PULPDENT®
Dental Innovation Since 1947

ACTIVA™ BioACTIVE

A Closer Look at BioACTIVE Materials

Changes everything you know about Composites,
Glass Ionomers and RMGIs

Third Edition

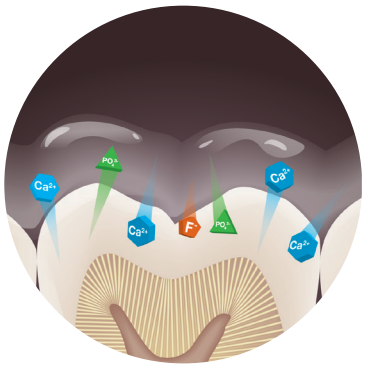
BioACTIVE Products for ProACTIVE Dentistry

Advances in dental materials make possible a proactive approach to patient treatment and oral health care. Bioactive materials that behave favorably in the moist oral environment, neutralize conditions that cause dental caries, provide prevention benefits, and maximize the potential for remineralization will become the accepted standard of care.

Mimics Nature

ACTIVA BioACTIVE dual cure products are the first dental resins that mimic the physical and chemical properties of teeth. They contain three key components:

- Bioactive ionic resin matrix
- Shock-absorbing rubberized resin component
- Reactive ionomer glass fillers.



These bioactive products actively participate in the cycles of ionic exchange that regulate the natural chemistry of our teeth and saliva and contribute to the maintenance of tooth structure and oral health.

Strong, Esthetic, BioActive

ACTIVA has the strength, esthetics and physical properties of composites and more release and recharge of calcium, phosphate and fluoride than glass ionomers,[1] combining the best attributes of both materials without compromising either one.

- Esthetic
- Chemically bonds
- Seals teeth against bacterial leakage[2,3]
- Releases/recharges calcium, phosphate and fluoride
- Provides long-term patient benefits

Stimulates Apatite Formation

ACTIVA elicits a natural response that stimulates apatite formation and the natural remineralization process that knits the restoration and tooth together and seals margins against microleakage, secondary caries, and failure. This is the essential requirement of bioactive materials.

Durable

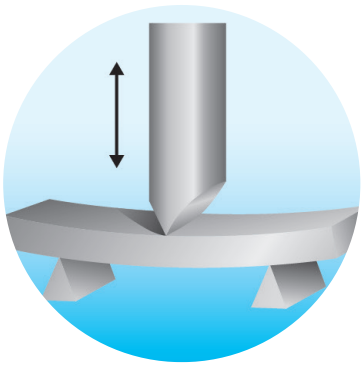
ACTIVA is durable and wear resistant.[27,28] Although the dual cure material contains water, it has extremely low solubility.[8,20] The ionic resin matrix facilitates the diffusion of calcium, phosphate and fluoride ions while still maintaining the excellent physical properties associated with resins and composites.

Tough, Fracture Resistant

ACTIVA BioACTIVE products contain a rubberized resin component that makes them tougher and more resistant to fracture and chipping than composites.[4,5,17,29,34]

Toughness, measured by deflection at break, is the ability of a strong, hard material to absorb stress without fracturing.

Deflection at break of ACTIVA is 2-3 times greater than composites and 5-10 times greater than GIs and RMGIs[4,5,17]



Dynamic " 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 can react to changes in the ambient conditions and are capable of this dynamic behavior.[6]

ACTIVA reacts to the continuous pH changes in the oral environment to help fortify and recharge the ionic properties of saliva, teeth and the material itself.[1,7,9] For this reason, ACTIVA is considered a "smart" material.

No Bisphenol A

- ACTIVA BioACTIVE products contain no Bisphenol A, no Bis-GMA, no BPA derivatives
- Two-paste, automix systems
- Three setting mechanisms: light cure, self-cure resin chemistry, and self-cure glass ionomer reaction

Bioactive Materials

Bioactive dental materials stimulate apatite formation that fills micro-gaps, seals margins against microleakage, and helps rebuild teeth. Bioactive materials that are strong, esthetic, and long-lasting offer an alternative to traditional composites, which are strong and esthetic but are passive and without bioactive potential, and to glass ionomers, that release a significant amount of fluoride but have poor esthetics and undesirable physical properties.

The development of bioactive materials is inspired by nature, where water is the source of life. In the oral cavity, saliva is the life source and is rich with water, proteins and ionic components.

The oral environment is exposed to continuous pH cycles, and saliva and tooth structure participate in an endless cycle of mineral exchange.

When the pH is low, the demineralization process releases calcium and phosphate ions from the tooth surface. As the pH rises, these ions are available to interact with fluoride ions in our saliva.

