

Caulk® Temporary Bridge Resin

DIRECTIONS FOR USE – ENGLISH

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

Caulk® Temporary Bridge Resin is a self-curing methacrylate formulation, intended for use as both a short- and long-term temporary crown and bridge material. This material is used to fabricate provisional restorations that restore function and esthetics during the period of construction of final restorations.

The powder is available in these BioForm® shades; 62 light and 65 medium.

COMPOSITION

Methyl Methacrylate Monomers
Polymerizable dimethacrylate resin
Catalyst
Stabilizers

INDICATION FOR USE

1. Direct fabrication of temporary (limited term) provisional veneers, inlays, onlays, crowns or bridges used in indirect restorative procedures.
2. Indirect fabrication of temporary (limited term) provisional veneers, inlays, onlays, crowns or bridges used in indirect restorative procedures.

CONTRAINDICATIONS

Caulk® Temporary Bridge Resin is contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins.

WARNINGS

1. Caulk® Temporary Bridge Resin contains polymerizable methyl methacrylate monomers. Do not breathe vapors. Use only in well ventilated areas. Avoid prolonged or repeated contact with skin and eyes. Irritation and possible corneal damage may result. Skin rash (allergic contact dermatitis) or other allergic reactions may result in susceptible individuals. Do not take internally.
Inhalation: Move subject to fresh air. Give oxygen or artificial respiration as required.
Eye Contact: Flush eyes with copious amounts of water for at least 15 minutes and consult a physician. Wear suitable protective eyewear before use.
Skin Contact: Caulk® Temporary Bridge Resin contains polymerizable monomers which can cause skin sensitization (allergic contact dermatitis) in susceptible individuals. Wash skin with soap and water after contact and consult a physician if irritation persists. Wear suitable protective gloves and clothing before use.
Oral Mucosa Contact: Avoid contact with oral soft tissues. If accidental contact occurs, flush mucosa with plenty of water and expectorate water. If sensitization of mucosa 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 immediately.
2. **Danger:** Extremely flammable. Caulk® Temporary Bridge Resin contains Methyl Methacrylate. Use only in well ventilated areas. Keep away from heat, sparks and open flame.
3. The polymerization reaction of Caulk® Temporary Bridge Resin is exothermic. Do not apply directly to pulp tissue. Monitor curing carefully to prevent overheating of tooth preparation. (See *Step-By-Step Instructions*)

PRECAUTIONS

1. This product is intended to be used only 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 eyewear, mask, clothing and gloves. Protective eyewear is recommended for patients.
3. The Caulk® Temporary Bridge Resin containers should be tightly closed immediately after use. Replace original cap tightly after each use.
4. The setting reaction is exothermic. To avoid tissue injury, final setting should occur outside of the mouth, or continuously cooled with air water spray if allowed to set on tooth preparations. (See *Step-By-Step Instructions*)

STORAGE

Caulk® Temporary Bridge Resin should be stored in the original containers only, kept out of direct sunlight and stored in a well-ventilated place. Store at or below room temperature (25°C/ 77° F). 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. Inhalation of vapors may cause varying degrees of damage to the affected tissue and also increased susceptibility to respiratory illness. (See *Warnings*)

3. Product may cause pulpal effects. (See *Warnings and Precautions*)

INTERACTIONS

1. Caulk® Temporary Bridge Resin will adhesively bond to most dental adhesives. Use of a dentin/enamel adhesive on the preparation prior to restoration fabrication may make restoration removal and cleanup difficult.
2. Caulk® Temporary Bridge Resin will adhesively bond to freshly placed methacrylate and composite core buildup materials. Buildups should be fully cured, prepared, and rinsed thoroughly with forceful air/water spray before application of Caulk® Temporary Bridge Resin. If surfaces were not prepared or instrumented, wipe thoroughly with alcohol soaked gauze, then rinse with air/water spray. Apply a thin film of lubricating medium (e.g. petroleum jelly) to any exposed methacrylate/composite core material.
3. Eugenol containing 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.

