

parkell 37% PHOSPHORIC ACID
ETCHING gel

(P) 5210

A00973rev*1017

parkell

STORE THE PRODUCT TIGHTLY SEALED, AWAY FROM DIRECT SUNLIGHT, EXTREME COLD (BELOW 34°F/1°C) OR HIGH HEAT (ABOVE 86°F/30°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

Parkell's Etching Gel is an aqueous gel preparation of 37% phosphoric acid (CAS No. 7664-38-2), with a nano-silica thickener. It is designed for precision etching of dental enamel, dentin and/or cementum prior to adhesive bonding with either the Total-Etch or Selective-Etch Techniques.

Parkell's Etching Gel is packaged in hand-dispensed, disposable plastic syringes, and applied through thin, bendable, single-use, disposable applicator needle tips. The gel's consistency provides optimal thixotropic flow and uniform tooth surface coverage that works with any etching technique. The bright blue color makes the product easy to see on the surface of a tooth, while allowing complete rinse off after etching.

INDICATIONS FOR USE

Parkell's Etching Gel is indicated for etching of dental enamel, dentin and/or cementum prior to adhesive bonding. The gel may be used in the Total-Etch or Selective-Etch Techniques, or to enhance the enamel etch of Self-Etch Bonding Agents.

CONTRAINDICATIONS, PRECAUTIONS AND WARNINGS FOR PARKELL'S ETCHING GEL

- Parkell's Etching Gel is for dental use only, and should not be swallowed. It should be kept away from children.
- It is contraindicated for use on or by persons who are allergic to or sensitive to phosphoric acid. 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, immediately flush area with copious amounts of water and obtain professional medical care.
- This product may cause burns to skin, eyes and mucous membranes. Protect the patient and clinician with rubber dam, proper intra-oral evacuation, and other suitable isolation methods during use. If the product gets in the eyes, rinse with copious water for several minutes. Remove contact lenses, if possible, and continue rinsing. Immediately call a poison control center, hospital or physician.
- Confine areas to be etched with appropriate measures to protect gingiva and adjacent teeth from inadvertent contact with gel.
- Avoid contamination of product and packages. Do not mix components with those of other materials. Do not return dispensed components to their original container. Dispose of leftover material in accordance with all federal, state, and local regulations.
- Parkell's Etching Gel is acidic, and may cause corrosion on some plastic or metal surfaces (even stainless steel), if left in extended contact. To protect dental instruments, rinse off the etchant from these surfaces immediately after each use.
- Dispensing needle tips are for single-patient use only. To prevent cross infection, do not reuse needle tips, and dispose of them in compliance with all federal, state and local laws.
- Do not force the needle tip into the soft tissues, as it is not an injector.
- Etching times and activity of the Parkell's Etching Gel will vary based upon temperature, humidity, age and storage conditions. Shelf life will be reduced if not stored properly in a cool, dark place.
- Consult the online Safety Data Sheet (SDS) at www.parkell.com for further information.

KIT INCLUDES:

- (3) 2ml, hand-dispensed syringes of 37% blue phosphoric acid gel
- (30) Single-use, gel application tips
- (1) Instructions for Use

Replacement gel application tips (REF S383) are available in bags of 30.

GENERAL INSTRUCTIONS FOR USE

1. After tooth preparation is complete, rinse with water and dry the prep with oil-free compressed air. Disinfection and de-oiling of the preparation using appropriate cleansers and solvents such as Parkell's Cavidry™ (Stock No. S099) should occur now.
2. Apply appropriate pulpal protection to deep areas of the preparation.
3. Prepare the dispensing syringe as follows:
 - a. Remove the shipping cap from the syringe and set it aside for recapping after use.
 - b. Depress the plunger to initiate the flow of a small amount of gel from the syringe orifice onto a paper pad. Wipe off the excess.
 - c. Twist a needle tip onto the syringe until it is hand-tight. Make sure tip is fully locked onto the syringe, or extrusion pressure may cause it to come off when the plunger is squeezed.
 - d. Carefully bend the needle to the desired angle. If tip kinks, discard it and use another one.
 - e. Start the flow through the needle tip by slowly expressing a small amount onto a paper pad.
4. **Etching Techniques:**
 - a. **Total Etch Technique:**
 - i. Place etching gel on enamel first, agitating the needle tip for 10 seconds.
 - ii. Next, extrude etching gel onto the dentin for an additional 10-15 seconds.
 - iii. Alternatively, the etching gel may be applied to both enamel and dentin simultaneously for a total of 20 seconds.
 - iv. Rinse etching gel off with water for 20 secs. and blow dry for 20 sec. with dry, oil-free air.
 - v. The etched enamel will appear dull and frosty, while etched dentin or cementum will simply appear dull.
 - b. **Selective Etch Technique**
 - i. Apply etching gel onto enamel only. Leave for 20 sec.
 - ii. Rinse with water for 20 sec. and dry with oil- and water-free air.
 - iii. The etched enamel surface should appear dull and frosty.
5. After etching, apply the adhesive of your choice, using the instructions for the material used.
6. Needle tips are for single-use on one patient only. After use, remove the needle tip and dispose of it in accordance with applicable safety and environmental regulations.
7. Recap the syringe with the shipping cap and disinfect the syringe as detailed below.

DISINFECTION OF COMPONENTS

After each use, syringe 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. 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 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.

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



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