



Adhesive Luting Cement System

Instructions for Use

REFI S380-RD

Description:

all conditions.

Precautions:

away from children.

Parkell, Inc.,

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Parkell's C&B-Metabond® R&D is a 4-META-

based, non-eugenol, self-cured resin cement

designed to provide ultra-high bond strength

such as when adhering probes, bars, plate, or

the like to bone for research purposes only

C&B-Metabond R&D contains 4-META, a high

performance adhesive monomer that creates

excellent bonds to many surfaces via

layer. Additionally, the system uses a

penetration and the formation of a hybrid

tri-n-butylborane (TBB) catalyst to ensure

complete methacrylate polymerization under

· If product contacts the eyes, flush with

· C&B-Metabond is not for internal

water and obtain medical care immediately.

consumption,. The product should be kept

Some C&B-Metabond components are

if not handled properly. The Universal

Spilled or unused Catalyst should be

should be saturated with water before

resins, and is not for use on animals or, by

those persons treating animals, which or

methacrylates or similar materials. Contact

human tissues (mucosa, eyes, nose, etc.)

discontinue use, flush area with copious

· Avoid open flame, and exercise caution in

analgesia or other oxidizing agents. Use in

the presence of nitrous oxide/oxygen

· Do not use on surfaces that have been

contaminated with eugenol (ZOE, etc.).

of desensitizers, varnishes or liners.

mix it in the chilled porcelain dish.

· Adhesion will be reduced by prior application

· Cement sets rapidly when warm, so always

Avoid contamination of product. Do not mix

components with those of other materials.

their original container. Dispose of leftover

Do not return dispensed components to

Working & setting times will vary based

upon temperature, humidity, product age

and storage conditions. Shelf life will be

disposed of in accordance with all applicable

· C&B-Metabond components should be

· Consult the Safety Data Sheet (SDS) for

advice on the safe handling of product.

federal, state and local regulations.

reduced if not stored properly.

amounts of water and obtain medical care

Catalyst is highly reactive with air.

blotted up with paper or cloth, and

C&B-Metabond contains methacrylate

between uncured resins and sensitive

inflammatory reactions. If this occurs,

may cause irritation, dermatitis or

if necessary

well-ventilated areas.

material properly.

disposal as hazardous waste.

who are sensitive to acrylates,

flammable, or may promote combustion

on non-human subjects only.

sealed in a cool, dark, low humidity environment. Refrigeration is acceptable, but not required, for all components **EXCEPT THE CATALYST** SYRINGE. DO NOT FREEZE ANY COMPONENTS. The Catalyst syringe should be stored at room temperature only.

Store all components tightly

Bring all components to room

temperature before use.

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Surface Preparation Prior

1. Surfaces being bonded together must be clean and free of plaque, debris, greases, oils and other contaminants. solvents like acetone or ethyl alcohol work well to

- 2. The substrate surface may be roughened prior to bonding to maximize bond strength (such as through use of a Microetcher with 50 micron aluminum oxide at 65-80 psi). For other materials, strong etching acids may be necessary. Consult the material's
- 3. Chemical Priming of Substrate Surfaces:
- a. Metal: C&B-Metabond bonds tenaciously to non-precious metal alloys without special pretreatment other than sandblasting. The durability of the bond to precious and noble alloys can be significantly improved by first sandblasting, and then priming with
- b. Porcelain & Lithium Disilicate: C&B- Metabond will bond to porcelain or lithium disilicate surfaces that have been etched with hydrofluoric acid and primed with a ceramic primer such as Ea-Z-y Primer (available separately from Parkell).
- c. Zirconia: C&B-Metabond will adhere well to sandblasted zirconia that has been primed with Ea-Z-y Primer (available separately from Parkell).

Pre-lubrication:

C&B-Metabond cement sets extremely hard, and sticks tenaciously to anything it touches. It must be cleaned up before it has completely set or removal will be very difficult later. To facilitate cement clean-up, water soluble lubricants such as "K-Y®" jelly or glycerine, or Parkell's Blu-Sep™, should be applied over any areas of concern before seating of the prosthesis. This will preclude the cement from inadvertently sticking to neighboring areas Oil-based lubricants like petroleum jelly or mineral oil may be used as well, although these lubricants will not rinse off with water, and will require more work.

Choosing the Right C&B-Metabond Powder:

- 1. The Clear L-Powder is used where radiolucency is preferred such as for x-ray imaging studies. The Clear L-Powder cement mix sets to final hardness earlier than the Radiopaque L-Powder, within 10 min.
- 2. The Radiopaque L-Powder is used in situations, where the cement may need to be seen on x-ray. The cement mix has a

You may mix the Clear and Radiopaque L-Powders to adjust radiopacity or achieve an esthetic result.

Kit Contains:

Components may be purchased as a kit or individually

- 3 g Clear L-Powder (violet cap) EF S399-RD
- · 3 g Radiopaque White L-Powder (sea-green cap) 🖭 S396-RD
- 10 ml Quick Base Liquid (blue cap) **ஊ** S398-RD
- · Universal Gold Label TBB Catalyst (0.7 ml) № S371-RD
- Ceramic Mixing Dish with Thermometer EF S387-RD
- Precision Bendable Applicators **ஊ** S379-RD
- Accessories

to Bonding:

- accomplish this, immediately followed by a water rinse and air drying.
- manufacturer for details.
- specialized metal primers.

C&B-Metabond cement is provided with two different powders.

radiopacity of 270% of aluminum.

Liquid Dispensing Procedure:

Dispensing liquids should ALWAYS be done

- 1. Hold the bottle or syringe perpendicular to the mixing well, not sideways or at an angle!
- 2. Dispense the drops slowly with a gentle squeeze of the bottle sides, or a slow twist of the dispensing screw, allowing the drops to fully form and fall by gravity into the well. If resistance is felt, check for a blockage at the orifice and clear as described above.
- 3. Re-cap the container immediately to prevent evaporation.

The Proper Sequence for Mixing **C&B-Metabond:**

1. Dispense 4 drops of Quick Base into one well of the mixing dish.

- 2. Dispense 1 drop of Universal Catalyst into the same well.
- 3. Dispense 2 level scoops of L-Powder into the same well, using the "Scoop Leveling Bar" built into the mouth of the powder tubs. Stir the mix for about 5 seconds to incorporate all the powder.

NOTE: You can actually dispense 1 - 2 1/2 scoops of powder into the well, depending on the viscosity you desire. Varying the powder ratio as described will not significantly change the set physical properties.

Self-Cure Product Timing (from start of mix):

- · Working Time (extra-oral; in chilled porcelain mixing dish at 40°F / 4°C) 2:00 to 3:00 minutes.
- Setting Time (intra-oral; at mouth temperature 98°F / 37°C) 5:00 to 10:00 minutes.

Achieving Adequate Working Time:

The moment you add the powder to the base and catalyst, C&B-Metabond begins setting. To allow adequate working time, the material must be cooled during mixing using the specially-designed ceramic mixing dish that has been stored in the freezer.

There is a liquid crystal thermometer affixed to the front, which will be at the left end of the scale when you remove the dish from the freezer. To prolong working time, the dish may be placed on a freezer pack during use. Alternatively, the dish may be stored in the freezer upside down while the base is filled with water. When removed from the freezer, the base of the dish will be filled with ice.

How to Mix & Use C&B-Metabond:

STEP #1: Preliminary Steps Whenever Using C&B-Metabond

Every use of C&B-Metabond for cementation or bonding begins with the same steps (previously described):

- A. Treat the surfaces being bonded, as described in the section: "Surface Preparation (Prior to Bonding)".
- B. Treat the bone surfaces being bonded as described in the section: "Etching Procedure".
- C. To facilitate clean-up, lubricate the operative site as described in the section: "Prelubrication".
- D. Choose the desired powder as described in the section: "Choosing the Right C&B-Metabond Powder".
- E. Proceed to STEP #2 below.

probes, or the like.

STEP #2: Choosing the Right Mixing Method Based Upon the Task

- A. The "Bulk-Mix" Technique: Proceed to STEP #3 (Bulk)
 - · Used for cementation of bars, plates,
 - · Powder/Liquid Ratio may be adjusted if a
 - thinner or thicker viscosity is needed.
 - Multiple batches for long-span bridges
 - · should be mixed simultaneously with a trained staff.
 - · Requires use of a chilled mixing dish to prolong working time.
- B. The "Brush-Dip" or "Neelon" or "Salt & Pepper" Technique:
 - Proceed to STEP #3 (Brush) · Powder/Liquid ratio not important, as the mix is made by the clinician
 - using the brush. · Working time may be greatly extended.
 - · Does not require use of a chilled mixing dish.

