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## INSTRUCTION FOR USE

### Preva MTA Putty

#### (Bioceramic Root Repair Material)

Preva MTA Putty is a bioactive bioceramic, resin-free, ready-to-use material designed for use in endodontic and vital pulp therapy procedures. It consists of an extremely fine inorganic powder of tricalcium and dicalcium silicate dispersed in an organic medium. The material sets in vivo in the presence of moisture from surrounding tissues. No mixing is required.

#### COMPOSITION

Tricalcium Silicate, Dicalcium Silicate, Tricalcium Aluminate, Zirconium Oxide, Paste-forming agent

#### PROPERTIES

Bioactive bioceramic, Resin-free, Radiopaque

Does not discolor teeth

Working time at room temperature: >10 hours

Initial setting time at 37°C (moist environment): approximately 4–5 hours

Solubility: <4%

Dimensional stability: slight expansion (+0.05% to +0.10%)

#### INDICATIONS

- Vital Pulp Therapy
- Indirect pulp capping
- Direct pulp capping
- Partial pulpotomy
- Full pulpotomy
- Apexogenesis
- Cavity liner and base in deep or recurrent carious lesions
- Endodontic Procedures
- Root perforation repair
- Root resorption repair
- Apexification
- Retrograde (root-end) filling

It may also be used, when applicable, in combination with CeraBio RCS bioceramic sealer for complete endodontic obturation.

#### CONTRAINDICATIONS

- Known hypersensitivity to high pH (caustic) materials
- Patients with known idiosyncratic reactions to any component
- Do not misuse or use outside the intended indications

#### WARNINGS

- The unset material is alkaline (high pH) and may cause reversible irritation or inflammation of oral mucosa.
- Avoid direct contact of unset paste with soft tissues.
- If hemorrhage cannot be controlled within 10 minutes during vital pulp therapy, irreversible pulpitis may be present and this product may not be indicated.

- Close the syringe tightly after each use.
- Do not leave the syringe uncapped.
- Avoid contaminating the material. Do not use metal spatulas inside the syringe.

#### PRECAUTIONS

- Avoid contact of unset putty with skin or oral mucosa. In case of contact, rinse immediately with water.
- Wear protective gloves and eye protection during use.
- Keep syringe tightly sealed. Recap immediately after use.
- Store in the protective laminated pouch to prevent moisture intrusion.
- Do not overfill root canals during obturation or apexification.
- If syringe tips are used, always use a new tip for each patient/application.
- Avoid touching the syringe tip to contaminated surfaces.
- When used intraorally, cover the syringe body with a disposable protective sleeve.
- Supplied in clean, non-sterile packaging.

#### ADVERSE EFFECTS

- When stored and used according to instructions, no known systemic side effects are expected.
- Direct contact of unset paste with oral mucosa may cause irritation or ulceration due to its caustic nature.

#### INSTRUCTIONS FOR USE

##### A. DIRECT & INDIRECT PULP CAPPING, BASE & LINER

Note: For indirect pulp capping, base, or liner applications, proceed directly to Step (4).

1. Isolate the tooth using a rubber dam. Prepare the cavity using a high-speed bur.
2. Remove caries using a round bur at low speed or hand instruments.
3. Control hemorrhage using an appropriate hemostatic solution.

If bleeding persists after 10 minutes, reassess diagnosis.

4. Apply Preva MTA Putty to the exposed pulp or cavity floor using a suitable applicator. Maintain a minimum thickness of 1.5 mm.
5. Remove excess material with a cotton pellet slightly moistened with sterile water or saline.
6. Restore immediately with light-cured composite, glass ionomer, RMGI, compomer, luting cement, or crown. A flowable composite, RMGI, ZOE, or similar material may be placed as an intermediate layer before final restoration.
7. Monitor pulp vitality clinically and radiographically.

