



Introductory Bottle Kit (S264)  
Liquid Refill Bottle, 5ml (S265)

The Parkell logo, consisting of the word "parkell" in a lowercase, bold, sans-serif font with a registered trademark symbol.

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## PRODUCT DESCRIPTION

Parkell® Universal Adhesive (hereinafter “Parkell® Universal”) is a single-bottle, self-etching, self-priming, light-cured dental adhesive that uses a unique blend of 4-META and MDP monomers to enhance surface penetration and promote strong, long-lasting dental bonds. Parkell Universal:

- gives clinicians the option to acid-etch dentin or **CUT** enamel surfaces before use. **UNCUT** enamel should be surface roughened or pre-etched with appropriate acid etchants before bonding.
- may be cured with any presently-available dental curing device (LED, Halogen, Plasma Arc (PAC) or Laser) that can produce light from 430-480nm at an intensity of >600 mW/cm<sup>2</sup>.
- has an initial pH of approximately 2.0, making it compatible with light-cured, self-cured or dual-cured resins without additional activators.
- bonds to all dental hard tissues (enamel, dentin, cementum), and all presently-available dental materials, when utilized with appropriate chemical primers and surface treatments.
- works with all dental etching techniques (total etch, selective etch or self-etch).
- provides strong adhesion in direct or indirect restorative situations, with a film thickness of 3-8 microns.

## INDICATIONS FOR USE

Parkell® Universal is indicated for:

- Direct dental restorations (e.g., resin-based composites, resin-modified glass ionomers, resin core build-ups, compomers).
- Indirect dental restorations (e.g., metal, resin-based composite, dental ceramics such as porcelain, pressed ceramic, lithium disilicate, lithium silicate or zirconia).
- Desensitization of dentin.
- Sealing of dentin, cementum or enamel.

## CONTRAINDICATIONS, PRECAUTIONS AND WARNINGS

- Parkell® Universal is not for internal consumption, other than as a cured dental restorative material. The bottle should be kept away from children.
- Parkell® Universal is **CONTRAINDICATED** for use on or by persons who are sensitive to acrylates, methacrylates, or related chemicals.
- Protect patient’s eyes when using this and all dental materials.
- Parkell® Universal contains flammable solvents. **AVOID OPEN FLAME.** Use in well-ventilated areas.
- Parkell® Universal is acidic. Contact with oral mucosa may cause temporary blanching, which should resolve within 24 hours. Isolation with a well-fitting rubber dam, proper intra-oral evacuation and post-operative water rinsing minimizes this effect.
- Avoid contamination of product. Do not mix components with those of other materials. Do not return dispensed components to their original container. Dispose of leftover material properly.
- Avoid contact with freshly-mixed eugenol-containing products, which will inhibit polymerization. Proper removal of these products before applying Parkell® Universal will eliminate this inhibition.
- Working & setting times will vary based on temperature, humidity, product age and storage conditions.

## KIT INCLUDES:

- Parkell® Universal Liquid (5ml bottle)
- 50 precision brush applicators and dispensing well.

## SUGGESTED SURFACE PREPARATION AND ROUGHENING PRIOR TO BONDING

Surfaces being bonded must be free of plaque, debris, grease, oil and other contaminants. Solvents such as Parkell’s **Cavidry™ Cleaning Agent (HS099)**, acetone or ethyl alcohol work well to accomplish this. Saturate a cotton pledget with solvent and scrub the surface for 5-10 seconds to dissolve the contaminants. Rinse the prep with water **BEFORE** the solvent evaporates and capture the water and dissolved oil in a high-volume evacuator. This will leave the prep hydrated, clean, de-greased and dry.

1. Surfaces should be roughened prior to bonding to maximize bond strength. Dental “sandblasters” do an excellent job at roughening certain ceramics, plastics and metals, much better than rotary abrasives. For other materials like enamel, dentin, cementum or other ceramics and metals, appropriate dental etching acids may be used. Consult the material manufacturer for specific details.
2. After surface roughening, certain restorative surfaces will require pre-treatment using appropriate chemical primers prior to bonding:
  - a. Noble or precious metal surfaces should be covered with one generous coat of Parkell’s **MTL-V™ Primer (S413)** or equivalent. After the solvent evaporates (in about 2 minutes), what remains is a layer that will bond to methacrylate-based resin cements.

Ceramic surfaces such as porcelain, lithium disilicate, lithium silicate or zirconia should be covered with one generous coat of Parkell’s **EaZy Primer™ (S388)** or equivalent. After the solvent evaporates, what remains is a layer that will bond to methacrylate-based resin cements.

## DIRECTIONS FOR DIRECT OR INDIRECT RESTORATIVE USE

1. Establish dental anaesthesia and apply rubber dam for isolation.
2. Cut tooth preparation. Clean and degrease surface as described above.
3. **Tooth Etching Guidelines when using Parkell® Universal**
  - a. **CUT ENAMEL OR NORMAL DENTIN-etching is not required.** However, bonds to these surfaces will be stronger and more stain-resistant with a 10-15 sec, 30-40% phosphoric acid pre-etch prior to application of adhesive.
  - b. **SCLEROTIC DENTIN, ROOT DENTIN, CEMENTUM-etching is recommended.** Bonds to these surfaces will be stronger and more stain-resistant with a 10-15 sec, 30-40% phosphoric acid pre-etch such as Parkell’s **37% Phosphoric Acid Etching Gel (S276)** prior to application of adhesive.
  - c. **UNCUT ENAMEL-etching is required.** Bonds to these surfaces must be etched with a 10-15 sec, 30-40% phosphoric acid pre-etch prior to application of adhesive.
4. **Into the included mixing well, dispense 1-3 drops of Parkell® Universal from the dispensing bottle.**
5. Rub the liquid onto prepared tooth surfaces with applicator brush and keep moist with liquid for 20 sec.
6. Apply a second coat of Parkell® Universal on top of the first coat and keep moist for 20 seconds.

