

Grey MTA Plus[®]

ROOT & PULP TREATMENT MATERIAL

DIRECTIONS FOR USE

For MSDS go to

<http://avalonbiomed.com/product-info/>

For other languages, go to:

<http://avalonbiomed.com/product-info/>

Grey MTA Plus ROOT & PULP TREATMENT MATERIAL

is a powder & gel system consisting of an extremely fine, radiopaque, inorganic powder of tricalcium and dicalcium silicate, which sets with the included water-based MTA Plus gel, or water.

The powder is supplied in a protective, desiccant-lined container for freshness. All components of Grey MTA Plus are manufactured in the USA or EU.

Caution: US Federal law restricts this device to the sale by or on the order of a dentist. For professional dental use only.

INDICATIONS: Grey MTA Plus ROOT AND PULP TREATMENT MATERIAL is intended for use in dental procedures that contact pulp and periradicular tissues, as well as obturation and sealing of root canals.

Dental procedures contacting vital pulp tissue are:

- Pulpotomies,
- Pulp capping,
- Cavity lining, or
- Base beneath a filling material.

Dental procedures possibly contacting the periradicular tissues are:

- Root-end filling,
- Apexification,
- Perforation repair,
- Root resorption,
- Sealing, or
- Obturation (pulpectomy).

CONTRAINDICATIONS:

- Hypersensitivity against caustic (high pH) solutions.
- Do not use for primary tooth pulpectomy (root canal filling treatment).

WARNINGS: Grey MTA Plus powder is alkaline, as are all tricalcium silicates.

PRECAUTIONS:

- o 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.
- o Grey MTA Plus powder and gel must be kept well sealed.
- o PROTECT the powder from humidity. Close the container.
- o DO NOT contaminate the powder or gel with an unclean or moist instrument.
- o 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: None known.

STORAGE: Store at room temperature (25°C/75°F); do not refrigerate. Keep bottles tightly closed. Moisture will reduce the shelf life of the powder. Exposure of the gel will cause drying and possibly formation of a film at the tip.

ADA 57, ISO 6876 and ISO 9917 criteria-

- o Working Time at room temperature: ~10 min when thickly mixed with gel; however, addition of more gel may extend the working time if the mixture begins to dry.
- o Initial Setting Time at 37°C: ~15 min when thickly mixed with gel; otherwise longer for sealer (~3 hr.)
- o Flow: 25-29 mm when mixed 1:1 Powder:Gel, otherwise less.
- o Film thickness: <50 µm when mixed 1:1 Powder:Gel, otherwise larger.
- o Solubility: <3%.
- o Dimensional stability after 30 days: <+0.01% expansion.
- o Radiopacity: 5 mm equivalent of aluminum.
- o Compressive strength: 80 MPa after 7 days when mixed 3:1 Powder:Gel.
- o Pb and As: < 2 ppm.
- o Washout resistant within 3 min.

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.

STEP-BY-STEP INSTRUCTIONS:

Dosage and Mixing:

See mixing video. Go to:

<http://avalonbiomed.com/videos/>

a) Dispense 1 scoop (about 0.10 gm) of Grey MTA Plus powder on a glass slab. Split the powder into 2.

b) Dispense one small drop of Grey MTA Plus Gel.

NOTE: The gel imparts washout resistance (for easier rinsing) and faster setting, which water does not.

c) Gradually mix the gel into ½ of the powder until the desired putty-like consistency is obtained.

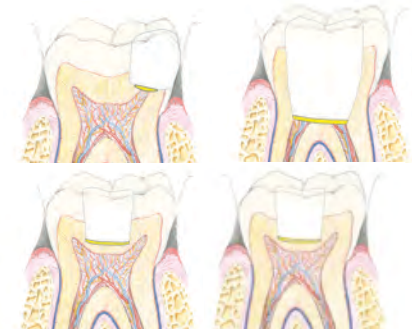
If used for some procedures, a thinner, syrupy, stringy consistency may be desired. Thoroughly mix to hydrate the powder.

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 may be used to rewet the powder before it sets.

DETAILED PROCEDURAL DIRECTIONS FOR USE

Grey MTA Plus material is yellow in the drawings.

1. PULP CAPPING, PULPOTOMY or CAVITY LINER/BASE:



- Complete a cavity preparation outline under rubber dam isolation, using a high-speed bur and constant water-cooling.
- Excavate all carious tooth structure using a round bur in a hand piece at low speed, or use hand instruments.
- Gently rinse the exposed pulp with a NaOCl solution.
- Control hemorrhage with a cotton pellet soaked in 5.25-8.0% NaOCl for as long as 10 minutes.
- If hemorrhaging is still present after 10 minutes, diagnosis is irreversible pulpitis and a full pulpotomy is performed (or the pulp is extirpated).

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.
- Gently rinse the exposed pulp with a NaOCl solution.
- Control hemorrhage with cotton pellet soaked in 5.25-8.0% NaOCl for 5-10 minutes.

NOTE: Ensure that hemostasis is achieved.

For a base, cavity liner, pulp exposure or pulpotomy:

- Disinfect the cavity preparation with NaOCl or chlorhexidine solution.
- Gently wash the cavity preparation with water from a two-way air-water syringe, and gently dry the preparation with air.
- Use a small applicator of your choice to apply mixed Grey MTA Plus material on the exposed pulp and the surrounding dentin or over the floor of the cavity preparation at a minimum thickness of 1.5 mm.
- Remove excess material at the site with a damp cotton pellet. Rinse gently.
- Place a composite material or a glass ionomer restorative material over the Grey MTA Plus 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:



1. Debride, clean, and shape the root canal system using intra-canal instruments under rubber dam isolation.
2. Rinse the root canal with a NaOCl solution (3.0 to 6.0%).

For root apexification:

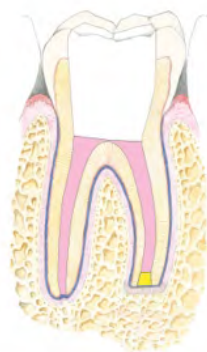
- Dry the canal system with paper points, being careful not to extend the points beyond a wide-open apex.
- Gently compact Grey MTA Plus in the apical region, to create a 3 to 5 mm apical barrier.
- Confirm placement with a radiograph.
- Rinse gently.
- Apply about 2 mm of a glass ionomer, acid-etch, and place a composite.

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.

For resorption or perforations:

- Isolate the resorptive defect site or perforation.
- Obturate the canal space apical to the defect with MTA Plus, or with sealer and gutta percha.
- Dispense the Grey MTA Plus material into the defect site.
- Gently compact the mixed Grey MTA Plus material using a small amalgam plugger, cotton pellets or paper points.
- Confirm the placement with a radiograph.
- Rinse gently.
- When the Grey MTA Plus 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 3-4 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 mixed Grey MTA Plus material into the root-end cavity using a "plastic" instrument or other small carrier.
- e. Remove excess material and clean the resected root surface with a slightly moist cotton pellet.
- f. Rinse gently.
- g. Confirm placement with a radiograph.
- h. Close the surgical site.

4. OBTURATION/SEALING 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 intra-canal instruments under rubber dam isolation and NaOCl.
- b. After completed canal preparation, rinse the root canal with a NaOCl solution (3.0 to 6.0%)
- c. Remove the smear layer with EDTA (15-17% for 60 sec).
- d. If desired, perform a final disinfection with, for instance, 2% chlorhexidine rinse for 60 sec.
- e. Dry the canal system with paper points.
- f. For complete obturation, gently compact the Grey MTA Plus material into the canals and ensure placement with a radiograph.
- g. For filling techniques where most of the canal is obturated by endodontic point material, apply a light coating of Grey MTA Plus 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 overextension of the material beyond the apex.
- h. Coat the disinfected and dried obturation points with the Grey MTA Plus material and insert them into the canal.
- i. Confirm placement of the material in the complete root canal system with a radiograph.

NOTE: For removal of Root Canal Fillings, if Grey MTA Plus 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 Grey MTA Plus material is used for obturation, use ultrasonic instruments.



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R ⓘ ☂ CE 0297
Prescription only.
Follow instructions for use.
Keep powder dry.