



PULP TREATMENT MATERIAL FOR CHILD AND ADOLESCENT DENTISTRY

INSTRUCTIONS FOR USE

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For Professional Dental Use Only.

NuSmile® NeoMTA® Pulp Treatment Material

is a Powder and 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. The NuSmile® NeoMTA® formula was developed to prevent discoloration from medicaments, or when used under full coverage zirconia or composite restorations. This material will not discolor over time or from exposure to light in primary or permanent teeth.

INDICATIONS

DENTAL PROCEDURES CONTACTING VITAL PULP TISSUE SUCH AS:

- PULPOTOMY AND APEXOGENESIS
- DIRECT AND INDIRECT PULP CAPPING
- BASE/LINER

DENTAL PROCEDURES CONTACTING THE PERIRADICULAR TISSUES SUCH AS:

- ROOT APEXIFICATION

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

NuSmile NeoMTA 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.
- NuSmile NeoMTA 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 a contaminated surface (mixing pad/glass slab) or touching the tip of the Gel bottle with unclean gloves/hands.
- NuSmile NeoMTA 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 obturating (root 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 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 (~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, @ 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.

STEP-BY-STEP INSTRUCTIONS

DOSAGE AND MIXING:

1. Dispense 1 scoop (0.05 gm or 0.1gm) of NuSmile NeoMTA Powder on a glass slab or a non-absorbent pad.
2. Dispense one drop of NuSmile NeoMTA Gel as a streak 0.5"-0.75" long next to the Powder.

NOTE: *The Gel imparts washout resistance (for easier rinsing) and faster setting, which other liquids do not. Mixture is immediately washout resistant (within 3 min. from start of mixing)*

3. 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.
 - **Pulpotomy**-mix to firm putty
 - **Pulp capping, base/liner**-mix to firm putty or thinner if desired
 - **Apexification**-mix to firm putty/clay
4. 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.
5. If the mixture is too tacky add a small amount of Powder. For future mixtures, use less Gel.

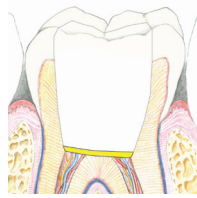
See detailed clinical directions on reverse side.

DETAILED CLINICAL DIRECTIONS FOR USE

(NuSmile NeoMTA material is shown in yellow in the drawings.)

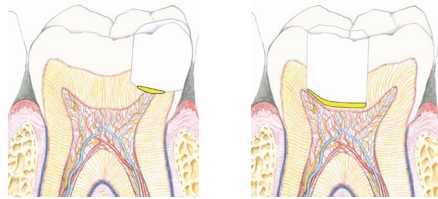
PULPOTOMY AND APEXOGENESIS:

- Complete a cavity preparation under rubber dam isolation, using a high-speed bur.
- 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.
- In single-rooted teeth, remove the pulp to the level of the cemento-enamel junction or slightly below this level.
- Gently rinse the exposed pulp using NaOCl (3.0-6.0%), chlorhexidine, or sterile saline solution.
- Control hemorrhage using a cotton pellet, under pressure, soaked in the same solution as in step e above. If hemorrhaging is still present after 10 minutes, the diagnosis is irreversible pulpitis and a full pulpectomy is typically performed instead.
- Use applicator of your choice to apply mixed NuSmile NeoMTA material on the exposed pulp. Dispense the NeoMTA to 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.
- Excess material may be removed using a slightly damp cotton pellet.
- NeoMTA is immediately washout resistant (within 3 min. from start of mixing). You can restore directly over NeoMTA with a suitable composite or luting cement. Alternatively you may use a light cure glass ionomer, composite, RMGI, ZOE or other suitable



- material to secure the MTA prior to final tooth restoration.
- Assess the pulp vitality as needed, and confirm with a radiograph.

DIRECT AND INDIRECT PULP CAPPING:



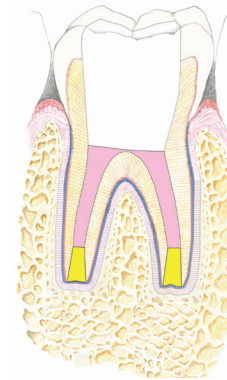
Direct Cap

Indirect Cap

- Complete a cavity preparation under rubber dam isolation, using a high-speed bur.
- Excavate all carious tooth structure using a round bur in a handpiece at low speed, or use hand instruments.
- Gently rinse the cavity preparation using a NaOCl (3.0-6.0%), chlorhexidine, or sterile saline solution.
- Control hemorrhage using a cotton pellet, under pressure, soaked in the same solution as in step c above.
- Use applicator of your choice to apply mixed NuSmile NeoMTA material on the exposed pulp. Dispense the NeoMTA to the floor of the cavity preparation, maintaining a minimum thickness of 1.5mm.
- Excess material may be removed using a slightly damp cotton pellet.
- NeoMTA is immediately washout resistant (within 3 min. from start of mixing). You can restore directly over NeoMTA with a suitable composite or luting cement. Alternatively you may use a light cure glass ionomer, composite, RMGI, ZOE or other suitable material to secure the MTA prior to final tooth restoration.

- Assess the pulp vitality as needed, and confirm with a radiograph.
NOTE: NuSmile NeoMTA may also be used as a base/liner if desired.

ROOT APEXIFICATION :



- Debride, clean and shape the root canal system using intra-canal instruments under rubber dam isolation.
- Gently rinse the cavity preparation using a NaOCl (3.0-6.0%), chlorhexidine, or sterile saline solution.
- Dry the canal system with paper points, being careful not to extend the points beyond a wide-open apex.
- Gently compact NuSmile NeoMTA in the apical region, to create a 3 to 5mm apical barrier.
- Confirm placement with a radiograph.
- Obturate the remaining canal space and close the coronal access.
- A full coverage restoration is normally placed following apexification.

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:

