



# 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](http://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<br>3315 West 12th St<br>Houston, TX 77008 USA<br>+1.713.861.0033 |                 |
|  | Consult Instructions For Use                        |  | Catalog Number                                                    |                                                                                       |                 |
|  |                                                     |  | KinderDent GmbH<br>Gutenbergstraße 7<br>Weyhe, D-28844<br>Germany |                                                                                       |                 |
|  |                                                     |  |                                                                   |                                                                                       |                 |

