

ACTIVA™ BioACTIVE-CEMENT™

Self-adhesive • Dual Cure • Fluoride Releasing • Moisture Tolerant • Radiopaque

Contains No Bisphenol A, No Bis-GMA, No BPA derivatives

ACTIVA BioACTIVE-CEMENT is an ionic resin cement indicated for indirect applications. It stimulates mineral apatite crystal formation at the material-tooth interface. This natural remineralization process knits together the restoration and the tooth, penetrates and fills microgaps, and seals margins against microleakage and failure.

ACTIVA is the first dental cement with a bioactive resin matrix, shock-absorbing resin component, and reactive ionomer glass fillers that mimic the physical and chemical properties of natural teeth. It is durable and insoluble, and it releases and recharges more calcium, phosphate and fluoride than glass ionomer and traditional RMGI cements. The patented rubberized-resin provides a durable, resilient interface between the tooth and restoration. ACTIVA contains no Bisphenol A, No Bis-GMA, and No BPA derivatives.

ACTIVA is a dynamic material that reacts to pH changes in the mouth. It continuously releases and recharges its ionic components and actively participates in the ionic exchange with saliva and tooth structure that is essential for maintaining healthy teeth. For this reason, ACTIVA can be called a "smart" material.

ACTIVA Cement is available in A2 and translucent shades. It is a self-adhesive, moisture tolerant, two-paste material in an automix syringe system. The material has three setting mechanisms; it cures by light and has both glass ionomer and composite self-cure setting reactions.

PRODUCT DESCRIPTION

Bioactive dual cure resin cement.

INDICATIONS

Recommended as a bioactive cement for indirect restorations including zirconia, CAD/CAM and glass ceramic restorations, all ceramic, resin, metal/PFM, and preformed stainless steel and zirconia pediatric crowns. ACTIVA forms a strong bond to zirconia, ceramic, resin and metal.

CONTRAINDICATIONS

Not recommended for porcelain veneers. For Maryland Bridges, a dual cure bonding agent is recommended.

HOW TO USE THE AUTOMIX SYRINGE

1. Remove cap. If necessary bleed the syringe so that base and catalyst are equal at the orifice of the syringe barrels. Place a mixing tip on the automix syringe.
2. To ensure an even mix of base and catalyst, dispense 1-2 mm onto a pad and discard this material. ACTIVA is air inhibited and does not set in the presence of oxygen.
3. Dispense cement directly into the restoration.
4. Use a new mix tip for each patient. Do not cross-contaminate base and catalyst.



EU Importers

Leibetseder
Dentalwarenhandel
GmbH
Hans-Zach-Straße 2
4210 Gallneukirchen
Austria

Bohumila Sieglová
Kolmá 303
25203 Řitka
Czech Republic

Hu-Fa Dental a.s.
Moravní 909
765 02 Otrokovice
Czech Republic

Cenger Scandinavia A/S
Urlevvej 6 B
8783 Hornslyd
Denmark

Dansk Nordenta A/S
Nydamsvej 8
8362 Hørning
Denmark

Plandent OY
Asentajankatu 6 B
00880 Helsinki
Finland

OPSYSE
18 Allée du Fenouil
ZA Saint Louis
84250 Le Thor
France

KinderDent GmbH
Gutenbergstraße 7
28844 Weyhe
Germany

Ortho Organizers GmbH
Lauenbühlstraße 59
88161 Lindenberg im
Allgäu
Germany

Dental Medical Ireland
Kellystown House
Kellystown Lane, Leixlip
Co. Kildare, W23 VF9P
Ireland

Ravelli S.p.A.
Via Darwin 32-34
20019 Settimo Milanese
Italy

Virdental, UAB
Artojų g. 52B, Garliavos
Apylinkių seniūnija
Teleičių kaimas
53273, Kauno Rajonas
Lithuania

Hofmeester Dental B.V.
Andries Copierhof 2
3059 LM Rotterdam
Netherlands

Equadent Sp z o.o.
ul. Pck 12
62-500 Konin
Poland

Lifco Dental AB
Verkmästaregatan 1
745 39 Enköping
Sweden

UNIDENT AB
Västerhavsvägen 2
311 77 Falkenberg
Sweden

SAFETY DATA SHEET



SCAN ME

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ACTIVA™ BioACTIVE-CEMENT™ INSTRUCTION MANUAL

