

INSTRUCTIONS FOR USE

Rx Only
For Safety Data Sheet (SDS) go to www.parkell.com



Dual-Cured, Bulk-fill Restorative Composite
with Nano-Hydroxyapatite

S232 - Intro Kit
S231 - Enamel Shade Refill
S233 - Universal Shade Refill

parkell

A00991rev*0118

STORE THIS PRODUCT TIGHTLY SEALED, AWAY FROM EXTREME COLD (BELOW 39°F/4°C), DIRECT LIGHT, OR HIGH HEAT (ABOVE 77°F/25°C).

Refrigeration is acceptable but not essential. Do not freeze. Bring chilled material to room temperature before use. Do not store near eugenol-containing materials.

PRODUCT DESCRIPTION

HyperFIL® HAp is a strong, highly radiopaque, dual-cured composite restorative material containing nano-hydroxyapatite. It can create quick and easy bulk-fill direct or indirect tooth-colored posterior restorations. The presence of nano-hydroxyapatite gives these restorations a brighter, whiter and more life-like appearance.

HyperFIL HAp will light-cure to a depth of 3-4mm in 40 seconds with any dental curing device producing light from 430-480nm at an intensity of >600mW/cm². It will also completely self-cure to any depth in 4 minutes at mouth temperature. With excellent flow, dual-cure, and low polymerization shrinkage, HyperFIL HAp is an ideal bulk-fill restorative material. Flowable liners or incremental layering are unnecessary, and appropriate wedging and matrixing techniques will assure that interproximal contacts are tight to resist food impaction.

INDICATIONS FOR USE

HyperFIL HAp is indicated for strong posterior composite restorations where a precise shade match is not critical, but heavy occlusal loads are anticipated.

CONTRAINDICATIONS FOR USE

HyperFIL HAp is contraindicated for use on or by persons who are sensitive to acrylates, methacrylates or related monomers.

INTRO KIT INCLUDES:

- (1) 10ml (22gm) auto-mix cartridge of HyperFIL HAp Enamel Shade dental restorative composite.
- (1) 10ml (22gm) auto-mix cartridge of HyperFIL HAp Universal Shade dental restorative composite.
- (1) Dispensing gun for 10ml cartridge (Stock No. S327).
- Brown-base 1:1 mixing tips (Refill Stock No. S328).
- Snap-in intra-oral tips (Stock No. S329).
- Instructions for Use.

AVAILABLE REFILL SHADES ARE:

- Universal (A2/B2) (Stock No. S233) – a shade for monolithic, bulk-fill replacement of amalgams.
- Enamel (A1/B1) (Stock No. S231) – a shade for veneering posterior restorations to simulate enamel.

CLINICAL PRECAUTIONS AND WARNINGS

- The clinical requirements of the patient must be considered prior to selecting any restorative material.
- HyperFIL HAp is for professional dental use only, and should be kept away from children.
- The material is not for internal consumption, other than as a cured restorative material.

- Contact between this product and sensitive or inflamed human soft tissues (mucosa, eyes, nose, etc.) may cause irritation, dermatitis or inflammatory reactions. If this occurs, discontinue use, flush the area with copious amounts of water and obtain professional medical care.
- Use a rubber dam, proper intra-oral evacuation, and other suitable isolation methods to prevent contamination of restorations by saliva, blood or other fluids.
- This product may generate significant heat when setting in large masses. The amount and timing of this heat depends on the volume of material. Take appropriate steps to cool the material if heat is detected, and do not leave the patient alone during curing. After initial use, discard the shipping cap and store the cartridge in a cool, dark place, with the used mixing tip tightly screwed on as a seal. Do not replace mixing tip until ready for next use.
- HyperFIL HAp is sensitive to light. Excessive exposure will shorten working time and result in premature polymerization. Protect the restoration from ambient light until ready to light-cure. Use of some medicaments (desensitizers, varnishes, liners, products with eugenol) under this material is not recommended, as they may reduce bond strength or inhibit resin curing.
- Avoid contamination of product and packages. Do not mix this product with other materials, and do not return dispensed material to its original container. Dispose or disinfect all components that contact patient fluids following accepted infection control protocols and applicable regulations.
- Do not force the intra-oral tip into the soft tissues, as it is not an injector.
- Working time, setting time, chemical activity and shelf life of the product are estimates. They will vary based upon temperature, humidity, age and storage conditions, among other variables, and will be reduced if the material is not stored properly.
- Excessive or intense squeezing force on cartridge-dispensing guns may cause gun breakage or cartridge cracking. Slow and steady force is preferred for dispensing these materials.
- Consult the online Safety Data Sheet (SDS) at www.parkell.com for advice on safe handling.

