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Calcium Hydroxide Root Canal Filling Material

DSI ApexSil Cal

INSTRUCTIONS FOR USE

DESCRIPTION

DSI ApexSil Cal is a non-eugenol polymeric, radiopaque calcium hydroxide-based bioceramic root canal filling material. ApexSil Cal is a two-component, base and activator system supplied in two tubes (or in a dual-barrel syringe).

COMPOSITION

Base: N-Ethyl-o/p-TolueneSulphonamide, Calcium Oxide, Portland Cement, Zinc Oxide, Titanium Dioxide, Zinc Stearate, Hydrogenated resin, Fumed silica.

Catalyst: Ethylene Glycol Salicylate, Butylene Glycol, Tri-calcium Phosphate, Zinc Oxide, Titanium Dioxide, Fumed Silica, Barium zirconate, Zinc Stearate, N-Ethyl O/p Toluenesulphonamide, colourant.

INDICATIONS: 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 ApexSil Cal (Base/Catalyst Tubes): Dispense both Base and Catalyst paste to a ratio of 1:1 volume onto a mixing pad and using the spatula mix the paste for 15-20 sec. or until a creamy homogeneous consistency is obtained.

Application of ApexSil Cal: As a standard technique, ApexSil Cal 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 ApexSil Cal 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 ApexSil Cal 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 min. Dip disinfected and dry points into ApexSil Cal and insert them into the canal with a slow pumping motion. Calpex is packaged in a multiple-dose container (Tube / Cartridge). Opening and closing 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 and used shall not be reused. ApexSil Cal 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 ApexSil Cal in the root canal is dependent upon the availability of moisture.

Warning: The sealer may cause sensitization in susceptible people. Do not use ApexSil Cal in people allergic to any components of this product. 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 membranes should be avoided. In case of contact, immediately remove the material with cotton and wash thoroughly with water and soap. In case of skin sensitization or rash, discontinue use and seek medical attention. Do not swallow or take it internally. If accidental swallowing occurs, drink lots of water. If nausea or illness develops, seek medical attention. 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 ApexSil Cal composition require that it is used only in situations where it can be protected adequately from the intraoral environment.
4. To achieve good results, the use of a rubber dam or adequate isolation is recommended.
5. ApexSil Cal 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.
8. Refrigerated storage is acceptable when not in use. Allow material to reach room temperature prior to use. Protect from moisture. Do not freeze.
















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

STORAGE: 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 storing at temperatures between 10°C (50°F) and 24°C (75°F) and keeping the cap tightly closed. Shelf life: 3 Years from the date of manufacturing.

PACKAGING: Base Paste 12.5g / Catalyst Paste 7.5g, Mixing Pad.

Ref: ASIL-CAL

SYMBOLS

| | | | |
|------------------------------------------------------------------------------------|-----------------------------------------|-------------------------------------------------------------------------------------|--------------------------|
|  | Consult instructions for use |  | Medical Device |
|  | Caution, consult accompanying documents |  | Use by Prescription only |
|  | Temperature limit |  | Manufacturer |
|  | Keep away from sunlight |  | Catalogue number |
|  | Keep dry |  | Batch code |
|  | Non-sterile product |  | Use by |
|  | Do not use if package is damaged |  | Date of Manufacture |
|  | Keep Out of Reach of Children | | |

Failure to comply with the conditions of storage leads to a change of the working characteristics of the material and decrease the shelf life of the material.

The manufacturer is not responsible for any loss of quality caused by the failure to comply with terms of transportation, storage and use established by the manufacturer for this product. Responsibility for the use of the material for purposes other than those specified by the manufacturer falls on the user.