

BioRoot® Flow

Active Biosilicate Technology®

Bioactive mineral root canal sealer

Presentation

BioRoot® Flow - REF 340S/2	BioRoot® Flow – REF 340S/0.5
1 syringe of 2.0g of paste contained in a foil	1 syringe of 0.5g of paste contained in a foil
20 tips contained in a sachet	5 tips contained in a sachet
1 finger-grip contained in a sachet	1 finger-grip contained in a sachet

Composition

White to slightly grey paste containing tricalcium silicate, propylene glycol, povidone, calcium carbonate, AEROSIL, zirconium oxide, acrylamide / sodium acryloyldimethyltaurate copolymer, isohexadecane, polysorbate.

Properties

BioRoot® Flow is a bioactive mineral root canal sealer based on Septodont patented and innovative mineral micro-aggregate chemistry “Active Biosilicate Technology” that offers:

- Biocompatibility: high mineral purity and monomer free formulation reducing the risk of adverse tissue reaction.
- Bioactive properties: hydroxyapatite formation at the tooth-sealer interface and mineralization of dentinal structure.
- Alkaline pH.
- Sealing properties: crystallization of the material inside the dentin tubules creating a tight seal.
- Retreatable: if a retreatment is needed, BioRoot® Flow can be easily removed from the root canal.

Intended use

Permanent root canal sealer.

Target group(s)

Target population

Permanent and mature teeth (from 8 years – 25 kg).

Intended users

Dental healthcare professional.

Clinical benefit

Preservation of the tooth functionality.

Performances characteristics

Technical performance

Hermetically seal the root canal.

Technical specifications

Working time	≥ 1h
Setting time*	45min – 8h
Radiopacity*	≥ 3mm Al

*Performed according to the EN ISO 6876:2012

Clinical performance

Permanent root canal obturation of mature teeth.

Indications for use

Permanent root canal filling in combination with gutta-percha points in case of inflamed or necrotic pulp.

Permanent root canal filling in combination with gutta-percha points following a retreatment procedure.

Contra indication

Hypersensitivity to one or more components.
Immature or temporary teeth.

Expected lifetime

At least 2 years.

Instruction for use

Placement into the root canal

- 1/ Perform the root canal cleaning and shaping procedure using standard endodontic procedures.
- 2/ Flush with sterile saline solution to remove any residue of irrigant and dry without totally dehydrating the root canal.
- 3/ Take out the syringe from the protective foil (set aside the foil for further storage).
- 4/ Remove the syringe cap from the syringe. Place the tip by twisting it into the threads of the Syringe Tip to “lock” it. Tips are flexible and can be bent to facilitate the access to the root canal.

PRECAUTION: Ensure that the tip is correctly locked to avoid tip disassembly.

- 5/ The finger grip can be locked to the syringe to facilitate the extraction of the product.

PRECAUTION: Ensure that the finger-grip is correctly locked to avoid finger-grip disassembly.

- 6/ Check the free flow of the cement by extruding a small amount of cement before the procedure. In case of clogging, the syringe should be discarded.

- 7/ Insert the tip of the syringe into the canal, pull back 2mm and inject the required quantity of BioRoot® Flow.

- 8/ Complete the obturation by inserting the gutta-percha master cone (single cone technique) or several gutta-percha points (lateral condensation technique).

Cleaning and storage of the syringe

- 1/ Unscrew the tip and dispose of it.
- 2/ Remove any excess of paste from the syringe with a dry and clean tissue and recap the syringe.

PRECAUTION: Ensure that the cap is correctly locked to avoid cap disassembly.

- 3/ Clean the syringe and the finger-grip with ethanol and store them in the protective foil.

Retreatment procedure

Remove the existing sealer (BioRoot® Flow or other sealer) using conventional removal techniques. Follow instructions for use given in the section “Placement into the root canal”.

Warnings and precautions for use

Precautions for use

- Only use the supplied tips and finger-grip with BioRoot® Flow, to avoid component disassembly during the procedure.
- Use the paste within 4 months after the first opening.
- If the syringe, the cap, or the finger-grip falls on the floor clean it with ethanol to avoid contamination.
- BioRoot® Flow may cause eye irritation and skin burn. Do not use BioRoot® Flow without appropriate personal protective equipment.
- Use a rubber dam to ensure that the cement is not in contact with the mucosa or swallowed.
- In order to avoid performance issues (paste extrusion, consistency of the paste) during the next endodontic procedure, recap the syringe and store in the foil after use.

Warnings

- If the tip falls on the floor dispose it to avoid contamination.
- Do not reuse the extruded paste on several patients to avoid cross contamination.
- The working length in the root canal should not exceed 2 mm from the radiological apex to avoid apical extrusion.
- Using BioRoot® Flow without gutta-percha points jeopardizes endodontic and retreatment procedures.
- The tip is intended for single-use. Discard the disposable tips after each application to avoid any risk of cross contamination.
- Clean the syringe and the finger-grip after use to avoid cross contamination.

Side-effects

Possible hypersensitivity to one of the components of BioRoot® Flow.

Please report any serious incident that occurred in relation to the device to Septodont (vigilance@septodont.com) and to the local competent authority for medical devices.

Disposal

Dispose the used tips in a biohazardous waste bin.

No specific recommendations for disposal of other BioRoot® Flow components.

Storage

Store between 5°C (41°F) and 30°C (86°F); protect from moisture.

Caution: Federal law restricts this device to sale by or on order of a dentist.

	Storage temperature range
	Consult instructions for use
	Keep dry, protect from excessive humidity, rain or damp conditions.
Rx only	By prescription only
	Catalogue number
	Manufactured by
	Distributed by

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