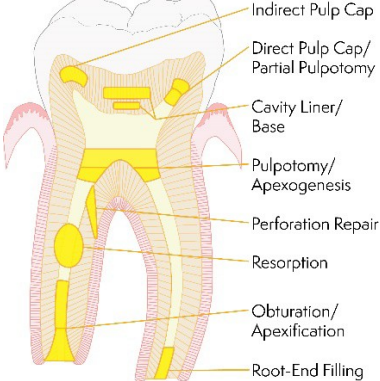


FAQ – NeoPUTTY™ Root & Pulp Treatment Material

CHOOSING A PRODUCT

<p>What is NeoPUTTY™?</p>	<p>NeoPUTTY is a premixed bioactive bioceramic root & pulp treatment consisting of an extremely fine, inorganic powder of tricalcium/dicalcium silicate in a water-free organic liquid. The product is packaged ready-to-use. No mixing is required. NeoPUTTY is designed to set in vivo in the presence of moisture from the surrounding tissues.</p>
<p>How does NeoPUTTY set?</p>	<ul style="list-style-type: none"> • NeoPUTTY is formulated with a water-free organic liquid. NeoPUTTY only sets in vivo or moisture. Setting begins in the presence of moisture from the apical tissues, dentinal tubules, or pulp. • NeoPUTTY is different from our NeoMTA® 2, which is packaged as a powder and a gel and requires mixing. NeoMTA 2 begins setting when the powder and gel are mixed and continues in vivo.
<p>What do you mean by wash-out resistance and is Avalon Biomed NeoPUTTY 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. We test product stability through wash-out testing.</p> <p>NeoPUTTY is immediately wash-out resistant. You can gently rinse and complete the restoration or cement a crown, immediately after placing NeoPUTTY.</p>
<p>What is the difference between NeoMTA® 2 and NeoPUTTY™?</p>	<ul style="list-style-type: none"> • NeoPUTTY does not need mixing – it is a uniform, firm, low-tack putty from beginning to end with no dry out between uses. • NeoPUTTY has about 25% higher radiopacity than NeoMTA 2 (8.1 vs 6.5 mm equivalent aluminum). • NeoPUTTY syringes have zero waste – the syringes allow efficient unit-dose dispensing to the end of the syringe which has a positive placement plunger tip. • NeoMTA 2 is a Powder/Gel product designed for 13 vital pulp and endodontic uses, including obturation and sealing (<i>refer to NeoMTA 2 IFU</i>).
<p>What are the similarities between NeoMTA 2 and NeoPUTTY?</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 (tantallite) for radiopacity. Neither NeoMTA 2 or NeoPUTTY 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. <p><small>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.</small></p>

	<p>² Marciano MA, Duarte MA, Camilleri J. Dental discoloration caused by bismuth oxide in MTA in the presence of sodium hypochlorite. <i>Clin Oral Investig.</i> 2015;19(9):2201-2209.</p>
<p>What are the indications for use for NeoPUTTY?</p>	 <p>There are 12 indications for use. Read IFU prior to use, available at avalonbiomed.com</p>
<p>What makes NeoPUTTY different from resin-based materials that contain some MTA?</p>	<p>Unlike inert, resin-based materials containing some MTA,...</p> <p>NeoPUTTY is:</p> <ul style="list-style-type: none"> • Bioactive; NeoPUTTY 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>³ Adigüzel 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>⁴ Collado-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. NeoPUTTY is non-staining because it contains tantalite as the radiopacifier, which does not cause staining.</p>

<p>Is Avalon Biomed NeoPUTTY the same as Portland cement?</p>	<p>No: While both Portland cement and MTA contain tricalcium silicate, they are not the same. 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. All Avalon Biomed MTA-based products, including NeoPUTTY, 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 is Avalon Biomed NeoPUTTY?</p>	<p>Avalon Biomed NeoPUTTY has the highest radiopacity in its class with 8.1 mm Al equivalent.</p>

DOSE INFORMATION

<p>What Kit sizes are available? How many cases can I treat with each kit?</p>	<table border="1" data-bbox="483 947 922 1073"> <thead> <tr> <th data-bbox="483 947 721 989">Kit Size (gm)</th> <th data-bbox="721 947 922 989"># of Doses</th> </tr> </thead> <tbody> <tr> <td data-bbox="483 989 721 1031">0.65</td> <td data-bbox="721 989 922 1031">9</td> </tr> <tr> <td data-bbox="483 1031 721 1073">1.2</td> <td data-bbox="721 1031 922 1073">16</td> </tr> </tbody> </table> <p data-bbox="963 968 1442 1062"><i>*The # of doses varies depending on the treatment. A dose size of 0.075 gm was used here.</i></p>	Kit Size (gm)	# of Doses	0.65	9	1.2	16
Kit Size (gm)	# of Doses						
0.65	9						
1.2	16						

