

parkell®

Predicta® cement

BIOACTIVE

Self-Adhesive Resin Cement (REF S630, S631, S632)

Instructions for Use

 Parkell, Inc.,
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  MADE IN
USA
A01167_revD0324

Rx Only—product is intended for use by a licensed dental professional.
For Safety Data Sheet (SDS) go to www.parkell.com.

Description:

Predicta Bioactive Cement is an easy-to-use, self-adhesive, bioactive, radiopaque, dual-cure, strong permanent cement. The cement's high bond strength to dentin and enamel eliminates the need for a separate bonding agent, which simplifies the cementation process. Predicta® Bioactive Cement fills and seals microgaps with robust hydroxyapatite formation at the margin, and thereby alleviates or prevents microleakage, which is otherwise associated with recurrent decay.¹ By combining all the properties and performance benefits of premium universal resin cements with bioactivity, it gives crown margins unprecedented protection against secondary caries.

Indications for Use:

Predicta Bioactive Cement is intended for the cementation of indirect restoratives, including ceramic, zirconia, composite, and metal-based inlays, onlays, crowns, bridges, and posts.

Technical Information:

Indirect Restoratives (e.g., Crowns, Bridges)

- **Work Time:** 1 minute at room temperature
- **Set Time (Self-cure):** 4 – 5 minutes from start of mixing at mouth temperature.
- **Set Time (Light-cure):** 20 seconds (direct exposure at restoration margin)

Post Cementations

- **Work Time:** Direct placement in the mouth will reduce worktime. The actual decrease can vary (sometimes significantly) based on patient's mouth temperature at the treatment site.
- **Set Time (Self-cure):** 4 – 5 minutes from start of mixing at mouth temperature.
- **Set Time (Light-cure):** 20 seconds (for post stabilization at the orifice. Depth of cure will depend on access and intensity of light.)

Important Tips for Best Results:

- Ability to light-cure under restorations is dependent on the translucency of the restoration and the intensity of the curing light.
- Onset of self-cure gel phase will be dependent on how long it takes for the restoration to be seated in the mouth as well as the mouth temperature of the patient.
- Phosphate contamination of zirconia restorations from saliva during try-in will impact adhesion. Always consult with the lab or the manufacturer of the zirconia on how best to clean the intaglio.
- If refrigerated, always bring to room temperature before use.
- Curing Light Minimum Requirements: Blue-light emitting at 430 – 480 nm, with a minimum intensity of 600mW/cm2.

Contraindications:

- Patients with a history of sensitivity to this product.
- Not for use on or by persons who are methacrylate sensitive.
- Not for use as a veneer cement.

Precautions:

- Protect the patient's eyes when using all dental materials.
- For dental use only.
- Keep all components away from children.
- Contact between Predicta Bioactive Cement and sensitive, or inflamed soft tissues (mucosa, eyes, nose, and the like), may cause irritation, dermatitis, and/or inflammatory reactions. If this occurs, discontinue use, flush area with copious amounts of water, and consult a physician.
- Use a rubber dam or other suitable isolation methods to prevent contamination of surfaces.
- Do not apply eugenol containing products to any surface prior to or during cementation. They will reduce the efficacy of the cement.

Instructions for Cementation of Crowns, Bridges, Inlays and Onlays:

1. Prepare restorative surfaces for bonding to Cement.
 - a. **Metal Surfaces:** Cement bonds to non-precious metal alloys without special pretreatment other than microetching (sandblasting with 50-micron aluminum oxide). The durability of the bond to precious and noble dental alloys can be significantly improved by sandblasting the metal surface and priming it with a metal primer such as Parkell's Brush&Bond® MAX (available separately).
 - b. **Porcelain & Lithium Disilicate Surfaces:** Cement will bond well to hydrofluoric acid-etched porcelain or lithium disilicate surfaces that have been primed with Parkell's Ea-Z-Y Primer™ (available separately) or any silane containing ceramic primer. (**Important: Laboratory or dental manufacturer's instructions for pre-treatment always take precedence.**)
 - c. **Zirconia Surfaces:** Cement will bond well to sandblasted zirconia surfaces without the need of an additional primer. For cases where additional retention may be a benefit, an MDP containing Zirconia primer such as Parkell's Ea-Z-Y Primer is recommended. (**Important: Laboratory or dental manufacturer's instructions for pre-treatment always take precedence.**)
2. Remove temporary restoration and clean off remaining temporary cement and debris from tooth. Prepare the surface for cementation, using appropriate cleaners and disinfectants.
3. Rinse the preparation with water and lightly dry with air or cotton. Do not desiccate the tooth.
4. (Optional) Apply releasing agent such as Parkell's BluSep™ (available separately) to non-bonded surfaces to simplify post-insertion clean up and cement removal.
5. Priming the tooth surface is not required as the cement will adhere to appropriately cleaned untreated enamel and dentin on its own. For less retentive preps, where additional adhesion may be beneficial, a bonding agent that is dual-cure compatible can be applied to enamel and dentin as per the manufacturer's instructions.
6. Remove the cap from the cement syringe (do not discard as it will be used later to recap and reseal the cartridge) and bleed enough out to assure that cement is dispensing from both orifices of the syringe. Attach the 1:1 straight mixing tip that came with the cement onto the syringe, bleed a small amount of cement onto a pad through the tip to ensure an even mix, and immediately dispense directly into the restoration.
7. Fully seat restoration onto prep allowing excess cement to extrude from all margins. Hold restoration in place while gently removing gross excess while it is still soft.
 - **Self-cure only flash removal:** While maintaining pressure on the restoration, continue to check the flash with an explorer for the onset of the gel phase, at which time the cement will easily peel away from the margin. (Onset of gel phase will vary based on the factors mentioned in the "Important Tips for Best Results" section above.
 - **Tack cure flash removal:** Using a curing light, expose the marginal flash for 1-2 seconds. The excess cement will now be partially polymerized for easier removal. (**Important: Overexposure, or use of a higher-powered curing light will result in a more advanced polymerization of the cement, which will make it harder and more difficult to remove.**)
8. Continue to maintain consistent pressure on the restoration until the 4-5 minutes for total set time has elapsed before final cleanup and occlusal adjustment. This final cure time may be shortened for translucent restorations by exposing all surfaces (facial, lingual, occlusal, mesial, distal) with a 30 second exposure from any dental curing light meeting the minimum requirements previously listed.

