

PRESIDENT heavy body

The Original

Instructions for use

EN

Please read the Instructions for Use carefully before using the product.

PRODUCT DESCRIPTION

PRESIDENT The Original is a two-component impression material based on addition-curing polyvinylsiloxanes. This includes the correction materials (PRESIDENT The Original regular body, light body and Xtra light body) and the tray materials (PRESIDENT The Original putty, putty soft, fast putty soft, putty super soft, heavy body and MonoBody). After manual mixing of base and activator or mixing with the mixing tip, the PRESIDENT The Original 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

PRESIDENT The Original 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 PRESIDENT The Original heavy body

Addition-curing silicone elastomer, heavy-bodied consistency.

- Polyvinylsiloxanes
- Colour: caramel

INDICATIONS FOR USE

- Impression material for pick-up impression in the double mix technique
- Tray material for corrective impression technique
- Tray material for dual arch technique

CONTRAINDICATIONS

- Do not use in the case of known allergies to ingredients of the PRESIDENT The Original impression materials.
- Loose teeth can be further loosened or extracted by taking an impression.

SAFETY INSTRUCTIONS

⚠ WARNING

- 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.

NOTICE

- Always wear non-latex gloves when working. Skin secretions, latex gloves and surfaces contaminated by latex gloves have a negative effect on the setting process of polyvinylsiloxanes. Only touch the material and the surfaces of which the impression is taken (teeth, preparations, retraction cords etc.) with vinyl / nitrile gloves. Compounds containing eugenol or haemostatic substances can also impede perfect setting. If hydrogen peroxide is used for disinfection, it is recommended to thoroughly rinse with lukewarm water afterwards in order to avoid bubble formation. In order to guarantee good cohesion with the correction material, the primary impression should be carefully cleaned and dried before further use.
- High temperatures accelerate setting, low temperatures slow down the setting process.
- Material combinations with impression materials of other manufacturers are not permitted.
- 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 use of PRESIDENT The Original impression materials in the patient's mouth may only be undertaken by specialist personnel such as dentists and dental assistants with special qualifications. Suitable for all patient groups.

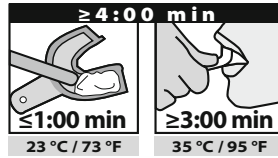
PREPARATION

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 or spraying a thin layer of COLTENE Adhesive or Adhesive AC 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 or Adhesive AC Instructions for Use.

PROPER USE

Processing times



Mixing

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. Wipe off the cartridge outlet channels with paper towels.
5. Attach the appropriate mixing tip to the outlet channel of the cartridge and turn ¼ revolution clockwise (90 °) until it is securely fastened.
6. Press out the impression material with a smooth, constant actuation of the lever. Avoid abrupt movement. Releasing the lever stops the flow of material.

Mixing Tip turquoise

After use, wipe off the mixing tip turquoise with disinfectant and do not remove! The mixing tip serves as seal until the next application and prevents contamination of the material. Store in horizontal position. Only 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. To guarantee trouble-free application, we recommend that the COLTENE mixing tip turquoise be used exclusively.

Impression

Insert the impression tray with the impression material into the oral cavity and press for 2-3 seconds and keep in situ until set completely.

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 „Processing times“, 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 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.

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 compressed air.

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 benzene.

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 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.

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 ACCORDING TO ISO 4823

Measurements were taken at 23°C / 73°F room temperature and 50% relative humidity.

Mixing time (15ml):	0:15 min
Total working time:	1:00 min
Oral setting time (35 °C / 95 °F):	3:00 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.

SAFETY DATA SHEET

www.coltene.com



Glossary

	Consult instructions for use
	Keep away from sun light
	Temperature limitation
	Notified body registration number
	Identification for Russia
	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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