

PERFIT

Duplication Silicone Material

Instructions for use

Version: 01
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1. Compositions:

The product is in paste form. It's composed of synthetic rubber, fillers and so on. It can be changed from the plastic state into the solid state through the polymerization reaction.

2. Type:

Non-reversible duplicating materials.

3. Indications for Use:

This product is used for the full or partial model duplication in the dental laboratory.

4. Series:

A-Silicone for Gingival Mask, C-Silicone for Laboratory, A-Silicone for Laboratory.

5. Technical parameters:

Technical parameters \ Series	A-Silicone for Gingival Mask	C-Silicone for Laboratory	A-Silicone for Laboratory
Mixing time	--	0:30	0:30
Total working time	≤1:30	1:00-2:00	≤1:30

Note: The above total working time is determined under temperature of 23 C and humidity of 50%. It will be shorter if temperature rises, and it will be longer if temperature drops.

6. Instructions:

a) A-Silicone for Gingival Mask

1) Preparatory work

Daub separating agent on the impression part of gingiva where will be duplicated.

2) Mixing of material

Insert the A-Silicone for Gingival Mask into dispenser, close the localizer of the dispenser, and attach the mixer to the bio-cartridge of the product. The product material can be mixed during it passes cross the bio-cartridge. Inject the silicone material on the place where to be duplicated until the material to be cured.

3) Perfuse model

After the A-Silicone for Gingival Mask is cured (8~10min), pour the well mixed liquid plaster into the complete impression in regular way and duplicate the impression. The duplication is completed after the plaster is cured for the dental technicians' use.

b) C-Silicone for Laboratory/A-Silicone for Laboratory

1) Applied to make prosthesis or denture base:

(1) Mix and cover silicone

After solidification of plaster mold, remove water on surface of wax pattern.

C-Silicone for Laboratory: Take 1 or more base material based on wax pattern's size using the measuring spoon. Spread them on the palm of your hand. Press the edge of the measuring spoon onto the material once for each spoonful used.

For every spoonful used, apply 2-3 strips of catalyst which are about 4cm long. (More catalyst, faster curing; less catalyst, slower curing.) Press the well-mixed silicone on surface of prosthesis or wax pattern denture base tightly

A-Silicone for Laboratory: Take the same volume or mass of the base and the catalyst with measuring spoons of different colors according to the wax pattern's size, mix the base and the catalyst well, and then press the mixture on the surface of prosthesis or wax pattern denture base tightly.

(2) Remove wax and fill in denture base material

Make a barb on the surface of silicone which is pressed on surface of prosthesis or wax pattern denture base. After silicone curing (6-8 minutes), fill plaster in model box in normal way, heat the

model box under temperature without melting wax pattern. Open model box and take out soft wax pattern, and then use boiling water to wash off residual wax on teeth surface. Brush separating agent evenly on surface of plaster which contacts denture base, and leave it to dry. Fill in denture base material after, and wait for its curing. Remove silicone, adjust and polish denture base, then the prosthesis or denture base is completed.

2) Applied to partial denture:

(1) Mix and cover silicone

Use above mentioned way to mix material. Press the well-mixed silicone on surface of prosthesis or wax pattern denture base tightly.

(2) Remove wax and fill in denture base material

After curing (6-8 minutes), remove silicone and acrylic teeth, use boiling water to wash off residual wax. Make at least two holes on both sides of silicone. Brush some binding agent on buccal and labial surface of teeth, and reset teeth on silicone impression. Brush some separating agent on plaster that contacts denture base, reset silicone impression on plaster model, and connect edge and plaster model with binding agent. Inject denture base resin from one hole on the silicone slowly, and the other holes are used to exhaust air. When denture base resin starts to getting solid, place the whole package inside autoclave. After curing according to denture base resin molding process, remove silicone, grind and polish partial denture, then the partial denture is completed.

7.Storage condition:

Sealed and stored in cool place, and storage temperature is 5-25 °C. Under this temperature the silicone material is steady and can cast plaster molds several times after weeks.

8.Shelf life: 2 years















9.Precautions for use:

- 1) After taking base or catalyst, put on the lids on tightly, and the lids should not be interchangeable.
- 2) Use the suggested amount of base and catalyst, otherwise working time and curing time can be longer or shorter.
- 3) This product is impression material for dental laboratory use only, which should be kept away from children.
- 4) Waste silicone after taken mode should be treated centralized.
- 5) Suggest to use PVC gloves to avoid catalyst of Partial model silicone to contact skin or eye. Wash with plenty of water and soap, if catalyst contacts skin accidentally. Seek medical attention after wash with plenty of water if catalyst contacts eye. Seek medical attention immediately when catalyst is swallowed.
- 6) To the allergic individuals, polysiloxane may cause inflammation or other allergic reactions.
- 7) The product is for single use.
- 8) Do not use after expiration date.
- 9) Do not use for indications or applications that are not specifically noted in the instructions for use.
- 10) Mixing Tips are for single use only.

Note:

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.

10.Symbols for use in the labeling

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|---|--|---|---------------------------|---|-----------------------------|---|------------------|
|  | ---Manufacturer |  | ---Temperature limit |  | ---Caution |  | ---Use-by date |
|  | ---Medical device |  | ---Batch code |  | ---Unique device identifier |  | ---Do not re-use |
|  | ---Consult instructions for use |  | ---Country of manufacture | | | | |
|  | ---Authorized representative in the European Community | | | | | | |
|  | ---Caution: U.S. Federal Law restricts this device to sale by or on the order of a dentist or professionals. | | | | | | |
|  | ---Catalyst |  | ---Base | | | | |

Shandong Huge Dental Material Corporation

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

Tel: +86 633 2277268

marketing@hugedental.com

www.hugedental.com

 MedNet EC-REP GmbH

Borkstrasse 10, 48163 Muenster, Germany