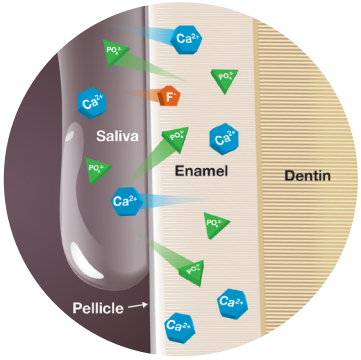
Bioactive materials imitate nature and participate in this dynamic ionic exchange. They are water-based or have the capacity for significant water transport or storage and continuously release and recharge their ionic components.[6]

They react to the changes in the oral environment to bring about advantageous changes in the properties of saliva, teeth and the materials themselves. This is often referred to as "smart" behavior.[6]

Saliva is a natural caries protection agent and contains the minerals that maintain the integrity of the enamel surface.

It helps maintain the health of the hard and soft tissues, removes waste, and is the first line of defense against microbial invasion.

Bioactive dental materials help regulate the chemistry of teeth and saliva and contribute to the maintenance of oral health.



Ionic Resins

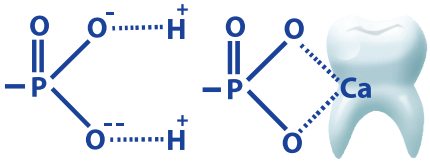
ACTIVA BioACTIVE dual cure products are formulated with a patented, ionic-resin (Embrace resin) that contains a small amount of water. It is bioactive, mimics nature and responds to changes in the oral environment.[9]

The ionic resin is moisture friendly, which is a requirement of bioactive materials. Water placed next to the ionic resin mixes with the resin.

ACTIVA's ionic resin contains phosphate acid groups that improve the interaction between the resin and the reactive glass fillers and enhance the interaction with tooth structure.

Through an ionization process that is dependent upon water, hydrogen ions break off from the phosphate groups and are replaced by calcium in tooth structure.

This ionic interaction binds the resin to the minerals in the tooth, forming a strong resin-hydroxyapatite complex and a positive seal against microleakage.[2,3,14,15,16,19]



ACTIVA participates in a dynamic system of ionic exchange with saliva and tooth structure, continuously releasing and recharging calcium, phosphate and fluoride ions and reacting to pH changes in the mouth.[1,7,9,11]

Unique properties of the ionic resin:

- Significantly releases and recharges with fluoride[1,7,11]
- Releases a great amount of phosphate[11]
- Intimate adaptation to tooth structure.[2,3,10]
- Exceptional marginal integrity[10,15,16]
- Seals against bacterial leakage[2,3]

ACTIVA™ BioACTIVE PRODUCT REVIEW

BioACTIVE–RESTORATIVE™
BioACTIVE–CEMENT™
BioACTIVE–BASE/LINER™
ACTIVA™ kids BioACTIVE–RESTORATIVE™

The US Food & Drug Administration has allowed the claim that ACTIVA BioACTIVE products contain a bioactive resin matrix and bioactive fillers, ushering in a new category of bioactive dental products.

ACTIVA stimulates apatite formation and the natural remineralization process that knits the restoration and the tooth together and seals margins against microleakage, secondary caries, and failure. This is the essential requirement of bioactive materials.

ACTIVA combines all the benefits of composites and glass inomers while eliminating the disadvantages associated with those materials.

ACTIVA BioACTIVE-BASE/LINER is more bioactive and has greater release and recharge of calcium, phosphate and fluoride than glass inonomers in a strong, resilient resin matrix that will not chip or crumble. The Base/Liner adheres to dentin and does not require etching or bonding agents.

ACTIVA BioACTIVE-RESTORATIVE and **ACTIVA Kids** combine the esthetics, strength and resilience of composites with bioactive properties and fluoride release that are superior to glass ionomers. [1,2,3,4,5,17]

ACTIVA BioACTIVE-CEMENT is effective with all substrates, and its ability to absorb shock and stress acts like a ligament to resist fracture and chipping.

ACTIVA products are the first bioactive dental materials with an ionic resin matrix, a shock-absorbing resin component and bioactive fillers that mimic the physical and chemical properties of natural teeth. They are durable, wear and fracture resistant, chemically bond to teeth, seal against bacterial microleakage, and release and recharge with calcium, phosphate and more fluoride ions than glass ionomers,[1,7,11] delivering long-term benefits and better oral health care for your patients.

ACTIVA contains no Bisphenol A, No Bis-GMA and no BPA derivatives.

3 Key Components

An unparalleled combination of physical and chemical properties delivers bioactivity, toughness, resilience, durability and marginal integrity.

