

Instructions for Use

Predicta™ core

BIOACTIVE

Rx Only
For Safety Data Sheet (SDS)
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A01062rev*0219

Flowable Dual-Cure Core Build-Up Composite
Available Shades: Tooth (S601) & White (S600)

Stackable Dual-Cure Core Build-Up Composite
Available Shades: Tooth (S606) & White (S605)

PRODUCT DESCRIPTION

Predicta™ Bioactive Core is a dual-cured, core build-up composite reinforced with zirconia nano-filler for added strength. It is available in high viscosity “stackable” and low viscosity “flowable” consistencies. Both viscosities are suitable for the reconstruction of broken-down or endodontically-treated teeth. They differ in their flowability when dispensed, as well as in their ability to “self-level”. Depending on the preference of the clinician, either material may be dispensed using the included hand syringe plunger, or a 5 ml, 1:1 Cartridge Dispensing Gun, available separately.

Predicta Core 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.

The product is radiopaque and light-curable to a depth of 4 mm in 20-40 seconds with a dental curing light which emits blue light at 430-480 nm and a minimum intensity of 600mW/cm². It will also self-cure to any depth in 5 minutes at mouth temperature. The material possesses high compressive, tensile, and flexural strength. The dual-cure capacity makes incremental layering unnecessary.

INDICATIONS

- All types of core build-ups.
- Cementation of root posts.

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 Core may be used as the core build-up material and/or the post luting agent when fabricating extremely high-strength cores for vital or non-vital teeth.

In deciding which viscosity of Predicta Bioactive Core would be appropriate for an individual case, Stackable or Flowable, Practitioners should consider the internal shape of the preparation. If the shape has minimal internal complexity, either product would be well-suited. However, if the internal shape is excessively irregular, or has intricate undercuts, then the lower viscosity “Flowable” product may be a more optimum choice.

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 root canal and 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 Bond.
5. For restorations that will be immediately prepped and impressioned, where the strongest immediate bond is

required, light-cure a thin layer of the material 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 and light-cure to create a strong core build-up that is ready for immediate crown preparation.

6. Apply the desired matrix or core-former and tooth separation device to create a tight contact, if necessary.
7. Double-bleed the cartridge as follows:
 - a. Insert the black plunger into the rear of the cartridge, OR insert the cartridge into a 1:1, 5 ml 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 Core through the mixer and onto a pad, and immediately go to the next step.
8. 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. For more precise application of material, Brown-base, 1:1 static mixers with integral 19-gauge metal needle tips are available separately (30/pkg-S622).
9. If desired, insert a properly-treated endodontic post into the canal and hold in place for 10 seconds to equalize hydrostatic insertion pressure.
10. Surround the head of the post with more Predicta Bioactive Core, slightly overfilling the matrix. Compress the composite mass to remove air bubbles.
11. To minimize shrinkage stress, allow the material to self-cure for 1-2 minutes before light curing.
12. Light-cure each surface for 20-40 seconds to a depth of 4 mm with any curing light, to assure the hardest possible surface finish. Actual clinical depth of cure and timing depends on factors such as time, light intensity,

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device condition, distance between the light and the restoration, resin thickness and material shade.

13. Allow the restoration to “finish” its self-cure to the bottom of the prep at mouth temperature for 4 minutes total elapsed time. This will assure a strong bond between the core and the tooth.
14. Remove the matrix band or core former and prepare the material for the desired crown design.
15. 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/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.”

PHYSICAL PROPERTIES AND WORKING PARAMETERS

Compressive Strength: **360 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
S600	Predicta™ Bioactive Core Flowable Paste	White
S601	Predicta™ Bioactive Core Flowable Paste	Tooth
S605	Predicta™ Bioactive Core Stackable Paste	White
S606	Predicta™ Bioactive Core Stackable Paste	Tooth

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.

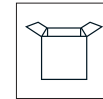
EXPLANATION OF SYMBOLS USED:



Manufacturer.



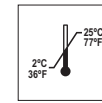
Store product tightly sealed away from direct sunlight.



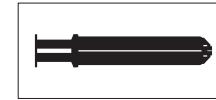
Package contents.



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):
Directa AB, P.O. Box 723, Finvids väg 8, SE-194 27 Upplands Väsby - Sweden



300 Executive Dr., Edgewood, NY 11717 USA • 800-243-7446 • Parkell.com

