


FAQ – Avalon Biomed NeoSEALER[®] Flo Endodontic Sealer

CHOOSING A PRODUCT

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| <p>What is NeoSEALER[®] Flo?</p> | <p>NeoSEALER Flo is a premixed bioactive bioceramic endodontic sealer incorporating an extremely fine, inorganic powder of tricalcium/dicalcium silicate in an organic liquid. 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;">  </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 foil pouch along with 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. |

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| <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>NeoSEALER Flo 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. • 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, Göğebakan 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.</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 |

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| | <ul style="list-style-type: none"> • 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> |
| How radiopaque is NeoSEALER Flo? | 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. |

PRODUCT PRESENTATION

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| What Kit sizes are available and how many tips are included with each kit? | Kit Size (g) | Tips | <i>*Depending on the market, the kit may be packaged with either Flex Flo Tips™, Flo Tips™ or Basic Flex Tips™.</i> |
| | 2.2 | 20 | |
| | 4.4 | 40 | |

APPLICATION, WORKING & SETTING TIME; RETREATMENT

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| Does NeoSEALER Flo come with a dispensing tip? | <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 Flex Flo Tips with the 2.2 or 4.4 g kits, respectively.</u> The Flex Flo Tip is designed to significantly reduce product waste compared to other dispensing tips.</p> <p><i>*Depending on the market, the kit may be packaged with either Flex Flo Tips™, Flo Tips™ or Basic Flex Tips™.</i></p> |
| What is the difference between Flex Flo Tip and conventional tips on the market? | <p>Our unique Flex 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 Flex Flo Tips with the 2.2 or 4.4 g kits, respectively. Depending on the market, the kit may be packaged with either Flex Flo Tips™, Flo Tips™ or Basic Flex Tips™. |
| Can I use NeoSEALER Flo without the Flex Flo Tip? | NeoSEALER Flo may be dispensed without the Flex 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. |
| Can I use any dispensing tip with NeoSEALER Flo? | Any 25.5-gauge or larger dispensing tip designed with a luer-lock fitting may be fitted to the NeoSEALER Flo syringe, however we recommend the smallest diameter tip used be Avalon Biomed's 25.5-gauge Flex Flo Tip. |
| 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. |

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| 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 non-cytotoxic, biocompatible paste such that if overfill occurs it may <u>not</u> result in a significant inflammatory response. Resorption in the periapical tissue may occur over years. However, caution should be exercised to NOT overfill the root canal forcing a large amount of sealer beyond the apex of the root. If a large amount of sealer is overfilled into the mandibular canal (inferior alveolar canal), the clinician should assess if the overfilled material should be removed 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. <i>Carrillo CA, Kirkpatrick T, Freeman K, Makins SR, Aldabbagh M, Jeong JW. Retrievability of Calcium Silicate-based Root Canal Sealers During Retreatment: An Ex Vivo Study. J Endod. 2022 Jun;48(6):781-786. doi: 10.1016/j.joen.2022.02.009. Epub 2022 Feb 25. PMID: 35219747</i> |

CLEANUP AND STORAGE

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| 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 55°F(13°C), it may be difficult to dispense. Restoring the product to room temperature will return the product to its original properties. Restoring the product to room temperature will return the product to its original properties. |
| 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

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| Does Avalon Biomed sell any other premixed bioactive bioceramics? | Yes, Avalon Biomed also manufactures NeoSEALER EZFlo, and NeoPUTTY, a premixed bioactive bioceramic Root & Pulp treatment paste packaged in a syringe. |
| Does Avalon Biomed sell a light-curing MTA product? | <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.

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.