

COE-SOFT™ PRINT

RESILIENT DENTURE LINER

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

RECOMMENDED INDICATIONS

A temporary lining for acrylic and 3D Printed dentures. For use in chairside procedures.

CONTRAINDICATIONS

Avoid use of this product in patients with known allergies to methacrylate monomer, methacrylate polymer, or salicylates.

DIRECTIONS FOR USE

Product Handling:

Use caution when opening. COE-SOFT PRINT 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 liquid or inhale 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.

I. Preparation of the denture:

Relieve and roughen the area of the denture to be relined. Clean and dry the denture thoroughly to remove all residue. It is important that the denture is completely dry to avoid moisture contamination of the bonding agent.

Apply COE-SOFT PRINT BONDING AGENT to the bonding surface with the provided cap brush and gently dry with clean, dry and oil-free air. Do not contaminate the surface with latex gloves, powder from gloves, etc.

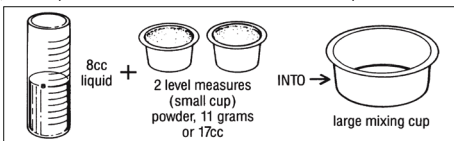
Note: Close the bottle with the cap immediately after use. Do not contaminate the bonding agent bottle with moisture, to avoid it becoming cloudy.

Coat labial and buccal surfaces of the denture with COE LUBRICANT. Do not apply coating within 3mm (1/8 inch) of the peripheral border. If the denture has plastic teeth also protect them with COE LUBRICANT.

Note: COE-SOFT PRINT will not adhere to surfaces coated with COE LUBRICANT.

II. Preparation of COE-SOFT PRINT:

Recommended powder / liquid ratio is 11g powder to 8cc liquid. Always use GCA measuring cups provided in the product package for exact measures. Pour the liquid into the large mixing cup. Then add the powder slowly. Stir mixture thoroughly for 30 seconds. A suitable spatula is provided for this purpose. To avoid introducing bubbles into the mixture, do not spatulate for more than 30 seconds. Do not whip.



III. Application:

Spread the mixture of COE-SOFT PRINT over the area to be relined. Seat the denture in the manner of taking an impression and instruct the patient to close lightly into occlusion. After 5 minutes instruct the patient to move lips and cheeks so that a muscle trimmed periphery is obtained. Remove the denture and rinse under cold water. Trim away excess material. Re-seat the denture and instruct the patient to close FIRMLY into occlusion and to hold this position for 5 minutes. Remove the denture and rinse again in cold water.

IV. Finishing:

Peak curing temperature: Approximately 37C/99F at 6-15 minutes when tested according to ADA/ANSI specification number 17. When curing is complete, trim away excess. For smoothing the edges use a hot spatula.

V. Patient Advice:

Advise the patient NOT to use a brush or abrasive (such as toothpaste) on the lining. Cleaning is best achieved by holding it under cold running water and wiping with wet cotton.

STORAGE

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

CLEANING AND DISINFECTING RECOMMENDATION

MULTI-USE DELIVERY SYSTEMS: To avoid cross-contamination between patients the bottles and measuring devices require mid-level disinfection. Immediately after use inspect the bottles, measuring devices and label for deterioration. Discard if damaged.

DO NOT IMMERGE. Thoroughly clean bottles and measuring devices 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-SOFT PRINT Professional Package

COE-SOFT PRINT Powder, 156 g

COE-SOFT PRINT Liquid, 5.5 oz (163 mL)

CAUTION

1. Improper powder/liquid ratio may cause undesired sensitivity.
2. Personal protective equipment (PPE) such as gloves, face masks and safety eyewear should always be worn.
3. If a patient notices damage to denture (e.g., chipping, delamination, distortion, etc.) or changes in tissue condition (e.g., inflammation, discomfort, allergic reaction, etc.) have patient discontinue use and return for evaluation and consultation.
4. Ensure good ventilation/exhaustion at the workplace. Keep ignition sources away.
5. In thicker applications, peak temperature may exceed that stated above. If excessive volume of material is accidentally applied, contact a physician.

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.gc.dental/america>

They can also be obtained from your supplier.

Rx Only



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