

SECTION XI: TOXICOLOGICAL INFORMATION

Carcinogens: None known.

SECTION XII: ECOLOGICAL INFORMATION

This material contains hazardous components. Allow materials to cure prior to disposal.

SECTION XIII: DISPOSAL CONSIDERATIONS

Dispose of safely in accordance with local, state, and federal regulations.

SECTION XIV: TRANSPORT INFORMATION

Stable under normal conditions of use, transportation, and storage.

SECTION XV: REGULATORY INFORMATION

510k #: K102753

SECTION XVI: OTHER INFORMATION

None

The data and information given in this msds are accurate on the date of preparation. It does not indicate any warranty or representation. We disclaim all liability relating to use of this material since this is beyond our control.

PURELIFE TEMPORARY CROWN & BRIDGE MATERIAL

PureLife Temporary Crown & Bridge Material is a syringeable bis-acryl composite for chairside provisional restorations. PureLife Temporary Crown & Bridge Material is fast and accurate, especially when used in conjunction with a quality vinyl polysiloxane impression material such as PureLife VPS Impression Material. PureLife Temporary Crown & Bridge Material is available in 6 shades: A1, A2, A3, A3.5, B1, and Bleach BL. All are delivered in 76g (50mL) cartridges designed to fit on a 10:1 style automix gun. Ten waste saver tips are included per kit.

INDICATIONS

Fabrication of provisional crowns, bridges, inlays, onlays, partial crowns and veneers.

PRECAUTIONS

1. PureLife Temporary Crown & Bridge Material contains methacrylate monomers which can cause allergic reactions in susceptible individuals. Avoid contact between uncured product and skin, oral soft tissues or eyes. Do not take internally. Consult MSDS for more information.
2. Use as directed. This product is intended for use by dental practitioners only. Wear appropriate personal protective equipment.
3. PureLife Temporary Crown & Bridge Material will adhesively bond to most dental adhesives and the air inhibited layer of fresh resin-based restoratives, making provisional removal for trimming difficult.
4. Contact with Eugenol containing products may interfere with the hardening of PureLife Temporary Crown & Bridge Material.
5. PureLife Temporary Crown & Bridge Material MUST BE REMOVED FROM THE PATIENT PRIOR TO 30 DAYS.

TIMING

- 0:00-0:40 — Insertion in the mouth
2:00-2:30 — Removal from the mouth (if removed)
2:30-4:30 — Trimming/Finishing
5:00 — Final Hardness

RECOMMENDED METHOD

PRELIMINARY IMPRESSION: Prior to tooth preparation, place some flexible vinyl polysiloxane (PureLife Medium Body FS recommended) on a TRIPLE TRAY* and make a closed bite impression. Stiff heavy body materials (such as those for bite registration) must be avoided, as once removed, they will not go back well into undercuts. Alginate is an alternative, although less satisfactory.

PREP AND FINAL IMPRESSION: Prepare subject tooth and complete final impression. To preclude bonding to PureLife Temporary Crown & Bridge Material, cover any composite buildup with a separating agent.

IMMEDIATELY PRIOR TO USE: Remove cap and eject a pea size quantity of material out of the bare cartridge end. Eject slowly until a steady flow exudes from both compartments. Wipe off the end (without cross mixing) and install the mixing tip.

*Not a PureLife trademark.

FABRICATE TEMPORARY

1. CEMENTATION METHOD:

1. Discard first pea size of mixed material and inject PureLife Temporary Crown & Bridge Material into the prep areas of the preliminary impression (using care to avoid trapping air bubbles) and have patient close on the tray.
2. Remove the tray when PureLife Temporary Crown & Bridge Material has reached its elastic phase (approx. 2 minutes after injection). The provisional restoration will be retained in the tray and be slightly flexible. Remove excess material around the margins



while it is still in the tray using an amalgam carver or #15 scalpel. Ensure composite is not locked into proximal undercuts.

3. Immediately reset the tray and restoration in the mouth until completion of cure (approx. 5 minutes after injection).
4. Remove the provisional restoration from the mouth and complete trimming and finishing with a diamond. Cement into place using a non-eugenol temporary cement.
5. Porosity can be filled with flowable composite and light cured.

Note: If undercuts exist, such as inlay or onlay, brush non-eugenol cement (such as Nogenol) into the undercuts and let it set before placing the PureLife Temporary Crown & Bridge Material.

2. SHRINK FIT METHOD:

1. Discard first pea size of mixed material and inject PureLife Temporary Crown & Bridge Material into the prep areas of the preliminary impression (using care to avoid trapping air bubbles) and have patient close on the tray.
2. Remove the tray when PureLife Temporary Crown & Bridge Material has reached its trimming/finishing phase. Ideally the tray comes off the provisional restoration, leaving it firmly seated on the teeth. If not, immediately reseat the restoration on the teeth.
3. Trim off the flash with a small Retract instrument, moving it vertically to cleave the flash off the margins. Alternatively use a #15 scalpel blade to trim off flash. (approx. 3 minutes after injection).
4. Porosity can be filled with flowable composite and light cured.
5. For removal, the restoration will need to be split with a diamond and pried off.

