

ROOT X

Root Canal Sealer



TECHNICAL & SAFETY INSTRUCTIONS FOR USE

Product Description: ROOT-X is a zinc oxide-based root canal sealer intended for use in endodontic treatment. When mixed, it forms a smooth, workable paste that provides an effective seal between the root canal wall and the core filling material. The material exhibits good flow, adequate working time, excellent lubricating properties during obturation, antibacterial activity, and is designed to be non-irritating to periapical tissues when used as directed.

Intended Use: ROOT-X is intended for permanent sealing of root canals during endodontic treatment in combination with gutta-percha or other suitable root canal obturation materials.

Indications for Use: ROOT-X is indicated for: 1. Permanent sealing of prepared root canals during endodontic treatment. 2. Obturation of root canals in combination with gutta-percha. 3. Filling root canals with normal or complex anatomical morphology. 4. Endodontic treatment of teeth requiring root canal obturation following cleaning and shaping. 5. Sealing accessory canals and irregularities within the root canal system.

Contraindications: 1. Do not use in patients with known hypersensitivity or allergy to zinc oxide, eugenol (if applicable), or any component of the product. 2. Do not use in cases where adequate canal debridement and disinfection have not been completed. 3. Not intended for direct pulp capping.

Powder: Base matrix, radiopaque components, functional modifiers, and processing additives.; **Liquid:** Reactive liquid medium, plasticizing agents, and stabilizing agents

Directions for Use: 1. Complete cleaning, shaping, and irrigation of the root canal using standard endodontic procedures. 2. Dry the canal thoroughly using sterile paper points. 3. Dispense the required amount of powder and liquid onto a clean mixing pad or glass slab. 4. Mix the powder into the liquid gradually using a stainless-steel spatula until a smooth, homogeneous, creamy consistency is obtained. 5. Apply the mixed sealer into the prepared root canal using a lentulo spiral, file, paper point, or by coating the gutta-percha cone. 6. Insert the gutta-percha cone and complete obturation using the preferred endodontic technique. 7. Remove excess material from the pulp chamber and verify the obturation radiographically. 8. Seal the access cavity with an appropriate restorative material.

Mixing Ratio: Mix the powder and liquid according to the recommended consistency required for root canal obturation. Adjust slightly, if necessary, to obtain a smooth and workable paste.

Working Time: Approximately 4–8 minutes depending on ambient temperature and humidity.

Setting Time: Approximately 24 hours under clinical conditions.

Warnings: 1. For professional dental use only. 2. Avoid contact with skin, eyes, and oral soft tissues. 3. Do not ingest. 4. Use only after complete cleaning and drying of the root canal. 5. Do not use after the expiry date.

Precautions: 1. Use appropriate personal protective equipment (PPE). 2. Avoid contamination of the powder and liquid during dispensing. 3. Close containers immediately after use. 4. Use freshly mixed material for each patient. 5. Dispose of unused material according to local regulations.

Adverse Effects: In susceptible individuals, temporary irritation or allergic reactions may occur due to sensitivity to one or more ingredients. Discontinue use if hypersensitivity develops and provide appropriate treatment.

Storage Conditions: Store in a cool, dry place. Store at 10°C–30°C. Protect from direct sunlight and moisture. Keep containers tightly closed after use.

Packaging: 1 × 15 gm Powder, 1 × 8 ml Liquid, — REF No.: ED15-03

Shelf Life: 3 years from the date of manufacture.

Disposal: Dispose of unused material, empty containers, and contaminated accessories in accordance with local biomedical waste disposal regulations.

NOTE: TO BE USED BY DENTAL PROFESSIONALS ONLY.

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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 DAMAGE" ☐ 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.