1. Patented bioactive ionic resin
2. Patented rubberized resin
3. Reactive ionomer glass

Key Properties:

- Natural esthetics - Highly polishable
- Tough, resilient – absorbs shock
- Resists fracture, wear, chipping and crumbling
- Releases and recharges calcium, phosphate and fluoride
- Chemically bonds – Seals against bacterial microleakage
- No sensitivity - Moisture tolerant - Simplified technique

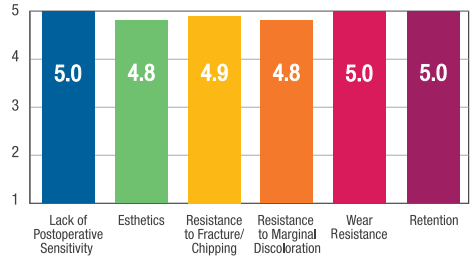
Special Features

- Automix syringe with unique precise placement mix tips
- O2 layer integrates with restorative composites
- No bonding agents required when retention form is adequate
- Ideal for bulk filling
- Light cure and self-cure
- Depth of cure with light: 4mm

THE DENTAL ADVISOR™

+++++

98% rating



Unique and unprecedented.
– Croll TP, Berg JH, Donly KJ

Outstanding results! – **Dr. Mark Cannon**

Truly impressive – **Dr. Josh Wren**

Totally cool and utterly awesome
– **Dr. Ted Croll**

ACTIVA BioACTIVE-RESTORATIVE

53-month Recall

1A December 2012
Failing amalgam restoration with mesial marginal ridge fracture.

Courtesy of Dr. John Comisi

1B December 2012
Prepared tooth.

1C December 2012
ACTIVA BioACTIVE-RESTORATIVE post op.

1D May 2017
53-month recall shows great esthetics, no wear or chipping, and no marginal staining.

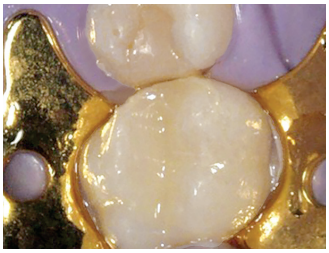
Replace Failed Composite with ACTIVA BioACTIVE-RESTORATIVE

2A Shows 10-second etch. After rinsing, all excess moisture is removed.

Courtesy of Dr. Mark Cannon

2B ACTIVA BioACTIVE-RESTORATIVE is placed using mixing tip with bendable metal cannula.

2C Explorer is used to create anatomy.

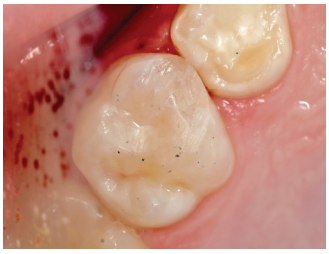


2D Shows finished and polished restoration.

Minimally Invasive Class II

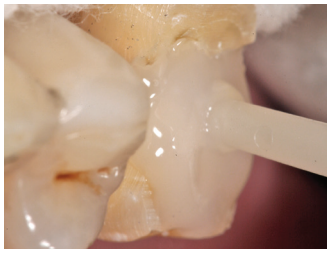
3A Shows minimally invasive tooth preparation.

Courtesy of Dr. Leon Katz



3B After 10-second etch and removal of excess moisture, shows esthetic ACTIVA restoration.

Core Build Up

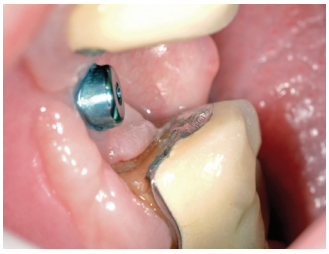


4A ACTIVA is used to build the core on a badly broken down molar.

Courtesy of Dr. Robert Lowe

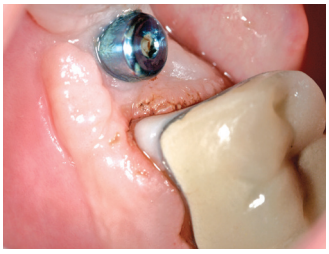
4B Tooth is ready to receive a crown.

Repairing Caries Under Crown Margin



5A Caries under crown margin has been removed. 10-second etch and removal of all excess moisture not shown.

Courtesy of Dr. Robert Lowe



5B Moisture-friendly ACTIVA bonds to tooth, metal and ceramics, and mimics the function of missing tooth structure.

Repairing Sensitive Cervical Lesions

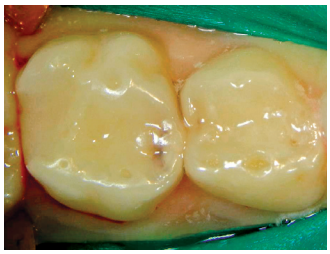
6A Shows cervical lesions of lower bicuspids.

Courtesy of Dr. C.H. Pameijer

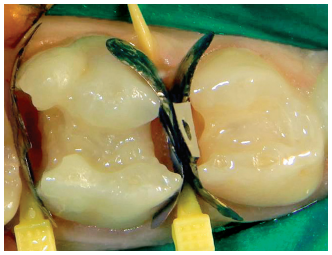
6B After etching, bonding agent was applied for added retention. ACTIVA provides esthetics, bioactivity, and patient comfort.

ACTIVA Kids

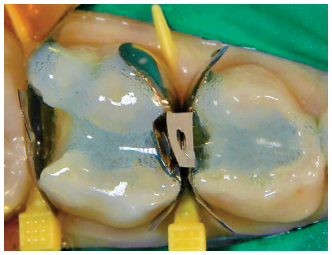
ACTIVA™ KIDS is easy to place and is an opaque white shade ideally suited for primary teeth.



