


FAQ – Avalon Biomed NeoSEALER™ Flo Endodontic Sealer

CHOOSING A PRODUCT

<p>What is NeoSEALER™ Flo?</p>	<p>NeoSEALER Flo is a premixed bioactive bioceramic endodontic sealer consisting of an extremely fine, inorganic powder of tricalcium/dicalcium silicate in an organic medium. The product is packaged ready-to-use. No mixing is required. NeoSEALER Flo is designed to set in vivo in the presence of moisture from the surrounding tissues.</p>
<p>What are the indications for use?</p>	<div style="text-align: center;">  <p>The diagram shows a cross-section of a tooth with a yellow pulp chamber and root canal. A bracket on the left side of the root canal is labeled 'NeoSEALER Flo', indicating the location of the sealer.</p> </div> <p>Obturation and sealing of root canals. Read IFU prior to use. To obtain, visit avalonbiomed.com</p>
<p>How does NeoSEALER Flo set?</p>	<ul style="list-style-type: none"> • NeoSEALER Flo is formulated with a water-free organic liquid. NeoSEALER Flo sets in vivo. Setting begins in the presence of moisture from the apical tissues and dentinal tubules. • NeoSEALER Flo 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 are the differences between NeoMTA® 2 and NeoSEALER Flo?</p>	<ul style="list-style-type: none"> • NeoSEALER Flo does not need mixing – it is a uniform sealer consistency from beginning to end. • Every NeoSEALER Flo Kit contains a syringe of premixed sealer paste packaged in a protective aluminum tube along with Flo Tip™ dispensing tips for precise placement and minimal product waste. • NeoSEALER Flo is indicated only for obturation and sealing of root canals. • NeoMTA 2 is a Powder/Gel hand-mix product designed for 13 vital pulp and endodontic uses, including obturation and sealing (<i>refer to NeoMTA 2 IFU</i>).
<p>What is the difference between NeoPUTTY and NeoSEALER Flo?</p>	<p>NeoSEALER Flo is specifically design for endodontic obturation with gutta percha, whereas NeoPUTTY is designed for 12 other vital pulp & endodontic procedures needing a thick putty-like material (<i>refer to NeoPUTTY IFU</i>).</p>
<p>What are the similarities between NeoMTA 2 and NeoSEALER Flo?</p>	<ul style="list-style-type: none"> • Both products are bioactive bioceramic MTAs. • Both products release calcium and hydroxide ions from the MTA, promoting hydroxyapatite (HA) formation on the MTA surfaces to enhance sealing and support healing. • Both products are resin-free for maximum bioactivity.

<p>What are the similarities between NeoMTA 2 and NeoSEALER Flo? <i>(continued)</i></p>	<ul style="list-style-type: none"> • 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 2 or NeoSEALER Flo contain bismuth oxide, which causes tooth discoloration². • Both products are indicated for endodontic sealing. • Both products have low water solubility (<3%) when set. • Both products are dimensionally stable on setting. • Both products are based on extremely fine tri/dicalcium silicate powders. <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. 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>Is NeoSEALER Flo non-staining?</p>	<p>YES. NeoSEALER Flo is non-staining because it contains tantalite as the radiopacifier, which does not cause staining.</p> <p>NOTE: Not all white MTA's are considered non-staining. White MTAs that contain bismuth oxide as the radiopacifier (e.g. ProRoot White MTA) will cause staining.</p>
<p>What makes NeoSEALER Flo different from resin-based materials that contain some MTA?</p>	<p>Unlike inert, resin-based materials containing some MTA,...</p> <p>NeoSEALER Flo is:</p> <ul style="list-style-type: none"> • Bioactive: NeoSEALER Flo releases calcium and hydroxide ions from the MTA, promoting hydroxyapatite (HA) formation on the MTA surfaces to enhance sealing and support healing. • Formulated with pure tri/dicalcium silicate powder and a radiopacifier. • Dimensionally stable – unlike resin-based materials that shrink. • Biocompatible, non-cytotoxic. • More radiopaque. • Resin-free for maximum MTA concentration and maximum bioactivity. [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.] <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. J Dent Res Dent Clin Dent Prospects. 2019;13(4):241-246. 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. Int Endod J. 2017;50 Suppl 2:e19-e30.</p>

<p>Is NeoSEALER Flo 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 NeoSEALER Flo, 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 NeoSEALER Flo?</p>	<p>NeoSEALER Flo has a radiopacity of 6 mm Al equivalent. Increasing the radiopacity would lower the bioactive MTA content and potentially compromise the product's ability to set.</p>

PRODUCT PRESENTATION

<p>What Kit sizes are available and how many tips are included with each kit?</p>	<table border="1"> <thead> <tr> <th>Kit Size (gm)</th> <th>Flo Tip™</th> </tr> </thead> <tbody> <tr> <td>2.2</td> <td>20</td> </tr> <tr> <td>4.4</td> <td>40</td> </tr> </tbody> </table>	Kit Size (gm)	Flo Tip™	2.2	20	4.4	40	<p><i>*Every NeoSEALER Flo kit contains 20 or 40 Flo Tips. These minimal waste tips ensure that product waste is minimized.</i></p>
Kit Size (gm)	Flo Tip™							
2.2	20							
4.4	40							

