



EDGEENDO®

EDGEBIOCERAMIC RETROFILL™
AND PERFORATION REPAIR MATERIAL

Instructions For Use

Contraindications:

- Do not use EDGEBIOCERAMIC RETROFILL™ AND PERFORATION REPAIR MATERIAL (EDGEBIOCERAMIC RETROFILL™) in patients with a known allergy to any of the product's ingredients. An allergic reaction may require re-treatment.

Precautions:



Do not use after the expiration date

- EDGEBIOCERAMIC RETROFILL™ is not designed to be sterilized. Failure to follow these instructions could damage the product resulting in procedural delays or user inconvenience.
- Cleaning:
 - 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 crosscontamination.
 - The EDGEBIOCERAMIC RETROFILL™ 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 EDGEBIOCERAMIC RETROFILL™ as the material may wash out of the placement site and require retreatment.

Storage:



Keep Dry



Store 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:

- Use the cap to keep the syringe tightly closed when the material is not in use. Keep the cap free of moisture.
- Keep EDGEBIOCERAMIC RETROFILL™ tightly sealed in its pouch and store at room temperature in a dry area to avoid moisture contact.

Warnings:



Irritant



Do not use if package is damaged

- Use personal protective equipment to avoid contact of EDGEBIOCERAMIC RETROFILL™ with the skin, mucus membranes and eyes. Unset material may cause irritation.
- 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.

- 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.
- EDGEBIOCERAMIC RETROFILL™ has not been tested on pregnant 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.

Product Description:

EDGEBIOCERAMIC RETROFILL™ is a ready-to-use, premixed bioceramic material developed for 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. EDGEBIOCERAMIC RETROFILL™ does not shrink during setting and demonstrates excellent physical properties. EDGEBIOCERAMIC RETROFILL™ is packaged in a preloaded syringe.

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. The working time is more than 30 minutes.

Setting Time:

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

Interactions:

The setting time of EDGEBIOCERAMIC RETROFILL™ is dependent upon the presence of moisture in the dentin. The amount of moisture necessary to complete the setting reaction is naturally present within the dentin. Therefore, it is not necessary to add moisture in the root canal prior to placing the material.



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**Directions For Use:**

1. Prior to the application of EDGEBIOCERAMIC RETROFILL™, thoroughly prepare and irrigate the root canal using standard endodontic techniques. Reference detailed instructions on reverse.
 2. Unscrew the cap from the syringe.
 3. 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 syringe for each application.
4. Immediately after removing the material screw the cap tightly back on the syringe.
 5. Use a sterile plastic instrument (of 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 an appropriate sized spoon excavator or disposable microbrush.
 7. Place the syringe into the foil pouch and be sure to seal the pouch. Store the pouch in a dry area at room temperature.

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 EDGEBIOCERAMIC RETROFILL™ 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 EDGEBIOCERAMIC RETROFILL™.
2. Place an adequate amount of the EDGEBIOCERAMIC RETROFILL™ 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 EDGEBIOCERAMIC RETROFILL™ 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 EDGEBIOCERAMIC RETROFILL™ 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 EDGEBIOCERAMIC RETROFILL™ and extend it onto sound dentin (cover the perforation material completely). Do not use composite material over the unset EDGEBIOCERAMIC RETROFILL™ 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 EDGEBIOCERAMIC RETROFILL™ cannot be obtained with glass ionomer in a single visit (gently pushing the EDGEBIOCERAMIC RETROFILL™ through the defect) gently place a moist cotton pellet over the EDGEBIOCERAMIC RETROFILL™ 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 Root Resorption defects requiring sealing of the perforation see "Repair of Root Perforation" directions. For Non-Perforating Internal Root Resorption defects, consider simply obturating using EdgeBioCeramic Sealer and 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 EDGEBIOCERAMIC RETROFILL™ 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 EDGEBIOCERAMIC RETROFILL™ into the retropreparation using a plastic instrument.



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3. Condense or compress the material into the preparation from the bottom up to avoid trapping air until the preparation is completely sealed.
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 EDGEBIOCERAMIC RETROFILL™ as necessary.
7. Close the surgical opening after confirming that the root end preparation has been sufficiently sealed.
8. EDGEBIOCERAMIC RETROFILL™ 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 EDGEBIOCERAMIC RETROFILL™ 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.
6. Fill the remaining root canal space.
 - a. 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 EdgeBioCeramic Sealer and Points.
7. Restore the access opening with your restorative material of choice.
8. EDGEBIOCERAMIC RETROFILL™ will remain as permanent part of the root canal apexification repair.

Symbol Table

Symbol	Meaning (Standard, If Applicable)
	Catalogue number (ISO 15223-1)
	Batch code (ISO 15223-1)
	Quantity in Package (N/A)
	Use-by date (ISO 15223-1)
	Do not re-use (ISO 15223-1)
	Do not use if package is damaged (ISO 15223-1)
	Consult Instructions For Use; Follow eIFU website listed (ISO 15223-1)
	Keep dry (ISO 15223-1)
	Temperature limit (Max - Min) (ISO 15223-1)
	Caution (ISO 15223-1)
	Irritant (GHS)
	Manufacturer: Indicates the medical device manufacturer (ISO 15223-1)

Manufactured By:

Innovative BioCeramix Inc.
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Burnaby, BC V3N 0E9
Canada

Manufactured For:

US Endodontics, LLC
2809 W. Walnut Street
Johnson City, TN 37604, USA
EdgeEndo.com

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

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