RX Only

SEE OTHER SIDE FOR MSDS SHEET

Instructions for Use
HyperFIL™ Dual-Cure Resin Composite

HyperFIL™ is a radiopaque, nanofilled dual-cure composite restorative designed for quick and easy placement of tooth-colored posterior restorations. It eliminates the need for flowable liners and incremental curing. It is available in a universal shade (approximately A2/B2) appropriate for posterior restorations where precise shade matching is not critical and an enamel shade (approximately A1/B1) suitable for posterior and anterior placement.

Shade: Universal (S326) (Approx. A2/B2);
Enamel (S323) (Approx. A1/B1)
Light-Cure: 40 seconds with any curing light
Self-Cure: 4 minutes

Indications:

For restorations where a precise shade match is not critical. As expressed from the cartridge, the material flows to conform well to the tooth surface. This high flowability may necessitate the use of special matrixing techniques where interproximal contacts must be restored.

Contraindications:

Not for use on or by persons with a sensitivity to methacrylates, dimethacrylates or similar resins.

Precautions:

When using any resin restorative material, avoid eugenol-containing cements or liners.

NOTE: Before placing HyperFIL, confirm that your bonding agent is compatible with dual-cure composites. HyperFIL bonds well to Parkell's Brush&Bond®, Touch&Bond® and Amalgambond®. However, some other bonding agents (particularly self-etchers) do not bond effectively to self-cure and dual-cure resins.

Instructions for use - Restorations

1.) Complete tooth preparation as usual. Apply and cure a bonding agent that is compatible with dual-cure resins.

2.) Double-bleed the cartridge:

a.) Place the HyperFIL cartridge into your dispensing gun. Remove and discard the cap. Bleed a small amount of material onto a pad to assure that material is flowing from both orifices. *(Fig 1)*

b.) Affix a mixing tip to the cartridge and then insert an intraoral tip into it. Express a small amount of HyperFIL through both tips on mixing pad. *(Fig 2)* Immediately proceed to step 3.

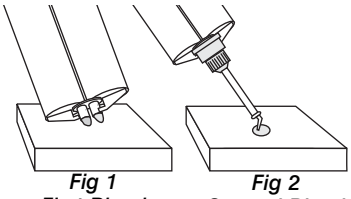

Fig 1
First Bleed

Fig 2
Second Bleed

3.) Place the intraoral tip into the bottom of the preparation to avoid trapping air and slowly express the composite as you withdraw the tip. Keep the tip immersed in the HyperFIL until the prep is adequately filled to eliminate air entrapment.

(It is not necessary to use a flowable liner to adapt to the prep floor, or to build/cure the restoration in incremental layers).

NOTE: If you are restoring a Class I preparation, after expressing the HyperFIL, press an alcohol-lubed gloved finger against the occlusal surface to assure good adaptation between the material and the preparation.

4.) Light cure the surface for at least 40 seconds with any curing light. NOTE: Even though HyperFIL is a dual-cure material, the surface MUST be light cured to assure shade stability and the hardest possible finish.

5.) Shape the restoration using conventional stones and wheels. Polish as usual using conventional rotary polishing points, or apply Parkell's DuraFinish™ composite glaze (Stock No. S295).

Instructions for use – Core Build Up

When using HyperFIL for cores that will be immediately prepped and impressioned, you want the strongest possible immediate bond. In this case it may be helpful to light-cure a thin layer of HyperFIL over the cured bonding agent first, before expressing the balance of the material.

Storage: Avoid excessive heat. Refrigeration is not essential, but it will prolong the shelf life of the product. Chilled material should be allowed to warm to room temperature before use. Do not store near eugenol-containing materials.

Available in:

10ml syringe with mixing and intraoral tips – S326, S323
Dispensing gun for 10ml syringe – S327

WARRANTY:

Parkell will replace defective material. **This warranty is in lieu of all warranties of merchantability, fitness for purpose or other warranties, express or implied.** Parkell does not accept liability for any loss or damage, direct, consequential or otherwise, arising out of the use of or the inability to use the product herein described. Before using, the user shall determine the suitability of the product for its intended use and the user assumes all risk and liability whatsoever in connection herewith.

PARKELL'S QUALITY SYSTEM IS CERTIFIED TO ISO13485 / ISO9001. MATERIAL SAFETY DATA SHEETS ARE ATTACHED TO THESE INSTRUCTIONS, AND CAN ALSO BE FOUND AT WWW.PARKELL.COM.

