

TimeLine™

Visible Light Cure Base/Liner Composition

DIRECTIONS FOR USE

Caution: This is a medical device. For dental use only.

USA: Rx only.

1. PRODUCT DESCRIPTION

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.

1.1. Indications

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

1.2. Contraindications

- TimeLine Base/Liner is contraindicated for use with patients who have a known hypersensitivity to methacrylate resins.
- TimeLine Base/Liner is contraindicated for direct application to dental pulp tissue (direct pulp capping).

1.3. Delivery Forms

TimeLine Base/Liner is available in tubes filled by weight. Air is included in each tube to ensure stability.

1.4. Composition

Urethane Dimethacrylate Resin, Barium Sulfate, Barium Alumino Borosilicate Glass, Sodium Fluoride, Phosphate bonder (Dipentaerythritol Penta Acrylate Phosphate), Photo accelerator, Silicon dioxide filler, Silane coupling agent, BHT (Stabilizer), Photo initiator (Camphorquinone), Synthetic Iron oxide pigments

1.5 Compatible Materials

- For added adhesion or for use on etched dentin, TimeLine Base/Liner is compatible with ProBOND® Dentin Primer (see complete Directions for Use).
- Cured TimeLine Base/Liner is chemically compatible with conventional methacrylate-based visible light cured adhesive, composite restorative and cement materials including Dentsply Sirona visible light cured adhesive, composite and compomer restorative and cement materials. It is physically compatible with amalgam restorative material.

2 GENERAL SAFETY NOTES

Be aware of the following general safety notes and the special safety notes in other chapters of these directions for use.



Safety alert symbol

This is the safety alert symbol. It is used to alert you to potential personal injury hazards. Obey all safety messages that follow this symbol to avoid possible injury.

2.1 Warnings



WARNING: This product can expose you to propylene oxide, which is known to the State of California to cause cancer. For more information, go to www.P65Warnings.ca.gov. Prior to use, read the Safety Data Sheet (SDS) information and product instructions.

TimeLine Base/Liner contains polymerizable methacrylate monomers which may be irritating to skin, eyes and oral mucosa and may cause allergic contact dermatitis in susceptible persons.

Avoid Eye Contact to prevent irritation and possible corneal damage. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.

Avoid Skin Contact to prevent irritation and possible allergic response. If contact with skin occurs immediately remove material with cotton and wash thoroughly with soap and water. In case of skin sensitization or rash, discontinue use and seek medical attention.

Avoid contact with oral soft tissues/mucosa to prevent inflammation. If accidental contact occurs, immediately remove material from the tissues. Flush mucosa with plenty of water after the restoration is completed and expectorate/evacuate the water. If inflammation of mucosa persists, seek medical attention.

TimeLine Base/Liner is not designed for use directly on phosphoric acid (etched) dentin. Use directly on etched dentin may lead to post-operative sensitivity or other pulpal effects. Cover any exposed etched dentin with ProBOND® Primer (available separately) according to the manufacturer's Directions for Use prior to TimeLine Base/Liner application (See Step-by-step Directions for Use).

2.2 Precautions

- 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.
- Wear suitable protective clothing, eyewear, and gloves. Protective eyewear is recommended for patients.
- 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.
- Devices marked "single use" on the labeling are intended for single use only. Discard after use. Do not reuse in other patients in order to prevent cross-contamination.
- The tubes cannot be reprocessed. To prevent tubes from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the tube is handled offside the dental unit with clean/disinfected gloves. During treatment clinicians with patient contact should not handle tubes.
- 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 Liner on enamel, cavity margins or leave exposed to oral environment (See Step-by-step Directions for Use).
- Insufficient data exist to support the use of TimeLine Base/Liner as a filling material, core build-up or luting cement.
- Insufficient data exist to support the use of TimeLine Base/Liner directly against phosphoric acid conditioned (etched) dentin.
- 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.
- 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).
- 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.
- 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.
- Use only in well ventilated areas.
- Allow TimeLine Base/Liner material to reach room temperature prior to use for optimum flow.

Interactions:

- Eugenol- and hydrogen peroxide-containing materials should not be used in conjunction with this product since they may interfere with hardening and cause softening of the polymeric components of the material.
- TimeLine Base/Liner is a visible light-cured material. Proceed immediately once material has been placed on mixing pad or protect from ambient light.

2.3 Adverse Reactions

- 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.
- Product may cause pulpal effects. See Contraindications, Warnings, Precautions.

2.4 Storage Conditions

Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product.

TimeLine Base/Liner material containers should be stored with the original cap only. Keep out of direct sunlight and store in a well ventilated place at refrigerated temperatures between 2°C/35°F and 8°C/46°F. 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.

3. 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® Prophylaxis 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 Base/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.



Curing time for ≤1 mm increments

6. Light cure the material with a suitable visible light curing unit designed to cure materials containing camphorquinone (CQ) initiator, i.e. peak spectral output 440-480 nm. 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.



Inadequate polymerization due to insufficient curing

- Check compatibility of curing light.
- Check curing cycle.
- Check curing output before each procedure.

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 polymerizable methacrylate adhesive/restorative. This film will bond to and cure with any Dentsply Sirona 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.

4. HYGIENE AND DISPOSAL

4.1 Tubes – cross-contamination



Cross-contamination Infection

- Tubes cannot be reprocessed.
- To prevent the tubes from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the tubes are handled with clean/ disinfected gloves. Do not reuse tubes if contaminated.
- Dispose of contaminated tubes in accordance with local regulations.

To prevent tubes from exposure to spatter or spray of body fluids or contaminated hands, or oral tissues, use of a protective barrier is recommended. The use of protective barriers is an additional precautionary measure against gross debris but not against all contamination. The barrier is designed for single use and must be disposed of after each use in accordance with local regulations.

Incidental contact of the tube with water, soap or a water-based hospital-level disinfection solution will not damage tube body. Do not allow any solution contact with contained material. Discard material that has been in contact with any fluid or non-sterile instrument.

Repeated liquid contact may damage label. Dry the tube with a lint-free single-use cloth.

NOTE: Vigorous wiping can destroy the label. Wipe syringe gently.

4.2. Disposal

Dispose of in accordance with local regulations.

5. LOT NUMBER, EXPIRATION DATE AND CORRESPONDENCE

- Do not use after expiration date. ISO standard is used: "YYYY/MM" or "YYYY-MM-DD."
- The following numbers should be quoted in all correspondences:
 - Reorder number
 - Lot number
 - Expiration date
- Any serious incident in relation to the product should be reported to the manufacturer and the competent authority according to local regulations.



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