

Bisco

CE 0459

TheraCal LC[®] *Light-Cured*

Resin-Modified Calcium Silicate Pulp Protectant/Liner

Instructions for Use



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

TheraCal LC[®]*

Resin-Modified Calcium Silicate Pulp Protectant/Liner

GENERAL INFORMATION

TheraCal LC is a light-cured resin-modified calcium silicate pulp protectant/liner designed to perform as a barrier and to protect the dental pulpal complex. **TheraCal LC's** precise placement allows its use in all deep cavity preparations. The light-cured set permits the practitioner immediate placement and condensation of the restorative material. Its proprietary formulation allows for a command set with a visible light curing unit while maintaining ease of placement due to thixotropic properties. The proprietary hydrophilic resin formulation creates a stable and durable liner or base.

Indications for Use:

1. **TheraCal LC** is intended for use as a direct pulp capping agent. It may be placed directly on pulpal exposures after hemostasis is obtained. It is indicated for any pulpal exposures, including:
 - Carious exposures
 - Mechanical exposures
 - Exposures due to trauma
2. **TheraCal LC** is intended as an indirect pulp capping agent in deep preparations, a protective liner in large preparations, base or sealer for use:
 - Under amalgam restorations
 - Under Class I and Class II composite restorations
 - Under other base materials
 - Under cements
 - As an alternative to calcium hydroxide
 - As an alternative to glass ionomer/RMGI
 - As an alternative to cavity varnish sealer
 - As an alternative to zinc phosphate
 - As an alternative to IRM/ZOE (Intermediate Restorative Material)

Warnings:

- **TheraCal LC** contains polymerizable methacrylate monomers. Avoid prolonged or repeated exposure with skin, oral soft tissues, and eyes. Irritation and possible corneal damage may result. Skin rash, oral mucosa irritation, or other allergic reactions (allergic contact dermatitis) may result in susceptible individuals. Do not take internally.
- **TheraCal LC** is not recommended for use with patients who have a history of severe allergic reaction to methacrylate resins.

Cautions:

- Cross-contamination: Product may contain items that are designed for one time use. Dispose of used or contaminated unit-dose components and accessories. Do not clean, disinfect or reuse.

Precautions:

- The essentially basic nature of **TheraCal LC** composition requires that it be used only in situations where it can be protected adequately from the intraoral environment. Do not place on enamel, cavity margins or leave exposed to oral environment.
- The success of pulp capping procedures may be influenced by preparation contamination. Use of a rubber dam or adequate isolation is recommended.
- Pulpal hemorrhage must be controlled prior to the application of **TheraCal LC**. If hemorrhage cannot be controlled, consideration should be given for the initiation of endodontic therapy over direct pulp capping procedures.
- If a thickness of material greater than 1 mm is desired, **TheraCal LC** should be applied and cured incrementally.
- **TheraCal LC** is a light-cured material. Proceed immediately once material has been dispensed.
- See individual component labels for specific expiration dates.
- Safety data sheet available on request.
- Safety data sheet available at www.Bisco.com.

INSTRUCTIONS FOR USE

1. Pulp Exposures (Direct Pulp Capping)

1. Under rubber dam isolation, complete cavity preparation.
2. First achieve hemostasis by placing a sterile cotton pellet dampened with sterile saline gently onto the exposure site.
3. Blot preparation with sterile cotton pellet. Leave visibly moist.
4. Apply **TheraCal LC** directly to the exposed pulp in incremental layers. Layer is not to exceed 1 mm in depth. Cover all the exposed areas and extend **TheraCal LC** at least 1 mm onto sound dentin surrounding the exposure. Light cure between layers.
5. Light cure each increment for 20 seconds.
6. Place desired adhesive, base, and/or restoration following manufacturer's directions. Continue restoring tooth.

2. Deep Preparations (Indirect Pulp Capping), Large Preparations (Liner), Base or Sealer

1. Isolate the tooth and perform conventional cavity preparation. Remove all infected carious tooth structure. Leave preparation visibly moist.
2. Apply the **TheraCal LC** directly to the cavity floor in incremental layers. Layer is not to exceed 1 mm in depth. Manipulate into a smooth surface covering all deep dentin areas. Light cure between layers.
3. Light cure each increment for 20 seconds.
4. Place desired adhesive, base, and/or restoration following manufacturer's directions. Continue restoring tooth.

DISPOSAL: Refer to community provisions relating to waste. In their absence, refer to national or regional provisions relating to waste.

HYGIENE: Re-cap syringes with the luer lock cap. Use of commonly available hygienic protective covering to avoid any contamination of syringes during treatment is recommended.

STORAGE: Store at room temperature (20°C/68°F - 25°C/77°F).

WARRANTY: BISCO, Inc. recognizes its responsibility to replace products if proven to be defective. BISCO, Inc. does not accept liability for any damages or loss, either direct or consequential, stemming from the use of or inability to use the products as described. Before using, it is the responsibility of the user to determine the suitability of the product for its intended use. The user assumes all risk and liability in connection therewith.

* TheraCal is a registered trademark of BISCO, Inc.

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