

parkell®

AMALGAMBOND® + PLUS

Self-Curing Bonding Agent

INSTRUCTIONS FOR USE

REF S370, S372, S371, S394,
S393, S374, S376

Mfd. in Japan for:

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A00079revN1221



Storage:

- **Catalyst syringe:** Room Temperature only
- **All other components:** Room temperature or refrigeration.



All components should be tightly sealed and stored in a cool, dark, low humidity environment when not in use. Any refrigerated components **MUST** be brought to room temperature before use.

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

Description:

Amalgambond® Plus is a self-cure bonding system for amalgam and composite resin restorations.

Indications for Use:

- Tooth bonding resin for use with composite resin restorations, amalgam alloys and as a bonding agent for inlays/onlays or laminates when used with appropriate composite luting resins.
- A pulp capping agent for vital pulp exposures prior to permanent tooth restoration.

Contraindications:

Not for use on or by persons who have a methacrylate or HEMA sensitivity. Use of protective gloves and a no-touch technique is recommended.

Precautions:

- **Caution:** Do not swallow. Not for internal use. Wash immediately if accidentally applied to skin, eyes or soft tissue.
- **Caution:** Eugenol inhibits the setting of Amalgambond. Do not use Amalgambond on surfaces contaminated with eugenol- based products such as ZOE.
- **Caution:** To prevent contamination of surfaces being bonded use a rubber dam.
- **Caution:** Use of retentive pins in conjunction with Amalgambond is not necessary
- **Caution:** Never use cavity varnish on tooth surface prior to Amalgambond.

Kit Includes (refills also available separately):

- Dentin Activator 'A' Universal Gel, 5 ml (REF S394)
- Adhesive Agent 'AA', 8 ml Liquid (REF S374)
- Base 'B', 5 ml Liquid (REF S372)
- Catalyst 'C', 0.7 ml Liquid (REF S371)
- HPA Powder, 2 g (REF S376)
- Precision Applicators, 50pc (REF S379)
- Accessories

Adverse Reactions:

BEFORE TREATMENT, inquiry should be made to determine whether the patient has had previous hypersensitivity reactions to any of the ingredients in Amalgambond. Amalgambond Adhesive Agent (AA) and Amalgambond Base contain HEMA (2-hydroxy-ethylmethacrylate), a known contact allergen. A small percentage of the population is known to have an allergic response to methacrylate resins. To reduce the risk of allergic response, minimize exposure to these materials. Use of protective gloves and a no-touch technique is recommended. Use in well-ventilated room.

Directions:

1. Prepare cavity for composite, amalgam or inlay restoration as usual.
2. Clean and lightly dry preparation.
CAUTION: To prevent Amalgambond Plus from adhering to metal matrices, coat the inner aspect of the band with a thin layer of wax, cavity varnish, or mineral oil. Failure to apply a separating medium to a metal matrix band may result restoration fracture when the band is removed due to adhesion of the alloy to the band.
3. Dispense 1 or 2 drops of DENTIN ACTIVATOR (A) into mixing well. Apply to exposed dentin for 10 seconds. Wash thoroughly and dry with oil-free, moisture-free air. DENTIN ACTIVATOR can also be used to etch enamel that surrounds preparations IF it is left on enamel for 30 seconds before water-rinsing.
4. Brush a thin layer of ADHESIVE AGENT (AA) onto activated dentin surfaces. Blow away "puddles" with a GENTLE air-stream to achieve an even, thin layer of coverage. Leave undisturbed for 30 seconds. While it is not necessary to apply ADHESIVE AGENT to etched enamel surfaces, bond strength will not be affected if some overruns onto the etched enamel.
5. **For Amalgam restorations**, begin trituration NOW, so alloy will be ready to condense as soon as the Amalgambond Plus resin mixture of base/catalyst has been applied to the tooth surface. (Alloy **MUST** be condensed while Amalgambond mix is still wet.)
6. Dispense 2 drops of BASE (B) and 1 drop of CATALYST (C) into a clean, dry mixing well. Mix thoroughly with GENTLE STIRRING for 3-5 seconds, and brush a thin, even layer onto dentin and enamel. When placing amalgam, begin condensation immediately, before the adhesive resin dries. For composites, allow the adhesive resin to dry for 60-90 seconds before applying the composite.

