration using a plastic matrix or appropriate placement instrument. For core buildups, syringe the glass ionomer into undercut areas, around pins, around posts and fill the preparation. Condensing the glass ionomer with a damp cotton pledget held with a cotton pliers rather than using a metal plugger can prevent incorporating surface voids in the material.
- 12. Curing.** Light cure the glass ionomer by exposing its entire surface area to 40 seconds of visible light from a 3M ESPE curing unit or other dental visible light curing unit of comparable intensity. **The maximum depth of material for light curing should not exceed 2 mm.** For core buildups where a metal matrix band has been placed, light cure the glass ionomer from the occlusal for 40 seconds.
Self cure set time is 4 minutes from the start of mix at oral cavity temperature. For core buildups, any soft axial areas may be light cured or allowed to self cure following matrix removal.
- 13. Finishing.** Immediately after curing, the glass ionomer restoration can be contoured using conventional rotary instruments under water spray. The Sof-Lex™ disc system, manufactured by 3M ESPE, used wet and Sof-Lex strips, manufactured for 3M ESPE, are recommended for polishing. Immediately after curing, the glass ionomer core buildup can be prepared using conventional rotary instruments with water spray.

Notes:

- The prepared glass ionomer core buildup is compatible with conventional impressioning materials.
- The prepared glass ionomer core buildup should be kept wet with saliva or lubricated to prevent bonding to chemical-cure provisionals.
- The prepared glass ionomer core buildup will not bond with temporary luting cements.

14. Finishing Gloss application. To maximize esthetics, apply the Vitremer finishing gloss to the polished restoration. Rinse and gently dry the restoration. Dispense a drop of the finishing gloss into a clean well or onto a clean mixing pad. Using a brush, apply a coating of the finishing gloss over the glass ionomer restoration and light cure for 20 seconds with a 3M curing unit.

For core buildups, application of the finishing gloss is not necessary.

Note:

- The finishing gloss is a light sensitive material. Protect it from ambient light by dispensing just prior to use and replacing vial cap immediately after dispensing.

II. As a Laminate/Sandwich Technique

Indication: The technique is indicated:

- a. where margins are located partially in dentin or aprismatic enamel as, for example, in deep Class II cavities. For cavities having complete prismatic enamel margins, a bonded composite restoration is preferred.
- b. where cavity design allows for a minimum composite restorative thickness of 2 mm on occlusal surfaces.

Instructions for Use

- 1. Shade selection:** Select desired shade of Z100™ Restorative, manufactured by 3M ESPE.
- 2. Isolation:** Rubber dam is the preferred method of isolation.
- 3. Cavity Preparation:** Prepare cavity with minimal tooth reduction and with rounded internal line angles.
- 4. Matrix placement:** Place matrix and wedge appropriately for the restoration.
- 5. Glass Ionomer Placement**
 - a. **Priming:** Apply Vitremer primer for 30 seconds to dentin and enamel surfaces to be covered by Vitremer Restorative base. Do not rinse. Air dry primer for about 15 seconds. Light Cure for 20 seconds.
 - b. **Dispensing/Mixing:** Dispense an equal number of scoops of Vitremer powder and drops of Vitremer liquid. Mix powder into liquid within 45 seconds. Back load material into delivery tip.
 - c. **Placement:** Syringe Vitremer restorative into prepared cavity. For Class II restorations, extend the restorative base no further than apical to the proximal contact point. Light cure for 40 seconds
 - d. **Refinement:** Loosen matrix. Using a rotary instrument, remove excess Vitremer primer and restorative base from the enamel margins and cavity walls to be bonded subsequently with the adhesive/composite systems.

Note: Omitting this step may lead to decreased bond strength of the adhesive/composite systems.

6. Adhesive System Application

- a. **Etching:** Apply Scotchbond™ etchant, manufactured by 3M ESPE, (35% phosphoric acid gel) to enamel and exposed dentin. Application of etchant to the Vitremer restorative base is not essential but will not adversely affect bonding to its surface. Wait 15 seconds. Rinse for 15 seconds. Air dry for 2 seconds.
- b. **Priming:** Apply Scotchbond Multi-Purpose primer, manufactured by 3M ESPE, to etched enamel, dentin and Vitremer restorative base. Dry gently for 5 seconds.
- c. **Adhesive application:** Apply Scotchbond Multi-Purpose adhesive to primed enamel, dentin and Vitremer restorative base. Light cure all surfaces for 10 seconds.

7. Composite Restorative Placement:

- a. For best results, do not bond buccal and lingual cusps together with a single restorative increment. Place Z100 Restorative in multiple increments. Light cure each increment for 40 seconds.
- b. Finish and polish to complete the restoration.

III. As an Interim Restoration

Indication: Posterior teeth having approximately one-half their coronal structure and number of cusps remaining, may be restored to occlusal function and proximal contact for a period lasting up to 3 months using Vitremer core buildup/restorative. The procedure may be advantageous when a short delay is desired before final restoration. Following the interim period, the restorative material may be prepared as a core buildup or base for final crown coverage or in suitable cases, a laminate or sandwich restoration.

Instructions for Use

- 1. Priming:** Apply Vitremer primer for 30 seconds to dentin and enamel surfaces. Do not rinse. Air dry primer for about 15 seconds. Light cure for 20 seconds.
- 2. Dispensing/Mixing:** Dispense an equal number of scoops of Vitremer powder and drops of Vitremer liquid. Mix powder into liquid within 45 seconds. Back load material into delivery tip.
- 3. Placement:** Syringe restorative into prepared cavity. Incremental placement is not required. Light cure exposed surfaces for 40 seconds.
- 4. Final restoration:** Prepare the restorative as a core buildup or base for final restoration following the interim period.

Storage & Use

1. This product is designed to be stored and used at room temperature. Shelf life at room temperature is 36 months. Ambient temperatures routinely higher than 27°C/80°F, or lower than 10°C/50°F may reduce shelf life. See outer package for expiration date.
2. The glass ionomer primer, liquid and finishing gloss are light sensitive materials. Protect them from ambient light exposure by dispensing just prior to use and replacing vial caps immediately after dispensing.
3. The Vitremer glass ionomer powder is sensitive to high humidity. Store with jar caps securely tightened and away from high humidity. No person is authorized to provide any information which deviates from the information provided in this instruction sheet.
4. Disinfect this product using an intermediate level disinfection process (liquid contact) as recommended by the Centers for Disease Control and endorsed by the American Dental Association. Guidelines for Infection Control in Dental Health-Care Settings – MMWR, December 19, 2003:52(RR-17), Centers for Disease Control and Prevention.

Disposal

See the Material Safety Data Sheet (available at www.3MESPE.com or through your local subsidiary) for disposal information.

Customer Information

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

Caution: U.S. Federal law restricts this device to sale or use on the order of a dental professional.

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.

3M ESPE Customer Care/MSDS Information:
U.S.A. 1-800-634-2249 and Canada 1-888-363-3685.

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