

INSTRUCTION FOR USE

BioActive 3D

(Next Generation Three Dimensional Bio Ceramic Root Canal Sealer with Strontium Glass)

COMPOSITION: Calcium Silicates (Dicalcium Silicate, Tricalcium Silicate, Tricalcium Aluminate), Calcium Hydroxide, Zirconium Oxide, Strontium Silicate Glass and Dispersing Agent.

PROPERTIES

BioActive 3D is a bioactive root canal sealer based on innovative mineral micro-aggregate chemistry "ActiveBiosilicateTechnology" that offers

- 1) Biocompatibility: high mineral purity and monomer free formulation reducing the risk of adverse tissue reaction
- 2) Bioactive properties: hydroxyapatite formation at the tooth-sealer interface and mineralization of dentinal structure
- 3) Alkaline pH
- 4) Sealing properties: crystallization of the material inside the dentin tubules creating a tight seal
- 5) Retreatable : if a retreatment is needed, BioActive 3D can be easily removed from the root canal
- 6) Strontium silicate base bio ceramic technology offers superior biocompatibility, Radiopacity and flowability.

INDICATION

Permanent root canal filling in combination with gutta-percha points in vital or necrotic pulp cases or after a retreatment procedure.

BioActive 3D is suitable for use in single, Multiple Gutta percha cone technique or cold lateral condensation.

SIDE EFFECTS

As far as all terms of storing, transporting and application are observed, there are no side effects

TECHNICAL INFORMATION

- Biocompatible Product ready for use.
- Setting time: 4.5 hours after insertion into the canal, at 95% RH, 37°C; Important: Dry with paper cones, but without excessively drying the canal; the moisture from the dentin tubes will initiate the material's setting reaction.
- Antibacterial and bacteriostatic due to its high alkalinity – pH:>12;
- High radiopacity: 8 mm of aluminum scale, according to the ISO 6876 standard.
- Does not suffer setting contraction.
- It can be used, in addition to conventional techniques, in single-cone techniques and thermoplastic filling.

USE TECHNIQUE

Use of Applicator Tips

1. Position the applicator tip in the syringe and perform the chemical decontamination of the assembly (tip +syringe)
2. We recommend using a disposable plastic cover on the syringe to avoid Cross-Contamination.
3. Confirm the material exists from the syringe before direct application to the canal.
4. Position the tip and syringe assembly properly into the canal and depress the plunger lightly to prevent excessive output of the product.
5. Before closing the syringe, retract the plunger to stop the outflow.
6. Clean any excess material on the tip of the syringe and close with appropriate pressure after use to prevent contact with moisture, which causes the product to dry.
7. Clean and disinfect the syringe in subsequent uses to avoid cross-contamination; in case of contamination with saliva or blood, discard it.

A. SEALING THE ROOT CANAL OF PERMANENT TEETH

Traditional technique – Lateral compression

1. Anesthetize, install absolute isolation and then perform the biomechanical preparation of root canal.
2. Remove the sealing tip and attach the applicator tip on the syringe.
3. Dry the canal only with absorbent paper cones without causing excessive dryness.
4. Apply BioActive 3D in the apical third of the canal directly with the syringe.
5. Insert the gutta percha cone in the canal according to the last file used covered with BioActive 3D.
6. X-ray for checking the correct filling of the canal.
7. Cut the cone at the desired height with heated instruments followed by vertical compression.
8. Remove excessive material with water from the canal walls, perform crown sealing and restoration.

Important:

- BioActive 3D can be used, in addition to conventional techniques, in single-cone technique and thermoplastic filling.
- Use conventional gutta removal techniques.

Single-cone technique

1. Anesthetize, install absolute isolation and then perform the biomechanical preparation of the canal.
2. Remove the sealing tip and attach the applicator tip to the syringe.
3. Dry the canal only with absorbent paper cones without causing excessive dryness.
4. Apply BioActive 3D in the apical third of the canal directly with the syringe.
5. Insert the gutta percha cone.
6. X-ray for checking the correct filling of the canal.