7. Blow a gentle stream of dry, oil-free air over the surface and into a high-volume evacuation tip for 10 seconds to evaporate the solvent, remove the dissolved smear layer and leave the adhesive behind.
8. Light-cure the remaining Parkell® Universal with any dental curing light (wavelength of 430-480nm at a minimum intensity of 600 mW/cm<sup>2</sup>), following these guidelines:
  - a. Halogen Light - 10 sec.
  - b. Light Emitting Diode (LED) Light - 10 sec.
  - c. High Intensity LED Light - 5 sec.
  - d. Plasma Arc Curing (PAC) Light or Laser - 3 sec.
9. Place direct composite restoration or indirect lab-fabricated restoration (e.g., crown, bridge, inlay, onlay) as per the instructions for the material being used.

#### **DIRECTIONS FOR USE AS A DESENSITIZER ON EXPOSED SENSITIVE DENTIN**

1. To minimize discomfort, establish anaesthesia if possible.
2. Gently clean the sensitive dentinal area with:
  - a. a slow-spinning rotary prophylaxis cup using wet pumice in warm water, if anaesthetized, or
  - b. hand rubbed with cotton roll dipped in warm water and wet pumice, if not anaesthetized.
3. Use a warm water rinse, or warm water on a cotton roll, to remove any residual pumice.
4. Dry the area with a cotton roll to blot the moisture from the tooth without using compressed air.
5. Apply Parkell® Universal onto prepared tooth surfaces and keep moist with liquid for 20 seconds.
6. Apply a second coat of Parkell® Universal on top of the first coat and keep moist for 20 seconds.
7. Blow a gentle stream of dry, oil-free air over the surface and into a high-volume evacuation tip for 10 seconds to evaporate the solvent, remove the dissolved smear layer and leave the adhesive behind.
8. Light-cure the remaining Parkell® Universal with a dental curing light as described above.
9. GENTLY air test the tooth for sensitivity, and reapply from Step #4 (if needed).
10. The tooth is now protected against hot and cold temperature changes. If discomfort persists after desensitization, evaluate the tooth for possible endodontic pathology.

#### **DIRECTIONS FOR USE ON PREPARED TEETH AS A PREP SEALANT / BOND ENHANCER**

1. Establish anaesthesia, cut the prep, take the impression.
2. Fabricate a resin temporary **BEFORE APPLYING** Parkell® Universal to the tooth. Clean off any residual uncured temporary resin or "slime" from the inside and outside of the temp and the outside of the prepped tooth with solvent. Rinse the prep with water **BEFORE** the solvent evaporates and capture the water and dissolved oil in a high-volume evacuator. This will leave the prep hydrated, clean, de-greased and dry.
3. Follow directions as specified above for dispensing Parkell® Universal.
4. Rub the Parkell® Universal onto prepared tooth surfaces and keep moist with liquid for 20 seconds. **SENSITIVITY?**
5. Reapply a second coat of Parkell® Universal on top of the first coat and keep moist for 20 seconds.
6. Blow a gentle stream of dry, oil-free air over the surface and into a high-volume evacuation tip for 10 seconds to evaporate the solvent, remove the dissolved smear layer and leave the adhesive behind.
7. Light-cure the remaining Parkell® Universal with a dental curing light as described above.
8. The prep is now protected against temperature changes, bacterial entry and acid attack. If discomfort persists after prep is sealed, evaluate the tooth for endodontic pathology.
9. Lubricate the coronal ¾ of the prep with a water-soluble lubricant, leaving only the margin unlubricated.

10. Cement the temporary crown with a non-eugenol cement or a resin cement like Parkell's **E.T.C.™ (S255)**. Carefully remove the excess cement from above and below the gingiva.
11. On the day of insertion, remove the temp and scale away any residual cement. Scrub the prep clean with a cotton pledget soaked in Cavidry™, acetone or ethyl alcohol. Prophylax the tooth with pumice and phosphoric acid gel on a rotary brush or cup for 10 seconds. Follow with a copious water rinse and lightly air dry, blowing into the high-volume evacuation tip.
12. Rejuvenate the surface with fresh coat of Parkell® Universal. Evaporate the solvent and air-thin the adhesive with a gentle air stream for 10 sec. Light cure as above.
13. Lute prosthesis to the cured Parkell® Universal with resin cement or resin-modified glass ionomer cement (RMGI).

#### **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 low-level (HIV/HBV claim) to intermediate-level (tuberculocidal claim) hospital disinfectant. **Follow the "Spray/Wipe/Spray" Technique, as specified by Recognized Infection Control Experts.** Afterwards, the chemical residue should be wiped off with a water-damp paper towel and air-dried. Utilize the surface disinfecting protocol of the disinfectant manufacturer. Consult [www.CDC.gov](http://www.CDC.gov) for the most recent version of the "Guidelines for Infection Control in Dental Health-Care Settings".

#### **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](http://www.parkell.com).

Safety Data Sheets (SDS) are available at [www.parkell.com](http://www.parkell.com). Parkell's Quality System is certified to ISO 13485.

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