**BioACTIVE® BioACTIVE Dual Cure Products**

**Product Description**

ACTIVA**™** BioACTIVE dual cure products are strong, durable, ionic restorative resins that have the esthetics and physical properties of composites. They release calcium, phosphate and fluoride, and have a greater potential to recharge these minerals than glass ionomers and traditional RMGls. ACTIVA**™** stimulates mineral apatite crystal formation at the material-tooth interface. This natural remineralization process knits the restoration and the tooth together, prevents and fills micro-gaps and seals margins against microleakage and failure.

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.

ACTIVA**™** BioACTIVE dual cure materials contain water, yet the material has extremely low solubility. 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.

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**


**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.

**How to Use the Automix Syringe**

Using high volume evacuation, compressed air and/or a cotton pellet, dry and remove all external moisture from the prepared tooth surface. Avoid pooling of water or bonding agent. Do not desiccate the tooth, which naturally contains a small amount of water.

**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.

**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/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/ucm404472.htm](http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/ucm404472.htm).
INDICATIONS FOR ACTIVA® BioACTIVE-RESTORATIVE™
Recommended as a bioactive filling material for pits, root surface cavities and Class I, II, 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. Total etch prepared surface for 10-15 seconds with Etch-Rite 38% phosphoric acid etching gel, or selective etch enamel for 15 seconds, rinse and lightly dry, removing all excess moisture with high volume evacuation, compressed air, and/or a cotton pellet, but do not desicate 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. 10 ensure an even mix of base and catalyst, dispense 1-2 mm of material onto a mixing pad and discard this material.
7. ACTIVA BioACTIVE-RESTORATIVE is a air and enamel replacement material. Place mix tip at cavity floor. Apply ACTIVA in increments of up to 4-mm, keeping mix tip submerged in the material. Light cure Rx 20 seconds between each layer. Anodentic self-cure setting time at mouth temperature is 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 and V restorations where there is no pulpal involvement, Rx indirect pulp capping, and for use with all composite and amalgam restorations.

CONTRAINDICATIONS FOR ACTIVA® BioACTIVE-BASE/LINER™
Not indicated Rx 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 desicate 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.
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 3 minutes.
8. Complete the restoration with ACTIVA BioACTIVE-RESTORATIVE, or restore with your preferred adhesive and composite bonding system. Finish and polish with your preferred adhesive and composite bonding system.

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.

PHYSICAL PROPERTIES

<table>
<thead>
<tr>
<th>RESTORATIVE</th>
<th>BASE/LINER</th>
</tr>
</thead>
<tbody>
<tr>
<td>Light cure setting time:</td>
<td>20 seconds (See note in step 6 above)</td>
</tr>
<tr>
<td>Depth of light cure:</td>
<td>4 mm</td>
</tr>
<tr>
<td>Initial self-cure setting time at 37°C:</td>
<td>216-3 minutes</td>
</tr>
<tr>
<td>Percentage filler by weight:</td>
<td>56%</td>
</tr>
<tr>
<td>Percentage reactive glass filler by weight:</td>
<td>21.8%</td>
</tr>
<tr>
<td>Fluoride release / day:</td>
<td>2.30 ppm</td>
</tr>
<tr>
<td>Fluoride release 28 days (cumulative):</td>
<td>940 ppm</td>
</tr>
<tr>
<td>Thermal strength:</td>
<td>103 MPa / 14,970 Psi</td>
</tr>
<tr>
<td>Thermal modulus:</td>
<td>4.3 GPa</td>
</tr>
<tr>
<td>Compressive strength:</td>
<td>280 MPa / 41,000 psi</td>
</tr>
<tr>
<td>Diametral tensile strength:</td>
<td>42 MPa / 6090 psi</td>
</tr>
<tr>
<td>Water sorption /1 week:</td>
<td>1.62%</td>
</tr>
<tr>
<td>Polymerization shrinkage:</td>
<td>1.7%</td>
</tr>
<tr>
<td>Firm thickness:</td>
<td>N/A</td>
</tr>
</tbody>
</table>

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