

BioACTIVE-RESTORATIVE™ **BioACTIVE-BASE/LINER™**



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Section 1: ACTIVA BioACTIVE OVERVIEW

ACTIVA BioACTIVE Restoratives

ACTIVA BioACTIVE products are strong, durable, ionic restorative resins that release and recharge more calcium, phosphate and fluoride and are more bioactive than glass ionomers and traditional RMGIs, and have the physical properties and esthetics of composites. They stimulate mineral apatite formation and 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 is different from traditional composites, RMGIs, GIs and Giomers

Traditional composites are strong and esthetic, but they have no bioactive potential and require bonding agents that have been shown to leak, cause white lines, staining and failure (Tay FR, Carvalho RM. Pashley DH. Water movement across bonded dentin – too much of a good thing. J Appl Oral Sci [online] 2004;12:12-25). Glass ionomers release significant amounts of fluoride, but they have poor esthetics and poor physical properties. RMGIs and giomers are a compromise between composites and GIs. ACTIVA combines the esthetics and physical properties of composites with more bioactivity than GIs, RMGIs and giomers. The rubberized-resin molecule in ACTIVA absorbs stress and dissipates forces like no other dental material. ACTIVA also benefits from ease of handling. ACTIVA is a bioactive restorative in a class of its own.

ACTIVA BioACTIVE-RESTORATIVE and ACTIVA BioACTIVE-BASE/LINER: Similarities and differences

These are similar, 2-part materials packaged in syringes with automix tips. The differences are the filler content, viscosity, esthetics and pH. The Restorative is 56% filled by weight, is thicker, does not slump, and provides slightly greater strength and wear resistance. It is available in A1, A2, A3, and A3.5 shades and is applied using a dispenser. The Base/Liner is 45% filled by weight, has a lower pH than the Restorative, and is designed to have more flow and the handling characteristics expected of a liner material. It is dentin shade and is dispensed by hand with a standard plunger type syringe.

Section 2: BIOACTIVITY DEFINED

Introducing bioactivity

The concept of bioactive materials was first introduced in 1969: "A bioactive material is one that elicits a specific biological response at the interface of the material, which results in the formation of a bond between the tissues and the material." (Hench LL, et al. Bonding mechanisms at the interface of ceramic prosthetic materials. J Biomed Mater Res 1972;2:117-141)

Properties of a bioactive dental material

Bioactive materials are moisture tolerant and contain zones or phases of water. They react to changes in the oral environment to bring about advantageous changes in the properties of saliva, teeth, and the materials themselves. (McCabe JF, et al. Smart materials in dentistry. Aust Dent J 2011;56 Suppl 1:3-10.) They release and recharge significant amounts of favorable ions, such as calcium, phosphate and fluoride, and they stimulate mineral apatite formation at the material-tooth interface.



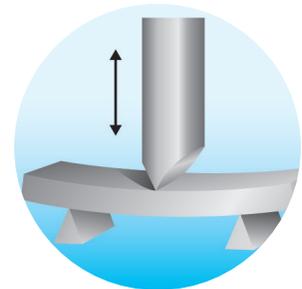
Bioactive claim for ACTIVA allowed by FDA

Pulpdent's 510(k) application for ACTIVA specifically claims that ACTIVA contains "both a bioactive resin matrix and bioactive glass fillers." We are not aware of any other restorative that is allowed by the FDA to make this claim.

Section 3: PHYSICAL AND CHEMICAL PROPERTIES

University testing on ACTIVA validates favorable physical and bioactive properties

ACTIVA has been tested and there are many publications in J Dent Res and other peer reviewed journals. These are documented on the ACTIVA website (www.activabioactive.com). Studies include Biocompatibility, Histopathological Evaluation, Bacterial Leakage, Microleakage, Fluoride Release, pH Dependence on Phosphate Release, Calcium Release, Flexural Strength and Fatigue, Deflection at Break, Water Absorption, Water Solubility, Compressive and Tensile Strength, Retention, Diffusion of Ions through Bonding Agents, and Apatite Formation. Additional studies are currently under way.



ACTIVA stimulates apatite formation

SEM evaluation of ACTIVA after 21 days in saline solution shows irregular amorphous structures. Chemical analysis of the surface shows 8.3% calcium, 9.4% phosphorous, and 28.6% oxygen, which indicates apatite formation.

Advantages of light cure vs. self-cure

ACTIVA will light cure to a depth of 4mm. It also self-cures at any thickness. Allowing ACTIVA to initially self-cure for 15-30 seconds may be advantageous and promote greater integration with tooth structure. It also reduces polymerization stresses. The material is yielding during the early self-cure polymerization phase, when polymer chains re-align and yield toward the stress (toward the point of attachment to the tooth). Light curing provides a greater conversion of double bonds, a more complete cure, and slightly greater physical properties, although this may not be clinically significant. Allowing an initial self-cure period followed by light curing may be beneficial.

