

Identification Number: 229AABZX00114000

Controlled Medical Device - Resin Material for Dental Milling and Machining

KZR-CAD HR BLOCK3 GAMMATHETA

[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]

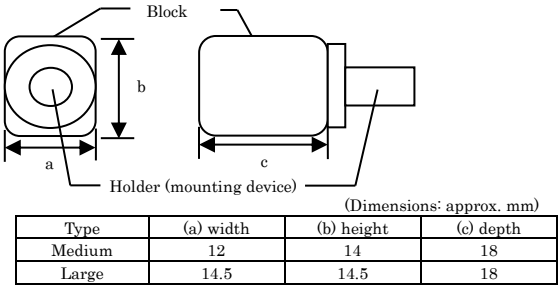
Repair a patient's teeth as a crown prosthesis.

[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



2. Shades: A1, A2, A3, A3.5

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 and the thickness should be 0.8 mm and over for premolars and 1.0 mm and over for molars.
- Form pit-and-fissure with thickness of 1.0 mm and over for premolars and 1.5 mm and over for molars. Form cusp with thickness of 1.3 mm and over for premolars and 1.5 mm and over for molars. Form axial surface with thickness of 1.3 mm and over for premolars and 1.5 mm and over for molars. Also, the corners should be rounded.
- Since the block is recessed 0.5 mm from the bonding surface with the holder (a mounting device), if the support pin is arranged in this recessed position, the workpiece may be detached during cutting. Pay attention to the arrangement of the support pins.
- Sandblast (at about 0.2 to 0.3 MPa) the adhering surface of dental restorations using alumina powder (about 50 μm). 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. However, when sandblasting is performed after trial fitting, cleaning with phosphoric acid etching material and etc. is unnecessary.
- 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 Prodcuts]

- *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, decide carefully whether or not 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.
- 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]

- ①This product must be stored in a cool and dry place, avoiding high temperatures, humidity and direct sunlight.
- ②Keep 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]

- ①This product must be used before the expiry date printed on the package.
- ②The expiry date printed on the package is based on the authentication by YAMAKIN.
- ③The 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]

5 pcs. per box (A1, A2, A3, A3.5)

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|  | | CE 0123 | |
|  YAMAKIN CO., LTD. 1090-3 Otani, Kamibun, Kagami-cho, Konan-shi, Kochi, 781-5451, Japan E-Mail : contact@yamakin-gold.co.jp | | <div>EC REP</div> MT Promedt Consulting GmbH Ernst-Heckel-Straße 7, 66386 St. Ingbert, Germany Tel : +49 6894 581020 Fax : +49 6894 581021 E-Mail : info@mt-procons.com | |