

NANOFIL Nova®

TheraCalm LC

Light-Cured Resin-Modified Calcium Silicate Pulp Protectant & Liner

Instructions for Use

General Information

NANOFILNova®Light-Cured Pulp Capping and Liner Composite is a light-cured modified composite, a resin-calcium silicate material designed for pulp capping and pulpal protection. It serves as a protective barrier for the dental pulp. Compared to traditional calcium hydroxide materials, the thixotropic properties of Nova®Light-Cured Pulp Capping and Liner Composite allow for precise placement and immediate setting, thereby significantly simplifying the clinical workflow; it is suitable for use in all deep cavity preparations. This allows the clinician to immediately proceed with the placement and filling of restorative materials following curing. Its unique formulation ensures a stable and durable alkaline substrate, while its shade—resembling deep dentin—provides the necessary aesthetic foundation for restorative procedures.

Indications for Use

1. Nova®Light-cured Pulp Capping and Liner Composite is indicated for use as a direct pulp-capping agent. It is suitable for any type of exposure of a healthy dental pulp, including traumatic exposures, mechanical exposures, and carious exposures.
2. Nova®Light-cured Pulp Capping and Liner Composite is indicated for use as a pulp-protecting agent during the preparation of deep cavities, as a protective liner during the preparation of large cavities, or as a base/sealer. This includes use beneath amalgam restorations, beneath Class I and Class II composite restorations, beneath other restorative materials, and beneath cements. It can be used as a substitute for calcium hydroxide, glass ionomers/ resin-modified glass ionomers, cavity varnishes, zinc phosphate cements, and IRM/ZOE (temporary restorative materials).

Model and Specification

Model: PCLC-1, PCLC-4

Loading capacity: 1.2g per syringe

Accessories:

For PCLC-1: 10 pieces of 19G disposable syringe tips per packag

Intended Users Dental Professionals

Precautions

- This product should be used only when the oral environment is adequately protected. (The success of pulp capping procedures may be compromised by contamination of the prepared site.)
- Do not apply to exposed enamel or cavity margins that are open to the oral environment.
- Prior to using this product, bleeding must be completely controlled. If bleeding cannot be controlled, preliminary dental treatment should be considered before proceeding with the pulp capping procedure.
- If a material thickness exceeding 1 mm is required, the material should be applied and cured in increments.
- This product is a light-curable material. Once the material application is complete, the curing procedure should be performed immediately.
- This product is applied directly. No etching or polishing is required.
- Recommended external light sources for curing: Dental LED lights or halogen lights. Recommended light intensity: $\geq 500 \text{ mW/cm}^2$; Wavelength range: 400–500 nm.
- The tip of the light source should be positioned approximately 1 mm away from the surface of the material.
- Curing depth of the material following recommended light exposure: The curing depth is no less than 0.5 mm.
- Avoid direct contact with uncured material (uncured resin may cause skin irritation in individuals with sensitivities. Avoid contact with the skin. If accidental skin contact occurs, rinse thoroughly with soap and water).
- Both patients and dental personnel should wear protective eyewear.
- When using dental adhesives, contamination by saliva will severely compromise the bonding efficacy to dentin.
- For the specific expiration date, please refer to the labels on the individual components.
- Instructions for Use are available upon request.
- Instructions for Use are also available at www.atmbio.com.

INSTRUCTIONS FOR USE

Direct Pulp Capping (for Pulp Exposure)

1. Place a rubber dam and complete the cavity preparation under moisture-free conditions.
2. Perform hemostasis: Take a sterile cotton pellet moistened with sterile saline solution and gently place it over the exposed pulp site.
3. Gently wipe the prepared cavity surface with a sterile cotton pellet to absorb excess moisture; ensure that the dentin surface remains visibly moist.
4. Directly apply Nova®Light-cured Pulp Capping and Liner Composite in layers over the exposed pulp surface. The thickness of each layer should not exceed 1 mm. Ensure that all exposed areas are completely covered and extend the Nova® Light-cured Pulp Capping and Liner Composite LC onto the surrounding healthy dentin, covering an area of at least 1 mm beyond the exposure site. Light cure each layer immediately after application.
5. Use an LED curing light with an intensity of 1000–1200 mW/cm², and light-cure each layer for 20 seconds.
6. Following the manufacturer's instructions, sequentially apply the required bonding agent, liner, and/or restorative material. Subsequently, proceed to complete the final restoration of the tooth.

Indirect Pulp Capping (for Extensive Cavity Preparation, Liner, Base, or Sealer Application)

1. Place a rubber dam and perform standard cavity preparation. Thoroughly remove all infected, carious tooth structure. Keep the dentin surface visibly moist.
2. Apply Nova®Light-cured Pulp Capping and Liner Composite directly to the floor of the cavity using an incremental layering technique; the thickness of each layer should not exceed 1 mm. Contour the material to achieve a smooth surface, ensuring that all deep dentin areas are covered. Light cure each layer individually.
3. Use an LED curing light with an intensity of 1000–1200 mW/cm², and light-cure each layer for 20 seconds.
4. Apply the required bonding agent, liner, and/or restorative filling material sequentially, in accordance with the manufacturer's instructions. Proceed to complete the dental restoration.

HYGIENE: It is recommended to use commercially available protective sleeves to prevent contamination of the syringe during treatment. This product may contain components designed for single use. Used or contaminated tips must be discarded; never clean, disinfect, or reuse them.

DISPOSAL: Extrude or collect excess material onto a mixing pad, light cure the excess material in increments until fully cured. Refer to local waste disposal regulations; if no such regulations exist, refer to national or regional waste disposal regulations.

WARRANTY: AT&M Biomaterials Co., Ltd. recognizes its responsibility to replace products if proven to be defective. AT&M Biomaterials Co., Ltd. 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.

The recommended condition of storage: Store in a cool, dry place at room temperature (17°C – 25°C). Avoid direct sunlight and contact with products containing eugenol. Tightly close the cap immediately after use.

Production Date: see the product package.

Expiration Date: see the product package.

Labeling instructions

						
Instructions for use	Warning	Product model	Manufacturing lot	Production date	Expiry date	Avoid direct sunlight



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