7A Pre-op shows secondary caries on restored molars



7B Prepared teeth



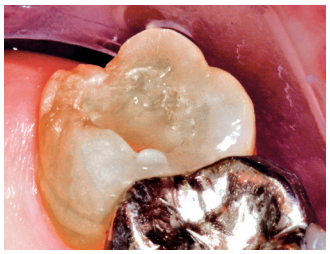
7C Teeth are etched for 10 seconds

7D Shows teeth restored with ACTIVA™ KIDS

Photos courtesy of Dr. Mark Cannon

ACTIVA BioACTIVE-BASE/LINER

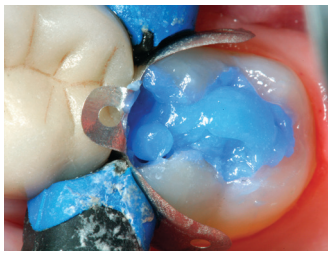
8A Shows prepared tooth after removing deep caries under a failed composite restoration.



8B Shows ACTIVA BioACTIVE-BASE/LINER placed and cured. No etching required. Note dentin shade match.

9A Prepared tooth

9B Shows ACTIVA BioACTIVE-BASE/LINER after light curing



9C Etch with Etch-Rite phosphoric acid gel

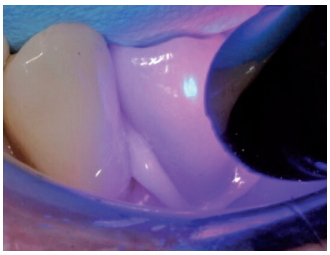
9D Finish restoration using composite or ACTIVA BioACTIVE-RESTORATIVE

Photos courtesy of Dr. Robert Lowe

ACTIVA BioACTIVE-CEMENT

A simple cementation procedure: self-adhesive, syringe delivery, no trituration, easy clean up

10A Tooth is prepared to receive a crown. Note retentive crown prep.



10B Crown filled with ACTIVA BioACTIVE-CEMENT is seated and tack cured 1-2 seconds.

10C Excess cement is easily removed

10D Shows finished case

Photos courtesy of Dr. G. Franklin Shull

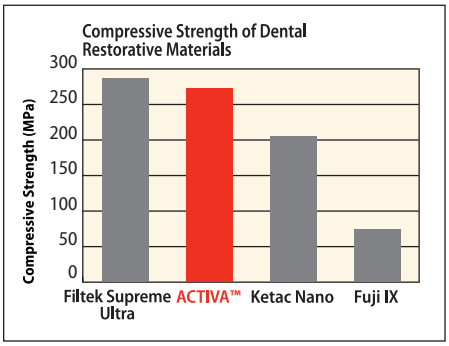
Physical Properties

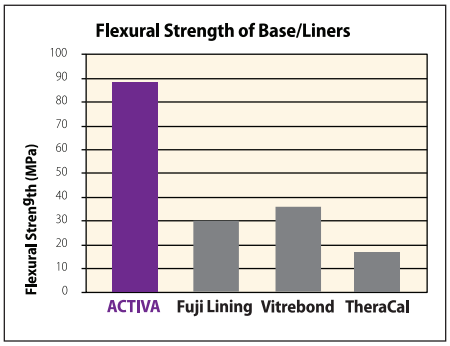
Strength

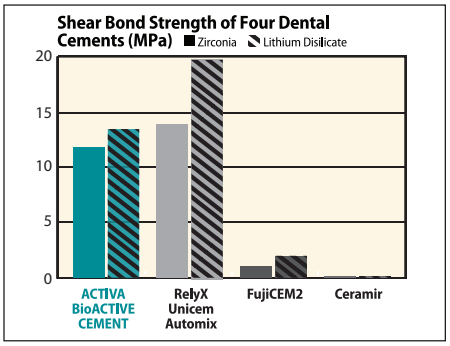
Compressive and Diametral Tensile Strength of ACTIVA BioACTIVE-RESTORATIVE is comparable to composites and far superior to glass ionomers and RMGIs.

Compressive and Flexural Strength of ACTIVA BioACTIVE-BASE/LINER is much greater than resin-modified base/liners and RMGIs.

Shear bond strength of ACTIVA BioACTIVE-CEMENT compares favorably with leading cements and is superior to RMGI and calcium aluminate-glass ionomer cements tested.

