



# ROOT & PULP TREATMENT MATERIAL

## 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 oral environment.

### MATERIAL CHARACTERISTICS

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

### INDICATIONS

Dental procedures contacting vital pulp tissue such as:

- Direct and indirect pulp capping
- Cavity liner and base
- Pulpotomy and apexogenesis

Dental procedures contacting periradicular tissue such as:

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

### CONTRAINDICATIONS

Hypersensitivity against caustic (high pH) solutions.

### 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.
- If using syringe tip with NeoPUTTY, ALWAYS use a new tip for each application.
- AVOID touching the syringe to a non-sterile 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](http://www.cdc.gov/infectioncontrol/pdf/guidelines/disinfection-guidelines-H.pdf)

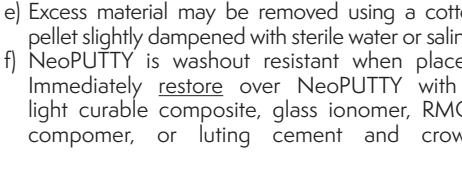
### ADA 57, ISO 6876 & 9917-1 CRITERIA

- 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.

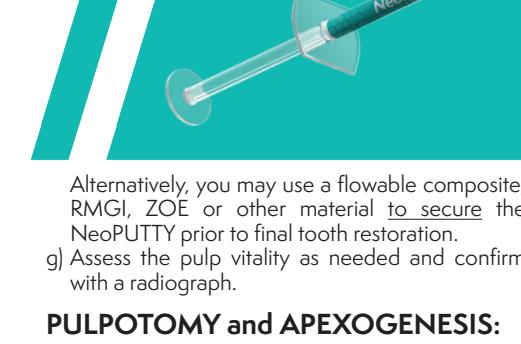
c) Control hemorrhage using a solution of your choice (e.g. sterile saline, sodium hypochlorite (1.25-6.0%) or chlorhexidine). If hemorrhage is still present after 10 minutes, the diagnosis is irreversible pulpitis and vital pulp therapy using NeoPUTTY may not be indicated.

- 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.

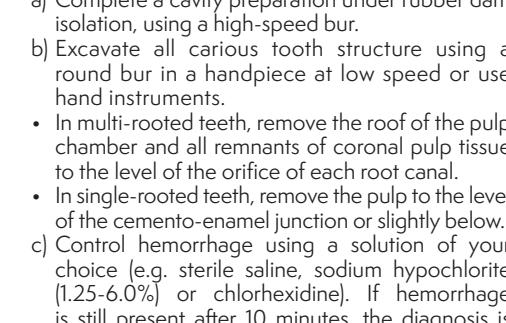
# NeoPUTTY™ Non-Staining BIOACTIVE Bioceramic



Alternatively, you may use a flowable composite, RMGI, ZOE or other material to secure the NeoPUTTY prior to final tooth restoration.

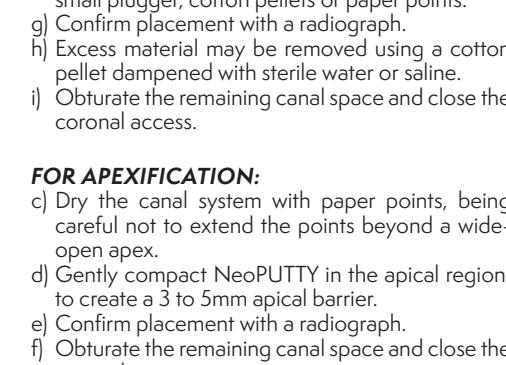
- g) Assess the pulp vitality as needed and confirm with a radiograph.

### 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.
- c) 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.
- d) In single-rooted teeth, remove the pulp to the level of the cemento-enamel junction or slightly below.
- e) 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.
- f) 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.
- g) 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.

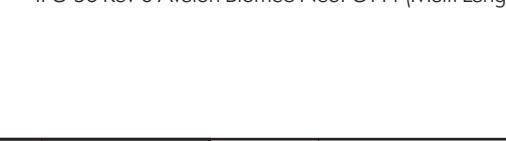
- FOR PERFORATION REPAIR or RESORPTION:**
- c) Isolate the defect site(s).
- d) Obtain the canal space apical to the defect.
- e) Dispense NeoPUTTY material into the defect site with an instrument of clinician's choice.
- f) Gently compact NeoPUTTY material using a small plunger, cotton pellets or paper points.
- g) Confirm placement with a radiograph.
- h) Excess material may be removed using a cotton pellet dampened with sterile water or saline.
- i) Obtain 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) Obtain 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.

IFU-56 Rev 0 Avalon Biomed NeoPUTTY (Multi Lang)

### SYMBOLS USED ON LABELING:

	Manufacturer		Caution		Expiration Date
<b>EC</b> <b>REP</b>	Authorized Representative in the European Community		Keep Dry		Irritant
<b>R</b> only	Prescription Only	<b>LOT</b>	Lot Number		Catalog Number
	Consult Instructions For Use	<b>REF</b>	Ref		CE 1639
					Mfg. by NuSmile, Ltd 3315 West 12th St Houston, TX 77008 USA +1.713.861.0033
					KinderDent GmbH Gutenbergstraße 7 Weyhe, D-28844 Germany
					<b>EC</b> <b>REP</b>

