AVALON BIOMED
Advanced Bioceramics

NeoMTA Plus® & Grey MTA Plus®

BIOCERAMIC ROOT & PULP TREATMENT MATERIAL

INSTRUCTIONS FOR USE

For additional information, go to avalonbiomed.com

- SDS
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For Professional Dental Use Only.

Avalon Biomed NeoMTA Plus & **Grey MTA Plus ROOT & PULP TREATMENT MATERIAL** is a Powder & Gel system consisting of an extremely fine, inorganic Powder of tricalcium and dicalcium silicate, which is mixed with the supplied water-based Gel to initiate the setting reaction. The Powder is supplied in a protective, desiccant–lined container for freshness. This material is both bioactive and radiopaque.

Stainproof **NeoMTA Plus** 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:

- Pulpotomy and Apexogenesis
- Direct and Indirect pulp capping
- Cavity liner/Base

Dental procedures contacting the periradicular tissues such as:

- Root apexification
- Root resorption
- Perforation repair
- Root-end filling
- Sealing/Obturation of root canals

CONTRAINDICATIONS

- Hypersensitivity against caustic (high pH) solutions.
- Do not use for primary tooth pulpectomy (root canal filling), unless the permanent successor tooth is absent.

WARNINGS

NeoMTA and **Grey MTA Plus** Powders are 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** and **Grey 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 contaminate the Gel. Avoid contamination by insertion of unclean instruments into plugged bottle tip, removing the bottle tip, touching the bottle tip to contaminated surface (mixing pad/glass slab) or touching the tip of the Gel bottle with unclean gloves/hands.
- Avalon Biomed **MTA Plus** products are provided in clean non-sterile packaging. Clinician should follow their established protocols for cleaning and disinfection. See: ***www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines.pdf***
- DO NOT overfill the root canals when sealing/obturating.
- Setting of tricalcium silicates is inhibited in acidic environments such as infected sites. Chlorhexidine may also slow the setting of MTA Plus

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, do not refrigerate. Keep bottles tightly closed. Moisture will reduce the shelf life of the Powder.

STEP-BY-STEP INSTRUCTIONS

DOSAGE AND MIXING:

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

a. Dispense 1 scoop (0.1 gm) of **NeoMTA** or **Grey MTA Plus** Powder on a glass slab or a non-absorbent pad.

b. Dispense one or two drops 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 immediately washout resistant (within 3 min. from start of mixing).

c. Gradually add Gel into the Powder. Incorporate the Gel by spatulating the Powder/Gel mixture firmly against the glass slab while mixing to ensure all of the Powder is thoroughly wetted by the Gel until a putty-like consistency is obtained. For some procedures, mixing to a thinner, syrupy, stringy consistency may be desired.

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 reduce evaporation. If the mixture becomes dry, extra Gel may be used to rewet the material before it sets.

e. If the mixture is too tacky, add a small amount of Powder. For future mixtures, use less Gel.

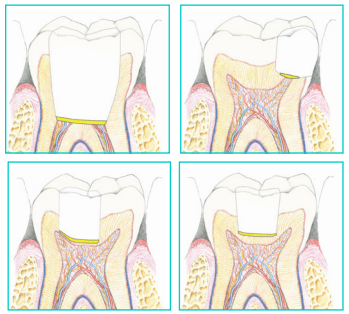
ADA 57, ISO 6876 and ISO 9917 Criteria

- 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, <+0.1% 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 and **Grey MTA Plus** material is shown in yellow in the drawings.

1. **PULPOTOMY, DIRECT** and **INDIRECT PULP CAPPING,** or **CAVITY LINER/BASE:**



a. Complete a cavity preparation under rubber dam isolation, using a high-speed bur.

__NOTE:__ if Indirect pulp capping or liner/base, skip to step e. If pulpotomy or direct pulp capping continue to b.

b. Excavate all carious tooth structure using a round bur in a handpiece at low speed, or use hand instruments.

