

Prisma® VLC Dycal®

Visible Light Cured Calcium Hydroxide Base/Liner

DIRECTIONS FOR USE

Caution: U.S. federal law restricts this device to sale by or on the order of a dentist

Prisma® VLC Dycal® calcium hydroxide base/liner is a one-component, rigid-setting, visible light cured material designed for use in direct and indirect pulp capping and as a protective base/liner under dental adhesives, varnishes, filling materials, cements, and other base materials. It will not inhibit the polymerization of acrylic and composite restorations. This material flows readily and wets dentin easily. The material has superior physical properties, is minimally affected by phosphoric acid, and possesses a very low water solubility in comparison to conventional calcium hydroxide preparations.

COMPOSITION

Calcium Hydroxide; Barium Sulfate; Urethane Dimethacrylate Resin; photoinitiator; stabilizer; pigments

INDICATIONS FOR USE

1. Application to exposed, vital pulp tissue (direct pulp capping).
2. Application to dentin as a protective barrier between restorative materials and deep vital dentin (indirect pulp capping) or where dentin to restorative material contact is not desired.

CONTRAINDICATIONS

Prisma® VLC Dycal® Base/Liner is contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins.

WARNINGS

Prisma® VLC Dycal® Base/Liner 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.

Eye Contact: Before using this product, wear protective glasses as well as covering the patient's eyes. In case of eye contact, flush with flowing water for 15 minutes and seek medical attention.

Skin Contact: Avoid prolonged or repeated exposure to skin. If contact with skin occurs immediately wipe off thoroughly with cotton and alcohol and then wash thoroughly with soap and water. If skin rash or sensitization or other allergic reaction occurs, discontinue use and seek medical attention.

Oral mucosa contact: Avoid contact with oral soft tissues. If accidental contact occurs, rinse well with water and then expectorate. Contact of the material may cause soft tissue irritation. This is most often a temporary phenomenon and should disappear within one day. If the condition persists, seek medical attention.

Ingestion: Do not swallow or take internally. If accidental swallowing occurs, drink lots of water. If nausea or illness develop, seek medical attention. Contact regional Poison Control Center if necessary.

PRECAUTIONS

1. This product is intended to be used as specifically outlined in the *Directions for Use*. Any use of this product inconsistent with the *Directions for Use* is at the discretion and sole responsibility of the practitioner.
2. Wear suitable protective clothing, eyewear, and gloves.
3. The essentially basic nature of Prisma® VLC Dycal® Liner composition requires that it be used only in situations where it can be protected adequately from the intraoral environment. After the Prisma® VLC Dycal® Liner has been completely visible light cured, cover with cavity varnish, dentin adhesive, or restorative material per manufacturer's directions. Do not place on enamel, cavity margins or leave exposed to oral environment. See *Step-by-Step Directions for Use*
4. Insufficient data exist to support the use of Prisma® VLC Dycal® Liner as a filling material, core build-up or luting cement.
5. Insufficient data exist to support the use of Prisma® VLC Dycal® Liner as a root canal dressing, medicament or repair material.
6. The success of pulp capping procedures may be influenced by preparation contamination. Use of a rubber dam or adequate isolation is recommended.
7. Pulpal hemorrhage must be controlled prior to the application of Prisma® VLC Dycal® Liner. If hemorrhage cannot be controlled, consideration should be given for the initiation of endodontic therapy over direct pulp capping procedures.
8. Studies have shown Prisma® VLC Dycal® Liner to be adequately strong to resist the packing pressures upon restorative materials during placement by usual procedures. Avoid the use of excessively small pluggers and/or high packing pressures, which might cause fractures of the material.
9. If a thickness of material greater than 1mm is desired, it should be applied and cured incrementally. As the material increases in thickness, the shade becomes more intense (white). See *Step-by-Step Directions for Use*
10. Tooth size, shape, dentinal radiopacity, exposure conditions, and thickness of the Prisma® VLC Dycal® and overlying restorative material may affect the ability to radiographically detect the material.
11. Prisma® VLC Dycal® Liner is a visible light-cured material. Proceed immediately once material has been placed on mixing pad or protect from ambient light.
12. The Prisma® VLC Dycal® Base/Liner container should be tightly closed immediately after use.
13. Use only in well ventilated areas.
14. Allow Prisma® VLC Dycal® Base/Liner material to reach room temperature prior to use for optimum flow.
15. **Storage:** Prisma® VLC Dycal® Base/Liner material containers should be stored with the original cap only, kept out of direct sunlight and stored in a well ventilated place at refrigerated temperature between 2°C/35°F and 8°C/46°F when not in use. Allow material to reach room temperature prior to use. Protect from moisture. Do not freeze. Do not use after expiration date.

