

KRIS BIO ACTIVE +

Bio Ceramic Root Canal Sealer

TECHNICAL & SAFETY INSTRUCTIONS FOR USE



COMPOSITION : Calcium Silicates, Calcium Aluminate, Calcium Hydroxide, Zirconium Oxide and Dispersing Agent.

PROPERTIES : Kris Bio Active+ is a bioactive mineral root canal sealer based on innovative mineral micro-aggregate chemistry "Active Biosilicate Technology" 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, Kris Bio Active+ can be easily removed from the root canal

INDICATION : Permanent root canal filling in combination with gutta-percha points in vital or necrotic pulp cases or after a retreatment procedure. Kris Bio Active+ is suitable for use in single cone technique or cold lateral condensation.

CONTRAINDICATION : Drug idiosyncrasy, Do not misuse

PRECAUTIONS : Wear safety goggles, mask and gloves when handling the product. In case of contact with eyes or skin. Wash with water:

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, according to ISO 6876; Important: Dry with paper cones, but without excessively drying the canal; the moisture from the dentin tubules will initiate the material's setting reaction; • Antibacterial and bacteriostatic due to its high alkalinity – pH:12.5; • 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 exits from the syringe before direct application to the channel; 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 Kris Bio Active+ 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 Kris Bio Active+; 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, with water, excessive material from the canal walls, perform crown sealing and restoration.

Important : • Kris Bio Active+ does not suffer setting contraction; • Kris Bio Active+ 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 on the syringe; 3. Dry the canal only with absorbent paper cones without causing excessive dryness; 4. Apply Kris Bio Active+ 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.

STORAGE : • Keep the product in a dry ventilated place between 15 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. • Product used exclusively by the dental surgeon. • Use absolute isolation in all indication:

- Do not use **Kris Bio Active+** 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: • 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. • 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. As far as all terms of storing, transporting and application are observed, there are no side effects

PRESENTATION : Paste 2 gm in Syringe.

SHELF LIFE : 3 years from the date of manufacturing.

Manufactured By :
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☒ Symbol for "BATCH CODE" ☒ Symbol for "USE BY" ⚠ Symbol for "NON STERILE" ☒ Symbol for "KEEP DRY" ☒ Symbol for "KEEP AWAY FROM SUNLIGHT" ☒ Symbol for "KEEP OUT OF THE REACH OF CHILDREN" ☒ Symbol for "MANUFACTURER NAME & ADDRESS" ☒ Symbol for "CONSULT INSTRUCTION FOR USE" ☒ Symbol for "CATALOGUE NUMBER" ☒ Symbol for "DO NOT USE IF PACKAGE IS DAMAGED" ☒ Symbol for "TEMPERATURE LIMITATION"

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding.