

SEALMAX-R (Instructions For Use)

INTENDED USE:

Sealing of root canals during obturation in the secondary dentition with or without the aid of obturation points (gutta-percha).

COMPOSITION:

Sealmax-R powder: Bismuth oxide, Methenamine, Titanium dioxide
Sealmax-R Liquid: Epoxy resin

PRODUCT DESCRIPTION:

Sealmax-R is a resin based root canal sealing material supplied in the form of powder and liquid. The powder and liquid are mixed to produce a root canal sealing material of excellent sealing capacity and tissue compatibility. As a result of its close adaptation to the walls and hydrophobic nature, Sealmax-R allows tight sealing of root canal during obturation.

Procedure & product handling:

Preparation Of The Root Canal:

- Prior to application of Sealmax-R, thoroughly clean the root canal.
- If an irrigating solution has been used, it is essential to make sure that the canal is free of any traces of irrigating solution, to avoid reaction of Sealmax-R with the irrigants.
- If sodium hypochlorite or ethylenediaminetetraacetic acid (EDTA) are used alternately for irrigation, use EDTA as the last irrigating agent.
- Thoroughly dry the root canal with paper points or by vacuum drying.

Dosage And Mixing: Powder and liquid are mixed to a homogeneous consistency at the ratio of 2:1 v/v on the mixing-pad provided using a spatula. String test can be used to confirm the consistency, which breaks when lifted 1.5 to 2.5 cm (1/2 to 1 inch) above the mixing-pad.

STEP-BY-STEP INSTRUCTIONS:

- Apply the mixed Sealmax-R 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 coating the walls of the root canal with the sealer.
- If Sealmax-R is used in combination with other obturation points and if there is the risk of overfilling, apply Sealmax-R in the canal using a spreader.
- Place Sealmax-R by a pumping action of the spreader with simultaneous movement in a counter-clockwise direction.
- Dip the disinfected and dry master cone (gutta-percha) into Sealmax-R and with pumping motions slowly push it into the canals. Additional gutta-percha points and lateral or vertical condensation methods can be applied for thorough obturation of the canal.

Removal of Root Canal Sealing: After the final setting in the root canal, Sealmax-R cannot be removed with conventional solvents. Reamers or rotary files should be used for mechanical removal of the sealer. If Sealmax-R was used in combination with gutta-percha points, the gutta-percha points can be removed using conventional techniques, followed by mechanical removal of the sealer.

Cleaning of Instruments: Spatulas and instruments used to carry the sealer should be cleaned immediately after use with alcohol or acetone.

Working Time: Working time for Sealmax-R ranges from 25 to 30 minutes after mixing the powder and liquid in the prescribed proportion at a temperature range of 20-30 °C.

Setting Time: The setting time is within 24 hours at body temperature after mixing as per instructions.

Caution / Warning:

1. Device to be used by a qualified dentist or dental technician only.
2. Do not insert material under pressure into the canal.
3. Sealmax-R contains epoxy resins which may cause sensitization in susceptible persons during the setting reaction.
4. Sealmax-R Powder & Sealmax-R Liquid to be strictly used together ONLY.

Precautions:

1. Avoid contact of the device with skin and mucosa, avoid contact with eyes. Avoid inhalation of fumes. Do not take internally.
2. **Eye contact:** if the product comes in contact with eye, it may cause irritation. In case of contact with eyes, rinse immediately with plenty of water and seek medical attention.
3. **Skin Contact:** Avoid contact of powder or resin and unset paste with skin or mucosa, it may cause skin sensitization. If contact with skin occurs immediately wipe off thoroughly with cotton and then wash well with soap and water. If skin rash and sensitization or other allergic reaction occurs discontinue use and seek medical attention.
4. Wear suitable gloves and protective glasses to avoid accidental exposure to skin and eyes.
5. Do not transfer the excess material back into the container to avoid contamination.

Contraindications:

1. Do not use the product if the patient is allergic to any of the ingredients.
2. Do not use the product on mucosa or skin.
3. Not Intended for use beyond the confinement of root canals of teeth.

Interactions With Other Dental Materials: Sealmax-R may react with the irrigating solutions accidentally left in the root canal after irrigation, hence advised to dry the canal completely before introducing the sealer. Kindly communicate and inform the manufacturer with complete details in case of any incidences of interaction not mentioned here.

Adverse Reactions: In individual cases, local and systemic allergic reactions may occur in individuals sensitive to the components of the sealing material. No such Reactions have been Noted. Kindly communicate and inform manufacturer in details of any instance.

Packaging: Multi dose container of powder and liquid, along with dispensing scoop and mixing pad.

Storage conditions: Keep Away from Direct Sunlight. Keep locked up and out of the reach of children. Store at a temperature between 10°C to 30°C.

Shelf life (2 years from the date of manufacturing) not affected after opening if stored in a cool dry place. Keep the powder and liquid containers tightly closed to avoid contamination.

Disposal Conditions: Dispose in accordance with local, state and federal environmental regulations.

This product is specially formulated for use in dentistry and to be used by qualified dental personnel.

Manufactured by: Shiva Products

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These instructions for use should be kept for the duration of product use.

- Symbol for "BATCH CODE"
 Symbol for "USE BY"
 Symbol for "NON STERILE"
 Symbol for "KEEP DRY"
- Symbol for "CAUTION"
 Symbol for "CONSULT INSTRUCTION FOR USE"
 Symbol for "CATALOGUE NUMBER"
- Symbol for "EUROPEAN COMMUNITY AUTHORIZED REPRESENTATIVE"
 Symbol for "DO NOT USE IF PACKAGE IS DAMAGE"
- Symbol for "KEEP OUT OF THE REACH OF CHILDREN"
 Symbol for "MANUFACTURER NAME & ADDRESS"
- Symbol for "TEMPERATURE LIMITATION"
 Symbol for "KEEP AWAY FROM SUNLIGHT"

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.