

Intermediate Restorative Material

DIRECTIONS FOR USE – ENGLISH

Caution: U.S. federal law restricts this device to sale by or on the order of a dentist.

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. It may also be used as a base under restorative materials and cements that do not contain resin components.

COMPOSITION

IRM® Material powder:

Zinc oxide
Poly-Methyl Methacrylate (PMMA) powder
Pigment.

IRM® Material liquid:

Eugenol
Acetic acid

INDICATIONS FOR USE

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

CONTRAINDICATIONS

1. IRM® Material is contraindicated for use with patients who have a known hypersensitivity or severe allergic reaction to eugenol, acrylate resins or any of the components.
2. IRM® Material is contraindicated for direct application to dental pulp tissue (direct pulp capping).
3. IRM® Material is contraindicated as a base under resin-containing adhesives, restoratives or cements because eugenol may interfere with the hardening and/or cause softening of the polymeric (resin) components.

WARNINGS

1. Liquid contains eugenol. Powder contains methacrylate resin (in dust form). Components and mixed material is irritating to skin and eyes. Avoid prolonged or repeated exposure of the IRM® Material with skin, oral soft tissues, and eyes. Skin rash, oral mucosa irritation, or other allergic reactions (allergic contact dermatitis) may result in susceptible individuals. Avoid prolonged inhalation. Do not take internally.
Eye Contact: Before using this product, wear protective glasses as well as covering the patient's eyes. In case of eye contact, flush with flowing water for 15 minutes and seek medical attention.
Skin Contact: Avoid prolonged or repeated exposure to skin. If contact with skin occurs immediately wipe off thoroughly with cotton and alcohol and then wash thoroughly with soap and water. If skin rash or sensitization or other allergic reaction occurs, discontinue use and seek medical attention.
Oral mucosa contact: Avoid contact with oral soft tissues. If accidental contact occurs, rinse well with water and then expectorate. Contact of the material may cause soft tissue irritation. This is most often a temporary phenomenon and should disappear within one day. If the condition persists, seek medical attention.
2. When designing the cavity preparation for subsequent resin-based restorations, remove all IRM® Material prior to placing the resin-based restoration; eugenol containing materials may adversely affect the polymerization and physical properties of the resin restorative material and/or adhesive agents.

PRECAUTIONS

1. 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.
2. Wear suitable protective mask, clothing, eyewear, and gloves. (See *Warnings*)
3. Use of a rubber dam or adequate isolation is recommended.
4. Always tightly close containers immediately after use.
5. 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.
6. 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.
7. Use in a well-ventilated area. Avoid inhaling dust particles from powder
8. IRM® Material liquid bottle contains excess liquid for the amount of powder in 1 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.

STORAGE

Store with original (not dropper cap) caps tightly closed in a well ventilated place at or below room temperature not exceeding 25°C/77°F. Allow material to reach room temperature prior to use. Do not store with or near materials containing polymeric resin components. Protect from moisture. Do not freeze. Do not use after expiration date.

ADVERSE REACTIONS

Product may irritate the eyes and skin. **Eye contact:** Irritation. **Skin contact:** Irritation or possible allergic response. Reddish rashes may be seen on the skin. **Mucous Membranes:** Inflammation, edema, sloughing. (See *Warnings*)

INTERACTIONS

IRM® Material should not be used in conjunction with resin-based adhesives, varnishes or restorations because eugenol may interfere with the hardening and/or cause softening of the polymeric components. (See *Contraindications, Warnings*)

STEP-BY-STEP INSTRUCTIONS FOR USE

1. Intermediate (Temporary) Restoration

1.1 Cavity Preparation

- 1.1.1 Isolate the field of operation in preferred manner. Rubber dam is recommended.
- 1.1.2 Cavity preparation must provide for the mechanical retention of the IRM® Material.
- 1.1.3 If caries is present, completely excavate using low-speed and/or hand instrumentation.
- 1.1.4 Place matrix and wedge where indicated.
- 1.1.5 Gently dry preparation with cotton pellet. Avoid desiccation.

1.2 Pulp Protection: For direct and indirect pulp capping, cover the dentin close to the pulp (less than 1mm) with a hard setting calcium hydroxide liner (Dycal® Liner, see complete *Directions for Use*).

1.3. Dispensing IRM® Intermediate Restorative Material

- 1.3.1 Before dispensing, fluff powder (tumble the powder bottle) to assure uniform bulk density of contents. Using the CAULK POWDER SCOOP #1 (large), fill measuring scoop to excess without packing – then 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).
- 1.3.2 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:** Keep powder and liquid separated until ready for spatulation.

1.4. Mixing IRM® Intermediate Restorative Material

- 1.4.1 Use a spatulation technique that quickly and thoroughly combines 50% of the dispensed powder into all the dispensed liquid.
- 1.4.2 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.

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.

1.5 Placement of mixed IRM® Intermediate Restorative material

- 1.5.1 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.
- 1.5.2 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.
- 1.5.3 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.
- 1.6 Periodically evaluate IRM® Material intermediate restoration until final restoration is indicated. The IRM® Material intermediate restoration should be removed and final restoration completed within 1 year of placement.

2. Protective Base

When used as a protective base, final restorative material used must not contain polymeric resin components (e.g. final restoration of amalgam, gold)

- 2.1 Complete cavity preparation and pulp protection as outlined in steps 1.1 and 1.2.
- 2.2 Dispense and mix IRM® Material components as outlined above in section 1.3 and 1.4.
- 2.3 Apply mixed material to desired dentin surfaces and depth as outlined above in section 1.5.1.

- 2.4 Following completion of set (approximately 5 minutes from start of mix) cavity refinement may be completed.
- 2.5 Complete restoration per restorative material manufacturer's directions for use.

CLEANING AND DISINFECTION INSTRUCTIONS

Use of protective barriers is recommended to avoid package contamination. Repeated disinfection may cause damage to the labels.

CLEANING AND DISINFECTION OF POWDER MEASURE SCOOP

The powder (scoop) measure may be cleaned by scrubbing with hot water and soap or detergent. The scoop, if exposed spatter or spray of body fluids or that may have been touched by contaminated hands, or oral tissues, should be disinfected with a hospital-level disinfectant. Acceptable disinfectants are EPA-registered as tuberculocidal. Disinfect the scoop by spraying with any recommended hospital-level dual or synergized quaternary ammoniums or immersing in hospital-level disinfectant such as dual or synergized quaternaries or glutaraldehyde for the contact time recommended by the disinfectant manufacturer for optimum results. Spraying with glutaraldehyde is not recommended. Chlorine based (bleach), some phenolic-based agents and iodophor-based products should not be used as they may cause surface staining and/or color alteration. Agents containing organic solvents, such as alcohol, should be avoided, as they may tend to dissolve the plastic. Water-based disinfectant solutions are preferred. The disinfectant manufacturer's directions should be followed properly for optimum results.

Following disinfection, thoroughly rinse and dry the scoop before storage. Autoclaving the scoop is not recommended.

LOT NUMBER AND EXPIRATION DATE

1. Do not use after expiration date. ISO standard uses: "YYYY/MM."
2. The following numbers should be quoted in all correspondences:

- Reorder number
- Lot number on package
- Expiration date

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