

Instructions for Use

Predicta™ bulk

BIOACTIVE

Rx Only
For Safety Data Sheet (SDS)
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A01061rev*0219

Bulk-Fill Dual-Cure Composite

Available Shades: A1/B1 (S615) & A2/B2 (S616)

Low-Viscosity (LV) Bulk-Fill Dual-Cure Composite

Available Shades: A1/B1 (S610) & A2/B2 (S611)

PRODUCT DESCRIPTION

Predicta™ Bioactive Bulk materials are dual-cured, bulk-fill resin composites, which are easy-to-place and combine excellent strength with exceptional durability, and optical characteristics close to those of natural teeth. Predicta Bioactive Bulk is bioactive and releases calcium and phosphate ions, to stimulate mineral apatite formation and remineralization at the material-tooth interface. Such bioactivity is known in the field to equate to stronger bonds between the restoration and tooth, penetration and filling of micro-gaps, reduction in sensitivity, guarding against secondary caries, and sealing of margins against microleakage and failure.

Predicta Bioactive Bulk materials are suitable for direct or indirect restorations. The Bulk material portfolio contains two viscosities to best suit the technique of the user; Bulk-Fill and Bulk-Fill Low-Viscosity (LV). Both versions are highly radiopaque and are light-curable to a depth of 4 mm in 20-40 seconds with a dental curing light emitting blue light at 430 - 480nm, with a minimum intensity of 600 mW/cm². Moreover, both products will self-cure to any depth in approximately 5 minutes at mouth temperature. The materials possess high compressive, tensile, and flexural strength. Their dual-cure capacity makes incremental layering unnecessary.

INDICATIONS

- Class I, II, III, IV, and V restorations, including root surface cavities, and post cementing.

CONTRAINDICATIONS

- Not for use on or by persons who are sensitive to acrylates, methacrylates, or related monomers or polymers.

BASIC SAFETY INSTRUCTIONS

- Keep out of reach of children.
- For dental use only.
- Avoid contact with skin. In the event of accidental skin contact, wash the affected area immediately with soap and warm water.
- Use a rubber dam, proper intra-oral evacuation, and other suitable isolation methods to prevent contamination of restorations by saliva, blood or other fluids.

- Use of some medicaments (desensitizers, varnishes, liners, products with eugenol) under these materials is not recommended, as they may inhibit resin curing.
- Avoid contamination of products and packages. Do not mix these products with other materials, and do not return dispensed material to its original container. Dispose of, or disinfect, all components that contact patient fluids, following accepted infection control protocols and applicable regulations.
- Consult the online Safety Data Sheet (SDS) at www.parkell.com for advice on safe handling.

INSTRUCTIONS FOR USE - DIRECT RESTORATIONS

Predicta Bioactive Bulk restorative may be used and recommended for the construction of extremely high-strength posterior Class I, Class II or Class V dental restorations, endodontic post cementation, or tooth core build-ups on vital or non-vital teeth.

In deciding which viscosity of Predicta Bioactive Bulk restorative would be appropriate for an individual case, Bulk-Fill or Bulk-Fill Low-Viscosity (LV), consider the internal shape of the preparation. If the shape has minimal internal complexity, either product will be acceptable. However, if the internal shape is excessively irregular, or has intricate undercuts, then lower viscosity Bulk-Fill (LV) may be the better choice. Depending on the preference of the clinician, either material may be dispensed using the included hand syringe plunger, or a 1:1, 5 ml Cartridge Dispensing Gun (S620), available separately.

