

COE-RECT™

HARD DENTURE RELINE AND REPAIR MATERIAL

For use only by a dentist or physician in the recommended indications.

RECOMMENDED INDICATIONS

Self-curing, rigid denture liner for permanent hard relines. For use in chairside procedures.

CONTRAINDICATIONS

Patients who have shown sensitivity to the material. In case of allergy, please refer to physician.

DIRECTIONS FOR USE

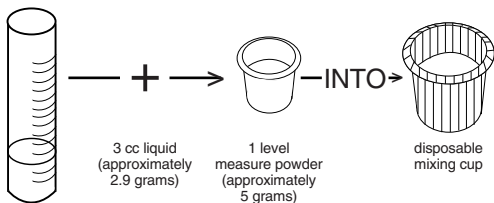
Product Handling:

Use caution when opening. COE-RECT Liquid is a highly flammable liquid and vapor; keep away from heat, hot surfaces, sparks, flames and other ignition sources. Use with adequate ventilation. Do not ingest or breathe vapor. Personal Protective Equipment (PPE) such as gloves, face masks and safety eyewear should always be worn. Check bottle with liquid before using. Make sure that upon removal of cap, the bottle opening has no obstructions. Some bottles may contain an insert (as a seal). The insert must be in the cap and not obstructing opening.

In case of contact, flush eyes with water for at least 15 minutes. Get prompt medical attention. If overcome by vapor, move to fresh air. If breathing is difficult, administer oxygen and seek medical attention. If swallowed, dilute by giving water to drink and seek medical attention. In case of contact with skin wash thoroughly with soap and water. Store securely. Store in a well-ventilated place. Keep cool. Dispose of all waste according to local regulations. For more information, read Safety Data Sheet (SDS).

SUGGESTED RELINE PROCEDURE

1. With a large bur, roughen area of denture to be rebased. Remove sufficient material to provide for the depth of the lining of COE-RECT. Use a coarse sandpaper disc to roughen the peripheral border. Remove all undercuts. Clean and dry the denture thoroughly.
2. Coat labial and buccal surfaces of the denture with COE LUBRICANT. Do not apply the lubricant within 1/8 inch of the peripheral border. If the denture has plastic teeth, protect them with a covering of COE LUBRICANT. COE-RECT will not adhere to surfaces protected by COE LUBRICANT.
3. Mix COE-RECT in proportions of: Pour the liquid into a disposable mixing cup and then add the powder slowly. Stir the mixture thoroughly for 30 seconds. To avoid the introduction of bubbles into the mix, do not spatulate more than 30 seconds. Mixing accessories are included in the professional package (not available separately).
4. Pour the COE-RECT mixture onto the tissue surface of the denture 1 minute after mixing. Evenly spread the mixture with the spatula. Allow the mixture to reach a honey-like consistency.
5. Have patient thoroughly rinse with cold water. Since an exothermic reaction is characteristic of self-curing acrylics, coat mucosal tissue with COE LUBRICANT just prior to placing denture in mouth, to insulate tissue and minimize sensation of heat.



6. Seat the denture as if you were taking an impression. Instruct the patient to close lightly into occlusion. This closing will distribute the COE-RECT evenly and force the excess material from the denture.
7. After 3 minutes instruct the patient to move the lips and cheeks so that a muscle-trimmed peripheral border is obtained. After muscle trimming, remove the denture and rinse under cold water. Trim away the excess material. Reseat the denture immediately.
8. Instruct the patient to hold the denture in occlusion until heat becomes uncomfortable. Remove denture from mouth carefully. Although the curing reaction is completed at 10 minutes, the material will continue to harden for approximately 8 more minutes.
9. After curing, trim away whatever excess has remained. COE-RECT may be finished and polished 15-20 minutes from the start of the procedure.

SUGGESTED REPAIR PROCEDURE

1. Acrylic repair liquid and COE-RECT Liquid are not interchangeable. Acrylic repair liquid is for repairs exclusively and cannot be used in the mouth.
2. Wet the exposed area with acrylic repair liquid. Sprinkle enough powder on the area to absorb the liquid. Add liquid and powder until the fracture is overfilled.
3. Allow the repair to completely harden before attempting to polish. Dry heat will hasten curing.

Note:

Irritation and sensitization have been reported in association with products that contain methacrylates. To reduce the risk of such occurrences, do not use this product with patients who have demonstrated sensitivity, avoid repeated and prolonged contact with uncured material, and discontinue use if sensitization occurs.

STORAGE

Recommended for optimal performance, store in a dry location at room temperature (70° to 77°F; 21° to 25°C).

Shelf-life: 3 years from date of manufacture.

DISINFECTANT RECOMMENDATION

MULTI-USE DELIVERY SYSTEMS: To avoid cross-contamination between patients this device requires mid-level disinfection. Immediately after use inspect device and label for deterioration. Discard device if damaged.

DO NOT IMMERSE. Thoroughly clean device to prevent drying and accumulation of contaminants. Disinfect with a mid-level registered healthcare-grade infection control product according to regional/national guidelines.

PACKAGES

COE-RECT Professional Package

Contains: One (6 oz) bottle of powder, one (6 oz) bottle of liquid, one (14 mL) repair liquid and accessories.

COE-RECT Liquid Refill (6 oz)

COE-RECT Powder Refill (6 oz)

COE-RECT Repair Liquid (14 mL)

Some products referenced in the present IFU may be classified as hazardous according to GHS. Always familiarize yourself with the Safety Data Sheets available for the Americas at:

<http://www.gcamerica.com/downloads>

They can also be obtained from your supplier.

Last Revised: 12/2015

Rx Only

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