BRASSELER USA

EndoSequence
Root Repair Material

EndoSequence® BC RRM™ Putty / BC Pediatric Putty Instructions for Use

Rx Only

For Dental Use Only

CONTRAINDICATION
- Do not use EndoSequence® BC RRM™ Putty / BC Pediatric Putty in patients with a known allergy to any of the product's ingredients. An allergic reaction may require re-treatment.

PRECAUTIONS
- Do not sterilize EndoSequence® BC RRM™ Putty / BC Pediatric Putty. 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 and jar/syringe cap (once it is tightly sealed onto the jar/syringe) prior to storage to reduce the risk of cross-contamination.
  b. The EndoSequence® BC RRM™ Putty / BC Pediatric Putty 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 EndoSequence® BC RRM™ Putty / BC Pediatric Putty as the material may wash out of the placement site and require re-treatment.

STORAGE
- EndoSequence® BC RRM™ Putty / BC Pediatric Putty 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 EndoSequence® BC RRM™ Putty / BC Pediatric Putty tightly sealed in its pouch and store at room temperature in a dry area to avoid moisture contact.

WARNINGS
- Use personal protective equipment to avoid contact of EndoSequence® BC RRM™ Putty / BC Pediatric Putty with the skin, mucus membranes and eyes. Unset EndoSequence® BC RRM™ Putty / BC Pediatric Putty 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.
- EndoSequence® BC RRM™ Putty / BC Pediatric Putty 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 sinus aspergillosis, paresthesia of anesthesia due to nerve impingement or may require surgical removal of the overfill.
- Carefully read package labeling to ensure use of the appropriate bioceramic material. Failure to do so may cause user or patient inconvenience.
- Multiple continuous applications of material using the syringe delivery system may cause hand fatigue.
- Please ensure that the carton and pouch have not been opened or damaged, as this indicates that the barriers have been breached.

ADVERSE REACTION
- If the patient should experience any unusual pain, swelling or discomfort orally or in the jaw region following treatment of EndoSequence® BC RRM™ Putty / BC Pediatric Putty, 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
- Moist cotton pellets
- Spoon excavator
- Disposable micro brushes
- Curettes

PRODUCT DESCRIPTION
EndoSequence® BC RRM™ Putty / BC Pediatric Putty Root Repair Material is a ready-to-use premixed bioceramic paste developed for permanent root canal repair and surgical applications. EndoSequence® BC RRM™ Putty / BC Pediatric Putty is an insoluble, radiopaque and aluminum-free material based on a calcium silicate composition, which requires the presence of water to set and harden. EndoSequence® BC RRM™ Putty / BC Pediatric Putty does not shrink during setting and demonstrates excellent physical properties.

EndoSequence® BC RRM™ Putty / BC Pediatric Putty is packaged in a:
- Preloaded syringe
- Preloaded jar

Definition
This product is not intended for absorbability or biological effects, or contains medicinal products and is not derived from biological raw materials.

INDICATIONS FOR USE
- Repair of Root Perforation
- Repair of Root Resorption
- Root End Filling
- Apexification
- Pulp Capping

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 extremely dry root canals.

COMPOSITION
Calcium silicates, zirconium oxide, tantalum pentoxide, calcium sulfate (anhydrous), calcium phosphate monobasic and filler agents.

INTERACTIONS
The setting time of EndoSequence® BC RRM™ Putty / BC Pediatric Putty 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, reaches the root canal by means of the dentinal tubules. 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 EndoSequence® BC RRM™ Putty / BC Pediatric Putty , thoroughly prepare and irrigate the root canal using standard endodontic techniques. Please refer to the detailed instructions on reverse.
2. Unscrew the cap from the jar or syringe.
3. Remove the desired amount of material from the:
   Jar
   - Use a sterile instrument and place the material on a glass slab/slide.
   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 or 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 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 EndoSequence® BC RRM™ Putty / BC Pediatric Putty from the jar and syringe and placing EndoSequence® BC RRM™ Putty / BC Pediatric Putty in the intended anatomic section of the root canal, to reduce cross-contamination.

INDICATIONS FOR USE
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 EndoSequence® BC RRM™ Putty / BC Pediatric Putty to the defect and seal all perforation margins.