STEP-BY-STEP INSTRUCTIONS

Direct Method

1. Preliminary Impression

- 1.1 Prior to preparation of the tooth/teeth, evaluate existing contours and anatomy. To duplicate existing anatomy proceed to primary impression. If contours or anatomy are deficient, wax or light cured composite may be placed and cured without bonding agent on the tooth/teeth as a mock up to approximate the desired contours. A missing tooth may be temporarily replaced with an acrylic denture tooth prior to preliminary impression. Restore damaged or missing teeth (or tooth) to contour with wax.
- 1.2 Make an alginate or silicone impression including tooth/teeth to be prepared following manufacturer's *Directions for Use*.
- 1.3 When removed from the mouth, trim the inter dental gingival areas out of the preliminary impression in the area(s) to be restored to provide bulk for the later finishing of the temporary restoration. In molar areas with absent teeth that were not replaced prior to impression, the carving in the interproximal areas should create a ridge for pontic contact between the prepared teeth. Note: Store alginate impressions at 100% humidity until Caulk® Temporary Bridge Resin material is to be inserted. **Technique Tip:** Alternatively, a vacuum-formed matrix may be constructed on a cast (with diagnostic wax-up, contour modification as indicated).

2. Prepare tooth/teeth

- 2.1 If pre-impression mock up wax or composite was placed, it should be removed. Prepare tooth/teeth, and build up as needed following manufacturer's *Directions for Use*. Ensure adequate reduction for material thickness, especially on functional occlusal surfaces
- 2.2 Trial-fit impression (or vacuum-formed matrix) made in *Step 1* to ensure adequate orientation. Rinse impression and lightly air dry. Block out noninvolved sockets of impression using moist cotton pellets.
- 2.3 Block out preparation undercuts with wax or suitable material, clean tooth/teeth preparation with alcohol soaked gauze and/or air water spray and lightly dry. Do not desiccate tooth structure. **Technique Tip:** A thin layer of water-soluble lubricating medium may be applied to the tooth preparation and soft tissues to facilitate removal of the curing Caulk® Temporary Bridge Resin.

3. Mixing and Application

- 3.1 Using the calibrated dropper supplied (marked 1mL), dispense required liquid into a clean dappen dish or mixing jar. A typical three (3)-unit bridge requires two (2) droppers (filled to the calibrated line) of liquid.
- 3.2 Add powder to the liquid in excess while tapping the dish or jar to cause particles to disperse through liquid. When liquid is absorbed, invert jar to discard excess powder. Stir mix with a few strokes of any convenient instrument. Let stand for approximately one (1) minute at 70°F, until mixture reaches the consistency of soft dough.
- 3.3 Using clean-gloved hands, form the dough-like resin into a roll and, using light finger pressure, press resin into the preliminary impression into the area of the preparation to gingival border.

Optional Pouring Procedure

Operators preferring to pour the resin mix into the impression (rather than placing it in a dough-like consistency) should use the following powder/liquid ratio: 4cc powder to 2mL liquid. Stir powder and liquid together in mixing jar until all powder particles are wetted. Pour mix into involved impression cavities. Allow mix to stand for approximately 1 minute at 70°F before seating loaded impression in mouth (Direct Method) or on stone cast (Indirect Method).

- Trim excess resin from border areas and remove block-out cotton pellets. Apply suitable lubricant to hard and soft tissues in operating field. Have patient rinse mouth, and then reseat the preliminary impression into the patient's mouth in the proper relative position.
- 3.4 Withdraw impression from mouth when the resin becomes rubbery (approx. 1 minute).
NOTE: The use of lubricant may assist in removal from the mouth.

4. Removal from Mouth

- 4.1 Remove the impression containing the Caulk® Temporary Bridge Resin restoration during the rubbery stage. Monitor the curing process carefully because removal of the temporary restoration is only possible during the elastic phase. Remove Caulk® Temporary Bridge Resin restoration from impression, or from mouth if it separates upon withdrawal. If the material remains on the preparation when the impression is removed, gently tease the restoration off with gauze. Use finger pressure only, and dislodge along the path of insertion. Do not rock or torque restoration off the preparation. Avoid the use of hemostats or other pliers that may distort the setting Caulk® Temporary Bridge Resin restoration.
- 4.2 At this rubbery phase, gross excess may be quickly trimmed with sharp scissors, being careful not to distort the restoration or margins.
- 4.3 Reseat the resin, while still rubbery to correct distortions that may occur during trimming. Check undercut areas and trim further, if necessary, for easy removal and subsequent reseating of temporary restoration.

