



VANNINI DENTAL
Industry
Italy

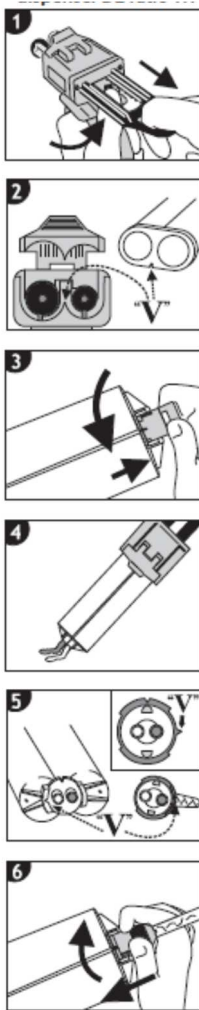
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VINYLPOLYSILOXANE BITE REGISTRATION MATERIAL

PRESTIGE BITE CAD CAM

Instructions for use with dispenser



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Instructions for use

INTENDED USE

Vinylpolysiloxane bite registration material.

PRODUCT DESCRIPTION

Prestige Bite CAD CAM has a hardness of 90 ± 5 Sh A and is scannable.

PACKING

50 ml cartridge

COMPOSITION

Vinylpolysiloxane, Silica Fillers, Inorganic Aluminium Fillers, Inorganic Aluminium Fillers, Organoplatinic complex, Pigments.

INSTRUCTIONS FOR USE

The devices are intended for use by dental sector professionals for the purpose of dental patient bite registration.

CONTRAINDICATIONS

Do not use on patients with known hypersensitivity to any of the components. For more information on the allergens contained in scents, please contact Vannini Dental.

WARNINGS

Secure undercuts before using the product. It is recommended to wrap the dispenser, the cartridge and the mixing tip in cellophane prior to use. This can be removed after use to disinfect the dispenser and tip. Use specific impression disinfectants to disinfect the bite registration. Do not disinfect the cartridge directly to avoid erasing important information (lot and expiry date). In the case of hypersensitivity, suspend use immediately and take steps to ensure the patient is safe and secure.

PRECAUTIONS

Wear suitable gloves and work clothes. We recommend the use of vinyl or nitrile gloves. Do not contaminate the material or the teeth/surfaces to register with gloves and/or accessories containing latex, sulphide based gingival displacement solutions, polyethers or the non-polymerised surface layers of acrylic or bis-acrylic resins. Residues of these materials could interfere with the setting of the product. If surfaces become contaminated, clean them with plenty of water, ethyl alcohol or other suitable solvents in the case of acrylic and bis-acrylic resins.

Use the product at an ambient temperature of 23°C/73°F (higher temperatures reduce working time, lower temperatures extend working time).

Do not use the product after the expiry date specified on the packaging. Store the product at a temperature between 5°C and 27°C. Do not store the product in direct sunlight. Do not throw the product into the environment. Dispose of the product in compliance with local legislation.

The product has not been tested for compatibility with accessories other than those with which it is supplied. Use of non-original accessories may cause events that lead to a reduction in the precision of bite registration. The use of non-original accessories is therefore not recommended.

SIDE EFFECTS

Irritation, redness or signs of hypersensitivity may occur in case of allergy to any of the components.

CLINICAL BENEFITS

Dimensionally stable material permits intraoral registration of the relative positions of the arches.

STEP-BY-STEP INSTRUCTIONS

Preliminary operations:

1. Read the instructions prior to use.
2. Wear suitable protective gloves and work clothes.

Assemble the device according to the following instructions.

3. Pull the dispenser rack as far back as it will go by raising the black lever below it. Lift the cartridge lock. (fig. 1)
4. Insert the cartridge making sure that it fits the right direction. The cartridge must be inserted with the "V" on its base facing downwards. The cartridge lock can now be lowered easily. (fig. 2)
5. With the cartridge in position on the dispenser, remove the cap by turning it 1/4 turn. Remove the cap in a clean motion and throw it away. (fig. 3)
6. Check that the two components come out together when you press gently on the dispenser lever.

Extrude a small quantity of product to equalize the flow of the two components. Clean the nozzle of the cartridge, removing excess product from the extrusion holes (fig. 4).

7. Insert the mixing tip in a clean motion so that the V-shaped notch on the coloured ring aligns with its housing on the cartridge. Turn the tip 1/4 turn, exerting pressure only on the coloured ring and not on the mixing tip itself. Use the green mixing tips. (fig. 5-6)

8. We recommend that you wrap the dispenser and cartridge in cellophane prior to use, removing the wrapping afterwards.

Using the device on the patient:

9. Secure undercuts before using the product.

10. Apply the product using the desired technique (occlusal or vestibular). If you use the occlusal technique, first extrude the material on to the teeth, then ask the patient to bite. For bite registrations performed using the vestibular technique, inject the product over the teeth with the arches in the position you wish to register.

11. Leave the tip on the cartridge.

Disinfection:

12. Thoroughly disinfect the tip without removing it from the cartridge, even after disinfection. Before the next use of the cartridge, remove the old mixing tip and fit a new one.

13. Disinfect the dispenser according to the manufacturer's instructions. Do not disinfect the cartridge directly to avoid erasing important information (lot and expiry date).

14. Rinse thoroughly and use specific VPS impression disinfectants to disinfect the bite registration. Quaternary ammonium salt based disinfectants or mixtures of alcohol and surface tension reducers have been tested. Please refer to the instructions for use for each specific impression disinfectant you wish to use to check compatibility and effectiveness.

SCANNABILITY OF BITE REGISTRATION

The bite registration can be scanned without using dulling sprays via specific scanners. Follow the scanner manufacturer's instructions.

TECHNICAL SPECIFICATIONS

Working time *	30"
Time in mouth*	1'15"
Hardness 1h	90±5 Shore A
Detail reproduction	20 µm
Linear dimensional variation (approx.) 7 days	0.25%

* The specified times refer to an in-house test conducted at a temperature of 35°C – 95°F.

STORAGE AND STABILITY

Use the product at an ambient temperature of 23°C/73°F (higher temperatures reduce working time, lower temperatures extend working time). Store unused product at a temperature between 5°C and 27°C. Do not store the product in direct sunlight. Do not use the product after the expiry date specified on the packaging. The bite registration can be sent to the laboratory like a normal impression, without special precautions, provided that it is protected from mechanical stress.

IMPORTANT REMARKS

Information provided in any way, even during demonstrations, does not invalidate the instructions for use. Users are required to check that the product is suitable for the foreseen application. The manufacturer cannot be held responsible for damage, including to third parties, deriving from failure to follow instructions or from unsuitability for an application. The manufacturer's liability is in any case limited to the value of the products supplied. Report any serious incident involving the medical device to the manufacturer and to the relevant authorities.