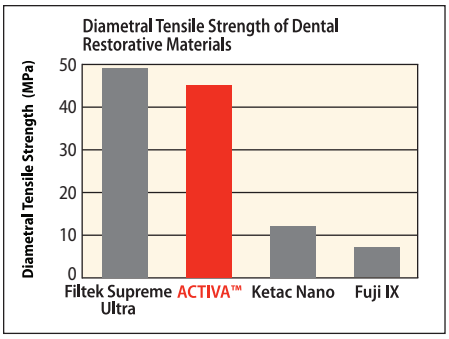


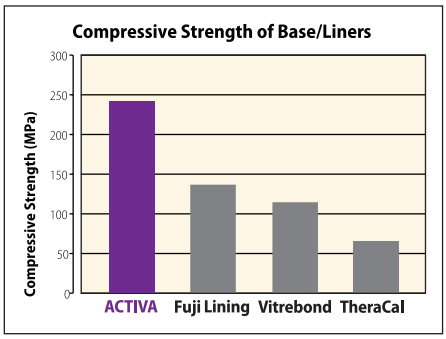




ACTIVA = Bioactive Cement; RelyX = Self-adhesive Cement; FujiCEM 2 = RMGI; Ceramir = Calcium Aluminate-GI

Source: University testing[38]





Filtek = Composite; ACTIVA = Bioactive Restorative; Ketac Nano = RMGI; Fuji IX = Glass Ionomer

Source: University testing[17]

(see back page for trademark information)

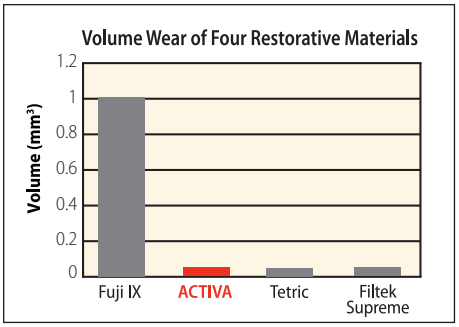
ACTIVA = Bioactive Base/Liner; Fuji Lining = RMGI; Vitrebond = RMGI; TheraCal = Resin-Modified Calcium Silicate

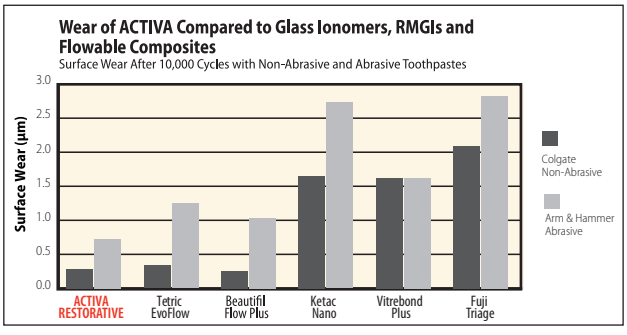
Source: Pulpdent testing[18]

Wear

Volume wear of ACTIVA BioACTIVE-RESTORATIVE is comparable to composites and far less than glass ionomer.

When evaluated for surface wear resistance, ACTIVA BioACTIVE-RESTORATIVE performed better than all other materials tested with abrasive toothpaste and was comparable to flowable composites with non-abrasive toothpaste.





Fuji IX = Glass Ionomer; ACTIVA = Bioactive Restorative; Tetric = Composite; Filtek Supreme = Composite

Source: University testing[27]

(see back page for trademark information)

ACTIVA = Bioactive Restorative; Tetric EvoFlow and Beautifil Flow Plus = Flowable Composite; Ketac Nano and Vitrebond Plus = RMGI; Fuji Triage = Glass Ionomer

Source: University testing[28]

Physical Properties

Toughness, Fatigue Limit, Deflection at Break

ACTIVA's rubberized resin component provides unparalleled toughness and resilience. Toughness, measured by deflection at break using a 3-point bend test, is the ability of a strong, hard material to absorb stress, dissipate forces and resist fracture when a load is applied. Fatigue limit is determined by the incremental load required to cause fracture within a defined number of cycles.

Deflection at Break of ACTIVA is 2-3 times greater than composites and 5-10 times greater than GIs and RMGIs.

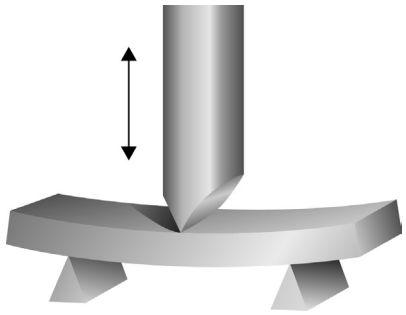
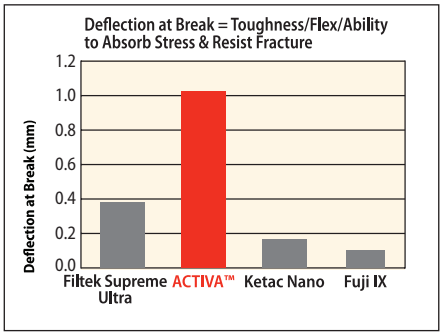


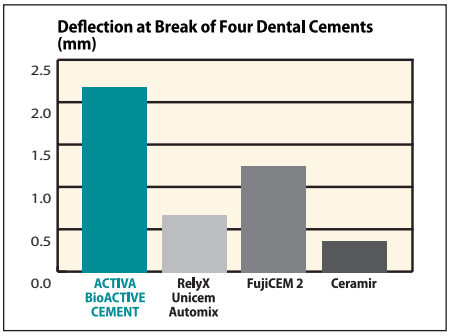
Illustration shows 3-point bend test



Filtek = Composite; ACTIVA = Bioactive Restorative; Ketac Nano = RMGI; Fuji IX = GI

