

Uniquely designed Flex Flo Tip incorporates a minimal waste barrel for 81% less waste, at no additional cost.

From Internal Report titled "Dispensing Tip Waste Measurement" By N Patel Dated 10/02/2020

Figure 1 & 2 depict the different types of tips evaluated.

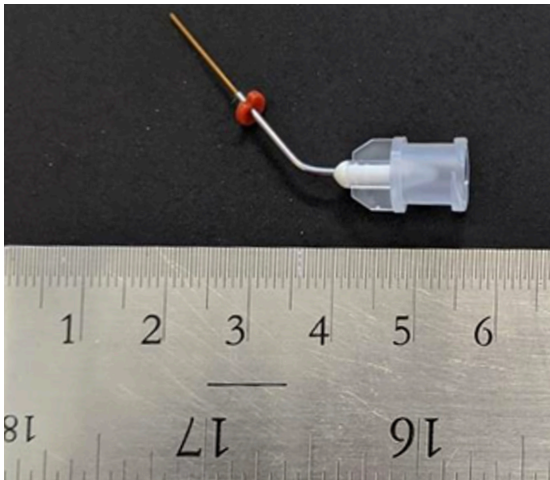


Figure 1: Flex Flo Tips™

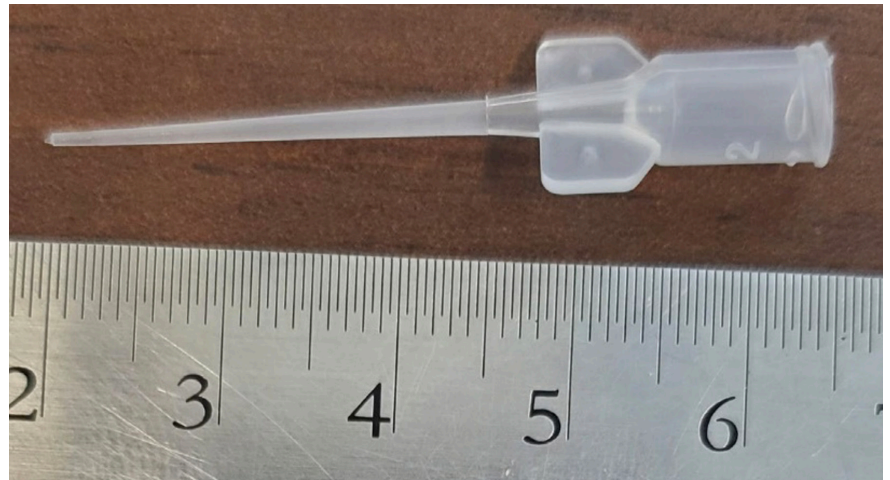


Figure 2: Brasseler standard tips (tips provided by Brasseler Endosequence HiFlow™)

RESULTS: Table 2 below shows the amount of waste left within each dispensing tip.

DISPENSING TIP	WASTE (GM)
Flex Flo Tips™	0.027
Flo Tips™	0.083
Brasseler standard tips (tips provided by Brasseler Endosequence HiFlow™)	0.139

DISCUSSION: The Flex Flo Tips™ had the lowest waste of 0.027 gm left while the Flo Tips™ had 0.083 gm left. However, both these wastes were considerably lower than the Brasseler standard tips, which had 0.139 gm left.

When comparing the Flex Flo Tips™ and the Flo Tips™ to Brasseler standard tips, Table 3 lists the amount of material saved. This is calculated by calculating the difference between the tip in question (either Flex Flo Tips™ or Flo Tips™) and the Brasseler standard tips, and then dividing the value obtained by the amount of waste in the Brasseler standard tip (0.139).

TABLE 3: Amount of Material Saved When Compared to Brasseler Standard Tips.