##### B. PULPOTOMY & APEXOGENESIS

1. Isolate with rubber dam and prepare the cavity.
  2. Remove all carious tissue.
- In multi-rooted teeth: Remove the coronal pulp to the level of the canal orifices (at or slightly below

the cemento-enamel junction).

- In single-rooted teeth: Remove the coronal pulp tissue to the canal orifice level.
  1. Achieve hemostasis (e.g., using Preva Hemostatic Solution).
  - If bleeding persists after 10 minutes, consider full pulpectomy.
  2. Apply Preva MTA Putty over the pulp tissue (minimum thickness 1.5 mm).
  3. Remove excess material with a moist cotton pellet.
  4. Restore immediately as described above.
  5. Confirm treatment with radiograph and follow up clinically.

##### C. PERFORATION REPAIR & ROOT RESORPTION

1. Isolate with rubber dam. Debride, clean, and shape the canal system.
2. Irrigate using PrevaSol, NaOCl (1.35–5.25%), or PrevaHex solution.
3. Isolate the defect site.
4. Obturate the canal space apical to the defect.
5. Place Preva MTA Putty into the defect using an appropriate carrier.
6. Gently compact with a small plugger, cotton pellet, or paper point.
7. Confirm placement radiographically.
8. Remove excess material with a moist cotton pellet.
9. Obliterate the remaining canal space and seal coronally.

##### D. APEXIFICATION

1. After cleaning and shaping, dry canals with paper points (do not extend beyond open apex).
2. Place and gently compact 3–5 mm of Preva MTA Putty in the apical region to create an apical barrier.
3. Confirm radiographically.
4. Obliterate the remaining canal space.
5. Place a full-coverage restoration as indicated.

##### E. RETROGRADE (ROOT END) FILLING

1. Surgically access and resect 2–4 mm of the root apex.
2. Prepare a 3–5 mm deep Class I root-end cavity using ultrasonic tips.
3. Achieve hemostasis and dry the site.
4. Place and gently compact Preva MTA Putty into the cavity using a plastic instrument or suitable carrier.
5. Remove excess material with a moist cotton pellet.
6. Rinse gently.
7. Confirm placement radiographically.
8. Close the surgical site.

##### PRESENTATION

Ref. No.: PL-0327- Preva MTA Putty – 2 × 0.50 g syringes

##### STORAGE

- Store between 5°C and 25°C.
- Keep in a dry place.
- Store syringe in the protective laminated pouch.

- Recap immediately after each use to prevent hardening.
- Do not use after the expiry date.

#### SHELF LIFE

3 years from the date of manufacture.

#### DISPOSAL

Dispose of product and packaging according to local regulations for dental and medical waste.

#### CONTACT

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Failure to comply with the specified storage conditions may alter the working characteristics of the material and reduce its shelf life.

The manufacturer is not responsible for any loss of quality resulting from non-compliance with the specified conditions for transportation, storage, and use of this product. The user assumes full responsibility for using the material for any purposes other than those specified by the manufacturer. This material is intended solely for professional dental use. Application must be carried out strictly according to the instructions for use. The manufacturer accepts no liability for damages resulting from failure to follow the provided instructions or for use beyond the stipulated applications. The user is responsible for assessing the material's suitability for any purpose not explicitly stated in this instruction sheet. The descriptions and data provided do not constitute a warranty of attributes and are not legally binding.

**This product is specially formulated for use in dentistry and to be used by qualified dental personnel**

Symbol for "TEMPERATURE LIMITATION"

Symbol for "KEEP OUT OF THE REACH OF CHILDREN"

Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"

Symbol for "KEEP AWAY FROM SUNLIGHT"

Symbol for "MANUFACTURER NAME & ADDRESS"

Symbol for "CONSULT INSTRUCTION FOR USE"

Symbol for "CATALOGUE NUMBER"

Symbol for "MEDICAL DEVICE" Symbol for "KEEP DRY"

Symbol for "NON STERILE" Symbol for "USE BY"

Symbol for "BATCH CODE" Symbol for "CAUTION"

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