

Denture Base Polymers Instructions for Use

Version: 02
Issuance Date: July 28, 2022

This product contains powder and liquid, wherein the powder is mainly composed of polymethyl methacrylate, and the main composition of the liquid is methyl methacrylate.

I . Indications for use:

This product is used for fabrication and repair of partial and full denture base for patients with missing teeth.

II . Main Technical Performance and Features:

No obvious air bubble and air clearance after polymerization.

Maximum residual monomer content (mass fraction): Type 1 Class 1 (A/B) $\leq 2.2\%$, Type 2 Class 1 $\leq 4.5\%$

III . Operating Procedures:

• Type 1 Class 1 A/B(Heat Curing):

1)Wax Pattern and Embedding Technique of Denture

Complete denture base wax pattern and plaster embedding with regular operation methods.

2) Dewaxing

After the gypsum is hardened, heat the molding flask at a temperature that does not melt the wax mold. Open the molding flask, take out the softened wax mold, and rinse the residual wax on the gypsum parting surface and the artificial tooth surface with boiling water.

3) Coating of the Denture Base Parting Agent

Use a brush to evenly coat the base resin on the surface of the gypsum cavity with a separating agent, and leave it to dry. Special attention should be paid to cover the ridge surface of the artificial tooth cap so as to prevent it from being stained with separating agent.

4) Mix powder and liquid

To produce denture base with uniform color, please shake it well before use. Prior to mixing, clean the mixing cap, and avoid any attached residue from the previous use. Stir thoroughly during mixing. Cap it and let stand after mixing.

- Type 1 Class 1 A(Traditional Heat Curing):

The standard powder/liquid ratio is 100 g powder/42-48 ml liquid, or can be adjusted slightly if necessary. At room temperature of 23 degrees Celsius, about 15-20 minutes to achieve the early filling of case status, duration of approximately 8-10 minutes.

- Type 1 Class 1 B(Fast Heat Curing):

The standard powder/liquid ratio is 24 g powder/10 ml liquid, or can be adjusted slightly if necessary. At room temperature of 23 degrees Celsius, about 14-16 minutes to achieve the early filling of case status, duration of approximately 8-10minutes.

If the temperature is lower, the time taken to reach the initial box-packing status should be slightly longer. If the temperature is higher, the time taken to reach the initial box-packing status should be slightly shorter, and duration should be shorter.

5) Resin filling and pressure test

Take out the resin that reacts to the dough stage from the mixing cup, wear protective gloves, rub and knead it into a filling shape according to the gypsum mold cavity, and fill it into the mold cavity, then cover it with polyethylene film, and close the other half of the mold box to deliver it into the press for testing. After the pressure test, open it to check the molding condition. If it is insufficient, make it up appropriately, and if it overflows, remove it appropriately. Repeat the procedure of pressure test for 2-3 times. Finally, remove the polyethylene film, close the other half of the molding flask and tighten the screws of it.

6) Heating polymerization

-Type 1 Class 1 A(Traditional Heat Curing):

Immerse the molding flask into the water bath, heat it slowly for 30 minutes to boil, and then keep it warm for 60 minutes after boiling. After heating for polymerization, this product can be bonded with synthetic polymer teeth in accordance with the ISO 22112 Standard.

-Type 1 Class 1 B(Fast Heat Curing):

Immerse the molding flask into 100 °C boiling water for 20 minutes. After heating for polymerization, this product can be bonded with synthetic polymer teeth in accordance with the ISO 22112 Standard.

7) Cooling

After polymerization and curing, turn off the power supply, keep the molding flask still in water for about 30 minutes to reach a temperature lower than 60 °C, and then take it out and immerse it in cold water at room temperature. After it is completely cooled, open the molding flask and take out the denture blank.

8) Grinding and Polishing

Carry out grinding and polishing in accordance with the regular method used by a dentist technician.

• Type 2 Class 1(Self Curing):

Mixing powder with liquid

The suggested powder-liquid ratio is 22 g /10ml, or can be adjusted slightly if necessary. Mix it gently, to avoid artificial bubble. Stand still after mixing. At room temperature of 23 degrees Celsius, wait about 3-5 minutes for the mix to achieve Pouring phase. Apply a little liquid on trimmed surfaces and use the mix to repair the denture base. Once in position do not disturb. It can be cured at room temperature. At room temperature of 23 degrees Celsius, it takes about 16-20 minutes to cure. It is suggested to immerse the mix along with the model into 40 °C, at least 2-3 bar, 10minutes after the initial curing in order to promote the curing completely. Perform occlusion adjustment, grinding, and polishing after cooling.

IV . Precautions

A.Safety Precaution

1)Dentist technicians who are hypersensitive to acrylate resin, and with a history of rash or dermatitis, etc., should avoid being exposed to this product. Also, the dentist should inquire whether the patient has such hypersensitivity history prior to installation of denture.

2)If the patient presents with allergic contact stomatitis, such as mild erythema or whitening mucosal surface, after installation of a denture made from this product, discontinue use immediately, and seek diagnosis and treatment by a specialist.

During operation, dentist technician should wear gloves, and avoid direct contact with liquid or non-hardening 3)powder-liquid mixture of this product; in case of contact, immediately rinse and clean the hands with running water and soap. In case of inadvertent contact with eyes, immediately rinse eyes with a large amount of water, and seek diagnosis and treatment from an ophthalmologist.

4) Notification of any serious incident any serious incident that has occurred in relation to the device should be reported to the manufacturer and the competent authority in your country.

B.Operational Precautions

1)The liquid of this product is inflammable, and should be put away from naked fire.

2)Maintain good appropriate ventilation and air exchange while using the liquid, and avoid to inhale it directly.

3)Mixing this product with other resin powder or liquid is prohibited.

4)In order to achieve better bonding of denture, the ridge of the denture cap can be roughened (such as grooving) and coated with an appropriate amount of denture base resin liquid during filling to make the surface to be infiltrated.

C.Storage Precautions

1)This product is a specific product for dentistry, and should not be used by any non-professionals; keep it out of the reach of children.

2)This product shall be stored in a ventilated place, and protected from naked fire, high temperature and direct sunshine.

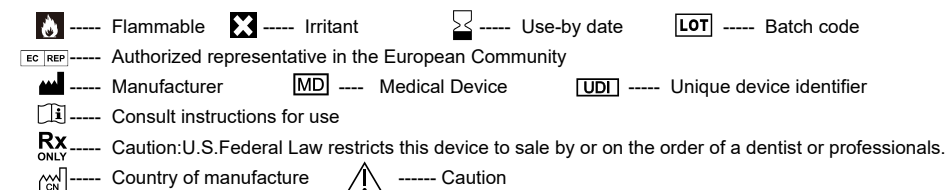
3)After use, fasten the bottle cap firmly and store it properly.

4)Shelf life: Liquid, 2 years; Powder, 3 years

V . Shade

This product is designed in 14 colors: A00; A1; A2; A3; A3.5; B1; 0 Completely transparent color; 1ST Gingiva red translucent color; 2ST Translucent color; 2S Gingiva red light transparent color; 3ST translucent color; 3S Gingiva red light transparent color; 1 Gingiva red light transparent color; V Gingiva red light transparent color.

Symbols for use in the labeling:



 Shandong Huge Dental Material Corporation

No. 68 Shanhai Road, Donggang District, Rizhao City, Shandong Province, 276800, P.R. China

Tel.: +86 633 2277268 E-mail:marketing@hugedental.com Http:// www.hugedental.com

 MedNet EC-REP GmbH

Borkstrasse 10, 48163 Muenster, Germany

