



ENDODONTIC SEALER

Non-Staining
BIOACTIVE
Bioceramic



NeoSEALER™ Flo

NeoSEALER™ Flo

COMPOSITION & DESCRIPTION

Bioactive paste 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 provided by the surrounding tissues.

MATERIAL CHARACTERISTICS

- Bioactive bioceramic
- Does not discolor teeth
- Radiopaque
- Resin-free

INDICATION

- Obturation and sealing of root canals.

CONTRAINDICATIONS

- Hypersensitivity against caustic (high pH) solutions.
- Do not use for primary tooth pulpectomy (root canal filling) unless the permanent successor tooth is absent.

ADVERSE REACTIONS

Reversible acute inflammation of the oral mucosa if contacted with the unset paste.

WARNINGS

NeoSEALER Flo is caustic, as are all tricalcium silicates.

INTERACTIONS WITH OTHER DENTAL MATERIALS

None known.

STORAGE

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.

PRECAUTIONS

- DO NOT overfill the root canals! When a large amount of material is overfilled in 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.
- MINIMIZE overextension of the material beyond the apex.
- AVOID contact of unset sealer with skin or oral mucosa. After incidental contact, wash and rinse with water.
- WEAR suitable gloves and protective glasses during use.
- NeoSEALER Flo MUST BE KEPT WELL SEALED. Immediately recap after each use.
- TO PROTECT against moisture intrusion, store NeoSEALER Flo in its protective aluminum container.
- ALWAYS use a new Flo Tip when applying NeoSEALER Flo.
- AVOID touching the syringe to a contaminated surface.
- COVER the syringe body with a disposable protective sleeve if used intraorally, to minimize contamination of the syringe.
- NeoSEALER Flo and Flo Tips are provided in clean non-sterile packaging. These products cannot be sterilized. Clinicians should follow their established protocols for cleaning and disinfection of the NeoSEALER Flo syringe between uses.

See: www.cdc.gov/infectioncontrol/pdf/guidelines-disinfection-guidelines-H.pdf

- Setting of tricalcium silicates is inhibited in acidic environments such as infected sites.

CLINICAL DIRECTIONS FOR USE:

- Excavate carious tooth structure using a round bur in a handpiece at low speed or use hand instruments.
- Debride, clean, shape and disinfect the root canal system using intra-canal instruments under rubber dam isolation.
- After preparation and irrigation of the root canal, including removal of smear layer, dry the canal using paper points to remove pooled irrigants or body fluids. Moisture is required for setting.
- NeoSEALER Flo may be used with or without the Flo Tip, but the Flo Tip is recommended.

USE WITHOUT the Flo Tip™:

- For obturation techniques where most of the canal is obturated by gutta percha points, first apply a light coating of NeoSEALER Flo material to the canal walls using a device of your choice.
- Second, coat the disinfected and dried gutta percha points with NeoSEALER Flo material before insertion.

USING the Flo Tip™:

- Attach the Flo Tip to the NeoSEALER Flo syringe.
- Insert the Flo Tip into the canal to the desired depth, taking care to not insert the end past the middle third of the root canal.
- DO NOT force the Flo Tip into the canal such that it seals against the canal walls. Doing so may force the sealer to be expressed beyond the apex.
- Apply gentle, steady pressure to the syringe plunger with a constant outward movement from the canal as the material is injected.
- If using a higher gauge (smaller diameter) dispensing tip, pump the syringe until NeoSEALER Flo is seen dispensing. Apply constant pressure to continue with the dispensing.

NOTE: NeoSEALER Flo may be difficult to dispense using higher gauge (smaller diameter) tips.

- Slowly, insert a single or multiple cones into the canal.
- Melt and cut off excess gutta percha at the orifice following the manufacturer's directions.
- Remove excess sealer with a moist cotton pellet.
- Confirm placement of the material in the complete root canal system and check for any over-extrusion with a radiograph.

OTHER APPLICATIONS:

NeoSEALER Flo may be used with NeoPUTTY™ for obturation of primary teeth with no successor, or otherwise unsalvageable teeth.

NOTE: For removal of root canal filling, use conventional instrumentation to remove set sealer, including hand/rotary files and ultrasonic instrument tips, as with any other sealer.

ADA 57, ISO 6876 & ISO 9917-1 Criteria

- Working Time at room temperature: >40 min.
- Initial Setting Time at 37°C, in vivo (or moist environment): 11 hrs ± 1 hr.
- Flow: >17 mm.
- Film thickness: <50 µm.
- Solubility: <3%.
- Dimensional stability: <1% shrinkage & <0.1% expansion.
- Radiopacity: 6 mm equivalent of aluminum.
- Pb and As: <2 ppm.

SYMBOLS USED ON LABELING: IFU-57 Rev 3 Avalon Biomed NeoSEALER Flo (Multi Lang)

	Manufacturer		Caution		Expiration Date
	Authorized Representative in the European Community		Keep Dry		Irritant
	Prescription Only		Lot Number	Mfg. by NuSmile, Ltd 3315 West 12th St Houston, TX 77008 USA +1.713.861.0033	
	Consult Instructions For Use		Catalog Number		
			KinderDent GmbH Gutenbergstraße 7 Weyhe, D-28844 Germany		



ROOT & PULP TREATMENT MATERIAL

NeoPUTTY™ Non-Staining BIOACTIVE Bioceramic



NeoPUTTY™

COMPOSITION & DESCRIPTION

Bioactive paste 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. NeoPUTTY is designed to set in vivo in the presence of moisture provided by the surrounding tissues.

MATERIAL CHARACTERISTICS

- Bioactive bioceramic
- Does not discolor teeth
- Radiopaque
- Resin-free

INDICATIONS

Dental procedures contacting vital pulp tissue such as:

- Indirect pulp cap
- Direct pulp cap
- Partial pulpotomy
- Cavity liner
- Base
- Pulpotomy
- Apexogenesis

Dental procedures contacting periradicular tissue such as:

- Perforation repair
- Resorption
- Obturation
- Apexification
- Root-end filling

CONTRAINDICATIONS

- Hypersensitivity against caustic (high pH) solutions.
- Do not use for primary tooth pulpectomy (obturation/root canal filling) unless the permanent successor tooth is absent.

ADVERSE REACTIONS

Reversible acute inflammation of the oral mucosa if contacted with the unset paste.

WARNINGS

NeoPUTTY is caustic, as are all calcium silicates.

INTERACTIONS WITH OTHER DENTAL MATERIALS

None known.

STORAGE

Store at room temperature. Do not refrigerate. To prevent hardening of the NeoPUTTY, immediately recap after each use. Store the syringe in the protective aluminum container provided.

PRECAUTIONS

- AVOID contact of unset putty with skin or oral mucosa. After incidental contact, wash and rinse with water.
- WEAR suitable gloves and protective glasses during use.
- NeoPUTTY MUST BE KEPT WELL SEALED. Immediately recap after each use.
- TO PROTECT against moisture intrusion, store NeoPUTTY in its protective aluminum container.
- DO NOT overfill the root canals when obturating or performing apexification.
- AVOID touching the syringe to a contaminated surface.
- COVER the syringe body with a disposable protective sleeve if used intraorally, to minimize contamination of the syringe.
- NeoPUTTY is provided in clean non-sterile packaging. This product cannot be sterilized. Clinicians should follow their established protocols for cleaning and disinfection of the NeoPUTTY syringe between uses.

See: www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf

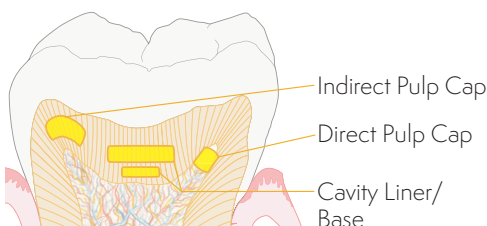
ADA 57, ISO 6876 & 9917-1 CRITERIA

- Working Time at room temperature: 10+ hrs.
- Initial Setting Time at 37°C, in vivo (or moist environment): ~4 hrs.
- Solubility: <3%.
- Dimensional stability: +0.08% expansion.
- Radiopacity: 8.1 mm equivalent of aluminum.
- Pb and As: <2 ppm.

CLINICAL DIRECTIONS FOR USE:

NeoPUTTY material is shown in **Yellow** in the drawings.

DIRECT and INDIRECT PULP CAPPING; BASE and LINER:



- a) Complete a cavity preparation under rubber dam isolation, using a high-speed bur.

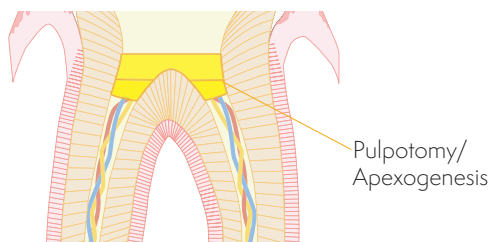
NOTE: If applying material for an indirect pulp cap, base or liner, skip to step d.

- b) Excavate carious tooth structure using a round bur in a handpiece at low speed or use hand instruments.
- c) Control hemorrhage using a solution of your choice (e.g. sterile saline, sodium hypochlorite (1.25-6.0%) or chlorhexidine). If hemorrhage is still present after 10 minutes, the diagnosis is irreversible pulpitis and vital pulp therapy using NeoPUTTY may not be indicated.
- d) Use applicator of your choice to apply NeoPUTTY material on the exposed pulp or the floor of the cavity preparation, maintaining a minimum thickness of 1.5mm.
- e) Excess material may be removed using a cotton pellet slightly dampened with sterile water or saline.
- f) NeoPUTTY is washout resistant when placed. Immediately restore over NeoPUTTY with a

light curable composite, glass ionomer, RMGI, compomer, or luting cement and crown. Alternatively, you may use a flowable composite, RMGI, ZOE or other material to secure the NeoPUTTY prior to final tooth restoration.

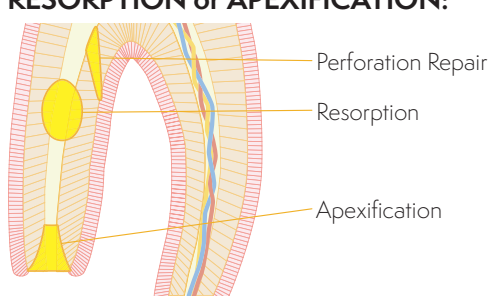
- g) Assess the pulp vitality as needed and confirm with a radiograph.

PULPOTOMY and APEXOGENESIS:



- a) Complete a cavity preparation under rubber dam isolation, using a high-speed bur.
- b) Excavate all carious tooth structure using a round bur in a handpiece at low speed or use hand instruments.
 - In multi-rooted teeth, remove the roof of the pulp chamber and all remnants of coronal pulp tissue to the level of the orifice of each root canal.
 - In single-rooted teeth, remove the pulp to the level of the cemento-enamel junction or slightly below.
- c) Control hemorrhage using a solution of your choice (e.g. sterile saline, sodium hypochlorite (1.25-6.0%) or chlorhexidine). If hemorrhage is still present after 10 minutes, the diagnosis is irreversible pulpitis and a full pulpectomy with obturation is typically performed instead.
- d) Use applicator of your choice to apply NeoPUTTY material on the exposed pulp or the floor of the cavity preparation, maintaining a minimum thickness of 1.5mm.
- e) Excess material may be removed using a cotton pellet slightly dampened with sterile water or saline.
- f) NeoPUTTY is washout resistant when placed. Immediately restore over NeoPUTTY with a light curable composite, glass ionomer, RMGI, compomer, or luting cement and crown. Alternatively, you may use a flowable composite, RMGI, ZOE or other material to secure the NeoPUTTY prior to final tooth restoration.
- g) Assess the pulp vitality as needed and confirm with a radiograph.

PERFORATION REPAIR, RESORPTION or APEXIFICATION:



- a) Debride, clean and shape the root canal system using intra-canal instruments under rubber dam isolation.
- b) Gently irrigate the root canals using a NaOCl (1.25-6.0%) or chlorhexidine solution.

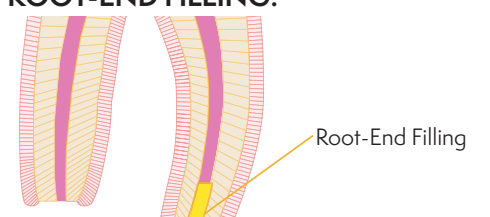
FOR PERFORATION REPAIR or RESORPTION:

- c) Isolate the defect site(s).
- d) Obturate the canal space apical to the defect.
- e) Dispense NeoPUTTY material into the defect site with an instrument of clinician's choice.
- f) Gently compact NeoPUTTY material using a small plugger, cotton pellets or paper points.
- g) Confirm placement with a radiograph.
- h) Excess material may be removed using a cotton pellet dampened with sterile water or saline.
- i) Obturate the remaining canal space and close the coronal access.

FOR APEXIFICATION:

- c) Dry the canal system with paper points, being careful not to extend the points beyond a wide-open apex.
- d) Gently compact NeoPUTTY in the apical region, to create a 3 to 5mm apical barrier.
- e) Confirm placement with a radiograph.
- f) Obturate the remaining canal space and close the coronal access.
- g) A full coverage restoration is normally placed following apexification.

ROOT-END FILLING:



- a) Surgically access the root-end and resect 2 to 4 mm of the root apex using a surgical bur.
- b) Prepare a Class I root-end cavity preparation 3 to 5mm deep with an ultrasonic tip.
- c) Isolate the area and achieve hemostasis.
- d) Dry the area.
- e) Gently compress the NeoPUTTY material in the root-end cavity using a "plastic" instrument or other small carrier or instrument.
- f) Excess material may be removed using a cotton pellet dampened with sterile water or saline.
- g) Rinse gently.
- h) Confirm placement with a radiograph.
- i) Close the surgical site.

OTHER APPLICATIONS:

NeoPUTTY may be used with or without NeoSEALER™ Flo for complete endodontic obturation when applicable.

SYMBOLS USED ON LABELING:

IFU-56 Rev 1 Avalon Biomed NeoPUTTY (Multi Lang)

	Manufacturer		Caution		Expiration Date
	Authorized Representative in the European Community		Keep Dry		Irritant
	Prescription Only		Lot Number	 	
	Consult Instructions For Use		Catalog Number		

