MD

AHL Generic CE 0123

EPOXY RESIN ROOT CANAL SEALER

ISO 6876:2012 Root canal sealing materials

DIRECTIONS FOR USE

FEATURES:
Root canal powder and resin are mixed to produce a root canal filling material of excellent sealing capacity as a result of its close adaptation to the root canal walls and its small contraction during setting.

INTENDED PURPOSE:
Endodontic sealer

INTENDED PATIENT POPULATION:
From child to geriatrics

INTENDED USER:
This product has been formulated for use in dentistry and is intended for use by dental professionals only.

CLINICAL BENEFIT:
To restore the function of the teeth and help maintain the integrity of the remaining tooth structure.

INDICATIONS FOR USE:
- Permanent obturation of root canals of teeth of the secondary dentition with the aid of obturation points.

CONTRA-INDICATIONS:
- Hypersensitivity against epoxy resins or other components of the root canal filling material

CONTENTS OF PACK:
Powder 8g, resin 10g, instructions for use.

PRECAUTIONS AND WARNINGS:
- Root canal powder and resin contain epoxy resin which may cause sensitisation in susceptible persons.
- During the setting reaction of materials, traces of formaldehyde may be produced.
- Do not use Root Canal Sealant in persons allergic to epoxy resins.
- Avoid contact of powder or resin and unset paste with skin or oral mucosa.
- After incidental contact, wash and rinse with plenty of water.
- Wear protective gloves and glasses.
- Root Canal Sealant may react with hydrogen peroxide accidentally left in the root canal after irrigation.

PROCEDURE

(1) CAVITY PREPARATION:
- Prior to application, thoroughly clean the root canal.
- If hydrogen peroxide has been used for irrigation, it is essential to make sure that the canal is free of any traces of rinsing solution.
- This is to avoid reaction of Root Canal Sealant with hydrogen peroxide which would result in the formation of bubbles.
- If sodium hypochlorite and hydrogen peroxide are used alternatingly for canal irrigation, use hypochlorite as the last agent.
- Thoroughly dry the root canal with sterile paper points.

(2) MIXING:
- Powder and resin are mixed on a glass slab using a metal spatula.
- 2 to 3 volume units of powder are mixed with 1 volume unit of resin.
- Mix at 22 – 24 °C.
- Mix to a homogeneous consistency which breaks when lifted 1.5 to 2.5 cm (1/2 to 1 inch) above the glass slab.
- If a particularly fluid mix is required, the glass slab may be carefully warmed before use.

Total mixing time: 30 seconds.
Working time: 4 hours from start of mix at 23°C.
Setting time: 20 hours from placement in the oral cavity.

(3) PLACEMENT:
- Apply the mixed cement onto the tip of a Lentulo spiral.
- To avoid the formation of air bubbles in the material and overfilling of the canal, advance the Lentulo spiral slowly to the apex running at very low speed.
- Withdraw Lentulo very slowly still running at low speed.
- If sealer is used in combination with gutta-percha points or other cores and if there is the risk of overfilling use reamers to apply sealer into the canal.
- Choose a reamer of the size of the last instrument used during apical root canal preparation.
- Place sealer by a pumping action of the reamer with simultaneous rotary movement in a counter clock direction. It is only necessary to apply a light coating of sealer
- Dip the disinfected and dry master point into sealer and with pumping motions slowly push it into the canals.
- Additional gutta-percha points and lateral or vertical condensation methods can be applied.

(4) Removal of Root Canal Filling:
- Once it has set, Root Sealer cannot be removed with conventional solvents.
- If Sealer was used in combination with gutta-percha points, the root canal fillings can be removed using conventional techniques for the removal of gutta-percha.

(5) Cleaning of Instruments:
- Spatulas, mixing slabs and instruments should be cleaned immediately after use with alcohol or acetone.

STORAGE:

Store in a cool, dry place (5-25ºC).
Always replace cap immediately after use.

EXPIRY:
The expiry date is shown in year, month format. Do not use the product after this date.

DISPOSAL:
Dispose of the contents and containers in accordance with relevant local and national requirements.

POSSIBLE SIDE EFFECTS / RESIDUAL RISKS:
- **Endodontic sealers containing epoxy resins, the following adverse reactions were reported:**
  - Reversible acute inflammation of the oral mucosa after contact with the unset paste.
  - In individual cases, local and systematic allergic reactions have been reported.
- **Endodontic treatment, the following adverse effects were reported:**
  - Postoperative pain.
  - Overfilling of the root canal.

BATCH CODE:
LOT The batch code gives an open date of manufacture in month, year, day format with a numerical suffix to uniquely identify the batch of material. Please quote this batch number in all correspondence.

DEVICE CODES:
REF 405XPL Powder 8g / Resin 10g

COMPOSITION:

Composition	% by weight
Radiopacifier	30 – 40
Setting agent	10 – 20
Pigments	0 – 5
Epoxy Resin	40 – 50

AHL operate a policy of continuing surveillance & monitoring of our products. If you experience any incidents relating to the use of this product, please immediately contact us at the below address stating the batch number shown on the packaging. If you experience any serious incident relating to the use of this product, please immediately contact AHL at the below address and the competent authority of the territory you are in.

A summary of safety & clinical performance (SSCP) is available via the EUDAMED database. https://ec.europa.eu/tools/eudamed

Caution: U.S. Federal Law restricts this device to sale by or on the order of a dental professional.

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FEEDBACK
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