

Product Description

Prime MTA BioPutty is a ready-to-use, premixed bioceramic putty, designed for pulp capping, permanent root repair, and root canal obturation/filling. It is an insoluble, radiopaque material that will draw moisture from surrounding tissues set and harden. Material is highly alkaline and non-staining characteristic.

Composition

TriCalcium Silicate, DiCalcium Silicate, Radiopacifiers, Paste forming agents, Zirconium Oxide & Fillers.

Intended Use

- Root and pulp treatment material including:
- Pulp Capping direct as well as indirect.
 - Permanent Obturation of root canals
 - Repair of Root Perforation Furcal and lateral.
 - Repair of Root Resorption
 - Root End Filling / Retrograde Filling
 - Apexification & Apexogenesis
 - Cavity Base / liner

Instructions for Use

1. Before applying Prime MTA BioPutty, thoroughly prepare and irrigate the site using standard techniques. Keep root canal and dentinal surfaces moist.
2. Remove the syringe cap and gently extrude the material by compressing the plunger.
3. Using a sterile plastic instrument, remove the required amount of material and place it onto the application site.
4. Remove any excess material with an instrument. After each use, tightly reattach the syringe cap, clean the syringe.
5. Do not reuse dispensed material; once removed, material should not be put back in syringe.
6. The setting time of the putty depends on moisture in the dentin and will be delayed in a dry environment.

A. Pulp Capping (Indirect)

1. Isolate the tooth with a rubber dam, do not apply on soft tissue and complete cavity preparation.
2. Remove all infected carious tissue with a round bur at low speed or hand instruments.
3. Rinse the cavity surface and remove excess moisture with a dry cotton pellet.
4. Apply a Prime MTA BioPutty 1.5mm to the floor of the dentin and pack it onto sound dentin. Remove excess with a hand excavator or damp cotton pellet.
5. Cover Prime MTA BioPutty with a thin layer of glass ionomer cement [eg Prime Cem] extending onto the cavity walls, and proceed with restoration as per the manufacturer's instructions.

B. Pulp Capping (Direct)

1. Isolate the tooth with a rubber dam and complete cavity preparation.
2. Remove all infected carious tissue with a round bur at low speed or hand instruments.
3. Rinse the cavity and pulp exposure site. If bleeding occurs, achieve haemostasis using a cotton pellet dampened with haemostatic material (e.g., RetraGel, RetraLiquid Dent Retract) or sterile saline. Persistent haemorrhage after 10 minutes may indicate irreversible pulpitis, making vital pulp therapy with Prime MTA BioPutty unsuitable.
4. Apply Prime MTA BioPutty to the exposure site, packing it onto sound dentin. Remove excess with a hand excavator or damp cotton pellet.
5. Cover Prime MTA BioPutty with a thin layer of glass ionomer cement [e.g. Prime Cem] extending onto the cavity walls and continue with the restoration as per the manufacturer's instructions.

C. Repair of Root Perforation/Resorption

1. Isolate the tooth with a rubber dam. Debride and irrigate the root canal using appropriate instruments.
2. Place a calcium hydroxide-based dressing (e.g., RC Cal, RC Cal-I or RC Pex) in the canal and apply a temporary restoration for one week.
3. At the next visit, remove the calcium hydroxide paste and control moisture with paper points.
4. Obturate the canal space apical to the defect. Identify and apply Prime MTA BioPutty, compact the material gently to the perforation using suitable instruments. Seal the canal with a temporary restoration. Confirm placement with radiograph.
5. At the subsequent visit, check if the material has set. If not, remove and reapply Prime MTA BioPutty. If set, obturate the root canal to complete the treatment.

D. Root End filling / Retrograde Filling

1. Surgically Access the root end and resect 2 to 3 mm of the root apex with a surgical bur.
2. Prepare the root end cavity to a depth of 3-5 mm using an ultrasonic tip.
3. Isolate the area and control moisture with paper points, and manage hemorrhage as needed [eg. Retraliquid, Retragel or Dent retract], dry the area.
4. Apply Prime MTA BioPutty to the root-end cavity using a plastic instrument or other small carrier, compact the material.
5. Remove excess material and clean the root surface.
6. Verify the placement of Prime MTA BioPutty with an radiograph.
7. Close the surgical site.

E. Apexification

1. Isolate the tooth with a rubber dam. Debride and irrigate the root canal.
2. Place a calcium hydroxide-based dressing (e.g. RC Cal, RC Cal-I or RC Pex) in the canal and apply a temporary restoration for one week.
3. At the next visit, remove the calcium hydroxide paste, clean the canal, and irrigate and dry the canal.
4. Gently compact Prime MTA BioPutty in the apical region creating a 3-5 mm apical barrier.
5. Remove excess material and clean the root surface.
6. Once Prime MTA BioPutty is fully set, obturate the root canal to complete the treatment.
7. Confirm placement with a radiograph.
8. Place full coverage restoration following apexification.

Precautions

1. Do not use Prime MTA BioPutty on individuals allergic to calcium silicates or any other components.
2. Wear appropriate protective clothing, eyewear, and gloves. Avoid eye contact. In case of contact, rinse immediately with water and seek medical help. Avoid skin contact to prevent irritation; wash thoroughly if contact occurs. Discontinue use and seek medical attention for skin sensitization or rash.
3. Do not ingest. If swallowed, drink plenty of water and seek medical help if nausea or illness occurs. Overfilling should be avoided; if it happens, remove the material if it extrudes into vital structures.
4. Use as directed in the Instructions for Use. Any deviation is the sole responsibility of the practitioner.
5. While using Prime MTA BioPutty require isolation from the intraoral environment.
6. Use a rubber dam or adequate isolation for optimal results. A moist root canal/dentin is necessary for proper setting.
7. Increased humidity and temperature will reduce working and setting times.
8. Do not overfill root canals during obturation or apexification.
9. Prime MTA BioPutty is provided in clean, non-sterile packaging.

SIDE EFFECTS

When storage, transportation, and application instructions are followed, there are no known side effects. Direct contact with oral mucosa may cause ulcers due to its caustic nature.

Shelf Life and Storage

24 months from date of manufacturing under proper storage.

Store in a cool dry environment, away from sunlight. Do not freeze. Always close the syringe cap immediately after use to avoid contamination.

Do not use after the expiry date. To prevent hardening, recap immediately after each use

Presentation

Regular Pack: 1 x 2g Premixed Syringe,

Disposal Conditions

Dispose of according to local regulations.

Not for medicinal use. For dental use by dental professionals only.

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.