Calibra® Esthetic Resin Cement

DIRECTIONS FOR USE – ENGLISH

Calibra® Esthetic Resin Cement is a visible light cured, dual cured or self cured high strength resin cement compatible with numerous dentin/enamel adhesive systems including ProBOND® All purpose Bonding agent, Prime&Bond® NT® Universal Dental Adhesive System and Prime&Bond® NT™ Dual Cure Universal Dental Adhesive System to adhesively bond and lute indirect restorations to tooth structure.

The use of a dentin/enamel adhesive is mandatory for use with Calibra® Esthetic Resin Cement. Prime&Bond® NT™ Adhesive or Prime&Bond® NT™ Dual Cure Universal Dental Adhesive is recommended for use with Calibra® Esthetic Resin Cement. Use of other dentin/enamel adhesive systems with Calibra® Esthetic Resin Cement is at the discretion and sole responsibility of the dental practitioner.

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

COMPOSITION

Calibra® Esthetic Resin Cement Base: Dimethacrylate Resins; Camphorquinone (CQ) Photoinitiator; Stabilizers; Glass Fillers; Fumed silica; Titanium Dioxide; Pigments

Calibra® Esthetic Resin Cement Catalyst: Dimethacrylate Resins; Catalyst; Stabilizers; Glass Fillers; Fumed silica; Titanium Dioxide; Pigments

Calibra® Silane Coupling Agent: Acetone; Ethyl Alcohol; Organo Silane

INDICATIONS

1. Adhesive cementation of ceramic, porcelain, composite inlays/onlays, veneers and crowns.
2. Adhesive cementation of all metal crowns, bridgess, inlays/onlays including precious, semi-precious and non-precious metals.
3. Adhesive cementation of PFM (porcelain fused to metal) crowns and bridges.
4. Adhesive cementation of prefabricated and cast posts.
5. Adhesive cementation of resin-bonded retainer bridges (Maryland bridges).

CONTRAINDICATIONS

1. Calibra® Esthetic Resin Cement is contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins or any of the components.
2. When used in self-cure or dual cure (limited or no light curing) techniques, Calibra® Esthetic Resin Cement is contraindicated for use with Xeno™ III Single Step Self-Etching Dental Adhesive.

WARNINGS

1. Calibra® Esthetic Resin Cement contains polymerizable methacrylate monomers. Avoid prolonged or repeated contact with skin (allergic contact dermatitis), oral soft tissues, and eyes. Avoid prolonged inhalation. Do not take internally.

Eye contact: Calibra® Esthetic Resin Cement contains methacrylates which may be irritating to eyes. Before using this product wear protective glasses as well as covering the patient’s eyes to protect from splashing material. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.

Skin contact: Calibra® Esthetic Resin Cement contains polymerizable monomers which can cause skin sensitization (allergic contact dermatitis) in susceptible individuals. If contact with skin occurs immediately wipe off thoroughly with cotton and alcohol and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs discontinue use and seek medical attention.

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 immediately.

Ingestion: Do not swallow or take internally. If accidental swallowing occurs, drink lots of water. If nausea or illness develop, seek medical attention immediately. Contact regional Poison Control Center if necessary.

2. Calibra® Silane Coupling Agent contains acetone. Do not breathe vapor.

Inhalation: Give oxygen or artificial respiration if necessary.

3. Calibra® Silane Coupling Agent in syringe should extrude easily: DO NOT USE EXCESSIVE FORCE. Excessive pressure may result in unanticipated extrusion of the material.

4. For full coverage vital crown preparations, acid-conditioning remains enamel only. Etching of full coverage dentin surfaces is not recommended to minimize the possibility of post-operative sensitivity.

PRECAUTIONS

1. Insufficient data exist to support the use of Calibra® Esthetic Resin Cement as a core build up, filling material, base or liner.
2. Insufficient data exist to support the use of Xeno™ III Self-Etch Adhesive with Calibra® Esthetic Resin Cement for veneer cementation-light cured.
3. 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.

4. Wear suitable protective eyewear, clothing and gloves. Protective eyewear is recommended for patients.

5. 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.

6. Increased temperature may accelerate the setting reaction. After placing Calibra® Cement in contact with tooth structure, e.g., within endodontic post space or in inlay/onlay preparations, immediately seat restoration. Any delay may allow polymerization to begin, which may prevent complete seating of the restoration.

7. As with any dual cure resin cement system, the use of a dual cure adhesive system such as Prime&Bond® NT™ Dual Cure Dental Adhesive system can shorten working time. This effect should be investigated in the laboratory prior to clinical use. Exercise caution when placing multiple units not to exceed available working time. Load and insure complete seating of each unit prior to loading successive units. The use of a fresh mix of cement is recommended if available working time is approached.

