

BISCO

TheraCal PT®Dual-Cured

Dual-Cured Resin-Modified Calcium Silicate Pulpotomy Treatment

Instructions for Use



 BISCO, Inc.
1100 W. Irving Park Road
Schaumburg, IL 60193
U.S.A.
1-800-247-3368
1-847-534-6000
www.bisco.com

IN-201-ZH
Rev. 8/26

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

en	Theracal PT**
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.	
Model specifications	Description
H-34112P-zh	Including TheraCal PT: H-34010 1Syringe(4g) AUTO-MIX CANNULA TIPS: X-81269P 15Mixing Tips
H-34113P-zh	Including TheraCal PT: H-34111 1Syringe(2g) AUTO-MIX CANNULA TIPS: X-81271P 8Mixing Tips

Specification:
Name of registrant/manufacturer: BISCO, Inc.
Residence/production address: 1100 W. Irving Park Road Schaumburg, IL 60193 U.S.A.
Contact details: 1-800-247-3368 / 1-847-534-6000 / www.bisco.com
Name of agent/after-sales service unit:Waterside Medical Group
Address of agent/after-sales service unit:East Half of 2nd Floor and 5th Floor, Building 3, Zone 3, No.20 Datong Road, High-Tech Zone, Suzhou, Jiangsu, China
Tel: 13818791340
Medical Device Registration No.:20263170262
Product Technical Requirement No.:20263170262
Revision date of the instructions:2026.7
Product performance, main structure composition
This product is resin-modified calcium silicate.

Scope of application / Indications
1.Pulpotomy
2.Direct pulp capping
3.Indirect pulp capping and cavity lining.

Contraindication
TheraCal PT is not recommended for use with patients who have a history of severe allergic reaction to methacrylate resins.

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 meth acrylate 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.
• Pulp 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.
• Protective eyewear should be worn by the patient and dental staff.
• 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.
• Safety data sheet available on request.
• Safety data sheet available at www.bisco.com.
• Instructions for Use available upon request.
• Instructions for Use available at www.bisco.com.

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.).

INSTRUCTION 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: 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.
Transport environment: Regular shipping, avoid direct sunlight, rain and snow.

Date of manufacture: See the label

Validity period: See the label

* BISCO and TheraCal PT are trademarks of BISCO, Inc., registered in the U.S. Patent and Trademark Office.

zh	盖髓剂使用说明书
【产品名称】：盖髓剂 【规格型号】：	
型号规格	描述
H-34112P-zh	包含 盖髓剂: H-34010 1支(4G) 盖髓剂附件-混合头: X-81269P 15支
H-34113P-zh	包含 盖髓剂: H-34111 1支(2G) 盖髓剂附件-混合头: X-81271P 8支

【注册人/生产企业名称】：必思科公司BISCO, INC.
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【联系方式】：1-800-247-3368 / 1-847-534-6000 / WWW.BISCO.COM
【代理人/售后服务单位名称】：倍恒医疗设备（苏州）有限公司
【代理人/售后服务单位地址】：苏州高新区综合保税区大同路20号3区3号3幢厂房二楼东半侧及五楼
【电话】：13818791340
【医疗器械注册证编号】：国械注进20263170262
【产品技术要求编号】：国械注进20263170262
【说明书的修订日期】：2026.7
【产品性能、主要结构组成】
本产品为树脂改性硅酸钙。
【适用范围】
1.牙髓切断术
2.直接盖髓
3.间接盖髓和垫底。

