3M ESPE Vitrebond[™] Light Cure Glass Ionomer Liner/Base

ENGLISH

General Information

Vitrebond[™] light cure glass ionomer liner/base, manufactured by 3M[™] ESPE[™], is comprised of a powder and a liquid component. The powder component is a light sensitive fluoro-aluminosilicate glass. The liquid component is a light sensitive polyalkenoic acid. The composition is a true glass ionomer exhibiting the major characteristics of glass ionomer products – it bonds to tooth structure, releases fluoride, and is a biocompatible material. Additionally, Vitrebond liner/base offers the unique combination of a prolonged working time with a very short set time achieved by exposure to light from a dental visible light curing unit. Polymerization by light exposure not only eliminates the set time waiting period common to auto set liners, it also provides enhanced mechanical and physical properties. Vitrebond light cure glass ionomer liner/base is indicated for lining and basing applications under composite, amalgam, ceramic, and metal restorations.

Indications

Vitrebond liner/base is indicated for lining and basing applications under the following restorations:

- Composite
- Amalgam
- Ceramic
- Metal

CONTRAINDICATIONS

Pulp Protection: Vitrebond liner/base is not indicated for direct pulp capping. If a pulp exposure occurs, cover the exposure with a calcium hydroxide material. Place the Vitrebond liner/base over the calcium hydroxide and surrounding dentin to seal and protect the exposure.

PRECAUTIONARY INFORMATION FOR PATIENTS:

This product contains 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:

This product contains 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.

INSTRUCTIONS FOR USE:

- Pulp Protection: Vitrebond liner/base is not indicated for direct pulp capping. If a pulp exposure occurs, cover the exposure with a calcium hydroxide material. Place the Vitrebond liner/base over the calcium hydroxide and surrounding dentin to seal and protect the exposure.
- Dentin Pretreatment: Dentin pretreatment is not recommended. The use of smear layer cleansers such as polyacrylic acid based solutions results in decreased adhesion of the liner/base.

3. Dispensing:

- 3.1. Both the Vitrebond light cure glass ionomer liner/base powder and the liquid are light sensitive. To prevent deactivation by light exposure, protect both from ambient light by replacing jar and vial caps immediately after dispensing and dispense powder and liquid just prior to mixing and placement.
- 3.2. A protective seal has been added to the Vitrebond powder bottle. Remove completely before use: Unscrew cap, peel off seal and discard, replace cap.
- 3.3. 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 one scoop of the powder onto the mixing pad.

- 3.4. To prevent air entrapment in the dropper tip, and to obtain the proper drop size, hold the liquid vial vertically and dispense one drop of the liquid onto the mixing pad. Before capping, hold the vial upright and allow the excess liquid to flow back into the tip to minimize waste.
- 3.5. One level scoop of loosely packed powder and one drop of liquid provide the recommended powder to liquid ratio of 1.4 to 1 by weight. The powder to liquid ratio may be altered to change the viscosity of the mix. Ratios ranging from 1 scoop powder/2 drops liquid to 2 scoops powder/1 drop liquid are acceptable. Mix ratios beyond this range are not recommended.
- 4. Mixing: Use a small cement spatula to rapidly mix (10-15 seconds) all the powder into the liquid. The mixed cement should have a smooth consistency and glossy appearance. Excessive spatulation will shorten working time. To minimize water evaporation and maximize working time, confine spatulation of the powder and liquid to a small area of the mixing pad, about one inch (2.5 cm) diameter.
- 5. Application and Curing: Avoid water and saliva contamination during application and setting of the liner/base. Rubber dam is the best means of isolation. Apply the mixed liner/base to the dentin surfaces of the prepared cavity in a thin layer (1/2mm or less) using a ball applicator or other suitable instrument. The Vitrebond liner/base has a minimum working time of 2 minutes 40 seconds at room temperature. Higher temperatures will shorten working time. Cure the Vitrebond liner/base by exposing it for 30 seconds to light from a 3M ESPE light curing unit or other curing unit of comparable intensity. The delayed auto-setting mechanism of the Vitrebond liner/base will ensure an eventual cure of material shielded from light polymerization such as in undercut areas. Where thicker applications of the liner/base are desired, best adhesion can be achieved by first placing and light curing a thin layer followed by placement of a second layer up to 2mm in depth and light curing for 30 seconds.
- Adhesive system: Continue with the bonding step of the restorative procedure starting with etching. Etchant on the liner/base is not deleterious. Refer to specific product instructions for details of use.

STORAGE AND USE:

- 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.
- Both the Vitrebond liner/base powder and liquid are light sensitive. To prevent deactivation of the materials, protect from ambient light. Replace jar and vial caps immediately after dispensing.
- 3. Disinfect the scoop and bottles using an intermediate level disinfection process (liquid contact) as recommended by the CDC (Centers for Disease Control) and endorsed by the ADA (American Dental Association). Guidelines for Infection Control in Dental Health-Care Settings –2003 (Vol. 52; No. RR- 17), Center for Disease Control and Prevention.
- 4. Do not expose materials to elevated temperature or intense light.

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: US 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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