

RODIN™ InteCem

Intermediate Restorative Material

Powder/Liquid For Hand Mixing Instructions For Use

1. Product Description

Rodin™ InteCem 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.

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

1.1 Indications

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

1.2 Contraindications

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

1.3 Delivery forms

- A powder / liquid version for hand mixing.

1.4 Composition

- | | |
|--------------------------|-----------|
| Powder: | Liquid: |
| • Zinc oxide | • Eugenol |
| • Polymethylmethacrylate | |
| • Zinc acetate | |

2. Safety Notes

See the Safety Data Sheet (available at www.pac-dent.com) for disposal & safety information.

2.1 Warnings

Liquid contains eugenol. Powder contains polymethylmethacrylate. 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 reduces 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. The product should be mixed in proportions of two levels scoops powder to three drops liquid 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.
- The 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 used.
- **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 cool, dry place.
- 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 hardsetting calcium hydroxide liner.

3.3 Dispensing and mixing

1. Before dispensing, fluff powder (tumble the powder bottle) to assure uniform bulk density of contents. Fill measuring scoop to excess without packing.
2. Dispense two level scoops 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 three drops of liquid for two level scoops of powder. After dispensing liquid, replace original cap immediately to prevent evaporation and subsequent contamination.

NOTICE

Premature setting of material.

Reduced working time: Keep powder and liquid separated until ready for spatulation.

4. Use a spatulation technique that quickly and thoroughly combines 50% of the dispensed powder into all the dispensed liquid.
5. Bring the remaining powder into the mix in two or three increments and spatulate thoroughly. The mix should be completed in approximately 1 minute.
6. Technique Tips:
 - Mixing should be completed in 45-60 seconds to a putty consistency.
 - 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.

3.4 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 as intermediate restorative material

1. Insert into the cavity and allow 4-6 minutes for proper hardening. 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. The intermediate restoration should be removed and final restoration completed within one year of placement.

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: 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 4-6 minutes from start of mixing) cavity refinement may be completed.
3. Complete restoration per restorative material manufacturer's Instructions for Use.

4. Hygiene

4.1 Disposal

Dispose of in accordance with local regulations.

5. Lot number (), expiration date () and correspondence

1. Do not use after expiration date. ISO standard is used: "YYYY-MM" or "YYYY-MM-DD".
2. The following numbers should be quoted in all correspondence:
 - Lot number
 - Expiration date
3. See SDS online www.pac-dent.com for further safety instructions.



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