FAQ – Avalon Biomed NeoSEALER™ Flo Endodontic Sealer

CHOOSING A PRODUCT

What is NeoSEALER™ Flo?	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.
What are the indications for use?	NeoSEALER Flo Obturation and sealing of root canals. Read IFU prior to use. To obtain, visit avalonbiomed.com
How does NeoSEALER Flo set?	• 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.
What are the differences between NeoMTA® 2 and NeoSEALER Flo?	• 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 *(refer to NeoMTA 2 IFU)*.
What is the difference between NeoPUTTY and NeoSEALER Flo?	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 *(refer to NeoPUTTY IFU)*.
What are the similarities between NeoMTA 2 and NeoSEALER Flo?	• 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.

What are the similarities between NeoMTA 2 and NeoSEALER Flo? *(continued)*	• Both products have initially high pH (alkaline/basic) when applied. Literature has shown such products to be antimicrobial in vitro[1]. • 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 discoloration[2]. • 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. *[1]The 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.* *[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.*
Is NeoSEALER Flo non-staining?	**YES.** NeoSEALER Flo is non-staining because it contains tantalite as the radiopacifier, which does not cause staining. **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.
What makes NeoSEALER Flo different from resin-based materials that contain some MTA?	Unlike inert, resin-based materials containing some MTA,… ## NeoSEALER Flo is: • **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.] *[3]Adıgüzel 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.* *[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. Int Endod J. 2017;50 Suppl 2:e19-e30.*

Is NeoSEALER Flo the same as Portland cement?	**No.** While both Portland cement and MTA contain tricalcium silicate, they are not the same. Portland cement is: • **An impure** industrial grade construction product • **A coarse powde**r that sets slowly • **NOT** a medical device • **NOT** cleared by the FDA • **NOT** radiopaque • **NOT** a highly refined powder **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.
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

What Kit sizes are available and how many tips are included with each kit?	Kit Size (gm)	Flo Tip™	*Every NeoSEALER Flo kit contains 20 or 40 Flo Tips. These minimal waste tips ensure that product waste is minimized.*
	2.2	20	
	4.4	40	

APPLICATION, WORKING & SETTING TIME; RETREATMENT

Does NeoSEALER Flo come with a dispensing tip?	Yes, NeoSEALER Flo was designed to be the most efficient and economical bioceramic sealer in the market. NeoSEALER Flo kit includes 20 or 40 Flo Tips with the 2.2 or 4.4 gm kits, respectively. The Flo Tip is designed to significantly reduce product waste compared to other dispensing tips.
What is the difference between Flo Tip and conventional tips on the market?	Our unique Flo Tip combines the following features and benefits: • **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.
Can I use NeoSEALER Flo without the Flo Tip?	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.
Can I use any dispensing tip with NeoSEALER Flo?	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™.

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 pooled 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: *ADA 57 std. <1% shrinkage & <0.1% expansion*
Is NeoSEALER Flo resorbable in the case of material extrusion into the periapical area?	NeoSEALER Flo is a biocompatible paste that will not result in a significant inflammatory response if a slight 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?	• 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

Does Avalon Biomed sell any other premixed bioactive bioceramics?	Yes, Avalon Biomed also manufactures NeoPUTTY™, a premixed bioactive bioceramic Root & Pulp treatment paste packaged in a syringe.
Does Avalon Biomed sell a light-curing MTA product?	• 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 formation[5]. • 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.*