

Calibra® Universal

Self-Adhesive Resin Cement

DENTSPLY

DIRECTIONS FOR USE – ENGLISH

For dental use only. USA: Rx only.

1. PRODUCT DESCRIPTION

Calibra® Universal Self-Adhesive Resin Cement is a two-component, dual cure, high strength self-adhesive cement which contains fluoride. Calibra® Universal Cement combines esthetic shading with a self-etching adhesive, making it suitable for the permanent cementation of metal, PFM, resin/composite, ceramic and porcelain inlays, onlays, crowns and bridges and endodontic posts without application of a separate dentin/enamel adhesive bonding agent/system. Cured Calibra® Universal Cement is essentially hydrophobic, minimizing post-cure water sorption, solubility and hygroscopic expansion.

1.1 Delivery forms (Some delivery forms may not be available in all countries)

Calibra® Universal Cement is available in:

- a convenient dual-barreled syringe
- 5 shades: translucent, bleach, light, medium, and opaque

1.2 Composition

Urethane Dimethacrylate; Di- and Tri-Methacrylate resins; Phosphoric acid modified acrylate resin; Barium Boron FluoroAluminoSilicate Glass; Organic Peroxide Initiator; Camphorquinone (CQ) Photoinitiator; Phosphene Oxide Photoinitiator; Accelerators; Butylated Hydroxy Toluene; UV Stabilizer; Titanium Dioxide; Iron Oxide; Hydrophobic Amorphous Silicon Dioxide Particles of inorganic filler range from 16nm to 7µm, average particle size 3.8µm, total filler 48.7% by volume.

1.3 Indications

Calibra® Universal Cement is intended for the cementation of indirect restorations including ceramic, composite and metal-based inlays, onlays, crowns, bridges, and posts.

1.4 Contraindications

1. Calibra® Universal Cement is contraindicated for use with patients who have a history of severe allergic reaction to methacrylate resins or any of the components.
2. Calibra® Universal Cement is contraindicated for direct application to dental pulp tissue (direct pulp capping).

1.5 Compatible adhesives

Calibra® Universal Cement is compatible with all DENTSPLY adhesives designed for use with dual cured resin based materials. For details, see complete directions for use of the respective adhesive. The use of other dentin and enamel adhesive systems is at the discretion and sole responsibility of the dental practitioner.

2. GENERAL SAFETY NOTES

Be aware of the following general safety notes and the special safety notes in other chapter 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

Calibra® Universal Cement is acidic in nature and contains polymerizable acrylate and 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. In case of contact, reddish rashes may be seen on the skin. If contact with skin occurs, immediately remove material with cotton and wash thoroughly with water and soap. 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 sensitization of mucosa persists, seek medical attention.

2.2 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. Some porcelain/ceramic manufacturers do not recommend the use of the self-adhesive cement category with posterior all-ceramic restorations fabricated with lower strength ceramics (flexural strength less than 250 MPa).
3. In cases of minimally retentive preparations, including Maryland bridges, conventional bonding should be considered.
4. Insufficient data exist to support the use of Calibra® Universal Cement for the cementation of veneers.
5. Wear suitable protective eyewear, clothing and gloves. Protective eyewear is recommended for patients.
6. 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.
7. The syringe cannot be reprocessed. To prevent the syringe and from exposure to spatter or spray of body fluids or contaminated hands it is mandatory that the syringe is handled with clean/disinfected gloves. As additional precautionary measure, syringe may be protected from gross contamination but not from all contamination by applying a protective barrier.
8. Syringe should be tightly closed by replacing the original cap immediately after use.
9. Calibra® Universal Cement behaves differently intraorally than in ambient operatory conditions. The set of Calibra® Universal Cement is accelerated by the warmth and moisture of the oral environment and/or ambient or operatory light. After placing Calibra® Universal 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.
10. Cement at the margins may appear set before cement under the restoration is set. Do not move, torque or disturb restoration until final set of the cement (6 minutes from the start of mix or in the case of light-transmissible restorations completion of light curing).
11. Pre-cementation tooth preparation should leave the tooth surface moist. Dry preparations (excessively air-dried or alcohol-dried), and wet preparations (with pooled surface water), may delay establishment of initial bond (see Step-by-Step Instructions).
12. Calibra® Universal Cement should extrude easily. DO NOT USE EXCESSIVE FORCE. Excessive pressure may result in unanticipated extrusion of the material or cause syringe rupture.

Interactions

- 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.
- Contact with some astringent solutions may interfere with hardening of the polymeric components of the material.
- Calibra® Universal Cement contains an optimized photoinitiator combination. Use of high power, broad spectrum output curing lights during cleanup may produce unexpected results, rapid hardening and shortened cleanup times. Monowave output LED lights with a single peak output around 470nm are recommended. Check curing light effect on mixed cement in the laboratory prior to clinical use.

2.3 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 (See Warnings)
2. Product may cause pulpal effects. (See Contraindications)
3. Residual hardened excess cement may lead to soft tissue injury or irritation (see Interactions and Step-by-Step instructions).

