

BioACTIVE-RESTORATIVE™ BioACTIVE-BASE/LINER™



ACTIVA™ BioACTIVE Dual Cure Products

Moisture Friendly • Dual Cure • Fluoride Releasing • Radiopaque
Contains No Bisphenol A, No Bis-GMA, No BPA derivatives

ACTIVA™ BioACTIVE dual cure products are strong, durable, ionic restorative resins that have the esthetics and physical properties of composites.^{1,2}

They release calcium, phosphate and fluoride, and have a greater potential to recharge these minerals than glass ionomers and traditional RMGIs. ACTIVA™ stimulates mineral apatite crystal formation at the material-tooth interface.^{3,4} This natural remineralization process knits the restoration and the tooth together, penetrates and fills micro-gaps and seals margins against microleakage and failure.

ACTIVA™ products react to pH changes in the oral environment. They actively participate in the ionic exchange with saliva and tooth structure that is essential for maintaining healthy teeth, and they continuously recharge the ionic components of saliva, teeth and the material itself. For this reason, ACTIVA™ can be called a “smart” material.

Unlike traditional materials that are hydrophobic, repel water, and are designed to be passive, ACTIVA™ is moisture friendly and plays a dynamic role in the mouth. Only moisture friendly materials that are partly water-based or have the capacity for significant water transport or storage can react to changes in the ambient conditions and are capable of this dynamic behavior.⁵

ACTIVA™ dual cure materials contain water, yet the material has extremely low solubility.⁶ The ionic resin matrix facilitates the diffusion of calcium, phosphate and fluoride ions while still maintaining the excellent physical properties associated with resins and composites.

The resin matrix displays exceptional marginal integrity, sealing ability against marginal leakage, and intimate adaptation to tooth structure.^{4,7,8} It contains an acidic monomer that improves the interaction between the resin component and the glass ionomer and enhances the interaction with tooth structure.

ACTIVA™ BioACTIVE dual cure products are two-paste systems in automix syringes. They have three setting mechanisms: light cure, self-cure resin chemistry, and self-cure glass ionomer reaction.

References

1. Girm V, et al. J Dent Res 93 (Spec Iss A) 1163, 2014 (www.iadr.org).
2. Garcia- Godoy F, Morrow BR. J Dent Res 94 (Spec Iss A) 3522, 2015 (www.iadr.org).
3. Chao W, et al. J Dent Res 95 (Spec Iss A) S 1313, 2016 (www.iadr.org).
4. Garcia-Godoy F, Morrow BR. J Dent Res 95 (Spec Iss A) 1828, 2016 (www.iadr.org).
5. McCabe JF, et al. Aust Dent J 2011 Jun;56 Suppl 1:3-10.
6. Hall J, et al. J Dent Res 95 (Spec Iss A) S1 126, 2016 (www.iadr.org)
7. Zmener O, Pameijer CH, et al. Submitted for publication Am J Dent.
8. Kane B, et al. Am J Dent 2009;22(2):89-91.

PRODUCT DESCRIPTION

ACTIVA™ BioACTIVE dual cure materials are the first dental restoratives with a bioactive resin matrix, shock-absorbing resin component, and reactive ionomer glass fillers designed to mimic the physical and chemical properties of natural teeth. They contain no Bisphenol A, no Bis-GMA and no BPA derivatives.

HOW TO USE THE AUTOMIX SYRINGE

1. Remove cap. If necessary bleed the syringe so that base and catalyst are 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.
3. Dispense material directly onto the tooth or into the restoration.
4. Discard mixing tip. Recap syringe. Do not cross-contaminate base and catalyst.

APPLY ACTIVA TO A DRY TOOTH SURFACE, BUT DO NOT DESICCATE THE TOOTH

Using high volume evacuation, compressed air and/or a cotton pellet, dry and remove all external moisture from the prepared tooth surface. Do not desiccate the tooth, which naturally contains a small amount of water. Ceramic, metal, resin desensitized, prehybridized, and cured composite surfaces should be dry.

INDICATIONS FOR ACTIVA™ BioACTIVE-RESTORATIVE™

Recommended as a bioactive filling material for pits, root surface cavities and Class I, II, III, IV and V restorations where there is no pulpal involvement.

CONTRAINDICATIONS FOR ACTIVA™ BioACTIVE-RESTORATIVE™

Not indicated for direct placement on the exposed pulp. See instructions for use.