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4. Remove any excess with a spoon excavator, or a micro brush and ensure EndoSequence® BC RRM™ Putty / BC Pediatric Putty is flush with the wall of the perforation cavity.
5. Take a radiograph to confirm an adequate seal. Add or remove EndoSequence® BC RRM™ Putty / BC Pediatric Putty as needed.
   a. Single Visit Perforation Repair (small defects):
   If you can plan to complete root canal therapy during the same visit, apply a thin layer of self-cure or dual cure glass ionomer cement over EndoSequence® BC RRM™ Putty / BC Pediatric Putty and extend it onto sound dentin (cover the perforation material completely). Do not use composite material over the unset EndoSequence® BC RRM™ Putty / BC Pediatric 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 EndoSequence® BC RRM™ Putty/BC Pediatric Putty cannot be obtained with a glass ionomer in a single visit; gently push EndoSequence® BC RRM™ Putty / BC Pediatric Putty through the defect, then gently place a moist cotton pellet over EndoSequence® BC RRM™ Putty / BC Pediatric Putty and seal the access opening. Remove the cotton during the second visit and complete the root canal procedure.
6. EndoSequence® BC RRM™ Putty / BC Pediatric Putty 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 Perforating Internal Root Resorption defects requiring sealing of the perforation see "Repair of Root Perforation" directions. If the resorptive pattern is complete and the putty cannot be easily placed, consider backfilling the entire resorptive defect with EndoSequence® BC RRM™ Injectable Root Canal Repair Filling Material. For Non-Perforating Internal Root Resorption defects, consider simply obturating using EndoSequence® BC Sealer/BC Sealer HiFlow™ Injectable Root Canal Sealer and gutta percha points.
   b. 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 EndoSequence® BC RRM™ Putty / BC Pediatric Putty into the defect reestablishing the lost contours of the natural tooth. Take a radiograph to confirm an adequate seal. Add or remove EndoSequence® BC RRM™ Putty/ BC Pediatric Putty as needed. Close the wound.
   - Supracrestal Defects
   A glass ionomer compound is recommended in such cases.
3. EndoSequence® BC RRM™ Putty / BC Pediatric Putty will remain as a permanent part of the root canal resorption repair.

ROOT END FILLING

1. Following apicoectomy and retropreparation, clean and disinfect the retropreparation as usual.
2. Place an adequate amount of EndoSequence® BC RRM™ Putty / BC Pediatric Putty into the retropreparation using a plastic instrument.
3. Condense or compress EndoSequence® BC RRM™ Putty / BC Pediatric Putty 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 EndoSequence® BC RRM™ Putty / BC Pediatric Putty to ensure its placement is adequate. If placement is inadequate, add or remove EndoSequence® BC RRM™ Putty / BC Pediatric Putty as necessary.
6. Close the surgical opening after confirming that the root end preparation has been sufficiently sealed.
7. EndoSequence® BC RRM™ Putty / BC Pediatric Putty will remain as a permanent part of the root canal root 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 therapy for a week.
4. Place EndoSequence® BC RRM™ Putty / BC Pediatric Putty into the capital area of the root 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 EndoSequence® BC RRM™ Putty / BC Pediatric Putty 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. EndoSequence® BC RRM™ Injectable Root Canal Repair Filling Material or EndoSequence® BC Sealer/BC Sealer HiFlow™ 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. EndoSequence® BC Sealer/BC Sealer HiFlow™ Injectable Sealer and gutta percha points).
7. Restore the access opening with your restorative material of choice.
8. EndoSequence® BC RRM™ Putty / BC Pediatric Putty will remain as a permanent part of the root canal apexification repair.

PULP CAPPING

Indirect

1. Indirect pulp caps have the best prognosis in cases of normal pulp or reversible pulpits. Do not attempt an indirect pulp cap in cases of irreversible pulpits.
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 EndoSequence® BC RRM™ Putty / BC Pediatric 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 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 EndoSequence® BC RRM™ Putty / BC Pediatric Putty .
2. Place an adequate amount of EndoSequence® BC RRM™ Putty / BC Pediatric 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.

U.S. Patent Nos.: 7,553,362, 7,575,628, 8,343,271, 8,475,811
European Patent Nos.: 1861341 A4, 2142225 B1

Glossary of Symbols:
www.Brasselerusadental.com/resources

Manufactured for
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