

MULTI-PURPOSE FOR EVERY PULP NEED

Avalon Biomed NeoMTA 2 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 water-based Gel before placement. The Powder is supplied in a protective, desiccant-lined container for long shelf life. NeoMTA 2 was developed to prevent discoloration from medications or exposure to light in primary or permanent teeth, including when used under full coverage zirconia or composite restorations. NeoMTA 2 is a radiopaque, bioactive bioceramic.

Indirect Pulp Cap
Direct Pulp Cap
Partial Pulpotomy
Cavity Liner/Base
Pulpotomy
Apexogenesis
Perforation Repair
Resorption
Sealing
Obturation/
Apexification
Root-End Filling

Non-Staining
BIOACTIVE
Bioceramic

AVALON BIOMED
 Advanced Bioceramics

ROOT & PULP TREATMENT MATERIAL

Does not discolor teeth
 For Professional Dental Use Only.
 Go to avalonbiomed.com for:
 - Safety Data Sheet
 - Frequently Asked Questions
 - Videos

INSTRUCTIONS FOR USE

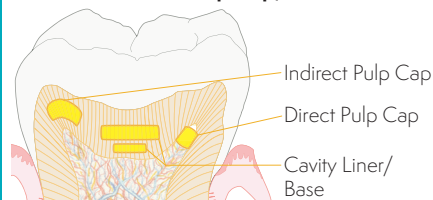
Root and Pulp Treatment Material

STEP-BY-STEP MIXING INSTRUCTIONS

1. Dispense 1 scoop (0.1gm) of NeoMTA 2 Powder on a glass slab.
 2. Dispense one or two drops of NeoMTA 2 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 when mixed as a putty.**
3. Gradually add as much Gel as necessary into the Powder to achieve the desired consistency. Incorporate the Gel by spatulating the Powder/Gel mixture firmly against the glass slab to ensure all of the Powder is thoroughly wetted by the Gel. Consistency for:
 - All procedures other than sealing - firm putty or thinner, if desired.
 - Sealing - syrupy, stringy mixture
 4. If the material is not to be used immediately, cover the mixed material with a gauze sponge moistened with 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.
 5. If the mixture is too tacky, add a small amount of Powder- less than 1/2 scoop. For future mixtures, use less Gel. Alternatively, spread out mixture to a thin layer on the glass slab to allow some drying. Then use the edge of a metal spatula to gather the material into a putty or other desired consistency.

CLINICAL DIRECTIONS FOR USE

NeoMTA 2 is shown in **Yellow**
Direct or Indirect Pulp Cap/Base or Liner

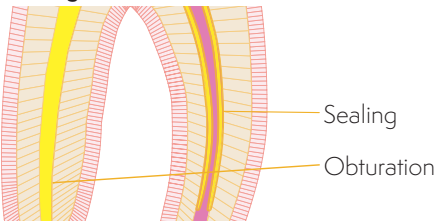


- a) Complete a cavity preparation under rubber dam isolation, using a high-speed bur.

NOTE: If applying material for an indirect pulp cap, base or liner; skip to step d.

Detailed clinical directions for use continued

Sealing & Obturation



- a) Debride, clean and shape the root canal system using intra-canal instruments under rubber dam isolation.
- b) Rinse the root canal using sodium hypochlorite (1.25 to 6.0%).
- c) Remove the smear layer with, for instance, 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.

For Sealing with Endodontic Points:

- Mix the NeoMTA 2 material to a syrupy, stringy consistency.
- Apply a light coating of NeoMTA 2 material on disinfected and dried obturation points and insert them into the canal.
- Confirm placement of the material in the complete root canal system with a radiograph.

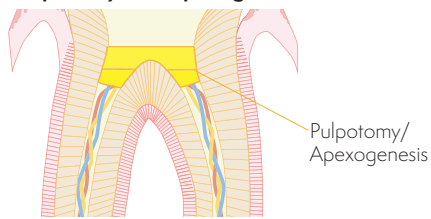
For Complete Obturation:

- gently compact the NeoMTA 2 material into the canals and confirm placement with a radiograph.

NOTE: For removal of Root Canal Fillings - If NeoMTA 2 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 2 material is used for obturation, use ultrasonic instruments.

- b) Excavate carious tooth structure using a round bur in a handpiece at low speed or use hand instruments.
- c) Control hemorrhage using a solution of your choice (e.g. sterile saline, sodium hypochlorite (1.25-6.0%) or chlorhexidine). If hemorrhage is still present after 10 minutes, the diagnosis is irreversible pulpitis and vital pulp therapy using MTA may not be indicated.
- d) Use applicator of your choice to apply mixed NeoMTA 2 material on the exposed pulp or the floor of the cavity preparation, maintaining a minimum thickness of 1.5mm.
- e) Excess material may be removed using a cotton pellet slightly dampened with sterile water or saline.
- f) NeoMTA 2 is washout resistant when placed. Immediately **restore** over NeoMTA 2 with a light curable composite, glass ionomer (RMGI or compomer), or luting cement and crown. Alternatively, you may use a flowable composite, RMGI, ZOE or other material **to secure** the NeoMTA 2 prior to final tooth restoration.

Pulpotomy and Apexogenesis



- a) Complete a cavity preparation under rubber dam isolation, using a high-speed bur.
- b) Excavate all carious tooth structure using a round bur in a handpiece at low speed, or use hand instruments.
 - 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.

- 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.
- MINIMIZE overextension of the material beyond the apex.

Contraindications

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

Warnings

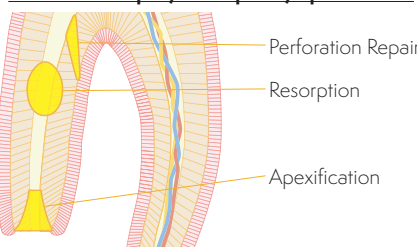
- NeoMTA 2 Powder is caustic, as are all tricalcium silicates.

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 2 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. Do not remove the dropper tip or insert any instrument into the bottle.
- AVOID touching the bottle tip to any non-sterile surface.
- NeoMTA 2 products are provided in clean non-sterile packaging. Clinician should follow their established protocols for cleaning and disinfection.

- In single-rooted teeth, remove the pulp to the level of the cemento-enamel junction or slightly below.
- c) Control hemorrhage using a solution of your choice (e.g. sterile saline, sodium hypochlorite (1.25-6.0%) or chlorhexidine). If hemorrhage is still present after 10 minutes, the diagnosis is irreversible pulpitis and a full pulpectomy with obturation is typically performed instead.
- d) Use an applicator of your choice to apply mixed NeoMTA 2 material on the exposed pulp or the floor of the cavity preparation, covering the pulp stumps while spreading the MTA to the edges of the surrounding dentin to a minimum thickness of 1.5mm.
- e) Excess material may be removed using a cotton pellet slightly dampened with sterile water or saline.
- f) NeoMTA 2 is washout resistant when placed. Immediately **restore** over NeoMTA 2 with a light curable composite, glass ionomer (RMGI or compomer), or luting cement and crown. Alternatively, you may use a flowable composite, RMGI, ZOE or other material **to secure** the NeoMTA 2 prior to final tooth restoration.
- g) Assess the pulp vitality as needed and confirm with a radiograph.

Perforation Repair/ Resorption /Apexification



NeoMTA 2 is shown in **Yellow**,
 Gutta percha and sealer is shown in **Pink**.

- a) Debride, clean and shape the root canal system using intra-canal instruments under rubber dam isolation.
 - b) Gently rinse the cavity preparation using sodium hypochlorite (1.25-6.0%) or chlorhexidine.
- For Perforation Repair or Resorption:**
- c) Isolate the defect site(s).
 - d) Obturate the canal space apical to the defect.

See: www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf

- DO NOT overfill the root canals when obturating or performing apexification.
- 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, do not refrigerate. Keep bottles tightly closed. Moisture will reduce the shelf life of the Powder.

ADA 57, ISO 6876 and ISO 9917-1 criteria

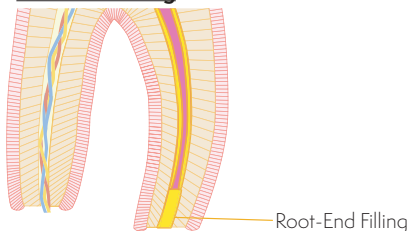
- Radiopacity 6.5 mm when mixed to putty consistency; 5.4 mm Al when mixed for sealer use.
- Working time at room temperature: ~10 minutes when mixed as a putty; however, addition of more gel may be used to extend the working time is the mixture begins to dry.
- Initial setting time for putty consistency @ 37°C =15 min.; final setting 1:45 hr.
- Flow: 20 mm for sealer use; > 15 mm as required.
- Film thickness: 38 to 46 µm for sealer use; < 50 µm, as required
- Solubility < 3%, as required.
- Dimensional stability <+0.1%, as required.
- Pb <100 ppm, As < 2 ppm, as required.

- e) Dispense NeoMTA 2 material into the defect site with an instrument of clinician's choice.
- f) Gently compact NeoMTA 2 material using a small amalgam plugger, cotton pellets or paper points.
- g) Confirm placement with a radiograph.
- h) Excess material may be removed using a cotton pellet slightly dampened with sterile water or saline.
- i) When the NeoMTA 2 material is firm (a few minutes), obturate the remaining canal space and close the coronal access as you do normally.

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 2 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.

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.
- d) Dry the area.
- e) Gently compress the NeoMTA 2 material in the root-end cavity using a "plastic" instrument or other small carrier.
- f) Excess material may be removed using a cotton pellet slightly dampened with sterile water or saline.
- g) Rinse gently.
- h) Confirm placement with a radiograph.
- i) Close the surgical site.

Symbols used on labeling:

	Manufacturer
	Authorized Representative in the European Community
	Prescription Only
	Consult Instructions For Use
	Caution
	Keep Dry
	Lot Number
	Catalog Number
	Expiration Date

Manufactured by:

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

CE
1639

KinderDent GmbH
 Gutenbergstraße 7
 Weyhe, D-28844
 Germany

Avalon Biomed NeoMTA 2