ADVERSE REACTIONS

1. Product may irritate the eyes and skin. Eye contact: irritation and possible corneal damage. Skin contact: irritation or possible allergic response. Reddish rashes may be seen on the skin. Mucous Membranes: inflammation, edema, sloughing. See Warnings
2. Product may cause serious health effects if ingested. See Warnings

STEP-BY-STEP DIRECTIONS FOR USE

1. Direct Pulp Capping
 - 1.1 Under rubber dam isolation, complete cavity preparation outline using high-speed burs under constant water-cooling.
 - 1.2 If caries is present, completely excavate using low-speed and/or hand instrumentation.
 - 1.3 Rinse the cavity and exposure site(s). Heavy bleeding may be controlled with a cotton pellet moistened with sterile saline.
 - 1.4 Gently dry preparation with cotton pellet. Avoid desiccation.
 - 1.5 Dispense Prisma® VLC Dycal® Liner on the parchment paper pad provided. Cover to avoid exposure to operatory light if not used immediately. Replace container cap.
 - 1.6 Using the ball-pointed Dycal® Liner applicator or similar instrument, place Prisma® VLC Dycal® Liner directly on the exposed pulp and cavity dentin judged to be less than 1mm remaining thickness in a thin layer. Avoid placing Prisma® VLC Dycal® Liner on enamel or the margins of the cavity. Avoid placing a large bulk of material. Prior to curing, if areas of insufficient thickness are evident, adequate coverage of the floor with Prisma® VLC Dycal® Liner may be assured by adding to these portions. However, do not exceed a thickness of 1mm, prior to curing. The ball of the instrument is approximately 0.7 mm in diameter which can be used as an indicator for the thickness of the material being placed. Material thickness should be approximately 0.8mm-1mm.
 - 1.7 Light cure the material with a suitable visible light curing unit designed to cure materials containing camphorquinone (CQ) initiator, i.e. spectral output containing 470 nm. Minimum light output must be at least 300mW/cm² exposure for at least 20 seconds. Refer to curing light manufacturer's recommendations for compatibility and curing recommendations.
 - 1.8 If a thickness of material greater than 1mm is desired, repeat placement step 1.6 and curing step 1.7, placing material in 0.8-1mm increments and curing, until desired thickness is reached.
Technique Tip: As the material increases in thickness, the shade becomes more intense (white.)
 - 1.9 Remove any material excess from retention areas, enamel, and/or margins with a sharp spoon excavator or a bur.
 - 1.10 Place desired adhesive, base, and/or restoration following manufacturer's directions.
 - 1.11 At the next appointment, assess the pulp vitality. Pulp vitality and status should be assessed radiographically every three to six months or as needed.
2. Indirect Pulp Capping, Protective Barrier
 - 2.1 Under suitable isolation, complete cavity preparation and caries removal. Wash cavity thoroughly with water spray and air dry.
 - 2.2 Dispense Prisma® VLC Dycal® Liner as outlined above in section 1.5.
 - 2.3 Apply material to desired dentin surfaces as outlined above in sections 1.6-1.8. Completely covering all cavity dentin as desired may require carrying additional material from pad to dentin surfaces. NOTE: If subsequent use of a dentin bonding agent is desired, place Prisma® VLC Dycal® Liner only on the deepest (less than 1mm remaining) dentin, leaving the rest of the cavity surface free for bonding.
 - 2.4 Following visible light curing (see section 1.7) remove any set excess from retention areas, enamel, and/or margins with a sharp spoon excavator or a bur.
 - 2.5 Complete restoration per restorative material manufacturer's directions for use.

CLEANING AND DISINFECTION INSTRUCTIONS

Tubes and caps may be cleaned by scrubbing with hot water and soap or detergent. Tubes should be wiped, not immersed. Tubes exposed to spatter or spray of body fluids, or touched by contaminated hands or oral tissues, should be disinfected with a hospital-level disinfectant. Acceptable disinfectants are those that are EPA registered as tuberculocidal. Iodophors, sodium hypochlorite (5.25%), chlorine dioxide and dual or synergized quaternary ammoniums are approved disinfectants. Do not immerse tubes in disinfectant. Disinfect the tubes by spraying or wiping. Spraying with glutaraldehyde is not recommended. Some phenolic-based agents and iodophor-based products may cause surface staining. Agents containing organic solvents such as alcohol may tend to degrade the tubes and caps. The disinfectant manufacturer's directions should be followed properly for optimum results. Water-based disinfectant solutions are preferred.

Dycal® Liner applicator instruments may be cleaned by scrubbing with hot water and soap or detergent. Applicator instruments exposed to spatter or spray of body fluids, or touched by contaminated hands or oral tissues must be steam autoclaved following autoclave manufacturer's recommended procedures. Allow instruments to dry prior to storage.

LOT NUMBER AND EXPIRATION DATE

1. Do not use after expiration date. ISO standard uses: "YYYY/MM."
2. The following numbers should be quoted in all correspondences:
 - Reorder number
 - Lot number on package
 - Expiration date

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