

MTA Plus**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 is 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 lining, or
- 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

b) Dispense one small drop of gel, OR some of the MTA Plus Liquid resistance (for easier rinsing) and faster setting, which the water does not.

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 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.

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 Plus material on the pulp exposure, or over the

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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 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. Apply about 2 mm of a glass ionomer, acid-etch, and place composite.

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 amalgam 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 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 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, and 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 are all calcium silicates.

Precautions :

◆ 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 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.

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

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