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TheraCem[®] Ca

Self-Adhesive Resin Cement

Instructions for Use



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Patent Pending

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

TheraCem®* Ca Self-Adhesive Resin Cement

GENERAL INFORMATION

TheraCem Ca is a self-etching, self-adhesive, dual-cured resin luting cement that is exclusively formulated for luting crowns, bridges, inlays, onlays and posts (prefabricated metal and non-metal/fiber posts, as well as cast posts). **TheraCem Ca** is a paste/paste, calcium-releasing, luting cement which requires no etching, no priming or bonding of the prepared surfaces. It is easy-to-use, requires only a short chair time, and produces a good bond to most dental materials. The cement is available in a Natural shade. It is radiopaque, allowing for easy identification on radiographs.

Indications for Use:

Use **TheraCem Ca** to cement the following:

1. Metal crowns, bridges, inlays, onlays (includes porcelain-fused -to- metal and composite-to-metal)
2. Porcelain, Ceramic Crowns, inlays, and onlays (includes alumina and zirconia)
3. Resin crowns, bridges, inlays, and onlays (resin-based composite/composite-ceramic hybrid)
4. Metal (prefabricated or cast) and non-metal/fiber endodontic posts
5. Implant supported restorations
6. Orthodontic Appliances (brackets, bands)s

Contraindication:

TheraCem Ca is not recommended for veneer cementation.

NOTE: It is recommended to use CHOICE™ 2 for veneer cementation.

Warnings:

- Avoid contact with the skin; unpolymerized (meth)acrylate resins may cause skin sensitization in susceptible persons. In case of contact, wash skin with soap and water.
- Saliva and oral fluid contamination will seriously compromise dentin bonding.

Cautions:

- Cross-contamination: Product may contain items that are designed for one time use. Dispose of used or contaminated accessories. Do not reuse.

Precautions:

- Working and Setting Times will be accelerated in the warm intraoral environment.
- Do not use hydrogen peroxide, EDTA, or eugenol containing materials prior to the adhesive procedure as these materials may inhibit bonding.
- Since ceramics and porcelains vary greatly, it is important to consult with the ceramic/porcelain manufacturer or your laboratory for instructions on proper surface treatment and proper prep design prior to using **TheraCem Ca**.
- Unpolymerized resins may cause skin sensitization in susceptible persons. Avoid contact with the skin. In case of contact with the skin, wash thoroughly with soap and water.
- To prevent polymerization or clogging, the Dual-Syringe static mixing tip should be left in place until the next application. If used intraorally, it should be wiped with disinfectant prior to storage.
- See individual component labels for specific expiration dates.
- Safety data sheet available on request.
- Safety data sheet available at www.Bisco.com.

TECHNICAL INFORMATION

Working Time: Minimum 1 minute (includes mixing) at 22°C (71.6°F)

Setting Time: Maximum 5 minutes at 37°C (98.6°F)

Working time and setting time may vary based on storage conditions, temperature, humidity, etc.

INSTRUCTIONS FOR USE

For: Crowns, Bridges, Inlays and Onlays

Preparation Procedures

NOTE: **TheraCem Ca** is a self-adhesive cement which does not require etching or priming of the prepared surfaces.

1. Remove the temporary restoration and all temporary cement residue.
2. Try-in the final restoration to ensure proper fit.
3. Clean the preparation with pumice and water. Rinse thoroughly.
4. Remove all surface water using a strong stream of air on the preparation for 3 to 5 seconds. Do not desiccate. (Protect the preparation from contamination. When applicable, use of a rubber dam is recommended.)

Cement Mixing Procedures

1. Remove the syringe cap or remove and discard the mixing tip from the dual-syringe.
2. Dispense a small amount of material onto a mixing pad to eliminate any voids in each chamber of the dual-syringe.
3. Attach a mixing tip to the dual-syringe by lining up the key and keyway. Then turn the brown locking mechanism clockwise.
4. Pressing the plunger will mix and dispense the **TheraCem Ca**. (See "TECHNICAL INFORMATION" Section for Working and Setting Time information.)

Cementation Procedures

1. Apply cement to the internal surfaces of the restoration. For inlays, it may be easier to apply the cement to the tooth preparation.
2. Seat the restoration and remove any excess cement. **HINT:** To aid in the removal of excess cement, initially light cure the margins for 2-3 seconds.
3. Light cure for 20-30 seconds, or allow to self cure. (When using self-cured mode, light curing the margins even briefly will expedite the final set.)

HELPFUL HINTS

- **TheraCem Ca** left on a mixing pad may not appear to set. This is due to oxygen inhibition of the polymerization process. Rest assured the cement will polymerize (set) in a normal fashion under the restoration.

For: Posts (pre-fabricated, metal, cast and non-metal/fiber posts)

Preparation Procedures

1. Prepare the post space per post manufacturer's instruction. Etching and bonding agents are not required.
2. Size and fit post to insure proper fit.
3. Clean post per manufacturer's instructions.

Cement Mixing Procedures

1. Remove the syringe cap or remove and discard the mixing tip from the dual-syringe.
2. Dispense a small amount of material onto a mixing pad to eliminate any voids in each chamber of the dual-syringe.
3. Attach a mixing tip to the dual-syringe by lining up the key and keyway. Then turn the brown locking mechanism clockwise.
4. Pressing the plunger will mix and dispense the **TheraCem Ca**. (See "TECHNICAL INFORMATION" Section for Working and Setting Time information.)

Cementation Procedures

1. For post cementation, using the root canal mixing tip inject **TheraCem Ca** into the canal. Start at the apical end of the canal and withdraw the tip slowly while keeping the tip in the cement to minimize voids. Coat the apical end of the post with cement.
2. Seat the post and remove any excess cement. **HINT:** To aid in the removal of excess cement, initially light cure the cement for 2-3 seconds.
3. Light cure for 20-30 seconds, or allow to self cure.
4. Proceed with core build-up procedure.

HYGIENE: Use of commonly available hygienic protective covering to avoid any contamination of the **TheraCem Ca** cement dual-syringes during the treatment is recommended.

DISPOSAL: Refer to community provisions relating to waste. In their absence, refer to national or regional provisions relating to waste.

STORAGE: Store at room temperature (20°C/68°F - 25°C/77°F)

WARRANTY: BISCO, Inc. recognizes its responsibility to replace products if proven to be defective. BISCO, Inc. does not accept liability for any damages or loss, either direct or consequential, stemming from the use of or inability to use the products as described. Before using, it is the responsibility of the user to determine the suitability of the product for its intended use. The user assumes all risk and liability in connection therewith.

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CHOICE is a trademark of BISCO, Inc.