

Jet Bite

Instructions for use

EN

Please read the Instructions for Use carefully before using the product. Keep for later reference.

PRODUCT DESCRIPTION

Jet Bite is a two-component material based on addition-curing polyvinylsiloxanes.

INTENDED USE

Jet Bite is intended for the registration of occlusion in cases where relationship between the relative positions of maxilla and mandible is required.

COMPOSITION

Addition-curing silicone elastomer, type B: bite registration material

- Polyvinylsiloxanes
- Colour: Base: yellow / Catalyst: white

INDICATIONS

Clinical situations which require an indirect restoration e.g. for the following diagnoses:

- Disorders of tooth development and eruption
- Diseases of dental hard tissues or discolorations
- Periodontal diseases leading to tooth loss
- Dentofacial anomalies

CONTRAINDICATIONS

- Do not use in case of known allergies to the ingredients of the product.

SAFETY INSTRUCTIONS

- Only supplied to dentists and dental laboratories or upon their instructions!
- Impression materials that came into contact with the oral mucosa may be contaminated. Observe disinfection instructions.
- Do not use latex gloves. Always use vinyl/nitrile gloves to touch the material and the surfaces of which the impression is taken (teeth, preparations, retraction cords etc.).
- High temperatures accelerate setting; low temperatures slow down the setting process
- Compounds containing eugenol or haemostatic substances can also inhibit setting.
- Contains nano materials (bonded particles)

SIDE EFFECTS / INTERACTIONS

No harmful reactions or secondary effect on the patients and / or dental personnel are known.

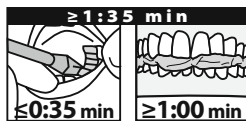
USER- / PATIENT GROUP

The product shall be used by qualified dental professionals only. Suitable for all patient groups including children, elderly people, pregnant and lactating women.

PREPARATION

1. Insert cartridge in dispenser.
2. Remove the safety cap.
3. Activate the lever and press a small amount of material onto a paper towel until equal amounts of base and catalyst are dispensed from the outlet channel. This ensures that the plungers are at the same height to achieve an optimal mix.
4. Attach the universal mixing tip onto the cartridge and twist a ¼ turn clockwise (90°) to lock it in place.
5. Optional: Place the spreader tip on the mixing tip.

PROPER USE



Dispense the bite registration material directly onto the occlusal surface of the lower teeth and move mandible into central occlusion. Optional, the material can also be applied to the lateral intercuspal position. Avoid abrupt movement.

Avoid using excessive amount of silicone for impression taking due to the risk of overflow material being swallowed.

TESTMETHOD FOR CORRECT APPLICATION

Always check intraorally whether the material is set or not. If the manual pressure test does not leave a pressure mark in the bite registration, it can be removed from the patient's mouth. However, if the test leaves a visible pressure mark in the material, the material is not yet fully set.

REPROCESSING, CLEANING, DISINFECTION AND MAINTENANCE

To prevent cross-contamination the use of cartridge sleeves is recommended. In case of suspected or identifiable contamination, please dispose of. The mixing tip serves as seal until the next application and prevents contamination of the material. Store the material in horizontal position. Remove the used mixing tip immediately before the next application, check again for smooth flow of the impression material and attach a new mixing tip. After cleaning, the final bite registration can be disinfected with dental disinfectant solutions (e.g. OPTIM 1 liquid, COLTENE) and dried using compressed air.

SHELF LIFE / STORAGE

- Expiry date: see primary packaging
- Storage temperature: 15-23°C / 59-73°F
- Relative humidity: 50% ± 10%
- Shelf life after first opening: 3 months

Protect against exposure to heat and sun. Avoid extreme temperature fluctuations.

DISPOSAL

Dispose of waste according to applicable legislation. Special country-specific regulations may apply. Can be disposed together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge. (Only dispose of completely emptied packages.)

TECHNICAL DATA

Measurements according to ISO 4823

Working time: 0:35 min
Time in mouth: 1:00 min

REPORTING OBLIGATION

All serious incidents occurring in conjunction with this product must be reported immediately to the manufacturer as well as to the competent authority.

In the unlikely event of inhalation, ingestion, eye contact, or similar incidents seek immediate medical attention from an appropriate medical specialist to mitigate potential harm.

SAFETY DATA SHEET
www.coltene.com



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GLOSSARY

	Consult instructions for use
	Keep away from sun light
	Temperature limitation
	Marking of Conformity Europe
	Identification for Ukraine
	Legal Manufacturer
	Expiry Date
	Batch Code
	RX only
	Medical Device
	Manufacturing Date
	Unique Device Identifier
	European Authorized Representative
	Importer
	Reference Number

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