Release and recharge of calcium, phosphate and fluoride ions

ACTIVA behaves like tooth structure. It releases ions during lower pH cycles and recharges when the oral pH rises. ACTIVA also stimulates formation of mineral apatite at the tooth/restorative interface.

Rubberized resin provides durability and fracture resistance

ACTIVA is a strong, hard material that provides excellent support for tooth structure. The modulus of elasticity is moderate, and the material is not brittle. The resin matrix includes a patented rubberized resin molecule that increases durability, absorbs shock and stress, and mimics the physical properties of dentin.

Wear resistance

ACTIVA BioACTIVE-RESTORATIVE has been tested for wear resistance at two universities using two different methods. Wear resistance is equivalent to Filtek Supreme and superior to GICs and RMGIs. The test results appear on the ACTIVA website (www.activabioactive.com).

Polymerization shrinkage

If ACTIVA is mixed and immediately light cured, the polymerization shrinkage is 1.7%; however, this is not what happens in clinical practice. Clinically the material is beginning to self-cure during placement. During this initial self-cure phase, the polymer chains have the ability to re-align themselves in the direction of the stress, which is toward the interface between the tooth and the material. This phenomenon reduces stress and shrinkage. By the time the material is light cured, some self-curing has already taken place, and the polymerization shrinkage is actually less than 1.7%. Therefore, allowing some self-cure time has advantages, and the timing of the restorative process has an effect on polymerization stress and shrinkage.

The integration of the material with the tooth may also mitigate stresses and shrinkage. The adaptation of the material to the tooth is palpable during placement. The material wants to integrate with the tooth and chemically bond; it does not want to separate from or be repelled by the tooth, as is the case with conventional composites.

Section 4: CLINICAL USE

Clinical trials

The first year of a clinical trial is scheduled for completion in 2015. The 6-month interim report shows excellent results. ACTIVA has been in clinical use since 2012. A 30-month follow up photograph of an ACTIVA restoration appears to the right.



Indications for ACTIVA BioACTIVE-RESTORATIVE

ACTIVA BioACTIVE-RESTORATIVE is indicated for all classes of cavities, bulk fill, and post and core build up procedures. It is a universal restorative that is both light cure and self-cure and is clinically proven for bulk filling. In deep cavities, it is advisable to place a 1-2mm insulating layer, light cure, and then proceed with bulk filling. This technique is recommended for bulk filling with all resins to reduce exothermic response and polymerization stress. For core build ups, use the technique for syringeable composite core material. A bonding agent is recommended if there is not sufficient retention form.

ACTIVA BioACTIVE-RESTORATIVE as a base/liner

ACTIVA BioACTIVE-RESTORATIVE can be used as a base/liner; however, for clinicians accustomed to using GICs, RMGIs or flowable composites as a base/liner, the handling and viscosity of ACTIVA BioACTIVE-BASE/LINER is exactly what they want and expect.

Etching and bonding with ACTIVA

ACTIVA BioACTIVE-BASE/LINER does not require etching or bonding agents. The material has self-etching and self-adhesive properties that are sufficient for base/liner applications.

ACTIVA BioACTIVE-RESTORATIVE requires a 10-second etch for best results. Bonding agents are only indicated for the Restorative material when there is little or no retention form in the preparation (for example, in a Class V prep). Bonding agents will increase bond strength when retention is a concern.

The effect of bonding agents on bioactivity

Our studies indicate that some bonding agents will delay the bioactive advantages of ACTIVA, but with few exceptions they will not significantly decrease the bioactivity over time. Most bonding agents are permeable, and the material-tooth interface begins the process of reaching a bioactive equilibrium after several weeks.

Apply ACTIVA to a moisture-free tooth surface, but do not desiccate the tooth

Using high volume evacuation 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.

Using ACTIVA with surface cleansing preparations

Do not use sodium hypochlorite before placing ACTIVA; it supersaturates the tooth surface with excess water. Gluma®, Concepsis® and CHG preparations do not appear to have this effect and are okay to use. It is important to remove all excess water from the tooth surface but not to desiccate the tooth. (® Not trademarks of Pulpdent)

Avoiding air bubbles when placing ACTIVA BioACTIVE-RESTORATIVE

ACTIVA BioACTIVE-RESTORATIVE is a heavy viscosity flowable, stackable, and injectable restorative. Keep the mix tip submerged in the material at all times, and allow the material to flow ahead of the mix tip. Do not withdraw the tip faster than the material fills the space or air bubbles will result. In small diameter and tunnel preps, start as deep in the prep as possible so that the material does not bridge the prep and trap air. Keep the tip submerged in the material and avoid pulling the tip in and out of the cavity prep. This simple injectable technique prevents air bubbles and voids, and is faster and provides a denser fill than placing traditional composites.