INSTRUCTIONS FOR USE — DIRECT RESTORATIONS

1. After caries removal and tooth preparation, rinse the prep with water and dry using oil-free air. Disinfect and de-oil the preparation with cleansers and solvents, e.g. Parkell's Cavidry™ (Stock No. S099).
2. Apply appropriate pulpal protection to deep prepared areas if the tooth is vital.
3. Prepare the dentin and enamel surfaces using your etching technique of choice (Selective Etch, Total Etch or Self-Etch).
4. Apply and fully cure a bonding agent that is compatible with dual-cure resins, such as Parkell's Brush&Bond®, Brush&Bond® Universal, Parkell® Universal Adhesive, Touch&Bond®, Amalgambond®, C&B-Metabond® or SEcure®. Remember that some other self-etching bonding agents do not bond effectively to self-cure and dual-cure resins. Confirm that your bonding agent works with dual-cure composites.
5. Apply the desired matrix system and tooth separation device (e.g. the Fendermate® Matrix System from DirectaDental). Tightly wedge and burnish the band to allow a broad, tight interproximal contact.

6. Double-bleed the cartridge as follows:
 - a. Place the HyperFIL HAp cartridge into the dispensing gun. Remove and **DISCARD THE SHIPPING CAP – DO NOT REUSE IT.**
 - b. Bleed a small amount of material onto a pad so material is flowing from both orifices.
 - c. Affix a mixing tip to the cartridge and affix an intraoral tip to the mixer. Express a pea-sized amount of HyperFIL HAp through mixing tip onto a mixing pad, and immediately proceed to next step.
7. HyperFIL HAp is a bulk-fill composite. It is not necessary to use a flowable liner to adapt to the prep floor, or to build and cure the restoration in incremental layers. However, if incremental placement is desired, no bonding agent is required between the layers.
8. Place the intraoral tip in the bottom of the preparation and slowly express the composite as you withdraw the tip. Keeping the tip immersed in the HyperFIL HAp to eliminate air entrapment. Slightly overfill the bulk-filled prep to allow for carving of occlusal anatomy later. You may wish to press a gloved finger or cotton pledget wet with alcohol against the margins for good marginal adaptation.
9. Light cure each surface for 40 seconds with any curing light, to assure shade stability and the hardest possible finish. Then allow the rest of the restoration to self-cure to the bottom for 4 minutes at mouth temperature.
10. Refine the shape with rotary abrasive points, wheels and stones. Adjust the occlusion with high-quality articulation products such as Parkell's Accufilm® Line. Finish the restoration with polishing points and pastes such as Parkell's Absolute Polishers™. Alternatively, you may achieve a durable, high-gloss surface with Parkell's DuraFinish™ composite glazes (Stock Nos. S295 - Original or S296 - AllCure).

INSTRUCTIONS FOR USE — CORE BUILD-UP

HyperFIL HAp may be used to fabricate extremely high-strength cores for vital and non-vital teeth. For restorations that will be immediately prepped and impressioned, where the strongest immediate bond is required, light-cure a thin layer of HyperFIL HAp over the cured bonding agent first, before expressing the balance of the material. Then bulk-fill the remaining core using conventional core forming and matrixing techniques to create a strong core build-up that is ready for crown preparation.

INSTRUCTIONS FOR USE — INDIRECT RESTORATIONS

The clinical procedure for indirect use of HyperFIL HAp is similar to the direct use of the product. The major difference is that the restoration is fabricated on a model outside of the mouth rather than in the mouth itself. Larger restorations are more easily created indirectly, without the need to deal with the tongue, saliva or patient movement. The resulting restoration will have better anatomic contours and greater strength.

Materials used to make an indirect model may include plaster, stone or Parkell's Mach II® or Mach-Slo™ VPS Die Silicones. The unique "flexible yet rigid" properties of the Mach VPS create a superior model and a very well-fitting composite restoration. Consult www.parkell.com for useful information on this technique.

DISINFECTION OF COMPONENTS

All components should be cleaned of debris with a water-damp paper towel and disinfected with a paper towel saturated with an EPA-registered, intermediate-level (HIV/HBV/tuberculocidal claim) hospital disinfectant. **Follow the surface disinfecting protocol of the disinfectant manufacturer, as specified by recognized infection control experts, or visit www.CDC.gov for the most recent version of the "Guidelines for Infection Control in Dental Health-Care Settings".**

STORAGE

Avoid excessive heat or light. Refrigeration is not essential but will prolong the shelf life of the product. Bring chilled material to room temperature before use. Do not store near eugenol-containing materials.

WARRANTY AND TERMS OF USE:

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. 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.

EC REP European Authorized Representative
(Not a dealer/distributor):
Directa AB - P.O. Box 723, Finvids väg 8
SE-194 27 Upplands Väsby - Sweden

parkell

300 Executive Dr., Edgewood, NY 11717 USA 🏢
Toll-Free: 1-800-243-7446 • Phone: (631) 249-1134
Fax: (631) 249-1242 • E-Mail: info@parkell.com
Web: www.parkell.com

CE 0120  MADE IN USA