

EndoSequence[®]

Root Repair Material BC RRM-Fast Set Putty™

Instructions For Use:

Contraindications:

Do not use EndoSequence Root Repair Material in patients with a known allergy to any of the product's ingredients.


Precautions:

-  Do not use after the expiration date
-  Do not use if package is damaged
-  Store at room temperature
-  Keep Dry

- Keep EndoSequence Root Repair Material tightly closed in its sealed package and store it at room temperature in a dry area, to avoid moisture contact, which could induce the setting process.
- Use the syringe cap to keep the syringe tightly closed when not using the material.

Warnings:

- Do not use excessive force to apply the material into the root canal, as this may cause acute pain to the patient.

 **Irritant:** Avoid contact of the material with the skin, mucus membranes and eyes. Unset EndoSequence Root Repair Material can cause irritation.

- Avoid storage near ammonia, ammonia nitrate or chlorine containing solutions. Avoid use of disinfection solutions containing any of these materials as an active ingredient.
- EndoSequence Root Repair Material has not been tested on pregnant or nursing mothers.
- Do not sterilize

Product Description:

EndoSequence Root Repair Material (BC RRM-Fast Set Putty™) is a ready-to-use, premixed, bioceramic paste developed for pulp capping, permanent root canal repair and surgical applications. It is an insoluble, radiopaque, and aluminum-free material based on a calcium silicate composition, which requires the presence of water to set and harden. BC RRM-Fast Set Putty™ does not shrink during setting and demonstrates excellent physical properties. BC RRM-Fast Set Putty™ is packaged in a preloaded syringe.

Indications For Use:

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

Working Time:

No mixing is required. The setting reaction does not begin until the material is placed in contact with a moist environment.

Setting Time:

The setting time is 20 minutes. In extremely dry conditions the setting time may be longer.

Composition:

Calcium silicates, zirconium oxide, tantalum pentoxide, calcium phosphate monobasic and filler agents.

Interactions:

The setting time of BC RRM-Fast Set Putty™ is dependent upon the presence of moisture in the dentin. The amount of moisture necessary to complete the setting reaction is natural present in dentin therefore it is not necessary to add additional moisture to the application site prior to placement.

Directions For Use:

Syringe:

1. Prior to the application of BC RRM-Fast Set Putty™, thoroughly prepare and irrigate the application site using standard techniques.
2. Remove the syringe cap from the syringe.
3. Gently and smoothly extrude the desired amount of the material from the syringe by compressing the plunger of the syringe. Note: BC RRM-Fast Set Putty™ is premixed and ready to apply so you only need to remove a very small amount of the material from the syringe for each application.
4. Remove the desired amount of material extruding from the syringe using a sterile plastic instrument (of your choice) and place the material on a clean glass slab. NOTE: Immediately after removing the material replace the cap back on the syringe.
5. Use a sterile plastic instrument (of your choice) to place the material onto the desired application site and gently compress the material with a sterile instrument of your choice.
6. Remove excess material from the application site with an appropriate sized spoon excavator or a disposable microbrush.
7. After each application place the syringe cap tightly onto the syringe hub, clean the outside of the syringe and remove any excess paste, and place the syringe into the foil pouch and ensure to seal the pouch. Store the pouch in a dry area at room temperature.

Note:

- Keep the syringe cap clean and free of moisture. When not in use, keep the syringe cap in the pouch.
- Disinfect the exterior surfaces of the syringe and syringe cap (once it is tightly sealed onto the syringe) prior to storage to reduce the risk of cross-contamination.
- The BC RRM-Fast Set Putty™ syringe can be mantled with a hygienic single-use dental barrier sleeve for infection control.

Indications For Use:

Pulp Capping: (Indirect)

1. Indirect pulp caps have the best prognosis in cases of normal pulp or reversible pulpitis. Do not attempt an indirect pulp cap in cases of irreversible pulpitis.
2. Isolate the operative area with a rubber dam.
3. Prepare the cavity shape 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 BC RRM-Fast Set Putty™ 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 and 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 BC RRM-Fast Set Putty™.
2. Place an adequate amount of the BC RRM-Fast Set Putty™ 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.

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 the BC RRM-Fast Set Putty™ to the defect and seal all perforation margins.
4. Remove any excess with a spoon excavator, or a micro brush and create a flush perforation cavosurface.
5. Take a radiograph to confirm an adequate seal. Add or remove BC RRM-Fast Set Putty™ material 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 the BC RRM-Fast Set Putty™ and extend it onto sound dentin (cover the perforation material completely). Do not use composite material over the unset BC RRM-Fast Set Putty™ as it will be difficult to create a bond. After the glass ionomer cap has set, complete the root canal procedure.
 - b. Two Visit Perforation Repair (large defects): If the perforation area is too large and safe coverage of the BC RRM-Fast Set Putty™ can not be obtained with glass ionomer in a single visit (gently pushing the BC RRM-Fast Set Putty™ material through the defect,) gently place a moist cotton pellet over the BC RRM-Fast Set Putty™ and seal the access opening. Remove the cotton during the second visit and complete the root canal procedure.

Repair of Internal Root Resorption:

For Perforating internal resorption defects requiring sealing of the perforation, see perforation repair directions above. If the resorptive pattern is complex and the putty cannot be easily placed, consider backfilling the entire resorptive defect with the BC RRM-Paste Syringeable™ material.

For Non-perforating Internal Root Resorption defects, consider simply obturating using BC Sealer™ and BC Points™.

Repair of External Root Resorption:

Subcrestal defects: Remove all affected cementum and dentin until all resorptive cells are removed. Condition the root surface as desired (citric acid etch.) Place BC RRM-Fast Set Putty™ into the defect reestablishing the lost contours of the natural tooth and close the wound.

Supracrestal defects: A glass ionomer compound is recommended in such cases.

Root End Filling:

1. Following apicoectomy and retropreparation clean and disinfect the retropreparation as usual.
2. Place an adequate amount of the BC RRM-Fast Set Putty™ material into the retropreparation using a plastic instrument.
3. Condense or compress the material into the preparation from the bottom up to avoid trapping air until the preparation is completely sealed.
-note: An alternative method is to inject BC RRM-Paste Syringeable™ material into the retropreparation first followed by a cap of BC RRM-Fast Set Putty™ to seal the top.
4. Remove or any excess material using a micro-brush or a curette.
5. Radiograph the placement of the material to ensure its placement is adequate.
6. If placement is inadequate add or remove BC RRM-Fast Set Putty™ as necessary.
7. Close the surgical opening after confirming that the root end preparation has been sufficiently sealed.
8. BC RRM-Fast Set Putty™ is intended as a definitive repair material.

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 therapy for a week.
4. Place EndoSequence Root Repair Material into the capital area of the root until an apical plug of at least 3-5mm in depth is created.
6. Radiograph the placement of the material to ensure an adequate plug has been established.
7. Fill the remaining root canal space.
 - a. To fill in the same visit, consider using BC RRM-Paste Syringeable™ 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 BC Sealer and BC Gutta Percha Points.
8. Restore the access opening with your restorative material of choice.
9. BC RRM-Fast Set Putty™ will remain as permanent part of the root canal apexification repair.



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