EC REP
CE 0120

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SECTION 1 – CHEMICAL PRODUCT AND COMPANY IDENTIFICATION

PARKELL, INC.
300A Executive Drive
Edgewood, NY 11717

Company Telephone Number: (631) 249-1134
24-Hour Emergency Phone: InfoTrac 1-800-535-5053

PRODUCT NAME: HyperFIL™

MSDS NO: S326-10 ml & S323-10 ml

SECTION 2 – COMPOSITION INFORMATION ON INGREDIENTS

HAZARDOUS COMPONENTS	CAS NUMBER	PEL	TLV	%
Uncured Methacrylate Ester Monomers	N/A	N/E	N/E	
Benzoyl Peroxide	94-36-0	5 mg/m^3	5 mg/m^3	
N,N Bis Hydroxyethyl-p-Toludine	3077-12-1	NE	NE	
Other ingredients:				
Silane treated glass fillers, initiators and stablizers				

SECTION 3 – HAZARDS IDENTIFICATION

EMERGENCY OVERVIEW:
POTENTIAL HEALTH EFFECTS
EYES: May cause irritation and damage if not removed promptly.
SKIN: Prolonged or repeated exposure to uncured material may cause irritation or skin rash especially in sensitive individuals.
INHALATION: Prolonged or excessive inhalation may cause respiratory tract irritation.
INGESTION: May be harmful if swallowed. Seek medical attention.
CHRONIC EFFECTS:
SIGNS & SYMPTOMS:
CARCINOGENECITY: No NTP? No IARC MONOGRAPHS? No OSHA?

SECTION 4 – FIRST-AID MEASURES

EYES: Flush with plenty of water. Contact physician.
SKIN: Wash with soap and water.
INHALATION: Remove to fresh air. If irritation persists, contact physician.
INGESTION: Contact a physician immediately.
NOTE TO PHYSICIANS:

SECTION 5 – FIRE-FIGHTING MEASURES

FLASH POINT (TCC): N/D FLAMMABLE LIMIT (air, % by vol.) UPPER: N/D LOWER: N/D
FLAMMABILITY CLASSIFICATION (CFR 1910.1200):
EXTINGUISHING MEDIA: Chemical Foam, CO_2, Dry Chemical
FIRE FIGHTING INSTRUCTIONS: Wear Self Contained Breathing Apparatus.
UNUSUAL FIRE & EXPLOSION HAZARDS: Heat can cause polymerization with rapid release of energy.
HAZARDOUS COMBUSTION PRODUCTS:

SECTION 6 – ACCIDENTAL RELEASE MEASURES

Absorb spills with inert material; keep spilled material in closed containers and dispose of as recommended. Avoid skin contact. Wear protective equipment.

SECTION 7 – HANDLING AND STORAGE

HANDLING: Avoid skin contact. Wear protective equipment.
STORAGE: Store in a cool, dry place away from heat, sunlight, oxidizing, reducing agents and ignition sources.

SECTION 8 – EXPOSURE CONTROLS / PERSONAL PROTECTION

ENGINEERING CONTROLS: Adequate ventilation to maintain PEL.
EYE/FACE PROTECTION: Safety glasses or goggles.
SKIN PROTECTION: Gloves - latex or other impervious rubber material.
RESPIRATORY PROTECTION: Use in a well ventilated area.
EXPOSURE GUIDELINES:

SECTION 9 - PHYSICAL AND CHEMICAL PROPERTIES

APPEARANCE AND ODOR: Colored paste with mild fruity ester-like odor.
BOILING POINT: N/D
VAPOR PRESSURE: Not Determined
VAPOR DENSITY (Air = 1): Not Determined
SOLUBILITY IN WATER: Insoluble
SPECIFIC GRAVITY (H_2O = 1): 2.0
PERCENT VOLATILES:
EVAPORATION RATE (Butyl Acetate = 1):
PH:

SECTION 10 – STABILITY AND REACTIVITY

STABILITY: Stable if stored as directed
HAZARDOUS POLYMERIZATION: Will not occur when using clinical amounts of this material.
CONDITIONS TO AVOID: Heat, sunlight, aging and contamination
INCOMPATIBILITY (Materials to avoid): Oxidizing agents, reducing agents, peroxides and free radical initiators.
HAZARDOUS DECOMPOSITION PRODUCTS: Oxides of carbon.

SECTION 11 – TOXICOLOGICAL INFORMATION

SECTION 12 – ECOLOGICAL INFORMATION

SECTION 13 – DISPOSABLE CONSIDERATIONS

Unpolymerized (uncured) material may be RCRA hazardous waste. Waste must be disposed of in accordance with federal, state, and local environmental control regulations.

SECTION 14 – TRANSPORT INFORMATION (not meant to be all-inclusive)

PROPER SHIPPING NAME: N/A
DOT HAZARD LABEL:
UN/NA NUMBER:

SECTION 15 – REGULATORY INFORMATION (not meant to be all-inclusive)

SECTION 16 – OTHER INFORMATION

HMIS CODES: HEALTH - 2 FLAMMABILITY - 1 REACTIVITY - 2
WORK/HYGIENIC PRACTICES: Handle in accordance with good personal hygiene and safety practices. These practices include; avoid unnecessary exposure and wash hands before eating, drinking or smoking.

DATE PREPARED: 03/26/12 PREPARED BY: R. Burke

To the best of our knowledge, the information on this MSDS sheet is accurate. However, the information is provided without any warranty, expressed or implied, regarding its correctness or completeness. Recipients are advised to confirm in advance of need that the information is current, applicable, and suitable to their circumstances. This information is not warranted to be whether originating with the company or not.