Light Cure Dental Adhesive Instructions for Use

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U.S. Federal Law restricts this device to sale by or on the order of a dental professional. Prior to use the product, please read the instruction carefully.

General Description

Light Cure Dental Adhesive is a universal self-etch dentine bonding agent specifically designed for meeting all your bonding needs. It is not only for direct bonding under a dental composite restorative or a resin modified glass ionomer cement restorative, but also for all indirect dental restoration cementation applications, either used as a strict self-etch dental bonding agent, or in combination with the traditional total etch or enamel etch procedures. In all of those cases, this dental bonding agent will give you exceptional results and predicting a reliable treatment outcome.

Indications

Light Cure Dental Adhesive can be used as a strict self-etch dental bonding agent, or in combination with the traditional total etch or enamel etch procedures:

- Direct bonding under a light-cured composite or compomer fillings/resin modified glass ionomer restoratives;
- Repair of dental restorations of ceramic, composites and/or metal alloys;
- Indirect dental restorations cementation applications in combination with resin cement for cementation of all sorts of dental restorations including crowns, bridges, inlays/onlays, veneers, dental posts and other restorations made from materials of metals/alloys, metal-ceramic, all-ceramic and/or porcelain, composites, and their combinations;
- Seal hypersensitive areas of teeth.

Contraindications

•Not for exposed pulp or pulpitis needing treatment.
•Patient known to be allergic to methacrylate resins should be avoided to use this product.

Side effects

•This product or one of its components may cause hypersensitive reactions.

Operating Procedures

1. Applying the bonding agent in self-etch mode:
a) Prepare tooth surface according to principles of adhesive dentistry. Make sure to clean and remove surface debris thoroughly from the preparation site.
b) Use oil-free air to dry the tooth surface for 2-3 seconds or use an absorbent pellet to blot the tooth dry. There should be a slight moist tooth surface but no visible water.
c) Dispense sufficient amount of the adhesive from the container, use a micro-applicator tip to apply to the tooth surface and rub it in evenly and thoroughly for 20 seconds to ensure a shiny surface.
d) Air dry for 10-15 seconds using a gentle stream of air to remove solvent in the adhesive. If surface shine disappears after drying, re-apply the adhesive and re-dry.
e) Light cure tooth for 10 seconds(with an output of >800mw/cm² light source).
f) Proceed with the restorative procedure following the respective product instructions.
2. Dental bonding using conventional total etch or enamel etch only technique:
a). Prepare tooth surface according to principles of adhesive dentistry. Make sure to clean and remove surface debris thoroughly from the preparation site.
b). Apply a commonly used phosphoric acid etching gel to both enamel and dentin surface (total etch) or to enamel surface only(enamel etch). Rinse the surfaces thoroughly following the phosphoric acid etching gel instructions.
c). It is important not to s plash etch into eyes, onto soft tissues or skin. Do not allow etched surface to become contaminated with saliva or blood during the bonding procedure.
d). Follow the steps of b)-f) above.
3. Sealing hypersensitive areas of teeth:
a). Clean tooth with an oil and fluoride-free polishing paste.
b). Proceed as described in section 1 b)-e).
c). Carefully remove oxygen-inhibited layer with an alcohol-soaked pellet after light curing. If the desensitization affect is not adequate, apply additional coats of the adhesive as described, light cure and remove the oxygen-inhibited layer with a damp pellet.

Note

•Refer to outer package for expiration date. Do not use after expiration date.
•For dental use only. Do not use for indications or applications that are not specifically noted in the instructions for use.
•Follow the Operating Procedures when using.
•Notification of any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in your country.

Precautions

•Disposable micro-applicator (micro-brush) is for single use only, to prevent cross-contamina

tions between patients.
•This product is easy to polymerization early if exposed to natural light or artificial light. Do not place under strong light during use.
•Flammable: Keep away from sources of ignition. Take precautionary measures against static discharges.
•Uncured methacrylate resin may cause contact dermatitis and damage the pulp. Avoid contact with skin, eyes and soft tissue. Wash thoroughly with water after contact.
•Disposal must be made in accordance with local regulations.
•If one of the following is noted, it is a sign that the material is losing its bonding efficacy and should no longer be used:
- Nothing comes out of the bottle when squeezed although there is material left inside.
- Solid or gel-like coagulation is detected in the liquid when dispensed.
- Threads are visible in the material during application with the micro brush.
•Keep out of the reach of children.

Storage
Light Cure Dental Adhesive should be stored at 2-25℃, away from direct light with the cap closed tightly. Use the material at normal room temperature.
Shelf life: 2 years from date of manufacture

Warranty
HUGE 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 products for user's application. If this product is defective within the warranty period, your exclusive remedy and HUGE's sole obligation shall be repair or replacement of the HUGE product.

Limitation of Liability
Except where prohibited by law, HUGE 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.

Symbols for use in the labeling

-- Use-by date
-- Caution
LOT -- Batch code
-- Temperature limit
-- Keep away from sunlight
-- Keep dry
-- Consult instructions for use
-- Manufacturer
-- Country of manufacture
MD --Medical device
UDI --Unique device identifier
EC REP -- Authorized representative in the European Community
Rx ONLY --Caution:U.S.Federal Law restricts this device to sale by or on the order of a dentist or professionals.

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