

RE-GEN™
**BIOACTIVE
ENDOSEALER**
BIOCERAMIC ROOT CANAL SEALER

REF 504753



Product Description:

Vista Apex's RE-GEN™ Bioactive EndoSealer is a premixed ready-to-use injectable BC paste developed for permanent root canal filling and sealing applications. The RE-GEN™ Bioactive EndoSealer is packaged in a pre-loaded syringe and is supplied with disposable single use applicator tips. This 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.

Contraindications:

- Do not use RE-GEN™ Bioactive EndoSealer in patients with a known allergy to any of the product's ingredients. An allergic reaction may require treatment.

Precautions:

- Consult accompanying Safety Data Sheet (SDS).
- Do not use after the expiration date.
- Discard the applicator tips after each application. Do not re-use the tips. Potential cross-contamination may occur if single use application tips are reused or not properly cleaned before use.
- RE-GEN™ Bioactive EndoSealer and application tips are not sterile and are not intended to be sterilized. Failure to follow these instructions could distort the tips and/or damage the product resulting in procedural delays or user inconvenience.
- 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.
- Ensure there is continuous flow of sealer 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 the RE-GEN™ Bioactive EndoSealer as the material may wash out of the placement site and require re-treatment.
- Do not open or tamper with the desiccant pouch. This is used to remove moisture inside the packaging.
- RE-GEN™ Bioactive EndoSealer must be kept in the resealable foil pouch with the desiccant packet at all times.

Storage:

- Store at room temperature between 2°C (36°F) and 30°C (86°F) and in a dry area to avoid moisture contact.

Warnings:

- Always check the expiration date prior to use.
- Do not use if package is damaged.
- Do not use excessive force to apply the material within the root canal.
- Do not ingest desiccant pouch.
- Although the product has been confirmed to be biocompatible for its intended use, apical extrusion of sealer material should be minimized.
- Always inspect the syringe prior to application.
- Always confirm sealer is extrudable through the attached applicator tip prior to applying in the root canal. If clogging is experienced, dispose of the applicator tip and use a new one.
- RE-GEN™ Bioactive EndoSealer has not been tested on pregnant or nursing mothers.

Best if Used By:

9 months after opening the sealed foil pouch.

Working Time:

The working time can be more than 4 hours at room temperature. The sealer can be applied directly into the canal. No mixing is required.

Setting Time:

Setting time is 1 hour. However, in very dry root canals, the setting time may be longer.

Directions for Use:

1. Use standard endodontic techniques to instrument, clean and disinfect canals thoroughly prior to applying the RE-GEN™ Bioactive EndoSealer.
2. Following your current procedure, dry the canal with paper points.
3. Sealer Delivery Methods:
Two effective delivery methods are described below. The clinician should utilize whichever method they are most comfortable with.
 - a. *Traditional Method:*
 - Coat the primary gutta percha point or a small hand file with sealer (extra-orally) and use the point/file to apply the sealer to canal walls.
 - b. *Tip Delivery Method:*
 - Remove the syringe cap from the RE-GEN™ Bioactive EndoSealer syringe.
 - Securely attach an applicator tip with a clockwise twist to the hub of the syringe.
 - Verify flow prior to applying intraorally. If resistance is met, replace tip and re-check.
 - Insert the tip of the syringe into the canal no deeper than the coronal one third (1/3).
 - Gently compress the plunger of the syringe to smoothly fill canal space up to canal orifice with the RE-GEN™ Bioactive EndoSealer material.
 - Use a small hand file to 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 seat to working length. The master gutta percha cone will carry enough sealer to the apex.
4. If needed, place in accessory cones to fill space.
5. Carefully trim excess gutta percha cones at the orifice using a hot heat source and remove any excess sealer with a moist cotton ball/swab.
6. After each application, remove the applicator tip from syringe and discard. Place the syringe cap tightly onto the syringe hub and remove any excess paste by cleaning the outside of the syringe. Place the syringe back into the foil pouch and store the pouch in a dry area at room temperature.

Removal of Root Canal Fillings:

Conventional techniques can be used for the removal of this sealer.

Note:

- Keep the syringe cap clean and free of moisture. When not in use, keep the capped syringe in the sealed foil pouch with the desiccant pouch.

	Manufacturer
	Consult instructions for use
	Keep dry
	Do not use if package is damaged
	Temperature limitations for storage
	Caution – consult accompanying documentation
	Do not re-use (applicator tips)
	Batch number
	Expiration date
	Manufactured date
	Warning: Can cause serious eye irritation, refer to SDS