

# A-Silicone for Bite Registration

## Instructions for Use

Version: 01  
Issuance Date: March 23, 2022

### 1. General Description

A-Silicone for Bite Registration is a vinylpolysiloxane (addition silicone), also known as A-Silicones, polyvinyl siloxanes (PVS), or vinyl polysiloxanes (VPS), especially made for bite registration work in the surgery and laboratory. It mainly contains polydimethylsiloxane, silica and platinum catalyst.

### 2. Indications for Use

A-Silicone for Bite Registration is indicated for making occlusal registrations.

### 3. Instructions for Use

- (1) Load A-Silicone for Bite Registration on the dispenser and close the locator on the top of the applicator.
- (2) Remove the cap and squeeze the dispenser to make sure the base and the catalyst in the tubes are in the same level.
- (3) Install the mixer, and directly extrude the mixed material into the tooth site needing bite registration. Let the material harden in terminal occlusion.
- (4) Remove the material after the recommended intraoral curing time.

Main technical parameter:

Technical parameter Item	Type	A-silicone for bite registration	
		Dispenser-mix Normal Set	Dispenser-mix Fast Set
Working-time		30"	12"
Minimum time in the oral cavity		1'30"	45"

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.

### 4. Operation notes

- (1) For sealing, do not remove the mixer after use, and replace it before next use.
- (2) Before each use, it is necessary to check whether the heights of materials in the two tubes are flush. If not, the materials in the tubes must be squeezed before use.
- (3) This product is addition-cure vinyl polysiloxane, and cannot be mixed with condensation cured polysiloxane or polyether silicone.

### 5. Cautions

- (1) Contact with latex gloves may prevent vinylpolysiloxane from setting. Avoid direct or indirect contact with latex gloves. Instead, wash your hands well to eliminate all traces of impurities or use vinyl gloves.
- (2) Vinylpolysiloxane are chemically resistant, so be careful not to stain your clothing.
- (3) The product is for single use.
- (4) It is suggested that do not remove the mixing tube after every using, which can be the head protector on double-rubber sleeve. When reused, abandon the used one and apply a new mixing tube and oral injection head; store the material in shady place.
- (5) Please clean the teeth before impression so as to prevent potential contaminant on teeth from influencing impression accuracy.

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.

### 6. Contraindications

In sensitive subjects, vinyl polysiloxanes may cause irritation or other allergic reactions.













### 7. Side effects

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

### 8. Storage

- (1) The product should be stored in a dry environment with the temperature of 5-25 °C, and it should be kept out of the reach of children.
- (2) The registration can be sent to the laboratory like a normal impression, without special precautions, provided that it is protected from mechanical stresses. Store at room temperature.
- (3) Shelf life: 2 years from date of manufacture

### 9. Symbols for use in the labeling

	— Temperature limit		— Batch code		— Consult instructions for use
	— Caution		— Do not re-use		— Country of manufacture
	— Use-by date		— Medical device		— Unique device identifier
	— Manufacturer		— 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				

 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