APPLICATION, WORKING & SETTING TIME; COMPLETING THE RESTORATION

<p>How much NeoPUTTY do I need to apply to ensure its effectiveness?</p>	<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 gently compact the NeoPUTTY in the apical region to create a 3 to 5mm thick apical barrier.
<p>Does NeoPUTTY come with an applicator tip?</p>	<p>No, NeoPUTTY kits do not include tips. Express the desired amount of NeoPUTTY on a pad. Use the instrument of your choice to deliver the putty to the treatment site. You may also use a syringe tip of your choice to dispense or apply NeoPUTTY directly, remembering this is a very thick paste. Immediately recap the syringe and replace in its protective aluminum container after each use.</p>
<p>What is the best instrument to use to place NeoPUTTY into the pulp chamber when performing a pulpotomy?</p>	<p>We recommend placing NeoPUTTY 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.</p>
<p>What is the best instrument to place NeoPUTTY for surgical procedures such as root-end filling, apexification or perforation repair?</p>	<p>Use any convenient instrument, to deliver a small cone or cylinder of NeoPUTTY 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.</p>
<p>What is the working time of NeoPUTTY?</p>	<p>Working time at room temperature is >1 hr. Unlike NeoMTA 2, NeoPUTTY is formulated with a water-free organic liquid. When applied, it requires moisture from the apical tissues, dentinal tubules or pulp tissue to set.</p>
<p>What is the setting time of NeoPUTTY?</p>	<p>NeoPUTTY will set in vivo in about 4 hrs. Setting begins in the presence of moisture from the apical tissues, dentinal tubules or pulp tissue.</p> <p>NOTE: <i>To prevent premature hardening of NeoPUTTY, immediately recap after each use.</i></p>
<p>Should I secure the NeoPUTTY prior to restoration?</p>	<p>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 NeoPUTTY prior to the final tooth restoration. If you use a</p>
<p></p>	<p>flowable composite that requires etching, etch the tooth, not the NeoPUTTY, then proceed with the restoration.</p>
<p>Can I place NeoPUTTY and complete the restoration before it is completely set?</p>	<p>Yes, you can complete the restoration or cement a crown immediately after placing NeoPUTTY. NeoPUTTY will harden/set underneath the restoration. NeoPUTTY is immediately wash-out resistant and dimensionally stable when placed with zero shrinkage and negligible expansion to ensure gap-free sealing.</p>

CLEANUP AND STORAGE

<p>What is the Shelf Life of NeoPUTTY?</p>	<ul style="list-style-type: none"> • The product has a 3-year shelf life. • To prevent hardening of the NeoPUTTY, immediately recap after each use. Store the syringe in the protective aluminum container provided.
<p>Should I refrigerate the kit or its components?</p>	<p>NO. Store and use at room temperature (at or above 72°F/22°C) for optimal handling and control (DO NOT refrigerate). If NeoPUTTY is stored or used at a temperature below 72°F(22°C), it may be difficult to dispense.</p> <p>NOTE: When using the Zero-Waste Dispensing Technique for NeoPUTTY, repeated pumping is required to dispense the product and some resistance will be felt while pumping. NeoPUTTY is thick and will not flow freely from the syringe so the pressure felt while pumping is NORMAL.</p>

OTHER

<p>Does Avalon Biomed sell any other premixed bioactive bioceramics?</p>	<p>Yes, Avalon Biomed also manufactures NeoSEALER Flo™, a premixed bioactive bioceramic root canal sealer paste packaged in a syringe.</p>
<p>Does Avalon Biomed sell a light-curing MTA product?</p>	<ul style="list-style-type: none"> • Avalon Biomed does not manufacture a light-curing MTA. We prefer to maximize the concentration of bioactive powders in Avalon Biomed 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. Avalon Biomed bioactive cements (MTAs) expand very slightly to ensure sealing. <p>⁵ <i>Formosa L M, Mallia B, Camilleri J The chemical properties of light and chemical curing composite with mineral trioxide aggregate filler. Dent Mater. 2013 Feb;29(2):e11-9.</i></p>