

parkell® *EPIC™-TMPT*

Composite Resin Dental Restorative Material

REF S356, S361, S362, S363, S357, S355, S364, S365,
S358, S366, S367, S368, S369, S360, S359, S356UD,
S361UD, S362UD, S363UD, S357UD, S360UD

Instructions for Use

A00597revI0122

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

Description:

Epic®-TMPT is a light-cured microfill composite resin restorative paste material with a bonded organic filler and a resilient TMPT resin matrix. It is available in a variety of shades for matching teeth in most esthetic situations.

Indications for Use:

Epic-TMPT is indicated for use in Class III and Class V restorations where radiopacity is not required, and where esthetics is a primary concern. It may also be used in small Class I restorations where all margins may be visually inspected.

Contraindications:

Epic-TMPT is not indicated for use on patients with sensitivity to methacrylate

resins. Epic-TMPT is radiolucent and should not be used in cases where radiographs are required to evaluate recurrent caries.

Precautions:

Avoid using eugenol-containing cements or liners under Epic-TMPT restorations.

Conformance to Standards:

The quality system of Parkell is certified to ISO 13485.

How Supplied:

Epic-TMPT is available in 3 gm syringes or 0.30 gm unit-dose capsules, designed to fit the Centrix gun or an equivalent device. Epic-TMPT is available in the following shades: Vita® - A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C2, C3, C4, and D4, as well as an Incisal Shade and a Universal Shade (between B2 and B3).

Directions for Use:

For best handling, use Epic-TMPT at room temperature. If the dispensed material will not be used immediately, protect it from ambient light to prevent premature polymerization. If the cavity is large or deep, use incremental filling techniques to assure adequate cure.

1. After preparing the surface, apply an appropriate dentin/enamel bonding agent. Epic-TMPT is compatible with all currently available bonding agents.
2. Dispense Epic-TMPT from the syringe onto a pad and place the appropriate amount onto the tooth using a plastic instrument. If using capsules, express directly from the capsule onto the tooth.
3. Polymerize the Epic-TMPT with any curing light for between 20 and 40 seconds. The actual time required will depend on the intensity of your light

and the shade and thickness of the material you use. For best results, test the material with your particular curing light to determine the optimal setting.

4. Epic-TMPT will polish quickly and easily to a high luster using suitable discs, points and polishing pastes.

Clinical Consideration:

Epic-TMPT is a relatively translucent material. In cases where you want to mask a surface (such as tetracycline stains or metal exposed by a porcelain fracture), it is recommended that a thin layer of opaque resin be placed prior to the final Epic-TMPT restoration. Safety Data Sheets (SDS) are available at www.parkell.com.

Storage & Infection Control:

Disinfect composite syringes with an EPA-approved, high-level surface disinfectant after use. Capsules are for single patient use, and should be discarded after use. Never store above 104° F (40° C). Refrigeration is not necessary. However, if stored in a refrigerator, allow the material to warm to room temperature before use. Do not store near eugenol-containing materials.

Formulated in Japan for:


















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Tips for Dental Practitioners:

The following information should help dental practitioners reduce the risk of cross-contamination between patients when using multiple-use dental dispensers: 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.

Explanation of Symbols Used:

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|  | • Professional use only |
|  | • Follow instructions for use |
|  | • Temperature limit |
|  | • Store product tightly sealed away from direct sunlight. |
|  | • Use-by date (expiration) |
|  | • Batch code |
|  | • Catalogue / stock number |
|  | • Unique Device Identifier |
|  | • Medical Device |
|  | • Package contents |
|  | • Do not use if package is damaged |
|  | • Single use only |
|  | • Manufacturer |
|  | • 3 gm syringe/paste |
|  | • 0.30 gm unit-dose capsule/paste |