Source: University testing[5,17]

(see back page for trademark information)

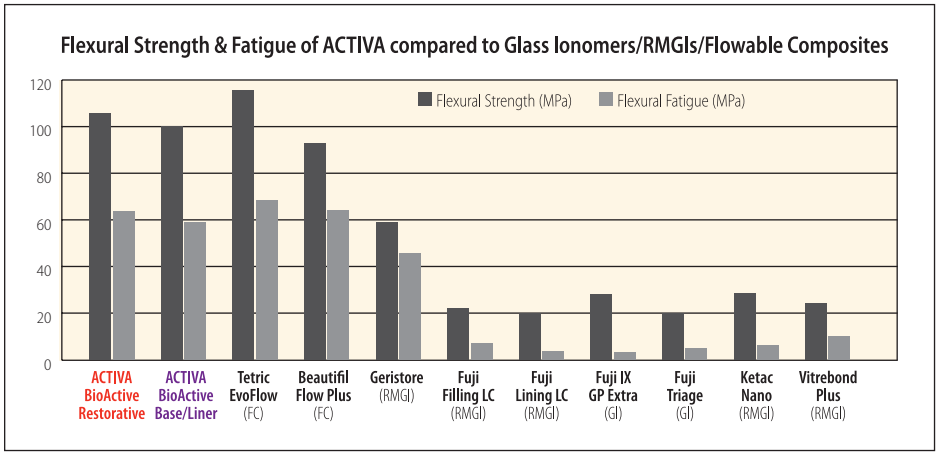


ACTIVA = Bioactive Cement; RelyX Unicem Automix = Self-adhesive Cement; FujiCEM 2 = RMGI; Ceramir = Calcium Aluminate-GI

Source: University testing[34]

Flexural Strength and Flexural Fatigue

Flexural strength and flexural fatigue measure the amount of stress a material can withstand, measured by deflection at break, and its endurance, measured by the number of repeated cycles before failure. ACTIVA meets the requirement of ISO 4049 for occlusal restorations and demonstrates flexural strength and flexural fatigue comparable to flowable composites (FC) and significantly greater than conventional RMGIs and GIs tested.



Source: University testing[29]

(see back page for trademark information)

Physical Properties

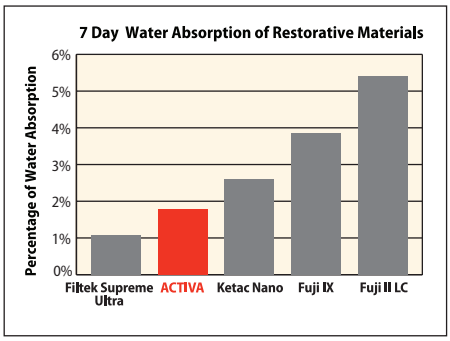
Water Absorption

A controlled and relatively low level of water absorption is advantageous for bioactive materials, which require water to unlock their bioactive properties and potential for ionic exchange. Excessive water absorption can compromise the physical properties of restorative and base/liner materials over time.

Water absorption of ACTIVA BioACTIVE-RESTORATIVE is significantly less than glass ionomers and RMGIs, and is designed to be slightly higher than composites, which are hydrophobic and not bioactive.

Water absorption of ACTIVA BioACTIVE-BASE/LINER is far less than RMGIs. Water absorption of TheraCal is 7 times greater than ACTIVA.

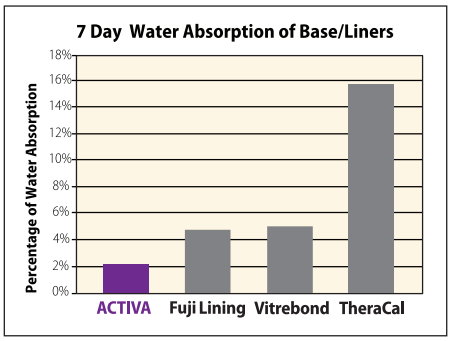
Water absorption of ACTIVA BioACTIVE-CEMENT compares with the leading self-adhesive cement and is far less than the RMGI and calcium aluminate-glass ionomer cements tested.



