

For better dentistry

DENTSPLY

Sedanol

Zinc-Oxide-Eugenol Cement

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Caution: For dental use only.

USA: Rx only

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1 Product description

Sedanol fast setting zinc-oxide-eugenol cement serves as temporary restoration and base under non-adhesive filling materials.

The product complies with the specification of ISO 3107 for type II materials.

Sedanol is a pure zinc-oxide-eugenol composition of white opaque color. The powder contains a small amount of eugenol which eases mixing.

1.1 Delivery forms

- A powder/liquid version for hand mixing.

1.2 Composition

Powder:

- Zinc oxide
- Eugenol
- Zinc acetate

Liquid:

- Eugenol

1.3 Indications

- Temporary restorations.
- Base under non-adhesive, restorative materials.

1.4 Contraindications

- Use with patients who have a known hypersensitivity or severe allergic reaction to eugenol or any of the other components.
- Direct application to dental pulp (direct pulp-capping).

2 Safety notes

Be aware of the following general safety notes and the special safety notes in other chapters of these Instructions for Use.



Safety alert symbol

- This is the safety alert symbol. It is used to alert you to potential personal injury hazards.
- Obey all safety messages that follow this symbol to avoid possible injury.

2.1 Warnings

Liquid contains eugenol. Components and mixed material may be irritating to skin, eyes and oral mucosa and may cause allergic contact dermatitis in susceptible persons.

- **Avoid eye contact** to prevent irritation and possible corneal damage. In case of contact with eyes rinse immediately with plenty of water and seek medical attention.
- **Avoid skin contact** to prevent irritation and possible allergic response. In case of contact, reddish rashes may be seen on the skin. If contact with skin occurs, remove material with cotton and alcohol and wash thoroughly with soap and water. In case of skin sensitization or rash, discontinue use and seek medical attention.
- **Avoid contact with oral soft tissues/mucosa** to prevent inflammation. If accidental contact occurs, remove material from the tissues. Flush mucosa with plenty of water and expectorate/evacuate the water. If inflammation of mucosa persists, seek medical attention.

2.2 Precautions

This product is intended to be used only as specifically outlined in these Instructions for Use.

Any use of this product inconsistent with these Instructions for Use is at the discretion and sole responsibility of the dental practitioner.

- Use protective measures for the dental team and patients such as glasses and rubber dam in accordance with local best practice.
- Contact with saliva, blood and sulcus fluid during application may cause failure of the restoration. Use adequate isolation such as rubber dam.
- Tightly close bottles immediately after use.
- Increased temperature and/or humidity reduce available working time and accelerate setting time. Material will set faster in the mouth than at the bench. Do not use bench cure rates to judge mouth cure rates.
- Use in a well-ventilated area. Avoid inhaling dust particles from powder.
- Interactions:
 - Do not use this product in conjunction with (meth)acrylate-based dental materials since it may interfere with the hardening of the (meth)acrylate-based dental materials.

2.3 Adverse reactions

- Eye contact: Irritation and possible corneal damage.
- Skin contact: Irritation or possible allergic response. Reddish rashes may be seen on the skin.
- Contact with mucous membranes: Inflammation. (See Warnings)

2.4 Storage conditions

Inadequate storage conditions may shorten the shelf life and may lead to malfunction of the product.

- Store with original (not dropper cap) caps tightly closed in a well-ventilated place at temperatures between 6 °C and 28 °C (43 °F and 82 °F).
- Allow material to reach room temperature prior to use.
- Do not store with or near materials containing (meth)acrylate resin components.
- Protect from moisture.
- Do not freeze.
- Do not use after expiration date.

3 Step-by-step instructions

3.1 Cavity preparation

1. Isolate the field of operation in preferred manner. Rubber dam is recommended.
2. Cavity preparation must provide for the mechanical retention of the product.
3. If caries is present, completely excavate using low-speed and/or hand instrumentation.
4. Place matrix and wedge where indicated.
5. Gently dry preparation with cotton pellet. Avoid desiccation.

3.2 Pulp protection

1. In deep cavities cover the dentin close to the pulp (less than 1 mm) with a hard-setting calcium hydroxide liner (Dycal[®] calcium hydroxide liner, see complete Instructions for Use).

3.3 Dosage and mixing

1. Place an appropriate amount of powder and liquid onto a clean glass slab¹.
2. Use a spatulation technique that quickly and thoroughly combines a small portion of the dispensed powder into all the dispensed liquid².
3. Bring small portions of powder into the mix in two or three increments and spatulate thoroughly. The mix should be completed in approximately 1 minute.
4. Technique Tips:
 - A proper mix will appear quite stiff and should be stropped (wiped vigorously) for 5 to 10 seconds.
 - A proper mix results in a putty-like consistency that is smooth and adaptable. If a dry, stiff or rubbery mix is obtained, additional liquid may be incorporated. If a sticky and soft mix is obtained, more powder may be added. Slight increments of powder should be incorporated until proper consistency is reached.
 - For room temperature and the recommended powder-liquid ratio, the mixing, working and setting time from start of mixing are given in the table below.

| | |
|----------------------|-----------|
| Mixing time | 1 minute |
| Minimal working time | 3 minutes |
| Latest setting time | 5 minutes |

¹ The Sedanol liquid container does not have a dropper, place liquid prior to first use into a smaller glass container furnished with a dropper or use a suitable clean pad for dosage of the material.

² For tests according to ISO 3107 the recommended powder : liquid ratio is: 1.12 g : 0.2 ml

3.4 Placement

1. Mixed material may be carried to the preparation with suitable placement instrument. Adapt, contour and shape with appropriate instruments. Technique Tip: Dipping the instrument into dry powder left on the pad before using to adapt material will facilitate placement and minimize sticking.

3.4.1 Use for temporary restoration

1. Trim excess material. Material may be smoothed by lightly burnishing. Initial set occurs approximately 3 minutes from start of mixing. Increased temperature, humidity, and powder/liquid ratio may accelerate set.
2. Upon set, remove matrix band if present. Check and adjust occlusion as needed. Additional carving or occlusal adjustment may be accomplished with a round bur. Avoid gouging material with sharp burs at high speed. Additional polishing is not recommended.
3. Periodically evaluate the intermediate restoration until final restoration is indicated.

3.4.2 Use as protective base

The product is a protective base for non-resin-containing restorative material, such as amalgam or gold.

NOTICE



Possible interactions with other dental materials

Restoration failure.

1. Do not use the product in conjunction with resin-based adhesives, varnishes or restoratives since eugenol may interfere with hardening and cause softening of (meth)acrylate-based dental materials.

1. Apply mixed material to desired dentin surfaces and depth.
2. Following completion of set (approximately 5 minutes from start of mixing) cavity refinement may be completed.
3. Complete restoration per restorative material manufacturer's Instructions for Use.

4 Lot number () and expiration date ()

1. Do not use after expiration date. ISO standard is used: "YYYY/MM"
2. The following numbers should be quoted in all correspondence:
 - Reorder Number
 - Lot number
 - Expiration date

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[These Instructions for Use are based on Master Version 01]



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