Instructions for Use Synthetic Polymer Teeth

This product is made from quality polymethylmethacrylate (PMMA) material added with cross-linking agents to improve the network structure. And this product is made through multiple thermal press against the unique nickel-based alloy composite mold, to ensure the accuracy.

1. Indications

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This product is mainly used to make complete dentures, movable partial dentures, and fixed crown restorations for patients with missing teeth, restore vocalization, beautify the face, and improve chewing ability.

2. Main technical properties and features

ISO 13485:2016

- 1) Dimensions of teeth: the dimensions of the teeth are not differ by more than 5 % from the values shown in the mould chart;
- 2) Colour and blending of shades: designed as per the natural tooth structure to make the tooth show the translucent opalescence effect in shade and it's transition for enamel and dentine;
- 3) No porosity and other defects: no porosity or defects, such as rough trimming, rough finish or visible impurities on the coronal surfaces;
- 4) Surface finish: the surface should be smooth, lustrous and non-porous, and it can be polished to restore the original finish;
- 5) Bonding to denture base polymer: well bonded to heat-polymerizable denture-base materials;
- 6) Colour stability: no perceptible colour change after ultraviolet radiation test;
- 7) Resistance to blanching, distortion and crazing: no blanching, distortion or crazing after boiling;
- 8) Dimensional stability: the dimensional change of a tooth is within ±2 % of its original mesio-distal dimension after heat curing treatment with denture base polymer.

3. Application

Used in conjunction with standard denture base resin materials, and used in accordance with the normal procedures of dental restoration technicians.

4. Packaging

Packaging specification: 28×1, 28×1×4, 6×1×16, 8×1×12, 4×1×16, 4×1, 6×1, 8×1, 14×1, teeth refill

Shade: A0, A00, A1, A2, A3, A3.5, A4, B1, B2, B3, B4, C1, C2, C3, C4, D2, D3, D4

5. Storage

Store in the well ventilated room with the relative humidity not more than 80% and with no corrosive gas.

6. Shelf life

10 years

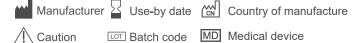
7. Precautions

- 1) Before filling of the base material, keep the product clean, and slightly roughen the back crest to make it easily bonded.
- 2) After modification and adjustment of the tooth surface, use fine polishing of the modified surface with the gel wheel head to avoid dyeing. Take care not to rub off the tooth surface texture when polishing the denture base.
- 3) Do not use flame to fuse the residual wax on the product surface to avoid burn down the tooth surface and crake due to inner stress.
- 4) The dentist should ask the patient whether he/she has the allergic history to acrylic acid resin before making the tooth inlaying.
- 5) The dentist should tell the patient to use the neutral detergent for the denture made from this product to avoid dyeing, when instructing the patient in use of the dentures.
- 6) This product is only used for dental material. One set denture can only to be used for one patient, and the operation shall be only made by the professionals. Take care not to let children access to the product.
- 7) Notification of any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in your country.

8. Contraindications

Not to be used for patient known to be allergic to methacrylate resins.

9. Symbols



EC REP Authorized representative in the European Community

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UDI Unique device identifier

Caution: U.S. Federal Law restricts this device to sale by or on the order of a dentist or professionals



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