

ACTIVA™ kids

BioACTIVE-RESTORATIVE™

Inspired by Nature. Created for Kids.



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

PULPDENT®

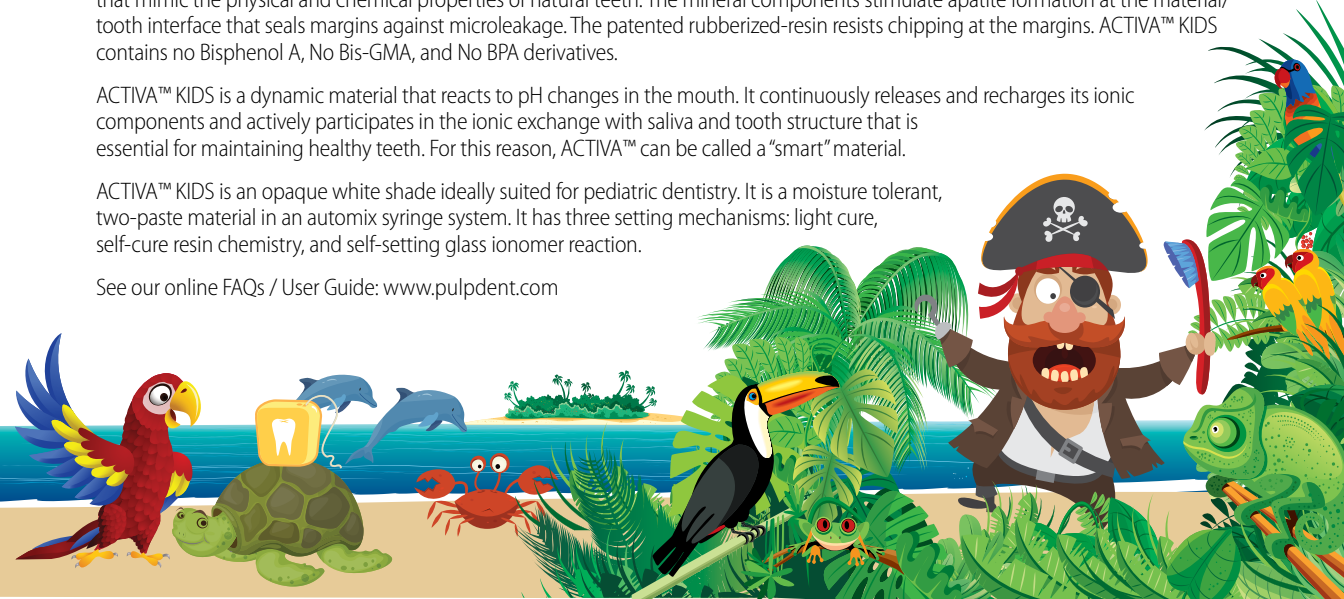
PRODUCT DESCRIPTION

ACTIVA™ KIDS is a strong, durable, dual cure ionic restorative with the esthetics and physical properties of composites.^{1,2} It releases and recharges calcium, phosphate and fluoride, and has a greater potential to recharge these minerals than glass ionomers and traditional RMGIs. It is the first dental restorative with a bioactive resin matrix, shock-absorbing resin component, and reactive ionomer glass fillers that mimic the physical and chemical properties of natural teeth. The mineral components stimulate apatite formation at the material/tooth interface that seals margins against microleakage. The patented rubberized-resin resists chipping at the margins. ACTIVA™ KIDS contains no Bisphenol A, No Bis-GMA, and No BPA derivatives.

ACTIVA™ KIDS 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™ KIDS is an opaque white shade ideally suited for pediatric dentistry. It is a moisture tolerant, two-paste material in an automix syringe system. It has three setting mechanisms: light cure, self-cure resin chemistry, and self-setting glass ionomer reaction.

See our online FAQs / User Guide: www.pulpdent.com



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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. ACTIVA™ is air inhibited and does not set in the presence of oxygen.
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 USE

Recommended as a bioactive filling material for pits, root surface cavities, and all classes of restorations where there is no pulpal involvement, and for cosmetic restoration of teeth treated with silver diamine fluoride.

CONTRAINDICATIONS

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

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 desiccate the tooth.
5. Apply a bonding agent of your choice in accordance with the manufacturer's instructions for use.
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™ KIDS 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 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.

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.

PHYSICAL PROPERTIES

Working time at room temperature:	90 seconds
Light cure setting time:	20 seconds (See note in step 6 above)
Depth of light cure:	4 mm
Self-cure anaerobic setting time at 37° C:	< 3 minutes
Percentage filler by weight:	56%
Percentage reactive glass filler by weight:	21.8%
Fluoride release 1 day:	230 ppm
Fluoride release 28 days (cumulative):	940 ppm
Flexural strength:	102 MPa/14,790 Psi
Flexural modulus:	4.3 GPa
Compressive strength:	280 MPa /40,600 Psi
Diametral tensile strength:	42 MPa /6090 Psi
Water sorption (1 week):	1.65%
Polymerization shrinkage:	1.7%

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 websites: <http://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DentalProducts/ucm404472.htm>