EndoSequence® BC RRM™ Instructions for Use

Rx Only

For Dental Use Only

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

PRECAUTIONS
- Discard the disposable BC Tips after each application. Potential cross-contamination may occur if single-use syringe BC Tips are reused or not properly cleaned before use.
- EndoSequence® BC RRM™ and the disposable BC Tips are not designed to be sterilized. Please do not sterilize EndoSequence® BC RRM™ or the disposable BC Tips. Failure to follow these instructions could distort the BC Tips and/or damage the product resulting in procedural delays or user inconvenience.
- Cleaning:
  a. 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.
  b. The EndoSequence® BC RRM™ syringe should be mantled with a hygienic single-use barrier sleeve for infection control for direct intra-oral use.
- Ensure there is continuous flow of material and 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™ as the material may wash out of the placement site and require re-treatment.

STORAGE
- EndoSequence® BC RRM™ 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 syringe cap to keep the syringe tightly closed when the material is not in use. Keep the syringe cap free from moisture.
  b. Keep EndoSequence® BC RRM™ 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™ with the skin, mucus membranes and eyes. Unset EndoSequence® BC RRM™ 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, pain or breakage of the syringe plunger.
- Always inspect the syringe prior to application into the site. Using a syringe with illegible reference markings could lead to overfilling or underfilling of the root canal site.
- EndoSequence® BC RRM™ has not been tested in pregnant women or nursing mothers.
- Procedural delays or user inconvenience may be experienced if the disposable BC Tip is not inspected prior to use. If the material does not flow out of the syringe BC Tip or if the syringe BC Tip feels stiff, discard the BC Tip and use a new one.
- 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 prior to initial use (arrives 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™, please advise the patient to seek medical attention.

INTERACTIONS WITH OTHER DENTAL MATERIALS
- None known

EQUIPMENT
- Moist cotton pellets
- Sterile plastic instrument (of your choice)
- Spoon excavator
- Disposable micro brushes
- Curettes

PRODUCT DESCRIPTION
EndoSequence® BC RRM™ Injectable Root Canal Repair Filling Material is a convenient ready-to-use white hydraulic premixed injectable BioAggregate paste developed for permanent root canal repair and filling applications. EndoSequence® BC RRM™ 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™ does not shrink during setting and demonstrates excellent physical properties.

EndoSequence® BC RRM™ is packaged in a preloaded syringe and is supplied with disposable BC Tips.

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, calcium phosphate monobasic and filler agents.

INTERACTIONS
The setting time of EndoSequence® BC RRM™ 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™, thoroughly prepare and irrigate the root canal using standard endodontic techniques. Please refer to the detailed instructions on reverse.
2. Remove the syringe cap from the syringe. Securely attach a disposable BC Tip with a clockwise twist to the hub of the syringe. The disposable BC Tip is flexible and can be bent to facilitate access to the root canal
3. Insert the BC Tip of the syringe into the root canal. Gently and smoothly dispense the material into the intended anatomic section of the root canal by compressing the plunger of the syringe.
4. Dispense the material while withdrawing the disposable BC Tip. Fill the intended root canal section completely; avoid the formation of air bubbles and overfilling.
5. Remove excess material with a moist cotton pellet.
6. After each application, remove the disposable BC Tip from the syringe with a counterclockwise twist to the hub of the syringe and discard. Clean the outside of the syringe and remove any excess paste, place the syringe cap tightly onto the syringe hub, and place the syringe into the foil pouch and ensure to seal the pouch. Store the pouch in a dry area at room temperature.

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™ to the defect and seal all perforation margins.

BRASSELER USA

EndoSequence Root Repair Material

EndoSequence® BC RRM™ Instructions for Use

4. Remove any excess with a spoon excavator, or a micro brush and ensure EndoSequence® BC RRM™ is flush with the wall of the perforation cavity.
5. Take a radiograph to confirm an adequate seal. Add or remove EndoSequence® BC RRM™ 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™ and extend it onto sound dentin (cover the perforation material completely). Do not use composite material over the unset EndoSequence® BC RRM™ 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™ cannot be obtained with a glass ionomer in a single visit; gently push EndoSequence® BC RRM™ through the defect, then gently place a moist cotton pellet over EndoSequence® BC RRM™ and seal the access opening. Remove the cotton during the second visit and complete the root canal procedure.
6. EndoSequence® BC RRM™ 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 backfill the entire resorptive defect with EndoSequence® BC RRM™. 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™ 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™ as needed. Close the wound.
      - Supracrestal Defects
        A glass ionomer compound is recommended in such cases.
3. EndoSequence® BC RRM™ 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™ into the retropreparation using a plastic instrument.
3. Condense or compress EndoSequence® BC RRM™ 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™ to ensure its placement is adequate. If placement is inadequate, add or remove EndoSequence® BC RRM™ as necessary.
6. Close the surgical opening after confirming that the root end preparation has been sufficiently sealed.
7. EndoSequence® BC RRM™ 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™ 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™ as needed.
6. Fill the remaining root canal space with a permanent filling material:
   a. To fill in the same visit
      Use EndoSequence® BC RRM™ 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™ 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™ 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™.
2. Place an adequate amount of EndoSequence® BC RRM™ 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
Brasseler U.S.A. Dental, LLC
One Brasseler Blvd.
Savannah, GA 31419 USA
Telephone 800-841-4522