

Instructions for Use

₪ S220, S222

Formulated in Japan for:



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A01159revA1021

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

Description:

Parkell's Brush&Bond® Max

- Works with all composite resins (self-cure, light-cure and dual-cure) with no additional activators.
- Works with all dental etching techniques (total etch, selective etch and self-etch).
- · Provides strong adhesion in direct or indirect restorative situations
- · Has a film thickness of 3-8 microns.
- Bonds to all presently-available dental resin-based composite materials.
- · Bonds to all dental hard tissues. (enamel, dentin and cementum)
- · Cures with all dental curing lights.

Indications for Use:

Brush&Bond Max is indicated for:

- · direct dental resin restorations;
- · indirect metal restorations
- · desensitization of dentin;
- · sealing of dentin, cementum or enamel.

Contraindications:

- Brush&Bond Max is contraindicated for use on or by persons who are sensitive to acrylates or methacrylates.
- Brush&Bond Max is is not for internal consumption, other than as a cured dental restorative material. Bottle should be kept away from children.

Before Using the Kit









- Open the back of the dispensing tube (the non-perforated cap). Remove the black bag containing the Brush&Bond® Standard Activator Brushes.
- 2. Cut the indicated end of the bag.
- Empty the brushes back into the tube (brush handle downward) and replace the cap.
- 4. To remove a brush, hold the tube vertically with the perforated cap downward. If a brush handle does not slide out of the hole, tap the side of the tube until a brush handle emerges. (Do not shake up and down.) When the tube is almost empty, it may be easier to simply remove the cover.

Precautions before Use:

- · Protect patient's eyes when using all dental materials.
- Liquid is acidic. Contact with oral mucosa may cause temporary blanching, which should resolve within 24 hours, and is reduced by use of a properly fitted rubber dam, intra-oral evacuation and post-operative rinsing.

Warnings During Use:

- Contains flammable solvents. AVOID OPEN FLAME. Use in well-ventilated areas.
- Store tightly sealed in a cool, dark, low-humidity environment, away from freezing temperatures.
- Avoid contamination of product. Do not mix components with those of other materials, or return dispensed components to their original container. Dispose of leftover material properly. Avoid contact with fresh eugenol-containing products.
- Working & setting times will vary based on temperature, humidity, product age and storage conditions.

The Brush&Bond Max Kit (EE S220) Includes:

- (1) 3ml bottle of Brush&Bond Max Liquid (REF S222)
- (100) Brush&Bond® Standard Activator Brushes (REF S286).
- (1) Mixing Well (REF S373).
- · Instructions for use

Storage

Store this product tightly sealed in a cool, dark, low-humidity environment at room temperature.

Directions for Direct or Indirect Restorative Use:

- 1. Tooth Etching Guidelines for Brush&Bond Max:
 - a. Cut enamel and normal dentin—etching is not required. However, bonds to cut enamel will be stronger and more stain-resistant with a 15 sec. 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 15 sec. phosphoric acid pre-etch prior to application of adhesive.
 - c. Uncut-enamel—etching is required. Bonds to these surfaces must be etched with phosphoric acid for 15 sec. prior to application of adhesive.
- 2. Dispense 1-3 drops of liquid into the mixing well provided and stir for 2 seconds with a Standard or Mini/Endo Activator Brush. The brushes contain chemical activators critical to the success of the bonding procedure. DO NOT SUBSTITUTE non-treated disposable brushes during this activation step. They will NOT activate the liquid! Only brushes impregnated with the activator chemistry will initiate the liquid for successful bonding.
- 3. Brushes are for a single activation of 1-3 drops only. If you need to activate another batch of liquid, **you MUST use a new brush**. Activated liquid in the mixing well should be covered and used within 3 minutes.
- Apply activated liquid onto prepared tooth surfaces and keep moist with liquid by reapplying for 20 seconds. Do not rub the material into the dentin, as this may result in post-op sensitivity and reduce bond strength
- 5. Evaporate the solvents and remove the dissolved smear layer by blowing it with a gentle air stream into the high-volume evacuator tip for 10 seconds.
- 6. Light-cure the remaining adhesive resin with your dental curing light for:
 - 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.
- Place compatible restoratives and cements for direct and indirect restorations: Brush&Bond Max is chemically compatible with conventional methacrylate based light-cure, self-cure and dual-cure restoratives and cements.

