BeautiCem SA

Dental Adhesive Resin Cement

PRECAUTIONS FOR DENTAL PERSONNEL AND PATIENTS

- 1. Do not use this product on patients with known allergies to methacrylate monomer.
- 2. Operators with known allergies to methacrylate monomer must not use this product.
- 3. Mixer tips provided are for single use only.
- 4. This product is intended for use by dental professionals only.
- 5. If any inflammation or other allergic reactions occur on either patient or operator, immediately discontinue use and seek medical advice.
- 6. Use protective plastic gloves etc. to avoid sensitization to this product. Avoid contact with intraoral tissue, skin and eyes. In case of accidental contact with oral soft tissue or skin, immediately blot with alcohol moistened cotton ball, and rinse with plenty of water. In case of contact with eyes, immediately flush the eyes with plenty of water and seek medical advice.
- 7. Only dental professionals must be in charge of use and storage of this product.

INDICATIONS

- 1. Cementation of metal-based inlays, onlays, crowns and bridges
- 2. Cementation of resin inlays, onlays, crowns and bridges
- 3. Cementation of alumina or zirconia inlays, onlays crowns and bridges
- 4. Cementation of indirect metal-core or resin-core restorations

DIRECTIONS FOR USE

- 1. Pretreatment of cavity and abutment tooth
 - ①Cleaning of cavity and abutment tooth
 - Thoroughly remove the temporary sealing or cement. Rinse with water and dry following the conventional method.
 - ②Isolation

Isolate with rubber dam etc. following the conventional method.

③Try-in the restoration

Try in the restoration to ensure proper fit and to adjust occlusion.

- 2. Pretreatment of restoration
 - 1Sandblasting

Sandblast the restoration surface with alumina sand (diameter of 50-100 μm).

Pressure of sandblast

Material to be cemented	Pressure	
	MPa	kgf/cm ²
Alumina, Zirconia	Approx. 0.2 - 0.3	2 - 3
Porcelain, Indirect composite resin	Approx. 0.1 - 0.2	1 - 2
Metal	Approx. 0.3 - 0.5	3 - 5

(2)(In the case where the restoration is made of porcelain only)

Dispense adequate amount of primer for ceramics (SHOFU PORCELAIN PRIMER) on a dish. Apply to the restoration surface to be cemented using a Micro Tip brush etc and dry naturally for 10sec.

Hand Mixing

3. Dispensing

Uncap the W-syringe cartridge. Gently place the syringe tips onto a mixing pad. Depress the plunger to dispense Paste A and B, confirming that the pastes are flowing evenly at the same level. After dispensing, clean the nozzle tips with a gauze etc. and replace the cap securely.

4. Mixing and Application

Mix the dispensed pastes sufficiently using a plastic spatula for 10 sec. Apply the mixture to the restoration surface to be cemented following the conventional method.

Auto-mixing

- 3. Preparation of the syringe
 - ① Turn the cap a 1/4 turn counterclockwise to align the projections on the caps with the grooves of the syringe. Remove the cap by holding the foot end of the cap and pulling downward.
 - ② Extrude some paste to check if the Paste A and B are dispensed equally. Check this before each use.
 - ③ Attach the mixer tip, aligning the projections on the mixer tip with the grooves on the syringe, and turn 90° in a clockwise direction.
- 4. Application

Gently depress the plunger to dispense the pastes. Apply the mixed paste to the surface of the restoration to be cemented.

Working time at room temperature (23 $^\circ C/73$ $^\circ F)$ is within 2mins. High temperature and/or intense light shorten the working time.

5. Placement

Seat the restoration onto cavity or abutment tooth. Hold in place with light pressure.

- 6. Removal of excess cement
 - (1) When using a light-curing unit (Halogen, LED or Plasma Arc light-curing unit)

Light-cure excess cement for approximately 2sec and remove the half-cured material using a probe etc.

0 For the areas where light does not reach

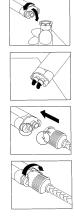
Leave 3-4mins after placing the restoration to allow the material to cure chemically. Then remove the half-cured material.