8. Calibra® Esthetic Resin Cement, when used with Catalyst for self-cure or dual cure should be mixed in equal volumes for optimum performance. Variations from this 1:1 ratio may shorten available working time and compromise final physical properties.

9. The Calibra® Esthetic Resin Cement and Calibra® Silane Coupling Agent containers should be tightly closed immediately after use.

10. The Calibra® Esthetic Resin Cement is a light-cured material. Proceed immediately once materials have been placed on mixing pad or protect from ambient light.

11. Use only in well ventilated areas.

12. Flammable: Calibra® Silane Coupling Agent contains acetone. Keep away from sources of ignition.

13. For use of phosphoric acid conditioners on full coverage vital crown preparations see Warnings.

14. The efficacy of Caulk® 34% Tooth Conditioning Gel as an etchant/cleanser of indirect restorations has not been demonstrated.

15. Variable in-vitro data exist regarding use of Calibra® Esthetic Resin Cement in dual-cured or self-cured (limited or no light curing) applications in
conjunction with some light-cured-only adhesives such as Prime&Bond® NT™ Universal Dental Adhesive without Self Cure Activator. Chemical/product incompatibility may adversely affect product efficacy, leading to premature restoration failure. (See Contraindications, Precautions)

16. Storage and Shelf Life: Calibra® Esthetic Resin Cement should be stored with the original cap only, kept out of direct sunlight and stored in a well ventilated place at refrigerated temperature between 2°C/35°F and 8°C/46°F when not in use. Allow material to reach room temperature prior to use. Calibra® Silane Coupling Agent, stored with the original cap only, should be kept out of direct sunlight and stored in a well ventilated place at room temperature not exceeding 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. Product may cause serious health effects if ingested. (See Warnings)
3. Phosphoric acid conditioners may cause pulpal effects. (See Contraindications and Warnings)
4. Inhalation of vapors may cause varying degrees of damage to the affected tissue and also increased susceptibility to respiratory illness. (See Precautions)
5. The following medical conditions are generally aggravated by exposure: Individuals with pre-existing skin disorders, eye problems or impaired liver, kidney and respiratory functions.

STEP-BY-STEP INSTRUCTIONS
The following preparatory steps apply to cementation of all types of indirect restorations:

I. Following removal of the temporary restoration and any remaining temporary cement, clean enamel and dentin as directed by the adhesive manufacturer’s directions.
II. Check the fit and esthetics of the restoration. Technique Tip: Occlusal adjustment of inlays/onlays/veneers is best accomplished after final cementation.

1. Try-In Paste (Optional)
   1.1 Dispense the appropriate shade of try-in paste from the syringe onto a clean mixing pad or glass slab. Load paste onto internal surfaces of the restoration and gently seat onto preparation. Clean excess with a cotton pellet and/or blunt explorer. The shade of the try-in paste is formulated to match the corresponding LIGHT-CURED base shade, alone, i.e., without mixed catalyst. Shades may be blended to achieve optimum esthetics. NOTE: The try-in paste will not polymerize, thus offers unlimited work time.
   1.2. Once fit and esthetics are verified, thoroughly rinse try-in paste from restoration and preparation surfaces using water.
2. The internal surface of the restoration should be clean and dry prior to cementation. Organic debris accumulated during try-in may be removed by cleaning with ethanol or acetone followed by cleaning in water in an ultrasonic cleaner. The surfaces of porcelain or ceramic restorations may be further cleaned by using a liquid or gel phosphoric acid etchant followed by thorough rinsing and drying.

III. TREATMENT OF THE RESTORATION
1. Metal Restorations
   1.1. Microetching (sandblasting with 50µ alumina) the internal surfaces of a metal restoration is recommended. Tin plating of high noble or gold metals is not required but will augment retention.
   1.2. Technique Tips For Maryland Bridges: The use of 180° wrap of wings, rest seats, parallelism and slots or grooves is necessary for appropriate retention. The metal wings of the Maryland Bridge should be perforated, electrolytically etched, laboratory chemically etched, or mechanically sandblasted with 50µ alumina. Chemical etching of the metal wings with Calibra® 34% Tooth Conditioner Gel (phosphoric acid) is not recommended. Etch should be verified under a microscope. For cementation, follow 2.0, Dual Cured directions.
2. Ceramic/Porcelain/Composite Restorations
   2.1. Microetching (sandblasting) with 50µ alumina (or hydrofluoric acid chemical etching of the internal surfaces of a ceramic restoration) is recommended.
   2.2. If the restoration has not been silane treated by the laboratory or if the internal silanated surface has been disturbed during try-in, apply Calibra® Silane Coupling Agent according to the following instructions.
   2.2.1. Treat inner surface of restoration as outlined above. Prior to applying