7. Cut the cone at the desired height with heated instruments followed by vertical compression.
8. Remove excessive material from the canal walls with suitable irrigating solutions for this purpose, perform crown sealing and restoration.

WARNING

-The sealer may cause sensitization in susceptible people. Do not use BioActive 3D in people allergies to any component of this product

-Avoid eye contact to prevent irritation. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention. Avoid skin contact to prevent possible allergic response. Unset material may cause irritation and therefore contact with skin and mucous membrane should be avoided. In case of contact, immediately remove material with cotton and wash thoroughly with water and soap. In case of skin sensitization or rash, discontinue the use and seek medical attention.

-Do not swallow or take it internally. If accidental swallowing occurs, drink lots of water. If nausea or illness develops, seek medical attention.

"Avoid overfilling. When overfilling occurs, the material is usually tolerated very well by the surrounding tissue. The material should be immediately removed in cases of extrusion in to the mandibular canal.

PRECAUTIONS

- Wear safety goggles, masks and gloves when handling the product.
- This product is intended to be used specifically outlined in the Instructions for use. Any use of this product inconsistent with the Instructions for use is at the discretion and sole responsibility of the practitioner. The solubility and essentially basic nature of BioActive 3D composition requires that it is used only in situations where it can be protected adequately from the intraoral environment.
- Use of a rubber dam is must before using product.
- Exposure to moisture and elevated temperature will affect the setting time and working time as well as the Consistency of the material.
- Pulling back the plunger will cause moisture in the air to entrap inside the syringe that may cause the premature setting of the material. Do not reuse the disposable syringe tips, to avoid potential cross contamination between the patients.

ADVERSE REACTION

Reversible acute inflammation of the oral mucosa may occur

INTERACTION WITH OTHER DENTAL MATERIALS

Unknown

CONTRAINDICATION

Drug idiosyncrasy,

In rare cases, this product may cause sensitization. In such cases, discontinue use and consult a physician.

Do not use it for purposes other than filling the root canal for dental purposes

Do not use on Patient with Hypersensitivity against calcium silicates or other components of the root canal filling material

PRESENTATION

Paste 3 gm in Syringe form	Ref. No. 004-09-003
Paste 2 gm in Syringe form	Ref. No. 004-09-002
Sample- BioActive 3D0.5g	Ref. No. 004-09-050S
Sample- BioActive 3D 1g	Ref. No. 004-09-001S

STORAGE

- Keep the product in a dry ventilated place between 5 and 30 C. Do not store it in a refrigerator.
- Do not store the product near ammonia, ammonium nitrate and products containing chlorine. Avoid using disinfectant solutions that contain any of these ingredients.
- Use absolute isolation in all indications, Dry the canal with paper cones, but without excessively drying the canal. The moisture from the dentin tubules will initiate the material's setting reaction
- Do not use BIOCERAMIC SEALER to fill canal without the gutta percha cones:
- The product is sensitive to moisture. So properly close the packaging with proper pressure to prevent dryness.
- Never store it in a refrigerator.
- Use the product only after controlling the infection, because at this stage the material's setting reaction does not occur due to the acidic pH in the area.
- Avoid causing excessive overflow of the product to the periapical region.
- After use, syringe must be kept inside aluminum self-seal pouch. material may harden inside due to its stringent hygroscopic nature, so proper storage protocol must be followed.

MANUFACTURER

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WARRANTY AND LIMITATION OF LIABILITY

- SafeEndo Dental India Pvt. Ltd. Will replace products that is proven to be defective. SafeEndo Dental India Pvt. Ltd. Does not accept the liability for any damage or loss, direct or consequential, stemming from the use of or inability to use the product described. Before using it, it is responsibility of user to determine the suitability of the product for its intended use. The user assumes all risks and liability in connection therewith.
- **Not For Medicinal use, For use in Dentistry By Dental Professional only**

