

CALAPEX

Non-eugenol, Calcium Hydroxide Based
Polymeric Root Canal Sealant

PREVESTDenPro®
THE FUTURE OF DENTISTRY

Product Description: Calapex is a non eugenol polymeric resin, radiopaque calcium hydroxide based bioceramic root canal filling material. Calapex is a two-component, base and activator system supplied in two tubes or in a dual-barrel syringe

Composition:

Base : N-Ethyl-o/p-Toluene Sulphonamide, Calcium Oxide, Zinc Oxide, Titanium dioxide and Fillers.

Catalyst: Ethylene Glycol Salicylate, Zinc Oxide, Titanium Dioxide, Fillers, Radiopacifiers and Colouring Pigment.

Intended purpose/Intended use: It is intended to be used for permanent obturation of root canals & is suitable for use in conjunction with all obturation techniques involving gutta percha.

Indications for use: It is a, radiopaque calcium hydroxide based bioceramic cement for the permanent obturation of root canals in combination with gutta-percha points or silver points.

Instructions for use: Mixing Calapex (Base/Catalyst Tubes) : Dispense both Base and Catalyst paste to a ratio of 1:1 volume on to a mixing pad and using the spatula mix the paste for 15-20 seconds or until a creamy homogeneous consistency is obtained. Automix Cartridge: Attach the mixing tips to the Automix Cartridge press the plunger of the cartridge to express a homogeneously mixed sealer paste. Manual Mix: Activate the plunger of the manual mix cartridge to dispense both Base and Catalyst paste to a ratio of 1:1 volume on to a mixing pad and using the spatula mix the paste for 15-20 seconds or until a creamy homogeneous consistency is obtained.

Application of Calapex : As a standard technique, Calapex is used together with gutta-percha or silver root canal points. When a thermoplasticized filling technique is used where most of the canal is obturated by endodontic point material, apply only a light coating of Calapex to the canal walls. For Master-Point-Technique, select a gutta-percha point with the size of the last instrument used for apical preparation. Apply Calapex to the canal walls with the help of the obturation point. Alternatively a lentulo spiral can be used. Avoid the formation of air bubbles in the material and overfilling of the canal by advancing the lentulo spiral slowly to the apex running at low speeds. Withdraw Lentulo very slowly still running at low speed. Working time 15-20 minutes. Dip disinfected and dry gutta percha points into Calapex and insert them into the canal with a slow pumping motion. Calpex is packaged in a multiple dose container (Tube/Cartridge). Opening and closing of the container does not affect the shelf life of the device. The dispensed material shall not be placed back in the container and the dose once applied or used shall not be reused. Calapex is the endodontic product for every dental practice. It can be used for all established and more recent root canal sealing techniques. It is also suitable for the single point method, thermoplasticize method and all condensation techniques. The setting time of Calapex in the root canal is dependent upon the availability of moisture.

Warnings:

1. The sealer which may cause sensitization in susceptible people. Do not use Calapex in people allergic to any components of this product.
2. Avoid eye contact to prevent irritation. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention. Avoid skin contact to prevent possible allergic response. Unset material may cause irritation and therefore contact with skin and mucous membrane should be avoided. In case of contact, immediately remove material with cotton and wash thoroughly with water and soap. In case of skin sensitization or rash, discontinue use and seek medical attention.
3. Do not swallow or take internally. If accidental swallowing occurs, drink lots of water. If nausea or illness develops, seek medical attention.
4. Avoid overfilling. When overfilling occurs, the material is usually tolerated very well by the surrounding tissue.

Precautions :

1. This product is intended to be used as specifically outlined in the Instruction for Use. Any use of this product inconsistent with the Instructions for use is at the discretion and sole responsibility of the practitioner.
2. Wear suitable protective clothing, eyewear, and gloves.
3. The solubility and essentially basic nature of Calapex composition requires that it is used only in situations where it can be protected adequately from the intraoral environment.
4. To achieve good results, use of a rubber dam or adequate isolation is recommended.
5. Calapex should be mixed in equal volumes for optimum performance. The mixed material should be homogeneous and streak free prior to application.
6. Increased humidity and elevated temperature will reduce available work time and set time.
7. Containers should be tightly closed immediately after use.

Contraindications: 1. Retrograde obturation. 2. Do not use Calapex in patients with a known allergy to any of the product's ingredients.

Storage Conditions: This product should be used at room temperature. Contact with water should be strictly avoided. Inadequate storage conditions could shorten shelf life and product performance. We recommend to store at temperatures between 10°C (50°F) and 24°C (75°F) and keep cap tightly closed for base and catalyst respectively. Refrigerated storage is acceptable when not in use. Allow material to reach room temperature prior to use. Do not freeze. Do not use after expiration date.

Shelf Life: 2 years from the date of manufacturing.

Presentation:

Ref. : 40041

1 x 20g Automix Cartridge, 20 x Mixing Tips.

Ref. : 40041-1

Net Content 20g, 1 x Base Paste, 1 x Catalyst Paste, 1 x Mixing Pad.

Ref. : 40041-2

1 x 20g Manual Mix Cartridge, Base & Catalyst, 1 x Mixing Spatula, 1 x Mixing Pad.

Disposal conditions : To be disposed off based on the prevailing rules of the country in which it is used.

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UDI Symbol for "UNIQUE DEVICE IDENTIFIER"

- LOT Symbol for "BATCH CODE" Symbol for "USE-BY DATE" Symbol for "NON STERILE" Symbol for "KEEP DRY"
- Symbol for "CAUTION" Symbol for "CONSULT INSTRUCTIONS FOR USE" REF Symbol for "CATALOGUE NUMBER"
- EC REP Symbol for "AUTHORIZED REPRESENTATIVE IN THE EUROPEAN COMMUNITY/EUROPEAN UNION"
- Symbol for "DO NOT USE IF PACKAGE IS DAMAGE" Symbol for "KEEP OUT OF THE REACH OF CHILDREN" Symbol for "MANUFACTURER"
- Symbol for "TEMPERATURE LIMIT" Symbol for "KEEP AWAY FROM SUNLIGHT" MD Symbol for "MEDICAL DEVICE"

The material has been developed solely for professional dental use. Application should be carried out strictly according to the instruction for use. Liability cannot be accepted for damages resulting from failure to observe the instructions of the stipulated area of applications. The user is responsible for testing the material for its suitability and use for any purpose not explicitly stated in this instruction sheet. Description and data constitute no warranty of attributes and are not binding. For feedback, complaints and reporting of unexpected events contact customer care.