2.4 Storage

Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product. Keep out of direct sunlight and store in a well ventilated place at temperatures between 2°-24°C/35°-75°F. 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:

The final shade of cured material is color stable. For color identification, please refer to the Try-In Paste section below.

Try-In Paste (optional)

1. Dispense the appropriate shade of Calibra® Try-In Paste (available separately) 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. Shades may be blended to achieve optimum esthetics. **Important Technique Tip:** Factors such as restoration shape, texture, thickness and shade(s) of the underlying and surrounding tooth structure contribute to final perceived shade. Try-in paste is a guide for cement shade range selection only. **NOTE:** The try-in paste will not polymerize, thus offers unlimited work time.
2. Once fit and esthetics are verified, thoroughly rinse try-in paste from restoration and preparation surfaces using water.

3.1 Preparation of the restoration

- Metal Restorations
Internal surfaces of restorations should be clean and dry prior to cementation. Internal surface microetching (sandblasting with 50µ alumina) of metal surfaces of the restoration is recommended. Calibra® Universal Cement has a chemical affinity for metal.
- Ceramic/Composite Restorations
Follow the dental laboratory or restoration manufacturer’s instructions for pre-treatment, if required. Restorations designed to be silanated or if the internal silanated surface has been disturbed during try-in, apply Calibra® Silane Coupling Agent (available separately) according to the manufacturer’s instructions.

3.2 Preparation of the tooth

Remove temporary restoration and excess temporary cement using an explorer, a rubber cup and a prophyl paste or water/flour of pumice. Rinse thoroughly and remove rinsing water completely by blowing gently with an air syringe or by blot drying with a dry cotton pellet. Dentin should be dried until there is no pooling of water, leaving a moist surface. Do not desiccate dentin. Avoid contamination. Etching of tooth surfaces is NOT recommended.



Delayed adhesion due to improper tooth structure treatment

- Tooth structure should be moist; Gently dry with air or blot with dry cotton
- Remove all pooled moisture
- Do not desiccate

Technique Tip: The adjacent teeth and/or the external surfaces of the restoration may be lubricated with a water soluble medium to ease clean up of excess cement.

3.3 Cementation technique

	Self Cure	Dual Cure – Non-Light Transmissible restorations	Light Cure – Light Transmissible Restorations
Type of Restoration	All	PFM, Zirconia, Alumina, opaque ceramics & composites	Translucent ceramics & composites
1. Fill & seat crown	Up to 2 min	Up to 2 min	Up to 2 min
Protect restoration from movement during gel phase cleanup through final set			
2. Remove excess: Gel stage from seating	1-2 min	Up to 5 sec per surface ¹ light cure	Up to 5 sec per surface ¹ light cure
Gel Duration	1 min	45 sec	45 sec
3. Stabilize	Constant Occlusal Pressure	Light cure margins 20-40 sec	Light cure margins 20-40 sec
4. Final Set	6 min from start of mix	6 min from start of mix	Upon completion of light curing each surface ² 10 sec

1. Buccal and Lingual 2. Buccal, Lingual and Occlusal



Danger of injury due to excessive force

- Apply slow and steady pressure on the syringe
- Do not use excessive force – syringe rupture may result

3.3.1 Dual Barreled syringe dispensed

1. Remove syringe cap. Dispense and discard a small amount of material from the dual-barreled syringe. Be sure material is flowing freely from both ports. Holding syringe vertically, carefully wipe away excess so base and catalyst do not cross contaminate and cause obstruction of the ports. Save syringe cap for replacement following use.
2. Install a mixing tip on the cartridge by lining up the v-shaped notch on the outside of the mixing tip with the v-shape notch on the syringe flange. Turn colored mixing tip cap 90 degrees in a clockwise direction to lock in place on syringe.
3. Gently depress syringe plungers to begin the flow of material. DO NOT USE EXCESSIVE FORCE. If force is encountered, remove syringe from operating field, remove and discard mixing tip. Check for obstruction and confirm material is flowing from both syringe barrels. Wipe barrels and install new mixing tip as outlined above. Dispense a small amount through the mixing tip onto a mixing pad and discard.
4. Without delay, using gentle pressure, apply a thin, uniform layer of cement to the entire internal surface of the restoration directly from the mixing tip. At room temperature, Calibra® Universal Cement offers a minimum work time of 2 minutes. **Technique Tip:** The mixing tip may be bent slightly to allow direct intraoral access for placement of cement into preparations with internal anatomy. For endodontic post spaces, use of a Lentulo Spiral or metal file to aid placement in the post space is recommended.
5. Immediately seat the restoration in the mouth. Verify complete seating. A gentle rocking or vibratory motion may be helpful to insure optimal seating.
6. Protect restoration from contamination and movement until the final set of the cement (6 minutes from start of mix or in the case of light-transmissible restorations, completion of light curing).

