PERFIT
Elastomeric Impression Material
Instructions for use

Version: 02
Issuance Date: June 14, 2024

"Caution: Federal law restricts this device to sale by or on the order of a dentist."

1. General Description:

The product is a kind of addition-cure silicone rubber impression material composed of vinyl polysiloxane and various fillers, with neutral smell and applicable to impression in dentistry. Based on demands of clinical impression, the product has been designed with: Type 0 (Putty Hand-mix); Type 1 (Heavy Body Dispenser-mix Normal Set); Type 1 (Heavy Body Dispenser-mix Fast Set); Type 1 (Heavy Body Auto-mix Normal Set); Type 1 (Heavy Body Auto-mix Fast Set); Type 2 (Regular Body); Type 3 (Light Body).

2. Intended use:

The Product is an addition-cure vinyl polysiloxane dental impression material that is used for all crown and bridge, edentulous, orthodontic and implant impression techniques.

3. Contraindications:

Not suitable for those who are allergic to silicone rubber material.

4. Main Ingredient:

The product consists of base and catalyst, in which matrix mainly contains vinyl terminated polydimethylsiloxane, fillers, pigment, softener, stabilizer and cross-linking agent; catalyst mainly contains vinyl terminated polydimethylsiloxane, platinum, fillers and pigment.

5. Main features and technical parameter:

The product has the following features:

(1) Sound mobility and plasticity, small volume shrinkage, vulcanized into elastomer at oral temperature after 3-5 min, easy to take out from month after impression, and great chemical stability.

(2) The impression made of this product is with high precision; can reappear fine structures inside oral cavity; is with good elastic recovery, enough tearing strength and dimension stability; can provide precise and reliable fundamental mode of morphology for department of stomatology in clinical.

(3) Compatibility with almost all molding materials. For a while after the impression produced, it can be refilled and disinfected.

Type / Technical parameter / Item	Type 0		Type 1				Type 2		Type 3	
	Putty Hand-Mix		Heavy Body Dispenser-Mix		Heavy Body Auto-Mix		Regular Body Dispenser-Mix		Light Body Dispenser-Mix	
	Normal Set	Fast Set	Normal Set	Fast Set	Normal Set	Fast Set	Normal Set	Fast Set	Normal Set	Fast Set
Mixing time	30″	30″	-	-	-	-	-	-	-	-
Working- time	1′30″	1′15″	2′00″	1′30″	2′00″	1′30″	2′00″	1′30″	2′15″	1′30″
Minimum time in the oral cavity	3′00″	2′30″	3′30″	3′00″	3′30″	3′00″	3′30″	3′00″	3′30″	2′30″

Tips: the above mentioned working time refers to that at room temperature (23°C) and normal air humidity (50%). With higher temperature the time can be shorter and with lower temperature the time can be longer.

6. Method of Operation:

(1) Selecting of tray:

First impression material including type 0, type 1, and type 2 can be applied to all standard trays. To raise the cohesiveness between silicone and tray, a thin layer of adhesive (for tray only, see use instruction of adhesive) can be used on top of the tray as appropriate.

(2) Mixing of material:

i. Mixing of Type 0 (Putty Hand-mix):

At room temperature, use spoons of different colors to take base and catalyst of the same weight or volume (Cover the lids immediately after this and don't exchange the lids), mix them together with finger tips, and knead them for at least 30 seconds, till they are evenly blended.

Rubber or emulsion gloves are forbidden during kneading the material (If you touched them before kneading, please clean and dry hands completely). Polyethylene gloves are suggested.

ii. Type 1 (Heavy Body Auto-mix):

Switch on the auto-mixer, press the button, the plunger automatically move upward until freely put the double-silicone tube in or out, stop pressing. Take off one cover of double-silicone tube, fix the mixer, screw tightly; then put the tray under the lower end of the mixer, press the button , the plunger automatically move downward, the material can be mixed uniformly, then inflow to the tray; stop pressing based on the demand amount, then the mixing done, backup. If the material needs dispensing into the impression syringe, just press , it can be mixed uniformly through the mixer, then flow into the syringe.

iii. Type 1 (Heavy Body Dispenser-mix), Type 2 & Type 3

Put any one kind of Type 1 (Heavy Body Dispenser-mix), Type 2 & Type 3 addition-cure silicone rubber impression material into glue gun, close locating plate on the top of glue gun, and place mixing tube into the other end of silicone rubber impression material, thus the silicone rubber impression material can directly be mixed and squeezed out though mixing tube. It is suggested that the mixing tube after every using should be retained and used as head protector on double-rubber sleeve. When reused, the original mixing tube is firstly abandoned and new mixing tube and oral injection head are installed for use.

(3) Impression Technique

i. Double-mixing Impression Technique

While the assistant mix type 0 or 1 silicone for first impression well and place it on the tray, the doctor can remove the gingival retraction cords and dispense type 2 or 3 silicone for second impression along the clean and dried teeth neck in the way of spiral and keeping top of oral tip be covered inside the silicone to avoid air. First and second impression material should be placed together inside the oral cavity, because the oral temperature is higher than outside, which will make the curing of second impression in the oral cavity faster than the curing of first impression on the tray. Put the tray into mouth for impression, and take the tray after the material solidifies.

ii. Corrected Impression Technique:

Clean and dry the first impression made by Type 0 (Putty Hand-mix) or Type 1, use the silicone cut to remove incomplete area and make discharge channel for type 3. Dispense type 3 on top of first impression and set the tray inside oral cavity with some pressure.