ACTIVA™ BioACTIVE-RESTORATIVE™ INSTRUCTIONS FOR USE

1. Set curing light to 20-second, low intensity setting.
2. Isolate and prepare tooth to receive a restoration. Ideal margin preparations are rounded with no sharp angles. In Class V lesions, bevel or undercut enamel.
3. Place appropriate pulp protection, if indicated.

4. Etch the prepared tooth with 37-38% phosphoric acid. Etching time for enamel is 20 seconds and for dentin is 15 seconds. Selective etch enamel if desired. After etching, rinse and lightly dry, removing all excess moisture with high-volume evacuation, compressed air, and/or a cotton pellet, but do not desiccate the tooth.
5. Apply a bonding agent of your choice.
6. Place a mix tip on the ACTIVA syringe. Insert syringe into ACTIVA-SPENSER and snap into place using firm pressure. Dispense material using gentle pressure. To ensure an even mix of base and catalyst, dispense 1-2mm of material onto a mixing pad and discard this material.
7. ACTIVA BioACTIVE-RESTORATIVE is a dentin and enamel replacement material. Place mix tip at cavity floor. Apply ACTIVA in increments of up to 4mm, keeping mix tip submerged in the material. Light cure for 20 seconds between each layer. Anaerobic selfcure setting time at mouth temperature is less than or equal to 3 minutes. If allowing to self-cure, cover exposed ACTIVA surfaces with an oxygen barrier, e.g. glycerin. Finish and polish in the usual manner.
8. ACTIVA can also be used with both open and closed sandwich techniques.

Note: *Allowing dual cure material to self-cure 20-30 seconds before light curing mitigates polymerization stress and exothermic reaction. Always use 20-second low intensity light setting. Do not exceed manufacturer's recommended curing time. Additional curing may generate excessive heat damaging to the pulp.*

INDICATIONS FOR ACTIVA™ BioACTIVE-BASE/LINER™

Recommended as a bioactive base and liner for Class I, II, III and V restorations where there is no pulpal involvement, for indirect pulp capping, and for use with all composite and amalgam restorations.

CONTRAINDICATIONS FOR ACTIVA™ BioACTIVE-BASE/LINER™

Not indicated for direct placement on the exposed pulp. See instructions for use.

ACTIVA™ BioACTIVE-BASE/LINER™ INSTRUCTIONS FOR USE

1. Set curing light to 20-second low intensity setting.
2. Isolate and prepare tooth to receive a restoration. Etching and bonding agents are not required.
3. Place appropriate pulp protection, if indicated.
4. lightly dry removing excess moisture with high volume evacuation, compressed air or cotton pellet. Do not desiccate tooth.
5. Place a mix tip on the ACTIVA syringe. To ensure an even mix of base and catalyst, dispense 1-2 mm of material onto a mixing pad and discard this material.
6. Open Sandwich Technique: Apply ACTIVA BioACTIVE-BASE/LINER to prepared surfaces and extend to the enamel-cavo surface margin. Massage into the dentin for 20 seconds and light cure using 20-second low intensity light setting. Initial self-cure setting time is 5 minutes. Continue with step 8.
7. Closed Sandwich Technique: Apply ACTIVA BioACTIVE-BASE/LINER to prepared surfaces. Do not extend the material over the enamel margins. Massage into the dentin for 20 seconds and light cure using 20-second low intensity light setting. Initial self-cure setting time is 5 minutes.
8. Complete the restoration with ACTIVA BioACTIVE-RESTORATIVE, or restore with your preferred adhesive and composite bonding system. Finish and polish as usual.

Note: *Allowing dual cure material to self-cure for 20-30 seconds before light curing mitigates polymerization stress and exothermic reaction. Always use 20-second low intensity light setting. Do not exceed manufacturer's recommended curing time. Additional curing may generate excessive heat damaging to the pulp.*

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>

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

CURING PROPERTIES	RESTORATIVE	BASE/LINER
Light cure setting time:	20 seconds (See note in instructions)	20 seconds (See note in instructions)
Working time at room temperature:	90 seconds	90 seconds
Initial self-cure setting time (mouth temperature):	≤ 3 minutes	≤ 5 minutes



EU Importers

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

Bohumila Siegllová
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



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

SAFETY DATA SHEET



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