

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
- Apexification
- Root-end filling

CONTRAINDICATIONS

- Hypersensitivity against caustic (high pH) solutions.
- Do not use for primary tooth pulpectomy with 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.

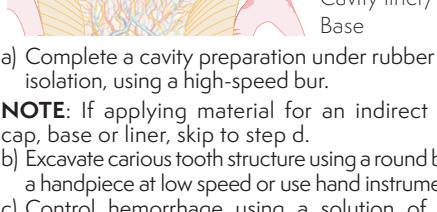
- Radiopacity: 8.4 mm equivalent of aluminum.

- 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:



- a) Complete a cavity preparation under rubber dam isolation.

- b) Excavate all 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).

- d) Use applicator of your choice to apply NeoPUTTY prior to final tooth restoration.

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

PERFORATION REPAIR, RESORPTION or APEXIFICATION:

- f) NeoPUTTY is washout resistant when placed.

- g) Immediately **restore** over NeoPUTTY with a light curable composite, glass ionomer, RMGI, compomer, or luting cement and crown.

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

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

FOR PERFORATION REPAIR or RESORPTION:

- c) Isolate the defect site(s).

- d) Obtrude 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) Obtrude 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 5 mm apical barrier.

- e) Confirm placement with a radiograph.

- f) Obtrude the remaining canal space and close the coronal access.

FOR 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 5 mm deep with an ultrasonic tip.

- c) Isolate the area and achieve hemostasis.

- d) Gently compress the NeoPUTTY material in the root-end cavity using a "plastic" instrument or other small carrier or instrument.

- e) Excess material may be removed using a cotton pellet dampened with sterile water or saline.

- f) Close the surgical site.

OTHER APPLICATIONS:

NeoPUTTY may be used for complete endodontic obturation when applicable.

SYMBOLS USED ON LABELING:

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

Mfg. by NuSmile, Ltd
3315 West 12th St
Houston, TX 77008 USA
+173.861.0033

CE 1639

MDSS GmbH
Schiffgraben 41
30175 Hannover
Germany

