

Instructions For Use

EDGE BIO CERAMIC™ SEALER

Contraindications:

- Do not use EdgeBioCeramic Sealer 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

 Consult accompanying Safety Data Sheet (SDS)

 Do not re-use the disposable syringe tips (Tips).

- Discard the Tips after each application. Potential cross contamination may occur if single use syringe tips are reused or not properly cleaned before use.
- EdgeBioCeramic Sealer and Tips are not designed to be sterilized. Failure to follow these instructions could distort the tips and/or 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 cross-contamination.
- The EdgeBioCeramic Sealer 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 Sealer, as the material may wash out of the placement site and require re-treatment.

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 syringe cap to keep the syringe tightly closed when the material is not in use. Keep the syringe cap free from moisture.
- Keep EdgeBioCeramic Sealer 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 Sealer 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 Sealer has not been tested on pregnant or nursing mothers.
- Procedural delays or user inconvenience may be experienced if the Tip is not inspected prior to use. If the material does not flow out of the syringe tip or if the syringe tip feels stiff, discard the 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.

Product Description:

EdgeBioCeramic Sealer is a premixed ready-to-use injectable bioceramic paste developed for permanent root canal filling and sealing applications. EdgeBioCeramic Sealer 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 Sealer does not shrink during setting and demonstrates excellent physical properties. EdgeBioCeramic Sealer is packaged in a pre-loaded syringe and is supplied with disposable Tips. EdgeBioCeramic Sealer may be delivered into the canal via the tips provided or it can be delivered via traditional methods.

Indications For Use:

- Permanent obturation of the root canal following vital pulp-extirpation.
- Permanent obturation of the root canal following removal of infected or necrotic pulp and placement of intracanal dressings.

Working Time:

No mixing is required. EdgeBioCeramic Sealer can be applied immediately and introduced directly into the root canal. The working time can be more than 4 hours at room temperature.

Setting Time:

Setting time is 4 hours. However, in very dry root canals, the setting time can be more than 10 hours.

Interactions:

The setting time of EdgeBioCeramic Sealer 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.

Removal of Root Canal Filling:

Conventional techniques can be used for the removal of EdgeBioCeramic Sealer as used in combination with gutta-percha points. Piezo Electric Ultrasonics (with water spray) can also be used.













Directions For Use:

- Prior to the application of EdgeBioCeramic Sealer, thoroughly prepare and irrigate the root canal using standard endodontic techniques.
- Dry the canal as you normally would using paper points.
- Sealer Delivery Methods:** both of the below sealer delivery methods are effective. The clinician should utilize whichever method they are most comfortable with.
 - Traditional Method:**
Coat the primary gutta percha point or a small hand file with sealer (extra-orally) and use the point or file to apply the sealer to the canal walls.
 - Tip Delivery Method:**
Remove the syringe cap from the EdgeBioCeramic Sealer syringe. Securely attach a Tip with a clockwise

twist to the hub of the syringe. The Tips are flexible and can be bent to facilitate access to the root canal. Insert the tip of the syringe into the canal no deeper than the coronal one third (1/3). Gently and smoothly dispense a small amount (1-2 reference markings) of EdgeBioCeramic Sealer into the root canal by compressing the plunger of the syringe. Using a #15 handfile or any comparable handfile, lightly coat the canal walls with the existing sealer in the canal. Then coat the master gutta percha cone with a thin layer of sealer and very slowly insert it into the canal. The master gutta percha cone will carry sufficient sealer to the apex.

Note: The precise fit of the gutta percha master cone creates excellent hydraulics and for that reason it is recommended that the practitioner use a small amount of sealer. Furthermore, it is also important to insert the master cone very slowly to its final working length. If using a warm vertical technique, see the instructions for use for your powered heat source.

- If desired, place additional gutta percha points into the canal using standard condensation techniques.
- Using a heat source, burn off the gutta percha cones at the orifice, apply a slight amount of vertical condensation, and remove any excess sealer with a moist cotton ball or swab.
- EdgeBioCeramic Sealer will remain part of the permanent root canal filling.
- After each application, remove the 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.

SYMBOL	MEANING (STANDARD, IF APPLICABLE)
	Manufacturer/Legal Manufacturer (ISO 15223-1)
	Catalogue Number (ISO 15223-1)
	Batch Code (ISO 15223-1)
	Quantity (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 (ISO 15223-1)
	Caution (ISO 15223-1)
	Keep Dry (ISO 15223-1)
	Temperature limit (Max - Min) (ISO 15223-1)
	Irritant (GHS)



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U.S. Patent Nos. 7,553,362, 7,575,628, 8,343,271,
8,475,811

European Patent Nos. 1861341 A4, 2142225 B1