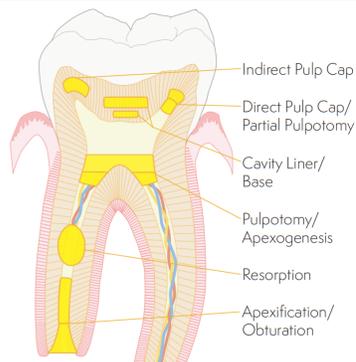


FAQ – NeoMTA® Products Root & Pulp Treatment Material

CHOOSING A PRODUCT

<p>What is NeoMTA® 2?</p>	<p>NeoMTA 2 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.</p>
<p>What do you mean by wash-out resistance and are NuSmile NeoMTA products immediately wash-out resistant?</p>	<p>One important characteristic that affects the performance of MTA-type products is its stability when placed in a tooth. A way to test the product's stability is through wash-out testing. NeoMTA products are immediately wash-out resistant. You can gently rinse and complete the restoration or cement a crown, immediately after placing NeoMTA products.</p>
<p>What are the improvements of NuSmile NeoMTA 2 compared to NuSmile NeoMTA?</p>	<ul style="list-style-type: none"> • NeoMTA 2 is designed to be easier to mix. • NeoMTA 2 has about 30% higher radiopacity than NeoMTA (6.5 vs 5.0 mm equivalent aluminum as a putty-like mixture). • NeoMTA 2 is brighter white.
<p>What are the similarities between NuSmile NeoMTA and NuSmile NeoMTA 2?</p>	<ul style="list-style-type: none"> • Both products are bioactive bioceramic MTAs. • Both products release calcium and hydroxide ions promoting the formation of hydroxyapatite from the surface to seal and support healing. • Both products are resin-free for maximum bioactivity. • Both products have initially high pH (alkaline/basic) when applied. Literature has shown such products to be antimicrobial in-vitro¹. • Both products are color stable, non-staining, containing tantalum oxide (tantalite) for radiopacity. Neither NeoMTA or NeoMTA 2 contain bismuth oxide, which causes tooth discoloration². • Both products are immediately wash-out resistant when placed. • Both products have low water solubility (<3%) when set. • Both products are dimensionally stable with negligible expansion on setting. • Both products contain extremely fine, hydraulic tri/dicalcium silicate powders. • Both products have shorter setting time (approximately 14 minutes when mixed to a putty consistency) compared to traditional MTA. • Both products include a proprietary Gel that allows the product to be mixed to a firm putty (like ZOE or IRM). <p>¹The anti-microbial effect against enterococcus faecalis and the compressive strength of two types of mineral trioxide aggregate mixed with sterile water or 2% chlorhexidine liquid. Holt DM, Watts JD, Beeson TJ, Kirkpatrick TC, Rutledge RE. J Endod. 2007 Jul;33(7):844-7.</p> <p>²Marciano MA, Duarte MA, Camilleri J. Dental discoloration caused by bismuth oxide in MTA in the presence of sodium hypochlorite. Clin Oral Investig. 2015;19(9):2201-2209.</p>
<p>What are the indications for use?</p>	<p>NuSmile NeoMTA and NeoMTA 2 have the same indications:</p>



There are 10 indications for use. Read IFU prior to use, available at nusmile.com

<p>What makes NuSmile NeoMTA products different from resin-based materials that contain some MTA?</p>	<p>Unlike inert, resin-based materials containing some MTA,...</p> <p>NeoMTA products are:</p> <ul style="list-style-type: none"> • Bioactive; releases calcium and hydroxide ions from the surface, promoting the formation of hydroxyapatite to ensure bioactive sealing. • Formulated with pure tri/dicalcium silicate powder and a radiopacifier. • Dimensionally stable – unlike resin-based materials that shrink. • Biocompatible, non-cytotoxic. • More versatile, having more treatment indications. • More radiopaque. • Resin-free for maximum MTA concentration and maximum bioactivity. [<i>Resin-based materials containing only <u>some</u> MTA-type cement have not consistently shown biocompatibility in cell cultures^{3,4}, demonstrating a toxicity that may be attributed to incomplete resin curing.</i>] <p>³Adıgüzel M, Ahmetoğlu F, Eldeniz AÜ, Tekin MG, Gögebakan B. Comparison of cytotoxic effects of calcium silicate-based materials on human pulp fibroblasts Mehmet. <i>J Dent Res Dent Clin Dent Prospects.</i> 2019;13(4):241-246.</p> <p>⁴Collado-González M, García-Bernal D, Oñate-Sánchez RE, et al. Cytotoxicity and bioactivity of various pulpotomy materials on stem cells from human exfoliated primary teeth. <i>Int Endod J.</i> 2017;50 Suppl 2:e19-e30.</p>
<p>Are all white MTAs non-staining?</p>	<p>No: White MTAs that contain bismuth oxide as the radiopacifier (e.g. ProRoot White MTA) will cause staining. All NuSmile MTA-based products, including NeoMTA 2, contain tantalite as the radiopacifier, which does not cause staining.</p>
<p>Are NuSmile NeoMTA products the same as Portland cement?</p>	<p>No: While both Portland cement and MTA contain tricalcium silicate, they are not the same.</p> <p>Portland cement is:</p> <ul style="list-style-type: none"> • An impure industrial grade construction product • A coarse powder that sets slowly • NOT a medical device • NOT cleared by the FDA • NOT radiopaque • NOT a highly refined powder. <p>Portland cement cannot meet the international dental standards, including ISO 6876, ISO 9917-1 or ADA 57 requirements. NuSmile NeoMTA products meet all dental quality standards and are manufactured in Houston, TX USA in an FDA-registered factory certified to ISO 13485.</p>
<p>How radiopaque are NuSmile NeoMTA products?</p>	<p>When mixed to a putty:</p> <ul style="list-style-type: none"> • The radiopacity of NeoMTA is 5.0mm Al equivalent. • The radiopacity of NeoMTA 2 is higher, 6.5mm Al equivalent.

