MTA Plus

PREVESTDenPro®
THE FUTURE OF DENTISTRY

VITAL PULP THERAPY &
ROOT TREATMENT MATERIAL

Product Description : MTA Plus 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 Silicates, Radiopacifiers and modifiers. The gel comprises of hydrated polymer gel.

Intended Purpose / Intended Use : It is intended to be used in root filling, repair of root perforations, pulp capping and apexification.

Indications for Use :
Dental procedures that contact vital pulp tissue such as :
- Pulp capping,
- Cavity liner/Base
- Pulpotomies.

Dental procedures that contact the periradicular tissues such as :
- Root-end filling,
- Apexification,
- Perforation repair,
- Root resorption,
- Sealing, or
- Obturation (pulpectomy).

Instructions for Use :
Dosage and Mixing :
a) Dispense 1 scoop of powder on a glass slab or a non-absorbent pad.
b) Dispense one small drop of gel, or some of the MTA Plus Liquid.
NOTE : MTA Plus 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 Plus 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 in ratio of 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 Instructions 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. Place freshly mixed MTA plus material on radicular pulp. After adequate setting, cover the material with the RMGIC/Chemical set GIC.

For a pulp exposure or pulpotomy :
Gently rinse the exposure with a saline solution. Control hemorrhage with pressure on the exposure site using a cotton pellet moistened with saline, a dilute solution of NaOCl (0.5-1.0%), or a mild hemostatic agent. Place freshly mixed MTA Plus material on radicular pulp. After adequate setting, cover the material with the RMGIC/Chemical set GIC.

For a base/liner :
Wipe the cavity preparation with a chlorhexidine solution. Use a small applicator to apply mixed MTA Plus material over the floor of 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 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 :
a. Debride, clean, and shape the root canal system using intra-canal 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 Plus in the apical region, to create a 3 to 5 mm apical barrier. Confirm placement with a radiograph. Rinse gently. The rest of the canal can be backfilled using thermoplasticized Gutta-percha.

For resorption or perforations :
Isolate the resorptive defect site or iatrogenic perforation. Obturate the canal space apical to the defect. Dispense the MTA Plus material into the defect site. Gently compact the MTA Plus material using a small MTA plugger, cotton pellets or paper points. Confirm the placement with a radiograph. Rinse gently. When the MTA Plus material is firm (a few minutes), obturate the remaining canal space with suitable material.

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 Plus 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 intra-canal instruments under rubber dam isolation.
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 Plus 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, apply a light coating of 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 over extension of the material beyond the apex.

f. Coat the disinfected and dried obturation points with the MTA Plus material and insert them in the canal.
g. Confirm placement of the material in the complete root canal system with a radiograph. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

Warnings :
MTA Plus powder is caustic, as all are calcium silicates.

Precautions :
- Avoid contact of unset mixed paste with skin or oral mucosa. After accidental contact, wash and rinse with water. Wear suitable gloves and protective glasses during use.
- MTA Plus 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

Contraindications :
Hypersensitivity against caustic (high pH) solutions.

Storage Conditions :
Store at temperature between 10°C(50°F) to 24°C(75°F). Close the cap carefully after use. Keep away from moisture. Shelf life not affected after opening if stored in a cool dry place.

Shelf Life :
3 Years from date of manufacturing

Presentation :
Ref : 40024
Trial Pack : 1 X 1g Powder, 1 X 2cc Gel, 1 X Measuring Spoon
Ref : 40025
Intro Pack : 1 X 2g Powder, 1 X 2cc Gel, 1 X Measuring Spoon
Ref : 40032
Economy Pack : 1 X 6g Powder, 1 X 9cc Gel, 1 X Measuring Spoon
Ref : 40024-1
MTA Plus AQUA:
1 x 0.14g Powder, 1 x 0.5ml Liquid
Ref : 40053
MTA Plus AQUA:
1 x 0.14g Powder, 1 x 1ml Liquid
NOTE : For removal of Root Canal Fillings, if 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 MTA Plus material is used for obturation, use ultrasonic instruments.

Disposal conditions : To be disposed off based on the prevailing rules of the country in which it is used.

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UDI Symbol for "UNIQUE DEVICE IDENTIFIER"
LOT Symbol for "BATCH CODE" Symbol for "USE-BY DATE" Symbol for "NON STERILE" Symbol for "KEEP DRY"
Symbol for "CAUTION" Symbol for "CONSULT INSTRUCTION FOR USE" REF Symbol for "CATALOGUE NUMBER"
EC REP Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION"
Symbol for "KEEP OUT OF THE REACH OF CHILDREN" Symbol for "MANUFACTURER" Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"
Symbol for "TEMPERATURE LIMIT" Symbol for "KEEP AWAY FROM SUNLIGHT" MD Symbol for "MEDICAL DEVICE"

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