

BioRoot™ RCS

Active Biosilicate Technology™

Presentation

Box for 35 applications, containing:

- 35 single-dose containers of 0.20mL liquid divided into 7 foils
- 1 bottle of 15 g powder
- 1 spoon

Composition

White to greyish white powder composed of tricalcium silicate, zirconium oxide and povidone.

Clear and colourless aqueous solution of calcium chloride and polycarboxylate.

Intended use

Permanent root canal sealer

Indications for use

Permanent root canal filling in combination with gutta-percha points in case of inflamed or necrotic pulp in the course of initial treatment or retreatment procedure.

Target group(s)

Target population

Mature permanent teeth.

Intended users

Dental healthcare professionals.

Clinical benefit

Preservation of the tooth functionality

Summary of safety and clinical performance is available, using Basic UDI-DI code 37601407000013GA, in the European database on medical devices (Eudamed):

<https://ec.europa.eu/tools/eudamed> or upon request (sscp@septodont.com) until EUDAMED is fully functional.

Performance characteristics

Technical performance

Hermetically seal the root canal.

Technical specifications

Working time*	10 min
Setting time*	45min – 4h
Radiopacity*	≥ 3mm Al

*Performed according to the EN ISO 6876:2012

Clinical performance

Permanent root canal obturation of mature permanent teeth.

Contra indication

Hypersensitivity to any components.

Immature or temporary teeth.

Expected lifetime

At least 5 years.

Instructions for use

Mixing instructions

- 1/ Aerate the powder by inverting the bottle of powder over twice and open the bottle.
- 2/ Using the spoon supplied in the box, take a leveled spoonful of powder and transfer it to the mixing pad.
- 3/ Detach a single-dose container of liquid. Twist the cap to open. Use the liquid in single-dose containers immediately after opening. Deposit 5 drops from the single-dose container onto the mixing pad without releasing the pressure.
- 4/ Gradually add the powder to the liquid and mix until obtaining a smooth paste (about 60 seconds). Use the paste immediately after mixing.
- 5/ Close the bottle of powder tightly and quickly after each use. Discard the single-dose container of liquid immediately after use and store the unopened remaining single-dose containers inside the foil to protect them from light.

6/ Immediately rinse and dry the spoon to remove any residual material.

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 remains of irrigant and dry without completely dehydrating the root canal
- 3/ Prepare BioRoot™ RCS according to the above-mentioned mixing instructions.
- 4/ Apply a coating of BioRoot™ RCS onto the canal walls using either a paper point or the gutta-percha point.
- 5/ Complete the obturation by inserting the gutta-percha master cone previously coated with BioRoot™ RCS (single cone technique) or several coated gutta-percha points (lateral condensation technique).
- 6/ It is recommended to take X-rays to ensure that root canals have been thoroughly filled and that the working length does not exceed 2 mm from the apex.

Retreatment procedure

Remove the existing sealer (BioRoot™ RCS or another sealer) using conventional removal techniques. Then follow instructions given in the sections “Mixing instructions” and “Placement into the root canal”.

Warnings and precautions for use

Precautions for use

- Use the powder within 6 months after first opening.
- Use the 5-liquid single-dose containers within 6 months after first opening of the foil.
- Do not reuse a previously opened single-dose container otherwise technical specifications are not guaranteed and may lead to the failure of the endodontic procedure.
- Protect the unused single dose containers from light after opening the foil because the light may affect the stability of the liquid.
- The device may cause eye and skin irritation. Do not manipulate the device without appropriate personal protective equipment.
- Use a rubber dam to ensure that the cement is not in contact with the mucosa or swallowed.
- Use exclusively the spoon provided with BioRoot™ RCS. Otherwise, technical specifications are not guaranteed and may lead to the failure of the endodontic procedure.
- Do not use BioRoot™ RCS powder with another liquid than BioRoot™ RCS liquid. Otherwise, technical specifications are not guaranteed and may lead to the failure of the endodontic procedure.

- Use the recommended ratio of liquid/powder. Otherwise, technical specifications are not guaranteed and may lead to the failure of the endodontic procedure.
- Do not use a warm technique obturation. Otherwise, technical specifications are not guaranteed and may lead to the failure of the endodontic procedure.

Warnings

- Do not use the mixed 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™ RCS without gutta-percha points jeopardizes endodontic and retreatment procedures.
- If a post placement is required, it should be performed after complete hardening of BioRoot™ RCS, i.e. after 1 month.

Side-effects

Possible hypersensitivity to any components of BioRoot™ RCS

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.

Storage

Store between 5°C and 30°C; protect from moisture.

Disposal

No specific recommendations

Access to the instructions for use

Please check regularly to see if the instructions for use have not been updated. The latest electronic instruction for use as well as historical versions can be downloaded and printed directly from the website <https://www.septodontcorp.com/bioroot-rcs-eifu/>.

A paper copy can be requested through the website <https://www.septodontcorp.com/bioroot-rcs-eifu/>.

Symbols



Medical Device



Unique device identifier



Period-after-opening



Authorised Representative in CH



UK responsible person



UK marking

EU-IFU must contain the following information:

- Date of CE mark :
(CE): YYYY-MM
- Revision date of the IFU:
YYYY-MM (will be determined when the artwork is done)

- Manufacturer:



SEPTODONT
58, rue du Pont de Créteil
94100 Saint-Maur-des-Fossés – France

- CE marking:



- UKCA marking



0086

- UKREP:



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