DOSE INFORMATION

What Kit sizes are available? How many cases can I treat with each kit?	We have one kit size for sale in the US and Canada, the 2.5 gm Professional Kit . Number of treatments: <ul style="list-style-type: none"> • 25 applications using the 0.1 gm large scoop • 50 applications using the 0.05 gm small scoop
How much Powder does the level scoop hold?	<ul style="list-style-type: none"> • Large scoop – 0.1 gm, enough for a pulpotomy on one or two primary posterior teeth. • Small scoop – 0.05 gm, enough for a pulpotomy on a primary anterior or posterior tooth, or for a direct or indirect pulp cap.

PREPARING FOR USE AND MIXING

Instructions for Use (IFU) & Tip Sheet	Read IFU prior to use. To obtain, visit nusmile.com									
Will I have enough Gel for the amount of Powder?	Yes, 4cc Gel is provided in the 2.5 gm Kit, which is more than enough Gel for the Powder.									
Can I use a paper pad to mix the Powder and Gel?	Yes, but make sure it's a high-quality, coated pad that doesn't absorb water; otherwise the Gel will be absorbed by the pad. We highly recommend using a glass slab for mixing NuSmile NeoMTA products. A glass slab also provides a more stable, firmer surface for complete mixing. Glass slabs are available for purchase separately.									
What liquid should I use – Gel or water?	Gel is recommended. Mixing the Powder with the Gel provides superior handling and immediate wash-out resistance so you can immediately complete the restoration with or without covering the MTA product depending on your preference.									
What is the composition of the Gel component of NuSmile NeoMTA products?	The Gel is a water-based (>50% water) liquid with proprietary ingredients. The Gel is non-cytotoxic, non-allergenic and non-sensitizing. All the components have been used successfully in other medical implant devices. The Gel enhances the properties of the Powder/Gel mixture for better handling, longer working time, immediate wash-out resistance and easier placement.									
What kind of mixing instrument should I use?	Use the spatula sold by NuSmile or a medium stiffness metal spatula. Metal spatulas are preferred over plastic spatulas because they allow easier mixing and fast incorporation of the fine powder and gel.									
What is the proper Powder/Gel ratio?	<table border="1"> <thead> <tr> <th>Procedure</th> <th>Approx. Gel amount required</th> </tr> </thead> <tbody> <tr> <td>For pulpotomies and apexification, a thicker consistency is usually preferred</td> <td>1-2 drops of Gel. (Dispense 1 drop of Gel near the Powder. A second drop can be placed nearby to adjust the viscosity or to rewet the material before it sets.)</td> </tr> <tr> <td>For pulp capping and base/liner, a thinner consistency is usually preferred</td> <td>2 drops of Gel. (Incorporate Gel into Powder gradually until desired consistency is achieved.)</td> </tr> <tr> <td colspan="2" style="text-align: center;"><i>*The Ratio of powder to gel should be adjusted to meet clinician's preference.</i></td> </tr> </tbody> </table>		Procedure	Approx. Gel amount required	For pulpotomies and apexification, a thicker consistency is usually preferred	1-2 drops of Gel. (Dispense 1 drop of Gel near the Powder. A second drop can be placed nearby to adjust the viscosity or to rewet the material before it sets.)	For pulp capping and base/liner, a thinner consistency is usually preferred	2 drops of Gel. (Incorporate Gel into Powder gradually until desired consistency is achieved.)	<i>*The Ratio of powder to gel should be adjusted to meet clinician's preference.</i>	
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What is the best mixing method to achieve a putty-like consistency?	<ul style="list-style-type: none"> • Dispense a level scoop of Powder onto a glass slab. • Dispense 1 drop of Gel. • Using a medium flex spatula, pull half of the first drop into the Powder. Mix the Powder and Gel thoroughly with a spatula. (Note: Always mix the Gel into the 									

	<p>Powder, not the Powder into the Gel. Otherwise, the Powder can become too wet and waste may occur).</p> <ul style="list-style-type: none"> • Gradually add more Gel for desired consistency. • If too dry, dispense another drop of gel, gradually add enough gel for desired consistency. If too wet, add more powder. • If not using immediately, cover with dampen dish or damp cotton gauze to delay setting. <p><i>(Once practiced, it takes less than 1 minute to mix to the desired consistency)</i></p>
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MIXTURE AND ADJUSTMENTS