ACTIVA = Bioactive Restorative; Filtek = Composite; Ketac Nano = RMGI, Fuji IX = GI; Fuji II LC = RMGI

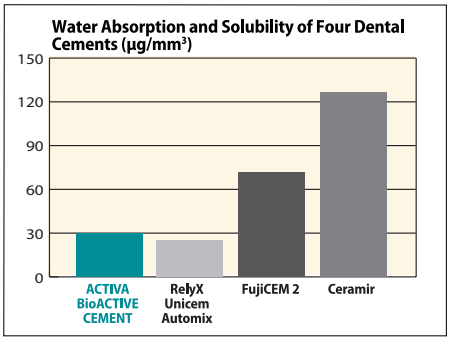
Source: Pulpdent testing[8]

(see back page for trademark information)



ACTIVA = BioACTIVE Base/Liner; Fuji Lining & Vitrebond = RMGI; TheraCal = Resin-Modified Calcium Silicate

Source: Pulpdent testing[20]



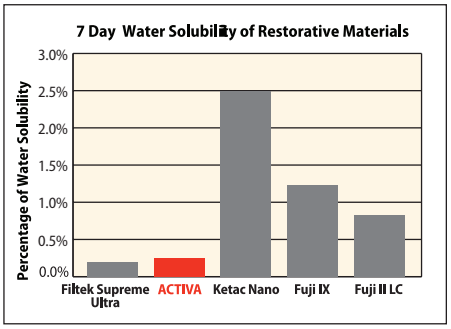
ACTIVA = Bioactive Cement; RelyX Unicem Automix = Self-adhesive Cement; FujiCEM 2 = RMGI; Ceramir = Calcium Aluminate-GI

Source: University testing[37]

Water Solubility

Low water solubility is important for ensuring the durability and longevity of a dental material. The patented resins and reactive glass fillers in ACTIVA products are balanced to deliver both bioactivity, which requires water, and durability. This unique combination of attributes, when combined with esthetics, sets ACTIVA apart from all other restorative materials.

ACTIVA has remarkably low water solubility that compares favorably with leading composites and is far lower than glass ionomers and RMGIs.

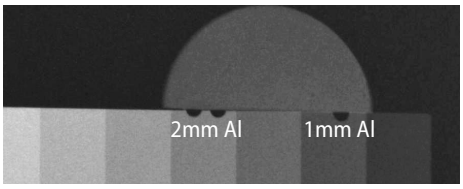


Source: Pulpdent testing[20]

(see back page for trademark information)

Radiopacity

The radiopacity of ACTIVA is equivalent to 1.5mm of aluminum.



Bioactive Properties

Apatite Formation

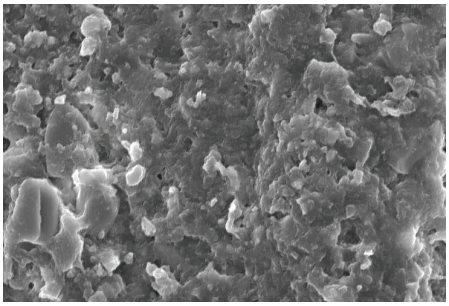
Apatite formation is the essential requirement of bioactive materials. ACTIVA stimulates mineral apatite formation and the natural remineralization process that knits the restoration and the tooth together and seals margins against microleakage, secondary caries, and failure.

ACTIVA responds to pH cycles and plays an active role in maintaining oral health with release and recharge of significant amounts of calcium, phosphate and fluoride. These mineral components stimulate formation of a protective/connective apatite layer and a natural bonded-seal at the material-tooth interface.

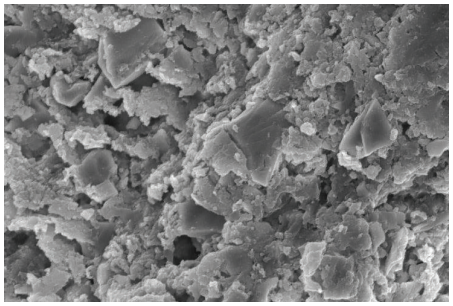
SEM Analysis of ACTIVA BioACTIVE-CEMENT after 21 Days in Saline

Compared to the no saline control, scanning electron microscope (SEM) imaging and energy-dispersive X-ray spectroscopy (EDS) after 21 days in saline shows significant increase in calcium and phosphorus ion concentrations, and decrease in carbon and silica ions, indicating that mineral apatite deposits are forming on the surface.

Source: University testing[35]



ACTIVA BioACTIVE-CEMENT Control, no saline 3000x

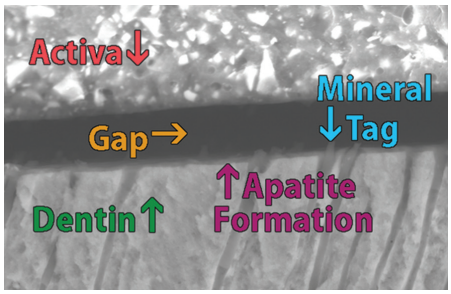


ACTIVA BioACTIVE-CEMENT 21 days in saline 3000x

SEM and EDS Analysis Verifies Bioactive Component

Scanning electron microscope (SEM) imaging and energy-dispersive X-ray spectroscopy (EDS) analysis of dentin discs treated with ACTIVA BioACTIVE-CEMENT and placed in phosphate buffered solution verifies the bioactive component of the material and demonstrates excellent dentinal tubule penetration. A layer of apatite formed and fused the dentin to ACTIVA. (The gap was produced when the specimen was fractured to make the SEM.)