Directions for Use as a Desensitizer on Exposed Cervical Dentin:

 Gently clean the sensitive cervical area with a rotary cup with warm, wet pumice. If too sensitive, hand prophy the surface with a cotton roll dipped in warm water and pumice.

- 2. Use a warm water rinse, or warm water on a cotton roll, to remove any residual pumice, and a dry cotton roll to blot the moisture from the tooth.
- Apply activated liquid to the exposed area and let it sit undisturbed for 20 seconds. Do not rub the material into the dentin, as this may cause post-op sensitivity.
- Evaporate the solvents and air-thin the liquid with a gentle air stream for 10 seconds.
- 5. Light-cure the remaining adhesive resin with a dental curing light.
- 6. Air test the tooth, and reapply from Step #4 (if needed).
- The tooth is now protected against hot and cold temperature changes.
 If discomfort persists after desensitization, evaluate the tooth for endodontic pathology.

Directions for Use on Prepared Teeth as a Prep Sealant/Bond Enhancer:

- Establish anaesthesia, cut your prep, take your impression, and fabricate your temporary BEFORE BRUSH&BOND Max is applied.
- Clean off any residual uncured temporary resin or "slime" from the inside
 of the temp and the outside of the prepped tooth with an appropriate
 solvent such as acetone or ethyl alcohol. Rinse the prep with water before
 the solvent cleaner evaporates, and gently dry with air. This will leave the
 prep clean, de-greased, and dry.
- 3. Follow directions as specified above for dispensing and activating the liquid.
- 4. Apply liquid and let it sit undisturbed for 20 seconds. Do not rub the material into the dentin, as this may cause post-op sensitivity.
- Evaporate the solvents and air-thin the liquid with a gentle air stream for 10 sec.
- 6. Light-cure the remaining adhesive resin with a dental curing light.
- 7. The prep is now protected against temperature changes, bacteria entry and acid attack. If discomfort persists after prep is sealed, evaluate the tooth for endodontic pathology.
- 8. Lubricate the coronal ¾ of the prep with a water-soluble lubricant, leaving only the margin unlubricated.
- Cement the temporary crown with a non-eugenol cement or a resin cement. Carefully remove the excess cement from above and below the gingiva.
- 10. On the day of insertion, remove the temp and scale away any residual cement. Scrub the prep clean with a cotton pledget soaked in acetone or ethyl alcohol. Prophy the tooth with pumice and phosphoric acid gel on a rotary brush or cup for 10 seconds. Follow with a water rinse and lightly air dry, blowing it into the high-volume suction tip.
- 11. Rejuvenate the surface with fresh coat of activated Brush&Bond Max Liquid. Evaporate the solvents and air-thin the adhesive with a gentle air stream for 10 sec. Light cure as above.
- 12. Lute your prosthesis to the cured bonding agent with a resin-based product.

Directions for Use with Air-Abraded Dental Alloys:

- For enhanced adhesion, surface roughness is required. Pre-treat the surface with appropriate etchants or abrasive blasting that are acceptable to the material's manufacturer before priming.
- Keep the metal surface moist with activated liquid for 15 seconds, and then evaporate the solvents and air-thin the liquid with a gentle air stream for 10 seconds
- Light-cure the remaining adhesive resin with a dental curing light and proceed to resin cementation or application of direct composite to the metal surface.

Disinfection of Containers:

The bottle and cap 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:

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.

Explanation of Symbols Used

| Explanation of Symbols Osed | |
|-----------------------------|--|
| R | Professional use only |
| (3) | Follow instructions for use |
| | Temperature limit |
| | • Flammable |
| <u>(1)</u> | Irritant (skin and eye) |
| * | Store product tightly sealed away from direct sunlight |
| | Use-by date (expiration) |
| LOT | • Batch code |
| REF | Catalogue / stock number |
| | Package contents |
| UDI | Unique Device Identifier |
| MD | Medical Device |
| | Do not use if package is damaged |
| 2 | Single use only |
| | Manufacturer |
| | • 3ml bottle / Liquid |
| 00 | Mixing Well |
| Standard Activator Brush | |

Emergency Phone (24 hrs.):

INFOTRAC

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