In order to have better connection of 2 materials, time between first impression and final impression should be no longer than 30 minutes.

iii. One-step Impression Technique:

Dispense Type 1or Type 2 on the tray and along temporary crown or implant. After that set the tray inside oral cavity with some pressure so the silicone can overflow. Keep the impression material fixed in the oral cavity, make sure the material fully solidifies, then take out the tray. Operation time see table of technical parameter.

(4) Taking out the impression:

Take out impression parallel to the butment long axis direction, and flush it clear with running water.

(5) Disinfection of impression

Silicone impression can be disinfected by standard disinfection fluid, such as DURR MD520. Please make sure the disinfection fluid can be applied for additional silicone.

Take out the impression from oral cavity and wash it under running water for 15 seconds. Then set it inside disinfection fluid for 10-15 minutes and another 15 seconds under running water. Do not get the material in touch with organic solvent or liquid with similar ingredient to avoid the material getting expanded and leading to imprecise impression.

(6) Model pouring and electroplating

After disinfect the impression, dry it and store it at room temperature (highest 25 ℃). Hard gypsum or super-hard gypsum are used for model pouring of impression and after they solidify, they can be taken out from impression easily. For better effect, suggesting that placing the impression still for 30 minutes after it is taken out from oral cavity, then the model pouring can begin.

The surface of silicone impression can also be electroplated of copper or silver.

(7) Storage of impression

The impression can be stored at room temperature (highest 25 ℃). At this temperature the impression is steady and can still be reused for model pouring many times after several weeks.

7. Precautions:

(1) For operation

a. When taking out impression, disposable polyethylene plastic gloves other than natural rubber or latex gloves are suggested to wear.

b. Do not exchange measuring spoons when picking impression material, to avoid pollution of matrix and catalyst.

c. After materials are taken, lids should be well covered at once; do not exchange lids; store the material in shady place;

d. The product is addition-cure silicone rubber, so do not mix its use with polycondensation silicone rubber or polyether impression material.

e. Follow the suggested amount of base and catalyst, otherwise working time and solidification time can be longer or shorter.

(2) For storage

a. This product is impression material for dental use only, which should be kept away from children.

b. This product should be sealed up and stored in dry and shady place, at temperature between 5-25℃.

(3) For use

a. If anaphylaxis happens to individual patient, immediately take out it. Those of hyperirritability constitution shall use with caution.

b. Please collect and process used silicone intensively in order to protect the environment.

c. For use only by dental professionals.

d. Do not use after expiration date.

e. Do not use for indications or applications that are not specifically noted in the instructions for use.

f. 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.

8. Valid time

3 years

9. Package and specification

Product:

Putty Hand-Mix: (22.3g base+22.3g catalyst)/set; (25g base+25g catalyst)/set; (27.8g base+27.8g catalyst)/set； (30g base+30g catalyst)/set; (35g base+35g catalyst)/set; (50g base+50g catalyst)/set; (400g base+400g catalyst)/set; (2kg base+2kg catalyst)/set; (10kg base+10kg catalyst)/set; (25kg base+25kg catalyst)/set;

Heavy Body Dispenser-Mix: 50ml/bio-cartridge, 2 bio-cartridges/box;

Heavy Body Auto-Mix: 380ml/bio-cartridge, 1 bio-cartridge/box;

Regular Body: 50ml/bio-cartridge, 2 bio-cartridges/box;

Light Body: 50ml/bio-cartridge, 2 bio-cartridges/box.

Accessory:

Impression tray: Upper tray(XS,S,M,L,XL)1 pcs/bag, Lower tray(XS,S,M,L,XL)1 pcs/bag;

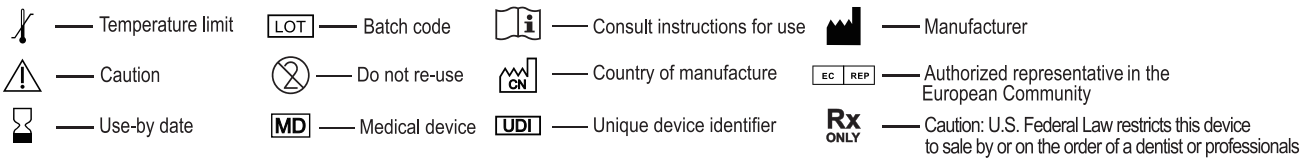
Mouth Stretcher: (XS,S,M,L,XL)1 pcs/bag;

Chewies: 2 pcs/bag;

Pullies: 2 pcs/bag;

Gloves: (XS,S,M,L,XL) 2 pcs/bag.

10.Symbols for use in the labelling



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

EC REP MedNet EC-REP GmbH

Borkstrasse 10, 48163 Muenster, Germany

CE