STEP #3 (BULK): Cementation Using the **Bulk-Mix Technique**

- A. Mix TWO liquid batches in TWO wells of the chilled mixing dish, using a ratio of 4 drops of Quick Base liquid to 1 drop Universal Catalyst for each batch. If you need a "double batch", mix 8 drops of Quick Base to 2 drops of Universal Catalyst. The mixed liquid remains active for up to 10 minutes, if the well is covered to reduce evaporation.
 - The first liquid mixture is NOT mixed with powder, and becomes the "activated primer". It is applied to the tooth and surfaces being bonded and is left wet (NOT air-dried).
 - The second liquid mixture normally receives 2 scoops of the desired shade of powder, and becomes the "cement mixture". Gently stir powder and liquid

- for 5 seconds to create a creamy cement. The powder/liquid ratio may be adjusted between 1 - 2 1/2 scoops to create the desired viscosity for the procedure being performed.
- B. Apply one generous coating of the C&B- Metabond "activated primer" liquid onto all bone and device surfaces being bonded to. DO NOT AIR-DRY.
- C. Load the "cement mixture" onto the surface of the device that will be bonded (and spread it thin over the entire surface.
- D. Immediately place the cement-coated device over the primed bone and apply constant but not excessive seating pressure until the unit is fully seated. Allow excess cement to extrude from all margins.
- E. The cement becomes rubbery soon after setting begins. Be careful not to pull the excess away from the margin once it has entered the rubbery stage, as this may allow marginal leakage later.
- F. Maintain seating pressure. BEGIN CLEANUP NOW, WHILE WAITING FOR THE SET (Go to STEPS #4, #5 & #6).

STEP #3 (BRUSH): Using the **Brush-Dip Technique**

- A. Mix ONE liquid batch in ONE well of the chilled mixing dish, using a ratio of 4 drops of Quick Base liquid to 1 drop Universal Catalyst, making the "activated primer". Do not mix this liquid with powder. It remains active in the dish for about 10 minutes, if covered,
- B. Place a scoop of the desired shade of powder in an adjacent well of the mixing dish.
- C. Wet a brush with the "activated primer" liquid and use it to moisten the surface. being bonded.
- D. Then use the same wet brush to pick up a ball of powder from the dish and apply the ball of C&B-Metabond to the wet surface to be covered. Repeat the steps until the surface is completely covered.
- E. Begin cleanup now while waiting for the set (Go to STEPS #4, #5 & #6).
- F. After 9-12 minutes depending on room temp, the C&B-Metabond coating may be checked for hardness.

STEP #4: Clean Up of Surfaces After Cementation

To effectively clean up excess cement, several methods have been developed. For example:

"The Soft Peel" - Wait approximately 2 minutes before attempting to remove excess cement. At this "gel" stage, C&B-Metabond will peel off with an instrument without smearing.

STEP #5: Clean Up of Instruments After Using C&B-Metabond

Cement adhering to metal instruments or the ceramic mixing dish NEEDS TO BE CLEANED before it has set. Do not wait! If any remains after setting, C&B-Metabond may be softened by soaking in organic solvents.

STEP #6: 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. 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"

Helpful Hints on Cementing Porcelain or Ceramic (Bulk-Mix):

- · Before cementation, the inner aspect of the surface being cemented should be roughened via acid-etching or sandblasting, and appropriately primed.
- · All-Ceramic: When used with Parkell's ceramic primer (Ea-Z-y Primer), C&B-Metabond is an excellent choice to cement all-ceramic substrates made of porcelain, lithium disilicate or high-strength ceramics. It will tightly adhere to these materials with the proper surface treatment. Additionally, the cement does not expand upon setting, so there is no danger of post- cementation expansion damage.

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:

i	• Follow instructions for use
1	•Temperature limit
	• Flammable
(!)	• Irritant (skin and eye)
*	Store product tightly sealed away from direct sunlight
	Use-by date (expiration)
	Package contents
	• Do not use if package is damaged
	• Single use only
LOT	• Batch code
REF	Catalogue / stock number
UDI	Unique Device Identifier

