SureFil™
High Density Posterior Restorative

Caution: U.S. Federal Law Restricts This Device To Sale By Or On The Order Of A Dentist.

Caulk SureFil™ High Density Posterior Restorative is a visible light activated, radiopaque restorative material designed for stress-bearing posterior restorations of primary and permanent teeth. It is to be used with Prime & Bond® NT™ Nano-Technology Light Cured Dental Adhesive System. The handling characteristics allow rapid, bulk placement and assist with establishment of properly located and shaped proximal contact areas. This one-component, Visible Light Cured SureFil™ is packaged in individual dose, light opaque cups.

INDICATION:
1. SureFil™ is indicated for cavity classes I, II, in posterior teeth.
2. SureFil™ may be used as an indirect restorative material and for the fabrication of inlays and onlays.

CONTRAINDICATIONS:
1. SureFil™ and Prime & Bond® NT™ Adhesive are contraindicated for use with patients that have a history of severe allergic reaction to methacrylate resins.
2. Prime & Bond® NT™ Adhesive is not indicated for direct application to dental pulp tissue (direct pulp capping).

WARNINGS:
1. SureFil™ and Prime & Bond® NT™ Adhesive both contain polymerizable monomers which can cause skin sensitization (allergic contact dermatitis) in susceptible individuals. Wash thoroughly with soap and water after contact. If skin sensitization or other allergic reaction occurs, discontinue use.
3. Prime & Bond® NT™ Adhesive contains methacrylate, which may be irritating to the eyes. If accidental contact occurs, rinse immediately with plenty of water and seek medical advice.
4. Caulk 34% Tooth Conditioner Gel contains phosphoric acid that can cause burns of soft tissue. Avoid contact with oral soft tissues, eyes and skin. If accidental contact occurs, immediately rinse with plenty of water and seek medical attention. Do not take internally.

PRECAUTIONS:
1. Caulk 34% Tooth Conditioner Gel in syringes should extrude easily: DO NOT USE EXCESSIVE FORCE. Replace original cap of Caulk 34% Tooth Conditioner Gel tightly after each use to avoid evaporation. Discard needle after use, as needles may clog if gel is allowed to dry inside.
2. Eugenol-containing dental materials (temporary restoratives) should not be used with SureFil™ or Prime & Bond® NT™ Adhesive because they may interfere with hardening and cause softening of the polymeric components of the materials.
3. The SureFil™ and Prime & Bond® NT™ contain photoinitiators for visible light cure. Protect from exposure to ambient light. The Prime & Bond® NT™ should be tightly closed immediately after use.

STORAGE CONDITIONS:
1. Keep out of sunlight.
2. Store at or below room temperature (75°F/25°C). Do not freeze.
3. Keep the SureFil™ and Prime & Bond® NT™ Adhesive in a well ventilated place.
4. At 75°F (25°C), SureFil™ has a shelf life of approximately three years from the date of manufacture. Prime & Bond® NT™ Adhesive has a shelf life of approximately 24 months.
Adverse Reactions:

Allergic contact dermatitis and other allergic reactions may occur in susceptible individuals.

STEP-BY-STEP INSTRUCTIONS FOR USE:

1. **Cavity Preparation**

   Cavity design requirements are essentially the same as conventional composite restorative preparation. Internal line and point angles should be rounded. No residual amalgam or other base material should be left in the internal forms of the preparation which would interfere with the Prime & Bond® NT™ Adhesive bond to tooth or with light transmission and the hardening of the restorative. Rinse completed preparation thoroughly with air/water spray.

2. **Pulp Protection**

   Prior to Acid-Etching in normal depth (routine) cavity preparations, where remaining dentin thickness is judged to be greater than 1mm, a calcium hydroxide base is not required. In all deep preparations, in close proximity to the pulp, less than 1mm remaining dentin thickness, place a calcium hydroxide liner such as Dycal® or Prisma® VLC Dycal® Base/Liner Composition.

3. **Placement Of Matrix**

   The use of a deadsoft, thin matrix band (i.e. Automatrix® II or a sectional matrix system) and subsequent burnishing of the matrix and will improve final inter-proximal contact and contour.

