

## Instructions For Use

**Caution:** US federal law restricts this product for sale by or on order of a dentist or physician.

**Product description:** ActaCal SEALER is a ready to use injectible bioceramic endodontic sealer based on MTA (Mineral Trioxide Aggregate), suitable for obturation of root canals including accessory and lateral canals and for the treatment of internal resorption. The product is a pre-mixed paste dispensed in a syringe with disposable intracanal delivery tips to be applied directly into the root canal system.

**Composition:** MTA Powder, Zirconium Oxide, Hydroxypropyl Methyl Cellulose, Polyethylene Glycol and Fumed Silica

**Intended use:** It is used as sealer for permanent filling of root canals. Indications for use :

1. Permanent obturation / filling of root canals which can be used with or without root canal obturation materials.
2. Treatment of internal resorption.

**Instructions for use:** The cement requires no mixing as it is supplied as a premixed paste in a preloaded syringe with disposable intracanal delivery tips. Prior to the application of the material, the prepared root canal should be dried using a paper point. Avoid over drying as the sealer needs moisture to completely set and harden. The dispensed material shall not be placed back in container and the dose once applied and used shall not be reused.

1. Sealer technique:
  - A. Conventional method: The sealer can be dispensed from the syringe on a mixing pad and delivered to the root canal space by carrying it with a gutta-purcha point or an endodontic instrument.
  - B. Tip delivery technique: Remove the syringe cap and attach the intracanal delivery tip. Insert the tip into the coronal third of the root canal space and smoothly dispense a small amount of material by compressing the syringe plunger. Coat the walls of the canals evenly using a #15 endodontic file or a gutta-purcha point. In case of lateral condensation place additional gutta-purcha points coated with the sealer.  
After obturation the gutta-purcha is cut at the orifice using a heat source. Excess sealer in the root canal chamber should be wiped off using a cotton balls or swabs.
2. Filling technique without obturation points: The material can also be used for filling the root canal space independently. In that case, proper care should be taken to prevent extrusion of material. An apical limiting barrier is strongly advised in such cases.

### Warnings:

1. The sealer may cause sensitization in susceptible people. Do not use ActaCal SEALER in people allergic to calcium silicates or any other 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 the use and seek medical attention.
3. Do not swallow or take internally. If accidental swallowing occurs, drink lot 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. The material should be immediately removed in cases of extrusion in to the mandibular canal.
5. Clean the coronal portion of the tooth after obturation to prevent unwanted discoloration.

### Precautions:

1. Do not use after the expiration date.
2. Do not re-use the disposable syringe tips. Potential cross contamination may occur if tips are re- used.
3. Closely follow the recommended storage conditions. Failure to do so will cause the material to prematurely set.

**Contraindications:** Hypersensitivity against calcium silicates or other components of the root canal filling material.

**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 temperature between 10°C (50°F) and 24°C (75°F) and keep syringe cap tightly closed.

**Shelf Life:** 3 years from the date of manufacturing.

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

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