IV. TOOTH CONDITIONING/DENTIN PRETREATMENT/ADHESIVE APPLICATION
1. Following restoration try-in, rinse preparation thoroughly with water spray and air dry.
2. Proceed with adhesive application as directed in the complete directions for use.
3. Always refer to and follow adhesive manufacturer’s complete directions for use for selection and application of the appropriate adhesive. Once the surfaces have been properly treated, they must be kept uncontaminated. Proceed immediately following adhesive application to cementation with Calibra® Esthetic Resin Cement, light cured base or dual or self cured with catalyst as indicated in the appropriate section below.

1.0 VENEER CEMENTATION – LIGHT-CURED
Before proceeding refer to above sections for Treatment of the Restoration and Tooth Conditioning/Dentin Pretreatment/Adhesive Application. Adhesives compatible with light-cured, CQ initiated methacrylates such as Prime&Bond® NT™ Light Cured Dental Adhesive are recommended. If veneer restorations exceed 1.0mm thickness, are heavily opaqued, or otherwise impede the transmission of light, operator is urged to follow section 2.0, Dual-Cured cementation technique. Apply adhesive to the internal bonding surface of the restoration if directed by adhesive manufacturer’s directions for use.

1.1. Cementation Technique
   1.1.1. Dispense the desired shade of Calibra® Esthetic Resin Cement base paste from the syringe directly onto the veneer. Protect cement from exposure to light.
   1.1.2. Seat the loaded veneer in place. Remove excess from the gingival margin with a blunt instrument. Briefly (10 seconds or less) light cure the gingival portion only to tack restoration in place. Remove any excess from proximal and lingual margins. Technique Tip: Placement of mylar strips between preparation and adjacent teeth prior to seating veneer aids in isolation and in excess cement clean up. After removing gingival excess and tacking veneer in place, remove interproximal excess cement by pulling mylar strip towards the facial, i.e., from tooth to restoration surface.
   1.1.3. Using a visible light, curing unit designed to cure CQ initiated methacrylates (spectral output including 470nm), with a minimum output of 550 mW/cm², light cure 20 seconds each from the Buccal, lingual, and interproximal aspects.
   1.1.4. Following the light cure check and adjust occlusion as necessary. Proceed to Finishing and Polishing section.

2.0 CROWN/Bridge/Inlay/Onlay CEMENTATION – DUAL CURED
Before proceeding refer to above sections for Treatment of the Restoration and Tooth Conditioning/Dentin Pretreatment/Adhesive Application. Adhesives (plus activators, if applicable) compatible with both light-cured, CQ initiated methacrylates and peroxide-amine initiated self-cured methacrylates such as Prime&Bond® NT™ Dual Cure Dental Adhesive System are recommended. Apply adhesive/activator (if applicable) to the internal bonding surface of the restoration if directed by adhesive manufacturer’s directions for use.

2.1. Cementation Technique
   2.1.1. Dispense the desired shade of Calibra® Esthetic Resin Cement base paste from the syringe onto a clean mixing pad. Dispense an equal amount of the desired viscosity of catalyst paste (Regular or High Viscosity). Mix the cement for 20-30 seconds. Technique Tip: As
with any dual cure resin cement system, the use of a dual cure adhesive system such as Prime&Bond® NT™ Dual Cure Dental Adhesive can shorten working time (See Precautions). Calibra® Esthetic Resin Cement base may be mixed with high Viscosity catalyst yielding a high Viscosity, "stay-put" thixotropic dual cured cement suitable for inlays, shallow onlays and veneers. Mixing Calibra® Esthetic Resin Cement base with Regular Viscosity catalyst yields an easier flowing dual cured cement suitable for large, multi-surface and full coverage restorations with higher hydraulic setting pressure.

2.1.2. Apply a uniform layer of cement on the entire internal surface of the restoration. For inlays/onlays, it may be helpful to apply a thin layer of cement to the internal portions of the tooth preparation to avoid any porosity or voids. Technique Tip: At room temperature, Calibra® Esthetic Resin Cement, in either viscosity, offers a minimum work time of 2 min. 30 sec, the mixing pad when protected from ambient light. If loaded into restoration lined with adhesive/activator mixture, room temperature work time (restoration setting time) will be less, (See Precautions)

2.1.3. Seat the restoration with gradual pressure. A gentle rocking or vibratory motion may be helpful to insure optimal seating.

