

Speedex Universal Activator

Instructions for use

EN

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

PRODUCT DESCRIPTION

Speedex is a two-component impression material based on condensation-type polysiloxanes. After manual mixing of base and activator, the Speedex materials form pastes which are used individually or in combination as dental impression material, usually together with a standard commercial or individual impression tray and using conventional impression techniques.

INTENDED USE

Speedex is intended for the recording of the current physical situation in a patient's mouth ("dental impression material") for the purpose of repairing, reshaping or replacing the patient's teeth.

COMPOSITION

Polysiloxane-based activator
Colour: green

INDICATION

Activator for Speedex putty; Speedex putty soft; Speedex light body; Speedex medium for creating dental impressions

- Primary impression for the correction impression technique
- Pick-up impression in the simultaneous mixing technique
- Impressions for study models, orthodontic models, keys and protective isolation of teeth during fitting of prostheses
- Correction material for the correction impression technique
- Syringe material for the two-phase impression technique
- Impression material for relining

CONTRAINDICATION

- Do not use in case of known allergies to ingredients of the Speedex impression materials
- Loose teeth can be further loosened or extracted by taking an impression
- Material combinations with impression materials of other manufacturers are not permitted

SAFETY INSTRUCTIONS

- Eyes, respiratory organs and skin can be irritated by Speedex Universal Activator
- Impressions that came into contact with the oral mucosa may be contaminated. Observe disinfection instructions
- Only supplied to dentists and dental laboratories or upon their instructions
- Contains nano materials (bonded particles)

SIDE EFFECTS / INTERACTIONS

No harmful reactions or secondary effects on 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 and pregnant women.

PROPER USE

The dosage of the Speedex Universal Activator varies depending on the combination of Speedex base materials (Speedex putty; Speedex putty soft; Speedex light body; Speedex medium). Detailed information on the application can be found in the instructions for use of the base materials. Make sure that the tubes are closed immediately after use.

Dosage method Activator with Speedex putty/putty soft:

Dose Speedex putty/putty soft with enclosed measuring-scoop (scrape off surplus). Spread out the material in the palm of hand. For each measuring scoop press the scoop rim once into the material on the hand. Apply one strand length of Speedex Universal Activator per circle diameter.

Dosage method Activator with Speedex light body & medium

Dispense Speedex Universal Activator and Speedex light body/medium on a mixing block in two equal strands.

⚠ Take the following safety precautions when working with Speedex Universal Activator:

- Protective glasses are recommended. In case of contact with eyes, rinse immediately with water and consult an ophthalmologist.
- Avoid direct skin contact
- Always wear protective gloves when working (vinyl gloves are recommended)
- Avoid inhalation or ingestion

TESTMETHOD FOR CORRECT APPLICATION

Material residue needs considerably more time to set at room temperature than in the patient's mouth. You should therefore check intraorally if the material is set before removing from the mouth. If the manual pressure test does not leave a pressure mark in the impression material after the time specified in the chapter on "Dosage", the impression 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 cured.

SHELF LIFE/STORAGE

- Expiry date: see label on 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. Close tube immediately after use.

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.)

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



GLOSSARY	
	Consult instructions for use
	Keep away from sun light
	Keep dry
	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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