

Revised November 25, 2020 (Revision 2)

Identification Number: 226AABZX00170000

Controlled Medical Device - Resin Material for Dental Milling and Machining

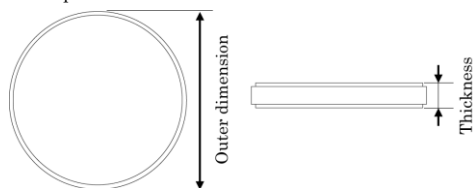
KZR-CAD HR Disc 2

[Indications]

Inlay, artificial teeth and crowns

[Contraindications and Prohibitions]**DO NOT ATTEMPT TO USE FOR PURPOSES OTHER THAN INTENDED USE.****DO NOT USE THIS PRODUCT ON PATIENTS WHO HAVE A HISTORY OF ALLERGY SUCH AS IRRITATION TO THIS PRODUCT OR TO METHACRYLIC ACID SERIES OR METHACRYLATE MONOMER.****[Shape, Composition and Principles]**

1. Shape

Outer dimension ϕ : Approx. 98 mm

Thickness: Approx. 14 mm

2. Shades (3Colors): A2, A3, A3.5

3. Composition

| State | Ingredients |
|----------------|---|
| Cured Material | Methacrylate monomer, inorganic fillers, pigments, etc. |

4. Principle

This product is a resin-based disc to be cut or milled with a dental computer-aided design and manufacturing unit for fabricating dental restorations such as inlays, artificial teeth or crowns.

[Intended use and effect/efficacy]

This product is a material to be cut or milled with a dental computer-aided design and manufacturing unit for fabricating polymeric restorations for dental use.

[Instructions]

1. Measure an abutment tooth model using a scanning machine.
2. Create milling data based on the measurement data with software.
3. Set this product in a milling machine and process it using the milling data. After completion of processing, eliminate surplus residue. Remove sawdust and other dust from the restoration.
4. Correct the shape and polish in accordance with normal practice. As a final polishing, polish it with a polishing paste which contains diamond such as C&B DIAMOND POLISHER or C&B NANO DIAMOND POLISHER, and etc. to glaze.
5. When additional layering or characterizing after milling is needed, follow the instructions for the dental resin for crowns and bridges such as TWiNY and etc. Before additional layering, surface treatment agents containing silane coupling agents such as Multi Primer Repair Liquid One etc. should be applied on the surface.

[N.B.: Technical Directions and Points for Attention]

1. When the caries is near the pulp and pulp capping is needed, pulp protection with a lining material containing calcium hydroxide preparation is required.
2. When using CAM software or a milling machine, follow the instruction manual provided for each device.
3. Check if it fits well before securing. Round off the external form and smoothen the surface.
4. Use suitable resin cement considering adhesiveness, color tone, and transparency with an abutment material.
5. When using resin cement, follow the instruction manual provided.
Before bond this product, surface treatment agents containing silane coupling agents should be applied
6. It is recommended to sandblast (at about 0.2 to 0.3 MPa) the adhering surface of dental restorations using alumina powder (50 μ m or smaller) and clean the adhering surface with alcohol, then dry with air which doesn't contain moisture or grease.
7. Form the margin area in deep chamfer or round shoulder with over 0.5 mm thickness.
8. Make the thickness of pit-and-fissure more than 1.0 mm and cusp more than 1.3 mm.

[Precautions]

1. Only adequately certified personnel should handle this product.
2. Do not use this product for any purposes other than those indicated under [Intended use and effect / efficacy].
3. Use this product only for computer-aided dental design and for manufacturing units which fit the size of this product.
4. In cases where risk of fracture due to malocclusion or bruxism is high, carefully judge to use this product, so as to avoid product fracture.
5. During milling and polishing of cured product, use a dust collector and an anti-dust mask to avoid inhaling dust.
6. Wear safety goggles to protect the eyes while milling and polishing this product.
7. Stop using this product immediately in cases of any signs of allergy such as irritation or rash appearing. If symptoms persist, seek medical advice.
8. Dentists should determine whether this product is suitable for use in each individual case.
9. Follow applicable local ordinances and regulations when discarding this product.
10. Do not use or store this product near naked flame.
11. Remove excess cement after fixing restoration.

[Other Cautions]

Advise daily oral cleaning for patients, since the fixed restoration may be stained or plaque-adherent depending on patients' dietary habits.

[Storage and Validity Period]**[Storage]**

- Store in a cool and dry place, avoiding high temperatures, humidity and direct sunlight.
- Keep out of reach of personnel other than dental staff.

[Package Contents]

1 disc per box (A2, A3, A3.5)

| | |
|---|---|
| YAMAKIN | CE 0123 |
|  YAMAKIN CO., LTD. <small>1090-3 Otani, Kamibun, Kagami-cho, Koran-shi, Kochi, 781-5451, Japan E-Mail : contact@yamakin-gold.co.jp</small> | EC REP MT Promed Consulting GmbH <small>Altentofstrasse 80, 86396 St. Ingbert, Germany Tel : +49 6894 551020 Fax : +49 6894 551021 E-Mail : info@mt-prococons.com</small> |