DISPENSING TIP	PERCENTAGE SAVED, COMPARED TO BRASSELER STD. TIPS
Flex Flo Tips™ (RMS 126 MST-Visco Tips)	81%

TABLE 4: In-House Waste Measuring Data

FLEX FLO		BRASSELER	
Tip #	Weight after dispensed (Grams)	Tip #	Weight after dispensed (Grams)
1	0.028	1	0.143
2	0.027	2	0.143
3	0.028	3	0.151
4	0.031	4	0.146
5	0.027	5	0.137
6	0.026	6	0.141
7	0.027	7	0.133
8	0.025	8	0.123
9	0.024	9	0.124
10	0.022	10	0.149
Average	0.027	Average	0.139
STD	0.002	STD	0.010

NeoSEALER Flo is RESIN-FREE, promoting the formation of hydroxyapatite (HA) on the MTA surfaces to enhance sealing and support healing

Resin Free – See SDS. NeoSEALER Flo contains no resins

 SAFETY DATA SHEET					
Product Name: Avalon Biomed NeoSEALER Flo, NeoPUTTY					
Product Name: Avalon Biomed NeoSEALER Flo & NeoPUTTY			SDS Code Number: SDS19		
Trade Name & Synonyms: NeoSEALER Flo, NeoPUTTY			Last Revision: N/A Effective Date: 04/06/2020		
Chemical Name: no name assigned to mixture			Manufactured by: NuSmile Ltd.		
CAS. Number: None assigned			Address: 3315 W. 12 th Street Houston, TX 77008 USA		
Grades or Minor Variant Identities: none			Websites: www.avalonbiomed.com		
Product Use (for Canada): Dental cement			Telephone Number: 713-861-0033; Int'l 1-800-346-5133		
			e-mail: info@avalonbiomed.com		
2. Hazard Identification					
Emergency Overview: Dry paste may irritate throat and respiratory system and cause coughing. Frequent inhalation of dust from dry paste over a long period of time increase the risk of developing lung diseases. Paste may cause permanent eye damage if left untreated. Paste has an irritating effect on moist skin. Prolonged contact may cause burns. It is unlikely that exposure to small amounts for short periods, may have any irritant or toxic effect.					
Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s) of hazardous component	Target Organ(s)
Eye	Can cause eye immediate or delayed irritation of cornea.	Single	Mild	-	-
Skin	Exposure may cause drying of the skin with mild irritation. Discomfort or pain cannot be relied upon to alert a person to a hazardous skin exposure.	Single	Mild	Acute irritation to skin and mucous membranes. Can aggravate other skin conditions.	-
Inhalation	Exposure may cause irritation to the moist mucous membranes of the nose, throat, and upper respiratory system.	Single	Mild	Frequent inhalation of large quantities of dry paste, over a long period of time increases the risk of lung diseases.	Lung
Ingestion	Internal discomfort or ill effects are possible if large quantities are swallowed.	Single	Mild	Acute irritation	-
Other	-	-	-	-	-
Medical Conditions Aggravated by Exposure: Pre-existing upper respiratory and lung diseases may be aggravated by inhalation.					
