parkell®

Rx Only—product is intended for use by a licensed dental professional. For Safety Data Sheet (SDS) go to www.parkell.com

E.T.C.™

Dual-Cure Easy Temporary Cement

Instructions for Use

REF S255

Parkell, Inc.,
300 Executive Dr., Edgewood, NY 11717 USA
(800) 243-7446 • www.parkell.com

MADE IN USA

A00624revI0722

Description:

E.T.C.™ is a resin-based, dual-cure, anti-microbial, temporary dental cement. It is translucent so that it blends well with tooth roots and crown margins, making it especially useful in anterior regions of the mouth.

Indications for Use:

E.T.C. is indicated for short to medium-term cementation of dental prostheses to enamel, dentin, cementum, amalgam, metal alloys, ceramics, composite cores or implants.

Contraindications:

Uncured E.T.C. should not be swallowed. This product is contraindicated for use on or by persons who are allergic to or sensitive to methacrylate resins or similar products. Symptoms may include dermatitis or inflammatory reactions. If this occurs, discontinue use and obtain medical care immediately.

Product Warnings and Clinical Information:

- Store product with cap, or used mixing tip tightly screwed on, in a cool, dark place. Avoid sunlight or nearby heat sources. Shelf life will be reduced if not stored properly.
- If product accidentally contacts skin, wash with copious amounts of water.
- If product accidentally contacts eyes, flush with water and obtain medical care immediately.
- Do not ingest the components of this product. Keep them away from children.
- **If this product sets in intra-oral undercuts, it may lock on, making prosthesis removal extremely difficult.**
- **If you coat the abutment with bonding agent prior to cementation, or cement over composite cores, or cement to implant abutments, partially lubricate the preps before cementing the prosthesis to allow removal later.**
- **To avoid leakage and discoloration, care should be taken to disinfect the prep prior to temporary cementation.**
- **Excessive or intense squeezing force on cartridge-based restorative materials may cause gun breakage or cartridge cracking. Slow and steady force is preferred for dispensing these materials.**
- **Stated work times and set times are estimates, and may vary based upon storage condition, temperature, humidity, age of product, when the cartridge was first opened, among other factors.**

Kit includes:

- (1) 5 ml Dual-Chamber Syringe (with plunger) of E.T.C. / paste
- (10) Brown-base, 1:1 Static Mixing Tips (REF S292 refill, 30 tips)
- Instructions for use

Product Timing:

- **Working Time (at intra-oral temperature 35°– 37° C):** 45-80 seconds
- **Setting Time (at intra-oral temperature 35°– 37° C):** 4:30 minutes (cooler material will be slower)
- **Light Cure:** 10 seconds (approx.)

Storage:

Store this product in a cool, dry place. Refrigeration (avoid freezing) can help provide a stable storage environment which is important for maintaining consistency of the materials properties up to the expiration date. Bring to room temperature before use.

General Instructions for Use:

1. Wash abutment with water and dry with air.
2. If the prep contains resin cores, or is coated with resin bonding agents, lubricate both the resin and dentin 1-2 mm above the margin to preclude the temporary from locking on to the prep. Leave the margin unlubricated for retention and resistance to leakage. You may use glycerin lubricant or a product like Parkell's Blu-Sep™ (REF S385), a water-soluble lubricating liquid that dries quickly to an easy-to-see blue film.
3. Before first use, remove and set aside the brown sealing cap and express out a small amount of E.T.C. through both round orifices onto a mixing pad. Wipe the end clean with a tissue.
4. Twist an unused brown-base mixing tip onto the cartridge and express a small amount of mixed E.T.C. onto a mixing pad to confirm good flow and mixture. Immediately express a small amount of cement into the clean and dry intaglio of the prosthesis. It is not necessary to fill the entire crown. A bead around the marginal area of the preparation works best, as it seals the margins without interfering with seating or creating excessive retention.
5. Seat prosthesis onto tooth, and immobilize until setting is evident.
6. Cleanup may begin as soon as the material reaches its gel stage. To assist in cleanup, excess E.T.C. may be gelled with brief (3 seconds) exposure to a curing light before removal.
7. Leave the used mixing tip in place on the cartridge to serve as the sealing cap between uses. The cartridge and used mixing tip may be disinfected with appropriate dental surface disinfectants. Check with the disinfectant manufacturer before use.
8. E.T.C. may also be hand-mixed by removing the sealing cap from dual-barrel syringe and dispensing equal amounts of base and catalyst onto a paper mixing pad. Spatulate until they are fully incorporated. Re-seal the cartridge with the original cap, taking care to align the 'V' on the cap with the notch on the cartridge collar. This will assure that the proper plugs fit the holes. (If the plugs are reversed, the cement may set prematurely in the syringe.)

Tips for Dental Practitioners for Cross-Contamination Control:

Apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient; use new, uncontaminated gloves when handling multiple-use dental dispensers; utilize dental assistants to dispense material for the dentist; avoid contact of the reusable parts (e.g., the body of the multiple-use dental dispenser) with the patient's mouth; do not reuse the multiple-use dental dispenser if it becomes contaminated; do not reprocess a contaminated multiple-use dental dispenser by using chemical wipes or disinfectants; do not immerse multiple-use dental dispensers in a high level chemical disinfectant, as this may damage the dispenser and the material contained in the device; do not sterilize multiple-use dental dispensers, as this may damage the material contained in the device.

Disposal of Material:

Before disposal, the product should be fully mixed with the mixing tip, cured and then discarded in the general refuse. All cartridges and mixing tips may be disposed of in normal refuse.

Events:

Reportable incidences should be reported to Parkell and the competent authority in which the user and or patient is established.

Warranty and Terms of Use:

For full Warranty and Terms of Use information, please see www.parkell.com. Safety Data Sheets (SDS) are available at www.parkell.com. Parkell's Quality System is certified to ISO 13485

Explanation of Symbols Used:

Rx	• Professional use only
	• Follow instructions for use
	• Temperature limit
	• Store product tightly sealed away from direct sunlight.
	• Use-by date (expiration)
LOT	• Batch code
REF	• Catalogue / stock number
UDI	• Unique Device Identifier
MD	• Medical Device
	• Package contents
	• Do not use if package is damaged
2	• Single use only
	• Manufacturer
	• Mixing Tip
	• 5ml Syringe (Paste) with Plunger