

ProRoot® MTA

(Mineral Trioxide Aggregate)

Root canal repair material

RX ONLY
DENTAL USE ONLY

DIRECTIONS FOR USE PROROOT® MTA

1) INDICATIONS FOR USE

ProRoot® MTA root repair material is indicated for use as:

- A root-end filling material;
- For the repair of root canals as an apical plug during apexification;
- For repair of root perforations during root canal therapy;
- As a consequence of internal resorption;
- As a pulp capping material;
- Pulpotomy of primary teeth in the child (ages >2-12 years) and adolescent (ages >12-21 years) pediatric patient populations.

2) CONTRAINDICATIONS

None known.

3) WARNINGS

ProRoot® MTA root repair material is a powder consisting of fine, hydrophilic particles that set in the presence of moisture. Hydration of the powder creates a colloidal gel that solidifies to form a strong impermeable barrier that fully cures over a four-week period.

4) PRECAUTIONS

- ProRoot® MTA root repair material must be stored in a dry area to avoid degradation by moisture.
- ProRoot® MTA root repair material must be kept in its sealed packaging prior to use to avoid degradation by moisture.
- ProRoot® MTA root repair material must be placed intra-orally immediately after mixing with liquid, to prevent dehydration during setting.

- When using ProRoot® MTA in an aesthetic zone, the clinician should consider the procedure being performed, the surface area exposed and the other restorative materials being used to achieve best results.
- Avoid skin contact to prevent irritation and possible allergic response. If contact with skin occurs, immediately remove material with cotton and wash thoroughly with water and soap. In case of skin sensitization or rash, discontinue use and seek medical attention.

5) ADVERSE REACTIONS

In the present technical state, no adverse reaction has been reported so far.

6) STEP BY STEP INSTRUCTIONS

6.1) ProRoot® MTA root repair material mixing instructions

Note:

ProRoot® MTA root repair material does not set as quickly as other cements. Careful mixing will make the material easier to handle.

- 1) Open a pouch of ProRoot® MTA root repair material and dispense the powder onto a mixing pad.
- 2) Pull off the end of a ProRoot® liquid micro-dose ampoule and squeeze out contents onto the mixing pad next to the root repair material.
- 3) Incorporate the liquid into the cement gradually using the ProRoot® MTA mixing stick.
- 4) Mix the material with the liquid for about one minute to ensure all the powder particles are hydrated.
- 5) One extra ampoule is provided or if needed, USP purified water or better can also be used. Discard the remaining liquid.

Note:

- 1) Adding too much, or too little liquid will reduce the ultimate strength of the material.
- 2) The ProRoot® MTA root repair material will set over a period of three hours.
- 3) Once mixed, evaporation of water from ProRoot® MTA affects handling. If more working time is needed, cover the mixed material with a moist gauze pad to prevent evaporation.

6.2) Repair of perforations secondary to internal resorption

- 1) Debride the root canal system under dental dam isolation using intracanal instruments and irrigate with NaOCl. Place calcium hydroxide paste in the root canal system for one week for disinfection.
- 2) Place a temporary restoration to seal the access opening.
- 3) After one week, isolate the tooth with a dental dam, remove the CaOH₂ from the canal system using NaOCl irrigation and then instrument as needed.
- 4) Dry the canals with paper points and identify the resorptive defect site.
- 5) Obturate all the canal space apical to the defect.
- 6) **PREPARE THE PROROOT® MTA ROOT REPAIR MATERIAL ACCORDING TO THE MIXING INSTRUCTIONS PROVIDED.**
- 7) Dispense the material using a carrier into the resorptive defect site. Compact the ProRoot® MTA root repair material into the cavity using a small amalgam plugger, cotton pellets or paper points.

- 8) Confirm the placement of ProRoot® MTA root repair material with a radiograph. If an adequate barrier has not been created, rinse the ProRoot® MTA root repair material out of the defect and repeat the procedure.
- 9) Remove excess moisture from a moistened pellet and place it in the canal. Seal the access preparation with a temporary restoration for a minimum of four hours.
- 10) Examine the ProRoot® MTA root repair material under dental dam isolation after four hours, or at another appointment, This material should be hard. If not, rinse and repeat the application.
- 11) Obturate the remaining canal space when the ProRoot® MTA root repair material is hardened, The ProRoot® MTA root repair material remains as a permanent part of the root canal filling.

6.3) Internal repair of iatrogenic perforations

- 1) Debride the root canal system under dental dam isolation using intra-canal instruments, and irrigate with NaOCl.
- 2) Dry the canal system with paper points and isolate the perforation.
- 3) Obturate all the canal space, apical to the perforation.
- 4) **PREPARE THE PROROOT® MTA ROOT REPAIR MATERIAL ACCORDING TO THE MIXING INSTRUCTIONS PROVIDED.**
- 5) Dispense the material using a carrier into the perforation site. Compact the ProRoot® MTA root repair material into the perforation site using a small plugger, cotton pellets or paper points.
- 6) Confirm placement of the ProRoot® MTA root repair material with a radiograph. If an adequate barrier has not been created, rinse the ProRoot® MTA root repair material out of the canal and repeat the procedure.
- 7) Remove excess moisture from a wet cotton pellet and place it in the canal. Seal the access preparation with a temporary restoration for a minimum of four hours.
- 8) Examine the ProRoot® MTA root repair material under dental dam isolation, after four hours, or at another appointment, This cement should be hard. If not, rinse and repeat the application.
- 9) Obturate the remaining canal space when the ProRoot® MTA root repair material is hardened. The ProRoot® MTA root repair material remains as a permanent part of the root canal filling.