Carcinogenicity (IARC, NTP): None known. Potential Environmental Effects: Powder with moisture hardens into a solid mass that is not biodegradable.					
3. Composition of Ingredients					
Hazardous Components	CAS. Number	Lowest Exposure Limits	%		
Ta ₂ O ₅ – Tantalite	1314-61-0	No TLV assigned.	<50		
3CaO·SiO ₂ –Tricalcium Silicate	12168-85-3	4 mg/m ³	<25		
CaAl ₂ O ₄ – Calcium Aluminate	65997-16-2	3 mg/m ³	<25		
2CaO·SiO ₂ –Dicalcium Silicate	10034-77-2	4 mg/m ³	<10		
3CaO·Al ₂ O ₃ – Tricalcium aluminate	12042-78-3	10 mg/m ³	<5		
CaSO ₄ · calcium sulfate	7778-18-9	5 mg/m ³	<1		
4. First Aid Measures					
Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Effects		
			Acute	Delayed	
Eye	Immediately flush eyes with plenty of water for 15 minutes, while holding eyelids apart. Remove contact lenses. Do not use eye ointments.	Get medical attention immediately, even if no symptoms develop.	-	-	
Skin	Immediately flush skin with plenty of cool soapy water. Remove contaminated clothing and wash contact areas thoroughly. Seek prompt medical attention.	Get medical attention.	-	-	
Inhalation	Move individual away from exposure into fresh air. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Keep patient warm.	Get medical attention.	-	-	
Ingestion	Seek prompt medical attention. Do not induce vomiting. Vomiting should only be induced by medical personnel. If vomiting occurs, keep the head lower than chest to avoid aspiration. Never give anything by mouth to an unconscious or convulsing person.	Get medical attention.	-	-	
Other	Seek medical advice after large-scale (>25 gm) exposure.	-	-	-	
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.					
5. Fire and Explosion Data					
Flashpoint & Method: > 200 °C (open cup)	Flammable (Explosive) Limits in Air LEL/UEL: not applicable	Autoignition Temperature: 260 °C	Other: Slight fire hazard. In case of combustion it may generate minor amounts of CO & CO ₂ .		
Flame Propagation or Burning Rate (for solids): not applicable	Properties Contributing to fire Intensity: none	Flammability Classification: 1			
Extinguishing Media: Water spray, alcohol resistant foam, carbon dioxide, or dry chemical.			Extinguishing Media to Avoid: None		
Protection and Procedures for Firefighters: Water jets should not be used directly on igniting products because it may disperse the material and intensify the fire. Self-contained breathing apparatus and protective clothing are required. Cool intact fire-exposed containers with water spray and remove them.					
Unusual Fire and Explosion Hazards: Irritating fumes may be released by thermal decomposition which may be hazardous to health. A fire may produce thick black smoke. Fumes of silicon dioxide or carbon monoxide and carbon dioxide may be evolved from material in a fire.					

Unmatched radiopacity of 8.1 mm Al equivalent.

From Internal Report titled "Radiopacities of Various MTA-type & competitive products" By C. Primus dated 2/11/2020

OBJECTIVE:

The aim of this study was to evaluate the radiopacity of 3 NuSmile MTA products (2 under development) and 14 other competitive products.

MATERIALS:

The samples included endodontic sealer and putty materials used for vital pulp therapy, endodontic surgery perforation repair (putty) or root canal sealing with gutta percha (sealer) (Table 1). The materials were mixed according to the IFUs provided in their kits.

TABLE 1: Products Tested in Alphabetical Order

PRODUCT NAME	TYPE
1. AH Plus	Sealer
2. AH 26	Sealer
3. Biodentine	Sealer
4. BioRoot RCS	Sealer
5. Edge BioCeramic sealer	Sealer
6. Endosequence BC sealer	Sealer
7. Endosequence BC Sealer HiFlow	Sealer
8. Endosequence Fast Set Putty	Putty
9. Endosequence Putty	Putty
10. Kerr Endo Pulp Canal Sealer	Sealer
11. MTA Angelus	Putty
12. MTA Fillapex	Sealer
13. MTA Repair HP	Putty
14. NeoMTA 2	Sealer & Putty
15. NeoSEALER Flo	Sealer
16. NeoPUTTY	Putty
17. Sprig Smart MTA	Putty

Unmatched radiopacity of 8.1 mm Al equivalent. *(continued)*

From Internal Report titled "Radiopacities of Various MTA-type & competitive products" By C. Primus dated 2/11/2020

TABLE 4: Summary of Radiopacity Results in Alphabetical Order

PRODUCT NAME	TYPE	NORMALIZED RADIOPACITY (mm Al)
AH Plus*	Sealer	13.4
AH 26*	Sealer	10.9
Biodentine	Putty	3.1
BioRoot RCS	Sealer	6.4
Edge Bioceramic	Sealer	8.1
Endosequence BC Sealer	Sealer	6.8
Endosequence BC Sealer HiFlow	Sealer	8.3
Endosequence Fast Set Putty	Putty	7.4
Endosequence Putty	Putty	7.7
Kerr Endo†	Sealer	11.3
MTA Angelus	Putty	4.9
MTA Fillapex*	Sealer	4.6
MTA Repair HP	Putty	4.1
NeoMTA 2	Sealer	5.5
NeoMTA 2	Putty	6.5
NeoSEALER Flo	Sealer	5.9
NeoPUTTY	Putty	8.1
Sprig Smart MTA	Putty	5.3

*These products are resin based; no tricalcium silicate. †This sealer is based on zinc oxide eugenol; no tricalcium silicate. All other products are tricalcium silicate based.

Unmatched radiopacity of 8.1 mm Al equivalent. (continued)

From Internal Report titled "Radiopacities of Various MTA-type & competitive products" By C. Primus dated 2/11/2020

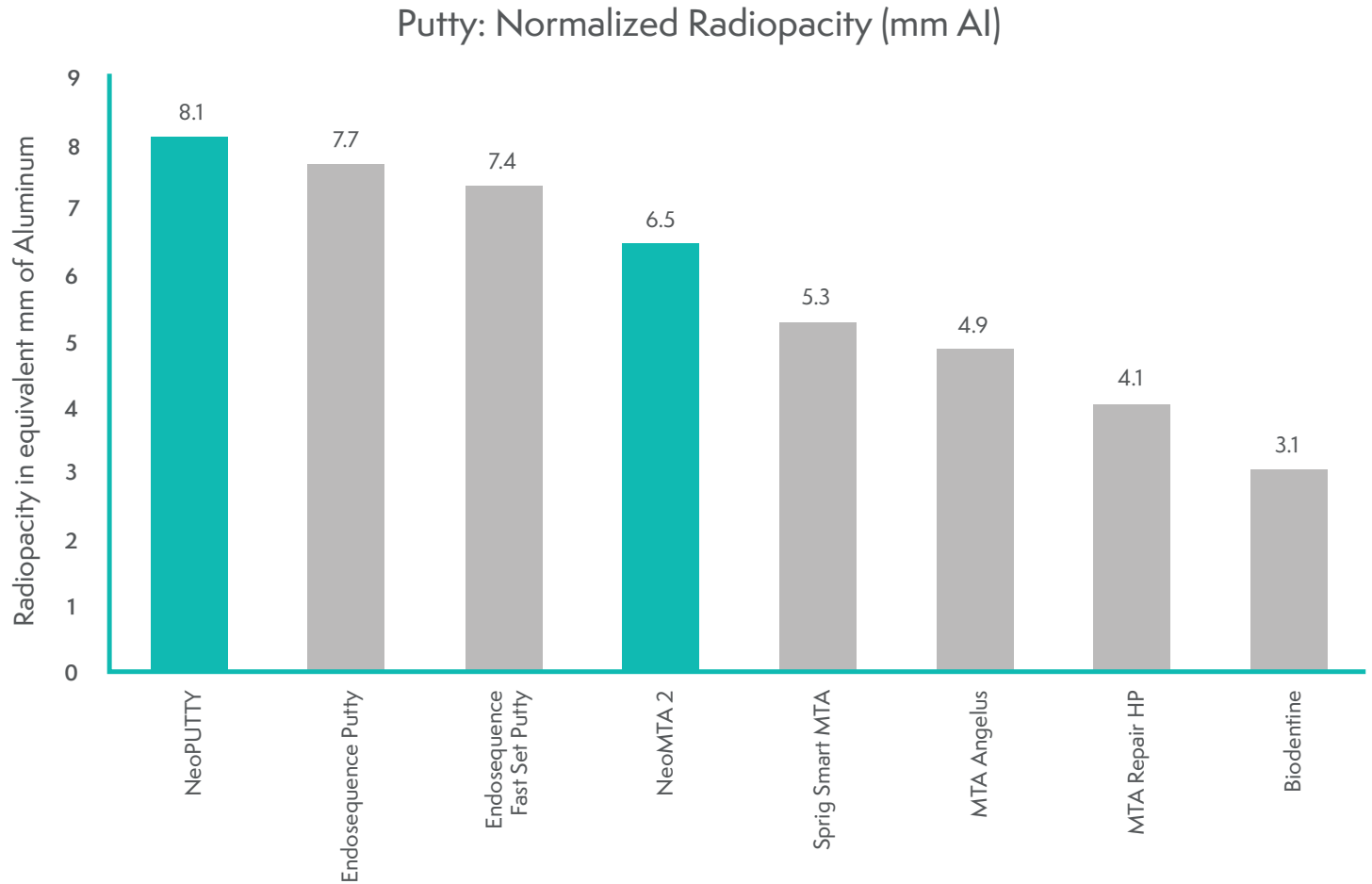



Figure 2b: Radiopacities of putty products.

NeoMTA 2 is dimensionally stable, non-staining, immediately wash-out resistant, RESIN-FREE and with high pH promotes osteogenic response.

Dimensional Stability from NeoMTA 2 Device Master Record:

TEST	PROTOCOL	CRITERIA FOR SUCCESS	MTA 2.2
Flow (mm)	ADA 57 ISO 6876	Flow>20 mm Flow>17 mm	32 @ P:G=3:2 21 @ P:G=3:2
Working Time (Min)	ADA 57 ISO 6876	To be stated	7 @ P:G=3:2 8 @ P:G=3:2
Setting Time (hours)	ADA 57 ISO 6876	To be stated	2:50 @ P:G=3:2
Film Thickness Measurement (µm)	ADA 57 ISO 6876	<50 µm	45±3 @ P:G=3:2
Dimensional Stability (Linear %)	ADA 57	<1% Shrinkage and 1<0.1% Expansion after 30 days	<0.026%
Solubility in water (weight %)	ADA 57 ISO 6876	<3% by weight after setting,	3.0 after 14 days @ P:G=3:2
Radiopacity (mm equivalent of Al)	ADA 57 ISO 6876	>3 mm of Equivalent Al	4.5 mm @ P:G=3:2
Compressive Strength (MPa)	ISO 9917-1	>50 MPa	57.6±6.5 MPa @ 2.75:1
Leachable As & Pb	ISO 9917-1	<2 ppm As; < 100 ppm Pb	Met Requirements

NeoMTA 2 is non-staining & Resin Free – See SDS. NeoMTA 2 contains Tantalum oxide as the radiopacifier shown in numerous studies to not cause staining whereas bismuth oxide (another commonly used radiopacifier) is known to stain, and contains no resins.

 SAFETY DATA SHEET					
Product Name: Avalon Biomed NeoMTA® 2 Powder					
1. Product and Company Identification					
Product Name: Avalon Biomed NeoMTA® 2 Powder			SDS Code Number: SDS9		
Trade Name & Synonyms: NeoMTA® 2 Powder			Last Revision: 2		Effective Date: 4/6/2020
Chemical Name: no name assigned to mixture			Manufactured by: NuSmile Ltd.		
CAS. Number: None assigned			Address: 3315 W 12 th Street, Houston, TX 77008 USA Website: www.avalonbiomed.com		
Grades or Minor Variant Identities: None			Telephone Number: 713-861-0033; Int'l 1-800-346-5133		
Product Use (for Canada): Powder for mixing with NeoMTA® 2 Gel for dental use.			e-mail: info@avalonbiomed.com		
2. Hazard Identification					
Emergency Overview Dust may irritate throat and respiratory system and cause coughing. Frequent inhalation of dust over a long period of time increase the risk of developing lung diseases. Dust or splashes from the mixed powder may cause permanent eye damage. Dust has an irritating effect on moist skin. Prolonged contact may cause burns.					
Routes of Exposure	Signs and Symptoms	Single, Repeated, or Lifetime Exposure	Severity (Mild, Moderate, Severe)	Acute and Chronic Health Effect(s) of hazardous component	Target Organ(s)
Eye	Can cause eye immediate or delayed irritation of cornea.	Single	Mild	-	-
Skin	Exposure may cause drying of the skin with mild irritations. Discomfort or pain cannot be relied upon to alert a person to a hazardous skin exposure.	Single	Mild	Acute irritation to skin and mucous membranes. Can aggravate other skin conditions.	-
Inhalation	Exposure may cause irritation to the moist mucous membranes of the nose, throat, and upper respiratory system.	Single	Mild	Frequent inhalation of large quantities, over a long period of time increases the risk of lung diseases.	Lung
Ingestion	Internal discomfort or ill effects are possible if large quantities are swallowed.	Single	Mild	Acute irritation	-
Other	-	-	-	-	-
Medical Conditions Aggravated by Exposure: Pre-existing upper respiratory and lung diseases may be aggravated by inhalation.					
Carcinogenicity (IARC, NTP): None known					
Potential Environmental Effects: Powder with moisture hardens into a solid mass that is not biodegradable.					
3. Composition of Ingredients					
Hazardous Components	CAS. Number	Lowest Exposure Limits	%		
3CaO•SiO ₂ - Tricalcium silicate	12168-85-3	4 mg/m ³	<50		
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CaSO ₄ - Calcium sulfate	7778-18-9	5 mg/ m ³	<5		
3CaO•Al ₂ O ₃ - Tricalcium Aluminate	12042-78-3	10 mg/m ³	<5		
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Routes of Exposure	First Aid Instructions	Immediate Medical Attention	Effects		
			Acute	Delaye	
Eye	Immediately flush eyes with plenty of water for 15 minutes, while holding eyelids apart. Remove contact lenses. Do not use eye ointments.	Get medical attention immediately, even if no symptoms	-	-	
Skin	Immediately flush skin with plenty of cool soapy water. Remove contaminated clothing and wash contact areas thoroughly. Seek prompt medical attention.	-	-	-	
Inhalation	Move individual away from exposure into fresh air. If not breathing, give artificial respiration. If not breathing, give artificial respiration. If breathing is difficult, administer oxygen. Keep patient warm.	Get medical attention.	-	-	
Ingestion	If ingestion occurs, flush mouth with water, and drink water or milk. Do not induce vomiting. If vomiting occurs, keep the head lower than chest to avoid aspiration into the lungs. Never give anything by mouth to an unconscious or convulsing person.	Get medical attention.	-	-	
Other	Seek medical advice after large-scale exposure (>100 gm)	-	-	-	
Note to Physicians (Treatment, Testing, and Monitoring): Treat symptomatically.					

NeoMTA 2 is immediately wash-out resistant:

From Internal Report titled " Washout Test Results, Round 2" by N. Patel dated 1/24/2020

BACKGROUND:

One characteristic that affects the performance of MTA-type products, whether in a pre-mixed form or separate powder-liquid format, is its stability when placed in a tooth. A way to test the product's stability is through washout testing. We have developed an in-house procedure to assess washout resistance. The greater the amount of material lost during the test, the lower the resistance.

OBJECTIVE:

The objective of this study was to assess (qualitatively and quantitatively) the washout resistance of various MTA-type products.

MATERIALS:

The materials tested included endodontic sealers and putty-like materials used for vital pulp therapy and endodontic surgery or perforation repair. See Table 1. Eight NuSmile/Avalon Biomed products were tested:

1. Prototype NeoPUTTY (MTA 2.3.2 Putty containing 80% powder),
2. MTA 2.1 powder with 2.1 gel (NeoMTA),
3. MTA 2.2 powder with MTA 2.2 gel (NeoMTA 2)

RESULTS:

PRODUCT NAME	% LOSS OF WEIGHT
Avalon Biomed NeoMTA 2	0.0
EdgeEndo Edge Bioceramic Retrofill and Perforation Material	8.1
Angelus Bio C Repair Putty	13.3
Avalon Biomed NeoPUTTY	15.0
Septodont Biodentine	40.4
Medcem MTA	100.0
MTA Angelus	100.0

DISCUSSION:

Any decrease or increase in weight less than 5% was considered as negligible weight change, due to the margin of error from the wicking of the excess water. A reading of '~0.0' in Table 2 replaced weight gains when measured.