Bio-LCB[®]

Light Cured Cavity Base and Liner

Instructions for Use



Caution: Federal law restricts this device to sale by or on the order of a licensed dentist.





CONSULT INSTRUCTIONS FOR USE



NONRETURNABLE IF SEAL IS BROKEN



Product Description

Bio-LCB™ is light-curved cavity liner. It is a radiopaque cavity liner and base material specially formulated for use with adhesives, composites and conventional restorative materials. It has a urethane dimethacrylate base and is similar in chemistry to dental composites.

These Instructions for Use must be kept for reference for the duration of product use.

Indications

- Protect pulp of the tooth
- · Lining under all filling materials

Composition

- Organic Matrix: UDMA Based
- Inorganic Filler: Silica
- · Additives: Initiator, Catalyst, Stabilizer, Others

Precautionary Measures

- The product contains substances that may cause an allergic reaction with skin contact in certain individuals.
- To reduce the risk of all allergic response, minimize exposure to these materials.
 In particular, avoid exposure to uncured product.
 If prolonged contact occurs, flush with large amounts of water. If allergic reaction occurs, seek medical attention as needed.

Safety data sheets can be obtained from http://edsdental.com/sds.html.

Application

- Isolate teeth being treated to avoid saliva and blood contamination. The tooth structure should be dried.
- 2. Prepare cavity and thoroughly clean and dry the teeth again.
- 3. Apply Bio-LCB[™] to the dentin.
- 4. Cure the Bio-LCB[™] with a suitable polymerization light.
- 5. Sufficient exposure to the curing light prevents incomplete polymerization.

For the recommendations regarding exposure time and light intensity see the following table.

Light Intensity (mW/cm2)	Exposure Time (sec)
≥500	20
≥1000	10

6. After light irradiation, apply necessary procedures.

Caution

- Bio-LCB is designed for sale and use by licensed dental care professionals only. It is not designed for sale nor is it suitable for use by non-dental professionals.
- Bio-LCB contains methacrylic monomer.
 Some patients can have a allergic reaction to monomer.
- 3. Do not use Bio-LCB for patients allergic to or hypersensitive to methacrylic monomers.
- 4. If Bio-LCB causes an allergic reaction or hypersensitive, discontinue its use immediately.
- 5. Avoid contact of Bio-LCB with eyes, mucosal membrane, skin and clothing.
- If Bio-LCB comes in contact with the eyes, thoroughly flush eyes with water and immediately contact an ophthalmologist.
- 7. This product prohibits the use of other uses or non-specialists.
- 8. Use a rubber dam to protect the throat.
- 9. DO NOT use Bio-LCB after the indicated expiration date on the syringe.
- 10. If refrigerated storage is used, allow product to reach room temperature prior to use.

Storage & Use

Bio-LCB is designed to be used at room temperature. If refrigerated storage is used allow product to reach room temperature prior to use. Shelf life at room temperature is 36 months. See outer package for expiration date. Ambient temperatures routinely higher than 27°C/80°F may reduce shelf life. Do not expose restorative materials in proximity to products containing eugenol.

Warranty

EDS warrants this product will be free from defects in material and manufacture. EDS, 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 EDS's sole obligation shall be repair or replacement of the EDS's product.

Limitation of Liability

Except where prohibited by law, EDS 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.

Customer Information

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

Disposal

See the Material Safety Data Sheet (available at http://edsdental.com/sds.html or through your local subsidiary) for disposal information.

