

## Instructions for use

(EN)

# PMMA DISK, PMMA BLOCK Acrylic resin for dental CAD/CAM technology

**【Intended Use】** PMMA DISK and PMMA BLOCK are acrylic resin materials for CAD/CAM milling machines.

**【Indication for use】** The indications are Surgical guides, Stent, Splint, Denture base, Crown, Bridge.

**【Intended Population】** People with some disease in their natural teeth, such as decayed or missing teeth

**【Intended User】** Dentists or dental technicians who make dental prosthesis.

**【Contra-indications】** Don't use in patients allergic to MMA.

**【Clinical benefits to be expected】** Expect to finally be able to chew food.

**【Performance characteristics】** Flexural strength:  $\geq 65\text{MPa}$ , Flexural modulus:  $\geq 2000\text{MPa}$ , Water sorption:  $\leq 32\mu\text{g}/\text{mm}^3$ , Solubility:  $\leq 1.6\mu\text{g}/\text{mm}^3$ , Residual MMA:  $\leq 2.2\%$

**【Information on the materials to which patients can be exposed】** PMMA, MMA, pigments and others. The elution of these components is less than  $1.6\mu\text{g}/\text{mm}^3$ .

**【SSCP】** It will be uploaded to EUDAMED.

### 【Directions for Use】

1. Make the plaster model. If necessary, make the wax pattern.
  - Handling this medical device should only be allowed by trained staff.
2. Scan the model with a scanner which corresponds to the CAD/CAM system in use. If necessary, scan the wax pattern.
3. Design the prosthetic restoration with design software which corresponds to the CAD/CAM system from the scanned data.
4. Place this item into the CAD/CAM milling machine. Cut this material using the designed data.
5. Remove the cut material and remove the cut waste by air or brush, etc.
6. Polish the sharpened materials.
7. In the of a denture base, the artificial teeth are installed with a bonding agent.
  - Follow the instructions for use of bonding agent.
8. Cleaning by ultrasonic bath with mild cleaning agent.

### 【Caution】

1. Use an appropriate CAD/CAM system.
2. Cutting shall be carried out in accordance with the instructions of the CAD/CAM system in use.

(Crown, Bridge)

1. Formed with a deep chamfer or shoulder so that the thickness of the margin section is at least 0.5 mm.
2. The external shape of the cavity shall be rounded and not in contact with the opposing tooth.
3. It should be formed and designed to ensure that the fissure is at least 1.0 mm thick and the occlusal apex is at least 1.3 mm thick.
4. When additional build-up is applied, build-up shall be applied to the fresh surface.
5. Pulp protection should be used if necessary in cases where the cavity is deep and close to the pulp.

(Multilayer)

1. Check the gradation direction before fixing it to the processing machine.

### 【Note】

1. In order to prevent dust from affecting the human body, protective goggles, a local dust absorber, or a dust-proof mask approved by a authorized institution shall be used during the polishing work of this product.
2. The use of appropriate adhesive material (e.g., temporary cement) should be used when placing the crown restoration.
3. Remove excess cement when placing a crown restoration.
4. Patients who develop hypersensitivity symptoms such as rashes, eczema, redness, ulcer, swelling, itchiness and numbness due to the use of this material should discontinue use and consult a doctor.
5. Operators with a history of hypersensitivity such as rashes and dermatitis to MMA-based monomers should not touch the material directly without gloves.
6. If the operators experience hypersensitivity symptoms such as rashes, eczema, redness, ulcer, swelling, itchiness and numbness due to the use of this material, discontinue use and consult a doctor.
7. Single use: Once machined, the dental prostheses cannot be used on another patient because it will not fit.

### 【Storage】

- Keep away from high temperatures, high humidity and direct sunlight.
- Properly store and control so that they are not accessed by non authorized personnel.



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### 【Disposal information】

Remaining stocks or used medical devices must be disposed of according to the corresponding national legal requirements.

### 【Manufactured by:】

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