NeoMTA Plus®

ROOT & PULP TREATMENT MATERIAL

DIRECTIONS FOR USE

For additional information, go to
www.AvalonBiomed.com/product-info/
- DFU in other languages
- SDS in multiple languages
- Product brochures
- Tip Sheet

For Professional Dental Use Only.

DESCRIPTION

NeoMTA Plus ROOT & PULP TREATMENT MATERIAL is a powder & gel system consisting of an extremely fine, inorganic powder of tricalcium and dicalcium silicate, which sets with water–based liquids or gels. The powder is supplied in a protective, desiccant–lined container for freshness. This material is both bioactive and radiopaque.

The **NeoMTA Plus** formula was developed to prevent discoloration from medicaments or exposure to light. This material will not discolor over time in primary or secondary teeth.

INDICATIONS

Dental procedures contacting vital pulp tissue such as:
- Pulp capping,
- Cavity lining,
- Base or
- Pulpotomies.

Dental procedures contacting the periradicular tissues such as:
- 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), unless the permanent successor tooth is absent.

WARNINGS

NeoMTA Plus powder is caustic, as are all tricalcium 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.
- **NeoMTA 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.
- Setting of tricalcium silicates is inhibited in acidic environments such as infected sites.

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.

STEP-BY-STEP INSTRUCTIONS for Dosage and Mixing

For **MTA Plus** Mixing Video, go to
http://avalonbiomed.com/videos/

a. Dispense 1 scoop (0.1 gm) of **NeoMTA Plus** powder on a glass slab or a non-absorbent pad.
b. Dispense one short streak of **MTA Plus** Gel next to the powder.

NOTE: The gel imparts washout resistance (for easier rinsing) and faster setting, which other liquids do not. The mixture is washout resistant within 3 min.

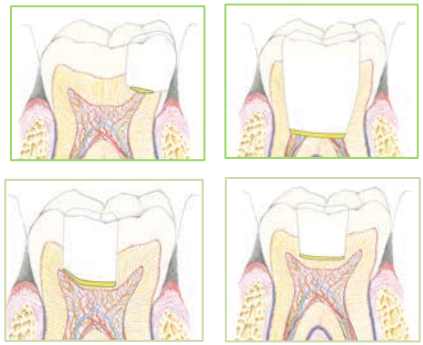
c. Gradually mix the gel into the powder until the desired putty-like consistency is obtained. For some procedures, a thinner, syrupy, stringy consistency may be desired. Thoroughly mix to hydrate the powder.
d. If the material is not to be used immediately, cover the mixed material with a moist gauze sponge (use sterile water), or a clean cover to prevent evaporation. Extra **MTA Plus** Gel may be used to rewet the powder before it sets.
e. If the mixture is too tacky, add a small amount of powder. For future mixtures, use less gel.

ADA 57, ISO 6876 and ISO 9917 Criteria
- 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.
- Initial Setting Time at 37°C: ~15 min when thickly mixed with gel; otherwise longer for sealer (~3 hr.)
- Flow: 25-29 mm when mixed 1:1 Powder:Gel, otherwise higher.
- Film thickness: <50 µm when mixed 1:1 Powder:Gel, otherwise larger.
- Solubility: <3%.
- Dimensional stability: After 30 days, at 3:1 Powder:Gel, <+0.01% expansion.
- Radiopacity: 5 mm equivalent of aluminum.
- Compressive strength: 80 MPa after 7 days when mixed 3:1 Powder:Gel.
- Pb and As: < 2 ppm.

CLINICAL DIRECTIONS FOR USE

NeoMTA Plus material is shown in yellow in all drawings.

PULP CAPPING, PULPOTOMY or CAVITY LINER/BASE



a. Complete a cavity preparation 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 handpiece 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 cementoenamel junction or slightly below this level.

For a pulp exposure or pulpotomy
- Gently rinse the exposed pulp with a NaOCl solution.
- Control hemorrhage with cotton pellet soaked in 5.25-8.0% NaOCl for as long as 10 minutes.

For a base/liner, pulp exposure or pulpotomy:
c. Disinfect the cavity preparation with NaOCl or chlorhexidine solution.
d. 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 **NeoMTA 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 **NeoMTA Plus** material. The glass ionomer should be an interim restoration prior to a placement of a final composite or other restorative material in permanent teeth.
- Assess the pulp vitality at three-month intervals or as needed, and confirm with a radiograph.

1. ROOT APEXIFICATION, RESORPTION or PERFORATIONS

- Debride, clean, and shape the root canal system using intra-canal instruments under rubber dam isolation.
- 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 **NeoMTA 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 restoration.

For resorption or perforations:

- Isolate the resorptive defect site or iatrogenic perforation.
- Obturate the canal space apical to the defect.
- Dispense the **NeoMTA Plus** material into the defect site with an instrument of clinician's choice.
- Gently compact the **NeoMTA Plus** material using a small amalgam plugger, cotton pellets or paper points.
- Confirm the placement with a radiograph.
- Rinse gently.
- When the **NeoMTA Plus** material is firm (a few minutes), obturate the remaining canal space and close the coronal access as you do normally.

2. 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 **NeoMTA Plus** material into the root-end cavity using a "plastic" instrument or other small carrier.
e. Remove excess material and clean the resected root tip with a slightly moist cotton pellet.
f. Rinse gently.
g. Confirm placement with a radiograph.
h. Close the surgical site.

3. 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. 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 **NeoMTA 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 **NeoMTA 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 **NeoMTA 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 **NeoMTA 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 **NeoMTA Plus** material is used for obturation, use ultrasonic instruments.

Symbols used on labeling:

	Consult instructions for use.
	Manufacturer
REF	Catalog number
LOT	Lot number
	Expiration date
Rx Only	Caution: Federal (USA) law restricts this device to sale by or on the order of a physician or practitioner.
	Caution, consult accompanying documents.
EC REP	Authorized Representative in the European Community
	Keep dry

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Revision 1601