3.4. Cleaning Marginal Excess Calibra® Universal Cement

3.4.1 Self-cure cleanup

The excess cement will reach the “gelled” state after approximately 1-2 minutes in the mouth, allowing easy removal. Excess cement will remain in the “gelled” state for approximately 1 minute. If exposed to directed operatory light, “gel” state may be reached sooner and remain “gelled” for a shorter period. Immediately after reaching the “gelled” state, floss interproximally, only in the direction of restoration seating, to remove excess cement. Complete excess cement removal using an instrument such as a rubber tip, a scaler or an explorer. **NOTE:** Cement within the crown has not yet set. Do not move, torque, or disturb the crown during cleanup. **Technique Tip:** Following all excess removal, exposed margins may be light cured 20-40 seconds to assist restoration stabilization.

3.4.2 Optional dual cure cleanup

Due to the dual cure property of Calibra® Universal Cement, the operator has the option of utilizing a curing light to facilitate cleanup. Light curing to facilitate cleanup must be accomplished within the first minute following intraoral insertion. Excess cement cleanup may begin immediately following a brief exposure with the curing light. Conventional powered quartz tungsten halogen or LED lights producing only one peak wavelength around 470nm are recommended. Use of narrow spectrum output lights or high power, broad spectrum output halogen or LED lights may produce unexpected results. Light curing mixed cement after one minute, or continuously at one spot for more than 5 seconds, at any time, will cause cement to adhesively set, making cleanup difficult.

Immediately after seating is verified, briefly light cure excess cement at the margins by constantly moving the curing light tip around the margins for no more than 5 seconds per surface. Excess cement will reach a “gelled” state after this brief (< 5 second) cure.



Residual excess cement – overcure during cleanup

- Monowave (470nm) LED or conventional halogen lights are recommended
- High power, dual or broad spectrum lights may cause premature hardening of excess cement
- Evaluate curing light/cement interaction in laboratory prior to clinical use

The excess cement will remain in the “gelled” state for approximately 45 seconds following light exposure. All excess cement must be removed before final self-cure set is achieved, as outlined above. **NOTE:** Cement within the crown has not yet gelled or set. Do not move, torque, or disturb the crown during cleanup. Following all excess removal, exposed margins may be light cured 20-40 seconds to assist restoration stabilization.

Important Technique Tips:

- When simultaneously cementing multiple single units or bridgework, it is recommended to employ the light cure cleanup on one or two adjacent units only, allowing other units’ excess to self cure, providing ample cleanup time.
- Clean excess cement from metal instruments immediately as set cement will adhere to the instrument.

3.5 Curing

- Non-Light-Transmissible restorations (Self-Cure)
For metallic, thick or heavily opaqued ceramic or composite, or restorations that otherwise impede the transmission of light, once cleanup is completed and restoration is stabilized, allow Calibra® Universal Cement to self cure without disturbing for 6 minutes from start of mix. Protect restoration from contamination and movement during the setting time. Following the self cure set, check and adjust occlusion and polish as necessary. Patient may then be dismissed.



Inadequate retention due to insufficient stabilization

- Stabilize restoration during cleanup
- Protect restoration from movement during setting
- Allow cement to self-cure without disturbing for 6 minutes

- Light-Transmissible restorations (Light-Cure)

For most non-metallic, light-transmissible ceramic or composite restorations, Calibra® Universal Cement may be visible light cured. Once cleanup is completed and restoration is stabilized, light cure all areas of the restoration using a visible light, curing unit designed to cure CQ initiated methacrylates (spectral output including 470nm), with a minimum output of 550mW/cm² for 10 seconds from each direction – buccal, lingual and occlusal. Following the light curing, check and adjust occlusion and polish as necessary.



Inadequate polymerization due to insufficient curing

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

3.6 Finishing and polishing

- 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.
- Polish final restoration using Enhance® PoGo® Polishing system or Prisma® Gloss™ Polishing Paste and Prisma® Gloss™ Extra Fine Polishing Pastes. (See complete Directions for Use supplied with polishing product chosen).
- All shades of Calibra® Universal Cement are radio-opaque, with a 1mm radio-opacity equivalent to 1.8mm radio-opacity of aluminum. Aluminum has a radio-opacity equivalent to that of dentin. Thus 1mm of material having a radio-opacity equivalent to 1mm of aluminum has a radio-opacity equivalent to that of dentin.

4. HYGIENE



Cross-contamination

- Do not reuse single use products. Dispose of in accordance with local regulations.
- Syringe cannot be reprocessed. Dispose of contaminated syringe in accordance with local regulations.

4.1 Cleaning and Disinfection

To prevent 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 syringe contamination. The use of protective barriers is an additional precautionary measure against gross contamination but not against all contamination. Handling with clean/disinfected gloves, syringes may be disinfected with a water-based hospital-level disinfection solution according to national/local regulations. Repeated disinfection may damage label. **NOTE:** Destruction of the label by vigorous wiping. Wipe syringe gently.

5. 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
 - Expiration date



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