

Dycal®

Calcium Hydroxide Liner

DIRECTIONS FOR USE – ENGLISH

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

Dycal® Calcium Hydroxide Liner is a two-component, rigid-setting, self-curing material designed for use in direct and indirect pulp capping and as a protective liner under dental adhesives, varnishes, filling materials, cements, and other base materials. It will not inhibit the polymerization of acrylic and composite restorations.

COMPOSITION

Dycal® Liner Base paste: disalicylate ester of 1,3, butylene glycol; calcium phosphate; calcium tungstate; zinc oxide; iron oxide

Dycal® Liner Catalyst paste: calcium hydroxide; ethyl toluenesulfonamide; zinc stearate; titanium dioxide; zinc oxide; iron oxide

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

None known.

WARNINGS

1. Avoid prolonged or repeated exposure of the Dycal® Liner material 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.

2. Dycal® Liner should not be used with patients who have a history of severe allergic reaction to any of the components.

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 solubility and essentially basic nature of Dycal® Liner composition requires that it be used only in situations where it can be protected adequately from the intraoral environment. After the Dycal® Liner has completely set, 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 Dycal® Liner as a base, filling material, core build-up or luting cement.
5. Insufficient data exist to support the use of 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 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 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. Apply Dycal® Liner as a thin layer; use of multiple layers or one thick layer does not improve functionality.
10. Dycal® Liner should be mixed in equal volumes (1.17 to 1.00 by weight) for optimum performance. The mixed material should be homogeneous and streak free prior to application. Variations may affect the radiopacity, strength, and durability of the material.
11. Tooth size, shape, dentinal radiopacity exposure conditions, and restorative material may affect the ability to radiographically detect the material.
12. Increased humidity and elevated temperature will reduce available work time and set time. Dycal® Liner sets faster in the mouth than on the bench.
13. The Dycal® Liner base and catalyst containers should be tightly closed immediately after use.
14. Use only in well ventilated areas.
15. **Storage:** Store with original caps tightly closed in a well ventilated place at or below room temperature not exceeding 25°C/77°F. Refrigerated storage is acceptable 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*)
3. Inhalation of vapors may cause varying degrees of damage to the affected tissue and also increased susceptibility to respiratory illness. (See *Precautions*)

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) with 2.6%-5% NaOCl. 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 equal volumes of base and catalyst pastes on the parchment paper pad provided. Replace container caps. Using a Dycal® Liner applicator, stir immediately to mix thoroughly until a uniform color is achieved. Do not over-spatulate. Complete mixing within 10 seconds.
NOTE: Do not attempt to control the setting time by increasing or decreasing the amount of catalyst dispensed.

- 1.6. Using the ball-pointed Dycal® Liner applicator or similar instrument, place the mix directly on the exposed pulp and cavity dentin judged to be less than 1.0mm remaining thickness in a thin layer. Avoid placing Dycal® Liner on enamel or the margins of the cavity. Avoid placing a large bulk of material. Material thickness should be approximately 0.8mm-1mm.
 - 1.7. Allow the Dycal® Liner to completely set. The mixed material will set in approximately 2-3 minutes on the mixing pad under normal room conditions (70°F with 50% relative humidity). Set time is shorter in the mouth due to moisture and temperature.
 - 1.8. Remove any set excess from retention areas, enamel, and/or margins with a sharp spoon excavator or a bur.
 - 1.9. Place desired adhesive, base, and/or restoration following manufacturer's directions.
 - 1.10. 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 and mix Dycal® Liner components as outlined above in section 1.5.
 - 2.3. Apply mixed material to desired dentin surfaces as outlined above in sections 1.6-1.8. Quick application of the mixed material into the cavity takes advantage of the essential flowability of the mass for efficient placement before setting starts. 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 Dycal® Liner only on the deepest (less than 1mm remaining) dentin, leaving the rest of the cavity surface free for bonding.
 - 2.4. Following completion of set (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.

Manufactured in the U.S.A. by:
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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 EPA registered as tuberculocidal. Iodophors, sodium hypochlorite (5.25%), chlorine dioxide and dual or synergized quaternaries are approved disinfectants. Do not immerse tubes in disinfectant. Disinfect the tubes by spraying or wiping with any recommended hospital-level surface disinfectant for the contact time recommended by the disinfectant manufacturer for optimum results. 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.

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