Virtually Impossible Situations:

For stronger, super-retentive amalgam bonds to teeth whose preparation leave little or no support, HPA powder is recommended. To make an HPA mix, dispense 3 drops BASE, 1 drop CATALYST, 1 scoop HPA powder into mixing well and GENTLY STIR. Apply a thin layer of this mixture to the preparation. Condense amalgam while this HPA mixture is still wet. **NEVER USE HPA POWDER WITH COMPOSITE**

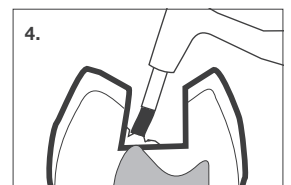
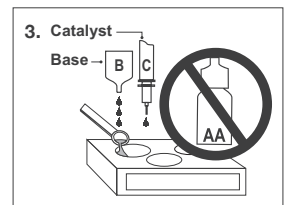
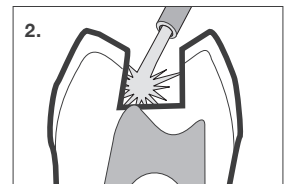
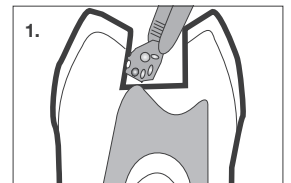
Directions for An Adhesive Pulp Cap:

An Amalgambond pulp cap is not an alternative to endodontic therapy. A tooth suffering irreversible pulpitis, or one that has limited recuperative power, requires a root canal.

However, if the exposure is small, with fresh bleeding, Amalgambond can serve as an excellent capping material, particularly if the patient is young so the pulp has strong recuperative powers.

If you intend to bond an amalgam restoration and have good access to the exposure, place your lubricated matrix before beginning the cap. If it is hard to see, however, band the tooth after Step 5.

1. Apply the Green Dentin Activator for 10 seconds to both the exposure and the preparation. (The ferric chloride in the solution should control the bleeding.)
2. Rinse the tooth thoroughly. Then lightly dry it to eliminate standing water.
3. Do NOT apply the "AA" solution at this stage. (This 35% aqueous solution of HEMA might irritate the exposed pulp.) Mix Amalgambond-Plus with the HPA powder (3 drops base, 1 drop catalyst, one scoop HPA powder.)
4. Apply the adhesive to the exposure and the dentin immediately surrounding it.
5. Allow the adhesive to polymerize. This will seal the exposure.
6. Apply the AA component to the entire preparation. Allow it to sit undisturbed for 30 seconds, then gently blow off any puddles.



7. Mix the Amalgambond using the appropriate Base : Catalyst ratio (with or without the HPA powder.)

8. Brush the mixture onto the preparation.

If you're using composite, allow the adhesive to cure thoroughly (60-90 seconds) before beginning the buildup.

If you're using amalgam, begin lightly condensing as soon as the adhesive has been applied to the tooth. Do not apply too much pressure or you may disrupt the pulp cap. Since spherical alloys condense easily at low pressure, they're probably a better choice for pulp caps.

Helpful Hints:

Low-viscosity composite resins "wet" adhesively-prepared surfaces better than high-viscosity composites. If high-viscosity restoratives are preferred, apply a thin layer of UNFILLED OR FLOWABLE COMPOSITE RESIN and cure before applying the high-viscosity composite.

For Additions to Old Amalgams:

Air-abrade surface of old filling with 50 micron Aluminum Oxide until "frosty". Use DENTIN ACTIVATOR on adjacent dentin. Apply thin, even layers of ADHESIVE AGENT and Amalgambond Plus resin, and condense new alloy before the adhesive resin dries. For even stronger bonds use HPA powder as directed in the 'Virtually Impossible Situations' section of this manual.

For Direct Composites, Composite Inlays or Veneers:

Place composite restorative AFTER Amalgambond Plus adhesive resin has dried completely. Do not use HPA powder when placing composites.

For Apicoectomy or Endo-Access Seals:

HPA POWDER is NOT recommended. Condense amalgam BEFORE Amalgambond Plus resin has dried.





















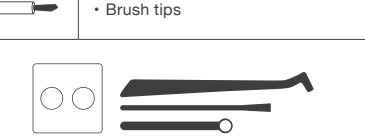


Disinfection of Containers:

Bottles, caps and reusable accessories 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 waterdamp 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:

	• Professional use only
	• Follow instructions for use
	• Temperature limit
	• Flammable
	• Irritant (skin and eye)
	• Store product tightly sealed away from direct sunlight.
	• Use-by date (expiration)
	• Batch code
	• Catalogue / stock number
	• Unique Device Identifier
	• Medical Device
	• Package contents
	• Do not use if package is damaged
	• Single use only
	• Manufacturer
	• 5ml bottle / Liquid
	• 6ml bottle / Liquid
	• 8ml bottle / Liquid
	• 2gm bottle / Powder
	• Brush tips
	• Mixing/Application accessories
	• Activator Brush
	• Catalyst