Caution: Rx Only

Parkell Epic®-TMPT
Composite Resin Dental Restorative Material

Device Description
Epic-TMPT is a light-cured microfill composite resin restorative 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.

Intended Use / Indications
Epic-TMPT is intended for use in Class III, V and selected Class I, II and IV restorations, where esthetics is a prime concern. Though Epic-TMPT is not radiopaque, it demonstrates a very low wear rate, and therefore can be used in selected Class I and Class II restorations along with a radiopaque basing material.

Contraindications
Epic-TMPT is not intended for use on patients with sensitivity to methacrylate resins.

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

Adverse Events
None known.

Conformance to Standards
The quality system of Parkell is certified to ISO 13485/9001.

How Supplied
Epic-TMPT is available in 3gm syringes or 0.30gm 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) Though an unfilled resin may be used prior to applying Epic-TMPT, this is generally not necessary because of Epic-TMPT's excellent flow properties.
3) 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.
4) 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.
5) 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.

Storage and 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.

Warranty
Parkell will replace defective material. Parkell does not accept liability for any loss or damage, direct, indirect or consequential, arising out of use of or the inability to use the product described herein. Before using, the user shall determine the suitability of the product for its intended uses and the user assumes all risk whatsoever in connection herewith.

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MATERIAL SAFETY DATA SHEET

SECTION I - PRODUCT IDENTIFICATION

PRODUCT NAME: **EPIC® - TMPT COMPOSITE** **STOCK NO:** **S360, etc.**
DOT HAZARD LABEL: None UN NUMBER: None
PROPER SHIPPING NAME: None DATE PREPARED: 10/13/09
NFPA CODES: HEALTH -1 FLAMMABILITY - 0 REACTIVITY -1

SECTION II - HAZARDOUS INGREDIENTS/IDENTITY INFORMATION

HAZARDOUS COMPONENTS	CAS NUMBER	PEL	TLV	%
Di-2-Methacryloxethyl 2,2,4trimethylhexamethylenedicarbamate	No number	NA	NA	
Amorphous micro silica (SiO_2)	61790-53-2	80 mg/m^3	10 mg/m^3	

SECTION III - PHYSICAL & CHEMICAL CHARACTERISTICS

BOILING POINT: +300° F SPECIFIC GRAVITY (H_2O = 1): 1.43 (paste)
VAPOR PRESSURE: Almost 0 PERCENT VOLATILES: Almost 0
VAPOR DENSITY (Air = 1): NE EVAPORATION RATE (Butyl Acetate = 1): Almost 0
APPEARANCE AND ODOR: Tan paste without odor.

SECTION IV - FIRE AND EXPLOSION HAZARD DATA

FLASH POINT (TCC): +300° F FLAMMABLE LIMIT (air, % by vol.) UPPER: N E LOWER: NE
EXTINGUISHER MEDIA: Foam, dry chemical, carbon dioxide.
SPECIAL FIRE FIGHTING PROCEDURES: During emergency conditions, overexposure to thermal decomposition products may cause health hazard. Self contained breathing apparatus should be worn.
UNUSUAL FIRE & EXPLOSION HAZARDS: When exposed to flame, emits toxic fumes and gases.

SECTION V - REACTIVITY DATA (PHYSICAL HAZARDS)

STABILITY: [X] STABLE [ ] UNSTABLE
CONDITIONS TO AVOID: Heat and light.
INCOMPATIBILITY (Materials to avoid): Polymerization catalyst (peroxides, persulfates, light, heat, nitric acid and other strong oxidizers, ammonia and amines, halogens and halogen compounds).
HAZARDOUS DECOMPOSITION PRODUCTS: Thermal-oxidative degradation can produce toxic and corrosive materials, including carbon monoxide.
HAZARDOUS POLYMERIZATION: [X] MAY OCCUR [ ] WILL NOT OCCUR
CONDITIONS TO AVOID: Hazardous polymerization may occur, especially when heated or catalyzed.

SECTION VI - HEALTH HAZARD DATA

PRIMARY ROUTE(S) OF ENTRY: [X] EYES [X] SKIN INHALATION [X] INGESTION
HEALTH HAZARDS (Acute & Chronic): Ingestion may cause headache, dizziness, nausea, tinnitus, dispnea, etc. May cause corrosion after contact is made with human eyes. Primary irritant on human skin, repeated prolonged contact can cause irreversible damage to human skin. Inhalation is not hazard unless heated at high temperature. When heated, vapor can cause irritation of the upper respiratory tract and mucous membranes, and, high concentrations can cause symptoms similar to those which may be experienced upon ingestion.
SIGNS & SYMPTOMS OF EXPOSURE: See above.
CARCINOGENICITY: [No] NTP? [No] IARC MONOGRAPHS? [No] OSHA?
EMERGENCY AND FIRST AID PROCEDURES:
INHALATION: Remove victim to fresh air. If cough or other respiratory symptoms develop, consult medical personnel. If not breathing, give artificial respiration, preferably mouth-to-mouth. If breathing is difficult, give oxygen. Consult medical personnel.
EYES: Immediately flush with copious amounts of water for at least 15 minutes. Get medical attention.
SKIN: Wash skin with copious amounts of soap and water. Wash contaminated clothing and decontaminate footwear before reuse.
INGESTION: Induce vomiting. Get medical attention immediately.

SECTION VII - SPECIAL PRECAUTIONS AND SPILL OR LEAK PROCEDURES

PRECAUTIONS TO BE TAKEN IN HANDLING & STORAGE: Do not store under pure nitrogen or sparge with nitrogen or oxygen-free gas. Store away from direct sunlight, source of heat, and polymerization catalyst mentioned in SECTION V.
OTHER PRECAUTIONS: Prevent contact with eyes, skin, or clothing. Do not ingest.
STEPS TO BE TAKEN IN CASE MATERIAL IS RELEASED OR SPILLED: Clean-up small spills and residues with absorbent paper or cloth towel.
WASTE DISPOSAL METHODS (Consult federal, state, and local regulations): Dispose of in accordance with Federal, State, and local regulations.

SECTION VII - SPECIAL PROTECTION INFORMATION/CONTROL MEASURES

RESPIRATORY PROTECTION: NIOSH approved respiratory protection for organic gasses, if needed.
VENTILATION: General ventilation and local exhaust ventilation where gas evaporation can occur (very high temperature or such).
PROTECTIVE GLOVES: Rubber or PVC Gloves.
EYE PROTECTION: Safety glasses or full face shield.
OTHER PROTECTIVE CLOTHING OR EQUIPMENT: Safety shower and eyewash station.
WORK/HYGIENIC PRACTICES: Wash hands before eating, drinking or smoking.