My Powder/Gel mixture is sticky, what should I do?	<ul style="list-style-type: none"> • Add a small amount of Powder (less than 1 scoop). • 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. • To prevent a sticky mixture, for future mixes use less Gel when mixing.
My Powder/Gel mixture dried out, what should I do?	<ul style="list-style-type: none"> • Add ½ drop of Gel to gradually break up the matrix to achieve the desired consistency. This method works well before the mixture is set within the first ½ hour after mixing. Alternatively, cover the mixed MTA with a moist gauze “tent” or a dampen dish to avoid drying out.

APPLICATION, WORKING & SETTING TIME; COMPLETING THE RESTORATION

How much NuSmile NeoMTA product do I need to apply to ensure its effectiveness?	<ul style="list-style-type: none"> • For a pulpotomy, liner, base or pulp cap apply a layer at least 1.5mm thick. • For root apexification compact the NeoMTA product in the apical region to create a 3 to 5 mm apical barrier.
What is the best instrument to use to place NeoMTA products into the pulp chamber when performing a pulpotomy?	We recommend placing NeoMTA products with a plastics instrument, Hollenbach instrument, amalgam carrier, or an MTA carrier. The material can be <u>gently</u> spread with a moist cotton pellet, amalgam plugger, or ball burnisher.
What is the best instrument to place NuSmile NeoMTA products for apexification or pulpectomy (where there is no successor tooth)?	Use any convenient instrument, to deliver a small cone or cylinder of NeoMTA product to the site. A Messing gun, amalgam carrier, Dovgan MTA carrier, or the MAP™ system may be used. Reversed paper points or gutta percha points can guide the putty in the root to the apex for apexification.
What is the working time for NuSmile NeoMTA products?	Working time at room temperature is about 14 minutes when mixed as a putty, and 21 minutes when mixed to a thinner consistency. The working time can be extended if needed by covering the mixed cement with a moist gauze “tent” or a dampen dish or by rehydrating the mixed material with more Gel.
What is the setting time for NuSmile NeoMTA products?	<ul style="list-style-type: none"> • When the powder is mixed to a putty-like consistency using the gel, the resulting putty is immediately wash-out resistant. • A thick mixture takes about 14 minutes to set within the tooth. • A thinner, sealer-type mixture will set in about 1 hour 10 minutes.
Should I secure the NeoMTA product prior to restoration?	It's not required but a quick and easy method is to apply a layer of a flowable composite, light-cure glass ionomer, RMGI, IRM®, ZOE or any other restorative material over the NeoMTA product prior to the final tooth restoration. If you use a flowable composite that requires etching, etch the tooth, not the NeoMTA product, then proceed with the restoration.

Can I place the NuSmile NeoMTA product and complete the restoration before the MTA is completely set?	Yes, you can complete the restoration or cement a crown immediately after placing the NeoMTA product. The NeoMTA product will harden/set underneath the restoration. The NeoMTA product is immediately wash-out resistant and dimensionally stable when placed with zero shrinkage and negligible expansion to ensure gap-free sealing.
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CLEANUP AND STORAGE

What is the shelf life of NuSmile NeoMTA products?	<ul style="list-style-type: none"> The products have a 3-year shelf life. Do not leave the Powder or Gel containers open. The Powder can absorb humidity, which reduces shelf life by increasing the set time and reducing the compressive strength. After expiration, the Gel may be too thin to be satisfactory.
Should I refrigerate the kit or its components?	No, this doesn't help extend the shelf life, and the humidity of the refrigerator may cause the Powder to absorb more moisture and deteriorate.
How do I clean up NuSmile NeoMTA product after it has set?	Use alcohol or water for cleanup. If the MTA is completely set, soak the glass slab or instrument in vinegar or water until the cement softens.

OTHER

Does NuSmile sell any premixed bioactive bioceramic MTA?	Yes, NuSmile manufactures NeoPUTTY™, a premixed Root & Pulp bioactive bioceramic MTA paste packaged in a syringe.
Does NuSmile sell a light-curing MTA?	<ul style="list-style-type: none"> NuSmile does not manufacture a light-curing MTA. We prefer to maximize the concentration of bioactive powders in NuSmile products and deliver them in a formula that allows the bioactive powders to readily hydrate and form Ca(OH)₂ for hydroxyapatite formation⁵. Light-curable and dual-cure MTA products contain resins which dilute and inhibit the MTA's bioactivity. Resins never cure 100%. Uncured resin leaves cytotoxic monomers in the MTA-resin matrix and in contact with the pulp. Resins shrink during curing; they are not dimensionally stable. NuSmile bioactive cements (MTAs) expand very slightly to ensure sealing. <p>⁵ Formosa L M, Mallia B, Camilleri J <i>The chemical properties of light and chemical curing composite with mineral trioxide aggregate filler. Dent Mater. 2013 Feb;29(2):e11-9.</i></p>