

C-Root BP

CAUTION: U.S. Federal Law restricts this device to sale by or on the order of a dentist.

Rx Only

PRODUCT TRADE NAME

- C-Root BP

COMMON NAME

- Bioceramic Root Repair Material

MODEL

- C-Root BP

SPECIFICATIONS

- Preloaded Syringe: 2g, 1g, 0.5g

PRODUCT DESCRIPTION

C-Root BP Bioceramic Root Repair Material (C-Root BP) is a ready-to-use premixed bioceramic paste developed for permanent root canal repair and surgical applications. C-Root BP is an insoluble, radiopaque, and aluminum-free material based on a strontium silicate composition, which requires the presence of water to set and harden. C-Root BP does not shrink during setting and demonstrates excellent physical properties. C-Root BP is packaged in a preloaded syringe.

INDICATIONS FOR USE

- Repair of Root Perforation
- Repair of Root Resorption
- Root End Filling
- Apexification
- Pulp Capping

REPAIR OF ROOT PERFORATION

1. Perforations have the best chance of success the sooner they are repaired. Repair the perforation as soon as it occurs or is noted.
2. After isolation with a rubber dam, the area surrounding the perforation should be thoroughly and carefully cleaned and disinfected.
3. Obtain adequate hemostasis from the perforation site and apply C-Root BP to the defect and seal all perforation margins.
4. Remove any excess with a spoon excavator, or a micro brush and ensure C-Root BP in flush with the wall of the perforation cavity.
5. Take a radiograph to confirm an adequate seal. Add or remove C-Root BP as needed.

- A. Single Visit Perforation Repair (small defects):
If you plan to complete root canal therapy during the same visit, apply a thin layer of self-cure or dual cure glass ionomer cement over C-Root BP and extend it onto sound dentin (cover the perforation material completely). Do not use composite material over the unset C-Root BP as it is difficult to create a bond. After the glass ionomer coverage has set, complete the root canal procedure.
 - B. Two Visit Perforation Repair (large defect):
If the perforation area is too large and safe coverage of C-Root BP cannot be obtained with a glass ionomer in single visit, gently push C-Root BP through the defect, then gently place a moist cotton pellet over C-Root BP and seal the access opening. Remove the cotton during the second visit and complete the root canal procedure.
6. C-Root BP will remain as a permanent part of the root canal perforation repair.

REPAIR OF ROOT RESORPTION

1. Isolate the operative area with a rubber dam.
2. Identify and treat the type of defect as per:
 - A. Repair of Internal Root Resorption
For Perforated Internal Root Resorption defects requiring sealing of the perforation, see "Repair of Root Perforation" directions. If the restorative pattern is complete and the putty cannot be easily placed, consider backfilling the entire restorative defect with Bioceramic Root Repair Material (C-Root BP). For Non-Perforated Internal Root Resorption defects, consider simply obturating using C-Root SP Injectable Root Canal Bioceramic Sealer and gutta-percha points.
 - B. Repair of External Root Resorption
 - Subcrestal Defects
Remove all affected cementum and dentin until all restorative cells are removed. Condition the root surface as desired (citric acid etch), place C-Root BP into the defect to reestablish the lost contours of the natural tooth. Take a radiograph to confirm an adequate seal. Add or remove C-Root BP as needed. Close the wound.
 - Supracrestal Defects
A glass ionomer compound is recommended in such cases.
3. C-Root BP will remain as a permanent part of the root canal resorption repair.

ROOT END FILLING

1. Following apicoectomy and retro preparation, clean and disinfect the retro preparation as usual.
2. Place an adequate amount of C-Root BP into the retro preparation using a plastic instrument.
3. Condense or compress C-Root BP into the preparation from the bottom up to avoid trapping air until the preparation is completely sealed.
4. Remove any excess material using a micro brush or curette.
5. Radiograph the placement of C-Root BP to ensure its placement is adequate. If placement is inadequate, add or remove C-Root BP as necessary.
6. Close the surgical opening after confirming that the root end preparation has been sufficiently sealed.
7. C-Root BP will remain as a permanent part of the root canal end-filling repair.

