TimeLine™
VLC Base/Liner Composition

DIRECTIONS FOR USE – ENGLISH

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

TimeLine™ Base/Liner is a one-component, light cured, fluoride releasing adhesive base/liner material designed to serve as a hard-setting protective base/liner underneath amalgam and composite restorations. For optimum bonding of TimeLine™ to dentin, the use of ProBOND Dentin Primer (available separately) is recommended prior to application. This material flows readily and wets dentin easily. The material has superior physical properties, is minimally affected by phosphoric acid, and possesses very low water solubility in comparison to conventional glass ionomer base/liner preparations.

COMPOSITION
Barium sulfate; barium aluminumsilicate glass; sodium fluoride; fumed silica; Urethane Dimethacrylate Resin; photoinitiator; PENTA (Dipentaerythrol pentacrylate phosphoric acid ester); stabilizer; pigments

INDICATIONS FOR USE
Application to dentin as a protective barrier between restorative materials and vital dentin where dentin to cavity restorative material contact is not desired.

CONTRAINDICATIONS
1. TimeLine™ Base/Liner is contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins.
2. TimeLine™ Base/Liner is contraindicated for direct application to dental pulp tissue (direct where dentin to cavity restorative material contact is not desired.

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. Eugenol-containing dental materials should not be used in conjunction with this product because they may interfere with hardening and cause softening of the polymeric components of the material.
4. The nature of TimeLine™ Base/Liner composition requires that it be used only in situations where it can be protected adequately from the intraoral environment. After the TimeLine™ Base/Liner has been completely visible light cured, cover with cavity varnish, dentin adhesive, or restorative material per manufacturer’s directions. Do not place TimeLine™ Base/Liner on enamel, cavity margins or leave exposed to oral environment. (See Step-by-Step Instructions)
5. Insufficient data exist to support the use of TimeLine™ Base/Liner as a filling material, core build-up or luting cement.
6. Insufficient data exist to support the use of TimeLine™ Base/Liner directly against phosphoric acid conditioned (etched) dentin.
7. ProBOND™ Primer (available separately) is the only dentin conditioning agent recommended for use in conjunction with TimeLine™ Base/Liner. Refer to manufacturer’s complete Directions for Use prior to use. Insufficient data exist to support the use of other adhesives, desensitizing agents and/or cavity cleansing agents in conjunction with TimeLine™ Base/Liner.

8. Contact with saliva, blood and/or some astringent solutions during placement may cause failure of the restoration. Use of a rubber dam or adequate isolation is recommended.
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 Instructions)
10. Tooth size, shape, dental radiopacity, exposure conditions, and thickness of the TimeLine™ Base/Liner and overlying restorative material may affect the ability to radiographically detect the material.
11. TimeLine™ Base/Liner is a visible light-cured material. Proceed immediately once material has been placed on mixing pad or protect from ambient light.
12. The TimeLine™ Base/Liner container should be tightly closed immediately after use. NOTE: TimeLine™ Base/Liner tubes are filled by weight. Air is included in each tube to ensure stability. Tubes should be allowed to refill with air after dispensing before closing.
13. Use only in well ventilated areas.
14. Allow TimeLine™ Base/Liner material to reach room temperature prior to use for optimum flow.
15. Storage: TimeLine™ 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 temperatures between 2°C/35°F and 8°C/46°F when not in use. Separation of solid and liquid phase of the base composition is accelerated at elevated temperatures. 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. Skin 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. Product may cause pulpal effects. (See Contraindications, Warnings, Precautions)

STEP-BY-STEP INSTRUCTIONS – BASE OR CAVITY LINER

1. Cleaning: Clean uninstrumented enamel and dentin with a rubber cup and pumice or a cleaning paste such as Nupro® Phosphor Paste. Wash thoroughly with water spray and air dry. Clean freshly instrumented enamel and dentin with water spray and then air dry. Do not desiccate dentin.
2. Pulp Protection: For direct and indirect pulp capping, cover the dentin close to the pulp (less than 1mm) with a hard setting calcium hydroxide liner (Dycal® Liner) leaving the rest of the cavity surface free for bonding/lining.
3. Tooth Conditioning/Dentin Pretreatment, ProBOND® Primer Application (Optional): In most clinical situations, bonding of TimeLine™ Base/Liner material to available dentin using ProBOND® Primer is strongly recommended. Refer to ProBOND® All Purpose Bonding Agent directions for use for tooth conditioning and/or ProBOND® Primer application. Once the surfaces have been properly treated, they must be kept uncontaminated. Proceed immediately to placement of TimeLine™ Liner material (step 4).
4. Dispense TimeLine™ Base/Liner material on the parchment paper pad provided. Cover to avoid exposure to operatory light if not used immediately. Replace container cap.
5. Using a ball-pointed Dycal® Liner applicator or similar instrument, place TimeLine™ Base/Liner material on the cavity dentin. Avoid placing TimeLine™ Base/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 with TimeLine™ Base/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 of the thickness of the material being placed. Material thickness should be approximately 0.8mm-1mm.
6. Light cure the material with a suitable visible light curing unit designed to cure materials containing camphorquinone (CQ) initiator, i.e. spectral output containing 470nm. Minimum light output must be at least 550mW/cm² exposure for at least 20 seconds. Refer to curing light manufacturer’s recommendations for compatibility and curing recommendations. NOTE: After curing, a thin, air-inhibited film will be present on the exposed surface of the material. Do not disturb this film if completing restoration with a VLC polymericizable methacrylate adhesive/restorative. This film will bond to and cure with any DENTSPLY-manufactured VLC composite, adhesive and/or restorative material placed over the cured TimeLine™ Base/Liner. If restoring with non-VLC cured and/or non-adhesive material (e.g., amalgam restorative material) wipe the air-inhibited film off the surface of TimeLine™ Base/Liner with a damp cotton pellet and dry the cavity.
7. If a thickness of material greater than 1mm is desired, repeat placement step 5 and curing step 6, 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).
8. Remove any material inadvertently applied to enamel and/or margins with a sharp spoon excavator or a bur.
9. Complete the Restoration: Place desired adhesive, base, and/or restoration following manufacturer’s directions.
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.

Dyca® 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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