



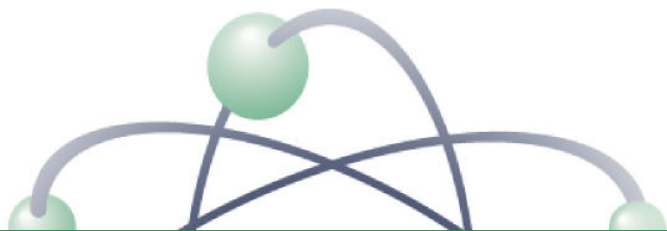
VISTA APEX

RE-GEN™

PATENT PENDING

BIOACTIVE ENDOPUTTY

REF 504756



Product Description:

Vista Apex's RE-GEN™ Bioactive EndoPutty is a hydraulic, ready-to-use injectable bioceramic, bioactive root repair paste developed for permanent root canal repair of root perforation and root resorption, and root end filling, apexification and pulp capping applications. Vista Apex's RE-GEN™ Bioactive EndoPutty is an insoluble, radiopaque material based on a calcium sodium phosphosilicate and calcium aluminate cement composition, which requires the presence of water to set and harden.

Indications for Use:

- Repair of Root Perforation
- Repair of Root Resorption
- Root End Filling
- Apexification
- Pulp Capping

Contraindications:

- Do not use Vista Apex's RE-GEN™ Bioactive EndoPutty 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).
- Vista Apex's RE-GEN™ Bioactive EndoPutty is a caustic material.
- Avoid contact of the unset putty with skin or oral mucosa. After incidental contact, wash and rinse with water.
- Wear suitable gloves and protective glasses during use.
- Vista Apex's RE-GEN™ Bioactive EndoPutty must be kept well sealed to prevent premature hardening of the putty material. Immediately recap after each use.
- Do not use after the expiration date.
- Vista Apex's RE-GEN™ Bioactive EndoPutty is not sterile and is not intended to be sterilized.
- 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.
- Do not overfill the root canals when obturating or performing apexification.
- Ensure that any bleeding is under control prior to placing RE-GEN™ Bioactive EndoPutty as the material may wash out of the placement site and require re-treatment.

Storage:

- Store at room temperature between 2C (36F) and 30C (86F).
- When not in use, store the capped syringe in the foil pouch with the desiccant card and reseal the foil pouch closed. This will prevent premature hardening of the putty material within the syringe.

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 to the treatment site.
- Always inspect the syringe prior to application.
- Vista Apex's RE-GEN™ Bioactive EndoPutty has not been tested on pregnant or nursing mothers.

Working Time:

Working time is within 4 hours at room temperature. 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 – Root Perforation & Root Resorption:

1. Debride, clean and shape the root canal system using intra-canal instruments under rubber dam isolation.

2. Gently irrigate the root canals using a NaOCl (1.25-6.0%) or chlorhexidine solution.
3. Isolate the defect site(s).
4. Obturate the canal space apical to the defect.
5. Dispense Vista Apex's RE-GEN™ Bioactive EndoPutty material into the defect site with an instrument of clinician's choice.
6. Gently compact Vista Apex's RE-GEN™ Bioactive EndoPutty material using a small plugger, cotton pellets or paper points.
7. Confirm placement with a radiograph.
8. Excess material may be removed using a cotton pellet dampened with sterile water or saline.
9. Obturate the remaining canal space and close the coronal access.

Directions for Use – Root End Filling:

1. Surgically access the root-end and resect 2 to 4mm of the root apex using a surgical bur.
2. Prepare a Class I root-end cavity preparation 3 to 5mm deep with an ultrasonic tip.
3. Isolate the area and achieve hemostasis.
4. Dry the area.
5. Gently compress the Vista Apex's RE-GEN™ Bioactive EndoPutty material in the root-end cavity using a “plastic” instrument or other small carrier or instrument.
6. Excess material may be removed using a cotton pellet dampened with sterile water or saline.
7. Rinse gently.

Directions for Use – Apexification:

1. Debride, clean and shape the root canal system using intra-canal instruments under rubber dam isolation.
2. Gently irrigate the root canals using a NaOCl (1.25-6.0%) or chlorhexidine solution.
3. Dry the canal system with paper points, being careful not to extend the points beyond a wide-open apex.
4. Gently compact Vista Apex's RE-GEN™ Bioactive EndoPutty in the apical region, to create a 3 to 5mm apical barrier.
5. Confirm placement with a radiograph.
6. Obturate the remaining canal space and close the coronal access.
7. A full coverage restoration is normally placed following apexification.

Directions for Use – Direct and Indirect Pulp Capping:










1. Complete a cavity preparation under rubber dam isolation, using a high-speed bur.
NOTE: If applying material for an indirect pulp cap, base or liner, skip to step 4.
2. Excavate carious tooth structure using a round bur in a handpiece at low speed or use hand instruments.
3. Control bleeding, if present, following your standard protocols. If bleeding is still present after 10 minutes, the diagnosis may be irreversible pulpitis and vital pulp therapy using Vista Apex's RE-GEN™ Bioactive EndoPutty may not be indicated.
4. Use an applicator of your choice to apply Vista Apex's RE-GEN™ Bioactive EndoPutty material on the exposed pulp or the floor of the cavity preparation, maintaining a minimum thickness of 1.5mm.
5. Excess material may be removed using a cotton pellet slightly dampened with sterile water or saline.
6. Immediately restore over Vista Apex's RE-GEN™ Bioactive EndoPutty with a light curable material (e.g. composite, glass ionomer, RMGI), or luting cement and crown. Alternatively, you may use a flowable composite, RMGI, ZOE or other material to secure the Vista Apex's RE-GEN™ Bioactive EndoPutty prior to final tooth restoration.
7. Assess the pulp vitality as needed and confirm with a radiograph.

Removal of Root Canal Fillings:

Conventional techniques can be used for the removal of this putty material.

Note:

- Keep the syringe cap clean and free of moisture. When not in use, keep the syringe cap in the pouch.

	Manufacturer
	Consult instructions for use
	Keep dry
	Do not use if package is damaged
	Temperature limitations for storage
	Caution – consult accompanying documentation
	Batch number
	Expiration date
	Manufactured date

