REV-05-2024 30005940 05.24

Speedex light body

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
Condensation-type silicone elastomer, free-flowing consistency.
- Polysiloxane
- Colour: dark blue

INDICATIONS
- 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.

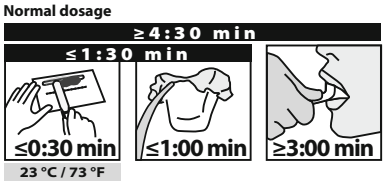
USER- / PATIENT GROUP
The product shall be used by qualified dental professionals only. Suitable for all patient groups including children, elderly people and pregnant women.

PREPARATION
Trays
All impression trays that have been designed for dental use, either prefabricated or individual, can be used for impression taking. For perfect adhesion, we recommend applying a thin layer of COLTENE Adhesive to the trays before use. This prevents detachment of the impression material during removal from the oral cavity. Detailed information on the application can be found in the COLTENE Adhesive Instructions for Use.

PROPER USE
Dosage
Dispense Speedex Universal Activator and Speedex light body on a mixing block in two equal strands. Make sure that the tubes are closed immediately after use.

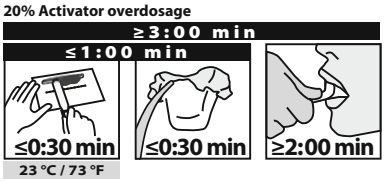
⚠ Take the following safety precautions when working with Speedex Universal Activator:
- Protective glasses are recommended. In case of contact with eyes, rinse immediately with water and consult an ophthalmologist
- Avoid direct skin contact
- Always wear protective gloves when working (vinyl gloves are recommended)
- Avoid inhalation or ingestion

APPLICATION TIME
Normal dosage

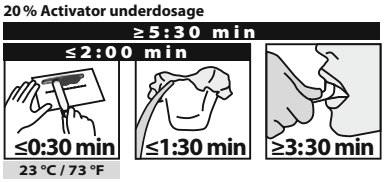


Intensive mixing, high temperatures and humidity accelerate the curing of the impression materials. Low temperatures slow down the curing process. By over- and underdosing the Speedex Universal Activator the processing time can be accelerated or slowed down.

20% Activator overdosage



20 % Activator underdosage



Mixing
Take up one component (Universal Activator or light body) with spatula and spread evenly on the other component. Then pick up both components with the spatula and spread out on the mixing block. Repeat this procedure until the mixture is homogeneous. Please observe the specified processing times.

Impression
Depending on the impression method, apply the impression material in the patient's mouth or to the impression tray. Insert the impression tray into the oral cavity and press for 2-3 seconds and keep in situ until set completely.

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

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.

REPROCESSING, CLEANING, DISINFECTION AND MAINTENANCE
Cleaning of the impression
After cleaning, the final impressions can be disinfected with commercially available disinfectant solutions (e.g. Dürr Dental SE, MD 520 impression disinfection) specifically designed for dental impression materials and dried using air pressure. If hydrogen peroxide is used for disinfection, it is recommended to thoroughly rinse with lukewarm water afterwards in order to avoid bubble formation.

Cleaning of trays
The impression can be removed with a blunt instrument. Adhesive residues can be dissolved by placing in commercially available universal solvents or benzine.

Manufacture of models
The ideal time lies between 30 min and 72 h after taking the impression. The surface tension will be reduced and pouring will be facilitated if the impression is briefly washed out with a detergent and rinsed thoroughly in lukewarm clear water afterwards. All industry-standard dental stone model materials (e.g. Fujirock Dental Stone, Hard Rock Dental Stone) can be used

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 container and tubes 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.)

TECHNICAL DATA
Technical data according to ISO 4823
The technical data were determined at 23 °C / 73 °F and 50 % relative humidity.

Mixing time:	00:30 min
Processing time:	≤1:30 min
Oral setting time:	3:00 min
Mixing ratio light body/Activator:	5 ml / 1 ml 5 g / 0.88 g

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

CE 0123

GLOSSARY	
	Consult instructions for use
	Keep away from sun light
	Keep dry
	Temperature limitation
CE	**Marking of Conformity Europe**
	Identification for Ukraine
	Legal Manufacturer
	Expiry Date
LOT	**Batch Code**
Rx ONLY	**RX only**
MD	**Medical Device**
	Manufacturing Date
UDI	**Unique Device Identifier**
EC REP	**European Authorized Representative**
	Importer
REF	**Reference Number**

COLTENE International Dental Group

Dent4You AG
Bahnhofstrasse 2
CH-9435 Heerbrugg

Manufactured by
Coltène/Whaledent AG
Feldwiesenstrasse 20
CH-9450 Altstätten

Customer Center
service@coltene.com

COLTENE