

Identification Number: 227AFBZX00042000

Dental Material 2, Dental Crown Material
 Controlled Medical Device – Ceramics materials (70802000)

ZEO CE LIGHT ZR

[Contraindications and Prohibitions]

Do not use this product on patients who have a history of allergy such as rash or irritation to crown restorations with this product or similar products.

[Shapes, Composition and Principles]

This product consists of the following items and contains the ingredients listed below:

| Item | State | Ingredients |
|------------|--------|--|
| Liner | Paste | Glass powder in the system SiO ₂ , pigment, polyethylene glycol, etc. |
| Dentine | Powder | Glass powder in the system SiO ₂ , pigment, etc. |
| Enamel | Powder | Glass powder in the system SiO ₂ , pigment, etc. |
| Accent | Powder | Glass powder in the system SiO ₂ , pigment, etc. |
| Supplement | Powder | Glass powder in the system SiO ₂ , pigment, etc. |
| Stain | Paste | Glass powder in the system SiO ₂ , pigment, propylene glycol, etc. |

[Intended use and effect / efficacy]

This product is used to produce restorations made from dental ceramics.

[Product Specification]

Physical Property (Test method: ISO6872:2015)

| Item | Requirement |
|------------------------------|---|
| Flexural strength | More than 50 MPa |
| Chemical solubility | Max. 100 micro-gram/ |
| Liner thermal expansion | Shall not deviated by more than 0.5 × 10 ⁻⁶ /K from the stated value Stated value: Firing 2 times, 4 times Liner: 10.0 Dentine, Enamel: 9.6 |
| Glass transition temperature | Shall not deviated by more than 20 degrees C. Degree from the stated value. Start Value: Firing 2 times, 4 times Liner: 610 degrees C Dentine, Enamel: 590 degrees C |

[Firing Schedule]

| | Dry Time (min.) | Start Temp. (°C) | Heat Rate (°C/min.) | Firing Temp. (°C) | Hold Time | Reducing Pressure (kPa) |
|------------|-----------------|------------------|---------------------|-------------------|-----------|-------------------------|
| Liner | 5-10 | 450-500 | 60 | 920-940 | 1 | 97 |
| Dentine | 6-9 | 550-600 | 60 | 900-920 | 1 | 97 |
| Self-Glaze | 4 | 550-600 | 60 | 880-900 | 1 | Air |
| Supplement | 6 | 550-600 | 60 | 800-850 | 1 | 97 |
| Stain | 4 | 550-600 | 45-60 | 850-870 | 1 | 97 |

(NOTE)

- In case where Stain is used on the surface of Zirconia, Heat Rate should be set 45°C/min. In case where Stain is used for Ceramics, it should be set 60°C/min.
- Conditions, such as the above schedule is a guideline, not precise data. Conditions of firing are different depending on kinds or shapes of furnaces. Confirm the temperature and time by test firing before clinical case.

[Operating Instructions]

1. Liner Application and Firing

- ① In case where using Liner, paste type, agitate Liner in the container, scoop requisite amount on the pallet and then mix it until it reaches a uniform consistency by a spatula.
- ② Apply Liner thinly and condense lightly then fire as above mentioned schedule.

2. Dentine, Enamel and Accent Application and Firing

Mix each Dentine, Enamel, Accent with distilled water, and build up to the crown form. Fire as above mentioned schedule after condensation and water absorption.

3. Correction to shape and Glaze Firing

- ① Correct the shape using a carborundum, diamond point or white point.
- ② After correction to shape, clean by an ultrasonic cleaner with diluted water or alcohol. Then fire for glaze.
- ③ If necessary, build up by applying Stain or Supplement and fire.

[Technical Directions and Points for Attention]

1. Do not use this product in combination with other products.
2. Do not grind or polish this product in the mouth.

[Precautions]

1. Precautions

- ① Stop using this product and seek medical attention if any sign of allergy, such as rash, eczema, redness, ulcer, swelling, itching, numbness and etc. appears in patients.
- ② Operators who have a history of allergy such as irritation or rash to this product or organic solvent must wear plastic gloves to avoid direct skin contact. Operators must discontinue using and seek medical attention if any sign of allergy, such as rash, eczema, redness, ulcer, swelling, itching, numbness and etc.
- ③ In case of eye contact, immediately flush with running water and consult a physician.

2. Important Basic Cautions

- ① When grinding and polishing this product, use exhaust fan and anti-dust mask approved by your local public safety agency in order to avoid inhaling dust. Wear safety goggles to protect the eyes.
- ② Provide adequate ventilation during operation.

[Handling and Storage]

Keep out of reach of personnel other than dental staff.

[Expiry Date]

1. This product must be used before the expiry date printed on the package.
2. The expiry date printed on the package is based on our authentication.
3. The expiry date printed on the package refers to use expiry date.

* (ex.: YYYY-MM means the last day of YYYY (year)/MM (month) as the expiry date)

[ZEO CE LIGHT ZR: Package]

| Item | Shade | State |
|------------|---|--------|
| Liner | L-A(1,2,3,3.5,4), L-B(1,2,3,4), L-C(1,2,3,4), L-D(2,3,4), L-G(1,2,3,4,5,Or), L-W(1,2,3,4) | Paste |
| Dentine | D-A(1,2,3,3.5,4), D-B(1,2,3,4), D-C(1,2,3,4), D-D(2,3,4), D-W(1,2,3,4) | Powder |
| Enamel | E-(1,2,3,4), OE(1,2,3,4,Amber) | Powder |
| Accent | Opal 1, Opal 2, Snow White, White, Vanilla, Milky, Yellow Ocher, Mamelon Vanilla, Mamelon Orange, Mamelon Yellow, Occlusal Brown, Occlusal Orange, Occlusal Enamel, T-Natural, T-Glass, T-Clear, T-Opacity, T-Buffer, T-Amber, T-Salmon, T-Gray, T-Violet, T-Blue, T-Baby Pink, T-Pink, G(1,2,3,4,5,6,7,Or) | Powder |
| Supplement | SUP-(D,E,T) | Powder |
| Stain | Glaze, White, Milky, Light Orange, Orange, Brown, Dark Brown, Gray, Violet, Blue, Pink, Yellow, Black, Indigo, Dark Pink, Amber, Khaki, Buff, Fluorescent, Opal Glaze | Paste |

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