PULPDENT®



ACTIVA™ BioACTIVE-CEMENT™ INSTRUCTIONS FOR USE

Instructions for Crown, Inlay and Onlay Cementation

1. Clean and prepare restoration in accordance with manufacturer's or laboratory's instructions.
2. Remove any temporary cement from the prepared tooth surfaces. It is best to use temporary cements that do not contain eugenol.
3. Rinse tooth with water. Dry and remove all moisture from the tooth surface with high volume evacuation, compressed air, and/or a cotton pellet. Do not desiccate the tooth, which naturally contains a small amount of water.
4. For non-retentive crown preparations, or when retention is a concern, use of a bonding agent is recommended.
5. If cementing to existing ceramic, metal, glass ionomer, resin desensitized or cured composite surfaces, clean and etch or abrade the previously restored surface, rinse and dry. Be sure to dry these restored surfaces before applying cement.
6. Place a mixing tip on the double barrel syringe and dispense cement. To ensure an even mix of base and catalyst, dispense 1-2mm onto a pad and discard.
7. Place cement and seat the restoration in the usual manner.
8. To remove excess from margins, tack cure margins with a curing light for 1-2 seconds and gently tease away excess with a suitable instrument. Maintain positive pressure on the restoration for 2 minutes.
9. Working time at room temperature is 90 seconds. Light cure setting time is 20 seconds per surface. Self-cure anaerobic setting time at 37° C is equal to or less than 5 minutes from beginning of mix.

Instructions for Post Cementation

1. Prepare the post space and follow steps #3 and #5 above. Remove all water from the post space.
2. Place the mix tip with bendable metal cannula deep into the post hole and backfill the post space without creating voids. Seat post with a gentle up and down motion, and remove excess cement.
3. Light cure for 40 seconds. ACTIVA BioACTIVE-CEMENT cures with all lights. Self-cure anaerobic setting time at 37°C is equal to or less than 5 minutes from beginning of mix.
4. Proceed with restoration.

Instructions for Splinting Materials

1. Etch tooth surfaces and rinse with water. Dry and remove all moisture from the tooth surfaces with high volume evacuation, compressed air, and/or a cotton pellet. Do not desiccate the teeth, which naturally contain a small amount of water.
2. Bonding agents are not required but may be used if desired.
3. Place splinting material and bond to place with cement in the usual manner.
4. Light cure each surface for 20 seconds.

IMPORTANT NOTES:

Zirconia restorations

- Phosphates in saliva will inhibit adhesion to zirconia. After try-in, ALWAYS decontaminate zirconia. Rinse with water and air-abrade the internal surface of the restoration with aluminum oxide or treat with a phosphate-removing cleanser.
- ACTIVA bonds tenaciously to zirconia. It is not necessary to use a primer or bonding agent on the zirconia surface.

Ceramic restorations

- Treat internal surface of ceramic restorations with Porcelain Etch Gel and Silane Bond Enhancer in accordance with manufacturer's instructions.

Core build-ups

- When cementing to composite, glass ionomer, or amalgam core build-ups, clean, mechanically roughen, rinse and thoroughly dry the core material.
- When cementing crowns on shallow cores and when retention form is not ideal, the use of a bonding agent is recommended.

Metal copings

- ACTIVA bonds tenaciously to metal copings.

CAUTION

Uncured material may cause eye or skin irritation on contact. Dental professionals should wear safety glasses and surgical gloves. Do not exceed manufacturer's recommended curing time for the light you are using.

STORAGE AND HANDLING

- Store tightly sealed in original container at cool room temperature. Avoid direct light, extremes of temperature, contamination and sources of ignition.
- Shelf life of unopened product: 2 years from date of manufacture.
- Re-cap immediately after use.

REPORTING OF SERIOUS INCIDENTS

Any serious incidents involving the device should be reported to the manufacturer and the Competent Authority of the Member State in which the incident occurred, or other appropriate regulatory body. Reports of serious incidents should be sent to: Pulpdent Corporation, 80 Oakland Street, Watertown, MA 02472 USA Tel: 617-926-6666 / Fax: 617-926-6262 / www.pulpdent.com / email: pulpdent@pulpdent.com

Note: Apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient. For additional information, refer to: <http://www.fda.gov/Medical-devices/dental-devices/multiple-use-dental-dispenser-devices>

Note: Refer to Safety Data Sheet for a list of materials present in this product

CURING PROPERTIES

Working time at room temperature	90 seconds
Light cure setting time	20 seconds
Initial self-cure setting time (mouth temperature)	≤ 5 minutes

 **PULPDENT® Corporation**
80 Oakland Street • Watertown, MA 02472 • U.S.A.
Tel. (617) 926-6666 / (800) 343-4342 / Fax (617) 926-6262
pulpdent@pulpdent.com • www.pulpdent.com