APPLICATION, WORKING & SETTING TIME; RETREATMENT

<p>Does NeoSEALER Flo come with a dispensing tip?</p>	<p>Yes, NeoSEALER Flo was designed to be the most efficient and economical bioceramic sealer in the market. <u>NeoSEALER Flo kit includes 20 or 40 Flo Tips with the 2.2 or 4.4 gm kits, respectively.</u> The Flo Tip is designed to significantly reduce product waste compared to other dispensing tips.</p>
<p>What is the difference between Flo Tip and conventional tips on the market?</p>	<p>Our unique Flo Tip combines the following features and benefits:</p> <ul style="list-style-type: none"> • Minimal waste barrel significantly reduces product waste compared to conventional tips. • Minimal waste tips provided at no additional cost. Every NeoSEALER Flo kit includes 20 or 40 Flo Tips with the 2.2 or 4.4 gm kits, respectively.
<p>Can I use NeoSEALER Flo without the Flo Tip?</p>	<p>NeoSEALER Flo may be dispensed without the Flo Tip and used with the traditional cone buttering technique to coat the canal walls with an instrument and to coat the gutta percha points prior to its insertion.</p>
<p>Can I use any dispensing tip with NeoSEALER Flo?</p>	<p>Yes, any dispensing tip designed with a luer-lock fitting may be fitted to the NeoSEALER Flo syringe, however we recommend the smallest tip used to be a 29-gauge tip, such as an Ultradent NaviTip™.</p>

Can I use any brand of gutta percha with NeoSEALER Flo?	Yes, however some brands of gutta percha points are waxy and the sealer may not appear to adhere to the point outside the root.
Do I need to completely dry the canals before applying NeoSEALER Flo?	NO. Moisture is required for setting of the sealer, supplied by the dentinal tubules and apical tissues. Clean & shape the canals and remove the smear layer. Remove <u>pooled</u> irrigants or excessive moisture from surrounding tissues with absorbent points.
What is the working time of NeoSEALER Flo?	Working time at room temperature is > 40 min. Setting begins in the presence of moisture provided by the surrounding tissues.
What is the final setting time of NeoSEALER Flo?	NeoSEALER Flo will set in vivo in 11 hrs ± 1 hr. The body fluids from the dentinal tubules and apical tissues cause the product to set.
Is NeoSEALER Flo dimensionally stable?	Yes, unlike resin-based sealers NeoSEALER Flo is dimensionally stable and meets the ADA 57 standard: <i>ADA 57 std. <1% shrinkage & <0.1% expansion</i>
Is NeoSEALER Flo resorbable in the case of material extrusion into the periapical area?	NeoSEALER Flo is a biocompatible paste that will <u>not</u> result in a significant inflammatory response if a <u>slight</u> overfill occurs. Resorption in the periapical tissue may occur over years. However, it's important to NOT overfill the root canal forcing a large amount of sealer to be expressed beyond the apex of the root! When a large amount of material is overfilled into 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.
Can the NeoSEALER Flo be removed for re-retreatment?	Yes. Use conventional instrumentation, including hand/rotary files and ultrasonic instrument tips, to remove NeoSEALER Flo if it was placed with one or more gutta percha points.

CLEANUP AND STORAGE

What is the Shelf Life of NeoSEALER Flo?	<ul style="list-style-type: none"> The product has a 2-year shelf life. Store at room temperature for optimal handling (do not refrigerate). To prevent hardening of the NeoSEALER Flo, immediately recap after each use. Store the syringe in the protective aluminum container provided.
Should I refrigerate the kit or its components?	NO. Store and use at room temperature (at or above 72°F/22°C) for optimal handling and control (DO NOT refrigerate). If NeoSEALER Flo is stored or used at a temperature below 72°F(22°C), it may be difficult to dispense.
How do I clean instruments that have contacted NeoSEALER Flo?	Warm water may be used to clean instruments if the material has not hardened. If hardened clean with vinegar or other mild acid. NOTE: NeoSEALER Flo is a non-sterile product. Follow your established cleaning and sterilization procedures for instruments as appropriate.

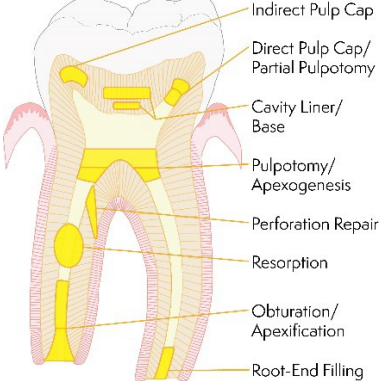
OTHER

<p>Does Avalon Biomed sell any other premixed bioactive bioceramics?</p>	<p>Yes, Avalon Biomed also manufactures NeoPUTTY™, a premixed bioactive bioceramic Root & Pulp treatment 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 which promotes 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 may leave cytotoxic monomers in the MTA-resin matrix and in contact with the pulp. • Resins shrink during curing; they are not as dimensionally stable as MTAs. Avalon Biomed bioactive cements (MTAs) are dimensionally stable and meet the ADA 57 standard. <p><small>⁵ Lee, Y. Shin, S.O. Kim, H.S. Lee, H.J. Choi, J.S. Song, Comparative Study of Pulpal Responses to Pulpotomy with ProRoot MTA, RetroMTA, and TheraCal in Dogs' Teeth, J Endod 41(8) (2015) 1317-24.</small></p>

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 (tantalite) 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. Clin Oral Investig. 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>³Adigüzel M, Ahmetoğlu F, Eldeniz AÜ, Tekin MG, Gögebakan B. Comparison of cytotoxic effects of calcium silicate-based materials on human pulp fibroblasts Mehmet. J Dent Res Dent Clin Dent Prospects. 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. Int Endod J. 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 1066"> <thead> <tr> <th>Kit Size (gm)</th> <th># of Doses</th> </tr> </thead> <tbody> <tr> <td>0.65</td> <td>9</td> </tr> <tr> <td>1.2</td> <td>16</td> </tr> </tbody> </table> <p><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: To prevent premature hardening of NeoPUTTY, immediately recap after each use.</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>