【禁忌症】
于有甲基丙烯酸酯树脂严重过敏反应史的患者，不推荐使用THERACAL PT盖髓剂。
【警告】
THERACAL PT盖髓剂含有可聚合的甲基丙烯酸酯单体。避免与皮肤、口腔软组织和眼睛长时间或反复接触。否则可能会导致刺激和潜在的角膜损伤。易感个体可能出现皮疹、口腔粘膜刺激或其他过敏反应（如过敏性接触性皮炎）。请勿内服。
• 对于有甲基丙烯酸酯树脂严重过敏反应史的患者，不推荐使用 THERACAL PT盖髓剂。
【注意事项】
交叉污染：
• 本产品可能包含设计为一次性使用的物品。请丢弃使用过的或已污染的尖端。不要清洁、消毒或重复使用。
• 建议使用常见的卫生保护套，以避免治疗过程中注射器的污染。如果注射器被污染，请丢弃。不要清洁或消毒。
【使用前注意事项】
• 盖髓手术的成功与否可能会受到制剂污染的影响。建议使用橡皮障或适当的隔离措施。
• 患者的疼痛史会影响使用的合理性。
• 在使用 THERACAL PT盖髓剂之前，必须先控制牙髓出血。如果出血不能得到控制，则应考虑开始牙髓治疗，而不是直接进行牙髓切断术。
• 患者和牙科工作人员应佩戴防护眼镜。
• THERACAL PT盖髓剂是一种双重固化材料。材料分配完毕后请立即进行操作。
• 为防止聚合或堵塞，双注射器混合头应保留至下次使用。如果在口腔内使用，应在存放使用前用消毒剂擦拭混合喷嘴。
• 氯己定和次氯酸钠同时使用时可能会产生染色。如果同时使用，中间应使用生理盐水冲洗。
• 使牙髓失去活力的程序(如甲氧甲酚)可以防止继发性牙桥的形成。

【技术信息】
工作时间：在35°C时至少45秒
固化时间：在35°C时最多5分钟
工作时间和固化时间可能会因储存条件（如温度、湿度等）而有所不同。
【使用说明】
• THERACAL PT盖髓剂混合使用过程
1)取下双注射器或混合头的注射器盖。
2)在混合垫上分配少量材料，以消除双注射器各腔中的空隙。
3)对齐键和键槽，将混合喷嘴安装到双针筒上。然后顺时针旋转锁定。
4)按下柱塞将混合并分配 THERACAL PT盖髓剂。(有关工作和凝固时间的信息，请参见技术信息部分)。

• 牙髓切断术
1) 在橡皮障隔离下，用圆头钻和/或手动挖掘机去除受感染的牙本质。
2) 进入牙髓腔，使用无菌车针或器械去除受感染的冠状牙髓。
3) 如果牙髓出血，首先用无菌棉球蘸无菌生理盐水（或首选替代溶液）止血。
4) 如果牙齿近壁缺失，则在牙齿周围制作基质
5) 将THERACAL PT盖髓剂 直接放入牙髓腔，并确保与牙髓腔壁和边缘的良好适应性。
6) 光照固化 THERACAL PT盖髓剂 10 秒钟。
7) 按照生产商提供的牙齿修复说明，放置所需的粘合剂、基底和/或修复体。

• 牙髓暴露（直接盖髓）
1) 在橡皮障隔离下，完成空腔准备。
2) 首先，将蘸有无菌生理盐水（或首选替代溶液）的无菌棉球轻轻放在暴露部位，实现止血。
3) 用无菌棉球轻轻擦拭吸干制剂。保持明显湿润。
4) 将 THERACAL PT盖髓剂 直接涂抹在暴露的牙髓上。覆盖所有暴露区域，并将 THERACAL PT盖髓剂扩展到暴露区域周围的健全牙本质上至少1 毫米。
5) 光照固化 THERACAL PT盖髓剂 10 秒钟。
6) 按照制造商的说明放置所需的粘合剂、基底和/或修复体。继续修复牙齿。

• 在各种基底上使用，保护衬洞和垫底
1) 在橡皮障隔离下，进行传统的牙洞预备。去除所有受感染的龋齿结构。让预备液保持明显湿润。
2) 将 THERACAL PT盖髓剂直接涂抹在龋洞底部。使其成为覆盖所有深层牙本质区域的光滑表面。
3) 光照固化 THERACAL PT盖髓剂 10 秒钟。
【使用环境】
建议使用常用的卫生保护套，以避免在治疗过程中污染 THERACAL PT盖髓剂注射器。
【储存环境】：室温（20°C/68°F - 25°C/77°F）下干燥保存。THERACAL PT盖髓剂注射器应保留在包装袋中，直至准备使用。打开包装袋后，请在90天内使用 THERACAL PT盖髓剂。
【运输环境】：常规运输，避免阳光直射和雨雪浸淋。
【生产日期】：见标签
【有效期】：见标签

* BISCO 和THERACAL PT是BISCO, INC. 在美国专利商标局注册的商标。