PURELIFE TEMPORARY CROWN & BRIDGE MATERIAL BRIDGE FABRICATION

Three units is the recommended maximum span. To add strength the proximals of posteriors, the connector areas should be modified to add bulk, prior to taking the preliminary impression. In the posterior, both buccal and lingual can be modified. In the anterior, most of the modification should be done on the lingual to preserve esthetics. The preferred block-out material is Ultradent Blue Blockout, but soft wax can also be used.

ADDITIONAL REINFORCEMENT: Wet Ribbond™ (or some other fiber) with E-Bond™, or Accolade™ flowable composite. Place the wetted fiber into the occlusal aspect of the preliminary impression. Using PureLife Temporary Crown & Bridge Material, infuse the fiber reinforcement and fill the remainder of the impression. Seat the filled preliminary impression in the mouth. Remove at approximately 2 minutes after injection. The reinforced provisional bridge will remain in the preliminary impression when it is removed from the mouth. Finish and cement as indicated in the recommended procedure.

*Not a PureLife trademark.

HELPFUL HINTS

- When starting with a new cartridge: place cartridge in gun, remove cap, and extrude a small amount of material to insure both sides are flowing. NOTE: Always bleed the cartridge before installing a new tip.
- Make sure to mount the mixing tip properly. The tip has different size bores, and a notch to indicate proper orientation. Incorrectly mounting the tip can damage cartridge or cause cross-contamination.
- Waste the first pea size amount of mixed material that is extruded from tip to insure a full mix.
- Do not remove tip after use, it will serve as a new cap. Do not use cartridge intra-orally.
- A slightly gummy air inhibited layer will remain on the hardened surface of the provisional restoration. This layer allows bubble and margin defects to be minimized by directly bonding with a flowable composite such as StarFlow. The layer is easily removed with ethyl alcohol or polishing wheels/brushes.
- Exposure to temperatures below 74 °F will extend the setting time of PureLife Temporary Crown & Bridge Material. Set times are based on room temperature material. Refrigeration greatly retards set times.
- Normally there is no need for occlusal adjustments if vinyl polysiloxane is used.

STORAGE

Store PureLife Temporary Crown & Bridge Material at temperatures lower than 82 °F(28 °C). Refrigeration may extend shelf life. Do not freeze. Do not use after expiration date.

MATERIAL SAFETY DATA SHEET

SECTION I: IDENTIFICATION

Company: PureLife Dental
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Prepared: December 2012

SECTION II: HAZARD(S) IDENTIFICATION

OSHA Permissible Exposure Limits: None
Other Exposure Limit Used: None
ACGIH Threshold Exposure Limit: None
Chronic, Other: None

SECTION III: COMPOSITION/INFORMATION ON INGREDIENTS

HAZARDOUS COMPONENT	% BY WEIGHT
Multifunctional Methacrylates	40-50
Malonylurea Derivative	Trace
Glass/Silica Filler	40-45
Polyvinyl esters	5-10

SECTION IV: FIRST-AID MEASURES

Primary Routes of Exposure: Skin, ingestion
Signs of Exposure: Severe skin or eye irritation, redness or burning sensation.
Ingestion may cause nausea.
Medical Conditions Generally Aggravated by Exposure: Allergies to methacrylates.
First Aid Procedures: For Skin— Wash off infected area with soap and water. For Ingestion— Seek medical advice, carry container with label and MSDS. For Eyes— Rinse immediately with plenty of water and consult physician.

SECTION V: FIRE-FIGHTING MEASURES

Flash Point: >1000C
Extinguishing Media: Carbon dioxide, foam, dry chemical
Special Fire Fighting Procedures: None
Flammable limits: ND
Unusual Fire and Explosion Hazards: Polymerizes upon heating.

SECTION VI: ACCIDENTAL RELEASE MEASURES

None

SECTION VII: HANDLING AND STORAGE

Spill Management: Use absorbent to collect the material. Wash contaminated surfaces with Soap and water

SECTION VIII: EXPOSURE CONTROLS/PERSONAL PROTECTION

Respiratory: None
Eye Protection: Safety goggles
Gloves: Surgical, rubber/PVC gloves
Other Clothing and Equipment: Face Mask
Ventilation: None required, local exhaust recommended

SECTION IX: PHYSICAL AND CHEMICAL PROPERTIES

Vapor Pressure: Negligible
Vapor Density: >1
Evaporation Rate: <1
Solubility in Water: Slight
Boiling Point: ND
Specific Gravity: >1
Appearance and Odor: Tooth colored paste, slight odor

SECTION X: STABILITY AND REACTIVITY

Stable (x) Unstable ()
Conditions to Avoid: Heat in excess of 250C, direct sunlight or intense light.
Incompatibility: Free radical initiators, oxidizing agents
Hazardous Decomposition Products: Acrylic smoke
Hazardous Polymerization: May occur () Will not occur (x)