   **PRE-WEDGING IS ADVOCATED TO ACHIEVE SLIGHT SEPARATION AND FACILITATE ACCEPTABLE PROXIMAL CONTACT.**

4. **Tooth Conditioning/Dentin Pretreatment**

   When Prime & Bond® NT™ is used as a bonding agent for direct composite materials, it is recommended to follow the total etch technique described below:

   4.1 **Application of Caulk 34% Tooth Conditioner Gel**

   After application of rubber dam or other suitable isolation technique, apply Caulk 34% Tooth Conditioner Gel. Attach disposable needle to end of syringe. Turn tip 1/4 to 1/2 turn to assure it is fully seated. Tug tip to be certain it is locked into the wall of the syringe. Needle tip may be bent for easy access. Gently extrude Caulk 34% Tooth Conditioner Gel (34% phosphoric acid) to the cavity surfaces starting at the enamel margins. For best results, condition enamel for at least 15 seconds and dentin for 15 seconds or less.

   4.2 **Rinsing and Blot Drying**

   Remove gel with aspirator tube and/or vigorous water spray and rinse conditioned areas thoroughly for at least 10 seconds. Blot dry conditioned areas with a moist cotton pellet. For best results, saturate a cotton pellet and remove excess water from the pellet by blotting it on a gauze pad before using the pellet to blot the tooth. Proceed immediately to application of Prime & Bond® NT™ Adhesive.

   Important Note:
   • The goal of blot drying is to provide the correct amount of “wetness” on the tooth surface by removing all excess moisture and yet avoiding desiccating the dentin. Do not rub the tooth surface when blot drying. Dentin should be blotted until there is no pooling of water, leaving a moist, glistening surface.
   • Once the surfaces have been properly treated, they must be kept uncontaminated. If salivary contamination occurs, repeat procedure beginning at step 4.1.

5. **Application of Prime & Bond® NT™ Nano-Technology Light Cured Adhesive System**

   5.1 Dispense Prime & Bond® NT™ Adhesive directly onto a clean disposable brush provided or place 2-3 drops of Prime & Bond® NT™ Adhesive into a clean well. Replace cap promptly.

   5.2 Using the disposable brush supplied, immediately apply generous amounts of Prime & Bond® NT™ Adhesive to thoroughly wet all the tooth surfaces. This surface should remain fully wet for 20 seconds and may necessitate additional applications of Prime & Bond® NT™ Adhesive.

   5.3 Remove excess solvent by gently drying with clean, dry air from a dental syringe for at least 5 seconds. **Surface should have a uniform glossy appearance.** If not, repeat steps 5.2 and 5.3.
5.4 Cure Prime & Bond® NT™ Adhesive for 10 seconds using a curing light (i.e., ProLite®, Spectrum™ or QHL75™).

Important Note:
When using a high performance unit such as the curing lights manufactured by DENTSPLY, a curing time of 10 seconds is sufficient. For curing lights with an output lower than 300 mw/cm², a curing time of 20 seconds should be observed.

6. **Placement of SureFil™ High Density Posterior Restorative**

**INDIVIDUAL DOSE CUPS**

6.1 Remove protective covering. Place material onto a clean mixing pad, dappen dish. Use the unit dose cup, inverted over remaining material, to protect SureFil™ from premature polymerization via ambient light while current increment is adapted and light cured.

6.2 Load nonstick, plastic insert type amalgam carrier or cut a suitable section with a sharp instrument.

6.3 **A)** Class II - Fill the proximal box in bulk (up to 5 mm), level with the pulpal floor. Firmly adapt material to cavity walls and stabilize matrix band by stepping a clean non serated condenser (plunger) from middle to edges, reducing incorporated air and eliminating voids. Use an amalgam condenser to pack the material. **Light cure** for 40 seconds.¹ The remainder of the preparation is filled in bulk (up to 5 mm).

**B)** Class I - SureFil™ may be placed in bulk (up to 5 mm).

6.4 Prior to final light curing, contour and shape with the operator’s choice of clean carving and burnishing instruments.²

**Important Technique Note:**
To minimize finishing time, contour marginal ridge first before occlusal anatomy. Carve margins and anatomy to final form. SureFil™ resists slumping, allowing carving of the majority of anatomical form prior to Visible Light Curing.

