

Intermediate Restorative Material

DIRECTIONS FOR USE – ENGLISH

For dental use only.
USA: Rx only.

1. PRODUCT DESCRIPTION

IRM® Intermediate Restorative Material is a polymer-reinforced zinc oxide-eugenol composition restorative material designed for intermediate restorations intended to remain in place for no longer than one year. IRM® Intermediate Restorative Material may also be used as a base under restorative materials and cements that do not contain resin components.

1.1 Delivery forms

- A powder/liquid version for hand mixing
- Alternatively available as:
 - IRM® Caps™ Intermediate Restorative Material for machine mixing

1.2 Composition

Powder: Zinc oxide; Poly-Methyl Methacrylate (PMMA) powder; Zinc Acetate; Pigment
Liquid: Eugenol; Acetic acid

1.3 Indications

- Intermediate (temporary, less than 1 year) direct restorative filling material
- Base material under non-resin-containing permanent restorations

1.4 Contraindications

- Use with patients who have a known hypersensitivity or severe allergic reaction to eugenol, or any of the components.
- Direct application to dental pulp tissue (direct pulp capping).
- Base under resin-containing adhesives, restoratives or cements.

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

1. Liquid contains eugenol. Powder contains polymethacrylate. Components and mixed material may be irritating to skin, eyes and oral mucosa and may cause allergic contact dermatitis in susceptible individuals.
 - **Avoid Eye Contact** to prevent irritation and possible corneal damage. In case of eye contact, 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, immediately 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, immediately remove material from the tissues. Flush mucosa with plenty of water after the restoration is completed and expectorate/evacuate the water. If inflammation of mucosa persists, seek medical attention.
2. Improved or reinforced Zinc oxide – eugenol products such as IRM® Material are not suitable for use as root canal filling materials as inconsistent, incomplete or delayed resorption may occur.

2.2 Precautions

- This product is intended to be used as specifically outlined in the Directions for Use. Any use of this product inconsistent with the Directions for Use is at the discretion and sole responsibility of the practitioner.
- Insufficient data exist to support the use of IRM® Material in a root canal as a cement, dressing, medicament or repair material.
- 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 containers immediately after use.
- Increased temperature and/or humidity reduce available work time and accelerate set time. Material will set faster in the mouth than at the bench. Do not use bench cure rates to judge mouth cure rates.
- IRM® Material should be mixed in equal proportions (1 level scoop powder to 1 drop liquid, 6:1 by weight) for optimum performance. The mixed material should be homogeneous and streak free prior to application. Variations may affect the strength and durability of the material.
- Use in a well-ventilated area. Avoid inhaling dust particles from powder

- IRM® Material liquid bottle contains excess liquid for the amount of powder in one powder bottle. Providing excess allows for some natural liquid evaporation over repeated openings. Liquid bottle (containing remaining liquid) should be discarded and properly disposed after all powder is used. Remaining liquid may become brown in color and should not be further used.
- Prevent bottle from contamination by aerosols and/or contaminated gloves or hands.
- **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

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

- Store with **original cap** (not dropper cap) tightly closed in a well ventilated place at temperatures between 10-24°C/50-75°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

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

3.3 Dispensing IRM® Material

1. Before dispensing, fluff powder (tumble the powder bottle) to assure uniform bulk density of contents. Fill measuring scoop to excess without packing; then
2. Level scoop with spatula. Dispense 1 level scoop of powder onto a clean, non-absorbent mixing pad or glass slab. Larger restorations may require additional scoop(s).
3. Using the dropper cap, dispense one drop of liquid for each level scoop of powder. After dispensing liquid, replace original cap immediately to prevent evaporation and subsequent contamination.

NOTE: Premature setting of material. Keep powder and liquid separated until ready for spatulation.

3.4 Mixing IRM® Material

1. Use a spatulation technique that quickly and thoroughly combines 50% of the dispensed powder into all the dispensed liquid.
2. Bring the remaining powder into the mix in 2 or 3 increments and spatulate thoroughly. The mix should be completed in approximately one (1) minute.

3. 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 working 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.

3.5 Placement of mixed IRM® Material

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.

1. Use as Intermediate Restorative Material
 - Trim excess material. Material may be smoothed by lightly burnishing. Initial set occurs approximately 5 minutes from start of mix. Increased temperature, humidity, and powder/liquid ratio may accelerate set.

- 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.
- Periodically evaluate the intermediate restoration until final restoration is indicated. The intermediate restoration should be removed and final restoration completed within 1 year of placement.

2. Use as Protective Base

This product is a protective base for restorative material not containing polymeric resin components (e.g. final restoration of amalgam, gold). **NOTE:** Possible interactions. The product should not be used in conjunction with resin-based adhesives, varnishes or restoratives since eugenol may interfere with hardening and cause softening of (meth)acrylate based dental materials.

- Apply mixed material to desired dentin surfaces and depth.
- Following completion of set (approximately 5 minutes from start of mix) cavity refinement may be completed.
- Complete restoration per restorative material manufacturer's directions for use.

4. HYGIENE



Cross-contamination

- Use protective barrier or touch bottle only with non-contaminated gloves or hands.
- If not protected keep bottle out of spray of bodily fluids.

4.1 Cleaning and disinfecting the powder measuring scoop

- Clean scoop by scrubbing with hot water and soap or detergent.
- Disinfect scoop, if exposed spatter or spray of body fluids, contaminated hands, or oral tissues with a hospital-level disinfectant solution according to national/local regulations. Use of chlorine- (bleach), glutaraldehyde-, phenolic-, iodophor- or organic solvent (e.g. alcohol) based or containing products may over time affect the scoop.
- Follow the disinfectant manufacturer's directions for optimum results.
- After disinfection, thoroughly rinse and dry the scoop before storage.
- Do not autoclave the scoop.

5. 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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