1. Based on multiple in vitro university studies.

9. A post cementation bite wing x-ray is recommended to confirm there is no residual cement remaining interproximal.
10. Issue appropriate post-op instructions and dismiss the patient.
11. Discard the used mixing tip and recap the syringe with the original sealing cap.
12. Disinfect the syringe as per the disinfection instructions below.

Instructions for Cementation of Posts:

1. Select the appropriate post for the canal space and prepare its surface as per the post manufacturer's instructions.
2. Prepare the post space to accommodate the selected post.
3. Use appropriate irrigants to remove residual debris that was caused by canal shaping, then clean the canal by rinsing with water, then lightly dry with air, cotton, or paper points. Do not desiccate the canal.
4. Using a bonding agent on the canal walls is not required as the cement will adhere to appropriately cleaned untreated dentin on its own. For shorter posts, where additional adhesion may be beneficial, a bonding agent that is dual-cure compatible can be applied to the canal walls as per the manufacturer's instructions.
5. Remove the cap from the cement syringe and bleed enough out to assure that cement is dispensing from both orifices. Attach the 1:1 angled intraoral mixing tip that came with the cement onto the syringe, bleed a small amount of cement onto a pad through the tip to ensure an even mix, and immediately place the tip deep into the canal and slowly backfill until the canal is appropriately filled for the post style being used.
6. Seat the post into cement filled canal using a slow, even, up and down motion until the post has reached the bottom of the post space.
7. The top 2 mm of cement can be light-cured to stabilize the post in the canal. Final self-cure of the cement deeper down the post space will take between 4 to 5 minutes.

Kits Include:

- (1) 5ml Automix Syringe containing Predicta Bioactive Cement – S630, S631, S632
- (5) Brown Base/Clear Mixer (1:1) – Refill  S633
- (5) Endo Intraoral Tips – Refill  S335
- (10) Brown Base/Clear Mixing Tip (1:1) – Refill  S292

Tips for Dental Practitioners:

The following information should help dental practitioners reduce the risk of cross-contamination between patients when using multiple-use dental dispensers: apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient; use new, uncontaminated gloves when handling multiple-use dental dispensers; utilize dental assistants to dispense material for the dentist when appropriate; avoid contact of the reusable parts (e.g., the body of the multiple-use dental dispenser) with the patient's mouth; do not reuse the multiple-use dental dispenser if it becomes contaminated; do not immerse multiple-use dental dispensers in a high level chemical disinfectant, as this may damage the dispenser and the material contained in the device; do not sterilize multiple-use dental dispensers, as this may damage the material contained in the device. The cartridge and dispensing gun can be cleaned of debris with an EPA-registered low-level to intermediate-level hospital disinfectant. The used mixing tip should be discarded, and the original cap should be cleaned to remove residual cement then reattached to the cartridge to reseal until next use. Utilize the surface disinfecting protocol of the disinfectant manufacturer. Consult www.CDC.gov for the most recent version of the "Guidelines for Infection Control in Dental Health-Care Settings."

Storage and Shelf Life:

- **Storage:** Refrigeration (preferred) or room temperature storage is acceptable at 2-25°C (36-77°F). Do not freeze. Syringe must be tightly sealed and placed in a dry environment away from direct sunlight between use. **If refrigerated, always bring to room temperature before use.**

Warranty and Terms of Use:

For full Warranty and Terms of Use information, please go to www.parkell.com. Safety Data Sheets (SDS) are available at www.parkell.com. Parkell's Quality System is certified to ISO 13485.

Emergency Phone (24 hrs.):

INFOTRAC

- North America: 1-800-535-5053
- International: 1-352-323-3500

Explanation of Symbols Used:

	• Professional use only
	• Follow instructions for use
	• Temperature limit
	• Store product tightly sealed away from direct sunlight
	• GHS02: Danger or Warning, Flammable
	• GHS05: Danger or Warning, Corrosive cat. 1
	• GHS07: Warning, Toxic cat. 4, Irritant cat. 2 or 3, Lower systemic health hazards
	• GHS08: Danger or Warning, Systemic health hazards
	• GHS09: Environment Category 1-3, Regulation (EC) No 1272/2008 (CLP): Hazardous to aquatic environment
	• Use-by date (expiration)
	• Package contents
	• Batch code
	• Catalogue / stock number
	• Unique Device Identifier
	• Medical Device
	• Do not use if package is damaged
	• Single use only
	• Manufacturer
	• Mixing & Intraoral tips
	• 5ml syringe/paste

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