Prisma® VLC Dycal®
Visible Light Cured Calcium Hydroxide Base/Liner

DIRECTIONS FOR USE – ENGLISH

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
1. This product is intended to be used as specifically outlined in the Directions for Use.
2. Use of a rubber dam or adequate isolation is recommended.
3. Product may irritate the eyes and skin.
4. Product may cause serious health effects if ingested.
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).

ADVERSE REACTIONS
1. Product may irritate the eyes and skin. Eye contact: irritation or 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

1. Insufficient data exist to support the use of Prisma® VLC Dycal® Liner as a filling material, core build-up or luting cement.
2. Insufficient data exist to support the use of Prisma® VLC Dycal® Liner as a root canal dressing, medicament or repair material.
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

PRECAUTIONS
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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. 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.
   1.7 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.
   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.
   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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