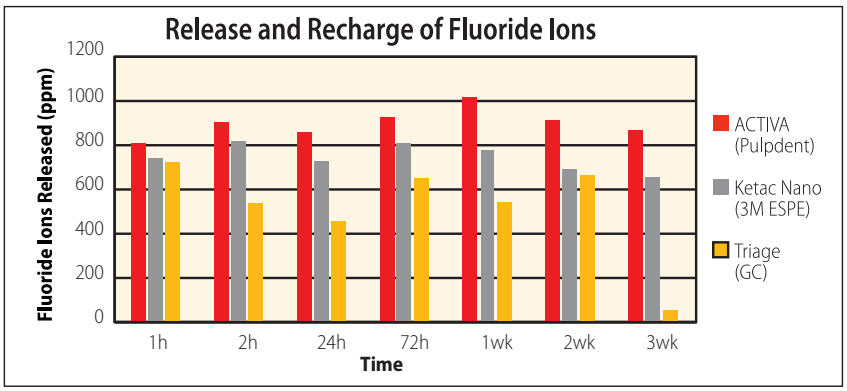
Source: University testing[41]



Fluoride Release and Recharge

ACTIVA releases and recharges with fluoride, providing long-term patient benefits for improved oral health care.

University testing using fluoride ion concentration gradient diffusion methodology shows the pattern of release and recharge of ACTIVA, Ketac Nano and Triage. The study concludes that "at the seven time points tested, the new bioactive material [ACTIVA] has statistically greater fluoride release after recharge at 24 hours, 1 week and 3 weeks than the other groups tested."[1]

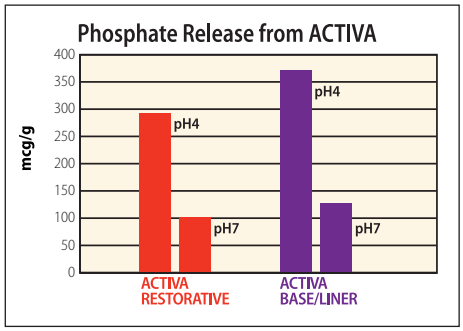


Source: University testing[1] (see back page for trademark information)

Bioactive Properties

Phosphate Release

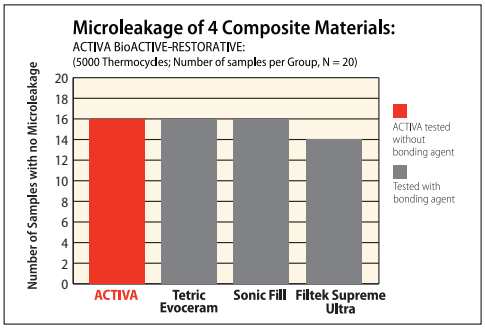
ACTIVA is a "smart" material that responds to pH cycles in the mouth. During low pH demineralization cycles, ACTIVA releases more phosphate. The phosphate ions can reside in the pellicle layer or saliva and are available to interact with calcium and fluoride ions during higher pH cycles.



Source: Pulpdent testing[9]

Microleakage

ACTIVA BioACTIVE-RESTORATIVE, when tested in vitro for microleakage ***without a bonding agent,*** compares favorably with leading composites tested ***with a bonding agent*** (Scotchbond Universal Adhesive, 3M ESPE).

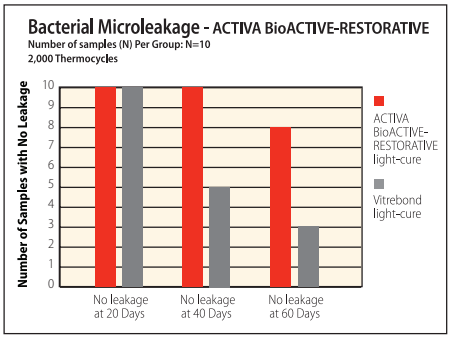


Source: University testing[16] (see back page for trademark information)

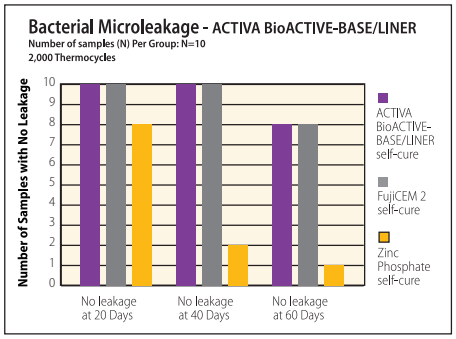
Bacterial Microleakage

ACTIVA BioACTIVE-RESTORATIVE outperforms a leading RMGI when tested for bacterial microleakage in vitro after 2,000 thermocycles.

ACTIVA BioACTIVE-BASE/LINER compares favorably with a leading resin modified glass ionomer material when tested for bacterial microleakage in vitro after 2,000 thermocycles.



Source: University testing.[3]
(see back page for trademark information)



Source: University testing.[2]

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