5. Curing and Finishing

- 5.1 The temporary appliance may be cured in or out of the mouth. **Technique Tip:** If left in the mouth for curing, to avoid possible gingival irritation, remove to trim and relieve the temporary appliance while in the rubbery stage. To avoid overheating of the tooth when the appliance is left in, use an air and/or water spray to cool the appliance. If cured out of the mouth (recommended) place setting restoration in warm water and allow to set.
- 5.2 After cure is complete (approx. 10 minutes from beginning of mix), finish and polish the temporary appliance. Remove the excess material and proximal undercuts with rotary instruments. Establish final contours. Return appliance to the mouth, confirm fit and adjust occlusion as necessary. If additions are necessary, see *Step 7, Repairing/Modifying the Temporary Restoration*.
- 5.3 Restoration may be polished with flour of pumice and acrylic polish. Caulk® Temporary Bridge Resin is also compatible with many light cured methacrylate-based tints and glaze/polishing materials (see complete *Directions for Use* supplied with polishing product chosen).

6. Luting the Temporary Restoration

- 6.1 If increased retention is desired, microetching (sandblasting) with 50µ alumina the internal surfaces of the restoration is recommended. The internal surface of the restoration should be clean and dry prior to cementation.
- 6.2 Caulk® Temporary Bridge Resin temporary restorations can be cemented with most commonly used temporary luting agents. See manufacturer's complete *Directions for Use* for compatibility and specific technique. Most eugenol-containing temporary cements are compatible with Caulk® Temporary Bridge Resin material. However, they can have a deleterious influence on resin-containing luting systems chosen for final restoration cementation.

7. Correcting and Repairing the Temporary Restoration

- 7.1 **Freshly made restorations:** If the appliance, after finishing, is deficient in some area, more resin can be added. Using a small brush, wet contacting surface of appliance with liquid. Pick up powder particles on wet brush and apply over surface of appliance. Build to proper contour. Cure as previously described. Finish, polish and cement as outlined above. **Technique Tip:** Dispense a small amount of liquid into a dappen dish to use for corrections and/or repairs. Do not allow powder or used brush to contaminate liquid in the bottle.
- 7.2 **Restorations in service:** Caulk® Temporary Bridge Resin temporary restorations are characterized by excellent mechanical properties. However, should breakage occur, the following procedures are recommended. Roughen the surfaces of the breakpoint with a coarse diamond bur and place undercuts in the adjacent areas. Prepared parts may be placed intraorally to assure fit and proper alignment. If fractured sections do not approximate, consideration should be given to remaking, rather than repairing the restoration. Use freshly mixed Caulk® Temporary Bridge Resin material to connect the parts. Hold in place for 1 minute and allow to fully cure for a minimum of 10 minutes. Remove and finish and polish as outlined above.

STEP-BY-STEP INSTRUCTIONS

Indirect Method

Follow the same construction procedure as detailed for the **Direct Method**, except use a working model in the form of a stone cast made from an alginate or silicone impression. All work is performed on the cast instead of in the mouth.

Technique Tip: Liberally lubricate the stone cast prior to placing the Caulk® Temporary Bridge Resin for ease of removal.

Technique Tips to avoid breakage:

- Be sure adequate preparation reduction/occlusal clearance exists.
- Adjust occlusion removing undesirable contacts.
- Allow adequate bulk for connectors in multiple unit provisional restorations.
- Avoid squeezing the Caulk® Temporary Bridge Resin restoration with pliers when removing restoration.
- Caulk® Temporary Bridge Resin restorations are durable under usual provisional conditions. Many factors contribute to the longevity, thus no definitive lifespan can be stated. However, if final restorations are not planned to follow in timely succession, consideration must be given to subsequent removal and restoration remake.

CLEANING AND DISINFECTION INSTRUCTIONS

Use of protective barriers is recommended to avoid package contamination. Repeated disinfection may cause damage to the labels.

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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