Creating occlusal anatomy with ACTIVA BioACTIVE-RESTORATIVE

The traditional technique for packable/sculptable composite restorations is to carve anatomy in the occlusal surface, light cure, check the bite, and make further adjustments. This technique is a holdover from amalgam fillings. By using the flowable restorative technique with ACTIVA and leaving the tip submerged in the material during placement, the clinician has choices for creating occlusal anatomy. ACTIVA does not slump and can be shaped with an instrument during the self-cure stage, i.e., before light curing. Alternatively, the clinician can slightly overfill above the enamel margin placing extra material where a missing cusp would be, and light cure. A finishing carbide or diamond instrument can be used to carve and shape anatomy. Before light curing, some clinicians have the patient bite down on a thin film to create anatomy.

Finishing and polishing ACTIVA BioACTIVE-RESTORATIVE

Trim and finish ACTIVA with your preferred rotary instruments. Achieve a high polish by using a diamond impregnated silicone polishing system with water.

Using ACTIVA in combination with traditional composites

ACTIVA BioACTIVE-RESTORATIVE and BASE/LINER are bioactive restoratives with an oxygen inhibited (O₂) layer and will bond to all other composites. Follow the instructions for the conventional composite with respect to etching, bonding, and layering composite. If the ACTIVA surface is uncontaminated and sticky with the O₂ layer, add composite directly to ACTIVA. If ACTIVA has been contaminated, or if the O₂ layer has been removed, briefly etch ACTIVA and apply a bonding resin. The O₂ layer – or resin wetted surface – plays an important role whenever a heavy body composite is placed on top of a cured resin surface.

Section 5: THE PATIENT AND THE PRACTICE

Introducing ACTIVA to your patients

Practitioners can now use bioactive restorative materials that become part of the tooth and deliver the minerals teeth need to stay healthy. Let your patients know you have incorporated these advances in dental materials into your practice. Explain to them the direct benefits bioactive materials provide for their teeth and oral health. Your concern for their health is paramount in their minds and strengthens the dentist-patient relationship.



Position your practice for growth

Being a leader in bioactive materials is a practice builder and differentiates the practice from others. Patients want to know what is new and better in dentistry, and your practice will be recognized for patient education, advanced techniques, and better patient care. Bioactive materials promote prevention and patient health as opposed to just maintenance. You will discuss the benefits of this proactive care with your patients, and they will talk about this with their families and friends.

Addressing patient concerns about BPA

ACTIVA BioACTIVE materials contain no Bisphenol A, no Bis-GMA and no BPA derivatives. ACTIVA is the perfect restorative choice for concerned patients and indicates your awareness of their concerns. This serves as another way to build your practice and benefit your patients.

Excellence and efficiency

ACTIVA delivers better patient outcomes in less time. The elimination in most cases of bonding agents provides considerable time savings. ACTIVA is faster to place than traditional heavy body composites, integrates and chemically bonds to tooth structure, eliminates voids and sensitivity, and provides esthetic, durable restorations with exceptional bioactive properties.

Section 6: CLINICAL TECHNIQUE/HELPFUL HINTS

Clinical tips for completely restoring a tooth using only ACTIVA BioACTIVE-RESTORATIVE.

1. After preparing the tooth, if you use cavity cleansers and disinfectants, remember that they contain water. This excess water must be removed completely before placing ACTIVA. Do not use sodium hypochlorite. It disrupts the cell walls, releases structural water from the tooth, and results in too much water on the surface.
2. Etch the dentin and enamel for 10 seconds with 37-38% phosphoric acid. If you use a selective etch technique (etching only enamel), then etch enamel for 15-20 seconds. Rinsing off the etch gel will modify the dentin sufficiently. Rinse well.
3. Use high volume evacuation directly on the prepared tooth surface for 2-3 seconds to remove all external moisture. You can also dab and dry the tooth surface with a cotton pellet. Do not desiccate the tooth, which naturally contains a small amount of water. The tooth should not appear chalky or frosty.
4. Place the ACTIVA tip into the preparation and allow the material to slowly flow ahead of the tip onto the dentin. Keep the tip submerged in the material at all times while you move the tip to the desired areas. Take your time, allowing the ionic activity to interact, integrate and create chemical bonds with the dentin.
5. In deep preparations, place a 1-2mm insulating layer and light cure to create a thermal barrier. Then bulk fill to the occlusal surface. For best results, light cure from both the buccal and lingual aspects.



6. **ACTIVA BioACTIVE-RESTORATIVE** does not slump and can be shaped prior to curing. After curing, occlusal anatomy can be modified with a rotary instrument.
7. Note: In most cases bonding agents are not required. In preparations with little or no retention form, or when retention is a concern, a bonding agent is recommended.

Clinical tips for using **ACTIVA BioACTIVE-BASE/LINER followed by **ACTIVA BioACTIVE-RESTORATIVE** and/or a traditional composite.**

1. **ACTIVA BioACTIVE-BASE/LINER** does not require etching or bonding.
2. When using **ACTIVA BioACTIVE-BASE/LINER** as the first layer, light cure and proceed following the directions for **ACTIVA BioACTIVE-RESTORATIVE** and/or a traditional composite.
3. When layering resins, it is best to apply incremental layers to a resin-wetted surface. An oxygen inhibited (O₂) layer is adequate for this purpose.
4. Follow instructions for the restorative material being used.

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