

BISCO

TheraCal PT[®]

***Dual-
Cured***

***Dual-Cured Resin-Modified Calcium
Silicate Pulpotomy Treatment***

Instructions for Use



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

TheraCal PT®

Dual-Cured Resin-Modified Calcium Silicate Pulpotomy Treatment

GENERAL INFORMATION

TheraCal PT is a biocompatible, dual-cured, resin-modified calcium silicate that is used to treat exposed dentin. **TheraCal PT**'s precise placement allows its use in deep cavity preparations. The dual-cured set permits immediate placement of the restorative material. Its proprietary formulation allows for a command set with a light curing unit while maintaining ease of placement due to thixotropic properties.

Primary Indication for Use:

1. Pulpotomy

Secondary Indications for Use:

2. Pulp exposures (direct pulp capping)
3. Protective liner (indirect pulp capping) and base for use under a variety of substrates

Warnings:

- **TheraCal PT** contains polymerizable methacrylate monomers. Avoid prolonged or repeated exposure with skin, oral soft tissues, and eyes. Irritation and possible corneal damage may result. Skin rash, oral mucosa irritation, or other allergic reactions (allergic contact dermatitis) may result in susceptible individuals. Do not take internally.
- **TheraCal PT** is not recommended for use with patients who have a history of severe allergic reaction to methacrylate resins.

Cautions:

Cross-contamination:

- Product may contain items that are designed for one time use. Dispose of used or contaminated tips. Do not clean, disinfect or reuse.
- Use of commonly available hygienic protective covering to avoid any contamination of syringes during treatment is recommended. If syringe becomes contaminated, discard. Do not clean or disinfect.

Precautions:

- The success of pulp capping procedures may be influenced by preparation contamination. Use of a rubber dam or adequate isolation is recommended.
- Patient history of pain influences appropriateness of usage.
- Pulpal hemorrhage must be controlled prior to the application of **TheraCal PT**. If hemorrhage cannot be controlled, consideration should be given for the initiation of endodontic therapy over direct pulp capping procedures.
- **TheraCal PT** is a dual-cured material. Proceed immediately once material has been dispensed.
- To prevent polymerization or clogging, the dual-syringe mixing tip should be left in place until the next application. If used intraorally, wipe mixing tip with disinfectant prior to storage.
- When chlorhexidine and sodium hypochlorite are used together staining can occur. If used together there should be a saline rinse between.
- Procedures that de-vitalize the pulp (for example, formocresol) may prevent secondary bridge formation.
- See individual component labels for specific expiration dates.

Technical Information

Working Time: Minimum 45 seconds at 35°C

Setting Time: Maximum 5 minutes at 35°C

Working time and setting time may vary based on storage conditions (i.e. temperature, humidity, etc.).

INSTRUCTIONS FOR USE

TheraCal PT Mixing Procedures

- 1) Remove the syringe cap from the dual-syringe or mixing tip.
- 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 locking mechanism clockwise.
- 4) Pressing the plunger will mix and dispense the **TheraCal PT**. (See Technical Information section for working and setting time information.)

Pulpotomy

- 1) Under rubber dam isolation, remove the infected dentin with a round bur and/or a hand excavator.
- 2) Gain access to the pulp chamber and remove the infected coronal pulp using sterile burs or instruments.
- 3) If there is bleeding in the pulp, first achieve hemostasis by placing a sterile cotton pellet dampened with sterile saline (or preferred alternative solution).
- 4) Adapt a matrix around the tooth if a proximal wall is missing.
- 5) Place **TheraCal PT** directly in the pulp chamber, and ensure good adaptation to the cavity walls and margins.
- 6) Light cure **TheraCal PT** for 10 seconds.
- 7) Place desired adhesive, base, and/or restoration following manufacturer's directions for restoring tooth.

Pulp Exposures (Direct Pulp Capping)

- 1) Under rubber dam isolation, complete cavity preparation.
- 2) First achieve hemostasis by placing a sterile cotton pellet dampened with sterile saline (or preferred alternative solution) gently onto the exposure site.
- 3) Gently blot preparation with sterile cotton pellet. Leave visibly moist.
- 4) Apply **TheraCal PT** directly to the exposed pulp. Cover all the exposed areas and extend **TheraCal PT** at least 1mm onto sound dentin surrounding the exposure.
- 5) Light cure **TheraCal PT** for 10 seconds.
- 6) Place desired adhesive, base, and/or restoration following manufacturer's directions. Continue restoring tooth.

Protective Liner and Base for use under a variety of substrates

- 1) Under rubber dam isolation, perform conventional cavity preparation. Remove all infected carious tooth structure. Leave preparation visibly moist.
- 2) Apply the **TheraCal PT** directly to the cavity floor. Manipulate into a smooth surface covering all deep dentin areas.
- 3) Light cure **TheraCal PT** for 10 seconds.

HYGIENE AND DISINFECTION: Use of commonly available hygienic protective covering to avoid any contamination of the **TheraCal PT** syringes during treatment is recommended.

STORAGE: Store in a dry place at room temperature (20°C/68°F - 25°C/77°F). **TheraCal PT** syringe should remain in the pouch until ready to use. Once pouch is opened, use TheraCal PT within 90 days.

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.

* TheraCal PT is a registered trademark of BISCO, Inc.

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