6.4) Root apexification

- 1) Debride the root canal system, under dental dam isolation, using intra-canal instruments, and irrigate with NaOCl.
- 2) Dry the canal system with paper points and for disinfection place calcium hydroxide paste in the root canal system for one week. Place a temporary restoration to seal the access opening.
- 3) After one week, isolate the tooth with a dental dam, remove the CaOH₂ from the canal system using NaOCl irrigation and then instrument as needed. Dry the canal(s) with paper points.
- 4) **PREPARE THE PROROOT® MTA ROOT REPAIR MATERIAL ACCORDING TO THE MIXING INSTRUCTIONS PROVIDED.**
- 5) Dispense the material using a carrier into the root canal. Compact the ProRoot® MTA root repair material using a small plugger, cotton pellets or paper points. Establish a three to five millimeter apical barrier of ProRoot® MTA root repair material.
- 6) Confirm placement of the ProRoot® MTA root repair material with a radiograph. If an adequate barrier has not been created, rinse the ProRoot® MTA root repair material out of the canal and repeat the procedure.
- 7) Remove excess moisture from a moistened pellet and place it in the canal. Seal the access preparation with a temporary restoration for a minimum of four hours.

- 8) Examine the ProRoot® MTA root repair material under dental dam isolation, after four hours, or at another appointment. This material should be hard. If not, rinse and repeat the application.
- 9) Obturate the remaining canal space when the ProRoot® MTA root repair material is hardened. The ProRoot® MTA root repair material remains as a permanent part of the root canal filling.

6.5) Root-end filling

- 1) Gain access to the root-end and resect the root with a surgical bur.
- 2) Prepare a class I root-end cavity preparation using an ultrasonic tip to the depth of three to five millimeters.
- 3) Isolate the area. Dry the root-end cavity with paper points. Achieve with an ultrasonic tip hemostasis with CollaPlug®, or similar material.
- 4) **PREPARE THE PROROOT® MTA ROOT REPAIR MATERIAL ACCORDING TO THE MIXING INSTRUCTIONS PROVIDED.**
- 5) Dispense the material into the root-end cavity using a carrier. Compact the ProRoot® MTA root repair material into the cavity using a small plugger.
- 6) Remove excess cement and clean the surface of the root with a moist piece of gauze or Telfa®.
- 7) Confirm placement of the ProRoot® MTA root repair material with a radiograph. The ProRoot® MTA root repair material remains as a permanent part of the root canal filling.

6.6) Pulp capping







- 1) Complete a cavity preparation outline under dental dam isolation, using high-speed burs, under constant water cooling.
- 2) Excavate any carious tooth structure using a round bur in a hand piece at low speed or use hand instruments.
- 3) Rinse the cavity and exposure site(s) with 2.6% - 5% NaOCl. Heavy bleeding may be controlled with a cotton pellet moistened with NaOCl.
- 4) **PREPARE PROROOT® MTA ACCORDING TO MIXING INSTRUCTIONS PROVIDED.**
- 5) Apply a small amount of ProRoot® MTA over the exposure using a small ball applicator, or similar device.
- 6) Remove the excess moisture at the site with a dry cotton pellet.
- 7) Apply a small amount of Dyract Flow™ flowable compomer (or an equivalent light-cured resin, glass-ionomer liner) to cover the ProRoot® MTA material, and light cure according to its instructions.
- 8) Etch the remaining cavity walls with 34% - 37% phosphoric acid gel for 15 seconds. Rinse thoroughly.
- 9) Dry the cavity gently, leaving the dentin moist, but not wet. Apply Prime & Bond NT material, or an equivalent bonding material. Cure according to its instructions.
- 10) Place TPH Spectrum composite material or an equivalent composite resin to complete the restoration. Cure according to its instructions.
- 11) Assess the pulp sensibility (responsiveness to tests) every 6 months and evaluate the tooth radiographically every three to six months or as needed.

6.7) Pulpotomy of primary teeth within the pediatric patient population

- 1) When pulpotomy is indicated for primary teeth by clinical and radiographic signs and symptoms, the specific tooth and adjacent area should be properly anesthetized and dental dam isolation secured.

- 2) Remove the decay completely prior to pulpal access using a high-speed handpiece and a carbide bur* with water coolant.
- 3) Remove the roof of the chamber through de-roofing followed by removal of over-hang structure to straighten the dentin walls of the chamber allowing direct access to the pulp tissue.
- 4) Use a slow-speed handpiece or spoon excavator with a medium or large round bur to remove the bulk of coronal pulp tissue.
- 5) Achieve hemostasis with direct pressure on sterile cotton pellets in contact with the radicular pulp orifice(s).
- 6) Prepare ProRoot® MTA by mixing the MTA powder with sterile saline on a clean glass slab using a metal mixing spatula. Apply 3:1 powder/saline ratio according to the manufacturer's recommendations in order to obtain a putty consistency.
- 7) Remove excess moisture on the surface of the MTA mix with a sterile cotton pellet.
- 8) Use an amalgam carrier to deliver the MTA mix onto the pulp stumps and chamber floor then compact the mix lightly with a slightly moistened sterile cotton pellet to ensure an even coverage of 3- to 4-mm thickness.
- 9) Fill the pulp chamber with a restorative material such as glass ionomer liner or compomer; the tooth is then prepared coronally, a SSC is fitted and occlusion checked if required.
- 10) Cement the SSC and double check the occlusion. A postprocedure periapical radiograph should be taken as a baseline record if required.
- 11) Evaluate the pulpotomized tooth clinically and radiographically at each 6-month recall examination.

*The type of bur should be selected based on the size of the tooth receiving the pulpotomy procedure. For example, a no. 330 carbide bur is suitable for pulpotomy of a primary molar tooth.

Symbols	EN
	Consult instructions for use
	Store in a cool dry place
	For single use only
	Opened packages are not replaced
	Manufacturer
	Expiry date

Made in USA

EC	REP
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