

# MTA ROOT-X PRO

## Advanced Root Repair Material

### TECHNICAL & SAFETY INSTRUCTIONS FOR USE



**Product Description :** MTA Root-X Pro is a powder & gel system consisting of an extremely fine, inorganic powder of Tri-calcium and Di calcium Silicate, which sets with water or gel. The powder is supplied in a protective desiccant-lined container for freshness.

**Composition :** Powder consists of mixture of Calcium Oxide, Silicon Oxide, Bismuth Oxide and Gel in hydrated polymer gel.

**Indications :** Dental procedures that contact vital pulp tissue such as : • Pulp capping, • Cavity lining, • Pulpotomies. Dental procedures that contact the periodontal tissues such as : • Root-end filling, • Apexification, • Perforation repair, • Root resorption, • Sealing, or • Obturation (pulpotomy).

**Contraindications :** Hypersensitivity against caustic (high pH) solutions.

**Warning :** MTA Root-X Pro powder is caustic, as are all calcium silicates.

**Precaution :** ♦ AVOID contact of unset mixed paste with skin or oral mucosa. After incidental contact, wash and rinse with water. Wear suitable gloves and protective glasses during use. ♦ MTA Root-X Pro powder and gel must be kept well sealed. ♦ Protect the powder from humidity. Close the container. ♦ Do not contaminate the powder with an unclean or moist instrument. ♦ Do not overfill the root canals when obturating or sealing.

**ADVERSE REACTIONS :** Reversible acute inflammation of the oral mucosa if contacted with the unset paste.

**INTERACTIONS WITH OTHER DENTAL MATERIALS :** Unknown

**STEP-BY-STEP INSTRUCTIONS : Dosage and Mixing :** a) Dispense 1 scoop of powder on a glass slab or a nonabsorbent pad. b) Dispense one small drop of gel, OR some of the MTA Root-X Pro Liquid from 1 ampoule next to the powder. **NOTE :** The gelparts washout resistance (for easier rinsing) and faster setting, which the water does not. **NOTE :** MTA Root-X Pro Liquid ampoules are larger than unit-dose size. c) Gradually mix the liquid or gel into the powder until the desired putty like consistency is obtained. For some procedures, a thinner syrupy, stringy consistency may be desired. Thoroughly mix to hydrate the powder. d) If the material is not to be used immediately, cover the mixed material with a moist gauze sponge (use sterile water), or a clean cover to prevent evaporation. Extra gel or MTA Root-X Pro liquid may be used to rewet the powder before it sets. ♦ Setting Time at 37°C : < 1 hr. when thickly mixed with gel. ♦ Film thickness < 50 µm when mixed 1:1 Powder:Gel, otherwise higher. ♦ Solubility < 2%. ♦ Dimensional stability after 30 days < +0.1% expansion. ♦ Radiopacity : 5 mm equivalent of aluminum. ♦ Compressive strength 80MPa after 7 days when mixed 3:1 Powder : Gel. ♦ Pb and As : < 2 ppm This material has been developed for professional dental use. Application should be carried out strictly according to the directions for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of application. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Descriptions and data constitute no warranty of attributes and are not binding.

#### DETAILED PROCEDURAL DIRECTIONS FOR USE :1. PULP CAPPING, PULPOTOMY or CAVITY LINER/BASE :

a. Complete a cavity preparation outline under rubber dam isolation, using a high-speed bur and constant water-cooling. b. Excavate all carious tooth structure using a round bur in a hand piece at low speed, or use hand instruments. **For a pulpotomy :** Remove the roof of the pulp chamber and all remnants of coronal pulp tissue to the level of the orifice of each root canal in multi-rooted teeth. In single-rooted teeth, remove the pulp to the level of the cemento-enamel junction or slightly below this level. **For a pulp exposure or pulpotomy :** Gently rinse the exposure with a saline solution. Control hemorrhage with pressure on the exposure using a cotton pellet moistened with saline, a dilute solution of NaOCl (0.5-1.0%), or a mild hemostatic agent. **For a base/liner, pulp exposure or pulpotomy :** Wipe the cavity preparation with a chlorhexidine solution. Use a small applicator to apply mixed MTA Root-X Pro material on the pulp exposure, or over the floor of the cavity preparation. Remove excess material at the site with a dry cotton pellet. Rinse gently Place a composite material or a glass ionomer restorative material over the MTA Root-X Pro material. The glass ionomer should be an interim restoration prior to a placement of a final composite or other restorative material. Assess the pulp vitality at three-month intervals or as needed and confirm with a radiograph.

#### 2. ROOT-APEXIFICATION or RESORPTION or PERFORATIONS :

A. Debride, clean, and shape the root canal system using intracanal instruments under rubber dam isolation.

b. Rinse the root canal with a NaOCl solution (3.0 to 6.0%). **For root apexification :** Dry the canal system with paper points, being careful not to extend the points beyond a wide-open apex. Gently compact MTA Root-X Pro in the apical region, to create a 3 to 5 mm apical barrier. Confirm placement with a radiograph. Rinse gently. Apply about 2 mm of a glass ionomer, acid etch, and place composite. **For resorption or perforations :** Isolate the restorative defect site or iatrogenic perforation. Obtrurate the canal space apical to the defect. Dispense the MTA Root-X Pro material into the defect site. Gently compact the MTA Root-X Pro material using a small amalgam plunger, cotton pellets or paper points. Confirm the placement with a radiograph. Rinse gently. When the MTA Root-X Pro material is firm (a few minutes), obturate the remaining canal space and close the coronal access as you do normally.

**3. ROOT-END FILLING :** a. Surgically access the root-end and resect 2-4 mm of the root apex using a surgical bur. b. Prepare a Class I root-end cavity preparation 3 to 5 mm deep with an ultrasonic tip. c. Isolate the area and achieve hemostasis. Dry the area. d. Gently compress the MTA Root-X Pro material into the root-end cavity using a "plastic" instrument or other small carrier. e. Remove excess material and clean the root tip with a slightly moist cotton pellet. f. Rinse gently. g. Confirm placement with a radiograph. h. Close the surgical site.

**4. SEALING & OBTURATION OF ROOT CANALS :** DO NOT overfill the root canals! When a large amount of material is overfilled in the mandibular canal (inferior alveolar canal), immediate surgical removal of the material should be considered, as with all root canal materials, according to state-of-the-art policy. a. Debride, clean and shape the root canal system using intracanal instruments under rubber dam solution. b. Rinse the root canal with a NaOCl solution (3.0 to 6.0%). c. Dry the canal system with paper points. d. For complete obturation, gently compact the MTA Root-X Pro material into the canals and ensure placement with a radiograph. e. For filling techniques where most of the canal is obturated by endodontic point material, and apply a light coating of MTA Root-X Pro material (mixed with the gel to a syrupy, stringy consistency) to the canal walls. AVOID the formation of air bubbles in the material. DO NOT use a pumping action. AVOID overfilling of the canal. MINIMIZE over extension of the material beyond the apex. f. Coat the disinfected and dried obturation points with the MTA Root-X Pro material and insert them in the Canal. g. Confirm placement of the material in the complete root canal system with a radiograph.

**Storage Conditions :** Store at temperature between 10°C to 24°C. Close the cap carefully after use.

Keep away from moisture. Shelf life not affected after opening if stored in a cool dry place.

**Warning :** Avoid prolonged or repeated contact with skin (allergic contact dermatitis), and eyes. Avoid prolonged inhalation. Do not take it internally. Contact with the skin may cause irritation, burns of hypersensitivity. If contact with skin occurs immediately wipe off thoroughly with cotton and alcohol and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs discontinue use and seek medical attention. If the product comes into contact with the eyes, rinse thoroughly with fresh water and consult a physician. It should not be used with patients who have a history of severe allergic reaction to any of the components.

**Presentation :** 1 x 1 gm, 1 x 2 ml RefNo. ED16-03

**Shelf Life :** 3 Years from date of manufacturing

**NOTE :** For removal of Root Canal Fillings, if MTA Root-X Pro material is used with gutta-percha points, the root canal fillings can be removed using standard mechanical techniques for the removal of gutta-percha. If only MTA Root-X Pro material is used for

**NOTE: TO BE USED BY DENTAL PROFESSIONAL ONLY**

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**LOT** Symbol for "BATCH CODE" **U** Symbol for "USE BY" **NS** Symbol for "NON STERILE" **KD** Symbol for "KEEP DRY" **CA** Symbol for "CAUTION"  
**EEPC** SYMBOL FOR EUROPEAN COMMUNITY AUTHORIZED REPRESENTATIVE **KA** Symbol for "KEEP AWAY FROM SUNLIGHT"  
**K** Symbol for "KEEP OUT OF THE REACH OF CHILDREN" **M** Symbol for "MANUFACTURER NAME & ADDRESS" **C** Symbol for "CONSULT INSTRUCTION FOR USE" **REF** Symbol for "CATALOGUE NUMBER" **DN** Symbol for "DO NOT USE, IF PACKAGE IS DAMAGED"  
**T** 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.