

Speedex Universal Activator

Instructions for use

EN

Carefully read the instructions prior to use.

Product description

Speedex[®] is a two-component impression material based on condensation-type polysiloxanes. 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. This includes base materials (Speedex[®] putty soft; Speedex[®] putty; Speedex[®] light body; Speedex[®] medium) and the universal activator (Speedex[®] Universal Activator). 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.

Composition Speedex Universal Activator

Polysiloxane-based activator.
Shade: green

Indications for Use

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 the 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

⚠️ WARNING

- Eyes, respiratory organs and skin can be irritated by Speedex Universal Activator
- Impressions that come into contact with the oral mucosa may be contaminated. Observe disinfection instructions
- Only supplied to dentists and dental laboratories or upon their instructions
- Carefully read the Speedex instructions for use before using

Side effects / Interactions

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

Users

The use of Speedex impression materials in the patient's mouth may only be undertaken by specialist personnel such as dentists and dental assistants with special qualifications.

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 (from 2019). 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)
- Do not swallow or ingest

Test methods 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 and 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. Close tube immediately after use.

Disposal

Speedex impression materials can be disposed in small quantities in household waste. Special country-specific regulations may apply.

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.

For SDS see

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

Reference Number

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