

Prior to use carefully read the
Instruction For Use

Product Description:

Prime BioTemp is a ready-to-use bioceramic paste designed for use as an intracanal dressing prior to root canal filling. It is also suitable for cases involving perforation and both internal and external resorptions.

Delivery Form / Presentation:

- 1 x 3 gram syringe
- Capillary Tips x 5

Indication for Use:

Prime BioTemp belongs to the category of endodontic filling material, primarily composed of Calcium Silicates and radiopacifiers. It is intended for patients requiring endodontic procedures, serving as an intracanal dressing during endodontic treatment. Use as an intracanal dressing for endodontic treatments involving pulp necrosis, refractory lesions, retreatments, persistent fistulas, and excessive exudate. In cases of perforations and internal or external resorptions, prior to using Prime MTA Bioceramic sealer, Prime MTA BioPutty, or Prime MTA Packable. For apexification – to assist in root apex formation in cases of pulp necrosis.

CONTRAINDICATION

Do not use in patients with known sensitivity to any of the product's components.

COMPOSITION

Calcium silicates, Barium Sulphate & Paste forming agent

TECHNICAL INFORMATION

- High alkalinity.
- Sufficient radiopacity.

Important: As an intracanal dressing, Prime BioTemp is not meant to set within the root canal.

Precaution:

- The product is sensitive to moisture; ensure the syringe is capped when not in use, avoid drying out.
- Do not reuse applicator tips.
- Clean and disinfect the syringe for subsequent uses to prevent cross-contamination.
- Disinfect the applicator tip before use and dispose of it after use.
- Avoid excessive product extrusion into the periradicular area.
- Wear protective goggles, mask, and gloves when handling the product. If contact with eyes or skin occurs, rinse immediately with water.
- Do not use after the expiration date.
- Do not use if the packaging is damaged.
- Product not tested on pregnant women, breastfeeding mothers.
- The product should remain in the root canal temporarily (not exceeding 21 days).
- Keep out of reach of children.

Step by step instructions:

A. USE OF APPLICATOR TIPS

1. It is advisable to use a disposable plastic cover on the syringe to prevent cross-contamination.
2. Ensure material flows from the syringe before applying it directly to the canal.
3. Position the syringe and tip correctly in the canal and press the plunger gently to avoid excessive extrusion.
4. Before closing the syringe, retract the plunger to stop the flow.
5. Wipe any excess material from the syringe tip and close cap properly after use to prevent moisture from entering.
6. Clean and disinfect the syringe for future use. Discard if contaminated with saliva or blood.

B. INTRACANAL APPLICATION

1. Administer anesthesia, place a rubber dam for isolation, and perform biomechanical preparation of the canal. For internal resorption, use curettes to remove tissue.
2. Dry the canal using absorbent paper points.
3. Remove the cap and dispense the material from the syringe tip.
4. Attach the applicator tip to the syringe.
5. Insert the syringe tip near the root apex.
6. Apply Prime BioTemp by gradually retracting the syringe to ensure complete filling of the canal.
7. Remove any excess paste from the pulp chamber.
8. Perform coronal sealing and a temporary restoration according to the instructions for the materials used.
9. Take a radiograph to confirm proper canal filling.

Important: Prime BioTemp should not remain in the root canal for more than 21 days.

C. MATERIAL REMOVAL:

1. Administer anesthesia and place a rubber dam for isolation.
2. Remove Prime BioTemp using **Prime's Sodium Hypochlorite** along with a K-file in a filing motion against the canal walls.
3. Irrigate with **Prime's Dent Wash** [17% EDTA solution], and if possible, activate the solution with an ultrasonic tip, alternating with Sodium Hypochlorite in three cycles of 10 seconds each.
4. For intracanal dressing of teeth with pulp necrosis and retreatments, fill the canal with Prime Bioceramic Sealer, following the material's instructions for use.
5. In cases involving perforations or resorptions, apply Prime MTA Bioceramic Sealer, Prime MTA BioPutty, or another suitable repair material, following the respective instructions prior to obturation or dressing change.
6. Seal the coronal opening.
7. Take radiographs and conduct follow-up.

STORAGE

- Store in cool and dry.
- Do not Freeze.
- Keep the syringe properly closed with cap.

DISPOSAL METHOD

Dispose of the product according to national laws and local authority recommendations for proper disposal.

Note: The material has been developed for professional dental use and it is to be used by a dental professional only. Application should be carried out strictly according to the instruction for use. User is responsible for testing the material for its suitability. The manufacturer cannot be held liable for damages resulting from failure to observe the indication and procedure of use as mentioned in the instructions for use. The user should not use material for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding.