

NeoPUTTY® Non-Staining BIOACTIVE Bioceramic



INSTRUCTIONS FOR USE



NeoPUTTY®

COMPOSITION & DESCRIPTION

Multi-purpose root and pulp treatment 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

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 tricalcium 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. 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

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

ADA 57, ISO 6876 & 9917-1 CRITERIA

- Working Time at room temperature: >1 hr.

- Initial Setting Time at 37°C, in vivo (or moist environment): ~4 hrs.

- Solubility: <3%.

- Dimensional stability: < 0.1% expansion.

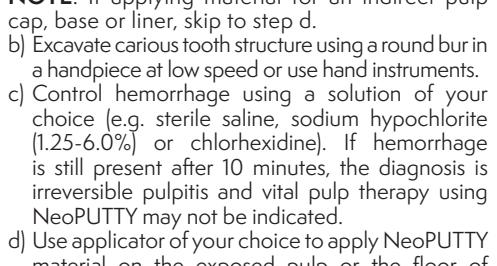
- Radiopacity: 8.4 mm equivalent of aluminum.

- 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:



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

- Excavate all carious tooth structure using a round bur in a handpiece at low speed or use hand instruments.

- 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 is typically performed instead.

- 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 1.5 mm.

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

SYMBOLS USED ON LABELING:

	Manufacturer		Medical Device
	Authorized Representative in the European Community		Date of Manufacture
	Prescription Only		Catalog Number
	Consult Instructions For Use		Expiration Date
	Caution		Irritant

Mfg. by NuSmile, Ltd
3315 West 12th St
Houston, TX 77008 USA
+1713.861.0033

CE 1639

MDSS GmbH
Schiffgraben 41
30175 Hannover Germany