APEXIFICATION (Apical Barrier)

1. Isolate the operative area with a rubber dam.
2. Open and debride the root canal, irrigate thoroughly and dry the root canal.
3. If further disinfection is required, consider Calcium Hydroxide medicament for a week.
4. Place C-Root BP into the apical of the root canal until an apical

- plug of at least 3–5mm in depth is created.
5. Radiograph the placement of the material to ensure an adequate plug has been established. Add or remove C-Root BP as needed.
6. Fill the remaining root canal space with a permanent filling material.
 - A. To fill in the same visit
Use the filling material (i.e. C-Root Injectable Root Canal Repair Filling Material or C-Root SP Injectable Root Canal Sealer) to backfill the remaining portion of the canal.
 - B. To fill with gutta-percha
During a subsequent visit, place a provisional in the access and revisit in a week to fill the remaining portion of the canal with a permanent sealer (i.e. C-Root SP Injectable Sealer and gutta-percha points).
7. Restore the access opening with your restorative material of choice.
8. C-Root BP will remain as a permanent part of the root canal apexification repair.

PULP CAPPING

1. Indirect pulp capping has the best prognosis of normal pulp or reversible pulpitis. Do not attempt an indirect pulp capping in cases of irreversible pulpitis.
2. Isolate the operative area with a rubber dam.
3. Prepare the cavity by removing any decay with a high-speed bur under a constant cooling water spray.
4. Before exposure occurs (0.5–1mm from the pulp), disinfect the internal surfaces of the cavity preparation and remove excessive moisture with a cotton pellet (do not air dry).
5. Place an adequate amount of C-Root BP over the affected dentin near the pulp, extending onto normal dentin.
6. Remove excess with a spoon excavator or a micro brush.
7. Place a thin layer of glass ionomer cement over the repair material extending laterally onto clean dentin.
8. Once the glass ionomer is set, proceed to restore with a final restoration.

DIRECT

1. Once an exposure occurs, wash and disinfect the area thoroughly, control hemostasis, and prepare the exposure site for repair with C-Root BP.
 2. Place an adequate amount of C-Root BP over the perforation using a plastic instrument and remove excess with a curette and/or micro brush.
 3. It is recommended to fill the entire cavity with a reinforced glass ionomer core material and observe the tooth for 4–6 weeks prior to final restoration with a composite material. The glass ionomer core can be used as a base during the subsequent visit.
- Note: For deciduous teeth with substantial exposures, consider removing the pulp and following instructions 1–3 above.

CONTRAINDICATION

- Do not sterilize C-Root BP. Failure to follow these instructions could damage the product, resulting in procedural delays or user inconvenience.

PRECAUTIONS

- Do not sterilize C-Root BP. Failure to follow these instructions could damage the product, resulting in procedural delays or user inconvenience.
- Cleaning:
 - A. Disinfect the exterior surfaces of the jar, syringe a jar/syringe cap (once it is tightly sealed onto the jar/syringe) prior to storage to reduce the risk of cross-contamination.
 - B. The C-Root BP syringe should be mantled with a hygienic single-use barrier sleeve for infection control for direct intra-oral use.
- Ensure the placement site is completely filled. Failure to do so may result in procedural delays.
- Ensure that any bleeding is under control prior to placing C-Root BP as the material may wash out of the placement site and require re-treatment.

STORAGE

- C-Root BP must be stored in a dry area at room temperature.
- Closely follow the recommended storage conditions. Failure to do so will cause the material to prematurely set resulting in re-treatment of material placement or user inconvenience. To avoid prematurely inducing the setting process closely follow these guidelines.
 - A. Use the cap to keep the jar or syringe tightly closed when the material is not in use. Keep the cap free from moisture.
 - B. Keep C-Root BP tightly sealed in its pouch and store at room temperature in a dry area to avoid moisture contact.