2.1.4. Remove gross excess from marginal areas. Use an instrument such as a blunted explorer, periodontal probe or a clean, dry brush tip. Restoration should not be moved or torqued during removal of gross excess cement. Special attention should be paid to interproximal areas using floss to remove excess cement. Technique Tip: A 10 second light "pre-cure" of excess cement at the margins will cause cement to "gel", allowing easy cleanup. Technique Tip: Apply moderate and consistent pressure to the restoration throughout the self-cure set time of approximately 6 minutes from the beginning of mixing.

2.1.5. Once stabilized, light cure, using a visible light, curing unit designed with a minimum output of 550 mW/cm². Cure all marginal areas of the restoration for 20 seconds from each direction - buccal, lingual and occlusal.

2.1.6. Following the self-cure set check and adjust occlusion as necessary. Proceed to Finishing and Polishing section.

3.0 ENDODONTIC POSTS

Before proceeding refer to above sections for Treatment of the Restoration and Tooth Conditioning/Dentin Pretreatment/Adhesive Application. Adhesives (plus activators, if applicable) compatible with both light-cured, CQ initiated methacrylates and peroxide-amine initiated self-cured methacrylates such as Prime&Bond® NT™ Dual Cure Dental Adhesive System are recommended. Apply adhesive/activator (if applicable) to the bonding surface of the post if directed by adhesive manufacturer's directions for use.

3.1. Cementation Technique

3.1.1. Dispense the desired shade of Calibra® Esthetic Resin Cement base paste from the syringe onto a clean mixing pad. A light base shade e.g., Translucent will allow maximum light transmission. Dispense an equal amount of Regular Viscosity catalyst paste. Mix the cement for 20-30 seconds. Technique Tip: As with any dual cure resin cement system, the use of a dual cure adhesive system such as Prime&Bond® NT™ Dual Cure Dental Adhesive can shorten working time. (See Precautions)

3.1.2. Spread mixed Calibra® Esthetic Resin Cement components on surface of post and/or into the post preparation with a syringe tip, Lentulo Spiral or metal file.

3.1.3. Seat post immediately. Clean up excess with appropriate instruments. A 10 second light exposure "pre-cure" of excess cement at the margins will cause cement to "gel", allowing easy cleanup.

3.1.4. Stabilize post until cement sets. Apply moderate and consistent pressure to the restoration throughout the self-cure set time of approximately 6 minutes from the beginning of mixing.

3.1.5. Once stabilized, light cure, using a visible light, curing unit designed to cure CQ initiated methacrylates (spectral output including 470nm), with a minimum output of 550 mW/cm². Cure all accessible areas of the post for 20 seconds.

3.1.6. Proceed with core build-up and/or preparation.

FINISHING AND POLISHING

1. Removal of resin flash is best accomplished with the Enhance® Finishing System of points, cups and discs. The Enhance® System will remove flash and finish restoration margins without removal of or trauma to the enamel.

2. Polish final restoration using PoGo® Polishing system or Prism® Gloss® Polishing Paste and Prisma® Gloss® Extra Fine Polishing Pastes. (See complete Directions for Use supplied with polishing product chosen).

CLEANING AND DISINFECTION

To prevent Calibra® Esthetic Resin Cement and Calibra® Silane Coupling Agent syringes from exposure to spatter or spray of body fluids or contaminated hands, or oral tissues, use of a protective barrier is recommended to avoid package contamination. Repeated disinfection may damage label. The supplied mixing spatula may be cleaned by scrubbing with hot water and soap or detergent. Do not autoclave spatula. Disinfect as outlined below.

DISINFECTION OF RE-USABLE MIXING SPATULA

The spatula, if exposed to spatter or spray of body fluids or that may have been touched by contaminated hands, or oral tissues, should be disinfected with a hospital-level disinfectant. Acceptable disinfectants are EPA-registered as tuberculocidal. Iodophors, sodium hypochlorite (5.25%), chlorine dioxide and dual or synergized quaternaries are approved disinfectants. Disinfect the spatula by spraying with or immersing in any recommended hospital-level disinfectant for the contact time recommended by the disinfectant manufacturer for optimum results. 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 dissolve the plastic. The disinfectant manufacturer’s directions should be followed properly for optimum results. Water-based disinfectant solutions are preferred.

LOT NUMBER AND EXPIRATION DATE

1. Do not use after expiration date. ISO standard is used: “YYYY/MM”

2. The following numbers should be quoted in all correspondence.

• Reorder Number
• Lot number on syringe/bottle
• Expiration date on syringe

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