IRM® Caps™

DENTSPLY CAULK

CE 0120

Directions for use – ENGLISH

CLASSIFICATION
Intermediate Restorative Material
Type III, Class I
Caution: U.S. Federal law restricts this device to sale by or on the order of a dentist.

COMPOSITION
IRM® Caps™ intermediate restorative material powder is composed of zinc oxide and PMMA powder (polymer reinforced). The liquid is eugenol with acetic acid added.

INDICATIONS
IRM® is a reinforced zinc oxide-eugenol composition for intermediate restorations lasting up to one year. It can also be used as a base under non-resin restorations.

CONTRAINDICATIONS
IRM® is contraindicated for use with patients who have a known hypersensitivity to eugenol or acrylate resins.

IRM® IS CONTRAINDICATED AS A BASE UNDER RESIN RESTORATIVES BECAUSE EUGENOL MAY INTERFERE WITH THE HARDENING AND/OR CAUSE SOFTENING OF THE POLYMERIC COMPONENTS.

WARNINGS
1. IRM® liquid is irritating to skin and eyes. Repeated contact may cause allergic dermatitis.
   Eye & Skin Contact: Flush eyes with copious amounts of water for at least 15 minutes and consult a physician if irritation persists. Wear suitable protective eyewear, clothing and gloves. Flush skin with flowing water then wash skin with soap and water after contact and consult a physician if irritation persists.
2. When designing the cavity preparation for resin-based restorations, remove all IRM® prior to placing the resin-based restoration; eugenol containing materials can adversely effect the polymerization and physical properties of the resin restorative material and/or bonding agents.

PRECAUTIONS
1. This product is intended to be used only 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. Increased temperature and/or humidity reduce available worktime.
3. Slow speed amalgamators or slow speeds on amalgamators are not recommended.
4. Storage and Shelf Life: Store in ambient temperature out of direct sunlight and heat. Do not store above 77°F (25°C). Do not use after expiration date. This product has a three-year shelf life from the date of manufacture.

ADVERSE REACTIONS
1. Allergic contact dermatitis and other allergic reactions may occur in susceptible individuals. (See Warnings and Precautions statements)
2. When designing the cavity preparation remove all IRM® prior to use of a resin based restoration. (See Contraindications and Warnings.)

STEP BY STEP INSTRUCTIONS FOR USE
Cavity Preparation
1. Cavity preparation must provide for the mechanical retention of the material.
2. Isolate field of operation in usual manner.
3. Dry cavities with cotton; avoid prolonged air-drying.
4. In all deep preparations (close proximity to the pulp), use a thin layer of Dycal® calcium hydroxide composition.

Mixing
1. To activate the IRM® Caps™, hold vertically, grasp bottom half and FIRMLY TIGHTEN the top (see Fig. 1). As top is tightened, you will feel a "snap" as the liquid is released. Continue tightening until you are sure it cannot be seated further.


Figure 1

2. This complete tightening forces the liquid into the mixing chamber, thereby assuring proper handling and physical characteristics. Without delay, insert capsule (bottom first) into the amalgamator arms (see Fig. 2). Figure 4 gives approximate mixing times for various amalgamators. These are suggested ranges; however, your clinical experience in obtaining a good mix consistency with your unit remains the best guide to mixing time. Use the first five caps to establish the best mix time (See Guidelines for Optimal Mix).

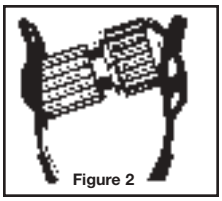
Figure 2

3. Remove press cap (see Fig. 3) to gain access to the mixed IRM®.

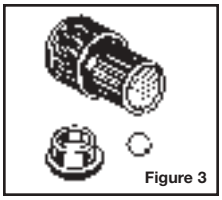
Figure 3

Approximate Mixing Time (in seconds)

AMALGAMATORS	SETTING	SECONDS
ProMix™	High Speed (Rabbit)	12
Vari-Mix® - III	High Speed	12
Silamat** Model C		8
Wig-L-Bug®**	High Speed	10
Wig-L-Bug®** Model 80	High Speed	10
Pelton-Crane**		30
Capmaster**	Not Recommended	

***Not products of DENTSPLY Caulk*

Figure 4

Guidelines for Optimal Mix

1. Clinical experience with your amalgamator is the best guide to mixing the IRM® Caps™. Variation in amalgamators (even from the same manufacturer) will occur and the trituration speed of amalgamators will vary with the line voltage on which they are operated. High-speed amalgamators such as Caulk's ProMix™ are recommended for best results.
2. If a dry, stiff, or rubbery mix is obtained, reduce trituration time, keep speed the same.
3. If a sticky and soft mix is obtained, increase trituration time, keep speed the same. Sticky mixes should be allowed to set a bit before application, or rolled in IRM® powder to eliminate stickiness.
4. If trituration results in a non-coalesced mass (i.e. small balls), increase trituration time, keep speed the same.
5. If the mixed mass of IRM® does not appear in the press cap (see Fig. 3) then either replace the press cap and mull for 5 seconds or insert a small ended plugger into the cap and remove the mixed mass.

IRM® Placement

1. After proper mixing, place IRM® intermediate restorative directly into cavity preparation.
2. Use conventional method to matrix application, when indicated.
3. Have patient occlude, then trim excess material.
4. Initial set is about (5) minutes from start of mix.
5. When carving or adjustment is necessary, use a small round bur.

DISINFECTION

IRM® Caps™ are a one-time use product.

LOT NUMBER AND EXPIRATION DATE

1. Do not use after expiration date.
2. The following numbers should be quoted in all correspondences.
   - Reorder number
   - Lot number on the cartridge
   - Expiration date

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