

Adhesive

Instruction for use

EN

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

PRODUCT DESCRIPTION

COLTENE Adhesive is a universal adhesive for sili-cone-based impression materials for use in dentistry. It can be used for all conventional impression trays (e.g. metal).

INTENDED USE

A thin layer of COLTENE Adhesive serves as an adhesive between the impression material and the impression tray. It prevents the impression material from detaching from the impression tray during removal.

COMPOSITION

Main component: Polysiloxane

INDICATION

- No direct medical indication.
- Used in combination with medical devices.

CONTRAINDICATION

- In case of known allergies to the main ingredient of COLTENE Adhesive, do not use.

SAFETY INSTRUCTIONS

- Use only in well-ventilated areas!
- Keep away from sources of ignitions!
- Always wear gloves.
- Close bottle immediately after use!
- The use of COLTENE Adhesive may only be under-taken by specialist personnel such as dentists and dental assistants with special qualifications.

SIDE EFFECTS / INTERACTIONS

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

USERS / PATIENT GROUPS

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

PROPER USE

Line all trays with a layer of COLTENE Adhesive as thin as possible and let the applied layer dry for at least 1 min, or dry it with compressed air.
Close bottle immediately after use!

REPROCESSING, CLEANING, DISINFECTION AND MAINTENANCE

Cleaning of trays

The impression material can be removed with a blunt instrument. Soaking in a universal commercial solvent or petroleum ether will dissolve COLTENE Adhesive. These solvents should only be used in a well-ventilated area. The trays can be cleaned and disinfected as usual.

SHELF LIFE / STORAGE

COLTENE Adhesive fulfils the intended use at least until the expiry date, which is displayed on the containers, in a well-sealed bottle at a temperature of 15-23 °C / 59-73 °F and 50 % relative air humidity. Shelf life after first opening 3 months.

DISPOSAL

Dispose of waste according to applicable legislation. Do not allow to enter into surface water or drains. Can be burnt together with household waste in compliance with official regulations in contact with approved waste disposal companies and with authorities in charge.

REPORTING OBLIGATION

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

In the unlikely event of inhalation, ingestion, eye con-tact, or similar incidents seek immediate medical atten-tion 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
	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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