7. Final cure

Light-cure each surface and marginal area for prescribed time using a dental light-curing unit. However, for the area where the light does not reach, hold the restoration in place for 5mins after seating in order to allow it to cure chemically. Use the following light-curing time for each unit; Halogen light-curing unit (light source: Halogen, wavelength: 400-500nm, light intensity: 500mW/cm²) : 20sec., LED light-curing unit (light source: Blue LED (with a single emission peak), wavelength: 440-490nm, light intensity: 1000mW/cm²) : 10sec., and Plasma Arc light-curing unit (light source: Xenon lamp, wavelength: 400-500nm, light intensity: 1000mW/cm²): 9sec.

NOTE ON USE

- 1. In the case where prepared surface is close to the pulp, cap the pulp with pulp capping agent. (Do not use eugenol containing lining material.)
- 2. Avoid contamination of the restoration surface to be cemented. If the surface is contaminated by saliva or blood, thoroughly clean the surface with an alcohol moistened cotton ball.
- 3. Allow to reach room temperature before use.



- 4. Using polyester matrix between preparation and adjacent teeth prior to placement of the restoration aids in isolation and easy removal of excess cement.
- 5. Tightly close the cap after each use and store in a refrigerator (1-10°C/34~55 °F) when not in use. Make sure the cap is securely closed to avoid polymerization due to ambient light.
- 6. Remove any hardened paste plugging the opening of the nozzle before use.
- 7. Use saliva ejector during procedures to eliminate water or saliva in patient's mouth.
- 8. Follow the manufacturers' instructions for the dental materials or instruments to be used in conjunction with this product.
- 9. When using Opaque color, light-curing should not be employed to remove excess material. Leave 3-4mins to allow it to be half-cured, then remove.
- 10. Attach the mixer tip, aligning the projections on the mixer tip with the grooves on the syringe, and turn 90° in a clockwise direction.
- 11. Close the cap immediately after each use. Attach a new mixer tip before use.
- 12. Thoroughly remove the material remaining inside the cap before replacing it.
- 13. Avoid any source of ignition since this product is flammable.
- 14. Use protective glasses or light blocking plate in order to avoid looking directly at the curing light.
- 15. Do not use this product for any purposes other than specifically outlined in the INDICATIONS in these Directions for Use.
- 16. Use this product within the expiration date indicated on the package and container.
 (Example S YYYY XX→Shelf life: at the end of XX month, YYYY year)

STORAGE

1. Store in a refrigerator (1-10°C/ 34-50 °F). Avoid high temperature and high humidity. Keep away from direct sunlight and any source of ignition.

COMPOSITION

Paste A : UDMA, Fluoroboroaluminosilicate glass, Silicate glass, Reaction initiator and others Paste B : UDMA, 2-HEMA, Carboxylic acid monomer, Phosphonic acid monomer, zirconium silicate, Polymerization initiator and others

PACKAGING

Hand Mixing : 10mL: 1 (Clear, Ivory or Opaque) (Spatula: 1 and Mixing Pad: 1) Auto-mixing : 5mL:1 (Clear, Ivory or Opaque) (Mixer Tip : 10pcs)

CAUTION: U.S. Federal Laws restrict this device to sale by or on the order of a dentist.

01_2011xx



Manufactured by SHOFU INC. 11 Kamitakamatsu-cho, Fukuine, Higashiyama-ku, Kyoto 605-0983, Japan SHOFU INC. Singapore Branch 10 Science Park Road, #03-12, The Alpha, Science Park II, Singapore 117684 SHOFU DENTAL CORPORATION 1225 Stone Drive, San Marcos, California 92078-4059, USA SHOFU DENTAL CORPORATION 1225 Stone Drive, San Marcos, California 92078-4059, USA SHOFU DENTAL CORPORATION 1225 Stone Drive, San Marcos, California 92078-4059, USA SHOFU DENTAL CORPORATION 1225 Non 645 Jiye Road, Sheshan Industrial Park, Songjiang, Shanghai 201602, China [EC [REP] SHOFU DENTAL GmbH Am Brüll 17, 40878 Ratingen, Germany www.shofu.de