188*230mm 正面 反面

PMMA BLOCK

Instructions for Use

Version: 05
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This product is a homogeneous, high-polymer material made from quality polymethylmethacrylate (PMMA) added with cross-linking agents to improve the network structure through a unique polymerization molding technology.

Ⅰ. Target population

This product is applied to dentition-missing patients who need dental restoration or patients who need therapeutic restoration.

Ⅱ.Indications

PMMA BLOCK are particularly suitable for dental restorations produced by CAD/CAM milling technology.

Indications for Use:

-Anterior and posterior crowns;
-Anterior and posterior bridges;
-Permanent restorations for removable denture;
-Implant surgical guide;
-Removable structures for therapeutic restorations (night guards, bite splints or occlusal splints).

Ⅲ. Contraindications

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

Ⅳ.Side effects

This product or one of its components may cause hypersensitive reactions.

Ⅴ.Technical Parameters

Properties	Standard	Typical materials properties
Flexural strength	≥80MPa	140Mpa
Water absorption	≤32μg/mm^3	16.3μg/mm^3
Solubility	≤1.6μg/mm^3	0.12μg/mm^3
Residual methyl methacrylate monomer	≤2.2%	0.5%

Note: The typical data represents the test results from product sampling, and only reflects the performance metrics achieved by a specific batch of products under standard testing environments and conditions, without constituting a commitment or guarantee of the performance for all batches of products.

Ⅵ.Operating Procedures

1.Procedure

Product shade can be selected according to the shade guide. After being milled by computer-aided manufacturing (CAM), use a fine cross-cut tungsten carbide bur to cut off the sprue. If white spots are visible caused by the diamond tools, these spots can be easily removed with a tungsten carbide bur without affecting the quality of the product. Try-in the restoration to test its fit and occlusion.

2.Polishing

Restorations can be pre-polished with a suitable silicone polisher and a small goat-hair brush. Standard acrylic polishing agents are also suitable for intraoral use. Avoid creating excessive heat. Careful polishing is absolutely necessary to achieve perfect results in order to avoid accumulation of plaque and other related negative effects on shade.

3.Cleaning

Place the finished restoration in the ultrasonic unit for about 1 minute. Content of the alkaline cleaning solution should be a maximum of 10% and a maximum temperature of 40°C. Avoid cleaning with steam and compressive stress.

Ⅶ.Storage Condition

This product should be stored in a dry place; avoid sunlight. Storage temperature: -18℃ to 33℃.

Ⅷ. Precautions

1.Product must be worked on with a local dust extraction system.
2.Wear a face mask and protective glasses to prevent inhalation of grinding dusts, contact with eyes, skin or mucosa.
3.Use with caution if one is allergic to acrylic resin materials.
4.Ensure restoration is properly cleaning before placing into the patient's mouth.
5.This product is a special material for the department of stomatology; Restoration is for one-time use only and to be used only by certified professionals. Keep product away from children.
6.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.

Ⅸ. Disposal

Dispose in accordance with local regulations.

X.Symbols for use in the labeling

Manufacturer | Use-by date | Country of manufacture | UDI Unique device identifier
Caution | LOT Batch code | MD Medical device | Consult instructions for use
EC REP Authorized representative in the European Community | Temperature limit
Rx ONLY Caution: U.S. Federal Law restricts this device to sale by or on the order of a dentist or professionals

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