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 appropriate cleansers and solvents.
2. Apply pulpal protection to deep excavation areas on vital teeth, if needed.
3. Prepare the tooth surfaces using an etching technique compatible with your bonding agent (Selective-Etch, Total-Etch or Self-Etch).
4. Apply and fully cure a bonding agent that is compatible with dual-cure resins, such as AmalgamBond® Plus, Brush&Bond®, Brush&Bond® Universal or Parkell® Universal Adhesive.
5. Apply the desired matrix or core former and tooth separation device to create a tight contact.
6. Double-bleed the cartridge as follows:
 - a. Insert the black plunger into the rear of the cartridge, OR insert the cartridge into a 5 ml, 1:1 cartridge dispensing gun (if greater force is desired).
 - b. Remove and discard the shipping cap - DO NOT REUSE IT.
 - c. Bleed a small amount of material onto a pad so it is flowing from both orifices.
 - d. Affix a brown-base, 1:1 static mixer to the cartridge and bend the integral 17-gauge metal needle tip to the desired angle. The cartridge may now be protected with a disposable plastic barrier sleeve. Express a pea-sized amount of Predicta Bioactive Bulk restorative through the mixer and onto a pad, and immediately go to the next step.
7. Place the intraoral metal needle tip in the bottom of the prep to be filled, and slowly express the composite as you withdraw the tip, keeping the tip immersed in the material to eliminate air entrapment. Slightly overfill the prep to allow for carving the anatomy later. For more precise application of material, Brown-base, 1:1 static mixers with integral 19-gauge metal needle tips are available separately (30pcs, SKU# S622).
8. To minimize shrinkage stress, allow the material to self-cure for 1-2 minutes before light curing.
9. Light-cure each surface for 20-40 seconds to a depth of 3-4 mm with the appropriate curing light, to assure shade stability and the hardest possible surface finish. Actual clinical depth of cure depends on factors such as time, light intensity, device condition, distance between the light and the restoration, resin thickness and material shade.
10. Allow the restoration to "finish" its self-cure to the bottom of the prep at mouth temperature for 5 minutes total elapsed time. This will assure a strong bond between the restoration and the tooth.
11. Remove the matrix band or core former and refine the restoration with rotary abrasive points, wheels and stones. Adjust the occlusion and polish as appropriate.

Continued



12. After use, leave the used mixing tip in place on the cartridge to seal out air between uses. Do not re-use the brown shipping cap. The cartridge and used static mixer should not be directly sprayed with or soaked in disinfectant. They may be cleaned of debris with a damp paper towel and disinfected as detailed below.

DISINFECTION OF COMPONENTS

All components should be cleaned of debris with a water-damp paper towel and disinfected with a disposable towel saturated with an EPA-registered, intermediate-level (HIV/HSV/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."

PHYSICAL PROPERTIES AND WORKING PARAMETERS

Compressive Strength: **350 Mpa**

Flexural Strength: **130 Mpa**

Barcol Hardness: **≥ 70**

Radiopacity (vs. Aluminum): **280%**

Work Time of Self-cure (25°C): **1-2 min**

Set Time of Self-cure (37°C): **5 min**

STORAGE AND SHELF LIFE

Store in a dry place at 2 - 25°C (36 - 77°F). Store tightly sealed, away from direct light. Do not freeze. Use at room temperature. Do not store near eugenol-containing materials. Do not use after the expiration date.

AVAILABLE PRODUCTS

SKU#	PRODUCT DESCRIPTION	SHADE
S610	Predicta™ Bioactive Bulk-Fill (LV) Paste	A1/B1
S611	Predicta™ Bioactive Bulk-Fill (LV) Paste	A2/B2
S615	Predicta™ Bioactive Bulk-Fill Paste	A1/B1
S616	Predicta™ Bioactive Bulk-Fill Paste	A2/B2

AVAILABLE ACCESSORIES

SKU#	PRODUCT DESCRIPTION
S620	5 ml Dispensing Gun
S621	17-Gauge Dispensing Tips (30pcs)
S622	19-Gauge Dispensing Tips (30pcs)

WARRANTY:

For full Warranty and Terms of Use information, please visit our website at www.parkell.com. Parkell's Quality System is certified to ISO 13485.

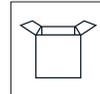
EXPLANATION OF SYMBOLS USED:



Manufacturer.



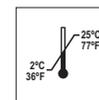
Store product tightly sealed away from direct sunlight.



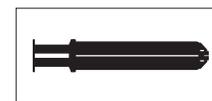
Package contents.



Single use only.



Store product above 2°C and below 25°C (36° - 77°F).



5 ml Syringe.



Dispensing Tips.



European Authorized Representative (Not a dealer/distributor):
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