For Pulpotomy Only:

- In multi-rooted teeth, 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 single-rooted teeth, remove the pulp to the level of the cemento-enamel junction or slightly below this level.

c. Gently rinse the exposed pulp or cavitiy preparation using NaOCl (3.0-6.0%) or chlorhexidine.

d. Control hemorrhage using a cotton pellet, under pressure, soaked in the same solution as in step c above. If hemorrhaging is still present after 10 minutes, the diagnosis is irreversible pulpitis and a full pulpectomy is typically performed instead.

e. Use applicator of your choice to apply mixed **NeoMTA** or **Grey MTA Plus** material on the exposed pulp, or pulp stumps and the surrounding dentin; or over the floor of the cavity preparation to a minimum thickness of 1.5mm.

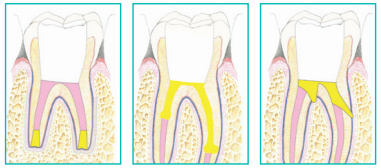
f. Excess material maybe removed using a slightly damp cotton pellet. Rinse gently.

Continued clinical directions on reverse side.

g. Place a composite material or a glass ionomer restorative material over the **NeoMTA** or **Grey MTA Plus** material. The glass ionomer should be an interim restoration prior to a placement of a final composite or other permanent restoration in permanent teeth.

h. Assess the pulp vitality as needed, and confirm with a radiograph.

2. ROOT APEXIFICATION, RESORPTION or **PERFORATION:**



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

b. Gently rinse the root canal with a NaOCl solution (3.0-6.0%) or chlorhexidine.

For Root Apexification:

c. Dry the canal system with paper points, being careful not to extend the points beyond a wide-open apex.

d. Gently compact **NeoMTA** or **Grey MTA Plus** in the apical region, to create a 3 to 5mm apical barrier.

e. Confirm placement with a radiograph.

f. Obturate the remaining canal space and close the coronal access.

g. A full coverage restoration is normally placed following apexification.

For Resorption or **Perforation:**

c. Isolate the resorptive defect site or iatrogenic perforation.

d. Obturate the canal space apical to the defect.

e. Dispense the **NeoMTA** or **Grey MTA Plus** material into the defect site with an instrument of clinician's choice.

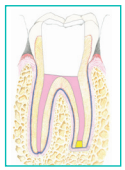
f. Gently compact the **NeoMTA** or **Grey MTA Plus** material using a small amalgam plugger, cotton pellets or paper points.

g. Rinse gently.

h. Confirm the placement with a radiograph.

i. 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 to 4mm of the root apex using a surgical bur.

b. Prepare a Class I root-end cavity preparation 3 to 5mm deep with an ultrasonic tip.

c. Isolate the area and achieve hemostasis. Dry the area.

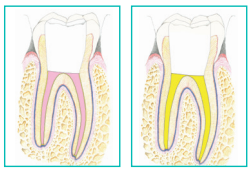
d. Gently compress the **NeoMTA** or **Grey MTA Plus** material into the root-end cavity using a "plastic" instrument or other small carrier.

e. Remove excess material and clean the resected root tip with a slightly moist cotton pellet. Rinse gently.

f. Confirm placement with a radiograph.

g. Close the surgical site.

4. SEALING/OBTURATION OF ROOT CANALS:



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 (3.0-6.0%).

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. **Using MTA Plus for Sealing with Endodontic Points:**

- Apply a light coating of **NeoMTA** or **Grey MTA Plus** material (mixed with the Gel to a syrupy, stringy consistency) to the canal walls.
- Coat the obturation points with the mixed **NeoMTA** or **Grey MTA Plus** material and insert in the canal.

f. **Using MTA Plus for Complete Obturation:**

- Gently compact the **NeoMTA** or **Grey MTA Plus** material into the 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.

AVOID the formation of air bubbles in the material.

DO NOT use a pumping action.

MINIMIZE overextension of the material beyond the apex.

g. Confirm placement of the material in the complete root canal system with a radiograph.

NOTE: *For removal of Root Canal Fillings - If NeoMTA or 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 NeoMTA or Grey MTA Plus material is used for obturation, use ultrasonic instruments.*

Symbols used on labeling:

	Manufacturer
EC REP	Authorized Representative in the European Community
Rx only	Prescription Only
	Consult Instructions For Use
	Caution
	Keep Dry
LOT	Lot Number
REF	Catalog Number
	Expiration Date

Manufactured by:

NuSmile, Ltd.
3315 West 12th St.
Houston, TX 77008
+1.713.861.0033
USA

EC REP **KinderDent GmbH**
GutenbergstraBe 7
Weyhe, D-28844
Germany

CE 0120