WARNING

- Use personal protective equipment to avoid contact of C-Root BP with the skin, mucous membranes, and eyes. Unset C-Root BP may cause irritation. Please refer to the Safety Data Sheet (SDS) for the first aid procedures.
- Do not use excessive force to apply the material into the root canal as this may cause patient sensitivity/discomfort or breakage of the syringe plunger.



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Chinese Patent ZL 2018 1 0902541.1
U.S. Patent Appl. No. 17/266,102
Japanese Patent No. 7483708
European Patent Appl. No. 19847130.2

- C-Root BP has not been tested in pregnant women or nursing mothers.
- Always check the expiration date of the product to prevent procedural delays or user inconvenience (e.g. material becomes brittle or will not set).
- Overfilling the root canal may lead to patient sensitivity, foreign body inflammation, maxillary sinusitis, paresthesia of anesthesia due to nerve impingement, or may require surgical removal of the overfilled material.
- Carefully read package labeling to ensure the use of the appropriate bio ceramic material. Failure to do so may cause user or patient inconvenience.
- Please ensure that the carton and pouch have not been opened or damaged, as this indicates that the barriers have been breached.
- Multiple continuous applications of material using the syringe delivery system may cause hand fatigue.

ADVERSE REACTION

- If the patient experiences any unusual pain, swelling, or discomfort orally or in the jaw region following treatment of C-Root BP, please advise the patient to seek medical attention.

INTERACTIONS WITH OTHER DENTAL MATERIALS

- None known.

EQUIPMENT

- Sterile instrument
 - Sterile plastic instrument (of your choice)
 - Clean glass slab/slide
 - Spoon excavator
 - Disposable micro brushes
 - Curettes
- C-Root BP is packaged in a preloaded syringe.

WORKING TIME

No mixing is required. The setting reaction begins as soon as the material is placed in contact with a moist environment.

SETTING TIME

Setting time is a minimum of 2 hours in normal conditions, but can take longer to set in the extremely dry root canals.

COMPOSITION

Zirconium Oxide, Strontium Silicates, Calcium Phosphates, Calcium Hydroxide, Tantalum Oxide and Filler Agents.

INTERACTIONS

The setting time of C-Root BP is dependent upon the presence of moisture in the dentin. The setting reaction can proceed quickly in root canals, which have been inadequately dried. The amount of moisture required for the setting reaction to occur can be from dental tubules, and perforated area. Therefore, it is not necessary to add moisture in the root canal prior to placing the material.

DIRECTIONS FOR USE:

1. Prior to the application of C-Root BP, thoroughly prepare and irrigate the root canal using standard endodontic techniques. Please refer to the detailed instructions.
 2. Unscrew the cap from the jar or syringe.
 3. Remove the desired amount of material from the syringe.
 - Gently and smoothly extrude the desired amount of material from the syringe by compressing the plunger.
- Note: Only a small amount of material is necessary to be removed from the jar of syringe for each application.
4. Immediately after removing the material screw the cap tightly back on the jar or syringe.
 5. Use a sterile plastic instrument (or your choice) to place the material into the intended anatomic section of the root canal and compress the material with the plastic instrument.
 6. Remove excess material with a moist cotton pellet, an appropriate-sized spoon excavator or disposable the micro brush.
 7. Place the jar or syringe into the foil pouch and be sure to seal the pouch. Store the pouch in a dry area at room temperature.

Note: For each application, always use a clean sterile instrument and a clean sterile plastic instrument when removing C-Root BP from the jar and syringe and placing C-Root BP in the intended anatomic section of the root canal, to reduce cross-contamination.

KEY TO SYMBOLS

	Manufacturer
	Date of manufacturer
	Use-by date
	Batch code
	Catalogue number
	Do not use if package is damaged
	Medical device
	UDI
	Consult instructions for use
	Caution
	Rx only
	Keep dry
	Irritant(GHS)