ACTIVA™ BioACTIVE-CEMENT™

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

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

PRODUCT DESCRIPTION

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 micro-gaps, 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.

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.

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. The tooth should not appear chalky or frosty. Ceramic, metal, resin desensitized or pre-hybridized dentin, and cured composite surfaces should be dry .

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ACTIVA™ BioACTIVE-CEMENT™ INSTRUCTION MANUAL

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 pre-hybridized teeth, 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 is 90 seconds. Light cure setting time is 20 seconds per surface. Anaerobic self-cure setting time at mouth temperature is less than 3 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. Anaerobic self-cure setting time at mouth temperature is less than 3 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.
- hen 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.

PHYSICAL PROPERTIES

Working time at room temperature	90 seconds
Light cure setting time	20 seconds
Self-cure anaerobic setting time at 37°C	< 3 minutes
Percentage reactive glass filler by weight	47%
Fluoride release 1 day	360ppm
Fluoride release 28 days (cumulative)	1,300ppm

Flexural strength	88.4 MPa / 12,800 Psi
Flexural modulus	3.7 GPa
Compressive strength	210 MPa / 30,500 Psi
Diametral tensile strength	37 MPa / 5365 Psi
Water sorption (1 week)	2.30%
Film thickness	11 microns

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.

Note: Apply disposable barrier sleeves/wraps over multiple-use dental dispensers before use with each patient. For additional information, refer to the following website: http:/ /www.fda.gov/Medical Devices/ProductsandMedicalProcedures/DentalProducts/ucm404472.htm.