It is strongly recommended that the instrument used to contour cavosurface margins (occlusal and proximal) should be lubricated from time to time with a thin coat of residual Prime & Bond® NT™ to ensure optimal marginal adaptation.³

6.5 Light cure each area of the restoration surface with a Curing light, i.e., Spectrum™, ProLite® or QHL75™ Curing Unit for at least 40 seconds.¹ The SureFil™ material should be additionally exposed to the curing unit through the proximal, lingual, and buccal enamel walls following matrix removal.

**FINISHING AND POLISHING**
Begin finishing immediately after matrix removal and final increment curing. Gross excess may be removed with Prisma® Finishing Burs or other carbide finishing burs. Additional finishing and polishing is obtained by use of Enhance® Discs, Cups or Points and interproximal strips. Alternatively, other standard aluminum oxide disc series and/or abrasive impregnated points may be used.

A high luster can be obtained on SureFil™ material by applying Prisma® Gloss™ followed by Prisma® Gloss™ Extrafine with Enhance® Polishing Foam Cups.

**Procedure**

**STEP 1:** Complete gross reduction of excess and general outline form of the restoration using Prisma® Finishing Burs, or diamond finishing instruments.

**STEP 2:** Insert an Enhance® Finishing Disc, Cup or Point into a latch conventional speed contra-angled handpiece and continue finishing. The aggressiveness of the Enhance® Disc is controlled by the pressure applied to the surface of the composite. The greater the pressure, the more material is removed; lighter pressure leaves a smooth surface without removing bulk.

**STEP 3:** Attach an Enhance® Polishing Cup to the provided mandrel by inserting the bayonet end of the mandrel into the opening on the narrow end of the cup. Rotating the mandrel 1/4 turn makes insertion easier. Make sure the mandrel inserts fully into the cup. Insert the mandrel into a conventional speed contra-angled handpiece.

**STEP 4:** Apply a small amount of Prisma® Gloss™ Material to the surface of the Enhance® Cup. Work the surface of the restoration, dry initially, at moderate speed and pressure. Use flat end and corner edge of cup.

**STEP 5:** To increase surface luster, ADD WATER IN SMALL AMOUNTS (i.e. dropwise) to dilute the paste using a light circular buffing motion. Repeat as needed to produce a smooth surface.

¹ Check curing light for minimum curing output of at least 300 mw/cm².
² Suggested instruments for carving may be either blunt round instruments such as PKT-3 or a round ice cream cone type instrument; alternative carving instruments include a cleoid-discoid, Walls or Hollenbeck carver. Be sure the instrument is lubricated with residual Prime & Bond® NT™ during the carving and contour process.
³ The Prime & Bond® NT™ should be previously dispensed to allow for solvent evaporation. It using product immediately dispensed, lightly apply air to material in the plastic dappen dish for evaporation of the acetone solvent prior to use as “modeling” liquid.
STEP 6: Rinse Prisma® Gloss™ from the tooth surface and Enhance® Cup. Apply Prisma® Gloss™ Extrafine Paste to the Enhance® Cup as described in step 4 and polish the surfaces dry at first, then adding increasing amounts of water for 15-30 seconds for final luster. The Enhance® Cup should be discarded after use.

Technique Hints:

1. The aggressiveness of the Enhance® Disc is controlled by the pressure applied to the surface of the composite. The greater the pressure, the more material is removed; lighter pressure leaves a smooth surface without removing bulk.

2. Polishing efficiency is greatly increased and splatter of Prisma®-Gloss™ is greatly reduced by rubbing paste into the surface of the Enhance® Polishing Cup before use. This procedure leaves a thin, adherent surface film of paste in the cup surface. Use the paste impregnated cup dry at low speed; after 30-60 seconds, apply a small amount of water to the tooth and cup. Use again at low speed for another 30-60 seconds to achieve high surface luster.

3. As with any rotary instrument, heat will build up when using the Enhance® Disc with prolonged contact. Use with intermittent pressure.

4. Use the flat end and corner edge of the Enhance® Polishing Cup. Excessive lateral pressure may dislodge cup from mandrel.

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