

Identification Number: 226AABZX00171000

Controlled Medical Device - Resin Material for Dental Milling and Machining

KZR-CAD HR BLOCK2

[Product description]

[Intended purpose]

This product is a fabrication material for cutting and processing using a computer-aided design and manufacturing unit in a dental laboratory to produce a dental polymer prosthesis.

[Indications]

Inlay, onlay and crowns

[Intended users]

Educated dental professionals who have theoretical and practical knowledge on usage of dental products.

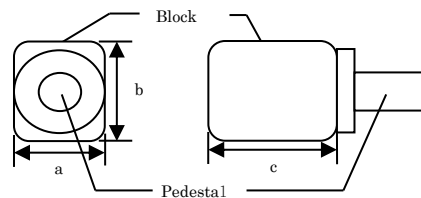
Patient target group: all patients requiring dental treatment, unless the patient's condition like a known allergy limits the use.

[Clinical Benefit]

Repair a patient's teeth as a crown prosthesis.

[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



(Dimensions: approx. mm)

Type	(a) width	(b) height	(c) depth
Small	10	12	15
Medium	12	14	18
Large	14.5	14.5	18

2. Shades: A1*, A2, A3, A3.5, A4*, A3-LT*, A2-GR*, A3-GR*, A3.5-GR*

*A1, A4, A3-LT, GR don't have medium size lineup.

3. Composition

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

4. Principle

This product is a resin-based block to be cut or milled with a dental computer-aided design and manufacturing unit for fabricating dental restorations such as inlays 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]

- Measure an abutment tooth model using a scanning machine.
- Create milling data based on measurement data, using software.
- Set up this product in a milling machine and process it using milling data. After completion of processing, eliminate surplus residue. Remove sawdust and other dust from the restoration.
- Correct the shape and polish in accordance with normal practice. As a final polishing, polish it with a polishing material*¹ to glaze.
- In cases where additional layering or characterizing after milling is needed, follow the instructions for the dental resin used for crowns and bridges*². Surface treatment with a surface preparation agent containing silane coupling agent*³ is required before additional layering.

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

- When using CAM software or milling machine, follow the instruction manual provided for each device and ensure the appropriate processing conditions for this product.
- Form the margin area in deep chamfer or round shoulder with over 0.8 mm thickness.
- Make the thickness of pit-and-fissure more than 1.0 mm and cusp more than 1.3 mm. Round off the shape for any angle areas.
- Sandblast (at about 0.2 to 0.3 MPa) the adhering surface of dental restorations using alumina powder (about 50 μ m). After trial fitting, clean the adhering surface with phosphoric acid etching solution, and wash and dry to remove any inhibitor of adhesion such as protein substances contained in saliva.
- For the adhering surface of the restorations, surface treatment using a surface preparation agent containing a silane coupling agent is required.
- After drying, use suitable resin cement considering adhesiveness, color tone, and transparency with abutment material.
- When using resin cement material, follow the instruction manual provided.
- Do not use glass ionomer-based resin cement to bond this product.

[Related Products]*¹ Diamond Polishers

- C&B Diamond Polisher
- C&B Nano Diamond Polisher

*² Composite Resin for Crowns and Bridges

- Luna-Wing
- TWiNY

*³ Surface preparation agent containing Silane Coupling Agent

- Multi Primer Repair Liquid One

[Precautions]

- Only adequately certified personnel should handle this product.
- Do not use this product for any purposes other than those indicated under [Intended use and effect / efficacy].
- Use this product only for computer-aided dental design and for manufacturing units which fit the size of this product.
- 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.
- During milling and polishing of cured product, use local exhaust fan and anti-dust mask as approved by your local authority to avoid inhaling dust.
- Wear safety goggles to protect the eyes while milling and polishing this product.
- The Small and Medium sizes of this product have a different width (a) and height (b). Since there are grooves in two directions in the block mounting device, setting is possible in whatever direction required for the particular type of clinical case. However, if the setting is made in the wrong direction, it may break or damage the milling bar or the milling machine. Be careful to do the setting in the correct direction.
- Dentists should determine whether this product is suitable for use in each individual case.
- Follow applicable local ordinances and regulations when discarding this product.
- Do not use or store this product near naked flame.
- Remove excess cement after fixing restoration.
- Do not use this product beyond the recommended cases, effects, and indications.
- Only qualified personnel may use this product.
- Dispose of this product as a medical waste to prevent infection.

[Important Basic Cautions]

- Stop using this product immediately if any signs of allergy, such as irritation or rash, appearing in patients. If symptoms persist, seek medical advice.
- Stop using this product immediately if any signs of allergy, such as irritation or rash, appearing in product users. If symptoms persist, seek medical advice.

[Other Cautions]

Advise patients to perform daily oral cleaning, as fixed restorations may become stained or accumulate plaque depending on their dietary habits.

[Handling and Storage]

- ① This product must be stored in a cool and dry place, avoiding high temperatures, humidity and direct sunlight.
- ② Keep out of reach of personnel other than dental staff.

[Note]

If a serious incident attributable to this product occurs, report it to the manufacturer shown below and the regulatory authorities of the country in which the user/patient resides.

[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 the authentication by YAMAKIN.
- ③ The expiry date printed on the package refers to use expiry date.
(e.g. YYYY-XX indicates YYYY 'Year' / MM 'month' (last day) as the expiry date)

[Package Contents]

5 pcs. per box (A1, A2, A3, A3.5, A4, A3-LT)

3 pcs. per box (A2-GR, A3-GR, A3.5-GR)

 YAMAKIN

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